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ciba

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September 12, 1994

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Dockets Management Branch (HFA-305)
Food and Drug Administration
Room 1-23
12420 Parklawn Drive
Rockville, MD 20857

Via Certified Mail/Return Receipt

Subject: OTC Docket No. 75-N-0183 (triclosan)

Dear Sir or Madam:

The purpose of this transmittal is to update Ciba-Geigy's OTC Docket for triclosan. As such, attached please find a transmittal document which lists the studies being submitted to our OTC Docket and three copies of each document submitted. Each study has been labeled by volume number, beginning with volume 101 and ending with volume 116. For your convenience, abstracts have been prepared for each study and are included with each study. Please contact me at (910) 632-7493 if you have any questions regarding this submission.

Sincerely,



Carl D. D'Ruiz, MPH
Manager, Regulatory Affairs and Compliance
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enclosure

cc: W. E. Gilbertson
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DOCKETS MANAGEMENT BRANCH

TRANSMITTAL DOCUMENT

1. NAME AND ADDRESS OF SUBMITTER

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2. REGULATORY ACTION OF SUPPORT FOR WHICH THIS PACKAGE IS SUBMITTED

The contents of this package are being submitted to the U.S. Food and Drug Administration for inclusion into OTC Docket Number 75N-0183 (triclosan - CAS No. 3380-34-5). A list of the studies being submitted is presented below. More specific information related to this product may be found in the cover letter and attachments accompanying this transmittal document.

3. TRANSMITTAL DATE: September 12, 1994

4. LIST OF SUBMITTED STUDIES

<u>OTC VOL. NO.</u>	<u>STUDY TITLE</u>
101	Borzelleca, J.F., Frankos, V.H., Johnson, E.M., Jordan, W., Squire, R.A., and Weil, C. <u>Selected Portions of the Report of the Expert Panel on the Safety of Triclosan in Toothpaste and Oral Rinse Products.</u> Environ Corporation Expert Panel Report. December 15, 1992.
102	Goodman, D.G. <u>Pathology Working Group Report on Triclosan Chronic Toxicity/ Carcinogenicity Study in Sprague-Dawley Rats.</u> Prepared by PATHCO, Inc. for Ciba-Geigy. January 23, 1990. Pathology Working Group members included: J.M. Cullen, D.G. Goodman, P.M. Newberne, R.M. Sauer, R.A. and Squire, J.M. Ward.
103	Jones, E. and Wilson, L. <u>Ames Metabolic Activation Test to Address the Potential Mutagenic Effect of Triclosan.</u> Environmental Safety Laboratory, Unilever Research Lab., Colworth House. Study No. KA 880169. September 9, 1988.
104	Henderson, L.M., Produlock, R.J., Haynes, P. and Meaking, K. <u>Mouse Micronucleous Test on Triclosan.</u> Environmental Safety Laboratory, Unilever Research Lab., Colworth House. Study No. KC 880168. August 12, 1988.
105	Henderson, L.M., Ransome, S.J., Brabbs, C.E., Tinner, A.J., Davies, S.E. and Loyd, A. <u>An Assessment of the Mutagenic Potential of Triclosan Using the Mouse Lymphoma TK Locus Assay.</u> Environmental Safety Laboratory, Unilever Research Lab., Colworth House. Study No. KM 880170. September 15, 1988.

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- 106 Riach, C.G., McBride, D, and O'Mailley. Triclosan: Assessment of Genotoxicity in an Unscheduled DNA Synthesis Assay Using Adult Rat Hepatocyte Primary Cultures. Inveresk Research International Limited. Project No. 738388. Report No. 4667. November 2, 1988.
- 107 Heidemann, H.G. Chromosome Aberration Assay in Chinese Hamster V79 Cells In Vitro with FAT 80'023/Q (Triclosan). Cytotest Cell Research GmbH & Co. KG. Project No. 179100. December 17, 1990.
- 108 Völkner, W. Chromosome Aberration Assay in Bone Marrow Cells of the Rat with FAT 80'023/Q (Triclosan). Cytotest Cell Research GmbH & Co. KG. Project No. 218305. April 23, 1991.
- 109 SanSebastian, J.R., et al. Rat Hepatocyte Primary Culture/DNA Repair Test on 39317. Pharmakon USA. Study No. PH 311-CP-001-93. June 24, 1993.
- 110 Stankowski, L.F., et al. Ames/Salmonella Plate Incorporation Assay on Test Article 39316 (CC# 14663-09). Pharmakon USA. Study No. PH 301-CP-001-93. Dec. 2, 1993
- 111 Ciba-Geigy. Summary of Current Available Safety Data on Triclosan. Triclosan Industry Alliance. August 15, 1994.
- 112 Goodman, D.G. Pathology Working Group Report on Triclosan 90-Day Subchronic Toxicity Study in Sprague-Dawley Rats. Prepared by PATHCO, Inc. for Ciba-Geigy. January 23, 1990. Pathology Working Group members included: J.M.Cullen, D.G. Goodman, P.M. Newberne, R.M. Sauer, R.A. and Squire, J.M. Ward.
- 113 Brooker, P.C., Gray. V.M., Howell, A. Analysis of Metaphase Chromosomes Obtained from CHO Cells Cultured In Vitro and Treated with Triclosan. Huntington Research Centre Ltd., ULR 214/88731. Unilever Test No. KC 880171. August 11, 1988.
- 114 Trutter, J.A. 13-Week Subchronic Oral Toxicity Study of Triclosan in CD-1® Mice. Hazleton Washington, Inc. Lab. Project I.D. No. 483-287. January 28, 1993.
- 115 Trutter, J.A. 13-Week Subchronic Oral Toxicity Study of Triclosan in CD-1® Mice (Volume 2). Hazleton Washington, Inc. Lab. Project I.D. No. 483-287. January 28, 1993.

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116 Trimmer, G.W. 90-Day Subchronic Dermal Toxicity Study in the Rat with Satellite Group with Irgasan DP 300 (MRD-92-399). Exxon Biomedical Sciences, Inc. Lab. Project I.D. 139910B. July 14, 1994.

Carl D'Ruiz

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OTC Vol. No. 101

OTC Docket Number 75N-0183 (triclosan)
September 12, 1994

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Borzelleca, J.F., Frankos, V.H., Johnson, E.M., Jordan, W., Squire, R.A., and Weil, C. Portions of the Report of the Expert Panel on the Safety of Triclosan in Toothpaste and Oral Rinse Products. Environ Corporation Expert Panel Report. December 15, 1992.

Summary

On November 29, 1990 and April 5, 1991, ENVIRON Corporation, at the request of the Colgate-Palmolive Company, assembled a group of scientists, recognized as experts in a variety of disciplines (including toxicology, pathology, pharmacokinetics, irritation/sensitization reactions, risk assessment, biostatistics), to serve as an Expert Panel that would independently review the Triclosan toxicologic data base.

The following individuals comprised the Expert Panel and attended the aforementioned meetings:

Dr. Joseph F. Borzelleca, Medical College of Virginia, Richmond, VA.
Dr. Vasilios H. Frankos, ENVIRON Corporation, Arlington, VA.
Dr. E. Marshall Johnson, Jefferson Medical Collage, Thomas Jefferson University, Philadelphia, PA
Dr. William Jordan, Dermatology Research, Richmond, VA.
Dr. Robert A. Squire, The John Hopkins University School of Medicine, Baltimore, MD.
Mr. Carrol Weil, Carrol S. Weil, Inc., Pittsburgh, PA.

The charge to the Expert Panel was to review the Triclosan toxicologic database and the estimated human daily exposure to Triclosan from use of oral care products (i.e., toothpaste and mouthwash), advise on the adequacy of the toxicologic data, and evaluate the safety of Triclosan for its proposed oral care product use.

Summary

This amended report (includes results of Lucker study, Reference Number 94 and three developmental toxicity studies recommended by the Expert Panel; Mouse, Reference

Number 95; Rabbit, Reference Number 96; Rat, Reference Number 97) presents the findings of the Expert Panel on the safety of triclosan used in oral rinse and toothpaste products, and represents an independent review of the triclosan toxicologic database. It is based on reviews and discussions of the database by all members of the Expert Panel on triclosan. The Panel concluded that the data base on triclosan is substantial and indicates that triclosan is safe for its proposed use in toothpaste and oral rinse products. This conclusion is based on large margins of safety between levels of human exposure and levels found to be without adverse effect (NOAEL) in animals.

Introduction

Triclosan (2,4,4'-trichloro-2'-hydroxydiphenyl ether or Irgasan DP 300), an antimicrobial agent, has been used extensively for 30 years in consumer products, principally in deodorants, soaps, and other dermatological preparations. Recently, the use of triclosan has been extended to oral health care products such as dentifrices. Safety data, both clinical and preclinical, is available in the literature, in a database submitted to the Antimicrobial I OTC Review Panel (Ciba-Geigy) and in a database generated by the Colgate-Palmolive Company (Reference No. 102).

The Colgate-Palmolive Company has developed Irgacare MP (triclosan) toothpaste and oral rinse for control of dental plaque. Irgacare MP toothpaste and oral rinse are formulated with pharmaceutical-grade triclosan, 2,4,4'-trichloro-2'-hydroxydiphenyl ether, manufactured by Ciba-Geigy Corporation for oral-care applications.

Irgacare MP toothpaste and oral rinse products are intended to inhibit formation of dental plaque through the antimicrobial action of its active ingredient, Irgacare MP (triclosan). Experts in oral care agree that inhibition of plaque is a highly promising approach to control of gingivitis, as well as to more severe forms of oral inflammatory disease.

Irgacare MP is a thoroughly characterized, effective nonionic antibacterial agent. It has excellent activity against both aerobic and anaerobic gram-positive, as well as gram-negative oral pathogens. When properly formulated into oral care products, it is retained well by plaque matrix and by oral mucous, achieves high salivary levels, and exhibits excellent antibacterial activity.

Unlike cationic antimicrobials which stain teeth, impair taste sensation and react with anionic surfactants, Irgacare MP leaves teeth free of stain. It is compatible with anionic formulation components and, in properly selected concentrations, has no adverse effect on taste. Thus, it offers distinct advantages over currently available plaque-inhibiting agents for formulation into effective and well-tolerated oral care products.

The terms Irgacare MP and triclosan are used interchangeably to describe the drug substance. Throughout its 30 year commercial history, triclosan was the name used most

often by Ciba-Geigy to denote this material in research reports, regulatory documents, and promotional activities. The term Irgacare MP was adopted during 1989 by Ciba-Geigy to denote the pharmaceutical grade of triclosan, which is manufactured and distributed specifically and solely for use in oral care products. Irgacare MP is distinguished from triclosan only by its more rigorous manufacturing and purity standards. They are otherwise identical.

After 30 years of worldwide use in dozens of consumer products, Irgacare MP (triclosan) has achieved an outstanding record of human safety with an estimated worldwide distribution of some 30 billion units. In recent years, Colgate-Palmolive and other manufacturers have utilized the antibacterial activity of Irgacare MP in selected oral care products. Since November 1989, Colgate toothpaste containing 0.3 percent Irgacare MP has been available to consumers in the United Kingdom, Australia, Greece, Denmark, and Italy. In the United Kingdom and Italy, toothpastes containing 0.2 percent Irgacare MP have been marketed by other manufacturers for more than three years.

In addition to this very large consumer experience and favorable safety record, Irgacare MP has been extensively studied in standard animal toxicity models and in human safety studies by Ciba-Geigy Corporation and Colgate-Palmolive Company. These studies have been reported in subjects which have received Irgacare MP for up to 13 weeks in Colgate-sponsored clinical trials of oral care products.

After review of this long record of safe use in consumer products, safety and efficacy in clinical trials, and excellent safety margins in comprehensive animal studies, the European Community Toxicology Board approved 0.3 percent Irgacare MP for use in cosmetic and oral care products, including toothpastes and oral rinses. In the United States, Irgacare MP toothpaste is presently under active investigation for control of plaque and gingivitis under Colgate-Palmolive Company IND 30,095.

Estimates of the expected adult human exposure to triclosan from oral hygiene products can be made based on four daily uses of toothpaste and twice daily use of oral rinse. Each brushing employs 1 gram of toothpaste (containing 3 mg of triclosan per gram of toothpaste) and each rinsing consists of 15 milliliters of oral rinse (containing 300 µg triclosan per milliliter rinse). This exposes the user to approximately 21 milligrams of triclosan applied daily to the oral cavity. It is estimated that 20 percent may be retained following expulsion of the residues of brushing and rinsing. If the average 70 kilogram adult then retains 4.2 milligrams of triclosan, the estimated exposure is 0.060 mg of triclosan per kilogram body weight on a daily basis (0.060 mg/kg/day). Likewise an estimate of the expected exposure to triclosan from oral hygiene products for children (under 6 years of age) can be made. However, children of this age group would be expected to brush only twice daily with one gram of toothpaste (Reference No. 101) containing 3 mg triclosan per gram of toothpaste, and not use the oral rinse product. Furthermore, children under 6 years of age have been observed to ingest approximately 25 percent of the toothpaste employed in brushing rather than expel the residues of brushing (Reference No. 101). Therefore, a child

(body weight of 20 kilograms) is exposed to 6 milligrams of triclosan applied daily to the oral cavity. If 25 percent of this amount is ingested, the average 20 kilogram child then retains approximately 1.5 milligrams of triclosan, and the estimated exposure is 0.075 mg of triclosan per kilogram body weight on a daily basis (0.075 mg/kg/day).

In addition, triclosan is contained in a variety of dermally-applied products. In conducting a safety assessment for triclosan, it is important to consider anticipated total exposure from all products containing triclosan and not just the amount contributed from use of toothpaste and oral rinse alone. ENVIRON conducted an exposure assessment for dermally-applied products containing triclosan (soaps; deodorants; face, hand, and body preps; foot deodorants/powders; surgical scrubs) and this assessment is attached as Appendix II.

The use of the aforementioned triclosan-containing products is almost exclusively limited to the adult population and not children. Therefore, estimates of dermal exposure will be applied only to estimates of total exposure to triclosan in adults and not to total triclosan exposure estimates for children. As reported in Appendix II, the most likely and upper bound estimates of triclosan exposure using the best available information on the extent of exposure from dermally-applied products is 0.013 mg/kg/day and 0.048 mg/kg/day, respectively. Addition of the upper bound estimate of triclosan exposure (from dermal product uses) to the estimate of exposure from use of oral hygiene products, results in a total adult exposure from all products containing triclosan of 0.108 mg/kg/day. Exposure to triclosan for children under 6 years of age remains at 0.075 mg/kg/day as a result of their infrequent use of triclosan-containing dermal products. These estimates of daily exposure to triclosan were used in the evaluation of the margin of safety associated with the use of triclosan in oral hygiene products.

**REPORT OF THE EXPERT PANEL
ON THE SAFETY OF TRICLOSAN
IN TOOTHPASTE AND
ORAL RINSE PRODUCTS**

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PREFACE

On November 29, 1990 and April 5, 1991, ENVIRON Corporation, at the request of the Colgate - Palmolive Company, assembled a group of scientists, recognized as experts in a variety of disciplines (including toxicology, pathology, pharmacokinetics, irritation/sensitization reactions, risk assessment, biostatistics), to serve as an Expert Panel that would independently review the Triclosan toxicologic data base.

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Dr. E. Marshall Johnson, Jefferson Medical College, Thomas Jefferson University, Philadelphia, PA.

Dr. William Jordan, Dermatology Research, Richmond, VA.

Dr. Robert A. Squire, The Johns Hopkins University School of Medicine, Baltimore, MD.

Mr. Carrol Weil, Carrol S. Weil, Inc., Pittsburgh, PA.

The charge to the Expert Panel was to review the Triclosan toxicologic database and the estimated human daily exposure to Triclosan from use of oral care products (i.e., toothpaste and mouthwash), advise on the adequacy of the toxicologic data, and evaluate the safety of Triclosan for its proposed oral care product use.

Prior to the November 29, 1990 meeting, panel members received ENVIRON summaries of toxicity study reports covering acute, subchronic, and chronic toxicity as well as reproductive, genetic, and clinical toxicity data and metabolism/pharmacokinetic study data. The ENVIRON summaries were designed to provide an initial review of the database for panel participants and are included in this report as Appendix I.

SUBCHRONIC TOXICITY STUDIES

The subchronic toxicity of triclosan has been evaluated in numerous animal studies (Reference Nos. 17-32, 52) employing several species (i.e., rats, mice, rabbits, dogs, baboons, and rhesus monkeys) and routes of administration (i.e., oral gavage, oral diet, dermal, inhalation). In total, the available data adequately characterize the subchronic toxicity of triclosan.

The toxicity elicited following administration of triclosan varied by the route of administration and more importantly, by species with the mouse, dog, and rabbit being most susceptible to toxic effects of triclosan followed by the rat and the baboon. In general, toxicity was primarily limited to hepatic effects with minimal renal and hematopoietic changes noted in several species. The baboon, however, exhibited only emesis and diarrhea following administration of triclosan for 52 weeks, at dosages higher than those eliciting systemic toxicity in other species.

A 90-day dietary feeding study employing rats administered dosages of triclosan of 0, 1000, 3000, and 6000 ppm (approximately 100, 300, and 600 mg/kg/day) was conducted and served as the range-finding study for a subsequent 2-year chronic toxicity/carcinogenicity study in rats. The Panel concluded that body weight changes (i.e., decreases) along with compound-related alterations in the liver at the mid and high dosage levels supported the selection of 3000 ppm as the high dosage level (MTD) for the subsequent 2-year carcinogenicity study in the rat. Furthermore, the Panel agreed that current guidelines on selection of the maximum tolerated dose, support the concept that "the MTD is a predicted value derived from observed toxicities in subchronic or range-finding studies. Based on this principle, if the highest dose was predicted from observed toxicities in subchronic studies, but adaptation occurred during chronic exposure to negate these toxic effects, then the chronic study would still meet scientific standards, and, thereby, would not need to be repeated because of an absence of an MTD" (Reference No. 106).

Current guidelines (Reference No. 103) suggest that the high-dose level of carcinogenicity studies, "should be sufficiently high to elicit signs of minimal toxicity without substantially altering the normal life-span of the animals due to effects other than tumors. Signs of toxicity are those that may be indicated by alterations in serum enzyme levels or slight depression of body weight gain (less than 10 percent)." The aforementioned 90-day range-finding study demonstrated decreases in mean body weight gain of 1,3,5 and 7% in mid-dose (3000 ppm) males and 1,7,12 and 20% in mid-dose females at weeks 1,3,6, and 12 of the study. High-dose (6000 ppm) males demonstrated decreases in mean body weight gains of 43, 19, 24, and 20% at weeks 1,3,6, and 12 of the study, while females (6000 ppm

level) demonstrated 47, 32, 31, and 34% depressions in mean body weight gain at the same body weight measurement periods. All high-dose body weight gain changes were statistically significant ($p < 0.01$) when compared to control group data (see Appendix III).

Furthermore, an independent pathology working group (PWG) review (see Appendix IV) revealed a high incidence of hepatic centrilobular hypertrophy in rats of the mid-dose group (3000 ppm), an incidence which was similar to that identified in the high-dose group. The PWG and Expert Panel both concluded that the 3000 ppm dose was the appropriate choice for the MTD in the 2-year carcinogenicity study based on median depressions of body weight gain (males, 4%; females, 9% of control) and the presence of histopathological lesions, which although not life threatening, were consistent with hepatic microsomal enzyme induction, and therefore sufficient to realize any carcinogenic potential. It is clear that the intent of current guidelines on selection of the maximum tolerated dose (MTD) was met. Minimal toxicity (i.e., depressions of body weight gain and hepatic changes) was elicited which could be predicted to not substantially alter the life-span of the animals. A concentration of 6000 ppm resulted in median body weight depressions of 22% and 33%; considered to be excessive for a lifespan study. This prediction was substantiated by the chronic toxicity/carcinogenicity study body weight gain data (measured at 52 weeks) which revealed median weight gain depressions of 3% and 12% of male and female controls at 3000 ppm and of 12% and 28% of male and female controls at 6000 ppm.

In summary, the Panel found that the subchronic studies database adequately characterized the subchronic toxicity of triclosan and appropriately supported the experimental design, including dose level selection, of subsequent chronic bioassays.

CHRONIC TOXICITY

Triclosan was administered to male and female Sprague-Dawley rats in the diet, at concentrations of 0, 300, 1000, and 3000 ppm for 13, 26, 52, 78, and 104 weeks (Reference No. 33). An additional group of rats was administered triclosan in the diet at a concentration of 6000 ppm for 52 weeks. The average daily intake (mg/kg/day) of triclosan on a body weight basis approximated 0, 16, 52, 168, and 418 mg/kg/day for males and 0, 20, 67, 218, and 532 mg/kg/day for females receiving 0, 300, 1000, 3000, and 6000 ppm triclosan in the diet, respectively. Sixty rats/sex/dose level received triclosan in the diet (0, 300, 1000, 3000 ppm) for the 2-year period while 5 or 10 additional rats/sex/dose level were administered triclosan for 13, 26, 52 or 78 weeks. The 6000 ppm dose level contained 20 rats/sex which were treated for one year.

There were no treatment-related effects on mortality during the course of the study, nor were there any overt clinical signs of toxicity observed which could be considered directly related to treatment. Dose-related changes were observed in mean body weight gain, as well as select hematology, clinical chemistry, and urinalysis parameters at various time periods post treatment, mainly in the 3000 and 6000 ppm dosage groups. Statistically significant decreases in mean body weight gain ($p < 0.05$) were observed in high-dose (6000 ppm) males and mid- and high-dose females throughout the study period (see Appendix III). Like previously conducted subchronic studies, toxicity was mainly hepatic in nature as identified by centrilobular hypertrophy and associated clinical chemistry changes.

In order to further define non-neoplastic and any potential preneoplastic changes in the study, an independent pathology working group (PWG) was assembled. The PWG reviewed select hepatic and pulmonary lesions identified in rats of all dosage levels (0, 300, 1000, 3000 and 6000 ppm). The PWG reported (see Appendix IV) that centrilobular hypertrophy was found in the 3000 and 6000 ppm dose level males and the 6000 ppm dose level females sacrificed at 52-weeks of the study. No hepatic putative preneoplastic or neoplastic lesions were found in increased incidences in any treatment group. In animals administered triclosan for 2-years (0, 300, 1000 and 3000 ppm), some non-neoplastic lesions (i.e., hepatocellular lesions-eosinophilic foci, zonal necrosis, focal necrosis, and cystic degeneration; pneumonitis of the lung) were increased in incidence in some-groups of treated rats, but none were dose-related nor increased in severity from those found in controls. The PWG found no evidence of any non-neoplastic, preneoplastic, or neoplastic lesions related to administration of triclosan. This substantiates the conclusion of the authors of the chronic toxicity report that the highest concentration of triclosan fed for two years, 3000 ppm, produced no evidence of carcinogenic effects.

In summary, the Panel found no evidence in the chronic studies to suggest a carcinogenic effect related to triclosan. Appropriate dose level selection (MTD) was based upon decreases in mean body weight gain (Appendix III) and the presence of compound - related histopathological lesions in a properly designed subchronic toxicity study. These conclusions were further confirmed by an independent pathology working group (Appendix IV). A NOAEL of 1000 ppm (approximately 52 mg/kg/day) was identified in the study.

GENETIC TOXICITY STUDIES

Triclosan was tested for mutagenic and genotoxic potential in numerous *in vitro* and *in vivo* assays employing bacterial, mammalian cell culture, and mouse DNA systems (Reference Nos. 37-51, 105). Only two tests demonstrated weak positive responses (i.e., genetic activity in MP-1 *S. cerevisiae*; mammalian spot test), which upon repetition were negative. In sum, triclosan produced negative results in all of the tests that measure actual mutagenicity or chromosomal breakage. Although several studies did not meet current GLP requirements, the Panel concluded that the current battery of genetic toxicity tests supports the conclusion that 1) triclosan is not genotoxic, and 2) the genetic toxicity database supports the lack of carcinogenic effect found in the rat chronic bioassay. The Panel however, recommended conduct of an Ames test and an unscheduled DNA synthesis (UDS) assay employing current protocols. These studies are currently in progress.

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APPENDIX C - C.V.s

D. G. Goodman, Chairperson

J. M. Cullen, Participant

P. M. Newberne, Participant

R. A. Squire, Participant

J. M. Ward, Participant

R. M. Sauer, Reviewing Pathologist

DAWN G. GOODMAN

EDUCATION:

Postdoctoral Fellowship Certificate in
Comparative Pathology, Johns Hopkins
University School of Medicine, 1972;
V.M.D. University of Pennsylvania, 1969;
B.S., George Washington University, 1965.

**BOARD
CERTIFICATION:**

Diplomate, American College of Veterinary
Pathologists, 1974.

EXPERIENCE:

1983 - Present	President and Senior Pathologist PATHCO, Inc Gaithersburg, Maryland.
1983 - 1985	Consulting Pathologist.
1982 - 1989	Adjunct Assistant Professor, Department of Pathology, University of Maryland School of Medicine, Baltimore, Maryland.
1981 - 1983	Associate Scientist and Senior Pathologist, Clement Associates, Inc., Arlington, Virginia
1980 - 1986	Lecturer, Neoplasms of Mice, Course on Pathology of Laboratory Animals, Armed Forces Institute of Pathology (AFIP), Washington, D.C.
1978 - Present	Visiting Lecturer in Comparative Medicine, Johns Hopkins University School of Medicine, Baltimore, Maryland.
1978 - 1986	Lecturer in Pathology, Johns Hopkins University School of Medicine, Baltimore, Maryland.
1978 - 1981	Director of Pathology, Clement Associates, Inc., Washington, D.C.
1978 - 1980	Lecturer, Graduate School, Foundation for Advanced Education in the Sciences, National Institutes of Health (NIH), Bethesda, Maryland.



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1977 - 1978 Veterinary Pathologist, Tumor Pathology Branch, Carcinogenesis Testing Program, Division of Cancer Cause and Prevention (DCCP), National Cancer Institute (NCI), NIH, Bethesda, Maryland.

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1975 - 1976 Veterinary Pathologist, Tumor Pathology Section, EPB, CP, DCCP, NCI, NIH, Bethesda, Maryland.

1974 - 1975 Director of Animal Disease Investigation Services, Comparative Pathology Section, Veterinary Resources Branch (VRB), Division of Research Services (DRS), NIH, Bethesda, Maryland.

1972 - 1975 Veterinary Pathologist, VRB, DRS, NIH, Bethesda, Maryland.

1972 U.S. Public Health Service (USPHS), NIH Special Research Fellow, Department of Pathology, Johns Hopkins University School of Medicine, Baltimore, Maryland.

1969 - 1972 USPHS Postdoctoral Fellow in Comparative Pathology, Johns Hopkins University School of Medicine, Baltimore, Maryland.

INDEPENDENT CONSULTATIONS:

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MEMBERSHIPS:

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American Association for the Advancement of Science
American Veterinary Medical Association
Association for Women Veterinarians
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Memberships (continued)

United States and Canadian Academy of Pathology
Mid-Atlantic Comparative Pathology Colloque
Society of Toxicologic Pathologists
Society of Toxicology
Veterinary Cancer Society

HONORS AND AWARDS:

Society of Phi Zeta (Veterinary Honor Society) - University of Pennsylvania

USPHS, NIH Special Research Fellowship (Canine Mammary Tumors)

COMMITTEES AND PROFESSIONAL ADVISORY ACTIVITIES:

Chairman, Subcommittee on Liver, Standardized System of Nomenclature and Diagnostic Criteria Committee, Society of Toxicologic Pathologists, 1989-Present

Pathology Working Group, National Toxicology Program, National Institute of Environmental Health Sciences (NIEHS), 1980-Present

Expert witness on carcinogenicity of PCB's, 1988

Chairman, Liaison Committee on Federal Regulations, American College of Veterinary Pathologists, 1979-1985

Workshop on Proliferative Lesions of the Rat Liver, National Toxicology Program, NIEHS, 1983

Expert witness on Carcinogenicity of TCDD and Silvex, Environmental Protection Agency Hearing to ban use of pesticides TCDD and Silvex, 1979

Participant, Mouse Liver Workshop, Environmental Protection Agency, 1980

Head, Pathology Working Group, Carcinogenesis Testing Program (CTP), DCCP, NCI, 1976-1978

Data Evaluation Group, CTP, DCCP, NCI, 1976-1978

Experimental Design Group, CTP, DCCP, NCI, 1976-1978

Committees (continued)

PHS Career Development Committee for Veterinarians OAM/PHS, DHE
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PUBLICATIONS:

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Sauer, R.M. Pathology Working Group Report on 2,3,7,8-
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Study in Sprague Dawley Rats. Pathology Review Participants:
Sauer, R.M., Brown, W.R., Maronpot, R.R., Newberne, P.M., Popf
J.A., Ward, J.M., and Goodman, D.G. Submitted to the Maine
Scientific Advisory Panel. March 13, 1990.

Sauer, R.M., and Goodman, D.G., (1990). Hepatotoxicity in Female
Sprague Dawley Rats Treated with 2,3,7,8-Tetrachlorodibenzo-p-
dioxin (TCDD). April 27, 1990.

Sauer, R.M., and Goodman, D.G. Hepatotoxicity in Female Sprague
Dawley Rats Treated with 2,3,7,8-Tetrachlorodibenzo-p-dioxin
(TCDD). 13-Week Subchronic Toxicity Study, June 8, 1990.

STUDY SETS:

Goodman, D.G., Bates, R.R., Ward, J.M., Frith, C.H., Sauer, R.M.,
Jones, S.J., Strandberg, J.D., Squire, R.A., Montali, R.J., and
Parker, G.A. Common Lesions in Aged B6C3F1 (C57BL/6Nx -
C3H/HeN)F1 and BALB/cStCr1(FC3H/Nctr Mice. Registry of
Veterinary Pathology, AFIP (1981)

Goodman, D.G., Anver, M.R., Ward, J.M., Sauer, R.M., Boorman,
G.A., Bates, R.R., Strandberg, J.D., Squire, R.A., Ines, G.D.,
Reznik, G., Parker, G.A., and Jones, S.R. Chemically Induced
Unusual Lesions in Rats. Registry of Veterinary Pathology, AFIP
(1984)

Goodman, D.G., Anver, M.R., Ward, J.M., Sauer, R.M., Strandberg J.D., Ines, G.D., Parker, G.A., Seely, J.C. Hildebrandt, P.K. Uriah, L., Experimentally Induced and Unusual Lesions in Mice. Registry of Veterinary Pathology, AFIP (In preparation).

PRESENTATIONS:

What a Toxicologic Pathologist Does. Division of Comparative Medicine Seminar, Johns Hopkins University School of Medicine (November 1988)

The Role of a Consultant in Safety Evaluation - Responsibility Industry and Government. General Principles in Toxicology and Toxicologic Pathology. Sponsored by Department of Pathology. Boston University School of Medicine, (August 1988)

The Role of a Consultant in Toxicology - Responsibility to Industry and Government. General Principles in Toxicology and Toxicologic Pathology. Sponsored by Department of Pathology. Boston University School of Medicine, (August 1987)

Observer Bias in Histopathologic Evaluation. Interdisciplinary Discussion Group on Carcinogenicity Studies, Sponsored by International Life Sciences Institute-Nutrition Foundation (June 1986)

Principles of Carcinogenesis/Comparative Aspects of Mammary and Liver Neoplasms in Rodents. Division of Comparative Medicine, Johns Hopkins University School of Medicine (January 1986)

Design and Interpretation of Carcinogenesis Bioassays. U.S. Department of Agriculture Continuing Education Program on Risk Assessment (October 1983)

Neoplasms of the Female Reproductive Tract. Seminar on Neoplasms in Mice. Sponsored by Intox Laboratories (June 1982)

Fundamentals of Carcinogenesis. D.C. Academy of Veterinary Medicine (January 1980)

Neoplastic Diseases of Rats and Mice. Course in Pathology of Laboratory Animals (AFIP) (August 1979)

Mammary Lesions in F344 Rats and B6C3F1 Mice. NCI Carcinogenesis Testing Program Workshop (June 1978)

Adrenal Lesions in F344 Rats. NCI Carcinogenesis Testing Program Workshop (June 1978)

**Mammary Carcinogenesis in Rodents--Viral and Chemical Etiology
Mid-Atlantic Comparative Pathology Colloquy (January 1978)**

**Animal Models for Cancer Research. 105th Annual Meeting of the
American Public Health Association (October 1977)**

**Neoplastic Diseases of Mice. Course in Pathology of Laboratory
Animals (AFIP) (September 1977)**

**Tumors of Rats and Mice. Veterinary Resources Branch Seminar,
(July 1977)**

**Animal Models in Cancer Research. USPHS Professional Association
Annual Meeting, San Francisco (April 1977)**

**Bioassay Program. Division of Laboratory Animal Medicine, Johns
Hopkins Hospital (January 1976)**

**New Zealand Mice as an Animal Model for Systemic Lupus
Erythematosus. National Capital Area Branch Association for
Laboratory Animal Science (September 1975)**

**Spontaneous Tumors in Mice. Interagency Collaborative Group on
Environmental Carcinogenesis (September 1975)**

**Spontaneous Tumors in Mice and Rats. Course in Pathology of
Laboratory Animals Course (AFIP) (September 1975)**

**Hepatic Nodule in a Rhesus Monkey. Primate Pathology Workshop
(March 1975)**

**Spontaneous Tumors in Mice. Course in Pathology of Laboratory
Animals (AFIP) (September 1974)**

**Uremic Myocarditis in a Rhesus Monkey. Primate Pathology Workshop
(March 1974)**

**Simian Hemorrhagic Fever. Division of Laboratory Animal Medicine
Johns Hopkins University School of Medicine (January 1974)**



Dawn G. Goodman, V.M.D.

NCI Chemicals Reviewed In
Pathology Working Group/Data Evaluation Group
National Cancer Institute/National Toxicology
Program Carcinogenesis Technical Report Series:

TR NO.	CHEMICAL	TR NO.	CHEMICAL
12	Endrin	5	Proflavine
13	Tetrachlorethylene	6	Nitrilotriacetic Acid (NT)
16	Phosphamidon		Nitrilotriacetic Acid Tri
17	Photodieldrin	7	Phenformin
18	3,3'-Iminobis-1-Propanol Dimethanesulfonate (ester) Hydrochloride (IPD)	8	Chlordane
19	Procarbazine	9	Hepatochlor
21,22	Dieldrin	39	Lasiocarpine
23	Picloram	40	Hexachlorophene
24	Malathion	41	Chlorothalonil
25	Chloramben	42	5-Azacytidine
27	1,1,2,2-Tetrachlorethane	43	Emetine
29	2-Methyl-1-Nitroanthraquinone	45	Chlorpropanide
30	Diarylanide Yellow	46	Ethionamide
31	Tolbutamide	47	4,4'-Thiodianiline
32	Isophosphanide	48	Pyrazinamide
33	Tetrachlorvinphos	49	Acronycine
35	Methoxychlor	50	Acetohexamide
36	Anthranilic Acid	51	Tolazamide
4	Dimethoate	52	3-Nitropropionic Acid
		53	2-Amino-5-Nitrothiazole
		54	2,4-Dinitrotoluene
		11	

<u>TR NO.</u>	<u>CHEMICAL</u>	<u>TR NO.</u>	<u>CHEMICAL</u>
57	B-TGdR	82	N-Phenyl-p-Phenylenediamine
58	Thio-Tepa	83	Daminozide
59	Estradiol Mustard	84	2,4-Diaminoanisole Sulfate
60	Phenesterin	85	4-Chloro-m-Phenylenediamine
61	Pentachloronitrobenzene	88	1H-Benzotriazole
62	Endosulfan	89	o-Anisidine Hydrochloride
63	4-Chloro-o-Phenylenediamine	90	Dicofol
64	1-Nitronaphthalene	91	Clonitralid
66	1,1-Dichloroethane	92	Hydrazobenzene
67	Aspirin, Phenacetin, Caffeine	93	3-Amino-9-Ethylcarbazole Hydrochloride
68	Hexachloroethane	94	4-Amino-2-Nitrophenol
69	Azinphosmethyl	95	3-(Chloromethyl) Pyridine Hydrochloride
70	Parathion	96	Coumaphos
71	L-Tryptophan	97	Titanium Dioxide
72	Phenoxybenzamine Hydrochloride	98	dl-Menthol
73	Allyl Chloride	99	Phenzopyridine Hydrochloride
74	1,1,2-Trichloroethane	100	Cupferron
75	Chlorobenzilate	101	Formulated Fenamino-sulf
76	Tris (2,3-Dibromopropyl) Phosphate	102	3-Sulfolene
77	Pyrimethamine	103	Fenthione
78	ICRF-159	104	Anilazine
80	1,4-Dioxane	105	m-Cresidine
81	Trimethylphosphate		



<u>TR NO.</u>	<u>CHEMICAL</u>	<u>TR NO.</u>	<u>CHEMICAL</u>
106	Trichlorofluomethane	132	2,5-Dithiobiurea
107	5-Nitro-o-Toluidine	133	3-Nitro-p-Acetophenetide
108	Direct Blue 6, Direct Black 38, Direct Brown 95	139	Triphenyltin Hydroxide
109	4-Nitroanthianilic Acid	140	Pivalolactone
110	Iodoform	141	1-Phenyl-3-Methyl-5-Pyra:
111	1-Amino-2-Methylanthraquinone	142	p-Cresidine
112	3-Amino-4-Ethoxyacetanilide	143	1,5-Napthalenediamine
113	2-Chloro-p-Phenylenediamine Sulfate	144	2-Aminoanthraquinone
114	2,3,5,6, Tetrachloro-4-Nitroanisole	145	3-Chloro-p-Toluidine
115	Sulfallate	146	Nithiazide
116	p-Anisidine Hydrochloride	147	Mexacarbate
117	6-Nitrobenzimidazole	148	1-Phenyl-2-Thiourea
118	5-Nitroacenapthene	149	N,N'-Diethylthiourea
120	Piperonyl Butoxide	168	N-(1-Napthyl)Ethylenedia
124	Piperonyl sulfoxide	171	2,4-Dimethoxyaniline Hydrochloride
125	Dioxathion	38	Arochlor 1254
126	2-5-Toluenediamine Sulfate		
127	5-Nitro-o-Anisidine		
128	3,3'-Dimethoxybenzidine-4,4'-Diisocyanate		
129	Trimethylthiourea		
130	Aniline Hydrochloride		
131	DDT, TDE and p,p'-DDE		



Dawn G. Goodman, V.M.D.

**CHAIRPERSON FOR PWG'S
CONDUCTED FOR NTP**

Two Year Studies

Chlorendic Acid	Technical Report No. 304
4-vinylcyclohexene	Technical Report No. 303
Styrene Oxide	
t-Butanol	
Diallylphthalate	Technical Report No. 284
Nitrofurazone	Technical Report No. 337
Nalidixic Acid	Technical Report No. 368
Gamma-Butyrolactone	
Resorcinol (also 15 mo. Interim)	
Diphenylhydantoin	
C.I. Pigment Red 3	
2,4-Diaminophenol HCL	

90-Day Studies

Promethazine HCL
Methdilazine HCL
1-Amino-2,4-Dibromo-
Anthraquinone
4-Hydroxyacetanilide
t-Butanol
Acetone
6-Methoxy-2-
Benzothiazolamine
Pentachlorobenzene
Meta-Nitrobenzoic Acid
2-Hydroxy-4-Methoxybenzophenone
Antimony Potassium Tartarate
Psoralens (4 compounds)

Interim Sacrifice

t-Butanol
Ochratoxin A

CURRICULUM VITAE

John Michael Cullen, V.M.D., Ph.D.
Diplomate, American College of Veterinary Pathologists

Address:

611 East Olive Street
Apex, NC 27502
(919) 362-5675

Present Position:

Associate Professor
Department of Microbiology, Parasitology and Pathology
College of Veterinary Medicine
North Carolina State University
Raleigh, North Carolina 27606
(919) 829-4350

Birthdate: July 27, 1949

Education:

Ph.D., Comparative Pathology, University of California, Davis, 1985.
V.M.D., University of Pennsylvania, 1975.
A.B., Biology, University of Pennsylvania, 1971.

Experience:

1989 Associate Professor of Veterinary Pathology, College of
Veterinary Medicine, North Carolina State University
1984-89 Assistant Professor of Veterinary Pathology, College of
Veterinary Medicine, North Carolina State University
Additional Appointment:
1988- Toxicology Faculty, North State Carolina University
1983-84 Senior Resident in Anatomic Pathology, Veterinary Medical
Teaching Hospital, University of California, Davis
1979-83 Resident, Anatomic Pathology, School of Veterinary Medicine,
University of California, Davis
1976-79 Private practice, small animal clinician
1975-76 Intern, Angell Memorial Animal Hospital, Boston, Massachusetts

Teaching Experience

Veterinary Curriculum

- 1) General Pathology, VMM 831, 1984-present
- 2) Systemic Pathology, VMM 451, 1984-1986
- 3) Lab Animal Medicine, VMC 853, 1985-present

Graduate Curriculum

- 1) Advanced Histopathology, VMS 642, 1984-present, (Course Coordinator)
- 2) Systemic Pharmacology and Toxicology, VMS 562, 1984-present
- 3) Medical Virology, VMM 651, 1986-present

1981-83 Primary responsibility for Junior year clinic in Pathology.
Responsibilities included orientation, informal lecture, and
direct supervision of necropsy procedure.

03-09-90

Professional Consultant Activities:

Consultant to National Toxicology Program at National Institute of Environmental Health Sciences, Research Triangle Park, North Carolina, 1984-present

Consultant to U.S. Environmental Protection Agency (HERL) UVB Health Effects Research Committee, July 1988.

Consultant to Stanford University Laboratory Animal Medicine Facility, 1987.

Short-Term Consultant, Pan American Health Organization, Suriname, South America, 1987.

Academic Responsibilities:

Graduate Student Committees:

PhD - Steven Holladay

MS - Doris Fultz (chairman)
- Derek Norford (chairman)
- Christopher Bowie

Residency Program in Veterinary Pathology at North Carolina State University, responsible for candidate recruitment and selection, as well administration of the program.

Academic Committees: Admissions, Student conduct (Chairman), Committee on committees, Medical Records, Open House.

External Review, Ph.D. Thesis: Studies of the Pathogenesis, Toxicology and Pathology of lupinosis and associated conditions. Murdoch University, Western Australia, 1988.

Veterinary Licenses:

California, Massachusetts, North Carolina.

Board Certifications:

Diplomate, American College of Veterinary Pathology, 1982.

Society Memberships:

American Veterinary Medical Association
American College of Veterinary Pathologists
North Carolina Society of Toxicology
American Association for the Study of Liver Disease
North Carolina Veterinary Medical Society
American Association of Avian Pathologists

Academic Awards:

Phi Zeta Member, 1987

Teacher of the Year, Class of 1990, 1988

CURRICULUM VITAE
John M. Cullen
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Fields of Special Interest:

Hepatic Pathology
Animal models of viral hepatitis
Mycotoxicology

Grants Awarded:

Principal Investigator of "Combined effects of aflatoxin B₁ and chronic duck hepatitis B virus infection on the incidence of hepatocellular carcinoma ducks." 1984, \$3,900, Faculty Research and Professional Development Fund.

Principal Investigator of "The role of cell cycle in aflatoxin B₁ induced hepatic carcinogenesis." 1985, \$22,300, North Carolina State Research Fund.

Principal Investigator of "Interactions of multiple concurrent naturally occurring mycotoxin administration on toxin metabolism, tissue residues, growth rates and toxicity of chickens." 1986, \$15,300, North Carolina State Research Fund.

Principal Investigator of "The role of cell cycle in aflatoxin-B₁ induced hepatic carcinogenesis." 1986, \$9,200, North Carolina State Research Fund.

Co-Investigator of "Ultrastructural and immunocytochemical studies on pituitary lesions induced by 2-mercaptobenzimidazole." 1986, \$14,106, NIH.

Co-Investigator of "Infant and adult rat susceptibility to aflatoxins B₁ and M₁." 1986, \$7,000, California Dairy Council.

Principal Investigator of "Cyclopaizonic Acid induced skeletal muscle injury in broiler chickens." 1987, \$14,300, North Carolina State Research Fund.

Principal Investigator of "Acute DHBV infection in geese. A model of HB infection." 1987, \$4,000, United Way.

Principal Investigator of "An animal model of hepatitis B infection in geese." 1987, \$24,800, North Carolina Board of Science and Technology.

Principal Investigator of "Acute and chronic DHBV infection in geese." 1987, \$6,550, North Carolina State Research Fund.

Principal Investigator of "Delta hepatitis virus production in woodchuck hepatitis virus infected woodchucks." 1987, \$8,000, DuPont de Nemours.

Principal Investigator of "Production of monoclonal antibodies to delta hepatitis virus, a human pathogen grown in woodchucks." 1988, \$24,800, North Carolina Biotechnology Center.

Principal Investigator of "Determination of tissue distribution of the human pathogen delta hepatitis virus in infected woodchuck (Maromota monax) by immunohistochemistry and in situ hybridization." 1988, \$19,600, North Carolina State Research Fund.

CURRICULUM VITAE

John M. Cullen

Page 4

Publications:

- 1989 Cullen, J.M., Marion, P. L., Newbold, J.N. A sequential histologic and immunohistochemical study of duck hepatitis B virus infection in Pekin ducks. Vet Path 26:164-172.
- 1989 Cullen, J.M., Levine J. Babesia microti Infection of Syrian Hamsters. An animal Model of Human disease. Comp Pathol Bull (Animal Models) 21:3-4.
- 1989 Bunch, S.E., Metcalf, M.R., Crane, S.W., Cullen, J.M. Idiopathic pulmonary thromboembolism and pleural effusion in a dog. J Am Vet Med Assoc (In press).
- 1989 Wilson, M.E., Hagler, W.M. Jr., Cullen, J.M., Ort, J.F., Cole, R.J. A toxicity of cyclopiazonic acid in selected avian species. In: Biodeterioration Research 2, G.C. Llewellyn and C.E. O'Rear (Eds.) Plenum Publishing Co., New York. 2:371-381.
- 1989 Bristol, D.G., Cullen, J.M. Use of a linear stapling device to construct an inverted, triangulated, end to end anastomosis of the equine jejunum. Cornell Vet 79:217-230.
- 1989 Corbett, W.T., Liew-A-Joe, R., Hunter, L., Grindem, C., Levy, M., Cullen, J. Epidemiologic survey of bovine diseases in Suriname, South America Bulletin of PAHO 106:314-320.
- 1989 Cullen, J.M., Marion, P. L., Sherman, G.J., Newbold, J. Hepatic neoplasia in aflatoxin B₁ treated, congenital duck hepatitis B virus-infected and virus free Pekin ducks (Cancer Research, accepted with revisions).
- 1988 MacLachlan N.J., Cullen J.M. The liver and pancreas In: Thompson, R.G. (ed.). Special Veterinary Pathology, B.C. Decker Inc. Toronto, Canada.
- 1988 Newbold, J., Cullen, J.M. Experimental transmission and subsequent replication of Duck Hepatitis B virus in domestic geese. In: Viral hepatitis and liver disease, A. Z. Zuckerman (Ed.) Alan R. Liss Inc., New York. pp. 513-516.
- 1988 Cullen, J.M., Wilson, M.S., Hagler, W.M., Ort, J.F., Cole, R.J. Histopathology of cyclopiazonic acid administration to broiler chickens. Am J Vet Res 49:728-732.
- 1988 Cullen, J.M., Newbold, J., Marion, P. Acute severe hepatic injury in D₁ infected geese. In: Viral Hepatitis and Liver Disease. A. Z. Zuckerman (Ed.) Alan R. Liss Inc., New York. pp. 517-522.
- 1988 Vaden, S.L., Bunch, S.E., Duncan, D.E., Cullen, J.M. Hepatotoxicity associated with heartworm preventive medication in a dog. J Am Vet Med Assoc 192:651-654.
- 1988 Bristol, D.G., Cullen, J.M. A comparison of three methods of end to end anastomosis in the equine small colon. Cornell Vet 78:325-337.

CURRICULUM VITAE

John M. Cullen

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Publications (continued):

- 1988 Cohn, L.A., Spaulding, K.A., Cullen, J.M., Hardie, E.M., MacLachlan, N., Breitschwerdt, E.B. Hepatic postsinusoidal venous obstruction in a dog. (Accepted, J Vet Int Med).
- 1988 Greene, R.T., Levine, J.F., Breitschwerdt, E.B., Walker, R.C., Berkhoff, H.A., Cullen, J.M., Nicholson, W.L. Clinical and serologic evaluations induced Borrelia burgdorferi infection in dogs. J Am Vet Med Assoc 49:752-757.
- 1987 Cullen, J.M., Ruebner, B.H., Hsieh, L.S., Hyde, D.M., and Hsieh, D.P.H. Carcinogenicity of aflatoxin M₁ in male Fischer rats compared to aflatoxin B₁. Cancer Research 47:1913-1917.
- 1987 Cullen, J.M. and Levine, J.F. Pathology of experimental Babesia microti infection in the Syrian hamster (Mesocricetus auratus auratus). Lab Anim Sci 36:640-643.
- 1987 Cullen, J.M., Burkes, E.J., Ruebner, B. Oral neoplasms in Fischer rats. J Dental Res 16:210-214.
- 1987 Marion, P., Cullen, J.M., Robinson, W.S., Azcarraga, R., Van Davelaar, M.J. Experimental transmission of duck hepatitis B virus to Pekin ducks and to domestic geese. Hepatology 7:724-731.
- 1987 Brownie, C.F., Cullen, J.M. Characterization of experimentally induced equine leukoencephalomalacia (ELEM) in ponies (Equus caballus): Preliminary report. Vet Hum Toxicol 29:34-38.
- 1987 Ling, G., Lowenstine, L., Cullen, J., Ackerman, N., and Ruby, A. Chronic urinary tract infection in dogs: Induction by inoculation with bacteria via percutaneous nephropylotomy. Am J Vet Res 48:794-798.
- 1987 Tate, L.P., Newman, H.C., Cullen, J.M., Sweeney, C. Neodymium (Nd):YAG Laser Surgery in the Equine Larynx: A Pilot Study. Lasers in Surgery & Medicine 6:470-472.
- 1987 Cullen, J.M., Whiteside, J., Umstead, J., Whitaker, M. A mixed germ cell sex cord tumor in a horse. Vet Pathol 24:575-577.
- 1987 Ling, G., Lowenstine, L., Cullen, J., Ackerman, N., and Ruby, A. Experimentally induced chronic urinary tract infection in dogs, resulting from introduction of bacteria by percutaneous nephropylotomy. Am J Vet Res 48:851-854.
- 1986 Gregory, C.R., Cullen, J.M., Pool, R., Vasseur, P.B. The canine sacroiliac joint. Spine 11:1044-1048.
- 1986 Hsieh, D.P.H., Cullen, J.M., Hsieh, L.S., Shao, Y., Reuben B. Cancer risks posed by aflatoxin M₁. In: Diet Nutrition in Cancer. Y. Hayashi (ed) VNU Sci Press, Utrecht pp. 57-65

CURRICULUM VITAE
John M. Cullen
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Publications (continued):

- 1986 Kitchell, B., Strombeck, D., Cullen, J., and Harrold, D. Clinical and Pathological Changes in Experimentally Induced Acute Pancreatitis in Ca Am J Vet Res 47:1170-1173.
- 1986 Gregory C.R., Gourley, I.M., Taylor, N.J., Cullen, J.M., Evans, A., Fsa C.D., Cowgill, L.D. Experience with cyclosporin A after renal allografting in two dogs. Vet Surg 17:441-443.
- 1985 Ling, G., Cullen, J., Kennedy, P., Ruby, A. and D. Brooks. Relationshi of upper and lower urinary tract infection and bacterial invasion of uroepithelium to antibody coated bacteria test results in female dogs. Am J Vet Res 46:499-504.
- 1984 Hseih, B.P.H., Cullen, J.M., Ruebner, B. Comparative hepatocarcinogeni of Aflatoxins B₁ and M₁ in one rat. Food Chem. Toxicol. 22:1027-1028.
- 1984 Couto, G., Cullen, J., Pedroia, U. and J. Turrell. Central nervous sys lymphosaroma in dogs. J Am Vet Med Assoc 184:809-813.
- 1983 Wong, M., Pedersen, N. and J. Cullen. Dirofilariasis in cats. JAAHA 19:855-864.
- 1980 Ricklefs, R.E., White, S.C., and Cullen, J. Postnatal development of Leach's Storm Petrel. Auk 97:768-781.
- 1980 Ricklefs, R.E., White, S.C., and Cullen, J. Energetics of postnatal growth in Leach's Storm-Petrel. Auk 97:566-575.

Abstracts:

- 1987 Cullen, J.M., Burkes, E.J., Ruebner, B.H. Oral neoplasms in fischer ra J Dental Res 66:644.
- 1987 Norford, D., Cullen, J.M., Meuten, D.J. Effects of 3-MBI in the pituit of Fischer rats. American College Vet Pathol Annual Meeting. Monterey, California.
- 1987 Cullen, J.M., Newbold, J., Marion, P.L. Histopathology of acute severe liver injury in domestic geese infected with DHBV. Med Virol 96:475.
- 1987 Coffey, M.T., Hagler, W.M., Cullen, J.M., Jones, E.E. Effect of multip mycotoxin contamination on the performance of swine. Annual Meeting of American Society of Animal Science. Utah State University July 1987.
- 1987 Coffey, M.T., Hagler, W.M., Cullen, J.M. The effect of L-Lysine and DL-methionine supplimentation on the response of weanling pigs to mycotoxin contaminated corn. J Anim Sci 66(Suppl 1):45.
- 1986 Cullen, J.M., Wilson, M., Hagler, W., Ort, J., Cole, R.J. Histopatholc of cyclopiazonic acid to broiler chicks. Poultry Science Assoc. Annua Meeting, August 1986, Raleigh, North Carolina.

PAUL MEDFORD NEWBERNE

BORN: November 4, 1920; Adel, Georgia

TITLE: Professor of Nutritional Pathology

Academic Degrees:

<u>D.V.M.</u>	Auburn University, Auburn, Alabama (Veterinary Medicine)	1950
<u>M.Sc.</u>	Auburn University, Auburn, Alabama (Veterinary Medicine)	1951
<u>Ph.D.</u>	Missouri University, Columbia, Missouri (Nutritional Biochemistry with minor in Human Pathology)	1958

APPOINTMENTS AND EXPERIENCE:

1950-1951	Instructor, Veterinary Pathology, Auburn University Auburn, Alabama
1951-1954	Director, Research and Diagnostic Laboratories, Jessa, Inc., Columbus, Georgia
1954-1956	Instructor, Veterinary Microbiology, School of Veterinary Medicine, Missouri University, Columbia, Missouri
1956-1958	Instructor, Agricultural Chemistry, Missouri University, Post-doctoral Fellowship, National Institute of Neurological Disease and Blindness, National Institutes of Health, Bethesda, Maryland
1958-1962	Animal Pathologist and Professor, Auburn University, Agricultural Experiment Station and School of Agriculture, Auburn, Alabama
1962-1965	Associate Professor, Nutritional Pathology, Department of Nutrition and Food Science, Massachusetts Institute of Technology, Cambridge, Massachusetts
1965-1984	Professor, Nutritional Pathology, Department of Applied Biological Sciences, Massachusetts Institute of Technology, Cambridge, Massachusetts
1984-	Professor Emeritus/Senior Lecturer, Department of Applied Biological Sciences, Massachusetts Institute of Technology, Cambridge, Massachusetts

APPOINTMENTS AND EXPERIENCE (CONT'D)

1984- Professor of Pathology, Boston University School of Medicine, Boston, Massachusetts

1985- Research Pathologist, Special Scientific Staff, Boston City Hospital and Mallory Institute of Pathology

MILITARY SERVICE:

1942-1945 (Navy) Naval aviator, discharged as Lieutenant

PROFESSIONAL AFFILIATIONS AND MEMBERSHIPS: PAST/PRESENT

Member, Board of Trustees, Forsyth Dental Center
New England Branch, American Association of Laboratory Animal Science
Teratology Society
American Academy of Clinical Toxicology
American Institute of Nutrition
American Society for Experimental Pathology
Society of Toxicology
New England Society of Pathologists
Massachusetts Pathology Society
American Veterinary Medical Association
American College of Veterinary Pathologists (Past President)
Editorial Board, Toxicology and Applied Pharmacology
Editorial Board, Cornell Veterinarian
Editorial Board, Journal of Environmental Pathology and Toxicology
Editorial Board, Cancer Detection and Prevention
Editorial Board, Nutrition Reports International
Editorial Board, American Journal of Veterinary Research
Editorial Board, Food and Chemical Toxicology
Editorial Board, Merck Veterinary Manual
Editorial Board, Drug-Nutrient Interactions
Editorial Board, Cancer Research (Associate Editor)
Editorial Board, Journal of Nutrition
Editorial Board, Fundamental and Applied Toxicology
Editorial Board, Journal Environmental Pathology, Toxicology, and Oncology
Editorial Board, Journal of Nutritional Biochemistry

Phi Kappa Phi
Omicron Delta Kappa
Gamma Sigma Delta
Phi Zeta
Cosmos Club

MEDICAL CERTIFICATION:

American College of Veterinary Pathologists, Diplomate, Former President
American Board of Toxicology, Certified Diplomate, Former Treasurer

HONORS AND AWARDS:

National Cancer Institute Research Career Award
E.A. Davis award for excellence in Clinical Small Animal Medicine
Cutler Fellowship for post-doctoral study in Animal Pathology
Post-doctoral Fellow, National Institute of Neurological Disease and
Blindness
FAMA Award, Contributions to Livestock and Poultry Industry
Borden Award NIH/FASEB
Fellow American Institute of Nutrition

PUBLICATIONS:

See attached list

RESEARCH AND TEACHING INTERESTS:

Pathology and biochemistry of diseases of nutritional origin particularly liver and gastrointestinal tract; nutritional carcinogenesis; food safety evaluation; nutritionally induced congenital abnormalities; nutritional toxicology and immunology; environmental toxicology; drug nutrient interactions. Teaching interests in the field of nutritional pathology, comparative pathology, drug safety; toxicology and food-borne diseases. For the past twenty years, advisor to more than 40 graduate students and 100 undergraduate students at Auburn University and at Massachusetts Institute of Technology. In 1962 organized teaching and research program in general area of food, nutrition and disease and how these interact in biological systems. Formal courses or seminars are taught including Diseases of Nutrition and Metabolic Origin, Comparative and Toxicologic Pathology and Nutritional Carcinogenesis. Actively engaged in research in nutritional biochemistry, pathology and toxicology.

DEPARTMENTAL AND INSTITUTE RESPONSIBILITIES:

Departmental
Carcinogenesis Hazards Committee

Institute
Preprofessional Advisory Committee
Animal Care Committee
Mallory Institute of Pathology Animal Facilities, Director

CONSULTANT TO:

American Cancer Society,
National Committee, Cancer Detection and Prevention
Federation, American Societies Experimental Biology (FASEB)
Committee, Health Aspects of Sugar Alcohol and lactose
FASEB-Conference on Tricothecenes (Chairman National Institutes of Health)
National Institute of Environmental Health Sciences on
Environmental Carcinogenesis
National Institute of Environmental Health Sciences, Second Task

Force on Human Health and the Environment, Safety of Foods
and Food Additives
National Cancer Institute, Nutrition and Cancer
National Heart and Lung Institute, Primates in Cardiovascular
Research
Nutrition Study Section (Past)
Animal Resources Advisory Board (Past)
Pathology Training Committee (Past)
National Toxicology Program, Peer Review Panel
Science Advisory Board, NCTR/FDA

National Academy of Sciences/National Research Council
Committee to Overview National Center for Toxicological Research
(NCTR) (Past)
Subcommittee on Pathology, NCTR (Chairman) (Past)
Committee on Laboratory Animal Diets (Chairman) (Past)
Food Protection Committee (Chairman) (Past)
Subcommittee on Toxicology (Past)
Committee on Food Irradiation (Past)
Committee on Clean Drinking Water (Past)
Subcommittee on Metalloids (Past)
Subcommittee on Nutrition (Past)
Committee on Guide to Care and Use of Laboratory Animals (Past)
Committee, Drinking Water and Health (Past)
Subcommittee, Contribution of Water to Human Mineral Requirements
(Chairman) (Past)

World Health Organization
Committee on Evaluation of Mycotoxins
Committee on Pesticides
Pathology of Nutritional Diseases

International Union Against Cancer - Vol. Hepatocellular Cancer,
1982; Nutrition and Cancer

International Union of Nutritional Sciences
Committee on Toxicology

Other

Armed Forces Institute of Pathology Veterinary and Comparative
Pathology
American Academy of Pediatrics Committee on Nutrition
National Association of Broadcasters Medical Advisory Board
Food and Drug Administration
Committee on Gastrointestinal Drugs
Subcommittee on Hepatotoxins
EPA Science Advisory Board
Committee, Airborne Carcinogens
Canadian Task Force, Environment and Cancer
WHO Committee on Liver Cancer
Thailand Advisory Environmental Toxicology Committee, Royal Thai
Government
Association of Medical Schools, Istanbul, Advisor for Research
Advisor, Chulabhorn Research Institute, Bangkok, Thailand

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3. Newberne, P.M.: Edema of the Glottis in the Chinchilla, Vet. Med. 47-51, 1951.
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5. Newberne, P.M.: Chinchilla Nutrition. The Auburn Veterinarian 8: 76-78, 1952.
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7. Newberne, P.M.: Scrotal Hernia in the Chinchilla, North American Veterinarian 33: 631, 1952.
8. Newberne, P.M.: Use of Estradiol Cyclopentylate (ECP) in Slow or Nonbreeding Chinchillas. Vet. Med. 47, October, 1952.
9. Newberne, P.M.: A Preliminary Report on the Blood Picture of the South American Chinchillas. J. A.V.M.A. 122: 221-222, 1953.
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BOOKS EDITED

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CHRONOLOGY OF EMPLOYMENT

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1976 - 1977 Chief, Carcinogen Bioassay and Program Resources Branch, Carcinogenesis Program, Division of Cancer Cause and Prevention, National Cancer Institute, Bethesda, Maryland.

1974 - 1976 Associate Chief, Experimental Pathology Branch, Carcinogenesis Program, Division of Cancer Cause and Prevention, National Cancer Institute, Bethesda, Maryland.

1973 - 1976 Head, Tumor Pathology Section, Carcinogenesis Program, Division of Cancer Cause and Prevention, National Cancer Institute, Bethesda, Maryland.

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- 1956 - 1960 Private Veterinary Practice, Fair Haven Animal Hospital, Fair, Haven, Vermont.

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SCIENTIFIC AND ADVISORY COMMITTEES

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1968 -1972	Chairman, Committee on Laboratory Animal Diseases, Institute of Laboratory Animal Resources, National Academy of Science, Washington, D.C.
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1971 - 1972	Chairman, Statutory Advisory Committee, Food and Drug Administration, Washington, D.C.
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1971 - 1973	Chairman, Medical Committee, Baltimore, Zoological Society.
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- 1982 Member, Four Nation Committee on the Evaluation
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- 1983 - 1984 Member, American Industrial Health Council Committee
on General Criteria for Assessing the Evidence
for Carcinogenicity of Chemical Substances,
Washington, D.C.
- 1983 Member, Panel of Experts, Rat Liver Tumor Workshop,
National Toxicology Program, Research Triangle
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BIBLIOGRAPHY

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Member, FDA Interagency Committee on Nitrite Research, 1978-1980.

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PUBLICATIONS:

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OTC Vol. No. 102

OTC Docket Number 75N-0183 (triclosan)
September 12, 1994

Ciba-Geigy Corporation
Chemicals Division
Greensboro, N.C. 27419

Goodman, D.G. Pathology Working Group Report on Triclosan Chronic Toxicity/Carcinogenicity Study in Sprague-Dawley Rats. Prepared by PATHCO, Inc. for Ciba-Geigy. January 23, 1990. Pathology Working Group members included: J.M. Cullen, D.G. Goodman, P.M. Newberne, R.M. Sauer, R.A. and Squire, J.M. Ward.

Summary and Conclusions of the Pathology Working Group Review

The Pathology Working Group (PWG) reviewed selected hepatic and pulmonary lesions found in Sprague-Dawley rats in a 52- and 104-week chronic toxicity/carcinogenicity study of triclosan. In the 52-week study, centrilobular hepatocellular hypertrophy was found at the top two dose levels in males and the highest dose in females. No hepatic putative preneoplastic or neoplastic lesions were found in increased incidences in any treated group. In the two-year study, some non-neoplastic lesions were increased in incidence in some groups of treated rats, but none were dose-related nor increased in severity from those found in controls. In the two-year study, the PWG review found no evidence of any lesions related to administration of triclosan.

75N-1834

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**PATHOLOGY WORKING GROUP
REPORT ON TRICLOSAN
CHRONIC TOXICITY/CARCINOGENICITY
STUDY IN SPRAGUE-DAWLEY RATS**

Submitted to:
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January 23, 1990

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	P. M. Newberne, Participant
	R. A. Squire, Participant
	J. M. Ward, Participant
	R. M. Sauer, Reviewing Pathologist

**TRICLOSAN TWO-YEAR CHRONIC
TOXICITY/CARCINOGENICITY STUDY**

PATHOLOGY WORKING GROUP (PWG)

SPECIES : Sprague-Dawley Rats

TYPE OF STUDY : Two-Year Chronic
Toxicity/Carcinogenicity Study

SPONSOR : Ciba-Geigy Corporation

LABORATORY : Ciba-Geigy Corporation

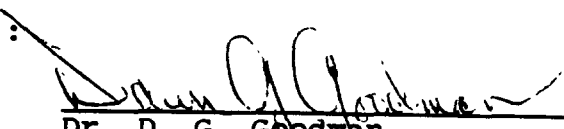
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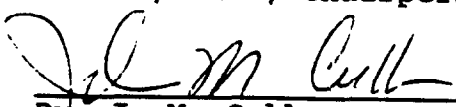
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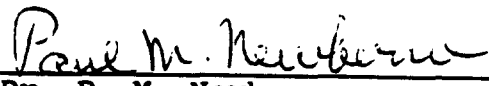
DATE OF PWG : December 20-21, 1990

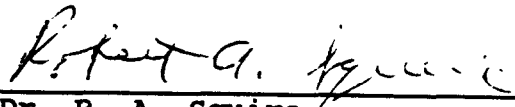
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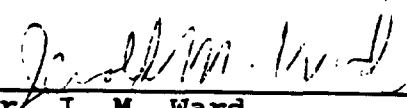
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**PATHOLOGY WORKING GROUP
REPORT ON TRICLOSAN CHRONIC
TOXICITY/CARCINOGENICITY STUDY
IN SPRAGUE-DAWLEY RATS**

**I. SUMMARY AND CONCLUSIONS OF THE PATHOLOGY WORKING GROUP
(PWG) REVIEW**

The PWG reviewed selected hepatic and pulmonary lesions found in Sprague-Dawley rats in a 52- and 104-week chronic toxicity/carcinogenicity study of triclosan. In the 52-week study, centrilobular hepatocellular hypertrophy was found at the top two dose levels in males and the highest dose in females. No hepatic putative preneoplastic or neoplastic lesions were found in increased incidences in any treated group. In the two-year study, some non-neoplastic lesions were increased in incidence in some groups of treated rats, but none were dose-related nor increased in severity from those found in controls. In the two-year study, the PWG review found no evidence of any lesions related to administration of triclosan.

II. INTRODUCTION

PATHCO, Inc., was requested to conduct an independent panel review of the slides from the two-year chronic toxicity/carcinogenicity study of triclosan in Sprague-Dawley rats conducted by Ciba-Geigy Corporation. Hematoxylin and eosin stained microscope slides for livers and lungs and the final study report, including all individual animal diagnoses were received by PATHCO, Inc. In this review, PATHCO was requested to pay particular attention to the lesions diagnosed by the Study Pathologist as centrilobular hypertrophy, telangiectasis and necrosis of the liver and alveolar foamy macrophages of the lung.

III. STUDY DESIGN

Triclosan was administered in the feed to male and female Sprague-Dawley rats for up to two years. The treatment groups, group size, and sacrifice schedule are given in Table I.

IV. CONDUCT OF THE PWG REVIEW

The Pathology Working Group was chaired by Dr. Dawn G. Goodman who organized and presented the material to a panel of four additional pathologists. The other members of the PWG were Dr. J. M. Cullen, Dr. P. M. Newberne, Dr. R. A. Squire, and Dr. J. M. Ward. C.V.s for the Chairperson, the PWG participants, and the reviewing pathologist are presented in the Appendix D.

A. Histopathologic Evaluation of Livers and Lungs Without Knowledge of Treatment - Reviewing Pathologist's Review

Prior to the PWG review, the animal numbers were randomized and coded from 1 to 370 for males and 1 to 370 for females on removable labels which were color coded by sex. Dr. Robert M. Sauer, the Reviewing Pathologist, reviewed all of the liver and lung slides without knowledge of treatment or diagnoses made previously.

Dr. Sauer was aware that centrilobular hypertrophy, telangiectasis, and necrosis of all types were of particular concern in the liver and alveolar foamy macrophages in the lung. However, Dr. Sauer evaluated the microscopic slides for all lesions, both neoplastic and nonneoplastic.

Once the review was completed, Dr. Sauer's diagnoses were decoded and Pathology Review Worksheets were prepared comparing his diagnoses with those of the Study Pathologist's (Appendix B). Both the Study Pathologist and the Reviewing Pathologist used the terms hypertrophy and necrosis in the liver and foamy macrophages in the lung; these diagnoses were matched. Telangiectasis of the liver, a term used by the Study Pathologist, was matched with cystic degeneration. In the liver the Study Pathologist used the term cellular alteration without identifying the cell type. The Reviewing Pathologist used the term focus of cellular alteration and classified these foci by cell type. The term cellular alteration was matched with any of the types of foci found. Hepatocellular vacuolation was matched with fatty change and hepatocellular neoplasms were appropriately matched.

Individual animals diagnoses made by the Reviewing Pathologist's were entered into the LABCAT computer system and summary incidence tables generated. These tables are included in Appendix C.

B. Chairperson's Review

Prior to the PWG review, the Chairperson reviewed the original pathology incidence tables for liver and lung, the Study Pathologist's report, the Pathology Review Worksheets (Appendix B), and the Reviewing Pathologist's summary incidence tables.

Based on this review, the Chairperson determined that in addition to hepatocellular centrilobular hypertrophy in both sexes, necrosis, telangiectasis/cystic degeneration of the liver in males, and foamy macrophages of the lung in both sexes, eosinophilic foci of the liver in males, and interstitial pneumonia of the lung in both sexes might be considered to be treatment related. The incidences of animals with the latter two lesions were slightly elevated in the Reviewing Pathologist's evaluation.

Accordingly, the Chairperson reviewed all of the slides with any of these lesions diagnosed by either the Study Pathologist or the Reviewing Pathologist. All diagnoses of hepatocellular neoplasms were also reviewed (Appendix B).

C. PWG Review

The PWG examined coded slides without knowledge of treatment or dose group. The PWG reviewed:

- 1) all examples of lesions diagnosed in males in the two-year study as eosinophilic foci of the liver by the Reviewing Pathologist or Chairperson,
- 2) all examples of necrosis of the liver in males in the two-year study diagnosed by the Study Pathologist, the Reviewing Pathologist, or the Chairperson,
- 3) selected examples of telangiectasis/cystic degeneration of the liver in males in the two-year study including examples of when the Study Pathologist, the Reviewing Pathologist and the Chairperson agreed, examples of when two of these pathologist's agreed and all livers where only one pathologist diagnosed the lesion,
- 4) all examples of centrilobular hypertrophy of the liver in both sexes from the 52-week study, diagnosed by the Study Pathologist, the Reviewing Pathologist or the Chairperson,

5) all hepatocellular neoplasms in both sexes diagnosed by the Study Pathologist, the Reviewing Pathologist, or the Chairperson,

6) selected examples of foamy macrophages of the lung in both sexes in the two-year study; the criteria for selection of examples are stated in 3), and

7) selected examples of interstitial pneumonia in both sexes in the two-year study including examples diagnosed by the Reviewing Pathologist and the Chairperson and examples diagnosed by only one pathologist.

Except for centrilobular hypertrophy of the liver, the PWG review was limited to the two-year study since there were no differences between treated and control animals in the interim sacrifices. Centrilobular hypertrophy of the liver was seen at the 13- and 26-week interim sacrifices as well as the 52-week interim sacrifice and was of primary concern at the later interval.

Each participant recorded his diagnoses and/or comments on his worksheets. The worksheets are on file at PATHCO, Inc. Each lesion was discussed by the group, re-examined if necessary, and the final opinions were recorded on the Chairperson's worksheets (Appendix A). In determining the PWG diagnosis, the diagnoses of the Chairperson and the four PWG members were considered. The PWG diagnosis for a lesion was determined when at least three out of the five pathologists agreed.

After the PWG completed the slide review, and diagnoses were recorded, the slides were decoded by treatment group, and the lesion incidences were tabulated, evaluated, and interpreted.

V. FINDINGS AND INTERPRETATIONS

A. Two-Year Study

1. Liver Lesions

a. Foci of cellular alteration

In male rats in the two-year study, the Reviewing Pathologist reported a slight increase in the incidence of eosinophilic foci in treated male rats compared

to controls. The incidences of basophilic foci and clear cell foci were comparable between treated and control groups of males in the two-year study and in the interim sacrifices. In female rats, the incidences of all types of foci were comparable between treated and control groups in the two-year study and in the various interim sacrifices.

Foci were characterized primarily by altered cytoplasmic tinctorial properties. Based on cytoplasmic staining with hematoxylin and eosin, they were classified as: basophilic, eosinophilic (ground glass), clear cell, or mixed type. Cellular atypia was generally absent. Foci of cellular alteration varied in size from a few cells to lesions that occupied multiple hepatic lobules, and there was generally clear demarcation between foci and surrounding liver. There was little or no alteration of the normal hepatic lobular architecture with foci; however, very large lesions or those with hypertrophied cells sometimes slightly compressed surrounding hepatic cords. Such compression was not as prominent a feature as in hepatocellular adenomas. Significant compression, lesion size, disruption of lobular or plate architecture or presence of cellular atypia were the primary criteria for distinguishing adenomas from foci.

The PWG reviewed all examples of eosinophilic foci diagnosed by the Reviewing Pathologist or the Chairperson in male rats in the two-year study. Their findings are listed in Table II. The PWG does not believe there is a compound related increase in eosinophilic foci.

b. Hepatocellular necrosis

The PWG reviewed all examples of hepatocellular necrosis of the liver in the males in the two-year study diagnosed by the Study Pathologist, the Reviewing Pathologist, or the Chairperson. Two types of necrosis were diagnosed: zonal necrosis and focal necrosis without zonal preference. The incidences of both types of necrosis are given in Table II. The two types of necrosis observed have different pathogenetic mechanisms and should not be combined for analysis. There was no evidence of a treatment effect with zonal necrosis, the type which would be associated with compound-related injury. Focal necrosis, which is unlikely to be related to a compound effect, was increased only in the lower doses. This was considered to be an incidental finding.

c. Focal hepatic cystic degeneration

Selected examples of focal hepatic cystic degeneration were reviewed by the PWG. The review included examples of lesions where the Study Pathologist, Reviewing Pathologist, and Chairperson concurred, examples of when two of these pathologists agreed and all lesions where only one pathologist made the diagnosis.

Two terms were used for this lesion, telangiectasis and cystic degeneration. The PWG preferred the term cystic degeneration (spongiosis hepatis) for the lesion observed in this study. The incidences are given in Table II.

Microscopically, focal hepatic cystic degeneration of the liver consisted of large vacuoles or cystic spaces, sometimes found in association with foci of cellular alteration or hepatocellular neoplasms. These spaces were filled with intact erythrocytes, degenerating erythrocytes, eosinophilic flocculent or fibrillar material, or eosinophilic proteinaceous fluid. The spaces were either not lined or were only partially lined by endothelium. In this study, the lesion was diagnosed whether or not it was a component of another lesion. Focal hepatic cystic degeneration is commonly seen with a variable incidence in aged Sprague-Dawley rats. In this study, it is not believed to be compound-related.

d. Hepatocellular neoplasms

The PWG reviewed all lesions diagnosed as hepatocellular neoplasms. The incidences were comparable among all groups (Table III).

2. Lung Lesions

The Study Pathologist reported an increased incidence of foamy alveolar macrophages in treated animals compared to controls. The Reviewing Pathologist confirmed this finding and also reported an increased incidence of interstitial pneumonia as well. The PWG reviewed selected examples of alveolar foamy macrophages in both sexes in the two-year study including examples of when the Study Pathologist, the Reviewing Pathologist, and the Chairperson agreed, examples of when two of these pathologists agreed and all lungs where only one pathologist diagnosed the lesion. The PWG also reviewed selected examples of

interstitial pneumonia in both sexes including examples diagnosed by the Reviewing Pathologist and the Chairperson and all lesions diagnosed by only one of these pathologists. The PWG believes that these two lesions are part of the same disease process and should not be diagnosed separately. They preferred the term pneumonitis to refer to this complex of lesions. The term pneumonitis, in the context of this report, refers to small focal accumulations of foamy alveolar macrophages, accompanied in some cases by thickening of alveolar walls, minimal fibrosis, mononuclear cell infiltration, and edema. The number of aggregates per lung was variable but low and the severity ranged from minimal to mild. In the opinion of the PWG, these focal areas would be disregarded by most pathologists as incidental background changes. Although the incidence of pneumonitis was increased in treated male rats (Table IV), the increase was not dose related. The morphology and degree of severity of the lesion was comparable between treated and control animals. That is, there was no dose-related increase in the severity of the lesion. The incidence in the low dose (300 ppm) group (50%) was the same as the incidence in the high dose group (3000 ppm) (48%), which received ten times the dose of the low dose group. Thus, the PWG believes the increased incidence in treated males is a spurious finding rather than compound-related. Similarly, the incidences in females were not significantly increased in any group.

B. 52-Week Study

1. Centrilobular hepatocellular hypertrophy

Centrilobular hypertrophy was reported in the 52-week interim sacrifice (Table V) and in earlier interim sacrifices. It was not found in the animals surviving for two years. The PWG reviewed all examples of this lesion from the 52-week sacrifice in both sexes. Based on this review, centrilobular hepatocellular hypertrophy is a compound-related effect at 6000 ppm in males at 52 weeks, and to a lesser extent in females. Hepatocellular hypertrophy was also present in a few males treated with 3000 ppm triclosan for 52 weeks.

Centrilobular hypertrophy consisted of enlarged hepatocytes surrounding the central vein. The cytoplasm of the cells was abundant and eosinophilic, often with a ground glass appearance and prominent cytoplasmic membranes. The nuclei were normal sized to slightly enlarged. In a few

animals, virtually the whole lobule was involved, resulting in a more diffuse pattern.

2. Foci of cellular alteration

The Reviewing Pathologist and the Chairperson confirmed that there was no treatment-related increase in hepatocellular foci in the 6000 ppm treated animals. In examining slides for centrilobular hepatocellular hypertrophy, the PWG was also able to note that no foci were present in these slides. There were no changes in the livers that could be considered preneoplastic.

TABLE I
Study Design

Dose (ppm)	No. Animals/sex/group	Duration of Treatment (weeks)
0	5	13
0	5	26
0	20	52
0	5	78
0	60	104
300	5	13
300	5	26
300	10	52
300	5	78
300	60	104
1000	5	13
1000	5	26
1000	10	52
1000	5	78
1000	60	104
3000	5	13
3000	5	26
3000	10	52
3000	5	78
3000	60	104
6000	20	52

TABLE II

INCIDENCES OF NONNEOPLASTIC HEPATOCELLULAR
 LESIONS IN MALE RATS IN THE TWO-YEAR STUDY

Group	CM	LM	MM	HM
Dose (ppm)	0	300	1000	3000
# Animals/group	60	60	60	60
Eosinophilc foci	3 (5%)	7 (12%)	4 (7%)	7 (12%)
Zonal Necrosis	2 (3%)	4 (7%)	1 (2%)	3 (5%)
Focal Necrosis	0	5 (8%)	6 (10%)	2 (3%)
Cystic degeneration	15 (25%)	12 (20%)	22 (37%)	23 (38%)

TABLE III

**INCIDENCES OF HEPATOCELLULAR NEOPLASMS
IN THE TWO-YEAR STUDY**

Group	C	LD	MD	HD
Dose (ppm)	0	300	1000	3000
# Animals/group	60	60	60	60

***** MALES *****

Hepatocellular adenoma	1 (2%)	1 (2%)	0	0
Hepatocellular carcinoma	1 (2%)	2 (3%)	3 (5%)	3 (5%)
Total Hepatocellular Neoplasms	2 (3%)	3 (5%)	3 (5%)	3 (5%)

***** FEMALES *****

Hepatocellular adenoma	3 (5%)	2 (3%)	0	0
Hepatocellular carcinoma	0	0	1 (2%)	0
Total Hepatocellular Neoplasms	3 (5%)	2 (3%)	1 (2%)	0

TABLE IV

**INCIDENCES OF PNEUMONITIS OF THE LUNG
IN THE TWO-YEAR STUDY**

Group	C	LD	MD	HD
Dose (ppm)	0	300	1000	3000
Males	17/59 (29%)	33/60 (55%)	31/60 (52%)	29/60 (48%)
Females	17/60 (28%)	19/60 (32%)	26/60 (43%)	22/59 (37%)

TABLE V**INCIDENCES OF CENTRIOLOBULAR HEPATOCELLULAR
HYPERTROPHY IN THE FIFTY-TWO WEEK STUDY**

Group	C	LD	MD	HD1	HD2
Dose (ppm)	0	300	1000	3000	6000
# Animals/group	20	10	10	10	20
<hr/>					
Males	0	0	0	3 (30%)	18 (90%)
Females	0	0	0	0	3 (15%)

APPENDIX A
Chairperson's Worksheets



PATHOLOGY WORKING GROUP CHAIRPERSON'S WORKSHEETS

CHEMICAL NAME: TriclosanSTUDY: 2-Year StudyCHAIRPERSON'S SIGNATURE: *[Signature]*SPECIES: Sprague-Dawley RatSEX: MaleORGAN: LiverDATE: December 20-21, 1990

Code No.	Animal No.	Dose Group	No. of Slides	Study Pathologist's Diagnoses (SP)	Reviewing Pathologist's Coded Review Diagnoses (RP)	Chairperson's Diagnoses	PWG Diagnoses
201	34-010	CM	1	-	Eosinophilic focus	Concur RP	Eosinophilic focus (5) Clear cell focus (2)
367	34-019	CM	2	Cellular alteration, minimal	Basophilic focus Eosinophilic focus Clear cell focus, multiple Cystic degeneration, mild	Concur RP Concur RP Concur RP Concur RP	Basophilic focus (5) Eosinophilic focus (4) Clear cell focus (1) Cystic degeneration, (5)
666	34-031	CM	1	-	Eosinophilic focus, multiple Cystic degeneration, minimal	Concur RP Concur RP	Eosinophilic focus (1) Clear cell focus (1) No foci (3) Cystic degeneration (5)

PATHOLOGY WORKING GROUP CHAIRPERSON'S WORKSHEETS

CHEMICAL NAME: Triclosan

STUDY: 2-Year Study

CHAIRPERSON'S SIGNATURE: *[Signature]*

SPECIES: Sprague-Dawley Rat

SEX: Male

ORGAN: Liver

DATE: December 20-21, 1990

Code No.	Animal No.	Dose Group	No. of Slides	Study Pathologist's Diagnoses (SP)	Reviewing Pathologist's Coded Review Diagnoses (RP)	Chairperson's Diagnoses	PWG Diagnoses
73	34-042	CM	1	Cellular alteration, minimal Telangiectasis, minimal	Eosinophilic focus Cystic degeneration, mild	Concur RP Concur RP	Eosinophilic focus (2) Basophilic focus (2) Clear cell focus (1) Cystic degeneration (5)
157	34-048	CM	1	-	Eosinophilic focus, multiple	Concur RP	Eosinophilic focus (1) Basophilic focus (1) Clear cell focus (3) No foci (1)
36	34-054	CM	1	Cellular alteration, minimal -	Eosinophilic focus -	Concur RP -	Eosinophilic focus (2) Clear cell focus (3) Cystic degeneration (2)

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PATHOLOGY WORKING GROUP CHAIRPERSON'S WORKSHEETS

CHEMICAL NAME: Triclosan

STUDY: 2-Year Study

CHAIRPERSON'S SIGNATURE: *Karen G. Goodman*

SPECIES: Sprague-Dawley Rat

SEX: Male

ORGAN: Liver

DATE: December 20-21, 1990

Code No.	Animal No.	Dose Group	No. of Slides	Study Pathologist's Diagnoses (SP)	Reviewing Pathologist's Coded Review Diagnoses (RP)	Chairperson's Diagnoses	PWG Diagnoses
293	34-055	CM	1	Cellular alteration, minimal Hepatocellular adenoma	Clear cell focus Basophilic focus	Clear cell focus, multiple Eosinophilic focus	No focus (4) Clear cell focus (1) Hepatocellular adenoma (4) Eosinophilic focus (1)
1	34-069	CM	1	Cellular alteration, minimal Hepatocellular adenoma Telangiectasis, minimal	Eosinophilic focus Clear cell focus Basophilic focus Cystic degeneration, mild	Concur RP Concur RP Concur RP Concur RP	Eosinophilic focus (4) Clear cell focus (4) Basophilic focus (5) Cystic degeneration (5)
215	34-113	LM	1	Cellular alteration, minimal -	Eosinophilic focus Clear cell focus, multiple Cystic degeneration, minimal	Concur RP Concur RP Concur RP	Eosinophilic focus (4) Basophilic focus (1) Clear cell focus (2) Cystic degeneration (4)

PATHOLOGY WORKING GROUP CHAIRPERSON'S WORKSHEETS

CHEMICAL NAME: Triclosan **STUDY:** 2-Year Study **CHAIRPERSON'S SIGNATURE:** [Signature]
SPECIES: Sprague-Dawley Rat **SEX:** Male **ORGAN:** L **DATE:** December 20-21, 1990

Code No.	Animal No.	Dose Group	No. of Slides	Study Pathologist's Diagnoses (SP)	Reviewing Pathologist's Coded Review Diagnoses (RP)	Chairperson's Diagnoses	PWG Diagnoses
41	34-121	LM	1	Cellular alteration, minimal	Eosinophilic focus	Concur RP Basophilic focus	Eosinophilic focus (1) Clear cell focus (1) Basophilic focus (2) No focus (2)
40 Page 31 of 550	34-126	LM	1	Cellular alteration, minimal -	Basophilic focus Eosinophilic focus Clear cell focus -	Concur RP Concur RP Concur RP -	Basophilic focus (4) Eosinophilic focus (5) Clear cell focus (1) Cystic degeneration (3)
165	34-129	LM	1	Hepatocellular adenoma	Eosinophilic focus, multiple	Concur RP	Eosinophilic focus (3) No lesion (2)
266	34-153	LM	1	- Telangiectasis, minimal	Eosinophilic focus Basophilic focus Cystic degeneration, mild	Concur RP Concur RP Concur RP	Eosinophilic focus (4) Basophilic focus (3) Cystic degeneration (5)

PATHOLOGY WORKING GROUP CHAIRPERSON'S WORKSHEETS

CHEMICAL No. 4: Triclosan

STUDY: 2-Year Study

CHAIRPERSON'S SIGNATURE: *[Signature]*

SPECIES: Sprague-Dawley Rat

SEX: Male

ORGAN: Liver

DATE: December 20-21, 1990

Code No.	Animal No.	Dose Group	No. of Slides	Study Pathologist's Diagnoses (SP)	Reviewing Pathologist's Coded Review Diagnoses (RP)	Chairperson's Diagnoses	PWG Diagnoses
364	34-157	LM	1	-	Eosinophilic focus	Concur RP	Eosinophilic focus (5) Basophilic focus (1)
86	34-160	LM	1	Cellular alteration, minimal Telangiectasis, minimal	Eosinophilic focus, multiple Clear cell focus, multiple Cystic degeneration, mild	Concur RP Concur RP Concur RP	Eosinophilic focus (4) Clear cell focus (2) Cystic degeneration (5)
160	34-162	LM	1	Cellular alteration, minimal -	Eosinophilic focus, multiple Basophilic focus -	Eosinophilic focus, single Concur SP Angiectasis	Eosinophilic focus (5) Clear cell focus (1) Cystic degeneration (1) Angiectasis (1)
112	34-163	LM	1	- -	Eosinophilic focus -	Concur SP Cystic degeneration minimal	No focus (5) Cystic degeneration (1)

PATHOLOGY WORKING GROUP CHAIRPERSON'S WORKSHEETS

CHEMICAL NAME: Triclosan

STUDY: 2-Year Study

CHAIRPERSON'S SIGNATURE: *David G. Goodman*

SPECIES: Sprague-Dawley Rat

SEX: Male

ORGAN: Liver

DATE: December 20-21, 1990

Code No.	Animal No.	Dose Group	No. of Slides	Study Pathologist's Diagnoses (SP)	Reviewing Pathologist's Coded Review Diagnoses (RP)	Chairperson's Diagnoses	PWG Diagnoses
130	34-164	LM	1	-	Eosinophilic focus	Basophilic focus	Eosinophilic focus (1) Basophilic focus (3) No focus (1)
100	34-198	MM	1	- Telangiectasis, minimal	Eosinophilic focus Cystic degeneration, mild	Concur RP Concur RP	Eosinophilic focus (2) No focus (3) Cystic degeneration (5)
179	34-190	MM	1	- -	Eosinophilic focus -	Concur SP -	Eosinophilic focus (3) No focus (2) Cystic degeneration (1)
268	34-200	HM	1	- Telangiectasis, minimal	Eosinophilic focus Clear cell focus Cystic degeneration, minimal	Concur SP Concur RP Concur RP	Eosinophilic focus (1) No focus (4) Cystic degeneration (5)

PATHOLOGY WORKING GROUP CHAIRPERSON'S WORKSHEETS

CHEMICAL N 3: Triclosan **STUDY:** 2-Year Study **CHAIRPERSON'S SIGNATURE:** [Signature]
SPECIES: Sprague-Dawley Rat **SEX:** Male **ORGAN:** Liver **DATE:** December 20-21, 1990

Code No.	Animal No.	Dose Group	No. of Slides	Study Pathologist's Diagnoses (SP)	Reviewing Pathologist's Coded Review Diagnoses (RP)	Chairperson's Diagnoses	PWG Diagnoses
14	34-201	MM	1	Cellular alteration, minimal -	Clear cell focus Eosinophilic focus -	Concur RP Concur SP Cystic degeneration minimal	Clear cell focus (1) Eosinophilic focus (4) Cystic degeneration (1)
243	34-204	MM	1	Cellular alteration, minimal Telangiectasis, minimal	Eosinophilic focus Cystic degeneration, minimal	Within normal limits Concur RP	No focus (5) Cystic degeneration (5)
161	34-209	MM	1	Cellular alteration, minimal Telangiectasis, minimal	Eosinophilic focus, multiple Cystic degeneration, minimal	Concur RP Concur RP	Eosinophilic focus (4) Basophilic focus (2) Clear cell focus (2) Cystic degeneration (5)
195	34-245	MM	1	- Telangiectasis, minimal	Eosinophilic focus Cystic degeneration, mild	Concur SP Concur RP	No focus (5) Cystic degeneration (5)

PATHOLOGY WORKING GROUP CHAIRPERSON'S WORKSHEETS

CHEMICAL NAME: Triclosan **STUDY:** 2-Year Study **CHAIRPERSON'S SIGNATURE:** [Signature]
SPECIES: Sprague-Dawley Rat **SEX:** Male **ORGAN:** Liver **DATE:** December 20-21, 1990

Code No.	Animal No.	Dose Group	No. of Slides	Study Pathologist's Diagnoses (SP)	Reviewing Pathologist's Coded Review Diagnoses (RP)	Chairperson's Diagnoses	PWG Diagnoses
250	34-249	MM	1	Cellular alteration, minimal Telangiectasis, minimal	Basophilic focus Eosinophilic focus Clear cell focus, multiple Cystic degeneration, minimal	Concur RP Concur RP Concur RP Concur RP	Basophilic focus (3) Eosinophilic focus (4) Clear cell focus (2) Cystic degeneration (5)
83	34-277	HM	1	Cellular alteration, minimal Telangiectasis, minimal	Basophilic focus Eosinophilic focus, multiple -	Concur RP Concur RP Cystic degeneration minimal	Basophilic focus (1) Eosinophilic focus (5) Cystic degeneration (5)
306	34-278	HM	1	Cellular alteration, minimal Telangiectasis, minimal	Basophilic focus Clear cell focus, multiple Cystic degeneration, minimal	Concur RP Concur RP Concur RP	Basophilic focus (4) Clear cell focus (2) Eosinophilic focus (5) Cystic degeneration (2)

PATHOLOGY WORKING GROUP CHAIRPERSON'S WORKSHEETS

CHEMICAL N. : Triclosan **STUDY:** 2-Year Study **CHAIRPERSON'S SIGNATURE:** *Sam L. G. ...*
SPECIES: Sprague-Dawley Rat **SEX:** Male **ORGAN:** Liver **DATE:** December 20-21, 1990

Code No.	Animal No.	Dose Group	No. of Slides	Study Pathologist's Diagnoses (SP)	Reviewing Pathologist's Coded Review Diagnoses (RP)	Chairperson's Diagnoses	PWG Diagnoses
191	34-285	HM	1	-	Eosinophilic focus Cystic degeneration, minimal	Concur SP Concur RP	Eosinophilic focus (3) Basophilic focus (2) Cystic degeneration (3)
158	34-296	HM	1	Cellular alteration, minimal	Eosinophilic focus	Angiectasis	Eosinophilic focus (1) No focus (4) Angiectasis(1)
62	34-302	HM	1	- Telangiectasis, minimal	Eosinophilic focus Basophilic focus Cystic degeneration, minimal	Concur RP Concur RP Concur RP	Eosinophilic focus (1) Basophilic focus (2) No focus (2) Cystic degeneration (4)
52	34-304	HM	1	Cellular alteration, minimal	Eosinophilic focus, multiple	Concur RP	Eosinophilic focus (2) Basophilic focus (3) Clear cell focus (1)



PATHOLOGY WORKING GROUP CHAIRPERSON'S WORKSHEETS

CHEMICAL NAME: Triclosan

STUDY: 2-Year Study

CHAIRPERSON'S SIGNATURE:

SPECIES: Sprague-Dawley Rat

SEX: Male

ORGAN: Liver

DATE: December 20-21, 1990

Code No.	Animal No.	Dose Group	No. of Slides	Study Pathologist's Diagnoses (SP)	Reviewing Pathologist's Coded Review Diagnoses (RP)	Chairperson's Diagnoses	PWG Diagnoses
261	34-308	HM	1	-	Eosinophilic focus	Concur RP	Eosinophilic focus (1)
				-	Cystic degeneration, minimal	Concur RP	No focus (4) Cystic degeneration (4)
15	34-310	HM	1	Cellular alteration, minimal	Eosinophilic focus	Within normal limits	No focus (5)
				Telangiectasis, minimal	Cystic degeneration, minimal	Concur RP	Cystic degeneration (3)
42	34-311	HM	1	-	Eosinophilic focus	Concur SP	Eosinophilic focus (3) Basophilic focus (2) No focus (1)
214	34-315	HM	1	-	Eosinophilic focus	Concur RP	Eosinophilic focus (1) Basophilic focus (3) No focus (1)

PATHOLOGY WORKING GROUP CHAIRPERSON'S WORKSHEETS

CHEMICAL NAME: Triclosan **STUDY:** 2-Year Study **CHAIRPERSON'S SIGNATURE:** [Signature]
SPECIES: Sprague-Dawley Rat **SEX:** Male **ORGAN:** Liver **DATE:** December 20-21, 1990

Code No.	Animal No.	Dose Group	No. of Slides	Study Pathologist's Diagnoses (SP)	Reviewing Pathologist's Coded Review Diagnoses (RP)	Chairperson's Diagnoses	PWG Diagnoses
226	34-316	HM	1	Cellular alteration, minimal -	Clear cell focus, multiple Cystic degeneration, minimal	Concur RP Eosinophilic focus Concur RP	Basophilic focus (2) Eosinophilic focus (2) No focus (1) Cystic degeneration (3)
249	34-318	HM	1	Hepatocellular adenoma	Eosinophilic focus, multiple Cystic degeneration, minimal	Concur RP Concur RP	Eosinophilic focus (4) Hepatocellular adenoma (2) Cystic degeneration (3)
247	34-321	HM	1	-	Eosinophilic focus Clear cell focus, multiple	Concur SP Focal fatty change	No foci (5)
223	34-323	HM	1	Cellular alteration, minimal Telangiectasis, minimal	Basophilic focus Eosinophilic focus Clear cell focus, multiple Cystic degeneration, minimal	Angiectasis Concur RP Concur RP Concur RP	Angiectasis(1) Eosinophilic focus (5) Clear cell focus (1) Cystic degeneration (5)

PATHOLOGY WORKING GROUP CHAIRPERSON'S WORKSHEETS

CHEMICAL NAME: Triclosan **STUDY:** 2-Year Study **CHAIRPERSON'S SIGNATURE:** [Signature]
SPECIES: Sprague-Dawley Rat **SEX:** Male **ORGAN:** Liver **DATE:** December 20-21, 1990

Code No.	Animal No.	Dose Group	No. of Slides	Study Pathologist's Diagnoses (SP)	Reviewing Pathologist's Coded Review Diagnoses (RP)	Chairperson's Diagnoses	PWG Diagnoses
257	34-328	HM	1	Hepatocellular carcinoma Telangiectasis, minimal	Hepatocellular carcinoma Eosinophilic focus Cystic degeneration, minimal	Hepatocellular carcinoma Concur RP Concur RP	Hepatocellular carcinoma Eosinophilic focus (1) Basophilic focus (1) Clear cell focus (1) No focus (2) Cystic degeneration (5)
212	34-329	HM	1	Cellular alteration, minimal	Eosinophilic focus	Concur RP	Eosinophilic focus (1) Basophilic focus (2) No focus (2)
144	34-279	HM	1	Cellular alteration, minimal Telangiectasis, minimal	Eosinophilic focus, multiple Telangiectasis, mild	Concur RP Angiectasis	Eosinophilic focus (5) Clear cell focus (1) Cystic degeneration (3) Angiectasis (2)

PATHOLOGY WORKING GROUP CHAIRPERSON'S WORKSHEETS

CHEMICAL NAME: Triclosan **STUDY:** 2-Year Study **CHAIRPERSON'S SIGNATURE:** [Signature]
SPECIES: Sprague-Dawley Rat **SEX:** Male **ORGAN:** Liver **DATE:** December 20-21, 1990

Code No.	Animal No.	Dose Group	No. of Slides	Study Pathologist's Diagnoses (SP)	Reviewing Pathologist's Coded Review Diagnoses (RP)	Chairperson's Diagnoses	PWG Diagnoses
137	34-026	CM	1	Lobule centro, focal coagulative necrosis, minimal Telangiectasis, minimal	- Cystic degeneration, mild	Centrilobular necrosis, minimal Concur RP	Zonal necrosis (5) Cystic degeneration (4)
281	34-043	CM	1	Lobule centro, necrosis, minimal	Centrilobular necrosis, mild	Concur RP	Zonal necrosis (5)
185	34-106	LM	1	Necrosis, moderate Histiocytic sarcoma	- Histiocytic sarcoma	(Part of tumor) Agree	Focal necrosis (1) (Necrosis part of tumor, do not diagnose) (4)
275	34-107	LM	1	Necrosis, minimal Telangiectasis, minimal	Centrilobular necrosis, mild Cystic degeneration, moderate	Concur RP Concur RP	Zonal necrosis (4) Focal necrosis (4) Cystic degeneration (4)
64	34-108	LM	2	Lobule centro, necrosis, moderate Hepatocellular carcinoma	Centrilobular necrosis, moderate Hepatocellular carcinoma	Agree Hepatocellular carcinoma	Zonal necrosis (4) No necrosis (1) Hepatocellular carcinoma

PATHOLOGY WORKING GROUP CHAIRPERSON'S WORKSHEETS

CHEMICAL NAME: Triclosan **STUDY:** 2-Year Study **CHAIRPERSON'S SIGNATURE:** [Signature]
SPECIES: Sprague-Dawley Rat **SEX:** Male **ORGAN:** Liver **DATE:** December 20-21, 1990

Code No.	Animal No.	Dose Group	No. of Slides	Study Pathologist's Diagnoses (SP)	Reviewing Pathologist's Coded Review Diagnoses (RP)	Chairperson's Diagnoses	PWG Diagnoses
279	34-109	LM	1	Focal coagulative necrosis, minimal	Necrosis, minimal	Concur RP	Focal necrosis (5)
181	34-114	LM	1	Focal coagulative necrosis, minimal	Necrosis minimal	Concur RP	Focal necrosis (5)
357	34-133	LM	1	- Telangiectasis, minimal	Necrosis, minimal Cystic degeneration, mild	Concur RP Concur RP	Focal necrosis (5) Cystic degeneration (3)
178	34-136	LM	1	Lobule centro, necrosis, moderate	Centrilobular necrosis, moderate	Agree	Zonal necrosis (5)
43	34-158	LM	1	Focal coagulative necrosis, moderate	Necrosis, mild	Concur RP	Zonal necrosis (1) Focal necrosis (4)
334	34-132	LM	1	Lobule centro necrosis, minimal	-	Necrosis, minimal	Zonal necrosis (3) Focal necrosis (2)
332	34-190	MM	1	Focal coagulative necrosis, minimal	Necrosis, minimal	Concur RP	Zonal necrosis (1) Focal necrosis (4)

PATHOLOGY WORKING GROUP CHAIRPERSON'S WORKSHEETS

CHEMICAL NAME: Triclosan

STUDY: 2-Year Study

CHAIRPERSON'S SIGNATURE: [Signature]

SPECIES: Sprague-Dawley Rat

SEX: Male

ORGAN: Liver

DATE: December 20-21, 1990

Code No.	Animal No.	Dose Group	No. of Slides	Study Pathologist's Diagnoses (SP)	Reviewing Pathologist's Coded Review Diagnoses (RP)	Chairperson's Diagnoses	PWG Diagnoses
140	34-195	MM	1	-	-	Necrosis, mild	Focal necrosis (5)
139	34-208	MM	1	Necrosis, minimal	Necrosis, mild	Concur RP	Focal necrosis (5) Zonal necrosis (2)
209	34-224	MM	1	Lobule centro necrosis, minimal	Centrilobular necrosis, moderate	Concur RP	Focal necrosis (5) Zonal necrosis (1)
238	34-232	MM	1	Lobule centro necrosis, minimal	Centrilobular necrosis, mild	Concur RP	Focal necrosis (3) Zonal necrosis (2)
8	34-238	MM	2	Focal coagulative necrosis, minimal Telangiectasis, moderate Hepatocellular adenoma	- Cystic degeneration, mild Hepatocellular carcinoma	Necrosis, minimal Concur RP Concur RP	Focal necrosis (5) Cystic degeneration (5) Hepatocellular carcinoma (5)

PATHOLOGY WORKING GROUP CHAIRPERSON'S WORKSHEETS

CHEMICAL N. 3: Triclosan **STUDY:** 2-Year Study **CHAIRPERSON'S SIGNATURE:** [Signature]
SPECIES: Sprague-Dawley Rat **SEX:** Male **ORGAN:** Liver **DATE:** December 20-21, 1990

Code No.	Animal No.	Dose Group	No. of Slides	Study Pathologist's Diagnoses (SP)	Reviewing Pathologist's Coded Review Diagnoses (RP)	Chairperson's Diagnoses	PWG Diagnoses
53	34-239	MM	1	Lobule centro necrosis, moderate	Centrilobular necrosis, moderate	Agree	Zonal necrosis (5)
82	34-284	HM	1	Lobule centro necrosis, minimal Telangiectasis, minimal	Centrilobular necrosis, mild Cystic degeneration, mild	Concur RP Concur RP	Zonal necrosis (5) Focal necrosis (1) Cystic degeneration (5)
45	34-286	HM	1	Focal coagulative necrosis, minimal Histiocytic sarcoma	- Histiocytic sarcoma	(Part of tumor) Agree	(Necrosis part of tumor, do not diagnose separately) (5)
327	34-294	HM	1	Lobule centro necrosis, moderate	Centrilobular necrosis, moderate	Agree	Zonal necrosis (5)
10	34-307	HM	1	Lobule centro necrosis, moderate	-	Centrilobular necrosis, moderate	Zonal necrosis (5)
318	34-317	HM	1	Focal coagulative necrosis, minimal	-	Necrosis, minimal	Focal necrosis (5)

PATHOLOGY WORKING GROUP CHAIRPERSON'S WORKSHEETS

CHEMICAL NAME: Triclosan

STUDY: 2-Year Study

CHAIRPERSON'S SIGNATURE: *[Signature]*

SPECIES: Sprague-Dawley Rat

SEX: Male

ORGAN: Liver

DATE: December 20-21, 1990

Code No.	Animal No.	Dose Group	No. of Slides	Study Pathologist's Diagnoses (SP)	Reviewing Pathologist's Coded Review Diagnoses (RP)	Chairperson's Diagnoses	PWG Diagnoses
50	34-326	HM	1	Focal coagulative necrosis, moderate	Necrosis, mild	Concur RP	Focal necrosis (5) Cystic degeneration (3)
192	34-024	CM	1	Telangiectasis, minimal	-	Concur RP	Cystic degeneration (1) Focal necrosis (1) No lesion (3)
203	34-044	CM	2	Telangiectasis, marked Hepatocellular carcinoma	Cystic degeneration, minimal Hepatocellular carcinoma	Concur RP Concur RP	Cystic degeneration (1) No lesion (4) Hepatocellular carcinoma (4) Hepatocellular adenoma (1)
342	34-111	LM	2	- Hepatocellular carcinoma	- Hepatocellular adenoma	Cystic degeneration minimal Angiectasis Hepatocellular carcinoma	Cystic degeneration (2) Hepatocellular carcinoma (5)

PATHOLOGY WORKING GROUP CHAIRPERSON'S WORKSHEETS

CHEMICAL NAME: Triclosan **STUDY:** 2-Year Study **CHAIRPERSON'S SIGNATURE:** *W. G. G. G.*
SPECIES: Sprague-Dawley Rat **SEX:** Male/Female **ORGAN:** Liver **DATE:** December 20-21, 1990

Code No.	Animal No.	Dose Group	No. of Slides	Study Pathologist's Diagnoses (SP)	Reviewing Pathologist's Coded Review Diagnoses (RP)	Chairperson's Diagnoses	PWG Diagnoses
277	34-119	LM	1	Telangiectasis, minimal	-	Cystic degeneration minimal	Cystic degeneration (1)
239	34-143	LM	1	Telangiectasis, minimal	-	Cystic degeneration minimal	Cystic degeneration (1)
G231	34-622	52-wk MF	1	Hepatocellular adenoma	Basophilic focus	Concur RP	No tumor (5)
G 1	34-556	78-wk LF	1	Hepatocellular adenoma	Telangiectasis, mild	Angiectasis	No tumor (5)
Y 4	34-186	78-wk LM	1	Hepatocellular adenoma	Eosinophilic focus	Concur RP	No tumor (4) Hepatocellular adenoma (1)
G 92	34-656	HF	1	Hepatocellular adenoma	Hepatocellular adenoma	Hepatocellular adenoma	No tumor (4) Hepatocellular adenoma (1)
G276	34-670	HF	1	Hepatocellular adenoma	Eosinophilic focus, multiple	Concur RP	No tumor (4) Hepatocellular adenoma (1)
G337	34-560	MF	1	Hepatocellular carcinoma	Hepatocellular adenoma	Hepatocellular carcinoma	Hepatocellular carcinoma (5)

PATHOLOGY WORKING GROUP CHAIRPERSON'S WORKSHEETS

CHEMICAL NAME: Triclosan **STUDY:** 2-Year Study **CHAIRPERSON'S SIGNATURE:** [Signature]
SPECIES: Sprague-Dawley Rat **SEX:** Male/Female **ORGAN:** Liver **DATE:** December 20-21, 1990

Code No.	Animal No.	Dose Group	No. of Slides	Study Pathologist's Diagnoses (SP)	Reviewing Pathologist's Coded Review Diagnoses (RP)	Chairperson's Diagnoses	PWG Diagnoses
G 49	34-587	MF	1	Hepatocellular adenoma	Eosinophilic focus	Basophilic focus	No tumor (4) Hepatocellular adenoma (1)
G340	34-515	LF	1	Hepatocellular adenoma	Eosinophilic focus	Concur RP	Hepatocellular adenoma (3) No tumor (2)
G194	34-532	LF	1	Hepatocellular adenoma	Hepatocellular adenoma	Hepatocellular adenoma	Hepatocellular adenoma
G115	34-402	CF	1	Hepatocellular adenoma	Eosinophilic focus	Concur RP	No tumor (5)
G 6	34-412	CF	2	Hepatocellular adenoma	Basophilic focus	Concur SP	Hepatocellular adenoma (5)
G 69	34-423	CF	1	Hepatocellular adenoma	Basophilic focus	Concur RP	Hepatocellular adenoma (4) No tumor (1)
G274	34-436	CF	1	Hepatocellular adenoma	Hepatocellular adenoma	Mixed cell focus, multiple	Hepatocellular adenoma (4) No tumor (1)
Y208	34-052	CM	1	-	Hepatocellular adenoma	Concur SP	No tumor (4) Hepatocellular adenoma (1)

PATHOLOGY WORKING GROUP CHAIRPERSON'S WORKSHEETS

CHEMICAL NAME: Triclosan **STUDY:** 2-Year Study **CHAIRPERSON'S SIGNATURE:** [Signature]
SPECIES: Sprague-Dawley Rat **SEX:** Male **ORGAN:** Liver **DATE:** December 20-21, 1990

Code No.	Animal No.	Dose Group	No. of Slides	Study Pathologist's Diagnoses (SP)	Reviewing Pathologist's Coded Review Diagnoses (RP)	Chairperson's Diagnoses	PWG Diagnoses
Y 56	34-125	LM	1	Hepatocellular adenoma	Basophilic focus, multiple	Concur RP	Hepatocellular adenoma (1) No tumor (4)
Y 77	34-131	LM	1	Hepatocellular carcinoma	Hepatocellular adenoma, multiple	Concur RP	Hepatocellular adenoma (4) Hepatocellular carcinoma (1)
Y132	34-213	MM	1	Hepatocellular carcinoma	Hepatocellular carcinoma	Hepatocellular carcinoma	Hepatocellular carcinoma (5)
Y265	34-247	MM	1	Hepatocellular carcinoma	Hepatocellular adenoma	Hepatocellular carcinoma	Hepatocellular carcinoma (5)
Y109	34-275	HM	1	Hepatocellular carcinoma	Hepatocellular adenoma	Hepatocellular carcinoma	Hepatocellular carcinoma (5)
Y194	34-287	HM	2	Hepatocellular carcinoma	Hepatocellular carcinoma	Hepatocellular carcinoma	Hepatocellular carcinoma (3) Hepatocellular adenoma (2)

PATHOLOGY WORKING GROUP CHAIRPERSON'S WORKSHEETS

CHEMICAL NAME: Triclosan **STUDY:** 2-Year Study **CHAIRPERSON'S SIGNATURE:** [Signature]
SPECIES: Sprague-Dawley Rat **SEX:** Male/Female **ORGAN:** Lung **DATE:** December 20-21, 1990

Code No.	Animal No.	Dose Group	No. of Slides	Study Pathologist's Diagnoses (SP)	Reviewing Pathologist's Coded Review Diagnoses (RP)	Chairperson's Diagnoses	PWG Diagnoses
Y 31	34-012	CM	1	Foamy macrophages, focal, minimal	Foamy macrophages, minimal	Agree	Pneumonitis(5)
Y235	34-017	CM	1	Foamy macrophages, focal, minimal Focal subacute lymphocytic inflammation, minimal	Foamy macrophages, moderate Interstitial pneumonia, mild	Concur RP Concur RP	Pneumonitis(5)
Y273	34-281	HM	1	Foamy macrophages, focal, minimal	Foamy macrophages, mild Interstitial pneumonia, minimal	Concur RP Concur RP	Pneumonitis(5)
Y143	34-282	HM	1	Foamy macrophages, focal, minimal	Foamy macrophages, mild	Concur RP	Pneumonitis(5)
Y 22	34-301	HM	1	Foamy macrophages, focal, minimal -	Foamy macrophages, mild Interstitial pneumonia, mild	Concur RP Concur RP	Pneumonitis(5)
Y218	34-309	HM	1	Foamy macrophages, focal, minimal	Foamy macrophages, minimal	Agree	Pneumonitis(3) No lesion (2)
G236	34-410	CF	1	Foamy macrophages, focal, minimal	Foamy macrophages, minimal Interstitial pneumonia, mild	Agree Concur RP	Pneumonitis(5)

PATHOLOGY WORKING GROUP CHAIRPERSON'S WORKSHEETS

CHEMICAL NAME: Triclosan **STUDY:** 2-Year Study **CHAIRPERSON'S SIGNATURE:** *Walter G. Lyman*
SPECIES: Sprague-Dawley Rat **SEX:** Female **ORGAN:** Lung **DATE:** December 20-21, 1990

Code No.	Animal No.	Dose Group	No. of Slides	Study Pathologist's Diagnoses (SP)	Reviewing Pathologist's Coded Review Diagnoses (RP)	Chairperson's Diagnoses	PWG Diagnoses
G 54	34-409	CF	1	Foamy macrophages, focal, minimal	Foamy macrophages, minimal Interstitial pneumonia, minimal	Agree Concur RP	Pneumonitis(5)
G 87	34-645	HF	1	Foamy macrophages, focal, minimal	Foamy macrophages, minimal Interstitial pneumonia, minimal	Agree Concur RP	Pneumonitis(5)
G248	34-655	HF	1	Foamy macrophages, focal, minimal	Foamy macrophages, mild Interstitial pneumonia, minimal	Concur RP Concur RP	Pneumonitis(5)
G344	34-701	HF	1	Foamy macrophages, focal, minimal	Foamy macrophages, mild Interstitial pneumonia, mild	Concur RP Concur RP	Pneumonitis(5)
G121	34-700	HF	1	- -	Foamy macrophages, minimal Interstitial pneumonia, minimal	Concur RP Concur RP	Pneumonitis(5)
G 62	34-528	LF	1	Foamy macrophages, focal, minimal	-	Concur SP	Pneumonitis(3) No lesion (2)
G 30	34-522	LF	1	-	Foamy macrophages, minimal	Concur RP	Pneumonitis(4) No lesion (1)

PATHOLOGY WORKING GROUP CHAIRPERSON'S WORKSHEETS

CHEMICAL NAME: Triclosan

STUDY: 2-Year Study

CHAIRPERSON'S SIGNATURE: *[Signature]*

SPECIES: Sprague-Dawley Rat

SEX: Male/Female

ORGAN: Lung

DATE: December 20-21, 1990

Code No.	Animal No.	Dose Group	No. of Slides	Study Pathologist's Diagnoses (SP)	Reviewing Pathologist's Coded Review Diagnoses (RP)	Chairperson's Diagnoses	PWG Diagnoses
G194	34-532	LF	1	-	Foamy macrophages, minimal Interstitial pneumonia, minimal	Concur RP Concur RP	Pneumonitis(3) No lesion (2)
G100	34-411	CF	1	Foamy macrophages, focal, minimal	-	Concur SP	Pneumonitis(3) No lesion (2)
Y152	34-292	HM	1	Foamy macrophages, focal, minimal	-	Concur SP	Pneumonitis(5)
Y111	34-293	HM	1	-	Foamy macrophages, minimal	Concur RP	Pneumonitis(5)
Y327	34-294	HM	1	Foamy macrophages, focal, minimal Fibrosarcoma, metastatic	- Histiocytic sarcoma	Concur SP Concur SP	Pneumonitis(4) No lesion (1) Sarcoma, present
Y 10	34-307	HM	1	Foamy macrophages, disseminated, focal, moderate Alveolar septa - Chronic hyperplasia, inflammation, minimal	- Interstitial pneumonia, moderate	Concur SP Concur RP	Pneumonitis(4) No lesion (1)
Y214	34-315	HM	1	Foamy macrophages, focal, minimal Alveolar septa - Mineralization, focal, minimal	- Interstitial pneumonia, mild	Concur SP Concur RP	Pneumonitis(5)

PATHOLOGY WORKING GROUP CHAIRPERSON'S WORKSHEETS

CHEMICAL NAME: Triclosan

STUDY: 2-Year Study

CHAIRPERSON'S SIGNATURE: *[Signature]*

SPECIES: Sprague-Dawley Rat

SEX: Male

ORGAN: Lung

DATE: December 20-21, 1990

Code No.	Animal No.	Dose Group	No. of Slides	Study Pathologist's Diagnoses (SP)	Reviewing Pathologist's Coded Review Diagnoses (RP)	Chairperson's Diagnoses	PWG Diagnoses
Y287	34-029	CM	1	-	Foamy macrophages, mild	Concur RP	Pneumonitis(4) No lesion (1)
Y 75	34-021	CM	1	Focal hemorrhage, minimal	Not remarkable	Interstitial pneumonia, minimal	Pneumonitis(1) No lesion (4)
Y264	34-049	CM	1	-	Foamy macrophages, minimal	Concur SP	No lesion (5)
Y145	34-051	CM	1	Foamy macrophages, focal, minimal	-	Concur RP	No lesion (5)
Y208	34-052	CM	1	Foamy macrophages, focal, minimal -	- Interstitial pneumonia, mild	Concur RP Concur RP	Pneumonitis(4) No lesion (1)
Y293	34-055	CM	1	Foamy macrophages, focal, minimal	-	Concur RP	Pneumonitis(3) No lesion (2)
Y230	34-068	CM	1	Foamy macrophages, focal, minimal	-	Concur RP	No lesion (5)
Y 74	34-110	LM	1	Foamy macrophages, focal, minimal	-	Concur RP	No lesion (5)
Y 59	34-115	LM	1	Foamy macrophages, focal, minimal -	- Interstitial pneumonia, moderate	Concur RP Concur RP	Pneumonitis(4) No lesion (1)

PATHOLOGY WORKING GROUP CHAIRPERSON'S WORKSHEETS

CHEMICAL NAME: Triclosan **STUDY:** 2-Year Study **CHAIRPERSON'S SIGNATURE:** [Signature]
SPECIES: Sprague-Dawley Rat **SEX:** Male **ORGAN:** Lung **DATE:** December 20-21, 1990

Code No.	Animal No.	Dose Group	No. of Slides	Study Pathologist's Diagnoses (SP)	Reviewing Pathologist's Coded Review Diagnoses (RP)	Chairperson's Diagnoses	PWG Diagnoses
Y 46	34-140	LM	1	Foamy macrophages, focal, minimal -	- Interstitial pneumonia, minimal	Concur RP Concur RP	Pneumonitis(3) No lesion (2)
Y 43	34-158	LM	1	Foamy macrophages, focal, minimal	-	Concur RP	Pneumonitis(3) No lesion (2)
Y130	34-164	LM	1	-	Foamy macrophages, minimal	Concur SP	Pneumonitis(3) No lesion (2)
Y221	34-192	MM	1	Foamy macrophages, focal, minimal -	- -	Concur RP Interstitial pneumonia, minimal	Pneumonitis(4) No lesion (1)
Y 14	34-201	MM	1	-	Interstitial pneumonia, mild Foamy macrophages, minimal	Concur RP Concur SP	Pneumonitis(5)
Y243	34-204	MM	1	Foamy macrophages, focal, minimal	-	Concur RP	Pneumonitis(4) No lesion (1)
Y132	34-213	MM	1	-	Foamy macrophages, minimal	Concur SP	No lesion (5)
Y 79	34-222	MM	1	-	Foamy macrophages, minimal	Concur SP	No lesion (5)



PATHOLOGY WORKING GROUP CHAIRPERSON'S WORKSHEETS

CHEMICAL No. 4: Triclosan

STUDY: 2-Year Study

CHAIRPERSON'S SIGNATURE:

SPECIES: Sprague-Dawley Rat

SEX: Male/Female

ORGAN: Lung

DATE: December 20-21, 1990

Code No.	Animal No.	Dose Group	No. of Slides	Study Pathologist's Diagnoses (SP)	Reviewing Pathologist's Coded Review Diagnoses (RP)	Chairperson's Diagnoses	PWG Diagnoses
Y209	34-224	MM	1	Foamy macrophages, focal, minimal -	- Interstitial pneumonia, mild	Concur RP Concur RP	Pneumonitis(3) No lesion (2)
Y244	34-235	MM	1	-	Foamy macrophages, minimal	Concur SP	Pneumonitis(2) No lesion (3)
Y317	34-242	MM	1	Foamy macrophages, focal, minimal	-	Concur RP	No lesion (5)
Y168	34-283	HM	1	-	Foamy macrophages, minimal	Concur SP	No lesion (5)
G223	34-397	CF	1	- -	Foamy macrophages, minimal -	Concur RP Interstitial pneumonia, minimal	Pneumonitis(1) No lesion (4)
G171	34-420	CF	1	-	Foamy macrophages, minimal	Concur SP	No lesion (5)
G 16	34-438	CF	1	-	Foamy macrophages, minimal	Concur SP	Pneumonitis(3) No lesion (2)
G303	34-479	LF	1	Foamy macrophages, focal, minimal -	- Interstitial pneumonia, minimal	Concur RP Concur RP	Pneumonitis(3) No lesion (2)

PATHOLOGY WORKING GROUP CHAIRPERSON'S WORKSHEETS

CHEMICAL NAME: Triclosan **STUDY:** 2-Year Study **CHAIRPERSON'S SIGNATURE:** [Signature]
SPECIES: Sprague-Dawley Rat **SEX:** Female **ORGAN:** Lung **DATE:** December 20-21, 1990

Code No.	Animal No.	Dose Group	No. of Slides	Study Pathologist's Diagnoses (SP)	Reviewing Pathologist's Coded Review Diagnoses (RP)	Chairperson's Diagnoses	PWG Diagnoses
G311	34-495	LF	1	Foamy macrophages, focal, minimal	-	Concur RP	Pneumonitis(4) No lesion (1)
G335	34-514	LF	1	Foamy macrophages, focal, minimal	-	Concur RP	No lesion (5)
G293	34-526	LF	1	-	Interstitial pneumonia, minimal	Concur SP	No lesion (5)
G273	34-533	LF	1	Foamy macrophages, focal, minimal	Metastatic carcinoma	Concur RP	Metastatic tumor (5) Pneumonitis(1)
G238	34-597	MF	1	Foamy macrophages, focal, minimal	-	Concur RP	Pneumonitis(2) No lesion (3)
G142	34-600	MF	1	-	Interstitial pneumonia, minimal	Concur RP	Pneumonitis(5)
				-	-	Foamy macrophages, minimal	
G264	34-615	MF	1	Alveolar septal cell-focal hypertrophy, minimal	Interstitial pneumonia, mild	Concur RP	Pneumonitis(5)
				-	Foamy macrophages, minimal	Concur SP	

PATHOLOGY WORKING GROUP CHAIRPERSON'S WORKSHEETS

CHEMICAL NAME: Triclosan **STUDY:** 2-Year Study **CHAIRPERSON'S SIGNATURE:** [Signature]
SPECIES: Sprague-Dawley Rat **SEX:** Female **ORGAN:** Lung **DATE:** December 20-21, 1990

Code No.	Animal No.	Dose Group	No. of Slides	Study Pathologist's Diagnoses (SP)	Reviewing Pathologist's Coded Review Diagnoses (RP)	Chairperson's Diagnoses	PWG Diagnoses
G127	34-647	HF	1	-	Foamy macrophages, minimal	Concur SP	Pneumonitis(3)
				-	-	Interstitial pneumonia, minimal	No lesion (2)
G284	34-682	HF	1	-	Foamy macrophages, minimal	Concur SP	No lesion (5)
				-	Interstitial pneumonia, minimal	Concur SP	
G289	34-689	HF	1	-	Foamy macrophages, minimal	Concur SP	No lesion (5)
G355	34-703	HF	1	-	Foamy macrophages, minimal	Concur SP	No lesion (5)

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PATHOLOGY WORKING GROUP CHAIRPERSON'S WORKSHEETS

CHEMICAL NAME: Triclosan **STUDY:** 52-Week Study **CHAIRPERSON'S SIGNATURE:** [Signature]
SPECIES: Sprague-Dawley Rat **SEX:** Male **ORGAN:** Liver **DATE:** December 20-21, 1990

Code No.	Animal No.	Dose Group	No. of Slides	Study Pathologist's Diagnoses (SP)	Reviewing Pathologist's Coded Review Diagnoses (RP)	Chairperson's Diagnoses	PWG Diagnoses
Y202	34-071	CM	1	-	Clear cell focus	Concur RP	-
Y170	34-073	CM	1	-	-	-	-
Y356	34-363	HM2	1	Hepatocytes, inclusion bodies, minimal Hepatocytes, hypertrophy, moderate	- Centrilobular hypertrophy, mild	(Part of hypertrophy) Agree	(Part of hypertrophy) Centrilobular hypertrophy (5)
Y253	34-361	HM2	1	Hepatocytes, hypertrophy, minimal	Centrilobular hypertrophy, mild	Concur RP	Centrilobular hypertrophy (5)
Y 89	34-377	HM2	1	Hepatocytes, inclusion bodies, minimal Hepatocytes, hypertrophy, minimal -	- Centrilobular hypertrophy, mild Necrosis, minimal	(Part of hypertrophy) Agree Concur RP	(Part of hypertrophy) Centrilobular hypertrophy (3) No lesion (2)
Y172	34-360	HM2	1	- -	Centrilobular hypertrophy, mild Clear cell focus	Concur RP Concur RP	Centrilobular hypertrophy (5)

PATHOLOGY WORKING GROUP CHAIRPERSON'S WORKSHEETS

CHEMICAL N^o : Triclosan **STUDY:** 52-Week Study

CHAIRPERSON'S SIGNATURE: [Signature]

SPECIES: Sprague-Dawley Rat

SEX: Male

ORGAN: Liver

DATE: December 20-21, 1990

Code No.	Animal No.	Dose Group	No. of Slides	Study Pathologist's Diagnoses (SP)	Reviewing Pathologist's Coded Review Diagnoses (RP)	Chairperson's Diagnoses	PWG Diagnoses
Y284	34-379	HM2	1	-	Centrilobular hypertrophy, mild	Concur RP	Centrilobular hypertrophy (4)
				-	Clear cell focus	Concur RP	No lesion (1)
Y 13	34-375	HM2	1	Hepatocytes, inclusion bodies, minimal Hepatocytes, hypertrophy, moderate	-	(Part of hypertrophy)	(Part of hypertrophy)
					-	Concur SP	Centrilobular hypertrophy (5)
Y325	34-376	HM2	1	Hepatocytes, inclusion bodies, minimal Hepatocytes, hypertrophy, moderate	-	(Part of hypertrophy)	(Part of hypertrophy)
					-	Concur SP	Centrilobular hypertrophy (5)
Y329	34-367	HM2	1	Hepatocytes, hypertrophy, moderate	-	Concur SP	Centrilobular hypertrophy (3) No lesion (2)
Y335	34-370	HM2	1	Hepatocytes, hypertrophy, moderate	-	Concur SP	Centrilobular hypertrophy (4) No lesion (1)



PATHOLOGY WORKING GROUP CHAIRPERSON'S WORKSHEETS

CHEMICAL NAME: TriclosanSTUDY: 52-Week StudyCHAIRPERSON'S SIGNATURE: W. L. G. G.SPECIES: Sprague-Dawley RatSEX: Male/FemaleORGAN: LiverDATE: December 20-21, 1990

Code No.	Animal No.	Dose Group	No. of Slides	Study Pathologist's Diagnoses (SP)	Reviewing Pathologist's Coded Review Diagnoses (RP)	Chairperson's Diagnoses	PWG Diagnoses
Y210	34-338	HM1	1	-	Centrilobular hypertrophy, mild	Centrilobular hypertrophy minimal	Centrilobular hypertrophy (2) No lesion (3)
Y 37	34-341	HM1	1	-	Centrilobular hypertrophy, mild	Concur RP	Centrilobular hypertrophy (5)
				-	Basophilic focus	Concur RP	
G126	34-441	CF	1	-	-	-	-
G301	34-442	CF	1	-	-	-	-
G239	34-731	HF2	1	-	Centrilobular hypertrophy, minimal	Concur RP	Centrilobular hypertrophy (2) No lesion (3)
G 46	34-749	HF2	1	-	Centrilobular hypertrophy, mild	Concur RP	Centrilobular hypertrophy (5)
G176	34-748	HF2	1	-	Centrilobular hypertrophy, minimal	Concur RP	Centrilobular hypertrophy (3) No lesion (2)
G306	34-746	HF2	1	-	Centrilobular hypertrophy, minimal	Concur RP	Centrilobular hypertrophy (2) No lesion (3)

PATHOLOGY WORKING GROUP CHAIRPERSON'S WORKSHEETS

CHEMICAL NAME: Triclosan

STUDY: 52-Week Study

CHAIRPERSON'S SIGNATURE: *[Signature]*

SPECIES: Sprague-Dawley Rat

SEX: Male/Female

ORGAN: Liver

DATE: December 20-21, 1990

Code No.	Animal No.	Dose Group	No. of Slides	Study Pathologist's Diagnoses (SP)	Reviewing Pathologist's Coded Review Diagnoses (RP)	Chairperson's Diagnoses	PWG Diagnoses
G 81	34-732	HF2	1	-	Centrilobular hypertrophy, minimal	Concur RP	Centrilobular hypertrophy (2) No lesion (3)
G165	34-733	HF2	1	-	Centrilobular hypertrophy, minimal	Concur RP	Centrilobular hypertrophy (5)
Y 29	34-336	HM1	1	-	Centrilobular hypertrophy, minimal	Concur RP	Centrilobular hypertrophy (3) No lesion (2)
Y351	34-342	HM1	1	-	Centrilobular hypertrophy, minimal	Concur RP	Centrilobular hypertrophy (4) No lesion (1)
				-	Clear cell focus	Concur RP	
Y310	34-364	HM2	1	-	Centrilobular hypertrophy, mild	Concur RP	Centrilobular hypertrophy (5)
Y298	34-371	HM2	1	-	Centrilobular hypertrophy, mild	Concur RP	Centrilobular hypertrophy (5)

PATHOLOGY WORKING GROUP CHAIRPERSON'S WORKSHEETS

CHEMICAL NAME: Triclosan **STUDY:** 52-Week Study **CHAIRPERSON'S SIGNATURE:** *Sam G. Goodman*
SPECIES: Sprague-Dawley Rat **SEX:** Male **ORGAN:** Liver **DATE:** December 20-21, 1990

Code No.	Animal No.	Dose Group	No. of Slides	Study Pathologist's Diagnoses (SP)	Reviewing Pathologist's Coded Review Diagnoses (RP)	Chairperson's Diagnoses	PWG Diagnoses
Y354	34-373	HM2	1	-	Centrilobular hypertrophy, mild	Concur RP	Centrilobular hypertrophy (5)
Y216	34-374	HM2	1	-	Centrilobular hypertrophy, mild	Concur RP	Centrilobular hypertrophy (5)
Y330	34-365	HM2	1	Hepatocyte, hypertrophy, minimal	Centrilobular hypertrophy, mild	Agree	Centrilobular hypertrophy (5)
Y 63	34-366	HM2	1	Hepatocyte, hypertrophy, moderate	Centrilobular hypertrophy, mild Clear cell focus	Agree Concur RP	Centrilobular hypertrophy (5)
Y259	34-369	HM2	1	Hepatocyte, hypertrophy, minimal	Centrilobular hypertrophy, minimal	Agree	Centrilobular hypertrophy (5)
Y278	34-372	HM2	1	Hepatocyte, hypertrophy, moderate	Centrilobular hypertrophy, mild	Agree	Centrilobular hypertrophy (5)
Y319	34-378	HM2	1	Hepatocyte, hypertrophy, minimal	Centrilobular hypertrophy, minimal Clear cell focus	Agree Concur RP	Centrilobular hypertrophy (5)

APPENDIX B
Pathology Review Worksheets

Pathology Review Worksheets
Ciba-Geigy
Chronic Toxicity/Carcinogenicity Study
PATHCO No. 90-128

Group I - Male, Two-Year Study

Code Number	Slide No.	No. of Slides	Organ	Study Pathologist's (SP) Diagnoses	Reviewing Pathologist's (RP) Coded Pathology Review	Chairperson's Diagnoses
201	34010	1	Liver	No deviation from normal morphology	Eosinophilic focus	Concur RP
					Clear cell focus, multiple	Concur RP
		1	Lung		NR	
76	34011	1	Liver	Hepatocytes, vacuolation, moderate	Fatty change, moderate	Concur RP
		1	Lung	Congestion, minimal		Concur SP
					Interstitial pneumonia, minimal	Concur RP
31	34012	1	Liver	Focal chronic lymphocytic inflam., minimal		
				Telangiectasis, minimal	Cystic degeneration, minimal	Concur RP
		1	Lung	Alveoli, accum. of foamy macrophages, focal, minimal	Foamy macrophages, minimal	Agree

Pathology Review Worksheets
Ciba-Geigy
Chronic Toxicity/Carcinogenicity Study
PATHCO No. 90-128

Group I - Male, Two-Year Study

Code Number	Slide No.	No. of Slides	Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
217	34013	1	Liver	Bile ducts, Focal hyperplasia, minimal Bile ducts, Cyst, minimal	 Basophilic focus	
		1	Lung	Alveoli, accum. of foamy macrophages, focal, minimal	Foamy macrophages, minimal	Agree
98	34014	1	Liver	Focal acute purulent inflammation, minimal Hepatocytes, vacuolation, minimal	 Fatty change, minimal	
		1	Lung		NR	
6	34015	1	Liver	Hepatocytes, vacuolation, minimal	Fatty change, focal	Concur RP
		1	Lung	Acute purulent inflammation, moderate Alveoli, accum. of foamy macrophages, focal, minimal	Inflammation, suppurative, moderate	Concur RP Concur SP

Pathology Review Worksheets
Ciba-Geigy
Chronic Toxicity/Carcinogenicity Study
PATHCO No. 90-128

Group I - Male, Two-Year Study

Code Number	Slide No.	No. of Slides	Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
256	34016	1	Liver	Malignant lymphoma	Lymphoma	
		1	Lung	Congestion, moderate Alveoli, edema, moderate	NR	
235	34017	1	Liver	Telangiectasis, minimal	Cystic degeneration, minimal	Concur RP
					Basophilic focus	Concur RP
					Clear cell focus, multiple	Concur RP
		1	Lung	Focal subacute lymphocytic inflam., minimal	Interstitial pneumonia, mild	Concur RP
				Alveoli, accum. of foamy macrophages, focal, minimal	Foamy macrophages, moderate	Concur RP
324	34018	1	Liver	Metastatic adrenal cort. carcinoma	NR	
				Congestion, minimal		
				Bile ducts, Focal hyperplasia, minimal		

Pathology Review Worksheets
Ciba-Geigy
Chronic Toxicity/Carcinogenicity Study
PATHCO No. 90-128

Group I - Male, Two-Year Study

Code Number	Slide No.	No. of Slides	Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
324	34018 continued	1	Lung	Metastatic adrenal cort. carcinoma Congestion, minimal	Metastatic tumor	
367	34019	2	Liver	Cellular alteration, minimal	Basophilic focus Eosinophilic focus Clear cell focus, multiple Cystic degeneration, mild	Concur RP Concur RP Concur RP Concur RP (within foci)
		1	Lung		NR	
267	34020	1	Liver	No deviation from normal morphology	Clear cell focus, multiple	Concur RP
		1	Lung	Alveoli, accum. of foamy macrophages, focal, minimal		Concur SP
					Interstitial pneumonia, minimal	Concur RP

Pathology Review Worksheets
Ciba-Geigy
Chronic Toxicity/Carcinogenicity Study
PATHCO No. 90-128

Group I - Male, Two-Year Study

Code Number	Slide No.	No. of Slides	Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
75	34021	1	Liver	Hepatocytes, vacuolation, minimal Bile ducts, Focal hyperplasia, minimal		Concur SP
					Clear cell focus, multiple	Concur RP
					Cystic degeneration, minimal	Concur RP
		1	Lung	Alveoli, focal hemorrhage, minimal	NR	Interstitial pneumonia, minimal
341	34022	1	Liver		Basophilic focus	
		1	Lung	Dis'm foc. subac lymphocytic inflam, minimal	NR	
38	34023	1	Liver	Congestion, minimal		Basophilic focus
		1	Lung	Congestion, minimal	NR	

Pathology Review Worksheets
Ciba-Geigy
Chronic Toxicity/Carcinogenicity Study
PATHCO No. 90-128

Group I - Male, Two-Year Study

Code Number	Slide No.	No. of Slides	Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
192	34024	1	Liver	Cellular alteration, minimal Telangiectasis, minimal Bile ducts, Focal hyperplasia, minimal	Clear cell focus, multiple	Concur RP Concur RP
		1	Lung	Alveoli, accum. of foamy macrophages, focal, minimal	Foamy macrophages, minimal	Agree
23	34025	1	Liver	Bile ducts, Focal hyperplasia, minimal	Bile duct hyperplasia, mild	
		1	Lung		Edema, mild	
137	34026	1	Liver	Cellular alteration, minimal Telangiectasis, minimal Lobule centro, focal coag- ulation necrosis, minimal	Cystic degeneration, mild	Concur RP Centrilobular necrosis, minimal
		1	Lung	Dis'm foc. subac lymphocytic inflam, minimal	NR	

Pathology Review Worksheets
Ciba-Geigy
Chronic Toxicity/Carcinogenicity Study
PATHCO No. 90-128

Group I - Male, Two-Year Study

Code Number	Slide No.	No. of Slides	Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
166	34027	1	Liver	No deviation from normal morphology	Clear cell focus, multiple	
		1	Lung		NR	
69	34028	1	Liver	Congestion, minimal	NR	
		1	Lung	Congestion, minimal	NR	
287	34029	1	Liver	Bile ducts, Focal hyperplasia, minimal	NR	
		1	Lung		Foamy macrophages, mild	Concur RP
142	34030	1	Liver	Bile ducts, Focal hyperplasia, minimal	NR	
		1	Lung		NR	
66	34031	1	Liver	No deviation from normal morphology	Eosinophilic focus, multiple	Concur RP
					Cystic degeneration, minimal	Concur RP

Pathology Review Worksheets
Ciba-Geigy
Chronic Toxicity/Carcinogenicity Study
PATHCO No. 90-128

Group I - Male, Two-Year Study

Code Number	Slide No.	No. of Slides	Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
66	34031	1	Lung		NR	
	continued					
18	34032	1	Liver	Cellular alteration, minimal	Fatty change, minimal	
				Bile ducts, Focal hyperplasia, minimal		
		1	Lung	Dis'm foc. subac lymphocytic inflam, minimal	NR	
134	34033	1	Liver	Telangiectasis, minimal	Cystic degeneration, minimal Fatty change, mild	Concur RP
		1	Lung		NR	
307	34034	1	Liver	Cellular alteration, minimal	Basophilic focus, multiple Clear cell focus, multiple Cystic degeneration, moderate	Concur RP Concur RP Concur RP

Pathology Review Worksheets
Ciba-Geigy
Chronic Toxicity/Carcinogenicity Study
PATHCO No. 90-128

Group I - Male, Two-Year Study

Code Number	Slide No.	No. of Slides	Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
307	34034 continued	1	Lung	Alveoli, accum. of foamy macrophages, focal, minimal	Foamy macrophages, minimal	Agree
					Interstitial pneumonia, minimal	Concur RP
95	34035	1	Liver		NR	
		1	Lung		NR	
300	34036	1	Liver	Congestion, minimal Bile ducts, Focal hyperplasia, minimal	NR	
		1	Lung		NR	
276	34037	1	Liver		NR	
		1	Lung		NR	
164	34038	1	Liver		Basophilic focus, multiple	

Pathology Review Worksheets
Ciba-Geigy
Chronic Toxicity/Carcinogenicity Study
PATHCO No. 90-128

Group I - Male, Two-Year Study

Code Number	Slide No.	No. of Slides	Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
164	34038	1	Lung		Interstitial pneumonia, minimal	Concur RP
continued						
81	34039	1	Liver	Hepatocytes, vacuolation, minimal	Periportal hepatocellular hypertrophy, mild Basophilic focus	
				Bile ducts, Focal hyperplasia, minimal	Bile duct hyperplasia, mild	
		1	Lung	Dis'm foc. subac lymphocytic inflam, minimal	Foamy macrophages, minimal	Concur RP
94	34040	1	Liver	Hepatocytes, vacuolation, minimal	Fatty change, minimal	
		1	Lung		NR	
106	34041	1	Liver	Focal subacute lymphocytic inflam., minimal	NR	

Pathology Review Worksheets
Ciba-Geigy
Chronic Toxicity/Carcinogenicity Study
PATHCO No. 90-128

Group I - Male, Two-Year Study

Code Number	Slide No.	No. of Slides	Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
106	34041 continued	1	Lung	Alveoli, accum. of foamy macrophages, focal, minimal	Foamy macrophages, mild	Concur RP
73	34042	1	Liver	Cellular alteration, minimal	Eosinophilic focus	Concur RP
				Telangiectasis, minimal	Cystic degeneration, mild	Concur RP
		1	Lung		NR	
281	34043	1	Liver	Lobule centro, necrosis, minimal	Centrilobular necrosis, mild	Concur RP
				Bile ducts, Focal hyperplasia, minimal		
		1	Lung		NR	
203	34044	2	Liver	Hepatocarcinoma	Hepatocellular carcinoma	Agree
				Telangiectasis, severe	Cystic degeneration, minimal	Concur RP
		1	Lung		NR	

Pathology Review Worksheets
Ciba-Geigy
Chronic Toxicity/Carcinogenicity Study
PATHCO No. 90-128

Group I - Male, Two-Year Study

Code Number	Slide No.	No. of Slides	Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
224	34045	1	Liver	No deviation from normal morphology	Basophilic focus	
		1	Lung	Alveoli, accum. of foamy macrophages, focal, minimal	NR	Concur RP
33	34046	1	Liver	Bile ducts, Focal hyperplasia, minimal	NR	
		1	Lung		NR	
200	34047	1	Liver	Telangiectasis, minimal	Cystic degeneration, moderate	Concur RP
					Clear cell focus, multiple	Concur RP
		1	Lung		NR	
157	34048	1	Liver	No deviation from normal morphology	Eosinophilic focus, multiple	
					Clear cell focus	
		1	Lung	Dis'm foc. subac lymphocytic inflam, minimal	NR	

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Group I - Male, Two-Year Study

Code Number	Slide No.	No. of Slides	Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
264	34049	1	Liver	Sarcoma, histiocytic	Histiocytic sarcoma	Agree
		1	Lung		Foamy macrophages, minimal	Concur SP
121	34050	1	Liver	Cellular alteration, minimal	Clear cell focus, multiple	Concur RP
				Telangiectasis, minimal	Cystic degeneration, mild	Concur RP
		1	Lung		NR	
145	34051	1	Liver	Bile ducts, Focal hyperplasia, minimal	NR	
		1	Lung	Alveoli, accum. of foamy macrophages, focal, minimal	NR	Concur RP
208	34052	1	Liver	Hepatocytes, vacuolation, minimal	Fatty change, mild	
					Hepatocellular adenoma	Concur SP
				Bile ducts, Focal hyperplasia, moderate	Bile duct hyperplasia, mild	

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Group I - Male, Two-Year Study

Code Number	Slide No.	No. of Slides	Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
208	34052	1	Lung	Alveoli, accum. of foamy macrophages, focal, minimal		Concur RP
	continued				Interstitial pneumonia, mild	Concur RP
326	34053	1	Liver	Cellular alteration, minimal	Clear cell focus, multiple	
		1	Lung	Alveoli, accum. of foamy macrophages, focal, minimal	Foamy macrophages, mild	Concur RP
					Interstitial pneumonia, mild	Concur RP
36	34054	1	Liver	Cellular alteration, minimal	Eosinophilic focus	Concur RP
					Clear cell focus, multiple	Concur RP
				Congestion, minimal		Concur SP
					Cystic degeneration, minimal	Concur RP
		1	Lung	Congestion, minimal	NR	

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Group I - Male, Two-Year Study

Code Number	Slide No.	No. of Slides	Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
293	34055	1	Liver	Cellular alteration, minimal	Clear cell focus	Clear cell focus, multiple
				Hepatocellular adenoma	Basophilic focus	Eosinophilic focus
				Focal acute purulent inflammation, minimal		
		1	Lung	Alveoli, accum. of foamy macrophages, focal, minimal	NR	Concur RP
229	34056	1	Liver	Congestion, minimal	Basophilic focus	
		1	Lung	Congestion, minimal	NR	
254	34057	1	Liver	Congestion, moderate	NR	
		1	Lung	Congestion, minimal	NR	
2	34058	1	Liver		NR	

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Group I - Male, Two-Year Study

Code Number	Slide No.	No. of Slides	Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
2	34058 continued	1	Lung	Congestion, minimal		
				Alveoli, accum. of foamy macrophages, focal, minimal	Foamy macrophages, minimal	Agree
206	34059	1	Liver	Congestion, minimal		
					Basophilic focus	Concur RP
					Cystic degeneration, minimal	Concur RP
352	34060	1	Lung		NR	
			Liver	Congestion, minimal		
					Centrilobular fatty change, minimal	
198	34061	1	Liver		NR	
					Clear cell focus, multiple	
			Liver	No deviation from normal morphology		
		1	Lung		NR	

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Group I - Male, Two-Year Study

Code Number	Slide No.	No. of Slides	Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
322	34062	1	Liver	Telangiectasis, minimal Congestion, minimal Bile ducts, Focal hyperplasia, minimal Glissons capsule, bacteria, moderate Glissons capsule, focal acute purulent inflammation, severe	Cystic degeneration, mild	Concur RP
		1	Lung	Congestion, minimal	NR	
225	34063	1	Liver	Cellular alteration, minimal	Clear cell focus, multiple	Concur RP
		1	Lung		NR	
9	34064	1	Liver	Congestion, minimal Hepatocytes, vacuolation, moderate	Fatty change, moderate Clear cell focus	
		1	Lung	Congestion, minimal	NR	

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Group I - Male, Two-Year Study

Code Number	Slide No.	No. of Slides	Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
355	34065	1	Liver	Bile ducts, Focal hyperplasia, minimal	NR	
		1	Lung	Alveoli, edema, minimal		
					Foamy macrophages, minimal	Concur RP
					Interstitial pneumonia, moderate	Concur RP
17	34066	1	Liver	No deviation from normal morphology	NR	
		1	Lung			
					Foamy macrophages, minimal	Concur RP
					Interstitial pneumonia, minimal	Concur RP
366	34067	1	Liver	Bile ducts, Focal hyperplasia, minimal	NR	
		1	Lung		NR	
230	34068	1	Liver	Bile ducts, Focal hyperplasia, moderate	NR	

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Group I - Male, Two-Year Study

Code Number	Slide No.	No. of Slides Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
230	34068 continued	1 Lung	Alveoli, accum. of foamy macrophages, focal, minimal	NR	Concur RP
1	34069	1 Liver	Cellular alteration, minimal	Eosinophilic focus	Concur RP
				Clear cell focus	Concur RP
			Hepatocellular adenoma	Basophilic focus	Concur RP
			Telangiectasis, minimal	Cystic degeneration, mild	Concur RP
		1 Lung		NR	

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Group II - Male, Two-Year Study

Code Number	Slide No.	No. of Slides	Organ	Study Pathologist's (SP) Diagnoses	Reviewing Pathologist's (RP) Coded Pathology Review	Chairperson's Diagnoses
320	34105	1	Liver	Cellular alteration, minimal	Clear cell focus, multiple	Concur RP
				Telangiectasis, minimal	Cystic degeneration, mild	Concur RP
		1	Lung	No deviation from normal morphology	NR	
185	34106	1	Liver	Sarcoma, histiocytic Necrosis, moderate	Histiocytic sarcoma	Agree (Part of tumor)
		1	Lung	Sarcoma, histiocytic Alveoli, hemorrhage, general, moderate	Histiocytic sarcoma	
275	34107	1	Liver	Necrosis, minimal	Centrilobular necrosis, mild	Concur RP
				Telangiectasis, minimal	Cystic degeneration, moderate	Concur RP
		1	Lung	Alveolar septa, focal mineralization, minimal	Interstitial pneumonia, moderate	Concur RP

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Group II - Male, Two-Year Study

Code Number	Slide No.	No. of Slides	Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
64	34108	2	Liver	Hepatocarcinoma	Hepatocellular carcinoma	Agree
				Congestion, minimal		
				Lobule centro, necrosis, moderate	Centrilobular necrosis, moderate	Agree
					Basophilic focus	
				Bile ducts, Focal hyperplasia, minimal	Bile duct hyperplasia, mild	
		1	Lung	Alveolar septa, focal mineralization, minimal		
					Interstitial pneumonia, minimal	Concur RP
279	34109	1	Liver	Focal coagulation necrosis, minimal	Necrosis, minimal	Concur RP
.		1	Lung		NR	
74	34110	1	Liver	No deviation from normal morphology	Clear cell focus, multiple	

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Group II - Male, Two-Year Study

Code Number	Slide No.	No. of Slides	Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
74	34110	1	Lung	Alveoli, accum. of foamy macrophages, focal, minimal	NR	Concur RP
	continued					
342	34111	2	Liver	Cellular alteration, minimal	Basophilic focus	Concur RP
				Hepatocarcinoma	Hepatocellular adenoma	Cystic degeneration, minimal Hepatocellular carcinoma Angiectasis
		1	Lung	Alveoli, accum. of foamy macrophages, focal, minimal	Foamy macrophages, minimal	Agree
					Interstitial pneumonia, minimal	Concur RP
204	34112	1	Liver	Congestion, minimal	Basophilic focus Clear cell focus	
				Bile ducts, Focal hyperplasia, minimal		

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Group II - Male, Two-Year Study

Code Number	Slide No.	No. of Slides Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
204	34112 continued	1 Lung	Congestion, minimal	NR	
215	34113	1 Liver	Cellular alteration, minimal	Eosinophilic focus	Concur RP
			Congestion, minimal	Clear cell focus, multiple	Concur RP
				Cystic degeneration, minimal	Concur RP
		1 Lung	Alveoli, accum. of foamy macrophages, focal, minimal	NR	Concur SP
181	34114	1 Liver	Focal coagulation necrosis, minimal	Necrosis, minimal	Concur RP
		1 Lung	Alveoli, accum. of foamy macrophages, focal, minimal	Foamy macrophages, minimal	Agree
59	34115	1 Liver	Telangiectasis, minimal	Cystic degeneration, minimal	Concur RP
			Congestion, minimal	Basophilic focus, multiple	Concur RP

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Group II - Male, Two-Year Study

Code Number	Slide No.	No. of Slides Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
59	34115 continued	1 Lung	Congestion, minimal		
			Alveoli, focal hemorrhage, minimal		
			Alveoli, accum. of foamy macrophages, focal, minimal		Concur RP
				Interstitial pneumonia, moderate	Concur RP
87	34116	1 Liver	Cellular alteration, minimal	Clear cell focus, multiple	
		1 Lung	Alveoli, accum. of foamy macrophages, focal, minimal	Foamy macrophages, minimal	Agree
108	34117	1 Liver	No deviation from normal morphology	Basophilic focus	
				Clear cell focus, multiple	
		1 Lung	Alveoli, accum. of foamy macrophages, focal, minimal	Foamy macrophages, minimal	Agree
				Interstitial pneumonia, minimal	Concur RP

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Group II - Male, Two-Year Study

Code Number	Slide No.	No. of Slides	Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
174	34118	1	Liver	Bile ducts, Focal hyperplasia, minimal	NR	
		1	Lung	Alveoli, accum. of foamy macrophages, focal, minimal	Foamy macrophages, mild	Concur RP
277	34119	1	Liver	Telangiectasis, minimal	NR	Cystic degeneration, minimal
		1	Lung	Alveoli, accum. of foamy macrophages, focal, minimal	Foamy macrophages, minimal	Agree
129	34120	2	Liver	Cellular alteration, minimal		
				Telangiectasis, minimal		Cystic degeneration, minimal
				Hepatocytes, vacuolation, minimal	Fatty change, minimal	Concur RP
		1	Lung		NR	

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Group II - Male, Two-Year Study

Code Number	Slide No.	No. of Slides Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
41	34121	1 Liver	Cellular alteration, minimal	Eosinophilic focus	Concur RP Basophilic focus, multiple
		1 Lung	Alveoli, accum. of foamy macrophages, focal, minimal Vein B lumen, thrombosis, severe	Foamy macrophages, minimal	Agree
127	34122	1 Liver		NR	
		1 Lung		NR	
358	34123	1 Liver	Telangiectasis, minimal Congestion, minimal	NR	Cystic degeneration, minimal
		1 Lung	Congestion, minimal	NR	
340	34124	1 Liver	Bile ducts, Focal hyperplasia, minimal	NR	

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Group II - Male, Two-Year Study

Code Number	Slide No.	No. of Slides	Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
340	34124	1	Lung	Edema, moderate	NR	
	continued					
56	34125	1	Liver	Cellular alteration, minimal		
				Hepatocellular adenoma	Basophilic focus, multiple	Concur RP
				Telangiectasis, minimal	Cystic degeneration, mild	Concur RP
				Congestion, minimal		
				Bile ducts, Focal hyperplasia, minimal		
		1	Lung	Congestion, minimal	NR	
40	34126	1	Liver	Cellular alteration, minimal	Basophilic focus, multiple	Concur RP
					Eosinophilic focus	Concur RP
					Clear cell focus, multiple	Concur RP
				Telangiectasis, minimal	Cystic degeneration, mild	Concur RP
		1	Lung	Alveoli, accum. of foamy macrophages, focal, minimal	NR	Concur SP

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Group II - Male, Two-Year Study

Code Number	Slide No.	No. of Slides	Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
71	34127	1	Liver		Basophilic focus, multiple Fatty change, mild	
		1	Lung		Interstitial pneumonia, minimal	Concur RP
90	34128	1	Liver	Congestion, minimal	NR	
		1	Lung	Congestion, minimal	Edema, moderate	
165	34129	1	Liver	Hepatocellular adenoma Congestion, minimal	Eosinophilic focus, multiple	Concur RP
		1	Lung	Congestion, minimal	NR	
299	34130	1	Liver		NR	
		1	Lung	Alveoli, accum. of foamy macrophages, focal, minimal	Foamy macrophages, mild	Concur RP

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Group II - Male, Two-Year Study

Code Number	Slide No.	No. of Slides	Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
77	34131	1	Liver	Hepatocarcinoma	Hepatocellular adenoma, multiple	Concur RP
				Telangiectasis, minimal	Cystic degeneration, mild	Concur RP
					Clear cell focus, multiple	Concur RP
						Mixed cell focus, multiple
		1	Lung	No deviation from normal morphology	NR	
334	34132	1	Liver	Congestion, moderate		
				Lobule centro, necrosis, minimal		Necrosis, minimal
					Periportal fatty change, mild	Concur RP
		1	Lung	Alveoli, accum. of foamy macrophages, focal, minimal	Foamy macrophages, minimal	Agree

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Group II - Male, Two-Year Study

Code Number	Slide No.	No. of Slides	Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
357	34133	1	Liver	Sarcoma, histiocytic		Kupffer cell hyperplasia, moderate
				Cellular alteration, minimal	Basophilic focus, multiple	Mixed cell focus
					Clear cell focus	Concur RP
				Telangiectasis, minimal	Cystic degeneration, mild	Concur RP
					Necrosis, minimal	Concur RP
		1	Lung	Alveoli, accum. of foamy macrophages, focal, minimal	NR	Concur SP
68	34134	1	Liver	Cellular alteration, minimal	Basophilic focus, multiple	
					Clear cell focus, multiple	
		1	Lung	Alveoli, accum. of foamy macrophages, focal, minimal	NR	Concur SP

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Group II - Male, Two-Year Study

Code Number	Slide No.	No. of Slides	Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
328	34135	1	Liver	Congestion, minimal		
					Clear cell focus, multiple	
				Bile ducts, Focal hyperplasia, minimal		
		1	Lung	Congestion, minimal		
				Alveoli, accum. of foamy macrophages, focal, minimal	Foamy macrophages, minimal	Agree
178	34136	1	Liver	Cellular alteration, minimal		
				Lobule centro, necrosis, moderate	Centrilobular necrosis, moderate	Agree
		1	Lung	Alveoli, accum. of foamy macrophages, focal, minimal	Foamy macrophages, minimal	Agree
349	34137	1	Liver		Periportal fatty change, minimal	

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Group II - Male, Two-Year Study

Code Number	Slide No.	No. of Slides	Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
349	34137 continued	1	Lung	Alveoli, accum. of foamy macrophages, focal, minimal	Foamy macrophages, mild	Concur RP
					Interstitial pneumonia, minimal	Concur RP
248	34138	1	Liver		NR	
		1	Lung	Alveoli, accum. of foamy macrophages, focal, minimal	Foamy macrophages, mild	Concur RP
116	34139	1	Liver	Congestion, minimal	NR	
		1	Lung	Congestion, minimal	Edema, moderate	
46	34140	1	Liver	Cellular alteration, minimal Telangiectasis, minimal	Clear cell focus, multiple Cystic degeneration, minimal	Concur RP Concur RP

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Group II - Male, Two-Year Study

Code Number	Slide No.	No. of Slides	Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
46	34140 continued	1	Lung	Alveoli, accum. of foamy macrophages, focal, minimal		Concur RP
					Interstitial pneumonia, minimal	Concur RP
290	34141	1	Liver	Congestion, minimal		
					Periportal fatty change, moderate	
		1	Lung	Bronchopneumonia, severe Alveoli, edema, moderate		
					Abscess, multiple, marked	
343	34142	1	Liver	Congestion, minimal	NR	
		1	Lung	Dis'm foc. subac lymphocytic inflam, minimal Congestion, minimal	NR	

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Group II - Male, Two-Year Study

Code Number	Slide No.	No. of Slides	Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
239	34143	1	Liver	Telangiectasis, minimal Congestion, minimal	NR	Cystic degeneration, minimal
		1	Lung	Congestion, minimal Alveoli, accum. of foamy macrophages, focal, minimal	Foamy macrophages, minimal	Agree
269	34144	1	Liver	Congestion, minimal Bile ducts, Focal hyperplasia, minimal	NR	
		1	Lung	Congestion, minimal Alveoli, accum. of foamy macrophages, focal, minimal	Foamy macrophages, minimal	Agree
78	34145	1	Liver	Telangiectasis, minimal	Cystic degeneration, minimal	Concur RP
		1	Lung	Alveoli, accum. of foamy macrophages, focal, minimal	Foamy macrophages, minimal	Agree

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Group II - Male, Two-Year Study

Code Number	Slide No.	No. of Slides Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
370	34146	1 Liver		NR	
		1 Lung	Focal hemorrhage, minimal Congestion, moderate	NR	
153	34147	2 Liver	Telangiectasis, minimal Congestion, minimal	Cystic degeneration, minimal	Concur RP
		1 Lung	Congestion, minimal Alveoli, accum. of foamy macrophages, focal, minimal	Foamy macrophages, minimal	Agree
96	34148	1 Liver	Telangiectasis, minimal	Cystic degeneration, mild	Concur RP
		1 Lung		Interstitial pneumonia, mild	Concur RP
159	34149	1 Liver	Telangiectasis, minimal Hepatocytes, vacuolation, minimal	Cystic degeneration, mild Centrilobular fatty change, mild	Concur RP Concur RP

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Group II - Male, Two-Year Study

Code Number	Slide No.	No. of Slides	Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
159	34149	1	Lung	Alveoli, accum. of foamy macrophages, focal, minimal	Foamy macrophages, minimal	Agree
	continued			Alveolar septa, focal mineralization, minimal		Concur SP
					Interstitial pneumonia, minimal	Concur RP
138	34150	1	Liver	Bile ducts, Focal hyperplasia, minimal	NR	
		1	Lung		NR	
32	34151	1	Liver		NR	
		1	Lung		NR	
295	34152	1	Liver	Congestion, minimal		
					Cystic degeneration, minimal	Concur RP
		1	Lung	Congestion, minimal	NR	

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Group II - Male, Two-Year Study

Code Number	Slide No.	No. of Slides	Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
266	34153	1	Liver	Telangiectasis, minimal	Cystic degeneration, mild	Concur RP
					Basophilic focus	Concur RP
					Eosinophilic focus	Concur RP
		1	Lung	Alveoli, accum. of foamy macrophages, focal, minimal		Concur SP
				Alveolar septa, focal mineralization, minimal		Concur SP
184	34154	1	Liver	Cellular alteration, minimal	Basophilic focus, multiple	Angiectasis
					Clear cell focus	Concur RP
		1	Lung	No deviation from normal morphology	Cystic degeneration, mild	Concur RP
					Interstitial pneumonia, minimal	Concur RP

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Group II - Male, Two-Year Study

Code Number	Slide No.	No. of Slides Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
272	34155	1 Liver	Cellular alteration, minimal	Basophilic focus	
				Clear cell focus, multiple	
			Telangiectasis, minimal	Cystic degeneration, mild	Concur RP
		1 Lung	No deviation from normal morphology	Interstitial pneumonia, minimal	Concur RP
183	34156	1 Liver	Telangiectasis, minimal	Cystic degeneration, mild	Concur RP
		1 Lung	Alveolar septa, focal mineralization, minimal	NR	
			Artery bronchial, medial calcification, moderate		
364	34157	1 Liver	Bile ducts, Focal hyperplasia, minimal		
				Eosinophilic focus	Concur RP
		1 Lung		NR	

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Group II - Male, Two-Year Study

Code Number	Slide No.	No. of Slides Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
43	34158	1 Liver	Acute purulent inflammation, moderate		
			Focal coagulation necrosis, moderate	Necrosis, mild	Concur RP
		1 Lung	Alveoli, accum. of foamy macrophages, focal, minimal	NR	Concur RP
35	34159	1 Liver	Congestion, minimal	NR	
		1 Lung	Congestion, minimal	NR	
86	34160	1 Liver	Cellular alteration, minimal	Eosinophilic focus, multiple	Concur RP
				Clear cell focus, multiple	Concur RP
			Telangiectasis, minimal	Cystic degeneration, mild	Concur RP
		1 Lung	No deviation from normal morphology	Foamy macrophages, minimal	Concur RP
				Interstitial pneumonia, minimal	

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Group II - Male, Two-Year Study

Code Number	Slide No.	No. of Slides	Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
57	34161	1	Liver	No deviation from normal morphology	Clear cell focus, multiple	
		1	Lung	Alveoli, accum. of foamy macrophages, focal, minimal	Foamy macrophages, minimal	Agree
160	34162	1	Liver	Cellular alteration, minimal	Eosinophilic focus, multiple	Eosinophilic focus
				Bile ducts, Focal hyperplasia, minimal	Basophilic focus	Angiectasis
		1	Lung	Alveoli, accum. of foamy macrophages, focal, minimal	Foamy macrophages, mild	Concur SP
					Interstitial pneumonia, minimal	Concur RP
112	34163	1	Liver	Bile ducts, Focal hyperplasia, minimal	Eosinophilic focus	Concur SP
						Cystic degeneration, minimal

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Group II - Male, Two-Year Study

Code Number	Slide No.	No. of Slides	Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
112 34163 continued		1	Lung		NR	
130 34164		1	Liver	Hepatocytes, vacuolation, minimal		Concur RP
					Eosinophilic focus	Basophilic focus
		1	Lung		Foamy macrophages, minimal	Concur SP

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Group III - Male, Two-Year Study

Code Number	Slide No.	No. of Slides	Organ	Study Pathologist's (SP) Diagnoses	Reviewing Pathologist's (RP) Coded Pathology Review	Chairperson's Diagnoses
332	34190	1	Liver	Focal coagulation necrosis, minimal	Necrosis, minimal	Concur RP
					Basophilic focus	
				Congestion, minimal		
		1	Lung	Congestion, minimal		
					Foamy macrophages, minimal	Concur RP
123	34191	1	Liver	Congestion, minimal	NR	
				Bile ducts, Focal hyperplasia, minimal		
		1	Lung	Congestion, minimal		
					Interstitial pneumonia, minimal	Concur RP
221	34192	1	Liver	Hepatocytes, vacuolation, minimal	Periportal fatty change, minimal	
				Bile ducts, Focal hyperplasia, minimal		

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Group III - Male, Two-Year Study

Code Number	Slide No.	No. of Slides	Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
221	34192 continued	1	Lung	Alveoli, accum. of foamy macrophages, focal, minimal	NR	Concur RP Interstitial pneumonia, minimal
188	34193	1	Liver	Hepatocytes, vacuolation, minimal Bile ducts, Focal hyperplasia, minimal	Centrilobular fatty change, marked	
		1	Lung		NR	
294	34194	1	Liver	Congestion, minimal	NR	
		1	Lung	Congestion, minimal Alveoli, accum. of foamy macrophages, focal, minimal	Foamy macrophages, minimal	Agree

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Group III - Male, Two-Year Study

Code Number	Slide No.	No. of Slides Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
140	34195	1 Liver	Telangiectasis, minimal		Concur RP
				Bile duct hyperplasia, mild	Necrosis, mild
		1 Lung		NR	
179	34196	1 Liver		Eosinophilic focus	Concur SP
				Fatty change, mild	Concur RP
		1 Lung	Bronchi mucosa, edema, moderate	NR	
205	34197	1 Liver	Telangiectasis, minimal	Cystic degeneration, minimal	Concur RP
			Bile ducts, Focal hyperplasia, minimal		
		Lung		Interstitial pneumonia, moderate	Concur RP
100	34198	1 Liver	Telangiectasis, minimal	Cystic degeneration, mild	Concur RP
				Eosinophilic focus	Concur RP

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Code Number	Slide No.	No. of Slides	Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
100	34198 continued	1	Lung	No deviation from normal morphology	NR	
171	34199	1	Liver		NR	
		1	Lung	Alveoli, accum. of foamy macrophages, focal, minimal	Foamy macrophages, minimal	Agree
					Interstitial pneumonia, minimal	Concur RP
268	34200	1	Liver	Telangiectasis, minimal	Cystic degeneration, moderate	Concur RP
				Congestion, minimal	Eosinophilic focus	Concur SP
					Clear cell focus	Concur RP
		1	Lung	Congestion, minimal	NR	

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Code Number	Slide No.	No. of Slides	Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
14	34201	1	Liver	Cellular alteration, minimal	Clear cell focus Eosinophilic focus	Concur RP Concur SP
				Hepatocytes, vacuolation, minimal		Concur SP Cystic degeneration, minimal
		1	Lung	No deviation from normal morphology	Interstitial pneumonia, mild Foamy macrophages, minimal	Concur RP Concur SP
28	34202	1	Liver	Telangiectasis, minimal		Cystic degeneration, minimal
					Clear cell focus, multiple	
		1	Lung	No deviation from normal morphology	NR	
251	34203	1	Liver	Congestion, minimal		
					Fatty change, minimal	

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Code Number	Slide No.	No. of Slides	Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
251	34203	1	Lung	Congestion, minimal	NR	
	continued			Alveoli, accum. of foamy macrophages, focal, minimal		Concur SP
243	34204	1	Liver	Cellular alteration, minimal	Eosinophilic focus	Within normal limits
				Telangiectasis, minimal	Cystic degeneration, minimal	Concur RP
				Bile ducts, Focal hyperplasia, minimal		
		1	Lung	Alveoli, accum. of foamy macrophages, focal, minimal	NR	Concur RP
58	34205	1	Liver	Telangiectasis, minimal		Cystic degeneration, minimal
					Clear cell focus, multiple	Concur RP
		1	Lung	Alveoli, accum. of foamy macrophages, focal, minimal	Foamy macrophages, minimal	Agree
					Interstitial pneumonia, minimal	Concur RP

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Group III - Male, Two-Year Study

Code Number	Slide No.	No. of Slides	Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
231	34206	1	Liver	Hepatocytes, vacuolation, minimal Bile ducts, Focal hyperplasia, minimal	Periportal fatty change, mild	
		1	Lung		Foamy macrophages, minimal	Concur RP
124	34207	1	Liver	Telangiectasis, minimal Congestion, minimal Bile ducts, Focal hyperplasia, minimal	Cystic degeneration, mild Periportal hepatocellular hypertrophy, mild	Concur RP
		1	Lung	Alveoli, accum. of foamy macrophages, focal, minimal Artery bronchial, medial calcification, moderate	Foamy macrophages, minimal Edema, moderate	Agree

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Group III - Male, Two-Year Study

Code Number	Slide No.	No. of Slides Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
139	34208	1 Liver	Necrosis, minimal Bile ducts, Focal hyperplasia, minimal	Necrosis, mild Bile duct hyperplasia, mild	Concur RP
		1 Lung		NR	
161	34209	1 Liver	Cellular alteration, minimal Telangiectasis, minimal Hepatocytes, vacuolation, minimal	Eosinophilic focus, multiple Cystic degeneration, minimal	Concur RP Concur RP
		1 Lung	No deviation from normal morphology	NR	
119	34210	1 Liver	Cellular alteration, minimal Congestion, minimal	Basophilic focus	
		1 Lung		NR	
347	34211	1 Liver		NR	

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Code Number	Slide No.	No. of Slides	Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
347	34211 continued	1	Lung		NR	
240	34212	1	Liver	Telangiectasis, moderate	Cystic degeneration, minimal	Concur RP
				Bile ducts, Focal hyperplasia, minimal	Clear cell focus, multiple	
		1	Lung	No deviation from normal morphology	NR	
132	34213	1	Liver	Hepatocarcinoma	Hepatocellular carcinoma	Hepatocellular carcinoma
				Congestion, minimal		
		1	Lung	Congestion, minimal		
					Foamy macrophages, minimal	Concur SP
288	34214	1	Liver	Bile ducts, Focal hyperplasia, minimal		
					Fatty change, minimal	

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Code Number	Slide No.	No. of Slides	Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
288	34214	1	Lung	Alveoli, accum. of foamy macrophages, focal, minimal	Foamy macrophages, mild	Concur SP
	continued					
312	34215	2	Liver	Sarcoma, histiocytic	Histiocytic sarcoma	
					Lymphoma	
		1	Lung	Sarcoma, histiocytic	Histiocytic sarcoma	
				Alveoli, hemorrhage, general, moderate		
				Alveoli, accum. of foamy macrophages, focal, minimal		Concur SP
				Alveoli, acute purulent inflammation, moderate		
30	34216	1	Liver	Cellular alteration, minimal	Clear cell focus, multiple	Concur RP
				Telangiectasis, minimal	Cystic degeneration, minimal	Concur RP
		1	Lung	Alveoli, accum. of foamy macrophages, focal, minimal	Foamy macrophages, minimal	Agree
					Interstitial pneumonia, minimal	Concur RP

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Code Number	Slide No.	No. of Slides	Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
211	34217	1	Liver	Cellular alteration, minimal	Clear cell focus, multiple	
		1	Lung	No deviation from normal morphology	Interstitial pneumonia, minimal	Concur RP
72	34218	1	Liver	Bile ducts, Focal hyperplasia, minimal	NR	
		1	Lung	Alveoli, accum. of foamy macrophages, focal, minimal	Foamy macrophages, minimal	Agree
120	34219	1	Liver		NR	
		1	Lung		NR	
190	34220	1	Liver	Cellular alteration, minimal Telangiectasis, minimal	Clear cell focus, multiple Cystic degeneration, minimal	Concur RP
		1	Lung	Alveoli, accum. of foamy macrophages, focal, minimal	Foamy macrophages, minimal	Agree

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Code Number	Slide No.	No. of Slides	Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
113	34221	1	Liver		Clear cell focus	
		1	Lung		NR	
79	34222	1	Liver	Cellular alteration, minimal	Clear cell focus, multiple	
		1	Lung	No deviation from normal morphology	Foamy macrophages, minimal	Concur SP
163	34223	1	Liver	Telangiectasis, minimal		Cystic degeneration, minimal
					Basophilic focus	Concur RP
					Clear cell focus	Concur RP
		1	Lung	Alveoli, accum. of foamy macrophages, focal, minimal	Foamy macrophages, mild	Concur RP
					Interstitial pneumonia, mild	Concur RP

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Code Number	Slide No.	No. of Slides	Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
209	34224	1	Liver	Lobule centro, necrosis, minimal Bile ducts, Focal hyperplasia, minimal	Centrilobular necrosis, moderate	Concur RP
		1	Lung	Alveoli, accum. of foamy macrophages, focal, minimal		Concur RP
					Interstitial pneumonia, mild	Concur RP
199	34225	1	Liver		NR	
		1	Lung	Alveoli, accum. of foamy macrophages, focal, minimal	Foamy macrophages, minimal	Agree
26	34226	1	Liver	Cellular alteration, minimal	Basophilic focus	Concur RP
					Clear cell focus	Concur RP
				Telangiectasis, minimal	Cystic degeneration, mild	Concur RP
				Bile ducts, Focal hyperplasia, minimal	Bile duct hyperplasia, mild	Concur RP

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Code Number	Slide No.	No. of Slides	Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
26 34226 continued		1	Lung	No deviation from normal morphology	Foamy macrophages, minimal	Concur RP
19 34227		1	Liver	Telangiectasis, minimal	Cystic degeneration, minimal	Concur RP
		1	Lung	Congestion, minimal	Edema, moderate	
136 34228		1	Liver	Bile ducts, Focal hyperplasia, minimal	NR	
		1	Lung		NR	
270 34229		1	Liver	Cellular alteration, moderate		Concur RP
				Hepatocytes, vacuolation, minimal	Centrilobular fatty change, minimal	Concur RP
		1	Lung		NR	
141 34230		1	Liver	No deviation from normal morphology	NR	

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Code Number	Slide No.	No. of Slides	Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
141	34230 continued	1	Lung	Alveoli, accum. of foamy macrophages, focal, minimal	NR	Concur SP
99	34231	1	Liver	Congestion, minimal	NR	
		1	Lung	Congestion, minimal	NR	
238	34232	1	Liver	Lobule centro, necrosis, minimal	Centrilobular necrosis, mild	Concur RP
		1	Lung		NR	
186	34233	1	Liver	No deviation from normal morphology	NR	
		1	Lung	No deviation from normal morphology	Foamy macrophages, minimal	Concur RP
					Interstitial pneumonia, minimal	Concur RP
131	34234	1	Liver	Cellular alteration, minimal	Clear cell focus, multiple	

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Code Number	Slide No.	No. of Slides	Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
131	34234	1	Lung	Alveoli, accum. of foamy macrophages, focal, minimal	Foamy macrophages, minimal	Agree
	continued				Interstitial pneumonia, minimal	Concur RP
244	34235	1	Liver	Telangiectasis, minimal	Cystic degeneration, mild	Concur RP
		1	Lung	No deviation from normal morphology	Foamy macrophages, minimal	Concur SP
363	34236	1	Liver	Bile ducts, Focal hyperplasia, minimal	NR	
		1	Lung		Foamy macrophages, minimal	Concur RP
					Interstitial pneumonia, minimal	Concur RP
67	34237	1	Liver	Congestion, minimal	NR	
		1	Lung	Congestion, minimal	NR	

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Code Number	Slide No.	No. of Slides	Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
8	34238	2	Liver	Focal hemorrhage, minimal		
				Cellular alteration, minimal		
				Hepatocellular adenoma	Hepatocellular carcinoma	Concur RP
				Focal coagulation necrosis, minimal		Necrosis, minimal
				Telangiectasis, moderate	Cystic degeneration, mild	Concur RP
				Hepatocytes, vacuolation, moderate		Fatty change, moderate
				Bile ducts, Focal hyperplasia, minimal		
		1	Lung	Alveoli, edema, minimal	Interstitial pneumonia, moderate	Concur RP
				Alveoli, accumulation of foamy macrophages, minimal		Foamy macrophages, mild
				Artery P Advent'ia, hemorrhage, general, minimal		

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Code Number	Slide No.	No. of Slides Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
53	34239	1 Liver	Congestion, minimal Lobule centro, necrosis, moderate Bile ducts, Focal hyperplasia, minimal	Centrilobular necrosis, moderate Periportal hepatocellular hypertrophy, moderate	Agree
		2 Lung	Hemangioendothelioma	Metastatic carcinoma	
237	34240	1 Liver	Cellular alteration, minimal Telangiectasis, minimal	Clear cell focus, multiple Cystic degeneration, minimal	Concur RP Concur RP
		1 Lung	No deviation from normal morphology	Foamy macrophages, minimal	Concur RP
193	34241	1 Liver	Bile ducts, Focal hyperplasia, minimal	Basophilic focus	
		1 Lung	Alveoli, accum. of foamy macrophages, focal, minimal	Foamy macrophages, minimal	Agree

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Code Number	Slide No.	No. of Slides	Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
317	34242	1	Liver	Cellular alteration, minimal	Clear cell focus, multiple	
				Telangiectasis, minimal	Cystic degeneration, minimal	Concur RP
		1	Lung	Alveoli, accum. of foamy macrophages, focal, minimal	NR	Concur RP
361	34243	1	Liver	Congestion, minimal	NR	
				Congestion, minimal	NR	
296	34244	1	Liver	No deviation from normal morphology	Clear cell focus, multiple	
				Alveoli, accum. of foamy macrophages, focal, minimal	Foamy macrophages, minimal	Agree
		1	Lung		Interstitial pneumonia, minimal	Concur RP

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Code Number	Slide No.	No. of Slides	Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
195	34245	1	Liver	Telangiectasis, minimal	Cystic degeneration, mild	Concur RP
				Hepatocytes, vacuolation, moderate	Centrilobular fatty change, moderate	Concur RP
				Bile ducts, Focal mineralization, minimal	Eosinophilic focus	Concur SP
		1	Lung	No deviation from normal morphology	NR	
103	34246	1	Liver	Cellular alteration, minimal	Clear cell focus, multiple	
				Telangiectasis, minimal	Cystic degeneration, minimal	Concur RP
		1	Lung	No deviation from normal morphology	NR	
265	34247	1	Liver	Hepatocarcinoma	Hepatocellular adenoma	Hepatocellular carcinoma
				Telangiectasis, minimal	Cystic degeneration, marked	Cystic degeneration, mild
		1	Lung	No deviation from normal morphology	NR	

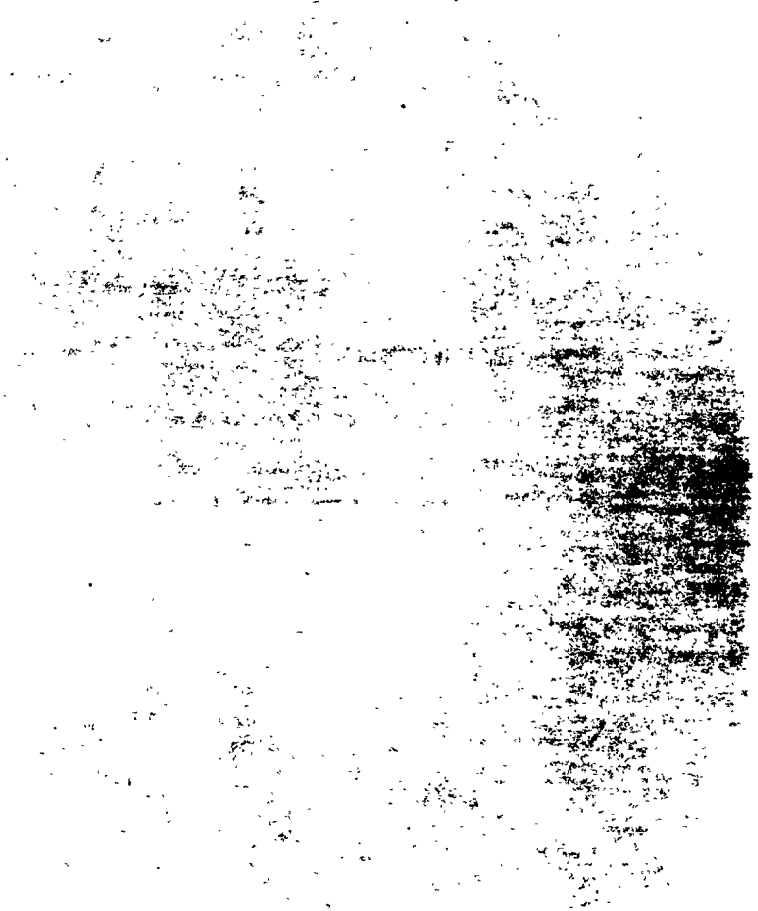
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Code Number	Slide No.	No. of Slides	Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
5	34248	1	Liver	No deviation from normal morphology	Basophilic focus	
					Clear cell focus, multiple	
		1	Lung	No deviation from normal morphology	Interstitial pneumonia, minimal	Concur RP
250	34249	1	Liver	Cellular alteration, minimal	Basophilic focus	Concur RP
					Eosinophilic focus	Concur RP
					Clear cell focus, multiple	Concur RP
				Telangiectasis, minimal	Cystic degeneration, minimal	Concur RP
				Bile ducts, focal hyperplasia, minimal		
		1	Lung	Alveoli, accum. of foamy macrophages, focal, minimal	Foamy macrophages, mild	Concur RP
					Interstitial pneumonia, mild	Concur RP

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Group IV - Male, Two-Year Study

Code Number	Slide No.	No. of Slides	Organ	Study Pathologist's (SP) Diagnoses	Reviewing Pathologist's (RP) Coded Pathology Review	Chairperson's Diagnoses
109	34275	1	Liver	Hepatocarcinoma	Hepatocellular adenoma	Hepatocellular carcinoma
				Hepatocytes, vacuolation, minimal	Fatty change, moderate	Concur RP
					Cystic degeneration, minimal	Concur RP (within tumor)
		1	Lung		NR	
346	34276	1	Liver	Telangiectasis, minimal	Cystic degeneration, minimal	Concur RP
					Clear cell focus, multiple	Concur RP
		1	Lung		NR	
83	34277	1	Liver	Cellular alteration, minimal	Basophilic focus	Concur RP
					Eosinophilic focus, multiple	Concur RP
				Telangiectasis, minimal		Cystic degeneration, mild
				Hepatocytes, vacuolation, minimal	Fatty change, minimal	Concur RP
		1	Lung	Alveoli, accum. of foamy macrophages, focal, minimal	Foamy macrophages, mild	Concur RP

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Group IV - Male, Two-Year Study

Code Number	Slide No.	No. of Slides	Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
306	34278	1	Liver	Cellular alteration, minimal	Basophilic focus	Concur RP
					Clear cell focus, multiple	Concur RP
						Eosinophilic focus
					Cystic degeneration, minimal	Concur RP
		1	Lung	Alveoli, accum. of foamy macrophages, focal, minimal	Foamy macrophages, minimal	Agree
					Interstitial pneumonia, minimal	Concur RP
144	34279	1	Liver	Cellular alteration, minimal	Eosinophilic focus, multiple	Concur RP
				Telangiectasis, minimal	Telangiectasis, mild	Angiectasis
		1	Lung		NR	
302	34280	1	Liver		NR	
		1	Lung	Congestion, minimal	NR	

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Code Number	Slide No.	No. of Slides	Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
273	34281	1	Liver	Telangiectasis, minimal	Cystic degeneration, minimal	Concur RP
					Basophilic focus	Concur RP
					Clear cell focus, multiple	Concur RP
		1	Lung	Alveoli, accum. of foamy macrophages, focal, minimal	Foamy macrophages, mild	Concur RP
					Interstitial pneumonia, minimal	Concur RP
143	34282	1	Liver		NR	
		1	Lung	Alveoli, accum. of foamy macrophages, focal, minimal	Foamy macrophages, mild	Concur RP
168	34283	1	Liver		NR	
		1	Lung		Foamy macrophages, minimal	Concur SP

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Code Number	Slide No.	No. of Slides	Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
82	34284	1	Liver	Telangiectasis, minimal	Cystic degeneration, mild	Concur RP
				Lobule centro, necrosis, minimal	Centrilobular necrosis, mild	Concur RP
				Hepatocytes, vacuolation, minimal	Fatty change, mild	Concur RP
					Periportal hepatocellular hypertrophy, moderate	Concur RP
			Lung	No deviation from normal morphology	NR	
191	34285	1	Liver	Congestion, minimal	Eosinophilic focus	Concur SP
					Cystic degeneration, minimal	Concur RP
		1	Lung	Congestion, minimal		
				Alveoli histiocyte, endogenous pigment, minimal		Concur SP
					Foamy macrophages, minimal	Concur SP

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Code Number	Slide No.	No. of Slides	Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
45	34286	1	Liver	Sarcoma, histiocytic Focal coagulation necrosis, minimal Congestion, minimal	Histiocytic sarcoma	Agree Part of sarcoma
		1	Lung	Sarcoma, histiocytic Hemorrhage, general, minimal Alveoli, accum. of foamy macrophages, focal, minimal	Histiocytic sarcoma Foamy macrophages, minimal	Agree Agree
194	34287	2	Liver	Hepatocarcinoma	Hepatocellular carcinoma	Hepatocellular carcinoma
		1	Lung		Interstitial pneumonia, minimal	Concur RP
51	34288	1	Liver		NR	
		1	Lung		NR	

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Code Number	Slide No.	No. of Slides	Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
245	34289		Liver	Malignant lymphoma	Lymphoma	
			Lung	No deviation from normal morphology	NR	
234	34290		Liver	Congestion, minimal	NR	
			Lung		NR	
93	34291		Liver	Bile ducts, Focal hyperplasia, minimal	Bile duct hyperplasia, mild	
			Lung	Alveoli, accum. of foamy macrophages, focal, minimal	Foamy macrophages, minimal	Agree
152	34292	1	Liver	Bile ducts, Focal hyperplasia, minimal	NR	
		1	Lung	Alveoli, accum. of foamy macrophages, focal, minimal	NR	Concur SP

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Code Number	Slide No.	No. of Slides	Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
111	34293	1	Liver	Hepatocytes, vacuolation, moderate Bile ducts, Focal hyperplasia, minimal	Fatty change, marked	
		1	Lung		Foamy macrophages, minimal	Concur RP
327	34294	1	Liver	Lobule centro, necrosis, moderate	Centrilobular necrosis, moderate	Agree
		2	Lung	Bilat, fibrosarcoma, metastatic	Histiocytic sarcoma	Concur SP
					Foamy macrophages, minimal	Concur RP
125	34295	1	Liver	Bile ducts, Focal hyperplasia, minimal	NR	
		1	Lung	Alveoli, accum. of foamy macrophages, focal, minimal	Foamy macrophages, minimal	Agree

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Group IV - Male, Two-Year Study

Code Number	Slide No.	No. of Slides	Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
158	34296	1	Liver	Cellular alteration, minimal	Eosinophilic focus	Angiectasis
				Hepatocytes, vacuolation, minimal	Periportal fatty change, moderate	Concur RP
		1	Lung	Alveoli, accum. of foamy macrophages, focal, minimal	Foamy macrophages, minimal	Agree
					Interstitial pneumonia, minimal	Concur RP
3	34297	1	Liver	Sarcoma, histiocytic	Histiocytic sarcoma	
		1	Lung	Sarcoma, histiocytic	Histiocytic sarcoma	
				Alveoli, hemorrhage, general, moderate		
148	34298	1	Liver	Congestion, minimal	NR	
		1	Lung	Congestion, minimal	NR	
176	34299		Liver	No deviation from normal morphology	Clear cell focus	

Pathology Review Worksheets

Ciba-Geigy

Chronic Toxicity/Carcinogenicity Study

PATHCO No. 90-128

Group IV - Male, Two-Year Study

Code Number	Slide No.	No. of Slides	Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
176	34299		Lung	Alveoli, accum. of foamy macrophages, focal, minimal	Foamy macrophages, minimal	Agree
	continued				Interstitial pneumonia, minimal	Concur RP
150	34300		Liver	No deviation from normal morphology	Clear cell focus	
			Lung	Alveoli, accum. of foamy macrophages, focal, minimal	Foamy macrophages, minimal	Agree
					Interstitial pneumonia, minimal	Concur RP
22	34301	1	Liver	Cellular alteration, minimal Focal acute purulent inflammation, minimal	Clear cell focus, multiple	
		1	Lung	Alveoli, accum. of foamy macrophages, focal, minimal	Foamy macrophages, mild	Concur RP
					Interstitial pneumonia, mild	Concur RP

Pathology Review Worksheets
Ciba-Geigy
Chronic Toxicity/Carcinogenicity Study
PATHCO No. 90-128

Group IV - Male, Two-Year Study

Code Number	Slide No.	No. of Slides	Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
62	34302	1	Liver	Telangiectasis, minimal	Cystic degeneration, minimal	Concur RP
				Hepatocytes, vacuolation, minimal		Concur SP
					Basophilic focus	Concur RP
					Eosinophilic focus	Concur RP
		1	Lung		NR	
122	34303	1	Liver	Telangiectasis, minimal	Cystic degeneration, minimal	Concur RP
				Bile ducts, Focal hyperplasia, minimal		
		1	Lung	Alveoli, accum. of foamy macrophages, focal, severe	Foamy macrophages, moderate	Concur RP
52	34304	1	Liver	Cellular alteration, minimal	Eosinophilic focus, multiple	Concur RP
		1	Lung		NR	
105	34305	1	Liver	Telangiectasis, minimal	Cystic degeneration, mild	Concur RP

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Group IV - Male, Two-Year Study

Code Number	Slide No.	No. of Slides Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
105 34305 continued		2 Lung	Alveoli, focal hemorrhage, minimal		
			Alveoli, accum. of foamy macrophages, focal, minimal	Foamy macrophages, moderate	Concur RP
			Alveoli, focal acute purulent inflammation, minimal	Interstitial pneumonia, moderate	Concur RP
291 34306		1 Liver	Hepatocytes, vacuolation, minimal		
				Cystic degeneration, minimal	Concur RP
		1 Lung	Alveoli, focal hemorrhage, minimal	NR	
10 34307		1 Liver	Lobule centro, necrosis, moderate		Centrilobular necrosis, moderate
				Fatty change, moderate	Concur RP

Pathology Review Worksheets
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PATHCO No. 90-128

Group IV - Male, Two-Year Study

Code Number	Slide No.	No. of Slides	Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
10	34307	1	Lung	Alveoli, accum. of foamy macrophag diss foc., moderate		Concur SP
	continued			Alveolar septa, chronic hyperplastic inflammation, minimal	Interstitial pneumonia, moderate	Concur RP
261	34308	1	Liver	No deviation from normal morphology	Eosinophilic focus	Concur RP
					Cystic degeneration, minimal	Concur RP
		1	Lung	No deviation from normal morphology		
				Alveoli, accum. of foamy macrophages, focal, minimal	Foamy macrophages, minimal	Agree
					Interstitial pneumonia, minimal	Concur RP
218	34309	1	Liver	Telangiectasis, minimal	Cystic degeneration, mild	Concur RP
		1	Lung	Alveoli, accum. of foamy macrophages, focal, minimal	Foamy macrophages, minimal	Agree

Pathology Review Worksheets
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PATHCO No. 90-128

Group IV - Male, Two-Year Study

Code Number	Slide No.	No. of Slides	Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
15	34310	1	Liver	Cellular alteration, minimal Telangiectasis, minimal	Eosinophilic focus Cystic degeneration, minimal	Within normal limits Concur RP
		1	Lung	Alveoli, accum. of foamy macrophages, focal, minimal	Foamy macrophages, minimal Interstitial pneumonia, minimal	Agree Concur RP
42	34311	1	Liver	Congestion, minimal	Eosinophilic focus	Within normal limits
		1	Lung	Congestion, minimal	NR	
220	34312	1	Liver	Telangiectasis, minimal	Cystic degeneration, mild Clear cell focus, multiple	Concur RP
		1	Lung		NR	
336	34313	1	Liver	No deviation from normal morphology	NR	

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PATHCO No. 90-128

Group IV - Male, Two-Year Study

Code Number	Slide No.	No. of Slides	Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
336	34313 continued	1	Lung	Alveoli, accum. of foamy macrophages, focal, minimal Alveolar septa, focal subacute lymphocytic inflam., minimal	Foamy macrophages, minimal	Agree
274	34314	1	Liver	Hepatocytes, vacuolation, moderate	Fatty change, moderate	
		1	Lung		NR	
214	34315	1	Liver	Hepatocytes, vacuolation, moderate	Periportal fatty change, mild Eosinophilic focus	Concur RP
		1	Lung	Alveoli, accum. of foamy macrophages, focal, minimal Alveolar septa, focal mineralization, minimal		Concur SP
					Interstitial pneumonia, mild	Concur RP

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Group IV - Male, Two-Year Study

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Pathology Review Worksheets
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Chronic Toxicity/Carcinogenicity Study
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Group IV - Male, Two-Year Study

Code Number	Slide No.	No. of Slides	Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
249	34318	1	Lung	Alveolar septa, focal mineralization, minimal		Concur SP
	continued				Interstitial pneumonia, minimal	Concur RP
48	34319	1	Liver	Telangiectasis, minimal	Cystic degeneration, minimal	Concur RP
				Hepatocytes, vacuolation, minimal	Fatty change, moderate	Concur RP
		1	Lung		NR	
303	34320	1	Liver	Telangiectasis, minimal	Cystic degeneration, minimal	Concur RP
					Clear cell focus, multiple	Concur RP
		1	Lung		NR	
247	34321	1	Liver	Congestion, minimal		
					Eosinophilic focus	Concur SP
					Clear cell focus, multiple	Focal fatty change
				Bile ducts, Focal hyperplasia, minimal		

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Group IV - Male, Two-Year Study

Code Number	Slide No.	No. of Slides	Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
223	34323	1	Lung	Dis'm foc. subac lymphocytic inflam, minimal	Interstitial pneumonia, minimal	Concur RP
	continued			Alveoli, accum. of foamy macrophages, focal, minimal		Concur RP
149	34324	1	Liver		Periportal fatty change, moderate	
		1	Lung	Alveoli, accum. of foamy macrophages, focal, minimal	Foamy macrophages, minimal	Agree
					Interstitial pneumonia, minimal	Concur RP
213	34325	1	Liver	No deviation from normal morphology	Basophilic focus	
					Clear cell focus, multiple	
		1	Lung	Focal chronic purulent inflam., minimal		
					Granuloma, minimal	

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Group IV - Male, Two-Year Study

Code Number	Slide No.	No. of Slides	Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
50	34326	1	Liver	Focal coagulation necrosis, moderate	Necrosis, mild	Concur RP
					Cystic degeneration, minimal	Concur RP
		1	Lung		NR	
344	34327	1	Liver	Congestion, minimal	NR	
		1	Lung	Congestion, minimal	NR	
257	34328	1	Liver	Hepatocarcinoma	Hepatocellular carcinoma	Hepatocellular carcinoma
				Telangiectasis, minimal	Cystic degeneration, minimal	Concur RP
					Eosinophilic focus	Concur RP
		1	Lung		NR	
212	34329	1	Liver	Cellular alteration, minimal	Eosinophilic focus	Concur RP
				Hepatocytes, vacuolation, minimal	Periportal fatty change, mild	Concur RP
				Bile ducts, Focal hyperplasia, minimal		

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Group IV - Male, Two-Year Study

Code Number	Slide No.	No. of Slides	Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
212	34329	1	Lung		NR	
continued						
233	34330	1	Liver	Hepatocytes, vacuolation, minimal	Periportal fatty change, minimal	
		1	Lung	Alveoli, accum. of foamy macrophages, focal, minimal	Foamy macrophages, mild	Concur RP
260	34331	1	Liver	Hepatocytes, vacuolation, minimal	Periportal fatty change mild	
		1	Lung		NR	
297	34332	1	Liver	Focal subacute lymphocytic inflam., minimal	NR	
		1	Lung	Dis'm foc. subac lymphocytic inflam, minimal	NR	
128	34333	1	Liver		Basophilic focus	
		1	Lung		NR	

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Group IV - Male, Two-Year Study

Code Number	Slide No.	No. of Slides	Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
236	34334	1	Liver	Congestion, minimal Hepatocytes, vacuolation, moderate	Periportal fatty change, moderate	
		1	Lung	Congestion, minimal Alveoli, accum. of foamy macrophages, focal, minimal	Foamy macrophages, mild	Concur RP

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Group I - Male, 78-Week Interim Sacrifice

Code Number	Slide No.	No. of Slides Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
102	34104	1 Liver	Hepatocytes, vacuolation, minimal	Eosinophilic focus	Concur RP
		0 Lung		No slide	

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Group II - Male, 78-Week Interim Sacrifice

Code Number	Slide No.	No. of Slides	Organ	Study Pathologist's (SP) Diagnoses	Reviewing Pathologist's (RP) Coded Pathology Review	Chairperson's Diagnoses
197	34185	1	Liver	Cellular alteration, minimal Bile ducts, Focal hyperplasia, minimal	Clear cell focus, multiple	
		0	Lung		No slide	
4	34186	1	Liver	Hepatocellular adenoma	Eosinophilic focus Clear cell focus, multiple	Concur RP Concur RP
		0	Lung		No slide	
151	34187	1	Liver	No deviation from normal morphology	Clear cell focus, multiple	
		0	Lung		No slide	
97	34188	1	Liver	Bile ducts, Focal hyperplasia, minimal	Clear cell focus	
		0	Lung		No slide	

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Group II - Male, 78-Week Interim Sacrifice

Code Number	Slide No.	No. of Slides Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
280	34189	1 Liver	No deviation from normal morphology	NR	
		0 Lung		No slide	

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Group III - Male, 78-Week Interim Sacrifice

Code Number	Slide No.	No. of Slides	Organ	Study Pathologist's (SP) Diagnoses	Reviewing Pathologist's (RP) Coded Pathology Review	Chairperson's Diagnoses
114	34270	1	Liver	No deviation from normal morphology	Clear cell focus	
		0	Lung		No slide	
309	34271	1	Liver	Telangiectasis, minimal	Cystic degeneration, minimal	Concur RP
		0	Lung		No slide	
118	34272	1	Liver	Cellular alteration, minimal	Clear cell focus, multiple	
		0	Lung		No slide	
91	34273	1	Liver	Congestion, severe Lobule centro, focal coagulation necrosis, moderate	NR	Centrilobular necrosis, moderate

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Group III - Male, 78-Week Interim Sacrifice

Code Number	Slide No.	No. of Slides Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
91	34273 continued	1 Lung	Congestion, minimal Alveoli, accum. of foamy macrophages, focal, minimal		Concur RP
				Interstitial pneumonia, mild	Concur RP
365	34274	1 Liver	Cellular alteration, minimal Congestion, minimal		
				Fatty change, minimal	
		1 Lung	Congestion, minimal	NR	

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Group IV - Male, 78-Week Interim Sacrifice

Code Number	Slide No.	No. of Slides	Organ	Study Pathologist's (SP) Diagnoses	Reviewing Pathologist's (RP) Coded Pathology Review	Chairperson's Diagnoses
362	34355	1	Liver	Cellular alteration, minimal Hepatocytes, hypertrophy, minimal Hepatocytes, vacuolation, minimal	Centrilobular hepatocellular hypertrophy, mild	Eosinophilic focus Concur RP
		0	Lung		No slide	
110	34356	1	Liver	Cellular alteration, minimal Hepatocytes, hypertrophy, minimal Hepatocytes, vacuolation, minimal	Clear cell focus, multiple	Concur RP Centrilobular hepatocell- ular hypertrophy, minimal
		0	Lung		No slide	
282	34357	1	Liver	No deviation from normal morphology	NR	Agree

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Group IV - Male, 78-Week Interim Sacrifice

Code Number	Slide No.	No. of Slides	Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
282	34357 continued	1	Lung	Alveoli, accum. of foamy macrophag diss foc., moderate	Foamy macrophages, marked	Concur RP
					Interstitial pneumonia, moderate	Concur RP
155	34358	1	Liver	Congestion, severe		
				Lobule centro, necrosis, minimal	Centrilobular necrosis, mild	Concur RP
		1	Lung	Mesothelioma, malignant	Alveolar/bronchiolar adenoma	
241	34359	1	Liver	Cellular alteration, minimal	Clear cell focus, multiple	Concur RP
				Focal chronic lymphocytic inflam., minimal		
		0	Lung		No slide	

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Group I - Male, 52-Week Interim Sacrifice

Code Number	Slide No.	No. of Slides	Organ	Study Pathologist's (SP) Diagnoses	Reviewing Pathologist's (RP) Coded Pathology Review	Chairperson's Diagnoses
12	34070	1	Liver		NR	
		1	Lung		NR	
202	34071	1	Liver		Clear cell focus	Concur RP
		1	Lung	Dis'm foc. subac lymphocytic inflamm, minimal	NR	
369	34072	1	Liver		Clear cell focus	
		1	Lung		No slide	
170	34073	1	Liver		NR	Agree
		1	Lung	Dis'm foc. subac lymphocytic inflamm, minimal	NR	
44	34074	1	Liver	Hepatocytes, vacuolation, minimal	NR	

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Group I - Male, 52-Week Interim Sacrifice

Code Number	Slide No.	No. of Slides	Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
44	34074	1	Lung		NR	
	continued					
175	34075	1	Liver	Focal coagulation necrosis, minimal		Necrosis, minimal
					Eosinophilic focus	Concur SP
		1	Lung	Dis'm foc. subac lymphocytic inflam, minimal	NR	
24	34076	1	Liver	Hepatocytes, vacuolation, minimal	NR	
		1	Lung	Dis'm foc. subac lymphocytic inflam, minimal	NR	
146	34077	1	Liver	Hepatocytes, vacuolation, minimal		Clear cell focus
		1	Lung	Dis'm foc. subac lymphocytic inflam, minimal	NR	

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Code Number	Slide No.	No. of Slides	Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
246	34078	1	Liver			Clear cell focus, multiple
		1	Lung	Dis'm foc. subac lymphocytic inflam, minimal	NR	
331	34079	1	Liver			NR
		1	Lung	Dis'm foc. subac lymphocytic inflam, minimal	NR	
263	34080	1	Liver			NR
		1	Lung	Dis'm foc. subac lymphocytic inflam, minimal	NR	
323	34081	1	Liver	Hepatocytes, vacuolation, minimal	NR	
				Portal triads, focal subacute, lymphocytic inflam., minimal		
		1	Lung	Dis'm foc. subac lymphocytic inflam, minimal	NR	

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Group I - Male, 52-Week Interim Sacrifice

Code Number	Slide No.	No. of Slides	Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
21	34082	1	Liver	Hepatocytes, vacuolation, minimal	NR	
		1	Lung	Dis'm foc. subac lymphocytic inflam, minimal	NR	
61	34083	1	Liver		NR	
		1	Lung	Dis'm foc. subac lymphocytic inflam, minimal	NR	
169	34084	1	Liver	Hepatocytes, vacuolation, minimal		Clear cell focus, multiple
		1	Lung	Dis'm foc. subac lymphocytic inflam, minimal	NR	
350	34085	1	Liver		NR	
		1	Lung	Dis'm foc. subac lymphocytic inflam, minimal	NR	

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Group I - Male, 52-Week Interim Sacrifice

Code Number	Slide No.	No. of Slides	Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
316	34086	1	Liver		Eosinophilic fouda	Concur SP
		1	Lung		NR	
187	34087	1	Liver		NR	
		1	Lung		NR	
25	34088	1	Liver	Hepatocytes, vacuolation, minimal	NR	
		1	Lung	Dis'm foc. subac lymphocytic inflam, minimal	NR	
104	34089	1	Liver		NR	
		1	Lung		NR	

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Group II - Male, 52-Week Interim Sacrifice

Code Number	Slide No.	No. of Slides Organ	Study Pathologist's (SP) Diagnoses	Reviewing Pathologist's (RP) Coded Pathology Review	Chairperson's Diagnoses
85	34165	1 Liver	No deviation from normal morphology	NR	
		0 Lung		No slide	
107	34166	1 Liver	No deviation from normal morphology	NR	
		0 Lung		No slide	
115	34167	1 Liver	No deviation from normal morphology	Clear cell focus	
		0 Lung		No slide	
27	34168	1 Liver	No deviation from normal morphology	Clear cell focus	
		0 Lung		No slide	
173	34169	1 Liver	No deviation from normal morphology	NR	

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Group II - Male, 52-Week Interim Sacrifice

Code Number	Slide No.	No. of Slides	Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
173	34169 continued	0	Lung		No slide	
154	34170	1	Liver	No deviation from normal morphology	NR	
		0	Lung		No slide	
321	34171	1	Liver	No deviation from normal morphology	NR	
		0	Lung		No slide	
117	34172	1	Liver	No deviation from normal morphology	NR	
		0	Lung		No slide	
305	34173	1	Liver	Hepatocytes, vacuolation, minimal		Clear cell focus, multiple
		0	Lung		No slide	

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Group II - Male, 52-Week Interim Sacrifice

Code Number	Slide No.	No. of Slides Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
292	34174	1 Liver	No deviation from normal morphology	Clear cell focus	
		0 Lung		No slide	

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Group III - Male, 52-Week Interim Sacrifice

Code Number	Slide No.	No. of Slides Organ	Study Pathologist's (SP) Diagnoses	Reviewing Pathologist's (RP) Coded Pathology Review	Chairperson's Diagnoses
7	34250	1 Liver	No deviation from normal morphology	Centrilobular fatty change, mild	
		0 Lung		No slide	
345	34251	1 Liver	Hepatocytes, vacuolation, minimal	Centrilobular fatty change, minimal	
		0 Lung		No slide	
147	34252	1 Liver	No deviation from normal morphology	NR	
		0 Lung		No slide	
333	34253	1 Liver	No deviation from normal morphology	Clear cell focus	
		0 Lung		No slide	
289	34254	1 Liver	No deviation from normal morphology	NR	

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Group III - Male, 52-Week Interim Sacrifice

Code Number	Slide No.	No. of Slides	Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
289	34254	0	Lung		No slide	
	continued					
156	34255	1	Liver	No deviation from normal morphology	NR	
		0	Lung		No slide	
135	34256	1	Liver	Hepatocytes, vacuolation, minimal	Fatty change, minimal	
		0	Lung		No slide	
11	34257	1	Liver	No deviation from normal morphology	Eosinophilic focus	Concur SP
		0	Lung		No slide	
359	34258	1	Liver	No deviation from normal morphology	NR	
		0	Lung		No slide	

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Group III - Male, 52-Week Interim Sacrifice

Code Number	Slide No.	No. of Slides Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
368	34259	1 Liver	No deviation from normal morphology	Clear cell focus	
		0 Lung		No slide	

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Group IV - Male, 52-Week Interim Sacrifice

Code Number	Slide No.	No. of Slides	Organ	Study Pathologist's (SP) Diagnoses	Reviewing Pathologist's (RP) Coded Pathology Review	Chairperson's Diagnoses
55	34335	1	Liver	Cellular alteration, minimal Hepatocytes, vacuolation, minimal	Eosinophilic focus	Concur RP Fatty change, minimal
		0	Lung		No slide	
29	34336	1	Liver	Hepatocytes, vacuolation, minimal	Centrilobular hepatocellular hypertrophy, minimal	Concur RP
		0	Lung		No slide	
182	34337	1	Liver	No deviation from normal morphology	NR	
		0	Lung		No slide	
210	34338	1	Liver	No deviation from normal morphology	Centrilobular hepatocellular hypertrophy, mild	Centrilobular hepato- cellular hypertrophy, minimal
		0	Lung		No slide	

Pathology Review Worksheets
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Group IV - Male, 52-Week Interim Sacrifice

Code Number	Slide No.	No. of Slides Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
207	34339	1 Liver	No deviation from normal morphology	NR	
		0 Lung		No slide	
301	34340	1 Liver	No deviation from normal morphology	Clear cell focus, multiple	
		0 Lung		No slide	
37	34341	1 Liver	Hepatocytes, vacuolation, minimal		Fatty change, minimal
				Basophilic focus	Concur RP
				Centrilobular hepatocellular hypertrophy, mild	Concur RP
		0 Lung		No slide	
351	34342	1 Liver	No deviation from normal morphology	Clear cell focus, multiple	Concur RP
				Centrilobular hepatocellular hypertrophy, mild	Concur RP

Pathology Review Worksheets
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Group IV - Male, 52-Week Interim Sacrifice

Code Number	Slide No.	No. of Slides Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
351 34342 continued		0 Lung		No slide	
314 34343		1 Liver	Hepatocytes, vacuolation, minimal	Centrilobular fatty change, minimal	
				Clear cell focus	
		0 Lung		No slide	
337 34344		1 Liver	No deviation from normal morphology	NR	
		0 Lung		No slide	

Pathology Review Worksheets
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Group V - Male, 52-Week Interim Sacrifice

Code Number	Slide No.	No. of Slides	Organ	Study Pathologist's (SP) Diagnoses	Reviewing Pathologist's (RP) Coded Pathology Review	Chairperson's Diagnoses
172	34360	1	Liver	Hepatocytes, vacuolation, minimal		
					Clear cell focus	Concur RP
					Centrilobular hepatocellular hypertrophy, mild	Concur RP
		1	Lung		Foamy macrophages, minimal	Concur RP
253	34361	1	Liver	Hepatocytes, hypertrophy, minimal	Centrilobular hepatocellular hypertrophy, mild	Concur RP
		1	Lung		NR	
49	34362	1	Liver		NR	
		1	Lung		NR	
356	34363	1	Liver	Hepatocytes, inclusion bodies, minimal		(Part of hypertrophy)
				Hepatocytes, hypertrophy, moderate	Centrilobular hepatocellular hypertrophy, mild	Agree

Pathology Review Worksheets
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Group V - Male, 52-Week Interim Sacrifice

Code Number	Slide No.	No. of Slides	Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
356	34363	1	Lung		Foamy macrophages, minimal	Concur RP
	continued				Interstitial pneumonia, minimal	Concur RP
310	34364	1	Liver		Centrilobular hepatocellular hypertrophy, mild	Concur RP
		1	Lung	Dis'm foc. subac lymphocytic inflam, minimal	NR	
330	34365	1	Liver	Hepatocytes, hypertrophy, minimal	Centrilobular hepatocellular hypertrophy, mild	Agree
				Hepatocytes, vacuolation, minimal		
		1	Lung		NR	
63	34366	1	Liver	Hepatocytes, hypertrophy, moderate	Centrilobular hepatocellular hypertrophy, mild	Agree
				Hepatocytes, vacuolation, minimal		Concur SP
					Clear cell focus	Concur RP

Pathology Review Worksheets
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Group V - Male, 52-Week Interim Sacrifice

Code Number	Slide No.	No. of Slides	Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
63	34366 continued	1	Lung	Dis'm foc. subac lymphocytic inflam, minimal	NR	
329	34367	1	Liver	Hepatocytes, hypertrophy, moderate	NR	Concur SP
		1	Lung		NR	
315	34368	1	Liver	Pyknosis, minimal	NR	
		1	Lung		NR	
259	34369	1	Liver	Hepatocytes, hypertrophy, minimal Hepatocytes, vacuolation, minimal	Centrilobular hepatocellular hypertrophy, mild	Agree
		1	Lung	Dis'm foc. subac lymphocytic inflam, minimal	NR	

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Group V - Male, 52-Week Interim Sacrifice

Code Number	Slide No.	No. of Slides	Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
335	34370	1	Liver	Hepatocytes, hypertrophy, moderate Hepatocytes, vacuolation, minimal	NR	Concur SP
		1	Lung		NR	
298	34371	1	Liver		Centrilobular hepatocellular hypertrophy, mild	Concur RP
		1	Lung		NR	
278	34372	1	Liver	Hepatocytes, hypertrophy, moderate Hepatocytes, vacuolation, minimal	Centrilobular hepatocellular hypertrophy, mild Clear cell focus	Agree
		1	Lung	Dis'm foc. subac lymphocytic inflam, minimal	NR	
354	34373	1	Liver		Centrilobular hepatocellular hypertrophy, mild	Concur RP

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Group V - Male, 52-Week Interim Sacrifice

Code Number	Slide No.	No. of Slides Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
354	34373 continued	1 Lung	Dis'm foc. subac lymphocytic inflam, minimal	NR	
216	34374	1 Liver		Centrilobular hepatocellular hypertrophy, mild	Concur RP
		1 Lung		NR	
13	34375	1 Liver	Hepatocytes, inclusion bodies, minimal	NR	(Part of hypertrophy)
			Hepatocytes, hypertrophy, moderate		Concur SP
		1 Lung	Dis'm foc. subac lymphocytic inflam, minimal	NR	
325	34376	1 Liver	Hepatocytes, inclusion bodies, minimal	NR	(Part of hypertrophy)
			Hepatocytes, hypertrophy, moderate		Concur SP
			Hepatocytes, vacuolation, minimal		

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Group V - Male, 52-Week Interim Sacrifice

Code Number	Slide No.	No. of Slides	Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
325	34376	1	Lung	Dis'm foc. subac lymphocytic inflam, minimal	NR	
	continued					
89	34377	1	Liver	Hepatocytes, inclusion bodies, minimal		(Part of hypertrophy)
				Hepatocytes, hypertrophy, minimal	Centrilobular hepatocellular hypertrophy, mild	Agree
					Necrosis, minimal	Concur RP
		1	Lung		NR	
319	34378	1	Liver	Hepatocytes, hypertrophy, minimal	Centrilobular hepatocellular hypertrophy, mild	Agree
				Hepatocytes, vacuolation, minimal		
					Clear cell focus, multiple	Concur RP
		1	Lung		NR	

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Group V - Male, 52-Week Interim Sacrifice

Code Number	Slide No.	No. of Slides	Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
284	34379	1	Liver	Hepatocytes, vacuolation, minimal	Clear cell focus Centrilobular hepatocellular hypertrophy, mild	Concur RP Concur RP
		1	Lung		NR	

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Group I - Male, 26-Week Interim Sacrifice

Code Number	Slide No.	No. of Slides Organ	Study Pathologist's (SP) Diagnoses	Reviewing Pathologist's (RP) Coded Pathology Review	Chairperson's Diagnoses
180	34095	1 Liver	No deviation from normal morphology	NR	
		0 Lung		No slide	
258	34096	1 Liver	No deviation from normal morphology	NR	
		0 Lung		No slide	
189	34097	1 Liver	No deviation from normal morphology	NR	
		0 Lung		No slide	
39	34098	1 Liver	No deviation from normal morphology	NR	
		0 Lung		No slide	
242	34099	1 Liver	No deviation from normal morphology	NR	

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Group I - Male, 26-Week Interim Sacrifice

Code Number	Slide No.	No. of Slides	Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
242	34099	0	Lung		No slide	
	continued					

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Group II - Male, 26-Week Interim Sacrifice

Code Number	Slide No.	No. of Slides Organ	Study Pathologist's (SP) Diagnoses	Reviewing Pathologist's (RP) Coded Pathology Review	Chairperson's Diagnoses
252	34180	1 Liver	No deviation from normal morphology	NR	
		0 Lung		No slide	
126	34181	1 Liver	No deviation from normal morphology	NR	
		0 Lung		No slide	
92	34182	1 Liver	No deviation from normal morphology	NR	
		0 Lung		No slide	
286	34183	1 Liver	No deviation from normal morphology	NR	
		0 Lung		No slide	
313	34184	1 Liver	No deviation from normal morphology	NR	

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Group II - Male, 26-Week Interim Sacrifice

Code Number	Slide No.	No. of Slides Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
313	34184 continued	0 Lung		No slide	

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Group III - Male, 26-Week Interim Sacrifice

Code Number	Slide No.	No. of Slides Organ	Study Pathologist's (SP) Diagnoses	Reviewing Pathologist's (RP) Coded Pathology Review	Chairperson's Diagnoses
16	34265	1 Liver	No deviation from normal morphology	Eosinophilic focus	Clear cell focus
		0 Lung		No slide	
338	34266	1 Liver	No deviation from normal morphology	NR	
		0 Lung		No slide	
54	34267	1 Liver	No deviation from normal morphology	NR	
		0 Lung		No slide	
222	34268	1 Liver	No deviation from normal morphology	NR	
		0 Lung		No slide	
84	34269	1 Liver	No deviation from normal morphology	Clear cell focus	

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Group III - Male, 26-Week Interim Sacrifice

Code Number	Slide No.	No. of Slides Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
84	34269 continued	0 Lung		No slide	

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Group IV - Male, 26-Week Interim Sacrifice

Code Number	Slide No.	No. of Slides Organ	Study Pathologist's (SP) Diagnoses	Reviewing Pathologist's (RP) Coded Pathology Review	Chairperson's Diagnoses
311	34350	1 Liver	No deviation from normal morphology	Centrilobular hepatocellular hypertrophy, mild	Concur RP
		0 Lung		No slide	
339	34351	1 Liver	No deviation from normal morphology	NR	Centrilobular hepato- cellular hypertrophy, minimal
		0 Lung		No slide	
262	34352	1 Liver	No deviation from normal morphology	Centrilobular hepatocellular hypertrophy, mild	Concur RP
		0 Lung		No slide	
348	34353	1 Liver	Focal acute purulent inflammation, minimal	Necrosis, minimal Centrilobular hepatocellular hypertrophy, mild	Concur RP Concur RP
		0 Lung		No slide	

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Group IV - Male, 26-Week Interim Sacrifice

Code Number	Slide No.	No. of Slides	Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
162	34354	1	Liver	No deviation from normal morphology	Centrilobular hepatocellular hypertrophy, mild	Concur RP
		0	Lung		No slide	

Group I - Male, 13-Week Interim Sacrifice

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Group I - Male, 13-Week Interim Sacrifice

Code Number	Slide No.	No. of Slides Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
167	34094 continued	0 Lung		No slide	

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Group II - Male, 13-Week Interim Sacrifice

Code Number	Slide No.	No. of Slides Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
285 34179 continued		0 Lung		No slide	

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Group III - Male, 13-Week Interim Sacrifice

Code Number	Slide No.	No. of Slides Organ	Study Pathologist's (SP) Diagnoses	Reviewing Pathologist's (RP) Coded Pathology Review	Chairperson's Diagnoses
34	34260	1 Liver	No deviation from normal morphology	NR	
		0 Lung		No slide	
353	34261	1 Liver	No deviation from normal morphology	NR	
		0 Lung		No slide	
133	34262	1 Liver	No deviation from normal morphology	NR	
		0 Lung		No slide	
308	34263	1 Liver	No deviation from normal morphology	NR	
		0 Lung		No slide	
228	34264	1 Liver	No deviation from normal morphology	NR	

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Group III - Male, 13-Week Interim Sacrifice

Code Number	Slide No.	No. of Slides Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
228	34264	0 Lung		No slide	
continued					

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Group IV - Male, 13-Week Interim Sacrifice

Code Number	Slide No.	No. of Slides	Organ	Study Pathologist's (SP) Diagnoses	Reviewing Pathologist's (RP) Coded Pathology Review	Chairperson's Diagnoses
60	34345	1	Liver	Hepatocytes, hypertrophy, minimal	NR	Centrilobular hepatocellular hypertrophy, minimal
		0	Lung		No slide	
47	34346	1	Liver	Hepatocytes, inclusion bodies, minimal		(Part of hypertrophy)
				Hepatocytes, hypertrophy, minimal	Centrilobular hepatocellular hypertrophy, mild	Agree
		0	Lung		No slide	
360	34347	1	Liver	Hepatocytes, inclusion bodies, severe	NR	(Part of hypertrophy)
				Hepatocytes, hypertrophy, minimal		Centrilobular hepatocellular hypertrophy, minimal
		0	Lung		No slide	
227	34348	1	Liver	Hepatocytes, inclusion bodies, severe		(Part of hypertrophy)
				Hepatocytes, hypertrophy, minimal	Centrilobular hepatocellular hypertrophy, mild	Agree

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Group IV - Male, 13-Week Interim Sacrifice

Code Number	Slide No.	No. of Slides	Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
227	34348 continued	0	Lung		No slide	
255	34349	1	Liver	Hepatocytes, inclusion bodies, severe		(Part of hypertrophy)
				Hepatocytes, hypertrophy, minimal	Centrilobular hepatocellular hypertrophy, mild	Agree
		0	Lung		No slide	

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Group I - Female, Two-Year

Code Number	Slide No.	No. of Slides	Organ	Study Pathologist's (SP) Diagnoses	Reviewing Pathologist's (RP) Coded Pathology Review	Chairperson's Diagnoses
307	34380	1	Liver	Bile ducts, Focal hyperplasia, minimal	NR	
		1	Lung		NR	
114	34381	1	Liver	Portal triads, fibrosis, focal, minimal	NR	
		1	Lung	Bronchopneumonia, minimal	Interstitial pneumonia, suppurative, mild	Agree
				Bronchiole lumen, foreign body, minimal		
38	34382	1	Liver	Cellular alteration, minimal	Eosinophilic focus	Concur RP
				Hepatocytes, vacuolation, moderate	Centrilobular fatty change, moderate	Concur RP
		1	Lung		NR	
97	34383	1	Liver	Hepatocytes, vacuolation, moderate	Periportal fatty change, moderate	
		1	Lung		NR	

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Group I - Female, Two-Year

Code Number	Slide No.	No. of Slides	Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
197	34384	1	Liver	Congestion, minimal Bile ducts, Focal hyperplasia, minimal	NR	
		1	Lung	Congestion, minimal	NR	
222	34385	1	Liver	Bile ducts, Focal hyperplasia, minimal	NR	
		1	Lung		NR	
88	34386	1	Liver	Cellular alteration, minimal Hepatocytes, vacuolation, minimal	Eosinophilic focus Periportal fatty change, minimal	Concur RP Concur RP Necrosis, minimal
		1	Lung		NR	
113	34387	1	Liver	Hepatocytes, vacuolation, minimal		
		1	Lung		Eosinophilic focus, multiple NR	Concur RP

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Code Number	Slide No.	No. of Slides	Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
206	34391	1	Lung		NR	
continued						
292	34392	1	Liver	No deviation from normal morphology	NR	
		1	Lung		NR	
124	34393	1	Liver	Hematopoiesis, minimal	NR	
		1	Lung	Alveoli, focal hemorrhage, moderate		
				Alveoli, edema, moderate		
				Alveoli, accum. of foamy macrophag diss foc., minimal	Foamy macrophages, minimal	Agree
				Alveolar septa, chronic lymphocytic inflammation, minimal	Interstitial pneumonia, moderate	Concur RP
346	34394	1	Liver	Congestion, minimal		
				Hepatocytes, vacuolation, minimal	Periportal fatty change, mild	

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Group I - Female, Two-Year

Code Number	Slide No.	No. of Slides	Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
346 continued	34394	1	Lung	Congestion, minimal	NR	
111	34395	1	Liver	Focal coagulation necrosis, minimal	NR	Necrosis, minimal
		1	Lung	Bronchopneumonia, minimal	Interstitial pneumonia, moderate	Concur RP
				Bronchiole lumen, foreign body, minimal		
					Foamy macrophages, minimal	Concur RP
260	34396	1	Liver	Hepatocytes, vacuolation, minimal		Concur SP
						Basophilic focus
					Eosinophilic focus	Concur RP
				Bile ducts, Focal hyperplasia, minimal		
		1	Lung		Foamy macrophages, minimal	Concur RP
223	34397	1	Liver	Congestion, minimal	NR	

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Group I - Female, Two-Year

Code Number	Slide No.	No. of Slides	Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
223	34397 continued	1	Lung		Foamy macrophages, minimal	Concur RP Interstitial pneumonia, minimal
23	34398	1	Liver		NR	
		1	Lung	Focal granulomatous inflammation, minimal Dis'm foc. subac lymphocytic inflam, minimal Alveoli, subacute purulent inflammation, minimal	Interstitial pneumonia, mild	Concur RP
70	34399	2	Liver	Congestion, minimal	NR	
		1	Lung		NR	
244	34400	1	Liver	Cellular alteration, minimal	Clear cell focus, multiple	Concur RP
		1	Lung		NR	

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Group I - Female, Two-Year

Code Number	Slide No.	No. of Slides	Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
119	34401	1	Liver	Congestion, minimal		
					Periportal fatty change, mild	
		1	Lung	Congestion, minimal	NR	
115	34402	1	Liver	Cellular alteration, minimal		Basophilic focus, multiple
				Hepatocellular adenoma	Eosinophilic focus	Concur RP
						Angiectasis
		1	Lung		NR	
269	34403	1	Liver	Congestion, minimal	NR	
		1	Lung		NR	
77	34404	1	Liver	No deviation from normal morphology	NR	

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Group I - Female, Two-Year

Code Number	Slide No.	No. of Slides	Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
77 34404 continued		1	Lung		NR	
267 34405		1	Liver		NR	
		1	Lung		NR	
29 34406		1	Liver	Hepatocytes, vacuolation, minimal	Periportal fatty change, mild	Concur RP
					Basophilic focus	Concur RP
		1	Lung	Alveoli, accum. of foamy macrophag diss foc., minimal	Foamy macrophages, minimal	Agree
207 34407		1	Liver	Cellular alteration, minimal	Eosinophilic focus, multiple	Focal fatty change
		1	Lung		NR	
359 34408		1	Liver	No deviation from normal morphology	NR	
		1	Lung		NR	

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Group I - Female, Two-Year

Code Number	Slide No.	No. of Slides	Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
54	34409	1	Liver	Cellular alteration, minimal Focal coagulation necrosis, minimal Bile ducts, Cyst, minimal	Eosinophilic focus, multiple Necrosis, mild	Concur RP Concur RP
		1	Lung	Alveoli, accum. of foamy macrophages, focal, minimal	Foamy macrophages, minimal Interstitial pneumonia, minimal	Agree Concur RP
236	34410	1	Liver	Hepatocytes, vacuolation, minimal	Focal fatty change	
		1	Lung	Alveoli, accum. of foamy macrophages, focal, minimal	Foamy macrophages, minimal Interstitial pneumonia, mild	Agree Concur RP
100	34411	1	Liver		NR	

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Group I - Female, Two-Year

Code Number	Slide No.	No. of Slides	Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
100	34411	1	Lung	Alveoli, accum. of foamy macrophages, focal, minimal	NR	Concur SP
	continued					
6	34412	2	Liver	Hepatocellular adenoma	Basophilic focus	Concur SP
		1	Lung		NR	
318	34413	1	Liver	No deviation from normal morphology	Basophilic focus	
		1	Lung	Alveoli, accum. of foamy macrophag diss foc., moderate	Foamy macrophages, moderate	Agree
					Interstitial pneumonia, mild	Concur RP
109	34414	1	Liver	Hepatocytes, vacuolation, minimal	Periportal fatty change, mild	
				Bile ducts, Focal hyperplasia, minimal		
		1	Lung		NR	

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Group I - Female, Two-Year

Code Number	Slide No.	No. of Slides	Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
61	34415	1	Liver		Basophilic focus	
		1	Lung		NR	
352	34416	1	Liver	Malignant lymphoma Focal coagulation necrosis, minimal	Centrilobular necrosis, mild	Concur RP
		1	Lung		NR	
271	34417	1	Liver	No deviation from normal morphology	Focal fatty change	
		1	Lung		Foamy macrophages, mild	Concur RP
75	34418	1	Liver	Hepatocytes, vacuolation, moderate	Centrilobular fatty change, moderate	
		1	Lung		NR	
190	34419	1	Liver	No deviation from normal morphology	Centrilobular necrosis, minimal	Concur RP

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Group I - Female, Two-Year

Code Number	Slide No.	No. of Slides	Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
190	34419	1	Lung		NR	
	continued					
171	34420	1	Liver	Cellular alteration, minimal	Basophilic focus	Concur RP
					Clear cell focus, multiple	Concur RP
		1	Lung		Foamy macrophages, minimal	Concur SP
74	34421	1	Liver	Bile ducts, Focal hyperplasia, minimal	NR	
		1	Lung	Alveolar septa, focal mineralization, minimal		
					Foamy macrophages, minimal	Concur RP
					Interstitial pneumonia, minimal	Concur RP
272	34422	1	Liver	Bile ducts, Focal hyperplasia, minimal	NR	
		1	Lung	Congestion, minimal	NR	

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Group I - Female, Two-Year

Code Number	Slide No.	No. of Slides	Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
69	34423	1	Liver	Hepatocellular adenoma Congestion, minimal	Basophilic focus	Concur RP
		1	Lung	Congestion, minimal	NR	
285	34424	1	Liver	Cellular alteration, minimal Hepatocytes, vacuolation, minimal	Basophilic focus Eosinophilic focus Periportal fatty change, mild	Basophilic focus, multiple Eosinophilic focus, multiple
		1	Lung		NR	
277	34425	1	Liver	Congestion, minimal	NR	
		1	Lung		NR	
134	34426	1	Liver	Hepatocytes, vacuolation, minimal	Periportal fatty change, minimal	
		1	Lung	Sarcoma, histiocytic	Metastatic tumor	

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Group I - Female, Two-Year

Code Number	Slide No.	No. of Slides	Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
150	34427	1	Liver	Congestion, minimal		
					Basophilic focus	
		1	Lung	Congestion, minimal	NR	
				Alveoli, focal hemorrhage, minimal		
216	34428	1	Liver	Focal coagulation necrosis, minimal	Necrosis, minimal	Concur RP
				Congestion, minimal		
		1	Lung	Congestion, moderate	NR	
				Alveoli, edema, moderate		
312	34429	1	Liver	Lobule centro, focal coagulation necrosis, moderate	Centrilobular necrosis, mild	Concur RP
		1	Lung	No deviation from normal morphology	Foamy macrophages, minimal	Concur RP
					Interstitial pneumonia, minimal	Concur RP

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Group I - Female, Two-Year

Code Number	Slide No.	No. of Slides	Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
334	34430	1	Liver	Focal coagulation necrosis, minimal	NR	Necrosis, minimal
		1	Lung		NR	
365	34431	1	Liver	Cellular alteration, minimal	Basophilic focus	Concur RP
		1	Lung		NR	
112	34432	1	Liver	Congestion, minimal Hepatocytes, vacuolation, minimal	Periportal fatty change, minimal	
		1	Lung	Congestion, minimal	NR	
193	34433	1	Liver	No deviation from normal morphology	NR	
		1	Lung		NR	

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Group I - Female, Two-Year

Code Number	Slide No.	No. of Slides	Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
333	34434	1	Liver	Congestion, minimal Bile ducts, Focal hyperplasia, minimal	NR	
		1	Lung		NR	
356	34435	1	Liver	Congestion, minimal	NR	
		1	Lung	Congestion, minimal		
					Foamy macrophages, minimal	Concur RP
274	34436	1	Liver	Cellular alteration, minimal Hepatocellular adenoma	Mixed cell focus Hepatocellular adenoma	Mixed cell focus, multiple (See foci above)
		1	Lung		NR	
95	34437	1	Liver	Cellular alteration, minimal	Mixed cell focus, multiple	Concur RP
		1	Lung		NR	

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Group I - Female, Two-Year

Code Number	Slide No.	No. of Slides	Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
16	34438	1	Liver	Hepatocytes, vacuolation, minimal	Periportal fatty change, mild	
		1	Lung		Foamy macrophages, minimal	Concur SP
347	34439	1	Liver	Congestion, minimal Bile ducts, Focal hyperplasia, minimal	Periportal fatty change, minimal	
		1	Lung	Congestion, minimal	NR	

Pathology Review Worksheets
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Group II - Female, Two-Year Study

Code Number	Slide No.	No. of Slides Organ	Study Pathologist's (SP) Diagnoses	Reviewing Pathologist's (RP) Coded Pathology Review	Chairperson's Diagnoses
208	34475	1 Liver	Congestion, minimal Bile ducts, Focal hyperplasia, minimal	NR	
		1 Lung		NR	
192	34476	1 Liver	Cellular alteration, minimal	Basophilic focus Eosinophilic focus Clear cell focus	Angiectasis Concur RP Concur RP
		1 Lung		NR	
99	34477	1 Liver	Bile ducts, Focal hyperplasia, minimal	NR	
		1 Lung	Alveoli, accum. of foamy macrophages, focal, minimal	Foamy macrophages, minimal Interstitial pneumonia, minimal	Agree Concur RP

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Group II - Female, Two-Year Study

Code Number	Slide No.	No. of Slides Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
291	34478	1 Liver	Hepatocytes, vacuolation, moderate	Periportal fatty change, moderate	
		1 Lung		NR	
303	34479	1 Liver	Focal subacute lymphocytic inflamm., moderate		
			Cellular alteration, moderate	Eosinophilic focus, multiple	Concur RP
			Focal coagulation necrosis, moderate		Necrosis, mild
		1 Lung	Alveoli, accum. of foamy macrophages, focal, minimal		Concur RP
				Interstitial pneumonia, minimal	Concur RP
327	34480	1 Liver	Cellular alteration, minimal	Clear cell focus	Concur RP
		1 Lung	No deviation from normal morphology	NR	

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Group II - Female, Two-Year Study

Code Number	Slide No.	No. of Slides	Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
68	34481	1	Liver	No deviation from normal morphology	NR	
		1	Lung	Alveoli, edema, minimal		
				Alveoli, accum. of foamy macrophages, focal, minimal	Foamy macrophages, mild	Concur RP
					Interstitial pneumonia, marked	Concur RP
210	34482	1	Liver		NR	
		1	Lung	Alveoli, accum. of foamy macrophages, focal, minimal	Foamy macrophages, mild	Concur RP
					Interstitial pneumonia, mild	Concur RP
313	34483	1	Liver	Hepatocytes, vacuolation, minimal	Periportal fatty change, mild	
		1	Lung		NR	
220	34484	1	Liver		NR	

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Group II - Female, Two-Year Study

Code Number	Slide No.	No. of Slides	Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
220	34484	1	Lung	Congestion, minimal	NR	
	continued					
324	34485	1	Liver	Bile ducts, Focal hyperplasia, minimal	NR	
		1	Lung		Foamy macrophages, minimal	Concur RP
					Interstitial pneumonia, minimal	Concur RP
107	34486	1	Liver		NR	
		1	Lung		NR	
243	34487	1	Liver	Cellular alteration, minimal	Basophilic focus	Concur RP
				Hepatocytes, vacuolation, moderate	Periportal fatty change, mild	Agree
				Bile ducts, Focal hyperplasia, minimal		
		1	Lung		NR	

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Group II - Female, Two-Year Study

Code Number	Slide No.	No. of Slides Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
43	34488	1 Liver	No deviation from normal morphology	NR	
		1 Lung		NR	
140	34489	1 Liver	No deviation from normal morphology	NR	
		1 Lung	No deviation from normal morphology	NR	
3	34490	1 Liver		NR	
		1 Lung	Alveoli, accum. of foamy macrophages, focal, minimal	Foamy macrophages, mild	Concur RP
				Interstitial pneumonia, minimal	Concur RP
266	34491	1 Liver	Congestion, minimal	NR	
		1 Lung		NR	

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Group II - Female, Two-Year Study

Code Number	Slide No.	No. of Slides	Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
315	34492	1	Liver	Cellular alteration, minimal	Eosinophilic focus	Concur RP
					Necrosis, minimal	Concur RP
					Periportal fatty change, minimal	Concur RP
		1	Lung	Alveoli, accum. of foamy macrophages, focal, moderate	Foamy macrophages, mild	Concur RP
					Interstitial pneumonia, mild	Concur RP
67	34493	1	Liver	Hepatocytes, vacuolation, moderate	Periportal fatty change, moderate	
		1	Lung		NR	
350	34494	1	Liver	Congestion, minimal	NR	
		1	Lung	Congestion, minimal	NR	
311	34495	1	Liver	Bile ducts, Focal hyperplasia, minimal	NR	

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Group II - Female, Two-Year Study

Code Number	Slide No.	No. of Slides	Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
311 continued	34495	1	Lung	Alveoli, accum. of foamy macrophages, focal, minimal	NR	Concur RP
290	34496	1	Liver	Cellular alteration, minimal	Basophilic focus, multiple Clear cell focus	Concur RP Concur RP
		1	Lung	No deviation from normal morphology	Foamy macrophages, minimal Interstitial pneumonia, minimal	Concur RP Concur RP
116	34497	1	Liver	Congestion, minimal Hepatocytes, vacuolation, minimal	Periportal fatty change, mild	
		1	Lung	Congestion, minimal	NR	
98	34498	1	Liver	Cellular alteration, minimal	Clear cell focus	
		1	Lung	No deviation from normal morphology	NR	

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Group II - Female, Two-Year Study

Code Number	Slide No.	No. of Slides	Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
256	34499	1	Liver	No deviation from normal morphology	NR	
		1	Lung	Alveoli, accum. of foamy macrophages, focal, minimal	Foamy macrophages, mild	Concur RP
					Interstitial pneumonia, mild	Concur RP
120	34500	1	Liver		Basophilic focus	
		1	Lung	Congestion, minimal		
				Subacute lymphocytic inflammation, minimal	Interstitial pneumonia, mild	Concur RP
				Alveoli, accum. of foamy macrophages, focal, moderate	Foamy macrophages, mild	Concur RP
132	34501	1	Liver	No deviation from normal morphology	NR	
		1	Lung	No deviation from normal morphology	Foamy macrophages, mild	Foamy macrophages, minimal

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Group II - Female, Two-Year Study

Code Number	Slide No.	No. of Slides Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
299	34502	1 Liver	Cellular alteration, minimal	NR	
		1 Lung	No deviation from normal morphology	NR	
329	34503	1 Liver	Hepatocytes, vacuolation, minimal Bile ducts, Focal hyperplasia, minimal	Periportal fatty change, mild	
		1 Lung		NR	
215	34504	1 Liver	Focal coagulation necrosis, minimal Hepatocytes, vacuolation, minimal	Necrosis, minimal	Concur RP
		1 Lung		NR	
181	34505	1 Liver	Cellular alteration, minimal	Basophilic focus Clear cell focus, multiple	

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Group II - Female, Two-Year Study

Code Number	Slide No.	No. of Slides	Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
181	34505 continued	1	Lung	No deviation from normal morphology	NR	
155	34506	1	Liver		NR	
		1	Lung		NR	
2	34507	2	Liver	Bile ducts, Focal hyperplasia, minimal	Histiocytic sarcoma	
		1	Lung	Sarcoma histiocytic	Histiocytic sarcoma	Agree
				Alveoli, accum. of foamy macrophages, focal, minimal	Foamy macrophages, minimal	Agree
230	34508	1	Liver		NR	
		1	Lung		NR	
19	34509	1	Liver	Hepatocytes, vacuolation, minimal	Periportal fatty change, mild	

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Group II - Female, Two-Year Study

Code Number	Slide No.	No. of Slides	Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
19	34509	1	Lung		NR	
	continued					
211	34510	1	Liver		NR	
		1	Lung	Dis'm foc. subac lymphocytic inflam, minimal	NR	
343	34511	1	Liver	No deviation from normal morphology	NR	
		1	Lung	Alveoli, accum. of foamy macrophages, focal, minimal	Foamy macrophages, minimal	Agree
156	34512	1	Liver	Cellular alteration, minimal Telangiectasis, minimal	Clear cell focus	Focal fatty change Concur RP
		1	Lung		NR	
320	34513	1	Liver	No deviation from normal morphology	Clear cell focus	

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Group II - Female, Two-Year Study

Code Number	Slide No.	No. of Slides Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
320 34513 continued		1 Lung	No deviation from normal morphology	NR	
335 34514		1 Liver		NR	
		1 Lung	Alveoli, accum. of foamy macrophages, focal, minimal	NR	Concur RP
340 34515		1 Liver	Cellular alteration, minimal Hepatocellular adenoma	Eosinophilic focus	Basophilic focus Concur RP
		1 Lung	No deviation from normal morphology	NR	
151 34516		1 Liver	Cellular alteration, minimal Bile ducts, Focal hyperplasia, minimal	Focal fatty change	
		1 Lung	Alveoli, accum. of foamy macrophages, focal, minimal	Foamy macrophages, mild	Concur RP

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Group II - Female, Two-Year Study

Code Number	Slide No.	No. of Slides Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
242	34517	1 Liver	Congestion, minimal	NR	
		1 Lung	Congestion, minimal	NR	
83	34518	1 Liver	No deviation from normal morphology	NR	
		1 Lung	Alveoli, accum. of foamy macrophages, focal, minimal	Foamy macrophages, minimal	Agree
				Interstitial pneumonia, minimal	Concur RP
21	34519	1 Liver	Congestion, minimal Hepatocytes, vacuolation, moderate Bile ducts, focal hyperplasia, minimal	Periportal fatty change, moderate	
		1 Lung		NR	
351	34520	1 Liver	No deviation from normal morphology	Periportal fatty change, minimal	

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Group II - Female, Two-Year Study

Code Number	Slide No.	No. of Slides	Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
351 continued	34520	1	Lung		NR	
257	34521	1	Liver	Cellular alteration, minimal	NR	
		1	Lung	Alveoli, focal hemorrhage, minimal		
				Alveoli, fibrosis, focal, minimal	Interstitial pneumonia, minimal	Concur RP
					Foamy macrophages, minimal	Concur RP
30	34522	1	Liver		NR	
		1	Lung		Foamy macrophages, minimal	Concur RP
128	34523	1	Liver	Cellular alteration, minimal	Eosinophilic focus	Concur RP
		1	Lung	No deviation from normal morphology	NR	

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Group II - Female, Two-Year Study

Code Number	Slide No.	No. of Slides	Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
80	34524	1	Liver		Basophilic focus	Concur RP
					Periportal fatty change, minimal	
		1	Lung		NR	
44	34525	1	Liver	Hepatocytes, vacuolation, minimal	Periportal fatty change, mild	
		1	Lung		NR	
293	34526	1	Liver	No deviation from normal morphology	Basophilic focus	
					Clear cell focus	
		1	Lung	No deviation from normal morphology	Interstitial pneumonia, minimal	Concur SP
172	34527	1	Liver		NR	
		1	Lung	Alveoli, focal subacute lymphocytic inflam., minimal	Interstitial pneumonia, minimal	Concur RP

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Group II - Female, Two-Year Study

Code Number	Slide No.	No. of Slides Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
62	34528	1 Liver	Cellular alteration, minimal Congestion, minimal		
			Bile ducts, Focal hyperplasia, minimal		
			Portal triads, fibrosis, focal, minimal		
		1 Lung	Congestion, minimal	NR	
			Alveoli, accum. of foamy macrophages, focal, minimal		Concur SP
185	34529	1 Liver		Clear cell focus	
			Bile ducts, Focal hyperplasia, minimal		
		1 Lung	No deviation from normal morphology	NR	
310	34530	1 Liver	Hepatocytes, vacuolation, minimal	Periportal fatty change, mild	

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Group II - Female, Two-Year Study

Code Number	Slide No.	No. of Slides	Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
310	34530	1	Lung		NR	
	continued					
145	34531	1	Liver	Congestion, minimal	NR	
		1	Lung		NR	
194	34532	1	Liver	Hepatocellular adenoma	Hepatocellular adenoma	Agree
					Basophilic focus, multiple	Concur RP
					Focal fatty change	Concur RP
						Eosinophilic focus
		1	Lung	No deviation from normal morphology	Foamy macrophages, minimal	Concur RP
					Interstitial pneumonia, minimal	Concur RP
273	34533	1	Liver	Telangiectasis, minimal	Cystic degeneration, minimal	Concur RP
				Congestion, minimal		
					Eosinophilic focus, multiple	Concur RP

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Group II - Female, Two-Year Study

Code Number	Slide No.	No. of Slides Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
273 34533 continued		1 Lung	Alveoli, accum. of foamy macrophages, focal, minimal	Metastatic carcinoma	Concur RP
174 34534		1 Liver	Hepatocytes, vacuolation, severe Bile ducts, Focal hyperplasia, minimal	Periportal fatty change, marked	
		1 Lung		NR	

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Group III - Female, Two-Year Study

Code Number	Slide No.	No. of Slides	Organ	Study Pathologist's (SP) Diagnoses	Reviewing Pathologist's (RP) Coded Pathology Review	Chairperson's Diagnoses
337	34560	1	Liver	Hepatocarcinoma	Hepatocellular adenoma Basophilic focus Focal fatty change	Hepatocellular carcinoma Concur RP
		1	Lung	Alveoli, accum. of foamy macrophages, focal, moderate	Foamy macrophages, moderate Interstitial pneumonia, mild	Agree Concur RP
163	34561	1	Liver	Bile ducts, Focal hyperplasia, minimal Glissons capsule, fibrosis, focal, minimal	Basophilic focus Periportal fatty change, minimal	
		1	Lung	Alveoli, accum. of foamy macrophages, focal, minimal	Foamy macrophages, minimal	Agree

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Group III - Female, Two-Year Study

Code Number	Slide No.	No. of Slides Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
196	34562	1 Liver	No deviation from normal morphology	NR	
		1 Lung	No deviation from normal morphology	NR	
302	34563	1 Liver	Focal coagulation necrosis, minimal	Necrosis, minimal	Concur RP
		1 Lung	No deviation from normal morphology	NR	
34	34564	1 Liver	No deviation from normal morphology	Basophilic focus	Within normal limits
				Mixed cell focus, multiple	Concur RP
		1 Lung	No deviation from normal morphology	NR	

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Group III - Female, Two-Year Study

Code Number	Slide No.	No. of Slides Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
279	34565	1 Liver	No deviation from normal morphology	Clear cell focus	
		1 Lung	No deviation from normal morphology	Foamy macrophages, minimal	Concur RP
				Interstitial pneumonia, minimal	Concur RP
66	34566	1 Liver		NR	
		1 Lung		NR	
331	34567	1 Liver		NR	
		1 Lung	Alveoli, accum. of foamy macrophages, focal, minimal	Foamy macrophages, mild	Concur RP
				Interstitial pneumonia, mild	Concur RP
9	34568	1 Liver	Bile ducts, Focal hyperplasia, minimal	Basophilic focus	

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Group III - Female, Two-Year Study

Code Number	Slide No.	No. of Slides	Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
9	34568	2	Lung	Alveoli, accum. of foamy macrophages, focal, minimal	Foamy macrophages, mild	Concur RP
	continued				Interstitial pneumonia, mild	Concur RP
82	34569	1	Liver		NR	
		1	Lung		NR	
125	34570	1	Liver	Hepatocytes, vacuolation, moderate	Periportal fatty change, moderate	
		1	Lung		NR	
123	34571	1	Liver	Bile ducts, Focal hyperplasia, minimal	NR	
		1	Lung	Congestion, minimal	NR	

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Group III - Female, Two-Year Study

Code Number	Slide No.	No. of Slides	Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
55	34572	1	Liver	Lobule centro, focal coagulation necrosis, minimal		Necrosis, minimal
					Eosinophilic focus	Concur RP
		1	Lung		Foamy macrophages, minimal	Concur RP
300	34573	1	Liver	Cellular alteration, minimal	Mixed cell focus Focal fatty change	Concur RP
		1	Lung	No deviation from normal morphology	NR	
173	34574	1	Liver	Congestion, minimal	Basophilic focus Eosinophilic focus, multiple	Concur RP Concur RP
		1	Lung	Congestion, minimal	NR	
65	34575	1	Liver	Bile ducts, Focal hyperplasia, minimal	NR	

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Group III - Female, Two-Year Study

Code Number	Slide No.	No. of Slides	Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
65	34575	1	Lung	Alveoli, accum. of foamy macrophages, focal, minimal	Foamy macrophages, minimal	Agree
	continued					
108	34576	1	Liver	Focal coagulation necrosis, moderate	Necrosis, mild	Concur RP
					Periportal fatty change, minimal	Concur RP
		1	Lung		NR	
130	34577	1	Liver	Metastatic islet cell carcinoma	Metastatic carcinoma	
		1	Lung	No deviation from normal morphology	NR	
48	34578	1	Liver	Telangiectasis, minimal	NR	Sinusoidal ectasia
		1	Lung	Alveoli, accum. of foamy macrophages, focal, minimal	Foamy macrophages, minimal	Agree
					Interstitial pneumonia, minimal	Concur RP

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Group III - Female, Two-Year Study

Code Number	Slide No.	No. of Slides	Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
149	34579	1	Liver		NR	
		1	Lung		NR	
259	34580	1	Liver		NR	
		1	Lung		NR	
10	34581	1	Liver	Bile ducts, Focal hyperplasia, minimal	NR	
		1	Lung		NR	
170	34582	1	Liver	Cellular alteration, minimal	Eosinophilic focus Clear cell focus, multiple	Concur RP Concur RP
		1	Lung	No deviation from normal morphology	NR	

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Group III - Female, Two-Year Study

Code Number	Slide No.	No. of Slides	Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
182	34583	1	Liver	Focal coagulation necrosis, minimal	Necrosis, minimal	Concur RP
		1	Lung	Alveoli, accum. of foamy macrophages, focal, moderate	Foamy macrophages, mild	Concur RP
					Interstitial pneumonia, minimal	Concur RP
249	34584	1	Liver	No deviation from normal morphology	Clear cell focus, multiple	
		1	Lung	Alveoli, accum. of foamy macrophages, focal, moderate	Foamy macrophages, mild	Concur RP
					Interstitial pneumonia, mild	Concur RP
296	34585	1	Liver	Malignant lymphoma	Lymphoma	
		1	Lung	Malignant lymphoma		Concur SP
				Alveoli, accum. of foamy macrophages, focal, minimal	Foamy macrophages, mild	Concur RP

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Group III - Female, Two-Year Study

Code Number	Slide No.	No. of Slides Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
228	34586	1 Liver	Congestion, minimal	NR	
		1 Lung	Alveoli, focal acute purulent inflammation, minimal	Pneumonia suppurative, mild	
49	34587	1 Liver	Hepatocellular adenoma	Eosinophilic focus	Basophilic focus
			Hepatocytes, vacuolation, minimal	Periportal fatty change, mild	Concur RP
		1 Lung		NR	
234	34588	1 Liver		NR	
		1 Lung		NR	
309	34589	1 Liver		NR	
		1 Lung		NR	
35	34590	1 Liver	Hepatocytes, vacuolation, moderate	Fatty change, marked	

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Group III - Female, Two-Year Study

Code Number	Slide No.	No. of Slides	Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
35	34590	1	Lung	Congestion, minimal	NR	
	continued					
179	34591	1	Liver	Cellular alteration, minimal	Clear cell focus	
		1	Lung	Bronchiole, diffuse acute purulent inflam., minimal	Interstitial pneumonia, minimal	Concur RP
				Bronchiole lumen, foreign body, minimal		
				Alveoli, accum. of foamy macrophages, focal, minimal	Foamy macrophages, minimal	Agree
159	34592	1	Liver	No deviation from normal morphology	NR	
		1	Lung		NR	
283	34593	1	Liver	Malignant lymphoma	Lymphoma	
		1	Lung		NR	

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Group III - Female, Two-Year Study

Code Number	Slide No.	No. of Slides	Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
122	34594	1	Liver	No deviation from normal morphology	NR	
		1	Lung	Alveoli, accum. of foamy macrophages, focal, minimal	Foamy macrophages, mild	Concur RP
4	34595	1	Liver	Congestion, minimal	NR	
		1	Lung	Congestion, minimal	NR	
93	34596	1	Liver	Cellular alteration, minimal	Mixed cell focus, multiple	Concur RP
		1	Lung	No deviation from normal morphology	NR	
238	34597	1	Liver	Hepatocytes, vacuolation, moderate	Periportal fatty change, moderate	
		1	Lung	Alveoli, accum. of foamy macrophages, focal, minimal	NR	Concur RP

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Group III - Female, Two-Year Study

Code Number	Slide No.	No. of Slides	Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
164	34598	1	Liver	Telangiectasis, minimal	Cystic degeneration, minimal	Concur RP
		1	Lung	No deviation from normal morphology	NR	
295	34599	1	Liver		Eosinophilic focus	Concur RP
		1	Lung		Foamy macrophages, mild	Concur RP
142	34600	1	Liver	Telangiectasis, minimal Congestion, minimal	Cystic degeneration, mild	Concur RP
		1	Lung		Interstitial pneumonia, minimal	Concur RP
						Foamy macrophages, minimal
8	34601	1	Liver	Bile ducts, Focal hyperplasia, minimal		
					Clear cell focus	
		1	Lung	No deviation from normal morphology	NR	

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Group III - Female, Two-Year Study

Code Number	Slide No.	No. of Slides	Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
226	34602	1	Liver	Hepatocytes, vacuolation, moderate	Periportal fatty change, moderate	Concur RP
					Basophilic focus	Concur RP
					Eosinophilic focus	Concur RP
					Mixed cell focus, multiple	Concur RP
		1	Lung	Bile ducts, Focal hyperplasia, minimal No deviation from normal morphology	Foamy macrophages, minimal	Concur RP
					Interstitial pneumonia, minimal	Concur RP
286	34603	1	Liver	Telangiectasis, minimal	Cystic degeneration, minimal	Concur RP
					Eosinophilic focus	Eosinophilic focus (with cystic degeneration)
		1	Lung		NR	

Pathology Review Worksheets
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Group III - Female, Two-Year Study

Code Number	Slide No.	No. of Slides	Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
57	34604	1	Liver	Cellular alteration, minimal	Basophilic focus, multiple	Concur RP
					Eosinophilic focus	Concur RP
				Telangiectasis, minimal	Cystic degeneration, minimal	Concur RP
				Bile ducts, Focal hyperplasia, minimal	Periportal fatty change, minimal	
		1	Lung	Alveoli, accum. of foamy macrophages, focal, moderate	Foamy macrophages, mild	Concur RP
					Interstitial pneumonia, mild	Concur RP
247	34605	1	Liver	Cellular alteration, minimal	Clear cell focus	
		1	Lung	No deviation from normal morphology	NR	
360	34606	1	Liver	No deviation from normal morphology	Basophilic focus	Concur RP
					Mixed cell focus	Concur RP

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Chronic Toxicity/Carcinogenicity Study
PATHCO No. 90-128

Group III - Female, Two-Year Study

Code Number	Slide No.	No. of Slides	Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
360	34606	1	Lung	Metastatic adrenal cort. carcinoma		
	continued					
				Alveoli, accum. of foamy macrophages, focal, minimal	Foamy macrophages, minimal	Concur RP
					Interstitial pneumonia, minimal	Concur RP
368	34607	1	Liver	Congestion, minimal		
					Basophilic focus	Concur RP
					Eosinophilic focus	Concur SP
					Periportal fatty change, minimal	
					Cystic degeneration, minimal	Concur RP
		1	Lung	Congestion, minimal	NR	
56	34608	1	Liver	Bile ducts, Focal hyperplasia, minimal	NR	
		1	Lung	Alveoli, acute purulent inflammation, moderate	Interstitial pneumonia, mild	Concur RP (with acute component)

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Group III - Female, Two-Year Study

Code Number	Slide No.	No. of Slides Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
135	34609	1 Liver	Congestion, minimal	NR	
		1 Lung	Congestion, minimal		
			Alveoli, accum. of foamy macrophages, focal, minimal	Foamy macrophages, minimal	Agree
39	34610	1 Liver	Telangiectasis, minimal	Cystic degeneration, minimal	Concur RP
				Eosinophilic focus	Concur RP
			Bile ducts, Focal hyperplasia, minimal		
		1 Lung	Alveoli, accum. of foamy macrophag diss foc., minimal	Foamy macrophages, mild	Concur RP
209	34611	1 Liver	No deviation from normal morphology	NR	
		1 Lung		Foamy macrophages, minimal	Concur RP
				Interstitial pneumonia, minimal	Concur RP

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Group III - Female, Two-Year Study

Code Number	Slide No.	No. of Slides	Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
187	34612	1	Liver	No deviation from normal morphology	NR	
		1	Lung	No deviation from normal morphology	NR	
167	34613	1	Liver	Bile ducts, Focal Focal hyperplasia, minimal	Periportal fatty change, minimal	
		1	Lung	No deviation from normal morphology	NR	
42	34614	1	Liver	Hepatocytes, vacuolation, minimal	Periportal fatty change, mild	
		1	Lung	Alveoli, accum. of foamy macrophages, focal, minimal	NR	Concur RP
264	34615	1	Liver		NR	

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Group III - Female, Two-Year Study

Code Number	Slide No.	No. of Slides	Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
264	34615	1	Lung	Alveoli septal cell, focal hypertrophy, minimal	Interstitial pneumonia, mild	Concur RP
continued					Foamy macrophages, minimal	Concur SP
18	34616	1	Liver	Congestion, minimal		
				Hepatocytes, vacuolation, minimal	Centrilobular fatty change, minimal	
		1	Lung	Congestion, minimal	NR	
177	34617	1	Liver	Cellular alteration, minimal	Basophilic focus	Concur RP
					Clear cell focus, multiple	Concur RP
					Mixed cell focus	Concur RP
		1	Lung	No deviation from normal morphology	Foamy macrophages, minimal	Concur RP
					Interstitial pneumonia, minimal	Concur RP

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Group III - Female, Two-Year Study

Code Number	Slide No.	No. of Slides	Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
288	34618	1	Liver	Congestion, minimal	Eosinophilic focus Focal fatty change	Concur RP Concur RP
		1	Lung	Congestion, minimal Alveoli, accum. of foamy macrophages, focal, minimal	Foamy macrophages, mild Interstitial pneumonia, minimal	Concur RP Concur RP
152	34619	1	Liver	Hepatocytes, vacuolation, severe	Fatty change, marked	
		1	Lung	Alveoli, accum. of foamy macrophages, focal, minimal	Foamy macrophages, minimal Interstitial pneumonia, minimal	Agree Concur RP

Pathology Review Worksheets
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Group IV - Female, Two-Year Study

Code Number	Slide No.	No. of Slides Organ	Study Pathologist's (SP) Diagnoses	Reviewing Pathologist's (RP) Coded Pathology Review	Chairperson's Diagnoses
87	34645	1 Liver	No deviation from normal morphology	NR	
		1 Lung	Alveoli, accum. of foamy macrophages, focal, minimal	Foamy macrophages, minimal Interstitial pneumonia, minimal	Agree Concur RP
341	34646	1 Liver	Cellular alteration, minimal	Basophilic focus, multiple Clear cell focus	Angiectasis Concur RP
		1 Lung		NR	
127	34647	1 Liver	No deviation from normal morphology	NR	
		1 Lung		Foamy macrophages, minimal	Concur SP Interstitial pneumonia, minimal
202	34648	1 Liver		NR	

Pathology Review Worksheets
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Group IV - Female, Two-Year Study

Code Number	Slide No.	No. of Slides	Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
202	34648	1	Lung	Alveoli, edema, minimal		
	continued			Alveoli, edema, moderate		
				Alveoli, accum. of foamy macrophages, focal, moderate	Foamy macrophages, mild	Concur RP
					Interstitial pneumonia, minimal	Concur RP
218	34649	2	Liver		NR	
		1	Lung		NR	
160	34650	1	Liver	Congestion, minimal	NR	
		1	Lung	Alveoli, subacute purulent inflammation, moderate	Pneumonia, suppurative, mild	
304	34651	1	Liver	Congestion, minimal		
				Hepatocytes, vacuolation, minimal	Periportal fatty change, mild	
		1	Lung	Congestion, minimal	NR	

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Group IV - Female, Two-Year Study

Code Number	Slide No.	No. of Slides Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
103	34652	1 Liver	Congestion, minimal	NR	
		1 Lung		NR	
235	34653	1 Liver	Hepatocytes, vacuolation, minimal	Periportal fatty change, minimal	
		1 Lung	Alveoli, accum. of foamy macrophages, focal, minimal	Foamy macrophages, mild	Concur RP
				Interstitial pneumonia, minimal	Concur RP
205	34654	1 Liver	Focal coagulation necrosis, minimal	Necrosis, minimal	Concur RP
			Telangiectasis, minimal		Concur RP
		1 Lung			
			Alveoli, accum. of foamy macrophages, focal, minimal	Foamy macrophages, minimal	Agree

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Group IV - Female, Two-Year Study

Code Number	Slide No.	No. of Slides Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
248	34655	1 Liver	No deviation from normal morphology	Periportal fatty change, minimal	
		1 Lung	Alveoli, accum. of foamy macrophages, focal, minimal	Foamy macrophages, mild	Concur RP
				Interstitial pneumonia, mild	Concur RP
92	34656	1 Liver	Hepatocellular adenoma	Hepatocellular adenoma	Hepatocellular adenoma
			Hematopoiesis, minimal	Lymphoma	
		1 Lung		NR	
183	34657	1 Liver	Cellular alteration, minimal	Basophilic focus	Concur RP
				Eosinophilic focus	Concur RP
		1 Lung		NR	

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Group IV - Female, Two-Year Study

Code Number	Slide No.	No. of Slides	Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
104	34658	1	Liver		NR	
		1	Lung		NR	
280	34659	1	Liver	Hepatocytes, vacuolation, minimal	Periportal fatty change, mild	
		1	Lung	Focal subacute lymphocytic inflam., minimal	Interstitial pneumonia, minimal	Concur RP
					Foamy macrophages, minimal	Concur RP
328	34660	1	Liver	Hepatocytes, vacuolation, minimal	Periportal fatty change, minimal	Concur RP
				Bile ducts, Focal hyperplasia, minimal		
					Eosinophilic focus	Concur RP
		1	Lung		NR	
314	34661	1	Liver	Focal coagulation necrosis, minimal	NR	Necrosis, minimal

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Group IV - Female, Two-Year Study

Code Number	Slide No.	No. of Slides	Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
314	34661	1	Lung		NR	
	continued					
60	34662	1	Liver	Hepatocytes, vacuolation, minimal	Periportal fatty change, mild	Concur RP
					Eosinophilic focus	Concur RP
		1	Lung		NR	
47	34663	1	Liver	Hepatocytes, vacuolation, moderate	Periportal fatty change, moderate	
		1	Lung	Alveoli, focal hemorrhage, minimal	NR	
227	34664	1	Liver		NR	
		1	Lung		NR	

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Group IV - Female, Two-Year Study

Code Number	Slide No.	No. of Slides	Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
214	34665	1	Liver	Cellular alteration, minimal Bile ducts, Focal hyperplasia, minimal	Mixed cell focus, multiple	Concur RP Basophilic focus
		1	Lung		NR	
59	34666	1	Liver	Sarcoma, histiocytic Necrosis, moderate	Lymphoma Necrosis, marked	Concur SP (Part of tumor)
		1	Lung	Sarcoma, histiocytic	Lymphoma	Concur SP
358	34667	1	Liver	Bile ducts, Focal hyperplasia, minimal	NR	
		1	Lung		NR	
76	34668	2	Liver	Cellular alteration, minimal Hepatocytes, vacuolation, minimal	Eosinophilic focus, multiple Periportal fatty change, minimal	Concur RP

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Group IV - Female, Two-Year Study

Code Number	Slide No.	No. of Slides	Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
76	34668	1	Lung	Alveoli, accum. of foamy macrophages, focal, minimal	Foamy macrophages, minimal	Agree
	continued				Interstitial pneumonia, minimal	Concur RP
157	34669	1	Liver	Lobule centro, necrosis, minimal	NR	Centrilobular necrosis, minimal
		1	Lung		NR	
276	34670	1	Liver	Hepatocellular adenoma	Eosinophilic focus, multiple	Concur RP
		1	Lung	Alveoli, accum. of foamy macrophages, focal, minimal	Foamy macrophages, mild	Concur RP
					Interstitial pneumonia, mild	Concur RP
253	34671	1	Liver	Bile ducts, Focal hyperplasia, minimal	NR	

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Group IV - Female, Two-Year Study

Code Number	Slide No.	No. of Slides	Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
253	34671 continued	1	Lung		Foamy macrophages, minimal Interstitial pneumonia, minimal	Concur RP Concur RP
323	34672	1	Liver		NR	
		1	Lung		NR	
143	34673	1	Liver	Portal triads, fibrosis, focal, minimal	NR	
		1	Lung		NR	
26	34674	1	Liver	Cellular alteration, minimal Congestion, minimal Hepatocytes, vacuolation, minimal	Basophilic focus Periportal fatty change, mild	Concur RP
		1	Lung	Congestion, minimal	NR	

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Group IV - Female, Two-Year Study

Code Number	Slide No.	No. of Slides	Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
153	34675	1	Liver	No deviation from normal morphology	Periportal fatty change, minimal	
		1	Lung	Alveoli, accum. of foamy macrophag diss foc., minimal	Foamy macrophages, mild	Concur RP
					Interstitial pneumonia, mild	Concur RP
353	34676	1	Liver	Sarcoma, histiocytic	Histiocytic sarcoma	
		1	Lung		Foamy macrophages, minimal	Concur RP
175	34677	1	Liver		NR	
		1	Lung		NR	
317	34678	1	Liver	No deviation from normal morphology	Basophilic focus	Concur SP
		1	Lung		NR	

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Group IV - Female, Two-Year Study

Code Number	Slide No.	No. of Slides	Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
79	34679	1	Liver		NR	
		1	Lung	Alveoli, accum. of foamy macrophages, focal, minimal	Foamy macrophages, mild	Concur RP
					Interstitial pneumonia, minimal	Concur RP
330	34680	1	Liver	Cellular alteration, minimal	Mixed cell focus	Concur RP
					Periportal fatty change, minimal	
		1	Lung		NR	
287	34681	1	Liver	Cellular alteration, moderate	Eosinophilic focus	Concur RP
		1	Lung	Alveoli, accum. of foamy macrophages, focal, minimal	Foamy macrophages, mild	Concur RP
284	34682	1	Liver	Congestion, minimal		
				Hepatocytes, vacuolation, moderate	Periportal fatty change, marked	

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Group IV - Female, Two-Year Study

Code Number	Slide No.	No. of Slides	Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
284	34682	1	Lung	Congestion, minimal		
	continued				Foamy macrophages, minimal	Concur SP
					Interstitial pneumonia, minimal	Concur SP
332	34683	2	Liver	Focal hemorrhage, minimal	NR	
		1	Lung		NR	
255	34684	1	Liver	No deviation from normal morphology	Periportal fatty change, minimal	
		1	Lung		Foamy macrophages, minimal	Concur RP
146	34685	1	Liver	Fatty infiltration, minimal	Periportal fatty change, mild	
		1	Lung		NR	

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Group IV - Female, Two-Year Study

Code Number	Slide No.	No. of Slides	Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
166	34686	1	Liver	Cellular alteration, minimal Bile ducts, Focal hyperplasia, minimal	NR	
		1	Lung		NR	
45	34687	1	Liver	Cellular alteration, minimal Bile ducts, Focal hyperplasia, minimal	Basophilic focus	
		2	Lung	Alveoli, adenoma	Alveolar/bronchiolar adenoma	Agree
189	34688	1	Liver	Cellular alteration, minimal Bile ducts, Focal hyperplasia, minimal	Basophilic focus, multiple	Concur RP
		1	Lung		NR	
289	34689	1	Liver	No deviation from normal morphology	NR	
		1	Lung		Foamy macrophages, minimal	Concur SP

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Group IV - Female, Two-Year Study

Code Number	Slide No.	No. of Slides	Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
63	34690	1	Liver	Cellular alteration, minimal	Basophilic focus	Concur RP
				Congestion, minimal		
				Bile ducts, Focal hyperplasia, minimal		
		1	Lung	Alveoli, accum. of foamy macrophag diss foc., minimal	Foamy macrophages, minimal	Agree
					Interstitial pneumonia, minimal	Concur RP
191	34691	1	Liver	Focal hyperplasia, moderate	Periportal fatty change, moderate	
		1	Lung		NR	
198	34692	1	Liver	Cellular alteration, minimal	Clear cell focus	

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Group IV - Female, Two-Year Study

Code Number	Slide No.	No. of Slides	Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
198	34692	1	Lung		Foamy macrophages, minimal	Concur RP
	continued				Interstitial pneumonia, minimal	Concur RP
101	34693	1	Liver		NR	
		1	Lung		NR	
89	34694	1	Liver		NR	
		1	Lung		Foamy macrophages, mild	Concur RP
261	34695	1	Liver	Cellular alteration, minimal	Eosinophilic focus	Concur RP
		1	Lung		NR	
178	34696	1	Liver		NR	
		1	Lung		NR	

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Group IV - Female, Two-Year Study

Code Number	Slide No.	No. of Slides Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
305	34697	1 Liver	Bile ducts, Focal hyperplasia, minimal	Necrosis, mild	Concur SP
		1 Lung		NR	
106	34698	1 Liver	Congestion, minimal Hepatocytes, vacuolation, minimal	Periportal fatty change, mild	
		1 Lung	Congestion, minimal	NR	
184	34699	1 Liver		NR	
		1 Lung		NR	
121	34700	1 Liver	Cellular alteration, minimal Hepatocytes, vacuolation, minimal	Eosinophilic focus	Concur RP Fatty change, mild

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Group IV - Female, Two-Year Study

Code Number	Slide No.	No. of Slides	Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
121	34700 continued	1	Lung		Foamy macrophages, minimal Interstitial pneumonia, minimal	Concur RP Concur RP
344	34701	1	Liver	Cellular alteration, minimal Bile ducts, Focal hyperplasia, minimal	Focal fatty change	
		1	Lung	Alveoli, accum. of foamy macrophages, focal, minimal	Foamy macrophages, mild Interstitial pneumonia, mild	Concur RP Concur RP
50	34702	1	Liver	No deviation from normal morphology	Clear cell focus	
		1	Lung	Alveoli, accum. of foamy macrophages, focal, minimal	Foamy macrophages, minimal Interstitial pneumonia, minimal	Agree Concur RP

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Group IV - Female, Two-Year Study

Code Number	Slide No.	No. of Slides	Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
355	34703	1	Liver		Centrilobular fatty change, minimal	
		1	Lung		Foamy macrophages, minimal	Concur SP
32	34704	1	Liver	Focal chronic lymphocytic inflam., minimal	NR	
		1	Lung	Bronchi lumen, foreign body, minimal		Concur SP
				Bronchi Lumen, acute purulent inflammation, minimal		
				Alveoli, accum. of foamy macrophages, focal, minimal		Concur SP
				Alveoli, focal chronic purulent inflam., moderate	Interstitial pneumonia, mild	Concur RP

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Group I - Female, 78-Week Interim Sacrifice

Code Number	Slide No.	No. of Slides Organ	Study Pathologist's (SP) Diagnoses	Reviewing Pathologist's (RP) Coded Pathology Review	Chairperson's Diagnoses
250	34470	1 Liver		NR	
		1 Lung		NR	
52	34471	1 Liver	Hepatocytes, vacuolation, minimal	NR	
		0 Lung		No slide	
138	34472	1 Liver	Focal coagulation necrosis, minimal	Necrosis, minimal	Concur RP
		0 Lung		NR	
13	34473	1 Liver	No deviation from normal morphology	NR	
		0 Lung		No slide	
5	34474	1 Liver	Cellular alteration, minimal	Clear cell focus	
		0 Lung		No slide	

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Group II - Female, 78-Week Interim Sacrifice

Code Number	Slide No.	No. of Slides	Organ	Study Pathologist's (SP) Diagnoses	Reviewing Pathologist's (RP) Coded Pathology Review	Chairperson's Diagnoses
246	34555	1	Liver		NR	
		1	Lung		NR	
1	34556	1	Liver	Hepatocellular adenoma Hepatocytes, vacuolation, moderate Bile ducts, Focal hyperplasia, minimal	Telangiectasis, mild	Angiectasis Fatty change, moderate
		1	Lung		NR	
336	34557	1	Liver	No deviation from normal morphology	NR	
		0	Lung		No slide	
147	34558	1	Liver	No deviation from normal morphology	Clear cell focus	
		0	Lung		No slide	

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Group II - Female, 78-Week Interim Sacrifice

Code Number	Slide No.	No. of Slides Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
15	34559	1 Liver	No deviation from normal morphology	NR	
		0 Lung		No slide	

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Group III - Female, 78-Week Interim

Code Number	Slide No.	No. of Slides	Organ	Study Pathologist's (SP) Diagnoses	Reviewing Pathologist's (RP) Coded Pathology Review	Chairperson's Diagnoses
316	34640	1	Liver	Bile ducts, Focal hyperplasia, minimal	NR	
		0	Lung		No slide	
237	34641	1	Liver	No deviation from normal morphology	NR	
		0	Lung		No slide	
241	34642	1	Liver	No deviation from normal morphology	Eosinophilic focus	Concur RP
		0	Lung		No slide	
275	34643	1	Liver	Cellular alteration, minimal	Mixed cell focus Periportal fatty change, minimal	Concur RP
		0	Lung		No slide	

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Group III - Female, 78-Week Interim

Code Number	Slide No.	No. of Slides Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
265	34644	1 Liver	No deviation from normal morphology	Clear cell focus	
		0 Lung		No slide	

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Group IV - Female, 78-Week Interim

Code Number	Slide No.	No. of Slides	Organ	Study Pathologist's (SP) Diagnoses	Reviewing Pathologist's (RP) Coded Pathology Review	Chairperson's Diagnoses
141	34725	1	Liver		Basophilic focus	Concur RP
					Clear cell focus	Concur RP
				Bile ducts, Focal hyperplasia, minimal		
		0	Lung		No slide	
254	34726	1	Liver	No deviation from normal morphology	NR	
		0	Lung		No slide	
263	34727	1	Liver	No deviation from normal morphology	NR	
		0	Lung		No slide	
348	34728	1	Liver	No deviation from normal morphology	NR	
		0	Lung		No slide	

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Group IV - Female, 78-Week Interim

Code Number	Slide No.	No. of Slides	Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
240	34729	1	Liver	No deviation from normal morphology	Clear cell focus	
		0	Lung		No slide	

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Group I - Female, 52-Week Interim Sacrifice

Code Number	Slide No.	No. of Slides Organ	Study Pathologist's (SP) Diagnoses	Reviewing Pathologist's (RP) Coded Pathology Review	Chairperson's Diagnoses
203	34440	1 Liver		NR	Agree
		1 Lung		Interstitial pneumonia, minimal	Concur RP
126	34441	1 Liver		NR	Agree
		1 Lung		NR	
301	34442	1 Liver		NR	Agree
		1 Lung		NR	
364	34443	1 Liver		NR	
		1 Lung		Foamy macrophages, minimal	Concur RP
102	34444	1 Liver		NR	

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PATHCO No. 90-128

Group I - Female, 52-Week Interim Sacrifice

Code Number	Slide No.	No. of Slides	Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
102	34444 continued	1	Lung	Alveoli septal cell, focal hyperplasia, moderate		
					Interstitial pneumonia, minimal	Concur RP
129	34445	1	Liver		NR	
		1	Lung	Dis'm foc. subac lymphocytic inflam, minimal	NR	
367	34446	1	Liver	NR	NR	
		1	Lung	NR	NR	
105	34447	1	Liver		NR	
		1	Lung	Dis'm foc. subac lymphocytic inflam, minimal	NR	
366	34448	1	Liver		NR	
		1	Lung		NR	

Pathology Review Worksheets
Ciba-Geigy
Chronic Toxicity/Carcinogenicity Study
PATHCO No. 90-128

Group I - Female, 52-Week Interim Sacrifice

Code Number	Slide No.	No. of Slides	Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
73	34449	1	Liver		NR	
		1	Lung		Foamy macrophages, minimal Interstitial pneumonia, minimal	Concur RP Concur RP
117	34450	1	Liver		NR	
		1	Lung		NR	
370	34451	1	Liver		NR	
		1	Lung		NR	
169	34452	1	Liver		NR	
		1	Lung		NR	
298	34453	1	Liver		NR	

Pathology Review Worksheets
Ciba-Geigy
Chronic Toxicity/Carcinogenicity Study
PATHCO No. 90-128

Group I - Female, 52-Week Interim Sacrifice

Code Number	Slide No.	No. of Slides	Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
298	34453	1	Lung		Foamy macrophages, minimal	Concur RP
	continued				Interstitial pneumonia, minimal	Concur RP
361	34454	1	Liver		NR	
		1	Lung		Foamy macrophages, minimal	Concur RP
148	34455	1	Liver		NR	
		1	Lung		NR	
144	34456	1	Liver		NR	
		1	Lung		NR	
294	34457	1	Liver		Eosinophilic focus	Concur SP
		1	Lung		NR	

Pathology Review Worksheets
Ciba-Geigy
Chronic Toxicity/Carcinogenicity Study
PATHCO No. 90-128

Group I - Female, 52-Week Interim Sacrifice

Code Number	Slide No.	No. of Slides	Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
270	34458	1	Liver		NR	
		1	Lung		NR	
94	34459	1	Liver		NR	
		1	Lung		NR	

Pathology Review Worksheets
Ciba-Geigy
Chronic Toxicity/Carcinogenicity Study
PATHCO No. 90-128

Group II - Female, 52-Week Interim Sacrifice

Code Number	Slide No.	No. of Slides Organ	Study Pathologist's (SP) Diagnoses	Reviewing Pathologist's (RP) Coded Pathology Review	Chairperson's Diagnoses
251	34535	1 Liver	No deviation from normal morphology	NR	
		0 Lung		No slide	
58	34536	1 Liver	No deviation from normal morphology	NR	
		0 Lung		No slide	
199	34537	1 Liver	No deviation from normal morphology	NR	
		0 Lung		No slide	
232	34538	1 Liver	No deviation from normal morphology	NR	
		0 Lung		No slide	
233	34539	1 Liver	No deviation from normal morphology	NR	

Pathology Review Worksheets
 * Ciba-Geigy
 Chronic Toxicity/Carcinogenicity Study
 PATHCO No. 90-128

Group II - Female, 52-Week Interim Sacrifice

Code Number	Slide No.	No. of Slides Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
233	34539 continued	0 Lung		No slide	
25	34540	1 Liver	No deviation from normal morphology	Clear cell focus, multiple	
		0 Lung		No slide	
154	34541	1 Liver	No deviation from normal morphology	NR	
		0 Lung		No slide	
281	34542	1 Liver	No deviation from normal morphology	NR	
		0 Lung		No slide	
221	34543	1 Liver	No deviation from normal morphology	Basophilic focus	
		0 Lung		No slide	

Pathology Review Worksheets
Ciba-Geigy
Chronic Toxicity/Carcinogenicity Study
PATHCO No. 90-128

Group II - Female, 52-Week Interim Sacrifice

Code Number	Slide No.	No. of Slides Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
268	34544	1 Liver	No deviation from normal morphology	NR	
		0 Lung		No slide	

Pathology Review Worksheets
Ciba-Geigy
Chronic Toxicity/Carcinogenicity Study
PATHCO No. 90-128

Group III - Female, 52-Week Interim

Code Number	Slide No.	No. of Slides	Organ	Study Pathologist's (SP) Diagnoses	Reviewing Pathologist's (RP) Coded Pathology Review	Chairperson's Diagnoses
326	34620	1	Liver	No deviation from normal morphology	NR	
		0	Lung		No slide	
17	34621	1	Liver	No deviation from normal morphology	Clear cell focus	
		0	Lung		No slide	
231	34622	1	Liver	Hepatocellular adenoma	Basophilic focus Clear cell focus	Concur RP Concur RP
		0	Lung		No slide	
118	34623	1	Liver	No deviation from normal morphology	NR	
		0	Lung		No slide	
369	34624	1	Liver	No deviation from normal morphology	Clear cell focus	

Pathology Review Worksheets
Ciba-Geigy
Chronic Toxicity/Carcinogenicity Study
PATHCO No. 90-128

Group III - Female, 52-Week Interim

Code Number	Slide No.	No. of Slides	Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
369	34624	0	Lung		No slide	
	continued					
96	34625	1	Liver	Cellular alteration, minimal	Basophilic focus	
		0	Lung		No slide	
278	34626	1	Liver	No deviation from normal morphology	NR	
		0	Lung		No slide	
217	34627	1	Liver	No deviation from normal morphology	NR	
		0	Lung		No slide	
362	34628	1	Liver	No deviation from normal morphology	NR	
		0	Lung		No slide	

Pathology Review Worksheets
 Ciba-Geigy
 Chronic Toxicity/Carcinogenicity Study
 PATHCO No. 90-128

Group III - Female, 52-Week Interim

Code Number	Slide No.	No. of Slides Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
110	34629	1 Liver	No deviation from normal morphology	NR	
		0 Lung		No slide	

Pathology Review Worksheets
Ciba-Geigy
Chronic Toxicity/Carcinogenicity Study
PATHCO No. 90-128

Group IV - Female, 52-Week Interim

Code Number	Slide No.	No. of Slides	Organ	Study Pathologist's (SP) Diagnoses	Reviewing Pathologist's (RP) Coded Pathology Review	Chairperson's Diagnoses
325	34705	1	Liver		NR	
		1	Lung		NR	
319	34706	1	Liver	No deviation from normal morphology	NR	
		0	Lung		No slide	
27	34707	1	Liver	No deviation from normal morphology	NR	
		0	Lung		No slide	
139	34708	1	Liver	No deviation from normal morphology	NR	
		0	Lung		No slide	
133	34709	1	Liver	No deviation from normal morphology	NR	

Pathology Review Worksheets
Ciba-Geigy
Chronic Toxicity/Carcinogenicity Study
PATHCO No. 90-128

Group IV - Female, 52-Week Interim

Code Number	Slide No.	No. of Slides	Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
133	34709	0	Lung		No slide	
	continued					
85	34710	1	Liver	No deviation from normal morphology	NR	
		0	Lung		No slide	
338	34711	1	Liver	No deviation from normal morphology	NR	
		0	Lung		No slide	
213	34712	1	Liver	No deviation from normal morphology	NR	
		0	Lung		No slide	
188	34713	1	Liver	No deviation from normal morphology	NR	
		0	Lung		No slide	

Pathology Review Worksheets
Ciba-Geigy
Chronic Toxicity/Carcinogenicity Study
PATHCO No. 90-128

Group IV - Female, 52-Week Interim

Code Number	Slide No.	No. of Slides Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
24	34714	1 Liver	No deviation from normal morphology	NR	
		0 Lung		No slide	

Pathology Review Worksheets
Ciba-Geigy
Chronic Toxicity/Carcinogenicity Study
PATHCO No. 90-128

Group V - Female, 52-Week Interim

Code Number	Slide No.	No. of Slides	Organ	Study Pathologist's (SP) Diagnoses	Reviewing Pathologist's (RP) Coded Pathology Review	Chairperson's Diagnoses
12	34730	1	Liver		NR	
		1	Lung		NR	
239	34731	1	Liver		Centrilobular hepatocellular hypertrophy, minimal	Concur RP
		1	Lung		NR	
81	34732	1	Liver		Centrilobular hepatocellular hypertrophy, minimal	Concur RP
		1	Lung		NR	
165	34733	1	Liver		Centrilobular hepatocellular hypertrophy, minimal	Concur RP
		1	Lung		Foamy macrophages, minimal	Concur SP
297	34734	1	Liver		NR	

Pathology Review Worksheets
Ciba-Geigy
Chronic Toxicity/Carcinogenicity Study
PATHCO No. 90-128

Group V - Female, 52-Week Interim

Code Number	Slide No.	No. of Slides	Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
297	34734 continued	1	Lung	Alveoli, accum. of foamy macrophages, focal, minimal	Foamy macrophages, minimal	Agree
					Interstitial pneumonia, minimal	Concur RP
137	34735	1	Liver		NR	
		1	Lung		NR	
195	34736	1	Liver		NR	
		1	Lung		NR	
131	34737	1	Liver		NR	
		1	Lung	Focal subacute lymphocytic inflamm., minimal	Interstitial pneumonia, mild	Concur RP
51	34738	1	Liver		NR	
		1	Lung		NR	

Pathology Review Worksheets
Ciba-Geigy
Chronic Toxicity/Carcinogenicity Study
PATHCO No. 90-128

Group V - Female, 52-Week Interim

Code Number	Slide No.	No. of Slides	Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
162	34739	1	Liver		NR	
		1	Lung		Foamy macrophages, minimal	Concur SP
258	34740	1	Liver		NR	
		1	Lung		Foamy macrophages, minimal	Concur RP
					Interstitial pneumonia, minimal	Concur RP
72	34741	1	Liver		NR	
		1	Lung		Foamy macrophages, minimal	Concur RP
					Interstitial pneumonia, minimal	Concur RP
363	34742	1	Liver		NR	
		1	Lung		Foamy macrophages, minimal	Concur RP
186	34743	1	Liver		NR	

Pathology Review Worksheets
Ciba-Geigy
Chronic Toxicity/Carcinogenicity Study
PATHCO No. 90-128

Group V - Female, 52-Week Interim

Code Number	Slide No.	No. of Slides	Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
186	34743 continued	1	Lung		NR	
78	34744	1	Liver		NR	
		1	Lung		Foamy macrophages, minimal	Concur RP
91	34745	1	Liver		NR	
		1	Lung		NR	
306	34746	1	Liver		Centrilobular hepatocellular hypertrophy, minimal	Concur RP
		1	Lung		NR	
201	34747	1	Liver		NR	
		1	Lung		NR	
176	34748	1	Liver		Centrilobular hepatocellular hypertrophy, minimal	Concur RP

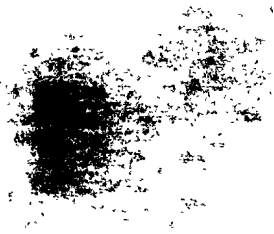
Pathology Review Worksheets
Ciba-Geigy
Chronic Toxicity/Carcinogenicity Study
PATHCO No. 90-128

Group V - Female, 52-Week Interim

Code Number	Slide No.	No. of Slides Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
176 34748 continued		1 Lung		NR	
46 34749		1 Liver		Centrilobular hepatocellular hypertrophy, mild	Concur RP
		1 Lung		NR	

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Pathology Review Worksheets
Ciba-Geigy
Chronic Toxicity/Carcinogenicity Study
PATHCO No. 90-128

Group I - Female, 26-Week Interim Sacrifice

Code Number	Slide No.	No. of Slides Organ	Study Pathologist's (SP) Diagnoses	Reviewing Pathologist's (RP) Coded Pathology Review	Chairperson's Diagnoses
36	34465	1 Liver	No deviation from normal morphology	NR	
		0 Lung		No slide	
342	34466	1 Liver	No deviation from normal morphology	Basophilic focus	Concur RP
		0 Lung		No slide	
345	34467	1 Liver	No deviation from normal morphology	NR	
		0 Lung		No slide	
22	34468	1 Liver	No deviation from normal morphology	NR	
		0 Lung		No slide	
161	34469	1 Liver	No deviation from normal morphology	NR	

Pathology Review Worksheets
Ciba-Geigy
Chronic Toxicity/Carcinogenicity Study
PATHCO No. 90-128

Group I - Female, 26-Week Interim Sacrifice

Code Number	Slide No.	No. of Slides Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
161	34469 continued	0 Lung		No slide	

Pathology Review Worksheets
Ciba-Geigy
Chronic Toxicity/Carcinogenicity Study
PATHCO No. 90-128

Group II - Female, 26-Week Interim Sacrifice

Code Number	Slide No.	No. of Slides Organ	Study Pathologist's (SP) Diagnoses	Reviewing Pathologist's (RP) Coded Pathology Review	Chairperson's Diagnoses
245	34550	1 Liver	No deviation from normal morphology	NR	
		0 Lung		No slide	
229	34551	1 Liver	No deviation from normal morphology	NR	
		0 Lung		No slide	
11	34552	1 Liver	No deviation from normal morphology	NR	
		0 Lung		No slide	
349	34553	1 Liver	No deviation from normal morphology	NR	
		0 Lung		No slide	
41	34554	1 Liver	No deviation from normal morphology	NR	

Pathology Review Worksheets
Ciba-Geigy
Chronic Toxicity/Carcinogenicity Study
PATHCO No. 90-128

Group II - Female, 26-Week Interim Sacrifice

Code Number	Slide No.	No. of Slides Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
41	34554 continued	0 Lung		No slide	

Pathology Review Worksheets
Ciba-Geigy
Chronic Toxicity/Carcinogenicity Study
PATHCO No. 90-128

Group III - Female, 26-Week Interim

Code Number	Slide No.	No. of Slides	Organ	Study Pathologist's (SP) Diagnoses	Reviewing Pathologist's (RP) Coded Pathology Review	Chairperson's Diagnoses
53	34635	1	Liver	No deviation from normal morphology	NR	
		0	Lung		No slide	
40	34636	1	Liver	No deviation from normal morphology	NR	
		0	Lung		No slide	
252	34637	1	Liver	No deviation from normal morphology	NR	
		0	Lung		No slide	
225	34638	1	Liver	Hepatocytes, vacuolation, minimal		Eosinophilic focus, multiple Concur RP
		0	Lung		No slide	

Pathology Review Worksheets
Ciba-Geigy
Chronic Toxicity/Carcinogenicity Study
PATHCO No. 90-128

Group III - Female, 26-Week Interim

Code Number	Slide No.	No. of Slides	Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
357	34639	1	Liver	No deviation from normal morphology	NR	
		0	Lung		No slide	

Pathology Review Worksheets
Ciba-Geigy
Chronic Toxicity/Carcinogenicity Study
PATHCO No. 90-128

Group IV - Female, 26-Week Interim

Code Number	Slide No.	No. of Slides Organ	Study Pathologist's (SP) Diagnoses	Reviewing Pathologist's (RP) Coded Pathology Review	Chairperson's Diagnoses
224	34720	1 Liver	No deviation from normal morphology	NR	
		0 Lung		No slide	
14	34721	1 Liver	No deviation from normal morphology	Basophilic focus	
				Clear cell focus	
		0 Lung		No slide	
219	34722	1 Liver	No deviation from normal morphology	Basophilic focus	
		0 Lung		No slide	
262	34723	1 Liver	No deviation from normal morphology	NR	
		0 Lung		No slide	

Pathology Review Worksheets
Ciba-Geigy
Chronic Toxicity/Carcinogenicity Study
PATHCO No. 90-128

Group IV - Female, 26-Week Interim

Code Number	Slide No.	No. of Slides	Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
321	34724	1	Liver	No deviation from normal morphology	NR	
		0	Lung		No slide	

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Pathology Review Worksheets
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Chronic Toxicity/Carcinogenicity Study
PATHCO No. 90-128

Group I - Female, 13-Week Interim Sacrifice

Code Number	Slide No.	No. of Slides Organ	Study Pathologist's (SP) Diagnoses	Reviewing Pathologist's (RP) Coded Pathology Review	Chairperson's Diagnoses
90	34460	1 Liver	No deviation from normal morphology	NR	
		0 Lung		No slide	
354	34461	1 Liver	Focal subacute lymphocytic inflamm., minimal	NR	
		0 Lung		No slide	
168	34462	1 Liver	No deviation from normal morphology	Basophilic focus	Concur RP
				Clear cell focus	Concur RP
		0 Lung		No slide	
71	34463	1 Liver	No deviation from normal morphology	NR	
		0 Lung		No Slide	

Pathology Review Worksheets
Ciba-Geigy
Chronic Toxicity/Carcinogenicity Study
PATHCO No. 90-128

Group I - Female, 13-Week Interim Sacrifice

Code Number	Slide No.	No. of Slides Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
158	34464	1 Liver	No deviation from normal morphology	NR	
		1 Lung	Focal hemorrhage, minimal Dis'm foc. subac lymphocytic inflam, minimal	NR	

Pathology Review Worksheets
Ciba-Geigy
Chronic Toxicity/Carcinogenicity Study
PATHCO No. 90-128

Group II - Female, 13-Week Interim Sacrifice

Code Number	Slide No.	No. of Slides	Organ	Study Pathologist's (SP) Diagnoses	Reviewing Pathologist's (RP) Coded Pathology Review	Chairperson's Diagnoses
84	34545	1	Liver	No deviation from normal morphology	NR	
		0	Lung		No slide	
37	34546	1	Liver	No deviation from normal morphology	NR	
		0	Lung		No slide	
339	34547	1	Liver	Focal subacute lymphocytic inflam., minimal	NR	
		0	Lung		No slide	
212	34548	1	Liver	No deviation from normal morphology	NR	
		0	Lung		No slide	
28	34549	1	Liver	Focal subacute lymphocytic inflam., minimal	NR	

Pathology Review Worksheets
Ciba-Geigy
Chronic Toxicity/Carcinogenicity Study
PATHCO No. 90-128

Group II - Female, 13-Week Interim Sacrifice

Code Number	Slide No.	No. of Slides Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
28	34549	0 Lung		No slide	
continued					

Pathology Review Worksheets
Ciba-Geigy
Chronic Toxicity/Carcinogenicity Study
PATHCO No. 90-128

Group III - Female, 13-Week Interim

Code Number	Slide No.	No. of Slides Organ	Study Pathologist's (SP) Diagnoses	Reviewing Pathologist's (RP) Coded Pathology Review	Chairperson's Diagnoses
20	34630	1 Liver	No deviation from normal morphology	NR	
		0 Lung		No slide	
308	34631	1 Liver	No deviation from normal morphology	NR	
		0 Lung		No slide	
33	34632	1 Liver	No deviation from normal morphology	NR	
		0 Lung		No slide	
282	34633	1 Liver	No deviation from normal morphology	NR	
		0 Lung		No slide	
200	34634	1 Liver	No deviation from normal morphology	NR	

Pathology Review Worksheets
Ciba-Geigy
Chronic Toxicity/Carcinogenicity Study
PATHCO No. 90-128

Group III - Female, 13-Week Interim

Code Number	Slide No.	No. of Slides	Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
200	34634	0	Lung		No slide	
continued						

Pathology Review Worksheets
Ciba-Geigy
Chronic Toxicity/Carcinogenicity Study
PATHCO No. 90-128

Group IV - Female, 13-Week Interim

Code Number	Slide No.	No. of Slides Organ	Study Pathologist's (SP) Diagnoses	Reviewing Pathologist's (RP) Coded Pathology Review	Chairperson's Diagnoses
64	34715	1 Liver	No deviation from normal morphology	NR	
		0 Lung		No slide	
322	34716	1 Liver	No deviation from normal morphology	NR	
		0 Lung		No slide	
86	34717	1 Liver	No deviation from normal morphology	NR	
		0 Lung		No slide	
204	34718	1 Liver	No deviation from normal morphology	NR	
		0 Lung		No slide	

Pathology Review Worksheets
Ciba-Geigy
Chronic Toxicity/Carcinogenicity Study
PATHCO No. 90-128

Group IV - Female, 13-Week Interim

Code Number	Slide No.	No. of Slides	Organ	Study Pathologist's Diagnoses	Reviewing Pathologist's Coded Pathology Review	Chairperson's Diagnoses
7	34719	1	Liver	No deviation from normal morphology	NR	
		0	Lung		No slide	

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APPENDIX C

Summary Tables Based on Coded Pathology Review

TRICLOSAN: 2-YEAR ORAL
ADMINISTRATION TO RATS
TWO-YEAR STUDY
PATHCO No. 90-128

Project Summary Table

SUMMARY: Incidence of NEOPLASTIC and NON-NEOPLASTIC Microscopic Findings

PROJECT ID. NO: 90-128A

FATES: ALLSEX: MALE

GROUP:

0 ppm

300 ppm

1000 ppm

3000 ppm

NUMBER OF ANIMALS:

60

60

60

60

	#	#	#	#
	# Ex			
LIVER	60	60	60	60
Eosinophilic focus	5	7	7	11
Centrilobular fatty change	1	1	3	1
Periportal fatty change	0	3	2	7
Eosinophilic focus, multiple	1	3	1	4
Basophilic focus, multiple	2	7	0	0
Clear cell focus, multiple	14	13	14	10
Basophilic focus	11	7	7	9
Necrosis	0	4	2	1
Focal fatty change	1	0	0	0
Centrilobular necrosis	1	3	3	2
Hepatocellular adenoma	1	1	1	1
Clear cell focus	3	3	5	2
Histiocytic sarcoma	1	1	1	2
Cystic degeneration	15	19	19	22
Lymphoma	1	0	1	1
Fatty change	7	2	3	7
Bile duct hyperplasia	3	1	3	1
Periportal hepatocel. hypertro	1	0	2	0
Hepatocellular carcinoma	0	1	2	2
Hepatocel. adenoma, multiple	0	1	0	0
Telangiectasis	0	0	0	1
Periportal hepatocel. hyperpla	0	0	0	1
LUNG	# Ex 59	60	60	60
Foamy macrophages	13	22	24	26
Interstitial pneumonia	9	15	16	16
Histiocytic sarcoma	0	0	0	1
Inflammation, suppurative	1	0	0	0
Edema	1	2	2	0
Abscess, multiple	0	1	0	0
Granuloma	0	0	0	1

TRICLOSAN: 2-YEAR ORAL
ADMINISTRATION TO RATS
78 WEEK INTERIM SACRIFICE
PATHCO No. 90-128

Project Summary Table

SUMMARY: Incidence of NEOPLASTIC and NON-NEOPLASTIC Microscopic Findings

PROJECT ID. NO: 90-1288

FATES: ALLSEX: MALE

GROUP:

0 ppm

300 ppm

1000 ppm

3000 ppm

NUMBER OF ANIMALS:

5

5

5

5

	#	#	#	#
LIVER	# Ex 5	5	5	5
Clear cell focus	0	1	1	0
Eosinophilic focus	1	1	0	0
Clear cell focus, multiple	1	3	1	2
Cystic degeneration	1	0	1	0
Fatty change	0	0	1	0
Centril. hepatocel. hypertrop.	0	0	0	1
Centrilobular necrosis	0	0	0	1
LUNG	# Ex 2	0	2	2
Foamy macrophages	1	0	0	1
Interstitial pneumonia	1	0	1	1
Alveolar/bronchiolar adenoma	0	0	0	1

TRICLOSAN: 2-YEAR ORAL
ADMINISTRATION TO RATS
52 WEEK INTERIM SACRIFICE
PATHCO No. 90-128

Project Summary Table

SUMMARY: Incidence of NEOPLASTIC and NON-NEOPLASTIC Microscopic Findings

PROJECT ID. NO: 90-128C

FATES: ALLSEX: MALE

GROUP:	0 ppm	300 ppm	1000 ppm	3000 ppm	6000 ppm
NUMBER OF ANIMALS:	20	10	10	10	20

	#	#	#	#	#
LIVER	# Ex 20	10	10	10	20
Eosinophilic focus	2	0	1	1	0
Clear cell focus, multiple	2	1	0	2	1
Basophilic focus	0	0	0	1	0
Clear cell focus	3	3	2	1	4
Centril. hepatocel. hypertrop.	0	0	0	4	14
Centrilobular fatty change	0	0	2	1	0
Fatty change	0	0	1	0	0
Necrosis	0	0	0	0	1
 LUNG	# Ex 19	0	0	0	20
Interstitial pneumonia	0	0	0	0	1
Foamy macrophages	0	0	0	0	2

TRICLOSAN: 2-YEAR ORAL
ADMINISTRATION TO RATS
26 WEEK INTERIM SACRIFICE
PATHCO No. 90-128

Project Summary Table

SUMMARY: Incidence of NEOPLASTIC and NON-NEOPLASTIC Microscopic Findings

PROJECT ID. NO: 90-1280

FATES: ALLSEX: MALE

GROUP:

0 ppm

300 ppm

1000 ppm

3000 ppm

NUMBER OF ANIMALS:

5

5

5

5

		#	#	#	#
LIVER	# Ex	5	5	5	5
Clear cell focus		0	0	1	0
Eosinophilic focus		0	0	1	0
Centril. hepatocel. hypertrop.		0	0	0	4
Necrosis		0	0	0	1
LUNG	# Ex	0	0	0	0

TRICLOSAN: 2-YEAR ORAL
ADMINISTRATION TO RATS
13 WEEK INTERIM SACRIFICE
PATHCO No. 90-128

Project Summary Table

SUMMARY: Incidence of NEOPLASTIC and NON-NEOPLASTIC Microscopic Findings

PROJECT ID. NO: 90-128E

FATES: ALLSEX: MALE

GROUP:

0 ppm

300 ppm

1000 ppm

3000 ppm

NUMBER OF ANIMALS:

5

5

5

5

		#	#	#	#
LIVER	# Ex	5	5	5	5
Centril. hepatocel. hypertrop.		0	0	0	3
LUNG	# Ex	0	0	0	0

11

TRICLOSAN: 2-YEAR ORAL
ADMINISTRATION TO RATS
TWO-YEAR STUDY
PATHCO No. 90-128

Project Summary Table

SUMMARY: Incidence of NEOPLASTIC and NON-NEOPLASTIC Microscopic Findings

PROJECT ID. NO: 90-128A

FATES: ALLSEX: FEMALE

GROUP:	0 ppm	300 ppm	1000 ppm	3000 ppm
NUMBER OF ANIMALS:	60	60	60	60

	#	#	#	#
LIVER	# Ex 60	60	60	60
Eosinophilic focus	5	4	10	6
Centrilobular fatty change	2	0	1	1
Periportal fatty change	12	14	10	16
Eosinophilic focus, multiple	4	2	1	2
Basophilic focus, multiple	1	2	1	2
Mixed cell focus, multiple	2	0	3	2
Clear cell focus, multiple	2	1	3	0
Basophilic focus	9	6	9	5
Necrosis	2	2	3	3
Focal fatty change	2	2	3	1
Centrilobular necrosis	3	0	0	0
Mixed cell focus	1	0	2	0
Hepatocellular adenoma	1	1	1	1
Clear cell focus	0	8	4	3
Histiocytic sarcoma	0	1	0	1
Centril. hepatocel. hypertroph	0	1	0	0
Cystic degeneration	0	1	6	0
Lymphoma	0	0	2	2
Fatty change	0	0	2	0

	# Ex 60	60	60	60
LUNG	# Ex 60	60	60	60
Interstitial pneumonia, suppur	1	0	0	0
Foamy macrophages	14	17	24	24
Interstitial pneumonia	8	15	18	17
Pneumonia, suppurative	0	0	1	1
Alveolar/bronchiolar adenoma	0	0	0	1

TRICLOSAN: 2-YEAR ORAL
ADMINISTRATION TO RATS
78 WEEK INTERIM SACRIFICE
PATHCO No. 90-128

Project Summary Table

SUMMARY: Incidence of NEOPLASTIC and NON-NEOPLASTIC Microscopic Findings

PROJECT ID. NO: 90-1288

FATES: ALLSEX: FEMALE

GROUP:

0 ppm

300 ppm

1000 ppm

3000 ppm

NUMBER OF ANIMALS:

5

5

5

5

		#	#	#	#
LIVER	# Ex	5	5	5	5
Necrosis		1	0	0	0
Clear cell focus		1	1	1	2
Telangiectasis		0	1	0	0
Eosinophilic focus		0	0	1	0
Mixed cell focus		0	0	1	0
Periportal fatty change		0	0	1	0
Basophilic focus		0	0	0	1

LUNG	# Ex	2	2	0	0
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TRICLOSAN: 2-YEAR ORAL
ADMINISTRATION TO RATS
52 WEEK INTERIM SACRIFICE
PATHCO No. 90-128

Project Summary Table

SUMMARY: Incidence of NEOPLASTIC and NON-NEOPLASTIC Microscopic Findings

PROJECT ID. NO: 90-128C

FATES: ALLSEX: FEMALE

GROUP:	0 ppm	300 ppm	1000 ppm	3000 ppm	6000 ppm
NUMBER OF ANIMALS:	20	10	10	10	20

	#	#	#	#	#
LIVER	# Ex 20	10	10	10	20
Eosinophilic focus	1	0	0	0	0
Clear cell focus, multiple	0	1	0	0	0
Basophilic focus	0	1	2	0	0
Clear cell focus	0	0	3	0	0
Centril. hepatocel. hypertrop.	0	0	0	0	6
LUNG	# Ex 20	0	0	1	20
Interstitial pneumonia	4	0	0	0	4
Foamy macrophages	4	0	0	0	7

TRICLOSAN: 2-YEAR ORAL
ADMINISTRATION TO RATS
26 WEEK INTERIM SACRIFICE
PATHCO No. 90-128

Project Summary Table

SUMMARY: Incidence of NEOPLASTIC and NON-NEOPLASTIC Microscopic Findings

PROJECT ID. NO: 90-1280

FATES: ALLSEX: FEMALE

GROUP:

0 ppm

300 ppm

1000 ppm

3000 ppm

NUMBER OF ANIMALS:

5

5

5

5

		#	#	#	#
LIVER	# Ex	5	5	5	5
Basophilic focus		1	0	0	2
Eosinophilic focus, multiple		0	0	1	0
Clear cell focus		0	0	0	1
LUNG	# Ex	0	0	0	0

TRICLOSAN: 2-YEAR ORAL
ADMINISTRATION TO RATS
13 WEEK INTERIM SACRIFICE
PATHCO No. 90-128

Project Summary Table

SUMMARY: Incidence of NEOPLASTIC and NON-NEOPLASTIC Microscopic Findings

PROJECT ID. NO: 90-128E

FATES: ALLSEX: FEMALE

GROUP:

0 ppm

300 ppm

1000 ppm

3000 ppm

NUMBER OF ANIMALS:

5

5

5

5

LIVER

Ex

#

#

#

#

5

5

5

5

Basophilic focus

1

0

0

0

Clear cell focus

1

0

0

0

LUNG

Ex

1

0

0

0

APPENDIX D - C.V.s

D. G. Goodman, Chairperson

J. M. Cullen, Participant

P. M. Newberne, Participant

R. A. Squire, Participant

J. M. Ward, Participant

R. M. Sauer, Reviewing Pathologist

DAWN G. GOODMAN

EDUCATION:

Postdoctoral Fellowship Certificate in
Comparative Pathology, Johns Hopkins
University School of Medicine, 1972;
V.M.D. University of Pennsylvania, 1969;
B.S., George Washington University, 1965.

**BOARD
CERTIFICATION:**

Diplomate, American College of Veterinary
Pathologists, 1974.

EXPERIENCE:

1983 - Present	President and Senior Pathologist PATHCO, Inc. Gaithersburg, Maryland.
1983 - 1985	Consulting Pathologist.
1982 - 1989	Adjunct Assistant Professor, Department of Pathology, University of Maryland School of Medicine, Baltimore, Maryland.
1981 - 1983	Associate Scientist and Senior Pathologist, Clement Associates, Inc., Arlington, Virginia.
1980 - 1986	Lecturer, Neoplasms of Mice, Course on Pathology of Laboratory Animals, Armed Forces Institute of Pathology (AFIP), Washington, D.C.
1978 - Present	Visiting Lecturer in Comparative Medicine, Johns Hopkins University School of Medicine, Baltimore, Maryland.
1978 - 1986	Lecturer in Pathology, Johns Hopkins University School of Medicine, Baltimore, Maryland.
1978 - 1981	Director of Pathology, Clement Associates, Inc., Washington, D.C.
1978 - 1980	Lecturer, Graduate School, Foundation for Advanced Education in the Sciences, National Institutes of Health (NIH), Bethesda, Maryland.

Dawn G. Goodman, V.M.D.

1977 - 1978 Veterinary Pathologist, Tumor Pathology Branch,
Carcinogenesis Testing Program, Division of
Cancer Cause and Prevention (DCCP), National
Cancer Institute (NCI), NIH, Bethesda,
Maryland.

1976 - 1977 Acting Head, Tumor Pathology Section,
Experimental Pathology Branch (EPB),
Carcinogenesis Program (CP), DCCP, NCI,
Bethesda Maryland.

1975 - 1976 Veterinary Pathologist, Tumor Pathology
Section, EPB, CP, DCCP, NCI, NIH, Bethesda,
Maryland.

1974 - 1975 Director of Animal Disease Investigation
Services, Comparative Pathology Section,
Veterinary Resources Branch (VRB), Division of
Research Services (DRS), NIH, Bethesda,
Maryland.

1972 - 1975 Veterinary Pathologist, VRB, DRS, NIH,
Bethesda, Maryland.

1972 U.S. Public Health Service (USPHS), NIH Special
Research Fellow, Department of Pathology, Johns
Hopkins University School of Medicine,
Baltimore, Maryland.

1969 - 1972 USPHS Postdoctoral Fellow in Comparative
Pathology, Johns Hopkins University School of
Medicine, Baltimore, Maryland.

INDEPENDENT CONSULTATIONS:

Clement Associates, Inc., Arlington, Virginia
Gillette Medical Evaluations Laboratory, Rockville, Maryland
Environ Corporation, Washington, D.C.

MEMBERSHIPS:

American College of Veterinary Pathologists
American Association for the Advancement of Science
American Veterinary Medical Association
Association for Women Veterinarians
D.C. Academy of Veterinary Medicine

Memberships (continued)

United States and Canadian Academy of Pathology
Mid-Atlantic Comparative Pathology Colloque
Society of Toxicologic Pathologists
Society of Toxicology
Veterinary Cancer Society

HONORS AND AWARDS:

Society of Phi Zeta (Veterinary Honor Society) - University of Pennsylvania

USPHS, NIH Special Research Fellowship (Canine Mammary Tumors).

COMMITTEES AND PROFESSIONAL ADVISORY ACTIVITIES:

Chairman, Subcommittee on Liver, Standardized System of Nomenclature and Diagnostic Criteria Committee, Society of Toxicologic Pathologists, 1989-Present

Pathology Working Group, National Toxicology Program, National Institute of Environmental Health Sciences (NIEHS), 1980-Present

Expert witness on carcinogenicity of PCB's, 1988

Chairman, Liaison Committee on Federal Regulations, American College of Veterinary Pathologists, 1979-1985

Workshop on Proliferative Lesions of the Rat Liver, National Toxicology Program, NIEHS, 1983

Expert witness on Carcinogenicity of TCDD and Silvex, Environmental Protection Agency Hearing to ban use of pesticides TCDD and Silvex, 1979

Participant, Mouse Liver Workshop, Environmental Protection Agency, 1980

Head, Pathology Working Group, Carcinogenesis Testing Program (CTP), DCCP, NCI, 1976-1978

Data Evaluation Group, CTP, DCCP, NCI, 1976-1978

Experimental Design Group, CTP, DCCP, NCI, 1976-1978

Committees (continued)

PHS Career Development Committee for Veterinarians OAM/PHS, DHEW,
1977-1978

PUBLICATIONS:

Dunnick, J.K., Forbes, P.D., Eustis, S.L., Hardisty, J.F., and Goodman, D.G. Tumors of the Skin in the HRA/SKH Mouse after Treatment with 8-Methoxypsoralen and UVA Radiation. Fund. Appl. Toxicol. (In Press).

Frith, C.H., Goodman, D.G., and Boyson, B.G. "The Mouse. Pathology and Organ Weights." In Gad, S. and Chengelis, C., eds. Animal Models in Toxicology, Marcel Dekker, Inc., New York (In Press).

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Goodman, D.G., and Hildebrandt, P.K. Papillary Adenoma, endometrium, rat. In Jones, T.C., Mohr, U. and Hunt, R.D., eds. Genital System, Monographs on Pathology of Laboratory Animals. Springer-Verlag, New York. pp. 78-80, (1987)

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Goodman, D.G., and Hildebrandt, P.K. Stromal sarcoma, endometrium, rat. In Jones, T.C., Mohr, U. and Hunt, R. D., eds. Genital System, Monographs on Pathology of Laboratory Animals. Springer-Verlag, New York. pp. 70-72, (1987)

Goodman, D.G., and Hildebrandt, P.K. Squamous cell carcinoma, endometrium/cervix, rat. In Jones, T.C., Mohr, U. and Hunt, R.D., eds. Genital System, Monographs on Pathology of Laboratory Animals. Springer-Verlag, New York. pp. 82-83, (1987)

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Goodman, D.G., Boorman, G.A., and Strandberg, J.D. Selection and use of the B6C3F1 mouse and F344 rat in toxicity and carcinogenicity evaluation. In Milman, H.A. and Weisburger, E.K., eds. Handbook of Carcinogen Testing, Noyes Publications; pp. 282-325, (1985)

Goodman, D.G. Subcapsular cell hyperplasia, adrenal, mouse. In Jones, T.C., Mohr, U. and Hunt, R.D., eds. Endocrine System, Monographs on Pathology of Laboratory Animals. Springer-Verlag, New York. pp. 66-68, (1983)

Goodman, D.G., and Strandberg, J.D. Neoplasms of the female reproductive system. In Foster, H.L., Small, J.D., and Fox, J.G., eds. The Mouse in Biomedical Research. Volume 4. Experimental Biology & Oncology. Academic Press, New York. Section IX. pp. 397-411, (1982)

Strandberg, J.D., and Goodman, D.G. Neoplasms of the cardiovascular system. In Foster, H.L., Small, J.D., and Fox, J.G., eds. The Mouse in Biomedical Research. Volume 4. Experimental Biology and Oncology. Academic Press, New York. pp. 539-545, (1982)

Goodman, D.G., Ward, J.M., Squire, R.A., Paxton, M.B., Reichardt, W.D., Chu, K.C., and Linhart, M.S. Neoplastic and nonneoplastic lesions in aging Osborne-Mendel rats. Toxicol. Appl. Pharmacol. 55:433-447, (1980)

Altman, N.H., and Goodman, D.G. Neoplastic diseases. In Baker, H., ed. The Biology of the Laboratory Rat. Vol. 1. Biology and Diseases, Academic Press, New York. pp. 334-377, (1980)

Strandberg, J.D., Leary, S.L., and Goodman, D.G. Secretory epithelial abnormalities overlying gastric carcinoids in Mastomys. South Africa Cancer Bull. 24:382-389, (1980)

Goodman, D.G., Ward, J.M., Squire, R.A., Chu, K.C., and Linhart, M.S. Neoplastic and nonneoplastic lesions in aging F344 rats. *Toxicol. Appl. Pharmacol.* 48:237-248 (1979)

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Ward, J.M., Goodman, D.G., Squire, R.A., Chu, K.C., and Linhart, M.S. Neoplastic and nonneoplastic lesions in aging (C57BL/6N x C3H/HeN)F1 (B6C3F1) mice. *JNCI* 63:839-854, (1979)

Ward, J.M., Bernal, E., Buratto, B., Goodman, D.G., Strandberg, J.D., and Schueler, R. Histopathology of neoplastic and nonneoplastic hepatic lesions in mice fed diets containing tetrachlorvinphos. *JNCI* 63:111-118, (1979)

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Squire, R.A., Goodman, D.G., Valerio, M.G., Fredrickson, T., Strandberg, J.D., Levitt, M.H., Lingeman, C.H., Harshbarger, J.C., and Dawe, C.J. Tumors. In Bernirschke, K., Garner, F.M., and Jones, T.C., eds. *Pathology of Laboratory Animals.* Springer-Verlag, New York. Vol. 2, pp. 1052-1283, (1978)

Young, H.A., Wenk, M.L., Goodman, D.G., and Scolnick, E.M. Expression of RNA of an endogenous replication-defective retrovirus in rat mammary adenocarcinomas induced by 7, 12-dimethylbenz(a)anthracene. *JNCI* 61:1329-1337, (1978)

Ward, J.M., Goodman, D.G., Griesemer, R.A., Hardisty, J.F., Schueler, R.L., Squire, R.A., and Strandberg, J.D. Quality assurance for pathology in rodent carcinogenesis tests. *J. Environ. Pathol. Toxicol.* 2:371-378, (1978)

Priester, W.A., Goodman, D.G., and Theilen, G.H. Nine simultaneous primary tumors in a boxer dog. *J. Am. Vet. Med. Assoc.* 170:823-826, (1977)

Moon, R.C., Grubbs, C.J., Sporn, M.B., and Goodman, D.G. Retinyl acetate inhibits mammary carcinogenesis induced by N-methyl-N-nitroso urea. *Nature* 267:620-621, (1977)

Grubbs, C.J., Moon, R.C., Squire, R.A., Farrow, G.M., Stinson, S.F., Goodman, D.G., Brown, C.C., and Sporn, M.B. 13-cis-Retinoic acid: Inhibition of bladder carcinogenesis induced in rats by N-butyl-N-(4-hydroxybutyl) nitrosamine. *Science* 198:743-744, (1977)

Morton, R.O., Goodman, D.G., Gershwin, M.E., Squire, R.A., and Steinberg, A.D. Suppression of autoimmunity and lymphoid proliferation in NZB mice with steroid-sensitive X-radiation-sensitive syngeneic young thymocytes. *Arthritis Rheum.* 19:1347-1350, (1976)

Steinberg, A.D., Gerber, N.L., Gershwin, M.E., Morton, R.O., Goodman, D.G., Chused, T.M., Hardin, J.A., and Barthold, D.R. Loss of suppressor T-cells in the pathogenesis of autoimmunity. In Singhal, S.K., and Sinclair, St. C., eds. *Suppressor Cells in Immunity*. University of Western Ontario, London Ont. pp. 174-180, (1975)

Scott, R.M., Faraci, R.P., Goodman, D.G., Militano, T.C., Geelhoed, G.W. and Chretien, P.B. The role of inflammation in bronchial stump healing. *Ann. Surg.* 181:381-395, (1975)

Strandberg, J.D., and Goodman, D.G. Animal model: Canine mammary neoplasia. *Am. J. Pathol.* 75:225-228, (1974)

Carb, A.V., and Goodman, D.G. Oesophagael carcinoma in the dog. *J. Small Anim. Pract.* 14:91-99, (1973)

Goodman, D.G., and Garner, F.M. A comparison of methods for finding Nosema cuniculi in rabbit urine. *Lab. Anim. Sci.* 22:568-572, (1972)

Bush, M., Pieroni, D.R., Goodman, D.G., White, R.I., Thomas, J., and James, A.E. Tetrolology of Fallot in a cat. *J. Am. Vet. Med. Assoc.* 161:1679-1686, (1972)

ABSTRACTS:

Goodman, D.G. Animal models for cancer research. 105th Annual Meeting, American Public Health Association (1977)

Blitzer, B.L., Waggoner, J.G., Jones, E.A., Gralnick, H., Towne, D., Butler, J., Weise, V., Kopin, I., Walters, I., Teychenne, P., Goodman, D., and Berk, P. An animal model of fulminant hepatic failure (FHF). *Gastroenterology* (1977) (Abstract)

Grubbs, C.J., Moon, R.C., Sporn, M.B., and Goodman, D.G.
Suppression of NMU-induced mammary cancer by vitamin A acetate.
Am. Assoc. Cancer Res. (1977) (Abstract)

Altman, N.H., and Goodman, D.G. Spontaneous tumors in rats. J.
Am. Vet. Med. Assoc. (1976) (Abstract)

UNPUBLISHED DOCUMENTS IN THE PUBLIC DOMAIN:

Goodman, D.G. Pathology Working Group Report on Chlordane in F344
Rats. Pathology Review Participants: Goodman, D.G., Macklin,
A.W., Maronpot, R.R., Popp, J.A., Squire, R.A., Ward, J.M.,
Anver, M.R. Submitted to ICF-Clement. September 11, 1987.

Sauer, R.M. Pathology Working Group Report on 2,3,7,8-
Tetrachlorodibenzo-p-dioxin Chronic Toxicity/Carcinogenicity
Study in Sprague Dawley Rats. Pathology Review Participants:
Sauer, R.M., Brown, W.R., Maronpot, R.R., Newberne, P.M., Popp,
J.A., Ward, J.M., and Goodman, D.G. Submitted to the Maine
Scientific Advisory Panel. March 13, 1990.

Sauer, R.M., and Goodman, D.G., (1990). Hepatotoxicity in Female
Sprague Dawley Rats Treated with 2,3,7,8-Tetrachlorodibenzo-p-
dioxin (TCDD). April 27, 1990.

Sauer, R.M., and Goodman, D.G. Hepatotoxicity in Female Sprague
Dawley Rats Treated with 2,3,7,8-Tetrachlorodibenzo-p-dioxin
(TCDD). 13-Week Subchronic Toxicity Study, June 8, 1990.

STUDY SETS:

Goodman, D.G., Bates, R.R., Ward, J.M., Frith, C.H., Sauer, R.M.,
Jones, S.J., Strandberg, J.D., Squire, R.A., Montali, R.J., and
Parker, G.A. Common Lesions in Aged B6C3F1 (C57BL/6Nx -
C3H/HeN)F1 and BALB/cStCrl(FC3H/Nctr Mice. Registry of
Veterinary Pathology, AFIP (1981)

Goodman, D.G., Anver, M.R., Ward, J.M., Sauer, R.M., Boorman,
G.A., Bates, R.R., Strandberg, J.D., Squire, R.A., Imes, G.D.,
Reznik, G., Parker, G.A., and Jones, S.R. Chemically Induced and
Unusual Lesions in Rats. Registry of Veterinary Pathology, AFIP
(1984)

Goodman, D.G., Anver, M.R., Ward, J.M., Sauer, R.M., Strandberg, J.D., Imes, G.D., Parker, G.A., Seely, J.C. Hildebrandt, P.K. and Uriah, L., Experimentally Induced and Unusual Lesions in Mice. Registry of Veterinary Pathology, AFIP (In preparation).

PRESENTATIONS:

What a Toxicologic Pathologist Does. Division of Comparative Medicine Seminar, Johns Hopkins University School of Medicine (November 1988)

The Role of a Consultant in Safety Evaluation - Responsibility to Industry and Government. General Principles in Toxicology and Toxicologic Pathology. Sponsored by Department of Pathology. Boston University School of Medicine, (August 1988)

The Role of a Consultant in Toxicology - Responsibility to Industry and Government. General Principles in Toxicology and Toxicologic Pathology. Sponsored by Department of Pathology. Boston University School of Medicine, (August 1987)

Observer Bias in Histopathologic Evaluation. Interdisciplinary Discussion Group on Carcinogenicity Studies, Sponsored by International Life Sciences Institute-Nutrition Foundation (June 1986)

Principles of Carcinogenesis/Comparative Aspects of Mammary and Liver Neoplasms in Rodents. Division of Comparative Medicine, Johns Hopkins University School of Medicine (January 1986)

Design and Interpretation of Carcinogenesis Bioassays. U.S. Department of Agriculture Continuing Education Program on Risk Assessment (October 1983)

Neoplasms of the Female Reproductive Tract. Seminar on Neoplasms in Mice. Sponsored by Intox Laboratories (June 1982)

Fundamentals of Carcinogenesis. D.C. Academy of Veterinary Medicine (January 1980)

Neoplastic Diseases of Rats and Mice. Course in Pathology of Laboratory Animals (AFIP) (August 1979)

Mammary Lesions in F344 Rats and B6C3F1 Mice. NCI Carcinogenesis Testing Program Workshop (June 1978)

Adrenal Lesions in F344 Rats. NCI Carcinogenesis Testing Program Workshop (June 1978)

Mammary Carcinogenesis in Rodents--Viral and Chemical Etiology. Mid-Atlantic Comparative Pathology Colloquy (January 1978)

Animal Models for Cancer Research. 105th Annual Meeting of the American Public Health Association (October 1977)

Neoplastic Diseases of Mice. Course in Pathology of Laboratory Animals (AFIP) (September 1977)

Tumors of Rats and Mice. Veterinary Resources Branch Seminar, NIH (July 1977)

Animal Models in Cancer Research. USPHS Professional Association Annual Meeting, San Francisco (April 1977)

Bioassay Program. Division of Laboratory Animal Medicine, Johns Hopkins Hospital (January 1976)

New Zealand Mice as an Animal Model for Systemic Lupus Erythematosus. National Capital Area Branch Association for Laboratory Animal Science (September 1975)

Spontaneous Tumors in Mice. Interagency Collaborative Group on Environmental Carcinogenesis (September 1975)

Spontaneous Tumors in Mice and Rats. Course in Pathology of Laboratory Animals Course (AFIP) (September 1975)

Hepatic Nodule in a Rhesus Monkey. Primate Pathology Workshop (March 1975)

Spontaneous Tumors in Mice. Course in Pathology of Laboratory Animals (AFIP) (September 1974)

Uremic Myocarditis in a Rhesus Monkey. Primate Pathology Workshop (March 1974)

Simian Hemorrhagic Fever. Division of Laboratory Animal Medicine, Johns Hopkins University School of Medicine (January 1974)

NCI Chemicals Reviewed In
Pathology Working Group/Data Evaluation Group
National Cancer Institute/National Toxicology
Program Carcinogenesis Technical Report Series:

<u>NO.</u>	<u>CHEMICAL</u>	<u>TR NO.</u>	<u>CHEMICAL</u>
	Endrin	5	Proflavine
	Tetrachlorethylene	6	Nitrilotriacetic Acid (NTA) and Nitrilotriacetic Acid Trisodium Salt, Monohydrate (Na ₃ NTA.H ₂ O)
	Phosphamidon		
	Photodiieldrin	7	Phenformin
	3,3'-Iminobis-1-Propanol Dimethanesulfonate (ester) Hydrochloride (IPD)	8	Chlordane
	Procarbazine	9	Hepatochlor
		39	Lasiocarpine
22	Dieldrin	40	Hexachlorophene
	Picloram	41	Chlorothalonil
	Malathion	42	5-Azacytidine
	Chloramben	43	Emetine
	1,1,2,2-Tetrachlorethane	45	Chlorpropamide
	2-Methyl-1-Nitroanthraquinone	46	Ethionamide
	Diarylanide Yellow	47	4,4'-Thiodianiline
	Tolbutamide	48	Pyrazinamide
	Isophosphamide	49	Acronycine
	Tetrachlorvinphos	50	Acetohexamide
	Methoxychlor	51	Tolazamide
	Anthranilic Acid	52	3-Nitropropionic Acid
	Dimethoate	53	2-Amino-5-Nitrothiazole
		54	2,4-Dinitrotoluene

<u>O.</u>	<u>CHEMICAL</u>	<u>TR NO.</u>	<u>CHEMICAL</u>
	B-TGdR	82	N-Phenyl-p-Phenylenediamine
	Thio-Tepa	83	Daminozide
	Estradiol Mustard	84	2,4-Diaminoanisoie Sulfate
	Phenesterin	85	4-Chloro-m-Phenylenediamine
	Pentachloronitrobenzene	88	1H-Benzotriazole
	Endosulfan	89	o-Anisidine Hydrochloride
	4-Chloro-o-Phenylenediamine	90	Dicofol
	1-Nitronapthalene	91	Clonitralid
	1,1-Dichloroethane	92	Hydrazobenzene
	Aspirin, Phenacetin, Caffeine	93	3-Amino-9-Ethylcarbazole Hydrochloride
	Hexachloroethane	94	4-Amino-2-Nitrophenol
	zinphosmethyl	95	3-(Chloromethyl) Pyridine Hydrochloride
	Parathion	96	Coumaphos
	L-Tryptophan	97	Titanium Dioxide
	Phenoxybenzamine Hydrochloride	98	dl-Menthol
	Allyl Chloride	99	Phenzopyridine Hydrochloride
	1,1,2-Trichloroethane	100	Cupferron
	Chlorobenzilate	101	Formulated Fenaminosulf
	Tris (2,3-Dibromopropyl) Phosphate	102	3-Sulfolene
	Pyrimethamine	103	Fenthione
	ICRF-159	104	Anilazine
	1,4-Dioxane	105	m-Cresidine
	Trimethylphosphate		

<u>NO.</u>	<u>CHEMICAL</u>	<u>TR NO.</u>	<u>CHEMICAL</u>
5	Trichlorofluomethane	132	2,5-Dithiobiurea
7	5-Nitro-o-Toluidine	133	3-Nitro-p-Acetophenetide
3	Direct Blue 6, Direct Black 38, Direct Brown 95	139	Triphenyltin Hydroxide
3	4-Nitroanthianilic Acid	140	Pivalolactone
0	Iodoform	141	1-Phenyl-3-Methyl-5-Pyrazolone
1	1-Amino-2-Methylanthraquinone	142	p-Cresidine
2	3-Amino-4-Ethoxyacetanilide	143	1,5-Napthalenediamine
3	2-Chloro-p-Phenylenediamine Sulfate	144	2-Aminoanthraquinone
4	2,3,5,6, Tetrachloro-4-Nitroanisole	145	3-Chloro-p-Toluidine
5	Sulfallate	146	Nithiazide
5	p-Anisidine Hydrochloride	147	Mexacarbate
7	6-Nitrobenzimidazole	148	1-Phenyl-2-Thiourea
3	5-Nitroacenapthene	149	N,N'-Diethylthiourea
0	Piperonyl Butoxide	168	N-(1-Napthyl)Ethylenediamine
4	Piperonyl sulfoxide	171	2,4-Dimethoxyaniline Hydrochloride
5	Dioxathion	38	Arochlor 1254
5	2-5-Toluenediamine Sulfate		
7	5-Nitro-o-Anisidine		
3	3,3'-Dimethoxybenzidine-4,4'-Diisocyanate		
0	Trimethylthiourea		
0	Aniline Hydrochloride		
4	DDT, TDE and p,p'-DDE		

Dawn G. Goodman, V.M.D.

**CHAIRPERSON FOR PWG'S
CONDUCTED FOR NTP**

Two Year Studies

Chlorendic Acid	Technical Report No. 304
4-vinylcyclohexene	Technical Report No. 303
Styrene Oxide	
t-Butanol	
Diallylphthalate	Technical Report No. 284
Nitrofurazone	Technical Report No. 337
Nalidixic Acid	Technical Report No. 368
Gamma-Butyrolactone	
Resorcinol (also 15 mo. Interim)	
Diphenylhydantoin	
C.I. Pigment Red 3	
2,4-Diaminophenol HCL	

90-Day Studies

Promethazine HCL
Methdilazine HCL
1-Amino-2,4-Dibromo-
Anthraquinone
4-Hydroxyacetanilide
t-Butanol
Acetone
6-Methoxy-2-
Benzothiazolamine
Pentachlorobenzene
Meta-Nitrobenzoic Acid
2-Hydroxy-4-Methoxybenzophenone
Antimony Potassium Tartarate
Psoralens (4 compounds)

Interim Sacrifice

t-Butanol
Ochratoxin A

CURRICULUM VITAE

John Michael Cullen, V.M.D., Ph.D.
Diplomate, American College of Veterinary Pathologists

Address:

611 East Olive Street
Apex, NC 27502
(919) 362-5675

Present Position:

Associate Professor
Department of Microbiology, Parasitology and Pathology
College of Veterinary Medicine
North Carolina State University
Raleigh, North Carolina 27606
(919) 829-4350

Birthdate: July 27, 1949

Education:

Ph.D., Comparative Pathology, University of California, Davis, 1985.
V.M.D., University of Pennsylvania, 1975.
A.B., Biology, University of Pennsylvania, 1971.

Experience:

1989 Associate Professor of Veterinary Pathology, College of
Veterinary Medicine, North Carolina State University
1984-89 Assistant Professor of Veterinary Pathology, College of
Veterinary Medicine, North Carolina State University
Additional Appointment:
1988- Toxicology Faculty, North State Carolina University
1983-84 Senior Resident in Anatomic Pathology, Veterinary Medical
Teaching Hospital, University of California, Davis
1979-83 Resident, Anatomic Pathology, School of Veterinary Medicine,
University of California, Davis
1976-79 Private practice, small animal clinician
1975-76 Intern, Angell Memorial Animal Hospital, Boston, Massachusetts

Teaching Experience

Veterinary Curriculum

- 1) General Pathology, VMM 831, 1984-present
- 2) Systemic Pathology, VMM 451, 1984-1986
- 3) Lab Animal Medicine, VMC 853, 1985-present

Graduate Curriculum

- 1) Advanced Histopathology, VMS 642, 1984-present, (Course Coordinator)
- 2) Systemic Pharmacology and Toxicology, VMS 562, 1984-present
- 3) Medical Virology, VMM 651, 1986-present

1981-83 Primary responsibility for Junior year clinic in Pathology.
Responsibilities included orientation, informal lecture, and
direct supervision of necropsy procedure.

Professional Consultant Activities:

Consultant to National Toxicology Program at National Institute of Environmental Health Sciences, Research Triangle Park, North Carolina, 1984-present

Consultant to U.S. Environmental Protection Agency (HERL) UVB Health Effects Research Committee, July 1988.

Consultant to Stanford University Laboratory Animal Medicine Facility, 1987.

Short-Term Consultant, Pan American Health Organization, Suriname, South America, 1987.

Academic Responsibilities:

Graduate Student Committees:
PhD - Steven Holladay

MS - Doris Fultz (chairman)
- Derek Norford (chairman)
- Christopher Bowie

Residency Program in Veterinary Pathology at North Carolina State University, responsible for candidate recruitment and selection, as well as administration of the program.

Academic Committees: Admissions, Student conduct (Chairman), Committee on committees, Medical Records, Open House.

External Review, Ph.D. Thesis: Studies of the Pathogenesis, Toxicology and Pathology of lupinosis and associated conditions. Murdoch University, Western Australia, 1988.

Veterinary Licenses:

California, Massachusetts, North Carolina.

Board Certifications:

Diplomate, American College of Veterinary Pathology, 1982.

Society Memberships:

American Veterinary Medical Association
American College of Veterinary Pathologists
North Carolina Society of Toxicology
American Association for the Study of Liver Disease
North Carolina Veterinary Medical Society
American Association of Avian Pathologists

Academic Awards:

Phi Zeta Member, 1987
Teacher of the Year, Class of 1988, 1989

Fields of Special Interest:

Hepatic Pathology
Animal models of viral hepatitis
Mycotoxicology

Grants Awarded:

Principal Investigator of "Combined effects of aflatoxin B₁ and chronic duck hepatitis B virus infection on the incidence of hepatocellular carcinoma in ducks." 1984, \$3,900, Faculty Research and Professional Development Fund.

Principal Investigator of "The role of cell cycle in aflatoxin B₁ induced hepatic carcinogenesis." 1985, \$22,300, North Carolina State Research Fund.

Principal Investigator of "Interactions of multiple concurrent naturally occurring mycotoxin administration on toxin metabolism, tissue residues, growth rates and toxicity of chickens." 1986, \$15,300, North Carolina State Research Fund.

Principal Investigator of "The role of cell cycle in aflatoxin-B₁ induced hepatic carcinogenesis." 1986, \$9,200, North Carolina State Research Fund.

Co-Investigator of "Ultrastructural and immunocytochemical studies on pituitary lesions induced by 2-mercaptobenzimidazole." 1986, \$14,106, NIH.

Co-Investigator of "Infant and adult rat susceptibility to aflatoxins B₁ and M₁." 1986, \$7,000, California Dairy Council.

Principal Investigator of "Cyclopaizonic Acid induced skeletal muscle injury in broiler chickens." 1987, \$14,300, North Carolina State Research Fund.

Principal Investigator of "Acute DHBV infection in geese. A model of HBV infection." 1987, \$4,000, United Way.

Principal Investigator of "An animal model of hepatitis B infection in geese." 1987, \$24,800, North Carolina Board of Science and Technology.

Principal Investigator of "Acute and chronic DHBV infection in geese." 1987, \$6,550, North Carolina State Research Fund.

Principal Investigator of "Delta hepatitis virus production in woodchuck hepatitis virus infected woodchucks." 1987, \$8,000, DuPont deNemours.

Principal Investigator of "Production of monoclonal antibodies to delta hepatitis virus, a human pathogen grown in woodchucks." 1988, \$24,800, North Carolina Biotechnology Center.

Principal Investigator of "Determination of tissue distribution of the human pathogen delta hepatitis virus in infected woodchuck (*Maromota monax*) by immunohistochemistry and in situ hybridization." 1988, \$19,600, North Carolina State Research Fund.

CURRICULUM VITAE

John M. Cullen

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Publications:

- 1989 Cullen, J.M., Marion, P. L., Newbold, J.N. A sequential histologic and immunohistochemical study of duck hepatitis B virus infection in Pekin ducks. Vet Path 26:164-172.
- 1989 Cullen, J.M., Levine J. Babesia microti Infection of Syrian Hamsters: An animal Model of Human disease. Comp Pathol Bull (Animal Models) 21:3-4.
- 1989 Bunch, S.E., Metcalf, M.R., Crane, S.W., Cullen, J.M. Idiopathic pulmonary thromboembolism and pleural effusion in a dog. J Am Vet Med Assoc (In press).
- 1989 Wilson, M.E., Hagler, W.M. Jr., Cullen, J.M., Ort, J.F., Cole, R.J. Acute toxicity of cyclopiazonic acid in selected avian species. In: Biodeterioration Research 2, G.C. Llewellyn and C.E. O'Rear (Eds.) Plenum Publishing Co., New York. 2:371-381.
- 1989 Bristol, D.G., Cullen, J.M. Use of a linear stapling device to construct an inverted, triangulated, end to end anastomosis of the equine jejunum. Cornell Vet 79:217-230.
- 1989 Corbett, W.T., Lieuw-A-Joe, R., Hunter, L., Grindem, C., Levy, M., Cullen, J. Epidemiologic survey of bovine diseases in Suriname, South America Bulletin of PAHO 106:314-320.
- 1989 Cullen, J.M., Marion, P. L., Sherman, G.J., Newbold, J. Hepatic neoplasms in aflatoxin B₁ treated, congenital duck hepatitis B virus-infected and virus free Pekin ducks (Cancer Research, accepted with revisions).
- 1988 MacLachlan N.J., Cullen J.M. The liver and pancreas In: Thompson, R.G. (ed.). Special Veterinary Pathology, B.C. Decker Inc. Toronto, Canada.
- 1988 Newbold, J., Cullen, J.M. Experimental transmission and subsequent replication of Duck Hepatitis B virus in domestic geese. In: Viral hepatitis and liver disease, A. Z. Zuckerman (Ed.) Alan R. Liss Inc., New York. pp. 513-516.
- 1988 Cullen, J.M., Wilson, M.S., Hagler, W.M., Ort, J.F., Cole, R.J. Histopathology of cyclopiazonic acid administration to broiler chickens. Am J Vet Res 49:728-732.
- 1988 Cullen, J.M., Newbold, J., Marion, P. Acute severe hepatic injury in DHBV infected geese. In: Viral Hepatitis and Liver Disease. A. Z. Zuckerman (Ed.) Alan R. Liss Inc., New York. pp. 517-522.
- 1988 Vaden, S.L., Bunch, S.E., Duncan, D.E., Cullen, J.M. Hepatotoxicity associated with heartworm preventive medication in a dog. J Am Vet Med Assoc 192:651-654.
- 1988 Bristol, D.G., Cullen, J.M. A comparison of three methods of end to end anastomosis in the equine small colon. Cornell Vet 78:325-337.

CURRICULUM VITAE

John M. Cullen

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Publications (continued):

- 1988 Cohn, L.A., Spaulding, K.A., Cullen, J.M., Hardie, E.M., MacLachlan, N.J., Breitschwerdt, E.B. Hepatic postsinusoidal venous obstruction in a dog. (Accepted, J Vet Int Med).
- 1988 Greene, R.T., Levine, J.F., Breitschwerdt, E.B., Walker, R.C., Berkhoff, H.A., Cullen, J.M., Nicholson, W.L. Clinical and serologic evaluations of induced Borrelia burgdorferi infection in dogs. J Am Vet Med Assoc 49:752-757.
- 1987 Cullen, J.M., Ruebner, B.H., Hsieh, L.S., Hyde, D.M., and Hsieh, D.P.H. Carcinogenicity of aflatoxin M₁ in male Fischer rats compared to aflatoxin B₁. Cancer Research 47:1913-1917.
- 1987 Cullen, J.M. and Levine, J.F. Pathology of experimental Babesia microti infection in the Syrian hamster (Mesocricetus auratus auratus). Lab Anim Sci 36:640-643.
- 1987 Cullen, J.M., Burkes, E.J., Ruebner, B. Oral neoplasms in Fischer rats. J Dental Res 16:210-214.
- 1987 Marion, P., Cullen, J.M., Robinson, W.S., Azcarraga, R., Van Davelaar, M.J. Experimental transmission of duck hepatitis B virus to Pekin ducks and to domestic geese. Hepatology 7:724-731.
- 1987 Brownie, C.F., Cullen, J.M. Characterization of experimentally induced equine leukoencephalomalacia (ELEM) in ponies (Equus caballus): Preliminary report. Vet Hum Toxicol 29:34-38.
- 1987 Ling, G., Lowenstine, L., Cullen, J., Ackerman, N., and Ruby, A. Chronic urinary tract infection in dogs: Induction by inoculation with bacteria via percutaneous nephropylotomy. Am J Vet Res 48:794-798.
- 1987 Tate, L.P., Newman, H.C., Cullen, J.M., Sweeney, C. Neodymium (Nd):YAG - Laser Surgery in the Equine Larynx: A Pilot Study. Lasers in Surgery and Medicine 6:470-472.
- 1987 Cullen, J.M., Whiteside, J., Umstead, J., Whitaker, M. A mixed germ cell-sex cord tumor in a horse. Vet Pathol 24:575-577.
- 1987 Ling, G., Lowenstine, L., Cullen, J., Ackerman, N., and Ruby, A. Experimentally induced chronic urinary tract infection in dogs, resulting from introduction of bacteria by percutaneous nephropylotomy. Am J Vet Res 48:851-854.
- 1986 Gregory, C.R., Cullen, J.M., Pool, R., Vasseur, P.B. The canine sacroiliac joint. Spine 11:1044-1048.
- 1986 Hsieh, D.P.H., Cullen, J.M., Hsieh, L.S., Shao, Y., Reuben B. Cancer risks poses by aflatoxin M₁. In: Diet Nutrition in Cancer. Y. Hayashi (ed) VNU Sci Press, Utrecht pp. 57-65

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John M. Cullen

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Publications (continued):

- 1986 Kitchell, B., Strombeck, D., Cullen, J., and Harrold, D. Clinical and Pathological Changes in Experimentally Induced Acute Pancreatitis in Cats. *Am J Vet Res* 47:1170-1173.
- 1986 Gregory C.R., Gourley, I.M., Taylor, N.J., Cullen, J.M., Evans, A., Fsaee, C.D., Cowgill, L.D. Experience with cyclosporin A after renal allografting in two dogs. *Vet Surg* 17:441-443.
- 1985 Ling, G., Cullen, J., Kennedy, P., Ruby, A. and D. Brooks. Relationship of upper and lower urinary tract infection and bacterial invasion of uroepithelium to antibody coated bacteria test results in female dogs. *Am J Vet Res* 46:499-504.
- 1984 Hseih, B.P.H., Cullen, J.M., Ruebner, B. Comparative hepatocarcinogenicity of Aflatoxins B₁ and M₁ in one rat. *Food Chem. Toxicol.* 22:1027-1028.
- 1984 Couto, G., Cullen, J., Pedroia, U. and J. Turrell. Central nervous system lymphosarcoma in dogs. *J Am Vet Med Assoc* 184:809-813.
- 1983 Wong, M., Pedersen, N. and J. Cullen. Dirofilariasis in cats. *JAAHA* 19:855-864.
- 1980 Ricklefs, R.E., White, S.C., and Cullen, J. Postnatal development of Leach's Storm Petrel. *Auk* 97:768-781.
- 1980 Ricklefs, R.E., White, S.C., and Cullen, J. Energetics of postnatal growth in Leach's Storm-Petrel. *Auk* 97:566-575.

Abstracts:

- 1987 Cullen, J.M., Burkes, E.J., Ruebner, B.H. Oral neoplasms in fischer rats. *J Dental Res* 66:644.
- 1987 Norford, D., Cullen, J.M., Meuten, D.J. Effects of 3-MBI in the pituitary of Fischer rats. *American College Vet Pathol Annual Meeting.* Monterey, California.
- 1987 Cullen, J.M., Newbold, J., Marion, P.L. Histopathology of acute severe liver injury in domestic geese infected with DHBV. *Med Virol* 96:475.
- 1987 Coffey, M.T., Hagler, W.M., Cullen, J.M., Jones, E.E. Effect of multiple mycotoxin contamination on the performance of swine. *Annual Meeting of American Society of Animal Science.* Utah State University July 1987.
- 1987 Coffey, M.T., Hagler, W.M., Cullen, J.M. The effect of L-Lysine and DL-methionine supplementation on the response of weanling pigs to mycotoxin contaminated corn. *J Anim Sci* 66(Suppl 1):45.
- 1986 Cullen, J.M., Wilson, M., Hagler, W., Ort, J., Cole, R.J. Histopathology of cyclopiazonic acid to broiler chicks. *Poultry Science Assoc. Annual Meeting, August 1986, Raleigh, North Carolina.*

11

1

PAUL MEDFORD NEWBERNE

BORN: November 4, 1920; Adel, Georgia

TITLE: Professor of Nutritional Pathology

Academic Degrees:

<u>D.V.M.</u>	Auburn University, Auburn, Alabama (Veterinary Medicine)	1950
<u>M.Sc.</u>	Auburn University, Auburn, Alabama (Veterinary Medicine)	1951
<u>Ph.D.</u>	Missouri University, Columbia, Missouri (Nutritional Biochemistry with minor in Human Pathology)	1958

APPOINTMENTS AND EXPERIENCE:

1950-1951	Instructor, Veterinary Pathology, Auburn University Auburn, Alabama
1951-1954	Director, Research and Diagnostic Laboratories, Jessca, Inc., Columbus, Georgia
1954-1956	Instructor, Veterinary Microbiology, School of Veterinary Medicine, Missouri University, Columbia, Missouri
1956-1958	Instructor, Agricultural Chemistry, Missouri University, Post-doctoral Fellowship, National Institute of Neurological Disease and Blindness, National Institutes of Health, Bethesda, Maryland
1958-1962	Animal Pathologist and Professor, Auburn University, Agricultural Experiment Station and School of Agriculture, Auburn, Alabama
1962-1965	Associate Professor, Nutritional Pathology, Department of Nutrition and Food Science, Massachusetts Institute of Technology, Cambridge, Massachusetts
1965-1984	Professor, Nutritional Pathology, Department of Applied Biological Sciences, Massachusetts Institute of Technology, Cambridge, Massachusetts
1984-	Professor Emeritus/Senior Lecturer, Department of Applied Biological Sciences, Massachusetts Institute of Technology, Cambridge, Massachusetts

APPOINTMENTS AND EXPERIENCE (CONT'D)

1984- Professor of Pathology, Boston University School
of Medicine, Boston, Massachusetts

1985- Research Pathologist, Special Scientific Staff,
Boston City Hospital and Mallory Institute of
Pathology

MILITARY SERVICE:

1942-1945 (Navy) Naval aviator, discharged as Lieutenant

PROFESSIONAL AFFILIATIONS AND MEMBERSHIPS: PAST/PRESENT

Member, Board of Trustees, Forsyth Dental Center
New England Branch, American Association of Laboratory Animal Science
Teratology Society
American Academy of Clinical Toxicology
American Institute of Nutrition
American Society for Experimental Pathology
Society of Toxicology
New England Society of Pathologists
Massachusetts Pathology Society
American Veterinary Medical Association
American College of Veterinary Pathologists (Past President)
Editorial Board, Toxicology and Applied Pharmacology
Editorial Board, Cornell Veterinarian
Editorial Board, Journal of Environmental Pathology and Toxicology
Editorial Board, Cancer Detection and Prevention
Editorial Board, Nutrition Reports International
Editorial Board, American Journal of Veterinary Research
Editorial Board, Food and Chemical Toxicology
Editorial Board, Merck Veterinary Manual
Editorial Board, Drug-Nutrient Interactions
Editorial Board, Cancer Research (Associate Editor)
Editorial Board, Journal of Nutrition
Editorial Board, Fundamental and Applied Toxicology
Editorial Board, Journal Environmental Pathology, Toxicology, and
Oncology
Editorial Board, Journal of Nutritional Biochemistry

Phi Kappa Phi
Omicron Delta Kappa
Gamma Sigma Delta
Phi Zeta
Cosmos Club

MEDICAL CERTIFICATION:

American College of Veterinary Pathologists, Diplomate, Former
President
American Board of Toxicology, Certified Diplomate, Former Treasurer

HONORS AND AWARDS:

National Cancer Institute Research Career Award
F A. Davis award for excellence in Clinical Small Animal Medicine
Miller Fellowship for post-doctoral study in Animal Pathology
Post-doctoral Fellow, National Institute of Neurological Disease and
Blindness
FAMA Award, Contributions to Livestock and Poultry Industry
Borden Award NIH/FASEB
Fellow American Institute of Nutrition

PUBLICATIONS:

See attached list

RESEARCH AND TEACHING INTERESTS:

Pathology and biochemistry of diseases of nutritional origin particularly liver and gastrointestinal tract; nutritional carcinogenesis; food safety evaluation; nutritionally induced congenital abnormalities; nutritional toxicology and immunology; environmental toxicology; drug nutrient interactions. Teaching interests in the field of nutritional pathology, comparative pathology, drug safety; toxicology and food-borne diseases. For the past twenty years, advisor to more than 40 graduate students and 100 undergraduate students at Auburn University and at Massachusetts Institute of Technology. In 1962 organized teaching and research program in general area of food, nutrition and disease and how these interact in biological systems. Formal courses or seminars are taught including Diseases of Nutrition and Metabolic Origin, Comparative and Toxicologic Pathology and Nutritional Carcinogenesis. Actively engaged in research in nutritional biochemistry, pathology and toxicology.

DEPARTMENTAL AND INSTITUTE RESPONSIBILITIES:

Departmental
Carcinogenesis Hazards Committee

Institute
Preprofessional Advisory Committee
Animal Care Committee
Mallory Institute of Pathology Animal Facilities, Director

CONSULTANT TO:

American Cancer Society,
National Committee, Cancer Detection and Prevention
Federation, American Societies Experimental Biology (FASEB)
Committee, Health Aspects of Sugar Alcohol and lactose
FASEB-Conference on Tricothecenes (Chairman National Institutes of Health)
National Institute of Environmental Health Sciences on
Environmental Carcinogenesis
National Institute of Environmental Health Sciences, Second Task

Force on Human Health and the Environment, Safety of Foods
and Food Additives
National Cancer Institute, Nutrition and Cancer
National Heart and Lung Institute, Primates in Cardiovascular
Research
Nutrition Study Section (Past)
Animal Resources Advisory Board (Past)
Pathology Training Committee (Past)
National Toxicology Program, Peer Review Panel
Science Advisory Board, NCTR/FDA

National Academy of Sciences/National Research Council
Committee to Overview National Center for Toxicological Research
(NCTR) (Past)
Subcommittee on Pathology, NCTR (Chairman) (Past)
Committee on Laboratory Animal Diets (Chairman) (Past)
Food Protection Committee (Chairman) (Past)
Subcommittee on Toxicology (Past)
Committee on Food Irradiation (Past)
Committee on Clean Drinking Water (Past)
Subcommittee on Metalloids (Past)
Subcommittee on Nutrition (Past)
Committee on Guide to Care and Use of Laboratory Animals (Past)
Committee, Drinking Water and Health (Past)
Subcommittee, Contribution of Water to Human Mineral Requirements
(Chairman) (Past)

World Health Organization
Committee on Evaluation of Mycotoxins
Committee on Pesticides
Pathology of Nutritional Diseases

International Union Against Cancer - Vol. Hepatocellular Cancer,
1982; Nutrition and Cancer

International Union of Nutritional Sciences
Committee on Toxicology

Other

Armed Forces Institute of Pathology Veterinary and Comparative
Pathology
American Academy of Pediatrics Committee on Nutrition
National Association of Broadcasters Medical Advisory Board
Food and Drug Administration
Committee on Gastrointestinal Drugs
Subcommittee on Hepatotoxins
EPA Science Advisory Board
Committee, Airborne Carcinogens
Canadian Task Force, Environment and Cancer
WHO Committee on Liver Cancer
Thailand Advisory Environmental Toxicology Committee, Royal Thia
Government
Association of Medical Schools, Istanbul, Advisor for Research
Advisor, Chulabhorn Research Institute, Bangkok, Thailand

Journal Publications:

1. Newberne, P.M. and Burnett, S.E.: Cestodiasis in the Chinchilla, Vet. Med. 46: 156-157, 1951.
2. Newberne, P.M.: An Introduction to the Chinchilla, The Auburn Veterinarian 7: 59-61, 1951.
3. Newberne, P.M.: Edema of the Glottis in the Chinchilla, Vet. Med. 47-51, 1951.
4. Newberne, P.M. Diseases and Treatments for the Chinchilla. The Auburn Veterinary Handbook, May, 1952.
5. Newberne, P.M.: Chinchilla Nutrition. The Auburn Veterinarian 8: 76-78, 1952.
6. Newberne, P.M.: Urinary Calculus in the Chinchilla. North American Veterinarian 33: 334, 1952.
7. Newberne, P.M.: Scrotal Hernia in the Chinchilla, North American Veterinarian 33: 631, 1952.
8. Newberne, P.M.: Use of Estradiol Cyclopentylate (ECP) in Slow or Nonbreeding Chinchillas. Vet. Med. 47, October, 1952.
9. Newberne, P.M.: A Preliminary Report on the Blood Picture of the South American Chinchillas. J. A.V.M.A. 122: 221-222, 1953.
10. Newberne, P.M.: An Outbreak of Bacterial Gastro-enteritis in the South American Chinchilla. North American Veterinarian 34: 187-188, 1953.
11. Newberne, P.M.: Treatment of Anomalies of the Eye of the South American Chinchilla. Vet. Med. 47: 126, 1953.
12. Newberne, P.M. and Siebold, H.R.: Malignant Lymphoma in a Chinchilla. North American Veterinarian, August, 1954.
13. Newberne, P.M. and Hayes, F.A.: Ceasarean Section in the Chinchilla. Vet. Med. 49: 246-248, 1953.
14. Hayes, F.A. and Newberne, P.M.: Chinchilla Therapeutics: Dosage Interval and Administration. Auburn Veterinarian, August, 1954.
15. Newberne, P.M. and Newberne J.W.: Diverticulum of the Bladder in a Chinchilla. North American Veterinarian, August, 1954.
16. Newberne, P.M., Muher, M.E., Craghead, B.S. and O'Dell, B.L.: An Abnormality of the Proventriculus of the Chick. J. A.V.M.A. 128: 553-555, 1956.

17. Newberne, P.M. and Buck, W.V.: Studies on Drug Toxicity in Chicks. 1. The influence of Various Levels of Megasul on Growth and Development of Chicks. Poul. Sci. 45: 1044-1049, 1956.
18. Newberne, P.M. and McDougale, H.C.: Studies on Drug Toxicities in Chicks. 2. The Influence of Various Levels of Sulfaguinoxaline on Growth and Development of Chicks. Poul. Sci. 35: 1259-1264, 1956.
19. Newberne, P.M. and Buck, W.V.: Studies on Drug Toxicity in Chicks. 3. The Influence of Various Levels of Nicarbazin on Growth and Development of Chicks. Poul. Sci. 36: 304-312, 1957.
20. Newberne, P.M. and McEuen, G.L.: Studies on Drug Toxicities in Chicks. 4. The Influence of Various Levels of Nitrofurazone on Growth and Development of Chicks. Poul. Sci. 36: 739-743, 1957.
21. Newberne, P.M. and McEuen, G.L.: Studies on Drug Toxicities in Chicks. 5. The Influence of Various levels of DPPD on Growth and Development of Chicks. Poul. Sci. 35: 744-747, 1957.
22. Newberne, P.M., Laerdal, O.A., Savage, J. and O'Dell, B.L.: A Surgical Method for the Separation of Urine and Feces in Young Chicks. Poul. Sci. 36: 821-824, 1957.
23. Newberne, P.M., Laerdal, O.A., Savage, J. and O'Dell, B.L.: A Direct Method for Determination of Digestibility in Growing Chickens. Poul. Sci. 36: 815, 1957.
24. Newberne, P.M., and O'Dell, B.L.: The Histopathology of Hydrocephalus in Rats Due to Vitamin B₁₂ Deficiency. Proc. Soc. Exptl. Bio. Med. 97: 62, 1958.
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CURRICULUM VITAE

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DATE AND PLACE OF BIRTH: July 1, 1930
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CITIZENSHIP: United States
MARITAL STATUS: Married, 1950, 3 children
EDUCATION: June, 1948 - graduated from high school
June, 1952 - B.S. University of Vermont
June, 1956 - D.V.M., Cornell University
June, 1964 - Ph.D., Cornell University

BOARD CERTIFICATION: 1965, Diplomate, American College of
Veterinary Pathologists

CHRONOLOGY OF EMPLOYMENT

1984 - date Professor of Comparative Medicine, Joint Appointment in Pathology, The Johns Hopkins University School of Medicine, Baltimore, Maryland.

1982 - date Adjunct Professor of Pathology, University of Maryland School of Medicine, Baltimore, Maryland.

1980 - date President, Robert A. Squire Associates, Inc., Ruxton, Maryland.

1976 - 1977 Director, Carcinogenesis Bioassay Program, Division of Cancer Cause and Prevention, National Cancer Institute, Bethesda, Maryland.

1976 - 1977 Chief, Carcinogen Bioassay and Program Resources Branch, Carcinogenesis Program, Division of Cancer Cause and Prevention, National Cancer Institute, Bethesda, Maryland.

1974 - 1976 Associate Chief, Experimental Pathology Branch, Carcinogenesis Program, Division of Cancer Cause and Prevention, National Cancer Institute, Bethesda, Maryland.

1973 - 1976 Head, Tumor Pathology Section, Carcinogenesis Program, Division of Cancer Cause and Prevention, National Cancer Institute, Bethesda, Maryland.

CURRICULUM VITAE CONT'D.
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CHRONOLOGY OF EMPLOYMENT CONT'D.

1973 - 1976	Expert Consultant, Carcinogenesis Program, Division of Cancer Cause and Prevention, National Cancer Institute, Bethesda, Maryland.
1970 - 1975	Associate Professor of Pathobiology, The Johns Hopkins University, School of Hygiene and Public Health, Baltimore, Maryland.
1968 - 1984	Associate Professor of Comparative Medicine, Associate Professor of Pathology, The Johns Hopkins University School of Medicine, Baltimore, Maryland.
1968 - 1973	Director, Laboratory Animal and Comparative Pathology Training Program (USPHS-NIH), The Johns Hopkins University, School of Medicine, Baltimore, Maryland.
1966 - 1973	Head, Comparative Pathology Program, The Johns Hopkins University School of Medicine, Baltimore, Maryland.
1966 - 1973	Pathologist, Baltimore Zoo, Baltimore, Maryland.
1965 - 1973	Director, Animal Tumor Clinic, The Johns Hopkins University School of Medicine, Baltimore, Maryland.
1964 - 1968	Assistant Professor of Pathology, and Assistant Professor of Animal Medicine, The Johns Hopkins University School of Medicine, Baltimore, Maryland.
1962 - 1964	USPHS-NIH Postdoctoral Fellow, Cornell University, Ithaca, N.Y.
1961 - 1962	Instructor in Pathology, Cornell University, Ithaca, N.Y.
1956 - 1960	Private Veterinary Practice, Fair Haven Animal Hospital, Fair, Haven, Vermont.

SOCIETIES

American Veterinary Medical Association
Alpha Zeta (Agricultural Honorary Society)
American Association for Cancer Research
International Academy of Pathology
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SOCIETIES CONT'D.

American Association for the Advancement of
Science
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SCIENTIFIC AND ADVISORY COMMITTEES

1965	Special Task Force, Joint Committee on Veterinary Education, The American Veterinary Medical Association, Washington, D.C.
1968 -1972	Chairman, Committee on Laboratory Animal Diseases, Institute of Laboratory Animal Resources, National Academy of Science, Washington, D.C.
1968 - 1978	Member, Advisory Committee to Registry of Comparative Pathology, Armed Forces Institute of Pathology (Universities Associated for Research and Education in Pathology), Washington, D.C.
1971 - 1972	Chairman, Statutory Advisory Committee, Food and Drug Administration, Washington, D.C.
1971 - 1974	Member, Scientific Advisory Council, Morris Animal Foundation, Denver, CO.
1971 - 1975	Chairman, Advisory Council, New York State Veterinary College, Cornell University, Ithaca, N.Y.
1971 - 1973	Chairman, Medical Committee, Baltimore, Zoological Society.
1971 - 1978	Board of Trustees, Baltimore Zoological Society.
1974	Panel Member, National Cancer Program's Planning Conference, Washington, D.C.
1975 - 1976	Member, Advisory Council, New York State Veterinary College, Cornell University, Ithaca, N.Y.
1975 - 1978	Member, Toxicology Advisory Committee, Food and Drug Administration, Washington, D.C.
1975 - 1976	Leader, Pathology Working Group, Committee for the Review of Data on Carcinogenicity of Cyclamates, convened by the National Cancer Institute for the Food and Drug Administration.

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SCIENTIFIC AND ADVISORY COMMITTEES CONT'D.

1976 - 1982	Consultant, Cancer Assessment Group, Environmental Protection Agency, Washington, D.C.
1976 - 1982	Member, Committee on Histologic Classification of Laboratory Animal Tumors, Institute of Laboratory Animal Resources, National Research Council, National Academy of Science, Washington, D.C.
1977 - date	Member, Scientific Advisory Board, Charles River Breeding Laboratories, Wilmington, Mass.
1977 - 1982	Chairman, Committee on Histologic Classification of Laboratory Animal Tumors, Institute of Laboratory Animal Resources, National Research Council, National Academy of Science, Washington, D.C.
1977 - 1978	Consultant, Carcinogenesis Program, National Cancer Institute, Bethesda, Maryland.
1977 - 1980	Member, Science Advisory Board, National Center for Toxicological Research, Jefferson, Arkansas.
1977 - 1982	Member, Scientific Committee, Food Safety Council, Washington, D.C.
1978 - 1984	Member, Advisory Council, New York State College of Veterinary Medicine, Cornell University, Ithaca, N.Y.
1978 - 1986	Director, Toxicology Forum, Washington, D.C.
1979 - date	Director-at-Large, Universities Associated for Research and Education in Pathology, Bethesda, Maryland.
1980 - 1982	Chairman, The Nutrition Foundation Expert Committee on the Safety of Lead and Lead Salts in Food, Washington, D.C.
1980 - 1986	Member, Advisory Committee to Registry of Environmental Pathology, International Academy of Pathology, AFIP, Washington, D.C.
1980 - date	Member, Expert Committee on Pathology and Toxicology, International Life Sciences Institute, Washington, D.C.
1980 - date	Member, Regulatory Liaison Committee, American College of Veterinary Pathologists.

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SCIENTIFIC AND ADVISORY COMMITTEES CONT'D.

- 1982 - 1984 Member, Committee on Chemical Environmental Mutagens,
Board on Toxicology and Environmental Health
Hazards, National Academy of Sciences, Washington,
D.C.
- 1982 - 1983 Member, The Nutrition Foundation International
Expert Advisory Group on the Relevance of Mouse
Hepatoma to Human Carcinogenic Risk, Washington,
D.C.
- 1982 Member, Four Nation Committee on the Evaluation
of the Safety of BHA, Food and Drug Administration,
Washington, D.C.
- 1983 - 1984 Member, American Industrial Health Council Committee
on General Criteria for Assessing the Evidence
for Carcinogenicity of Chemical Substances,
Washington, D.C.
- 1983 Member, Panel of Experts, Rat Liver Tumor Workshop,
National Toxicology Program, Research Triangle
Park, North Carolina.
- 1986 Councilor, Carcinogenesis Specialty Section,
Society of Toxicology.
- 1986 - 1987 Member, Expert Panel, Carcinogenicity of 2,4-D,
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BIBLIOGRAPHY

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- 1978 Member, Education Committee - Carcinogenesis Program, American College of Veterinary Pathologists
- 1979 - 1985 Co-Chairman, Infectious Disease Specialty Group, American College of Veterinary Pathologists
- 1981 - Editorial Board, PATHOLOGY OF LABORATORY ANIMALS (International Life Sciences Institute - ILSI)
- 1987 - 1989 Co-editor, Pathology of Laboratory Animals - Hemopoietic System (ILSI)
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Professional Advisory and Consultant Activities:

Member, Discussion Group-Criteria for Tumor Diagnosis and Classification of Malignancy. Conference on Carcinogenesis Testing in the Development of New Drugs, May 23-25, 1973, Washington, D.C., National Academy of Sciences.

Member, FDA, FD&C Red No. 40 Second Interim Working Group, December, 1977-1981.

Consultant and Expert Witness, FDA Hearing on Denial of Petition for Listing of FD&C Red No. 4 for Use in Marishino Cherries and Ingested Drugs, April 12, 1978, Rockville, Maryland.

Member, FDA Interagency Committee on Nitrite Research, 1978-1980.

Member, Project Group on Standardization of Measurements and Tests, Task Force on Cancer and Heart and Lung Disease, Environmental Protection Agency, 1979.

Consultant, Scientific Advisory Board, National Center for Toxicological Research, Jefferson, Arkansas, 1979.

Member, Mouse Lymphoma Study Group, 1979. Sponsored by the Nutrition Foundation.

Consultant, Division of Pathology, Bureau of Foods, Food and Drug Administration, 1978-1982.

Member, Working Group on Evaluation of Carcinogenic Risk of Chemicals to Man, International Agency for Research in Cancer, Lyon, France, February 10-17, 1981.

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- 1966 Cornell University Clinical Conference Award
- 1974 National Academy of Sciences Travel Grant to the International Cancer Congress, Florence, Italy
- 1979 Special Achievement Group Award, NCI Carcinogenesis Testing Program
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Alternate Member, TSCA Interagency Testing Committee, 1981-1983.

Consultant, Carcinogen Identification and Risk Assessment Branch, Occupational, Safety and Health Administration, Dept. of Labor, Washington, D.C., 1979-1981.

Expert Witness, State of California, Department of Health, OSHA, Sacramento, California, November 12, 1981, Hearing on Standards for Occupational Exposure Levels to 1,2-Dibromoethane.

Consultant, Chemical Pathology Branch, National Toxicology Program, National Institute of Environmental Health Sciences, Research Triangle Park, North Carolina, 1982-1983.

Expert Witness, Occupational Safety and Health Administration, U.S. Department of Labor, Informal Public Hearing on Occupational Exposure to Ethylene Oxide, Washington, D.C., July 26, 1983.

Member, Consensus Workshop on Formaldehyde - Carcinogenicity, Histopathology, Genotoxicity Panel, Food and Drug Administration, National Center for Toxicological Research, Little Rock, Arkansas, October 3-6, 1983.

Expert Witness, Melvin D. Reuber v. United States of America, Washington, D.C., May 3, 1984.

Ad Hoc Consultant, National Toxicology Program, Peer Review Bioassay Panel, July 26, 1984.

Member, Committee on the Carcinogenicity of Cyclamates, 1984-1985, National Research Council, National Academy of Sciences.

Member, Color Additive Scientific Review Panel, FDA, 1985.

Co-Organizer, US-Japan Seminar on "Development of New-Medium-Term Bioassays for Carcinogens," US-Japan Cooperative Cancer Research Program, Honolulu, Hawaii, December 15-17, 1987.

Organizing Committee, Conference on "Mouse Liver Carcinogenesis," Austin, Texas, November 30-December 3, 1988.

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Bioassay of Environmental Chemicals, Bio-Research, Cambridge, MA, 68-1311, 1972 (Co-P.O.)

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Bioassay of Environmental Chemicals, Dow Chemical Co., Indianapolis, IN, 72-3254, 1972-73 (Co-P.O.)

Bioassay of Environmental Chemicals, Hazleton Labs., Inc., Vienna, VA, 70-2209, 72-3278, 1972-74 (Co-P.O.)

Bioassay of Environmental Chemicals, Litton Bionetics Inc., Kensington, MD, 71-2146, 72-3252, 1972-74 (Co-P.O.)

Bioassay of Environmental Chemicals, Mason Research Institute, Worcester, MA, 71-2144, 72-3255 (Co-P.O.)

Biology of the Mouse Liver Tumor, University of California, Davis, N01-CP-65845, 1978-79

Bioassay of Environmental Chemicals, Hazleton Laboratories, Vienna, VA, 1978-81 (Co-P.O.)

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Comparative Carcinogenesis Data Base and Quantitative Species Comparison, Y01-CP-15791, Lawrence Berkeley Laboratory, Berkeley, California, 1981-83

Operation of a Registry of Tumors in Lower Animals - N01-CP-26000, Smithsonian Institution, Washington, D.C., 1982 - 1983

Laboratory Rodent and Rabbit Facility as a Resource to the Laboratory of Experimental Pathology, Microbiological Associates, Bethesda, MD, N01-CP-15744, 1982-83; N01-CP-41014, 1983

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Animal Production, Frederick Cancer Research Facility, Harlan Sprague Dawley, Inc., Frederick, MD, N01-CM-23911, 1982-1987

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Pre Veterinary, Rutgers University, New Brunswick, New Jersey 1945-1948. V.M.D, University of Pennsylvania, Philadelphia, Pennsylvania, 1948-1952.

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EXPERIENCE:

1983 - Present	Vice President and Senior Pathologist PATHCO, Inc., Gaithersburg, Maryland
1974 - 1982	Chief, Veterinary Sciences, Gillette Medical Evaluation Laboratories, Rockville, Maryland.
1969 - 1976	Clinical Professor of Pathology, School of Medicine, George Washington University, Washington, D.C.
1968 - 1974	Pathologist, National Zoological Park, Smithsonian Institution, Washington, D.C.
1968 - Present	Consulting Pathologist
1966 - 1968	Associate Professor of Pathology, School of Veterinary Medicine, University of Pennsylvania, Philadelphia, Pennsylvania.
1961 - 1965	Head, Laboratory of Pathology, School of Veterinary Medicine, University of Pennsylvania.
1961 - 1968	Assistant Professor, Graduate School of Arts and Sciences, University of Pennsylvania, Philadelphia, Pennsylvania.
1960 - 1966	Assistant Professor of Pathology, School of Veterinary Medicine, University of Pennsylvania, Philadelphia, Pennsylvania.
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1955 - 1958 Small Animal Practice.

1954 - 1955 Instructor in Pathology, School of Veterinary Medicine, University of Pennsylvania, Philadelphia, Pennsylvania.

1952 - 1954 Field Veterinarian, State of New Jersey Bureau of Animal Industry.

CONSULTATIONS:

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1965 -1968 Lecturer in Pathology, Philadelphia College of Pharmacy and Science.

1961 - 1968 Haskell Laboratories for Toxicology and Industrial Medicine, E. I. DuPont de Nemours, Newark, Delaware.

1961 - 1965 William Douglas McAdams, New York, N.Y.

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MEMBERSHIPS:

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HONORS:

Society of Alpha Zeta - Rutgers University Society of Phi Zeta - University of Pennsylvania Society of Sigma Xi - University of Pennsylvania Norden Distinguished Teacher Award - University of Pennsylvania, 1963

COMMITTEES AND EXTRACURRICULAR RESPONSIBILITIES:

1981 - Present	Pathology Working Group Chairman, National Toxicology Program, NIEHS, Research Triangle, North Carolina
1968 - 1978	ACVP Site Committee Chairman
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1967	ACVP Education Committee
1965	President, Society of Phi Zeta, University of Pennsylvania
1964 - 1966	ACVP Chairman, Committee on Surgical Pathology for 1966 AVMA Convention, Louisville
1964 - 1968	Secretary of Faculty, School of Veterinary Medicine, University of Pennsylvania
1963	ACVP Examination Committee (substitute)
1962 - 1968	Faculty Advisor, Omega Tau Sigma Fraternity, University of Pennsylvania

PUBLICATIONS:

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ORAL PRESENTATIONS, UNPUBLISHED:

Zoonoses Associated with Captive Monkeys Presented before the Laboratory Section of the American Public Health Association at the 7th Annual Meeting in Atlantic City, N.J., October 20, 1959.

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Monkey Health Problems Presented before the 52nd Annual Conference for Veterinarians at New York State Veterinary College, Cornell University, January 7, 1960.

Problems Associated with Pet Monkeys Presented at the Ellin Speyer Memorial Animal Hospital, New York City, January 20, 1961.

Chairman, Clinico-Pathologic Conference, Rutgers Veterinary Symposium, May 3, 1961.

Monkey Diseases PADOLA-Armed Forces Institute of Pathology, September 28, 1961.

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Clinical Symposium Presented for Academy of Veterinarians, Washington, D.C., February 6, 1964.

Clinico-Pathologic Symposium Presented for the Southern California Veterinary Medical Association, September 9, 1964. Disneyland, California.

Clinico-Pathologic Symposium Presented for the Hospital Staff Women's S.P.C.A., New York, N.Y., December 2, 1964.

Clinico-Pathologic Symposium Presented for the Maryland State Veterinary Medical Association, December 4, 1964. Baltimore, Maryland.

Clinico-Pathologic Symposium Presented for the Westchester Veterinary Medical Association, January 20, 1966. Tarrytown, N.Y.

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Robert M. Sauer, V.M.D.

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OTC Vol. No. 103

OTC Docket Number 75N-0183 (triclosan)

September 12, 1994

Ciba-Geigy Corporation

Chemicals Division

Greensboro, N.C. 27419

Jones, E. and Wilson, L. Ames Metabolic Activation Test to Address the Potential Mutagenic Effect of Triclosan. Environmental Safety Laboratory, Unilever Research Lab., Colworth House. Study No. KA 880169. September 9, 1988.

Study Summary

The number of microcolonies obtained from microscopic examination of the background lawn in the dose range finding test are shown in Table 1. Triclosan was toxic towards the tester strains at the higher dose levels. Therefore 1.5 µg/plate was chosen as the top dose level in the mutation tests.

The mean number of revertant colonies, together with the individual plate counts for Triclosan obtained in the first mutation test with tester strains TA 1535, TA 1537, TA 98 and TA 100 are shown in Table 2. Positive control mutability checks are shown in Table 3.

The mean number of revertant colonies, together with the individual plate counts for Triclosan obtained in the second mutation test with tester strains TA 1535, TA 1537, TA 98 and TA 100 are shown in Table 4. Positive control mutability checks are shown in Table 5.

No substantial increases in revertant colony numbers of any of the four tester strains were observed following treatment with Triclosan at any dose level, either in the presence or absence of metabolic activation (S-9 mix). Toxicity was observed at the higher dose levels tested.

Conclusions and Comments

It is concluded that no evidence of mutagenic potential of Triclosan was obtained in this bacterial test system at the dose levels used.

75N-0183H

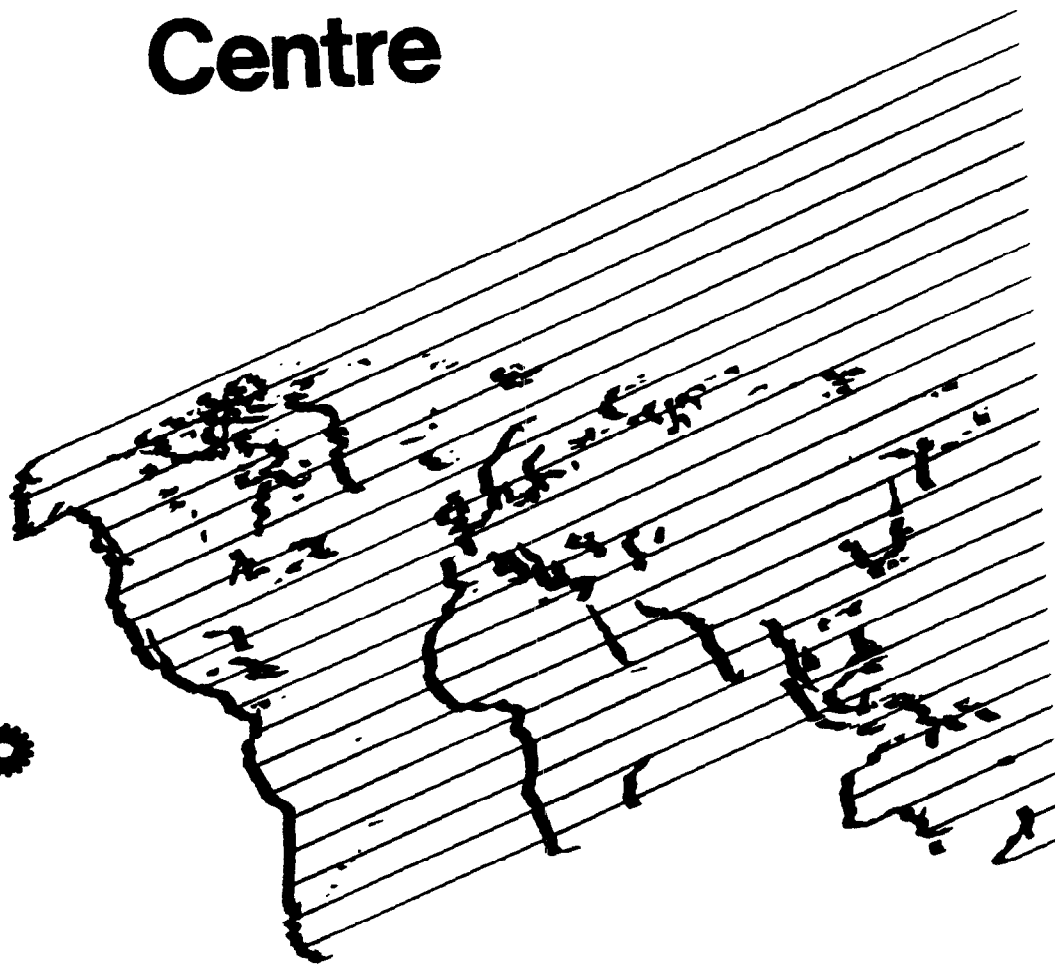
C 1

HRC Report

TRICLOSAN

AMES METABOLIC ACTIVATION TEST
TO ASSESS THE POTENTIAL
MUTAGENIC EFFECT

Huntingdon Research Centre



CONFIDENTIAL

ULR 215/88704
Unilever Study No: KA 880169

AMES METABOLIC ACTIVATION TEST TO
ASSESS THE POTENTIAL MUTAGENIC EFFECT OF
TRICLOSAN

Addressee:

Dr. J. Hope,
Environmental Safety Laboratory,
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Huntingdon Research Centre Ltd.,
HUNTINGDON,
Cambridgeshire,
PE18 6ES.

Report issued 9 September 1988

We the undersigned, hereby declare that the work was performed under our supervision according to the procedures herein described, and that this report provides a correct and faithful record of the results obtained.



Eryl Jones, B.Sc., A.I.M.L.S., M.I.Biol.,
Study Director - Microbial Mutation,
Department of Mutagenesis and Cell Biology



Lesley A. Wilson, HNC,
Scientific Officer,
Department of Mutagenesis and Cell Biology

COMPLIANCE WITH GOOD LABORATORY PRACTICE STANDARDS

To the best of my knowledge and belief the study described in this report was conducted in compliance with the following Good Laboratory Practice Standards:

United States Food and Drug Administration
Title 21 Code of Federal Regulations Part 58
Federal Register 22 December 1978 and subsequent Amendments

Environmental Protection Agency Toxic Substances Control:
Good Laboratory Practice Regulations: 40 CFR Part 792
Federal Register Volume 48 No. 220 pp. 53922 (1983)

Japan Ministry of Health and Welfare
Notification No. 313 Pharmaceutical Affairs Bureau
31 March 1982

Japan Ministry of Agriculture, Forestry and Fisheries
Notification No. 59 Nohsan 3850
Director-General of Agricultural Production Bureau,
10 August, 1984

Organization for Economic Co-operation and Development
ISBN 92-64-12367-9, Paris 1982

Good Laboratory Practice, The United Kingdom Compliance
Programme, Department of Health & Social Security 1986



Eryl Jones, B.Sc., A.I.M.L.S., M.I.Biol.,
Study Director

9/9/88

Date

QUALITY ASSURANCE STATEMENT

Certain studies of short duration, such as that described in this report, are conducted at HRC in a setting which involves frequent repetition of similar or identical procedures. At or about the time the study described in this report was in progress, 'process-based' inspections were made by the Quality Assurance Department of critical procedures relevant to this study type. For the inspection of any given procedure, at least one study was selected without bias. The findings of these inspections were reported promptly to the Study Director and to HRC management.

This report has been audited by the HRC Quality Assurance Department. It is considered to be an accurate presentation of the procedures and practices employed during the course of the study and an accurate presentation of the findings.



Peter H.C.V. Richold, B.Sc.,
Systems Compliance Auditor

25.7.88

Date

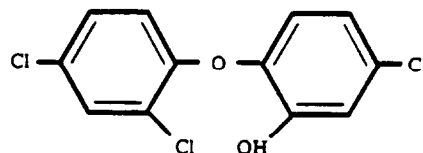
BACTERIAL REVERSE GENE MUTATION ASSAY - THE AMES TEST

The object of this study is to assess the mutagenic potential of the test material in a bacterial system.

COMPOUND: Triclosan

Alternative names: (1) 2,4,4'-trichloro-2'-hydroxy diphenyl ether
(2) Irgasan DP 300

Structural formula:



Sample Number: S 15155 T01.

Purity: ≥99%.

Storage conditions: Stored at room temperature.

Expiry date: Later than March 1989.

Appearance: White powder.

METHOD: The method used is as described in Appendix 1.

The experiments described in this report were carried out between 13 April 1988 and 2 May 1988.

Solvent: Dimethylsulphoxide.

Dose levels: Dose range finding test: 5000, 500, 50,
5, 0.5,
0.05 µg/plate.

Mutation tests: 1.5, 0.5, 0.15,
0.05, 0.015 µg/plate.

Dosing solutions were returned to the Sponsor for analysis of achieved concentration. The analysis supported the nominal concentrations. The raw data of the analysis are retained by the Sponsor (Sponsor's analytical reference ANY 88.38).

Protocol approval signed by:

Study Director - E. Jones - 3 March 1988

HRC Management - Dr. D. H. Christopher - 3 March 1988

Sponsor - M. Richold - 11 March 1988

RESULTS

The number of microcolonies obtained from microscopic examination of the background lawn in the dose range finding test are shown in Table 1. Triclosan was toxic towards the tester strains at the higher dose levels. Therefore 1.5 µg/plate was chosen as the top dose level in the mutation tests.

The mean number of revertant colonies, together with the individual plate counts for Triclosan obtained in the first mutation test with tester strains TA 1535, TA 1537, TA 98 and TA 100 are shown in Table 2. Positive control mutability checks are shown in Table 3.

The mean number of revertant colonies, together with the individual plate counts for Triclosan obtained in the second mutation test with tester strains TA 1535, TA 1537, TA 98 and TA 100 are shown in Table 4. Positive control mutability checks are shown in Table 5.

No substantial increases in revertant colony numbers of any of the four tester strains were observed following treatment with Triclosan at any dose level, either in the presence or absence of metabolic activation (S-9 mix). Toxicity was observed at the higher dose levels tested.

CONCLUSIONS AND COMMENTS

It is concluded that no evidence of mutagenic potential of Triclosan was obtained in this bacterial test system at the dose levels used.

TABLE 1

Dose range finding test on Triclosan microscopic examination of
background lawn to assess percentage survival

Dose level (µg/plate)	Metabolic activation	TA 1535	% survival	TA 1537	% survival	TA 98	% survival	TA 100	% survival
5000.00	-	0	-	0	-	0	-	0	-
500.00	-	0	-	0	-	0	-	0	-
50.00	-	0	-	0	-	0	-	0	-
5.00	-	0	-	205	57.7	0	-	1	0.1
0.50	-	740	66.7	360	101.4	145	55.8	780	71.6
0.05	-	850	76.6	460	129.6	180	69.2	1000	91.7
Solvent	-	1110		355		260		1090	
5000.00	+	0	-	0	-	0	-	0	-
500.00	+	0	-	0	-	0	-	0	-
50.00	+	0	-	0	-	0	-	0	-
5.00	+	1800	89.1	1320	72.5	1000	64.1	0	-
0.50	+	1750	86.6	1240	68.1	1320	84.6	1260	78.8
0.05	+	1810	89.6	1300	71.4	1360	87.2	1340	83.8
Solvent	+	2020		1820		1560		1600	

The counts obtained are the number of microcolonies present per field of view

TABLE 2

Test 1

Triclosan - revertant colony numbers obtained per plate using
bacterial strains TA 1535, TA 1537, TA 98 and TA 100

Strain	Dose level (µg/plate)	Metabolic activation	Mean revertant colony counts	SD	Individual revertant colony counts
TA 1535	1.500	-	3	0.6	4,3,3
	0.500	-	8	1.0	7,9,8
	0.150	-	6	1.0	5,6,7
	0.050	-	7	2.1	5,8,9
	0.015	-	8	0.6	9,8,8
	0.000	-	8	1.5	10,7,8
	Solvent	-	8	1.0	8,7,9
	1.500	+3%	-	-	IL, IL, IL
	0.500	+3%	6	2.9	4,4,9
	0.150	+3%	9	1.5	7,10,9
	0.050	+3%	7	3.5	10,7,3
	0.015	+3%	9	2.1	11,10,7
	0.000	+3%	8	1.5	7,10,8
	Solvent	+3%	9	1.5	9,7,10
	1.500	+10%	3	2.6	2,6,1
	0.500	+10%	2	0.6	2,3,2
	0.150	+10%	10	1.5	10,9,12
	0.050	+10%	7	2.6	9,4,8
	0.015	+10%	8	2.1	7,6,10
	0.000	+10%	11	3.5	8,15,11
	Solvent	+10%	11	1.0	11,10,12
TA 1537	1.500	-	11	2.1	10,13,9
	0.500	-	8	2.1	6,10,9
	0.150	-	10	3.6	7,14,9
	0.050	-	16	2.5	18,13,16
	0.015	-	14	6.2	7,19,16
	0.000	-	15	4.0	13,20,13
	Solvent	-	15	3.8	18,11,17
	1.500	+3%	-	-	IL, IL, IL
	0.500	+3%	7	1.5	8,5,7
	0.150	+3%	5	1.5	6,5,3
	0.050	+3%	8	2.3	9,9,5
	0.015	+3%	6	2.1	4,7,8
	0.000	+3%	10	5.3	14,4,12
	Solvent	+3%	9	0.6	9,9,10
	1.500	+10%	-	-	IL, IL, IL
	0.500	+10%	6	1.0	6,7,5
	0.150	+10%	5	1.5	5,4,7
	0.050	+10%	8	1.2	9,7,7
	0.015	+10%	9	2.5	9,11,6
	0.000	+10%	9	1.7	8,11,8
	Solvent	+10%	10	3.2	9,8,14

- Absence
+ Presence
SD Standard deviation
IL Incomplete bacterial lawn

TABLE 2
(continued)

Strain	Dose level (µg/plate)	Metabolic activation	Mean revertant colony counts	SD	Individual revertant colony counts
TA 98	1.500	-	7	6.7	0,9,13
	0.500	-	22	1.5	21,22,24
	0.150	-	20	8.6	29,12,18
	0.050	-	26	7.4	32,29,18
	0.015	-	23	6.7	31,19,20
	0.000	-	21	6.6	28,20,15
	Solvent	-	17	3.5	17,14,21
	1.500	+3%	-	-	IL, IL, IL
	0.500	+3%	15	5.0	10,20,14
	0.150	+3%	25	1.2	24,26,24
	0.050	+3%	13	3.0	10,16,13
	0.015	+3%	25	2.6	28,23,24
	0.000	+3%	23	8.5	32,15,23
	Solvent	+3%	27	0.6	27,27,28
	1.500	+10%	-	-	IL, IL, IL
	0.500	+10%	10	2.0	8,12,10
	0.150	+10%	17	1.7	19,16,16
	0.050	+10%	20	3.5	22,22,16
	0.015	+10%	15	3.6	18,16,11
	0.000	+10%	16	5.9	9,18,20
	Solvent	+10%	19	2.1	20,21,17
TA 100	1.500	-	-	-	IL, IL, IL
	0.500	-	89	10.0	97,78,93
	0.150	-	99	2.0	101,97,99
	0.050	-	102	17.3	92,92,122
	0.015	-	97	11.2	100,107,85
	0.000	-	100	11.5	112,89,100
	Solvent	-	89	5.9	96,85,87
	1.500	+3%	-	-	IL, IL, IL
	0.500	+3%	78	25.1	107,64,63
	0.150	+3%	104	9.2	115,99,99
	0.050	+3%	98	20.6	122,85,88
	0.015	+3%	112	8.1	116,103,118
	0.000	+3%	100	15.7	118,88,95
	Solvent	+3%	85	7.9	94,79,82
	1.500	+10%	-	-	IL, IL, IL
	0.500	+10%	58	4.4	53,60,61
	0.150	+10%	91	12.2	102,94,78
	0.050	+10%	96	7.8	87,98,102
	0.015	+10%	93	10.2	86,105,89
	0.000	+10%	119	5.3	123,113,121
	Solvent	+10%	102	10.8	105,111,90

- Absence
+ Presence
SD Standard deviation
IL Incomplete bacterial lawn

TABLE 3

Test 1

Mutability tests with bacterial strains TA 1535,
TA 1537, TA 98 and TA 100

Strain	Compound	Dose level (µg/plate)	Metabolic activation	Mean revertant colony counts	SD	Individual revertant colony counts
TA 1535	ENNG	5.0	-	192	53.9	181,145,251
TA 1537	9 AC	80.0	-	1597	155.3	1624,1430,1737
TA 98	NF	1.0	-	104	23.0	124,79,110
TA 100	ENNG	3.0	-	348	37.7	313,343,388
TA 1535	AA	2.0	+3%	180	18.6	175,165,201
TA 1537	AA	2.0	+3%	156	16.8	169,137,162
TA 98	AA	0.5	+3%	729	83.1	783,770,633
TA 100	AA	1.0	+3%	1190	19.7	1193,1208,1169
TA 1535	AA	2.0	+10%	100	7.0	107,100,93
TA 1537	AA	2.0	+10%	126	26.4	149,131,97
TA 98	AA	0.5	+10%	317	26.7	342,321,289
TA 100	AA	1.0	+10%	692	66.1	616,729,732

- Absence
+ Presence
SD Standard deviation
ENNG N-ethyl-N'-nitro-N-nitrosoguanidine
9 AC 9-aminoacridine
AA 2-aminoanthracene
NF 2-nitrofluorene

TABLE 4

Test 2

Triclosan - revertant colony numbers obtained per plate using
bacterial strains TA 1535, TA 1537, TA 98 and TA 100

Strain	Dose level (µg/plate)	Metabolic activation	Mean revertant colony counts	SD	Individual revertant colony counts
TA 1535	1.500	-	-	-	NL,NL,NL
	0.500	-	8	3.2	9,4,10
	0.150	-	8	4.0	6,6,13
	0.050	-	11	1.5	12,9,11
	0.015	-	12	2.5	14,12,9
	0.000	-	11	1.7	9,12,12
	Solvent	-	9	2.5	11,6,9
	1.500	+10%	1	1.0	2,0,1
	0.500	+10%	8	2.1	7,10,6
	0.150	+10%	9	1.5	11,9,8
	0.050	+10%	9	1.5	9,10,7
	0.015	+10%	9	0.0	9,9,9
	0.000	+10%	13	2.3	14,14,10
	Solvent	+10%	11	1.0	10,12,11
	1.500	+30%	4	2.6	1,5,6
	0.500	+30%	12	1.5	10,13,12
	0.150	+30%	9	1.0	8,9,10
	0.050	+30%	10	2.0	12,10,8
	0.015	+30%	9	4.6	5,8,14
	0.000	+30%	9	2.6	7,8,12
	Solvent	+30%	12	3.5	12,8,15
TA 1537	1.500	-	14	0.6	15,14,14
	0.500	-	15	4.7	17,10,19
	0.150	-	15	3.2	11,17,16
	0.050	-	13	3.5	13,17,10
	0.015	-	11	2.9	9,14,9
	0.000	-	13	3.1	14,10,16
	Solvent	-	15	2.0	13,15,17
	1.500	+10%	-	-	IL, IL, IL
	0.500	+10%	6	2.9	8,3,8
	0.150	+10%	7	1.0	6,7,8
	0.050	+10%	8	1.2	7,7,9
	0.015	+10%	12	1.5	12,10,13
	0.000	+10%	9	2.1	10,7,11
	Solvent	+10%	10	2.6	11,7,12
	1.500	+30%	5	2.1	6,3,7
	0.500	+30%	5	2.1	7,3,6
	0.150	+30%	9	4.5	14,5,9
	0.050	+30%	9	1.2	10,8,8
	0.015	+30%	10	1.5	10,9,12
	0.000	+30%	14	2.5	11,16,14
	Solvent	+30%	12	4.2	15,7,13

- Absence
+ Presence
SD Standard deviation
NL No bacterial lawn
IL Incomplete bacterial lawn

TABLE 4
(continued)

Strain	Dose level (µg/plate)	Metabolic activation	Mean revertant colony counts	SD	Individual revertant colony counts
TA 98	1.500	-	9	5.9	11,13,2
	0.500	-	12	2.5	10,12,15
	0.150	-	15	6.0	9,21,15
	0.050	-	21	7.5	13,22,28
	0.015	-	16	2.1	17,18,14
	0.000	-	23	3.2	24,19,25
	Solvent	-	23	2.0	23,25,21
	1.500	+10%	11	4.4	6,13,14
	0.500	+10%	10	3.0	10,7,13
	0.150	+10%	18	7.0	25,11,17
	0.050	+10%	15	2.5	15,13,18
	0.015	+10%	18	1.2	17,19,17
	0.000	+10%	22	0.6	21,22,22
	Solvent	+10%	18	2.1	19,16,20
	1.500	+30%	10	5.6	16,5,9
	0.500	+30%	15	3.1	18,12,16
	0.150	+30%	15	2.6	18,13,14
	0.050	+30%	19	6.4	15,15,26
	0.015	+30%	15	0.6	15,15,16
	0.000	+30%	25	1.2	24,26,24
	Solvent	+30%	23	7.1	29,15,24
TA 100	1.500	-	56	31.6	83,63,21
	0.500	-	91	14.6	103,75,96
	0.150	-	111	17.6	98,104,131
	0.050	-	99	12.3	89,96,113
	0.015	-	106	10.2	94,113,110
	0.000	-	115	12.7	129,113,104
	Solvent	-	106	11.5	94,106,117
	1.500	+10%	47	5.3	51,49,41
	0.500	+10%	100	4.6	95,103,103
	0.150	+10%	91	12.7	81,105,86
	0.050	+10%	95	8.5	92,89,105
	0.015	+10%	90	7.2	88,84,98
	0.000	+10%	103	6.1	96,106,107
	Solvent	+10%	101	6.1	102,94,106
	1.500	+30%	70	1.5	68,71,70
	0.500	+30%	83	11.7	73,81,96
	0.150	+30%	88	19.0	70,87,108
	0.050	+30%	82	15.1	99,71,75
	0.015	+30%	85	8.7	75,89,91
	0.000	+30%	98	12.2	87,95,111
	Solvent	+30%	92	3.2	91,90,96

- Absence
+ Presence
SD Standard deviation

TABLE 5

Test 2

Mutability tests with bacterial strains TA 1535,
TA 1537, TA 98 and TA 100

Strain	Compound	Dose level (µg/plate)	Metabolic activation	Mean revertant colony counts	SD	Individual revertant colony counts
TA 1535	ENNG	5.0	-	352	87.8	251,402,404
TA 1537	9 AC	80.0	-	1737	45.1	1699,1787,1726
TA 98	NF	1.0	-	88	9.5	89,97,78
TA 100	ENNG	3.0	-	396	13.8	391,386,412
TA 1535	AA	2.0	+10%	125	23.9	146,130,99
TA 1537	AA	2.0	+10%	132	13.5	118,133,145
TA 98	AA	0.5	+10%	240	7.2	234,238,248
TA 100	AA	1.0	+10%	620	43.0	570,643,646
TA 1535	AA	2.0	+30%	59	5.0	64,59,54
TA 1537	AA	2.0	+30%	82	2.1	81,80,84
TA 98	AA	0.5	+30%	111	9.2	103,121,109
TA 100	AA	1.0	+30%	366	11.0	375,354,370

- Absence
+ Presence
SD Standard deviation
ENNG N-ethyl-N'-nitro-N-nitrosoguanidine
9 AC 9-aminoacridine
AA 2-aminoanthracene
NF 2-nitrofluorene

APPENDIX 1

Experimental Procedure

1. MATERIALS

1.1 Bacterial strains

The following strains are used in the Ames test:

S.typhimurium TA 1535 his G46 rfa Δ uvrB
S.typhimurium TA 1537 his C3076 rfa Δ uvrB
S.typhimurium TA 98 his D3052 rfa Δ uvrB pKM 101
S.typhimurium TA 100 his G46 rfa Δ uvrB pKM 101

All four strains are defective in DNA repair capacity (Δ uvrB) and have a defective lipopolysaccharide barrier on the cell wall (rfa). These two properties confer extra sensitivity to DNA damage and also greater permeability of large molecules into the cell. Strains TA 98 and TA 100 also contain a resistance transfer factor (plasmid pKM 101). This factor, which confers resistance to ampicillin, enhances the operation of an error-prone repair system.

The strains are tested routinely for cell membrane permeability and where applicable for ampicillin resistance.

For use in tests sub-cultures are grown in Nutrient Broth (Oxoid) at 37°C for 10 hours. This culture provides approximately 2×10^8 organisms per ml which is assessed photometrically.

1.2 Positive controls

(a) With S-9 mix

2-Aminoanthracene at 2 μ g/plate for strains TA 1535 and TA 1537.

2-Aminoanthracene at 0.5 μ g/plate for strain TA 98.

2-Aminoanthracene at 1 μ g/plate for strain TA 100.

(b) Without S-9 mix

2-Nitrofluorene at 1 μ g/plate for strain TA 98.

9-Aminoacridine at 80 μ g/plate for strain TA 1537.

N-Ethyl-N'-nitro-N-nitrosoguanidine at 5 μ g/plate for strain TA 1535.

N-Ethyl-N'-nitro-N-nitrosoguanidine at 3 μ g/plate for strain TA 100.

(OECD 471/ULR-4-B)

APPENDIX 1

(continued)

2. PROCEDURE

2.1 Preliminary toxicity test

The following procedure is carried out on each bacterial strain:

Four concentrations of test substance are assessed for toxicity using the four tester strains. The highest concentration is usually 0.05 g of test substance dissolved in 1 ml of solvent. Three 10-fold serial dilutions of the top concentration are also tested. The chosen solvent is used as the negative control.

0.1 ml of a bacterial culture containing approximately 2×10^8 cells/ml, and 0.5 ml S-9 mix (see Section 3) or 0.5 ml 0.1 M sodium orthophosphate buffer (pH 7.4) are placed in glass bijou bottles. 0.1 ml of the test solution is added and the mixture incubated at 37°C for 60 mins. The mixture is then centrifuged at 2500 rpm for 20 minutes (Centaur 2 centrifuge, MSE) the supernatant discarded and the pellet resuspended in 0.5 ml of saline. 2 ml histidine deficient agar is then added and the mixture is thoroughly shaken and overlaid onto previously prepared plates containing 25 ml minimal agar. Single petri dishes are used for each dose level. They are incubated at 37°C for 24 hours. After this period the plates are examined microscopically to assess the survival of the background bacterial lawn. Any toxic effects of the test substance are detected by a substantial reduction in the number of microcolonies in the background bacterial lawn.

2.2 Ames test procedure

(a) Without metabolic activation

The following procedure is carried out on each tester strain.

0.1 ml aliquots of bacterial suspension and 0.5 ml of sterile 0.1 M sodium orthophosphate buffer (pH 7.4) are added to each of one set of sterile bijou bottles.

0.1 ml of the test compound is added to cultures at five concentrations separated by half-log 10 intervals. The negative control is the chosen solvent. The appropriate positive control is also included. Three bottles are used at each dose level.

APPENDIX 1

(continued)

The mixture of bacteria, buffer and test solution is then incubated at 37°C for 60 mins. The mixture is then centrifuged at 2500 rpm for 20 minutes (centaur 2 centrifuge, MSE), the supernatant discarded and the pellet resuspended in 0.5 ml of saline. 2.0 ml of histidine deficient agar is then added to each of the bottles, thoroughly mixed and then overlaid onto previously prepared plates containing 25 ml of minimal agar. Plates are incubated for 72 hours at 37°C.

Colonies are counted using a Biotran Automatic Colony Counter, and the mean number of revertant colonies per treatment group assessed.

(b) With metabolic activation

- (i) Methodology is as described in 2.2 (a) except that 0.5 ml of liver homogenate S-9 mix (10%) (see Section 3) is added to bijou bottles in place of sterile buffer.
- (ii) Methodology is as described in 2.2 (a) except that 0.5 ml of liver homogenate S-9 mix (3%) (see Section 3) is added to bijou bottles in place of sterile buffer.

Plates will be prepared without the addition of bacteria in order to assess the sterility of the test compound and S-9 mix.

2.3 Second mutation test

The procedure outlined in Section 2.2 is repeated at a later date. The S-9 mixes used (see Section 2.2 (a) (i) and (ii)) will contain 10% and 30% S-9 fraction. The levels of S-9 fraction to be used may be altered following assessment of the results of the first test. The concentrations of test substance used in the second test may also be altered if indicated by the results of the first test.

APPENDIX 1

(continued)

3. PREPARATION OF LIVER HOMOGENATE S-9 FRACTION

Species:	Rat
Strain:	CD (Sprague-Dawley-derived).
Source:	Charles River UK Limited, Manston Road, Margate, Kent, England.
Age range:	7-8 weeks on arrival.
Weight range:	180-220 g on arrival.
Diet:	Labsure's Laboratory Diet No. 1.
Number used:	7-13

3a. Stimulation of rat liver enzymes

Mixed-function oxidase systems in the rat liver are stimulated following a single i/p injection of Aroclor 1254 (diluted in Arachis oil to 200 mg/ml) at a dosage of 500 mg/kg. On the fifth day of induction, following an overnight starvation, the rats are killed and their livers aseptically removed.

3b. Preparation of liver homogenate "S-9"

1. All steps are at 0-4°C using sterile solutions and glassware. The livers are placed in beakers containing 0.15 M potassium chloride. After weighing, the livers are transferred to a beaker containing 0.15 M KCl (3 ml KCl: 1 g liver), minced with a sterile scalpel and homogenised in an Ultra Turrax homogeniser. This homogenate is centrifuged for 10 minutes at 9000 x 'g' and the supernatant divided into 15 ml aliquots. These are frozen on dry ice and stored at -80°C, and tested with the carcinogen 7,12-dimethylbenzanthracene before use.

11. Preparation of "S-9 mix"

S-9 mix contains: S-9 fraction in the range 3 - 30%, Mg Cl₂ (8 mM), KCl (33 mM), sodium orthophosphate buffer pH 7.4 (100 mM), glucose- 6-phosphate (5 mM), NADP (4 mM). All the cofactors are filter-sterilized before use.

(OECD 471/ULR-4-B)

APPENDIX 1

(continued)

4. ASSESSMENT OF RESULTS

The mean number of revertant colonies for all treatment groups is compared with those obtained for negative and positive control groups. The effect of metabolic activation is assessed by comparing the results obtained both in the presence and absence of the liver microsomal fraction for each treatment group.

A compound is deemed to provide evidence of mutagenic potential if a statistically significant dose-related increase in the number of revertant colonies of at least twice the concurrent solvent control is obtained in two separate experiments.

5. MAINTENANCE OF RECORDS

All data are kept in a loose-leaved laboratory notebook which is held in the Department of Mutagenesis and later transferred, together with a mastercopy of the final report, to the Archive Department, Huntingdon Research Centre Ltd., Huntingdon, Cambs, U.K.

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(OECD 471/ULR-4)

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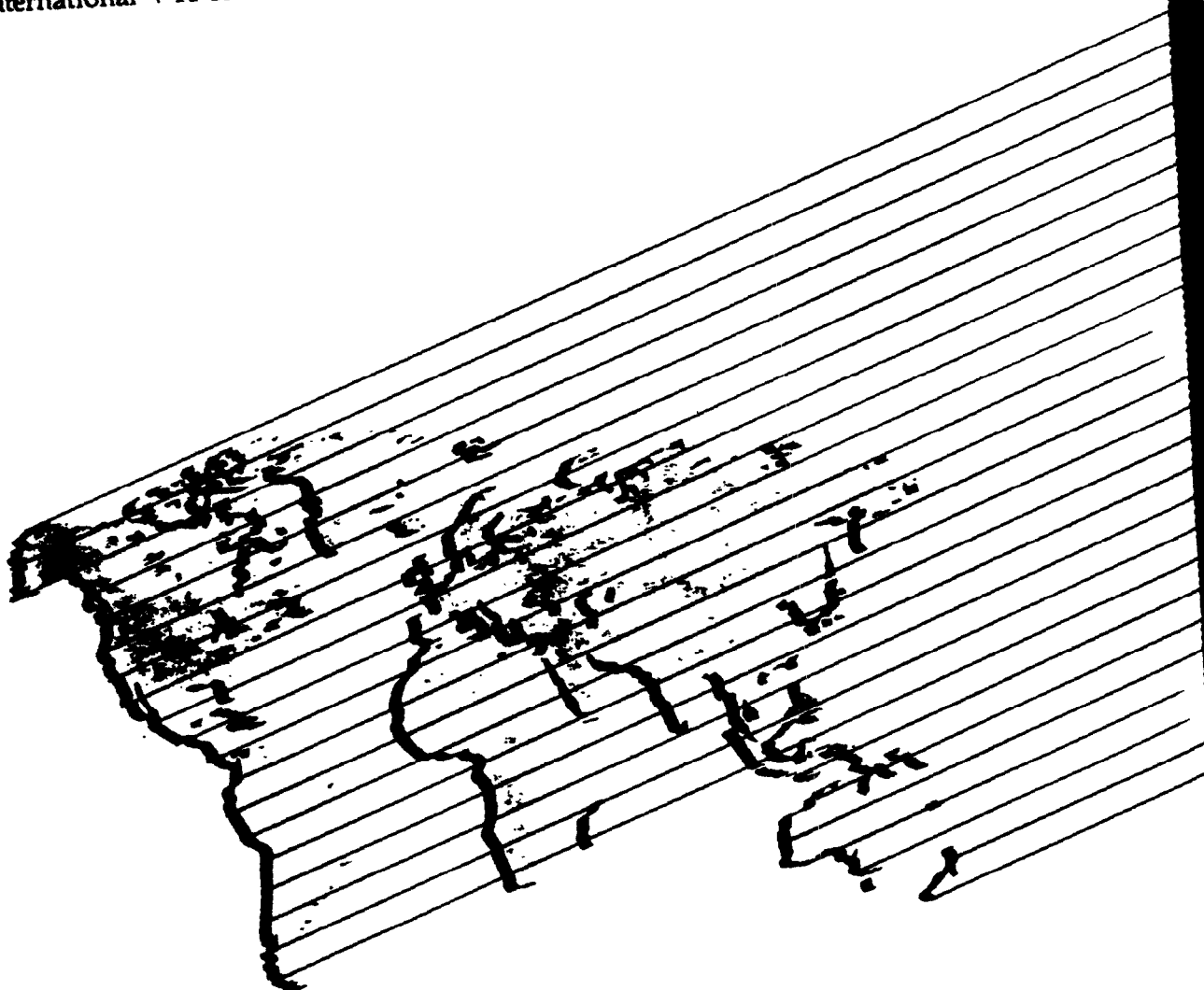
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OTC Vol. No. 104

OTC Docket Number 75N-0183 (triclosan)
September 12, 1994

Ciba-Geigy Corporation
Chemicals Division
Greensboro, N.C. 27419

Henderson, L.M., Produlock, R.J., Haynes, P. and Meaking, K. Mouse Micronucleous Test on Triclosan. Environmental Safety Laboratory, Unilever Research Lab., Colworth House. Study No. KC 880168. August 12, 1988.

Study Summary

In this assessment of the effect of Triclosan on the incidence of micronucleated polychromatic erythrocytes in mice, a dosage of 5000 mg/kg body weight was administered orally, by intragastric gavage. A preliminary toxicity test had been carried out to determine the toxicity of Triclosan. As no toxicity was observed at a dose level of 5000 mg/kg, the highest dose recommended for acute toxicity testing (9), was chosen for the main test.

Negative and positive control groups were dosed in an identical manner, orally by intragastric gavage. The negative control group received the vehicle, 1% aqueous methylcellulose. The positive control group was treated with mitomycin C, at 12 mg/kg.

Bone marrow smears were obtained from the negative control and test compound groups at 3 sampling times; these being 24, 48 or 72 hours after dosing. Bone marrow smears were obtained from the positive control group 24 hours after dosing. One smear from each animal was examined for the presence of micronuclei in 1000 polychromatic erythrocytes. The ratio of polychromatic to normochromatic erythrocytes was assessed by examination of at least 1000 erythrocytes from each animal. A record of the incidence of micronucleated normochromatic erythrocytes was also kept.

At all sampling times, mice treated with Triclosan showed no significant increase in the frequency of micronucleated polychromatic erythrocytes.

Small but statistically significant decreases in the ratios of polychromatic to normochromatic erythrocytes were observed at the 24 hour and 48 hour sampling times. No such decrease was observed for the p/n ratio at the 72 hour sampling time. These decreases in the p/n ratio may be indicative of slight bone marrow cell toxicity.

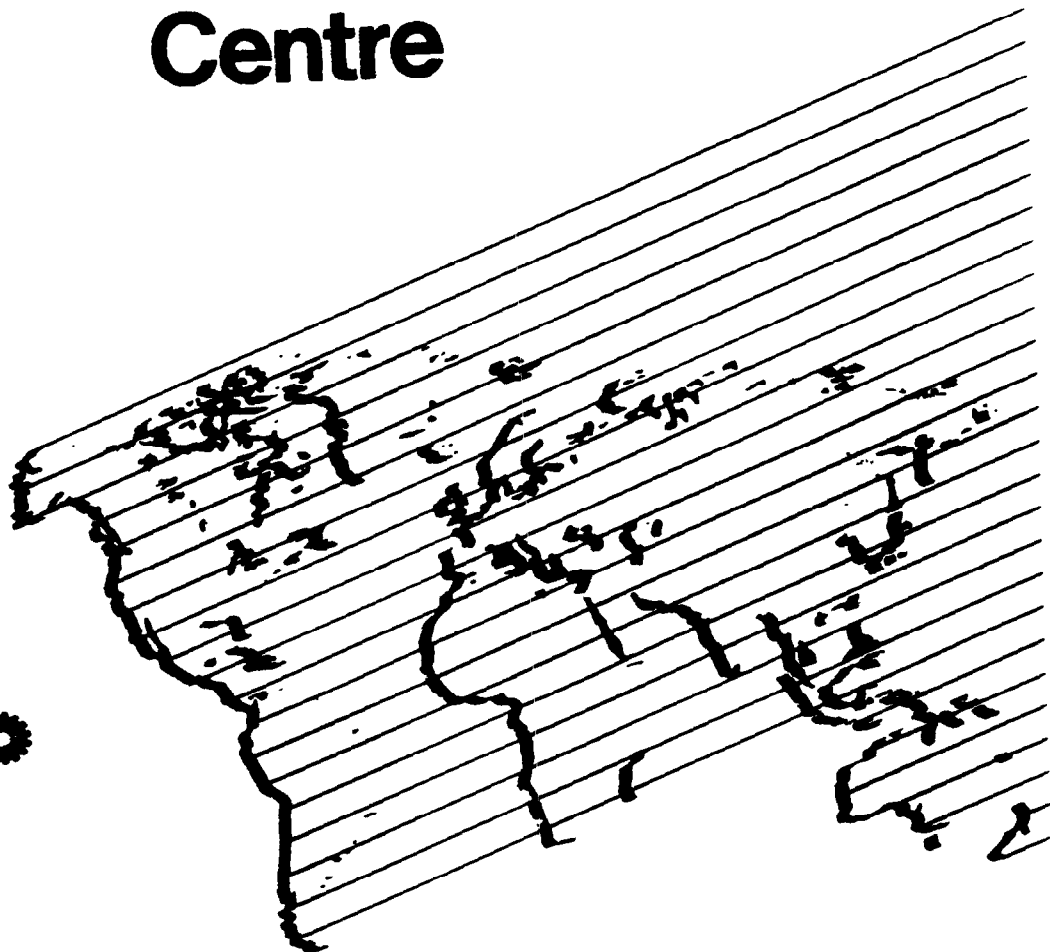
The positive control compound, mitomycin C, produced large, highly significant increases in the frequency of micronucleated polychromatic erythrocytes together with decreases in the ratio of polychromatic to normochromatic erythrocytes.

It is concluded from the results obtained that Triclosan shows no evidence of mutagenic potential when administered orally in this in vivo test procedure.

HRC Report

TRICLOSAN
MOUSE MICRONUCLEUS TEST

**Huntingdon
Research
Centre**



CONFIDENTIAL

HRC Schedule No.: ULR 213/88492
Unilever Study No.: KC 880168

MOUSE MICRONUCLEUS TEST
ON
TRICLOSAN

Addressee:

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Report issued: 12 August 1988.

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We the undersigned, hereby declare that the work was performed under our supervision according to the procedures herein described, and that this report provides a correct and faithful record of the results obtained.




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COMPLIANCE WITH GOOD LABORATORY PRACTICE STANDARDS

To the best of my knowledge and belief the study described in this report was conducted in compliance with the following Good Laboratory Practice Standards:

United States Food and Drug Administration
Title 21 Code of Federal Regulations Part 58
Federal Register 22 December 1978 and subsequent Amendments

Japan Ministry of Health and Welfare
Notification No. 313 Pharmaceutical Affairs Bureau
31 March 1982

Organization for Economic Co-operation and Development
ISBN 92-64-12367-9, Paris 1982

Good Laboratory Practice, The United Kingdom Compliance
Programme, Department of Health & Social Security 1986




Leigh M. Henderson, B.Sc., Ph.D.,
Study Director

12/8/88
Date

QUALITY ASSURANCE STATEMENT

Certain studies of short duration, such as that described in this report, are conducted at HRC in a setting which involves frequent repetition of similar or identical procedures. At or about the time the study described in this report was in progress, 'process-based' inspections were made by the Quality Assurance Department of critical procedures relevant to this study type. For the inspection of any given procedure, at least one study was selected without bias. The findings of these inspections were reported promptly to the Study Director and to HRC management.

This report has been audited by the HRC Quality Assurance Department. It is considered to be an accurate presentation of the procedures and practices employed during the course of the study and an accurate presentation of the findings.



Peter H.C.V. Richold, B.Sc.,
Systems Compliance Auditor

10.8.88
Date

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SUMMARY

1. In this assessment of the effect of Triclosan on the incidence of micronucleated polychromatic erythrocytes in mice, a dosage of 5000 mg/kg bodyweight was administered orally, by intragastric gavage. A preliminary toxicity test had been carried out to determine the toxicity of Triclosan. As no toxicity was observed a dose level of 5000 mg/kg, the highest dose recommended for acute toxicity testing (9), was chosen for the main test.
2. Negative and positive control groups were dosed in an identical manner, orally by intragastric gavage. The negative control group received the vehicle, 1% aqueous methylcellulose. The positive control group was treated with mitomycin C, at 12 mg/kg.
3. Bone marrow smears were obtained from the negative control and test compound groups at 3 sampling times; these being 24, 48 or 72 hours after dosing. Bone marrow smears were obtained from the positive control group 24 hours after dosing. One smear from each animal was examined for the presence of micronuclei in 1000 polychromatic erythrocytes. The ratio of polychromatic to normochromatic erythrocytes was assessed by examination of at least 1000 erythrocytes from each animal. A record of the incidence of micronucleated normochromatic erythrocytes was also kept.
4. At all sampling times, mice treated with Triclosan showed no significant increase in the frequency of micronucleated polychromatic erythrocytes.
5. Small but statistically significant decreases in the ratios of polychromatic to normochromatic erythrocytes were observed at the 24 hour and 48 hour sampling times. No such decrease was observed for the p/n ratio at the 72 hour sampling time. These decreases in the p/n ratio may be indicative of slight bone marrow cell toxicity.
6. The positive control compound, mitomycin C, produced large, highly significant increases in the frequency of micronucleated polychromatic erythrocytes together with decreases in the ratio of polychromatic to normochromatic erythrocytes.
7. It is concluded from the results obtained that Triclosan shows no evidence of mutagenic potential when administered orally in this in vivo test procedure.

INTRODUCTION

This report describes the experiments performed between 15 March 1988 and 5 April 1988 to assess, by means of the micronucleus test (1 - 2), the mutagenic effects of Triclosan administered orally to mice. The procedures used were based on the recommendations of the OECD (7) and EEC Annex V Committee (8).

Protocol for proposed study issued
and approved by Study Director: 3 March 1988.

Protocol approved by:

HRC management: 3 March 1988.

Sponsor: 11 March 1988.

In mitotic cells in which chromosomal damage has been caused by the test compound or its metabolites, acentric fragments of the chromosomes do not separate at the anaphase stage of cell division. After telophase these fragments may not be included in the nuclei of the daughter cells and hence will form single or multiple micronuclei (Howell-Jolly bodies) in the cytoplasm of these cells. Micronuclei are seen in a wide variety of cells, but erythrocytes are chosen for examination since micronuclei are easily detected in this cell type.

A few hours after the last mitosis is completed, erythroblasts expel their nucleus. Young erythrocytes, less than 24 hours old, stain blue with Giemsa due to the presence of minute fragments of nuclear material in the cytoplasm. This material is mainly ribonucleic acid (RNA) and it gradually disappears so that more mature erythrocytes, known as normochromatic erythrocytes, stain pink with Giemsa. The young blue-staining cells are known as polychromatic erythrocytes and micronuclei are readily detected in this cell type. If scoring is restricted to these cells, virtually all the chromosome damage detected will have been caused during the recent exposure to the test agent.

Substances which interfere with the mitotic spindle apparatus will cause non-disjunction (unequal separation of the chromosomes at anaphase resulting in aneuploidy) or lagging chromosomes at anaphase which may not be incorporated into the daughter nuclei. These lagging chromosomes would then not be excluded from the erythroblast at the same time as the nucleus and would hence give rise to micronuclei.

Normochromatic erythrocytes may also be examined for the presence of micronuclei. No substantial increases in the incidence of micronuclei in normochromatic erythrocytes would usually be expected 24 hours after administration of a chromosome-damaging agent; any micronucleus-like artifacts (which could otherwise possibly give a false positive result) are therefore readily distinguishable in this cell type (4).

Any toxic effects of the test compound on the immature nucleated cells may lead either to a reduction in cell division or to cell death. These effects in turn lead to a reduction in cell numbers and to compensate for this, peripheral blood is shunted into the bone marrow (3). If the ratio of the polychromatic to the normochromatic erythrocytes is scored and found to be statistically significantly less than the control value, this is taken as being indicative of toxicity.

Mitomycin C, a known mutagen, was used as a positive control.

All slides and raw data (or exact copies thereof) together with a master copy of this report are stored in the archives of Huntingdon Research Centre Ltd., Huntingdon, England.

PROCEDURE

1. Animals

All animals in this study were Specific Pathogen Free CD-1 outbred mice of Swiss origin weighing between 22 and 24 grams and approximately 35 days old, on despatch. The animals were obtained from Charles River U.K. Limited, Margate, Kent, England on 11 March 1988 (preliminary toxicity test) and 18 March 1988 (main test).

On arrival, the weight of the animals was checked, the animals were randomly assigned to groups, and tail marked. Each group of 2 or 5 mice was kept in a plastic disposable cage and maintained in a controlled environment with 30 changes of air per hour and the thermostat set at 22°C. The room was illuminated by artificial light for 12 hours per day. All animals were allowed free access to pelleted Labsure LAD 1 rodent breeding diet and tap water. They were acclimatised for approximately four days, examined daily for signs of reaction and were weighed prior to dosing.

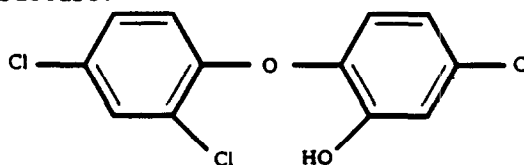
2. Test compound

Identity: Triclosan.

Chemical name: 2,4,4'-trichloro-2'-hydroxydiphenyl ether.

Chemical formula: $C_{12}H_7Cl_3O_2$.

Chemical structure:



Mol. wt 289.5

Batch number: S 15155 T01.

Purity: >99%.

Description: Off-white powder.

Storage: Room temperature in the light.

Stability: Stability of the test compound is the responsibility of the Sponsor.

Solubility: Almost insoluble in water (0.001%).

Solution/suspensions of Triclosan were prepared in 1% aqueous methylcellulose (obtained from British Celanese Ltd.) using a Silverson high-speed mixer, at the concentrations shown below.

Samples of each of the dosing solution/suspensions used were retained and returned to the Sponsor for analysis

Analysis of the dosing solution/suspensions used in the main test supported the nominal concentration. Raw data of the analysis is retained by the Sponsor (Analytical reference no. ANY 88.29).

3. Positive control compound

Mitomycin C, obtained from Sigma London Chemical Company Limited (batch number 96F-0547-1), was used as the positive control compound. It was prepared as a solution in sterile 0.9% saline at a concentration of 0.6 mg/ml.

4. Dose administration

All animals in all groups were dosed orally by intragastric gavage with the standard volume of 20 ml/kg bodyweight (9). The animals were deprived of diet overnight prior to and for two hours after oral dosing.

5. Preliminary toxicity test

Increasing dosages of Triclosan were administered, up to a maximum of 5000 mg/kg.

Twelve male and twelve female mice were used in this experiment. The experimental design is shown below:

Experimental design

Group	Material	Concentration of material in suspension/solution (mg/ml)	Dosage (mg/kg)	Number of mice	
				♂	♀
1	Vehicle control	-	0	2	2
2	Triclosan	15.625	312.5	2	2
3		31.250	625.0	2	2
4		62.500	1250.0	2	2
5		125.000	2500.0	2	2
6		250.000	5000.0	2	2

Following dosing, the animals were observed regularly during the working day for a period of 72 hours, and any mortalities or signs of malreaction during the experiment were recorded.

: 4 :

6. Micronucleus test

From the results obtained in the preliminary toxicity study, a dosage of 5000 mg per kg bodyweight was chosen for the micronucleus test. Thirty-nine male and thirty-nine female mice were used in this part of the study and the experimental design is shown below:

Experimental design

Group	Material	Concentration of material in suspension/solution (mg/ml)	Dosage (mg/kg)	Number of mice	
				♂	♀
1	Vehicle control	-	-	15	15
2	Triclosan	250.0	5000	15+4*	15+4*
3	Mitomycin C (positive control)	0.6	12	5	5

* Spare animals, dosed concurrently to replace any that might die

Following dosing the animals were examined regularly, and any mortalities or clinical signs of reaction to the test compounds were recorded. Five males and five females from the negative control and test compound groups were sacrificed 24, 48 and 72 hours after dosing. The positive control group was sacrificed 24 hours after dosing. The animals were killed by cervical dislocation and both femurs dissected out from each animal. The femurs were cleared of tissue and one epiphysis removed from each bone. A direct bone marrow smear was made onto a slide containing a drop of calf serum. One smear was made from each femur. The prepared smears were air-dried and fixed in methanol (>10 minutes) and air-dried. The smears were then stained for 10 minutes in 10% Giemsa (prepared by 1 : 9 dilution of standard Gurr's R66 Giemsa (BDH) with distilled water). Following rinsing in distilled water, the smears were differentiated in buffered distilled water (pH 6.8) for 10 minutes. After air-drying, the smears were mounted with coverslips using DPX (5).

The stained smears were examined (under code) by light microscopy to determine the incidence of micronucleated cells per 1000 polychromatic erythrocytes per animal. The ratio of polychromatic to normochromatic erythrocytes for each animal was assessed by examination of at least 1000 erythrocytes. A record of the number of micronucleated normochromatic erythrocytes was also kept as recommended by Schmid (4).

RESULTS

1. Preliminary toxicity test

Mortality data are presented in Appendix 1.

The details of any toxic reactions observed are given in Appendix 2.

From the results of the preliminary toxicity test, a dose of 5000 mg/kg was chosen for the micronucleus test - this is the maximum recommended amount of test substance to be used in acute toxicity testing (9).

2. Micronucleus test

The results of the micronucleus test on Triclosan at the 24, 48 and 72 hour kill times are presented in Tables 2, 3 and 4 respectively. Table 1 gives a summary of the results and the results of statistical analysis. Appendix 4 summarises the vehicle control micronucleated polychromatic erythrocyte counts obtained in previous, unrelated experiments.

(a) Signs and mortalities

No animals died after treatment with Triclosan in the main study. Clinical signs are detailed in Appendix 3.

(b) Micronucleated polychromatic erythrocyte counts (mnp)

Triclosan did not cause any statistically significant increases in the number of micronucleated polychromatic erythrocytes at any of the three kill times - ($P > 0.05$ using Wilcoxon's sum of ranks test (6)).

Mitomycin C caused large, highly significant increases ($P < 0.001$) in the frequency of micronucleated polychromatic erythrocytes.

(c) Micronucleated normochromatic erythrocytes (mnn)

Triclosan did not cause any substantial increases in the incidence of micronucleated normochromatic erythrocytes at any of the three kill times.

(d) Ratio of polychromatic to normochromatic erythrocytes (p/n)

At the 24 hour and 48 hour sampling times, small but statistically significant decreases in the ratios of polychromatic to normochromatic erythrocytes were observed - $P < 0.05$ using Wilcoxon's sum of ranks test (6). No such decreases in the p/n ratio were observed at the 72 hour sampling time. These decreases in the p/n ratio may be indicative of slight bone marrow cell toxicity.

Mitomycin C also caused a statistically significant decrease in the p/n ratio ($P < 0.05$), indicating slight bone marrow cell toxicity.

CONCLUSION

From the results obtained it is concluded that Triclosan shows no evidence of mutagenic potential when administered orally in this in vivo test procedure.

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TABLE 1

Summary of results - group totals/means for the entire
experiment and results of statistical analysis

Kill	Compound & dosage	Ratio p/n		Incidence mnp		Incidence mnn
		Mean	P	Mean o/oo	P	Total o/oo
24 hour	Vehicle control	0.987	-	0.7	-	0.2
	Triclosan (5000 mg/kg)	0.736	0.032	0.5	0.515	0.2
	Mitomycin C (12 mg/kg)	0.624	0.014	58.6	<0.001	0.5
48 hour	Vehicle control	1.110	-	0.6	-	0.2
	Triclosan (5000 mg/kg)	0.660	0.022	0.2	0.860	0.0
72 hour	Vehicle control	1.126	-	0.8	-	0.2
	Triclosan (5000 mg/kg)	1.485	0.962	0.0	0.938	0.2

P Result of statistical analysis using Wilcoxon's sum of ranks
test (1-sided probabilities)
p/n Ratio of polychromatic to normochromatic erythrocytes
mnp Number of micronucleated polychromatic erythrocytes observed
mnn Number of micronucleated normochromatic erythrocytes observed
o/oo Number per thousand cells

TABLE 2

Incidence of micronucleated erythrocytes and the ratio of polychromatic to normochromatic erythrocytes - 24 hour kill

Test substance	Dosage (mg/kg)	Animal number and sex	Ratio p/n	mnp	n	mnn
Vehicle control	-	201♂	1.196	3	460	0
		202♂	0.616	1	646	0
		203♂	1.266	0	448	0
		204♂	1.484	0	417	1
		205♂	1.246	0	447	0
		206♀	1.053	0	506	0
		207♀	0.657	0	616	0
		208♀	1.080	1	497	0
		209♀	0.730	0	588	0
		210♀	0.544	2	649	0
Triclosan	5000	211♂	0.650	0	629	0
		212♂	0.491	0	682	0
		213♂	1.985	1	341	0
		214♂	0.728	1	604	0
		215♂	0.659	1	610	0
		216♀	0.643	1	644	0
		217♀	0.732	0	586	0
		218♀	0.433	1	699	1
		219♀	0.443	0	697	0
		220♀	0.594	0	682	0
Mitomycin C	12	221♂	0.599	68	643	0
		222♂	0.670	48	643	0
		223♂	0.959	75	531	1
		224♂	0.786	84	565	1
		225♂	0.809	60	556	1
		226♀	0.358	43	752	0
		227♀	0.561	52	668	0
		228♀	0.213	57	832	0
		229♀	0.742	57	590	0
		230♀	0.543	42	668	0

p/n Ratio of polychromatic to normochromatic erythrocytes
mnp Number of micronucleated polychromatic erythrocytes observed
n Total number of normochromatic erythrocytes examined for micronuclei
mnn Number of micronucleated normochromatic erythrocytes observed

TABLE 3

Incidence of micronucleated erythrocytes and the ratio of polychromatic to normochromatic erythrocytes - 48 hour kill

Test substance	Dosage (mg/kg)	Animal number and sex	Ratio p/n	mnp	n	mnn
Vehicle control	-	301♂	0.987	0	520	1
		302♂	1.350	0	437	0
		303♂	1.705	0	370	0
		304♂	1.569	1	408	0
		305♂	1.316	0	433	0
		306♀	0.404	0	727	0
		307♀	1.416	2	418	0
		308♀	0.968	0	527	0
		309♀	0.504	2	681	0
		310♀	0.880	1	549	0
Triclosan	5000	311♂	0.414	0	718	0
		312♂	1.014	0	503	0
		313♂	0.802	0	565	0
		314♂	0.425	0	751	0
		315♂	0.580	0	647	0
		316♀	1.018	0	500	0
		317♀	0.640	0	625	0
		318♀	0.662	0	603	0
		319♀	0.432	0	757	0
		320♀	0.610	2	644	0

p/n Ratio of polychromatic to normochromatic erythrocytes
mnp Number of micronucleated polychromatic erythrocytes observed
n Total number of normochromatic erythrocytes examined for micronuclei
mnn Number of micronucleated normochromatic erythrocytes observed

TABLE 4

Incidence of micronucleated erythrocytes and the ratio of polychromatic to normochromatic erythrocytes - 72 hour kill

Test substance	Dosage (mg/kg)	Animal number and sex	Ratio p/n	mnp	n	mnn
Vehicle control	-	401♂	0.781	4	566	1
		402♂	1.404	0	446	0
		403♂	1.255	1	455	0
		404♂	0.803	2	563	0
		405♂	1.475	1	415	0
		406♀	1.311	0	450	0
		407♀	0.632	0	625	0
		408♀	1.894	0	350	0
		409♀	0.605	0	636	0
		410♀	1.097	0	484	0
Triclosan	5000	411♂	1.856	0	353	0
		412♂	1.539	0	401	0
		413♂	0.729	0	582	0
		414♂	1.280	0	450	0
		415♂	1.808	0	359	0
		416♀	1.537	0	397	0
		417♀	1.457	0	409	0
		418♀	1.093	0	496	0
		419♀	1.351	0	430	1
		420♀	2.200	0	325	0

p/n Ratio of polychromatic to normochromatic erythrocytes
 p Total number of polychromatic erythrocytes examined for micronuclei
 mnp Number of micronucleated polychromatic erythrocytes observed
 n Total number of normochromatic erythrocytes examined for micronuclei
 mnn Number of micronucleated normochromatic erythrocytes observed

APPENDIX 1

Preliminary toxicity test - mortality data

Group	Material	Dosage (mg/kg)	Mortality ratio (No. of deaths) (No. dosed)		
			♂	♀	Combined
1	Vehicle	-	0/2	0/2	0/4
2 }	Triclosan	312.5	0/2	0/2	0/4
3 }		625.0	0/2	0/2	0/4
4 }		1250.0	0/2	0/2	0/4
5 }		2500.0	0/2	0/2	0/4
6 }		5000.0	1/2	0/2	1/4

APPENDIX 2
Clinical signs
Preliminary toxicity study

Treatment	Vehicle		Triclosan									
Dosage (mg/kg)	-		312.5		625		1250		2500		5000	
Approximate time after dosing (hr : min)	♂	♀	♂	♀	♂	♀	♂	♀	♂	♀	♂	♀
: 30	0	0	0	0	0	0	0	0	0	0	0	0
1 : 00	0	0	0	0	1A, 2A	1A, 2A	1A, 2A	1A, 2A	1A, 2A	1A, 2A	1A, 2A	1A, 2A
2 : 00	0	0	1A, 2A	1A, 2A	1A, 2A	1A, 2A	1A, 2A	1A, 2A	1A, 2A	1A, 2A,	1A, 2A,	1A, 2A,
									3A, 6A	3A, 6A	3A, 6A	3A, 6A
3 : 00	0	0	0	0	1A, 2A	1A, 2A	1A, 2A	1A, 2A	1A, 2A	1A, 2A	1A, 2A	1A, 2A
4 : 00	0	0	0	0	0	0	0	0	0	0	0	0
5 : 00	0	0	0	0	0	0	0	0	0	0	0	0
6 : 00	0	0	0	0	0	0	0	0	0	0	0	0
22 : 00	0	0	0	0	0	0	0	0	0	0	0	0
24 : 00	0	0	0	0	0	0	0	0	0	0	0	0
30 : 30	0	0	0	0	0	0	0	0	0	0	0	0
46 : 00	0	0	0	0	0	0	0	0	0	0	0	0
											1A, 2A,	
48 : 00	0	0	0	0	0	0	0	0	0	0	3A	0
											1A, 2A,	
54 : 30	0	0	0	0	0	0	0	0	0	0	3A	0
70 : 30	0	0	0	0	0	0	0	0	0	0	1A, 2A	0
72 : 00	0	0	0	0	0	0	0	0	0	0	1A, 2A	0

Degree of reaction: 0 no reaction, A slight, (x) dead, where x is the number found dead
Type of reaction: 1 pilo-erection, 2 hunched posture, 3 waddling, 6 ptosis

APPENDIX 3
Clinical signs
Main test

Treatment	Vehicle		Triclosan		mitomycin C	
Dosage (mg/kg)	-		5000		12	
Approximate time after dosing (hr : min)	♂	♀	♂	♀	♂	♀
: 15	0	0	1A, 2A	1A, 2A	0	0
: 30	0	0	1A, 2A	1A, 2A	0	0
1 : 00	0	0	1A, 2A	1A, 2A	0	0
2 : 00	0	0	1A, 2A	1A, 2A	0	0
3 : 00	0	0	1A, 2A	1A, 2A	0	0
4 : 00	0	0	(■1A, 2A, 9A) 0	(•1A, 2A) 0	0	0
5 : 00	0	0	(■1A, 2A, 9A) 0	(•1A, 2A) 0	0	0
6 : 00	0	0	(■1A, 2A) 0	0	0	0
22 : 00	0	0	0	0	0	0
24 : 00	0	0	0	0	0	0
30 : 00	0	0	0	0		
46 : 00	0	0	0	0		
48 : 00	0	0	0	0		
54 : 00	0	0	0	0		
70 : 00	0	0	0	0		
72 : 00	0	0	0	0		

Degree of reaction: 0 no reaction, A slight
 Type of reaction: 1 pilo-erection, 2 hunched posture, 9 diarrhoea
 ■ One animal only
 • Two animals only

APPENDIX 4

Mouse micronucleus test - historical control values

This summary presents a cumulative total of results for vehicle control animals used in previous, unrelated experiments during the period March 1980 to April 1988.

Cumulative results for 4061 animals

mnp	0	1	2	3	4	5	6	7	>7
Frequency	1685	1552	592	174	42	8	5	3	0

mnp The incidence of micronucleated cells
 per thousand polychromatic erythrocytes
Frequency The number of times that the result has
 been obtained

The individual animal mean mnp is 0.87 and the group means range from 0.1 to 2.5 for experiments with ten animals in the control group.

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OTC Vol. No. 105

OTC Docket Number 75N-0183 (triclosan)
September 12, 1994

Ciba-Geigy Corporation
Chemicals Division
Greensboro, N.C. 27419

Henderson, L.M., Ransome, S.J., Brabbs, C.E., Tinner, A.J., Davies, S.E. and Loyd, A. An Assessment of the Mutagenic Potential of Triclosan Using the Mouse Lymphoma TK Locus Assay. Environmental Safety Laboratory, Unilever Research Lab., Colworth House. Study No. KM 880170. September 15, 1988.

Study Summary

Triclosan was tested for mutagenic potential in an in vitro mammalian cell mutation assay. This test system is based on detection and quantitation of forward mutation in a subline of mouse lymphoma L5178Y cells, from the heterozygous condition at the thymidine kinase locus (TK +/-) to the thymidine kinase deficient genotype (TK -/-). Two independent tests in the absence of exogenous metabolic activation and two independent tests in the presence of S-9 mix were carried out.

Mouse lymphoma L5178Y cells were treated with Triclosan up to the concentration expected to induce cell survival of 10% relative to the controls. Thus the highest concentration assessed for mutant induction in the absence of S-9 mix was 20 µg/ml (Test 1) and 15 µg/ml (Test 2) and the presence of S-9 mix was 15 µg/ml in both tests.

Treatment with Triclosan failed to induce increases in mutant frequency, which would be indicative of a positive response, in any of the tests either in the absence or the presence of S-9 mix.

It is concluded that Triclosan does not demonstrate mutagenic potential in this in vitro test system.

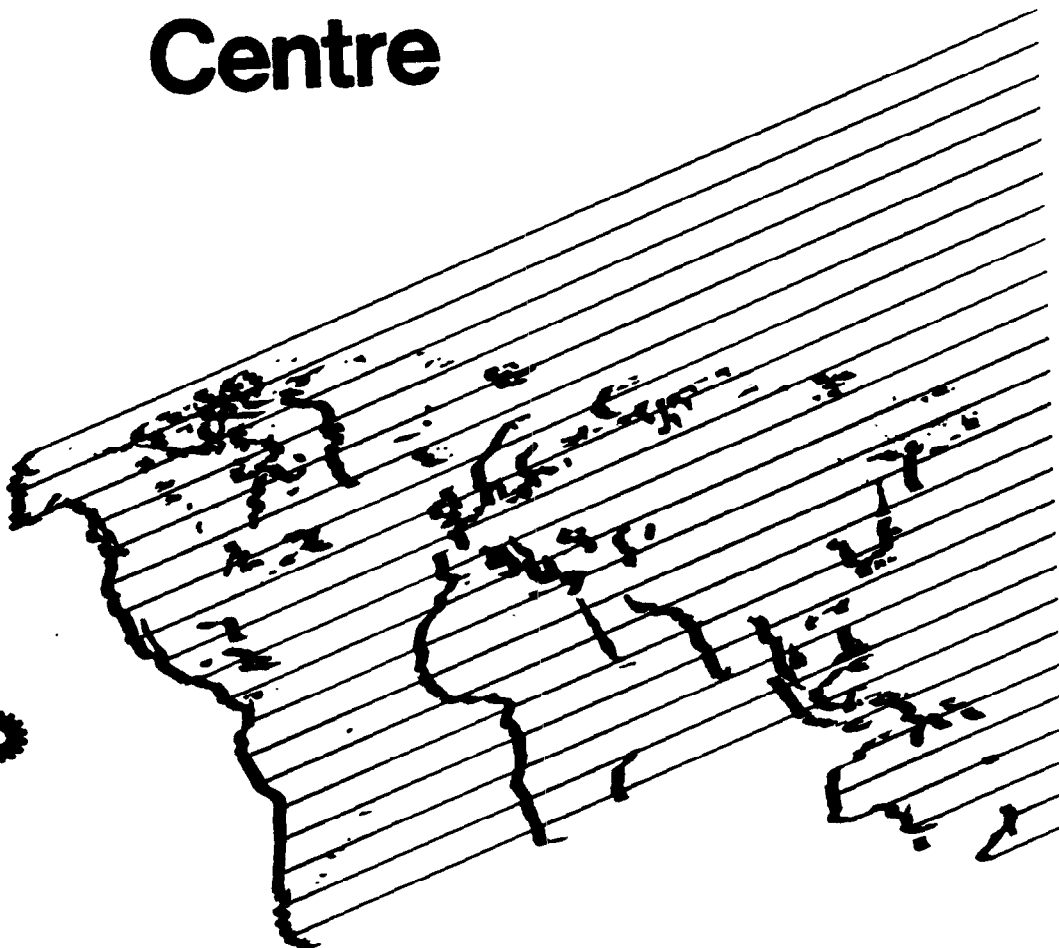
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HRC Report

TRICLOSAN

AN ASSESSMENT OF THE MUTAGENIC
POTENTIAL USING THE MOUSE
LYMPHOMA TK LOCUS ASSAY

Huntingdon Research Centre



AN ASSESSMENT OF THE MUTAGENIC
POTENTIAL OF
TRICLOSAN
USING THE MOUSE LYMPHOMA
TK LOCUS ASSAY

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COMPLIANCE WITH GOOD LABORATORY PRACTICE STANDARDS

To the best of my knowledge and belief the study described in this report was conducted in compliance with the following Good Laboratory Practice Standards:

United States Food and Drug Administration
Title 21 Code of Federal Regulations Part 58
Federal Register 22 December 1978 and subsequent Amendments

Japan Ministry of Health and Welfare
Notification No. 313 Pharmaceutical Affairs Bureau
31 March 1982

Organization for Economic Co-operation and Development
ISBN 92-64-12367-9, Paris 1982

Environmental Protection Agency Toxic Substances Control: Good Laboratory Practice Regulations:
40 CFR Part 792 Federal Register Vol 48 No. 230 pp 53922, 1983

Good Laboratory Practice, The United Kingdom Compliance
Programme, Department of Health & Social Security 1986



Leigh M. Henderson, B.Sc., Ph.D.,
Study Director

15.9.88
Date

QUALITY ASSURANCE STATEMENT

Certain studies of short duration, such as that described in this report, are conducted at HRC in a setting which involves frequent repetition of similar or identical procedures. At or about the time the study described in this report was in progress, 'process-based' inspections were made by the Quality Assurance Department of critical procedures relevant to this study type. For the inspection of any given procedure, at least one study was selected without bias. The findings of these inspections were reported promptly to the Study Director and to HRC management.

This report has been audited by the HRC Quality Assurance Department. It is considered to be an accurate presentation of the procedures and practices employed during the course of the study and an accurate presentation of the findings.


Peter H.C.V. Richold, B.Sc.,
Systems Compliance Auditor

14.9.88
Date

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SUMMARY

1. Triclosan was tested for mutagenic potential in an in vitro mammalian cell mutation assay. This test system is based on detection and quantitation of forward mutation in a subline of mouse lymphoma L5178Y cells, from the heterozygous condition at the thymidine kinase locus (TK⁺/.) to the thymidine kinase deficient genotype (TK⁻/.). Two independent tests in the absence of exogenous metabolic activation and two independent tests in the presence of S-9 mix were carried out.
2. Mouse lymphoma L5178Y cells were treated with Triclosan up to the concentration expected to induce cell survival of 10% relative to the controls. Thus the highest concentration assessed for mutant induction in the absence of S-9 mix was 20 µg/ml (Test 1) and 15 µg/ml (Test 2) and the presence of S-9 mix was 15 µg/ml in both tests.
3. Treatment with Triclosan failed to induce increases in mutant frequency, which would be indicative of a positive response, in any of the tests either in the absence or the presence of S-9 mix.
4. It is concluded that Triclosan does not demonstrate mutagenic potential in this in vitro test system.

INTRODUCTION

The compound Triclosan was tested for potential mutagenicity in the mouse lymphoma L5178Y cell mutation test (Clive & Spector 1975). In this in vitro system it is possible to detect and quantify forward mutation from a wild type cell, which is heterozygous at the thymidine kinase locus (TK ⁺/.), to the homozygous thymidine kinase deficient form (TK ⁻/.). The agent used to select for the mutant phenotype is the thymidine analogue trifluorothymidine (TFT); TK ⁻/.. mutants, unlike the TK ⁺/.. form, are resistant to the otherwise lethal effects of TFT. The experimental methods employed are based on those published by Clive & Spector (1975) and Amacher et al. (1979; 1980a; 1980b).

MATERIALS AND METHODS

Cells

Mouse lymphoma L5178Y cells (3.7.2c) were obtained from Dr. J. Cole, Sussex University. These cells are heterozygous at the thymidine kinase locus (TK $\frac{+}{-}$). They were maintained routinely as suspensions in roller culture, and grew with a population doubling time of approximately 12 hours. Cells were stored in polypropylene ampoules in a freezing mixture consisting of heat-inactivated horse serum (Imperial Laboratories) containing 10% dimethylsulphoxide (DMSO), at -196°C . All cells used in these tests were taken from the same frozen batch.

Spontaneous TK $\frac{+}{-}$ mutants were eliminated from the cultures by a 24 hour incubation in the presence of methotrexate ($0.3\text{ }\mu\text{g/ml}$), thymidine ($9\text{ }\mu\text{g/ml}$), hypoxanthine ($15\text{ }\mu\text{g/ml}$) and glycine ($22.5\text{ }\mu\text{g/ml}$) followed by 24 hours incubation in similar medium without methotrexate, two days prior to storage at -196°C .

Media

The culture medium was RPMI 1640; 10 x concentrated stock solutions were obtained from Imperial Laboratories. Single strength medium was supplemented with sodium pyruvate, $110\text{ }\mu\text{g/ml}$, pluronic F68, 1 mg/ml and gentamicin, $50\text{ }\mu\text{g/ml}$. The concentration of sodium bicarbonate, 2 mg/ml , allowed equilibration with a gas phase of 5% CO_2 in air. The medium used for suspension culture, R10P, contained 10% heat-inactivated horse serum (Imperial Laboratories) pre-screened for optimal growth promotion. Cloning medium consisted of R20P medium, in which the serum content had been increased to 20% and the pluronic content reduced to 0.2 mg/ml , containing 0.36% Noble agar (Difco). Noble agar was prepared from dry powder on the day of the test as a 4% solution in normal saline. Selective medium consisted of cloning medium containing $4\text{ }\mu\text{g}$ trifluorothymidine (TFT)/ml (Sigma London Chemical Co. Ltd). Stock solutions of TFT, at a concentration of 0.4 mg/ml in normal saline, were prepared under subdued lighting as TFT is light sensitive, filter sterilised and stored frozen until required.

The medium used during the exposure of the cells to the test compound consisted of hepes-buffered RPMI 1640 (Dutch Modification), denoted R_0 , and was obtained as a single strength solution from Imperial Laboratories. Pluronic F68 and sodium pyruvate were not added. R_0 containing 5% heat-inactivated horse serum is subsequently referred to as R_s .

Preparation of S-9 mix

1. Liver fraction

Specific Pathogen Free CD rats of the Sprague-Dawley strain weighing 180-220 g and six to eight weeks of age were obtained from Charles River U.K. Ltd., Margate, Kent, England. Following acclimatisation for one week, each animal was injected intraperitoneally with Aroclor 1254 diluted in Arachis oil to a concentration of 200 mg/ml, at a dosage of 500 mg/kg bodyweight, to induce microsomal enzyme activity. The animals were killed by cervical dislocation 5 days after being injected and following a 16 hour fast. Under aseptic conditions the livers were removed, weighed and placed in 250 mM sucrose solution, before being transferred to an IKA Ultra Turrax homogeniser. The ratio of liver to sucrose solution was 1 : 3, weight : volume. Following preparation, the homogenates were centrifuged at 9000 g for 10 minutes. The supernatant fraction, S-9, was dispensed into aliquots and stored at -80°C until required.

2. Cofactor mix

Isocitric acid (trisodium salt, trihydrate obtained from Sigma London Chemical Co. Ltd.) at a concentration of 15 mg/ml and NADP (obtained from Koch-Light) at a concentration of 8 mg/ml were dissolved in ice cold R₀, and rapidly neutralised with 1N sodium hydroxide solution before being filter sterilised. Immediately before use this cofactor solution was mixed with liver S-9 and cold R₀ in a 3 : 1 : 16 v/v ratio; the resultant S-9 mix was kept on ice whilst being dispensed.

Test compound

Triclosan was received as an off-white powder, Unilever sample number S15155 T01 and was stored at room temperature. Purity of this batch of Triclosan was given as >99% by the Sponsor. Solubility of Triclosan in dimethylsulphoxide (DMSO) was 500 mg/ml but solubility in the culture medium was found to be between 100 and 200 µg/ml. Stability data on Triclosan in DMSO were not provided by the Sponsor but the solutions were used within 1 hour of preparation. Information on the expiry date of Triclosan was given as greater than 1 year by the Sponsor and all tests were carried out prior to this time.

Triclosan was dissolved and diluted in dimethylsulphoxide (DMSO) on the morning of the test. The final concentration of DMSO in the cultures was 1% v/v.

The dosing solutions were returned to the Sponsor for analysis of achieved concentration.

The final concentrations ($\mu\text{g/ml}$) were as follows:

Preliminary toxicity test: 1, 5, 10, 25, 50, 100, 200, 250

Mutation tests: -S-9 mix	Test 1	1	2.5	5	7.5	10	15	20	25
	Test 2	1	2.5	5	7.5	10	15	20	

Mutation tests: +S-9 mix	Test 1	0.5	1	2	3.5	5	7.5	10	15
	Test 2	1	2.5	5	7.5	10	15	20	

Positive controls

The positive control compound for the tests carried out in the absence of S-9 mix was ethyl methane sulphonate (EMS) (Sigma London Chemical Co. Ltd. Batch No. 95F-0226). EMS was dissolved in DMSO and used at a final concentration of 500 $\mu\text{g/ml}$.

In the presence of metabolic activation the positive control was 20-methylcholanthrene (20-MC) (Sigma London Chemical Co. Ltd. Batch No. 70F-0306) at a final concentration of 2.5 $\mu\text{g/ml}$; the solvent was DMSO.

Preliminary toxicity test

A suspension of cells was prepared in a 50 : 50 mixture of conditioned medium (obtained by the removal of cells from an exponentially growing culture by centrifugation) and R₁ at a cell population density of $1 \times 10^6/\text{ml}$. This culture was rolled at 37°C whilst the compound dilutions and S-9 mix were prepared.

3 ml aliquots of cell suspension were dispensed into universal containers, followed by 2 ml R₀ or S-9 mix. 50 μl of compound solution or DMSO in the case of the controls were then added. Two cultures per dose level were prepared, one with and one without S-9 mix.

The universal containers were placed on the roller apparatus at 37°C for 3 hours. After incubation, the cells were washed once with R10P, the contents of each container transferred to a pre-gassed (5% CO₂ : 95% air) Corning roller bottle containing 30 ml growth medium, and placed on the roller apparatus. Cell population growth was monitored at 24 and 48 hours after treatment by counting the cells using a Coulter electronic particle counter, Model ZM.

Mutation test

The mutation test was carried out as described for the preliminary toxicity test with the following modifications. 200 µl aliquots of the solvent control, test compound or positive controls were added to 50 ml Corning centrifuge tubes after 12 ml of cell suspension and 8 ml of R₀ or S-9 mix. After the test incubation the cells were washed once with R10P. The contents of each centrifuge tube were transferred to a pre-gassed Corning plastic roller bottle containing 60 ml growth medium, R10P. Two cell cultures were treated for each dose level. The compound was tested for mutagenic potential in the presence and absence of S-9 mix in separate assays.

In each assay at least five concentrations of the test substance were originally chosen to constitute the treatment groups. After growth in suspension had been monitored for a 48 hour period following treatment the most appropriate treatment groups were chosen for subsequent cloning in agar and assessment of mutant colony numbers. The 48 hour period allows for expression of induced mutation.

24 hours after treatment, 1 ml samples were removed from each culture, counted on the Coulter counter, and the cell suspensions diluted with R10P to restore the cell population density to 2×10^5 cells/ml.

48 hours after treatment the cells were cloned in soft agar to permit measurement of levels of viability and induced mutation. From each culture a total of 600 cells were plated in cloning medium for estimation of viability (200 cells/90 mm petri dish) and a total of 3×10^6 cells in selective medium for quantitation of mutation (10^6 cells/90 mm petri dish). The stock solution of TFT was thawed in the dark, and the TFT incorporated into the selective medium under subdued lighting immediately before the plates were dispensed. Cell suspensions were pipetted into the petri dishes using disposable 25 ml pipettes. The plates were allowed to gel at room temperature, before being incubated at 37°C in a humidified atmosphere of 5% CO₂ in air. For each of the negative control cultures two determinations of mutation and viability were made by performing independent dilutions. After 12 days incubation, colonies with diameter greater than 200 µm were counted using an electronic colony counter (Biotran Mark III, New Brunswick Scientific Co. Inc.).

Assessment of results

Growth in suspension was calculated as follows:

$$\frac{\text{Cell count 24 hours post treatment}}{2^{**} \times 10^5} \times \frac{\text{Cell count 48 hours post treatment}}{2^* \times 10^5}$$

* or previous day's cell count if less than 2×10^5 /ml

** or 1×10^5 in the preliminary toxicity test calculations

Cell survival was defined as:

$$\frac{\text{Suspension growth (\% Control)} \times \text{Viability in agar (\% Control)}}{100}$$

Mutant frequency was defined as the number of mutant colonies/10⁶ viable cells and calculated as follows:

$$\frac{600}{\text{Total number of viable colonies}} \times \frac{\text{Total number of mutant colonies}}{3}$$

The general method of statistical analysis was by analysis of variance of the mutant frequencies. This was carried out after the data had been transformed by natural log transformation since Irr and Snee (1982) have shown that the random variation in results from the L5178Y cell TK locus mutation assay can be adequately described by a lognormal distribution. The difference between each treated group and the control mutant frequency was tested for significance by a one sided t-test.

The criteria which must be satisfied before a positive response may be claimed are:

1. The induction of at least a two-fold increase in mutant frequency relative to the concurrent control by the test agent.
2. The demonstration of a statistically significant response.
3. Evidence of a dose-related response.
4. The response must be reproducible.

The experiments were carried out from 21 March 1988 to 11 May 1988 at Huntingdon Research Centre Ltd.

Date of Protocol issue: 3 March 1988.

Date of Protocol approval by Study Director: 3 March 1988.

Date of Protocol approval by HRC Management: 3 March 1988.

Date of Protocol approval by Sponsor: 11 March 1988.

Storage of data

The raw data on the analysis of achieved concentration is held by the Sponsor (Sponsor's analytical reference no. ANY 88.30).

All other raw data together with a master copy of this final report are located in the Archives at the Huntingdon Research Centre Ltd., Huntingdon, England.

RESULTS AND CONCLUSION

Triclosan was tested for mutagenic potential in the *in vitro* mouse lymphoma thymidine kinase locus assay. Four independent assays were carried out, two in the absence of exogenous metabolic activation and two in the presence of S-9 mix.

In the preliminary toxicity test, treatment with 1 - 100 µg Triclosan/ml induced relative growth in suspension of 109 - 2% in the absence of S-9 mix and 86 - 2% in the presence of S-9 mix. The 10% survival level was expected to be induced between 10 and 25 µg Triclosan/ml both in the absence and the presence of S-9 mix and the concentrations used in the main tests were based on this data.

Measurements of osmolality were made on the supernatants from the two highest concentrations (50 µg/ml and 100 µg/ml) and two control treatments in the preliminary toxicity test (Appendix 1). No significant differences were seen between the treated cultures and the control cultures.

Tables 1 - 6 and Figures 1 and 2 show the data obtained from the tests in the absence of S-9 mix. Cytotoxicity was induced in the absence of S-9 mix after treatment with 1 - 25 µg Triclosan/ml in test 1 and 1 - 20 µg/ml in test 2. Cultures treated with 1 and 2.5 µg/ml in test 1 and 1 µg/ml in test 2 were discarded in favour of cultures treated with higher concentrations of Triclosan. Cultures treated with 25 µg/ml in test 1 and 20 µg/ml in test 2 were discarded due to excess toxicity (Tables 1 and 4). The cells from the remaining cultures were expressed for viability and induced mutation. Cell survival levels of 87 - 8% in test 1 and 100 - 9% in test 2, relative to the controls, were induced after treatment with 5 - 20 µg/ml and 2.5 - 15 µg/ml, respectively. There was a two-fold increase in mutant frequency at the top dose level only (15 µg/ml in the second test) but in these cultures the relative survival was less than 10%. Therefore the criteria for determining a positive response were not fully satisfied. EMS, the positive control, induced highly significant increases in mutant frequency in both tests (Tables 2, 3, 5 and 6).

Tables 7 - 12 and Figures 3 and 4 show the data obtained from the tests in the presence of S-9 mix. Treatment with Triclosan induced cytotoxicity in the presence of S-9 mix at concentrations of 0.5 - 15 µg/ml in test 1 and 1 - 20 µg/ml in test 2. Cultures treated with 0.5, 1 and 2 µg/ml were discarded in test 1 in favour of cultures treated with higher concentrations of compound and cultures treated with 20 µg/ml in test 2 were discarded due to excess toxicity. Cultures treated with 5 µg/ml in test 1 and 2.5 µg/ml in test 2 were discarded in favour of cultures with approximately 100% relative growth in suspension. The cell survival from the remaining cultures was 64 - 19% in test 1 and 88 - 7% in test 2, relative to the controls. In both tests a dose response to Triclosan was observed but the mutant frequency of the treated cultures was less than two-fold background where the relative survival exceeded 10%. Therefore the criteria for a positive response were not fulfilled. 20-Methylcholanthrene, the positive control, induced highly significant increases in mutant frequency in both tests.

The analysis of achieved concentration of the dosing solutions carried out by the Sponsor verified the nominal concentrations (data held by Sponsor).

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KM 880170

CONCLUSION

It is concluded that Triclosan does not demonstrate mutagenic potential in this in vitro mammalian cell mutation assay.

REFERENCES

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TABLE 1

Growth in suspension of L5178Y cells after treatment with
Triclosan in the absence of S-9 mix

(Test 1)

Concentration of Triclosan ($\mu\text{g/ml}$)	Cells/ml $\times 10^{-5}$		Suspension growth	% Control	Mean % control
	24 hours	48 hours			
0 (DMSO control)	5.18 5.36	6.71 6.12	8.69 8.20	8.45	100
1.0+	5.20 5.04	8.03 8.24	10.44 10.38	124 123	124
2.5+	4.68 4.73	6.96 8.20	8.14 9.70	96 115	106
5.0	4.14 4.03	8.14 8.61	8.42 8.67	100 103	102
7.5	2.80 3.28	9.34 8.94	6.54 7.33	77 87	82
10.0	2.61 2.76	9.65 7.82	6.30 5.40	75 64	70
15.0	0.82 0.57	4.61 2.65	2.31 1.33	27 16	22
20.0	0.33 0.35	1.77 1.47	0.89 0.74	11 9	10
25.0++	0.26 0.28	1.04 1.09	0.52 0.55	6 7	7
EMS (500 $\mu\text{g/ml}$)	3.54 3.66	6.59 8.32	5.83 7.61	69 90	80

+ Cultures discarded in favour of cultures treated with higher concentrations of compound

++ Cultures discarded due to excess toxicity

TABLE 2

Viability and mutation of L5178Y cells in soft agar culture after treatment with Triclosan
in the absence of S-9 mix

(Test 1)

Concentration of Triclosan (µg/ml)	No. of colonies on non-selective plates					Survival (% control)	Mean % survival	No. of colonies on selective plates				Mutant frequency (x 10 ⁻⁶)*		Mean mutant frequency (x 10 ⁻⁶)
	Plate no.			Total	Viability (% control)			Plate no.			Total			
	1	2	3					1	2	3				
0 (DMSO control)	167	175	198	540	596	100	100	100	40	39	31	110	41	43
	220	186	198	604					33	53	48	134	44	
	223	203	214	640					46	49	61	156	49	
	200	199	C	399(599)					51	56	55	162	54	
5.0	176	171	148	495	83	83	87	46	34	45	125	51	56	
	168	195	163	526				88	91	44	52	62		158
7.5	177	172	166	515	86	66	67	39	30	44	113	44	44	
	149	150	168	467				78	68	31	34	38		103
10.0	163	173	178	514	86	65	69	41	56	51	148	58	57	
	198	263	205	666				112	72	60	70	58		188
15.0	164	171	168	503	84	23	19	40	46	38	124	49	52	
	172	159	193	524				88	14	45	51	49		145
20.0	149	164	158	471	79	9	8	42	45	51	138	59	81	
	134	129	120	383				64	6	73	62	61		196
EMS (500 µg/ml)	175	190	159	524	88	61	63	292	352	364	1008	385	422	
	124	156	144	424				71	64	314	331	329		974

* Where replicate determinations of mutant frequency from a single culture were made, the mean mutant frequency for that culture is shown

C Contaminated

() Figure in brackets is adjustment made for contaminated plates and is used in all calculations.
The adjustment is calculated using:

$$\begin{aligned}
 & \frac{\text{No. of colonies counted}}{\text{No. of uncontaminated plates counted}} \times \text{No. of plates seeded} \\
 \text{Survival (\% control)} &= \frac{\text{Suspension growth (\% control)} \times \text{viability in agar (\% control)}}{100} \\
 \text{Mutant frequency (per } 10^6 \text{ viable cells)} &= \left(\frac{600}{\text{Total no. of colonies on non-selective plates}} \right) \times \left(\frac{\text{Total no. of colonies on selective plates}}{3} \right)
 \end{aligned}$$

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TABLE 3

Statistical analysis of data from test carried out in the
absence of S-9 mix

(Test 1)

Concentration of Triclosan ($\mu\text{g/ml}$)	Back-transformed mean mutant frequency	Significance levels compared to solvent control
0 (DMSO control)	47.276	
5.0	55.313	NS
7.5	43.992	NS
10.0	56.997	NS
15.0	51.935	NS
20.0	77.556	5%
EMS (500 $\mu\text{g/ml}$)	420.313	0.1%

NS Non-significant

TABLE 4

Growth in suspension of L5178Y cells after treatment with
Triclosan in the absence of S-9 mix

(Test 2)

Concentration of Triclosan ($\mu\text{g/ml}$)	Cells/ml $\times 10^{-5}$		Suspension growth	% Control	Mean % control
	24 hours	48 hours			
0 (DMSO control)	5.56 5.57	8.02 8.15	11.15 11.35	11.25	100
1.0+	5.89 5.64	7.90 8.23	11.63 11.60	103 103	103
2.5	5.30 5.34	8.97 8.88	11.89 11.85	106 105	106
5.0	4.70 4.18	8.64 8.51	10.15 8.89	90 79	85
7.5	2.87 3.35	9.17 8.80	6.58 7.37	58 66	62
10.0	1.56 2.33	8.59 10.12	4.30 5.89	38 52	45
15.0	0.36 0.45	1.92 2.25	0.96 1.13	9 10	10
20.0++	0.23 0.31	0.92 1.13	0.46 0.57	4 5	5
EMS (500 $\mu\text{g/ml}$)	4.37 5.10	9.33 7.81	10.19 9.96	91 89	90

- + Cultures discarded in favour of cultures treated with higher concentrations of compound
++ Cultures discarded due to excess toxicity

TABLE 5

Viability and mutation of L5178Y cells in soft agar culture after treatment with Triclosan
in the absence of S-9 mix

(Test 2)

Concentration of Triclosan (µg/ml)	No. of colonies on non-selective plates					Survival (% control)	Mean % survival	No. of colonies on selective plates				Mutant frequency (x 10 ⁻⁶)*	Mean mutant frequency (x 10 ⁻⁶)							
	Plate no.			Total	Viability (% control)			Plate no.			Total									
	1	2	3					1	2	3										
0 (DMSO control)	195 137	156 152	165 147	516 436	479	100	100	100	28 34	38 36	37 26	103 96	40 44	42	43					
	134 144	168 179	176 162	478 485					37 33	45 28	30 31	112 92	47 38			43				
2.5	167 146	148 143	151 153	466 442					97 92	103 97	100	34 34	32 39				46 39	112 112	48 51	50
5.0	148 162	168 158	159 C	475 320 (480)					99 100	89 79	84	35 34	50 54				31 43	116 131	49 55	
7.5	166 161	183 159	166 171	515 491	108 103	63 68	66	48 51	48 47	45 46	141 144	55 59	57							
10.0	133 129	163 140	127 141	423 410	88 86	33 45	39	52 43	38 39	37 49	127 131	60 64		62						
15.0	142 142	137 149	141 163	420 454	88 95	8 10	9	48 64	61 75	69 61	178 200	85 88			87					
EMS (500 µg/ml)	110 108	121 96	128 99	359 303	75 63	68 56	62	263 319	264 358	264 313	791 990	441 653				547				

* Where replicate determinations of mutant frequency from a single culture were made, the mean mutant frequency for that culture is shown

C Contaminated

() Figure in brackets is adjustment made for contaminated plates and is used in all calculations.
The adjustment is calculated using:

$$\begin{aligned}
 & \frac{\text{No. of colonies counted}}{\text{No. of uncontaminated plates counted}} \times \text{No. of plates seeded} \\
 & \text{Survival (\% control)} = \frac{\text{Suspension growth (\% control)} \times \text{viability in agar (\% control)}}{100} \\
 & \text{Mutant frequency (per } 10^6 \text{ viable cells)} = \left(\frac{600}{\text{Total no. of colonies on non-selective plates}} \right) \times \left(\frac{\text{Total no. of colonies on selective plates}}{3} \right)
 \end{aligned}$$

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TABLE 6

Statistical analysis of data from test carried out in the
absence of S-9 mix

(Test 2)

Concentration of Triclosan ($\mu\text{g/ml}$)	Back transformed mean mutant frequency	Significance levels compared to solvent control
0 (DMSO control)	42.479	
2.5	49.501	NS
5.0	51.935	NS
7.5	56.940	5%
10.0	61.992	1%
15.0	86.488	0.1%
EMS (500 $\mu\text{g/ml}$)	536.464	0.1%

NS Non-significant

TABLE 7

Growth in suspension of L5178Y cells after treatment with
Triclosan in the presence of S-9 mix

(Test 1)

Concentration of Triclosan ($\mu\text{g/ml}$)	Cells/ml $\times 10^{-5}$		Suspension growth	% Control	Mean % control
	24 hours	48 hours			
0 (DMSO control)	5.40 5.40	6.80 6.10	9.18 8.24	100	100
0.5+	5.45 5.79	6.14 5.47	8.37 7.92	96 91	94
1.0+	5.60 5.19	7.26 5.16	10.16 6.70	117 77	97
2.0+	4.66 4.55	8.83 7.86	10.29 8.94	118 103	111
3.5	3.79 3.81	8.96 10.15	8.49 9.67	97 111	104
5.0+++	2.82 3.28	8.84 8.33	6.23 6.83	72 78	75
7.5	2.48 2.28	7.95 8.82	4.93 5.03	57 58	58
10.0	1.79 1.61	4.00 5.75	2.00 2.88	23 33	28
15.0	1.24 1.36	4.60 3.44	2.30 1.72	26 20	23
20-Methyl- cholanthrene (2.5 $\mu\text{g/ml}$)	4.24 4.11	4.33 6.26	4.59 6.43	53 74	64

- + Cultures discarded in favour of cultures treated with higher concentrations of compound
+++ Cultures discarded in favour of cultures with approximately 100% relative growth in suspension

TABLE 8

Viability and mutation of L5178Y cells in soft agar culture after treatment with Triclosan
in the presence of S-9 mix

(Test 1)

Concentration of Triclosan (µg/ml)	No. of colonies on non-selective plates				Survival (% control)	% survival	No. of colonies on selective plates				Mutant frequency (x 10 ⁻⁶)*	Mean mutant frequency (x 10 ⁻⁶)							
	Plate no.			Total			Viability (% control)	Plate no.					Total						
	1	2	3					1	2	3									
0 (DMSO control)	145 185	152 220	141 171	438 576	544	100	100	50 50	48 37	47 46	145 133	66 46	56	60					
	190 178	222 178	218 174	630 530				68 56	48 67	66 59	182 182	58 69			64				
3.5	156 80	138 72	144 88	438 240				81 44	79 49	64	40 25	58 24				59 26	157 75	72 63	68
7.5	137 110	150 92	137 85	424 287				78 53	44 31	38	58 58	61 43				64 32	183 133	86 93	
10.0	239 125	272 149	257 144	768 418	141 77	32 25	29	144 2	112 3	141 1	397 6	103 -	-						
15.0	135 166	153 160	117 171	405 497	74 91	19 18	19	65 86	71 99	79 93	215 278	106 112		109					
20-Methyl-cholanthrene (2.5 µg/ml)	202 171	210 173	210 166	622 510	114 94	60 70	65	339 248	315 229	367 261	1021 738	328 289			309				

* Where replicate determinations of mutant frequency from a single culture were made, the mean mutant frequency for that culture is shown

$$\text{Survival (\% control)} = \frac{\text{Suspension growth (\% control)} \times \text{viability in agar (\% control)}}{100}$$

$$\text{Mutant frequency (per } 10^6 \text{ viable cells)} = \left(\frac{600}{\text{Total no. of colonies on non-selective plates}} \right) \times \left(\frac{\text{Total no. of colonies on selective plates}}{3} \right)$$

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TABLE 9

Statistical analysis of data from test carried out in the
presence of S-9 mix

(Test 1)

Concentration of Triclosan ($\mu\text{g/ml}$)	Back-transformed mean mutant frequency	Significance levels compared to solvent control
0 (DMSO control)	59.859	
3.5	67.357	NS
7.5	89.389	1%
10.0*	-	-
15.0	108.962	0.1%
20-Methyl- cholanthrene (2.5 $\mu\text{g/ml}$)	307.969	0.1%

NS Non-significant

* Statistical analysis not carried out due to poor
growth in one set of mutation plates

TABLE 10

Growth in suspension of L5178Y cells after treatment with
Triclosan in the presence of S-9 mix

(Test 2)

Concentration of Triclosan ($\mu\text{g/ml}$)	Cells/ml $\times 10^{-5}$		Suspension growth	% Control	Mean % control
	24 hours	48 hours			
0 (DMSO control)	4.95 4.75	11.09 8.16	13.72 9.69	11.71	100
1.0	4.70 4.32	11.33 10.93	13.31 11.80	114 101	108
2.5+++	3.53 2.50	11.07 14.79	9.77 9.24	83 79	81
5.0	2.14 2.09	11.47 10.05	6.14 5.25	52 45	49
7.5	1.35 1.98	5.47 10.67	2.74 5.34	23 46	35
10.0	1.00 0.97	3.45 4.13	1.73 2.07	15 18	17
15.0	0.73 0.77	2.13 2.48	1.07 1.24	9 11	10
20.0++	0.54 0.61	2.52 1.47	1.26 0.74	11 6	9
20-Methyl- cholanthrene (2.5 $\mu\text{g/ml}$)	4.84 3.95	9.27 10.90	11.22 10.76	96 92	94

++ Cultures discarded due to excess toxicity

+++ Cultures discarded in favour of cultures with approximately
100% relative growth in suspension

TABLE 11

Viability and mutation of L5178Y cells in soft agar culture after treatment with Triclosan
in the presence of S-9 mix

(Test 2)

Concentration of Triclosan (µg/ml)	No. of colonies on non-selective plates					Survival (% control)	Mean % survival	No. of colonies on selective plates				Mutant frequency (x 10 ⁻⁶)*	Mean mutant frequency (x 10 ⁻⁶)	
	Plate no.			Total	Viability (% Control)			Plate no.			Total			
	1	2	3					1	2	3				
0 (DMSO control)	146	139	132	417	445	100	100	40	43	46	129	62 } 67	58	
	153	160	134	447				44	54	64	162			56 } 48
	174	C	C	174(522)				48	50	48	146			
	139	129	127	395				28	25	24	77			
1.0	118	122	126	366	82	93	88	39	48	39	126	69	58	
	130	111	125	366				25	29	30	84			46
5.0	117	114	108	339	76	40	40	42	34	C	76(114)	67	80	
	115	151	125	391				62	51	69	182			93
7.5	159	153	165	477	107	25	39	70	75	72	217	91	82	
	186	132	179	497				44	65	69	178			72
10.0	117	129	122	368	83	12	13	74	58	80	212	115	99	
	119	108	113	340				50	49	42	141			83
15.0**	83	75	117	275	62	7		81	86	85	252	183		
20-Methyl-cholanthrene (2.5 µg/ml)**	174	189	185	548	123	113		262	284	252	798	291		

* Where replicate determinations of mutant frequency from a single culture were made, the mean mutant frequency for that culture is shown

** Results from one culture reported due to contamination in the viability plates from the replicate culture

C Contaminated

() Figure in brackets is adjustment made for contaminated plates and is used in all calculations.
The adjustment is calculated using:

$$\frac{\text{No. of colonies counted}}{\text{No. of uncontaminated plates counted}} \times \text{No. of plates seeded}$$

$$\text{Survival (\% control)} = \frac{\text{Suspension growth (\% control)} \times \text{viability in agar (\% control)}}{100}$$

$$\text{Mutant frequency (per } 10^6 \text{ viable cells)} = \left(\frac{600}{\text{Total no. of colonies on non-selective plates}} \right) \times \left(\frac{\text{Total no. of colonies on selective plates}}{3} \right)$$

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TABLE 12

Statistical analysis of data from test carried out in the
presence of S-9 mix

(Test 2)

Concentration of Triclosan ($\mu\text{g/ml}$)	Back-transformed mean mutant frequency	Significance levels compared to solvent control
0 (DMSO control)	56.713	
1.0	56.317	NS
5.0	78.965	NS
7.5	80.964	NS
10.0	97.710	5%
15.0*	-	-
20-Methyl- cholanthrene (2.5 $\mu\text{g/ml}$)*	-	-

NS Non-significant

* Statistical analysis not carried out due to contamination
in one set of the viability plates

FIGURE 1

Survival and mutant frequency of L5178Y cells treated
with Triclosan in the absence of S-9 mix

(Test 1)

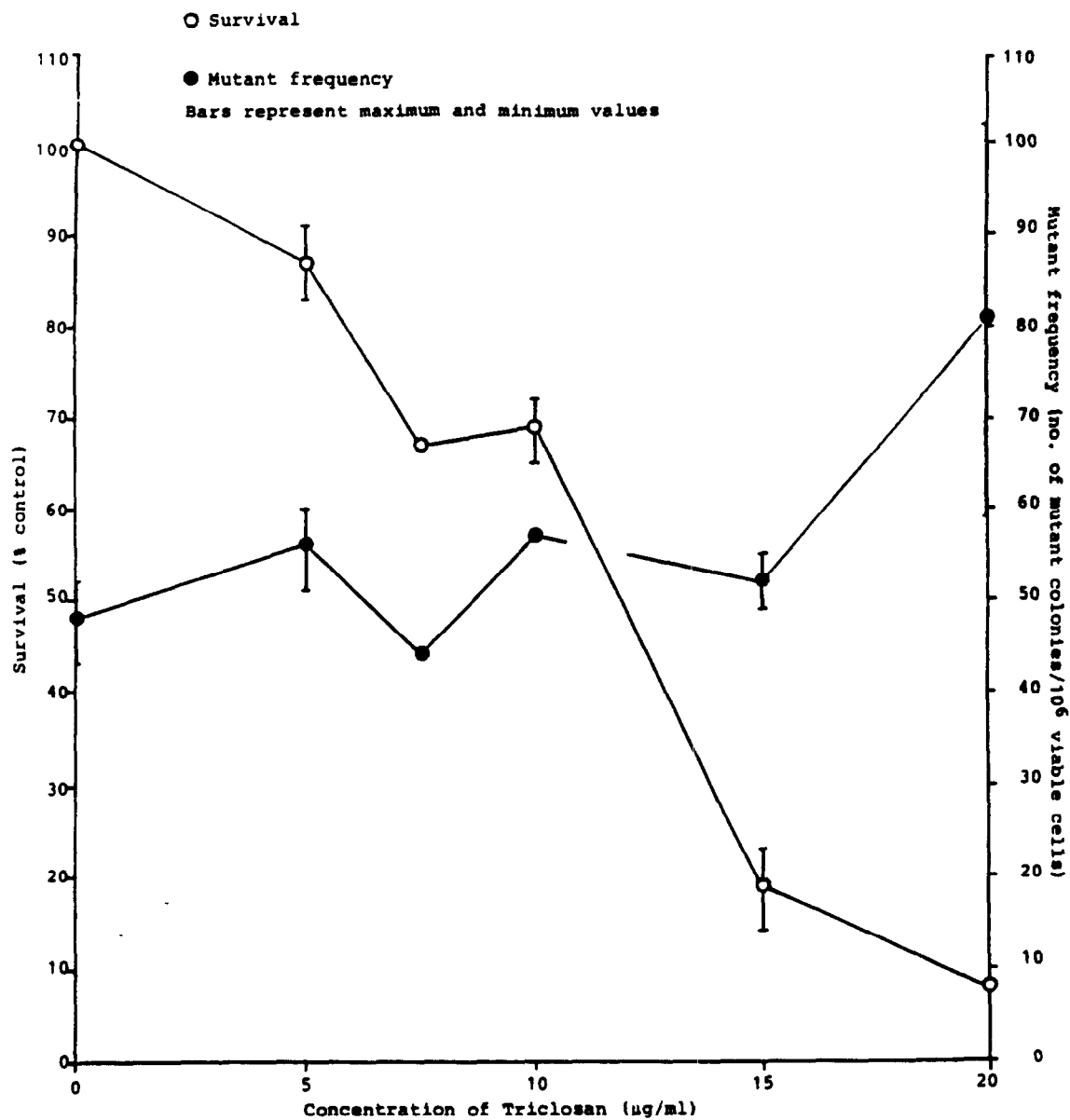


FIGURE 2

Survival and mutant frequency of L5178Y cells treated
with Triclosan in the absence of S-9 mix

(Test 2)

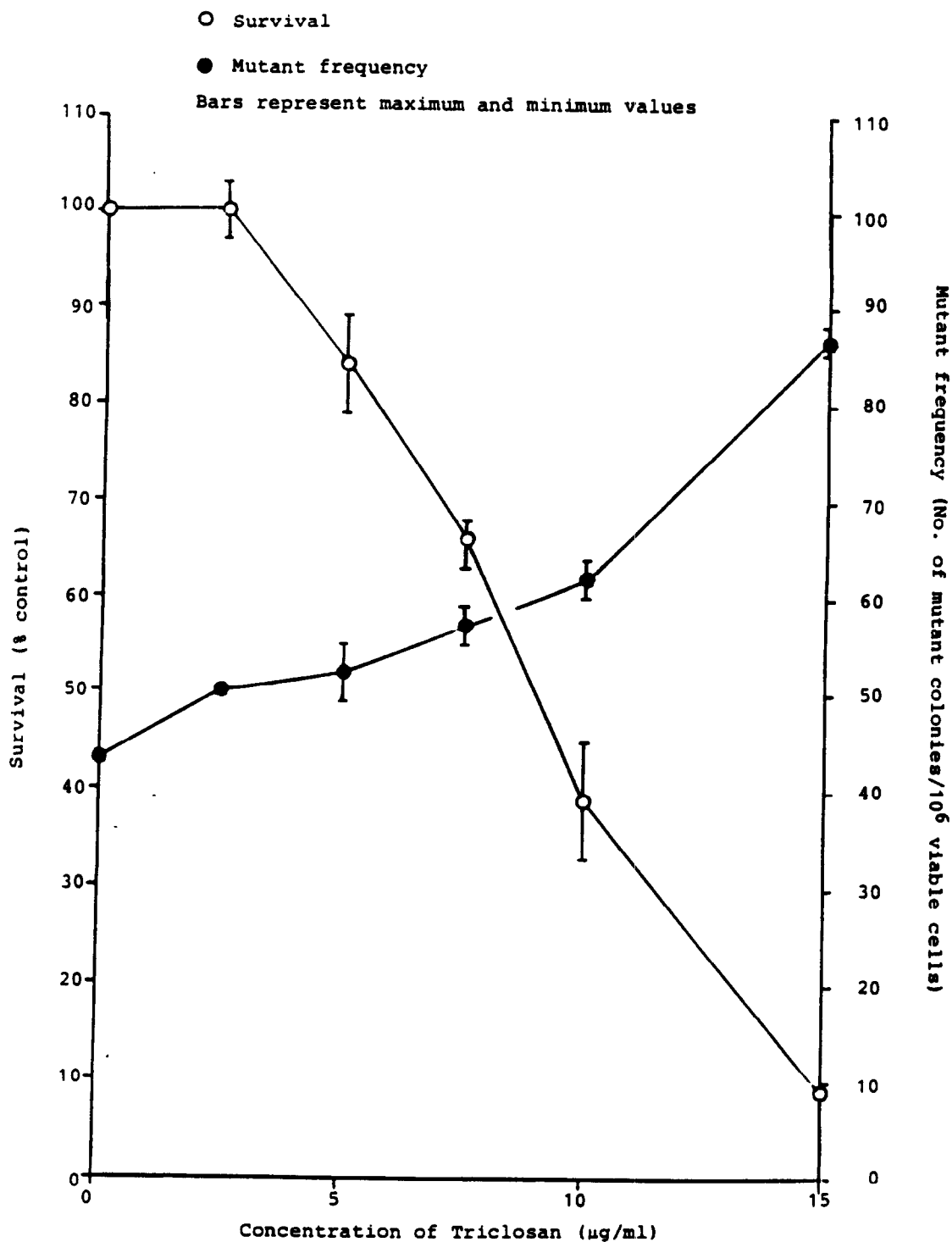


FIGURE 4

Survival and mutant frequency of L5178Y cells treated
with Triclosan in the presence of S-9 mix

(Test 2)

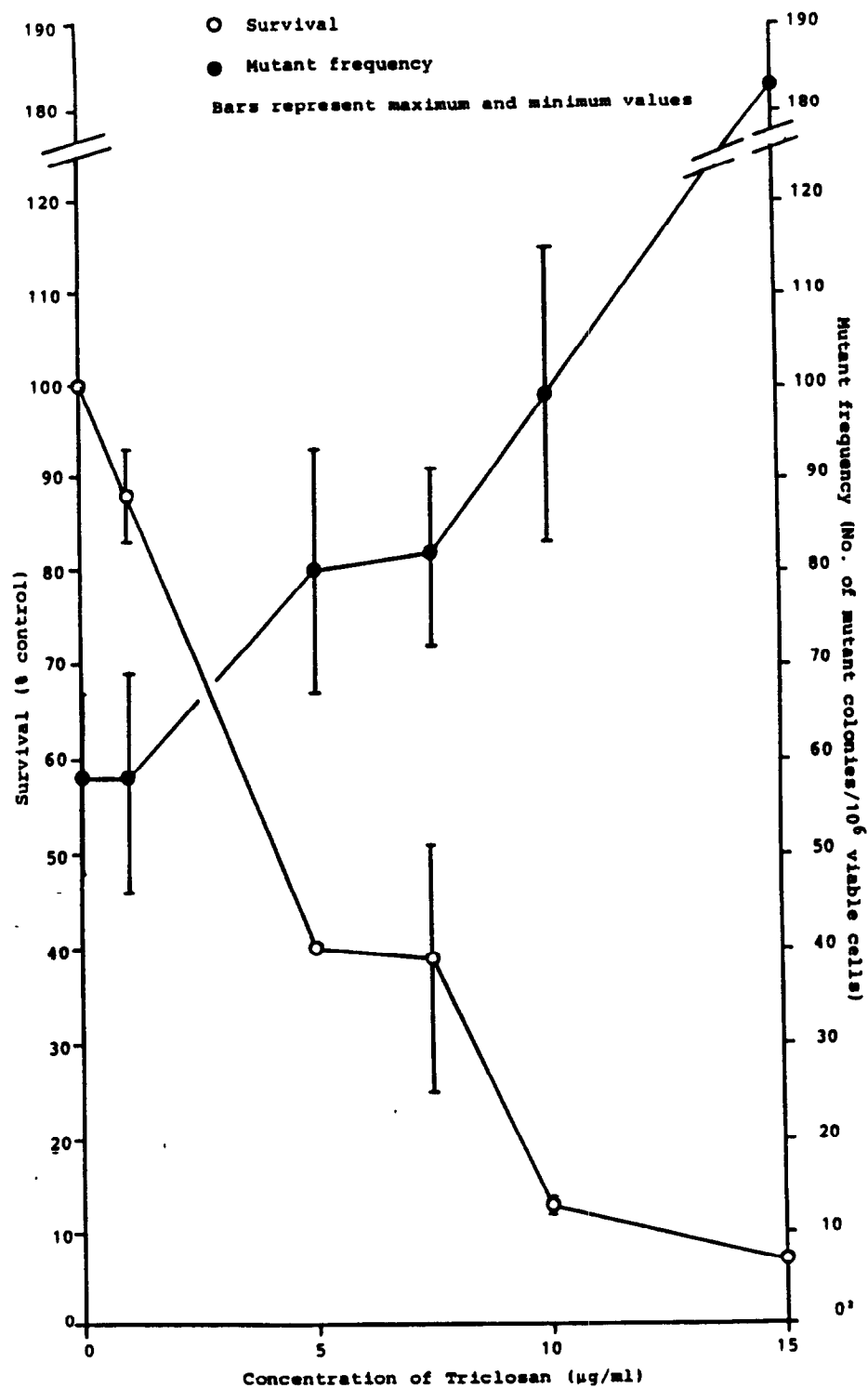
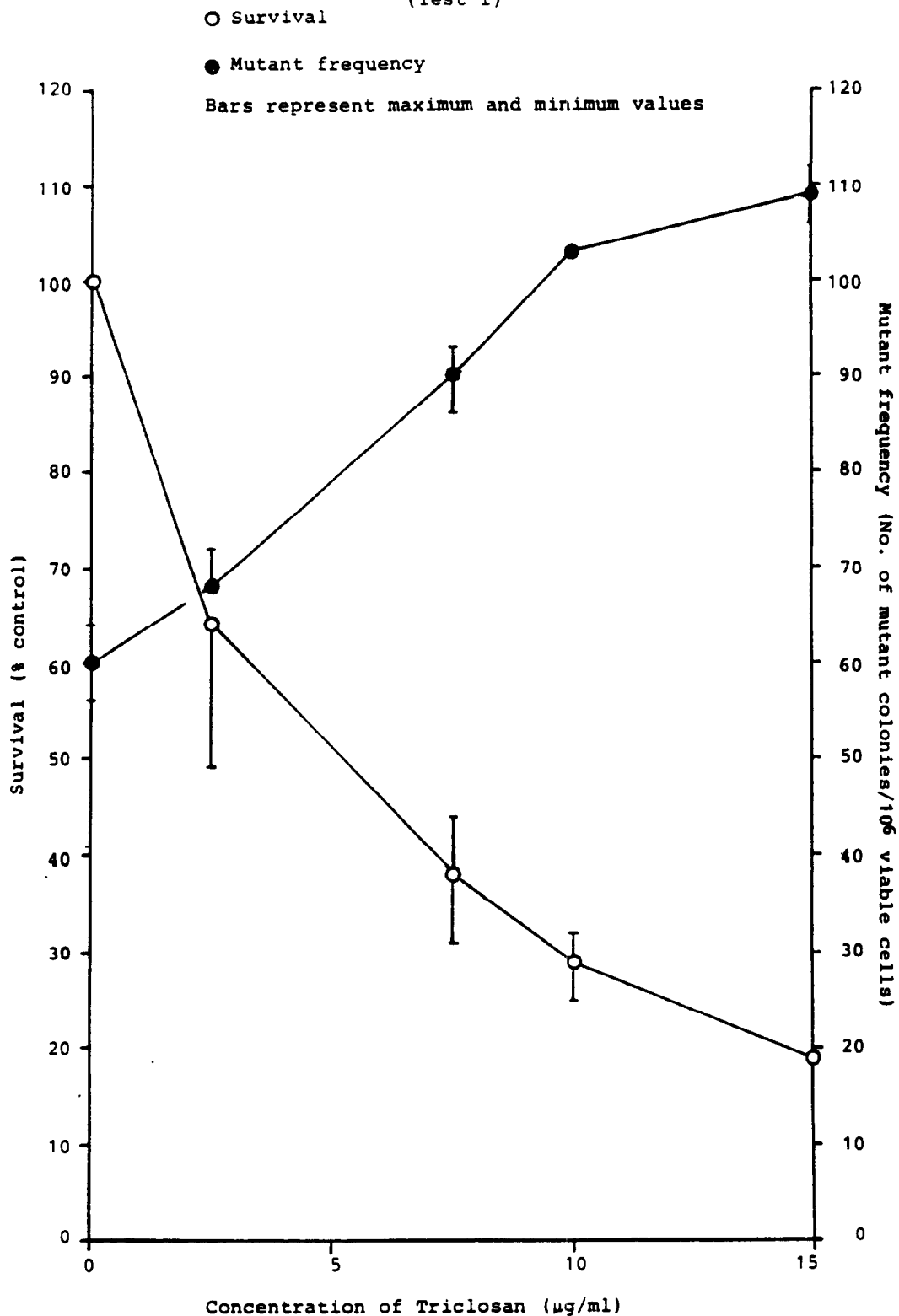


FIGURE 3

Survival and mutant frequency of L5178Y cells treated
with Triclosan in the presence of S-9 mix

(Test 1)



APPENDIX 1

Osmolality measurements from the preliminary
toxicity test

Concentration of Triclosan ($\mu\text{g/ml}$)	Metabolic activation	Osmolality (mOsm/kg)
0 (DMSO control)	-	410 416
50	-	418
100	-	416
0 (DMSO control)	+	434 432
50	+	432
100	+	428

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OTC Vol. No. 106

OTC Docket Number 75N-0183 (triclosan)
September 12, 1994

Ciba-Geigy Corporation
Chemicals Division
Greensboro, N.C. 27419

Riach, C.G., McBride, D, and O'Mailley. Triclosan: Assessment of Genotoxicity in an Unscheduled DNA Synthesis Assay Using Adult Rat Hepatocyte Primary Cultures. Inveresk Research International Limited. Project No. 738388. Report No. 4667. November 2, 1988.

Study Summary

Triclosan was tested for its ability to induce unscheduled DNA synthesis (UDS) in primary cultures of adult rat hepatocytes (HPCs) as measured by silver grain counts in photographic emulsion formed by radiation from [^3H]-thymidine taken up by the cells. Cultures were established with cells derived from the collagenase-perfused liver of a young, adult, male, Fischer 344 rat. In the first experiment, 8 one-half decreasing concentrations of Triclosan from $80\text{ }\mu\text{g.ml}^{-1}$ to $0.6\text{ }\mu\text{g.ml}^{-1}$ were tested. In the second experiment the range was lowered to give concentrations of $20\text{ }\mu\text{g.ml}^{-1}$ to $0.16\text{ }\mu\text{g.ml}^{-1}$. Toxicity of Triclosan was observed in the range of $5\text{-}80\text{ }\mu\text{g.ml}^{-1}$.

Both direct and indirect acting positive controls demonstrated the sensitivity of the test system.

No evidence of unscheduled DNA synthesis was seen at any concentration of Triclosan in either experiment.

It is concluded that Triclosan does not induce unscheduled DNA synthesis in cultured primary rat hepatocytes, when tested in dimethylsulphoxide at concentrations extending into the toxic range.

TRICLOSAN: ASSESSMENT OF GENOTOXICITY IN AN UNSCHEDULED
DNA SYNTHESIS ASSAY USING ADULT RAT HEPATOCYTE PRIMARY CULTURES

IRI Project No. 738388
Unilever Study No. KU 880258



CONFIDENTIAL

INVERESK RESEARCH INTERNATIONAL
Report No. 4667

TRICLOSAN: ASSESSMENT OF GENOTOXICITY IN AN UNSCHEDULED
DNA SYNTHESIS ASSAY USING ADULT RAT HEPATOCYTE PRIMARY CULTURES

IRI Project No. 738388
Unilever Study No. KU 880258

Study completed on:

21 September 1988

Author:

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Total Number of Pages: 119

AUTHENTICATION

'I, the undersigned, hereby declare that this work was performed under my direction and in accordance with the principles of Good Laboratory Practice. The study was conducted according to the procedures herein described and this report represents a true and accurate record of the results obtained.'



C.G. Riach, B.Sc.
Study Director

Date:

ISSUED

17 FEB 1993



Report No. 4667

QUALITY ASSURANCE STATEMENT

The execution of this type of short-term study is not individually inspected. The processes involved are inspected at intervals according to a pre-determined schedule.

This report has been audited by IRI Quality Assurance Personnel according to the appropriate Standard Operating Procedure and is considered to describe the methods and procedures used in the study. The reported results accurately reflect the original data of the study.

IRI Project No. 738388Report No. 4667

Signed: D. Wilson
(Quality Assurance)

Date: 2nd November 1988

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PERSONNEL INVOLVED IN PROJECT 738388

Study Director/
Project Leader:

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SUMMARY

Triclosan was tested for its ability to induce unscheduled DNA synthesis (UDS) in primary cultures of adult rat hepatocytes (HPCs) as measured by silver grain counts in photographic emulsion formed by radiation from [^3H]-thymidine taken up by the cells. Cultures were established with cells derived from the collagenase-perfused liver of a young, adult, male, Fischer 344 rat. In the first experiment, 8 one-half decreasing concentrations of Triclosan from $80\text{ }\mu\text{g.ml}^{-1}$ to $0.6\text{ }\mu\text{g.ml}^{-1}$ were tested. In the second experiment the range was lowered to give concentrations of $20\text{ }\mu\text{g.ml}^{-1}$ to $0.16\text{ }\mu\text{g.ml}^{-1}$. Toxicity of Triclosan was observed in the range $5\text{--}80\text{ }\mu\text{g.ml}^{-1}$.

Both direct and indirect acting positive controls demonstrated the sensitivity of the test system.

No evidence of unscheduled DNA synthesis was seen at any concentration of Triclosan in either experiment.

It is concluded that Triclosan does not induce unscheduled DNA synthesis in cultured primary rat hepatocytes, when tested in dimethylsulphoxide at concentrations extending into the toxic range.

INTRODUCTION

The purpose of this study was to assess the potential of Triclosan to induce unscheduled DNA synthesis in primary cultures of adult rat hepatocytes. A major advantage of using primary hepatocyte cultures is that liver has the broadest capability of any mammalian organ for biotransformation of xenobiotics and the cultured cells retain much of this metabolic capability for some hours after their removal from the liver.

This report describes the methods used and results obtained in tests being conducted at the Inveresk Gate laboratories of Inveresk Research International Limited between 3 May and 21 September 1988.

All data generated and recorded during this study will be stored in the Scientific Archives of Inveresk Research International Limited for 10 years after issue of the final report. At the end of the 10 year period the Sponsor will be consulted regarding the disposal or continued storage of raw data.

EXPERIMENTAL PROCEDURE

MATERIALS

Test Substance

Triclosan (Sample No. S15155 T01) was received from Unilever Research on 27 April 1988. The substance, a white powder, was stored in a glass bottle in the dark at ambient temperature.

Chemicals

2-Acetylaminofluorene (2-AAF) and 4,4'-bis dimethylaminobenzophenone (Michler's ketone) were obtained from Aldrich Chemical Company, Gillingham, Dorset, England. Thymidine, collagenase Type I, insulin, ethylene glycol-bis-(β -aminoethyl ether) N,N'-tetra acetic acid (EGTA), dexamethasone, N-2-hydroxyethylpiperazine-N'-2-ethanesulphonic acid (HEPES) and gentamycin were obtained from Sigma Chemical Company Limited, Poole, Dorset, England. Williams' medium E (WME) was obtained from Flow Laboratories, Irvine, Scotland. Hanks' balanced salt solution, Mg^{++} and Ca^{++} free and trypan blue stain were obtained from Gibco Europe Limited, Paisley, Scotland. Foetal calf serum was obtained from Biological Industries, Cumbernauld, Scotland. D19 developer and Unifix powder were obtained from Kodak Limited, Chalon-Sur-Saone, France. [3H]-thymidine (21 Ci.mM⁻¹) was obtained from Amersham International PLC, Bucks., England. K2 photographic emulsion was obtained from Ilford Limited, Basildon, Essex, England.

Test Solutions

Triclosan and 2-AAF were dissolved and diluted in dimethylsulphoxide. Michler's ketone was dissolved and diluted in ethanol.

All Triclosan dosing solutions were returned to the Sponsor for analysis of achieved concentration. The results of these analyses

supported the nominal concentrations. The raw data from these analyses will be retained by the Sponsor under reference numbers ANY 88.52 and ANY 88.57.

Culture Materials

Nunc multiwell culture plates were obtained from Gibco Europe Limited, Paisley, Scotland. Lux thermanox plastic coverslips were obtained from Flow Laboratories, Irvine, Scotland.

Animal

The young, adult, male, Fischer 344 rats were supplied by Charles River (U.K.) Limited, Margate, Kent, England.

METHODS

Isolation of Primary Cultures of Adult Rat Hepatocytes

Primary cultures of adult rat hepatocytes (HPCs) were initiated according to the modified procedures of Williams et al (1982). The young, adult, male, 344 rat was killed by an atmosphere of CO₂, followed by cervical dislocation.

Two diagonal incisions were made from the pubis to the rib cage. The triangular flap of ventral tissues was held anteriorly with forceps and the liver exposed. The liver was removed from the body and placed on to bolting cloth stretched over a beaker. The liver was perfused with sterile Solution I, which consisted of 0.5 mM ethylene glycol-bis-(β -aminoethyl ether) N,N'-tetra acetic acid (EGTA) in Ca⁺⁺, Mg⁺⁺ free Hanks' balanced salt solution buffered with 10 mM N-2-hydroxy-ethylpiperazine-N'-2-ethanesulphonic acid (HEPES) (Sigma), pH adjusted to 7.35 with 1 N NaOH. Solution I was warmed to 42°C in a water bath and pumped via silicon tubing by a peristaltic pump to an 18 gauge cannula at a rate of about 15 ml.min⁻¹. The cannula was carefully

inserted via the vena cava into a hepatic vein. By sequentially inserting the cannula into several hepatic veins, each liver lobe was cleared of blood and the liver was seen to blanch. Perfusion was then continued with about 180 ml of a sterile Solution II, containing approximately 100 units.ml⁻¹ Type I collagenase in WME buffered with 10 mM HEPES, pH adjusted to 7.35. The rat liver was perfused with this solution for about 12 min at a rate of about 15 ml.min⁻¹.

Following perfusion, the liver was removed to a sterile Petri dish containing warm WME where it was trimmed of extraneous fat and connective tissues. In a fresh Petri dish containing Solution II, the capsule of the liver was opened at numerous points on the inferior surface with small scissors and removed. Cells were detached by gentle combing, leaving a fibrous plug of hepatic connective tissue and vessels to be discarded. Using a wide bore pipette, 25 ml samples of the hepatocyte suspension were filtered into 50 ml centrifuge tubes through a sterile gauze in a glass funnel. The volume was then brought to 50 ml per tube with WME supplemented with 10% calf serum, 10⁻⁷ M insulin, 10⁻⁷ M dexamethasone and 50 µg.ml⁻¹ gentamycin (WMES). Cells were sedimented at 50 x g for 2.5 min, resuspended in WMES and gently mixed by inverting each tube several times. A 10-fold dilution of the rat cell suspension was prepared, then 0.5 ml of the diluted rat hepatocytes added to 0.1 ml of 0.5% trypan blue stain for determination of viability using a haemocytometer.

For HPC/DNA repair studies, cell suspensions containing at least 1 x 10⁵ cells in 1 ml WMES were immediately seeded on to 13 mm diameter coverslips in multiwell dishes and placed in a 95% air, 5% CO₂ humidified 37°C incubator. Two hours after seeding, coverslips were washed with 1 ml of WME leaving only attached viable cells.

HPC/DNA Repair Assay

Immediately after washing, Triclosan and 10 µCi.ml⁻¹ tritiated thymidine ([³H]-TdR), were added to the culture in 1 ml serum-free

WME. In the first experiment, Triclosan was tested in quadruplicate wells at the following concentrations: 0.6, 1.3, 2.5, 5, 10, 20, 40 and 80 $\mu\text{g}.\text{ml}^{-1}$. Additionally, the direct acting positive control, Michler's ketone (4, 8 and 16 $\mu\text{g}.\text{ml}^{-1}$), the indirect acting positive control, 2-AAF (1.1, 2.2 and 4.5 $\mu\text{g}.\text{ml}^{-1}$) and the solvent control, DMSO (2 cultures) were tested in parallel with the test sets. For the second experiment, Triclosan was tested at concentrations of 0.16, 0.3, 0.6, 1.3, 2.5, 5, 10 and 20 $\mu\text{g}.\text{ml}^{-1}$.

HPCs were incubated at 37°C for a total of 18-20 h in the presence of the Triclosan/tritiated thymidine mixture. Each culture was rinsed in 3 successive 1 ml washes of WME containing 1 mM thymidine after which 3 of each set of 4 cultures were treated with 1% sodium citrate for 10 min to allow the nuclei to swell, which permits better quantification of nuclear grains. The fourth culture was used to monitor the toxicity of each treatment; viable cell count (trypan blue exclusion) was determined to estimate cell survival relative to the vehicle control. The cell cultures for autoradiography were fixed in three 30 min changes of methanol:glacial acetic acid (3:1), air dried, and coverslips mounted cell surface upwards upon glass slides with D.P.X. Using a Kodak Beehive safelight fitted with a red filter, slides were dipped into K2 emulsion, prewarmed for 1 h at 48°C. Slides were dried and then placed in a plastic slide box which was wrapped in foil and stored at -20°C.

After 7 days, autoradiographs were developed in D19 developer for 4 min, placed in a stop bath of acidified tap water for 30 s, immersed in fixer for 5-10 min, then washed in running tap water for 5 min.

Slides were stained in methyl-green/pyronin Y solution, washed, air dried and coverslipped with D.P.X.

Quantification of Repair Synthesis

The cells were examined microscopically at approximately 1000 x magnification under oil immersion using a Leitz Dialux 20L microscope. Unscheduled DNA synthesis (UDS) was measured by counting nuclear grains and subtracting the average number of cytoplasmic grains in 3 nuclear-sized areas adjacent to each nucleus (background count). This value was referred to as the net nuclear grain count. The coverslips were coded to prevent bias while grain counting. The data were recorded as the average net grain counts for 3 cultures.

Evaluation Criteria

The net nuclear grain count was determined for 50 randomly selected cells on each coverslip. Only normally-appearing nuclei were scored and any occasional nuclei blackened by grains too numerous to count were excluded as cells in which replicative DNA synthesis occurred rather than repair synthesis. If the actual count for any nucleus was less than zero (i.e. cytoplasmic count is greater than nuclear count), then the negative value was used in the calculation of the mean value. The mean net nuclear grain count was determined from the triplicate coverslips (150 total nuclei) for each treatment condition.

Several criteria have been established which, if met, provide a basis for classifying a test material as positive in the UDS assay. These criteria are formulated on the basis of published results and laboratory experience and are used in lieu of a statistical treatment to indicate a positive response. While the criteria are arbitrary guidelines that may not be applicable to all assays and may need revision as the data base alters, they represent a reasonable approach to the evaluation of the test material.

The test material was considered to be positive in the UDS assay at concentrations that caused:

1. An increase in the mean net nuclear grain count to at least 6 grains per nucleus in excess of the concurrent vehicle control value, and/or
2. The percentage nuclei with 6 or more net grains to increase above 10% of the examined population, in excess of the concurrent vehicle control value and/or
3. The percentage nuclei with 20 or more net grains to reach or exceed 2.0% of the examined population.

If the vehicle controls had shown an average of 6 net grains per nucleus, or 10% of the cells had 6 or more net grains per nucleus, or 1% of the cells had 20 or more net grains per nucleus, the assay would have been considered invalid.

The test material was considered inactive in this assay if none of the above conditions was met and if the assay included the maximum applied dose or other doses that are shown to be toxic by the survival measurements. If little or no toxicity was demonstrated for any of the applied doses and the test material remained soluble in the culture medium, the assay would have been considered inconclusive and would have been repeated with higher doses after consultation with the sponsor. However, a concentration of 5 mg.ml⁻¹ would not have been exceeded.

The positive control nuclear labelling was not used as a reference point to estimate mutagenic or carcinogenic risks associated with the UDS activity of the test material, but only to demonstrate that the cell population employed was responsive and the method was adequate for the detection of unscheduled DNA synthesis.

RESULTS AND DISCUSSION

Cell Viability at the Completion of the Dosing Period (Tables 1 and 3)

In the first experiment, cell viabilities for Solvent Controls 1 and 2 were 75.6 and 76.1% respectively. The % survival for cultures treated with Triclosan, compared to the controls was 93, 91 and 95% for 0.6, 1.3 and 2.5 $\mu\text{g} \cdot \text{ml}^{-1}$ respectively. There was a suggestion of some toxicity at 5 $\mu\text{g} \cdot \text{ml}^{-1}$ where survival was 87%. At concentrations of 10-80 $\mu\text{g} \cdot \text{ml}^{-1}$, no cells remained viable at the end of the exposure period. Cell monolayers were present, however, at all these concentrations, and so autoradiography was performed on all cultures treated with Triclosan.

In the second experiment, cell viabilities for Solvent Controls 1 and 2 were 75.3 and 61.7% respectively. The % survival for cultures treated with Triclosan compared to the controls was in the order of 50-60% in the range 0.16 to 5 $\mu\text{g} \cdot \text{ml}^{-1}$. At 10 $\mu\text{g} \cdot \text{ml}^{-1}$, survival was 14% and at 20 $\mu\text{g} \cdot \text{ml}^{-1}$ complete killing was observed. Again, autoradiography was performed on all Triclosan-treated cultures.

Unscheduled DNA Synthesis Assay (Tables 2 and 4)

Actual recorded data are presented in the Appendix.

Vehicle Controls

In the first experiment, primary cultures of adult rat hepatocytes treated with DMSO had mean net grains per nucleus of -0.78 and -0.26, while both duplicate cultures had 1.33% of nuclei giving ≥6 net grains.

In the second experiment, Solvent Controls 1 and 2 had mean net grains per nucleus of 0.37 and -0.95, while the % nuclei giving ≥ 6 net grains was 3.00 and 0 respectively.

In neither experiment were any nuclei detected yielding ≥ 20 net grains per nucleus.

The vehicle controls were considered valid, having met the requirements as specified by the acceptance criteria.

Positive Controls

With the exception that, in the first experiment, no nuclei with 20 or more net grains were recorded for the lowest concentration of Michler's ketone, all concentrations of both Michler's ketone (direct acting control) and 2-AAF (indirect acting control) satisfied all 3 criteria for a positive response in both experiments.

Triclosan

In the first experiment, primary cultures of adult rat hepatocytes were treated with concentrations of 0.6, 1.25, 2.5, 5, 10, 20, 40 and 80 $\mu\text{g Triclosan.ml}^{-1}$. Under microscopic examination it was decided that the autoradiographs of the cultures treated with 20, 40 and 80 $\mu\text{g Triclosan.ml}^{-1}$ were too badly affected by toxicity to extract meaningful results.

No significant increases in UDS were obtained by any of the 3 criteria with any of the remaining 5 dose levels of Triclosan.

In the second experiment, the rat hepatocyte cultures were treated with 0.16, 0.3, 0.6, 1.3, 2.5, 5, 10 and 20 $\mu\text{g Triclosan.ml}^{-1}$. On this occasion, only the 20 $\mu\text{g.ml}^{-1}$ culture was judged to be too badly affected by toxicity for scoring.

No increases in UDS were obtained by any of the 3 criteria with any of the tested concentrations of Triclosan.

CONCLUSION

It is concluded that Triclosan does not induce unscheduled DNA synthesis in cultured rat hepatocytes when tested in dimethylsulphoxide at concentrations extending into the toxic range.

REFERENCE

- (1) Williams, G.M., Laspia, M.F. and Dunkel, V.C. (1982). Mut. Res.,
97, 359-370.

TABLE 1

Unscheduled DNA Synthesis with Triclosan
Cell Viability at the Completion of the Dosing Period
Experiment 1

Compound ($\mu\text{g}\cdot\text{ml}^{-1}$)	% Viable Cells	% Survival *
Dimethylsulphoxide		
10 μl added		
Solvent I	75.6	100
Solvent II	76.1	100
Michler's ketone		
4	65.1	86
8	54.0	71
16	49.5	65
2-Acetylaminofluorene		
1.1	52.2	69
2.2	39.7	52
4.5	44.5	59
Triclosan		
0.6	70.7	93
1.3	68.7	91
2.5	72.0	95
5	65.8	87
10	0	0
20	0	0
40	0	0
80	0	0

At least 200 cells are counted to obtain estimates of viability, except in cases of severe toxicity where few cells are present

* = Viability/vehicle mean

TABLE 2

Unscheduled DNA Synthesis with Triclosan
Summary of Results
Experiment 1

Compound ($\mu\text{g}\cdot\text{ml}^{-1}$)	Cells Scored	Mean Net Grains	% Nuclei With ≥ 6 Net Grains	% Nuclei With ≥ 20 Net Grains	Slide Code
Dimethylsulphoxide (10 μl added)					
Solvent I	150	-0.78	1.33	0	F
Solvent II	150	-0.26	1.33	0	D
Michler's ketone					
4	150	7.63	64.00	0	J
8	150	11.23	88.00	2.67	E
16	150	8.80	70.67	2.00	C
2-Acetylamino- fluorene					
1.1	150	14.13	97.33	10.00	H
2.2	150	17.39	97.33	30.67	P
4.5	150	21.07	100.00	43.33	I
Triclosan					
0.625	150	0.22	1.33	0	O
1.25	150	-0.90	3.33	0	L
2.5	150	1.03	6.67	0	M
5	150	0.03	0.67	0	K
10	150	0.32	0.67	0	A
20*	-	-	-	-	N
40*	-	-	-	-	B
80*	-	-	-	-	G

* = Toxic

TABLE 3

Unscheduled DNA Synthesis with Triclosan
Cell Viability at the Completion of the Dosing Period
Experiment 2

Compound ($\mu\text{g}\cdot\text{ml}^{-1}$)	% Viable Cells	% Survival *
Dimethylsulphoxide		
10 μl added		
Solvent A	75.3	110
Solvent B	61.7	90
Michler's ketone		
4	56.7	83
8	46.6	68
16	39.8	58
2-Acetylamino- fluorene		
1.1	50.6	74
2.2	50.5	74
4.5	43.8	64
Triclosan		
0.16	43.9	64
0.3	37.1	54
0.6	38.2	56
1.3	37.5	55
2.5	42.0	61
5	38.9	57
10	9.5	14
20	0	0

At least 200 cells are counted to obtain estimates of viability,
except in cases of severe toxicity where few cells are present

* = Viability/vehicle mean

TABLE 4

Unscheduled DNA Synthesis with Triclosan
 Summary of Results
 Experiment 2

Compound ($\mu\text{g} \cdot \text{ml}^{-1}$)	Cells Scored	Mean Net Grains	% Nuclei With ≥ 6 Net Grains	% Nuclei With ≥ 20 Net Grains	Slide Code
Dimethylsulphoxide (10 μl added)					
Solvent I	100	0.37	3.00	0.00	F
Solvent II	150	-0.95	0.00	0.00	A
Michler's ketone					
4	150	12.98	85.33	10.00	I
8	150	12.92	88.00	12.67	O
16	150	11.54	79.33	12.67	N
2-Acetylamino- fluorene					
1.1	150	28.97	100.00	83.33	J
2.2	150	28.35	100.00	80.67	K
4.5	150	39.84	100.00	96.00	M
Triclosan					
0.16	150	0.04	0.67	0.00	G
0.3	150	-0.79	0.67	0.00	B
0.6	150	-0.90	0.00	0.00	D
1.3	150	-1.06	0.67	0.00	L
2.5	150	-1.23	2.00	0.00	E
5	150	-0.36	0.67	0.00	P
10	150	0.21	0.00	0.00	H
20*	-	-	-	-	C

* = Toxic

APPENDIX

Unscheduled DNA Synthesis
Score Sheets

PROJECT NO. : 738388
 CLIENT : UNILEVER
 TEST MATERIAL: TRICLOSAN
 EXPT. DATE : JUNE/28/88
 SLIDE LETTER : A1

EXAMINER : M.D'MAILLEY
 DATE EXAMINED : JULY/14/88
 EXPERIMENT NO. 1

NO. OF grains/ nucleus	cytoplasmic grains		net grains/ nucleus
2	0	0	0 2.00
7	4	5	1 3.67
0	6	3	2 4.33
3	3	0	1 1.67
1	2	2	1 -0.67
2	1	0	1 1.33
2	3	0	2 0.33
1	0	2	1 0.00
1	1	1	0 0.33
2	2	1	0 1.00
0	1	1	0 -0.67
3	2	1	0 2.00
3	2	0	0 2.33
3	3	1	0 1.67
3	1	0	1 2.33
9	4	4	1 6.00
3	3	1	3 0.67
3	3	4	1 0.33
3	3	0	3 1.00
3	0	2	1 2.00
1	2	0	1 0.00
2	2	2	0 0.67
0	1	2	0 -1.00
1	1	2	1 -0.33
2	2	2	1 0.33
1	0	1	1 0.33
3	3	5	1 0.00
2	2	0	1 1.00
2	1	1	3 0.33
3	0	2	0 2.33
1	1	1	0 0.33
2	1	0	3 0.67
1	2	3	0 -0.67
1	1	2	3 -1.00
2	1	0	1 1.33
0	1	1	2 -1.33
0	2	2	0 -1.33
1	2	3	1 -1.00
1	1	0	1 0.33
1	1	0	0 0.67
0	1	0	2 -1.00
0	2	0	1 -1.00
2	1	0	1 1.33
2	1	0	0 1.67
1	3	3	2 -1.67
1	1	0	1 0.33
1	1	1	0 0.33
2	1	3	3 -0.33
0	3	1	0 -1.33
1	2	0	0 0.33

total net mean grain count : 0.64

nuclei with >=4 grains : 1
 nuclei with >=20 grains : 0

PROJECT NO. : 738388
 CLIENT : UNILEVER
 TEST MATERIAL: TRICLOSAN
 EXPT. DATE : JUNE/28/88
 SLIDE LETTER : A2

EXAMINER : M.O'MAILLEY
 DATE EXAMINED : JULY/14/88
 EXPERIMENT NO.1

NO. OF grains/ nucleus	cytoplasmic grains		net grains/ nucleus
1	3	0	1 -0.33
3	0	1	2 2.00
3	1	4	3 0.33
2	2	1	2 0.33
2	2	3	1 0.00
5	4	2	1 2.67
6	3	2	1 4.00
3	2	1	1 1.67
3	2	0	2 1.67
4	3	1	2 2.00
2	1	0	0 1.67
1	1	1	1 0.00
0	0	0	0 0.00
3	2	0	0 2.33
1	4	3	3 -2.33
2	1	1	0 1.33
3	3	2	3 0.33
3	3	1	3 0.67
2	2	0	2 0.67
0	1	2	0 -1.00
2	2	3	0 0.33
1	5	2	3 -2.33
2	2	2	2 0.00
0	2	3	0 -1.67
2	2	2	1 0.33
0	1	0	2 -1.00
2	1	2	0 1.00
3	3	2	2 0.67
2	0	1	0 1.67
3	1	2	2 1.33
2	2	1	0 1.00
2	2	1	1 0.67
1	3	1	1 -0.67
2	4	0	2 0.00
1	0	2	1 0.00
2	3	1	0 0.67
2	2	2	3 -1.00
2	2	2	1 0.33
2	2	2	1 0.33
0	2	3	0 -1.67
0	0	0	0 0.00
3	3	0	1 1.67
1	1	0	1 0.33
1	1	1	0 0.33
0	1	1	1 -1.00
1	2	0	1 0.00
0	0	1	0 -0.33
0	1	1	0 -0.67
1	2	0	1 0.00
2	2	1	0 1.00

total net mean grain count : 0.39

nuclei with >=6 grains : -0

nuclei with >=20 grains : 0

PROJECT NO. : 738388
 CLIENT : UNILEVER
 TEST MATERIAL: TRICLOSAN
 EXPT. DATE : JUNE/28/88
 SLIDE LETTER : A3

EXAMINER : M.O'MAILLEY
 DATE EXAMINED : JULY/15/88
 EXPERIMENT NO. 1

NO. OF grains/ nucleus	cytoplasmic grains		net grains/ nucleus	
3	1	1	0	2.33
1	1	0	1	0.33
0	3	1	2	-2.00
0	1	1	0	-0.67
2	1	0	1	1.33
0	1	0	1	-0.67
0	1	2	0	-1.00
1	0	2	3	-0.67
1	0	0	2	0.33
0	1	1	0	-0.67
2	2	0	1	1.00
1	2	0	1	0.00
0	1	1	2	-1.33
1	1	0	3	-0.33
0	3	1	0	-1.33
1	1	0	3	-0.33
3	0	2	2	1.67
1	3	0	0	0.00
0	2	0	2	-1.33
1	2	0	1	0.00
0	0	2	1	-1.00
3	2	0	2	1.67
2	0	1	0	1.67
0	1	2	1	-1.33
1	3	0	0	0.00
0	1	1	0	-0.67
1	2	0	1	0.00
2	1	1	1	1.00
1	2	1	0	0.00
1	0	1	0	0.67
1	0	2	1	0.00
1	2	1	2	-0.67
3	2	2	1	1.33
3	0	2	3	1.33
1	1	1	1	0.00
2	1	3	0	0.67
2	0	0	5	0.33
0	3	1	0	-1.33
0	0	1	2	-1.00
2	2	2	2	0.00
1	2	0	1	0.00
0	2	3	0	-1.67
0	2	2	1	-1.67
3	1	1	0	2.33
0	2	1	0	-1.00
0	1	4	1	-2.00
1	3	0	1	-0.33
2	1	1	0	1.33
2	2	2	1	0.33
1	1	0	1	0.33

total net mean grain count : -0.06

nuclei with >=6 grains : 0
 nuclei with >=20 grains : 0

mean of coverslip one : 0.64

mean of coverslip two : 0.39

MEAN OF ALL THREE COVERSLEPS : 0.32

TOTAL PERCENT
 OF NUCLEI WITH >=6 GRAINS : 0.67

TOTAL PERCENT
 OF NUCLEI WITH >=20 GRAINS : 0.00

PROJECT NO. : 738388
CLIENT : UNILEVER EXAMINER : M.O'MAILLEY
TEST MATERIAL: TRICLOSAN DATE : JULY/14/88
EXPT. DATE : JUNE/28/88 EXPERIMENT NO.1
SLIDE LETTER : B1

NO. OF		net
grains/ nucleus	cytoplasmic grains	grains/ nucleus

NUCLEI APPEAR DAMAGED. UNABLE TO SCORE COVERSIP.
POSSIBLY DUE TO TOXICITY.

PROJECT NO. : 738388
CLIENT : UNILEVER EXAMINER : M.O'MAILLEY
TEST MATERIAL: TRICLOSAN DATE : JULY/14/88
EXPT. DATE : JUNE/28/88 EXPERIMENT NO. 1
SLIDE LETTER : B2

NO. OF		net
grains/ nucleus	cytoplasmic grains	grains/ nucleus

NUCLEI APPEAR DAMAGED. UNABLE TO SCORE COVERSLIP.
POSSIBLY DUE TO TOXICITY.

PROJECT NO. : 738388
CLIENT : UNILEVER
TEST MATERIAL: TRICLOSAN
EXPT. DATE : JUNE/28/88
SLIDE LETTER : B3

EXAMINER : M.O'MAILLEY

DATE : JULY/14/88

EXPERIMENT NO.1

NO. OF		net
grains/ nucleus	cytoplasmic grains	grains/ nucleus

NUCLEI APPEAR DAMAGED. UNABLE TO SCORE COVERSIP.
POSSIBLY DUE TO TOXICITY.

PROJECT NO. : 738388
 CLIENT : UNILEVER EXAMINER : M.O'MAILLEY
 TEST MATERIAL: TRICLOSAN DATE EXAMINED : JULY/15/88
 EXPT. DATE : JUNE/28/88 EXPERIMENT NO. 1
 SLIDE LETTER : C1

NO. OF grains/ nucleus	cytoplasmic grains		net grains/ nucleus	
15	0	9	0	9.33
7	2	4	11	1.33
20	0	4	4	14.67
0	2	0	0	7.33
14	7	9	9	5.67
5	5	10	0	0.00
5	4	3	1	2.33
0	5	4	0	2.33
19	9	0	2	15.33
11	3	6	3	7.00
20	2	12	3	14.33
12	3	2	2	9.67
3	0	2	1	2.00
4	2	0	3	2.33
25	2	0	6	22.33
15	11	3	2	9.67
5	1	2	5	2.33
16	4	6	0	10.00
5	6	1	0	2.67
3	1	4	2	0.67
6	2	3	5	2.67
14	0	2	2	12.67
10	0	1	1	9.33
10	12	6	0	9.33
5	4	2	3	2.00
5	6	4	1	1.33
4	2	4	0	2.00
13	0	1	1	9.67
15	12	7	9	5.67
12	2	6	7	7.00
13	15	13	0	1.00
4	1	0	1	3.33
7	0	0	1	6.67
10	0	1	1	9.33
30	0	10	0	21.33
19	1	3	3	16.67
15	4	0	1	13.33
16	4	9	9	8.67
20	4	2	3	17.00
12	6	3	0	9.00
13	5	7	0	9.00
10	4	5	9	12.00
20	1	6	10	14.33
27	2	16	17	15.33
10	0	13	2	10.33
21	9	16	14	0.00
17	12	9	10	6.67
24	15	13	4	13.33
13	9	14	11	1.67
10	1	4	0	0.33

total net mean grain count : 8.17

nuclei with ≥ 6 grains : 32
 nuclei with ≥ 20 grains : 2

PROJECT NO. : 738388
 CLIENT : UNILEVER
 TEST MATERIAL: TRICLOSAN
 EXPT. DATE : JUNE/28/88
 SLIDE LETTER : C2

EXAMINER : M.O'MAILLEY
 DATE EXAMINED : JULY/15/88
 EXPERIMENT NO. 1

NO. OF grains/ nucleus	cytoplasmic grains		net grains/ nucleus
27	11	7	4 19.67
21	4	7	2 16.67
19	9	14	15 6.33
42	19	23	15 23.00
25	10	15	5 15.00
27	11	6	17 15.67
17	14	3	10 8.00
14	12	6	8 5.33
10	15	13	10 5.33
18	9	7	4 11.33
23	11	4	10 12.00
9	5	6	5 3.67
16	5	2	4 12.33
13	1	2	1 11.67
18	3	8	6 12.33
13	8	8	7 5.33
21	13	3	2 15.00
12	7	5	5 6.33
19	8	7	5 12.33
23	12	6	16 11.67
17	6	4	5 12.00
14	6	13	11 4.00
8	5	6	4 3.00
17	9	5	6 10.33
21	9	4	8 14.00
24	14	11	5 14.00
8	2	1	1 6.67
8	1	1	1 7.00
10	5	5	2 6.00
21	9	15	6 11.00
20	9	9	8 11.33
19	9	7	7 11.33
16	4	2	3 13.00
27	12	17	13 13.00
20	3	2	3 17.33
18	5	3	8 15.33
14	2	1	1 12.67
8	2	2	1 6.33
11	5	8	4 5.33
9	4	6	6 3.67
7	2	1	3 5.00
20	9	7	9 11.67
13	6	2	3 9.33
13	7	4	3 8.33
20	5	12	3 13.33
20	12	8	6 11.33
14	9	8	4 7.00
20	10	3	6 13.67
15	8	9	6 7.33
10	7	6	6 3.67

total net mean grain count : 10.34

nuclei with >=6 grains : 48
 nuclei with >=20 grains : 1

PROJECT NO. : 738388
 CLIENT : UNILEVER
 TEST MATERIAL: TRICLOSAN
 EXPT. DATE : JUNE/28/88
 SLIDE LETTER : C3

EXAMINER : M.O'MAILLEY
 DATE EXAMINED : JULY/15/88
 EXPERIMENT NO.1

NO. OF grains/ nucleus	cytoplasmic grains		net grains/ nucleus	
13	8	8	15	2.67
13	7	4	5	7.67
11	4	3	6	6.67
13	9	4	18	5.33
24	14	10	8	13.33
22	8	5	2	17.88
12	2	8	3	7.67
11	4	7	6	5.33
15	15	0	2	9.33
13	10	10	4	5.88
15	3	3	5	11.33
13	5	1	3	10.88
12	6	7	6	5.67
10	5	5	6	4.67
15	5	7	4	9.67
18	9	7	3	11.67
8	5	4	9	2.88
11	3	4	3	7.67
10	2	5	3	6.67
13	5	5	6	7.67
17	7	5	8	10.33
15	11	11	3	6.67
23	6	4	5	10.88
17	5	1	4	13.67
16	10	5	7	8.67
16	2	7	4	11.67
18	5	11	7	10.33
3	8	1	2	2.88
8	5	6	5	2.67
9	9	5	1	4.88
7	8	6	1	2.88
16	3	5	3	12.33
8	5	5	2	4.88
11	4	2	5	7.33
8	1	2	1	6.67
14	4	8	2	9.33
13	2	6	5	8.67
7	9	2	5	1.67
11	3	3	4	7.67
12	2	5	4	8.33
7	7	6	7	8.33
10	2	2	2	8.88
9	1	3	2	7.88
13	1	3	0	11.67
23	7	4	8	16.67
7	1	2	2	5.33
14	4	4	3	10.33
17	14	9	9	6.33
12	6	11	7	4.88
16	3	6	5	11.33
				total net mean grain count : 7.88
				nuclei with >=6 grains : 34
				nuclei with >=20 grains : 8
				mean of coverslip one : 8.17
				mean of coverslip two : 10.34
				MEAN OF ALL THREE COVERSLEPS : 8.88
				TOTAL PERCENT
				OF NUCLEI WITH >=6 GRAINS : 70.67
				TOTAL PERCENT
				OF NUCLEI WITH >=20 GRAINS : 2.88

PROJECT NO. : 738388
 CLIENT : UNILEVER EXAMINER : M.O'MAILLEY
 TEST MATERIAL: TRICLOSAN DATE EXAMINED : JULY/15/88
 EXPT. DATE : JUNE/28/88 EXPERIMENT NO. 1
 SLIDE LETTER : D1

NO. OF grains/ nucleus	cytoplasmic grains		net grains/ nucleus
4	4	6	3 -0.33
2	1	2	5 -0.67
2	4	4	2 -1.33
7	5	2	6 2.67
5	4	3	1 2.33
7	7	4	5 1.67
1	2	3	3 -1.67
4	2	2	1 2.33
4	8	3	3 2.88
4	3	3	1 1.67
1	4	1	2 -1.33
2	2	3	3 -0.67
2	3	3	1 -0.33
3	2	5	6 -1.33
1	2	3	3 -1.67
1	4	1	2 -1.33
7	7	1	7 2.88
6	5	1	8 1.33
3	3	3	2 0.33
5	5	3	3 1.33
2	3	3	2 -0.67
1	1	1	2 -0.33
3	3	2	3 0.33
2	4	4	2 -1.33
5	3	4	4 1.33
2	3	8	3 0.88
9	4	7	3 4.33
6	5	6	4 1.88
3	1	3	2 1.88
5	6	2	5 0.67
3	6	2	1 0.88
3	2	2	1 1.33
2	1	4	3 -0.67
2	3	5	2 -1.33
5	2	6	4 1.88
4	4	1	5 0.67
3	4	6	2 -1.88
1	2	3	2 -1.33
4	4	3	6 -0.33
5	4	4	3 1.33
5	7	3	4 0.33
6	7	1	4 2.88
7	10	3	4 1.33
5	3	8	4 0.88
7	9	7	3 0.67
4	4	3	3 0.67
6	3	3	4 2.67
4	5	3	4 0.88
10	6	5	7 4.88
6	6	3	4 1.67

total net mean grain count : 0.53

nuclei with ≥ 6 grains : 0
 nuclei with ≥ 20 grains : 0

PROJECT NO. : 738388
 CLIENT : UNILEVER
 TEST MATERIAL: TRICLOSAN
 EXPT. DATE : JUNE/28/88
 SLIDE LETTER : D2

EXAMINER : M.O'MAILLEY
 DATE EXAMINED : JULY/15/88
 EXPERIMENT NO.1

NO. OF grains/ nucleus	cytoplasmic grains	net grains/ nucleus
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5	4	8	9	-2.88
7	7	5	9	0.88
8	1	5	8	-2.88
6	9	6	11	-2.67
8	11	13	9	-3.88
7	12	3	12	-2.88
6	5	5	12	-1.33
6	6	3	2	2.33
16	10	7	11	6.67
6	9	8	6	-1.67
12	11	12	9	1.33
12	13	12	7	1.33
5	6	5	5	-0.33
7	7	5	8	0.33
12	6	3	3	8.88
5	8	5	8	-2.88
3	4	11	5	-3.67
15	11	12	11	3.67
8	1	8	2	-1.88
1	1	4	6	-2.67
2	6	1	8	-0.33
2	3	8	5	-0.67
5	9	5	9	-2.67
2	2	2	1	0.33
11	19	14	11	-3.67
1	3	1	2	-1.88
4	1	1	4	2.88
8	1	2	2	-1.67
2	1	3	3	-0.33
8	1	2	8	-1.88
8	3	2	2	-2.33
5	3	2	4	2.88
7	1	3	3	4.67
3	3	6	5	-1.67
6	6	3	2	2.33
4	4	3	6	-0.33
9	6	6	9	2.88
4	5	2	4	0.33
2	3	2	2	-0.33
6	11	15	4	-4.88
8	10	8	4	0.67
9	14	11	9	-2.33
2	9	7	6	-5.33
2	8	12	14	-9.33
10	15	13	10	-2.67
6	3	11	3	0.33
7	12	10	4	-1.67
4	8	9	3	-2.67
9	13	5	7	0.67
4	10	14	7	-6.33

total net mean grain count : -0.71

nuclei with >=6 grains : 2
 nuclei with >=20 grains : 0

PROJECT NO. : 738388
 CLIENT : UNILEVER
 TEST MATERIAL: TRICLOSAN
 EXPT. DATE : JUNE/28/88
 SLIDE LETTER : D3

EXAMINER : M.O'MAILLEY
 DATE EXAMINED : JULY/15/88
 EXPERIMENT NO. 1

NO. OF grains/ nucleus	cytoplasmic grains	net grains/ nucleus	
1	1	1	2 -0.33
0	2	4	2 -2.67
4	4	3	4 0.33
1	1	4	2 -1.33
2	1	6	3 -1.33
6	3	7	10 -0.67
2	3	3	4 -1.33
3	3	3	2 0.33
4	4	3	2 1.00
6	6	8	6 -0.67
4	2	3	3 1.33
4	3	6	4 -0.33
5	1	3	2 3.00
5	5	6	3 0.33
0	2	2	0 -1.33
2	5	3	1 -1.00
5	1	3	4 2.33
0	2	1	3 -2.00
2	2	4	1 -0.33
0	2	3	5 -3.33
6	2	1	3 4.00
4	7	2	6 -1.00
4	4	3	2 1.00
7	7	2	2 3.33
4	6	3	4 -0.33
3	2	3	2 0.67
1	2	3	1 -1.00
0	3	2	5 -3.33
0	0	3	3 -2.00
3	6	2	2 -0.33
1	3	3	1 -1.33
0	2	6	1 -3.00
3	1	3	6 -0.33
1	6	3	1 -2.33
0	1	1	3 -1.67
1	6	1	4 -2.67
3	2	4	3 0.00
1	1	2	2 -0.67
1	1	4	2 -1.33
1	7	2	4 -3.33
1	5	1	3 -2.00
3	2	3	4 0.00
3	3	7	2 -1.00
1	2	2	1 -0.67
1	7	4	1 -3.00
1	2	3	1 -1.00
3	3	2	4 0.00
3	3	2	3 0.33
2	3	3	4 -1.33
4	2	3	2 1.67

total net mean grain count : -0.61

nuclei with >=6 grains : 0

nuclei with >=20 grains : 0

mean of coverslip one : 0.53

mean of coverslip two : -0.71

MEAN OF ALL THREE COVERSLEPS : -0.26

TOTAL PERCENT
OF NUCLEI WITH >=6 GRAINS : 1.33

TOTAL PERCENT
OF NUCLEI WITH >=20 GRAINS : 0.00

PROJECT NO. I 738388
 CLIENT IUNILEVER
 TEST MATERIAL:TRICLOSAN
 EXPT. DATE IJUNE/28/88
 SLIDE LETTER IE1

EXAMINER I M.O'MAILLEY
 DATE EXAMINED I JULY/18/88
 EXPERIMENT NO.1

NO. OF grains/ nucleus	cytoplasmic grains		net grains/ nucleus	
11	3	9	3	6.00
17	10	11	6	8.00
9	1	2	8	5.33
14	6	10	7	6.33
25	10	12	21	8.00
10	3	8	7	4.00
12	11	1	3	7.00
12	5	2	4	8.33
9	5	6	8	5.33
10	3	8	7	4.00
8	4	4	5	3.67
12	6	6	1	7.67
10	10	13	5	8.67
11	4	6	4	6.33
28	8	18	10	16.00
16	5	10	11	7.33
16	2	5	4	12.33
18	10	3	4	12.33
6	2	2	9	1.67
13	5	2	4	9.33
9	7	5	8	5.00
18	9	3	6	12.00
21	9	8	12	11.33
12	2	5	5	8.00
20	12	9	4	11.67
28	11	16	9	16.00
28	7	11	12	10.00
19	5	4	3	15.00
16	10	8	16	4.67
13	3	13	5	6.00
23	17	17	7	9.33
20	14	11	13	7.33
15	11	13	14	2.33
17	9	9	7	8.67
18	2	1	5	7.33
22	10	10	9	12.33
15	2	1	2	13.33
25	16	10	18	10.33
15	10	5	10	6.67
27	12	12	4	17.67
28	15	13	15	5.67
14	8	5	5	8.00
21	13	10	7	11.00
21	16	7	6	11.33
24	6	5	10	17.00
16	1	2	3	14.00
15	6	1	4	11.33
28	11	12	6	10.33
20	14	12	6	9.33
18	10	11	6	9.00

total net mean grain count : 8.83

nuclei with >=6 grains : 39
 nuclei with >=20 grains : 8

PROJECT NO. : 738388
 CLIENT : UNILEVER
 TEST MATERIAL: TRICLOSAN
 EXPT. DATE : JUNE/28/88
 SLIDE LETTER : E2

EXAMINER : M.O'MAILLEY
 DATE EXAMINED : JULY/18/88
 EXPERIMENT NO.1

NO. OF grains/ nucleus	cytoplasmic grains		net grains/ nucleus
16	8	4	6 10.00
34	21	8	16 19.00
21	6	7	7 14.33
21	8	13	11 18.33
20	7	5	3 15.00
19	7	9	8 11.00
16	10	3	8 9.00
23	3	5	12 16.33
22	8	8	13 12.33
21	13	5	15 18.00
23	10	10	14 11.67
20	11	13	7 9.67
19	11	3	9 11.33
14	9	13	11 3.00
15	6	11	8 6.67
19	5	5	4 14.33
32	16	13	3 21.33
11	10	5	6 4.00
29	11	11	13 17.33
24	9	12	7 14.67
26	9	6	13 16.67
20	11	9	11 9.67
14	7	3	10 7.33
19	8	9	9 18.33
17	8	5	8 10.00
23	7	4	7 17.00
28	13	7	11 17.67
23	11	10	6 14.00
28	13	6	6 19.67
32	15	12	8 20.33
23	18	17	6 9.33
25	7	7	6 18.33
31	13	18	12 19.33
20	9	9	12 18.00
14	8	3	11 6.67
15	4	3	4 11.33
13	4	5	2 9.33
26	14	14	5 15.00
26	11	9	10 16.00
28	9	12	16 15.67
23	10	9	10 13.33
16	6	3	11 9.33
18	5	12	10 9.00
24	5	6	10 17.00
17	7	4	4 12.00
19	2	4	6 15.00
18	6	4	7 12.33
29	15	21	12 13.00
22	11	10	8 12.33
27	19	8	17 12.33

total net mean grain count : 12.81

nuclei with >=6 grains : 48
 nuclei with >=20 grains : 2

PROJECT NO. : 738388
 CLIENT : UNILEVER
 TEST MATERIAL: TRICLOSAN
 EXPT. DATE : JUNE/28/88
 SLIDE LETTER : E3

EXAMINER : M.O'MAILLEY
 DATE EXAMINED : JULY/18/88
 EXPERIMENT NO. 1

NO. OF grains/ nucleus	cytoplasmic grains		net grains/ nucleus	
25	11	11	12	13.67
24	10	7	7	16.00
28	11	7	9	19.00
17	11	10	13	5.67
25	8	11	11	15.00
28	14	14	9	15.67
25	9	5	9	17.33
26	7	14	11	15.33
26	11	7	7	17.67
38	9	9	12	28.00
14	9	10	11	4.00
24	13	8	7	14.67
18	5	7	9	11.00
34	25	12	14	17.00
29	14	9	7	19.00
22	20	19	18	3.00
21	14	9	9	10.33
18	11	12	13	6.00
18	8	10	6	10.00
25	7	6	7	18.33
16	11	5	3	9.67
16	7	11	8	7.33
21	6	13	8	12.00
41	18	20	21	21.33
15	10	8	6	7.00
33	17	12	17	17.67
19	12	9	6	10.00
31	17	20	20	12.00
21	9	4	5	15.00
16	3	10	7	9.33
15	11	9	6	6.33
29	14	11	12	16.67
25	12	9	15	13.00
27	9	13	7	17.33
28	16	12	15	13.67
21	21	6	10	8.67
27	15	11	9	15.33
23	12	12	5	13.33
31	14	18	23	12.67
25	15	16	16	9.33
21	15	14	10	8.00
20	2	4	4	16.67
11	12	9	10	8.67
13	3	6	8	7.33
21	18	10	12	7.67
20	9	16	7	9.33
8	4	3	9	2.67
13	3	7	3	8.67
18	15	8	12	6.33
24	17	13	9	11.00
				total net mean grain count : 12.05
				nuclei with >=6 grains : 45
				nuclei with >=20 grains : 2
				mean of coverslip one : 8.83
				mean of coverslip two : 12.81
				MEAN OF ALL THREE COVERSLEPS : 11.23
				TOTAL PERCENT
				OF NUCLEI WITH >=6 GRAINS : 88.00
				TOTAL PERCENT
				OF NUCLEI WITH >=20 GRAINS : 2.67

PROJECT NO. : 738388
 CLIENT : UNILEVER
 TEST MATERIAL: TRICLOSAN
 EXPT. DATE : JUNE/28/88
 SLIDE LETTER : F1

EXAMINER : M.O'MAILLEY
 DATE EXAMINED : JULY/18/88
 EXPERIMENT NO. 1

NO. OF grains/ nucleus		cytoplasmic grains	net grains/ nucleus	
4	4	3	2	1.00
3	0	6	6	-1.00
4	4	2	4	0.67
7	4	5	7	1.67
0	9	3	6	2.00
6	9	0	5	-1.33
5	12	1	3	-0.33
5	10	4	7	-2.00
7	6	6	7	0.67
12	9	7	0	4.00
1	5	12	0	-4.67
0	1	2	1	-1.33
4	6	1	5	0.00
0	1	2	0	-1.00
1	1	6	1	-1.67
1	3	2	0	-0.67
3	2	1	3	1.00
0	1	0	0	-0.33
2	1	0	3	0.67
2	5	1	4	-1.33
1	2	3	2	-1.33
2	2	1	2	0.33
5	4	3	3	1.67
2	3	2	0	0.33
1	12	2	7	-6.00
3	2	6	2	-0.33
7	3	4	3	3.67
0	3	0	2	-4.33
1	3	1	1	-0.67
3	3	4	3	-0.33
4	4	5	6	-1.00
2	4	2	1	-0.33
3	4	2	7	-1.33
1	0	6	6	-5.67
7	5	7	0	0.33
2	3	6	3	-2.00
1	1	2	0	0.00
3	3	5	0	0.33
2	6	2	3	-1.67
2	0	4	1	0.33
3	1	3	5	0.00
1	5	2	0	-4.00
9	7	3	6	3.67
2	0	7	0	-5.67
0	0	0	0	0.00
3	4	1	4	0.00
10	4	4	4	6.00
5	0	0	9	-3.33
4	6	6	4	-1.33
1	6	2	4	-3.00

total net mean grain count : -0.59

nuclei with ≥ 6 grains : 1
 nuclei with ≥ 20 grains : 0

PROJECT NO. : 738388
 CLIENT : UNILEVER
 TEST MATERIAL: TRICLOSAN
 EXPT. DATE : JUNE/28/88
 SLIDE LETTER : F2

EXAMINER : M.O'MAILLEY
 DATE EXAMINED : JULY/18/88
 EXPERIMENT NO.1

NO. OF grains/ nucleus	cytoplasmic grains		net grains/ nucleus	
3	2	2	2	1.00
1	0	1	2	0.00
2	1	5	5	-1.67
3	2	1	4	0.67
0	1	4	5	-3.33
4	3	2	4	1.00
2	4	5	5	-2.67
3	3	3	2	0.33
0	0	2	2	-1.33
2	6	8	6	-4.67
1	6	4	4	-3.67
5	5	7	6	-1.00
9	9	3	6	3.00
2	5	4	4	-2.33
0	0	0	10	-0.67
3	7	3	9	-3.33
13	11	3	9	5.33
9	6	0	3	3.33
0	7	6	0	1.00
9	4	10	0	1.67
7	0	7	0	-0.67
7	5	6	6	1.33
0	0	13	9	-2.00
1	3	0	2	-0.67
4	9	5	4	-2.00
3	7	3	4	-1.67
2	1	3	2	0.00
2	2	1	2	0.33
2	6	4	1	-1.67
2	3	2	2	-0.33
6	10	3	7	-0.67
3	2	2	3	0.67
4	3	4	2	1.00
1	2	2	2	-1.00
4	4	4	6	-0.67
2	5	1	3	-1.00
2	3	3	4	-1.33
2	3	3	3	-1.00
6	0	4	5	0.33
2	3	2	3	-0.67
7	7	6	9	-0.33
2	3	3	3	-1.00
2	1	0	2	1.00
1	2	1	3	-1.00
3	4	4	6	-1.67
3	9	3	4	-2.33
0	2	1	0	-1.00
1	1	2	0	0.00
3	5	2	5	-1.00
2	5	1	3	-1.00

total net mean grain count : -0.55

nuclei with ≥ 6 grains : 0
 nuclei with ≥ 20 grains : 0

PROJECT NO. : 738388
 CLIENT : UNILEVER EXAMINER : M.O'MAILLEY
 TEST MATERIAL: TRICLOSAN DATE EXAMINED : JULY/18/88
 EXPT. DATE : JUNE/28/88 EXPERIMENT NO.1
 SLIDE LETTER : F3

NO. OF grains/ nucleus	cytoplasmic grains		net grains/ nucleus	
1	9	6	4	-5.33
4	5	5	5	-1.00
4	8	6	6	-2.67
8	4	6	8	2.00
4	4	3	5	0.00
1	1	4	6	-2.67
5	6	7	7	-1.67
2	2	4	7	-2.33
7	10	4	9	-0.67
5	5	3	4	1.00
5	5	3	10	-1.00
5	8	11	6	-3.33
2	8	2	1	1.00
1	4	3	3	-2.33
13	9	8	4	6.00
4	5	8	7	-2.67
4	4	3	2	1.00
8	3	2	3	-2.67
8	5	7	1	-4.33
4	4	3	2	1.00
7	16	4	7	-2.00
4	5	1	6	0.00
6	4	3	7	1.33
2	8	4	5	-1.00
4	2	3	7	0.00
3	3	5	7	-2.00
3	5	5	5	-2.00
3	5	7	6	-3.00
8	5	6	10	1.00
3	4	4	8	-2.33
14	13	13	10	2.00
6	10	9	6	-2.33
11	12	10	8	1.00
6	4	7	6	0.33
8	5	1	3	-3.00
2	5	7	2	-2.67
2	1	5	6	-2.00
2	3	4	6	-2.33
2	7	6	2	-3.00
5	8	8	6	-2.33
6	7	7	7	-1.00
3	6	5	8	-3.33
4	10	9	7	-4.67
6	5	4	7	0.67
7	7	9	8	-1.00
2	2	4	3	-1.00
5	6	6	6	-1.00
2	3	1	3	-0.33
4	2	4	3	1.00
4	10	9	7	-4.67

total net mean grain count :	-1.21
nuclei with >=6 grains	1
nuclei with >=20 grains	0
mean of coverslip one	-0.59
mean of coverslip two	-0.55
MEAN OF ALL THREE COVERSLEPS	-0.78
TOTAL PERCENT OF NUCLEI WITH >=6 GRAINS	1.33
TOTAL PERCENT OF NUCLEI WITH >=20 GRAINS	0.00

PROJECT NO. : 738388
CLIENT : UNILEVER EXAMINER : M.O'MAILLEY
TEST MATERIAL: TRICLOSAN DATE : JULY/18/88
EXPT. DATE : JUNE/28/88 EXPERIMENT NO.1
SLIDE LETTER : G1

NO. OF		net
grains/ nucleus	cytoplasmic grains	grains/ nucleus

NUCLEI APPEAR DAMAGED. UNABLE TO SCORE COVERSIP.
POSSIBLY DUE TO TOXICITY.

PROJECT NO. : 738388
CLIENT : UNILEVER
TEST MATERIAL: TRICLOSAN
EXPT. DATE : JUNE/28/88
SLIDE LETTER : G2

EXAMINER : M.O'MAILLEY

DATE : JULY/18/88

EXPERIMENT NO.1

NO. OF grains/ nucleus	cytoplasmic grains	net grains/ nucleus
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NUCLEI APPEAR DAMAGED. UNABLE TO SCORE COVERSLIP.
POSSIBLY DUE TO TOXICITY.

PROJECT NO. : 738388
CLIENT : UNILEVER
TEST MATERIAL: TRICLOSAN
EXPT. DATE : JUNE/28/88
SLIDE LETTER : G3

EXAMINER : M.O'MAILLEY

DATE : JULY/18/88

EXPERIMENT NO.1

NO. OF		net
grains/ nucleus	cytoplasmic grains	grains/ nucleus

NUCLEI APPEAR DAMAGED. UNABLE TO SCORE COVERSLIP.
POSSIBLY DUE TO TOXICITY.

PROJECT NO. : 738388
 CLIENT : UNILEVER EXAMINER : M.O'MAILLEY
 TEST MATERIAL: TRICLOSAN DATE EXAMINED : JULY/18/88
 EXPT. DATE : JUNE/28/88 EXPERIMENT NO.1
 SLIDE LETTER : H1

NO. OF grains/ nucleus	cytoplasmic grains		net grains/ nucleus	
26	15	3	12	16.00
17	7	5	6	11.00
27	10	10	13	16.00
22	7	7	8	14.67
23	7	9	10	14.33
10	10	13	7	8.00
23	5	11	7	15.33
15	12	9	5	6.33
24	7	12	4	16.33
20	12	8	9	10.33
17	5	7	8	10.33
17	7	5	8	10.33
19	7	4	10	12.00
22	7	8	4	15.67
22	11	8	4	14.33
36	6	9	10	27.67
17	5	13	10	7.67
20	12	8	5	19.67
26	8	3	3	21.33
20	10	6	5	21.00
10	12	10	5	9.00
27	11	8	14	16.00
19	4	5	9	13.00
20	6	7	7	13.33
17	8	6	5	10.67
15	9	13	6	5.67
21	6	10	8	13.00
22	9	7	6	14.67
22	10	4	11	13.67
13	7	3	5	8.00
22	4	7	9	15.33
19	10	2	4	13.67
35	21	14	21	16.33
20	9	2	5	22.67
35	9	4	12	26.67
24	8	3	5	18.67
27	15	8	16	14.00
25	9	6	13	15.67
27	12	12	5	17.33
26	20	7	11	13.33
26	11	10	8	16.33
31	13	11	19	16.67
25	5	9	12	16.33
19	14	11	10	7.33
20	13	10	8	17.67
16	8	6	5	9.67
21	8	7	5	14.33
26	11	11	7	16.33
25	10	8	5	17.33
25	6	8	11	16.67

total net mean grain count : 14.55

nuclei with ≥ 6 grains : 49
 nuclei with ≥ 20 grains : 5

PROJECT NO. : 738388
 CLIENT : UNILEVER
 TEST MATERIAL: TRICLOSAN
 EXPT. DATE : JUNE/28/88
 SLIDE LETTER : H2

EXAMINER : M. O'MAILLEY
 DATE EXAMINED : JULY/18/88
 EXPERIMENT NO. 1

NO. OF grains/ nucleus	cytoplasmic grains		net grains/ nucleus
21	2	5	12 14.67
21	13	12	13 8.33
17	4	9	4 11.33
25	11	7	6 17.00
17	3	9	7 10.67
14	10	6	5 7.00
19	5	7	6 13.00
21	5	8	14 12.00
23	16	10	11 10.67
21	6	8	4 15.00
18	5	4	4 13.67
23	12	9	6 14.00
17	10	5	2 11.33
17	6	3	4 12.67
19	2	3	2 16.67
20	8	0	4 16.00
23	5	6	5 17.67
20	3	10	5 14.00
20	7	11	8 11.33
28	1	4	6 24.33
27	17	14	5 15.00
34	10	9	10 24.33
30	9	4	6 23.67
23	11	5	14 13.00
28	5	8	5 22.00
35	13	14	13 21.67
30	12	17	7 18.00
27	12	4	11 18.00
22	5	8	6 15.67
24	14	9	7 14.00
28	8	8	9 19.67
27	16	11	10 14.67
33	10	16	11 20.67
31	12	24	23 11.33
20	12	11	5 10.67
20	14	14	10 7.33
26	8	11	8 17.00
14	17	7	13 1.67
31	18	13	18 14.67
25	17	5	12 13.67
19	11	6	8 10.67
16	8	8	7 8.33
31	9	8	7 25.67
18	4	9	12 9.67
23	6	10	14 13.00
14	8	5	2 9.00
21	6	5	3 16.33
22	7	9	2 16.00
22	7	6	5 16.00
29	8	8	6 21.67

total net mean grain count : 14.69

nuclei with ≥ 6 grains : 49
 nuclei with ≥ 20 grains : 8

PROJECT NO. : 738388
 CLIENT : UNILEVER
 TEST MATERIAL: TRICLOSAN
 EXPT. DATE : JUNE/28/88
 SLIDE LETTER : H3

EXAMINER : M.O'MAILLEY
 DATE EXAMINED : JULY/19/88
 EXPERIMENT NO.1

NO. OF grains/ nucleus	cytoplasmic grains		net grains/ nucleus	
24	7	10	3	17.33
25	11	11	5	16.00
23	10	10	11	12.67
17	9	6	5	10.33
24	7	13	9	14.33
19	4	2	4	15.67
16	1	8	5	11.33
22	7	8	4	15.67
26	7	12	5	18.00
22	9	10	4	14.33
13	5	4	3	9.00
20	5	9	2	14.67
22	14	13	16	7.67
18	5	6	11	10.67
13	7	3	5	8.00
16	8	3	4	11.00
22	9	11	11	11.67
16	6	4	5	11.00
21	13	13	14	7.67
30	2	6	7	25.00
22	4	11	9	14.00
22	12	15	9	10.00
19	6	7	12	10.67
22	6	9	8	14.33
19	9	3	5	13.33
23	9	14	4	14.00
22	9	3	6	16.00
17	15	9	5	7.33
19	8	11	9	9.67
25	14	4	6	17.00
29	12	14	4	19.00
26	11	9	8	16.67
27	14	11	4	17.33
25	9	7	6	17.67
20	5	4	4	15.67
29	10	6	10	20.33
19	3	4	6	14.67
20	4	1	3	17.33
25	10	15	21	9.67
16	3	7	2	12.00
15	15	8	9	4.33
21	7	8	10	12.67
21	4	11	11	12.33
24	8	11	9	14.67
15	5	5	7	9.33
22	4	10	9	14.33
18	3	7	4	13.33
13	2	2	1	11.33
18	15	21	8	3.33
18	7	4	5	12.67

total net mean grain count : 13.14

nuclei with >=6 grains : 48
 nuclei with >=20 grains : 2

mean of coverslip one : 14.55

mean of coverslip two : 14.69

MEAN OF ALL THREE COVERSLEPS : 14.13

TOTAL PERCENT
 OF NUCLEI WITH >=6 GRAINS : 97.33

TOTAL PERCENT
 OF NUCLEI WITH >=20 GRAINS : 10.00

PROJECT NO. : 738388
 CLIENT : UNILEVER
 TEST MATERIAL: TRICLOSAN
 EXPT. DATE : JUNE/28/88
 SLIDE LETTER : 11

EXAMINER : M.O'MAILLEY
 DATE EXAMINED : JULY/19/88
 EXPERIMENT NO. 1

NO. OF grains/ nucleus	cytoplasmic grains		net grains/ nucleus
15	6	9	3 9.00
23	8	4	3 18.00
22	4	5	7 16.67
16	5	6	6 10.33
16	7	5	8 9.33
24	4	5	6 19.00
27	1	5	3 24.00
21	10	6	15 10.67
22	11	12	8 11.67
18	5	4	5 13.33
18	4	7	2 13.67
23	13	9	3 14.67
28	16	10	12 15.33
21	7	2	5 16.33
20	9	6	4 13.67
9	2	3	4 6.00
23	10	9	7 14.33
13	7	2	6 8.00
18	3	5	6 13.33
15	4	8	8 8.33
28	5	2	2 25.00
21	3	5	7 16.00
22	6	8	3 16.33
24	6	6	8 17.33
26	9	4	6 19.67
22	15	8	13 10.00
31	8	13	4 22.67
29	7	12	9 19.67
23	6	5	7 17.00
24	10	8	4 16.67
25	10	10	9 15.33
29	10	8	6 21.00
28	13	7	5 19.67
33	6	7	8 26.00
31	24	8	8 17.67
28	6	8	5 13.67
23	13	8	9 13.00
14	5	7	5 8.33
13	6	1	6 8.67
19	6	7	11 11.00
23	3	5	3 19.33
23	13	7	7 14.00
14	5	6	3 9.33
20	10	5	3 14.00
27	11	13	17 13.33
30	10	14	20 15.33
35	12	7	5 27.00
24	4	13	10 15.00
22	7	7	9 14.33
23	4	5	7 17.67

total net mean grain count : 15.19

nuclei with ≥ 6 grains : 50
 nuclei with ≥ 20 grains : 6

PROJECT NO. : 738388
 CLIENT : UNILEVER
 TEST MATERIAL: TRICLOSAN
 EXPT. DATE : JUNE/28/88
 SLIDE LETTER : I2

EXAMINER : M.O'MAILLEY
 DATE EXAMINED : JULY/19/88
 EXPERIMENT NO.1

NO. OF grains/ nucleus	cytoplasmic grains		net grains/ nucleus
44	6	2	1 41.00
38	4	10	4 32.00
38	11	9	1 31.00
41	5	9	10 33.00
22	4	7	4 17.00
27	8	7	8 19.33
26	3	9	5 20.33
31	9	6	9 23.00
26	4	9	3 20.67
41	6	11	10 32.00
38	6	5	11 30.67
48	6	6	13 39.67
54	12	18	10 40.67
34	16	17	9 20.00
38	6	5	7 32.00
18	3	6	5 13.33
31	4	3	4 27.33
32	4	6	9 25.67
42	5	9	7 35.00
31	6	5	2 26.67
43	8	8	5 36.00
29	11	4	4 22.67
27	2	2	7 23.33
49	3	6	7 43.67
28	1	3	8 18.67
29	2	2	5 26.00
25	9	5	2 19.67
39	5	5	3 34.67
49	6	8	3 43.33
51	7	9	7 43.33
26	5	3	2 22.67
30	4	6	5 25.00
41	5	5	7 35.33
43	3	3	5 39.33
38	7	6	4 24.33
54	9	9	3 47.00
45	3	6	7 39.67
43	11	4	7 35.67
49	15	8	5 39.67
44	4	2	7 39.67
31	3	3	3 28.00
39	8	5	6 32.67
41	13	9	7 31.33
24	4	5	4 19.67
44	3	4	9 38.67
54	10	10	11 43.67
47	9	8	8 38.67
45	6	11	10 36.00
48	4	5	5 43.33
56	12	7	8 47.00

total net mean grain count : 31.58

nuclei with ≥ 6 grains : 58
 nuclei with ≥ 20 grains : 44

PROJECT NO. : 738388
 CLIENT : UNILEVER
 TEST MATERIAL: TRICLOSAN
 EXPT. DATE : JUNE/28/88
 SLIDE LETTER : I3

EXAMINER : M.D'MAILLEY
 DATE EXAMINED : JULY/19/88
 EXPERIMENT NO. 1

NO. OF grains/ nucleus	cytoplasmic grains		net grains/ nucleus	
24	3	9	4	18.67
21	6	2	6	16.33
19	3	7	7	13.33
27	2	1	7	23.67
22	2	8	7	16.33
22	6	7	4	16.33
29	2	9	6	23.33
28	2	1	5	25.33
25	5	3	5	28.67
27	1	9	4	22.33
25	6	3	7	19.67
26	8	3	3	21.33
23	8	6	3	28.00
25	4	4	7	28.00
28	2	2	5	25.00
23	5	2	3	19.67
31	6	2	4	27.00
18	2	3	1	16.00
28	4	6	4	15.33
16	6	5	9	9.33
19	4	6	6	13.67
17	9	6	2	11.33
18	5	1	4	6.67
21	6	4	3	16.67
15	4	1	6	11.33
26	4	3	8	21.00
13	6	4	5	8.00
18	6	8	2	15.33
32	6	6	5	26.33
18	3	4	9	12.67
18	6	2	6	13.33
28	1	4	7	24.00
22	9	1	4	17.33
19	1	1	7	16.00
24	1	1	4	22.00
28	2	4	1	17.67
22	8	2	5	19.67
17	4	2	8	15.00
16	3	4	5	12.00
15	2	3	6	11.33
17	4	3	8	14.67
18	8	8	3	14.33
13	5	3	6	8.33
15	3	3	4	11.67
15	7	8	3	9.00
26	6	7	1	21.33
16	8	4	4	18.67
19	9	3	4	13.67
14	4	5	2	18.33
11	4	8	7	7.33

total net mean grain count : 16.45

nuclei with ≥ 6 grains : 58
 nuclei with ≥ 20 grains : 15

mean of coverslip one : 15.19

mean of coverslip two : 31.58

MEAN OF ALL THREE COVERSLIPS : 21.87

TOTAL PERCENT
 OF NUCLEI WITH ≥ 6 GRAINS : 100.00

TOTAL PERCENT
 OF NUCLEI WITH ≥ 20 GRAINS : 43.33

PROJECT NO. : 738388
 CLIENT : UNILEVER
 TEST MATERIAL: TRICLOSAN
 EXPT. DATE : JUNE/28/88
 SLIDE LETTER : J1

EXAMINER : M.O'MAILLEY
 DATE EXAMINED : JULY/19/88
 EXPERIMENT NO.1

NO. OF grains/ nucleus	cytoplasmic grains		net grains/ nucleus
5	5	1	8 3.00
9	2	4	2 6.33
20	7	5	4 14.67
20	5	4	5 15.33
9	3	5	7 4.00
11	8	4	2 6.33
10	8	1	2 9.00
15	6	3	5 10.33
25	6	9	9 17.00
11	8	5	8 4.00
20	6	12	9 11.00
16	3	2	2 13.67
7	0	2	5 4.67
15	10	8	6 7.00
11	4	2	1 8.67
7	2	5	4 3.33
9	3	5	5 4.67
6	6	3	6 1.00
7	2	1	7 3.67
10	7	4	4 5.00
10	3	4	5 14.00
14	4	5	4 9.67
14	4	9	4 8.33
12	3	4	4 8.33
25	10	9	5 17.00
27	9	4	16 17.33
8	5	3	6 3.33
9	6	8	1 4.00
25	9	10	6 16.67
10	2	6	5 5.67
7	3	3	4 3.67
5	5	5	6 -0.33
24	12	7	5 16.00
17	13	7	4 9.00
10	14	9	4 9.00
9	4	3	6 4.67
10	3	8	9 3.33
25	8	6	12 16.33
11	7	3	4 6.33
19	11	2	5 13.00
13	8	6	6 6.33
15	2	4	7 10.67
21	13	4	9 12.33
12	4	3	3 8.67
13	6	2	5 8.67
13	9	6	5 6.33
10	5	1	7 5.67
13	6	2	7 8.00
13	9	8	9 4.33
16	10	7	6 8.33

total net mean grain count : 8.35

nuclei with >=6 grains : 32
 nuclei with >=20 grains : 0

PROJECT NO. : 738388
 CLIENT : UNILEVER
 TEST MATERIAL: TRICLOSAN
 EXPT. DATE : JUNE/28/88
 SLIDE LETTER : J2

EXAMINER : M.O'MAILLEY
 DATE EXAMINED : JULY/28/88
 EXPERIMENT NO. 1

NO. OF grains/ nucleus	cytoplasmic grains		net grains/ nucleus	
16	11	5	6	8.67
13	6	3	2	9.33
6	5	2	5	2.00
17	4	4	9	11.33
15	2	4	3	12.00
9	3	8	2	4.67
10	7	3	4	5.33
14	7	3	5	9.00
19	7	11	5	11.33
17	3	11	9	9.33
12	4	3	5	8.00
9	5	8	1	7.00
15	12	9	1	7.67
12	1	2	3	10.00
9	1	2	3	7.00
5	1	3	1	3.33
11	4	3	4	7.33
13	1	4	2	10.67
17	5	5	11	10.00
10	1	2	2	8.33
7	1	3	3	4.67
13	8	3	7	7.00
14	2	7	4	9.67
12	3	4	6	7.67
13	5	2	4	9.33
21	9	6	10	12.67
16	3	2	4	13.00
15	7	2	0	12.00
8	2	5	1	5.33
7	6	3	3	3.00
18	5	6	6	12.33
13	8	6	6	6.33
28	10	11	6	19.00
12	12	6	6	4.00
15	2	8	10	8.33
13	6	12	3	6.00
13	2	3	4	10.00
17	5	7	5	11.33
14	3	2	1	12.00
13	7	1	2	9.67
10	4	2	5	6.33
10	4	3	5	6.00
18	12	7	12	7.67
11	4	5	5	6.33
13	6	4	6	7.67
12	8	2	5	9.67
12	3	4	3	8.67
13	7	5	3	8.00
7	3	2	4	4.00
6	3	2	3	3.33

total net mean grain count : 8.27

nuclei with ≥ 6 grains : 48

nuclei with ≥ 20 grains : 0

PROJECT NO. : 738388
 CLIENT : UNILEVER
 TEST MATERIAL: TRICLOSAN
 EXPT. DATE : JUNE/28/88
 SLIDE LETTER : J3

EXAMINER : M.O'MAILLEY
 DATE EXAMINED : JULY/28/88
 EXPERIMENT NO. 1

NO. OF grains/ nucleus	cytoplasmic grains		net grains/ nucleus	
17	8	9	4	10.00
14	3	4	6	9.67
8	7	4	5	2.67
10	8	5	8	3.00
14	4	3	7	9.33
5	2	2	5	2.00
9	3	2	3	6.33
17	6	1	4	13.33
6	3	6	0	3.00
17	8	6	8	9.67
25	9	7	8	17.00
17	0	1	0	16.67
13	13	3	8	5.00
12	7	7	6	5.33
18	6	7	6	11.67
12	7	8	9	4.00
10	3	4	4	6.33
5	4	4	2	1.67
4	2	1	2	2.33
9	4	1	3	6.33
9	2	2	3	6.67
9	4	1	4	6.00
10	1	2	1	8.67
17	2	7	6	12.00
5	2	1	1	3.67
11	4	5	3	7.00
14	4	2	4	10.67
12	6	9	10	3.67
8	3	5	2	4.67
19	7	8	8	11.33
14	13	9	8	4.00
12	4	2	8	7.33
10	6	3	6	5.00
7	3	3	3	4.00
2	7	5	1	-2.33
6	2	1	4	3.67
19	6	6	8	12.33
14	9	8	10	5.00
3	2	2	2	1.00
8	5	4	4	3.67
2	1	6	5	-2.00
8	3	3	3	5.00
9	1	3	2	7.00
8	6	5	6	2.33
15	2	2	7	11.33
13	9	6	7	5.67
10	1	3	3	7.67
10	4	3	2	7.00
6	3	2	4	3.00
7	6	3	4	2.67

total net mean grain count :	6.26
nuclei with >=6 grains :	24
nuclei with >=20 grains :	0
mean of coverslip one :	8.35
mean of coverslip two :	8.27
MEAN OF ALL THREE COVERSGLIPS :	7.63
TOTAL PERCENT OF NUCLEI WITH >=6 GRAINS :	64.00
TOTAL PERCENT OF NUCLEI WITH >=20 GRAINS :	0.00

PROJECT NO. : 738388
 CLIENT : UNILEVER
 TEST MATERIAL: TRICLOSAN
 EXPT. DATE : JUNE/28/88
 SLIDE LETTER : K1

EXAMINER : M.D'MAILLEY
 DATE EXAMINED : JULY/28/88
 EXPERIMENT NO. 1

NO. OF grains/ nucleus	cytoplasmic grains		net grains/ nucleus	
7	5	8	4	1.33
1	5	1	3	-2.00
7	4	5	5	2.33
3	2	2	3	0.67
4	5	6	5	-1.33
9	11	3	10	1.00
9	5	5	7	3.33
5	13	7	11	-5.33
6	7	9	13	-3.67
7	7	9	11	-2.00
10	9	11	14	-1.33
8	11	6	6	0.33
8	7	4	8	1.67
4	3	3	8	-0.67
8	7	9	13	-1.67
6	9	3	5	0.33
5	9	6	5	-1.67
9	4	6	4	4.33
7	5	8	5	1.00
4	3	4	6	-0.33
4	5	5	5	-1.00
7	8	10	5	-0.67
7	5	5	4	2.33
7	3	4	9	1.67
9	9	3	5	3.33
6	10	6	7	-1.67
7	4	6	5	2.00
7	7	6	5	1.00
4	4	3	2	1.00
4	3	2	1	2.00
2	3	1	2	0.00
11	3	8	5	5.67
4	3	6	2	0.33
3	4	3	2	0.00
7	10	8	10	-2.33
3	3	6	8	0.00
5	5	5	2	1.00
2	4	3	4	-1.67
4	3	5	6	-0.67
4	6	6	6	-2.00
7	3	5	4	3.00
4	3	4	4	0.33
6	3	5	5	1.67
4	3	3	4	0.67
6	6	13	7	-2.67
4	5	3	4	0.00
7	5	5	4	2.33
5	6	5	9	-1.67
3	2	4	4	-0.33
4	6	5	4	-1.00

total net mean grain count : 0.18

nuclei with ≥ 6 grains : 0
 nuclei with ≥ 20 grains : 0

PROJECT NO. : 738388
 CLIENT : UNILEVER
 TEST MATERIAL: TRICLOSAN
 EXPT. DATE : JUNE/28/88
 SLIDE LETTER : K2

EXAMINER : M.O'MAILLEY
 DATE EXAMINED : JULY/28/88
 EXPERIMENT NO. 1

NO. OF grains/ nucleus	cytoplasmic grains		net grains/ nucleus
2	2	2	1 0.33
4	6	0	3 1.00
4	7	3	2 0.00
3	2	3	2 0.67
2	2	2	2 0.00
1	1	2	1 -0.33
5	6	3	5 0.33
3	5	6	4 -2.00
2	4	1	8 -2.33
3	4	2	7 -1.33
9	10	10	9 -0.67
10	4	9	4 4.33
6	3	10	4 0.33
2	4	1	7 -2.00
5	5	2	3 1.67
4	3	2	6 0.33
3	4	4	2 -0.33
10	8	10	7 1.67
6	2	5	3 2.67
4	3	5	3 0.33
12	5	6	2 7.67
5	2	3	3 2.33
7	3	11	4 1.00
3	5	4	2 -0.67
4	4	4	4 0.00
6	4	4	6 1.33
1	2	1	1 -0.33
2	3	0	1 0.67
4	4	4	3 0.33
10	5	4	6 5.00
3	2	2	4 0.33
1	3	2	2 -1.33
3	4	4	3 -0.67
2	3	4	6 -2.33
4	5	5	6 -1.33
3	6	2	6 -1.67
3	4	3	4 -0.67
4	6	4	4 -0.67
4	7	6	4 -1.67
6	2	4	4 2.67
7	2	4	2 4.33
6	5	4	3 2.00
5	3	5	4 1.00
8	8	7	9 0.00
4	6	4	3 -0.33
6	4	7	8 -0.33
8	7	8	11 -0.67
5	3	3	3 2.00
8	8	4	10 0.67
5	4	4	3 1.33

total net mean grain count : 0.49

nuclei with >=6 grains : 1
 nuclei with >=20 grains : 0

PROJECT NO. : 738388
 CLIENT : UNILEVER
 TEST MATERIAL: TRICLOSAN
 EXPT. DATE : JUNE/28/88
 SLIDE LETTER : K3

EXAMINER : M.O'MAILLEY
 DATE EXAMINED : JULY/21/88
 EXPERIMENT NO. 1

NO. OF grains/ nucleus	cytoplasmic grains		net grains/ nucleus	
10	8	12	9	0.33
5	5	2	6	0.67
3	6	9	7	-4.33
3	3	4	5	-1.00
3	4	2	5	-0.67
4	4	3	5	0.00
8	5	4	5	-4.67
3	6	5	2	-1.33
2	3	3	6	-2.00
3	5	2	6	-1.33
2	2	4	2	-0.67
5	5	5	3	0.67
3	4	4	2	-0.33
4	5	3	3	0.33
3	4	4	3	-0.67
2	3	2	6	-1.67
2	2	2	6	-1.33
2	4	4	3	-1.67
5	2	3	5	1.67
3	2	5	3	-0.33
4	2	3	3	1.33
5	5	6	5	-0.33
8	7	3	2	-4.00
2	2	4	4	-1.33
6	4	4	5	1.67
7	6	10	7	-0.67
4	2	2	9	-0.33
1	5	5	3	-3.33
3	5	3	3	-0.67
1	3	6	1	-2.33
4	5	2	2	1.00
4	2	4	6	0.00
1	4	5	3	-3.00
3	2	7	3	-1.00
5	4	3	4	1.33
3	3	1	4	0.33
3	3	5	6	-1.67
2	2	5	4	-1.67
2	2	1	3	0.00
4	6	4	2	0.00
7	3	3	5	3.33
3	2	1	2	1.33
2	3	9	2	-2.67
4	4	5	9	-2.00
5	5	3	2	1.67
3	5	3	2	-0.33
1	2	1	2	-0.67
4	2	4	4	0.67
4	5	8	3	1.33
4	4	1	4	1.00
				total net mean grain count : -0.59
				nuclei with >=6 grains : 0
				nuclei with >=20 grains : 0
				mean of coverslip one : 0.18
				mean of coverslip two : 0.49
				MEAN OF ALL THREE COVERSLEPS : 0.03
				TOTAL PERCENT
				OF NUCLEI WITH >=6 GRAINS : 0.67
				TOTAL PERCENT
				OF NUCLEI WITH >=20 GRAINS : 0.00

PROJECT NO. : 738388
 CLIENT : UNILEVER
 TEST MATERIAL: TRICLOSAN
 EXPT. DATE : JUNE/28/88
 SLIDE LETTER : L1

EXAMINER : M.O'MAILLEY
 DATE EXAMINED : JULY/21/88
 EXPERIMENT NO.1

NO. OF grains/ nucleus	cytoplasmic grains		net grains/ nucleus	
5	1	3	4	2.33
12	5	2	4	8.33
14	1	4	3	11.33
5	1	7	4	1.00
5	3	2	2	2.67
4	4	4	2	0.67
2	5	5	4	-2.67
4	3	7	4	-0.67
3	9	5	5	-3.33
3	4	4	2	-0.33
3	3	2	3	0.33
5	1	2	4	2.67
8	10	13	11	-3.33
5	5	3	5	0.67
8	9	9	7	-0.33
4	7	3	4	-0.67
5	2	4	5	1.33
3	8	8	5	-4.00
3	3	9	4	-2.33
4	4	5	6	-1.00
9	7	8	5	2.33
4	5	3	6	-0.67
4	5	3	4	0.00
3	2	3	4	0.00
10	3	4	5	6.00
6	10	6	10	-2.67
5	6	4	10	-1.67
1	6	4	3	-3.33
5	7	2	8	-0.67
6	6	9	4	-0.33
12	9	8	10	3.00
6	5	3	3	2.33
5	3	2	3	2.33
2	1	2	2	0.33
7	7	7	2	1.67
6	6	10	8	-2.00
2	8	7	4	-4.33
4	6	3	3	0.00
5	8	6	8	-2.33
3	3	8	6	-2.67
4	3	4	2	1.00
3	2	9	3	-1.67
3	1	4	3	0.33
4	3	1	2	2.00
7	6	5	5	1.67
1	2	0	0	0.33
7	10	7	6	-0.67
4	0	3	4	1.67
9	14	8	6	-0.33
10	8	14	11	-1.00

total net mean grain count : 0.27

nuclei with ≥ 6 grains : 3
 nuclei with ≥ 20 grains : 0

PROJECT NO. : 738388
 CLIENT : UNILEVER
 TEST MATERIAL: TRICLOSAN
 EXPT. DATE : JUNE/28/88
 SLIDE LETTER : L2

EXAMINER : M.O'MAILLEY
 DATE EXAMINED : JULY/21/88
 EXPERIMENT NO. 1

NO. OF grains/ nucleus	cytoplasmic grains	net grains/ nucleus	
6	3	5	7 1.00
6	3	5	9 0.33
6	5	7	6 0.00
4	2	4	4 0.67
3	5	5	9 -3.33
3	3	3	2 0.33
7	7	7	7 0.00
5	3	5	5 0.67
8	2	7	5 3.33
3	5	1	4 -0.33
9	8	7	5 2.33
3	6	4	4 -1.67
5	2	4	5 1.33
6	4	6	6 0.67
3	4	3	3 -0.33
15	19	7	20 -0.33
5	4	9	8 -2.00
5	6	8	7 -2.00
14	12	16	4 3.33
8	5	7	2 3.33
9	5	5	5 4.00
6	5	5	3 1.67
5	4	4	2 1.67
9	2	2	3 6.67
3	4	2	3 0.00
2	5	3	3 -1.67
9	6	5	6 3.33
7	7	7	8 -0.33
8	5	6	4 3.00
8	6	4	4 3.33
7	6	4	2 3.00
2	3	3	3 -1.00
5	4	4	5 0.67
4	4	3	2 1.00
5	4	4	3 1.33
5	3	3	2 2.33
7	3	3	5 3.33
11	10	11	12 0.00
4	6	8	4 -2.00
5	4	3	5 1.00
5	4	3	6 0.67
8	5	8	9 0.67
8	4	1	4 5.00
6	12	8	12 -4.67
5	7	4	7 -1.00
5	6	3	2 1.33
3	7	9	6 -4.33
3	3	3	3 0.00
5	10	7	6 -2.67
11	6	8	7 4.00

total net mean grain count : 0.75

nuclei with >=6 grains : 1
 nuclei with >=20 grains : 0

PROJECT NO. : 738388
 CLIENT : UNILEVER
 TEST MATERIAL: TRICLOSAN
 EXPT. DATE : JUNE/28/88
 SLIDE LETTER : L3

EXAMINER : M.O'MAILLEY
 DATE EXAMINED : JULY/21/88
 EXPERIMENT NO.1

NO. OF grains/ nucleus	cytoplasmic grains		net grains/ nucleus	
7	12	10	9	-3.33
10	12	10	5	1.00
12	14	11	9	0.67
9	11	7	8	0.33
16	16	24	19	-3.67
8	12	13	12	-4.33
10	11	10	13	-1.33
4	9	7	6	-3.33
4	7	12	11	-6.00
7	9	13	9	-3.33
4	22	14	17	-13.67
3	19	11	1	-7.33
4	9	17	12	-8.67
2	7	7	14	-7.33
11	10	16	11	-1.33
7	10	12	10	-3.67
4	6	8	8	-3.33
1	7	12	9	-8.33
8	12	9	10	-2.33
2	3	8	6	-3.67
6	17	19	17	-11.67
5	13	18	19	-11.67
1	16	9	10	-10.67
7	18	22	24	-14.33
3	15	10	10	-8.67
5	7	12	17	-7.00
4	6	12	9	-5.00
5	16	14	9	-8.00
3	14	5	2	-4.00
2	7	7	8	-5.33
8	5	7	4	-5.33
8	16	4	11	-10.33
9	14	10	13	-3.33
5	11	16	10	-7.33
4	13	11	12	-8.00
3	12	8	9	-6.67
16	12	15	17	1.33
10	5	11	5	3.00
11	10	7	9	2.33
9	9	9	10	-0.33
6	8	3	4	1.00
13	13	11	11	1.33
10	8	5	8	3.00
12	15	9	14	-0.67
13	9	7	10	4.33
10	6	4	8	4.00
14	9	3	10	6.67
8	8	4	13	-0.33
10	11	8	10	0.33
8	12	9	7	-1.33

total net mean grain count : -3.71

nuclei with >=6 grains : 1
 nuclei with >=20 grains : 0

mean of coverslip one : 0.27

mean of coverslip two : 0.75

MEAN OF ALL THREE COVERSLEPS : -0.90

TOTAL PERCENT
 OF NUCLEI WITH >=6 GRAINS : 3.33

TOTAL PERCENT
 OF NUCLEI WITH >=20 GRAINS : 0.00

PROJECT NO. : 738388
 CLIENT : UNILEVER
 TEST MATERIAL: TRICLOSAN
 EXPT. DATE : JUNE/28/88
 SLIDE LETTER : M1

EXAMINER : M.O'MAILLEY
 DATE EXAMINED : JULY/21/88
 EXPERIMENT NO. 1

NO. OF grains/ nucleus	cytoplasmic grains		net grains/ nucleus	
9	7	7	5	2.67
5	5	6	4	0.00
7	5	4	4	2.67
10	4	3	6	5.67
4	5	5	4	-0.67
5	2	8	7	-0.67
5	6	4	4	0.33
14	9	11	7	5.00
13	9	11	9	3.33
6	4	10	12	-2.67
7	8	16	9	-4.00
9	13	9	8	-1.00
6	12	10	14	-6.00
3	4	9	5	-3.00
1	5	7	5	-4.67
5	11	8	11	-5.00
8	2	2	4	5.33
16	17	15	6	3.33
8	10	14	12	-4.00
7	2	3	3	4.33
2	3	3	1	-0.33
5	5	5	7	-0.67
12	4	4	3	0.33
12	6	10	9	3.67
7	5	3	1	4.00
1	3	3	1	-1.33
13	7	11	4	5.67
7	7	3	3	2.67
10	8	2	4	5.33
5	4	3	3	1.67
7	4	4	5	2.67
8	4	3	2	5.00
5	3	2	6	1.33
4	5	4	4	-0.33
3	3	4	1	0.33
3	3	4	2	0.00
10	5	4	4	5.67
9	1	6	7	4.33
12	6	5	5	6.67
8	8	9	6	0.33
9	3	5	5	4.67
12	8	6	3	6.33
6	4	3	2	3.00
5	7	3	4	0.33
7	4	3	2	4.00
7	6	3	3	3.00
4	4	6	5	-1.00
9	11	4	10	0.67
8	4	4	4	4.00
12	4	5	6	7.00

total net mean grain count : 1.76

nuclei with ≥ 6 grains : 4
 nuclei with ≥ 20 grains : 0

PROJECT NO. : 738388
 CLIENT : UNILEVER
 TEST MATERIAL: TRICLOSAN
 EXPT. DATE : JUNE/28/88
 SLIDE LETTER : M2

EXAMINER : M.O'MAILLEY
 DATE EXAMINED : JULY/21/88
 EXPERIMENT NO.1

NO. OF grains/ nucleus	cytoplasmic grains	net grains/ nucleus
7	11	4
3	2	2
10	7	9
8	3	8
4	8	3
9	6	6
4	4	3
9	10	6
6	1	5
9	12	14
8	5	6
9	13	12
11	10	15
6	4	7
6	10	6
5	3	9
4	8	12
8	6	7
5	5	2
10	1	2
7	5	2
3	4	5
3	2	2
4	6	2
10	10	9
4	5	5
9	2	4
15	4	8
2	5	3
11	2	2
8	4	4
4	10	7
6	5	5
9	16	7
13	3	8
5	3	5
9	14	17
6	8	9
6	6	7
10	5	7
8	11	6
9	4	10
10	6	5
9	7	6
7	14	20
8	14	5
5	2	1
7	6	7
11	13	6
1	2	2

total net mean grain count : 0.96

nuclei with ≥ 6 grains : 5
 nuclei with ≥ 20 grains : 0

PROJECT NO. : 738388
 CLIENT : UNILEVER
 TEST MATERIAL: TRICLOSAN
 EXPT. DATE : JUNE/28/88
 SLIDE LETTER : M3

EXAMINER : M.O'MAILLEY
 DATE EXAMINED : JULY/21/88
 EXPERIMENT NO.1

NO. OF grains/ nucleus	cytoplasmic grains		net grains/ nucleus	
3	2	6	2	-0.33
1	3	3	2	-1.67
3	4	3	2	0.00
3	3	2	2	0.67
1	3	3	3	-2.00
8	9	4	6	1.67
7	7	4	3	2.33
4	5	3	4	0.00
5	5	2	0	2.67
4	6	5	2	-0.33
8	8	12	8	-1.33
3	8	4	11	-4.67
2	2	3	7	-2.00
4	1	6	3	0.67
3	5	9	6	-3.67
9	4	8	8	2.33
5	1	5	3	2.00
4	6	4	4	-0.67
3	4	5	2	-0.67
10	7	8	4	3.67
9	7	7	8	1.67
4	6	1	3	0.67
3	5	6	7	-3.00
7	2	2	4	4.33
6	12	4	5	-1.00
7	10	6	6	-0.33
6	10	6	5	-1.00
4	4	2	1	1.67
4	3	2	1	2.00
4	0	5	1	2.00
6	8	7	5	-0.67
4	4	7	3	-0.67
6	2	4	4	2.67
3	3	1	2	1.00
8	7	2	5	3.33
11	3	1	3	0.67
3	5	7	6	-3.00
10	3	11	10	2.00
3	5	3	11	-3.33
3	1	3	2	1.00
3	1	4	3	0.33
9	7	2	9	3.00
8	6	5	2	3.67
5	3	4	2	2.00
2	5	3	3	-1.67
5	0	4	10	0.33
9	4	3	4	5.33
4	5	8	5	-2.00
3	11	15	7	-8.00
5	8	6	4	-1.00

total net mean grain count : 0.37

nuclei with ≥ 6 grains : 1
 nuclei with ≥ 20 grains : 0

mean of coverslip one : 1.76

mean of coverslip two : 0.96

MEAN OF ALL THREE COVERSLEPS : 1.03

TOTAL PERCENT
 OF NUCLEI WITH ≥ 6 GRAINS : 6.67

TOTAL PERCENT
 OF NUCLEI WITH ≥ 20 GRAINS : 0.00

PROJECT NO. : 738388
CLIENT : UNILEVER EXAMINER : M.O'MAILLEY
TEST MATERIAL: TRICLOSAN DATE : JULY/21/88
EXPT. DATE : JUNE/28/88 EXPERIMENT NO.1
SLIDE LETTER : N1

NO. OF		net
grains/ nucleus	cytoplasmic grains	grains/ nucleus

NUCLEI APPEAR DAMAGED. UNABLE TO SCORE COVERSLIP.
POSSIBLY DUE TO TOXICITY.

PROJECT NO. : 738388
CLIENT : UNILEVER EXAMINER : M.O'MAILLEY
TEST MATERIAL: TRICLOSAN DATE : JULY/21/88
EXPT. DATE : JUNE/28/88 EXPERIMENT NO.1
SLIDE LETTER : N2

NO. OF		net
grains/ nucleus	cytoplasmic grains	grains/ nucleus

NUCLEI APPEAR DAMAGED. UNABLE TO SCORE COVERSIP.
POSSIBLY DUE TO TOXICITY.

PROJECT NO. :738388
CLIENT :UNILEVER EXAMINER :M.O'MAILLEY
TEST MATERIAL:TRICLOSAN DATE :JULY/21/88
EXPT. DATE :JUNE/28/88 EXPERIMENT NO.1
SLIDE LETTER :N3

NO. OF		net
grains/ nucleus	cytoplasmic grains	grains/ nucleus

NUCLEI APPEAR DAMAGED.UNABLE TO SCORE COVERSIP.
POSSIBLY DUE TO TOXICITY.

PROJECT NO. : 738388
 CLIENT : UNILEVER
 TEST MATERIAL: TRICLOSAN
 EXPT. DATE : JUNE/28/88
 SLIDE LETTER : D1

EXAMINER : M.O'MAILLEY
 DATE EXAMINED : JULY/21/88
 EXPERIMENT NO.1

NO. OF grains/ nucleus	cytoplasmic grains		net grains/ nucleus	
10	7	14	9	0.00
7	3	3	10	1.67
6	3	7	7	0.33
6	5	10	7	-1.33
4	10	6	6	-3.33
3	2	4	3	0.00
4	3	2	4	1.00
9	11	12	10	-2.00
6	1	2	6	3.00
6	4	3	3	2.67
4	6	9	5	-2.67
6	2	1	3	4.00
4	2	1	3	2.00
4	5	3	2	0.67
4	7	3	5	-1.00
8	5	4	8	2.33
10	8	4	6	4.00
4	5	2	1	1.33
6	10	10	5	-2.33
5	5	4	7	-0.33
4	5	5	1	0.33
4	2	5	1	1.33
6	2	6	6	1.33
9	3	4	4	5.33
3	10	6	4	-3.67
6	6	5	5	0.67
11	12	10	7	-1.33
6	4	6	5	1.00
6	5	2	4	2.33
3	4	0	2	1.00
8	2	9	3	3.33
6	4	10	4	0.00
5	4	5	3	1.00
3	6	4	3	-1.33
6	5	3	4	2.00
2	4	6	3	-2.33
5	2	1	3	3.00
6	5	6	2	1.67
6	4	3	3	2.67
3	2	3	2	0.67
4	3	3	4	0.67
5	5	6	6	-0.67
6	12	8	7	-3.00
4	9	6	2	-1.67
7	6	4	6	1.67
7	5	5	5	2.00
9	4	6	11	2.00
4	6	6	6	-2.00
10	9	4	6	3.67
7	2	3	4	4.00

total net mean grain count : 0.71

nuclei with ≥ 6 grains : 0

nuclei with ≥ 20 grains : 0

PROJECT NO. : 738388
 CLIENT : UNILEVER
 TEST MATERIAL: TRICLOSAN
 EXPT. DATE : JUNE/28/88
 SLIDE LETTER : 02

EXAMINER : M.O'MAILLEY
 DATE EXAMINED : JULY/21/88
 EXPERIMENT NO. 1

NO. OF grains/ nucleus	cytoplasmic grains		net grains/ nucleus	
8	6	3	4	3.67
6	5	4	7	0.67
5	5	6	4	0.00
7	10	6	5	0.00
5	10	5	9	-3.00
6	3	3	5	2.33
4	6	8	5	-2.33
7	10	11	13	-4.33
9	6	6	2	4.33
6	6	7	10	-1.67
9	10	12	4	0.33
6	3	2	4	3.00
12	5	9	6	5.33
5	8	5	6	-1.33
2	3	4	2	-1.00
2	3	1	5	-1.00
3	5	3	3	-0.67
11	8	8	11	2.00
5	6	3	7	-0.33
1	3	8	2	-0.67
4	13	10	9	-6.67
3	3	1	4	0.33
4	6	4	7	-1.67
9	7	4	8	2.67
6	10	8	8	-2.67
8	7	12	4	0.33
5	3	5	11	-1.33
7	5	4	3	3.00
4	7	4	3	-0.67
3	1	2	4	0.67
7	7	7	10	-1.00
14	10	9	11	4.00
4	7	4	3	-0.67
6	4	4	5	1.67
2	2	3	3	-0.67
2	5	3	5	-2.33
5	4	2	3	2.00
8	7	8	5	1.33
3	3	7	2	-1.00
3	7	5	3	-2.00
2	5	8	7	-4.67
3	6	1	3	-0.33
8	7	5	10	0.67
5	11	10	5	-3.67
6	4	7	11	-1.33
4	8	7	5	-2.67
2	6	3	7	-3.33
7	9	5	4	1.00
5	7	7	7	-2.00
8	5	5	5	3.00

total net mean grain count : -0.25

nuclei with >=6 grains : 0
 nuclei with >=20 grains : 0

PROJECT NO. : 738388
 CLIENT : UNILEVER
 TEST MATERIAL: TRICLOSAN
 EXPT. DATE : JUNE/28/88
 SLIDE LETTER : 03

EXAMINER : M.O'MAILLEY
 DATE EXAMINED : JULY/22/88
 EXPERIMENT NO.1

NO. OF grains/ nucleus	cytoplasmic grains		net grains/ nucleus	
11	4	2	2	8.33
11	7	6	3	5.67
10	12	15	16	-4.33
3	4	4	2	-0.33
5	3	7	2	1.00
1	8	9	3	-5.67
6	4	3	6	1.67
4	6	6	2	-0.67
5	2	2	6	1.67
3	5	4	11	-3.67
10	9	5	15	0.33
10	4	7	6	4.33
8	21	12	14	-7.67
8	7	6	7	1.33
10	5	10	10	-1.00
1	10	7	5	-6.33
8	3	8	11	0.67
6	5	8	4	0.33
6	7	6	10	-1.67
13	10	15	15	-3.00
5	6	1	5	1.00
10	11	9	5	1.67
12	15	11	9	0.33
11	5	8	9	3.67
8	8	11	8	-1.00
5	13	10	3	-3.67
10	7	7	8	2.67
7	7	7	5	0.67
9	8	8	7	1.33
10	10	9	9	0.67
7	6	3	4	2.67
2	6	5	9	-4.67
7	4	2	4	3.67
7	4	2	3	4.00
8	3	3	6	-4.00
3	3	2	3	0.33
5	9	7	13	-4.67
9	9	11	4	1.00
5	10	2	5	-0.67
8	5	11	7	0.33
6	6	7	10	-1.67
5	1	3	2	3.00
4	10	2	5	-1.67
2	5	2	3	-1.33
9	6	5	4	4.00
6	3	5	3	2.33
16	3	4	4	12.33
5	4	4	2	1.67
4	7	7	8	-3.33
4	3	7	6	-1.33
				total net mean grain count : 0.21
				nuclei with >=6 grains : 2
				nuclei with >=20 grains : 0
				mean of coverslip one : 0.71
				mean of coverslip two : -0.25
				MEAN OF ALL THREE COVERSLEPS : 0.22
				TOTAL PERCENT
				OF NUCLEI WITH >=6 GRAINS : 1.33
				TOTAL PERCENT
				OF NUCLEI WITH >=20 GRAINS : 0.00

PROJECT NO. : 738388
 CLIENT : UNILEVER
 TEST MATERIAL: TRICLOSAN
 EXPT. DATE : JUNE/28/88
 SLIDE LETTER : P1

EXAMINER : M.O'MAILLEY
 DATE EXAMINED : JULY/22/88
 EXPERIMENT NO. 1

NO. OF grains/ nucleus	cytoplasmic grains		net grains/ nucleus
33	22	16	12 16.33
32	18	9	7 23.33
31	18	13	5 21.67
34	5	9	15 24.33
41	20	21	25 19.00
21	13	18	9 18.33
28	15	18	12 15.67
33	21	14	13 17.00
36	18	14	9 25.00
42	21	20	24 20.33
34	12	9	11 23.33
28	11	12	12 16.33
35	19	16	11 19.67
34	11	23	22 15.33
41	6	6	5 35.33
37	6	11	7 29.00
38	19	17	18 20.00
18	15	11	9 6.33
24	18	12	18 13.33
35	14	12	17 20.67
29	8	13	15 17.00
33	17	24	19 13.00
38	5	9	16 20.00
36	15	11	18 24.00
38	14	8	15 17.67
40	24	15	13 22.67
32	7	6	12 23.67
25	18	18	14 8.33
55	22	28	36 29.00
45	3	2	1 43.00
34	18	24	23 12.33
26	13	8	12 15.00
38	14	9	8 19.67
38	21	17	18 11.33
41	14	23	18 22.67
36	27	19	23 13.00
37	28	23	16 17.33
32	21	28	22 11.00
34	28	28	16 15.33
28	19	19	17 9.67
25	22	6	11 12.00
33	17	15	17 16.67
53	17	32	17 31.00
25	8	4	3 20.00
38	19	18	18 19.67
38	16	22	18 19.33
25	28	17	14 8.00
44	15	11	16 30.00
34	18	15	5 21.33
32	24	13	12 15.67

total net mean grain count : 19.03

nuclei with ≥ 6 grains : 50
 nuclei with ≥ 20 grains : 21

PROJECT NO. : 738388
 CLIENT : UNILEVER
 TEST MATERIAL: TRICLOSAN
 EXPT. DATE : JUNE/28/88
 SLIDE LETTER : P2

EXAMINER : M.O'MAILLEY
 DATE EXAMINED : JULY/22/88
 EXPERIMENT NO. 1

NO. OF grains/ nucleus	cytoplasmic grains		net grains/ nucleus	
33	17	22	17	14.33
28	18	15	16	14.33
33	33	31	24	3.67
25	16	11	12	12.00
34	16	11	18	21.67
33	16	19	7	19.00
31	13	9	8	21.00
30	20	21	22	9.00
39	20	14	24	19.67
32	13	16	12	18.33
25	22	18	20	5.00
29	25	18	17	9.00
33	15	19	6	19.67
36	36	24	22	8.67
32	13	26	18	13.00
31	31	14	13	11.67
40	15	13	20	24.00
38	14	17	12	23.67
29	12	18	18	15.67
37	24	12	16	19.67
37	11	5	12	27.67
33	11	13	21	18.00
26	12	4	4	19.33
32	14	5	6	23.67
19	11	9	11	8.67
22	9	18	13	11.33
30	15	11	6	19.33
25	8	9	4	18.00
28	5	5	7	22.33
23	4	4	8	17.67
36	8	6	7	29.00
36	8	12	11	25.67
28	11	14	8	17.00
26	17	12	14	11.67
32	19	16	12	16.33
38	15	11	12	17.33
37	11	9	14	25.67
40	18	6	14	38.00
34	8	13	9	24.00
18	6	9	2	12.33
18	15	18	11	6.00
31	20	14	18	13.67
30	19	11	14	15.33
39	14	14	24	21.67
46	13	18	5	36.67
40	17	22	12	23.00
31	15	11	15	17.33
41	13	14	16	26.67
32	27	20	18	13.00
36	15	25	13	18.33

total net mean grain count : 17.79

nuclei with >=6 grains : 48
 nuclei with >=20 grains : 16

PROJECT NO. : 738388
 CLIENT : UNILEVER EXAMINER : M.O'MAILLEY
 TEST MATERIAL: TRICLOSAN DATE EXAMINED : JULY/22/88
 EXPT. DATE : JUNE/28/88 EXPERIMENT NO. 1
 SLIDE LETTER : P3

NO. OF grains/ nucleus	cytoplasmic grains		net grains/ nucleus	
32	15	20	22	13.00
33	20	19	23	12.33
27	23	13	22	7.67
28	28	10	14	10.67
20	11	10	14	8.33
25	13	6	4	17.33
21	5	3	4	17.00
12	8	11	8	3.00
25	4	5	7	19.67
29	22	13	18	11.33
28	7	13	11	17.67
31	15	8	16	10.00
32	9	5	11	23.67
22	6	4	8	16.00
20	8	6	14	10.67
26	17	6	10	15.00
28	9	7	9	11.67
19	8	8	6	11.67
12	8	4	1	10.33
23	14	13	13	9.67
20	5	7	7	13.67
23	15	4	8	14.00
20	3	7	3	15.67
14	6	10	11	5.00
25	5	5	8	19.00
29	14	6	4	21.00
26	7	11	5	18.33
29	8	15	14	16.67
35	9	6	7	27.67
32	12	9	16	19.67
28	9	6	9	20.00
27	9	5	7	20.00
29	11	11	17	16.00
17	7	2	7	11.67
17	6	5	8	10.67
15	3	2	9	10.33
20	15	3	6	12.00
24	5	5	7	18.33
38	12	18	17	22.33
28	28	8	13	11.67
26	11	13	11	14.33
24	7	2	7	18.67
28	8	11	13	17.33
26	13	10	5	16.67
27	4	5	5	22.33
22	9	14	7	12.00
29	14	7	9	19.00
26	6	3	6	21.00
23	8	11	7	14.33
31	12	8	4	23.00
				total net mean grain count : 15.34
				nuclei with >=6 grains : 48
				nuclei with >=20 grains : 9
				mean of coverslip one : 19.03
				mean of coverslip two : 17.79
				MEAN OF ALL THREE COVERSLEPS : 17.39
				TOTAL PERCENT
				OF NUCLEI WITH >=6 GRAINS : 97.33
				TOTAL PERCENT
				OF NUCLEI WITH >=20 GRAINS : 30.67

PROJECT NO. : 738388
 CLIENT : UNILEVER EXAMINER : M.O'MAILLEY
 TEST MATERIAL: TRICLOSAN DATE : SEPTEMBER/6/88
 EXPT. DATE : AUGUST/24/88 EXPERIMENT NO.2
 SLIDE LETTER : A1

NO. OF grains/ nucleus	cytoplasmic grains		net grains/ nucleus	
7	8	6	10	-1.00
2	2	2	3	-0.33
4	4	10	3	-1.67
0	0	2	1	-1.00
0	2	1	1	-1.33
3	7	4	4	-2.00
7	7	12	5	-1.00
2	3	2	1	0.00
4	2	11	4	-1.67
3	3	3	3	0.00
0	10	3	2	-5.00
4	5	3	7	-1.00
10	6	9	3	4.00
12	10	11	10	1.67
5	4	5	6	0.00
5	5	7	6	-1.00
4	7	4	2	-0.33
7	5	5	5	2.00
6	3	6	4	1.67
2	3	6	4	-2.33
4	7	7	4	-2.00
3	4	9	4	-2.67
3	4	4	7	-2.00
3	4	7	7	-3.00
9	9	7	11	0.00
7	12	9	5	-1.67
4	7	6	12	-4.33
4	9	4	5	-2.00
12	11	12	13	0.00
1	5	3	4	-3.00
1	9	3	2	-3.67
3	5	3	5	-1.33
3	0	0	0	3.00
14	10	10	12	-2.00
5	4	6	9	-1.33
4	4	3	5	0.00
6	9	5	12	-2.67
9	5	7	7	2.67
6	7	4	5	0.67
3	3	5	8	-2.33
7	7	8	15	-3.00
5	6	6	5	-0.67
4	7	6	4	-1.67
4	7	5	6	-2.00
10	4	9	5	4.00
8	6	3	5	3.33
6	6	6	9	-1.00
12	8	14	4	3.33
4	9	7	4	-2.67
5	4	6	6	-0.33

total net mean grain count : -0.77

nuclei with ≥ 6 grains : 0
 nuclei with ≥ 20 grains : 0

PROJECT NO. : 738388
 CLIENT : UNILEVER
 TEST MATERIAL: TRICLOSAN
 EXPT. DATE : AUGUST/24/88
 SLIDE LETTER : A2

EXAMINER : M.O'MAILLEY
 DATE : SEPTEMBER/7/88
 EXPERIMENT NO.2

NO. OF grains/ nucleus	cytoplasmic grains	net grains/ nucleus
7	8	12
5	7	5
4	2	3
6	5	7
3	3	4
2	2	2
4	2	4
3	1	3
2	3	2
4	9	5
4	6	4
2	6	2
1	8	2
2	8	8
5	4	1
7	6	7
6	6	5
8	1	8
4	5	3
9	9	6
4	5	7
9	9	3
5	5	3
1	4	2
2	5	6
5	6	7
8	8	6
2	6	4
2	6	8
3	4	4
3	5	5
4	6	3
7	7	12
4	5	5
5	3	5
2	1	4
5	2	6
1	5	2
5	4	6
5	3	8
2	4	4
11	2	4
4	5	3
6	5	5
2	3	2
3	3	6
3	7	10
6	3	8
7	6	6
5	4	4

total net mean grain count : -0.59

nuclei with >=6 grains : 8
 nuclei with >=20 grains : 0

PROJECT NO. : 738388
 CLIENT : UNILEVER EXAMINER : M.O'MAILLEY
 TEST MATERIAL: TRICLOSAN DATE EXAMINED : SEPTEMBER/7/88
 EXPT. DATE : AUGUST/24/88 EXPERIMENT NO.2
 SLIDE LETTER : A3

NO. OF grains/ nucleus	cytoplasmic grains		net grains/ nucleus	
4	3	8	8	-2.33
2	2	3	9	-2.67
1	3	3	1	-1.33
7	4	3	5	3.00
7	6	5	6	1.33
1	4	4	4	-3.00
1	1	2	2	-0.67
6	10	9	3	-1.33
9	7	7	8	1.67
2	4	5	2	-1.67
8	7	7	6	1.33
5	7	5	4	-0.33
3	8	6	4	-3.00
3	3	1	6	-0.33
5	6	3	6	0.00
6	4	6	5	1.00
5	14	11	10	-6.67
7	6	8	7	0.00
2	10	3	2	-3.00
7	2	10	2	2.33
4	4	2	7	-0.33
4	5	4	5	-0.67
1	2	9	2	-3.33
12	8	10	11	2.33
2	15	7	7	-7.67
3	5	2	7	-1.67
8	12	11	15	-4.67
6	11	9	5	-2.33
1	7	6	3	-4.33
1	7	6	5	-5.00
4	6	10	4	-2.67
6	7	4	2	1.67
3	11	14	9	-8.33
3	3	3	5	-0.67
1	4	2	3	-2.00
2	11	6	6	-5.67
8	5	7	9	1.00
10	12	9	9	0.00
6	8	6	2	0.67
12	6	10	5	5.00
5	7	9	11	-4.00
6	10	6	5	-1.00
6	10	10	8	-3.33
11	13	8	13	-0.33
8	12	13	5	-2.00
7	10	6	6	-0.33
7	12	8	15	-4.67
5	7	8	7	-2.33
3	6	4	6	-2.33
14	11	19	12	0.00

total net mean grain count :				-1.49
nuclei with >=6 grains	:			0
nuclei with >=20 grains	:			0
mean of coverslip one	:			-0.77
mean of coverslip two	:			-0.59
MEAN OF ALL THREE COVERSLEPS	:			-0.95
TOTAL PERCENT				
OF NUCLEI WITH >=6 GRAINS	:			0.00
TOTAL PERCENT				
OF NUCLEI WITH >=20 GRAINS	:			0.00

PROJECT NO. : 738388
 CLIENT : UNILEVER EXAMINER : M.O'MAILLEY
 TEST MATERIAL: TRICLOSAN DATE : SEPTEMBER/7/88
 EXPT. DATE : AUGUST/24/88 EXPERIMENT NO.2
 SLIDE LETTER : B1

NO. OF grains/ nucleus	cytoplasmic grains	net grains/ nucleus	
6	8	10	8 -2.67
5	2	2	3 2.67
4	5	4	4 -0.33
5	11	6	5 -2.33
3	7	10	12 -6.67
6	7	9	9 -2.33
4	6	6	8 -2.67
6	8	2	4 1.33
2	4	2	4 -1.33
3	2	2	2 1.00
3	6	3	11 -3.67
7	7	7	8 -0.33
4	2	4	4 0.67
2	5	4	3 -2.00
3	4	3	7 -1.67
1	5	3	4 -3.00
10	12	12	9 -1.00
5	8	4	11 -2.67
11	5	5	6 5.67
5	3	7	3 0.67
6	5	4	8 0.33
4	13	10	10 -7.00
4	8	6	5 -2.33
1	4	1	1 -1.00
3	4	4	5 -1.33
3	4	2	3 0.00
7	8	9	9 -1.67
5	6	9	10 -3.33
6	4	3	9 0.67
4	3	8	5 -1.33
8	9	6	12 -1.00
8	5	10	14 -1.67
4	3	2	3 1.33
5	5	10	1 -0.33
10	9	18	12 -3.00
6	3	9	3 1.00
8	7	6	6 1.67
4	6	6	1 -0.33
7	8	8	7 -0.67
5	3	2	1 3.00
10	12	8	12 -0.67
13	5	4	4 8.67
9	17	9	5 -1.33
5	5	5	5 0.00
7	8	9	6 -0.67
15	5	13	14 4.33
11	8	5	7 4.33
12	13	10	6 2.33
5	7	8	5 -1.67
13	13	15	10 0.33

total net mean grain count : -0.44

nuclei with >=6 grains : 1
 nuclei with >=20 grains : 0

PROJECT NO. : 738388
 CLIENT : UNILEVER EXAMINER : M.O'MAILLEY
 TEST MATERIAL: TRICLOSAN DATE : SEPTEMBER/7/88
 EXPT. DATE : AUGUST/24/88 EXPERIMENT NO.2
 SLIDE LETTER : B2

NO. OF grains/ nucleus	cytoplasmic grains	net grains/ nucleus	
4	6	6	-2.00
4	2	1	1.33
1	4	2	-2.33
4	8	5	-3.00
4	6	5	-0.67
6	8	6	-0.33
6	3	7	0.67
2	3	4	-2.00
3	5	3	-1.00
6	5	9	-2.00
5	5	6	-1.00
2	4	3	-1.33
5	7	4	0.33
4	8	6	-1.67
5	4	5	0.33
3	5	4	-1.00
3	3	2	0.33
2	2	1	1.00
3	3	2	0.67
9	6	4	4.00
3	2	7	-2.00
4	1	7	-2.00
3	8	5	-3.67
8	6	11	0.67
2	6	6	-3.00
1	4	3	-2.00
8	6	2	4.33
6	3	9	1.33
4	4	5	0.33
2	6	2	-1.00
3	2	6	-0.33
5	6	4	0.00
4	4	5	-0.33
5	7	7	-2.33
6	4	4	1.67
1	7	3	-3.00
4	1	2	1.67
6	8	4	0.00
3	3	6	0.00
3	7	2	-2.67
1	3	6	-3.00
4	8	7	-4.33
2	2	6	-1.33
4	7	6	-3.33
2	8	12	-6.67
18	6	11	1.33
2	6	4	-3.33
3	4	7	-2.33
2	7	9	-5.33
7	8	8	-1.00

total net mean grain count : -1.03

nuclei with >=6 grains : 8
 nuclei with >=20 grains : 0

PROJECT NO. : 738388
 CLIENT : UNILEVER EXAMINER : M.D'MAILLEY
 TEST MATERIAL: TRICLOSAN DATE EXAMINED : SEPTEMBER/7/88
 EXPT. DATE : AUGUST/24/88 EXPERIMENT NO.2
 SLIDE LETTER : B3

NO. OF grains/ nucleus	cytoplasmic grains		net grains/ nucleus	
2	2	4	4	-1.33
3	1	4	5	-0.33
4	3	2	4	1.00
9	3	7	8	3.00
3	5	7	5	-2.67
6	5	5	7	0.33
5	7	8	3	-1.00
6	12	8	10	-4.00
4	5	7	4	-1.33
4	3	5	6	-0.67
4	3	4	4	-0.33
6	3	6	7	0.67
5	3	2	2	2.67
2	5	5	3	-2.33
4	6	6	4	-1.33
6	5	3	4	2.00
5	5	4	4	0.67
5	4	4	5	0.67
5	5	4	4	0.67
7	5	7	6	1.00
8	9	8	9	-0.67
5	6	2	5	0.67
3	6	5	5	-2.33
2	2	3	3	-0.67
5	3	3	3	2.00
3	2	2	3	0.67
5	6	8	5	-1.33
2	6	3	5	-2.67
7	10	11	13	-4.33
5	5	9	8	-2.33
5	4	4	4	1.00
6	7	8	7	-1.33
3	9	4	6	-3.33
5	4	4	11	-1.33
8	9	8	6	0.33
6	2	5	6	1.67
3	6	3	11	-3.67
3	8	6	6	-3.67
7	10	9	11	-3.00
7	8	11	6	-1.33
8	8	10	14	-2.67
2	1	4	6	-1.67
7	11	4	13	-2.33
3	3	2	3	0.33
3	7	3	4	-1.67
6	10	9	8	-3.00
5	4	6	8	-1.00
7	5	8	10	-0.67
9	11	15	9	-2.67
6	9	5	8	-1.33

total net mean grain count :	-0.90
nuclei with >=6 grains :	0
nuclei with >=20 grains :	0
mean of coverslip one :	-0.44
mean of coverslip two :	-1.83
MEAN OF ALL THREE COVERSLEPS :	-0.79
TOTAL PERCENT OF NUCLEI WITH >=6 GRAINS :	0.67
TOTAL PERCENT OF NUCLEI WITH >=20 GRAINS :	0.00

PROJECT NO. :738388
CLIENT :UNILEVER EXAMINER :M.O'MAILLEY
TEST MATERIAL:TRICLOSAN DATE :SEPTEMBER/7/88
EXPT. DATE :AUGUST/24/88 EXPERIMENT NO.2
SLIDE LETTER :C1

NO. OF		net
grains/ nucleus	cytoplasmic grains	grains/ nucleus

NUCLEI APPEAR DAMAGED.UNABLE TO SCORE COVERSLIP.
POSSIBLY DUE TO TOXICITY.

PROJECT NO. :738388
CLIENT :UNILEVER EXAMINER :M.O'MAILLEY
TEST MATERIAL:TRICLOSAN DATE :SEPTEMBER/7/88
EXPT. DATE :AUGUST/24/88 EXPERIMENT NO.2
SLIDE LETTER :C2

NO. OF		net
grains/ nucleus	cytoplasmic grains	grains/ nucleus

NUCLEI APPEAR DAMAGED.UNABLE TO SCORE COVERSLIP.
POSSIBLY DUE TO TOXICITY.

PROJECT NO. :738388
CLIENT :UNILEVER EXAMINER :M.O'MAILLEY
TEST MATERIAL:TRICLOSAN DATE :SEPTEMBER/7/88
EXPT. DATE :AUGUST/24/88 EXPERIMENT NO.2
SLIDE LETTER :C3

NO. OF		net
grains/ nucleus	cytoplasmic grains	grains/ nucleus

NUCLEI APPEAR DAMAGED.UNABLE TO SCORE COVERSIP.
POSSIBLY DUE TO TOXICITY.

PROJECT NO. : 738388
 CLIENT : UNILEVER EXAMINER : M.O'MAILLEY
 TEST MATERIAL: TRICLOSAN DATE : SEPTEMBER/7/88
 EXPT. DATE : AUGUST/24/88 EXPERIMENT NO.2
 SLIDE LETTER : D1

NO. OF grains/ nucleus	cytoplasmic grains	net grains/ nucleus	
4	6	7	11 -4.00
6	10	11	8 -3.67
5	9	2	7 -1.00
10	6	5	3 5.33
10	4	8	6 4.00
4	6	3	8 -1.67
6	7	11	9 -3.00
12	7	16	11 0.67
8	9	6	6 1.00
10	6	9	12 1.00
4	2	3	9 -0.67
4	7	5	4 -1.33
6	9	19	8 -6.00
9	11	14	12 -3.33
7	11	7	17 -4.67
5	6	8	8 -2.33
8	12	12	9 -3.00
1	1	4	4 -2.00
5	6	11	6 -2.67
5	12	13	6 -5.33
8	9	11	8 -1.33
7	13	11	7 -3.33
6	9	6	12 -3.00
11	5	11	7 3.33
5	7	5	3 0.00
6	10	4	8 -1.33
4	7	7	3 -1.67
9	9	8	8 0.67
8	6	19	8 -3.00
5	5	4	2 1.33
6	7	6	3 0.67
9	15	18	7 -4.33
4	7	3	6 -1.33
8	12	9	9 -2.00
4	7	4	6 -1.67
11	12	7	10 1.33
4	9	7	8 -4.00
3	4	7	4 -2.00
9	9	7	11 0.00
7	24	13	15 -10.33
10	13	5	6 2.00
9	12	15	20 -6.67
9	10	10	11 -1.33
6	9	12	10 -4.33
5	11	7	10 -4.33
6	18	12	8 -6.67
8	8	8	6 0.67
5	6	5	12 -2.67
13	10	9	10 3.33
4	6	5	7 -2.00

total net mean grain count : -1.73

nuclei with >=6 grains : 0
 nuclei with >=20 grains : 0

PROJECT NO. : 738388
 CLIENT : UNILEVER EXAMINER : M.O'MAILLEY
 TEST MATERIAL: TRICLOSAN DATE : SEPTEMBER/7/88
 EXPT. DATE : AUGUST/24/88 EXPERIMENT NO.2
 SLIDE LETTER : D2

NO. OF grains/ nucleus	cytoplasmic grains		net grains/ nucleus
6	8	4	4 0.67
5	8	3	7 -1.00
6	2	12	13 -3.00
5	6	6	10 -2.33
4	3	5	5 -0.33
8	6	3	7 2.67
4	8	10	8 -4.67
8	13	6	6 -0.33
16	11	7	7 7.67
7	6	5	6 1.33
10	12	10	10 -0.67
7	10	14	4 -2.33
5	10	6	10 -3.67
5	10	7	7 -3.00
6	8	9	12 -3.67
9	4	11	14 -0.67
12	11	5	7 4.33
5	7	13	9 -4.67
6	12	7	6 -2.33
8	9	10	13 -5.33
4	6	5	5 -1.33
3	8	7	9 -5.00
12	13	7	6 3.33
14	17	10	7 2.67
13	9	10	13 2.33
9	6	12	12 -1.00
7	10	14	4 -2.33
8	11	7	7 -0.33
4	4	6	6 -1.33
8	15	9	14 -4.67
10	15	17	21 -7.67
10	22	15	6 -4.33
6	8	6	5 -0.33
7	4	3	7 2.33
6	6	4	4 1.33
1	6	6	6 -5.00
4	6	9	2 -1.67
6	3	7	4 1.33
3	6	6	7 -3.33
7	10	14	3 -2.00
4	2	3	3 1.33
4	12	8	7 -5.00
8	7	5	6 2.00
12	10	13	14 -0.33
5	10	5	6 -2.00
4	5	4	5 -0.67
8	4	5	6 3.00
6	14	5	5 -2.00
7	9	10	6 -1.33
8	8	7	10 -0.33

total net mean grain count : -1.07

nuclei with ≥ 6 grains : 0
 nuclei with ≥ 20 grains : 0

PROJECT NO. : 738388
 CLIENT : UNILEVER EXAMINER : M.D'MAILLEY
 TEST MATERIAL: TRICLOSAN DATE EXAMINED : SEPTEMBER/7/88
 EXPT. DATE : AUGUST/24/88 EXPERIMENT NO.2
 SLIDE LETTER : D3

NO. OF grains/ nucleus	cytoplasmic grains		net grains/ nucleus	
4	7	13	5	-4.33
8	4	5	3	4.00
5	2	5	5	1.00
11	10	15	10	-0.67
6	8	6	6	-0.67
6	4	9	10	-1.67
8	2	3	3	5.33
5	4	3	2	2.00
5	7	4	5	-0.33
4	3	4	4	0.33
15	15	8	15	2.33
9	6	7	12	0.67
5	11	11	11	-6.00
5	9	9	3	-2.00
16	7	10	16	5.00
11	6	10	15	0.67
7	8	4	5	1.33
7	2	2	0	5.67
7	4	5	9	1.00
2	4	5	5	-2.67
5	1	5	2	2.33
4	5	3	5	-0.33
6	5	5	3	1.67
14	8	8	10	5.33
9	9	15	17	-4.67
12	12	11	8	1.67
11	13	11	20	-3.67
6	10	6	9	-2.33
19	10	12	20	2.33
18	17	17	11	3.00
3	2	3	0	1.33
2	1	3	2	0.00
7	11	7	6	-1.00
3	2	5	3	-0.33
2	2	1	2	0.33
4	1	3	2	2.00
8	7	5	5	2.33
4	4	2	6	0.00
4	3	3	3	1.00
4	9	8	6	-3.67
5	7	9	7	-2.67
6	9	4	9	-1.33
8	4	9	6	1.67
12	13	14	15	-2.00
3	7	4	3	-1.67
5	12	11	8	-5.33
13	16	10	15	-0.67
8	7	9	9	-0.33
6	8	12	11	-4.33
10	3	4	11	4.00

total net mean grain count :	0.11
nuclei with >=6 grains :	0
nuclei with >=20 grains :	0
mean of coverslip one :	-1.73
mean of coverslip two :	-1.07
MEAN OF ALL THREE COVERSGLIPS :	-0.90
TOTAL PERCENT OF NUCLEI WITH >=6 GRAINS :	0.00
TOTAL PERCENT OF NUCLEI WITH >=20 GRAINS :	0.00

PROJECT NO. : 738388
 CLIENT : UNILEVER
 TEST MATERIAL: TRICLOSAN
 EXPT. DATE : AUGUST/24/88
 SLIDE LETTER : E1

EXAMINER : M.O'MAILLEY
 DATE : SEPTEMBER/15/88
 EXPERIMENT NO.2

NO. OF grains/ nucleus	cytoplasmic grains		net grains/ nucleus
4	4	5	4 -0.33
4	4	11	6 -3.00
3	3	4	11 -3.00
2	4	9	3 -3.33
2	0	1	1 1.33
4	4	3	4 0.33
3	3	6	6 -2.00
4	0	3	12 -3.67
3	3	6	3 -1.00
2	2	1	0 1.00
2	1	6	5 -2.00
5	2	3	2 2.67
6	2	1	0 5.00
3	2	1	1 1.67
11	12	9	5 2.33
5	4	12	6 -2.33
3	7	8	5 -3.67
7	3	8	5 1.67
3	16	13	2 -7.33
7	3	7	6 1.67
4	4	17	4 -4.33
4	4	4	8 -1.33
3	5	6	3 -1.67
2	6	4	6 -3.33
5	2	4	7 0.67
9	8	19	11 -3.67
8	8	6	14 -1.33
6	6	5	7 0.00
4	6	3	2 0.33
8	12	15	9 -4.00
4	9	4	8 -3.00
2	11	8	8 -7.00
3	14	8	11 -8.00
6	5	5	8 0.00
1	5	4	6 -4.00
3	3	8	1 -1.00
5	13	8	4 -3.33
1	3	3	4 -2.33
5	12	12	9 -6.00
13	12	12	7 2.67
9	9	2	7 3.00
7	17	6	9 -3.67
8	19	20	12 -9.33
2	8	5	2 -3.00
8	3	5	6 3.33
5	9	3	5 -0.67
11	16	12	13 -2.67
7	3	4	7 2.33
8	12	14	7 -0.00
4	4	14	5 -3.67

total net mean grain count : -1.64

nuclei with ≥ 6 grains : 0
 nuclei with ≥ 20 grains : 0

PROJECT NO. : 738388
 CLIENT : UNILEVER
 TEST MATERIAL: TRICLOSAN
 EXPT. DATE : AUGUST/24/88
 SLIDE LETTER : E2

EXAMINER : M.O'MAILLEY
 DATE : SEPTEMBER/15/88
 EXPERIMENT NO.2

NO. OF grains/ nucleus	cytoplasmic grains	net grains/ nucleus
2	2	1
2	3	2
5	13	5
3	8	4
6	3	7
5	4	13
9	11	12
13	12	9
12	16	8
4	5	9
8	4	5
12	6	7
7	12	11
1	8	9
7	5	3
6	11	7
3	8	16
3	5	5
6	8	18
5	3	5
8	7	6
13	8	15
5	8	2
4	9	7
5	9	5
9	3	4
3	9	3
11	13	9
2	5	6
4	3	4
8	15	17
4	1	5
1	2	3
3	2	2
11	8	7
1	8	1
1	1	0
4	6	6
3	7	4
6	2	4
7	7	7
5	7	4
5	9	7
5	7	5
3	6	4
2	2	2
2	4	6
4	7	3
5	8	3
3	5	11

total net mean grain count : -1.07

nuclei with >=6 grains : 0
 nuclei with >=20 grains : 0

PROJECT NO. : 738388
 CLIENT : UNILEVER EXAMINER : M.O'MAILLEY
 TEST MATERIAL: TRICLOSAN DATE EXAMINED : SEPTEMBER/15/88
 EXFT. DATE : AUGUST/24/88 EXPERIMENT NO.2
 SLIDE LETTER : E3

NO. OF grains/ nucleus		cytoplasmic grains	net grains/ nucleus	
25	18	15	22	6.67
8	16	9	8	-3.00
26	23	15	24	5.33
6	9	9	7	-2.33
16	9	9	8	7.33
13	9	11	6	4.33
12	23	17	14	-6.00
8	12	9	9	-2.00
14	9	8	9	5.33
5	13	4	6	-2.67
6	15	15	8	-6.67
8	15	7	9	-2.33
2	7	13	11	-8.33
4	2	5	3	0.67
6	1	1	5	3.67
11	13	8	12	0.00
6	9	8	12	-3.67
12	14	5	9	2.67
8	7	9	7	0.33
7	7	16	13	-5.00
7	9	11	6	-1.67
5	6	13	8	-4.00
12	9	11	7	3.00
15	7	7	13	6.00
6	11	3	6	-0.67
7	12	5	11	-2.33
6	6	8	8	-1.33
5	17	9	13	-8.00
13	17	19	14	-3.67
6	7	6	9	-1.33
12	20	11	12	-2.33
8	7	8	26	-5.67
6	11	6	14	-4.33
5	4	4	7	0.00
6	8	8	8	-2.00
6	3	2	6	2.33
12	14	13	13	-1.33
3	2	5	3	-0.33
6	5	11	6	-1.33
11	20	19	18	-8.00
11	17	14	17	-5.00
9	5	8	7	2.33
3	5	2	4	-0.67
7	7	11	6	-1.00
9	9	8	5	1.67
4	13	9	11	-7.00
6	1	4	5	2.33
9	9	9	11	-0.67
6	2	8	8	0.00
5	6	2	2	1.67

total net mean grain count :	-0.98
nuclei with >=6 grains :	3
nuclei with >=20 grains :	0
mean of coverslip one :	-1.64
mean of coverslip two :	-1.07
MEAN OF ALL THREE COVERSLEPS :	-1.23
TOTAL PERCENT OF NUCLEI WITH >=6 GRAINS :	2.00
TOTAL PERCENT OF NUCLEI WITH >=20 GRAINS :	0.00

PROJECT NO. : 738388
CLIENT : UNILEVER EXAMINER : M.O'MAILLEY
TEST MATERIAL: TRICLOSAN DATE : SEPTEMBER/15/88
EXPT. DATE : AUGUST/24/88 EXPERIMENT NO.2
SLIDE LETTER : F1

NO. OF		net
grains/ nucleus	cytoplasmic grains	grains/ nucleus

UNABLE TO SCORE COVERSLIP
DUE TO LACK OF NUCLEI.

PROJECT NO. : 738388
 CLIENT : UNILEVER
 TEST MATERIAL: TRICLOSAN
 EXPT. DATE : AUGUST/24/88
 SLIDE LETTER : F2

EXAMINER : M.O'MAILLEY
 DATE : SEPTEMBER/15/88
 EXPERIMENT NO.2

NO. OF grains/ nucleus	cytoplasmic grains	net grains/ nucleus
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1	1	1	0.00
2	2	1	1.00
1	3	1	-0.67
1	4	1	-0.67
5	11	4	-1.00
2	1	0	1.33
1	2	0	0.00
2	1	0	1.67
7	15	12	-4.67
1	2	0	0.33
6	5	5	2.00
3	4	6	-1.00
4	2	3	2.00
8	15	8	-1.00
4	9	9	-3.67
5	6	3	0.00
6	4	7	0.33
2	2	1	1.00
3	4	5	-0.67
8	7	6	2.00
11	8	12	2.33
2	2	3	-0.67
16	14	17	3.67
12	13	9	0.33
9	5	18	-0.67
4	2	1	2.67
4	4	4	0.33
9	6	6	3.00
3	7	3	-1.67
2	3	1	0.33
6	2	4	2.67
4	4	7	-1.33
3	9	11	-6.00
5	9	3	-1.33
5	11	4	-1.00
6	11	5	-1.67
25	19	16	6.67
17	16	9	3.00
2	8	8	-6.33
3	5	3	-0.33
3	4	4	-1.00
8	12	16	-5.00
4	5	4	0.33
14	17	12	0.33
5	3	4	0.67
13	9	12	4.00
8	15	9	-2.00
7	5	15	-4.00
11	17	17	-6.33
2	13	13	-9.33

total net mean grain count : -0.40

nuclei with >=6 grains : 1
 nuclei with >=20 grains : 0

PROJECT NO. : 738388
 CLIENT : UNILEVER EXAMINER : M.O'MAILLEY
 TEST MATERIAL: TRICLOSAN DATE EXAMINED : SEPTEMBER/16/88
 EXPT. DATE : AUGUST/24/88 EXPERIMENT NO.2
 SLIDE LETTER : F3

NO. OF grains/ nucleus	cytoplasmic grains	net grains/ nucleus	
6	4	3	1.67
5	3	3	2.00
9	8	9	-0.67
5	4	11	-2.00
2	1	1	1.00
3	13	4	-5.00
5	2	1	3.00
1	4	5	-2.00
5	5	5	0.00
5	2	2	2.67
1	1	3	-0.33
6	1	3	4.33
3	2	4	0.67
9	12	9	0.33
5	1	3	2.67
7	11	6	0.00
4	2	5	0.67
5	4	2	2.33
4	3	7	-1.00
13	9	11	9 3.33
4	1	3	2 2.00
8	7	11	12 -2.00
6	7	11	11 -3.67
1	3	2	3 -1.67
6	9	9	4 -1.33
12	6	6	6 6.00
12	13	20	14 -3.67
9	9	8	7 1.00
7	4	16	7 -2.00
11	9	12	12 0.00
6	1	2	5 3.33
3	6	5	4 -2.00
4	7	2	11 -2.67
11	6	7	6 4.67
8	3	5	6 3.33
3	4	4	1 0.00
20	13	17	14 5.33
15	20	25	15 -5.00
15	12	8	7 6.00
9	16	8	8 -1.67
18	9	14	20 3.67
12	14	2	4 5.33
18	18	13	18 1.67
7	12	4	16 -3.67
7	17	15	12 -7.67
5	4	3	1 2.33
15	7	9	14 5.00
18	20	9	9 5.33
9	8	8	8 1.00
8	7	3	3 3.67
			total net mean grain count : 0.77
			nuclei with >=6 grains : 2
			nuclei with >=20 grains : 0
			mean of coverslip one : -0.40
			mean of coverslip two : -----
			MEAN OF ALL THREE COVERSGLIPS : 0.37
			TOTAL PERCENT
			OF NUCLEI WITH >=6 GRAINS : 3.00
			TOTAL PERCENT
			OF NUCLEI WITH >=20 GRAINS : 0.00

PROJECT NO. : 738388
 CLIENT : UNILEVER EXAMINER : M.O'MAILLEY
 TEST MATERIAL: TRICLOSAN DATE : SEPTEMBER/16/88
 EXPT. DATE : AUGUST/24/88 EXPERIMENT NO.2
 SLIDE LETTER : G1

NO. OF grains/ nucleus		cytoplasmic grains		net grains/ nucleus
5	16	5	9	-5.00
7	20	13	14	-8.67
9	9	6	11	0.33
4	6	7	7	-2.67
8	9	13	8	-2.00
6	7	7	15	-3.67
5	6	6	5	-0.67
5	8	7	4	-1.33
5	6	8	9	-2.67
2	3	3	3	-1.00
5	3	4	4	1.33
8	9	6	5	1.33
13	15	11	15	-0.67
9	9	4	8	2.00
5	13	12	11	-7.00
1	3	2	1	-1.00
4	1	1	1	3.00
9	9	4	9	1.67
14	22	6	6	2.67
8	9	6	11	-0.67
16	15	14	17	0.67
12	6	15	6	3.00
9	14	9	11	-2.33
13	7	15	7	3.33
10	9	8	11	0.67
8	6	11	12	-1.67
7	7	6	6	0.67
8	9	7	7	0.33
12	7	20	12	-1.00
17	24	7	13	2.33
13	16	9	16	-0.67
6	6	6	6	0.00
9	7	7	9	1.33
5	8	4	7	-1.33
3	2	4	5	-0.67
4	5	5	4	-0.67
6	6	7	9	-1.33
7	4	7	9	0.33
3	3	3	9	-2.00
2	4	0	0	0.67
4	3	4	3	0.67
3	3	4	3	-0.33
1	1	5	2	-1.67
12	7	6	5	6.00
4	5	14	3	-3.33
4	1	3	2	2.00
12	12	7	13	1.33
11	7	7	13	2.00
5	7	6	5	-1.00
2	4	3	2	-1.00

total net mean grain count : -0.37

nuclei with ≥ 6 grains : 1
 nuclei with ≥ 20 grains : 0

PROJECT NO. : 738388
 CLIENT : UNILEVER EXAMINER : M.O'MAILLEY
 TEST MATERIAL: TRICLOSAN DATE : SEPTEMBER/16/88
 EXPT. DATE : AUGUST/24/88 EXPERIMENT NO.2
 SLIDE LETTER : G2

NO. OF grains/ nucleus		cytoplasmic grains	net grains/ nucleus
2	3	2	3 -0.67
6	5	6	8 -0.33
7	2	2	1 5.33
4	2	3	2 1.67
5	2	2	0 3.67
3	2	4	2 0.33
2	1	3	1 0.33
4	2	5	2 1.00
2	2	3	5 -1.33
3	3	8	5 -2.33
3	2	1	0 2.00
3	3	3	1 0.67
3	4	4	4 -1.00
6	0	1	2 5.00
9	8	16	7 -1.33
4	3	3	4 0.67
5	4	1	2 2.67
4	2	5	3 0.67
2	3	3	6 -2.00
4	3	3	3 1.00
6	2	3	3 3.33
4	5	6	4 -1.00
2	3	6	7 -3.33
1	3	2	2 -1.33
2	3	3	2 -0.67
3	3	2	4 0.00
9	4	9	3 3.67
18	17	13	14 3.33
9	7	11	13 -1.33
3	3	2	1 1.00
5	4	4	4 1.00
15	18	13	9 1.67
6	12	7	5 -2.00
5	6	3	8 -0.67
7	6	8	9 -0.67
7	6	5	3 2.33
8	9	11	8 -1.33
9	12	4	6 1.67
5	4	2	1 2.67
8	11	15	8 -3.33
5	4	5	6 0.00
14	8	11	7 3.33
7	5	2	4 3.33
12	11	9	13 1.00
4	4	4	4 0.00
2	3	12	5 -4.67
6	6	11	8 -2.33
3	2	5	4 -0.67
8	19	13	11 -6.33
6	11	7	9 -3.00

total net mean grain count : 0.27

nuclei with >=6 grains : 0
 nuclei with >=20 grains : 0

PROJECT NO. : 738388
 CLIENT : UNILEVER EXAMINER : M.O'MAILLEY
 TEST MATERIAL: TRICLOSAN DATE EXAMINED : SEPTEMBER/16/88
 EXPT. DATE : AUGUST/24/88 EXPERIMENT NO.2
 SLIDE LETTER : G3

NO. OF grains/ nucleus	cytoplasmic grains	net grains/ nucleus	
6	6	9	11 -2.67
13	12	11	13 1.00
3	2	0	0 2.33
2	3	2	2 -0.33
1	12	4	2 -5.00
2	2	4	2 -0.67
1	2	3	1 -1.00
2	2	1	0 1.00
3	4	3	2 0.00
1	3	1	0 -0.33
4	3	1	2 2.00
1	2	2	1 -0.67
9	4	7	6 3.33
2	1	2	0 1.00
14	11	20	15 -1.33
5	5	6	4 0.00
3	4	2	2 0.33
1	0	0	0 1.00
15	0	14	13 3.33
3	1	10	6 -2.67
2	2	4	4 -1.33
4	4	2	5 0.33
3	8	6	2 -2.33
5	11	11	7 -4.67
1	2	1	1 -0.33
6	1	1	0 5.33
3	1	1	1 2.00
2	5	3	2 -1.33
2	5	5	2 -2.00
6	2	1	3 4.00
5	5	2	4 1.33
4	5	9	3 -1.67
1	2	0	1 0.00
3	1	1	1 2.00
1	2	2	1 -0.67
1	6	4	0 -2.33
2	2	0	0 1.33
1	0	3	1 -3.00
2	3	1	2 0.00
20	10	16	22 4.00
2	3	2	2 -0.33
4	1	2	0 3.00
0	0	0	1 -0.33
0	1	1	0 -0.67
2	2	0	1 1.00
3	2	0	1 2.00
1	1	0	0 0.67
5	3	6	2 1.33
10	9	8	7 2.00
1	0	1	0 0.67

total net mean grain count :	0.21
nuclei with >=6 grains :	0
nuclei with >=20 grains :	0
mean of coverslip one :	-0.37
mean of coverslip two :	0.27
MEAN OF ALL THREE COVERSLEPS :	0.04
TOTAL PERCENT OF NUCLEI WITH >=6 GRAINS :	0.67
TOTAL PERCENT OF NUCLEI WITH >=20 GRAINS :	0.00

PROJECT NO. : 738388
 CLIENT : UNILEVER
 TEST MATERIAL: TRICLOSAN
 EXPT. DATE : AUGUST/24/88
 SLIDE LETTER : H1

EXAMINER : M.O'MAILLEY
 DATE : SEPTEMBER/16/88
 EXPERIMENT NO.2

NO. OF grains/ nucleus	cytoplasmic grains		net grains/ nucleus	
1	1	1	0	0.33
0	1	2	0	-1.00
1	3	0	1	-0.33
0	3	5	2	-3.33
3	2	1	3	1.00
1	1	1	1	0.00
0	1	4	1	-2.00
0	1	2	2	-1.67
1	1	3	2	-1.00
2	2	2	2	0.00
1	1	2	2	-0.67
1	2	2	1	-0.67
0	1	2	0	-1.00
0	2	1	1	-1.33
1	0	1	1	0.33
0	1	1	1	-1.00
1	2	0	0	0.33
1	2	0	0	0.33
2	1	0	0	1.67
16	11	15	14	2.67
2	0	0	2	1.33
2	1	0	0	1.67
1	1	1	0	0.33
1	1	1	0	0.33
2	0	0	1	1.67
2	1	1	0	1.33
1	1	2	1	-0.33
1	2	1	1	-0.33
0	3	0	0	-1.00
1	0	1	0	0.67
0	1	1	2	-1.33
1	0	1	0	0.67
1	2	0	0	0.33
1	2	1	1	-0.33
0	0	0	0	0.00
1	0	1	1	0.33
0	1	1	0	-0.67
3	1	0	0	2.67
0	1	0	0	-0.33
1	1	0	0	0.67
1	2	1	0	0.00
0	3	0	1	-1.33
1	1	2	0	0.00
1	0	0	0	1.00
0	1	0	0	-0.33
0	1	0	1	-0.67
0	2	0	0	-0.67
0	3	1	2	-2.00
0	0	0	0	0.00
1	0	0	2	0.33

total net mean grain count : -0.07.

nuclei with >=6 grains : 0
 nuclei with >=20 grains : 0

PROJECT NO. : 738388
 CLIENT : UNILEVER EXAMINER : M.O'MAILLEY
 TEST MATERIAL: TRICLOSAN DATE : SEPTEMBER/16/88
 EXPT. DATE : AUGUST/24/88 EXPERIMENT NO.2
 SLIDE LETTER : H2

NO. OF grains/ nucleus	cytoplasmic grains		net grains/ nucleus
1	3	1	0 -0.33
0	0	0	0 0.00
1	2	0	0 0.33
0	1	0	0 -0.33
0	1	1	1 -1.00
1	0	1	0 0.67
0	2	1	0 -1.00
1	1	0	0 0.67
0	2	1	1 -1.33
3	1	1	1 2.00
0	0	0	1 -0.33
1	1	0	0 0.67
0	0	3	0 -1.00
2	0	2	2 0.67
2	1	0	0 1.67
1	0	1	0 0.67
2	1	0	0 2.67
2	1	0	0 1.67
2	0	1	1 1.33
2	0	0	0 2.00
1	0	0	0 1.00
0	0	0	0 0.00
0	0	0	0 0.00
0	1	0	0 -0.33
1	0	0	0 1.00
0	0	0	1 -0.33
0	2	1	0 -1.00
0	1	1	0 -0.67
0	2	1	0 -1.00
0	2	1	2 -1.67
14	14	10	9 0.33
13	11	12	16 0.00
12	6	15	14 0.33
8	6	11	9 -0.67
8	15	11	5 -2.33
3	1	4	2 0.67
0	2	3	0 -1.67
1	0	0	0 1.00
2	0	0	0 2.00
3	1	2	0 2.00
1	0	0	0 1.00
0	1	1	0 -0.67
0	1	0	0 -0.33
1	0	0	0 1.00
0	0	0	0 0.00
0	2	1	0 -1.00
2	4	0	0 0.67
2	1	1	0 1.33
1	1	1	1 0.00
0	1	0	1 -0.67

total net mean grain count : 0.19

nuclei with >=6 grains : 0
 nuclei with >=20 grains : 0

PROJECT NO. : 738388
 CLIENT : UNILEVER EXAMINER : M.D'MAILLEY
 TEST MATERIAL: TRICLOSAN DATE EXAMINED : SEPTEMBER/16/88
 EXPT. DATE : AUGUST/24/88 EXPERIMENT NO.2
 SLIDE LETTER : H3

NO. OF grains/ nucleus	cytoplasmic grains		net grains/ nucleus	
0	0	0	0	0.00
1	0	0	0	1.00
0	1	0	0	-0.33
1	1	0	0	0.67
1	0	0	0	1.00
0	1	0	0	-0.33
1	1	0	0	0.67
1	1	1	0	0.33
1	1	1	1	0.00
0	0	0	0	0.00
0	1	0	0	-0.33
4	1	0	1	3.33
1	0	1	0	0.67
1	1	0	0	0.67
0	1	0	0	-0.33
3	1	0	0	2.67
1	0	0	1	0.67
0	0	0	0	0.00
0	0	0	0	0.00
1	0	0	0	1.00
0	2	0	0	-0.67
1	0	0	0	1.00
0	2	0	2	-1.33
1	2	1	0	0.00
1	2	0	0	0.33
0	2	0	0	-0.67
0	1	1	0	-0.67
0	0	0	0	0.00
1	0	1	0	0.67
0	2	0	1	-1.00
0	2	1	0	-1.00
1	0	0	0	1.00
1	0	0	0	1.00
0	1	0	0	-0.33
2	0	0	0	2.00
1	0	2	0	0.33
2	0	0	0	2.00
1	0	1	0	0.67
2	1	0	0	1.67
1	0	1	0	0.67
0	0	0	0	0.00
0	0	1	0	-0.33
1	0	0	1	0.67
2	0	1	0	1.67
4	0	1	1	3.33
1	0	1	1	0.33
2	0	0	0	2.00
0	1	0	0	-0.33
0	0	0	0	0.00
2	0	0	1	1.67

total net mean grain count :	0.52
nuclei with >=6 grains :	0
nuclei with >=20 grains :	0
mean of coverslip one :	-0.07
mean of coverslip two :	0.19
MEAN OF ALL THREE COVERSLEIPS :	0.21
TOTAL PERCENT OF NUCLEI WITH >=6 GRAINS :	0.00
TOTAL PERCENT OF NUCLEI WITH >=20 GRAINS :	0.00

PROJECT NO. : 738388
 CLIENT : UNILEVER EXAMINER : M.O'MAILLEY
 TEST MATERIAL: TRICLOSAN DATE : SEPTEMBER/16/88
 EXPT. DATE : AUGUST/24/88 EXPERIMENT NO.2
 SLIDE LETTER : I1

NO. OF grains/ nucleus	cytoplasmic grains		net grains/ nucleus	
15	15	7	6	5.67
16	7	12	5	8.00
25	6	9	7	17.67
20	13	8	9	10.00
30	9	12	16	17.67
16	7	12	11	6.00
24	3	2	3	21.33
27	14	15	6	15.33
44	27	27	20	19.33
19	3	4	3	15.67
26	26	14	27	3.67
27	12	11	7	17.00
17	7	15	4	8.33
34	9	8	7	26.00
26	15	8	5	17.33
29	7	8	14	19.33
27	13	15	17	12.00
24	12	4	12	14.67
23	2	3	2	20.67
13	9	8	5	5.67
15	12	8	5	6.67
13	7	3	5	8.00
25	11	9	9	15.33
25	12	6	13	14.67
16	4	3	4	12.33
15	8	12	11	4.67
18	4	3	2	15.00
19	2	2	2	17.00
15	4	3	4	11.33
29	9	4	5	23.00
13	4	5	6	8.00
25	6	9	5	18.33
31	5	11	7	23.33
19	8	5	8	12.00
23	5	4	4	18.67
22	4	6	3	17.67
23	4	5	4	18.67
20	5	4	3	16.00
26	6	4	4	21.33
22	7	4	5	16.67
33	13	13	12	20.33
19	3	3	7	14.67
17	8	6	3	11.33
13	5	4	5	8.33
19	11	5	9	10.67
18	5	3	3	14.33
29	2	3	3	26.33
16	5	5	3	11.67
22	4	4	6	17.33
16	5	4	4	12.33

total net mean grain count : 14.55

nuclei with ≥ 6 grains : 46
 nuclei with ≥ 20 grains : 8

PROJECT NO. : 738388
 CLIENT : UNILEVER EXAMINER : M.O'MAILLEY
 TEST MATERIAL: TRICLOSAN DATE : SEPTEMBER/16/88
 EXPT. DATE : AUGUST/24/88 EXPERIMENT NO.2
 SLIDE LETTER : I2

NO. OF grains/ nucleus	cytoplasmic grains		net grains/ nucleus
6	3	2	3 3.33
13	2	2	2 11.00
19	4	3	2 16.00
1	2	2	1 -0.67
13	3	3	1 10.67
16	4	9	3 10.67
11	8	4	2 6.33
18	2	3	1 16.00
19	4	5	4 14.67
22	5	4	1 18.67
12	4	4	3 8.33
17	7	5	6 11.00
17	5	4	7 11.67
16	5	1	3 13.00
12	2	2	2 10.00
15	5	4	3 11.00
18	4	3	4 14.33
24	4	5	6 19.00
14	1	1	3 12.33
13	1	2	1 11.67
20	1	1	1 19.00
16	4	2	4 12.67
8	2	1	2 6.33
18	2	3	3 15.33
15	7	5	6 9.00
19	9	9	6 11.00
14	5	4	8 8.33
8	6	3	1 4.67
5	2	4	2 2.33
11	3	5	4 7.00
7	6	3	4 2.67
22	3	3	2 19.33
18	7	3	3 13.67
23	6	5	7 17.00
16	6	3	7 10.67
5	4	2	4 1.67
20	3	4	5 16.00
15	4	5	6 10.00
16	3	6	2 12.33
23	12	6	7 14.67
16	1	5	2 13.33
19	4	1	4 16.00
20	2	4	2 17.33
19	2	5	1 16.33
22	7	2	6 17.00
8	3	2	3 5.33
16	1	1	2 14.67
3	1	1	1 2.00
13	13	2	3 7.00
19	2	2	2 17.00

total net mean grain count : 11.37-

nuclei with >=6 grains : 42
 nuclei with >=20 grains : 0

PROJECT NO. : 738388
 CLIENT : UNILEVER EXAMINER : M.D'MAILLEY
 TEST MATERIAL: TRICLOSAN DATE EXAMINED : SEPTEMBER/16/88
 EXPT. DATE : AUGUST/24/88 EXPERIMENT NO.2
 SLIDE LETTER : 13

NO. OF grains/ nucleus	cytoplasmic grains		net grains/ nucleus	
7	1	2	0	6.00
9	9	4	2	4.00
6	1	2	3	4.00
6	4	4	2	2.67
19	3	1	0	17.67
11	5	5	3	6.67
8	2	2	4	5.33
22	14	8	8	12.00
16	11	5	2	10.00
34	19	16	13	18.00
17	9	11	9	7.33
18	9	8	9	9.33
24	2	3	5	20.67
30	3	4	2	27.00
28	4	3	5	24.00
23	4	9	7	16.33
23	8	13	8	13.33
23	8	7	8	15.33
24	3	12	7	16.67
30	6	5	4	25.00
22	7	4	5	16.67
19	4	14	7	10.67
12	6	3	2	8.33
39	5	4	3	35.00
28	11	6	9	19.33
19	11	2	4	13.33
37	7	8	4	30.67
15	5	2	3	11.67
19	1	3	1	17.33
19	1	2	1	17.67
19	13	8	2	11.33
26	11	5	6	18.67
31	9	14	8	20.67
15	2	2	2	13.00
14	3	4	3	10.67
14	2	3	2	11.67
13	4	5	3	9.00
15	5	3	3	11.33
24	11	11	8	14.00
19	5	5	3	14.67
20	7	5	3	15.00
13	2	0	1	12.00
7	2	5	3	3.67
17	3	2	2	14.67
5	2	1	0	4.00
2	0	0	0	2.00
5	5	0	2	2.67
5	3	2	1	3.00
11	6	9	4	4.67
16	3	2	6	12.33

total net mean grain count : 13.02

nuclei with ≥ 6 grains : 40

nuclei with ≥ 20 grains : 7

mean of coverslip one : 14.55

mean of coverslip two : 11.37

MEAN OF ALL THREE COVERSLEPS : 12.98

TOTAL PERCENT
OF NUCLEI WITH ≥ 6 GRAINS : 85.33

TOTAL PERCENT
OF NUCLEI WITH ≥ 20 GRAINS : 10.00

PROJECT NO. : 738388
 CLIENT : UNILEVER EXAMINER : M.O'MAILLEY
 TEST MATERIAL: TRICLOSAN DATE : SEPTEMBER/20/88
 EXPT. DATE : AUGUST/24/88 EXPERIMENT NO.2
 SLIDE LETTER : J1

NO. OF grains/ nucleus	cytoplasmic grains		net grains/ nucleus	
46	6	9	6	39.00
51	7	14	17	38.33
63	15	22	17	45.00
51	13	15	19	35.33
22	18	13	5	10.00
60	11	13	18	46.00
24	12	6	7	15.67
52	13	19	17	35.67
64	7	4	15	55.33
62	3	6	8	56.33
39	6	8	2	33.67
31	4	5	3	27.00
36	11	15	11	23.67
56	8	13	7	48.67
67	8	15	12	56.00
64	24	18	22	42.67
58	15	8	8	47.67
37	3	5	9	31.33
42	11	4	7	34.67
23	3	4	3	19.67
61	17	19	15	44.00
48	6	2	8	42.67
53	19	22	14	34.67
34	11	12	14	21.67
24	3	6	8	18.33
51	20	28	19	28.67
27	7	15	7	18.00
50	20	12	19	33.00
38	12	9	6	29.00
48	24	22	20	26.00
27	4	6	11	20.00
30	5	4	9	24.00
20	9	6	6	13.00
33	9	14	9	22.33
37	8	9	5	29.67
28	6	5	9	21.33
44	7	13	16	32.00
31	20	12	9	17.33
35	3	8	4	30.00
48	6	14	7	39.00
48	13	22	22	29.00
42	4	6	4	37.33
41	16	4	14	29.67
47	7	12	7	38.33
40	3	14	12	30.33
47	2	3	3	44.33
37	7	2	4	32.67
40	8	15	16	27.00
33	19	15	14	17.00
29	9	8	9	20.33

total net mean grain count : 31.85

nuclei with ≥ 6 grains : 50
 nuclei with ≥ 20 grains : 42

PROJECT NO. : 738388
 CLIENT : UNILEVER EXAMINER : M.O'MAILLEY
 TEST MATERIAL: TRICLOSAN DATE : SEPTEMBER/20/88
 EXPT. DATE : AUGUST/24/88 EXPERIMENT NO.2
 SLIDE LETTER : J2

NO. OF grains/ nucleus	cytoplasmic grains		net grains/ nucleus	
41	6	6	16	31.67
31	7	8	7	23.67
40	8	8	9	31.67
48	28	17	16	27.67
36	9	13	11	25.00
41	20	12	26	21.67
45	14	15	14	30.67
53	4	7	11	45.67
31	14	13	13	17.67
46	6	4	13	38.33
40	6	9	9	32.00
38	8	8	6	30.67
41	7	9	7	33.33
28	17	9	12	15.33
47	16	18	9	32.67
40	7	13	5	31.67
55	16	34	19	32.00
47	9	4	7	40.33
31	11	9	7	22.00
36	11	20	12	21.67
44	7	13	3	36.33
51	14	8	5	42.00
31	11	12	9	20.33
38	19	23	20	17.33
33	5	6	13	25.00
50	20	20	19	29.33
49	26	22	22	25.67
42	16	12	9	29.67
46	22	33	14	23.00
41	24	31	29	13.00
48	18	14	9	26.33
44	12	13	7	33.33
34	4	11	5	27.33
34	13	18	11	20.00
44	12	8	16	32.00
44	4	6	8	38.00
41	12	12	9	30.00
39	4	6	6	33.67
49	6	11	16	38.00
47	11	11	13	35.33
31	5	4	5	26.33
31	6	7	6	24.67
35	8	13	15	23.00
33	13	15	6	21.67
47	8	11	3	39.67
26	5	7	7	19.67
35	9	15	15	22.00
36	16	13	8	23.67
35	14	11	6	24.67
44	6	7	16	34.33

total net mean grain count : 28.41

nuclei with ≥ 6 grains : 50
 nuclei with ≥ 20 grains : 45

PROJECT NO. : 738388
 CLIENT : UNILEVER EXAMINER : M.O'MAILLEY
 TEST MATERIAL: TRICLOSAN DATE EXAMINED : SEPTEMBER/20/88
 EXPT. DATE : AUGUST/24/88 EXPERIMENT NO.2
 SLIDE LETTER : J3

NO. OF grains/ nucleus	cytoplasmic grains		net grains/ nucleus	
44	14	15	11	30.67
48	9	3	5	42.33
35	12	7	8	26.00
29	9	8	6	21.33
40	15	11	9	28.33
39	6	19	6	28.67
25	17	14	13	18.33
28	8	12	11	17.67
53	9	20	8	40.67
42	15	11	8	30.67
50	13	17	20	33.33
37	11	11	12	25.67
17	4	6	3	12.67
28	2	8	3	23.67
59	19	24	18	38.67
40	9	4	8	33.00
42	13	26	16	23.67
30	9	14	8	19.67
46	14	13	26	28.33
25	8	9	5	17.67
35	8	14	9	24.67
35	9	7	7	27.33
46	16	11	14	32.33
48	9	8	6	40.33
33	1	1	1	32.00
56	9	11	9	26.33
44	17	11	14	30.00
28	11	5	13	18.33
42	11	16	11	29.33
49	16	18	24	29.67
37	11	11	8	27.00
41	8	3	9	34.33
27	7	9	9	18.67
24	5	3	5	19.67
20	3	3	4	16.67
18	5	4	7	12.67
35	14	18	11	20.67
27	3	8	6	21.33
36	9	12	11	25.33
34	11	14	9	22.67
41	4	11	19	29.67
45	19	17	33	22.00
56	9	14	9	45.33
40	7	6	4	34.33
45	14	17	14	30.00
48	9	12	4	39.67
27	9	6	13	17.67
22	17	4	6	13.00
42	18	15	19	24.67
40	6	6	8	33.33

total net mean grain count : 26.64

nuclei with ≥ 6 grains : 50

nuclei with ≥ 20 grains : 38

mean of coverslip one : 31.85

mean of coverslip two : 28.41

MEAN OF ALL THREE COVERSLEPS : 28.97

TOTAL PERCENT
OF NUCLEI WITH ≥ 6 GRAINS : 100.00

TOTAL PERCENT
OF NUCLEI WITH ≥ 20 GRAINS : 83.33

PROJECT NO. : 738388
 CLIENT : UNILEVER EXAMINER : M.O'MAILLEY
 TEST MATERIAL: TRICLOSAN DATE : SEPTEMBER/20/88
 EXPT. DATE : AUGUST/24/88 EXPERIMENT NO.2
 SLIDE LETTER : K1

NO. OF grains/ nucleus	cytoplasmic grains		net grains/ nucleus
27	12	15	3 17.00
24	4	5	2 20.33
22	3	4	3 18.67
19	1	7	2 15.67
34	4	6	3 29.67
31	3	6	4 26.67
34	5	3	11 27.67
24	5	6	4 19.00
25	2	0	4 23.00
21	0	2	0 20.33
25	6	9	3 19.00
30	8	9	11 20.67
33	13	19	12 18.33
26	6	7	5 20.00
37	6	7	7 30.33
31	8	20	15 16.67
26	5	2	3 22.67
18	2	8	3 13.67
25	4	8	13 16.67
30	2	1	4 27.67
39	6	5	3 34.33
31	2	1	4 28.67
19	0	1	4 17.33
19	0	0	1 18.67
37	7	4	7 31.00
23	6	11	11 13.67
31	6	6	3 26.00
34	4	11	7 26.67
15	3	5	3 12.00
28	2	2	4 25.33
15	1	1	0 14.33
42	4	1	2 39.67
34	12	14	14 20.67
57	4	3	2 54.00
33	2	4	2 30.33
34	5	6	9 27.33
51	4	2	5 47.33
38	13	11	4 28.67
35	15	12	9 23.00
49	6	5	4 44.00
51	5	11	8 43.00
47	6	11	6 39.33
38	9	16	18 23.67
49	9	5	7 42.00
37	4	9	9 29.67
40	11	7	9 31.00
35	11	7	4 27.67
44	14	12	14 30.67
42	18	16	14 26.00
40	14	16	9 27.00

total net mean grain count : 26.13

nuclei with ≥ 6 grains : 50
 nuclei with ≥ 20 grains : 36

PROJECT NO. : 738388
 CLIENT : UNILEVER EXAMINER : M.O'MAILLEY
 TEST MATERIAL: TRICLOSAN DATE : SEPTEMBER/20/88
 EXPT. DATE : AUGUST/24/88 EXPERIMENT NO.2
 SLIDE LETTER : K2

NO. OF grains/ nucleus	cytoplasmic grains		net grains/ nucleus
22	9	5	6 15.33
33	8	3	9 26.33
17	4	4	7 12.00
28	7	5	3 23.00
30	4	5	1 26.67
27	8	13	3 19.00
20	5	7	2 15.33
33	6	9	7 25.67
34	9	5	5 27.67
31	5	7	11 23.33
34	9	4	4 28.33
34	3	4	5 30.00
22	5	4	7 16.67
17	2	2	1 15.33
30	7	6	8 23.00
38	4	6	4 33.33
26	5	1	3 23.00
41	3	2	3 38.33
19	2	1	2 17.33
40	8	2	2 38.67
41	9	7	7 33.33
29	9	9	11 19.33
34	8	8	2 28.00
38	9	14	8 27.67
41	4	4	2 37.67
16	2	3	1 14.00
19	3	2	3 16.33
22	3	5	4 18.00
38	7	6	9 30.67
39	11	12	17 25.67
35	8	7	4 28.67
42	5	8	11 34.00
47	8	13	12 36.00
45	5	2	2 42.00
34	7	5	3 29.00
34	7	15	8 24.00
43	4	3	7 38.33
34	5	3	3 30.33
39	15	11	12 26.33
35	5	1	3 32.00
36	5	8	8 29.00
38	17	11	13 24.33
40	9	4	6 33.67
40	15	14	13 26.00
34	11	3	4 28.00
45	11	8	4 37.33
26	3	1	0 24.67
49	12	9	8 39.33
40	13	9	11 29.00
38	5	13	6 30.00

total net mean grain count : 27.02

nuclei with >=6 grains : 50
 nuclei with >=20 grains : 39

PROJECT NO. : 738388
 CLIENT : UNILEVER EXAMINER : M.O'MAILLEY
 TEST MATERIAL: TRICLOSAN DATE EXAMINED : SEPTEMBER/20/88
 EXPT. DATE : AUGUST/24/88 EXPERIMENT NO.2
 SLIDE LETTER : K3

NO. OF grains/ nucleus	cytoplasmic grains		net grains/ nucleus	
48	13	11	14	35.33
36	18	6	14	23.33
45	6	11	8	36.67
39	18	14	20	21.67
67	15	11	18	52.33
45	8	16	17	31.33
40	14	17	22	22.33
44	25	25	30	17.33
42	16	17	16	25.67
37	8	17	15	23.67
39	17	12	17	23.67
49	7	17	7	38.67
46	24	13	17	28.00
29	12	14	9	17.33
44	19	18	14	27.00
30	9	13	13	18.33
48	17	16	18	31.00
48	18	13	16	32.33
47	9	6	11	38.33
40	18	12	22	22.67
52	5	8	8	45.00
45	14	15	7	33.00
48	17	12	23	38.67
57	20	18	15	39.33
40	25	19	20	18.67
56	25	25	17	33.67
50	16	16	13	35.00
39	12	15	13	25.67
63	12	20	14	47.67
46	17	13	12	32.00
48	29	16	26	24.33
60	23	22	35	33.33
40	18	13	11	26.00
49	6	11	8	40.67
50	11	14	13	37.33
53	20	18	13	36.00
42	13	20	22	23.67
63	14	25	18	44.00
45	23	8	11	31.00
42	12	13	16	28.33
44	24	9	11	29.33
45	9	14	13	33.00
47	7	14	8	37.33
56	20	20	22	35.33
62	15	15	12	48.00
49	9	8	14	38.67
58	15	20	11	42.67
55	6	23	15	39.67
55	23	24	25	31.00
46	19	18	16	26.33
				total net mean grain count : 31.91
				nuclei with >=6 grains : 50
				nuclei with >=20 grains : 46
				mean of coverslip one : 26.13
				mean of coverslip two : 27.02
				MEAN OF ALL THREE COVERSLIPS : 28.35
				TOTAL PERCENT
				OF NUCLEI WITH >=6 GRAINS : 100.00
				TOTAL PERCENT
				OF NUCLEI WITH >=20 GRAINS : 80.67

PROJECT NO. : 738388
 CLIENT : UNILEVER
 TEST MATERIAL: TRICLOSAN
 EXPT. DATE : AUGUST/24/88
 SLIDE LETTER : L1

EXAMINER : M.O'MAILLEY
 DATE : SEPTEMBER/20/88
 EXPERIMENT NO.2

NO. OF grains/ nucleus	cytoplasmic grains	net grains/ nucleus
7	12	11
6	11	6
0	0	0
1	2	1
3	2	0
1	2	0
2	2	1
5	8	5
3	2	5
6	3	6
4	5	5
5	5	6
4	4	5
4	4	8
5	6	11
9	7	5
6	8	6
7	8	11
14	9	11
4	4	6
8	6	6
5	6	4
2	4	4
5	2	6
3	4	5
7	14	11
2	2	9
7	6	5
5	7	6
7	4	7
6	5	5
7	5	5
2	4	4
5	4	2
3	5	4
7	8	6
8	4	11
2	2	5
3	7	3
4	3	3
4	15	7
7	6	7
11	20	8
4	16	8
18	16	14
9	15	16
2	7	6
15	12	8
2	7	6
3	6	6

total net mean grain count : -0.91

nuclei with >=6 grains : 0
 nuclei with >=20 grains : 0

PROJECT NO. : 738388
 CLIENT : UNILEVER EXAMINER : M.O'MAILLEY
 TEST MATERIAL: TRICLOSAN DATE : SEPTEMBER/20/88
 EXPT. DATE : AUGUST/24/88 EXPERIMENT NO.2
 SLIDE LETTER : L2

NO. OF grains/ nucleus	cytoplasmic grains		net grains/ nucleus
5	7	7	7 -2.00
5	4	3	4 1.33
6	8	9	4 -1.00
4	5	3	6 -0.67
5	4	8	8 -1.67
7	3	4	4 3.33
4	3	4	5 0.00
7	6	9	4 0.67
3	6	5	3 -1.67
1	2	2	1 -0.67
6	4	3	4 2.33
2	4	2	2 -0.67
3	3	3	3 0.00
3	4	6	1 -0.67
1	5	4	3 -3.00
4	3	8	3 -0.67
4	4	5	2 0.33
3	11	5	5 -4.00
6	3	4	3 2.67
3	6	8	5 -3.33
7	12	9	12 -4.00
13	15	15	6 1.00
1	4	5	2 -2.67
4	6	4	4 -0.67
15	13	7	7 6.00
2	4	6	6 -3.33
6	9	20	12 -7.67
7	14	9	6 -2.67
9	11	8	7 0.33
2	13	24	17 -16.00
11	16	12	15 -3.33
4	2	4	5 0.33
8	13	13	12 -4.67
14	15	13	18 -1.33
5	12	12	6 -5.00
9	6	9	17 -1.67
6	13	11	8 -4.67
5	9	4	8 -2.00
6	6	5	6 0.33
3	5	4	3 -1.00
4	5	4	2 0.33
4	5	3	5 -0.33
8	9	8	11 -1.33
5	7	6	3 -0.33
6	9	9	9 -3.00
6	9	12	13 -5.33
5	5	3	3 1.33
3	5	4	3 -1.00
4	6	5	5 -1.33
5	8	8	8 -3.00

total net mean grain count : -1.52

nuclei with >=6 grains : 1
 nuclei with >=20 grains : 0

PROJECT NO. : 738388
 CLIENT : UNILEVER EXAMINER : M.O'MAILLEY
 TEST MATERIAL: TRICLOSAN DATE EXAMINED : SEPTEMBER/20/88
 EXPT. DATE : AUGUST/24/88 EXPERIMENT NO.2
 SLIDE LETTER : L3

NO. OF grains/ nucleus	cytoplasmic grains		net grains/ nucleus	
2	4	5	3	-2.00
3	4	4	3	-0.67
3	4	5	5	-1.67
4	4	7	5	-1.33
2	4	4	1	-1.00
2	3	3	2	-0.67
2	7	2	2	-1.67
5	5	4	0	2.00
6	4	6	4	1.33
4	6	7	0	-3.00
7	2	6	5	2.67
9	5	9	3	3.33
9	3	3	9	4.00
5	5	6	3	0.33
2	4	1	0	0.33
2	3	2	2	-0.33
3	9	6	6	-4.00
4	0	1	1	3.33
2	2	1	2	0.33
6	22	9	0	-4.33
2	5	4	3	-2.00
4	4	2	1	1.67
3	3	3	0	1.00
3	1	3	2	1.00
3	3	2	0	1.33
1	2	4	1	-1.33
2	4	4	7	-3.00
14	9	8	12	4.33
6	2	7	4	1.67
2	5	7	3	-3.00
5	6	4	12	-2.33
8	8	13	6	-1.00
6	9	12	15	-6.00
5	9	7	5	-2.00
12	7	11	15	1.00
9	11	14	14	-4.00
7	12	13	12	-5.33
8	11	6	6	0.33
8	16	11	6	-3.00
11	17	15	9	-2.67
5	12	6	5	-2.67
4	1	2	5	1.33
6	5	7	5	0.33
6	7	7	8	-1.33
7	9	6	5	0.33
8	15	8	11	-3.33
5	9	9	6	-3.00
8	15	13	11	-5.00
13	7	5	11	5.33
14	20	11	20	-3.00

total net mean grain count :	-0.75
nuclei with >=6 grains :	0
nuclei with >=20 grains :	0
mean of coverslip one :	-0.91
mean of coverslip two :	-1.52
MEAN OF ALL THREE COVERSLEPS :	-1.06
TOTAL PERCENT OF NUCLEI WITH >=6 GRAINS :	0.67
TOTAL PERCENT OF NUCLEI WITH >=20 GRAINS :	0.00

PROJECT NO. : 738388
 CLIENT : UNILEVER
 TEST MATERIAL: TRICLOSAN
 EXPT. DATE : AUGUST/24/88
 SLIDE LETTER : M1

EXAMINER : M.O'MAILLEY

DATE : SEPTEMBER/20/88

EXPERIMENT NO.2

NO. OF grains/ nucleus	cytoplasmic grains	net grains/ nucleus
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49	9	25	22	30.33
67	12	8	7	58.00
48	13	5	6	40.00
49	9	9	15	38.00
50	8	13	4	41.67
51	14	15	13	37.00
55	11	11	7	45.33
60	19	16	31	38.00
63	13	17	16	47.67
42	13	13	9	28.33
39	15	11	17	24.67
75	16	13	11	61.67
85	19	13	12	70.33
53	17	17	15	36.67
56	11	15	9	44.33
61	20	16	17	43.33
66	18	25	18	45.67
48	11	8	16	36.33
42	11	13	5	32.33
66	4	8	6	60.00
51	12	7	12	40.67
52	11	14	18	37.67
60	6	12	11	50.33
63	15	23	29	40.67
57	9	13	19	43.33
46	4	9	2	43.00
45	8	5	8	38.00
77	31	12	28	53.33
60	8	9	12	50.33
47	8	11	8	38.00
51	14	4	14	40.33
50	7	12	15	38.67
46	19	11	14	31.33
47	12	16	12	33.67
45	7	11	14	34.33
60	22	12	22	41.33
51	7	12	8	42.00
64	18	25	24	41.67
48	5	13	12	38.00
33	14	17	5	21.00
52	16	18	11	37.00
59	26	29	25	32.33
50	12	19	17	34.00
60	13	14	6	49.00
52	24	15	7	36.67
49	13	17	18	33.00
49	18	23	16	30.00
53	17	20	16	35.33
56	7	7	8	50.67
63	24	25	35	35.00

total net mean grain count : 40.61

nuclei with ≥ 6 grains : 50
 nuclei with ≥ 20 grains : 50

PROJECT NO. : 738388
 CLIENT : UNILEVER
 TEST MATERIAL: TRICLOSAN
 EXPT. DATE : AUGUST/24/88
 SLIDE LETTER : M2

EXAMINER : M.O'MAILLEY
 DATE : SEPTEMBER/20/88
 EXPERIMENT NO.2

NO. OF grains/ nucleus	cytoplasmic grains		net grains/ nucleus
38	18	20	9 22.33
58	4	19	13 46.00
52	17	17	24 32.67
49	11	5	11 40.00
56	15	16	24 37.67
57	19	16	16 40.00
42	12	14	11 29.67
57	22	26	12 37.00
52	9	11	6 43.33
60	6	7	14 51.00
59	36	24	20 32.33
69	28	25	34 40.00
73	18	25	16 53.33
68	6	15	15 56.00
67	15	16	13 53.00
57	28	22	16 35.00
48	23	23	13 28.33
57	9	13	13 45.33
55	22	8	9 42.00
50	13	14	6 39.00
34	6	4	5 29.00
34	2	3	2 31.67
42	7	17	11 30.33
53	9	9	9 44.00
47	9	7	3 40.67
95	35	27	16 69.00
42	4	13	7 34.00
55	4	7	5 49.67
51	4	11	11 42.33
59	7	8	14 49.33
56	7	14	23 41.33
48	18	14	15 32.33
51	20	30	19 28.00
57	24	20	22 35.00
57	35	25	19 30.67
52	22	22	23 29.67
63	37	33	17 34.00
44	23	18	22 23.00
36	18	11	16 21.00
81	23	16	22 60.67
62	15	14	18 46.33
46	27	30	22 19.67
36	15	13	8 24.00
50	17	16	17 33.33
49	17	19	23 29.33
52	9	14	9 41.33
68	19	24	6 51.67
51	19	18	14 34.00
53	8	14	22 38.33
72	15	24	19 52.67

total net mean grain count : 38.61

nuclei with >=6 grains : 50
 nuclei with >=20 grains : 49

PROJECT NO. : 738388
 CLIENT : UNILEVER EXAMINER : M.O'MAILLEY
 TEST MATERIAL: TRICLOSAN DATE EXAMINED : SEPTEMBER/21/88
 EXPT. DATE : AUGUST/24/88 EXPERIMENT NO.2
 SLIDE LETTER : M3

NO. OF grains/ nucleus	cytoplasmic grains		net grains/ nucleus	
35	14	18	5	22.67
44	5	3	4	40.00
30	13	12	6	19.67
30	14	9	13	18.00
55	14	9	8	44.67
46	6	6	7	41.67
53	6	7	12	44.67
52	7	12	12	41.67
49	4	16	17	36.67
48	8	4	6	42.00
64	4	6	7	58.33
40	9	5	7	33.00
50	6	6	11	42.33
42	20	22	19	21.67
40	8	18	9	28.33
36	11	16	23	19.33
49	14	23	20	30.00
48	19	7	13	35.00
50	38	22	27	21.00
51	6	5	6	45.33
52	7	13	13	41.00
58	5	6	6	52.33
60	8	12	15	48.33
60	5	5	7	54.33
59	9	19	13	45.33
50	19	18	18	31.67
66	19	23	11	48.55
74	11	15	13	61.00
68	16	14	11	54.33
61	12	18	12	47.00
71	36	36	38	34.33
67	9	12	7	57.67
62	14	17	14	47.00
47	19	17	24	27.00
46	18	16	16	29.33
60	11	13	13	47.67
70	9	18	9	58.00
61	5	3	9	55.33
62	4	5	9	56.00
49	6	3	1	45.67
55	6	6	3	50.00
56	7	13	9	46.33
30	13	11	11	18.33
51	4	6	4	46.33
59	3	4	1	56.33
51	13	12	6	40.67
53	12	12	13	40.67
57	17	11	14	43.00
50	30	37	27	18.67
35	7	9	6	27.67

total net mean grain count :	40.31
nuclei with >=6 grains :	50
nuclei with >=20 grains :	45
mean of coverslip one :	40.61
mean of coverslip two :	38.61
MEAN OF ALL THREE COVERSLEPS :	39.84
TOTAL PERCENT OF NUCLEI WITH >=6 GRAINS :	100.00
TOTAL PERCENT OF NUCLEI WITH >=20 GRAINS :	96.00

PROJECT NO. : 738388
 CLIENT : UNILEVER EXAMINER : M.O'MAILLEY
 TEST MATERIAL: TRICLOSAN DATE : SEPTEMBER/21/88
 EXPT. DATE : AUGUST/24/88 EXPERIMENT NO.2
 SLIDE LETTER : N1

NO. OF grains/ nucleus	cytoplasmic grains		net grains/ nucleus
17	4	3	1 14.33
38	3	2	3 35.33
25	9	7	7 17.33
23	1	5	6 19.00
23	8	3	4 18.00
15	3	4	3 11.67
12	2	5	3 8.67
14	2	3	2 11.67
11	5	4	5 6.33
7	1	3	1 5.33
7	4	4	3 3.33
12	4	6	4 7.33
19	4	4	3 15.33
15	1	4	1 13.00
20	5	8	4 14.33
13	8	4	4 7.67
13	6	2	2 9.67
17	12	9	11 6.33
19	8	4	4 13.67
18	3	7	2 14.00
24	2	2	2 22.00
25	6	2	2 21.67
15	3	0	0 14.00
19	2	0	2 17.67
16	5	2	3 12.67
27	5	3	12 20.33
24	4	3	5 20.00
31	4	8	6 25.00
24	8	1	4 19.67
31	14	11	11 19.00
29	3	3	6 25.00
24	6	2	1 21.00
20	2	2	3 17.67
20	6	3	5 15.33
24	6	5	7 18.00
14	2	1	2 12.33
8	2	4	5 4.33
33	12	9	7 23.67
27	5	3	4 23.00
12	6	4	4 7.33
14	8	2	2 10.00
6	5	2	6 1.67
14	6	2	2 10.67
4	2	4	3 1.00
17	4	6	4 12.33
17	4	3	4 13.33
12	3	5	8 6.67
12	5	1	3 9.00
4	4	6	4 -0.67
8	5	3	4 4.00

total net mean grain count : 13.60

nuclei with >=6 grains : 43
 nuclei with >=20 grains : 10

PROJECT NO. : 738388
 CLIENT : UNILEVER EXAMINER : M.O'MAILLEY
 TEST MATERIAL: TRICLOSAN DATE : SEPTEMBER/21/88
 EXPT. DATE : AUGUST/24/88 EXPERIMENT NO.2
 SLIDE LETTER : N2

NO. OF grains/ nucleus	cytoplasmic grains		net grains/ nucleus
14	1	2	4 11.67
2	2	5	0 -0.33
8	2	3	1 6.00
3	2	0	0 2.33
9	1	1	0 8.33
8	5	4	4 3.67
15	4	4	1 12.00
4	0	1	0 3.67
12	4	1	2 9.67
6	3	3	0 4.00
6	2	0	2 4.67
6	2	1	0 5.00
22	7	5	5 16.33
27	4	3	0 24.67
20	0	5	3 20.33
20	2	1	1 18.67
5	2	0	2 3.67
22	2	3	5 18.67
24	5	1	3 21.00
15	7	5	6 9.00
18	2	1	1 16.67
10	6	9	7 5.67
11	2	3	2 8.67
28	12	6	0 21.00
18	2	8	5 13.00
10	2	3	6 9.00
11	5	2	3 7.67
10	3	3	4 9.67
13	4	5	4 8.67
19	11	3	6 12.33
19	7	9	9 10.67
17	3	4	4 13.33
18	2	2	4 15.33
11	3	5	2 7.67
19	2	3	2 16.67
7	1	4	3 4.33
9	4	4	7 4.00
13	1	1	4 11.00
18	3	2	2 15.67
11	3	3	1 8.67
20	3	2	3 17.33
28	4	4	7 23.00
27	3	3	2 24.33
29	9	9	6 21.00
11	4	2	6 7.00
19	1	0	3 17.67
26	5	6	6 20.33
25	4	8	3 20.00
22	1	5	3 19.00
20	1	2	3 18.00

total net mean grain count : 12.21

nuclei with >=6 grains : 39
 nuclei with >=20 grains : 9

PROJECT NO. : 738388
 CLIENT : UNILEVER EXAMINER : M.D. MAILLEY
 TEST MATERIAL: TRICLOSAN DATE EXAMINED : SEPTEMBER/21/88
 EXPT. DATE : AUGUST/24/88 EXPERIMENT NO.2
 SLIDE LETTER : N3

NO. OF grains/ nucleus	cytoplasmic grains		net grains/ nucleus	
9	1	1	1	8.00
6	2	5	2	3.00
8	4	4	4	4.00
9	2	1	0	8.00
7	0	2	1	6.00
6	1	0	0	5.67
0	2	1	0	-1.00
13	2	2	1	11.33
11	0	0	0	11.00
11	1	0	1	10.33
12	2	0	4	10.00
7	3	2	2	4.67
8	1	4	4	5.00
8	3	1	2	6.00
15	6	6	3	10.00
5	1	3	2	3.00
2	1	2	5	-0.67
7	2	2	1	5.33
3	1	1	1	2.00
8	2	3	0	6.33
13	3	3	4	9.67
15	1	4	7	11.00
15	6	2	2	11.67
9	5	1	3	6.00
20	0	2	3	16.33
20	5	8	4	14.33
16	5	3	5	11.67
20	3	2	2	17.67
11	1	1	3	9.33
18	2	8	6	12.67
8	3	4	7	3.33
13	3	1	4	10.33
12	5	4	5	7.33
9	7	7	4	3.00
11	3	2	4	8.00
19	3	0	5	16.33
13	1	4	0	11.33
20	5	3	4	16.00
18	8	5	5	12.00
18	3	6	7	12.67
19	11	6	8	10.67
18	5	7	7	11.67
13	5	4	4	8.67
16	11	5	11	7.00
20	4	6	6	14.67
12	6	2	7	7.00
17	4	3	6	12.67
12	6	8	8	4.67
16	11	5	8	8.00
19	3	4	6	14.67

total net mean grain count : 8.81

nuclei with ≥ 6 grains : 37
 nuclei with ≥ 20 grains : 0

mean of coverslip one : 13.60

mean of coverslip two : 12.21

MEAN OF ALL THREE COVERSLEPS : 11.54

TOTAL PERCENT
 OF NUCLEI WITH ≥ 6 GRAINS : 79.33

TOTAL PERCENT
 OF NUCLEI WITH ≥ 20 GRAINS : 12.67

PROJECT NO. : 738388
 CLIENT : UNILEVER EXAMINER : M.O'MAILLEY
 TEST MATERIAL: TRICLOSAN DATE : SEPTEMBER/21/88
 EXPT. DATE : AUGUST/24/88 EXPERIMENT NO.2
 SLIDE LETTER : 01

NO. OF grains/ nucleus	cytoplasmic grains		net grains/ nucleus	
26	5	2	3	22.67
23	3	3	6	19.00
27	11	11	11	16.00
16	6	4	15	7.67
20	8	4	3	17.67
15	6	7	11	7.00
33	2	3	5	29.67
18	5	3	12	11.33
22	7	6	5	16.00
37	16	16	7	24.00
24	5	9	8	16.67
18	7	11	9	9.00
25	2	2	3	22.67
15	2	2	1	13.33
24	8	4	7	17.67
30	15	13	6	18.67
30	5	2	2	27.00
26	11	7	4	18.67
17	2	1	1	15.67
18	5	2	2	15.00
19	8	5	5	13.00
16	2	5	8	13.67
31	2	2	1	29.33
19	12	14	15	5.33
19	7	2	8	16.00
19	2	4	2	16.33
12	3	3	3	9.00
28	7	8	5	21.33
14	1	0	4	12.33
9	2	1	1	7.67
7	0	0	0	7.00
5	1	2	2	3.33
8	1	1	1	7.00
13	5	7	4	7.67
12	1	2	1	10.67
14	3	2	3	11.33
12	2	4	3	9.00
14	6	2	2	10.67
20	8	4	2	15.33
13	1	2	1	11.67
13	0	4	2	11.00
18	2	1	0	17.00
22	5	4	3	18.00
13	4	4	2	9.67
4	3	2	0	2.33
15	5	1	3	12.00
8	2	2	6	4.67
7	1	2	2	5.33
3	4	0	3	0.67
16	9	6	6	9.00

total net mean grain count : 13.45

nuclei with >=6 grains : 44
 nuclei with >=20 grains : 7

PROJECT NO. : 738388
 CLIENT : UNILEVER EXAMINER : M.O'MAILLEY
 TEST MATERIAL: TRICLOSAN DATE : SEPTEMBER/21/88
 EXPT. DATE : AUGUST/24/88 EXPERIMENT NO.2
 SLIDE LETTER : 02

NO. OF grains/ nucleus	cytoplasmic grains		net grains/ nucleus
27	5	11	9 18.67
11	2	1	1 9.67
10	1	0	3 8.67
14	2	2	1 12.33
7	2	0	0 6.33
16	0	1	0 15.67
13	3	2	1 11.00
12	1	2	0 11.00
14	1	6	3 10.67
17	0	0	1 16.67
14	3	5	3 10.33
13	9	6	4 6.67
20	1	5	7 15.67
20	1	3	1 18.33
11	2	2	5 8.00
5	2	3	3 2.33
28	2	0	4 26.00
7	2	0	0 6.33
14	7	6	5 8.00
11	3	1	4 8.33
6	1	1	2 4.67
8	0	2	2 6.67
14	3	2	3 11.33
15	5	2	3 11.67
19	0	0	1 18.67
18	7	4	15 9.33
6	4	4	3 2.33
14	3	5	2 10.67
14	5	4	6 9.00
16	7	3	2 12.00
20	5	4	8 14.33
19	5	3	6 14.33
14	1	0	1 13.33
9	1	1	0 8.33
14	2	3	1 12.00
13	2	2	3 10.67
16	2	1	2 14.33
13	4	9	9 5.67
27	3	6	7 21.67
33	9	17	7 22.00
29	2	5	5 25.00
18	3	4	3 14.67
30	1	2	7 26.67
15	9	12	5 6.33
29	8	8	7 21.33
25	6	4	9 18.67
36	3	2	2 33.67
19	3	3	2 16.33
19	7	5	7 12.67
34	9	14	12 22.33

total net mean grain count : 13.23

nuclei with ≥ 6 grains : 46
 nuclei with ≥ 20 grains : 8

PROJECT NO. : 738388
 CLIENT : UNILEVER EXAMINER : M.O'MAILLEY
 TEST MATERIAL: TRICLOSAN DATE EXAMINED : SEPTEMBER/21/88
 EXPT. DATE : AUGUST/24/88 EXPERIMENT NO.2
 SLIDE LETTER : C3

NO. OF grains/ nucleus	cytoplasmic grains		net grains/ nucleus	
14	6	3	3	18.00
16	4	3	2	13.00
6	1	0	0	5.67
16	1	8	9	10.00
16	2	1	1	14.67
3	3	1	3	0.67
24	11	4	4	17.67
22	1	5	4	18.67
27	14	13	16	12.67
17	1	1	3	15.33
15	7	6	2	10.00
20	1	1	1	19.00
16	8	4	5	10.33
19	1	1	4	17.00
27	4	4	3	23.33
28	3	2	4	25.00
9	2	2	2	7.00
4	1	1	0	3.33
18	2	3	0	16.33
20	9	3	1	15.67
28	5	4	11	21.33
20	6	7	6	13.67
18	3	6	2	14.33
18	3	5	1	15.00
17	4	3	3	13.67
11	1	2	1	9.67
16	6	5	6	10.33
19	6	4	1	15.33
16	2	4	2	13.33
12	3	2	2	9.67
15	4	6	7	9.33
15	4	7	3	10.33
2	4	0	1	0.33
15	0	3	3	13.00
6	4	1	1	4.00
20	5	4	4	15.67
18	8	3	1	14.00
15	4	2	3	12.00
28	13	8	4	19.67
13	6	7	2	8.00
16	1	2	1	14.67
3	1	1	2	1.67
15	2	4	2	12.33
5	1	1	3	3.33
9	6	3	3	5.00
8	1	2	2	6.33
15	7	6	3	9.67
18	4	4	6	13.33
23	3	1	5	20.00
17	8	7	6	10.00

total net mean grain count :				12.09
nuclei with >=6 grains	:		42	
nuclei with >=20 grains	:		4	
mean of coverslip one	:		13.45	
mean of coverslip two	:		13.23	
MEAN OF ALL THREE COVERSLEPS	:		12.92	
TOTAL PERCENT				
OF NUCLEI WITH >=6 GRAINS	:		86.00	
TOTAL PERCENT				
OF NUCLEI WITH >=20 GRAINS	:		12.67	

PROJECT NO. : 738388
 CLIENT : UNILEVER
 TEST MATERIAL: TRICLOSAN
 EXPT. DATE : AUGUST/24/88
 SLIDE LETTER : F1

EXAMINER : M.D'MAILLEY
 DATE : SEPTEMBER/21/88
 EXPERIMENT NO.2

NO. OF grains/ nucleus	cytoplasmic grains		net grains/ nucleus	
6	2	4	4	2.67
4	11	5	2	-2.00
6	6	4	5	1.00
5	11	5	3	-1.33
11	7	9	5	4.00
8	6	5	4	3.00
3	3	2	4	0.00
6	5	7	6	0.00
2	0	1	1	1.33
0	3	0	0	-1.00
1	1	0	0	0.67
2	2	0	0	1.33
0	1	0	1	-0.67
1	0	0	1	0.67
1	0	0	0	1.00
0	0	2	0	-0.67
4	3	3	2	1.33
2	4	2	3	-1.00
0	2	0	1	-1.00
0	0	1	0	-0.33
2	1	0	0	1.67
1	2	1	1	-0.33
1	1	0	1	0.33
0	2	0	0	-0.67
0	1	0	0	-0.33
2	3	0	0	1.00
0	3	1	0	-1.33
0	0	2	1	-1.00
1	2	0	1	0.00
1	1	1	0	0.33
1	0	1	0	0.67
3	0	0	0	3.00
14	10	14	13	-1.00
2	2	2	3	-0.33
3	6	4	3	-1.33
1	1	0	1	0.33
0	1	2	0	-1.00
0	0	4	0	-1.33
1	0	0	1	0.67
5	5	6	4	0.00
2	2	3	1	0.00
2	4	2	3	-1.00
1	0	1	0	0.67
0	0	0	0	0.00
0	2	1	0	-1.00
0	1	0	0	-0.33
0	0	0	1	-0.33
2	1	1	0	1.33
1	3	0	2	-0.67
1	2	1	0	0.00

total net mean grain count : 0.14

nuclei with ≥ 6 grains : 0
 nuclei with ≥ 20 grains : 0

PROJECT NO. : 738388
 CLIENT : UNILEVER EXAMINER : M.O'MAILLEY
 TEST MATERIAL: TRICLOSAN DATE : SEPTEMBER/21/88
 EXPT. DATE : AUGUST/24/88 EXPERIMENT NO.2
 SLIDE LETTER : P2

NO. OF grains/ nucleus	cytoplasmic grains	net grains/ nucleus	
5	3	2	8 3.33
2	2	3	9 -2.67
6	12	7	4 -1.67
6	12	5	12 -3.67
5	2	1	2 3.33
3	3	6	3 -1.00
2	2	3	4 -1.00
3	12	8	6 -5.67
5	4	7	8 -1.33
11	3	5	3 7.33
2	1	5	3 -1.00
8	4	4	5 3.67
4	4	5	7 -1.33
7	5	8	8 0.00
2	5	7	1 -2.33
3	4	6	7 -2.67
8	11	11	7 -1.67
8	6	6	7 1.67
4	7	5	5 -1.67
3	4	3	3 -0.33
3	6	8	8 -4.33
5	4	5	6 0.00
6	14	9	11 -5.33
3	3	7	3 -1.33
2	4	1	2 -0.33
4	7	3	2 0.00
4	2	3	3 1.33
7	6	7	2 2.00
4	3	8	4 -1.00
9	12	7	11 -1.00
6	9	7	6 -1.33
5	9	3	8 -1.67
8	2	8	8 -0.67
4	1	2	2 2.33
3	2	3	6 -0.67
4	5	4	6 -1.00
5	13	8	3 -3.00
11	6	5	9 4.33
8	1	1	1 -1.00
6	3	13	7 -1.67
6	5	6	7 0.00
4	3	2	3 1.33
5	3	2	3 2.33
11	5	6	9 4.33
7	2	4	8 2.33
3	6	5	6 -2.67
2	5	4	3 -2.00
8	2	3	2 -2.33
1	3	2	1 -1.00
4	3	5	8 -1.33

total net mean grain count : -0.44

nuclei with >=6 grains : 1
 nuclei with >=20 grains : 0

PROJECT NO. : 738388
 CLIENT : UNILEVER EXAMINER : M.O'MAILLEY
 TEST MATERIAL: TRICLOSAN DATE EXAMINED : SEPTEMBER/21/88
 EXPT. DATE : AUGUST/24/88 EXPERIMENT NO.2
 SLIDE LETTER : P3

NO. OF grains/ nucleus	cytoplasmic grains		net grains/ nucleus	
5	2	4	3	2.00
6	6	6	6	0.00
2	3	2	3	-0.67
4	2	6	9	-1.67
4	8	14	13	-7.67
6	7	3	12	-1.33
5	2	3	4	2.00
4	11	8	9	-5.33
5	3	4	3	1.67
2	4	9	3	-3.33
7	12	9	11	-3.67
2	6	4	4	-2.67
4	4	2	7	-0.33
4	6	5	7	-2.00
5	6	6	4	-0.33
7	2	3	6	3.33
4	5	3	5	-0.33
3	5	4	8	-2.67
3	5	9	3	-2.67
5	2	2	7	1.33
3	5	5	8	-3.00
3	4	3	2	0.00
8	6	8	12	-0.67
9	4	3	9	3.67
5	2	7	4	0.67
4	4	5	4	-0.33
1	4	4	4	-3.00
7	5	6	4	2.00
5	4	3	7	0.33
3	2	2	1	1.33
2	6	4	5	-3.00
8	3	2	6	-3.67
8	4	4	5	3.67
2	4	2	3	-1.00
8	3	6	6	3.00
2	5	3	5	-2.33
3	7	2	4	-1.33
6	3	8	5	0.67
3	7	6	3	-2.33
8	12	16	12	-5.33
8	3	8	6	2.33
7	11	5	4	0.33
4	5	4	2	0.33
2	1	3	3	-0.33
4	6	3	3	0.00
6	5	14	6	-2.33
1	1	1	5	-1.33
4	5	4	13	-3.33
7	3	7	3	2.67
8	11	18	3	-2.67

total net mean grain count :			-0.79
nuclei with >=6 grains	:		0
nuclei with >=20 grains	:		0
mean of coverslip one	:		0.14
mean of coverslip two	:		-0.44
MEAN OF ALL THREE COVERSLEPS	:		-0.36
TOTAL PERCENT OF NUCLEI WITH >=6 GRAINS	:		0.67
TOTAL PERCENT OF NUCLEI WITH >=20 GRAINS	:		0.00

OTC Vol. No. 107

OTC Docket Number 75N-0183 (triclosan)
September 12, 1994

Ciba-Geigy Corporation
Chemicals Division
Greensboro, N.C. 27419

Heidemann, H.G. Chromosome Aberration Assay in Chinese Hamster V79 Cells In Vitro with FAT 80'023/Q (Triclosan). Cytotest Cell Research GmbH & Co. KG.
Project No. 179100. December 17, 1990.

Study Summary

The test article FAT 80'023/Q was assessed for its potential to induce structural chromosome aberrations in V79 cells of the Chinese hamster in vitro.

Preparation of chromosomes was done 7 h (high dose), 18 h (low, medium and high dose), and 28 h (high dose) after start of treatment with the test article. The treatment interval was 4 h.

In each experimental group two parallel cultures were used. Per culture 100 metaphases were scored for structural chromosomal aberrations.

The following dose levels were evaluated:

without S9 mix:	with S9 mix:
7 h: 1.0 µg/ml	7 h: 3.0 µg/ml
18 h: 0.1; 1.0; 3.0 µg/ml	18 h: 0.1; 1.0; 3.0 µg/ml
28 h: 3.0 µg/ml	28 h: 3.0 µg/ml

The concentration range of the test article applied had been determined in a pre-experiment using the plating efficiency assay as indicator for toxicity response. Treatment with concentrations higher than 3.0 (without S9 mix) and 10.0 µg/ml reduced distinctly the plating efficiency of the V79 cells.

75N.1834

C1

In the cytogenetic experiment, the mitotic index was reduced after treatment with the highest concentration at each fixation interval, except at interval 18 and 28 h in the presence of S9 mix.

There were biologically relevant increases in cells with structural aberrations after treatment with the test article at fixation intervals 18 h (with and without S9 mix) and 28 h (without S9 mix).

Appropriate reference mutagens were used as positive controls and showed distinct increases in cells with structural chromosome aberrations.

In conclusion, it can be stated that in the study described and under the experimental conditions reported, the test article induced structural chromosome aberrations as determined by the chromosomal aberration test in the V79 Chinese hamster cell line.

Therefore, FAT 80'023/Q is considered to be mutagenic in this chromosomal aberration test.

CCR

CCR - Cytotest Cell Research GmbH & Co. KG

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MAR 20 1991

SEAD

CCR PROJECT 179100

OK

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**CHROMOSOME ABERRATION ASSAY
IN CHINESE HAMSTER V79 CELLS
IN VITRO**

WITH

FAT 80'023/Q

REPORT

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PREFACE

GENERAL

Sponsor: CIBA GEIGY AG
K-1363.3.18
CH-4002 Basel
Switzerland

Study Monitor: Dr. A. Timm

Testing Facility: C C R
CYTOTEST CELL RESEARCH GMBH & CO. KG
D-6101 Roßdorf, F.R.G.

CCR Project No.: 179100

Test Article: FAT 80'023/Q

Title: Chromosome Aberration Assay
in Chinese Hamster V79 Cells
in vitro with FAT 80'023/Q

PROJECT STAFF

Director of CCR: Prof. Dr. Herbert G. Miltenburger

Study Director: Dr. Albrecht Heidemann

Management: Dr. Wolfgang Völkner

SCHEDULE

Date of Protocol: February 21, 1990

Start of Pre-Experiment: April 09, 1990

Start of Experiment: July 30, 1990

End of Experiment: October 01, 1990

Date of Draft: November 19, 1990

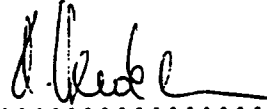
Date of Amendment (1st)
to Protocol: December 06, 1990

Date of Report: December 17, 1990

PROJECT STAFF SIGNATURES

Study Director:

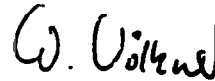
Dr. Albrecht Heidemann



.....
Date: December 17, 1990

MANAGEMENT:

Dr. Wolfgang Völkner



.....
Date: December 17, 1990

QUALITY ASSURANCE

The study was performed in compliance with:

"The OECD Principles of Good Laboratory Practice", Paris 1981.

"First Amendment of Chemical Law (F.R.D.) dated at September 16, 1980, adopted August 1, 1990, 6th passage, 19a ff. and two appendixes."

GUIDELINES

This study was conducted according to the procedures indicated by the following internationally accepted guidelines and recommendations:

First Addendum to the OECD Guideline for Testing of Chemicals, Section 4, No. 473, adopted May 26, 1983,

"In vitro Mammalian Cytogenetic Test"

EEC Directive 84/449, L 251, B 10, p. 131-133

Revised Chemical Substance Law (1987) according to the notification of December 9, 1986 by EA, Environmental Agency (No. 700);* MHW, Ministry of Health and Welfare (No. 1039) and MITI, Ministry of International Trade and Industry (No. 1014), Japan.

* does not include dose selection

"There were no circumstances that may have affected the quality or integrity of the study".

ARCHIVING

C C R, D-6101 Roßdorf, F.R.G. will archive the following data for 30 years:
raw data, protocol and copy of report.

The following specimen and samples will be archived for at least 12 years:
sample of test article, microscopic slides.

No raw data or material relating to the study will be discarded without the sponsor's prior consent.

STATEMENT OF COMPLIANCE

Project Number: 179100
Test Article: FAT 80'023/Q
Study Director: Dr. Albrecht Heidemann
Title: Chromosome Aberration Assay
in Chinese Hamster V79 Cells
in vitro with FAT 80'023/Q

To the best of my knowledge and belief, the study was conducted
in compliance with Good Laboratory Practice Regulations.

Study Director:

C C R

Dr. Albrecht Heidemann



.....

Date: December 17, 1990

QUALITY ASSURANCE UNIT

C C R, Cytotest Cell Research GmbH & Co KG,
In den Leppsteinswiesen 19, D-6101 Roßdorf, F.R.G.

STATEMENT

Project Number: 179100
Test Article: FAT 80'023/Q
Study Director: Dr. Albrecht Heidemann
Title: Chromosome Aberration Assay
in Chinese Hamster V79 Cells
in vitro with FAT 80'023/Q

This report was audited by the Quality Assurance Unit and study procedures were inspected on the following dates.

Dates of QAU Inspections / Audits


March 05, 1990
April 26, 1990
July 30, 1990
November 27, 1990

Dates of Reports to the Study Director and to Management

March 05, 1990
April 26, 1990
July 30, 1990
November 27, 1990

Head of
Quality Assurance Unit

Dipl. Biol. Ch. Bonk-Kassner

.....


Date: December 18, 1990

SUMMARY

The test article FAT 80'023/Q was assessed for its potential to induce structural chromosome aberrations in V79 cells of the Chinese hamster in vitro.

Preparation of chromosomes was done 7 h (high dose), 18 h (low, medium and high dose), and 28 h (high dose) after start of treatment with the test article. The treatment interval was 4 h.

In each experimental group two parallel cultures were used. Per culture 100 metaphases were scored for structural chromosomal aberrations.

The following dose levels were evaluated:

without S9 mix:	with S9 mix:
7 h: 1.0 µg/ml	7 h: 3.0 µg/ml
18 h: 0.1; 1.0 ; 3.0 µg/ml	18 h: 0.1; 1.0 ; 3.0 µg/ml
28 h: 3.0 µg/ml	28 h: 3.0 µg/ml

The concentration range of the test article applied had been determined in a pre-experiment using the plating efficiency assay as indicator for toxicity response. Treatment with concentrations higher than 3.0 (without S9 mix) and 10.0 µg/ml reduced distinctly the plating efficiency of the V79 cells.

In the cytogenetic experiment, the mitotic index was reduced after treatment with the highest concentration at each fixation interval, except at interval 18 and 28 h in the presence of S9 mix.

There were biologically relevant increases in cells with structural aberrations after treatment with the test article at fixation intervals 18 h (with and without S9 mix) and 28 h (without S9 mix).

Appropriate reference mutagens were used as positive controls and showed distinct increases in cells with structural chromosome aberrations.

CONCLUSION

In conclusion, it can be stated that in the study described and under the experimental conditions reported, the test article induced structural chromosome aberrations as determined by the chromosomal aberration test in the V79 Chinese hamster cell line.

Therefore, FAT 80'023/Q is considered to be mutagenic in this chromosomal aberration test.

OBJECTIVE

AIMS OF THE STUDY

This in vitro experiment was performed to assess the potential of the test article to induce structural chromosome aberrations by means of the chromosome aberration assay in the Chinese hamster cell line V79.

REASONS FOR THE STUDY

In vitro methods are valuable when it is desirable to accurately control the concentration and exposure time of cells to the test article under study. However, due to the limited capacity for metabolic activation of potential mutagens an exogenous metabolic activation system is necessary.

This in vitro test is an assay for the detection of structural chromosomal aberrations. These aberrations are frequently lethal to the damaged cells. However, cytogenetic damage in somatic cells is an indicator of a potential to induce more subtle chromosome damage that is compatible with cell division. Similar damage induced in germinal cells may lead to heritable cytogenetic abnormalities. Heritable cytogenetic abnormalities are known to have deleterious effects in man, e.g. induction of neoplastic events or birth defects.

The V79 cells were exposed to the test article both with and without exogenous metabolic activation. The cells were then harvested at sequential intervals and chromosome preparations were made. The stained preparations were examined and metaphase cells were scored for chromosomal aberrations.

Chromosomal aberrations are generally evaluated in first post-treatment mitoses. With the majority of chemical mutagens, induced aberrations are of the chromatid type, but chromosome type aberrations also occur.

The time at which the aberration frequency is at the maximum varies from agent to agent. Because different chemicals have effects at different parts of the cell cycle and V79 cultures are asynchronous, multiple post-treatment sample times are necessary to precisely define the response. Due to mitotic delay or metabolic and pharmacokinetic effects the appearance of the first post-treatment mitosis can be considerably delayed. Therefore samples taken at 7 h, 18 h and 28 h after beginning of treatment cover the intervals in which maximum aberration frequency is expected.

For the initial assessment of clastogenic activity a single dose level producing some indication of cytotoxicity (partial inhibition of mitosis) and sampling at 7 h, 18 h, and 28 h after beginning of treatment is recommended. To establish a dose response effect two additional dose levels were tested at the central sampling time 18 h after start of treatment.

To validate the test, reference mutagens were tested in parallel to the test article.

MATERIALS AND METHODS

THE TEST ARTICLE

Name: FAT 80'023/Q

Batch No.: EN 91390.76

Aggregate State
at RT: solid

Colour: white

Molecular Weight: 289.55

Purity: cf. Analytical Certificate in sponsor's file

Analysis: cf. Analytical Certificate in sponsor's file

Stability: Pure: stable for at least 24 months
In solvent: stable 48 hours in ethanol,
DMSO, DMF and hexan

Storage: room temperature

Expiration Date: November, 1992

On the day of the experiment (immediately before the experiment), the test article was dissolved in ethanol (Merck, D-6100 Darmstadt). The solvent was chosen according to its solubility properties and its relative nontoxicity for the cells. The final concentration of ethanol in the culture medium did not exceed 1 % v/v.

THE CONTROLS

The Negative Controls

Concurrent negative and solvent controls were performed.

The Positive Control Substances

Without metabolic activation

Name: EMS; Ethylmethanesulfonate
Supplier: Merck-Schuchardt, D-8000 München, F.R.G.
Catalogue no.: 820774
Dissolved in: nutrient medium
Final Concentration: 0.72 mg/ml = 5.76 mM
Solution prepared on day of experiment.

The stability of the positive control substance in solution was proven by the mutagenic response in the expected range.

With metabolic activation

Name: CPA; Cyclophosphamide
Supplier: SERVA, D-6900 Heidelberg, F.R.G.
Catalogue no.: 17681
Dissolved in: nutrient medium
Final Concentration: 1.40 µg/ml = 5.00 µM
Solution prepared on day of experiment.

The stability of CPA at room temperature is good. At 20° C only 1 % of CPA is hydrolysed per day in aqueous solution.

THE TEST SYSTEM

Reasons for the Choice of the Cell Line V79

The V79 cell line has been used for many years in in vitro experiments with success. Especially the high proliferation rate (doubling time 12 - 16 h in stock cultures) and a high plating efficiency of untreated cells (as a rule more than 50 %) both necessary for the appropriate performance of the study, recommend the use of this cell line. The cells have a stable karyotype with a modal chromosome number of 22.

Lacking metabolic activities of cells under in vitro conditions are a disadvantage of assays with cell cultures as many chemicals only develop mutagenic potential when they are metabolized by the mammalian organism. However, metabolic activation of chemicals can be achieved at least partially by supplementing the cell cultures with liver microsome preparations (S9 mix).

Cell Cultures

Large stocks of the V79 cell line (supplied by LMP, D-6100 Darmstadt) were stored in liquid nitrogen in the cell bank of C C R allowing the repeated use of the same cell culture batch in experiments. Before freezing, each batch was screened for mycoplasma contamination and checked for karyotype stability. Consequently, the parameters of the experiments remain similar because of the reproducible characteristics of the cells.

Thawed stock cultures were propagated at 37°C in 80 cm² plastic flasks (GREINER, D-7440 Nürtingen, F.R.G.). Seeding was done with about 5×10^5 cells per flask in 15 ml of MEM (minimal essential medium; SEROMED; D-1000 Berlin, F.R.G.) supplemented with 10 % fetal calf serum (FCS; Boehringer Mannheim, D-6800 Mannheim, F.R.G.). The cells are subcultured twice weekly. The cell cultures were incubated at 37°C and 4.5 % carbon dioxide atmosphere.

MAMMALIAN MICROSOMAL FRACTION S9 MIX

S9 (Preparation by C C R)

The S9 liver microsomal fraction was obtained from the liver of 8 - 12 weeks old male Wistar rats, strain WU (SAVO-Ivanovas, med. Versuchstierzuchten GmbH, D-7964 Kisslegg, F.R.G.; weight approx. 150 - 200 g) which received a single i.p. injection of 500 mg/kg b.w. Aroclor 1254 (Antechnika, D-7500 Karlsruhe, F.R.G.) in olive oil 5 days previously.

After cervical dislocation the livers of the animals were removed, washed in 150 mM KCl and homogenised. The homogenate, diluted 1:3 in KCl was centrifuged cold at 9,000 g for 10 minutes. A stock of the supernatant containing the microsomes was frozen in ampoules of 2 or 5 ml and stored at -70° C. Small numbers of the ampoules were kept at -20° C for only several weeks before use. The standardization of the protein content was made using the analysis kit of Bio-Rad Laboratories, D-8000 München: Bio-Rad protein assay, Catalogue 500 000 6.

The protein concentration in the S9 preparation is usually between 20 and 45 mg/ml. In the cytogenetic experiment the protein concentration was 30.3 mg/ml (Lot.Nr.:191289). In the pre-experiment it was 34.6 mg/ml (210389).

S9 Mix

Before the experiment an appropriate quantity of S9 supernatant was thawed and mixed with S9 cofactor solution to result in a final protein concentration of 0.3 mg/ml in the cultures. The composition of the cofactor solution was concentrated to yield the following concentrations in the S9 mix:

8 mM MgCl₂
33 mM KCl
5 mM glucose-6-phosphate
5 mM NADP
in 100 mM sodium-ortho-phosphate-buffer, pH 7.4.

During the experiment the S9 mix was stored in an ice bath. The S9 mix preparation was performed according to Ames et al. (1).

PRE-EXPERIMENT FOR TOXICITY

The toxicity of the test article was determined in a pre-experiment in order to establish a concentration dependent plating efficiency relationship. The experimental conditions in this pre-experiment were the same as described below for the experiment.

Toxicity of the test article was evidenced by a reduction in plating efficiency.

DOSE SELECTION

According to the results from this pre-experiment six concentrations (18 h interval) to be applied in the chromosomal aberration assay were chosen.

The highest dose level used was 10 mM unless limited by the solubility of the test article or that producing some indication of cytotoxicity (reduced plating efficiency and/or partial inhibition of mitosis).

If toxic effects were produced the highest dose level should reduce the plating efficiency to approximately 20 - 50 %. In addition, this concentration should suppress if possible mitotic activity (% cells in mitosis) by approximately 50 %, but not so great a reduction that insufficient scorable mitotic cells can be found.

According to the results of the pre-experiment and a preliminary cytogenetic experiment (failed due to high toxicity; data not reported) treatment was performed with the following concentrations:

without S9 mix:

7 h: 1.0; 3.0; 6.0; 10.0 µg/ml
18 h: 0.1; 0.5; 1.0; 3.0; 6.0; 10.0 µg/ml
28 h: 1.0; 3.0; 6.0; 10.0 µg/ml

with S9 mix:

7 h: 1.0; 3.0; 10.0; 20.0 µg/ml
18 h: 0.1; 0.5; 1.0; 3.0; 10.0; 20.0 µg/ml
28 h: 1.0; 3.0; 10.0; 20.0 µg/ml

Treatment interval 4 hours. Per experimental group duplicate cultures were used.

According to the criteria mentioned above one (7 h and 28 h) and three concentrations (18 h) were selected to evaluate metaphases for cytogenetic damage.

In the pre-experiment for toxicity the colony forming ability of the V79 cells was distinctly reduced after treatment with concentrations higher than 3.0 (without S9 mix) and 10.0 µg/ml (with S9 mix).

In the main experiment, cultures after treatment with 1.0 µg/ml (7 h without S9 mix) and 3.0 µg/ml (any other fixation interval with and without S9 mix) as highest concentrations were evaluated for cytogenetic damage. With higher dose levels none or not enough scorable metaphases could be found.

EXPERIMENTAL PERFORMANCE

Seeding of the Cultures

Two days old logarithmically growing stock cultures more than 50 % confluent were trypsinised and a single cell suspension was prepared. The trypsin concentration was 0.2 % in Ca-Mg-free salt solution (Trypsin: Difco Laboratories, Detroit, USA).

The Ca-Mg-free salt solution was composed as follows (per litre):

NaCl	8000 mg
KCl	400 mg
Glucose	1000 mg
NaHCO ₃	350 mg

The cells were seeded into Quadriperm dishes (Heraeus, D-6450 Hanau, F.R.G.) which contained microscopic slides (2 chambers per dish and test group). In each chamber 5×10^4 - 1×10^5 cells were seeded with regard to preparation time. The medium was MEM + 10 % FCS.

Treatment

After 48 h (7 h, 28 h preparation interval) and 55 h (18 h preparation interval) the medium was replaced with serum-free medium containing the test article, either without S9 mix or with 20 µl/ml S9 mix. After 4 h this medium was replaced with normal medium after rinsing twice with "saline G".

The "saline G" solution is composed as follows (per litre):

NaCl	8000 mg
KCl	400 mg
Glucose	1100 mg
Na ₂ HP0 ₄ ·7H ₂ O	290 mg
KH ₂ P0 ₄	150 mg
ph was adjusted to 7.2	

All incubations were done at 37° C in a humidified atmosphere with 4.5 % CO₂.

Preparation of the Cultures

5, 15.5 and 25.5 h after the start of the treatment colcemid was added (0.2 µg/ml culture medium) to the cultures. 2.0 h (7 h interval) or 2.5 h later, (18 h and 28 h interval) the cells were treated on the slides in the chambers with hypotonic solution (0.4 % KCl) for 20 min at 37° C. After incubation in the hypotonic solution the cells were fixed with 3 + 1 absolute methanol + glacial acetic acid. Two slides per group were prepared. After fixation the cells were stained with giemsa (Merck, D-6100 Darmstadt, F.R.G.).

Analysis of Metaphase Cells

Evaluation of the slides was performed using NIKON microscopes with 100x oil immersion objectives. Breaks, fragments, deletions, exchanges and chromosomal disintegrations were recorded as structural chromosome aberrations. Gaps were recorded as well but not included in the calculation of the aberration rates. At least 100 well spread metaphases per slide were scored for cytogenetic damage on coded slides. Only metaphases with characteristic chromosome numbers of 22 ± 1 were included in the analysis. To describe a cytotoxic effect the mitotic index (% cells in mitosis) was determined. In addition, the number of polyploid cells (% polyploid metaphases; in the case of this aneuploid cell line polyploid means a near tetraploid karyotype) was scored.

DATA RECORDING

The data generated were recorded in the laboratory protocol. The results are presented in tabular form, including experimental groups with the test article, negative and positive controls.

ACCEPTABILITY OF THE ASSAY

The chromosomal aberration assay is considered acceptable if it meets the following criteria:

- a) the number of aberrations found in the negative and/or solvent controls fall within the laboratory historical control data range: 0.00 % - 4.00 %.
- b) the positive control substances should produce significant increases in the number of cells with structural chromosome aberrations.

EVALUATION OF RESULTS

A test article is classified as mutagenic if it induces either a significant dose-related increase in the number of structural chromosomal aberrations or a significant positive response for at least one of the test points.

A test article producing neither a significant dose-related increase in the number of structural chromosomal aberrations nor a significant positive response at any one of the test points is considered non-mutagenic in this system.

This can be confirmed by means of the chi-square test.

However, both biological and statistical significance should be considered together.

BIOMETRY

Statistical significance at the five per cent level ($p < 0.05$) was evaluated by means of the chi-square test. Evaluation was performed only for cells carrying aberrations exclusive gaps.

Solvent control versus		fixation interval	S9 mix	p-value
Test group	1.0 μg	7 h	-	n.t.
"	3.0 μg	7 h	+	n.a.
"	0.1 μg	18 h	-	n.t.
"	1.0 μg	18 h	-	$0.9 > p > 0.1$
"	3.0 μg	18 h	-	$0.01 > p > 0.001^*$
"	0.1 μg	18 h	+	n.t.
"	1.0 μg	18 h	+	$0.9 > p > 0.1$
"	3.0 μg	18 h	+	$0.1 > p > 0.05$
"	3.0 μg	28 h	-	$0.001 > p > 0^*$
"	3.0 μg	28 h	+	n.t.

n.t. = not tested as the aberration rate is equal or lower than the spontaneous rate

n.a. = not appropriate for testing because only one slide could be scored

* aberration rate is statistically significant higher than the control rate

RESULTS

TABLES OF RESULTSPre-experiment for toxicity

In the pre-experiment the toxicity of the test article was examined with the plating efficiency (colony forming ability). The results are given below:

Table 1:

Plating Efficiency Assay (PE) without metabolic activation
Per flask 500 cells were seeded.

conc. per ml	colonies counted		mean	PE % relative
	flask I	flask II		
negative control	328	298	313.0	
Ethanol	318	307	312.5	100.0
0.01 µg	308	317	312.5	100.0
0.10 µg	308	302	305.0	97.6
1.00 µg	378	299	338.5	108.3
3.00 µg	272	325	298.5	95.5
6.00 µg	4	2	3.0	1.0
10.00 µg	4	1	2.5	0.8
30.00 µg	1	1	1.0	0.3
60.00 µg*	2	1	1.5	0.5

Table 2:

Plating Efficiency Assay (PE) with metabolic activation
Per flask 500 cells were seeded.

conc. per ml	colonies counted		mean	PE % relative
	flask I	flask II		
negative control	305	292	298.5	
Ethanol	281	287	284.0	100.0
0.01 µg	287	325	306.0	107.7
0.10 µg	322	288	305.0	107.4
1.00 µg	254	257	255.5	90.0
3.00 µg	273	279	276.0	97.2
6.00 µg	291	263	277.0	97.5
10.00 µg	292	265	278.5	98.1
30.00 µg	0	1	0.5	0.2
60.00 µg*	2	0	1.0	0.4

* precipitation in the culture medium

Test Report CCR Project 179100

Table 3a: mitotic index (7 h)

Test group	conc. per ml	S9 mix	fixation interval (h)	mitotic index per cent*		abs.	rel.
				slide 1	slide 2		
Solvent control	0.0 µg	-	7	1.8	1.3	1.6	100.0
Test article	1.0 µg	-	7	3.4	2.9	3.2	203.2
Test article	3.0 µg	-	7	0.3	0.3	0.3	19.4
Test article	6.0 µg	-	7	0.0	0.0	0.0	0.0
Test article	10.0 µg	-	7	0.0	0.0	0.0	0.0
Solvent control	0.0 µg	+	7	3.8	7.4	5.6	100.0
Test article	1.0 µg	+	7	8.1	9.5	8.8	157.1
Test article	3.0 µg	+	7	3.3	2.6	3.0	52.7
Test article	10.0 µg	+	7	0.0	0.0	0.0	0.0
Test article	20.0 µg	+	7	0.0	0.0	0.0	0.0

* The mitotic index was determined in 1000 cells from each of the two slides per test group.

Table 3b: mitotic index (18 h)

Test group	conc. per ml	S9 mix	fixation interval (h)	mitotic index per cent*		abs.	rel.
				slide 1	slide 2		
Negative control	0.0 µg	-	18	7.8	10.2	9.0	100.0
Solvent control	0.0 µg	-	18	11.8	9.0	10.4	100.0
Positive control	0.72 mg	-	18	10.1	12.3	11.2	124.4
Test article	0.1 µg	-	18	14.1	7.6	10.9	104.3
Test article	0.5 µg	-	18	12.8	13.8	13.3	127.9
Test article	1.0 µg	-	18	12.9	14.1	13.5	129.8
Test article	3.0 µg	-	18	6.3	9.5	7.9	76.0
Test article	6.0 µg	-	18	0.0	0.0	0.0	0.0
Test article	10.0 µg	-	18	0.0	0.0	0.0	0.0
Negative control	0.0 µg	+	18	14.2	12.5	13.4	100.0
Solvent control	0.0 µg	+	18	8.5	11.1	9.8	100.0
Positive control	1.4 µg	+	18	17.8	17.5	17.7	132.2
Test article	0.1 µg	+	18	10.8	9.1	10.0	101.5
Test article	0.5 µg	+	18	9.6	9.5	9.6	97.4
Test article	1.0 µg	+	18	9.8	14.2	12.0	122.4
Test article	3.0 µg	+	18	14.3	16.4	15.4	156.6
Test article	10.0 µg	+	18	0.0	0.0	0.0	0.0
Test article	20.0 µg	+	18	0.0	0.0	0.0	0.0

* The mitotic index was determined in 1000 cells from each of the two slides per test group.

Table 3c: mitotic index (28 h)

Test group	conc. per ml	S9 mix	fixation interval (h)	mitotic index per cent*		abs.	rel.
				slide 1	slide 2		
Solvent control	0.0 µg	-	28	8.5	14.5	11.5	100.0
Test article	1.0 µg	-	28	13.1	14.8	14.0	121.3
Test article	3.0 µg	-	28	7.3	9.4	8.4	72.6
Test article	6.0 µg	-	28	0.0	0.0	0.0	0.0
Test article	10.0 µg	-	28	0.0	0.0	0.0	0.0
Solvent control	0.0 µg	+	28	9.7	5.0	7.4	100.0
Test article	1.0 µg	+	28	16.7	15.8	16.3	221.1
Test article	3.0 µg	+	28	8.6	12.1	10.4	140.8
Test article	10.0 µg	+	28	0.0	0.0	0.0	0.0
Test article	20.0 µg	+	28	0.0	0.0	0.0	0.0

* The mitotic index was determined in 1000 cells from each of the two slides per test group.

Table 4: number of polyploid cells

Test group	conc. per ml	S9 mix	fixation interval (h)	polyploid cells*		total	mean
				slide 1	2		
Solvent control	0.0 µg	-	7	0.0	0.0	0.0	0.0
Test article	1.0 µg	-	7	0.0	0.0	0.0	0.0
Solvent control	0.0 µg	+	7	0.0	1.0	1.0	0.5
Test article	3.0 µg	+	7	1.0	0.0	1.0	0.5
Negative control	0.0 µg	-	18	1.0	4.0	5.0	2.5
Solvent control	0.0 µg	-	18	2.0	2.0	4.0	2.0
Positive control	0.72 mg	-	18	2.0	0.0	2.0	1.0
Test article	0.1 µg	-	18	0.0	1.0	1.0	0.5
Test article	1.0 µg	-	18	0.0	1.0	1.0	0.5
Test article	3.0 µg	-	18	0.0	0.0	0.0	0.0
Negative control	0.0 µg	+	18	2.0	2.0	4.0	2.0
Solvent control	0.0 µg	+	18	3.0	3.0	6.0	3.0
Positive control	1.4 µg	+	18	0.0	1.0	1.0	0.5
Test article	0.1 µg	+	18	1.0	1.0	2.0	1.0
Test article	1.0 µg	+	18	2.0	1.0	3.0	1.5
Test article	3.0 µg	+	18	2.0	0.0	2.0	1.0
Solvent control	0.0 µg	-	28	3.0	1.0	4.0	2.0
Test article	3.0 µg	-	28	2.0	4.0	6.0	3.0
Solvent control	0.0 µg	+	28	3.0	0.0	3.0	1.5
Test article	3.0 µg	+	28	2.0	1.0	3.0	1.5

* The number of polyploid cells was determined in 100 cells from each of the two slides per test group.

Structural chromosome aberrations

Table 5: mutagenicity data

fixation interval: 7 h
 experimental group: solvent control
 metabolic activation: - S9 mix

	number of cells analysed	aberrant cells incl. gaps	excl. gaps
Slide 1	100	3	2
Slide 2	100	2	2
Total	200	5	4

Types of aberrations found per slide

No.	g	ig	b	ib	f	if	d	id	ma	ex	cd
Slide 1	1	0	0	0	2	0	0	0	0	0	0
Slide 2	0	0	0	0	1	0	0	0	0	1	0
Total	1	0	0	0	3	0	0	0	0	1	0

Abbreviations in the tables:

g = gap; ig = iso-gap; b = break; ib = iso-break; f = fragment; if = iso-fragment; d = deletion;
 id = iso-deletion; ma = multiple aberration (= more than 5 events, excluding gaps, in one cell; only
 exchanges, but no other aberrations, were recorded in these cells);
 ex = exchange; cd = chromosomal disintegration (= pulverization)

Table 6: mutagenicity data

fixation interval: 7 h
 experimental group: test article (1.0 µg/ml)
 metabolic activation: - S9 mix

	number of cells analysed	aberrant cells incl. gaps	cells excl. gaps
Slide 1	100	3	2
Slide 2	100	0	0
Total	200	3	2

Types of aberrations found per slide

No.	g	ig	b	ib	f	if	d	id	ma	ex	cd
Slide 1	1	0	0	0	1	1	0	0	0	0	0
Slide 2	0	0	0	0	0	0	0	0	0	0	0
Total	1	0	0	0	1	1	0	0	0	0	0

Table 7: mutagenicity data

fixation interval: 7 h
 experimental group: solvent control
 metabolic activation: + S9 mix

	number of cells analysed	aberrant cells incl. gaps	cells excl. gaps
Slide 1	100	2	1
Slide 2	100	1	1
Total	200	3	2

Types of aberrations found per slide

No.	g	ig	b	ib	f	if	d	id	ma	ex	cd
Slide 1	1	0	0	0	3	0	0	0	0	0	0
Slide 2	1	0	0	0	1	0	0	0	0	0	0
Total	2	0	0	0	4	0	0	0	0	0	0

Table 8: mutagenicity data

fixation interval: 7 h
 experimental group: test article (3.0 µg/ml)
 metabolic activation: + S9 mix

	number of cells analysed	aberrant cells incl. gaps	excl. gaps
Slide 1	not scorable		
Slide 2	100	5	2
Total	100	5	2

Types of aberrations found per slide

No.	g	ig	b	ib	f	if	d	id	ma	ex	cd
Slide 1	not scorable										
Slide 2	3	0	0	0	2	0	0	0	0	0	0
Total	3	0	0	0	2	0	0	0	0	0	0

Table 9: mutagenicity data

fixation interval: 18 h
 experimental group: negative control
 metabolic activation: - S9 mix

	number of cells analysed	aberrant cells incl. gaps	cells excl. gaps
Slide 1	100	4	2
Slide 2	100	1	1
Total	200	5	3

Types of aberrations found per slide

No.	g	ig	b	ib	f	if	d	id	ma	ex	cd
Slide 1	2	0	0	1	1	0	0	0	0	0	0
Slide 2	0	0	0	0	0	0	0	0	1	0	0
Total	2	0	0	1	1	0	0	0	1	0	0

Table 10: mutagenicity data

fixation interval: 18 h
 experimental group: solvent control
 metabolic activation: - S9 mix

	number of cells analysed	aberrant cells incl. gaps	excl. gaps
Slide 1	100	4	3
Slide 2	100	7	3
Total	200	11	6

Types of aberrations found per slide

No.	g	ig	b	ib	f	if	d	id	ma	ex	cd
Slide 1	2	0	0	0	2	0	0	0	2	0	0
Slide 2	4	1	1	0	2	0	0	0	0	2	0
Total	6	1	1	0	4	0	0	0	2	2	0

Table 11: mutagenicity data

fixation interval: 18 h
 experimental group: positive control EMS (0.72 mg/ml)
 metabolic activation: - S9 mix

	number of cells analysed	aberrant cells incl. gaps	cells excl. gaps
Slide 1	100	46	45
Slide 2	100	30	28
Total	200	76	73

Types of aberrations found per slide

No.	g	ig	b	ib	f	if	d	id	ma	ex	cd
Slide 1	4	0	2	1	7	4	1	0	2	54	0
Slide 2	2	0	3	0	5	2	1	0	0	25	0
Total	6	0	5	1	12	6	2	0	2	79	0

Table 12: mutagenicity data

fixation interval: 18 h
 experimental group: test article (0.1 µg/ml)
 metabolic activation: - S9 mix

	number of cells analysed	aberrant cells incl. gaps	excl. gaps
Slide 1	100	4	3
Slide 2	100	2	1
Total	200	6	4

Types of aberrations found per slide

No.	g	ig	b	ib	f	if	d	id	ma	ex	cd
Slide 1	1	0	0	1	1	1	0	0	0	2	0
Slide 2	1	0	1	0	0	0	0	0	0	0	0
Total	2	0	1	1	1	1	0	0	0	2	0

Table 13: mutagenicity data

fixation interval: 18 h
 experimental group: test article (1.0 µg/ml)
 metabolic activation: - S9 mix

	number of cells analysed	aberrant cells incl. gaps	excl. gaps
Slide 1	100	6	5
Slide 2	100	7	4
Total	200	13	9

Types of aberrations found per slide

No.	g	ig	b	ib	f	if	d	id	ma	ex	cd
Slide 1	2	0	1	1	1	1	0	0	0	1	0
Slide 2	4	0	0	1	3	0	0	0	0	0	0
Total	6	0	1	2	4	1	0	0	0	1	0

Table 14: mutagenicity data

fixation interval: 18 h
 experimental group: test article (3.0 µg/ml)
 metabolic activation: - S9 mix

	number of cells analysed	aberrant cells incl. gaps	cells excl. gaps
Slide 1	100	14	13
Slide 2	100	10	9
Total	200	24	22

Types of aberrations found per slide

No.	g	ig	b	ib	f	if	d	id	ma	ex	cd
Slide 1	1	0	4	0	4	0	0	0	2	10	0
Slide 2	2	0	0	0	1	1	0	0	0	8	0
Total	3	0	4	0	5	1	0	0	2	18	0

Table 15: mutagenicity data

fixation interval: 18 h
 experimental group: negative control
 metabolic activation: + S9 mix

	number of cells analysed	aberrant cells incl. gaps	excl. gaps
Slide 1	100	3	1
Slide 2	100	3	2
Total	200	6	3

Types of aberrations found per slide

No.	g`	ig	b	ib	f	if	d	id	ma	ex	cd
Slide 1	2	0	1	0	0	1	0	0	0	0	0
Slide 2	1	0	0	0	0	0	0	0	1	3	0
Total	3	0	1	0	0	1	0	0	1	3	0

Table 16: mutagenicity data

fixation interval: 18 h
 experimental group: solvent control
 metabolic activation: + S9 mix

	number of cells analysed	aberrant cells incl. gaps	cells excl. gaps
Slide 1	100	4	2
Slide 2	100	4	3
Total	200	8	5

Types of aberrations found per slide

No.	g	ig	b	ib	f	if	d	id	ma	ex	cd
Slide 1	2	0	1	0	0	0	0	0	1	1	0
Slide 2	1	0	0	0	2	1	0	0	0	0	0
Total	3	0	1	0	2	1	0	0	1	1	0

Table 17: mutagenicity data

fixation interval: 18 h
 experimental group: positive control CPA (1.4 µg/ml)
 metabolic activation: + S9 mix

	number of cells analysed	aberrant cells incl. gaps	cells excl. gaps
Slide 1	100	21	20
Slide 2	100	21	16
Total	200	42	36

Types of aberrations found per slide

No.	g	ig	b	ib	f	if	d	id	ma	ex	cd
Slide 1	1	0	3	4	3	1	0	1	3	11	0
Slide 2	5	0	2	1	7	0	0	1	1	17	0
Total	6	0	5	5	10	1	0	2	4	28	0

Table 18: mutagenicity data

fixation interval: 18 h
 experimental group: test article (0.1 µg/ml)
 metabolic activation: + S9 mix

	number of cells analysed	aberrant cells incl. gaps	excl. gaps
Slide 1	100	3	0
Slide 2	100	3	1
Total	200	6	1

Types of aberrations found per slide

No.	g	ig	b	ib	f	if	d	id	ma	ex	cd
Slide 1	3	0	0	0	0	0	0	0	0	0	0
Slide 2	2	0	0	0	1	0	0	0	0	0	0
Total	5	0	0	0	1	0	0	0	0	0	0

Table 19: mutagenicity data

fixation interval: 18 h
 experimental group: test article (1.0 µg/ml)
 metabolic activation: + S9 mix

	number of cells analysed	aberrant cells incl. gaps	cells excl. gaps
Slide 1	100	3	2
Slide 2	100	16	5
Total	200	19	7

Types of aberrations found per slide

No.	g	ig	b	ib	f	if	d	id	ma	ex	cd
Slide 1	1	0	0	0	0	1	0	0	0	1	0
Slide 2	10	1	0	0	0	2	1	0	1	4	0
Total	11	1	0	0	0	3	1	0	1	5	0

Table 20: mutagenicity data

fixation interval: 18 h
 experimental group: test article (3.0 µg/ml)
 metabolic activation: + S9 mix

	number of cells analysed	aberrant cells incl. gaps	excl. gaps
Slide 1	100	5	4
Slide 2	100	10	9
Total	200	15	13

Types of aberrations found per slide

No.	g	ig	b	ib	f	if	d	id	ma	ex	cd
Slide 1	2	0	3	0	1	1	0	0	0	3	0
Slide 2	1	0	2	0	2	0	0	0	1	6	0
Total	3	0	5	0	3	1	0	0	1	9	0

Table 21: mutagenicity data

fixation interval: 28 h
 experimental group: solvent control
 metabolic activation: - S9 mix

	number of cells analysed	aberrant cells incl. gaps	excl. gaps
Slide 1	100	3	1
Slide 2	100	2	1
Total	200	5	2

Types of aberrations found per slide

No.	g	ig	b	ib	f	if	d	id	ma	ex	cd
Slide 1	2	0	0	0	1	0	0	0	0	0	0
Slide 2	1	0	1	0	0	0	0	0	0	0	0
Total	3	0	1	0	1	0	0	0	0	0	0

Table 22: mutagenicity data

fixation interval: 28 h
 experimental group: test article (1.0 µg/ml)
 metabolic activation: - S9 mix

	number of cells analysed	aberrant cells incl. gaps	excl. gaps
Slide 1	100	12	12
Slide 2	100	11	7
Total	200	23	19

Types of aberrations found per slide

No.	g	ig	b	ib	f	if	d	id	ma	ex	cd.
Slide 1	0	0	3	1	2	2	0	0	4	17	0
Slide 2	5	0	3	0	3	2	0	0	0	3	0
Total	5	0	6	1	5	4	0	0	4	20	0

Table 23: mutagenicity data

fixation interval: 28 h
 experimental group: solvent control
 metabolic activation: + S9 mix

	number of cells analysed	aberrant cells incl. gaps	cells excl. gaps
Slide 1	100	1	1
Slide 2	100	7	3
Total	200	8	4

Types of aberrations found per slide

No.	g	ig	b	ib	f	if	d	id	ma	ex	cd
Slide 1	0	0	0	0	0	2	0	0	0	0	0
Slide 2	4	0	0	1	1	0	0	0	0	1	0
Total	4	0	0	1	1	2	0	0	0	1	0

Table 24: mutagenicity data

fixation interval: 28 h
 experimental group: test article (3.0 µg/ml)
 metabolic activation: + S9 mix

	number of cells analysed	aberrant cells incl. gaps	cells excl. gaps
Slide 1	100	2	2
Slide 2	100	1	0
Total	200	3	2

Types of aberrations found per slide

No.	g	ig	b	ib	f	if	d	id	ma	ex	cd
Slide 1	0	0	0	0	1	0	0	0	1	0	0
Slide 2	1	0	0	0	0	0	0	0	0	0	0
Total	1	0	0	0	1	0	0	0	1	0	0

Summary of results

Table 25: mutagenicity data

fixation interval: 7 h

article	number of cells analysed	conc. per ml	S9 mix	per cent incl. gaps	aberrant excl. gaps	cells exchanges
Solvent- control	200	0.0 µg	-	2.50	2.00	0.50
Test- article	200	1.0 µg	-	1.50	1.00	0.00
Solvent- control	200	0.0 µg	+	1.50	1.00	0.00
Test- article	100*	3.0 µg	+	5.00	2.00	0.00

* one slide was not scorable due to poor metaphase quality

Table 26: mutagenicity data

fixation interval: 18 h after start of the treatment

Test group	number of cells analysed	conc. per ml	S9 mix	per cent incl. gaps	aberrant excl. gaps	cells exchanges
Negative-control	200	0.0 µg	-	2.50	1.50	0.00
Solvent-control	200	0.0 µg	-	5.50	3.00	1.00
Positive-control EMS	200	0.72 mg	-	38.00	36.50	31.00
Test-article	200	0.1 µg	-	3.00	2.00	1.00
Test-article	200	1.0 µg	-	6.50	4.50	0.50
Test-article	200	3.0 µg	-	12.00	11.00	6.50
Negative-control	200	0.0 µg	+	3.00	1.50	1.00
Solvent-control	200	0.0 µg	+	4.00	2.50	0.50
Positive-control CPA	200	1.4 µg	+	21.00	18.00	9.50
Test-article	200	0.1 µg	+	3.00	0.50	0.00
Test-article	200	1.0 µg	+	9.50	3.50	1.50
Test-article	200	3.0 µg	+	7.50	6.50	4.50

Table 27: mutagenicity data

fixation interval: 28 h after start of the treatment

Test group	number of cells analysed	conc. per ml	S9 mix	per cent incl. gaps	aberrant excl. gaps	cells exchanges
Solvent- control	200	0.0 µg	-	2.50	1.00	0.00
Test- article	200	3.0 µg	-	11.50	9.50	5.50
Solvent- control	200	0.0 µg	+	4.00	2.00	0.50
Test- article	200	3.0 µg	+	1.50	1.00	0.00

CONCLUSIONS

The test article FAT 80'023/Q was assessed for its potential to induce structural chromosome aberrations in V79 cells of the Chinese hamster in vitro in the absence and presence of metabolic activation by S9 mix.

Preparation of chromosomes was done 7 h (high dose), 18 h (low, medium and high dose) and 28 h (high dose) after start of the treatment with the test article. The treatment interval was 4 h.

In each experimental group two parallel cultures were used. Per culture 100 metaphases were scored for structural chromosome aberrations.

The following dose levels were evaluated:

without S9 mix:	with S9 mix:
7 h: 1.0 µg/ml	7 h: 3.0 µg/ml
18 h: 0.1.; 1.0; 3.0 µg/ml	18 h: 0.1.; 1.0; 3.0 µg/ml
28 h: 3.0 µg/ml	28 h: 3.0 µg/ml

In the pre-experiment on toxicity (colony forming ability) in the absence and presence of S9 mix after treatment with concentrations higher than 3.0 µg/ml (without S9 mix) and 10.0 µg/ml (with S9 mix) the colony forming ability was distinctly reduced.

In the cytogenetic experiment, the mitotic index was reduced after treatment with the highest concentrations at each fixation interval, except at interval 18 and 28 h in the presence of S9 mix.

With the test article FAT 80'023/Q significant and biologically relevant increases in the structural chromosomal aberration rate were observed when compared with the aberration range of the solvent controls. These results were obtained after treatment with 3.0 µg/ml at fixation intervals 18 h (with and without S9 mix) and 28 h (without S9 mix). At the 18 h fixation interval the increases were dose-dependent. In addition, 4.5 - 6.5 % of the cells treated with 3.0 µg/ml were carrying exchanges as compared to 0.0 - 1.0 % in the corresponding controls.

At fixation interval 18 h, in the presence of S9 mix, the increase was not statistically significant. However, the biological relevance was confirmed by the dose-dependency and the occurrence of cells carrying exchanges (4.5 %).

Table 4 shows the occurrence of polyploid metaphases. No relevant deviation from the control data was found after treatment with the test article.

EMS (0.72 mg/ml) and CPA (1.40 µg/ml) were used as positive controls and showed distinct increases in cells with structural chromosome aberrations.

In conclusion, it can be stated that in the described study and under the experimental conditions reported, the test article FAT 80'023/Q induced structural chromosome aberrations in the V79 Chinese hamster cell line.

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OTC Vol. No. 108

OTC Docket Number 75N-0183 (triclosan)
September 12, 1994

Ciba-Geigy Corporation
Chemicals Division
Greensboro, N.C. 27419

Völkner, W. Chromosome Aberration Assay in Bone Marrow Cells of the Rat with FAT 80'023/Q (Triclosan). Cytotest Cell Research GmbH & Co. KG. Project No. 218305. April 23, 1991.

Study Summary

The study was performed to investigate the potential of FAT 80'023/Q to induce chromosome aberrations in bone marrow cells of the rat.

The test article was suspended in 1% Carboxymethylcellulose. The volume administered orally was 10 ml/kg body weight (b.w.). 6 h, 24 h and 48 h after a single administration of the test article, the bone marrow cells were collected for chromosome aberration analysis. Ten animals (5 males and 5 females) per test group were evaluated for the occurrence of cytogenetic damage. Per animal 50 well spread metaphases were scored for gaps, breaks, fragments, deletions, exchanges and chromosomal disintegrations.

The test article was tested in this cytogenetic assay in the following dose level:

6 h, 24 h, 48 h preparation interval: 4000 mg/kg b.w.

The dose for the cytogenetic assay was determined in a pre-experiment for toxicity. 4000 mg/kg b.w. was the maximum tolerated dose. At no preparation interval the chromosome aberration frequency was significantly enhanced as compared to the negative control. An appropriate reference mutagen was used as positive control and showed a distinct increase of induced aberration frequency. In conclusion, it can be stated that during the mutagenicity test described and under the experimental conditions reported, the test article did not induce chromosome mutations as determined by the chromosome aberration test with bone marrow cells of the rat. Therefore FAT 80'023/Q is considered to be non-mutagenic in this chromosome aberration assay in vivo.

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CCR - Cytotest Cell Research GmbH & Co. KG

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CCR PROJECT 218305

CHROMOSOME ABERRATION ASSAY IN BONE

MARROW CELLS OF THE RAT

WITH

FAT 80'023/Q

REPORT

CCR - In den Leppsteinswiesen 19 - D-6101 Roddorf - F.R.G.
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PREFACE

GENERAL

Sponsor: CIBA-GEIGY AG
K-1363.318
CH-4002 Basel
Switzerland

Study Monitor: Dr. A. Timm

Testing Facility: C C R
CYTOTEST CELL RESEARCH GMBH & CO. KG
D-6101 Roßdorf

Analysis of
Microscopic slides: LMP
Laboratory for Mutagenicity Testing
D-6100 Darmstadt

CCR Project No.: 218305

Test Article: FAT 80'023/Q

Title: Chromosome Aberration Assay in Bone Marrow
Cells of the Rat with FAT 80'023/Q

PROJECT STAFF

Director of CCR: Dr. Hans-Emil Knoell
Scientific consultant: Prof. Dr. Herbert G. Miltenburger
Study Director: Dr. Wolfgang Völkner
Management: Dr. Albrecht Heidemann

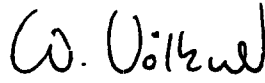
SCHEDULE

Date of Protocol: December 28, 1990
Start of Experiment: January 21, 1991
End of Experiment: April 18, 1991
Date of Draft: April 18, 1991
Date of Report: April 23, 1991

PROJECT STAFF SIGNATURES

Study Director:

Dr. Wolfgang Völkner


.....

Date: April 23, 1991

Management:

Dr. Albrecht Heidemann


.....

Date: April 23, 1991

QUALITY ASSURANCE

The study was performed in compliance with:

Chemikaliengesetz ("Chemicals Act") of the Federal Republic of Germany, Anlage 1 ("Annex 1"), dated March 14, 1990 (BGBl. I S. 521).

"The OECD Principles of Good Laboratory Practice", Paris 1981.

GUIDELINES

This study followed the procedures indicated by the following internationally accepted guidelines and recommendations:

Second Addendum to the OECD Guideline for Testing of Chemicals, Section 4, No. 475, adopted April 04, 1984, "In vivo Mammalian Bone Marrow Cytogenetic Test - Chromosomal Analysis".

EEC Directive 84/449, L 251, B 11, p. 134 - 136.

Environmental Protection Agency, Code of Federal Regulations, Title 40, Subpart F-Genetic Toxicity, Revision July 1, 1986

"In vivo mammalian bone marrow cytogenetics tests: Chromosomal analysis."

There were no circumstances that may have affected the quality or integrity of the study.

ARCHIVING

CCR, D-6101 Roßdorf will archive the following data for 30 years:
raw data, protocol and copy of report.

The following specimen and samples will be archived for at least 12 years:

samples of test article, microscopic slides.

No raw data or material relating to the study will be discarded without the sponsor's prior consent.

STATEMENT OF COMPLIANCE

- Project Number: 218305
Test Article : FAT 80'023/Q
Study Director: Dr. Wolfgang Völkner
Title : Chromosome Aberration Assay in Bone Marrow
Cells of the Rat with FAT 80'023/Q

To the best of my knowledge and belief, the study was conducted
in compliance with Good Laboratory Practice Regulations.

Study Director

C C R
Dr. Wolfgang Völkner

W. Völkner
.....

Date: April 23, 1991

QUALITY ASSURANCE UNIT

- C C R, Cytotest Cell Research GmbH & Co. KG,
in den Leppsteinswiesen 19, D-6101 Roßdorf

STATEMENT

Project Number: 218305
Test Article : FAT 80'023/Q
Study Director: Dr. Wolfgang Völkner
Title : Chromosome Aberration Assay in Bone Marrow
Cells of the Rat with FAT 80'023/Q

This report was audited by the Quality Assurance Unit and the study procedures were inspected on the following dates.

Dates of QAU Inspections/
Audits

Dates of Reports to the Study
Director and to Management

January 16, 1991
January 31, 1991
April 22/23, 1991

January 16, 1991
January 31, 1991
April 23, 1991

Head of
Quality Assurance Unit

Dipl. Biol. Christian Bonk-Kassner

.....

Date: April 23, 1991

SUMMARY

- This study was performed to investigate the potential of FAT 80'023/Q to induce chromosome aberrations in bone marrow cells of the rat.

The test article was suspended in 1 % Carboxymethylcellulose. The volume administered orally was 10 ml/kg body weight (b.w.). 6 h, 24 h and 48 h after a single administration of the test article the bone marrow cells were collected for chromosome aberration analysis. 10 animals (5 males, 5 females) per test group were evaluated for the occurrence of cytogenetic damage. Per animal 50 well spread metaphases were scored for gaps, breaks, fragments, deletions, exchanges and chromosomal disintegrations.

The test article was tested in this cytogenetic assay in the following dose level:

6 h, 24 h, 48 h preparation interval: 4000 mg/kg b.w.

The dose for the cytogenetic assay was determined in a pre-experiment for toxicity. 4000 mg/kg b.w. was the maximum tolerated dose.

At no preparation interval the chromosome aberration frequency was significantly enhanced as compared to the negative control.

An appropriate reference mutagen was used as positive control and showed a distinct increase of induced aberration frequency.

CONCLUSION

In conclusion, it can be stated that during the mutagenicity test described and under the experimental conditions reported, the test article did not induce chromosome mutations as determined by the chromosome aberration test with bone marrow cells of the rat.

Therefore FAT 80'023/Q is considered to be non-mutagenic in this chromosome aberration assay in vivo.

OBJECTIVE

AIMS OF THE STUDY

This in vivo experiment was performed to assess the mutagenic properties of the test article by means of the chromosome aberration test in bone marrow cells of the rat.

REASONS FOR THE STUDY

The bone marrow cytogenetic test is an assay for the detection of structural chromosomal aberrations. These aberrations are frequently lethal to the damaged cells. However, cytogenetic damage in somatic cells is an indicator of a potential to induce more subtle chromosome damage that is compatible with cell division. Similiar damage induced in germinal cells may lead to heritable cytogenetic abnormalities. Heritable cytogenetic abnormalities are known to have deleterious effects in man, e.g. induction of neoplastic events or birth defects.

Rats are exposed to the test article by an appropriate route and are sacrificed at sequential intervals. Chromosome preparations are made from bone marrow cells. The stained preparations are examined and metaphase cells are scored for chromosomal aberrations.

The bone marrow is the tissue of choice because it offers several advantages:

1. Low incidence of spontaneous chromosome aberrations.
2. Technical simplicity of the preparation.
3. High proportion of metaphase cells for analysis.

Chromosomal aberrations are generally evaluated in first post-treatment mitoses. With the majority of chemical mutagens, induced aberrations are of the chromatid type, but chromosome-type aberrations also occur (1).

The time at which the aberration frequency is at a maximum varies from agent to agent. Because different chemicals have effects at different parts of the cell cycle and the marrow cell population is asynchronous, multiple post-treatment sample times are necessary to precisely define the response. Due to mitotic delay or metabolic and pharmacokinetic effects the appearance of the first post-treatment mitosis can be considerably delayed.

Therefore samples taken at 6 h, 24 h and 48 h after treatment cover the intervals in which maximum aberration frequency is expected.

For the initial assessment of clastogenic activity a single dose level at the maximum tolerated dose or that producing some indication of cytotoxicity (partial inhibition of mitosis) and sampling at 6 h, 24 h, and 48 h after treatment is recommended. To validate the test, a reference mutagen is tested in parallel to the test article.

MATERIALS AND METHODS

- THE TEST ARTICLE

Name: FAT 80'023/Q

Batch No.: EN 91390.76

Aggregate State
at RT: solid

Colour: white

Purity: see Analytical Certificate in the sponsor's
file

Analysis: see Analytical Certificate in the sponsor's
file

Stability: Pure: at least 24 months
In vehicle: stable for 48 hours in ethanol,
DMSO, DMF, Hexan

Storage: room temperature

Expiration Date: November, 1992

On the day of the experiment, the test article was formulated in 1 % carboxymethylcellulose-suspension. The vehicle was chosen to its relative nontoxicity for the animals. All animals received a single standard dose volume adjusted to the body weight orally.

THE CONTROLS

The Negative Control

The vehicle of the test article was used as negative control.

Name:	Carboxymethylcellulose (1%)
Supplier:	SERVA, 6900 Heidelberg
Catalogue no.:	16110
Route and Frequency of Administration:	orally, singly
Volume Administered:	10 ml/kg b.w.

The Positive Control

Name:	CPA; Cyclophosphamide
Supplier:	SERVA, D-6900 Heidelberg
Catalogue no.:	17681
Dissolved in:	physiological saline
Dosing:	20 mg/kg b.w.
Route and Frequency of Administration:	orally, singly
Volume Administered:	10 ml/kg b.w.

Solution prepared on day of administration.

The stability of CPA at room temperature is good. At 20°C only
1 % of CPA is hydrolysed per day in aqueous solution.

THE TEST SYSTEM

Reasons for the Choice of the Experimental Animal Species

The rat is an animal which has been used for many years as suitable experimental animal in cytogenetic investigations. In addition, the rat is an experimental animal used in many physiological, pharmacological and toxicological studies.

There are many data available from such investigations which may be helpful in the interpretation of results from the cytogenetic assay (2,3,5,6). Data from such experiments also may be useful for the design and the performance of the chromosome aberration test.

Strain:	rat (Wistar)
Source:	SAVO med. Versuchstierzuchten GmbH D-7964 Kisslegg
Number of Animals:	60 (30 males/30 females)
Initial Age at Start of Acclimatization:	minimum 7 weeks
Acclimatization:	minimum 5 days
Initial Body Weight at Start of Treatment:	approximately 140 - 160 g

According to the suppliers assurance the animals were in healthy condition. The animals underwent quarantine in the animal house of C C R for a minimum of five days after their arrival. During this period the animals must not show signs of illness or altered behaviour.

The animals were distributed into the test groups at random and identified by cage number.

Husbandry

- The animals were kept conventionally. The experiment was conducted under standard laboratory conditions.

Housing:	single
Cage Type:	Makrolon Type I, with wire mesh top (EHRET GmbH, D-7830 Emmendingen 14)
Bedding:	granulated soft wood bedding (ALTROMIN, D-4937 Lage/Lippe)
Feed:	pelleted standard diet (ALTROMIN 1324, D-4937 Lage/Lippe)
Water:	tap water, ad libitum (Gemeindewerke, D-6101 Roßdorf)
Environment:	temperature $21 \pm 3^{\circ}\text{C}$ relative humidity 30-70 % artificial light 6.00 a.m. - 6.00 p.m.

EXPERIMENTAL PERFORMANCEPre-Experiment for Toxicity

A preliminary study on acute toxicity was performed with the same strain and under identical conditions as in the mutagenicity study.

Dose Selection

It is generally recommended to use the maximum tolerated dose or the highest dose than can be formulated and administered reproducibly. The volume administered should be compatible with the physiological space available.

The maximum tolerated dose level is determined to be the dose that causes toxic reactions without having major effects on survival within 48 hours.

Study Procedure

Test Groups:

Six males and six females were assigned to each test group. The animals were identified by their cage number as shown below in the table.

Test group	hours post-treatment		
	6 h male/female	24 h male/female	48 h male/female
Negative control	- / -	13-18/19-24	- / -
Test article	1- 6/ 7-12	25-30/31-36	49-54/55-60
Positive control	- / -	37-42/43-48	- / -

Treatment:

Approximately 18 hours before treatment with the test article the animals received no food but water ad libitum. At the beginning of the treatment the animals were weighed and the individual volume to be administered was adjusted to the animal's body weight. The animals received the test article once. Twelve animals, six males and six females, were treated per dose group.

Prior (2.5 hours) to sacrifice, animals were injected intraperitoneally with the spindle inhibitor colcemid (2.0 mg/kg b.w.), to arrest cells in metaphase.

Preparation of the Animals:

The animals were sacrificed by cervical dislocation. The femora were removed, the epiphyses were cut off and the marrow was flushed out with hypotonic Potassium chloride solution (0.56 % w/v, prewarmed to 37 °C). The hypotonic cell suspension was then incubated for 20 min at 37 °C. The cells were sedimented by a brief centrifugation, the hypotonic supernatant was discarded and the cell pellet was fixed with 3:1 absolute methanol:glacial acetic acid fixative for 60 min. Then the cell pellet was gently resuspended and stored overnight at 4°C. Prior to making slides the fixative was changed and enough fixative was added to make a relatively thin cell suspension. The fixative-cell suspension was spread by flame-drying and stained with Giemsa solution. Cover slips were mounted with EUKITT (KINDLER, D-7800 Freiburg). At least one slide was made from each bone marrow sample.

Analysis of Metaphase Cells:

Evaluation of the slides was performed using NIKON microscopes with 100 x oil immersion objectives. Gaps, breaks, fragments, deletions, exchanges and chromosomal disintegrations were recorded as structural chromosome aberrations. At least 50 well spread metaphases per animal were scored for cytogenetic damage on coded slides. Only metaphases with the characteristic chromosome number of 42 were included in the analysis (4). To describe a cytotoxic effect the mitotic index (% cells in mitosis; 1000 cells were scored) was determined.

Five animals per sex and group were evaluated as described. The remaining animal of each test group was evaluated in case an animal died in its test group spontaneously or due to gavage error.

DATA RECORDING

- The data generated are recorded in the laboratory protocol. The results are presented in tabular form, including experimental groups, negative and positive control.

EVALUATION OF RESULTS

A test article is classified as mutagenic if it induces either a statistically significant dose-related increase in the number of structural chromosomal aberrations or a reproducible statistically significant positive response for at least one of the test points.

A test article producing neither a statistically significant dose-related increase in the number of structural chromosomal aberration nor a statistically significant and reproducible positive response at anyone of the test points is considered non-mutagenic in this system.

This can be confirmed by means of the nonparametric Mann-Whitney test (7).

However, both biological and statistical significance should be considered together.

BIOMETRY

- Statistical significance at the five per cent level ($p < 0.05$) was evaluated by means of the non-parametric Mann-Whitney test.

Negative control versus Test group	Significance
4000 mg/kg b.w.; 6 h	n.t.
4000 mg/kg b.w.; 24 h	-
4000 mg/kg b.w.; 48 h	n.t.

- = not significant; + = significant; n.t. = not tested

RESULTS**PRE-EXPERIMENT FOR TOXICITY**

In two subsequent pre-experiments 4 animals per dose received orally 5000, or 4000 mg/kg, respectively, FAT 80'023/Q.

The treated animals expressed toxic reactions as shown below in the tables:

Dose: 5000 mg/kg b.w.:

toxic reactions	hours post-treatment male/female				
	1 h	6 h	24 h	48 h	72 h
reduction of spontaneous activity	1/1	2/2	2/1	1/2	
eyelid closure			1/0		
apathy			2/1	1/1	
death				1/0	

Dose: 4000 mg/kg b.w.:

toxic reactions	hours post-treatment male/female				
	1 h	6 h	24 h	48 h	72 h
reduction of spontaneous activity	1/0	1/1			

To avoid the loss of animals for evaluation in the mutagenicity assay the maximum tolerated dose was estimated to be 4000 mg/kg body weight.

Summary of Results

experimental group	dose mg/kg b.w.	preparation p. admin. hours	number of cells scored	I aberrant cells		mitotic index %
				incl. gaps	excl. gaps	
1 test article	4000	6	500	0.6	0.6	5.75
2 negative control	0	24	500	1.0	0.8	5.78
3 test article	4000	24	500	1.4	1.4	5.58
4 positive control	20	24	500	18.8	18.4	4.57
5 test article	4000	48	500	0.8	0.2	6.25

Analysis of aberration types in each 500 cells

group	g	ig	b	ib	f	if	d	id	ma	ex	cd
1	0	0	0	0	3	0	0	0	0	0	0
2	1	0	0	1	3	0	0	0	0	0	0
3	0	0	0	1	6	1	0	0	0	0	1
4	7	0	14	0	27	0	1	0	36	129	0
5	2	1	1	0	0	0	0	0	0	0	0

Abbreviations in the tables:

g = gap; ig = iso-gap; b = break; ib = iso-break; f = fragment; if = iso-fragment; d = deletion; id = iso-deletion; ma = multiple aberration (= more than 5 events, excluding gaps, in one cell; only exchanges, but no other aberrations, were recorded in these cells);

ex = exchange; cd = chromosomal disintegration (= pulverization)

Tables of results I - V

Table I: Chromosome aberrations in bone marrow cells of rats scoring 6 h after treatment
Experimental group: Test article

animal no.	sex	number of cells scored	dose mg/kg b.w.	aberrant incl. gaps	cells excl. gaps	mitotic index (%)
1	m	50	4000	1	1	6.2
2	"	50	"	0	0	6.0
3	"	50	"	1	1	9.8
4	"	50	"	0	0	5.5
5	"	50	"	0	0	4.7
7	f	50	"	0	0	3.6
8	"	50	"	0	0	6.2
9	"	50	"	1	1	3.7
10	"	50	"	0	0	6.4
11	"	50	"	0	0	5.4
mean of males (m)				0.4	0.4	6.44
mean of females (f)				0.2	0.2	5.06
mean of m + f				0.3	0.3	5.75

Analysis of aberration types in each 50 cells

animal no.	g	ig	b	ib	f	if	d	id	ma	ex	cd
1	0	0	0	0	1	0	0	0	0	0	0
2	0	0	0	0	0	0	0	0	0	0	0
3	0	0	0	0	1	0	0	0	0	0	0
4	0	0	0	0	0	0	0	0	0	0	0
5	0	0	0	0	0	0	0	0	0	0	0
7	0	0	0	0	0	0	0	0	0	0	0
8	0	0	0	0	0	0	0	0	0	0	0
9	0	0	0	0	1	0	0	0	0	0	0
10	0	0	0	0	0	0	0	0	0	0	0
11	0	0	0	0	0	0	0	0	0	0	0
Total	0	0	0	0	3	0	0	0	0	0	0

Table II: Chromosome aberrations in bone marrow cells of
rats scoring 24 h after treatment
Experimental group: Negative control

animal no.	sex	number of cells scored	dose mg/kg b.w.	aberrant cells incl. gaps	cells excl. gaps	mitotic index (%)
13	m	50	0	1	1	6.8
14	"	50	"	2	2	4.7
15	"	50	"	0	0	4.8
16	"	50	"	1	1	6.7
17	"	50	"	1	0	3.5
19	f	50	"	0	0	7.5
20	"	50	"	0	0	6.6
21	"	50	"	0	0	5.8
22	"	50	"	0	0	6.1
23	"		"	not scorable		
24	"	50	"	0	0	5.3
mean of males (m)				1.0	0.8	5.30
mean of females (f)				0.0	0.0	6.26
mean of m + f				0.5	0.4	5.78

Analysis of aberration types in each 50 cells

animal no.	g	ig	b	ib	f	if	d	id	ma	ex	cd
13	0	0	0	0	1	0	0	0	0	0	0
14	0	0	0	1	1	0	0	0	0	0	0
15	0	0	0	0	0	0	0	0	0	0	0
16	0	0	0	0	1	0	0	0	0	0	0
17	1	0	0	0	0	0	0	0	0	0	0
19	0	0	0	0	0	0	0	0	0	0	0
20	0	0	0	0	0	0	0	0	0	0	0
21	0	0	0	0	0	0	0	0	0	0	0
22	0	0	0	0	0	0	0	0	0	0	0
23	not scorable										
24	0	0	0	0	0	0	0	0	0	0	0
Total	1	0	0	1	3	0	0	0	0	0	0

Table III: Chromosome aberrations in bone marrow cells of
rats scoring 24 h after treatment
Experimental group: Test article

animal no.	sex	number of cells scored	dose mg/kg b.w.	aberrant cells incl. gaps	cells excl. gaps	mitotic index (%)
25	m	50	4000	1	1	5.5
26	"	50	"	1	1	5.8
27	"	50	"	0	0	5.4
28	"	50	"	0	0	4.9
29	"	50	"	0	0	9.3
31	f	50	"	2	2	4.4
32	"	50	"	1	1	7.6
33	"	50	"	1	1	4.8
34	"	50	"	1	1	4.0
35	"	50	"	0	0	4.1
mean of males (m)				0.4	0.4	6.18
mean of females (f)				1.0	1.0	4.98
mean of m + f				0.7	0.7	5.58

Analysis of aberration types in each 50 cells

animal no.	g	ig	b	ib	f	if	d	id	ma	ex	cd
25	0	0	0	0	1	0	0	0	0	0	0
26	0	0	0	0	1	0	0	0	0	0	0
27	0	0	0	0	0	0	0	0	0	0	0
28	0	0	0	0	0	0	0	0	0	0	0
29	0	0	0	0	0	0	0	0	0	0	0
31	0	0	0	1	0	1	0	0	0	0	0
32	0	0	0	0	1	0	0	0	0	0	0
33	0	0	0	0	0	0	0	0	0	0	1
34	0	0	0	0	3	0	0	0	0	0	0
35	0	0	0	0	0	0	0	0	0	0	0
Total	0	0	0	1	6	1	0	0	0	0	1

Table IV: Chromosome aberrations in bone marrow cells of
rats scoring 24 h after treatment
Experimental group: Positive control

animal no.	sex	number of cells scored	dose mg/kg b.w.	aberrant cells		mitotic index (%)
				incl. gaps	excl. gaps	
37	m		20	not estimated		
38	"	50	"	2	2	3.2
39	"	50	"	6	6	3.3
40	"	50	"	11	10	7.5
41	"	50	"	5	5	4.4
42	"	50	"	17	17	3.6
43	f		"	not scorable		
44	"	50	"	7	6	5.9
45	"	50	"	24	24	5.9
46	"	50	"	5	5	4.4
47	"	50	"	10	10	3.8
48	"	50	"	7	7	3.7
mean of males (m)				8.2	8.0	4.40
mean of females (f)				10.6	10.4	4.74
mean of m + f				9.4	9.2	4.57

Analysis of aberration types in each 50 cells

animal no.	g	ig	b	ib	f	if	d	id	ma	ex	cd
37	not estimated										
38	0	0	1	0	0	0	0	0	1	4	0
39	1	0	0	0	5	0	0	0	1	6	0
40	1	0	0	0	2	0	0	0	8	27	0
41	0	0	2	0	3	0	1	0	0	4	0
42	0	0	1	0	3	0	0	0	6	23	0
43	not scorable										
44	1	0	1	0	0	0	0	0	4	17	0
45	3	0	2	0	10	0	0	0	12	13	0
46	0	0	3	0	1	0	0	0	2	6	0
47	0	0	2	0	0	0	0	0	2	17	0
48	1	0	2	0	3	0	0	0	0	12	0
Total	7	0	14	0	27	0	1	0	36	129	0

Table V: Chromosome aberrations in bone marrow cells of rats scoring 48 h after treatment
Experimental group: Test article

animal no.	sex	number of cells scored	dose mg/kg b.w.	aberrant cells		mitotic index (%)
				incl. gaps	excl. gaps	
49	m	50	4000	not scorable		
50	"	50	"	0	0	3.9
51	"	50	"	0	0	4.9
52	"	50	"	0	0	3.8
53	"	50	"	1	0	4.8
54	"	50	"	0	0	4.4
55	f	50	"	not scorable		
56	"	50	"	0	0	8.3
57	"	50	"	1	0	11.2
58	"	50	"	0	0	5.8
59	"	50	"	2	1	5.8
60	"	50	"	0	0	9.6
mean of males (m)				0.2	0.0	4.36
mean of females (f)				0.6	0.2	8.14
mean of m + f				0.4	0.1	6.25

Analysis of aberration types in each 50 cells

animal no.	g	ig	b	ib	f	if	d	id	ma	ex	cd
49	not scorable										
50	0	0	0	0	0	0	0	0	0	0	0
51	0	0	0	0	0	0	0	0	0	0	0
52	0	0	0	0	0	0	0	0	0	0	0
53	1	0	0	0	0	0	0	0	0	0	0
54	0	0	0	0	0	0	0	0	0	0	0
55	not scorable										
56	0	0	0	0	0	0	0	0	0	0	0
57	0	1	0	0	0	0	0	0	0	0	0
58	0	0	0	0	0	0	0	0	0	0	0
59	1	0	1	0	0	0	0	0	0	0	0
60	0	0	0	0	0	0	0	0	0	0	0
Total	2	1	1	0	0	0	0	0	0	0	0

CONCLUSIONS

- This study was performed to assess the potential of FAT 80'023/Q to induce chromosome aberrations in bone marrow cells of the rat.

The test article was formulated in 1 % carboxymethylcellulose-suspension. The volume administered orally was 10 ml/kg body weight (b.w.). 6 h, 24 h and 48 h after a single application of the test article the bone marrow cells were collected for chromosome aberration analysis. 10 animals (5 males, 5 females) per test group were evaluated for the occurrence of cytogenetic damage. Per animal 50 well spread metaphases were scored for gaps, breaks, fragments, deletions, exchanges and chromosomal disintegrations.

The test article was tested in this cytogenetic assay in the following dose level:

6 h, 24 h, 48 h preparation interval: 4000 mg/kg b.w.

This dose level was determined in pre-experiments for toxicity to be the maximum tolerated dose. After administration of higher doses animals died.

As determined by the evaluation of mitotic indices 4000 mg/kg b.w. of the test article did not induce cytotoxic effects.

As compared to the negative control value treatment with the test article did not result in a significant enhancement of the aberration frequency at any preparation interval.

One chromosomal disintegration was observed at preparation interval 24 hours after administration of the test article. This single event is not considered to be of special relevance but is regarded as having occurred spontaneously.

Cyclophosphamide (20 mg/kg b.w.) was used as positive control and showed a distinct increase of induced aberration frequency.

CONCLUSION

In conclusion, it can be stated that during the mutagenicity test described and under the experimental conditions reported, FAT 80'023/Q did not induce chromosome mutations as determined by the chromosome aberration test with bone marrow cells of the rat.

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OTC Vol. No. 109

OTC Docket Number 75N-0183 (triclosan)
September 12, 1994

Ciba-Geigy Corporation
Chemicals Division
Greensboro, N.C. 27419

SanSebastian, J.R., et al. Rat Hepatocyte Primary Culture/DNA Repair Test on 39317. Pharmakon USA. Study No. PH311-CP-001-93. June 24, 1993.

Study Summary

Potential to induce unscheduled DNA synthesis of Triclosan was evaluated in primary culture of rat hepatocytes. Hepatocytes were isolated from the liver of a Fischer 344 rat by the two-step in situ perfusion. Aliquots of 1×10^5 viable hepatocytes were inoculated into 12 well cluster dishes containing 15 mm diameter Thermanox plastic coverslips and 2 ml Williams' medium E (WME) supplemented with 10% calf serum. The hepatocytes were allowed to attach for approximately 2 hours in an incubator humidified to 95-100% at 37°C in an atmosphere of 5% CO₂ in air. Triclosan, solvent (DMSO), or positive (2AAF) control articles were added to each well containing 2 ml of serum-free and 10 µCi/ml of ³H-thymidine (specific activity 50-80 Ci/mM). Eighteen to 20 hours of exposure, the cultures were washed and the cells on coverslips were fixed in 100% ethanol: glacial acetic acid (3:1), air-dried, and mounted cell surface up on glass slides with Permaslip. Slides were dipped in NTB-2 photographic emulsion in the dark, allowed to dry overnight and stored at 4°C in light-proof slide boxes for one week. After seven days of exposure time, autoradiographs were developed. Unscheduled DNA synthesis, evidenced by a net increase in black silver grains over the nucleus, was quantified by determining nuclear and cytoplasmic grain counts using an Artek 880 automated colony counter with microscopic/video camera attachment interfaced to an Apple II computer for data acquisition. A total of 150 hepatocytes were scored for each dose level. The cytoplasmic grain count was subtracted from the corrected nuclear grain count to determine the net nuclear grains count (NNG). Generally, solvent and/or untreated controls have an NNG count ≤0 with a percentage of cells in repair ranging from 0 to 10%. A positive response consists of a mean NNG count greater than 5 with 70-100% of the hepatocytes in repair.

Triclosan was dissolved in dimethylsulfoxide (DMSP) and added to the culture medium to obtain a final concentration of 0.05, 0.1, 0.25, 0.5, 1, 2.5, 5, 10, 25, 50, 100, or 250 µg/ml. Each treatment was representative of triplicate cultures. Three concurrent controls were also evaluated in triplicates: an untreated medium control (WME), a DMSO

control, and a positive control ($1 \times 10^{-7}M$ of 2-acetamidoflourene - 2AAF-). Microscopic examination of the coverslips indicated that Triclosan was cytotoxic at concentrations $\geq 5 \mu g/ml$ as evidenced by the low grain incorporation. Therefore $2.5 \mu g/ml$ was the highest concentration considered for evaluation of DNA repair test. Lower concentrations scored for unscheduled DNA synthesis included 0.25, 0.5, and $1 \mu g/ml$.

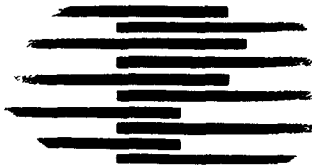
Results

Autoradiographic analyses of the hepatocytes treated with Triclosan revealed mean NNG counts below 0 with the percent of cells in repair ranging from 0 to 6%. Similarly, the untreated media and DMSO controls had the mean NNG counts and the percent of cells in repair comparable with Triclosan-treated groups. The positive control (2AAF) yielded a mean NNG count of 21.2 ± 16.6 and 88.7% of the hepatocytes in repair.

In summary, Triclosan did not induce unscheduled DNA synthesis (repair) in rat primary hepatocytes under the criteria and experimental conditions of the test protocol.

PHARMAKON USA

P.O. Box 609
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Rat Hepatocyte Primary Culture/DNA
Repair Test on 39317

PH 311-CP-001-93

Submitted to

Colgate-Palmolive
Piscataway, New Jersey

Juan R. SanSebastian
Juan R. SanSebastian, Ph.D.
Study Director

June 24, 1993
Date

JM Morgan
Test Facility Management

June 24, 1993
Date

062393

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Colgate-Palmolive Study CP# 93-013

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SUMMARY

The study was designed to evaluate the potential of the test article 39317 to induce Unscheduled DNA Synthesis (UDS) in primary cultures of rat hepatocytes. The liver of a male Fischer 344 rat was perfused, excised and combed yielding 19.8×10^5 hepatocytes/ml of medium with 97% viability. Triplicate cultures were inoculated with 1×10^5 viable cells and treated with 39317 dissolved in dimethylsulfoxide (DMSO) at doses of 0.05, 0.1, 0.25, 0.5, 1, 2.5, 5, 10, 25, 50, 100 and 250 $\mu\text{g/ml}$ (final concentrations in treatment medium). Concurrently, three sets of control cultures were evaluated: an untreated control (WME), a negative control [dimethylsulfoxide (DMSO)] and a positive control (2-acetamidofluorene; 2AAF). The final concentration of 2AAF in the treatment medium was $1 \times 10^{-7}\text{M}$.

Prior to scoring, the coverslips were prescreened for toxicity and it was observed that 39317 was not scoreable at doses $\geq 5 \mu\text{g/ml}$ due to toxicity. Therefore, the highest dose scored in the DNA Repair Test was 2.5 $\mu\text{g/ml}$ with three additional doses of 0.25, 0.5 and 1 $\mu\text{g/ml}$.

Unscheduled DNA Synthesis (Repair) was quantified by a net nuclear increase of black silver grains for 50 hepatocytes/coverslip. This value was determined by subtracting the highest of three adjacent cytoplasmic counts from the nuclear counts. Three coverslips per each dose point were evaluated for a total of 150 hepatocytes/dose. The coverslips were evaluated at a magnification of approximately 1500X.

The test article 39317, did not produce a mean net nuclear grain (NNG) count ≥ 5 at any of the dose levels tested. The solvent and positive controls employed in the evaluation of the test article induced mean NNG counts that were within the criteria for a valid test.

Therefore, the test article 39317, was considered negative in inducing Unscheduled DNA Synthesis (Repair) in primary hepatocytes under the criteria and the experimental conditions of the test protocol.

Pharmakon Study # PH 311-CP-001-93
Colgate-Palmolive Study CP# 93-013

STUDY DESCRIPTIVE

Sponsor: Colgate-Palmolive
909 River Road
P.O. Box 1343
Piscataway, NJ 08855-1343

Test Facility: Pharmakon Research International, Inc.
P.O. Box 609
Waverly, PA 18471

Study Number: PH 311-CP-001-93

Colgate-Palmolive
Study No.: CP# 93-013

Study Monitor: Gabriela Adam-Rodwell, Ph.D.
Colgate-Palmolive

Study Director: Juan R. SanSebastian, Ph.D.
Pharmakon Research International, Inc.

Date Protocol
Signed by
Study Director: March 3, 1993

Date Assay
Initiated: March 11, 1993

Date Assay
Completed: April 23, 1993

Technical
Performance: Susan M. Lucenti, B.S., LATG
Pharmakon Research International, Inc.

Pharmakon
Reference: Notebook # 1771 pages 1-62

Records
Maintained: All correspondence pertinent to the
study between the sponsor and Pharmakon
Research International, Inc., including
protocol, amendments to the protocol,
raw data, autoradiographs, test article
weight or volume, dispensation reports,
quality assurance reports and the final
report are maintained in the Pharmakon
Archives located at Biofor, LTD., P.O.
Box 629, Waverly, PA 18471.

Pharmakon Study # PH 311-CP-001-93
Colgate-Palmolive Study CP# 93-013

TEST SYSTEM

Purpose: To evaluate the potential of 39317 to induce Unscheduled DNA Synthesis (UDS) in primary cultures of rat hepatocytes. UDS was measured on the basis of incorporation of tritiated-thymidine (³H-TdR) into DNA. The amount of radioactivity incorporated into the nucleus of exposed cells to 39317 was measured and compared to unexposed cells to determine the extent of repair (UDS) occurring in the DNA.

Justification of the Test System: Primary culture of rat hepatocytes have been shown to incorporate ³H-TdR into DNA due to UDS induced by known carcinogens (Laishes and Williams, 1976 and Williams, 1977 and 1978).

MATERIALS AND METHODS

Species: *Rattus norvegicus*. Strain: Fischer 344

Negative Control: Dimethylsulfoxide (DMSO)
Lot # 887134
Fisher Scientific Co.,
Pittsburgh, PA 15219

Positive Control: 2-acetamidofluorene (2AAF); [Cas #53-96-3] Aldrich Chemical Company, Inc., Milwaukee, WI 53233

Test Article: The test article, 39317, was received by Pharmakon Research on February 26, 1993 in a clear, colorless, glass bottle and was described as a white powder. Normal precautions were used in handling it. Stability and purity of 39317 was the responsibility of the Sponsor. For the purposes of this study, the test article was stored at room temperature in the container received from the Sponsor. All required dilutions were made with DMSO, prior to dosing. At the time of testing, 39317 was described as a white powder, hence, there was no apparent change in its physical state during storage.

Test Article Preparation: Aliquots of the test article, 39317, were weighed and solubilized with DMSO. Each stock solution and the positive control (2AAF) were prepared 100 times the final concentration and dosed at 20 µl per 2 ml treatment volume. All serial dilutions were prepared from the stock prior to treatment. (See raw data page 4). Sample of test article carrier mixtures were taken prior to dosing and sent to the Sponsor for concentration analysis (See APPENDIX I).

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Perfusion Media: Medium A consists of 0.5 mM ethylene-glycol-bis-(B-aminoethyl ether)-N-N'-tetraacetic acid (EGTA) in Ca^{2+} -, Mg^{2+} - free Hank's balanced salt solution buffered with 10 mM N-2-hydroxyethylpiperazine-N'-2-ethanesulfonic acid (HEPES), adjusted to pH 7.35, sterilized through a 0.2 μ filter and dispensed into a sterile bottle with 0.35 ml gentamicin solution (50 mg/ml). The solution was maintained at 37°C in a water bath.

Medium B was prepared by dissolving Collagenase (Worthington Biochemical; Lot #S1C279A) 100 Units/ml in serumless Williams' Medium E (GIBCO), buffered with 10 mM HEPES, adjusted to pH 7.35. Gentamicin was added to give a final concentration of 0.05 mg/ml. This perfusion media was sterilized through a 0.45 μ filter unit and placed in a 37°C water bath before and during perfusion.

Isolation of Adult Rat Hepatocytes: Hepatocytes were isolated by the two-step in situ perfusion method of Seglen (1976) as modified by Williams et al., (1977, 1978 and 1982) with additional modifications of Kornbrust and Barfknecht (1984 a,b). This protocol consisted of three main steps as described below:

1. Surgical Technique: Two male Fischer 344 rats (265 gm) supplied by Taconic Farms, housed in accordance with the "Guide for the Care and Use of Laboratory Animals", were anesthetized with 50 mg/kg of sodium pentobarbital by intraperitoneal injection. A ventral midline incision was made from the xiphisternum to the pubic bone to expose the peritoneal cavity. The hepatic portal vein was cannulated to allow entrance of perfusion media, using a 21 gauge butterfly needle.
2. Two-step in situ Perfusion Procedure:
 - a. Pre-perfusion: Using a Manostat Ministaltic pump, the liver was perfused with Ca^{2+} -free medium A just until blanching commenced. (The Ca^{2+} -free is effective in cleaving the desmosomes and other junctional complexes cementing the hepatocytes.) Blanching was regulated by adjusting the flow from the Ministaltic pump at a very low flow rate. At this point, the subhepatic inferior vena cava was severed. The speed of the pump was increased to 40 ml/min for 4 minutes. To provide an exit for sufficient back pressure for full

circulation of the perfusion medium to the whole liver, the diaphragm was cut open and the thoracic inferior vena cava severed. The subhepatic vena cava was clamped above the cut, keeping the flow rate continuous at 40 ml/min.

- b. Perfusion: The liver was then perfused with 250 ml Ca^{2+} -rich medium B containing a proteolytic enzyme collagenase to dissociate the hepatocytes at a flow rate of 20 ml/min for 10 minutes (collagenase activity is Ca^{2+} dependent; Seglen, 1972.) To maintain body temperature, a 40-watt lamp was positioned approximately 6 cm above the liver during the perfusion.
3. Post-perfusion (Dissociation of Hepatocytes): The liver was excised and placed in 50 ml of serumless WME in a sterile culture dish. The liver was trimmed of fat, excess connective tissue and any sections of liver that still showed signs of blood. The liver was then transferred to a sterile (100 x 25 mm) culture dish containing 50 ml of Medium B. The liver was held by the connective tissue in the porta hepatis, and the capsular membrane of the liver was opened and removed at several points on the dorsal surface with the aid of a scalpel and forceps. Cells were detached by gently combing the liver with a 3/4" camel's hair brush. Detachment was complete when only fibrous tissue remained. The cells were then aliquoted into 50 ml centrifuge tubes by pipetting gently with a sterile 10 ml polystyrene pipet. The volume of each tube was adjusted to 35-40 ml with WME supplemented to 10% v/v calf serum. The tubes were allowed to stand in a vertical position for 10 minutes to flocculate the hepatocytes. Viability of the resuspended hepatocytes was measured by the criterion of Trypan Blue exclusion. The perfused liver yielded 19.8×10^5 hepatocytes/ml of medium with 97% viability.

Treatment with Test and Control Articles: Aliquots of 1×10^5 viable hepatocytes were inoculated into 12 well cluster dishes containing 15 mm diameter Thermanox® plastic coverslips and 2 ml WME medium supplemented with 10% calf serum. The hepatocytes were allowed to attach for approximately 2 hours in an incubator humidified to 95-100% at 37°C in an atmosphere of 5% CO_2 in air. The hepatocyte cultures were rinsed with WME serum-free medium. Then, 20 μl of the test, negative (DMSO) or positive (2AAF) control articles were added to each well containing 2 ml of the

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Colgate-Palmolive Study CP# 93-013

serum-free medium and 10 $\mu\text{Ci/ml}$ of ^3H -thymidine (New England Nuclear, specific activity 50-80 Ci/mM). Eighteen to twenty hours after exposure, the cultures were washed three times with 3 ml of phosphate buffered saline by aspiration.

Cell Fixation: The cells on coverslips were swelled in 1% sodium citrate for 10-15 minutes and fixed in three 10-minute changes of 100% ethanol:glacial acetic acid (3:1). The fixed cultures were then washed twice with approximately 2 ml volumes of dH_2O . The coverslips were air-dried and mounted cell surface up on glass slides with Permaslip®.

Autoradiography and Staining: This stage was performed under safe light conditions. Slides were dipped in NTB-2 photographic emulsion (Eastman Kodak) in the dark, allowed to dry overnight and stored at 4°C in light-proof slide boxes containing desiccant for one week. After seven days of exposure time, autoradiographs were developed for 4 minutes in D19 (Eastman Kodak) at approximately 15°C, washed in deionized water with 5 ml glacial acetic acid for 30 seconds, immersed in Fixer (Eastman Kodak) for 10 minutes, washed in running tap water for 5 minutes, dried, stained in Harris' Alum Hematoxylin followed by a dip rinse in acid alcohol, rinsing in running tap water for 2-5 minutes and a dip rinse in ammonium water. The slides were then rinsed in running tap water for 2-5 minutes, dipped in 70% ethyl alcohol, followed by a 10-60 second counterstain in a 1% aqueous Eosin Y solution. The slides were then rinsed in 3 separate baths of 95% ethyl alcohol for 2 minute intervals, followed by rinsing in 3 separate baths of 100% ethyl alcohol for 2 minute intervals. The slides were air-dried, and coverslipped with Permaslip®. Excess emulsion was scraped off.

Dosage Selection: The test article, 39317, was evaluated in a preliminary screen to determine if 39317 would precipitate out of solution. Stock solutions of 10, 25, 50, 100, 250 and 500 mg/ml were prepared and 50 μl of each solution was added to 5 ml of serum-free medium. Stock solutions ≥ 50 mg/ml produced a precipitate when added to the aqueous medium while the 25 mg/ml solution was turbid and 10 mg/ml solution did not appear to change the medium. Therefore, the 25 mg/ml was selected as the highest stock solution dosed in the assay. The test article, 39317, was evaluated in triplicate hepatocyte cultures at doses of 0.05, 0.1, 0.25, 0.5, 1, 2.5, 5, 10, 25, 50, 100 and 250 $\mu\text{g/ml}$ along with concurrent untreated (WME), negative (DMSO) and positive (2AAF) controls. At the 25 $\mu\text{g/ml}$ dose level, the

medium became turbid when the treatment was added to aqueous medium. Coverslips from each dose were prescreened for toxicity by visual inspection under a microscope. The analysis of the coverslips indicated that doses $\geq 5 \mu\text{g/ml}$ was toxic to the hepatocytes as evidenced by the low grain incorporation. Therefore, doses of 0.25, 0.5, 1 and 2.5 $\mu\text{g/ml}$ were scored for the assay. Analytical results of the test article performed by the sponsor indicated the actual concentrations were 0.3, 0.6, 1.18 and 3 $\mu\text{g/ml}$ (See Appendix I).

Data Quantitation: Unscheduled DNA Synthesis, evidenced by a net increase in black silver grains over the nucleus, was quantified by determining nuclear and cytoplasmic grain counts using an Artek 880 automated colony counter with microscopic/video camera attachment interfaced to an Apple II computer for data acquisition. A total of 150 hepatocytes/dose point were scored for autoradiographic UDS determinations. A correction coefficient was calculated by the following method. An area/grain ratio was obtained by visually scoring an area of each slide containing 3-5 nuclear grains and then obtaining an object area count with Artek Model 880 Colony Counter. The total number of the visual count was divided by the total number of the object area counts. This value served as a correction coefficient.

The cytoplasmic grain count was quantitated by randomly selecting the highest grain count of three nuclear-sized areas adjacent to each nucleus. This value was subtracted from the corrected nuclear grain count to determine the NNG count. Scheduled DNA synthesis was evidenced by nuclei blackened with grains too numerous to count.

Criteria for a Valid Test: The data of the HPC/DNA repair Assay are reported as mean grains/nucleus from the triplicate wells. Solvent and/or untreated controls should have a NNG count ≤ 0 with 0-10% of the hepatocytes in repair (percentage of nuclei with NNG ≥ 5). Also, the positive control, 2AAF, should yield a mean NNG count that is ≥ 5 (within one standard deviation of the mean historical value) with 70-100% of the hepatocytes in repair (See the following chart).

PHARMAKON HISTORICAL DATA - January, 1993

Control	Trials	Mean	One Standard Deviation
WME	78	-12.242	9.475
DMSO	27	-14.267	8.475
2AAF	78	20.875	6.603

RESULTS AND DISCUSSION

Autoradiographic analyses of DNA-repair for the test article 39317 are found in Table 1. NNG counts represent the difference between the nuclear count and the highest of three cytoplasmic silver grain counts. Each treatment was representative of triplicate cultures. The highest dose level scored in the study was 2.5 μ g/ml. Additional levels scored were 0.25, 0.5, and 1 μ g/ml as well as the untreated, negative and positive controls.

Analysis of the data for 39317 did not produce mean NNG counts ≥ 5 at any of the doses scored. In addition, the percentage of hepatocytes in repair ranged from 0 to 6.0 % (Table 1). The negative and positive control values were -21.6 ± 13.4 and 21.2 ± 16.6 with 0.0 and 88.7 % hepatocytes in repair, respectively. These values were within the criteria for a valid assay.

CONCLUSION

In conclusion, the test article 39317 at the doses scored was negative in inducing Unscheduled DNA Synthesis (DNA-repair) in rat primary hepatocytes under the criteria and experimental conditions of the test protocol.

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Williams, G.M., E. Bermudez and D. Scaramuzzino (1977). Rat Hepatocyte Primary Cell Culture. III. Improved Dissociation and Attachment Techniques and the Enhancement of Survival by Culture Medium. In Vitro 13: 809-817.

Williams, G. M. (1978). Further Improvements in the Hepatocyte Primary Culture DNA Repair Test for Carcinogens. Detection of Carcinogenic Biphenyl Derivatives. Cancer Letters 4: 69-75.

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Table 1 - Autoradiographic Analysis of DNA Repair in the
 Rat Hepatocyte Primary Culture

Treatment	Dose μg/ml	NNG x ± SD ^a	Percent of Cells in Repair ^b
Untreated	0	-19.0 ± 12.5	0.0
DMSO ^c	0	-21.6 ± 13.4	0.0
2AAF ^d	0.022	21.2 ± 16.6*	88.7
39317	0.25	-23.4 ± 13.3	0.7
39317	0.5	-25.8 ± 15.2	0.0
39317	1.0	-21.3 ± 14.2	2.7
39317	2.5	-17.1 ± 14.3	6.0

*Positive finding. Mean NNG count ≥ 5 .

^aMean of 150 hepatocytes scored per dose point.

^bThe percentage of cells that have NNG count ≥ 5 .

^cDMSO dosed at 1% (v/v).

^d2AAF = 2-acetamidofluorene (1×10^{-7} M).

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Colgate-Palmolive Study CP# 93-013

QUALITY ASSURANCE UNIT (QAU) STATEMENT

PHARMAKON RESEARCH INTERNATIONAL, INC.
Waverly, PA 18471

STUDY TITLE: Rat Hepatocyte Primary Culture/DNA
Test on 39317

STUDY DIRECTOR: Juan R. SanSebastian, Ph.D.

The following study inspections have been performed by the Quality Assurance Unit (QAU) and the results have been reported to the study director and management on the date(s) indicated.

The following inspections were performed:

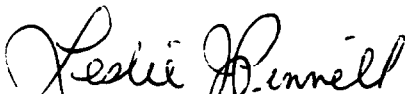
Phase	Date(s)
Isolation Phase	March 11, 1993
Treatment	March 11, 1993
Scoring	April 21, 1993
Reporting	April 28, 1993 May 25, 1993

Date(s) QAU Report Issued To:

STUDY DIRECTOR: April 28, 1993; May 25, 1993

MANAGEMENT: April 28, 1993; May 25, 1993

Date of last QAU facility inspection: April 5, 1993



Leslie J. Pinnell, M.S.
Manager, Quality Assurance

June 24, 1993
Date

Pharmakon Study # PH 311-CP-001-93
Colgate-Palmolive Study CP# 93-013

COMPLIANCE STATEMENT

This study was conducted in compliance with the Principles of Good Laboratory Practice (GLP) as promulgated by the following regulatory agencies:

U.S. Food and Drug Administration, as stated in the Federal Register, 21 CFR Part 58, Friday, September 4, 1987.

U.S. Environmental Protection Agency as stated in the Federal Register, 40 CFR Part 792, Thursday, August 17, 1989.

Organisation for Economic Co-operation and Development Guidelines for Testing Chemicals (OECD), ISBN 92-64 12221-4, adopted by the council at its 535th meeting on 12th May, 1981.

Study No.: PH 311-CP-001-93

To the best of my knowledge, this study was conducted in accordance with applicable Good Laboratory Practice regulations; there were no deviations from these regulations that impacted on study conclusions.

Juan San Sebastian
Juan R. San Sebastian, Ph.D.
Study Director

June 24, 1993
Date

Pharmakon Study # PH 311-CP-001-93
Colgate-Palmolive Study CP# 93-013

APPENDIX I

Analytical Report of Test Article Concentrations

ANALYTICAL CHEMISTRY REPORT

INTRODUCTION

Potential genotoxic effect of Sample No. 39317 was evaluated in a Rat Hepatocyte Primary Culture/DNA Repair Test. The study was conducted at Pharmakon Research International, Inc., (Pharmakon Study No. PH 311-CP-001-93; Colgate Study No. CP 93-0013). The test article was characterized by determining the infrared spectrum (IR), melting point, and purity (alkalimetric assay) prior to the study initiation. In addition, a certificate of analysis was provided by the manufacturer and is maintained in the study file at Colgate-Palmolive Company.

METHODOLOGY

The analytical method for determination of test article concentration in the carrier mixture was validated prior to the study initiation. This method confirmed with SPI: LAB 7612-05 and is maintained on files at Colgate-Palmolive Company. Concentration analyses were performed on samples prepared at Pharmakon Research International, Inc. The test article was dissolved in dimethylsulfoxide (DMSO) at concentrations ranging from 5 µg/ml to 25000 µg/ml. A 25 ml aliquot was sampled from each concentration level and shipped to Colgate-Palmolive Company on the day of preparation (March 11, 1993).

RESULTS AND DISCUSSION

Infrared spectrum, melting point, and purity were within specifications for the test article indicating that the bulk chemical was stable.

The results of concentration analyses are presented in Table 1. The test article recovery was within ± 10 of the nominal concentration for solutions with concentrations ranging from 2500 to 25000 µg/ml. At lower concentration, there was an inverse relationship between the concentration of solutions and percent recovery of the test article; the percent recovery ranged from 111% at a concentration of 500 µg/ml to 137% at a concentration of 5 µg/ml.

Gabriela Adam-Rodwell

Gabriela Adam-Rodwell, Ph.D.
Research Associate, PSA

Date May 20, 1993

Thomas Wolf

Thomas Wolf, Ph.D.
Head of QAU

Date May 20, 1993

TABLE 1

**Concentration Verification Analysis Data
for Sample No. 39317 in DMSO Solutions**

Test Article	Nominal Concentration ($\mu\text{g/ml}$)	Actual Concentration ($\mu\text{g/ml}$)	Recovery (%)
-----------------	--	---	-----------------

Samples prepared on 03/11/93 and analyzed on 03/12/93

DMSO control	0	0.36	NA
39317-1	25000	27400	110
39317-7	250	299	120
39317-12	5	6.8	136

Samples prepared on 03/11/93 and analyzed on 3/23/93

DMSO control	0	0.42	NA
39317-1	25000	25260	101
39317-2	10000	9670	97
39317-3	5000	5471	109
39317-4	2500	2720	109
39317-5	1000	1087	109
39317-6	500	555	111
39317-7	250	300	120
39317-8	100	118	
39317-9	50	59.6	119
39317-10	25	30.4	122
39317-11	10	12.8	128
39317-12	5	6.86	137

NA = not applicable

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Colgate-Palmolive Study CP# 93-013

APPENDIX II

Protocol, Amendment and Addendum

PHARMAKON

PHARMAKON

Research International Inc
P O Box 609
Waverly, Pennsylvania
8471-0609

Telephone
1-800-555-2411
Telex
1-800-3450

Protocol-311

Rat Hepatocyte Primary Culture/DNA Repair Test

Sponsor: Colgate-Palmolive
909 River Road
Piscataway, NJ 08855-1343

Testing Facility: Pharmakon Research International, Inc.
Waverly, Pennsylvania 18471

Test Facility
S.O.P. No.: PH-311

Study No.: PH 311-CP-001-93

Colgate-Palmolive
Study No.: CP #93-013

Purpose of
the Study: To evaluate the ability of the test article to interact with DNA by exposing rat liver cells to the test article and tritiated thymidine ($[^3\text{H}]$ -thymidine). The amount of radioactivity incorporated into the nucleus of exposed cells is measured and compared to unexposed cells to determine the extent of repair occurring in the DNA.

This study protocol was designed to comply with the U.S. Environmental Protection Agencies Federal Register, Vol. 50, No. 188, Friday, September 27, 1985.

Ownership of
the Study: The Sponsor owns the study. All raw data, analysis and reports are the property of the Sponsor. If it becomes necessary to make changes in the approved protocol, the revisions and the reasons for change will be documented, reported to the Sponsor, and will become part of the permanent file for the study. Protocol amendments must have signed approval from the Sponsor prior to issuance of the final report.

Study Monitor: Gabriela Adam-Rodwell, Ph.D.
Colgate-Palmolive

Study Director: Juan R. SanSebastian, Ph.D.
Pharmakon Research International, Inc.

Protocol-311
Rat Hepatocyte Primary Culture/DNA Repair Test

O.A.U.
Responsible Leslie J. Pinnell, M.S.
Personnel: Pharmakon Research International, Inc.

Date of
Performance: The proposed date of study initiation is generally four weeks from the receipt of the test article and signed protocol.

Good Laboratory
Practice
Statement: This study will be conducted in compliance with the Good Laboratory Practice Regulations for non-clinical laboratory studies as developed by the U.S. Food and Drug Administration, Drug Administration, as indicated in the 21 CFR, Part 58 and the U.S. Environmental Protection Agency as stated in the 40 CFR, Part 792 as well as the Organisation for Economic Co-operation and Development Guidelines for Testing Chemicals (OECD), ISBN 92-64-12221-4, adopted by the council at its 535th meeting on 12th May, 1981.

IACUC Statement: Protocol-311 has been reviewed by the Institutional Animal Care and Use Committee (IACUC) and complies with acceptable standard animal welfare and humane care.

Tentative Date
of Submission of
Final Report: A draft report will be submitted for review to the Sponsor approximately four weeks following completion of the study. The Sponsor will be supplied with three copies of the final report, one with original signatures.

Records
Maintained: All correspondence pertinent to the study between the sponsor and Pharmakon Research International, Inc., protocol, amendments to the protocol, raw data, autoradiographs, test chemical weight and volume, dispensation reports, quality assurance reports and the final report will be maintained in the Pharmakon Archives.

Analytical
Chemistry: Analysis and stability of the test article and test article/carrier mixture is the responsibility of the sponsor.

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Rat Hepatocyte Primary Culture/DNA Repair Test

Twenty-five mL aliquots of the test article solvent mixture will be collected from all test solutions prepared for the study and shipped to the Sponsor for analysis of concentration; a 25 mL aliquot of solvent (DMSO) will be also snipped to the Sponsor.

CONTROL ARTICLES

Untreated Control: Williams Medium E without serum (WME)
Negative Control: Dimethylsulfoxide (DMSO)
spectrophotometric grade (1% v/v).
Negative Control: Williams' Media E without serum (WME)
Positive Control Article: 2-Acetamidofluorene (2-AAF) or any other suitable inducer of unscheduled DNA synthesis (UDS).

TEST SYSTEM

Species: Rattus norvegicus
Strain: Fischer 344
Supplier Taconic Farms, Germantown, NY or any
Source: U.S.D.A. acceptable source.
Sex: Male
Weight at
Initiation: 150 - 300 grams (adult rats)
Acclimation Five days or at the discretion of
Period: attending veterinarian
Justification
for Selection of
the Test System: Rat Hepatocytes in Primary Culture have been shown to incorporate [³H]-thymidine into DNA due to unscheduled DNA Synthesis induced by known carcinogens (Williams, 1977 and 1978).

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HUSBANDRY

Research Facility Registration: U.S.D.A. Registration No. 23-R-107 under the Animal Welfare Act 74: SC 2131 et seq.

Animal Rooms: Isolated by test system. Rooms are maintained at a temperature of $22^{\circ}\text{C} \pm 4^{\circ}\text{C}$ and a relative humidity of $55\% \pm 15$ with a 12-hour light/dark cycle.

Housing: Rats housed individually in stainless steel $\frac{1}{2}$ " wire mesh cages. Size in accordance with the "Guide for the Care and Use of Laboratory Animals" of the Institute of Laboratory Animal Resources, National Research Council.

Sanitization: Waste material is removed daily. Cages and feeders are sanitized every two weeks.

Food: Harlan Teklad Rodent Diet®, ad libitum, or any other appropriate lab chow checked daily and added or replaced as needed. Feeders are designed to reduce soiling, bridging, and scattering.

Food Analysis: There are no contaminants that are reasonably expected to be present in the dietary material known to be capable of interfering with the purpose or conduct of the study.

Water: Fresh tap water, ad libitum.

Water Analysis: Water is monitored periodically for contaminants according to Standard Operating Procedure PH-018.

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METHODS

Isolation of
Adult Rat
Hepatocytes:

Hepatocytes are isolated by the two-step in situ perfusion method of Seglen (1976) as modified by Williams et al, (1977, 1978 & 1982) with additional modifications of Kornbrust and Barfknecht (1984).

Perfusion Media:

Medium A - 0.5 mM ethylene-glycol-bis-(B-aminoethyl ether)-N-N' - tetra acetic acid (EGTA) in Ca++-Mg++free Hank's balanced salt solution buffered with 10mM N-2-hydroxyethyl-piperazine-N'-2-ethanesulfonic acid (Hepes), pH adjusted to 7.35, sterilized through a 0.2 μ filter and dispensed into a sterile bottle. Gentamicin is added to a final concentration of 50 μ g/mL. Maintain the solution at 37°C in a water bath.

Medium B - Collagenase 100 Units/mL prepared in WME buffered with 10mM Hepes, pH adjusted to 7.35. Gentamicin is added to a final concentration of 50 μ g/mL. This perfusion media is sterilized through a 0.45 μ filter unit and placed in a 37°C water bath before and during perfusion.

Surgical and
Perfusion
Procedure:

Male Fischer rats (150-300 gm) are anesthetized with 50 mg/kg of sodium pentobarbital by intraperitoneal injection. A ventral midline incision is made from the xiphisternum to the pubic bone to expose the peritoneal cavity. The hepatic portal vein is cannulated to allow entrance of perfusion medium, using a 21 gauge butterfly needle. Using a Manostat Ministaltic pump the liver is perfused with Medium A until blanching just commences. Blanching is regulated by adjusting the flow from the Ministaltic pump at a very low flow rate. At this point the subhepatic inferior vena cava is severed and the speed of the pump is increased to 40 mL/min for 4 minutes.

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To provide an exit for sufficient back pressure for full circulation of perfusion medium to the whole liver, the diaphragm is cut open and the thoracic vena cava severed. The subhepatic inferior vena cava is immediately clamped above the cut keeping the flow rate continuous at 40 mL/min. The liver is then perfused with Medium B at a flow rate of 20 mL/min. for 10 minutes. To maintain the perfusion temperature, a 40-watt lamp is positioned approximately 6 cm above the liver during the perfusion.

Dissociation of Hepatocytes:

The liver is excised and placed in 50 mL of warm WME in a sterile culture dish. The liver is trimmed of fat, excess connective tissue and any sections of liver that still show signs of blood. The liver is then transferred to a clean, sterile (100 x 25 mm) culture dish with 50 mL of warm Medium B. The liver is held by the connective tissue in the porta hepatis, and the capsular membrane of the liver is opened and removed at several points on the dorsal surface with the aid of a scalpel and forceps. Cells are detached by gently combing the liver with a 3/4" camel hair brush. The detachment is complete when only a fibrous tissue remains. The cells are then aliquotted into 50 mL centrifuge tubes by pipetting gently with a 10 mL pipet. The volume of each tube is brought to 35-40 mL with Williams' Media E supplemented to 10% v/v with calf serum (WMES). The tubes are allowed to stand in a vertical position for 10 minutes to pellet the hepatocytes. Viability of the resuspended hepatocytes is measured by trypan blue dye exclusion. Suspension cultures with viabilities of less than 80% are not used.

Dosage Selections:

The test article will be dissolved in DMSO and then added to WME to achieve ten dose levels which span five logs

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Rat Hepatocyte Primary Culture/DNA Repair Test

(0.5 - 5000 $\mu\text{g/mL}$). The highest concentration of solvent should not exceed 1% in the medium. Prior to scoring, all doses are pre-screened for their toxic effect on primary hepatocytes by visual inspection. Toxicity is evidenced by abnormal cell morphology, staining characteristics, cell detachment and/or a substantial reduction in grains relative to the solvent control.

The highest concentration to be scored in the assay is that of maximum solubility or the concentration which just causes abnormal cell morphology and had enough scorable hepatocytes. Three lower concentrations, each in triplicate culture, will be scored as well as the untreated, negative and positive controls.

Test Protocol:

Cell Exposure: An aliquot of 1×10^5 viable hepatocytes are inoculated into each well of 12 well cluster culture dishes (Costar) containing Thermanox plastic coverslips (Flow) in 2 mL of WMES. The hepatocytes are allowed to attach for approximately 2 hours in a 37°C CO₂ incubator. The cultures are rinsed and refed with WME serum-free medium containing test compound and 10 $\mu\text{C/mL}$ of ³H-thymidine (New England Nuclear, specific activity 50-80Ci/mM). Eighteen to twenty hours after exposure, the cultures are washed three times with 3 mL volumes of Phosphate Buffered Saline by aspiration.

Cell fixation: The cells on coverslips are swelled in 1% sodium citrate for 10-15 minutes and fixed in three 10-minute changes of 100% ethanol: glacial acetic acid (3:1). The fixed cultures are then washed twice with approximately 2 mL volumes of dH₂O. The coverslips are air dried and mounted cell surface up on glass slides with permount. Slides are dipped in NTB-2

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photographic emulsion (Eastman Kodak) in the dark, allowed to dry overnight and stored at 4°C in light-proof slide boxes containing drierite as a desiccant for one week.

Staining: After seven days of exposure time, autoradiographs are developed in D19 (Eastman Kodak) for 4 minutes, washed in deionized water with 5 mL glacial acetic acid for 30 seconds, immersed in Fixer (Eastman Kodak) for 10 minutes, washed in running tap water for 5 minutes, dried, stained in Harriss Alum Hematoxylin followed by a dip rinse in acid alcohol with rinsing in running tap water for 2-5 minutes and a dip rinse in ammonium water.

The slides are then rinsed in running tap water for 2-5 minutes, dipped in 70% ethyl alcohol, followed by a 10-60 second counterstain with a 1% aqueous Eosin Y solution. The slides are then rinsed in 3 separate baths of 95% ethyl alcohol for 2 minute intervals, followed by rinsing in 3 separate baths of 100% ethyl alcohol for 2 minute intervals. The slides are air-dried, and coverslipped with Permaslip®. Excess emulsion is scraped off.

Data
Quantitation:

Unscheduled DNA Synthesis (repair) evidenced by a net increase in black silver grains over the nucleus is quantified by determining nuclear and cytoplasmic grain counts using an Artek 880 automated colony counter with microscopic/video camera attachment. The cytoplasmic grain count is subtracted from the nuclear grain count yielding the net nuclear grain (NNG) count value. When such values are negative, they will be recorded and reported as such. A total of 150 cells/dose point (50 per culture) will be counted for autoradiographic UDS determinations. A correction coefficient is calculated by the following method. An area/grain

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ratio is obtained by visually scoring an area of each slide containing 3-5 nuclear grains and then obtaining an object area count by the Artek Model 880 Colony Counter. A minimum of five such areas are scored for each slide and the total of the visual counts is divided by the total of the object area counts. This value serves as a correction coefficient.

The cytoplasmic grain count is quantitated by randomly selecting the highest of three nuclear-sized areas adjacent to each nucleus. This value is subtracted from the uncorrected nuclear grain (NG) count to determine the NNG count value. Replicative DNA synthesis is evidenced by nuclei blackened with grains too numerous to count. The data of the HPC/DNA Repair Assay are reported as mean net grains/nucleus from the triplicate wells.

Criteria for a Valid Test:

To be a valid UDS assay, solvent and untreated controls should have a mean NNG count of ≤ 0 with 0-10% hepatocytes in repair and the positive control, 1×10^{-7} M 2AAF, should yield a mean NNG count of ≥ 5 with 70-100% hepatocytes in repair.

The test compound is reported positive when the minimum NG count of 5 per nuclei is consistently observed in triplicate wells and a dose response profile is also observed or a reproducible positive response at any one of the test points is observed. Due to the need to initially screen a chemical over a wide range of doses, an adequate dose response may not be attained, and the chemical may be classified as a "suspect" genotoxicant. To resolve the genotoxic potential of the chemical, the percent of cells in DNA Repair (% of cells with ≥ 5 NNG) will be considered in the evaluation and/or the sponsor may choose to initiate a

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second experiment with dose levels closely bracketing the positive response which resulted in classifying the chemical as a "suspect" genotoxic agent. A population average between 0 NG and 5 NG would be considered a marginal response. In similar cases, additional information is required to confirm either positive or negative response below 5 NG(1).

Animal Care
Provisions:

This study will be conducted in accordance with the current guidelines for animal welfare (NIH Publication 86-23, 1985). No alternative test systems exist which have been adequately validated to permit replacement of the use of live animals in this study. The requirement for this study by the regulatory agency indicated on the signature page is predicated on the basis that animal safety data constitute an appropriate and ethical prerequisite to testing new chemical compounds in humans and that data generated will be predictive of the effects in humans. Every effort has been made to obtain the maximum amount of information while reducing to a minimum the number of animals required for this study. The use of appropriate sedatives, analgesics, anesthetics or other medical treatments to alleviate pain will not be utilized in this study, unless otherwise indicated in the protocol, due to the interference of these treatments with the scientific data being generated. The use of pharmaceuticals to alleviate pain or distress may interfere with the compound being tested, thereby invalidating the data collected which would in turn require repeat testing and increase the number of animals utilized. The study will be terminated in part or whole for humane reasons if unnecessary pain occurs. To the best of our knowledge, this study is not unnecessary or duplicative.

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References:

- Butterworth, B. E., J. Ashby, E. Bermudez, D. Casciano, J. Mirsalis, G. Probst and G. Williams. A Protocol and Guide for the In Vitro Rat Hepatocyte DNA-repair Assay. Mutation Res. 189:113-121 (1987).
- Kornbrust, D.J. and Barfknecht, T.R. Comparison of Rat and Hamster Hepatocyte Primary Culture/DNA Repair Assays Environ. Mutagen. 6:1-11 (1984)
- Laishes, B. A., and G. M. Williams. Conditions Affecting Primary Cell Cultures of Functional Adult Rat Hepatocytes. I. The Effect of Insulin. In Vitro 12: 521-532 (1976).
- Laishes, B. A., and G. M. Williams. Conditions Affecting Primary cell Cultures of Function Adult Rat Hepatocytes. II. Dexamethasone Enhanced Longevity and Maintenance of Morphology. In Vitro 12: 821-832 (1976).
- Seglen, P. O. Preparation of Isolated Rat Liver Cells. Methods Cell Biol. 13: 29-83 (1976).
- Williams, G. M., E. Bermudez and D. Scaramuzzino. Rat Hepatocyte Primary cell Culture. III. Improved Dissociation and Attachment Techniques and the Enhancement of Survival by Culture Medium. In Vitro 13: 809-817 (1977).
- Williams, G. M. Detection of Chemical Carcinogens by Unscheduled DNA Synthesis in Rat Liver Primary Cell Cultures. Cancer Res. 37: 1845-1851 (1977).
- Williams, G. M. Further Improvements in the Hepatocyte Primary Culture DNA Repair Test for Carcinogens. Detection of Carcinogenic Biphenyl Derivatives. Cancer Letters 4: 69-75 (1978).

CYTPT\311.COL

Protocol-311
Rat Hepatocyte Primary Culture/DNA Repair Test

APPENDIX A
Test Article Information

I Identification:

Test Article (Sample #): 19317
CC#: 14663-09
Physical Description: Powder, white, odorless
Purity: 100.5% (alkalimetric assay)
Expiration Date: February 23, 1994
Density/Specific Gravity: _____
Solubility (check one): Water _____ Acetone X
Ethanol X Corn Oil _____ DMSO X
Other (please specify) NaOH 0.01N
Chemical Classification: Flammable _____ Corrosive _____
Other _____

II Storage Information:

(check one):
Room Temperature X Refrigerator _____
Freezer _____ Other (specify) _____

III Handling Information:

Known Hazards: None

Precautions: Routine use of protective clothing
includes laboratory coats, latex
gloves, dust masks, and safety
glasses.

Other recommended precautions None

In Case of Emergency Related to
this substance, contact:

Gabriela Adam-Rodwell, Ph.D. of Colgate at (908)878-6143
(person) (company/ (phone number)
division)

IV Disposition:

All materials will be returned to the Sponsor three
months following submission of the final report to
the Sponsor. Person and address to whom test
articles are to be returned.

Name: Gabriela Adam-Rodwell, Ph.D.
Address: 909 River Road
Piscataway, NJ 08855-1343

V Signature: Adam-Rodwell Date: 3/4/93

Protocol Amendment 1
Rat Hepatocyte Primary Culture/DNA Repair Test
Pharmakon Study # PH 311-CP-001-93
Colgate-Palmolive # 93-013

CONTROL ARTICLES
Page 3 (para. 4)

Original Statement

Negative Control: Williams' Medium E
without serum (WME)

Corrected Statement:

Sentence should be deleted.

Reason for
Amendment:

Redundant statement.

Data Quantitation:
page 9 (para.2,
line 5)

Original Statement:

This value is subtracted from the
uncorrected nuclear grain (NG) count to
determine the NNG count value.

Corrected Statement:

This value is subtracted from the
corrected nuclear grain (NG) count to
determine the NNG count.

Reason for
Amendment:

Typographical error.

Additional Reference:

Williams, G.M., M.F. Laspia and V.C.
Dunkel (1982), Reliability of the
Hepatocyte Primary Culture/DNA
Repair Test in Testing of Coded
Carcinogen and Non-Carcinogens.
Mutation Res. 97: 359-370.

Reason for Addendum:

Inadvertently omitted.

Juan R. San Sebastian
Juan R. SanSebastian, Ph.D.
Study Director

4 June 93
Date

Gabriela Adam-Rodwell
Gabriela Adam-Rodwell, Ph.D.
Colgate-Palmolive

6/14/93
Date

Pharmakon Study # PH 311-CP-001-93
Colgate-Palmolive Study CP# 93-013

APPENDIX III

Raw Data

NOTEBOOK # 1771

PHARMAXON RESEARCH INTERNATIONAL, INC.

Genetic Toxicology
Study Assignment

Study Number Phax-CP-141-93 Protocol Available ☒ yes ☐ no (circle)

Study Description Reproductive Primary Antithymic / DNA Repair Test

Study Director James H. Brown, Ph.D.

Technical Performance James H. Brown

Standard Operating Procedure Phax

Sponsor Chas. Pfizer & Co.

119 Green Road

Piscataway, NJ 08855

Monitor Richard A. Adams - Redwood, Ph.D., Chas. Pfizer & Co.

Test Article sample # 57317 CCE 14613-89

Physical Description white powder

Date of Study:

Initiation 3-4-93

Completion 4-3-93

Solubility 16.541 13449 93

Sponsor's Suggestion? ☒ yes ☐ no (circle)

Solubility Assay conducted? ☒ yes ☐ no (circle)

Vehicle (Solvent) dimethyl sulfoxide Source: Fisher Scientific

Lot No. 877134

Comments CP 593-913

Study Director James H. Brown Date April 26, 1993

Page 1

CHARTS (1)

NOTEBOOK # 1571
CP# 93-613

PHARMAKON RESEARCH INTERNATIONAL, INC.

TITLE: Rat Hepatocyte Primary Culture/DNA Repair Test STUDY NO. PH-1-101-73

Sponsor: Colgate-Palmolive Date Initiated: 3-11-93

Test Article: Amphipol 5 59817 Date Terminated: 4-23-93

Description: white powder

Solubility Test (mg/ml): @ 500 mg/ml

	WME	dH ₂ O	DMSO		
Weight					
Tare					
Compd wt.			1481.94 mg		
Vehicle added			4.96 ml		
Solubility			soluble		
			3-10-93		

Vehicle: dimethylformamide

Species: Rat Strain: Fischer 344

Animal P.O. # 5911-020493A

Date Rec'd.: 4-11-93

Sex: Male

Source: Thomson Farms

Weight: 465 gms

Food Lot # 10 41792
P0011593

Date Rec'd.: 1-2-93
4-23-93

Scale #: 36

Comments: Thomson Farms
Flow Rate: 4.96 ml/min (A) = 1.58 ml
solubility (B) = 1.58 ml
Substance: 3-11-93 SWL

Preliminary screen to determine if the test article would precipitate out of solution [0.5ml and 5ml of serum-free medium]

500 mg/ml → precipitate
Investigator Pharmakon Date 3-11-93
L1: 0.5 → 500 mg/ml (1ml 500 mg/ml + 1ml dH₂O) → precipitate
L1: 5 → 100 mg/ml (0.5ml 500 mg/ml + 4.5ml dH₂O) → precipitate
L1: 10 → 50 mg/ml (0.5ml 500 mg/ml + 4.5ml dH₂O) → precipitate
Study Director Pharmakon Date 3-11-93
L1: 20 → 25 mg/ml (0.1ml 500 mg/ml + 1.9ml dH₂O) → precipitate
L1: 50 → 10 mg/ml (0.1ml 500 mg/ml + 4.9ml dH₂O) → clear
OK 3/10/93 ghd
L1: 100 mg/ml (clear 3-11-93)

MISC2

page 1

Inventory
Ready
6.00 mg
1481.94 mg

3-10-93

EXPERIMENTAL CONDITIONS

CPR 93-013

Rat Hepatocyte Primary Culture/DNA Repair Test

Mutagenicity Assay

Study No.: 1258-CP-01-93 Date Initiated: 3-11-93
 Sponsor: Colgate Technologies Date Completed: 4-23-93
 Test Article: Sample # 29917 Description: undiluted, 100% stock

Test Article Weight

Test Article Dilutions

Weight:

Tare:

Test Article Weight: 1.258.02 mg

$\frac{1.258 \text{ mg}}{0.025 \text{ ml}} = 50 \text{ mg/ml}$
 $\frac{1.258 \text{ mg}}{0.025 \text{ ml}} = 50 \text{ mg/ml}$

Comments: 100% stock = 50 mg/ml 100% stock = 50 mg/ml 100% stock = 50 mg/ml

OR 2.5 mg/ml as preliminary screening for solubility at

was determined that 29917 at doses of 2.5, 5, 10, 25, and 50 mg/ml

Positive Control: 100% stock 100% stock 100% stock

Weight: 2.2 mg/ml 0.22 mg/ml 0.022 mg/ml

Tare:

Positive Control Weight: 5.6 mg

1.002 mg/ml
0.044 mg/ml

Final concentration of DMSO in treatment medium = 1 x 10⁻⁴

Collagenase Preparation:

100 Units/ml Total 300 ml (30,000 units)

Northington/Cat. # 4176

Lot # 51C-279A 225 units/mg

$\frac{30,000 \text{ units}}{225 \text{ units/mg}} = 133.3 \text{ mg}$

100% stock 100% stock 100% stock

TA 0.00 mg
1210.00 mg 0.00 mg 0-11-93
1210.00 mg 0.00 mg 0-11-93
1210.00 mg 0.00 mg 0-11-93

TA 0.00 mg
5.60 mg 0.00 mg 0-11-93

Investigator 3-11-93
Date

Study Director 3-11-93
Date

1210.00

Study Number: P4811-CP-001-43 Date of Initiation: 5-11-93
Test Article: Amoxicillin F59817
CE# 14663-83

Test Article Preparation:

Highest dose: 250 mg/ml

Standardized (final conc) = 0.05, 0.1, 0.25, 0.5, 1, 2.5, 5, 10, 25, 50, 100
and 250 mg/ml

Stock conc (100 = final conc) = 5, 10, 25, 50, 100, 250, 500, 1000, 2500,
5000, 10,000 and 25,000 mg/ml

250 mg/ml 250 mg/ml ①
* 25,000 mg/ml → 250 mg/ml
→ 1:2.5 → 10,000 mg/ml (12 ml 25,000 mg/ml + 18 ml 0.450) → 100 mg/ml
→ 1:5 → 5,000 mg/ml (5.5 ml 25,000 mg/ml + 22 ml 0.450) → 50 mg/ml
→ 1:10 → 2,500 mg/ml (3 ml 25,000 mg/ml + 27 ml 0.450) → 25 mg/ml
→ 1:25 → 1,000 mg/ml (1.25 ml 25,000 mg/ml + 30 ml 0.450) → 10 mg/ml
→ 1:50 → 500 mg/ml (0.6 ml 25,000 mg/ml + 29.4 ml 0.450) → 5 mg/ml
* → 1:100 → 250 mg/ml (0.5 ml 25,000 mg/ml + 49.5 ml 0.450) → 2.5 mg/ml
→ 1:2.5 → 100 mg/ml (12 ml 250 mg/ml + 18 ml 0.450) → 1 mg/ml
→ 1:5 → 50 mg/ml (5.5 ml 250 mg/ml + 22 ml 0.450) → 0.5 mg/ml
→ 1:10 → 25 mg/ml (3 ml 250 mg/ml + 27 ml 0.450) → 0.25 mg/ml
→ 1:25 → 10 mg/ml (1.25 ml 250 mg/ml + 30 ml 0.450) → 0.1 mg/ml
* → 1:50 → 5 mg/ml (0.6 ml 250 mg/ml + 29.4 ml 0.450) → 0.05 mg/ml
OK 3-11-93
JH
Stock solutions at
25,000 and 250 mg/ml

① Media became turbid when 250 treatment was added to the organisms
media 3-11-93

James H. Hunsicker 3-11-93
Investigator Date

James H. Hunsicker 3-11-93
Study Director Date

CRMAN2

NOTEBOOK # 1771

TITLE: Rat Hepatocyte Primary Culture/DNA Repair Test STUDY NO.: Inst. CP-001-93

Sponsor: Allyl Polychloride Date Initiated: 3-11-93

Test Article: Ames 0.34217 06014663-19 Date Terminated: 3-23-93

Description: white powder 16.544 23649-93

Cell Suspension Preparation:

Cell Suspension A: Cell Viability $\frac{19}{21}$ (Living Cells) $\frac{21}{21}$ (Total Cells) $\times 100 = 91\%$

Cell Count: $\frac{21}{4}$ (Total Cells) $\times \frac{6}{5} \times 10^4 \times 20 \times .91 = 1.0 \times 10^5$ viable cells/ml of stock suspension

Cell Suspension B: Cell Viability $\frac{39}{40}$ (Living Cells) $\frac{40}{40}$ (Total Cells) $\times 100 = 97\%$

Cell Count: $\frac{39}{4}$ (Total Cells) $\times \frac{6}{5} \times 10^4 \times 20 \times .97 = 1.9 \times 10^5$ viable cells/ml of stock suspension

Cell Suspension To Be Used: B

1×10^5 viable cells/ml for seeding: $\frac{1.9 \times 10^5}{\text{ml}} = \frac{1 \times 10^5}{x}$
 $x = .05$ ml of stock suspension
for seeding to give 1×10^5
viable cells/well.

Schedule of Assay: 3-11-93 Treatment

3-17-93 WTB-2

3-23-93 Fixation

David M. Schmitt 3-23-93
Investigator Date

Maurice Schmitt April 26, 1993
Study Director Date

page 5

MISC2

NOTEBOOK # 1171
CP-93-013

TITLE: Rat Hepatocyte Primary Culture/DNA Repair Test STUDY NO.: 7801-CP-001-93

Sponsor: Adyco-Palmolive Date Initiated: 3-11-93
Test Article: Genexin 0-51917 Date Terminated: 3-25-93
025 19663-89 16 CAL 234p 93
Description: _____

Concentration ug/ml	Complete Cell Detachment	Most Cells Detached	Abnormal Cell Morphology	Low Overall Grain Incorporation
250				/
100				/
50		/		/
25				/
10		/		/
5				/
2.5	/			
1	/			
0.5	/			
0.25	/			
0.1	/			
0.05	/			

Comments: These levels evaluated: 0.05, 0.5, 1 and 2.5 ug/ml

David F. Schmitt 3-23-93
Investigator Date
16291 234p 93
Frank A. Kerkorian April 26, 1993
Study Director Date

NOTEBOOK NO: 1771

PHARMAKON RESEARCH INTERNATIONAL INC.

DISTRIBUTION OF NET NUCLEAR COUNTS

INVESTIGATOR: SUSAN M. LUCENTI
DATE: 4-21-93
STUDY NUMBER: PH311CP00193
CODE: WME
DISTRIBUTION FILE NAME: PH311-CP-001-93/WME

(NET VALUES) (RECURRENCE)

-66	1
-49	1
-48	1
-46	2
-45	2
-40	2
-39	2
-37	3
-36	3
-35	2
-34	2
-33	2
-32	1
-31	5
-30	2
-29	1
-28	4
-27	5
-26	1
-25	0
-24	6
-23	1
-22	2
-21	0
-20	7
-19	5
-18	4
-17	6
-16	4
-15	9
-14	5
-13	5
-12	5
-11	7
-10	3
-9	3
-8	3

Susan M. Lucenti 4/22/93
INVESTIGATOR DATE

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OVERALL C:

PARADIGM RESEARCH INTERNATIONAL INC.
NUCLEAR AND CYTOPLASMIC COUNTS
RAT HEPATOCYTE PRIMARY CULTURE/DNA REPAIR ASSAY

INVESTIGATOR: SUSAN M. LICENTI
DATE: 4-19-93
CODE: WME-1
STUDY NUMBER: PH311CP00193 DECODED DOSE: 09017
CORRECTION FACTOR: 1
FILE NAME: R-011-01-001-01/1

SAMPLE	1	2	3	4	5	6	7	8
NUCLEUS COUNT	18	12	30	10	78	20	44	16
CYTO COUNT #1	18	43	35	20	41	20	46	43
CYTO COUNT #2	27	24	29	12	26	20	49	16
CYTO COUNT #3	27	20	21	10	46	24	47	20
NET VALUE *	-8	-31	-5	-7	-8	-11	-5	-16
SAMPLE	9	10	11	12	13	14	15	16
NUCLEUS COUNT	20	16	17	26	18	21	17	15
CYTO COUNT #1	29	30	40	60	55	28	55	21
CYTO COUNT #2	30	30	47	82	52	33	56	36
CYTO COUNT #3	33	28	25	85	42	47	59	36
NET VALUE *	-16	-14	-30	-49	-37	-27	-39	-20
SAMPLE	17	18	19	20	21	22	23	24
NUCLEUS COUNT	43	38	27	22	27	19	40	20
CYTO COUNT #1	42	43	29	24	26	15	20	21
CYTO COUNT #2	45	41	36	1	17	22	55	30
CYTO COUNT #3	24	28	30	20	10	14	71	29
NET VALUE *	-2	-3	-29	-2	1	-3	-21	-20
SAMPLE	25	26	27	28	29	30	31	32
NUCLEUS COUNT	15	17	55	24	27	29	20	22
CYTO COUNT #1	32	38	72	32	30	30	28	55
CYTO COUNT #2	36	56	68	41	45	42	40	32
CYTO COUNT #3	47	42	63	10	21	31	40	30
NET VALUE *	-32	-39	-17	-17	-8	-10	-10	-7
SAMPLE	33	34	35	36	37	38	39	40
NUCLEUS COUNT	33	55	42	47	35	40	22	24
CYTO COUNT #1	49	32	50	45	38	55	57	20
CYTO COUNT #2	28	35	52	50	46	51	58	22
CYTO COUNT #3	44	57	42	52	30	55	52	41
NET VALUE *	-16	-2	-10	-5	-11	-21	-33	-16

Susan M. Licenti 4/20/93
INVESTIGATOR DATE

SAMPLE	41	42	43	44	45	46	47	48
NUCLEUS COUNT	8	10	11	13	10	11	17	16
CYTO COUNT #1	17	10	11	10	11	13	11	11
CYTO COUNT #2	10	10	11	14	16	17	20	21
CYTO COUNT #3	15	19	18	11	17	25	27	20
NET VALUE *	-25	-17	-11	-14	-7	-14	-20	-45

SAMPLE	49	50
NUCLEUS COUNT	75	55
CYTO COUNT #1	75	32
CYTO COUNT #2	74	78
CYTO COUNT #3	69	45
NET VALUE *	-40	-17

* NET COUNT = NUCLEUS - MAXIMUM OF CYTO COUNTS
 MEAN NET VALUE = -19.6
 STANDARD DEVIATION = 15.1

James H. Lawrence 19 Apr 93
 INVESTIGATOR DATE

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NOTES: 01.11.

PHARMACON RESEARCH INTERNATIONAL INC.

NUCLEAR AND CYTOPLASMIC COUNTS
RAT HEPATOCYTE PRIMARY CULTURE/DNA REPAIR ASSAY

INVESTIGATOR: SUSAN M. LUCCENT

DATE: 4-19-93

CODE: WME-2

STUDY NUMBER: PH311CP00193 DECODED DOSE: 09717

CORRECTION FACTOR: 1

FILE NAME: PH311-CP-001-93/2

SAMPLE	1	2	3	4	5	6	7	8
NUCLEUS COUNT	62	55	50	57	57	56	54	42
CYTO COUNT #1	67	56	51	52	55	52	40	41
CYTO COUNT #2	68	57	48	50	51	57	40	42
CYTO COUNT #3	53	42	46	56	56	47	50	56
NET VALUE +	-25	-17	-21	-15	-34	-11	-6	0
SAMPLE	9	10	11	12	13	14	15	16
NUCLEUS COUNT	58	59	50	41	55	56	52	50
CYTO COUNT #1	41	54	56	71	51	55	50	57
CYTO COUNT #2	41	49	55	67	53	72	70	51
CYTO COUNT #3	58	41	56	45	48	52	48	56
NET VALUE +	-20	-15	-6	-30	-28	-36	-31	-33
SAMPLE	17	18	19	20	21	22	23	24
NUCLEUS COUNT	52	51	54	55	55	58	51	54
CYTO COUNT #1	68	64	65	68	59	56	57	41
CYTO COUNT #2	57	47	68	62	40	56	41	41
CYTO COUNT #3	55	56	94	55	50	58	55	54
NET VALUE +	-16	-15	-40	-35	-17	0	-6	-7
SAMPLE	25	26	27	28	29	30	31	32
NUCLEUS COUNT	49	61	69	57	64	40	46	50
CYTO COUNT #1	65	75	75	77	75	78	57	55
CYTO COUNT #2	65	58	81	84	49	50	44	54
CYTO COUNT #3	83	75	51	94	55	88	52	44
NET VALUE +	-34	-14	-12	-37	-11	-48	-11	-15
SAMPLE	33	34	35	36	37	38	39	40
NUCLEUS COUNT	39	53	46	56	47	61	47	56
CYTO COUNT #1	65	50	58	79	70	56	75	47
CYTO COUNT #2	60	52	60	83	67	49	64	51
CYTO COUNT #3	40	49	61	62	41	72	65	54
NET VALUE +	-36	-19	-15	-27	-20	-11	-28	-18

Susan M. Luccent
INVESTIGATOR

4/29/93
DATE

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SAMPLE	41	42	43	44	45	46	47	48
NUCLEUS COUNT	39	50	50	53	40	34	45	46
CYTO COUNT #1	46	59	43	37	50	45	59	37
CYTO COUNT #2	59	40	57	54	57	50	55	38
CYTO COUNT #3	50	55	50	52	56	50	55	54
NET VALUE *	-20	-9	-27	-15	-27	-19	-24	-15

SAMPLE	49	50
NUCLEUS COUNT	22	33
CYTO COUNT #1	42	37
CYTO COUNT #2	28	45
CYTO COUNT #3	50	45
NET VALUE *	-31	-12

* NET COUNT = NUCLEUS - MAXIMUM OF CYTO COUNTS
 MEAN NET VALUE = -20.8
 STANDARD DEVIATION = 10.9

James H. Stewart 19 Apr 13
 INVESTIGATOR DATE

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NOTEBOOK: 10:1771

PHARMACON RESEARCH INTERNATIONAL INC.
NUCLEAR AND CYTOPLASMIC COUNTS
RAT HEPATOCYTE PRIMARY CULTURE/DNA REPAIR ASSAY

INVESTIGATOR: SUSAN M. LUCENT
DATE: 4-19-93
CODE: WME-7 STUDY NUMBER: PH311CP00193 DECODED DOSE: 29017
CORRECTION FACTOR: 1
FILE NAME: PH311-CP-001-93/3

SAMPLE	1	2	3	4	5	6	7	8
NUCLEUS COUNT	18	25	30	62	53	71	56	45
CYTO COUNT #1	27	40	48	68	67	78	61	49
CYTO COUNT #2	27	33	34	86	81	72	64	38
CYTO COUNT #3	30	37	57	78	77	47	71	29
NET VALUE *	-19	-15	-27	-24	-28	-7	-15	-11
SAMPLE	9	10	11	12	13	14	15	16
NUCLEUS COUNT	33	56	60	41	57	53	36	30
CYTO COUNT #1	49	75	71	61	66	56	41	36
CYTO COUNT #2	32	45	35	50	51	53	40	51
CYTO COUNT #3	38	66	63	40	42	60	53	46
NET VALUE *	-16	-10	-11	-20	-9	-7	-17	-11
SAMPLE	17	18	19	20	21	22	23	24
NUCLEUS COUNT	39	32	32	33	35	48	38	29
CYTO COUNT #1	42	58	57	44	43	90	35	31
CYTO COUNT #2	35	44	45	37	48	72	30	43
CYTO COUNT #3	31	34	46	47	42	93	38	48
NET VALUE *	-3	-26	-5	-24	-13	-35	0	-19
SAMPLE	25	26	27	28	29	30	31	32
NUCLEUS COUNT	72	81	55	47	64	33	34	48
CYTO COUNT #1	43	102	54	52	62	36	39	37
CYTO COUNT #2	32	85	73	56	62	47	38	43
CYTO COUNT #3	36	40	43	65	45	33	17	51
NET VALUE *	-24	-21	-18	-18	2	-24	-15	-12
SAMPLE	33	34	35	36	37	38	39	40
NUCLEUS COUNT	56	32	33	49	39	41	43	41
CYTO COUNT #1	49	31	32	53	49	59	43	32
CYTO COUNT #2	61	24	34	41	51	77	45	51
CYTO COUNT #3	61	26	34	64	48	72	43	53
NET VALUE *	-5	1	-1	-15	-12	-36	-2	-12

Susan M. Lucent 19 Apr 93
INVESTIGATOR DATE

SAMPLE	41	42	43	44	45	46	47	48
NUCLEUS COUNT	78	57	47	40	46	36	52	53
CYTO COUNT #1	87	79	62	60	68	60	74	71
CYTO COUNT #2	88	88	57	51	68	53	54	57
CYTO COUNT #3	75	61	72	38	51	57	64	72
NET VALUE *	-45	-11	-35	-20	-22	-27	-22	-20

SAMPLE	49	50
NUCLEUS COUNT	40	68
CYTO COUNT #1	63	72
CYTO COUNT #2	36	37
CYTO COUNT #3	45	68
NET VALUE *	-46	-19

* NET COUNT = NUCLEUS - MAXIMUM OF CYTO COUNTS
 MEAN NET VALUE = -16.5
 STANDARD DEVIATION = 11

James P. H. ... 1943
 INVESTIGATOR DATE

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NOTEBOOK NO: 1771

PHARMAKON RESEARCH INTERNATIONAL INC.

DISTRIBUTION OF NET NUCLEAR COUNTS

INVESTIGATOR: SUSAN M. LUCENTI
DATE: 4-21-73
CODE: DMSO
STUDY NUMBER: PH311CP00193
DISTRIBUTION FILE NAME: PH311-CP-001-73/DMSO

(NET VALUES) (RECURRENCE)

-74	1
-67	1
-59	1
-51	2
-45	2
-43	1
-42	1
-41	2
-40	1
-39	2
-38	1
-37	1
-36	2
-35	2
-34	3
-33	2
-32	1
-31	3
-30	3
-29	4
-28	4
-27	7
-26	5
-25	5
-24	5
-23	6
-22	2
-21	7
-20	3
-19	2
-18	5
-17	4
-16	3
-15	8
-14	5
-13	5
-12	4

Susan M. Lucenti 4/21/73
INVESTIGATOR DATE

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PAGE _____

-11	1
-10	1
-9	1
-8	1
-7	1
-6	1
-5	1
-4	1
-3	1
-2	1
-1	1
0	1
1	1
2	1
3	1

3 FILES

PH311-CP-001-73/4

PH311-CP-001-73/5

PH311-CP-001-73/6

TOTAL MEAN VALUE: -21.6

TOTAL STANDARD DEV: 13.4

Robert H. Hines 21 Nov 93
INVESTIGATOR DATE

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NOTEBOOK NO: 1771

PARADIGM RESEARCH INTERNATIONAL INC.

NUCLEAR AND CYTOPLASMIC COUNTS
RAT HEPATOCYTE PRIMARY CULTURE/DNA REPAIR ASSAY

INVESTIGATOR: SUSAN M. LUCCENTI

DATE: 4-19-93

CODE: DMSO-1

STUDY NUMBER: PH311CP00193 DECODED DOSE: C9317

CORRECTION FACTOR: .

FILE NAME: PH311-CP-301-93/4

SAMPLE	1	2	3	4	5	6	7	8
NUCLEUS COUNT	70	50	50	11	9	45	59	70
CYTO COUNT #1	54	40	51	29	37	51	45	45
CYTO COUNT #2	59	48	44	22	14	37	42	41
CYTO COUNT #3	44	32	43	31	44	57	82	47
NET VALUE *	-27	-18	-21	-20	-35	-14	-23	-14
SAMPLE	9	10	11	12	13	14	15	16
NUCLEUS COUNT	45	24	26	31	15	29	25	18
CYTO COUNT #1	76	38	34	57	49	53	46	53
CYTO COUNT #2	68	28	27	35	29	53	33	51
CYTO COUNT #3	84	24	40	40	36	37	29	56
NET VALUE *	-39	-14	-14	-26	-34	-24	-23	-40
SAMPLE	17	18	19	20	21	22	23	24
NUCLEUS COUNT	37	35	44	45	19	54	25	41
CYTO COUNT #1	78	73	45	54	18	70	50	52
CYTO COUNT #2	42	66	52	56	49	56	52	43
CYTO COUNT #3	33	44	51	52	39	51	51	48
NET VALUE *	-5	-38	-8	-17	-30	-42	-27	-11
SAMPLE	25	26	27	28	29	30	31	32
NUCLEUS COUNT	37	39	18	35	34	30	23	39
CYTO COUNT #1	65	62	47	47	62	31	17	34
CYTO COUNT #2	71	50	43	54	65	36	23	37
CYTO COUNT #3	96	59	40	36	52	31	21	51
NET VALUE *	-59	-33	-29	-19	-31	-11	0	-12
SAMPLE	33	34	35	36	37	38	39	40
NUCLEUS COUNT	25	28	25	19	10	19	14	25
CYTO COUNT #1	26	32	37	27	21	40	53	47
CYTO COUNT #2	26	27	23	37	30	31	40	42
CYTO COUNT #3	15	27	36	32	38	40	47	50
NET VALUE *	-1	-4	-12	-18	-28	-21	-39	-25

Susan M. Luccenti 19 Apr 93
INVESTIGATOR DATE

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SAMPLE	41	42	43	44	45	46	47	48
NUCLEUS COUNT	24	22	42	30	46	37	33	22
CYTO COUNT #1	33	49	47	54	51	53	59	26
CYTO COUNT #2	29	31	21	43	48	42	47	25
CYTO COUNT #3	38	40	27	49	49	36	41	35
NET VALUE *	-28	-27	-5	-24	-5	-16	-26	-12

SAMPLE	49	50
NUCLEUS COUNT	24	19
CYTO COUNT #1	27	33
CYTO COUNT #2	20	21
CYTO COUNT #3	20	28
NET VALUE *	-3	-15

* NET COUNT = NUCLEUS - MAXIMUM OF CYTO COUNTS
 MEAN NET VALUE = -21.0
 STANDARD DEVIATION = 12.0

Robert H. Lumbardi 19 Apr 23
 INVESTIGATOR DATE

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1075501 01.177

PHARMACON RESEARCH INTERNATIONAL INC.

NUCLEAR AND CYTOPLASMIC COUNTS
RAT HEPATOCYTE PRIMARY CULTURE DNA REPAIR ASSAY

INVESTIGATOR: SUSAN M. LUCCENT
DATE: 4-19-93
CODE: DMSO-3 STUDY NUMBER: PHC11-0F00191 REDUCED DOSE: 19717
CORRECTION FACTOR: 1
FILE NAME: PHC11-0F-001-07/5

SAMPLE	1	2	3	4	5	6	7	8
NUCLEUS COUNT	25	22	17	38	35	33	40	33
CYTO COUNT #1	46	47	37	81	51	47	60	58
CYTO COUNT #2	79	52	36	68	57	65	57	44
CYTO COUNT #3	29	57	42	62	54	51	54	35
NET VALUE +	-21	-35	-25	-43	-22	-32	-24	-15
SAMPLE	9	10	11	12	13	14	15	16
NUCLEUS COUNT	28	35	30	22	36	29	39	42
CYTO COUNT #1	43	50	60	73	59	44	47	53
CYTO COUNT #2	53	36	45	69	57	37	71	57
CYTO COUNT #3	33	52	56	55	52	41	47	46
NET VALUE +	-25	-17	-30	-51	-23	-15	-24	-23
SAMPLE	17	18	19	20	21	22	23	24
NUCLEUS COUNT	51	33	50	52	52	41	49	50
CYTO COUNT #1	125	78	52	75	79	66	43	47
CYTO COUNT #2	103	70	60	88	67	72	49	78
CYTO COUNT #3	100	46	72	70	51	45	54	52
NET VALUE +	-74	-45	-23	-36	-27	-31	-15	-18
SAMPLE	25	26	27	28	29	30	31	32
NUCLEUS COUNT	44	50	57	49	45	45	28	47
CYTO COUNT #1	77	76	52	54	73	74	58	59
CYTO COUNT #2	95	81	59	72	74	71	45	67
CYTO COUNT #3	97	60	66	93	63	74	65	72
NET VALUE +	-51	-21	-5	-34	-26	-29	-45	-29
SAMPLE	33	34	35	36	37	38	39	40
NUCLEUS COUNT	35	24	37	54	29	38	45	16
CYTO COUNT #1	71	63	54	16	68	49	58	38
CYTO COUNT #2	70	45	51	47	32	48	48	70
CYTO COUNT #3	92	65	42	58	55	28	35	30
NET VALUE +	-67	-41	-17	-4	-39	-11	-13	-22

Susan M. Luccent 19 Apr 93
INVESTIGATOR DATE

SAMPLE	41	42	43	44	45	46	47	48
NUCLEUS COUNT	70	41	74	70	77	78	74	76
CYTO COUNT #1	39	51	30	46	48	51	45	46
CYTO COUNT #2	29	49	40	45	54	53	49	50
CYTO COUNT #3	27	79	34	52	55	70	54	71
NET VALUE *	-6	-10	-6	-19	-28	-1	-70	-6

SAMPLE	49	50
NUCLEUS COUNT	47	51
CYTO COUNT #1	65	43
CYTO COUNT #2	63	48
CYTO COUNT #3	56	64
NET VALUE *	-18	-13

* NET COUNT = NUCLEUS - MAXIMUM OF CYTO COUNTS
 MEAN NET VALUE = -26.4
 STANDARD DEVIATION = 15.2

James H. Churnick 19 Apr 82
 INVESTIGATOR DATE

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NOTEBOOK NO: 1771

PHARMACON RESEARCH INTERNATIONAL INC.

NUCLEAR AND CYTOPLASMIC COUNTS
RAT HEPATOCYTE PRIMARY CULTURE/DNA REPAIR ASSAY

INVESTIGATOR: SUSAN M. LUCENTI
DATE: 4-10-93
CODE: DMSO-1 STUDY NUMBER: PH311CP00193 DECODED DOSE: 39317
CORRECTION FACTOR: .86
FILE NAME: PH311-CP-001-93/6

SAMPLE	1	2	3	4	5	6	7	8
NUCLEUS COUNT	45.6	35.0	49	49	34.4	33.2	24.9	18.9
CYTO COUNT #1	53.0	49.9	57.6	55	43	37.8	43	29.2
CYTO COUNT #2	69.7	67.9	49	65.4	37.8	40.4	36.1	30.1
CYTO COUNT #3	65.4	54.2	49.9	55	32.7	36.1	26.7	24.4
NET VALUE *	-24.1	-32.6	-8.6	-16.4	-8.6	-17.2	-18.1	-15.5
SAMPLE	9	10	11	12	13	14	15	16
NUCLEUS COUNT	16.0	21.5	20.6	37	37.8	38.7	31	31.8
CYTO COUNT #1	18.1	31	24.1	65.4	43.9	61.9	33.5	47.0
CYTO COUNT #2	17.2	17.2	24.1	36.1	50.7	45.6	37.8	26.1
CYTO COUNT #3	17.2	25.8	18.1	50.7	49.9	46.4	27.5	38.7
NET VALUE *	-1.8	-9.5	-3.5	-28.4	-12.9	-23.2	-6.8	-15.5
SAMPLE	17	18	19	20	21	22	23	24
NUCLEUS COUNT	37	33.5	15.5	31.8	23.2	33.5	22.4	24.1
CYTO COUNT #1	62.8	38.7	34.4	42.1	47.0	31	23.8	24.9
CYTO COUNT #2	41.0	43.9	41.0	51.6	35.0	29.2	22.4	35.0
CYTO COUNT #3	45.9	26.7	34.4	30.1	21.5	24.9	22.4	40.1
NET VALUE *	-25.8	-10.4	-25.8	-19.8	-24.1	2.5	-3.4	-16.0
SAMPLE	25	26	27	28	29	30	31	32
NUCLEUS COUNT	31	30.1	26.7	21.5	21.5	41.0	45.6	44.7
CYTO COUNT #1	20.6	37.8	32.7	29.2	15.5	63.6	53.0	55.9
CYTO COUNT #2	30.1	37	39.6	27.5	24.1	55.9	32.2	31.4
CYTO COUNT #3	30.1	24.1	47.0	41.0	35.8	72.2	67.9	61.1
NET VALUE *	.9	-7.7	-20.6	-19.8	-4.3	-30.9	-26.6	-26.7
SAMPLE	33	34	35	36	37	38	39	40
NUCLEUS COUNT	41.0	23.2	33.5	54.2	43	47.0	20.6	42.1
CYTO COUNT #1	48.2	74	49	69.7	51.6	53.0	43.9	49
CYTO COUNT #2	55.9	61.1	40.4	74.8	61.1	61.1	41.0	43
CYTO COUNT #3	42.1	70.5	27.5	55	64.5	47.0	57.6	46.4
NET VALUE *	-14.6	-50.8	-15.5	-20.6	-21.5	-10.8	-37	-5.9

Susan M. Lucenti 4/10/93
INVESTIGATOR DATE

PAGE #1

SAMPLE	41	42	43	44	45	46	47	48
NUCLEUS COUNT	37.8	42.1	40.4	36.1	31	39.6	51.6	45.6
CYTO COUNT #1	45.6	56.6	57.9	45.6	56.8	30.6	54.2	56.6
CYTO COUNT #2	37.8	40	49	42.1	58.5	35.0	59.0	57.6
CYTO COUNT #3	34.4	39.6	24.9	49	50.7	49.9	59.0	49
NET VALUE *	-7.8	-14.7	-27.5	-12.9	-27.5	-10.0	-7.7	-12

SAMPLE	49	50
NUCLEUS COUNT	24.1	26.7
CYTO COUNT #1	55.4	32.7
CYTO COUNT #2	53.0	34.4
CYTO COUNT #3	40.4	26.7
NET VALUE *	-41.0	-7.7

* NET COUNT = NUCLEUS - MAXIMUM OF CYTO COUNTS
 MEAN NET VALUE = -17
 STANDARD DEVIATION = 10.9

James M. Luciani 20 Apr 99
 INVESTIGATOR DATE

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NOTEBOOK NO: 177

PHARMACON RESEARCH INTERNATIONAL INC.
DISTRIBUTION OF NET NUCLEAR COUNTS

INVESTIGATOR: SUSAN M. LUENTI
DATE: 4-22-93
STUDY NUMBER: PH311CP00197
CODE: 2AAF
DISTRIBUTION FILE NAME: PH311-CP-001-PS/2AAF

(NET VALUES) (RECURRENCE)

-10	1
-1	3
0	1
1	1
2	1
3	1
4	0
5	7
6	7
7	0
8	5
10	1
11	1
12	4
13	4
14	6
15	1
16	4
17	1
18	1
19	1
20	11
21	0
22	4
24	1
26	1
27	7
28	0
29	0
30	4
31	1
32	1
34	4
35	1
36	5
37	1
40	1

Susan M. Luenti _____
INVESTIGATOR DATE

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42	1
44	1
45	1
48	1
49	1
53	1
55	1
56	1
63	1
64	1
67	1
78	1
79	1

3 FILES

PHC11-CP-001-93/7
PHC11-CP-001-93/8
PHC11-CP-001-93/9

TOTAL MEAN VALUE: 21.2
TOTAL STANDARD DEV: 16.6

<i>James M. Lawrence</i>	<i>22 June 93</i>
INVESTIGATOR	DATE

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NOTES: 10:1771

PHARMACON RESEARCH INTERNATIONAL INC.

NUCLEAR AND CYTOPLASMIC COUNTS
RAT HEPATOCYTE PRIMARY CULTURE/DNA REPAIR ASSAY

INVESTIGATOR: SUSAN M. LUENTI
DATE: 4-21-93
CODE: 2AAF-1 STUDY NUMBER: PH311CP00193 DECODED DOSE: 09317
CORRECTION FACTOR: 1.06
FILE NAME: PH311-CP-001-93/7

SAMPLE	1	2	3	4	5	6	7	8
NUCLEUS COUNT	65.7	94.0	50	60.4	56.2	91.6	78.2	100.7
CYTO COUNT #1	26.5	66.8	27.6	33.9	12.7	14.6	22.0	43.5
CYTO COUNT #2	75	57.2	38.2	33.9	6.4	6.4	12.7	47.7
CYTO COUNT #3	19.1	56.2	39.2	38.7	8.5	13.6	15.9	50
NET VALUE *	10.7	27.5	13.8	26.5	43.5	66.8	15.9	47.7
SAMPLE	9	10	11	12	13	14	15	16
NUCLEUS COUNT	65.7	50.9	68.9	126.1	144.2	57.0	57.2	57.0
CYTO COUNT #1	45.6	32.9	52.5	99.6	110.2	31.6	17	45.6
CYTO COUNT #2	48.8	39.2	58.0	85.9	90.1	85.9	21.2	58.0
CYTO COUNT #3	39.2	32.9	59.4	98.6	61.5	67.8	19.1	59.4
NET VALUE *	16.9	11.7	6.4	26.5	34	7.4	36	33.9
SAMPLE	17	18	19	20	21	22	23	24
NUCLEUS COUNT	67.8	66.8	48.8	42.4	59.4	68.9	146.0	53
CYTO COUNT #1	59.4	61.5	14.8	17	43.5	23.0	33.7	28.5
CYTO COUNT #2	59.7	57.2	10.6	19.1	42.4	32.9	17.1	47.7
CYTO COUNT #3	44.5	45.6	23.6	25.4	30.7	25.4	50.9	20.7
NET VALUE *	9.4	5.0	20.2	17	15.9	36	52.6	5.0
SAMPLE	25	26	27	28	29	30	31	32
NUCLEUS COUNT	40.7	31.6	79.5	99	70	80.7	42.4	54.1
CYTO COUNT #1	7.4	43.5	51.9	27.6	35	53.6	18.2	18.2
CYTO COUNT #2	10.5	50.9	46.6	33.9	37.1	33.9	28.6	42.4
CYTO COUNT #3	18	46.6	11.7	21.2	24.4	42.4	20.1	22.0
NET VALUE *	22.0	30.7	27.6	55.1	32.9	20.1	4.2	11.7
SAMPLE	33	34	35	36	37	38	39	40
NUCLEUS COUNT	75.0	38.2	32.9	37.1	41.0	63.6	59.4	55.7
CYTO COUNT #1	54.1	21.2	26.5	18	33.9	54.1	28.6	58.7
CYTO COUNT #2	46.6	30.7	21.2	28.6	26.5	55.1	44.5	54.7
CYTO COUNT #3	44.5	25.4	27.6	31.8	35	58.0	54.1	27.6
NET VALUE *	21.2	7.5	5.0	5.0	6.0	5.0	5.0	.

Susan M. Luenti
INVESTIGATOR DATE

SAMPLE	41	42	43	44	45	46	47	48
NUCLEUS COUNT	128.5	41.5	50.9	109.2	130.4	46.6	41.5	57.5
CYTO COUNT #1	34.7	38.5	34.4	47.7	26.5	38.2	39.2	35
CYTO COUNT #2	41.5	30.7	19.1	49.8	51.9	40.5	27.5	71
CYTO COUNT #3	49.8	57.1	50.7	31.6	44.5	26.5	28.6	59.4
NET VALUE *	60.6	2.1	20.2	27.6	78.5	6.0	2.1	26.5

SAMPLE	49	50
NUCLEUS COUNT	53	51.9
CYTO COUNT #1	31.8	61.5
CYTO COUNT #2	27.6	43.5
CYTO COUNT #3	22.9	36
NET VALUE *	20.1	-9.6

* NET COUNT = NUCLEUS - MAXIMUM OF CYTO COUNTS
MEAN NET VALUE = 22.5
STANDARD DEVIATION = 19.1

James H. L. L. 21 Apr 73
INVESTIGATOR DATE

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NOTEBOOK NO: 1771

PHARMACON RESEARCH INTERNATIONAL INC.

NUCLEAR AND CYTOPLASMIC COUNTS
RAT HEPATOCYTE PRIMARY CULTURE/DNA REPAIR ASSAY

INVESTIGATOR: SUSAN M. LUCENT

DATE: 4-21-93

CODE: 2AAF-2

STUDY NUMBER: PH311CP00193 DECODED DOSE: 09017

CORRECTION FACTOR : 1

FILE NAME: PH311-CP-001-93/8

SAMPLE	1	2	3	4	5	6	7	8
NUCLEUS COUNT	45	40	52	49	64	66	52	44
CYTO COUNT #1	25	32	15	24	41	33	38	22
CYTO COUNT #2	24	22	18	43	15	31	30	22
CYTO COUNT #3	25	19	15	37	44	37	30	25
NET VALUE +	20	8	14	5	20	29	14	11
SAMPLE	9	10	11	12	13	14	15	16
NUCLEUS COUNT	55	80	102	93	86	80	104	77
CYTO COUNT #1	36	27	53	64	53	52	58	53
CYTO COUNT #2	36	17	50	71	76	56	90	40
CYTO COUNT #3	49	40	40	53	53	55	52	74
NET VALUE +	6	40	49	22	10	18	44	-1
SAMPLE	17	18	19	20	21	22	23	24
NUCLEUS COUNT	45	87	50	51	42	67	92	74
CYTO COUNT #1	28	71	43	19	34	46	37	55
CYTO COUNT #2	45	79	39	20	16	28	17	72
CYTO COUNT #3	31	71	33	24	10	19	17	57
NET VALUE +	0	8	7	27	8	21	55	4
SAMPLE	25	26	27	28	29	30	31	32
NUCLEUS COUNT	62	58	117	127	102	56	48	75
CYTO COUNT #1	45	34	62	51	56	44	31	40
CYTO COUNT #2	50	32	73	72	58	17	38	42
CYTO COUNT #3	24	20	34	98	34	14	42	48
NET VALUE +	12	24	44	29	64	12	5	27
SAMPLE	33	34	35	36	37	38	39	40
NUCLEUS COUNT	101	70	76	93	66	69	34	121
CYTO COUNT #1	55	63	58	49	30	35	22	19
CYTO COUNT #2	56	29	50	35	32	47	20	39
CYTO COUNT #3	54	63	39	60	23	24	28	47
NET VALUE +	45	7	18	33	74	32	56	73

Susan M. Lucent *4-21-93*
INVESTIGATOR DATE

SAMPLE	41	42	43	44	45	46	47	48
NUCLEUS COUNT	69	72	60	69	45	54	55	57
CYTO COUNT #1	33	40	43	34	33	40	31	51
CYTO COUNT #2	39	56	46	41	18	51	33	38
CYTO COUNT #3	20	34	36	35	19	32	35	26
NET VALUE *	36	16	14	37	26	2	4	10

SAMPLE	49	50
NUCLEUS COUNT	60	65
CYTO COUNT #1	25	37
CYTO COUNT #2	47	39
CYTO COUNT #3	38	39
NET VALUE *	13	26

* NET COUNT = NUCLEUS - MAXIMUM OF CYTO COUNTS
 MEAN NET VALUE = 22.6
 STANDARD DEVIATION = 17.5

Armand H. L. L. L. 22 Apr 93
 INVESTIGATOR DATE

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NOTEBOOK NO: 1771

PHARMACON RESEARCH INTERNATIONAL INC.
NUCLEAR AND CYTOPLASMIC COUNTS
RAT HEPATOCYTE PRIMARY CULTURE/DNA REPAIR ASSAY

INVESTIGATOR: SUSAN M. LUCENTI
DATE: 4-22-90
CODE: 39317 *NAF-3*
10-20-90 10:20 PM 93 STUDY NUMBER: PH311CP00193 DECODED DOSE: 39317
CORRECTION FACTOR: 1
FILE NAME: PH311-CP-001-93/9

SAMPLE	1	2	3	4	5	6	7	8
NUCLEUS COUNT	64	74	87	128	113	71	89	67
CYTO COUNT #1	46	69	69	92	77	51	72	56
CYTO COUNT #2	42	54	72	92	55	70	78	42
CYTO COUNT #3	45	51	55	93	42	78	50	79
NET VALUE +	19	5	15	35	36	20	11	7
SAMPLE	9	10	11	12	13	14	15	16
NUCLEUS COUNT	78	94	54	57	96	83	61	86
CYTO COUNT #1	59	49	34	46	52	39	74	54
CYTO COUNT #2	59	44	26	51	51	36	42	79
CYTO COUNT #3	54	52	27	45	72	68	36	60
NET VALUE +	19	40	20	6	24	15	19	7
SAMPLE	17	18	19	20	21	22	23	24
NUCLEUS COUNT	91	74	64	75	50	70	70	86
CYTO COUNT #1	51	44	42	46	25	21	73	51
CYTO COUNT #2	55	38	38	75	30	71	40	56
CYTO COUNT #3	71	70	44	79	22	72	77	50
NET VALUE +	20	4	20	0	20	27	20	26
SAMPLE	25	26	27	28	29	30	31	32
NUCLEUS COUNT	59	54	57	65	52	70	71	61
CYTO COUNT #1	45	33	26	28	40	79	24	47
CYTO COUNT #2	45	32	36	52	34	40	38	70
CYTO COUNT #3	76	19	43	42	61	79	60	40
NET VALUE +	14	22	14	10	1	20	10	24
SAMPLE	33	34	35	36	37	38	39	40
NUCLEUS COUNT	67	62	76	67	90	54	45	47
CYTO COUNT #1	39	40	49	44	40	35	22	31
CYTO COUNT #2	46	33	41	54	80	55	21	40
CYTO COUNT #3	38	36	46	36	45	51	28	14
NET VALUE +	21	19	27	10	10	11	17	4

Susan M. Lucenti *4/22/90*
INVESTIGATOR DATE

NOTES: NO: 177.

PHARMACON RESEARCH INTERNATIONAL INC.

DISTRIBUTION OF NET NUCLEAR COUNTS

INVESTIGATOR: SUSAN M. LUCENTI
DATE: 4-23-93
CODE: 0.25 UG/ML STUDY NUMBER: PH311CP00193
DISTRIBUTION FILE NAME: PH311-CP-001-93/0.25

(NET VALUES) (RECURRENCE)

-70	1
-50	1
-48	1
-46	1
-45	1
-43	1
-42	1
-41	1
-39	1
-38	4
-37	0
-36	0
-35	1
-34	1
-33	1
-32	5
-31	5
-30	1
-29	1
-28	4
-27	1
-26	5
-25	8
-24	1
-23	1
-22	4
-21	1
-20	6
-19	0
-18	4
-17	1
-16	7
-15	1
-14	5
-12	6
-11	1
-10	4

Susan M. Lucenti *4-23-93*
INVESTIGATOR DATE

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1.0	1
1.0	1
1.7	1
1.0	1
1.0	1
1.4	1
1.3	1
0	1
(11)	1
4	1
6	1

7 FILES

PH311-CP-001-93/19
PH311-CP-001-93/20
PH311-CP-001-93/21

TOTAL MEAN VALUE: -20.4
TOTAL STANDARD DEV: 10.0

James H. Lumsden 23 Dec 93
INVESTIGATOR DATE

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NOTEBOOK 10:1771

PHARMACON RESEARCH INTERNATIONAL INC.

NUCLEAR AND CYTOPLASMIC COUNTS
RAT HEPATOCYTE PRIMARY CULTURE/DNA REPAIR ASSAY

INVESTIGATOR: SUSAN M. LUCCENTI
DATE: 4-23-93
CODE: 0.25 UG/ML-1 STUDY NUMBER: PH311CP00193 DECODED DOSE: 19317
CORRECTION FACTOR: 1
FILE NAME: PH311-CP-001-93/19

SAMPLE	1	2	3	4	5	6	7	8
NUCLEUS COUNT	47	57	58	44	45	55	51	55
CYTO COUNT #1	78	100	58	70	54	70	59	70
CYTO COUNT #2	52	56	44	70	43	51	51	55
CYTO COUNT #3	47	55	52	55	51	50	55	40
NET VALUE +	-31	-70	-20	-26	-16	-25	-73	-14
SAMPLE	9	10	11	12	13	14	15	16
NUCLEUS COUNT	54	18	42	50	58	70	55	59
CYTO COUNT #1	51	75	58	96	94	76	57	72
CYTO COUNT #2	56	50	52	84	51	57	53	54
CYTO COUNT #3	44	28	36	66	66	50	52	70
NET VALUE +	-37	-17	-16	-40	-36	-40	-72	-11
SAMPLE	17	18	19	20	21	22	23	24
NUCLEUS COUNT	52	49	57	58	70	75	52	50
CYTO COUNT #1	50	55	57	47	58	56	48	40
CYTO COUNT #2	50	57	44	57	48	51	50	55
CYTO COUNT #3	52	51	46	44	40	48	57	51
NET VALUE +	-38	-16	-20	-29	-25	-15	-21	-11
SAMPLE	25	26	27	28	29	30	31	32
NUCLEUS COUNT	57	59	75	57	47	58	51	55
CYTO COUNT #1	56	50	57	46	50	55	59	40
CYTO COUNT #2	59	71	60	49	51	55	55	45
CYTO COUNT #3	59	52	58	47	40	55	54	55
NET VALUE +	-19	-52	-22	-12	-3	-26	-25	-20
SAMPLE	33	34	35	36	37	38	39	40
NUCLEUS COUNT	54	58	58	19	15	16	55	50
CYTO COUNT #1	82	55	58	53	55	72	45	55
CYTO COUNT #2	54	57	56	57	55	42	58	51
CYTO COUNT #3	57	60	52	53	10	29	59	51
NET VALUE +	-48	-78	-34	-48	-53	-26	-10	-10

Susan M. Luccenti 4/23/93
INVESTIGATOR DATE

SAMPLE	41	42	43	44	45	46	47	48
NUCLEUS COUNT	77	60	57	55	53	51	51	50
CYTO COUNT #1	14	19	24	20	15	15	15	14
CYTO COUNT #2	23	20	24	16	22	21	23	23
CYTO COUNT #3	28	22	24	20	29	29	28	26
NET VALUE *	-29	-19	-27	-25	-25	-21	-20	-18

SAMPLE	49	50
NUCLEUS COUNT	56	55
CYTO COUNT #1	20	15
CYTO COUNT #2	20	18
CYTO COUNT #3	27	15
NET VALUE *	-24	7

* NET COUNT = NUCLEUS - MAXIMUM OF CYTO COUNTS
 MEAN NET VALUE = -27.6
 STANDARD DEVIATION = 12.8

Armed M. L. L. L. 45 Nov 13
 INVESTIGATOR DATE

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NOTESBOOK NO: 1771

PHARMACON RESEARCH INTERNATIONAL INC.

NUCLEAR AND CYTOPLASMIC COUNTS
RAT HEPATOCYTE PRIMARY CULTURE/DNA REPAIR ASSAY

INVESTIGATOR: SUSAN M. LUCENT
DATE: 4-23-93
CODE: 0.25 UG/ML-2 STUDY NUMBER: PH311CP00193 DECODED DOSE: 09317
CORRECTION FACTOR: 1
FILE NAME: PH311-CF-001-93/20

SAMPLE	1	2	3	4	5	6	7	8
NUCLEUS COUNT	36	59	47	55	56	59	51	74
CYTO COUNT #1	50	46	55	54	40	60	52	74
CYTO COUNT #2	49	53	62	45	77	57	50	56
CYTO COUNT #3	44	62	60	55	49	50	51	77
NET VALUE +	-17	-4	-18	2	-41	-24	-10	-1
SAMPLE	9	10	11	12	13	14	15	16
NUCLEUS COUNT	54	59	69	47	52	60	48	64
CYTO COUNT #1	86	59	66	50	88	84	87	46
CYTO COUNT #2	91	67	95	56	90	88	70	51
CYTO COUNT #3	76	71	65	63	63	62	76	75
NET VALUE +	-37	-12	-26	-16	-41	-29	-39	-11
SAMPLE	17	18	19	20	21	22	23	24
NUCLEUS COUNT	55	50	40	50	48	51	56	60
CYTO COUNT #1	71	50	62	62	52	58	66	56
CYTO COUNT #2	52	60	59	41	55	57	62	57
CYTO COUNT #3	45	57	45	62	50	47	65	57
NET VALUE +	-38	-10	-19	-29	-7	-7	0	-27
SAMPLE	25	26	27	28	29	30	31	32
NUCLEUS COUNT	51	60	59	55	67	49	77	40
CYTO COUNT #1	84	57	62	40	60	51	80	58
CYTO COUNT #2	88	56	80	58	76	94	77	47
CYTO COUNT #3	75	72	69	60	45	41	82	51
NET VALUE +	-27	-12	-21	-5	-2	-45	-2	-11
SAMPLE	33	34	35	36	37	38	39	40
NUCLEUS COUNT	53	58	29	39	35	41	41	55
CYTO COUNT #1	55	42	43	51	66	66	71	77
CYTO COUNT #2	41	55	49	39	60	57	48	71
CYTO COUNT #3	31	54	54	49	57	49	65	48
NET VALUE +	-8	-16	-20	-22	-31	-25	-20	-42

Susan M. Lucent INVESTIGATOR *4/23/93* DATE

SAMPLE	41	42	43	44	45	46	47	48
NUCLEUS COUNT	54	55	51	58	55	42	45	50
CYTO COUNT #1	51	56	57	44	56	56	55	47
CYTO COUNT #2	50	51	56	51	22	10	55	54
CYTO COUNT #3	50	50	27	55	41	50	59	55
NET VALUE *	-36	1	-26	-15	-15	-14	-10	-5

SAMPLE	49	50
NUCLEUS COUNT	60	57
CYTO COUNT #1	78	74
CYTO COUNT #2	70	54
CYTO COUNT #3	76	43
NET VALUE *	-18	-37

* NET COUNT = NUCLEUS - MAXIMUM OF CYTO COUNTS
 MEAN NET VALUE = -19.7
 STANDARD DEVIATION = 12.6

James H. Hunt *2/16/73*
 INVESTIGATOR DATE

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NOTEBOOK NO: 1771

PHARMACON RESEARCH INTERNATIONAL INC.

NUCLEAR AND CYTOPLASMIC COUNTS
RAT HEPATOCYTE PRIMARY CULTURE/DNA REPAIR ASSAY

INVESTIGATOR: SUSAN M. LUCENTI

DATE: 4-23-93

CODE: 0.25 UG/ML-T

STUDY NUMBER: PH311CP00193 DECODED DOSE: 09317

CORRECTION FACTOR: 1

FILE NAME: PH311-CF-001-93/21

SAMPLE	1	2	3	4	5	6	7	8
NUCLEUS COUNT	47	56	65	66	65	71	63	78
CYTO COUNT #1	57	70	91	93	65	72	69	77
CYTO COUNT #2	52	58	78	83	51	44	67	77
CYTO COUNT #3	59	66	59	105	59	68	64	58
NET VALUE +	-20	-32	-26	-39	0	0	-5	-20
SAMPLE	9	10	11	12	13	14	15	16
NUCLEUS COUNT	45	62	72	26	42	40	49	53
CYTO COUNT #1	50	56	82	39	68	58	59	60
CYTO COUNT #2	40	55	64	55	47	72	61	48
CYTO COUNT #3	35	49	54	72	43	51	50	77
NET VALUE +	-5	0	-10	-46	-26	-32	-12	-14
SAMPLE	17	18	19	20	21	22	23	24
NUCLEUS COUNT	46	40	26	29	39	32	38	40
CYTO COUNT #1	55	67	41	45	53	63	67	81
CYTO COUNT #2	64	64	50	38	47	49	62	75
CYTO COUNT #3	60	76	40	46	42	18	74	73
NET VALUE +	-18	-36	-24	-17	-14	-31	-36	-41
SAMPLE	25	26	27	28	29	30	31	32
NUCLEUS COUNT	38	48	35	26	44	75	50	44
CYTO COUNT #1	56	49	64	68	41	91	74	64
CYTO COUNT #2	53	39	55	61	39	96	75	65
CYTO COUNT #3	60	76	37	54	48	62	79	59
NET VALUE +	-22	-28	-29	-42	0	-21	-29	-25
SAMPLE	33	34	35	36	37	38	39	40
NUCLEUS COUNT	35	31	55	49	36	68	81	58
CYTO COUNT #1	81	33	54	74	68	102	79	73
CYTO COUNT #2	68	68	34	69	71	105	96	40
CYTO COUNT #3	72	41	64	65	62	96	81	61
NET VALUE +	-46	-37	-9	-25	-35	-37	-15	-12

INVESTIGATOR: Susan M. Lucenti DATE: 23 Apr 93

SAMPLE	41	42	43	44	45	46	47	48
NUCLEUS COUNT	54	48	74	45	54	43	50	70
CYTO COUNT #1	49	52	88	58	59	79	66	89
CYTO COUNT #2	57	63	65	51	76	75	63	74
CYTO COUNT #3	72	80	55	79	70	64	55	60
NET VALUE +	-38	-32	-14	-34	-22	-36	-16	-19

SAMPLE	49	50
NUCLEUS COUNT	67	45
CYTO COUNT #1	64	49
CYTO COUNT #2	47	51
CYTO COUNT #3	65	74
NET VALUE +	2	-29

+ NET COUNT = NUCLEUS - MAXIMUM OF CYTO COUNTS
 MEAN NET VALUE = -22.9
 STANDARD DEVIATION = 13.5

James P. H. [Signature] 10 Apr 68
 INVESTIGATOR DATE

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NOTEBOOK 40:171

PHARMAKON RESEARCH INTERNATIONAL INC.

DISTRIBUTION OF NET NUCLEAR COUNTS

INVESTIGATOR: SUSAN M. LUCENTI
DATE: 4-23-93
CODE: 0.5 UG/ML STUDY NUMBER: PH311-CP00193
DISTRIBUTION FILE NAME: PH311-CP-001-93/0.5 UG/ML

(NET VALUES) (RECURRENCE)

-80	1
-81	1
-59	2
-57	1
-54	2
-53	3
-51	3
-50	2
-49	2
-47	1
-46	2
-44	4
-43	1
-42	1
-41	1
-38	2
-37	2
-36	1
-35	2
-34	2
-33	8
-32	1
-31	7
-30	2
-29	5
-28	3
-27	6
-26	2
-25	5
-24	1
-23	6
-22	4
-21	3
-20	3
-19	5
-18	5
-17	5

Susan M. Lucenti *4-23-93*
INVESTIGATOR DATE

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PAGE _____

-16	
-15	
-14	
-13	
-12	4
-11	(1)
-10	(1)
-9	5
-8	4
-7	1
-6	1
-5	
-4	
-3	
-2	
-1	1
0	2
1	
2	

3 FILES

PH311-CP-001-93/16
PH311-CP-001-93/17
PH311-CP-001-93/18

TOTAL MEAN VALUE: -25.8
TOTAL STANDARD DEV: 15.2

James D. Schmitt 4/3/93
INVESTIGATOR DATE

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NOTEBOOK NO:1771

PHARMACON RESEARCH INTERNATIONAL INC.

NUCLEAR AND CYTOPLASMIC COUNTS
RAT HEPATOCYTE PRIMARY CULTURE/DNA REPAIR ASSAY

INVESTIGATOR:SUSAN M. LUCENTI

DATE:4-22-93

CODE:0.5 UG/ML-1

STUDY NUMBER:PH311CP00193 DECODED DOSE:39317

CORRECTION FACTOR : 1

FILE NAME: PH311-CP-001-93/16

SAMPLE	1	2	3	4	5	6	7	8
NUCLEUS COUNT	35	21	26	43	35	35	22	40
CYTO COUNT #1	58	41	33	68	62	60	78	86
CYTO COUNT #2	46	31	21	57	45	58	59	74
CYTO COUNT #3	44	29	34	66	70	44	56	50
NET VALUE *	-23	-20	-8	-25	-35	-25	-46	-14
SAMPLE	9	10	11	12	13	14	15	16
NUCLEUS COUNT	46	40	46	27	22	26	29	24
CYTO COUNT #1	50	49	67	59	26	32	90	43
CYTO COUNT #2	42	42	48	35	25	39	80	52
CYTO COUNT #3	56	27	55	52	41	51	54	62
NET VALUE *	-10	-9	-21	-32	-19	-25	-51	-36
SAMPLE	17	18	19	20	21	22	23	24
NUCLEUS COUNT	22	39	47	25	26	23	30	30
CYTO COUNT #1	61	50	38	47	57	51	62	53
CYTO COUNT #2	66	69	40	35	50	44	40	54
CYTO COUNT #3	47	38	59	47	48	22	63	100
NET VALUE *	-44	-30	-12	-22	-31	-28	-33	-77
SAMPLE	25	26	27	28	29	30	31	32
NUCLEUS COUNT	49	74	24	32	56	35	24	32
CYTO COUNT #1	129	91	65	59	53	48	73	87
CYTO COUNT #2	74	104	32	63	51	36	44	36
CYTO COUNT #3	103	105	37	35	55	31	38	78
NET VALUE *	-80	-31	-41	-31	1	-31	-49	-44
SAMPLE	33	34	35	36	37	38	39	40
NUCLEUS COUNT	18	30	27	40	39	53	30	17
CYTO COUNT #1	29	84	50	52	90	95	24	30
CYTO COUNT #2	27	49	52	51	83	73	49	55
CYTO COUNT #3	51	61	77	51	73	33	59	33
NET VALUE *	-33	-54	-50	-12	-51	-42	-39	-18

Susan M. Lucenti INVESTIGATOR 4-22-93 DATE

SAMPLE	41	42	43	44	45	46	47	48
NUCLEUS COUNT	20	51	76	61	43	44	25	40
CYTO COUNT #1	68	105	79	97	90	91	101	50
CYTO COUNT #2	74	90	95	114	91	101	91	71
CYTO COUNT #3	48	78	90	90	87	87	90	86
NET VALUE *	-51	-54	1	-50	-49	-57	-46	-43

SAMPLE	49	50
NUCLEUS COUNT	20	26
CYTO COUNT #1	41	49
CYTO COUNT #2	57	42
CYTO COUNT #3	41	21
NET VALUE *	-37	-33

* NET COUNT = NUCLEUS - MAXIMUM OF CYTO COUNTS
 MEAN NET VALUE = -33.7
 STANDARD DEVIATION = 16.1

Amos H. Johnson 22 Apr 69
 INVESTIGATOR DATE

NOTEBOOK: 10:1771

PHARMAKON RESEARCH INTERNATIONAL INC.

NUCLEAR AND CYTOPLASMIC COUNTS
RAT HEPATOCYTE PRIMARY CULTURE/DNA REPAIR ASSAY

INVESTIGATOR: SUSAN M. LUCENTI
DATE: 4-23-93
CODE: 0.5 UG/ML-2 STUDY NUMBER: PH311CP00193 DECODED DOSE: 39217
CORRECTION FACTOR: 1
FILE NAME: PH311-CP-001-93/17

SAMPLE	1	2	3	4	5	6	7	8
NUCLEUS COUNT	36	55	51	69	47	55	62	59
CYTO COUNT #1	51	70	78	76	70	62	45	69
CYTO COUNT #2	68	78	81	56	58	53	59	64
CYTO COUNT #3	53	52	73	51	52	63	52	51
NET VALUE *	-32	-20	-30	-7	-20	-8	2	-10
SAMPLE	9	10	11	12	13	14	15	16
NUCLEUS COUNT	36	54	63	62	64	55	59	54
CYTO COUNT #1	64	88	84	53	74	55	58	61
CYTO COUNT #2	74	107	82	60	96	49	52	60
CYTO COUNT #3	59	67	64	44	56	64	56	57
NET VALUE *	-38	-53	-21	2	-32	-9	-19	-27
SAMPLE	17	18	19	20	21	22	23	24
NUCLEUS COUNT	76	52	35	21	38	39	24	41
CYTO COUNT #1	73	68	33	41	58	49	36	59
CYTO COUNT #2	99	75	63	34	56	49	32	40
CYTO COUNT #3	22	79	35	34	48	40	33	40
NET VALUE *	-23	-27	-28	-30	-20	-10	-12	-18
SAMPLE	25	26	27	28	29	30	31	32
NUCLEUS COUNT	38	31	46	42	35	35	34	39
CYTO COUNT #1	50	58	38	59	61	53	50	43
CYTO COUNT #2	36	56	35	59	62	77	43	38
CYTO COUNT #3	38	35	46	64	56	65	50	39
NET VALUE *	-12	-27	0	-22	-27	-22	-16	-5
SAMPLE	33	34	35	36	37	38	39	40
NUCLEUS COUNT	33	28	44	56	59	46	48	43
CYTO COUNT #1	39	30	44	70	55	65	71	53
CYTO COUNT #2	48	33	52	61	60	55	50	38
CYTO COUNT #3	48	37	49	60	45	63	54	56
NET VALUE *	-15	-9	-8	-14	-1	-19	-23	-17

Susan M. Lucenti 20 April 93
INVESTIGATOR DATE

SAMPLE	41	42	43	44	45	46	47	48
NUCLEUS COUNT	58	50	61	57	60	58	44	59
CYTO COUNT #1	42	74	64	59	65	64	75	57
CYTO COUNT #2	61	91	58	24	57	47	56	55
CYTO COUNT #3	44	57	69	22	59	65	60	53
NET VALUE *	-5	-31	-8	-2	-5	-27	-29	-59

SAMPLE	49	50
NUCLEUS COUNT	47	55
CYTO COUNT #1	73	44
CYTO COUNT #2	63	60
CYTO COUNT #3	67	53
NET VALUE *	-26	-27

* NET COUNT = NUCLEUS - MAXIMUM OF CYTO COUNTS
 MEAN NET VALUE = -19
 STANDARD DEVIATION = 12.9

James H. Church 23 Apr 13
 INVESTIGATOR DATE

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PHARMACON RESEARCH INTERNATIONAL INC.

NUCLEAR AND CYTOPLASMIC COUNTS
RAT HEPATOCYTE PRIMARY CULTURE/DNA REPAIR ASSAY

INVESTIGATOR: SUSAN M. LUCENTI

DATE: 4-23-93

CODE: 0.5 UG/ML-3

STUDY NUMBER: PH311CP00193 DECODED DOSE: 39317

CORRECTION FACTOR: 1

FILE NAME: PH311-CP-001-93/18

SAMPLE	1	2	3	4	5	6	7	8
NUCLEUS COUNT	107	91	82	87	71	73	56	79
CYTO COUNT #1	123	85	117	104	89	71	53	45
CYTO COUNT #2	94	92	101	94	80	86	45	50
CYTO COUNT #3	128	93	83	80	89	78	49	40
NET VALUE *	-21	-2	-35	-17	-18	-13	-17	-14
SAMPLE	9	10	11	12	13	14	15	16
NUCLEUS COUNT	44	33	86	99	68	85	66	86
CYTO COUNT #1	43	47	66	143	69	110	111	50
CYTO COUNT #2	44	58	103	158	86	114	116	106
CYTO COUNT #3	59	42	119	102	84	76	76	122
NET VALUE *	-15	-25	-33	-59	-18	-29	-50	-36
SAMPLE	17	18	19	20	21	22	23	24
NUCLEUS COUNT	62	34	42	52	26	26	44	40
CYTO COUNT #1	96	52	75	67	57	51	54	54
CYTO COUNT #2	74	47	56	69	56	49	64	55
CYTO COUNT #3	43	24	19	52	51	51	46	75
NET VALUE *	-34	-18	-33	-17	-31	-25	-20	-11
SAMPLE	25	26	27	28	29	30	31	32
NUCLEUS COUNT	65	38	52	44	55	39	43	53
CYTO COUNT #1	106	57	78	59	74	38	49	39
CYTO COUNT #2	126	67	74	66	58	48	72	31
CYTO COUNT #3	125	57	50	52	58	48	46	31
NET VALUE *	-61	-29	-26	-22	-19	-9	-29	-24
SAMPLE	33	34	35	36	37	38	39	40
NUCLEUS COUNT	70	55	55	58	61	56	41	29
CYTO COUNT #1	54	79	52	65	66	70	84	40
CYTO COUNT #2	87	102	72	86	75	44	85	47
CYTO COUNT #3	71	56	70	78	60	65	57	38
NET VALUE *	-17	-47	-17	-28	-14	-14	-44	-18

Susan M. Lucenti 4/23/93
INVESTIGATOR DATE

SAMPLE	41	42	43	44	45	46	47	48
NUCLEUS COUNT	54	67	67	56	47	56	48	64
CYTO COUNT #1	56	100	78	85	59	70	61	57
CYTO COUNT #2	54	65	59	75	63	58	62	70
CYTO COUNT #3	73	66	73	78	60	57	61	95
NET VALUE *	-19	-33	-11	-29	-16	-14	-14	-31

SAMPLE	49	50
NUCLEUS COUNT	41	66
CYTO COUNT #1	85	75
CYTO COUNT #2	57	74
CYTO COUNT #3	50	58
NET VALUE *	-44	-9

* NET COUNT = NUCLEUS - MAXIMUM OF CYTO COUNTS
 MEAN NET VALUE = -24.6
 STANDARD DEVIATION = 12.7

James P. McNamee 20 Apr 82
 INVESTIGATOR DATE

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NOTEBOOK NO: 1771

PHARMACON RESEARCH INTERNATIONAL INC.

DISTRIBUTION OF NET NUCLEAR COUNTS

INVESTIGATOR: SUSAN M. LUCENTI

DATE: 4-22-93

CODE: 1 UG/ML

STUDY NUMBER: PH311CP00193

DISTRIBUTION FILE NAME: PH311-CP-001-93/1 UG/ML

(NET VALUES) (RECURRENCE)

-78	1
-54	1
-53	1
-52	1
-50	1
-47	1
-46	1
-45	2
-44	2
-43	1
-41	1
-40	2
-37	2
-36	5
-35	2
-34	2
-33	1
-32	1
-31	2
-30	5
-29	5
-28	7
-27	8
-26	4
-25	2
-23	3
-22	5
-21	6
-20	4
-19	4
-18	3
-17	6
-16	4
-15	3
-14	1
-13	3

Handwritten notes:
-25: 23.0, 24.0, 25.0, 26.0, 27.0, 28.0, 29.0, 30.0, 31.0, 32.0, 33.0, 34.0, 35.0, 36.0, 37.0, 38.0, 39.0, 40.0, 41.0, 42.0, 43.0, 44.0, 45.0, 46.0, 47.0, 48.0, 49.0, 50.0, 51.0, 52.0, 53.0, 54.0, 55.0, 56.0, 57.0, 58.0, 59.0, 60.0, 61.0, 62.0, 63.0, 64.0, 65.0, 66.0, 67.0, 68.0, 69.0, 70.0, 71.0, 72.0, 73.0, 74.0, 75.0, 76.0, 77.0, 78.0, 79.0, 80.0, 81.0, 82.0, 83.0, 84.0, 85.0, 86.0, 87.0, 88.0, 89.0, 90.0, 91.0, 92.0, 93.0, 94.0, 95.0, 96.0, 97.0, 98.0, 99.0, 100.0
-23: 23.0, 24.0, 25.0, 26.0, 27.0, 28.0, 29.0, 30.0, 31.0, 32.0, 33.0, 34.0, 35.0, 36.0, 37.0, 38.0, 39.0, 40.0, 41.0, 42.0, 43.0, 44.0, 45.0, 46.0, 47.0, 48.0, 49.0, 50.0, 51.0, 52.0, 53.0, 54.0, 55.0, 56.0, 57.0, 58.0, 59.0, 60.0, 61.0, 62.0, 63.0, 64.0, 65.0, 66.0, 67.0, 68.0, 69.0, 70.0, 71.0, 72.0, 73.0, 74.0, 75.0, 76.0, 77.0, 78.0, 79.0, 80.0, 81.0, 82.0, 83.0, 84.0, 85.0, 86.0, 87.0, 88.0, 89.0, 90.0, 91.0, 92.0, 93.0, 94.0, 95.0, 96.0, 97.0, 98.0, 99.0, 100.0

Susan M. Lucenti *22 Apr 93*
INVESTIGATOR DATE

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PAGE _____

-12	1
-11	1
-10	5
-9	2
-8	4
-7	4
-6	1
-5	1
-4	1
-3	2
-2	4
-1	2
0	1
1	1
2	3
4	1
5	1
6	2
7	1

3 FILES

PH311-CP-001-93/13
PH311-CP-001-93/14
PH311-CP-001-93/15

TOTAL MEAN VALUE: -21.3
TOTAL STANDARD DEV: 14.2

James H. Tinsdale 22 Apr 83
INVESTIGATOR DATE

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NOTEBOOK NO:1771

PHARMAKON RESEARCH INTERNATIONAL INC.

NUCLEAR AND CYTOPLASMIC COUNTS
RAT HEPATOCYTE PRIMARY CULTURE/DNA REPAIR ASSAY

INVESTIGATOR:SUSAN M. LUCENTI
DATE:4-22-93
CODE:1 UG/ML-1 STUDY NUMBER:PH311CP00193 DECODED DOSE:39017
CORRECTION FACTOR : .87
FILE NAME: PH311-CP-001-93/13

SAMPLE	1	2	3	4	5	6	7	8
NUCLEUS COUNT	35.7	27.6	37.4	45.2	48.7	44.4	45.2	47.8
CYTO COUNT #1	58.3	46.1	60	60	52.2	59.2	56.5	70.5
CYTO COUNT #2	67	48.9	42.6	61.8	45.2	53.9	59.2	61.8
CYTO COUNT #3	63.5	33.9	37.4	59.2	56.5	48.7	53.9	68.7
NET VALUE *	-31.3	-18.3	-22.6	-16.6	-7.8	-14.8	-14	-22.7
SAMPLE	9	10	11	12	13	14	15	16
NUCLEUS COUNT	56.5	19.1	9.6	20	11.3	37.4	33.9	28.7
CYTO COUNT #1	75.7	28.7	26.1	60	55.7	50.5	57.4	50.5
CYTO COUNT #2	68.7	26.1	29.6	32.2	42.6	53.1	55.7	46.1
CYTO COUNT #3	57.4	26.1	38.3	6.1	38.4	44.4	38.4	40
NET VALUE *	-19.2	-9.6	-28.7	-40	-44.4	-15.7	-23.5	-21.8
SAMPLE	17	18	19	20	21	22	23	24
NUCLEUS COUNT	27	26.1	30.4	43.5	67	64.4	50.5	35.7
CYTO COUNT #1	63.5	17.4	52.2	41.8	82.6	94	61.8	56.5
CYTO COUNT #2	48.9	33.1	35.7	52.2	80.9	87	57.4	39.1
CYTO COUNT #3	27.8	58.3	34.8	72.2	62.6	94	31.3	34.8
NET VALUE *	-36.5	-32.2	-21.8	-28.7	-15.6	-29.6	-11.3	-20.8
SAMPLE	25	26	27	28	29	30	31	32
NUCLEUS COUNT	47.8	18.3	42.6	41.8	52.2	19.1	31.3	43.5
CYTO COUNT #1	42.6	46.1	33.1	53.9	87	40	76.8	80
CYTO COUNT #2	77.4	35.7	51.3	49.6	81.8	45.2	64.4	54.8
CYTO COUNT #3	60	67.9	55.7	94	53.9	33.1	54.8	34.8
NET VALUE *	-29.6	-49.6	-13.1	-52.2	-34.8	-26.1	-45.3	-36.5
SAMPLE	33	34	35	36	37	38	39	40
NUCLEUS COUNT	49.6	54.8	54.8	40	56.5	65.2	32.2	22.8
CYTO COUNT #1	94	82.6	63.5	49.6	85.3	59.2	69.6	26.1
CYTO COUNT #2	73.1	67.9	69.6	45.2	53.1	72.2	48.7	35.7
CYTO COUNT #3	44.4	67.9	58.3	50.5	53.1	65.2	49.6	33.1
NET VALUE *	-44.4	-27.8	-14.8	-10.5	-28.8	-7	-37.4	-10.1

Susan M. Lucenti 4-22-93
INVESTIGATOR DATE

SAMPLE	41	42	43	44	45	46	47	48
NUCLEUS COUNT	36.5	39.6	27	13	40	36.5	32.2	36.5
CYTO COUNT #1	66.1	34.8	48.7	30.4	45.2	72.2	41.8	114.6
CYTO COUNT #2	66.1	36.5	31.0	24.4	42.6	55.7	50.5	80
CYTO COUNT #3	43.5	54.8	32.2	33.5	57.4	46.1	51.0	36.0
NET VALUE *	-29.6	-25.2	-21.7	-17.4	-17.4	-35.7	-19.1	-78.0

SAMPLE	49	50
NUCLEUS COUNT	53.9	56.5
CYTO COUNT #1	107	87
CYTO COUNT #2	73.9	81.8
CYTO COUNT #3	47	102.7
NET VALUE *	-53.1	-46.2

* NET COUNT = NUCLEUS - MAXIMUM OF CYTO COUNTS
 MEAN NET VALUE = -27.2
 STANDARD DEVIATION = 14.1

James P. Schmitt
 INVESTIGATOR *2002 Nov 19*
DATE

NOTEBOOK NO: 1771

PHARMAKON RESEARCH INTERNATIONAL INC.

NUCLEAR AND CYTOPLASMIC COUNTS
RAT HEPATOCYTE PRIMARY CULTURE/DNA REPAIR ASSAY

INVESTIGATOR: SUSAN M. LUCCENT
DATE: 4-22-93
CODE: 109/ml-2
STUDY NUMBER: PH311CP00190 DECODED DOSE: ~~100 µg/ml~~ ^{375/2}
CORRECTION FACTOR: .95 ^{14.444}
FILE NAME: PH311-CP-001-93/14 ^{28 April 93}

SAMPLE	1	2	3	4	5	6	7	8
NUCLEUS COUNT	37	76.9	35.1	30.4	17.1	40.6	20.9	29.4
CYTO COUNT #1	64.0	102.6	40.8	36	50.0	58.9	40.8	24.7
CYTO COUNT #2	38.9	116.8	35.1	58.9	26.6	57.9	-5.6	31.7
CYTO COUNT #3	63.6	97.8	38	39.9	22.8	47.5	40.8	37
NET VALUE *	-27.6	-39.9	-5.7	-28.5	-32.2	-18.1	-24.7	-7.6
SAMPLE	9	10	11	12	13	14	15	16
NUCLEUS COUNT	39.9	24.7	30.4	25.6	28.5	7.6	12.3	10.4
CYTO COUNT #1	47.5	32.0	24.7	55.1	48.4	19.9	13.0	31.0
CYTO COUNT #2	60.8	45.6	21.8	39.9	40.6	26.6	15.0	24.7
CYTO COUNT #3	49.4	45.6	26.6	40.8	48.4	25.6	15.2	32.0
NET VALUE *	-20.9	-20.9	0.8	-29.5	-19.9	-19	-2.9	-21.9
SAMPLE	17	18	19	20	21	22	23	24
NUCLEUS COUNT	19.9	19	10.4	17.1	16.1	20.9	13.0	19
CYTO COUNT #1	32.0	16.1	19	26.6	23.7	19.9	39.9	38
CYTO COUNT #2	38	27.5	21.8	27.5	28.5	13.7	39.9	46.0
CYTO COUNT #3	33.2	43.7	18	12.0	19	21.8	25.6	43.7
NET VALUE *	-18.1	-24.7	-11.4	-10.4	-12.4	-1.9	-26.6	-27.6
SAMPLE	25	26	27	28	29	30	31	32
NUCLEUS COUNT	33.2	28.5	31.0	47.5	21.8	31.0	22.8	37
CYTO COUNT #1	50.0	42.7	76	40.8	19.9	77.5	65.5	53.0
CYTO COUNT #2	41.8	48.4	57	41.8	32.0	59.2	52.2	54.1
CYTO COUNT #3	30.4	35.1	61.7	36.1	47.5	70.0	56	51.0
NET VALUE *	-17.1	-19.9	-44.7	5.7	-25.7	-46.6	-42.7	-17.1
SAMPLE	33	34	35	36	37	38	39	40
NUCLEUS COUNT	29.4	33.2	58.9	38	53.2	57	44.6	47.5
CYTO COUNT #1	47.5	58.9	90.2	46.5	74.1	73.1	72.0	71.0
CYTO COUNT #2	57	47.5	80.7	50.0	53.2	65.5	58.9	66.5
CYTO COUNT #3	47.5	45.6	93.1	47.5	63.6	47.5	46.5	55.1
NET VALUE *	-27.6	-25.7	-34.2	-12.0	-20.9	-16.1	-27.6	-25.7

Susan M. Luccent
INVESTIGATOR DATE

SAMPLE	41	42	43	44	45	46	47	48
NUCLEUS COUNT	48.4	51.0	40.8	32.7	31.0	57.9	29.4	34.2
CYTO COUNT #1	39	47.5	38	57.5	44.5	73.7	40.8	55.1
CYTO COUNT #2	41.5	53.2	72.2	47.5	38.5	46.5	53.1	75.5
CYTO COUNT #3	37	24.7	64.5	58.5	31.0	59.5	40.8	77.1
NET VALUE +	6.6	-1.9	-71.4	-26.5	-13.0	-12.4	-23.9	-22.9

SAMPLE	49	50
NUCLEUS COUNT	42.7	34.2
CYTO COUNT #1	46.5	53.2
CYTO COUNT #2	49.4	61.7
CYTO COUNT #3	32.0	37
NET VALUE +	-6.7	-27.5

+ NET COUNT = NUCLEUS - MAXIMUM OF CYTO COUNTS
 MEAN NET VALUE = -20.1
 STANDARD DEVIATION = 12.2

James H. Richards *22 Apr 19*
 INVESTIGATOR DATE

PHARMACON RESEARCH INTERNATIONAL INC.
 NUCLEAR AND CYTOPLASMIC COUNTS
 RAT HEPATOCYTE PRIMARY CULTURE/DNA REPAIR ASSAY

INVESTIGATOR: SUSAN M. LUCENTI
 DATE: 4-22-93
 CODE: 1 UG/ML-T STUDY NUMBER: PH311CP00193 DECODED DOSE: 79317
 CORRECTION FACTOR: .95
 FILE NAME: PH311-CP-001-93/15

SAMPLE	1	2	3	4	5	6	7	8
NUCLEUS COUNT	67.4	21.6	25.6	54.1	72.2	72.2	76.9	72.6
CYTO COUNT #1	59.9	26.6	41.6	52.6	91.2	59.7	31.7	77.3
CYTO COUNT #2	57	49.4	51.0	52.7	95.5	92.6	93.6	59.8
CYTO COUNT #3	78.8	40.7	59.8	58.9	68.4	65.5	61.7	76.3
NET VALUE +	-11.4	-27.6	-34.2	-28.5	-19	-10.4	-3.7	1.3
SAMPLE	9	10	11	12	13	14	15	16
NUCLEUS COUNT	72.2	77.9	67.4	64.6	70.3	57	56	57
CYTO COUNT #1	72.2	114.9	89.7	65.5	57	57	52.2	-11.3
CYTO COUNT #2	64.6	95.9	56	74.1	56	47.5	60.8	18
CYTO COUNT #3	71.2	75	64.6	42.7	68.4	64.6	49.4	58.9
NET VALUE +	0	-37	-21.9	-9.5	1.9	-7.3	-4.6	-1.9
SAMPLE	17	18	19	20	21	22	23	24
NUCLEUS COUNT	68.4	55.1	50.2	59.9	57	58.4	54.1	-6.1
CYTO COUNT #1	58.9	51.7	77.9	66.4	90.2	57.4	74.1	45.6
CYTO COUNT #2	70.3	57.4	50.2	76	72.1	48.4	49.4	53.3
CYTO COUNT #3	67.4	63.4	71.2	62.4	66.5	66.5	51.7	75.1
NET VALUE +	-11.9	-23.6	-24.7	-36.1	-35.1	1	-20	-12.3
SAMPLE	25	26	27	28	29	30	31	32
NUCLEUS COUNT	52.7	50.9	90.1	115.9	67.4	51.7	73.9	-11.6
CYTO COUNT #1	59.8	55.1	129.2	114	66.4	75	45.6	93.8
CYTO COUNT #2	48.4	55.1	96.9	68.4	57	77.3	56.3	40.7
CYTO COUNT #3	55.1	55.1	98.7	90.2	59.7	55.5	50.6	71.2
NET VALUE +	-3.6	5.7	-36.1	1.9	-1.9	-16.2	-24.7	-34.2
SAMPLE	33	34	35	36	37	38	39	40
NUCLEUS COUNT	65.5	41.8	74.1	90.2	68.4	70.4	31.7	51.7
CYTO COUNT #1	92.1	42.7	39.3	62.6	71.2	48.4	50.7	52.7
CYTO COUNT #2	78.8	72.2	69.3	35.5	67.4	71.2	55.1	57
CYTO COUNT #3	72.2	55.1	56	61.7	40.6	55.5	24.7	63.4
NET VALUE +	-26.6	-70.4	-15.2	4.7	-2.8	-40.6	-7.3	-3.7

Susan M. Lucenti
 INVESTIGATOR DATE

SAMPLE	41	42	43	44	45	46	47	48
NUCLEUS COUNT	45.7	56	41.8	40.8	48.4	52.7	55.2	43.8
CYTO COUNT #1	40.8	48.4	57.9	52.0	49.7	45.6	56.1	52.2
CYTO COUNT #2	55.1	52.0	55.1	56	50.6	50.0	42.7	59.7
CYTO COUNT #3	44.8	58.4	59.9	70.7	59.9	55.5	53.9	56
NET VALUE +	-1.9	-10.4	-17.1	-19.8	-20.9	-7.6	-27.5	-26.8

SAMPLE	49	50
NUCLEUS COUNT	46.5	42.7
CYTO COUNT #1	72.2	62.7
CYTO COUNT #2	65.5	55.1
CYTO COUNT #3	45.6	55.1
NET VALUE +	-25.7	-20

* NET COUNT = NUCLEUS - MAXIMUM OF CYTO COUNTS
 MEAN NET VALUE = -16.7
 STANDARD DEVIATION = 14.2

James P. H. Smith *1969 Jan 9.3*
 INVESTIGATOR DATE

NOTEBOOK NO: 1771

PHARMANON RESEARCH INTERNATIONAL INC.

DISTRIBUTION OF NET NUCLEAR COUNTS

INVESTIGATOR: SUSAN M. LUCENTI
DATE: 4-22-93
CODE: 2.5 UG/ML STUDY NUMBER: PH311CP00193
DISTRIBUTION FILE NAME: PH311-CP-001-93/2.5 UG/ML

(NET VALUES) (RECURRENCE)

-59	1
-56	1
-54	1
-47	1
-45	1
-43	1
-41	1
-40	1
-39	3
-38	3
-37	3
-36	3
-35	1
-34	4
-32	3
-31	3
-30	4
-29	4
-28	1
-27	3
-26	3
-25	3
-24	7
-23	3
-22	3
-21	1
-20	1
-19	3
-18	3
-17	3
-16	3
-15	3
-14	1
-13	4
-12	4
-11	4
-10	3

Susan M. Lucenti 4-22-93
INVESTIGATOR DATE

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=AGE_____

-9	5
-8	5
-7	5
-6	5
-5	5
-4	7
-3	1
-2	7
-1	3
0	5
1	1
4	5
5	5
6	1
7	1
8	1

3 FILES

PH311-CP-001-93/10

PH311-CP-001-93/11

PH311-CP-001-93/12

TOTAL MEAN VALUE: -17.1

TOTAL STANDARD DEV: 14.3

<u>James M. Lumsden</u>	<u>22 Apr 93</u>
INVESTIGATOR	DATE

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NOTEBOOK NO: 1771

PHARMAKON RESEARCH INTERNATIONAL INC.
NUCLEAR AND CYTOPLASMIC COUNTS
RAT HEPATOCYTE PRIMARY CULTURE/DNA REPAIR ASSAY

INVESTIGATOR: SUSAN M. LUCENT
DATE: 4-22-93
CODE: 2.5 UG/ML-1
STUDY NUMBER: PH311CP00193 DECODED JOSE: 39317
CORRECTION FACTOR: .95
FILE NAME: PH311-CF-001-93/10

SAMPLE	1	2	3	4	5	6	7	8
NUCLEUS COUNT	71.2	68.4	88.0	89.0	85.5	88.0	45.6	78.8
CYTO COUNT #1	76	55.1	80.7	95	54.1	62.7	31.0	61.7
CYTO COUNT #2	47.5	66.5	70.0	85.5	78.8	77.9	51.0	56
CYTO COUNT #3	64.6	72.2	61.7	69.0	96.9	81.7	40.7	70.1
NET VALUE *	-4.8	-3.8	7.6	-5.7	-11.4	6.6	-5.7	5.7
SAMPLE	9	10	11	12	13	14	15	16
NUCLEUS COUNT	44.6	68.4	64.6	59.8	85.5	55.1	77.9	52.0
CYTO COUNT #1	57	59.8	58.9	58.4	74.1	55.1	76.9	70.0
CYTO COUNT #2	26.6	74.1	57.9	51.0	61.7	61.7	77.9	61.7
CYTO COUNT #3	38	61.7	68.4	44.6	80.7	56	39.0	64.6
NET VALUE *	-12.4	-5.7	-3.8	-8.6	4.8	-6.6	-11.4	-19.5
SAMPLE	17	18	19	20	21	22	23	24
NUCLEUS COUNT	76.9	77.9	58.9	40.8	46.5	59.9	29.4	41.5
CYTO COUNT #1	77.9	76	77.9	26.6	50.0	52.0	41.8	60.8
CYTO COUNT #2	88.0	71.2	103.3	37	59.9	28.5	42.7	50.0
CYTO COUNT #3	79.8	57.9	51.0	25.6	34.2	56	37	38
NET VALUE *	-11.4	1.9	-44.6	0.8	-3.8	-16.1	-10.0	-19
SAMPLE	25	26	27	28	29	30	31	32
NUCLEUS COUNT	40.6	55.1	38	27.5	40.8	24.7	35.1	20.7
CYTO COUNT #1	39.9	37	57	31.0	63.6	59.8	26.6	27.0
CYTO COUNT #2	41.8	60.8	62.7	42.7	49.4	57.9	23.7	34.0
CYTO COUNT #3	40.8	55.1	51.0	40.8	40.8	61.7	30.4	29.4
NET VALUE *	-1	-25.7	-24.7	-15.2	-22.8	-37	4.7	-10.5
SAMPLE	33	34	35	36	37	38	39	40
NUCLEUS COUNT	38	34.2	38	51.0	47.5	53.2	48.4	37
CYTO COUNT #1	29.4	41.8	56	46.5	54.1	91.7	57.9	57
CYTO COUNT #2	33.2	32.0	53.2	46.5	50.3	83.6	84.5	36
CYTO COUNT #3	36.1	56	44.6	61.7	54.1	80.7	83.6	20.9
NET VALUE *	1.9	-21.8	-18	-10.4	-6.6	-30.4	-36.1	-20

Susan M. Lucent 4/22/93
INVESTIGATOR DATE

SAMPLE	41	42	43	44	45	46	47	48
NUCLEUS COUNT	48.4	56	42.7	72.2	50.0	46.5	28.5	47.5
CYTO COUNT #1	48.4	56	73.1	55.1	75	43.7	59.8	59.8
CYTO COUNT #2	25.6	50.7	77.9	54.1	58.4	53.2	44.8	55.5
CYTO COUNT #3	55.1	55.2	50.2	56.5	52.2	45.7	48.4	56.4
NET VALUE *	3	3	-35.2	5.7	-24.7	-6.7	-31.0	-22.9

SAMPLE	49	50
NUCLEUS COUNT	40.8	38.9
CYTO COUNT #1	57.9	52.2
CYTO COUNT #2	59.8	46.5
CYTO COUNT #3	56	38
NET VALUE *	-19	-10.0

* NET COUNT = NUCLEUS - MAXIMUM OF CYTO COUNTS
 MEAN NET VALUE = -12.1
 STANDARD DEVIATION = 10

Amund H. Jensen 22 Apr 73
 INVESTIGATOR DATE

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NOTESBOOK NO:1771

PHARMACON RESEARCH INTERNATIONAL INC.

NUCLEAR AND CYTOPLASMIC COUNTS
RAT HEPATOCYTE PRIMARY CULTURE/DNA REPAIR ASSAY

INVESTIGATOR: SUSAN M. LUCENT
DATE: 4-22-93
CODE: 2.5 UG/ML-5
STUDY NUMBER: PH311CP00190 DECODED DOSE: 39317
CORRECTION FACTOR: .94
FILE NAME: PH311-CP-001-93/11

SAMPLE	1	2	3	4	5	6	7	8
NUCLEUS COUNT	45.1	35.7	37.6	60	27.0	24.4	23.5	30.8
CYTO COUNT #1	52.0	53.9	32	66.7	31	46.1	54.5	32
CYTO COUNT #2	68.6	54.9	41.4	84.0	53.9	49.6	49.8	27.7
CYTO COUNT #3	51.1	56.4	49.8	53.6	44.0	46.1	42.0	46.1
NET VALUE +	-23.5	-39.2	-12.2	-21.6	-36.6	-25.4	-31	4.7
SAMPLE	9	10	11	12	13	14	15	16
NUCLEUS COUNT	50.8	27.0	18.8	43.2	38.5	40.4	45.1	49.6
CYTO COUNT #1	39.5	45.1	58.0	38.5	48.9	47.9	47	46.1
CYTO COUNT #2	44.2	34.8	53.0	44.2	34.8	35.7	51.7	55.5
CYTO COUNT #3	38.5	27.0	39.5	43.2	36.7	45.1	62	58.0
NET VALUE +	0.0	-17.3	-39.5	-1	-10.4	-7.5	-16.9	-8.5
SAMPLE	17	18	19	20	21	22	23	24
NUCLEUS COUNT	28.2	23.5	36.7	38.5	20.7	37.6	42.0	48.9
CYTO COUNT #1	45.1	47.9	27.0	41.4	26.0	40.4	52.6	64.9
CYTO COUNT #2	62	50.8	40.4	37.6	25.4	35.7	83.7	56.4
CYTO COUNT #3	52.6	35.7	49.8	22.6	29.1	47	47.9	63
NET VALUE +	-33.8	-27.0	-10.1	-2.9	-8.4	-9.4	-41.4	-16
SAMPLE	25	26	27	28	29	30	31	32
NUCLEUS COUNT	63	56.4	101.5	63	74.0	58.0	76.1	44.2
CYTO COUNT #1	70.5	78	94.9	100.6	95.9	79.9	62	72.4
CYTO COUNT #2	92.1	74.0	126	110	101.5	74.0	64.9	84.0
CYTO COUNT #3	90.2	73.0	101.5	119.4	79	54.5	83.7	68.0
NET VALUE +	-29.1	-21.6	-24.5	-56.4	-27.2	-21.6	-7.6	-40.4
SAMPLE	33	34	35	36	37	38	39	40
NUCLEUS COUNT	23.5	32.9	17.9	37.6	41.4	29.1	26.0	45.1
CYTO COUNT #1	62	87.4	45.1	42.0	73.0	45.1	47	88.4
CYTO COUNT #2	82.7	68.6	57.0	52.6	70.5	53.6	60.2	91.8
CYTO COUNT #3	47.9	63.9	64.9	63	66.7	67.7	52.6	73.0
NET VALUE +	-59.2	-54.5	-47	-25.4	-31.9	-38.6	-33.9	-40.0

Susan M. Lucent INVESTIGATOR *4/22/93* DATE

SAMPLE	41	42	43	44	45	46	47	48
NUCLEUS COUNT	28.2	52.8	53.8	51	48.4	44.2	56.7	52
CYTO COUNT #1	42.3	83	91.2	87.7	84.9	23.5	48.9	58.8
CYTO COUNT #2	60.2	81.1	33.7	87.7	68.2	56.7	42.3	42.3
CYTO COUNT #3	46.1	69.6	76.1	86.7	43.2	46.1	47.9	53.8
NET VALUE +	-32	-17	-37.8	-36.7	-24.5	-1.9	-12.2	-21.8

SAMPLE	49	50
NUCLEUS COUNT	23.5	18.8
CYTO COUNT #1	49.8	44.2
CYTO COUNT #2	39.5	44.2
CYTO COUNT #3	52	51
NET VALUE +	-26.3	-25.4

+ NET COUNT = NUCLEUS - MAXIMUM OF CYTO COUNTS
 MEAN NET VALUE = -24.4
 STANDARD DEVIATION = 15.2

August H. J. J. J. *20 Aug 58*
 INVESTIGATOR DATE

NOTEBOOK NO:1771

PHARMAKON RESEARCH INTERNATIONAL INC.

NUCLEAR AND CYTOPLASMIC COUNTS
RAT HEPATOCYTE PRIMARY CULTURE/DNA REPAIR ASSAY

INVESTIGATOR:SUSAN M. LUCENTI

DATE:4-22-93

CODE:2.5 UG/ML-C

STUDY NUMBER:PH311CP00193 DECODED DOSE:39317

CORRECTION FACTOR : .94

FILE NAME: PH311-CF-001-93/12

SAMPLE	1	2	3	4	5	6	7	8
NUCLEUS COUNT	35.7	26.0	32	23.5	25.4	48.9	31	29.1
CYTO COUNT #1	48.9	10.0	69.6	38.5	33.7	43.2	41.4	63
CYTO COUNT #2	50.6	20.7	32.9	47.9	41.4	62	47.9	38.5
CYTO COUNT #3	60.9	28.2	10.0	30.1	49.8	63.9	47	32
NET VALUE *	-28.2	-1.9	-37.6	-24.4	-24.4	-15	-16.9	-30.9
SAMPLE	9	10	11	12	13	14	15	16
NUCLEUS COUNT	28.2	75.2	38.5	30.1	33.8	33.8	36.7	16.9
CYTO COUNT #1	40.2	105.0	36.7	25.4	29.1	26.0	37.6	18.8
CYTO COUNT #2	34.8	101.5	21.6	32	30.1	25.4	37.6	17.9
CYTO COUNT #3	33.8	25.4	28.2	25.4	35.7	39.5	29.1	20.7
NET VALUE *	-15	-30.1	1.8	-1.9	-1.9	-5.7	-9.9	-3.8
SAMPLE	17	18	19	20	21	22	23	24
NUCLEUS COUNT	16.9	25.4	22.6	24.4	16	59.2	20.7	30.1
CYTO COUNT #1	19.7	34.8	19.7	14.1	32	53.6	32.9	52.6
CYTO COUNT #2	20.5	34.8	25.4	24.4	32.9	41.4	34.8	35.7
CYTO COUNT #3	20.7	27.0	26.0	28.2	22.6	50.8	15	46.1
NET VALUE *	-0.0	-9.4	-3.7	-3.8	-16.9	5.6	-14.1	-22.5
SAMPLE	25	26	27	28	29	30	31	32
NUCLEUS COUNT	52.6	49.8	45.1	40.4	42.0	44.2	49.8	41.4
CYTO COUNT #1	63.9	55.0	63	51.7	48.9	52.6	44.2	30.8
CYTO COUNT #2	50.6	63	61.1	61.1	49.8	68.6	49.8	43.2
CYTO COUNT #3	38.5	57.0	69.6	63	71.4	63	39.5	26.0
NET VALUE *	-11.0	-13.2	-24.5	-22.6	-29.1	-24.4	0	-1.8
SAMPLE	33	34	35	36	37	38	39	40
NUCLEUS COUNT	32.9	32.9	40.4	20.7	53.6	52.6	38.5	36.7
CYTO COUNT #1	36.7	50.8	37.6	36.7	67.7	67.7	32	41.4
CYTO COUNT #2	25.4	47	42.3	39.5	80.8	65.8	35.7	53.6
CYTO COUNT #3	15	27.0	40.4	39.5	87.4	52.6	43.2	29.1
NET VALUE *	-3.8	-17.9	-1.9	-18.8	-33.8	-15.1	-4.7	-16.9

Susan M. Lucenti 4/22/93
INVESTIGATOR DATE

SAMPLE	41	42	43	44	45	46	47	48
NUCLEUS COUNT	49.8	42.5	45.1	16.9	21.6	20.7	35.7	22.6
CYTO COUNT #1	73.5	44.2	55.5	48.9	23.5	56.4	50.8	25.4
CYTO COUNT #2	79	44.2	60.2	39.5	38.5	53.6	56.4	23.5
CYTO COUNT #3	87.4	59.2	55.5	31	33.8	45.1	60.2	28.2
NET VALUE *	-37.6	-16.9	-15.1	-32	-16.9	-35.7	-24.5	-5.6

SAMPLE	49	50
NUCLEUS COUNT	41.4	27.3
CYTO COUNT #1	43.2	32
CYTO COUNT #2	22.6	32.9
CYTO COUNT #3	40.4	39.5
NET VALUE *	-1.8	-12.2

* NET COUNT = NUCLEUS - MAXIUM OF CYTO COUNTS
 MEAN NET VALUE = -15
 STANDARD DEVIATION = 11.7

David H. Schmitt *100 Apr 82*
 INVESTIGATOR DATE

OTC Vol. No. 110

OTC Docket Number 75N-0183 (triclosan)
September 12, 1994

Ciba-Geigy Corporation
Chemicals Division
Greensboro, N.C. 27419

Stankowski, L.F., et al. Ames/Salmonella Plate Incorporation Assay on Test Article 39316 (CC# 14663-09). Pharmakon USA. Study No. PH301-CP-001-93. Dec. 2, 1993.

Study Summary

This study was designed to evaluate the mutagenic potential of Triclosan in five strains of Salmonella typhimurium (TA1535, TA1537, TA1538, TA98, and TA100) in the presence and absence of an exogenous metabolic activation system (S9). The S9 mixture included 6% (v/v) Aroclor 1254-induced male Sprague-Dawley rat liver homogenate with the appropriate buffer and cofactors. Ames test measures the ability of a test article to induce reverse mutations at specific histidine loci in various strains of Salmonella. To determine the validity of the test, triplicate cultures of each tester strain were evaluated with known positive chemicals, including sodium azide (10 µg/plate in TA1537), and 2-nitrogluorene (5 µg/plate in TA1538 and TA98); 2-anthramine (2.5 µg/plate) was evaluated in all five tester strains in the presence of S9. In addition, triplicate cultures of each strain were evaluated with the appropriate solvent in the presence and absence of S9 to serve as negative solvent controls. To ensure the quality of aseptic technique and the sterility of the solvents, compounds and equipment, standard contamination evaluations were performed with each assay.

The highest dose used in the mutation assay was the concentration at which Triclosan induced a moderate inhibition of bacterial growth and was determined in a preliminary toxicity screen. Revertant colonies were enumerated on an Artek electronic colony counter interfaced with an IBM PC/AT computer for data acquisition. Solvent and positive controls were scored first, and Triclosan-treated colonies were scored only if the average negative control values were within historical control range. A positive result is defined as a statistically significant, dose-dependent increase in the number of histidine-independent revertants with at least one dose level inducing a mutant frequency that is two-fold the spontaneous solvent control value.

Toxicity of Triclosan was determined in a preliminary prescreen by evaluating the growth of the background lawn and/or frequency of spontaneous revertants. Triclosan was dissolved in dimethylsulfoxide (DMSO) and appropriate aliquots were added to the culture to

achieve concentrations of 50; 167; 500; 1670; and 5000 µg/plate in the absence of S9. Duplicate cultures were evaluated for each of these concentrations and for DMSO control in TA1538 and TA100. Triclosan produced complete toxicity at all concentrations tested. Therefore, lower concentrations were tested in a second prescreen and included 0.0050, 0.0167, 0.0500, 0.167, 0.500, 1.67, 5.00, 16.7, and 50.0 µg/plate in the presence and absence of S9. Results of this second prescreen indicated that Triclosan was not toxic to TA1538 strain at concentrations of 0.0050 to 1.67 µg/plate with S9 and 0.0050 µg/plate without S9 or to TA100 strain at concentrations of 0.0050 to 0.500 µg/plate with S9 and 0.0050 and 0.0167 µg/plate without S9.

Mutagenicity Assay

Based on the results of the prescreening studies, the following concentrations were selected for the mutagenicity assay: 0.0500, 0.167, 0.500, 1.67, 2.50, and 5.00 µg/plate with S9 and 0.00167, 0.00500, 0.0167, 0.0500, 0.100, 0.167 µg/plate without S9. Revertant frequencies for all concentrations of Triclosan in all tester strains with and without S9 approximated or were less than those observed in the concurrent negative control cultures. Inhibited growth occurred in all tester strains at concentrations of 2.50 and 5.00 µg/plate with S9 and 0.050, 0.010, and/or 0.167 µg/plate without S9. Only three concentration levels were acceptable for testing TA100 without S9. Thus, Triclosan was evaluated at lower concentrations, including 0.00167, 0.00050, 0.00167, 0.0050, 0.0100, 0.0167, 0.0333, 0.0500, 0.100, and 0.167 µg/plate without S9. Inhibited growth occurred at concentrations ≥ 0.0333 µg/plate. The revertant frequency was statistically increased in TA100 at a concentration of 0.0050 µg/plate. Although statistically significant this increase was not considered biologically relevant since it was only 1.5-fold control value and a similar trend was not apparent at higher concentrations. Nevertheless, Triclosan was re-evaluated in TA100 using the same concentrations. Inhibition of growth occurred again at concentrations ≥ 0.0333 µg/plate and the frequency of revertants in this final test was similar to control values.

In summary, the results of the present study indicate that Triclosan was not mutagenic in five strains of Salmonella typhimurium with or without exogenous metabolic activation.

PHARMAKON USA

P.O. Box 609
Waverly, Pennsylvania 18471-0609
Tel: (717) 586-2411
Fax: (717) 586-3450



AMENDED FINAL REPORT

Ames/Salmonella Plate Incorporation
Assay on Test Article 39316
(CC #14663-09)

Pharmakon Study No. PH 301-CP-001-93
Colgate-Palmolive Study No. CP-93-012

Reason for Amended Report: Correction of a typographical
error that appeared on pages 1
and 10.

Submitted to

Colgate-Palmolive
Piscataway, New Jersey


Leon F. Stankowski, Jr., Ph.D.
Study Director

2 DECEMBER 1993
Date


Test Facility Management

December 2, 1993
Date

101193

AMENDED FINAL REPORT

Pharmakon Study No. PH 301-CP-001-93

Colgate-Palmolive Study No. CP-93-012

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AMENDED FINAL REPORT

Pharmakon Study No. PH 301-CP-001-93

Colgate-Palmolive Study No. CP-93-012

SUMMARY

Test article 39316 was evaluated in the Ames/Salmonella Plate Incorporation Assay to determine its ability to induce reverse mutations at selected histidine loci in five tester strains of Salmonella typhimurium (TA1535, TA1537, TA1538, TA98 and TA100) in the presence and absence of an exogenous metabolic activation system (S9). Toxicity of 39316 was first evaluated in a prescreen by treating duplicate cultures of strains TA1538 and TA100 with 39316 at doses of 50.0, 167, 500, 1670 and 5000 µg/plate in the absence of S9. Results of the prescreen indicated 39316 produced complete toxicity in both tester strains at all doses evaluated. In addition, the test article precipitated from solution at a dose of 5000 µg/plate. Therefore, 39316 was re-evaluated in a second toxicity prescreen at doses of 0.00500, 0.0167, 0.0500, 0.167, 0.500, 1.67, 5.00, 16.7 and 50.0 µg/plate in the presence and absence of S9. Results of this second prescreen indicated 39316 was not toxic to strain TA1538 at doses of 0.00500 to 1.67 µg/plate with S9 and 0.00500 µg/plate without S9, or to strain TA100 at doses of 0.00500 to 0.500 µg/plate with S9 and 0.00500 and 0.0167 µg/plate without S9. Inhibited growth (characterized by a reduced background lawn and/or the presence of pindot colonies) was observed in strain TA1538 at doses of 5.00 µg/plate with S9 and 0.0167 to 0.500 µg/plate without S9, and in strain TA100 at doses of 1.67 and 5.00 µg/plate with S9 and 0.0500 to 5.00 µg/plate without S9. Complete toxicity was observed in strain TA1538 at doses of 16.7 and 50.0 µg/plate with S9 and 1.67 to 50.0 µg/plate without S9, and in strain TA100 at doses of 16.7 and 50.0 µg/plate with and without S9.

Based upon these findings, 39316 was evaluated in triplicate cultures in strains TA1535, TA1537, TA1538, TA98 and TA100 at doses of 0.0500, 0.167, 0.500, 1.67, 2.50 and 5.00 µg/plate with S9, and 0.00167, 0.00500, 0.0167, 0.0500, 0.100 and 0.167 µg/plate without S9. Six dose levels of 39316 were evaluated with and without S9 in the event of excessive toxicity at the highest dose levels evaluated in the mutation assay. The S9 mixture included 6% (v/v) Aroclor 1254-induced male Sprague-Dawley rat liver homogenate with the appropriate buffer and cofactors. Inhibited growth again was observed in all tester strains at doses of 2.50 and/or 5.00 µg/plate with S9, and 0.0500, 0.100 and/or 0.167 µg/plate without S9. Revertant frequencies for all doses of 39316 in all tester strains with and without S9 approximated or were less than those observed in the concurrent negative control cultures.

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SUMMARY (continued)

Due to excessive toxicity, however, only three acceptable dose levels remained for strain TA100 without S9. Therefore, 39316 was re-evaluated in strain TA100 at doses of 0.000167, 0.000500, 0.00167, 0.00500, 0.0100, 0.0167, 0.0333, 0.0500, 0.100 and 0.167 $\mu\text{g}/\text{plate}$ without S9. Inhibited growth again was observed at doses ≥ 0.0333 $\mu\text{g}/\text{plate}$. A statistically significant increase in revertant frequency, to approximately 1.5-fold control values, was observed at a dose of 0.00500 $\mu\text{g}/\text{plate}$. However, this increase apparently was not dose dependent (following a quadratic or higher-order response), and all observed revertant frequencies were within or below acceptable historical negative control values.

Therefore, 39316 was re-evaluated in strain TA100 in a second retest under identical conditions. Inhibited growth again was observed at doses ≥ 0.0333 $\mu\text{g}/\text{plate}$. Revertant frequencies for all doses of 39316 in this final retest approximated or were less than control values. No statistically significant or dose-dependent increases in revertant frequencies were observed. Thus, the slight increase observed in strain TA100 without S9 in the first retest is considered to be a statistical aberration due to random fluctuation of the spontaneous revertant frequency. All positive and negative control values in all assays were within acceptable limits.

The results of the present study indicate that sample #39316 was not mutagenic in the Ames/Salmonella Plate Incorporation Assay under the conditions, and according to the criteria, of the test protocol.

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Colgate-Palmolive Study No. CP-93-012

STUDY DESCRIPTIVE

Sponsor: Colgate-Palmolive
909 River Road
Piscataway, NJ 08855-1343

Study Number: PH 301-CP-001-93

Study Initiation: March 9, 1993

Date Assay Initiated: March 15, 1993

Date Assay Completed: March 31, 1993

Pharmakon Reference: Notebook #1630: page 3
#1729: page 305
#1779: pages 404-442

Study Monitor: Gabriela Adam-Rodwell, Ph.D.,
Colgate-Palmolive

Study Director: Leon F. Stankowski, Jr., Ph.D.,
Pharmakon Research International, Inc.

Technical Performance: Leon F. Stankowski, Jr., Ph.D., Teresa
A. Polinsky, M.S., Kathryn F. McLaren,
B.S., Diane M. Messina, A.A., and David
A. Schlosser

PURPOSE AND RATIONALE

This assay measures the ability of a test article to induce reverse mutations at specific histidine loci in various tester strains of Salmonella typhimurium (Ames, et al., 1975; Maron and Ames, 1983; Maron, et al., 1981). Five different Salmonella tester strains (TA1535, TA1537, TA1538, TA98 and TA100) are used to evaluate each test article over a wide range of concentrations in the presence and absence of an exogenous metabolic activation system (S9). Chemicals capable of inducing mutations have been demonstrated to increase the frequency of histidine revertants in selected Salmonella tester strains in the presence and/or absence of S9.

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TEST ARTICLE

The test article 39316, CC# 14663-09, was received by Pharmakon Research on February 26, 1993 in a clear glass container and was described as a white powder. Standard laboratory precautions were used in handling the test article. Information regarding technical aspects of the test article, as provided by the sponsor, was recorded in the sponsor's file. For the purposes of this study, the test article was stored at room temperature in the container received from the sponsor. At the time of testing the test article was described as a white powder. There was no apparent change in the physical state of the test article during storage. All required dilutions were made with dimethyl sulfoxide (DMSO), Lot #902873, supplied by Fisher Scientific (Fairlawn, NJ).

Dilutions were prepared the day of the test and typically are used within two hours of preparation. A 1-mL of each test article carrier mixture from the initial mutation assay was returned to the sponsor for subsequent analysis for concentration. The initial sampling deviated from the protocol specifications (25-mL samples requested). However, this protocol deviation did not preclude concentration analyses. For the two retests, 25-mL aliquots of the 5.00 mg/mL stock solutions, as well as 5.00 µg/mL dilutions prepared from them, were sent to the Sponsor for concentration analysis. The analytical chemistry report is included in Appendix I.

TEST SYSTEM

Test Organism/ Salmonella typhimurium - TA1535, TA1537,
Strains: TA1538, TA98 and TA100

Source: Dr. Bruce N. Ames
University of California
Biochemistry Dept.
Berkeley, California 94720

All strains contain a uvrB deletion mutation (affecting DNA excision repair), as well as an rfa mutation (affecting membrane permeability). In addition, strains TA98 and TA100 contain the plasmid pKM101, which enhances the error-prone DNA repair system normally present in this organism. Strains TA1535 and TA100 detect base pair substitution mutations affecting the hisG locus. In contrast, strains

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TA1538 and TA98 detect frameshift mutations affecting the hisD locus, while TA1537 detects frameshift mutations at the hisC locus. All tester strains were checked for the presence of the appropriate genetic markers on approximately a monthly basis.

Test Cultures

Fresh cultures for mutagenesis testing were prepared by quickly thawing a vial of frozen working stock cultures of each tester strain and transferring the culture to 25 mL of Oxoid Nutrient Broth #2. After growth for approximately 6 hours at 37°C in an orbital shaking incubator, samples of each culture were diluted 1:4 in de-ionized water and optical densities were determined at 650 nm. Cultures with optical densities of 0.40 to 0.60 (approximately $1-2 \times 10^9$ cells/mL; representative of cells in late exponential or early stationary phase) were utilized for this study.

Control Articles

Triplicate cultures of each strain were evaluated with the appropriate solvent in the presence and absence of S9 to serve as negative solvent controls. In order to validate the responsiveness of the test system, triplicate cultures of each tester strain were evaluated with known positive control chemicals. Positive controls evaluated in the absence of S9 were specific for each strain and included: TA1535 and TA100 - sodium azide (10.0 µg/plate; Sigma Chemical Company, Lot #56C-0263); TA1537 - 9-aminoacridine (150 µg/plate; Sigma Chemical Company, Lot #030567) and TA1538 and TA98 - 2-nitrofluorene (5.00 µg/plate; Aldrich Chemical Company, Lot #2610PE). 2-Anthramine (2.50 µg/plate; Sigma Chemical Company, Lot #33F-0816) was evaluated in all five tester strains in the presence of S9.

Metabolic Activation (S9) Mixture

The exogenous metabolic activation (S9) mixture contained 8 mM MgCl₂, 33 mM KCl, 4 mM NADP, 5 mM glucose-6-phosphate, 100 mM Na₂HPO₄ (pH 7.4) and 6% (v/v) Aroclor 1254-induced male Sprague-Dawley rat liver homogenate. The liver homogenate was prepared at Pharmakon Research according to recommended procedures (Ames, et al., 1975; Pharmakon SOP PH-351). For this and the last several lots of S9 prepared at Pharmakon, 6% S9 homogenate (v/v; final) has been used in

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the metabolic activation mixture. The concentration of liver homogenate in the metabolic activation mixture is optimized for each lot of S9 prepared, using three positive control articles (2-acetylaminofluorene, 2-anthramine, and benzo[a]pyrene; performed according to Pharmakon SOP PH-351).

TOXICITY PRESCREEN

Toxicity of the test article was determined in a preliminary toxicity prescreen by evaluating the growth of the background lawn and/or frequency of spontaneous revertants. The test article was evaluated at doses of 50.0, 167, 500, 1670 and 5000 µg/plate in the absence of S9. Each test article dose, as well as the appropriate solvent control, was evaluated in duplicate cultures in strains TA1538 and TA100. However, the test article produced complete toxicity in both tester strains at all doses evaluated. In addition, the test article precipitated from solution at a dose of 5000 µg/plate. Therefore, 39316 was re-evaluated at doses of 0.00500, 0.0167, 0.0500, 0.167, 0.500, 1.67, 5.00, 16.7 and 50.0 µg/plate in the presence and absence of S9.

Treatment with Test and Control Articles

Treatment was performed by combining 0.1 mL tester strain, 0.1 mL of the appropriate concentration of the test article or solvent and 2 mL of molten top agar (supplemented with 0.5 mM histidine/0.5 mM biotin). Cultures treated in the presence of S9 (in the second toxicity prescreen only) contained 0.5 mL of the S9 mixture. The tubes were vortexed and the mixture was poured onto minimal glucose plates, evenly distributed, and allowed to solidify. Within an hour the plates were inverted and incubated in the dark at 37°C for 48 hours. All cultures/plates were identified using computer-generated adhesive labels that included information regarding study number, date, strain, test/control article, and ±S9.

Scoring

Following the 48-hour incubation, the background lawn and spontaneous revertants were scored for normal, inhibited or no growth (Tables 1 and 2, pages 12 and 13). Inhibited growth was characterized by the absence of a confluent bacterial lawn and/or the presence of pindot colonies.

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MUTATION ASSAY

Salmonella which have undergone reversion to his⁺ form colonies in the absence of histidine. In contrast, his⁻ Salmonella can only undergo a limited number of doublings (due to the histidine supplement in the top agar) and form the typical background lawn. Mutation assays were performed in triplicate cultures in all five tester strains for each test article dose, as well as positive and solvent controls. Following incubation for 48 hours, revertant colonies were enumerated with an automated colony counter. Test article 39316 initially was evaluated at doses of 0.0500, 0.167, 0.500, 1.67, 2.50 and 5.00 µg/plate with S9, and 0.00167, 0.00500, 0.0167, 0.0500, 0.100 and 0.167 µg/plate without S9. The test article subsequently was re-evaluated twice in strain TA100 at doses of 0.000167, 0.000500, 0.00167, 0.00500, 0.0100, 0.0167, 0.0333, 0.0500, 0.100 and 0.167 µg/plate without S9.

Treatment with Test and Control Articles

Treatment for the mutation assay was performed exactly as described in the toxicity prescreen, except that the test and control articles were evaluated in triplicate cultures in all five tester strains in the presence and absence of S9.

Bacterial Contaminant Evaluation

To ensure the quality of aseptic technique, as well as the sterility of solvents, compounds and equipment, standard contamination evaluations were performed with each assay. The solvent, top agar, S9 mix, and highest dose of the test article were evaluated at the same volumes used in the assay. The test article, solvent and S9 mix were evaluated as in the mutation assay, but in the absence of added Salmonella. Top agar was also plated alone on minimal glucose plates. All plating was done in triplicate. Plates were incubated for 48 hours at 37°C and then scored for bacterial growth.

Scoring

Revertant colonies were enumerated on an Artek electronic colony counter interfaced with an IBM PC/AT computer for data acquisition. Solvent and positive controls were scored first, and test article treated cultures were scored only if

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the average negative control values were within historical ranges ($\bar{X} \pm 2SD$; see below). The results are summarized in Tables 3-5 (pages 14-16).

Historical Data - Spontaneous Revertants*

<u>Strain</u>	<u>S9</u>	<u>n</u>	<u>Average ($\pm 1SD$)</u>	<u>Range ($\bar{X} \pm 2SD$)</u>
TA1535	-	275	9.64 \pm 2.80	4.04 - 15.2
	+	275	10.2 \pm 2.80	4.55 - 15.8
TA1537	-	277	7.84 \pm 2.66	2.51 - 13.2
	+	262	9.14 \pm 2.79	3.56 - 14.7
TA1538	-	287	5.13 \pm 2.43	0.269 - 9.99
	+	291	12.2 \pm 3.83	4.53 - 19.9
TA98	-	286	19.3 \pm 5.22	8.91 - 29.8
	+	298	27.7 \pm 6.78	14.1 - 41.2
TA100	-	292	86.6 \pm 18.0	50.7 - 123
	+	294	98.8 \pm 17.9	63.0 - 135

*January 1, 1990 - February 28, 1993

Evaluation Criteria

A positive result is defined as a statistically significant, dose-dependent increase in the number of histidine-independent revertants with at least one dose level inducing a revertant frequency that is two-fold the spontaneous solvent control value. Statistical analyses were performed using the program developed by Snee and Irr (1981), with significance established at the 95% confidence limit. If the test article does not induce a statistically significant, dose-dependent increase in revertant frequency, but does induce a revertant frequency at one dose level that is two-fold the spontaneous control value, the result is considered equivocal. A negative result is defined as the absence of a statistically significant or dose-dependent increase in the number of histidine-independent revertants.

Statistical analyses are performed only when a 50% increase in revertant frequency, relative to the concurrent negative controls, is observed (doses producing moderate/severe or severe toxicity are excluded from statistical analyses due

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to excessive toxicity). This 50% "trigger" was selected based upon the normal, spontaneous variation observed among replicate negative control cultures (see previous page), as well as spontaneous fluctuation observed in this laboratory among groups of cultures treated with a variety of test articles judged to be negative in this assay.

Thus, any observed revertant frequencies for test article-treated cultures that are within 50% of control values are considered to approximate control values. Similarly, any revertant frequencies that are more than 50% above control values, but are not statistically significant, also are considered to approximate control values.

Records Maintained

All correspondence pertinent to the study between the sponsor and Pharmakon Research International, Inc., the protocol, amendments to the protocol, raw data, test article dispensation reports, quality assurance reports and the final report are maintained in the Pharmakon Archives.

Good Laboratory Practice Statement

This study was conducted in compliance with the Good Laboratory Practice Regulations for non-clinical laboratory studies as developed by the U.S. Food and Drug Administration (21 CFR, Part 58), the Organisation for Economic Co-operation and Development (OECD) Guidelines for Testing Chemicals (ISBN 92-64-12221-4), and the U.S. Environmental Protection Agency (40 CFR, Parts 160 and 792). There were no deviations from the GLP Regulations which affected the quality or integrity of the study. Q.A.U. findings derived from the inspections during the conduct of the study and from the audit of the final report are documented and have been provided to the study director and the test facility management.

RESULTS AND DISCUSSION

Toxicity of 39316 was first evaluated in a prescreen by treating duplicate cultures of strains TA1538 and TA100 with 39316 at doses of 50.0, 167, 500, 1670 and 5000 µg/plate in the absence of S9. Results of the prescreen (Table 1, page 12) indicated 39316 produced complete toxicity in both tester strains at all doses evaluated. In addition, the test article precipitated from solution at a dose of 5000

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µg/plate. Therefore, 39316 was re-evaluated in a second toxicity prescreen at doses of 0.00500, 0.0167, 0.0500, 0.167, 0.500, 1.67, 5.00, 16.7 and 50.0 µg/plate in the presence and absence of S9. Results of this second prescreen (Table 2, page 13) indicated 39316 was not toxic to strain TA1538 at doses of 0.00500 to 1.67 µg/plate with S9 and 0.00500 µg/plate without S9, or to strain TA100 at doses of 0.00500 to 0.500 µg/plate with S9 and 0.00500 and 0.0167 µg/plate without S9. Inhibited growth (characterized by a reduced background lawn and/or the presence of pindot colonies) was observed in strain TA1538 at doses of 5.00 µg/plate with S9 and 0.0167 to 0.500 µg/plate without S9, and in strain TA100 at doses of 1.67 and 5.00 µg/plate with S9 and 0.0500 to 5.00 µg/plate without S9. Complete toxicity was observed in strain TA1538 at doses of 16.7 and 50.0 µg/plate with S9 and 1.67 to 50.0 µg/plate without S9, and in strain TA100 at doses of 16.7 and 50.0 µg/plate with and without S9.

Based upon these findings, 39316 was evaluated in triplicate cultures in strains TA1535, TA1537, TA1538, TA98 and TA100 at doses of 0.0500, 0.167, 0.500, 1.67, 2.50 and 5.00 µg/plate with S9, and 0.00167, 0.00500, 0.0167, 0.0500, 0.100 and 0.167 µg/plate without S9. Six dose levels of 39316 were evaluated with and without S9 in the event of excessive toxicity at the highest dose levels evaluated in the mutation assay. The S9 mixture included 6% (v/v) Aroclor 1254-induced male Sprague-Dawley rat liver homogenate with the appropriate buffer and cofactors. Inhibited growth again was observed in all tester strains at doses of 2.50 and/or 5.00 µg/plate with S9, and 0.0500, 0.100 and/or 0.167 µg/plate without S9. Revertant frequencies for all doses of 39316 in all tester strains with and without S9 approximated or were less than those observed in the concurrent negative control cultures (Table 3, page 14).

Due to excessive toxicity, however, only three acceptable dose levels remained for strain TA100 without S9. Therefore, 39316 was re-evaluated in strain TA100 at doses of 0.000167, 0.000500, 0.00167, 0.00500, 0.0100, 0.0167, 0.0333, 0.0500, 0.100 and 0.167 µg/plate without S9. Inhibited growth again was observed at doses ≥0.0333 µg/plate. A statistically significant increase in revertant frequency, to approximately 1.5-fold control values, was observed at a dose of 0.00500 µg/plate (Table 4, page 15). However, this increase apparently was not dose dependent

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(following a quadratic or higher-order response), and all observed revertant frequencies were within or below acceptable historical negative control values.

Therefore, 39316 was re-evaluated in strain TA100 in a second retest under identical conditions. Inhibited growth again was observed at doses ≥ 0.0333 $\mu\text{g}/\text{plate}$. Revertant frequencies for all doses of 39316 in this final retest approximated or were less than control values (Table 5, page 16). No statistically significant or dose-dependent increases in revertant frequencies were observed. Thus, the slight increase observed in strain TA100 without S9 in the first retest is considered to be a statistical aberration due to random fluctuation of the spontaneous revertant frequency. All positive and negative control values in all assays were within acceptable limits.

CONCLUSION

The results of the present study indicate that sample #39316 was not mutagenic in the Ames/Salmonella Plate Incorporation Assay under the conditions, and according to the criteria, of the test protocol.

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Ames, B.N., J. McCann, and E. Yamasaki (1975) Methods for detecting carcinogens and mutagens with the Salmonella/microsome mutagenicity test, Mutation Res., 31:347-364.

Maron, D.M. and B.N. Ames (1983) Revised methods for the Salmonella mutagenicity test, Mutation Res., 113:173-215.

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TABLE 1. Original Toxicity Prescreen

<u>Dose (μg/plate)</u>	<u>Background Growth¹</u>	
	<u>TA1538</u>	<u>TA100</u>
0.00 ²	+	+
50.0	-	-
167	-	-
500	-	-
1670	-	-
5000 ^{ppt}	-	-

¹Evaluated in the absence of S9 only (duplicate plates).
Background growth evaluated for normal (+), inhibited (\pm)
or no growth (-).

²Solvent control (100 μ L/plate DMSO).

^{ppt}Test article precipitated from solution.

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TABLE 2. Second Toxicity Prescreen

<u>Dose (μg/plate)</u>	<u>Background Growth¹</u>			
	<u>TA1538</u>		<u>TA100</u>	
	<u>-S9</u>	<u>+S9</u>	<u>-S9</u>	<u>+S9</u>
0.00 ²	+	+	+	+
0.00500	+	+	+	+
0.0167	\pm^a/b	+	+	+
0.0500	\pm^a/b	+	\pm^a/b	+
0.167	\pm^c	+	\pm^c	+
0.500	$\pm^c/-$	+	\pm^c	+
1.67	-	+	\pm^c	\pm^a/b
5.00	-	\pm^c	\pm^c	\pm^c
16.7	-	-	-	-
50.0	-	-	-	-

¹Evaluated in the absence of S9 only (duplicate plates).
Background growth evaluated for normal (+), inhibited (\pm) or no growth (-).

²Solvent control (100 μ L/plate DMSO).

^aSlight toxicity.

^bModerate toxicity.

^cSevere toxicity.

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TABLE 3. Summary Data - Original Assay

CONTROLS						
AVERAGE REVERTANTS/PLATE						
SOLVENT CONTROLS	S9	TA1535	TA1537	TA1538	TA98	TA100
DMSO (100 UL)	(-)	11 (4)	6 (1)	6 (3)	16 (3)	85 (13)
DMSO (100 UL)	(+)	7 (2)	7 (2)	8 (3)	26 (6)	111 (3)
POSITIVE CONTROLS (UG/PL)						
SODIUM AZIDE	10.0 (-)	1295*(56)	--- (---)	--- (---)	--- (---)	805*(79)
9-AMINOACRIDINE	150 (-)	--- (---)	1206*(107)	--- (---)	--- (---)	--- (---)
2-NITROFLUORENE	5.00 (-)	--- (---)	--- (---)	606*(41)	532*(39)	--- (---)
2-ANTHRAMINE	2.50 (+)	112*(15)	419*(296)	1632*(244)	2162*(120)	2142*(52)
TEST ARTICLE: 39316						
AVERAGE REVERTANTS/PLATE						
DOSE LEVEL (UG/PL)	S9	TA1535	TA1537	TA1538	TA98	TA100
0.00167	(-)	6 (3)	5 (2)	4 (1)	19 (2)	94 (7)
0.00500	(-)	5 (2)	5 (1)	5 (1)	17 (2)	95 (16)
0.0167	(-)	11 (4)	4 (1)	3 (1)	19 (5)	67 (9)
0.0500	(-)	4 (1)	3 (1)a	1 (1)a/b	23 (6)	7 (1)b/c
0.100	(-)	1 (1)a/b	0 (1)c	0 (0)c	3 (2)a/b	0 (0)c
0.167	(-)	0 (1)c	0 (0)c	0 (0)c	0 (0)b/c	0 (0)c
0.0500	(+)	9 (2)	6 (2)	13 (3)	27 (9)	111 (17)
0.167	(+)	10 (2)	6 (3)	12 (4)	19 (1)	97 (8)
0.500	(+)	8 (3)	3 (1)	13 (4)	28 (2)	70 (10)
1.67	(+)	5 (4)	1 (0)	3 (3)	17 (3)	32 (5)
2.50	(+)	6 (1)	3 (1)	5 (1)a	21 (6)	39 (12)a
5.00	(+)	3 (3)a/b	0 (0)a/b	0 (0)c	12 (5)a/b	12 (7)b/c

*Positive Response: $\geq 2X$ Solvent (TA1535, TA1537, TA1538, TA98, TA100)

Data Reported as: Mean (Standard Deviation)

a/b/c = slight/moderate/severe toxicity.

No precipitate.

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TABLE 4. Summary Data - First Retest

CONTROLS		
AVERAGE REVERTANTS/PLATE		
SOLVENT CONTROLS	S9	TA100
DMSO (100 UL)	(-)	80 (6)
POSITIVE CONTROLS (UG/PL)		
SODIUM AZIDE	10.0 (-)	1061*(7)
TEST ARTICLE: 39316		
AVERAGE REVERTANTS/PLATE		
DOSE LEVEL (UG/PL)	S9	TA100
0.000167	(-)	101 (12)
0.00050	(-)	97 (25)
0.00167	(-)	98 (6)
0.00500	(-)	121 (28)
0.0100	(-)	108 (15)
0.0167	(-)	74 (12)
0.0333	(-)	39 (7)a
0.0500	(-)	15 (3)a/b
0.100	(-)	6 (2)c
0.167	(-)	0 (1)c

*Positive Response: $\geq 2X$ Solvent (TA100)
Data Reported as: Mean (Standard Deviation)
a/b/c = slight/moderate/severe toxicity.
No precipitate.

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TABLE 5. Summary Data - Second Retest

CONTROLS		
AVERAGE REVERTANTS/PLATE		
SOLVENT CONTROLS	S9	TA100
DMSO (100 UL)	(-)	75 (13)
POSITIVE CONTROLS (UG/PL)		
SODIUM AZIDE	10.0 (-)	1088*(55)
TEST ARTICLE: 39316		
AVERAGE REVERTANTS/PLATE		
DOSE LEVEL (UG/PL)	S9	TA100
0.000167	(-)	81 (13)
0.00050	(-)	77 (4)
0.00167	(-)	91 (13)
0.00500	(-)	91 (16)
0.0100	(-)	93 (6)
0.0167	(-)	75 (9)
0.0333	(-)	33 (8)a
0.0500	(-)	7 (6)a/b
0.100	(-)	3 (2)c
0.167	(-)	0 (0)c

*Positive Response: $\geq 2X$ Solvent (TA100)
Data Reported as: Mean (Standard Deviation)
a/b/c = slight/moderate/severe toxicity.
No precipitate.

AMENDED FINAL REPORT

Pharmakon Study No. PH 301-CP-001-93

Colgate-Palmolive Study No. CP-93-012

PROTOCOL DEVIATIONS

Analytical
Chemistry:

(pages 2-3)

Original Statement

Twenty-five mL aliquots of the test article-solvent mixture will be collected from all test solutions prepared for the study and shipped to the Sponsor for analysis of concentration; a 25 mL aliquot of solvent (DMSO) will be also shipped to the Sponsor.

Corrected Statement

One-mL aliquots of the test article carrier mixtures, as well as the solvent control, will be collected from all test solutions prepared for the initial mutation assay and shipped to the Sponsor for analysis of concentration; 25-mL aliquots of the 5.00 mg/mL stock solutions, the 5.00 µg/mL dilutions prepared from them, and the solvent control, will be sent to the Sponsor for concentration analysis for the subsequent retests in strain TA100 without S9.

Reason for
Deviations:

One-mL aliquots of the test article carrier mixtures and the solvent control were returned for the initial mutation assay due to a technical oversight. Sample sizes were increased to 25-mL for the two subsequent retests in strain TA100, but were limited to the 5.00 mg/mL stock solutions, the 5.00 µg/mL dilutions prepared from them, and the solvent control at the request of the Study Monitor (all dosing solutions used


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PROTOCOL DEVIATIONS

Reason for
Deviations:
(continued)

in these two retests were reported to be
below the limits of detection and unable
to be analyzed).



Leon F. Stankowski, Jr., Ph.D.
Study Director

2 December 1993
Date

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PROTOCOL AMENDMENT


Toxicity
Prescreen:
(pages 5-7)

Additional Statement


The test article will be re-evaluated in a second toxicity prescreen at doses of 0.00500, 0.0167, 0.0500, 0.167, 0.500, 1.67, 5.00, 16.7 and 50.0 μ g/plate in the presence and absence of S9.

Reason for
Amendment:

The test article produced complete toxicity at all doses evaluated in the original toxicity prescreen. In consultation with the Sponsor, a second toxicity prescreen was performed at the doses specified above. Each dose was evaluated with and without S9, based upon the previous finding of significant differences in toxicity in the presence and absence of S9 (personal communication from the Study Monitor).


Leon F. Stankowski, Jr., Ph.D.
Study Director

25 June 1993
Date


Gabriela Adam-Rodwell, Ph.D.
Study Monitor

6/24/93
Date

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QUALITY ASSURANCE UNIT STATEMENT

Study Director: Leon F. Stankowski, Jr., Ph.D.

The Quality Assurance Unit conducted the inspections listed below and reported the results to the study director and to management on the dates indicated.

The following inspections were performed:

<u>Interval</u>	<u>Date</u>
<u>Plating Phase</u>	March 23, 1993
<u>Scoring Phase</u>	March 25, 1993
<u>Reporting Phase</u>	March 31, 1993 May 28, 1993 June 11, 1993
<u>Amended Final</u>	October 22, 1993

Date QAU Report Issued

To Study Director

March 31, 1993
May 28, 1993
June 11, 1993
October 22, 1993

To Management

March 31, 1993
May 28, 1993
June 11, 1993
October 22, 1993

Date of last QAU facility inspection: September 16, 1993



Quality Assurance

2 December 93
Date

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COMPLIANCE STATEMENT

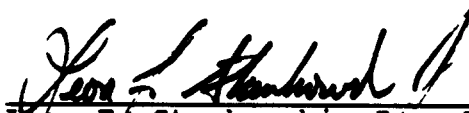
This study was conducted in compliance with the Principles of Good Laboratory Practice (GLP) as promulgated by the following regulatory agencies:

U.S. Food and Drug Administration, as stated in the Federal Register, 21 CFR Part 58.

U.S. Environmental Protection Agency as stated in the Federal Register, 40 CFR Parts 160 and 792.

Organisation for Economic Co-operation and Development Guidelines for Testing Chemicals (OECD), ISBN 92-64-12221-4.

"To the best of my knowledge, this study was conducted in accordance with applicable Good Laboratory Practice regulations; there were no deviations from these regulations that impacted on study conclusions."


Leon F. Stankowski, Jr., Ph.D.
Study Director

2 DECEMBER 1993
Date

AMENDED FINAL REPORT

Pharmakon Study No. PH 301-CP-001-93

Colgate-Palmolive Study No. CP-93-012

APPENDIX I.

ANALYTICAL CHEMISTRY REPORT

AMENDED FINAL REPORT

Pharmakon Study No. PH 301-CP-001-93
Colgate-Palmolive Study No. CP-93-012

ANALYTICAL CHEMISTRY REPORT

INTRODUCTION

Potential genotoxic effect of Sample No. 39316 was evaluated in Ames/*Salmonella* Plate Incorporation Assay. The study was conducted at Pharmakon Research International, Inc. (Pharmakon Study No. PH 301-CP-001-93, Colgate Study No. CP 93-0012). The test article was characterized by determining the infrared spectrum (IR), melting point, and purity (alkalimetric assay) prior to the study initiation. In addition, a certificate of analysis was provided by the manufacturer and is maintained in the study file at Colgate-Palmolive Company.

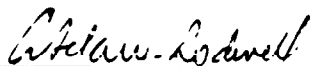
METHODOLOGY

The analytical method for determination of test article concentration in the carrier mixture was validated prior to the study initiation. This method confirmed with SPI LAB 7612-05 and is maintained on files at Colgate-Palmolive Company. Concentration analyses were performed on samples prepared at Pharmakon Research International, Inc. The test article was dissolved in dimethylsulfoxide (DMSO) at concentrations ranging from 0.00167 µg/ml to 5000 µg/ml. Concentrations below 5 µg/ml were too low for the analysis method. Therefore, samples were collected from each dosing solution with a concentration above 5 µg/ml and shipped to Colgate-Palmolive Company on the day of preparation (March 23, 26, and 29, 1993).

RESULTS AND DISCUSSION

Infrared spectrum, melting point, and purity were within specifications for the test article indicating that the bulk chemical was stable.

The results of concentration analyses are presented in Table 1. The test article recovery was within ± 11 of the nominal concentration for solutions with concentrations ranging from 25 to 5000 µg/ml. In contrast, percent recovery from solutions with lower concentrations was, in general, greater than recovery of the test article from solutions with higher concentrations.



Gabriela Adam-Rodwell, Ph.D.
Research Associate, PSA

Date May 20, 1993



Thomas Wolf, Ph.D.
Head of QUA

Date May 20, 1993

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Pharmakon Study No. PH 301-CP-001-93

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TABLE 1

Concentration Verification Analysis Data
for Sample No. 39316 in DMSO Solutions

Test Article	Nominal Concentration (µg/ml)	Actual Concentration (µg/ml)	Recovery %
Solutions prepared on 3/23/93 and analyzed on 3/30/93			
DMSO control	0	0.01	NA
39316-1	5000	5290	106
-2	50	55.4	111
-3	25	27.3	109
-4	16.7	18.8	113
-5	5	5.62	112
-6	1.67	1.81	108
-7	1.00	1.22	122
-8	0.50	0.59	118
-9 -11 concentration too low for analysis method			
Solutions prepared on 3/26/93 and analyzed on 3/30/93			
DMSO control	0	0.005	NA
39316	5000	5220	104
39316	5	5.66	113
Solutions prepared on 3/29/93 and analyzed on 3/30/93			
DMSO control	0	0.005	NA
39316	5000	5260	105
36316	5	5.32	106

NA - not applicable

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APPENDIX II.
STUDY PROTOCOL

AMENDED FINAL REPORT

Pharmakon Study No. PH 301-CP-001-93

PHARMAKON Colgate-Palmolive Study No. CP-93-012

PHARMAKON
Research International, Inc.
P.O. Box 600
Waverly, Pennsylvania 18471
Telephone (610) 845-1234
Telex 155 3451

Protocol-301STD

Ames/Salmonella Plate Incorporation Assay

Sponsor: Colgate-Palmolive
909 River Road
Piscataway, NJ 08855-1343

Testing Facility: Pharmakon Research International, Inc.
Waverly, PA 18471

Test Facility
SOP Number: PH-301

Study No.: PH 301-CP-001-93

Colgate-Palmolive
Study No.: CP# 93-012

Purpose of the Study: To evaluate the ability of a test article to induce reverse mutations in five *Salmonella typhimurium* tester strains in the presence and absence of an exogenous mammalian metabolic activation system (S9).

This study protocol was designed to comply with the Organisation for Economic Co-operation and Development (OECD) Guidelines for Testing Chemicals, ISBN 92-64-12221-4, as well as the U.S. Environmental Protection Agency, Federal Register, Vol. 50, No. 188, Friday, September 27, 1985.

Ownership of the Study: The Sponsor owns the study. All raw data, analysis, and reports are the property of the Sponsor. If it becomes necessary to make changes in the approved protocol, the revisions and the reasons for change will be documented, reported to the Sponsor, and will become part of the permanent file for the study. Protocol amendments must have signed approval from the Sponsor prior to issuance of the final report.

Study Monitor: Gabriela Adam-Rodwell, Ph.D., Colgate-Palmolive

Study Director: Leon F. Stankowski, Jr., Ph.D.

AMENDED FINAL REPORT

Pharmakon Study No. PH 301-CP-001-93

Colgate-Palmolive Study No. CP-93-012

Protocol-301

Ames/Salmonella Plate Incorporation Assay

O.A.U.

Responsible

Personnel:

Leslie J. Pinnell, M.S.

Rationale for

Test System:

Chemicals capable of inducing mutations have been shown to increase the reversion frequency at the histidine locus in selected tester strains of Salmonella typhimurium (Ames, et.al., 1975).

Date of

Performance:

The proposed date of study initiation is one week from the receipt of the test article and signed protocol. A draft report will be submitted for review to the Sponsor approximately two weeks following completion of the study. The Sponsor will be supplied with three copies of the final report, one with original signatures.

Good Laboratory

Practice

Statement:

This study will be conducted in compliance with the Good Laboratory Practice Regulations for non-clinical laboratory studies as developed by the U.S. Food and Drug Administration (21 CFR, Part 58), the Organisation for Economic Co-operation and Development (OECD) Guidelines for Testing Chemicals (ISBN 92-64-12221-4), the U.S. Environmental Protection Agency (40 CFR, Parts 160 and 792), and any subsequent revisions.

Records

Maintained:

All correspondence pertinent to the study between the Sponsor and Pharmakon Research, protocol, amendments to the protocol, raw data, test article weight or volume dispensation reports, quality assurance reports and the final report will be maintained in the Pharmakon Research Archives.

Raw Data:

Pharmakon Research Notebook standard forms or computer generated results.

Analytical

Chemistry:

Analysis and stability of the test article and test article carrier mixture is the responsibility of the Sponsor.

AMENDED FINAL REPORT

Pharmakon Study No. PH 301-CP-001-93

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Ames/Salmonella Plate Incorporation Assay

Twenty-five mL aliquots of the test article-solvent mixture will be collected from all test solutions prepared for the study and shipped to the Sponsor for analysis of concentration; a 25 mL aliquot of solvent (DMSO) will be also shipped to the Sponsor.

TEST SYSTEM

Organism: Salmonella typhimurium

Tester Strains: TA1535, TA1537, TA1538, TA98 and TA100

Source: Dr. Bruce N. Ames, University of California, Biochemistry Dept., Berkeley, CA 94720

Genetic Characteristics: All strains contain a uvrB deletion mutation (affecting DNA excision repair), as well as an rfa mutation (affecting membrane permeability). In addition, strains TA98 and TA100 contain the plasmid pKM101, which enhances the error-prone DNA repair system normally present in this organism. Strains TA1535 and TA100 detect base pair substitution mutations affecting the hisG locus. In contrast, strains TA1538 and TA98 detect frameshift mutations affecting the hisD locus, while TA1537 detects frameshift mutations at the hisC locus. All tester strains are checked for the presence of the appropriate genetic markers on approximately a monthly basis.

The Salmonella typhimurium tester strains are plated and checked for retention of their phenotypic characteristics using recommended procedures (Ames, et al., 1975; EPA, 1982; Maron and Ames, 1983; OECD, 1981) according to Standard Operating Procedure PH-339 on approximately a monthly basis. Phenotypic characteristics evaluated include the requirement of histidine for growth,

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Protocol-301

Ames/Salmonella Plate Incorporation Assay

crystal violet sensitivity, ampicillin resistance and UV sensitivity. The plates are incubated for 24 hours, at which time they are examined for the retention of the phenotypic markers.

Storage:

The tester strains are maintained at a temperature below -60°C, and with aliquots reserved as master or stock cultures.

Frozen Working Stock Cultures:

In order to avoid the effects of surface thawing and re-freezing of frozen permanent vials of bacterial stock, frozen working stock cultures are employed as a source of inoculum for mutagenesis testing. Frozen working stock cultures are prepared by scraping a wooden applicator stick over the surface of frozen master cultures and inoculating the scrapings into 25 mL of Oxoid Nutrient Broth #2. The cultures are grown for 6-10 hours at approximately 37°C in a shaker incubator. Following the 6- to 10-hour growth period, 1 mL aliquots of the culture (containing approximately 8% DMSO) are dispensed into Nunc vials, quick frozen in liquid N₂ or an ethanol-dry ice bath, and then stored at below -60°C. These frozen working stock cultures can be used as a source of inoculum for mutagenesis testing for approximately one year. New frozen working stock cultures are always made from frozen master cultures.

Working Cultures:

Fresh cultures for mutagenesis testing are prepared by quickly thawing a vial of frozen working stock cultures of each tester strain and transferring an aliquot of the culture to 125 mL screw-capped Erlenmeyer flasks containing 25 mL of Oxoid Nutrient Broth #2. The cultures are grown for approximately 6-10 hours at approximately 37°C in a shaker

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Ames/Salmonella Plate Incorporation Assay

incubator, shaking at approximately 120 rpm. Following a 1:4 dilution in de-ionized water, optical densities of the cultures are determined at 650 nm. Cultures are used when the optical densities have reached approximately 0.4-0.6 (late exponential or early stationary phase; approximately $1-2 \times 10^9$ cells/mL). Cultures are maintained on ice and then allowed to warm to room temperature before use.

TEST AND CONTROL ARTICLES

Negative (Solvent)
Controls:

All tester strains are plated with the appropriate solvent in the presence and absence of metabolic activation to serve as negative solvent controls.

Positive
Controls:

Positive controls to be evaluated in the absence of S9 are: TA1535 and TA100 - sodium azide (10.0 μ g/plate); TA1537 - 9-amino-acridine (150 μ g/plate); and TA1538 and TA98 - 2-nitrofluorene (5.00 μ g/plate). 2-Anthramine (2.50 μ g/plate) will be evaluated in all five tester strains in the presence of S9.

Test Article:

The test article will be dissolved in DMSO at a concentration of 25-100 mg/mL, depending on the homogeneity of the test solutions.

EXPERIMENTAL PROCEDURES

Aseptic
Technique:

All aseptic techniques, where possible, are carried out in a biological safety cabinet.

Toxicity
Prescreen:

Toxicity of the test article is determined in a preliminary toxicity prescreen by evaluating the growth of the background lawn and/or frequency of spontaneous revertants. If adequate solubility is achieved, the test article will be evaluated at doses of 50.0, 167, 500, 1670 and 5000 μ g/plate in the absence of S9. Each test article dose, as well as the appropriate solvent

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Ames/Salmonella Plate Incorporation Assay

control, will be evaluated in duplicate cultures in strains TA1538 and TA100 without S9. Treatments will be performed by combining 2 mL top agar (supplemented with 0.5mM histidine/0.5mM biotin), 0.1 mL tester strain and 0.1 mL or the appropriate volume of test article or solvent in sterile glass tubes preheated to approximately 45°C (up to 0.2 mL DMSO or 2.0 mL aqueous solvents may be used). The tubes are vortexed and the mixture is poured onto minimal glucose plates, evenly distributed, and allowed to solidify. Within an hour the plates are inverted and incubated in the dark at approximately 37°C for 48 hours. Following the 48-hour incubation, the background lawn and spontaneous revertants are scored for normal, inhibited or no growth. Inhibited growth is characterized by the absence of a confluent bacterial lawn and/or the presence of pindot colonies.

All cultures/plates are identified using computer-generated adhesive labels that contain information regarding study number, date, strain test/control article, S9, etc.

The test article dose found to produce moderate inhibition of bacterial growth in the preliminary toxicity screen will be the highest dose evaluated in the mutation assay. A minimum of five test article dose levels will be evaluated in each assay. If no toxicity is observed, a maximum of 10,000 µg/plate is considered acceptable. However, if limited by solubility, the test article will be used at the highest dose possible, and semi-log dilutions will be prepared for the lower doses. A minimum of 4 dose levels are required for an acceptable assay. If toxicity is too severe and fewer than 4 dose levels are

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Protocol-301

Ames/Salmonella Plate Incorporation Assay

available for evaluation, the assay will be repeated using lower test article doses.

Plate
Incorporation
Assay:

The plate incorporation assay uses five histidine auxotrophs of Salmonella typhimurium - strains TA1535, TA1537, TA1538, TA98 and TA100. The Ames Test is designed to detect specific locus mutations. The mutations detected include base pair substitutions, frameshift mutations, and small deletions and insertions within the target gene. Salmonella which have undergone reversion to his⁺ form colonies in the absence of histidine. In contrast, his⁻ Salmonella can only undergo a limited number of doublings (due to the histidine supplement in the top agar) and form the typical background lawn. Following incubation for 48 hours, revertant colonies are enumerated with an automated colony counter. All mutation assays are performed in triplicate cultures in all five tester strains for each test article dose, as well as positive and solvent controls.

Treatment with
Test and Control
Articles:

Treatment for the mutation assay will be performed exactly as described in the toxicity prescreen, except that the test and control articles will be evaluated in triplicate cultures in all five strains in the presence and absence of an exogenous metabolic activation system (S9). Cultures treated in the presence of S9 also contain 0.5 mL of the S9 mixture. The S9 mixture contains 8mM MgCl₂, 33mM KCl, 4mM NADP, 5mM glucose-6-phosphate, 100mM Na₂HPO₄ (pH 7.4) and Aroclor 1254-induced male Sprague-Dawley rat liver homogenate (S9). The S9 concentration is optimized for each lot of S9 used.

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Bacterial
Contaminant
Control:

To insure the quality of aseptic technique and also the sterility of solvents, test article and equipment, standard contamination evaluations are conducted with each assay. These contamination evaluations, each performed in triplicate, include the top dose of test article, as well as the top agar, solvent and S9 mix at the same volumes as in the assay. The test article, solvent or S9 mix are individually added to 2 mL supplemented top agar and poured onto minimal glucose plates. Top agar alone is also poured onto minimal glucose plates. Plates are incubated for 48 hours and scored for contamination.

Data Recording:

Standard form (Data Summary Sheet).

Scoring:

In scoring the assay, the positive and negative controls are evaluated first. If the negative control values do not fall within the range of acceptable historical values ($\bar{X} \pm 2SD$), or the positive controls do not produce at least a doubling in revertant frequencies, the remaining plates for that strain are not scored and the assay is repeated for that strain. For the test article treated cultures, the background lawn and spontaneous revertants are evaluated for normal, inhibited or no growth.

Evaluation:

In most tests with the Salmonella typhimurium Assay, results are either clearly positive or clearly negative. A positive result is defined as a statistically significant, dose-dependent increase in the number of histidine-independent revertants with at least one dose level inducing a mutant frequency that is two-fold the spontaneous solvent control value. Statistical analysis will be performed (if necessary) using the program(s) developed by Snee and Irr (1981) and/or Wilkinson (1986), with significance

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Ames/Salmonella Plate Incorporation Assay

established at the 95% confidence limit. If the test article does not induce a statistically significant, dose-dependent increase in revertant frequency but does induce a revertant frequency at one dose level that is two-fold the spontaneous control value, the result will be considered equivocal. A negative result is defined as the absence of a statistically significant or dose-dependent increase in the number of histidine-independent revertants.

Statistical analyses are performed only when a 50% increase in revertant frequency, relative to the concurrent negative controls, is observed. This 50% "trigger" was selected based upon the normal, spontaneous variation observed among replicate negative control cultures, as well as spontaneous fluctuation observed in this laboratory among groups of cultures treated with a variety of test article judged to be negative in this assay.

All equivocal or positive results are repeated in a confirmatory assay at no additional cost to the Sponsor. However, if S9 optimization is required, this will be at additional cost to the Sponsor.

S9 Optimization:

A test article may produce an equivocal response in the presence of S9 because of the well-documented role that S9 concentration plays in determining the mutagenicity of indirect-acting mutagens (either enhancing or decreasing their mutagenic potency). In the case of an equivocal result with S9 activation, it is recommended that the optimum S9 concentration for the particular test article be determined. The method employed utilizes the Salmonella tester strain(s) that gave the equivocal results in the initial assay, and the test article dose that gave the greatest increase in revertant frequency relative

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Protocol-301

Ames/Salmonella Plate Incorporation Assay

to the solvent control value in the initial mutation assay. However, the concentrations of S9 homogenate evaluated in the S9 mix are 0.5, 1.0, 2.0 and 4.0 times that utilized initially. The level of S9 maximizing the mutagenic response will be used in a confirmatory assay with the strain(s) exhibiting increased revertant frequencies.

Bibliography:

Ames, N., J. McCann and E. Yamasaki (1975) Methods for Detecting Carcinogens and Mutagens with the Salmonella/Mammalian-Microsome Mutagenicity Test, Mutation Res., 31:347-364.

EPA Health Effect Guidelines (1982).
Maron, D., J. Katzenellenbogen and B.N. Ames (1981) Compatibility of organic solvents with the Salmonella/Microsome Test, Mutation Res., 88:343-350.

Maron, D.M. and B.N. Ames (1983)
Revised methods for the Salmonella mutagenicity test, Mutation Res., 113:173-215.

Organisation for Economic Co-operation and Development (1981) Guidelines for Testing Chemicals, ISBN 92-64-12221-4.

Snee, R.D. and J.D. Irr (1981) Design of a statistical method for the analysis of mutagenesis at the hypoxanthine guanine phosphoribosyl transferase locus of cultured Chinese hamster ovary cells, Mutation Res., 85:77-93.

Wilkinson, L. (1986) Systat: the system for statistics, Systat, Inc., Evanston, IL.

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AMENDED FINAL REPORT

Pharmakon Study No. PH 301-CP-001-93
Colgate-Palmolive Study No. CP-93-012

Protocol-301
Ames/Salmonella Plate Incorporation Assay

Test Article: Sample #: 39316
CC# 14663-09

Analysis of Purity/Stability: Analysis of the purity and stability of the test article is the responsibility of the Sponsor.

Carrier Mixtures: Return test article carrier mixture to the Sponsor (Gabriela Adam-Rodwell, Ph.D.) following completion of the study.

Carrier mixtures will be discarded if no choice is indicated.

____ Return Test Article Carrier Mixtures to the Sponsor
____ Toxicity Prescreen
____ X Mutation Assay
____ Dispose of Test Article Carrier Mixtures

Person to whom carrier mixtures should be sent:

____ Gabriela Adam-Rodwell, Ph.D.
____ Colgate-Palmolive
____ 909 River Road
____ Piscataway, NJ 08855-1343

Shipping Instructions:

____ Securely packaged; shipped at ambient temperature.

Government Agency Submission: X FDA TSCA FIFRA
X EEC OECD MHW
 Other

AMENDMENTS

APPROVAL OF PROTOCOL

Date 3/10/92 Study Monitor Gabriela Adam-Rodwell
Date 9 MARCH 1993 Study Director Albert F. Hankins

AMENDED FINAL REPORT

Pharmakon Study No. PH 301-CP-001-93
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Protocol-301
Ames/Salmonella Plate Incorporation Assay

APPENDIX A
Test Article Information

I Identification:

Test Article (Sample #): 39316
CC #: 14663-09
Physical Description: Powder, white, odorless
Purity: 100.5% (alkalimetric assay)
Expiration Date: February 23, 1994
Density/Specific Gravity: _____
Solubility (check one): Water _____ Acetone X
Ethanol X Corn Oil _____ DMSO X
Other (please specify) NaOH 0.01N
Chemical Classification: Flammable _____ Corrosive _____
Other _____

II Storage Information:

(check one):
Room Temperature X Refrigerator _____
Freezer _____ Other (specify) _____

III Handling Information:

Known Hazards: None
Precautions: Routine use of protective clothing includes laboratory coats, latex gloves, dust masks, and safety glasses.
Other recommended precautions None

In Case of Emergency Related to
this substance, contact:

Gabriela Adam-Rodwell, Ph.D. of Colgate at (908)878-6143
(person) (company/ (phone number)
division)

IV Disposition:

All materials will be returned to the Sponsor three months following submission of the final report to the Sponsor. Person and address to whom test articles are to be returned.

Name: Gabriela Adam-Rodwell, Ph.D.
Address: 909 River Road
Piscataway, NJ 08855-1343

V Signature: Gabriela Adam-Rodwell Date: 3/18/93

AMENDED FINAL REPORT

Pharmakon Study No. PH 301-CP-001-93

Colgate-Palmolive Study No. CP-93-012

APPENDIX III.

STUDY RECORDS and INDIVIDUAL DATA

Notebook #1630: page 3
#1729: page 305
#1779: pages 404-442

Notebook #: 1779

Ames/Salmonella Toxicity Prescreen

Study #: PH301-CP-801-93 Date Initiated: 3/15/93
 Sponsor: COLGATE-PALMOLIVE Date Completed: 3/17/93
 Test Article: 39316 Solvent: DMSO
 lot #: CC# 14063-09 lot #: 902873
 description: WAXEY PEAR source: Fisher
 Treatment Conditions: PER SDP PH301-CP-801-93

Weights and Dilutions

Solvent: DMSO TA _____
 Compound Weight: 327.83 mg 8.88 g
 Solvent Volume: 6.35 mL 327.83 g
 Concentration: 50.0 mg/mL VFDR 4/15/93
 by: VFDR 3/15/93

Test Article Dilutions

all mg/mL; all DMSO
 50.0 $\xrightarrow{1:2}$ 16.7
 $\downarrow 1:10$ $\downarrow 1:10$
 5.00 1.67
 $\downarrow 1:10$
 0.500 OK DMS 3/15/93

by: VFDR 3/15/93

Results (duplicate plates)

Dose	TA1538	TA100
0 mg/mL	+	+
50.0	-	-
16.7	-	-
5.00	-	-
1.67	-	-
0.500 pt	-	-

(+) normal growth

(-) no growth

(+) see comments

Comments ppt - precipitate.

re-run @ 0.500, 0.167, 0.500, 1.67, 5.00, 16.7 & 50.0 mg/mL.

Tester Strain Densities

(OD₆₅₀; 1:4 dilution) Aliquot

TA1538 0.463 1/19/93 - B

TA100 0.421 1/19/93 - B

by: VFDR 3/15/93

*add also 0.00500 & 0.0167 mg/pt.

Sponsor) VFDR 3/17/93

Study Director

Date

NOTEBOOK #: 1779

Ames/Salmonella Toxicity Prescreen

Study #: PH301-CP-001-93 Date Initiated: 3-13-93
 Sponsor: Calgene-Palmolive Date Completed: 3/19/93
 Test Article: 39316 Solvent: DMSO
 lot #: CC # 14663-09 lot #: 902873
 description: white powder source: Fisher
 Treatment Conditions: Rev. SOP PH301-EPA/WHO
(Robot @ lower doses, ± 59)

Weights and Dilutions

Solvent: DMSO
 Compound Weight: 19.67 mg
 Solvent Volume: 15 to 3.93 ml
 Concentration: 500 mg/ml
 by: KEM 3-13-93

Test Article Dilutions

* 5.00 100% (all mg/ml, all DMSO)
 ↓ 1:10 0.500 1:2 0.167 1:10 0.0167 OK
 ↓ 1:10 0.0500 1:10 0.00500 1:10 0.000500 DMSO 3-13-93
 ↓ 1:10 0.00500 1:10 0.000500 1:10 0.0000500

by: KEM 3-13-93
 * Stock solution, not used for dosing

Tester Strain Densities

(OD₆₃₀; 1:4 dilution) Aliquot
 TA1538 0.506 1-19-93 -# 10
 TA100 0.535 1-19-93 -# 10
 by: DMM 2-17-93

TA
 TA
 8.00 mg
 19.67 mg
 KEM 3-13-93

Results (duplicate plates)

Dose	TA1538	TA100

2nd
not
streak

(+) normal growth
 (-) no growth
 (±) see comments

Comments

IFSA 3/19/93
 Study Director Date

P4 301-5001-93

Notebook #: 1779

59 Preparation

ml

0.4 M $MgCl_2$; 1.65 M KCl 0.6
 1.0 M Glucose-6- PO_4 0.15
 0.1 M NADP 1.2
 0.2 M Na_2HPO_4 (7.4) 1.5
 d_2-H_2O 11.25
 59 (lot # 12-17-91) 1.8
 by: TBC 3-17-93 Total 30.0 ml

Results (duplicate plates)

Dose	74550		74100	
	-59	+59	-59	+59
complete	+	+	+	+
0.0050	+	+	+	+
0.0167	±26	↓	±26	↓
0.0500	±26	↓	±26	↓
0.167	±2	↓	±2	↓
0.500	±/-	↓	±2	↓
1.67	-	±2	±2	±26
5.00	-	±2	±2	±2
16.7	-	-	-	-
50.0	-	-	-	-

±50% Moderate/Severe toxicity.
 + Normal growth.
 ± inhibited growth.
 - Complete toxicity.
 No precipitate.

Recommended doses: 0.00167, 0.00500, 0.0167, 0.0500, 0.100
 + 0.167 -59; and
 0.0500, 0.167, 0.500, 1.67, 5.00 +
 5.00 +59 (all $\mu g/plate$).

17502 3/19/93

406

Notebook #: 1779

Ames/Salmonella Mutagenicity Assay - Test Article/S9 Preparation

Study #: PH301-CP-001-93 Date Initiated: 3-23-93
 Sponsor: Colgate - Palmolive Date Completed: 3/25/93
 Test Article: 39316 Solvent: DMSO
 lot #: 14663-09 lot #: 902873
 description: white powder source: Fisher
 Treatment Conditions: PER SOP PH301-EPA/DECD

Weights and Dilutions

Compound Weight: 25.1mg
 Solvent Volume: 500.0 µl
 Concentration: 5.00 mg/ml
 by: KFM 3-23-93
 * 5.00 mg/ml $\xrightarrow{1:100}$ 0.05 mg/ml

Test Article Dilutions

50.0 $\xleftarrow{\text{All } \mu\text{g/ml, All DMSO}}$
 1:2 \rightarrow 25.0
 1:3 \rightarrow 16.7 $\xrightarrow{1:10}$ 1.67 $\xrightarrow{1:10}$ 0.167
 1:10 \rightarrow 5.00 $\xrightarrow{1:10}$ 0.500 $\xrightarrow{1:10}$ 0.0500
 1:5 $\xrightarrow{\text{Soc 3-23-93}}$ 1.00
 6.0 mg
 25.1 mg
 KFM 3-23-93
 by: KFM 3-23-93

S9 Preparation

0.4 M MgCl₂: 1.65 M KCl 2.0
 1.0 M Glucose-6-PO₄ 0.5
 0.1 M NADP 4.0
 0.2 M Na₂HPO₄ (7.4) 50.0
 d₁-H₂O 37.5
 S9 (lot # 1-19-92) 6.0
 by: Jmm 3-23-93 Total 100.0 ml

Tester Strain Densities

(OD₆₅₀; 1:4 dilution) Aliquot
 TA1535 0.480 1.443 -# 13
 TA1537 0.582 -#
 TA1538 0.516 -#
 TA98 0.484 -#
 TA100 0.464 -#
 by: Jmm 3-23-93

Positive controls were prepared
 on 7-23-92
 and stored as frozen aliquots at
 -20°C until use.

KFM 3/25/93
 Study Director Date

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PHARMAKON RESEARCH INTERNATIONAL, INC.
MICROBIAL MUTAGENICITY ASSAY

MEAN SUMMARY DATA

Sponsor: COLGATE-PALMOLIVE Date initiated: 03-27-1993
Test article: 39316 Date scored: 03-25-1993
Description: WHITE POWDER Study ID: CP9301A
Notebook #: 1779 Investigator: STAN OWSKI
Lot #: CC# 146aJ-09 Study director: STANKOWSKI
Assay description: AMES PLATE INCORP.
Other considerations: PER SOP PH301-EPA/DECD

CONTROLS

MEAN SPONTANEOUS REVERTANTS/PLATE						
SOLVENT CONTROLS	S-9	TA1535	TA1537	TA1538	TA98	TA100
DMSO (100 UL)	(-)	11 (4)	6 (1)	6 (3)	16 (3)	85 (13)
DMSO (100 UL)	(+)	7 (2)	7 (2)	8 (3)	26 (4)	111 (3)
POSITIVE CONTROLS UG/PL						
SODIUM AZIDE 10	(-)	12934 (36)	---	---	---	8034 (79)
9-ANTHRAQUINONE 150	(-)	---	12063 (107)	---	---	---
2-NITROFLUORENE 5	(-)	---	---	6064 (41)	3328 (37)	---
2-ANTHRANILINE 2.5	(+)	1128 (15)	4196 (296)	16328 (244)	21628 (120)	21428 (52)

TEST COMPOUND: 39316 STUDY: CP9301A

MEAN TOTAL REVERTANT COLONIES/PLATE						
DOSE LEVEL UG/PL	S-9	TA1535	TA1537	TA1538	TA98	TA100
0.00167	(-)	6 (3)	5 (2)	4 (1)	19 (2)	94 (7)
0.00500	(-)	5 (2)	5 (1)	5 (1)	17 (2)	95 (16)
0.0167	(-)	11 (4)	4 (1)	3 (1)	19 (5)	67 (9)
0.0500	(-)	4 (1)	3 (1) a	1 (1) ab	23 (6)	7 (1) bc
0.100	(-)	1 (1) ab	0 (1) e	0 (0) e	3 (2) ab	0 (0) e
0.167	(-)	0 (1) e	0 (0) e	0 (0) e	0 (0) bc	0 (0) e
0.500	(+)	9 (2)	6 (2)	13 (3)	27 (9)	111 (17)
0.167	(+)	10 (2)	6 (3)	12 (4)	19 (1)	97 (8)
0.500	(+)	8 (3)	3 (1)	13 (4)	28 (2)	70 (10)
1.67	(+)	5 (4)	1 (0)	3 (3)	17 (3)	32 (5)
2.50	(+)	6 (1)	3 (1)	5 (1) a	21 (6)	39 (12) a
5.00	(+)	3 (3) ab	0 (0) ab	0 (0) e	12 (5) ab	12 (7) bc

† Positive Response: Greater than or equal to 2 x Solvent (TA1535, TA1537, TA1538, TA98, TA100)

Data Reported as: Mean (Standard Deviation)

- Slightly / Moderate / Severe toxicity.
- No precipitate.

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USE 3/25/93

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PHARMACON RESEARCH INTERNATIONAL, INC.
MICROBIAL MUTAGENICITY ASSAY

INDIVIDUAL PLATE COUNT

Sponsor: COLGATE-PALMOLIVE Date initiated: 03-23-1993
Test article: 39216 Date scored: 03-25-1993
Description: WHITE POWDER Study ID: CP9301A
Notebook #: 1779 Investigator: STANKOWSKI
Lot number: CC# 14663-09 Study director: STANKOWSKI
Assay description: AMES PLATE INCORP.
Other considerations: PER SOP PHC01-EPA/OECD

CONTROLS-STUDY: CP9301A

CONTROL	DOSE S-9 UG/PL	SALMONELLA STRAINS (REV/PL)						
		TA1535	TA1537	TA1538	TA98	TA100		
DMSO (100 UL)	(-)	14	5	7	12	85		
		7	6	6	18	72		
		10	7	8	17	97		
		Mean:	11	6	8	16	85	
		Std Dev:	4	1	7	7	17	
DMSO (100 UL)	(+) 10	8	8	7	30	114		
		9	5	5	19	111		
		5	9	11	28	109		
		Mean:	7	7	8	26	111	
		Std Dev:	2	2	7	6	7	
SODIUM AZIDE	(-) 10	1230	--- N	--- N	--- N	746		
		1322	--- N	--- N	--- N	894		
		1325	--- N	--- N	--- N	774		
		Mean:	1295±	---	---	---	805±	
		Std Dev:	56	---	---	---	79	
5-AMINDACRIDINE	(-) 150	--- N	1122	--- N	--- N	---	N	
		--- N	1170	--- N	--- N	---	N	
		--- N	1326	--- N	--- N	---	N	
		Mean:	---	1206±	---	---	---	---
		Std Dev:	---	107	---	---	---	---

± Positive Response: Greater than or equal to 2 x Solvent (TA1535, TA1537, TA1538, TA98, TA100)

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VSD 3/25/93

PHARMAKON RESEARCH INTERNATIONAL, INC.
MICROBIAL MUTAGENICITY ASSAY

INDIVIDUAL PLATE COUNT

Sponsor: COLGATE-PALMOLIVE Date initiated: 03-23-1993
Test article: 39316 Date scored: 03-23-1993
Description: WHITE POWDER Study ID: CP9301A
Notebook #: 1779 Investigator: STANKOWSKI
Lot number: CC# 14663-09 Study director: STANKOWSKI
Assay description: AMES PLATE INCORP.
Other considerations: PER SOP PH301-EPA/OECD

CONTROLS-STUDY: CP9301A

CONTROL	S-9	DOSE UG/PL	SALMONELLA STRAINS (REV/PL)							
			TA1535	TA1537	TA1538	TA98	TA100			
2-NITROFLUORENE	(-)	5	---	N	---	N	629	534	---	N
			---	N	---	N	630	570	---	N
			---	N	---	N	538	495	---	N
			Mean:		---	---	606*	532*	---	
			Std Dev:		---	---	41	39	---	
2-ANTHRAMINE	(+) 2.5	98	147	1353	2247	2110				
		109	734	1738	2024	2202				
		128	377	1806	2214	2113				
		Mean:		112*	419*	1632*	2162*	2142*		
		Std Dev:		15	296	244	120	52		

* Positive Response: Greater than or equal to 2 : Solvent (TA1538, TA1537, TA1538, TA98, TA100)

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WSD 3/25/93

PHARMACON RESEARCH INTERNATIONAL, INC.
MICROBIAL MUTAGENICITY ASSAY

INDIVIDUAL PLATE COUNT

Sponsor: COLGATE-PALMOLIVE Date initiated: 07-25-1993
Test article: T9316 Date scored: 08-25-1993
Description: WHITE POWDER Study ID: CP9301A
Notebook #: 1779 Investigator: STANKOWSKI
Lot number: CC# 14663-09 Study director: STANKOWSKI
Assay description: AMES PLATE INCORP.
Other considerations: PER SOP PH301-EPA/DECD

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TEST ARTICLE: T9316 STUDY: CP9301A

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DOSE LEVELS	S-9	DOSE UG/PL	SALMONELLA STRAINS (REV/PL)				
			TA1538	TA1537	TA1538	TA98	TA100
T9316	(-)	0.00167	8	3	4	20	89
			8	5	5	17	92
			3	7	4	21	102
		Mean:	6	5	4	19	94
		Std Dev:	3	2	1	2	7
T9316	(-)	0.00500	7	6	6	17	101
			3	4	4	19	108
			5	5	4	16	77
		Mean:	5	5	5	17	95
		Std Dev:	2	1	1	2	16
T9316	(-)	0.0167	7	4	4	16	63
			14	5	7	16	60
			13	4	7	25	77
		Mean:	11	4	7	19	67
		Std Dev:	4	1	1	5	9
T9316	(-)	0.0500	3	4	0	27	6
			5	4	2	25	7
			4	2	1	16	8
		Mean:	4	3a	1ab	27	7bc
		Std Dev:	1	1	1	6	1

ab/c - see next page

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RSD 3/25/93

PHARMAKON RESEARCH INTERNATIONAL, INC.
MICROBIAL MUTAGENICITY ASSAY

INDIVIDUAL PLATE COUNT

Sponsor: COLGATE-PALMOLIVE Date initiated: 03-23-1993
Test article: 39316 Date scored: 03-25-1993
Description: WHITE POWDER Study ID: CP9301A
Notebook #: 1779 Investigator: STANKOWSKI
Lot number: CC# 14663-09 Study director: STANKOWSKI
Assay description: AMES PLATE INCORP.
Other considerations: PER SOP PH301-EPA/DECD

TEST ARTICLE: 39316 STUDY: CP9301A

DOSE LEVELS	S-C	DOSE UG/PL	SALMONELLA STRAINS (REV/PL)				
			TA1535	TA1537	TA1538	TA98	TA100
39316	(-)	0.100	1	0	0	5	0
			1	1	0	1	0
			2	0	0	3	0
			Mean:	1 <i>ab</i>	0 <i>c</i>	0 <i>c</i>	7 <i>ab</i>
			Std Dev:	1	1	0	2
39316	(-)	0.167	1	0	0	0	0
			0	0	0	0	0
			0	0	0	0	0
			Mean:	0 <i>c</i>	0 <i>c</i>	0 <i>c</i>	0 <i>c</i>
			Std Dev:	1	0	0	0
39316	(+) 1	0.0500	7	5	10	20	129
			10	5	10	24	96
			10	8	15	28	109
			Mean:	8	6	12	27
			Std Dev:	2	2	3	9
39316	(+) 2	0.167	8	5	16	20	91
			0	3	9	18	93
			12	9	11	18	106
			Mean:	10	6	12	19
			Std Dev:	2	3	4	1

all - see next page.

see next page

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USK 3/25/93

PHARMACON RESEARCH INTERNATIONAL, INC.
MICROBIAL MUTAGENICITY ASSAY

INDIVIDUAL PLATE COUNT

Sponsor: COLGATE-PALMOLIVE
Test article: J9316
Description: WHITE POWDER
Notebook #: 1779
Lot number: CC# 14663-09
Assay description: AMES PLATE INCORP.
Other considerations: FER SOP PH301-EPA/DECD

Date initiated: 03-23-1993
Date scored: 03-25-1993
Study ID: CP9301A
Investigator: STANKOWSKI
Study director: STANKOWSKI

TEST ARTICLE: J9316 STUDY: CP9301A

DOSE LEVELS	S-R	DOSE UG/PL	SALMONELLA STRAINS (REV/PL)				
			TA1538	TA1537	TA1538	TA98	TA100
J9316	(+) 0.500		5	7	15	26	65
			10	2	15	29	64
			0	7	8	29	81
		Mean:	8	7	15	28	70
		Std Dev:	7	1	4	2	10
J9316	(+) 1.67		8	1	2	19	37
			7	1	0	19	28
			1	1	1	13	31
		Mean:	5	1	3	17	32
		Std Dev:	4	0	3	5	5
J9316	(+) 2.50		6	4	4	28	49
			0	2	5	19	45
			5	7	5	16	26
		Mean:	6	7	5a	21	29a
		Std Dev:	1	1	1	5	12
J9316	(+) 5.00		4	0	0	7	12
			0	0	0	12	18
			0	0	0	16	5
		Mean:	0ab	0ab	0c	12ab	12bc
		Std Dev:	3	0	0	5	7

^a Slight/^b Moderate/^c Severe toxicity.

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GRK 3/25/93

PHARMACON RESEARCH INTERNATIONAL, INC.
MICROBIAL MUTAGENICITY ASSAY

INDIVIDUAL PLATE COUNT

Sponsor: COLGATE-PALMOLIVE
Test article: C9316
Description: WHITE POWDER
Notebook #: 1779
Lot number: CC# 14663-09
Assay description: AMES PLATE INCORP.
Other considerations: FER SOP PH301-EPA/OECD

Date initiated: 03-27-1997
Date scored: 03-25-1997
Study ID: CP9301A
Investigator: STANKOWSKI
Study director: STANKOWSKI

STERILITY CONTROLS (COLONIES/PLATE) FOR STUDY: CP9301A

SF SYSTEM

0
0
0

-16 precipitate.

TOP AGAR

0
0
0

SOLVENTS

0
0
0

SAMPLE

0
0
0

MISCELLANEOUS DATA FOR STUDY: CP9301A

COUNTER CALIBRATION #1 STANDARD: 1225 READING: 1224
COUNTER CALIBRATION #2 STANDARD: 1225 READING: 1224
COUNTER CALIBRATION TOLERANCE: 2 PERCENT

COUNTER SENSITIVITY: 7

READINGS TAKEN FROM: COUNTER

PRINTOUT OF COUNTER READINGS WAS NOT GENERATED
HISTORICAL DATA WAS NOT USED FOR CONTROL DATA (u. 2/28/93).

WAE - LSR 3/25/93

*update
WAE 3/25/93*

PAGE: *414*

WAE 3/25/93

1779

ANALYSIS OF MUTATION FREQUENCY

PROGRAM VERSION 4 REV. 1 PROGRAM DATE: 11/25/85

IBM-PC VERSION 4 REV. 1 RUN DATE: 3/25/93

CPT301A TA1330 +59

DATA TRANSFORMATION WILL BE $Y=(1+.20)$

INPUT DATA			
LINE#	DOSE	TRIAL #	RESULT
1	.00	1	7.0
2	.00	1	5.0
3	.00	1	11.0
4	.05	1	10.0
5	.05	1	13.0
6	.05	1	15.0
7	.17	1	16.0
8	.17	1	9.0
9	.17	1	11.0
10	.50	1	15.0
11	.50	1	15.0
12	.50	1	8.0
13	1.67	1	2.0
14	1.67	1	6.0
15	1.67	1	1.0
16	2.50	1	4.0
17	2.50	1	5.0
18	2.50	1	5.0

THAT 3-25-93

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PROGRAM VERSION 4 REV. 1 RUN DATE: 3/25/93

CP9301A TA1538 +59

1779

INPUT DATA				TRANSFORMED FREQUENCY		
DOSE	TRIAL	MUTATION FREQUENCY	NO. OF RESULTS	AVERAGE	AVERAGE	STD DEV
.000	1	7.0 5.0 11.0	3	7.7	1.4903	.1185
.050	1	10.0 13.0 15.0	3	12.7	1.6500	.0670
.167	1	16.0 9.0 11.0	3	12.0	1.6361	.0963
.500	1	15.0 15.0 8.0	3	12.7	1.6511	.1172
1.670	1	2.0 6.0 1.0	3	3.0	1.1932	.2189
2.500	1	4.0 3.0 5.0	3	4.7	1.3997	.0340
POOLED REPLICATE STANDARD DEVIATION =				.1230	TRANSFORMATION	
DEGREES OF FREEDOM = 12						.20
STANDARD DEVIATION					$\sqrt{1 + .001}$	
NUMBER OF RESULTS = 3						
UPPER CONTROL LIMIT = .2795						

TAP 3-25 93

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PROGRAM VERSION 4 REV. 1 RUN DATE: 3/25/93

CP9501A TA1538 +59

1779

STATISTICAL ANALYSIS OF MUTAGENICITY

DOSE	AVERAGE	T	PROB	MUTATION FREQUENCY
.000	1.4903			7.4
.030	1.6300	1.47	.1209	12.5
.167	1.6361	1.45	.1722	11.7
.500	1.6311	1.60	.1394	12.3
1.670	1.1932	-2.94	.0120	2.4
2.500	1.3997	-1.30	.2170	4.6

T IS STUDENT'S T-STATISTIC FOR THE COMPARISON OF EACH
DOSE LEVEL TO THE NEGATIVE CONTROL (DOSE = 0).

SOURCE OF VARIATION	DOSE-RESPONSE ANALYSIS OF VARIANCE			F RATIO	PROB
	DEGREES OF FREEDOM	SUM OF SQUARES	MEAN SQUARE		
TOTAL	17	.72			
TRIAL	0	.00			
DOSE	5	.54			
LINEAR	1	.31	.31	20.75	.0007
QUADRATIC	1	.03	.03	1.82	.2022
HIGHER ORDER	3	.20	.07	4.38	.0265
RESIDUAL	12	.18	.02		

DOSE X TRIAL INTERACTION
F RATIO DEGREES OF FREEDOM PROBABILITY

0 AND 12

A SIGNIFICANT DOSE-TRIAL INTERACTION INDICATES THAT THE
DOSE-RESPONSE RELATIONSHIP IS DIFFERENT IN THE DIFFERENT
TRIALS. THE DOSE-RESPONSE ANOVA ABOVE ASSUMES THAT THIS
INTERACTION IS NOT STATISTICALLY SIGNIFICANT.

MR 3-25-93

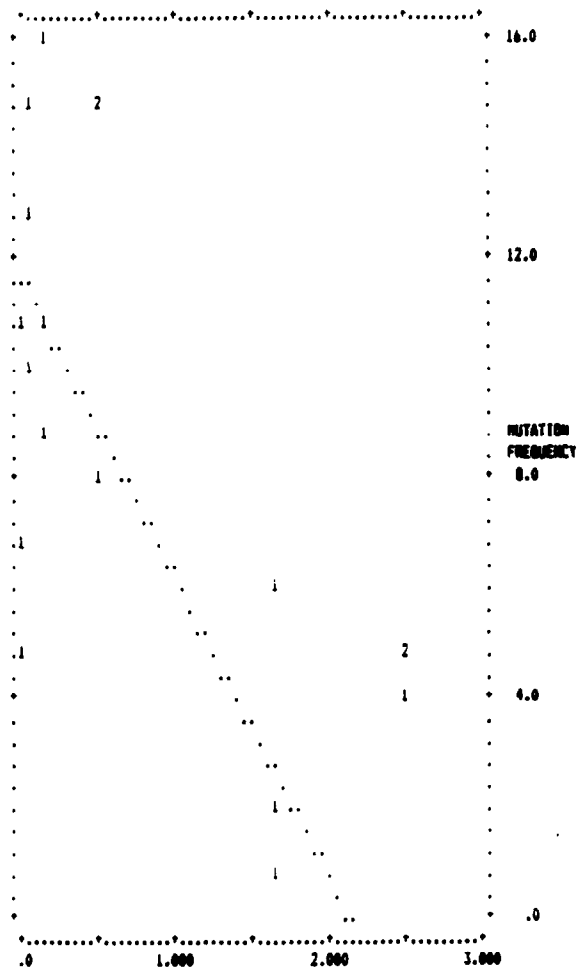
417

PROGRAM VERSION 3 REV. 4 RUN DATE: 3/25/93CP9301A TA1538 +59

NPTS= 18

R= -.6624

1779



	MUTATION FREQUENCY	DOSE
MEAN	.87770E+01	.81450E+00
STD DEV	.47340E+01	.97044E+00
MIN	.10000E+01	.00000E+00
MAX	.16000E+02	.25000E+01

DOSE-RESPONSE RELATIONSHIP	DOSE	SLOPE	CONFIDENCE	LIMITS
INTERCEPT = 11.60			LOWER	UPPER
SLOPE = -5.4707				
LACK OF FIT		LINEAR	-0.5969	-2.3445
		NONLINEAR	NONE FOUND	-.0164
P= 0.05 PROBABILITY= .0022				
DEGREES OF FREEDOM = 4, 12				
CONVERGENCE EPSILON	TEST	4 ITERATIONS		

TAP 3-25-93

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Notebook #: 1779

Ames/Salmonella Mutagenicity Assay - Test Article/S9 Preparation

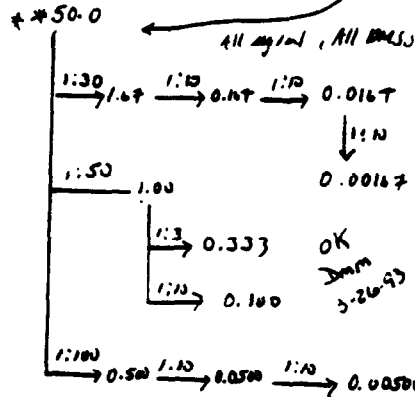
Study #: PH301-CP-001-93 Date Initiated: 3-26-93
 Sponsor: Colgate - Palmolive Date Completed: 3/20/93
 Test Article: 39316 Solvent: DMSO
 lot #: CC # 14663-04 lot #: 902873
 description: white powder source: Fisher
 Treatment Conditions: Retest TA100 - S9

Weights and Dilutions

Compound Weight: 197.6 mg
 Solvent Volume: 95 to 99.52 ml
 Concentration: * 5.00 mg/ml
 by: KFM 3-26-93

* 5.00 mg/ml $\xrightarrow{1:100}$ 0.05 mg/ml

Test Article Dilutions



by: KFM 3-26-93

0.8 mg
 197.6 mg
 LFM 3-26-93

S9 Preparation

0.4 M $MgCl_2$: 1.65 M KCl
 1.0 M Glucose-6-PO₄
 0.1 M NADP
 0.2 M Na₂HPO₄ (7.4)
 d1-H₂O
 S9 (lot #)
 by: Total

Tester Strain Densities

(OD₆₃₀: 1:4 dilution) Aliquots
 TA1535 -#
 TA1537 -#
 TA1538 -#
 TA98 -#
 TA100 0.511 1-19-93 -# 99
 by: Jmm 3-26-93

Positive controls were prepared on 7-23-92 and stored as frozen aliquots at -20°C until use.

VFH 3/20/93
 Study Director Date

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PHARMAKON RESEARCH INTERNATIONAL, INC.
MICROBIAL MUTAGENICITY ASSAY

MEAN SUMMARY DATA

Sponsor: COLGATE-PALMOLIVE
Test article: 39316
Description: WHITE POWDER
Notebook #: 1779
Lot #: CC# 14663-09
Assay description: AMES PLATE INCORP.
Other considerations: RETEST: TA100 -S9

Date initiated: 03-26-1993
Date scored: 03-28-1993
Study ID: CP93018
Investigator: STANKOWSKI
Study director: STANKOWSKI

CONTROLS

MEAN SPONTANEOUS REVERTANTS/PLATE

SOLVENT CONTROLS	S-9	TA100
DMSO (100 UL)	(-)	80 (6)

POSITIVE CONTROLS UG/PL

SODIUM AZIDE	10.0	(-)	10618 (7)
--------------	------	-----	-----------

TEST COMPOUND: 39316 STUDY: CP93018

MEAN TOTAL REVERTANT COLONIES/PLATE

DOSE LEVEL UG/PL	S-9	TA100
0.00017	(-)	101 (12)
0.00034	(-)	97 (12)
0.00167	(-)	98 (6)
0.00500	(-)	121 (28)
0.0100	(-)	108 (13)
0.0167	(-)	74 (12)
0.0333	(-)	79 (7) a
0.0500	(-)	15 (3) a/b
0.100	(-)	6 (2) c
0.167	(-)	0 (1) c

Handwritten notes:
3/28/93
Insufficient
fold over
over 27 out of 43
(tube empty)

Positive Response: Greater than or equal to 2 x Solvent (TA100)
Data Reported as: Mean (Standard Deviation)

- Slight/Moderate/Severe toxicity
- No precipitate.

PAGE: 420

3/28/93

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PHARMACON RESEARCH INTERNATIONAL, INC.
MICROBIAL MUTAGENICITY ASSAY

INDIVIDUAL PLATE COUNT

Sponsor: COLGATE-PALMOLIVE Date initiated: 07-26-1993
Test article: T9316 Date scored: 07-28-1993
Description: WHITE POWDER Study ID: CP9301B
Notebook #: 1779 Investigator: STANKOWSKI
Lot number: CC# 1466C-09 Study director: STANKOWSKI
Assay description: AMES PLATE INCORP.
Other considerations: RETEST: TA100 -S9

CONTROLS-STUDY: CP9301B

CONTROL	DOSE	SALMONELLA STRAINS (REV/PL)
	S-9 UG/PL	TA100
DMSO (100 UL)	(-)	74 81 85
	Mean:	80
	Std Dev:	0
SODIUM AZIDE	(-) 10.0	1056 1069 1058
	Mean:	1061.3
	Std Dev:	7

* Positive Response: Greater than or equal to 2 x Solvent (TA100)

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WSD 3/28/93

PHARMAKON RESEARCH INTERNATIONAL, INC.
MICROBIAL MUTAGENICITY ASSAY

INDIVIDUAL PLATE COUNT

Sponsor: COLGATE-PALMOLIVE
Test article: 39316
Description: WHITE POWDER
Notebook #: 1779
Lot number: CC# 14663-09
Assay description: AMES PLATE INCORP.
Other considerations: RETEST: TA100 -S9

Date initiated: 03-26-1993
Date scored: 03-28-1993
Study ID: CP9301B
Investigator: STANKOWSKI
Study director: STANKOWSKI

TEST ARTICLE: 39316 STUDY: CP9301B

DOSE LEVELS	S-9	DOSE UG/PL	SALMONELLA STRAINS (REV/PL) TA100
39316	(-)	0.00017	113 100 90 <i>MSR 3/28/93</i>
		Mean:	101
		Std Dev:	12
39316	(-)	0.00050	124 76 91
		Mean:	97
		Std Dev:	25
39316	(-)	0.00167	102 102 91
		Mean:	98
		Std Dev:	6
39316	(-)	0.00500	153 108 102
		Mean:	121
		Std Dev:	28

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MSR 3/28/93

PHARMACON RESEARCH INTERNATIONAL, INC.
MICROBIAL MUTAGENICITY ASSAY

INDIVIDUAL PLATE COUNT

Sponsor: COLGATE-PALMOLIVE
Test article: T971a
Description: WHITE POWDER
Notebook #: 1775
Lot number: CD# 1455T-09
Assay description: AMES PLATE INCORP.
Other considerations: RETEST. TA100 -85

Date initiated: 07-26-1991
Date scored: 07-28-1991
Study ID: CP9701B
Investigator: STANKOWSKI
Study director: STANKOWSKI

TEST ARTICLE: T971a STUDY: CP9701B

DOSE LEVELS	S-F	DOSE UG/PL	SALMONELLA STRAINS (REV/PL) TA100
T971a	-	1.0107	115 117 91
		Mean:	108
		Std Dev:	15
T971a	-	1.0167	85 62 74
		Mean:	74
		Std Dev:	12
T971a	(-)	0.0377	45 31 40
		Mean:	39 a
		Std Dev:	7
T971a	(-)	0.0500	16 12 17
		Mean:	15 a/b
		Std Dev:	5

a/b - see next page.

PAGE.

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CFSE 3/28/93

PHARMADON RESEARCH INTERNATIONAL, INC.
MICROBIAL MUTAGENICITY ASSAY

INDIVIDUAL PLATE COUNT

Sponsor: COLGATE-PALMOLIVE
Test article: TP016
Description: WHITE POWDER
Notebook #: 1775
Lot number: 004 14627-02
Assay description: AMES PLATE INCUB.
Other considerations: RETEST: TA100 -SP
Date initiated: 10-26-1997
Date scored: 11-26-1997
Stud. ID: DPPT016
Investigator: STANFOWSKI
Sponsor director: STANFOWSKI

TEST ARTICLE: TP016 STUDY: DPPT016

DOSE LEVEL	DOSE	SALMONELLA STRAINS (PE PL)
	UG PL	TA100
TP016	0.001	0
		0
		0
	Mean:	a C
	Std. Dev:	0
TP016	0.002	0
		0
		0
	Mean:	c
	Std. Dev:	0

a Slight / b Moderate / c Severe toxicity.

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USR 3/20/03

PHARMAKON RESEARCH INTERNATIONAL, INC.
MICROBIAL MUTAGENICITY ASSAY

INDIVIDUAL PLATE COUNT

Sponsor: COLGATE-PALMOLIVE	Date initiated: 03-26-1993
Test article: 39316	Date scored: 03-28-1993
Description: WHITE POWDER	Study ID: CP9301B
Notebook #: 1779	Investigator: STANKOWSKI
Lot number: CC# 14663-09	Study director: STANKOWSKI
Assay description: AMES PLATE INCORP.	
Other considerations: RETEST: TA100 -S9	

STERILITY CONTROLS (COLONIES/PLATE) FOR STUDY: CP9301B

S9 SYSTEM

*Not applicable
use 3/28/93*

TOP AGAR

- No precipitate.

SOLVENTS

SAMPLE

MISCELLANEOUS DATA FOR STUDY: CP9301B

COUNTER CALIBRATION #1 STANDARD: 1225 READING: 1226
COUNTER CALIBRATION #2 STANDARD: 1225 READING: 1225
COUNTER CALIBRATION TOLERANCE: 2 PERCENT

COUNTER SENSITIVITY: 7

READINGS TAKEN FROM: COUNTER

PRINTOUT OF COUNTER READINGS WAS NOT GENERATED
HISTORICAL DATA WAS NOT USED FOR CONTROL DATA (vs. 2/28/93 update).

205 - use 3/28/93

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use 3/28/93

U

1779

ANALYSIS OF MUTATION FREQUENCY

PROGRAM VERSION 4 REV. 1 PROGRAM DATE: 11/23/85

IBM-PC VERSION 4 REV. 1 RUN DATE: 3/28/93

CP9301B TA100 -59

DATA TRANSFORMATION WILL BE $Y=11+ .001$.20

INPUT DATA			
LINE#	DOSE	TRIAL #	RESULT
1	.000	1	74.0
2	.000	1	81.0
3	.000	1	85.0
4	.000167	1	113.0
5	.000167	1	100.0
6	.000167	1	90.0
7	.000500	1	124.0
8	.000500	1	74.0
9	.000500	1	91.0
10	.00167	1	102.0
11	.00167	1	102.0
12	.00167	1	91.0
13	.00500	1	133.0
14	.00500	1	100.0
15	.00500	1	102.0
16	.0100	1	116.0
17	.0100	1	117.0
18	.0100	1	91.0
19	.0167	1	85.0
20	.0167	1	82.0
21	.0167	1	74.0
22	.0333	1	45.0
23	.0333	1	31.0
24	.0333	1	40.0
25	.0500	1	16.0
26	.0500	1	12.0
27	.0500	1	17.0

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UPSR 3/28/93

PROGRAM VERSION 4 REV. 1 RUN DATE: 3/28/93

CP93010 TA100 -59

1779

INPUT DATA				TRANSFORMED FREQUENCY		
DOSE	TRIAL	MUTATION FREQUENCY	NO. OF RESULTS	AVERAGE	AVERAGE	STD DEV
.000	1	74.0 81.0 85.0	3	80.0	2.4016	.0337
.000167	1	113.0 100.0 90.0	3	101.0	2.5151	.0573
.000500	1	124.0 76.0 91.0	3	97.0	2.4883	.1240
.00167	1	102.0 102.0 91.0	3	98.3	2.5029	.0329
.00500	1	153.0 108.0 102.0	3	121.0	2.6625	.1135
.0100	1	116.0 117.0 91.0	3	108.0	2.5482	.0721
.0167	1	85.0 62.0 74.0	3	73.7	2.3398	.0745

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WSE 3/28/93

1779

.0333	1	45.0	3	38.7	2.0732	.0785
		31.0				
		40.0				

.0500	1	16.0	3	15.0	1.7157	.0632
		12.0				
		17.0				

POOLED REPLICATE STANDARD DEVIATION = .0785 TRANSFORMATION

DEGREES OF FREEDOM = 18	.20
STANDARD DEVIATION	Y=(11+ .00)
NUMBER OF RESULTS = 3	
UPPER CONTROL LIMIT = .1858	

428

USR 3/28/93

PROGRAM VERSION 4 REV. 1 RUN DATE: 3/28/93

1779

CP93018 TA100 -59

STATISTICAL ANALYSIS OF MUTAGENICITY

DOSE	AVERAGE	T	PROB	MUTATION FREQUENCY
.000	2.4016			79.9
.000167	2.5151	1.78	.0925	100.7
.000500	2.4883	1.36	.1915	95.4
.00167	2.5029	1.58	.1304	98.2
.00500	2.6025	3.14	.0056	119.4
.0100	2.5482	2.29	.0341	107.4
.0167	2.3398	-1.65	.1014	73.2
.0333	2.0732	-5.14	.0001	38.3
.0500	1.7157	-10.73	.0000	14.9

T IS STUDENT'S T-STATISTIC FOR THE COMPARISON OF EACH
DOSE LEVEL TO THE NEGATIVE CONTROL (DOSE = 0).

SOURCE OF VARIATION	DOSE-RESPONSE ANALYSIS OF VARIANCE			F RATIO	PROB
	DEGREES OF FREEDOM	SUM OF SQUARES	MEAN SQUARE		
TOTAL	26	2.07			
TRIAL	0	.00			
DOSE	8	1.96			
LINEAR	1	1.74	1.74	283.29	.0000
QUADRATIC	1	.12	.12	19.38	.0003
HIGHER ORDER	6	.11	.02	2.96	.0345
RESIDUAL	18	.11	.01		

DOSE X TRIAL INTERACTION
F RATIO DEGREES OF FREEDOM PROBABILITY

0 AND 18

A SIGNIFICANT DOSE-TRIAL INTERACTION INDICATES THAT THE
DOSE-RESPONSE RELATIONSHIP IS DIFFERENT IN THE DIFFERENT
TRIALS. THE DOSE-RESPONSE ANOVA ABOVE ASSUMES THAT THIS
INTERACTION IS NOT STATISTICALLY SIGNIFICANT.

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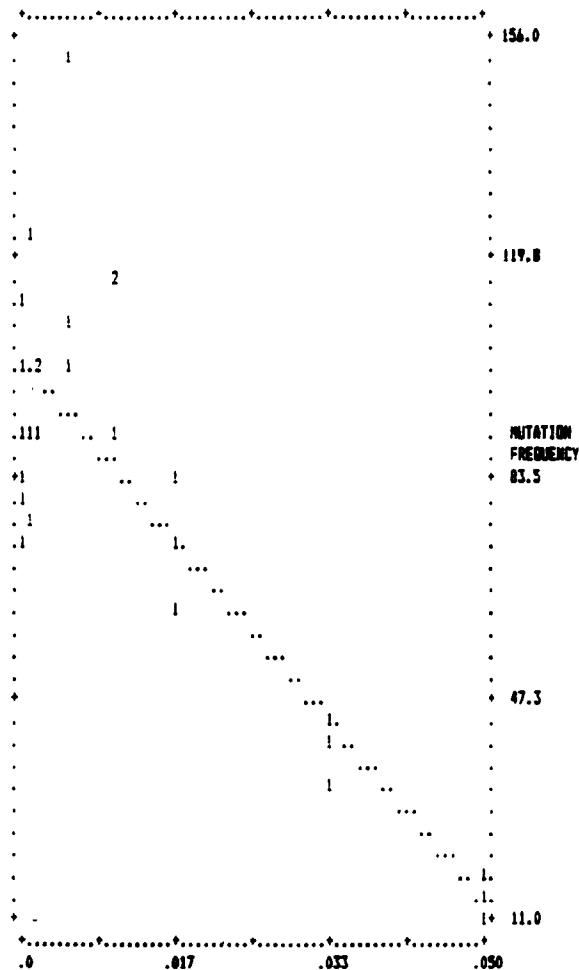
WFSH 3/28/93

PROGRAM VERSION 3 REV. 4 RUN DATE: 3/28/93CP93018 TA100 -59

1779

NPTS= 27

R= -.8427



	MUTATION FREQUENCY	DOSE
MEAN	.61407E+02	.13037E-01
STD DEV	.33324E+02	.14937E-01
MIN	.12000E+02	.00000E+00
MAX	.15300E+03	.30000E-01

DOSE-RESPONSE RELATIONSHIP	DOSE	SLOPE	CONFIDENCE	LIMITS
INTERCEPT = 103.14			LOWER	UPPER
SLOPE = .00000000				
LACK OF FIT		LINEAR	00000000	00000000
		NONLINEAR	00000000	00000000
F= 3.30 PROBABILITY= .0175				
DEGREES OF FREEDOM = 7, 18				
CONVERGENCE EPSILON	TEST	5 ITERATIONS		

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CPD 3/28/93

Notebook #: 1779

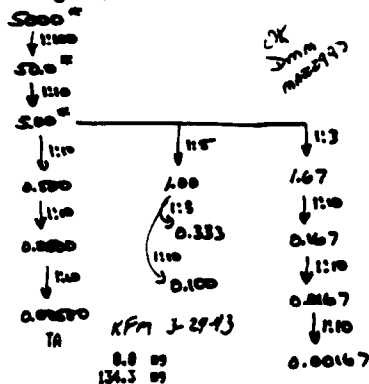
Ames/Salmonella Mutagenicity Assay - Test Article/S9 Preparation

Study #: PH301-CP-001-93 Date Initiated: 3/29/93
 Sponsor: Colgate - Palmolive Date Completed: 3/31/93
 Test Article: 39316 Solvent: DMSO
 lot #: CC# 14663-09 lot #: 902873
 description: white powder source: Fisher
 Treatment Conditions: Reconst: TA100 -39

Weights and Dilutions

Compound Weight: 134.3 mg
 Solvent Volume: 95 to 26.86 ml
 Concentration: 500 µg/ml
 by: KFM 3/29/93

Test Article Dilutions
 (all µg/ml; all DMSO)



by: KFM 3/29/93
 *stock solutions; not done.

S9 Preparation

0.4 M MgCl₂; 1.65 M KCl
 1.0 M Glucose-6-PO₄
 0.1 M NADP
 0.2 M Na₂HPO₄ (7.0)
 di-H₂O
 S9 (lot # _____)
 by: _____ Total _____

Tester Strain Densities

(OD₆₅₀; 1:4 dilution) Aliquot
 TA1535 _____ -# -#
 TA1537 _____ -# -#
 TA1538 _____ -# -#
 TA98 _____ -# -#
 TA100 0.449 1.0943 -# 14
 by: Wmm MAR2993

Positive controls were prepared
 on 7-23-92
 and stored as frozen aliquots at
 -20°C until use.

CSK 31 MAR 93
 Study Director Date

PHARMACON RESEARCH INTERNATIONAL, INC.
MICROBIAL MUTAGENICITY ASSAY

MEAN SUMMARY DATA

Sponsor: COLGATE-PALMOLIVE Date initiated: 03-29-1993
Test article: 3931a Date scored: 03-31-1993
Description: WHITE POWDER Study ID: CP9301C
Notebook #: 1779 Investigator: STANKOWSKI
Lot #: CC# 1466J-09 Study director: STANKOWSKI
Assay description: AMES PLATE INCORP.
Other considerations: RETEST: TA100 -59

CONTROLS

MEAN SPONTANEOUS REVERTANTS/PLATE			
SOLVENT CONTROLS		S-9	TA100
DMSO (100 UL)		(-)	75 (13)
POSITIVE CONTROLS US/PL			
SODIUM AZIDE	10.0	(-)	10000 (93)

TEST COMPOUND: 3931a STUDY: CP9301C

MEAN TOTAL REVERTANT COLONIES/PLATE

DOSE LEVEL US/PL		S-9	TA100
0.000167	<i>Inefficient fold size with smaller</i>	(-)	81 (13)
0.00050		(-)	77 (4)
0.00167		(-)	91 (13)
0.00500		(-)	91 (16)
0.0100		(-)	93 (6)
0.0167		(-)	75 (9)
0.0333		(-)	23 (8) a
0.0500		(-)	7 (6) a/b
0.100		(-)	3 (2) c
0.167		(-)	0 (0) c

* Positive Response: Greater than or equal to 2 x Solvent (TA100)
Data Reported as: Mean (Standard Deviation)

*a Slight / b Moderate / c Severe toxicity.
- No precipitate.*

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LRP 31 MAR 93

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PHARMAKON RESEARCH INTERNATIONAL, INC.
MICROBIAL MUTAGENICITY ASSAY

INDIVIDUAL PLATE COUNT

Sponsor: COLGATE-PALMOLIVE	Date initiated: 03-29-1993
Test article: C9316	Date scored: 03-31-1993
Description: WHITE POWDER	Study ID: CP9301C
Notepad #: 1779	Investigator: STANKOWSKI
Lot number: CC# 14663-09	Study director: STANKOWSKI
Assay description: AMES PLATE INCORP.	
Other considerations: RETEST: TA100 -S9	

CONTROLS-STUDY: CP9301C

CONTROL	DOSE	SALMONELLA STRAINS (REV/PL)
	S-9 UG/PL	TA100
DMSO (100 UL)	(-)	61 86 78
	Mean:	75
	Std Dev:	13
SODIUM AZIDE	(-) 10.0	1146 1036 1083
	Mean:	1088
	Std Dev:	55

† Positive Response: Greater than or equal to 2 x Solvent (TA100)

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WSP 31 MAR 93

PHARMAKON RESEARCH INTERNATIONAL, INC.
MICROBIAL MUTAGENICITY ASSAY

INDIVIDUAL PLATE COUNT

Sponsor: COLGATE-PALMOLIVE
Test article: 39316
Description: WHITE POWDER
Notebook #: 1779
Lot number: CC# 14663-09
Assay description: AMES PLATE INCORP.
Other considerations: RETEST: TA100 -S9

Date initiated: 03-28-1993
Date scored: 03-31-1993
Study ID: CP9301C
Investigator: STANKOWSKI
Study director: STANKOWSKI

TEST ARTICLE: 39316 STUDY: CP9301C

DOSE LEVELS	S-9	DOSE UG/PL	SALMONELLA STRAINS (REV/PL) TA100
39316	(-)	0.000167	86 91 86 Mean: 81 Std Dev: 13
39316	(-)	0.000500	72 79 80 Mean: 77 Std Dev: 4
39316	(-)	0.00167	93 102 77 Mean: 91 Std Dev: 13
39316	(-)	0.00500	78 86 109 Mean: 91 Std Dev: 16

*Insubt.
held
size*
*upst
3 AM 93*

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31 MAR 93

PHARMAKON RESEARCH INTERNATIONAL, INC.
MICROBIAL MUTAGENICITY ASSAY

INDIVIDUAL PLATE COUNT

Sponsor: COLGATE-PALMOLIVE Date initiated: 07-28-1993
Test article: 39316 Date scored: 07-31-1993
Description: WHITE POWDER Study ID: CP9301C
Notebook #: 1779 Investigator: STANKOWSKI
Lot number: CC# 14663-09 Study director: STANKOWSKI
Assay description: AMES PLATE INCORP.
Other considerations: RETEST: TA100 -S9

TEST ARTICLE: 39316 STUDY: CP9301C

DOSE LEVELS	S-9	DOSE UG/PL	SALMONELLA STRAINS (REV/PL) TA100
39316	(-)	0.0100	100 91 89 Mean: 93 Std Dev: 6
39316	(-)	0.0167	85 68 72 Mean: 75 Std Dev: 9
39316	(-)	0.0333	28 29 42 Mean: 33 a Std Dev: 8
39316	(-)	0.0500	13 6 2 Mean: 7 a/b Std Dev: 6

a/b - see next page.

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WFSR 31 MAR 93

PHARMACON RESEARCH INTERNATIONAL, INC.
MICROBIAL MUTAGENICITY ASSAY

INDIVIDUAL PLATE COUNT

Sponsor: COLGATE-PALMOLIVE	Date initiated: 03-29-1993
Test article: 39316	Date scored: 03-31-1993
Description: WHITE POWDER	Study ID: CP9301C
Notebook #: 1779	Investigator: STANKOWSKI
Lot number: CC# 14663-09	Study director: STANKOWSKI
Assay description: AMES PLATE INCORP.	
Other considerations: RETEST: TA100 -S9	

TEST ARTICLE: 39316 STUDY: CP9301C

DOSE LEVELS	S-9	DOSE UG/PL	SALMONELLA STRAINS (REV/PL) TA100
39316	(-)	0.100	4 3 1
		Mean:	3 c
		Std Dev:	2
39316	(-)	0.167	0 0 0
		Mean:	0 c
		Std Dev:	0

aslight/bModerate/cSevere toxicity.

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USA STANK 93

PHARMAKON RESEARCH INTERNATIONAL, INC.
MICROBIAL MUTAGENICITY ASSAY

INDIVIDUAL PLATE COUNT

Sponsor: COLGATE-PALMOLIVE
Test article: J9316
Description: WHITE POWDER
Notebook #: 1779
Lot number: CC# 14663-09
Assay description: AMES PLATE INCORP.
Other considerations: RETEST: TA100 -S9

Date initiated: 03-29-1993
Date scored: 03-31-1993
Study ID: CP9301C
Investigator: STANKOWSKI
Study director: STANKOWSKI

STERILITY CONTROLS (COLONIES/PLATE) FOR STUDY: CP9301C

S9 SYSTEM

0
0
0
✓ VSD - Not Applicable
VSD 31 MAR 93

TOP AGAR

0
0
0
- No precipitate.

SOLVENTS

0
0
0

SAMPLE

0
0
0

MISCELLANEOUS DATA FOR STUDY: CP9301C

COUNTER CALIBRATION #1 STANDARD: 1225 READING: 1226
COUNTER CALIBRATION #2 STANDARD: 1225 READING: 1226
COUNTER CALIBRATION TOLERANCE: 2 PERCENT

COUNTER SENSITIVITY: 7

READINGS TAKEN FROM: COUNTER

PRINTOUT OF COUNTER READINGS WAS NOT GENERATED
HISTORICAL DATA WAS NOT USED FOR CONTROL DATA (vs 20 Feb 93 update).
VSD - VSD 31 MAR 93

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U

VSD 31 MAR 93

1779

ANALYSIS OF MUTATION FREQUENCY

PROGRAM VERSION 4 REV. 1 PROGRAM DATE: 11/25/85

IBM-PC VERSION 4 REV. 1 RUN DATE: 3/31/93

CPY301C TA100 -59

.20

DATA TRANSFORMATION WILL BE Y=11+ .001

INPUT DATA

LINE#	DOSE	TRIAL #	RESULT
1	.00	1	61.0
2	.00	1	86.0
3	.00	1	78.0
4	.000167	1	66.0
5	.000167	1	91.0
6	.000167	1	86.0
7	.000500	1	72.0
8	.000500	1	79.0
9	.000500	1	80.0
10	.00167	1	93.0
11	.00167	1	102.0
12	.00167	1	77.0
13	.00500	1	70.0
14	.00500	1	86.0
15	.00500	1	109.0
16	.0100	1	100.0
17	.0100	1	91.0
18	.0100	1	89.0
19	.01677	1	85.0
20	.01677	1	68.0
21	.01677	1	72.0
22	.0333	1	28.0
23	.0333	1	29.0
24	.0333	1	42.0
25	.0500	1	13.0
26	.0500	1	6.0
27	.0500	1	2.0

Increment edit-
with 27 not 493
(hole entry)

WSE 31 MAR 93

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PROGRAM VERSION 4 REV. 1 RUN DATE: 3/31/93

1779

CPT501C TA100 -59

INPUT DATA				TRANSFORMED FREQUENCY		
DOSE	TRIAL	MUTATION FREQUENCY	NO. OF RESULTS	AVERAGE	AVERAGE	STD DEV
.000	1	61.0 86.0 78.0	3	75.0	2.3676	.0832
.000167	1	66.0 91.0 86.0	3	81.0	2.4046	.0817
.000900	1	72.0 79.0 80.0	3	77.0	2.3835	.0273
.00167	1	93.0 102.0 77.0	3	90.7	2.4605	.0702
.00300	1	78.0 86.0 109.0	3	91.0	2.4610	.0852
.0100	1	100.0 91.0 89.0	3	93.3	2.4770	.0307
.0167	1	83.0 68.0 72.0	3	75.0	2.3697	.0552

USL 31 MAR 93

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1779

.0333	1	28.0	3	33.0	2.0067	.0913
		29.0				
		42.0				
.0900	1	13.0	3	7.0	1.4166	.2611
		6.0				
		2.0				

POOLED REPLICATE STANDARD DEVIATION = .1091 TRANSFORMATION

DEGREES OF FREEDOM = 10 .29
 STANDARD DEVIATION
 NUMBER OF RESULTS = 3 $\chi^2(1) = .001$
 UPPER CONTROL LIMIT = .2241

* STANDARD DEVIATION IS SIGNIFICANTLY LARGE INDICATING THAT
 SOME ATYPICAL (IE OUTLIER) TEST RESULTS MAY BE PRESENT.

440

1582
 31 MAR 93

PROGRAM VERSION 4 REV. 1 RUN DATE: 3/31/93

1779

CPY301C TA100 -99

STATISTICAL ANALYSIS OF MUTAGENICITY

DOSE	AVERAGE	T	PROB	MUTATION FREQUENCY
.000	2.3676			74.4
.000167	2.4046	.42	.6827	80.4
.000500	2.3833	.18	.8599	76.9
.00167	2.4685	1.04	.3106	90.2
.00500	2.4610	1.05	.3082	90.3
.0100	2.4770	1.23	.2332	93.2
.0167	2.3697	.02	.9814	74.7
.0333	2.0067	-4.05	.0007	32.5
.0500	1.4166	-10.60	.0000	5.7

T IS STUDENT'S T-STATISTIC FOR THE COMPARISON OF EACH
DOSE LEVEL TO THE NEGATIVE CONTROL (DOSE = 0).

SOURCE OF VARIATION	DOSE-RESPONSE ANALYSIS OF VARIANCE				PROB
	DEGREES OF FREEDOM	SUM OF SQUARES	MEAN SQUARE	F RATIO	
TOTAL	26	3.10			
TRIAL	0	.00			
DOSE	8	2.89			
LINEAR	1	2.47	2.47	207.94	.0000
QUADRATIC	1	.39	.39	32.62	.0000
HIGHER ORDER	6	.03	.00	.39	.8700
RESIDUAL	18	.21	.01		

DOSE X TRIAL INTERACTION
F RATIO DEGREES OF FREEDOM PROBABILITY

0 AND 10

A SIGNIFICANT DOSE-TRIAL INTERACTION INDICATES THAT THE
DOSE-RESPONSE RELATIONSHIP IS DIFFERENT IN THE DIFFERENT
TRIALS . THE DOSE-RESPONSE ANOVA ABOVE ASSUMES THAT THIS
INTERACTION IS NOT STATISTICALLY SIGNIFICANT.

WSE
31 MAR 93

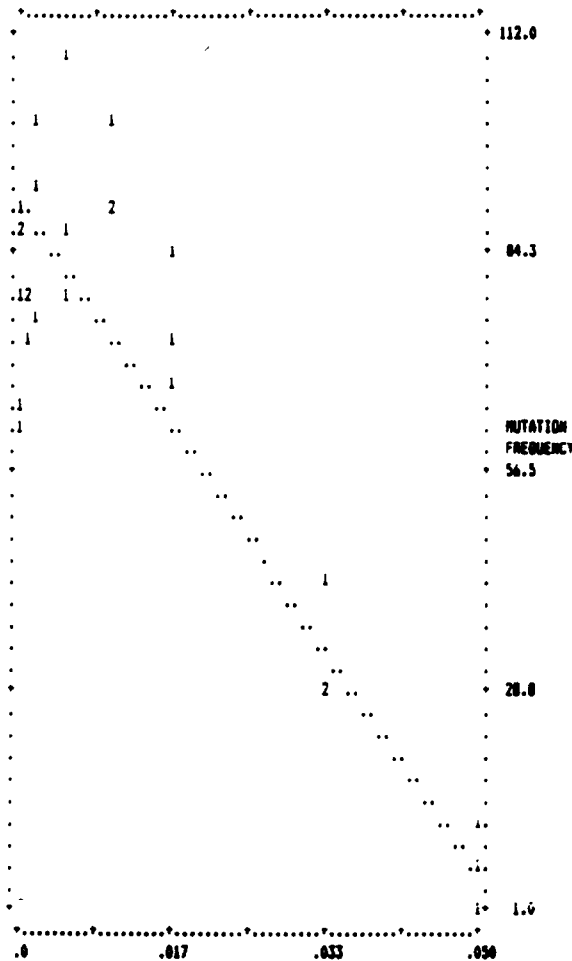
441

PROGRAM VERSION 3 REV. 4 RUN DATE: 3/31/93CP9301C TA100 -59

1779

NPTS= 27

R= -.8798



	MUTATION FREQUENCY	DOSE
MEAN	.69222E+02	.13037E-01
STD DEV	.29631E+02	.16937E-01
MIN	.20000E+01	.00000E+00
MAX	.10900E+03	.50000E-01

DOSE-RESPONSE RELATIONSHIP

INTERCEPT = 90.65
SLOPE = 0.00000000

LACK OF FIT

F= 1.47 PROBABILITY= .2401
DEGREES OF FREEDOM = 7, 10
CONVERGENCE EPSILON

DOSE	SLOPE	CONFIDENCE	LIMITS
		LOWER	UPPER
LINEAR	0.00000000	0.00000000	0.00000000
NONLINEAR	0.00000000	0.00000000	0.00000000

TEST 3 ITERATIONS

112

EXPERIMENTAL CONDITIONS

Ames Assay

Positive Control Preparation

Compound	Solvent	Weights	mg/ml	ug/plate
<u>Sodium Azide</u>	<u>d₄ H₂O</u>	Weight _____	<u>0.100</u>	<u>→ 10.0</u>
Supplier <u>Sigma</u>		Tare <u>0.00 mg</u>		
Lot # <u>J6C-0263</u>		Compd. wt. <u>67.2 mg</u>		
		Solvent q.s. to <u>3.36 ml</u>		
		* Concentration: <u>20.0 mg/ml</u>		
			1:200	0.8 mg 67.2 mg KPM 7-23-92
Compound	Solvent	Weights	mg/ml	ug/plate
<u>9-Aminacridine</u>	<u>DMSO</u>	Weight _____	<u>1.5</u>	<u>→ 150</u>
Supplier <u>Sigma</u>		Tare <u>0.00 mg</u>		
Lot # <u>030567</u>		Compd. wt. <u>177.6 mg</u>		
		qs to <u>5.92 ml</u>		
		Concentration: <u>30.0 mg/ml</u>		
			1:20	0.8 mg 177.6 mg KPM 7-23-92
Compound	Solvent	Weights	mg/ml	ug/plate
<u>2-Nitrofluorene</u>	<u>DMSO</u>	Weight _____	<u>0.0500</u>	<u>→ 5.00</u>
Supplier <u>Aldrich</u>		Tare _____		
Lot # <u>2610 PE</u>		Compd. wt. <u>54.8 mg</u>		
		qs to <u>2.74 ml</u>		
		Concentration: <u>20.0 mg/ml</u>		
			1:400	0.8 mg 54.8 mg KPM 7-23-92
Compound	Solvent	Weights	mg/ml	ug/plate
<u>ENNG</u>	<u>DMSO</u>	Weight _____	<u>0.0200</u>	<u>→ 2.00</u>
Supplier <u>Sigma</u>		Tare _____		
Lot # <u>123F 3660</u>		Compd. wt. <u>155 mg</u>		
		qs to <u>1.55 ml</u>		
		Concentration: <u>100 mg/ml</u>		
			1:100	0.8 mg 155 mg KPM 7-23-92
Compound	Solvent	Weights	mg/ml	ug/plate
<u>2-Androline</u>	<u>DMSO</u>	Weight _____	<u>0.800</u>	<u>→ 80.0</u>
Supplier <u>Sigma</u>		Tare <u>0.00 mg</u>		
Lot # <u>33F 0816</u>		Compd. wt. <u>123.9 mg</u>		
		qs to <u>6.30 ml</u>		
		Concentration: <u>20.0 mg/ml</u>		
			1:100	0.8 mg 123.9 mg KPM 7-23-92
Compound	Solvent	Weights	mg/ml	ug/plate
_____	_____	Weight _____	0.0250	→ 2.50
Supplier _____		Tare _____		
Lot # _____		Compd. wt. _____		

a Pharmacia; lot # 7892

b Fisher; lot # 902873

* Skittized with 0.2um filter

OK
Jmm
7-23-92

Notebook #: 1729

Screening of Salmonella Tester Strains

PURPOSE: To evaluate Salmonella tester strains for the retention of their characteristic genetic markers (per SOP PH339).

Date Initiated: 3-1-93

Date Completed: 3-2-93

	Strain							
	1335	1337	1338	97	98	100	102	104
	1-1-93	1-1-93	1-1-93	1-1-93	1-1-93	1-1-93	1-1-93	1-1-93
Aliquot #	5	5	5	3	5	5	3	3
OD ₆₅₀ (1:2 dil.)	0.474	0.508	0.555	0.323	0.701	0.767	0.449	0.764
<u>Genetic Traits</u>								
Histidine -	-	-	-	-	-	-	-	-
Histidine +	+	+	+	+	+	+	+	+
Crystal Violet	-	-	-	-	-	-	-	-
Ampicillin	-	-	-	+	+	+	+	+
Tetracycline	-	-	-	-	-	-	+	-
Chloramphenicol	-	-	-	-	-	-	-	-
UV-Light	-	-	-	-	-	-	+	-

(+) denotes growth
(-) denotes no growth

Strains have retained their genetic characteristics: Yes ☒
No ☐

TAP 3-2-93
Investigator Date

OTC Vol. No. 111

OTC Docket Number 75N-0183 (triclosan)

September 12, 1994

Ciba-Geigy Corporation

Chemicals Division

Greensboro, N.C. 27419

Ciba-Geigy. Summary of Current Available Safety Data on Triclosan. Triclosan Industry Alliance. August 15, 1994.

Study Summary

This report summarizes the available safety data on triclosan as of August 15, 1994. This summary was prepared to provide FDA staff with a concise but comprehensive summary of relevant safety data on triclosan. It includes data previously gathered and reviewed by an independent panel of toxicology and pathology experts convened by ENVIRON at the request of Ciba and Colgate-Palmolive, additional data developed since completion of the Expert Panel's review, and data made available from other members of the Industry Alliance that was not reviewed by the Expert Panel convened by ENVIRON (referred to as the "Expert Panel").

75N-183H

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**SUMMARY OF SELECTED SAFETY DATA ON TRICLOSAN
BEING SUBMITTED TO OTC DOCKET NUMBER 81N-0033 (triclosan)**

The safety assessment of triclosan described herein is based on relevant data in possession by or available to members of the Triclosan Industry Alliance as of August 15, 1994.

This current summary was prepared to provide FDA staff with a concise but comprehensive summary of selected safety data on triclosan. It includes a summary of data previously gathered and reviewed by an independent panel of toxicology and pathology experts convened by ENVIRON (referred to hereafter as the "Expert Panel") at the request of Ciba and Colgate-Palmolive; additional data developed since completion of the Expert Panel's review, and data made available from other members of the Industry Alliance that was not reviewed by the Expert Panel.

This summary reviews:

- | | |
|---|------|
| I. Subchronic Toxicity Studies | p. 2 |
| II. Chronic Toxicity/Oncogenicity Studies | p. 5 |
| III. Genetic Toxicity Studies | p. 7 |

and each section follows the format of:

- A. Synopsis of Studies Reviewed by the Expert Panel,
- B. Expert Panel Summary,
- C. Synopsis of Additional Studies (not reviewed by the Expert Panel),
- D. Summary of Additional Studies (not reviewed by the Expert Panel).

Unless otherwise noted, the reference numbers refer to those used in the Expert Panel Report. A partial list of references, those that are relevant to this submission, is included.

I. SUBCHRONIC TOXICITY STUDIES

I. A. Studies Reviewed by the Expert Panel

The subchronic toxicity of triclosan has been evaluated in numerous animal studies (Reference Nos. 17-32, 52) employing several species (i.e., rats, mice, rabbits, dogs, baboons, and rhesus monkeys) and routes of administration (i.e., oral gavage, oral diet, dermal, inhalation.) In total, the available data adequately characterize the subchronic toxicity of triclosan (see Summary Table 1, page 4).

The toxicity elicited following administration of triclosan varied by the route of administration and more importantly, by species with the mouse, dog, and rabbit being most susceptible to toxic effects of triclosan followed by the rat and the baboon. In general, toxicity was primarily limited to hepatic effects with minimal renal and hematopoietic changes noted in several species. The summary below describes a 90-day dietary feeding study in rats which served as the key range-finding study for a subsequent chronic toxicity/carcinogenicity study.

In this study (Reference No. 20), triclosan was administered at dietary concentrations of 0, 1000, 3000, and 6000 ppm representing average daily doses of approximately 0, 65, 203, and 433 mg/kg in males and 0, 82, 259, and 555 mg/kg in females, respectively. The Expert Panel concluded that body weight changes (i.e., decreases) along with compound-related alterations in the liver at the mid- and high-dose levels supported the selection of 3000 ppm as the highest dose (MTD) for the subsequent two-year carcinogenicity study in the rat. Furthermore, the Expert Panel agreed that current guidelines on selection of the maximum tolerated dose support the concept that "the MTD is a predicted value derived from observed toxicity in subchronic or range-finding studies. Based on this principle, if the highest dose was predicted from observed toxicity in subchronic studies, but adaptation occurred during chronic exposure to negate these toxic effects, then the chronic study would still meet scientific standards, and, thereby, would not need to be repeated because of an absence of an MTD" (Reference No. 106).

Current guidelines (Reference No. 103) suggest that the high-dose level of carcinogenicity studies "should be sufficiently high to elicit signs of minimal toxicity without substantially altering the normal life-span of the animals due to effects other than tumors. Signs of toxicity are those that may be indicated by alterations in serum enzyme levels or slight depression of body weight gain (less than ten percent)" (Reference 106). The aforementioned 90-day range-finding study demonstrated decreases in mean body weight gain of 1, 3, 5, and 7% in mid-dose (3000 ppm) males and 1, 7, 12, and 20% in mid-dose females at weeks 1, 3, 6, and 12 of the study. High-dose (6000 ppm) males demonstrated decreases in mean body weight gains of 43, 19, 24, and 20% at weeks 1, 3, 6, and 12 of the study, while females (6000 ppm level) demonstrated 47, 32, 31, and 34% depressions in mean body weight gain at the same body weight measurement periods. All high-dose body weight gain changes were statistically significant ($p < 0.01$) when compared to control group data (see Expert Panel Report, Appendix III). Furthermore, an independent pathology working group (PWG) review revealed a high incidence of hepatic centrilobular hypertrophy in rats of the mid-dose group (3000 ppm), an incidence which was similar to that identified in the high-dose group (Expert Panel Report Appendix IV). It was concluded by the PWG and the Expert Panel that the 3000 ppm dose was the appropriate choice for the MTD in the two-year carcinogenicity study based on median depressions of body weight gain (males, 4%; females, 9% of control) and the presence of histopathological lesions, which although not life threatening, were consistent with hepatic microsomal enzyme induction, and therefore sufficient to realize any carcinogenic potential.

It is clear that the intent of current guidelines on selection of the maximum tolerated dose (MTD) was met. Minimal toxicity (i.e., depressions of body weight gain and hepatic changes) was elicited which could be predicted to not substantially alter the life-span of the animals. A concentration of 6000 ppm resulted in

median body weight depressions of 22% and 33% which were considered excessive for a life-span study. This prediction was substantiated by the chronic toxicity/carcinogenicity study body weight gain data which revealed median weight gain depressions (12% and 28% of male and female controls, respectively) at 6000 ppm measured at 52 weeks.

I. B. Expert Panel Summary (of Above Studies)

The Expert Panel concluded that the subchronic database adequately characterized the subchronic toxicity of triclosan and appropriately supported the experimental design, including dose level selection, of the subsequent chronic bioassay.

I. C. Additional Studies (Not Reviewed by the Expert Panel)

Since the Panel's report, additional subchronic studies have been conducted or been made available to the Industry Alliance, including a 90-day dietary study in mice and a 90-day dermal study in rats. These studies are summarized below.

1. A 90-day dietary feeding study with male and female CD-1 mice was completed using seven dose levels, 0.0, 25, 75, 200, 350, 750, and 900 mg/kg of body weight (OTC Volumes 114 and 115). Hepatic hypertrophy, inflammation, and necrosis were evident in the males receiving 75 mg/kg and in the females receiving 200 mg/kg and higher doses. The severity of liver damage was correspondingly greater in those animals receiving higher doses. It was concluded that survival would be compromised in a carcinogenic study if the males received dosages greater than 200 mg/kg and the females received doses greater than 350 mg/kg. Dose-related decreases in mean erythrocyte count and hemoglobin values were also observed in males at doses of 25 mg/kg and higher, and in females at 75 mg/kg and higher.

2. A 90-day dermal toxicity study was carried out with Sprague-Dawley rats for which the following application regimen was used: The control group received the vehicle, propylene glycol (PPG), and the test groups received 10, 40, and 80 mg/kg applied to the skin daily, five days per week, for at least 90 days (OTC Volume 116). These doses correspond to triclosan concentrations of 0.5, 2.0, and 4.0 percent. Test mixtures were covered with a gauze pad which was secured with non-porous plastic tape and elastic wrap. A fifth group, treated dermally with 80 mg/kg, served as a satellite recovery group (28 additional days on study without treatment). Dermal effects were observed on days 0, 1, 4, and twice weekly thereafter until the completion of the study. Clinical observations, ophthalmoscopy, hematology, blood chemistry, urinalysis and histopathology were performed. There was no systemic toxicity evident at necropsy, and treatment-related effects were limited to dermal irritation. Erythema and/or edema were observed in all treatment groups at the site of skin application. Treatment-related histopathologic changes were confined to the treated areas of skin and consisted of a dose-related increase in the incidence and severity of epidermal hyperplasia/hyperkeratosis, sebaceous gland hyperplasia, dermal inflammation, focal epidermal necrosis, and exudate. In the satellite recovery group, these changes were less frequent and severe, but there was an increased incidence of dermal fibrosis. The dermal effects at 0.5 percent triclosan (10 mg/kg) were delayed in onset and significantly less severe than effects observed at 2.0 and 4.0 percent (40 and 80 mg/kg). Under the conditions of this study, a NOAEL for dermal effects was not identified. The NOAEL for systemic toxicity was considered to be 80 mg/kg.

I. D. Summary of Additional Studies (Not Reviewed by the Expert Panel)

The studies summarized in the table below, along with other existing and ongoing studies, will be taken into consideration when selecting an appropriate species and study design for subsequent chronic toxicity/carcinogenicity investigations.

Summary Table 1
Subchronic Toxicity Studies with Triclosan
(Includes studies reviewed and studies not reviewed by the Expert Panel)

Type of Study	Species	Doses (mg/kg/day)	NOEL (mg/kg)	Expert Panel Report Ref.	CIBA OTC File Ref.
90-day oral, feeding	rat	0, 125, 250, 500, and 1000	No NOEL ⁽¹⁾	17	Volume 2 Reference 5
90-day oral, feeding	rat	males: 0, 65, 203, 433 females: 0, 82, 259, and 555	males: 65 females: 82	20	Volume 2 Reference 8
90-day oral, feeding	dog	0, 5.0, 12.4, and 24.9	24.9	25	Volume 4 Reference 11
90-day oral, capsule	dog	0, 25, 50, 100, and 200	No NOEL ⁽²⁾	26	Volume 5 Reference 12
91-day oral, feeding	mouse	0, 25, 75, 200, 350, 750, and 900	No NOEL ⁽³⁾	not reviewed	Volumes 114 & 115
90-day oral, feeding	rabbit	0, 12.5, 25, 62.5, and 125	125	24	Volume 4 Reference 10
90-day dermal	rat	0, 10, 40, and 80 ⁽⁴⁾	No NOEL ⁽⁵⁾	not reviewed	Volume 116
90-day dermal	rabbit	0, 3, 15, and 30	3	29	Volume 6 Reference 18
90-day oral, capsule	baboon	0 and 3	3	27	Volume 5 Reference 13

(1) Histopathological changes in the liver and clinical chemistry changes observed at 125 mg/kg.

(2) Fatty liver changes observed at 25 and 50 mg/kg.

(3) Slight reduction in RBC count and reduction in serum cholesterol observed at 25 mg/kg.

(4) Represents suspensions of 0.5, 2.0, and 4.0 percent triclosan in PPG.

(5) Dermal irritation observed at all concentrations tested. An NOEL of 80 mg/kg/day for systemic toxicity was identified.

II. CHRONIC TOXICITY/ONCOGENICITY STUDIES

II. A. Studies Reviewed by the Expert Panel

1. In a one-year study in baboons, triclosan was administered via oral capsules at doses of 0, 30, 100, and 300 mg/kg for up to 367 days. There were no treatment-related changes in hematological or blood chemistry values. Intermittent diarrhea was observed at the 100 and 300 mg/kg levels. The severity of the diarrhea was dose-related. No test material-related histopathological findings were reported.

2. In a combination chronic toxicity/oncogenicity study with triclosan, male and female Sprague-Dawley rats were administered dietary concentrations of 0, 300, 1000, and 3000 ppm for 13, 26, 52, 78, and 104 weeks (Reference No. 33). The average daily intake (mg/kg/day) of triclosan on a body weight basis approximated 0, 16, 52, and 168 mg/kg/day for males; and 0, 20, 67, and 218 mg/kg/day for females receiving 0, 300, 1000, and 3000 ppm triclosan in the diet, respectively. Sixty rats/sex/dose level received triclosan in the diet (0, 300, 1000, 3000 ppm) for the two-year period while 5 or 10 additional rats/sex/dose level were administered triclosan for 13, 26, 52, or 78 weeks. A satellite group (20 rats/sex) was fed diet containing 6000 ppm triclosan (approximately 418 mg/kg/day for males and 532 mg/kg/day for females) for one year.

There were no treatment-related effects on mortality during the course of the study, nor were there any clinical signs of toxicity observed which could be considered related to treatment. Dose-related changes were observed in mean body weight gain, as well as select hematology, clinical chemistry, and urinalysis parameters at various time periods post-treatment, mainly in the 3000 and 6000 ppm groups. Statistically significant decreases in mean body weight gain ($p < 0.05$) were observed in high-dose (6000 ppm) males and mid- and high-dose females throughout the study period. Like previously conducted subchronic studies, toxicity was mainly hepatic in nature as identified by centrilobular hypertrophy and associated clinical chemistry changes.

In order to further define non-neoplastic and any potential preneoplastic changes in the study, an independent pathology working group (PWG) was assembled. The PWG reviewed select hepatic and pulmonary lesions identified in rats of all dosage levels (0, 300, 1000, 3000 and 6000 ppm). The PWG reported (Expert Panel Report Appendix IV) that centrilobular hypertrophy was found in the 3000 and 6000 ppm dose level males and the 6000 ppm dose level females sacrificed at 52-weeks of the study. No hepatic putative preneoplastic or neoplastic lesions were found in increased incidence in any treatment group. In animals administered triclosan for two years (0, 300, 1000, and 3000 ppm), some non-neoplastic lesions (i.e., hepatocellular lesions including eosinophilic foci, zonal necrosis, focal necrosis, and cystic degeneration and pneumonitis of the lung) were increased in incidence in some groups of treated rats, but none were dose-related nor increased in severity from those found in controls. The PWG found no evidence of any non-neoplastic, preneoplastic, or neoplastic lesions related to administration of triclosan. This substantiates the conclusion in the chronic toxicity/carcinogenicity study report that the highest concentration of triclosan fed for two years, 3000 ppm, produced no evidence of carcinogenic effects.

II. B. Expert Panel Summary

The Panel found no evidence in the chronic studies to suggest a carcinogenic effect related to triclosan. Appropriate dose level selection (MTD) was based upon decreases in mean body weight gain (Expert Panel Report Appendix III) and the presence of compound-related histopathological lesions in a properly designed subchronic toxicity study. These conclusions were further confirmed by an independent pathology working group (Expert Panel Report Appendix IV). An NOAEL of 1000 ppm (approximately 52 mg/kg/day) was identified in the study.

Summary Table 2
Chronic Toxicity Studies with Triclosan

Type of Study	Species	Doses (mg/kg/day)	NOEL (mg/kg)	Expert Panel Report Ref.	CIBA OTC File Ref.
1-year oral, capsule	baboon	0, 30, 100, and 300	30	28	Volume 5 Reference 14
2-year oral, feeding	rat	males: 0, 16, 52, 168, and 418 females: 0, 20, 67, 218, and 532	males: 52 females: 67	33	Volumes 7, 8, 9, and 10

III. GENETIC TOXICITY STUDIES

III. A. Studies Reviewed by Expert Panel

Triclosan has been tested for mutagenic and genotoxic potential in numerous *in vitro* and *in vivo* assays, among others are those listed below (References 37-51, 105).

- a) Ames tests
- b) Drosophila
- c) mouse lymphoma
- d) dominant lethal
- e) chromosome studies in male reproductive cells
- f) chromosome studies in somatic cells, and
- g) micronucleus assay

Of the 16 study reports/publications considered, only two tests demonstrated weak positive responses. These were genetic activity in MP-1 *S. cerevisiae* and the mammalian spot test, which upon repetition, were both negative.

III. B. Expert Panel Summary

Although several of the studies referenced above were conducted prior to the issuance of GLP requirements, the Expert Panel concluded that the current battery of genetic toxicity tests supports the conclusion that 1) triclosan is not genotoxic, and 2) the genetic toxicity database supports the lack of carcinogenic effect found in the two-year rat feeding study. However, the Panel recommended that an Ames test and an unscheduled DNA synthesis (UDS) assay employing current protocols be conducted.

III. C. Additional Studies (Not Reviewed by the Expert Panel)

Since the Expert Panel's review, additional studies have been performed and/or been made available to the Industry Alliance including the recommended Ames and UDS studies summarized below.

The Colgate-Palmolive Company recently sponsored an Ames assay (OTC Volume 110) and an unscheduled DNA (UDS) repair study (OTC Volume 109) with triclosan. The Ames study employed five strains of Salmonella typhimurium in the presence and absence of an exogenous metabolic activation system. Revertant frequencies for all concentrations of triclosan were similar to control values. The potential for triclosan to induce unscheduled DNA synthesis was evaluated in primary rat hepatocyte cultures. Autoradiographic analysis of the hepatocytes treated with triclosan revealed "cells in repair" levels similar to the untreated media and DMSO controls.

Independently, Unilever sponsored the studies listed in the table below:

Type of Study	OTC Volume Number
Ames assays	103
Unscheduled DNA repair	106
Mouse micronucleus	104
Mouse lymphoma studies	105

All of these *in vitro* tests were performed with and without S9 enzyme activation and showed that triclosan was not mutagenic. The *in vivo* micronucleus study further substantiated this finding.

Independent studies sponsored by Unilever and Ciba assessed the potential of triclosan to induce structural chromosome aberrations *in vitro*. In the Ciba study (OTC Volume 107), V-79 cells were treated with and without S9 mix at concentrations up to 3 ug/ml. Increases in cells with structural aberrations were observed after treatment with triclosan at fixation intervals of 18 and 28 hours at 3 ug/ml, a concentration which also produced cytotoxicity. In the Unilever study (OTC Volume 113), cultured Chinese Hamster ovary (CHO) cells were treated with triclosan at concentrations up to 1 ug/ml in the absence of metabolic activation and up to 38 ug/ml in its presence. No significant increase in chromosomal aberrations occurred at any concentration.

In a follow-up to the positive chromosome aberration study, Ciba conducted an *in vivo* study to assess the potential of triclosan to induce chromosome aberrations in bone marrow cells of the rat (OTC Volume 108). Triclosan was administered at a dose of 4000 mg/kg body weight, which was identified as the maximum tolerated dose. At 6, 24, and 48 hours after the single administration of triclosan, bone marrow cells from ten animals (five/sex) were collected for chromosome aberration analysis. Under these experimental conditions, triclosan did not induce chromosome aberrations *in vivo* in the bone marrow cells of the rat.

III. D. Summary Additional Studies (Not Reviewed by Expert Panel)

The Ciba *in vitro* chromosome aberration study gave a positive result at the highest concentration tested (3 ug/ml). A comparable study conducted by Unilever at higher concentrations (up to 38 ug/ml) was negative. In addition, the *in vivo* mouse micronucleus tests and rat bone marrow chromosome aberration studies were negative for mutagenic effects. These results provide significant substantiation to the Expert Panel's conclusion that triclosan is not genotoxic.

OVERALL SUMMARY

The toxicological database on triclosan in the areas of subchronic toxicity, chronic toxicity/carcinogenicity, and genetic toxicity is substantial and supports the safe use of this substance in its current applications.

SELECTED EXPERT PANEL REPORT REFERENCES

(The numbering system utilized is not consecutive because only selected portions of the Expert Panel Report are presently being submitted to the OTC file.)

17. CIBA-GEIGY. 1968. *Thirteen-week oral toxicity study in rat*. January 22.
18. Laboratorium fur Pharmakologie and Toxikologie. 1970. *Ninety days oral toxicity study in Sprague Dawley rats with CH 3565*. July 27.
19. Sterling - Winthrop Research Institute. 1973. *Oral administration of Irgasan DP300 to albino rats for three months*. March 16.
20. Litton Bionetics. 1983. *Ninety-day oral toxicity study in rats with FAT 80023/H*. October.
21. Biodynamics, Inc. 1990. *A 13-week oral toxicity study in rats via gastric intubation with active materials A (37935) and B (37928)*. May 21.
22. CIBA-GEIGY. 1987. *Twenty-eight-day oral toxicity study of triclosan in MAGf mice*. April 10.
23. CIBA-GEIGY. 1969. *Irgasan DP300 (GP 41353), 13-week oral toxicity study in rabbits*. March 31.
24. Laboratorium fur Pharmakologie and Toxikologie. 1970. *Ninety-day oral toxicity study in New Zealand white rabbits with CH 3565*. July 31.
25. Laboratorium fur Pharmakologie and Toxikologie. 1970. *Ninety-day oral toxicity in beagle dogs with CH 3565*. July 10.
26. CIBA-GEIGY. 1967. *Irgasan DP300 (GP 41353), 91-day oral toxicity study in dogs*. December 21.
27. CIBA-GEIGY. 1969. *Irgasan DP300 (GP 41353), oral toxicity study in baboons (repeated dosage for 4 and 13 weeks)*. April 17.
28. CIBA-GEIGY. 1975. *One-year oral toxicity study in baboons with compound FAT 80023/A*. July 28.
29. Laboratorium fur Pharmakologie and Toxikologie. 1970. *Ninety-days dermal toxicity of CH3565 in New Zealand white rabbits*. September 7.
30. Hazleton Laboratories America. 1979. *Ninety-day bathing study of newborn rhesus monkeys with triclosan soap solution*. April 26.

31. Laboratory Research Enterprises, Inc. 1973. *The systemic toxicological effects of three bacteriostats topically applied to the skin of young canines*. November 15.
32. CIBA-GEIGY. 1974. *Twenty-one-day inhalation study of triclosan (Irgasan DP300) in the rat*. July 24.
33. CIBA-GEIGY. 1986. *FAT 80023 (triclosan), two-year oral administration to rats*.
37. Zentrallaboratorium für Mutagenitätsprüfung der Deutschen Forschungsgemeinschaft. 1978. *Genetic activity of Irgasan DP300 in the MP-1 strain of S. Cerevisiae*. June 22.
38. CIBA-GEIGY. 1978. *Mutagenicity test on Saccharomyces Cerevisiae MP-1 in vitro with FAT 80023/A*. November 27.
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OTC Vol. No. 112

OTC Docket Number 75N-0183 (triclosan)
September 12, 1994

Ciba-Geigy Corporation
Chemicals Division
Greensboro, N.C. 27419

Goodman, D.G. Pathology Working Group Report on Triclosan 90-Day Subchronic Toxicity Study in Sprague-Dawley Rats. Prepared by PATHCO, Inc. for Ciba-Geigy. January 23, 1990. Pathology Working Group members included: J.M.Cullen, D.G. Goodman, P.M. Newberne, R.M. Sauer, R.A. and Squire, J.M. Ward.

Study Summary

Based on their review of the histopathologic lesion and the data from the 90-day subchronic study, the PWC believes that there is an adequate basis for selection of a maximum tolerated dose (MTD) for a chronic study. The PW believes that a dose of 3,000 ppm would be an appropriate MTD for a chronic study in rats. This conclusion is based on a combination of excessive decreases in body weight gain in the 6,000 ppm dose groups of both sexes and the presence of compound-related histopathologic lesions in both the 3,000 and 6,000 ppm doses group of both sexes.



**PATHOLOGY WORKING GROUP
REPORT ON TRICLOSAN
90-DAY SUBCHRONIC TOXICITY
STUDY IN SPRAGUE-DAWLEY RATS**

Submitted to:
CIBA-GEIGY Corporation
Ardsley, NY 10502

Prepared by:
Dawn G. Goodman, V.M.D.
Pathology Working Group Chairperson
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Veterinary Pathologists

PATHCO, Inc.
10075 Tyler Place, Suite 16
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January 23, 1990



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	D. G. Goodman, Chairperson
	J. M. Cullen, Participant
	P. M. Newberne, Participant
	R. A. Squire, Participant
	J. M. Ward, Participant
	R. M. Sauer, Reviewing Pathologist



TRICLOSAN SUBCHRONIC STUDY
PATHOLOGY WORKING GROUP (PWG)

SPECIES : Sprague-Dawley Rats

TYPE OF STUDY : 90-Day Subchronic Study

SPONSOR : Ciba-Geigy Corporation

LABORATORY : Litton Bionetics, Inc.

PATHOLOGIST : George A. Parker, D.V.M.

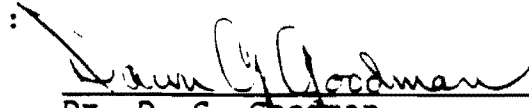
REVIEWING PATHOLOGIST : Robert M. Sauer, V.M.D.

DATE OF PWG : December 20, 1990


SITE OF PWG : PATHCO, Inc.
10075 Tyler Place, Suite 16
Ijamsville, MD 21754



PWG PARTICIPANTS



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PATHCO, Inc., Chairperson



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Dr. R. A. Squire
Robert A. Squire Associates
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Dr. J. M. Ward
Consultant



Dr. R. M. Sauer
PATHCO, Inc., Reviewing Pathologist



**PATHOLOGY WORKING GROUP
REPORT ON TRICLOSAN 90-DAY SUBCHRONIC
TOXICITY STUDY IN SPRAGUE-DAWLEY RATS**

**I. SUMMARY AND CONCLUSIONS OF THE PATHOLOGY WORKING GROUP
(PWG) REVIEW**

Based on their review of the histopathologic lesions and the data from the 90-day subchronic study, the PWG believes that there is an adequate basis for selection of a maximum tolerated dose (MTD) for a chronic study. The PWG believes that a dose of 3000 ppm would be an appropriate MTD for a chronic study in rats. This conclusion is based on a combination of excessive decreases in body weight gain in the 6000 ppm dose groups of both sexes and the presence of compound-related histopathologic lesions in both the 3000 and 6000 ppm dose groups of both sexes.

II. INTRODUCTION

PATHCO, Inc., was requested to conduct an independent panel review of the slides and data from the 90-day subchronic study of triclosan in Sprague-Dawley rats conducted by Litton Bionetics, Inc. This study was used to set the doses for the chronic toxicity/carcinogenicity study. The PWG was asked to determine what an appropriate MTD would be for a two-year study. Hematoxylin and eosin stained microscope slides for livers and the final study report, including all individual animal diagnoses were received by PATHCO, Inc.

III. STUDY DESIGN

Triclosan was administered in the feed to male and female Sprague-Dawley rats at dose levels of 0, 1000, 3000, or 6000 ppm for up to 90 days. There were 25 animals per sex per dose group at the start of the study. Ten animals per sex per group were sacrificed at 45 days.

IV. CONDUCT OF THE PWG REVIEW

The PWG was chaired by Dr. Dawn G. Goodman who organized and presented the material to a panel of four



additional pathologists. The other members of the PWG were Dr. J. M. Cullen, Dr. P. M. Newberne, Dr. R. A. Squire, and Dr. J. M. Ward. C.V.s for the Chairperson, the PWG participants, and the Reviewing Pathologist are presented in Appendix C.

A. Histopathologic Evaluation of Livers Without Knowledge of Treatment

Prior to the PWG review, the slides were randomized and coded from 1 to 100 for males and 1 to 100 for females on removable labels color coded by sex. Dr. Robert M. Sauer, the Reviewing Pathologist, reviewed all of the liver slides without knowledge of treatment or diagnoses made previously. The lesions to be reviewed were centrilobular hepatocellular hypertrophy and fatty change.

Once the review was completed, Dr. Sauer's diagnoses were decoded and Pathology Review Worksheets were prepared comparing his diagnoses with those of the Study Pathologist's (Appendix B). Cytomegaly was matched with hypertrophy and fatty metamorphosis with fatty change.

B. Chairperson's Review

Prior to the PWG review, the Chairperson reviewed the pathology incidence tables for liver, the Study Pathologist's report, the Pathology Review Worksheets (Appendix C), and the study protocol. The Chairperson reviewed all of the slides with hepatocellular cytomegaly/hypertrophy and fatty metamorphosis/fatty change diagnosed by either the Study Pathologist or the Reviewing Pathologist.

C. PWG Review

The PWG examined coded slides without knowledge of treatment or dose group. The PWG examined selected examples of livers for which the Study Pathologist, the Reviewing Pathologist, and the Chairperson all agreed on the diagnosis of centrilobular hypertrophy (cytomegaly) or of centrilobular fatty change. They also reviewed selected examples of livers where two of the three aforementioned pathologists agreed and all livers when only one pathologist had made a diagnosis of hypertrophy or fatty change. Livers from control animals were available for comparison.



Each participant recorded his diagnoses and/or comments on his worksheets. The worksheets are on file at PATHCO, Inc. Each lesion was discussed by the group, re-examined if necessary, and the final opinions were recorded on the Chairperson's worksheets (Appendix A). In determining the PWG diagnosis, the diagnoses of the Chairperson and the 4 PWG members were considered. The PWG diagnosis for a lesion was determined when at least 3 out of the 5 pathologists agreed.

After the PWG completed the slide review, and diagnoses were recorded, the slides were decoded by treatment group, and the lesion incidences were tabulated. The PWG evaluated lesion incidences.

The PWG had available to them the final study report. Information from this report was used by the PWG in their deliberations.

V. FINDINGS AND INTERPRETATIONS

The PWG reviewed examples of lesions where the Study Pathologist, the Reviewing Pathologist, and the Chairperson all agreed on the diagnosis and examples where two of these three pathologists agreed. Based on their review, which indicated PWG agreement in virtually every case, the PWG decided to accept the diagnosis when at least two of the aforementioned pathologists agreed. The incidences of centrilobular hypertrophy are presented in Table I.

The PWG preferred the term centrilobular hypertrophy to cytomegaly. Centrilobular hypertrophy consisted of enlarged hepatocytes surrounding the central vein. The cytoplasm of the cells was abundant and eosinophilic. The nuclei were normal-sized to slightly enlarged. In a few animals there were one to several clear round vacuoles in the cytoplasm of the hypertrophied cells (fatty change). This was not diagnosed as a separate lesion by the PWG. In most animals, centrilobular hypertrophy was mild. It was comparable in severity between the interim sacrifice and terminal sacrifice.

Based on their review of the histopathologic lesions and other data, the PWG believes there is an adequate basis for selection of a high dose for a chronic study. At 90 days, the 6000 ppm dose produced 16-24% depression in body weight gain. Histological lesions of hepatic centrilobular



hypertrophy were found in both sexes of the 6000 ppm dose groups. Although only a 0-7% weight gain depression was found in rats at 3000 ppm, a similar high incidence of hepatic centrilobular hypertrophy to that of the 6000 ppm groups was found. Determination of MTD dose for a two-year carcinogenicity study is based on an estimated maximum body weight depression of 10-15% for the 90-day study and/or the presence of any histological changes, including those which may be life-threatening or severely toxic. It seems reasonable from the 90-day data presented that the 3000 ppm dose is the best choice for the MTD in the two-year carcinogenicity study. This choice is based on a minimal weight depression and the presence of histopathologic lesions which although not life-threatening, were consistent with hepatic microsomal enzyme induction and, therefore, sufficient to realize any carcinogenic potential.



TABLE I
Incidence of Centrilobular Hepatocellular Hypertrophy

Group	C	LD	MD	HD
Dose	0	1000 ppm	3000 ppm	6000 ppm
No. Animals Per Group*	25	25	25	25
Male	0	4 (16%)	20 (80%)	21 (84%)
Female	1 (4%)	0	17 (68%)	23 (92%)

* Includes 45-day interim sacrifice and 90-day study animals

APPENDIX A
Chairperson's Worksheets



PATHOLOGY WORKING GROUP CHAIRPERSON'S WORKSHEETS

ICAL NAME: Triclosan **STUDY:** 90-Day Subchronic **CHAIRPERSON'S SIGNATURE:** [Signature]

IES: Sprague-Dawley Rat **SEX:** Male **ORGAN:** Liver **DATE:** December 20, 1990

Animal No.	Dose Group	No. of Slides	Study Pathologist's Diagnoses (SP)	Reviewing Pathologist's Coded Review Diagnoses (RP)	Chairperson's Diagnoses	PWG Diagnoses
8640	CN	1	-	-	-	-
8641	CN	1	-	-	-	-
8743	MM	1	Centrilobular cyto- megaly, mild	Centrilobular hepatocellu- lar hypertrophy, minimal	Agree	Centrilobular hypertrophy (5)
8760	MM	1	Centrilobular cyto- megaly, mild	Centrilobular hepatocellu- lar hypertrophy, minimal	Agree	Centrilobular hypertrophy (5)
8796	HM	1	Centrilobular meta- morphosis, fatty, minimal Centrilobular cyto- megaly, mild	Centrilobular fatty change, minimal Centrilobular hepatocellu- lar hypertrophy, minimal	Agree Agree	Centrilobular fatty change (5) Centrilobular hypertrophy (5)
8798	HM	1	Centrilobular meta- morphosis, fatty, mild Centrilobular cyto- megaly, mild	Centrilobular fatty change, minimal Centrilobular hepatocellu- lar hypertrophy, minimal	Agree Agree	Centrilobular fatty change (1) Not present (4) Centrilobular hypertrophy (5)



PATHOLOGY WORKING GROUP CHAIRPERSON'S WORKSHEETS

NICAL NAME: Triclosan **STUDY:** 90-Day Subchronic **CHAIRPERSON'S SIGNATURE:** [Signature]
CIES: Sprague-Dawley Rat **SEX:** Male/Female **ORGAN:** Liver **DATE:** December 20, 1990

de o.	Animal No.	Dose Group	No. of Slides	Study Pathologist's Diagnoses (SP)	Reviewing Pathologist's Coded Review Diagnoses (RP)	Chairperson's Diagnoses	PWG Diagnoses
0	8668	CF	1	-	-	-	-
7	8664	CF	1	-	-	-	-
	8812	HF	1	Centrilobular cyto- megaly, mild	Centrilobular hepatocellu- lar hypertrophy, minimal	Agree	Centrilobular hypertrophy (5)
3	8784	MF	1	Centrilobular cyto- megaly, mild	Centrilobular hepatocellu- lar hypertrophy, minimal	Agree	Centrilobular hypertrophy (5)
6	8776	MF	1	Centrilobular cyto- megaly, mild	Centrilobular hepatocellu- lar hypertrophy, minimal	Agree	Centrilobular hypertrophy (5)
6	8818	HF	1	Centrilobular cyto- megaly, mild	Centrilobular hepatocellu- lar hypertrophy, minimal	Agree	Centrilobular hypertrophy (5)
3	8689	LM	1	Centrilobular cyto- megaly, mild	-	Concur SP	Centrilobular hypertrophy (1) Normal (4)



PATHOLOGY WORKING GROUP CHAIRPERSON'S WORKSHEETS

ICAL NAME: Triclosan **STUDY:** 90-Day Subchronic **CHAIRPERSON'S SIGNATURE:** Nancy E. Goodman
IES: Sprague-Dawley Rat **SEX:** Male **ORGAN:** Liver **DATE:** December 20, 1990

le ..	Animal No.	Dose Group	No. of Slides	Study Pathologist's Diagnoses (SP)	Reviewing Pathologist's Coded Review Diagnoses (RP)	Chairperson's Diagnoses	PWG Diagnoses
1	8693	LM	1	-	Centrilobular hepatocellular hypertrophy, minimal	Concur RP	Centrilobular hypertrophy (4)
				-	Centrilobular fatty change, minimal	Concur RP	Normal (1) Centrilobular fatty change (3) Normal (2)
7	8700	LM	1	-	Centrilobular hepatocellular hypertrophy, minimal	Concur SP	Centrilobular hypertrophy (5)
7	8746	HM(I)	1	-	Centrilobular hepatocellular hypertrophy, minimal	Concur RP	Centrilobular hypertrophy (5)
	8749	HM(I)	1	Centrilobular metamorphosis, fatty, minimal	-	Concur SP	Centrilobular fatty change (1)
				Centrilobular cytomegaly, mild	-	Concur SP	Normal (4) Centrilobular hypertrophy (5)
6	8788	HM(I)	1	Centrilobular cytomegaly, mild	-	Concur SP	Centrilobular hypertrophy (2) Normal (3)



PATHOLOGY WORKING GROUP CHAIRPERSON'S WORKSHEETS

MICAL NAME: Triclosan

STUDY: 90-Day Subchronic

CHAIRPERSON'S SIGNATURE: [Signature]

ICIES: Sprague-Dawley Rat

SEX: Female

ORGAN: Liver

DATE: December 20, 1998

Slide No.	Animal No.	Dose Group	No. of Slides	Study Pathologist's Diagnoses (SP)	Reviewing Pathologist's Coded Review Diagnoses (RP)	Chairperson's Diagnoses	PWG Diagnoses
18	8677	CF	1	-	Centrilobular hepatocellular hypertrophy, minimal	Concur RP	Centrilobular hypertrophy (3) Normal (2)
21	8771	MF	1	Centrilobular cytomegaly, mild	-	Concur SP	Centrilobular hypertrophy (4) Normal (1)
78	8780	MF	1	-	Centrilobular hepatocellular hypertrophy, minimal	Concur RP	Centrilobular hypertrophy (5)
74	8785	MF(I)	1	-	Centrilobular hepatocellular hypertrophy, minimal	Concur RP	Centrilobular hypertrophy (4) Normal (1)
82	8814	HF	1	Centrilobular cytomegaly, mild Focal metamorphosis, fatty, mild	- Focal fatty change, minimal	Concur SP Agree	Centrilobular hypertrophy (5) Centrilobular fatty change (3) Normal (2)
68	8821	HF	1	Centrilobular cytomegaly, mild -	- Eosinophilic foci	Concur SP Concur SP	Centrilobular hypertrophy (5) -

APPENDIX B
Pathology Review Worksheets

Pathology Review Worksheets
Ciba-Geigy
Subchronic Toxicity/Carcinogenicity Study
PATHCO No. 90-128

Group I - Male

Code Number	Animal No.	No. of Slides Organ	Study Pathologist's (SP) Diagnoses	Reviewing Pathologist's (RP) Coded Pathology Review	Chairperson's Diagnoses
28	8637	1 Liver		NR	Agree
55	8638 I*	1 Liver		NR	Agree
99	8639	1 Liver		NR	Agree
49	8640	1 Liver		NR	Agree
59	8641 I	1 Liver		NR	Agree
76	8642	1 Liver		NR	
8	8643 I	1 Liver		NR	
13	8644 I	1 Liver		NR	
81	8645	1 Liver		NR	
41	8646 I	1 Liver		NR	
88	8647	1 Liver		NR	

* I - Interim Sacrifice

Pathology Review Worksheets
Ciba-Geigy
Subchronic Toxicity/Carcinogenicity Study
PATHCO No. 90-128

Group I - Male

Code Number	Animal No.	No. of Slides	Organ	Study Pathologist's (SP) Diagnoses	Reviewing Pathologist's (RP) Coded Pathology Review	Chairperson's Diagnoses
19	8648	1	Liver		NR	
42	8649	1	Liver		NR	
83	8650 I	1	Liver		NR	
35	8651	1	Liver		NR	
67	8652	1	Liver		NR	
6	8653	1	Liver		NR	
82	8654	1	Liver		NR	
34	8655	1	Liver		Centrilobular fatty change, minimal	Concur RP
46	8656 I	1	Liver	Polyangiitis, moderate	NR	
53	8657 I	1	Liver		NR	
30	8658 I	1	Liver		NR	
74	8659	1	Liver		NR	

Pathology Review Worksheets
Ciba-Geigy
Subchronic Toxicity/Carcinogenicity Study
PATMCO No. 90-128

Group I - Male

Code Number	Animal No.	No. of Slides Organ	Study Pathologist's (SP) Diagnoses	Reviewing Pathologist's (RP) Coded Pathology Review	Chairperson's Diagnoses
9	8640 I	1 Liver		NR	
39	8661	1 Liver		NR	

Pathology Review Worksheets
Ciba-Geigy
Subchronic Toxicity/Carcinogenicity Study
PATMCO No. 90-128

Group II - Male

Code Number	Animal No.	No. of Slides	Organ	Study Pathologist's (SP) Diagnoses	Reviewing Pathologist's (RP) Coded Pathology Review	Chairperson's Diagnoses
14	8687	1	Liver		NR	Agree
93	8688	1	Liver		NR	
33	8689	1	Liver	Centrilobular cytomegaly, mild	NR	Concur SP
4	8690	1	Liver		Centrilobular hepatocellular hypertrophy, minimal	Concur RP
61	8691	1	Liver		NR	
20	8692 I	1	Liver		NR	
44	8693	1	Liver		Centrilobular hepatocellular hypertrophy, minimal	Concur RP
					Centrilobular fatty change, minimal	Concur RP
90	8694 I	1	Liver		NR	Agree
80	8695	1	Liver		NR	
91	8696 I	1	Liver		NR	

Pathology Review Worksheets
Ciba-Geigy
Subchronic Toxicity/Carcinogenicity Study
PATHCO No. 90-128

Group II - Male

Code Number	Animal No.	No. of Slides	Organ	Study Pathologist's (SP) Diagnoses	Reviewing Pathologist's (RP) Coded Pathology Review	Chairperson's Diagnoses
40	8697	1	Liver		Centrilobular hepatocellular hypertrophy, minimal	Concur RP
21	8698	1	Liver		NR	
75	8699 I	1	Liver		NR	
27	8700	1	Liver		Centrilobular hepatocellular hypertrophy, minimal	Concur SP
16	8701 I	1	Liver		NR	
71	8702	1	Liver		NR	
65	8703 I	1	Liver		NR	
25	8704 I	1	Liver		NR	
32	8705	1	Liver		NR	
37	8706	1	Liver		NR	
89	8707 I	1	Liver		NR	

Pathology Review Worksheets
Ciba-Geigy
Subchronic Toxicity/Carcinogenicity Study
PATHCO No. 90-128

Group II - Male

Code Number	Animal No.	No. of Slides Organ	Study Pathologist's (SP) Diagnoses	Reviewing Pathologist's (RP) Coded Pathology Review	Chairperson's Diagnoses
22	8708	1 Liver		NR	
54	8709 I	1 Liver		NR	
24	8710	1 Liver		NR	
15	8711 I	1 Liver		NR	

Pathology Review Worksheets
Ciba-Geigy
Subchronic Toxicity/Carcinogenicity Study
PATHCO No. 90-128

Group III - Male

Code Number	Animal No.	No. of Slides	Organ	Study Pathologist's (SP) Diagnoses	Reviewing Pathologist's (RP) Coded Pathology Review	Chairperson's Diagnoses
50	8737	1	Liver	Centrilobular cytomegaly, mild	Centrilobular hepatocellular hypertrophy, minimal	Agree
94	8738	1	Liver	Centrilobular cytomegaly, mild	Centrilobular hepatocellular hypertrophy, minimal	Agree
43	8739	1	Liver	Centrilobular metamorphosis, fatty, minimal	Centrilobular fatty change, minimal	Agree
				Centrilobular cytomegaly, mild	Centrilobular hepatocellular hypertrophy, minimal	Agree
38	8740 I	1	Liver		NR	Agree
51	8741	1	Liver	Centrilobular cytomegaly, mild	Centrilobular hepatocellular hypertrophy, minimal	Agree
87	8742 I	1	Liver		Centrilobular hepatocellular hypertrophy, minimal	Concur RP
48	8743	1	Liver	Centrilobular cytomegaly, mild	Centrilobular hepatocellular hypertrophy, minimal	Agree
18	8744	1	Liver	Centrilobular cytomegaly, mild	Centrilobular hepatocellular hypertrophy, minimal	Agree

Pathology Review Worksheets
Ciba-Geigy
Subchronic Toxicity/Carcinogenicity Study
PATHCO No. 90-128

Group III - Male

Code Number	Animal No.	No. of Slides	Organ	Study Pathologist's (SP) Diagnoses	Reviewing Pathologist's (RP) Coded Pathology Review	Chairperson's Diagnoses
68	8745	1	Liver	Centrilobular metamorphosis, fatty, minimal	Centrilobular fatty change, minimal	Agree
				Centrilobular cytomegaly, mild	Centrilobular hepatocellular hypertrophy, minimal	Agree
47	8746 I	1	Liver	Inflammation, multifocal, minimal		
					Centrilobular hepatocellular hypertrophy, minimal	Concur RP
85	8747	1	Liver	Centrilobular cytomegaly, mild	Centrilobular hepatocellular hypertrophy, minimal	Agree
29	8748	1	Liver	Centrilobular cytomegaly, mild	Centrilobular hepatocellular hypertrophy, minimal	Agree
1	8749 I	1	Liver	Centrilobular metamorphosis, fatty, minimal	NR	Concur SP
				Centrilobular cytomegaly, mild		Concur SP
64	8750 I	1	Liver		Centrilobular hepatocellular hypertrophy, minimal	Concur RP
70	8751	1	Liver	Centrilobular cytomegaly, mild	Centrilobular hepatocellular hypertrophy, minimal	Agree

Pathology Review Worksheets
Ciba-Geigy
Subchronic Toxicity/Carcinogenicity Study
PATMCO No. 90-128

Group III - Male

Code Number	Animal No.	No. of Slides	Organ	Study Pathologist's (SP) Diagnoses	Reviewing Pathologist's (RP) Coded Pathology Review	Chairperson's Diagnoses
100	8752	1	Liver	Centrilobular cytomegaly, mild	Centrilobular hepatocellular hypertrophy, minimal	Agree
73	8753	1	Liver	Centrilobular cytomegaly, mild	Centrilobular hepatocellular hypertrophy, minimal	Agree
23	8754	1	Liver		Centrilobular hepatocellular hypertrophy, minimal	Concur RP
97	8755 I	1	Liver		NR	
62	8756 I	1	Liver		Centrilobular hepatocellular hypertrophy, minimal	Concur RP
45	8757 I	1	Liver		NR	
78	8758	1	Liver	Centrilobular cytomegaly, mild	Centrilobular hepatocellular hypertrophy, minimal	Agree
66	8759 I	1	Liver		NR	
31	8760	1	Liver	Centrilobular cytomegaly, mild	Centrilobular hepatocellular hypertrophy, minimal	Agree
11	8761 I	1	Liver		NR	

Pathology Review Worksheets
Ciba-Geigy
Subchronic Toxicity/Carcinogenicity Study
PATHCO No. 90-128

Group IV - Male

Code Number	Animal No.	No. of Slides	Organ	Study Pathologist's (SP) Diagnoses	Reviewing Pathologist's (RP) Coded Pathology Review	Chairperson's Diagnoses
95	8787	1	Liver	Centrilobular cytomegaly, mild	Centrilobular hepatocellular hypertrophy, minimal	Agree
36	8788 I	1	Liver	Centrilobular cytomegaly, mild	NR	Concur SP
84	8789	1	Liver	Centrilobular cytomegaly, mild	Centrilobular hepatocellular hypertrophy, minimal	Agree
56	8790 I	1	Liver		NR	Agree
5	8791	1	Liver	Centrilobular metamorphosis, fatty, minimal		Concur SP
				Centrilobular cytomegaly, mild	Centrilobular hepatocellular hypertrophy, minimal	Agree
96	8792 I	1	Liver	Centrilobular cytomegaly, mild	Centrilobular hepatocellular hypertrophy, minimal	Agree
58	8793 I	1	Liver		NR	
79	8794	1	Liver	Centrilobular cytomegaly, mild	Centrilobular hepatocellular hypertrophy, minimal	Agree

Pathology Review Worksheets
Giba-Gaigy
Subchronic Toxicity/Carcinogenicity Study
PATHCO No. 90-128

Group IV - Male

Code Number	Animal No.	No. of Slides	Organ	Study Pathologist's (SP) Diagnoses	Reviewing Pathologist's (RP) Coded Pathology Review	Chairperson's Diagnoses
86	8795	1	Liver	Centrilobular cytomegaly, mild	Centrilobular hepatocellular hypertrophy, minimal	Agree
3	8796	1	Liver	Centrilobular metamorphosis, fatty, minimal	Centrilobular fatty change, minimal	Agree
				Centrilobular cytomegaly, mild	Centrilobular hepatocellular hypertrophy, minimal	Agree
12	8797	1	Liver	Centrilobular metamorphosis, fatty, minimal		Concur SP
				Centrilobular cytomegaly, mild	Centrilobular hepatocellular hypertrophy, minimal	Agree
77	8798	1	Liver	Centrilobular metamorphosis, fatty, mild	Centrilobular fatty change, minimal	Agree
				Centrilobular cytomegaly, mild	Centrilobular hepatocellular hypertrophy, minimal	Agree
26	8799 I	1	Liver	Centrilobular cytomegaly, mild	Centrilobular hepatocellular hypertrophy, minimal	Agree
					Centrilobular fatty change, minimal	Concur RP

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Group IV - Male

Code Number	Animal No.	No. of Slides	Organ	Study Pathologist's (SP) Diagnoses	Reviewing Pathologist's (RP) Coded Pathology Review	Chairperson's Diagnoses
17	8800 I	1	Liver	Centrilobular cytomegaly, mild	Centrilobular hepatocellular hypertrophy, minimal	Agree
				Midlobular region metamorphosis, fatty, minimal	Centrilobular fatty change, minimal	Concur RP
69	8801	1	Liver	Centrilobular metamorphosis, fatty, minimal		Concur SP
				Centrilobular cytomegaly, mild	Centrilobular hepatocellular hypertrophy, minimal	Agree
7	8802	1	Liver	Centrilobular cytomegaly, mild	Centrilobular hepatocellular hypertrophy, minimal	Agree
96	8803 I	1	Liver	Undifferentiated leukemia	Leukemia	
63	8804 I	1	Liver		NR	
52	8805	1	Liver	Centrilobular cytomegaly, mild	Centrilobular hepatocellular hypertrophy, minimal	Agree
					Centrilobular fatty change, minimal	Concur RP

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PATHCO No. 90-128

Group IV - Male

Code Number	Animal No.	No. of Slides	Organ	Study Pathologist's (SP) Diagnoses	Reviewing Pathologist's (RP) Coded Pathology Review	Chairperson's Diagnoses
60	8806 I	1	Liver	Centrilobular metamorphosis, fatty, minimal	Centrilobular fatty change, minimal	Agree
				Centrilobular cytomegaly, mild	Centrilobular hepatocellular hypertrophy, minimal	Agree
10	8807	1	Liver	Centrilobular cytomegaly, mild	Centrilobular hepatocellular hypertrophy, minimal	Agree
72	8808	1	Liver	Centrilobular metamorphosis, fatty, mild	Centrilobular fatty change, minimal	Agree
				Centrilobular cytomegaly, mild	Centrilobular hepatocellular hypertrophy, minimal	Agree
2	8809	1	Liver	Centrilobular cytomegaly, mild	Centrilobular hepatocellular hypertrophy, minimal	Agree
57	8810	1	Liver	Centrilobular cytomegaly, mild	Centrilobular hepatocellular hypertrophy, minimal	Agree
92	8811 I	1	Liver	Centrilobular metamorphosis, fatty, minimal		Concur SP
				Centrilobular cytomegaly, mild	Centrilobular hepatocellular hypertrophy, minimal	Agree

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Group I - Female

Code Number	Animal No.	No. of Slides	Organ	Study Pathologist's (SP) Diagnoses	Reviewing Pathologist's (RP) Coded Pathology Review	Chairperson's Diagnoses
38	8662 I*	1	Lung		No liver slide	
30	8663	1	Liver		NR	
57	8664	1	Liver		NR	Agree
6	8665	1	Liver		NR	
76	8666 I	1	Liver		NR	Agree
12	8667 I	1	Liver		NR	
50	8668 I	1	Liver		NR	Agree
45	8669	1	Liver		NR	Agree
92	8670	1	Liver		NR	
98	8671	1	Liver		NR	
35	8672 I	1	Liver		NR	

* I - Interim Sacrifice

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Group I - Female

Code Number	Animal No.	No. of Slides	Organ	Study Pathologist's (SP) Diagnoses	Reviewing Pathologist's (RP) Coded Pathology Review	Chairperson's Diagnoses
80	8673	1	Liver		NR	
34	8674	1	Liver		NR	
49	8675	1	Liver		NR	
59	8676	1	Liver		NR	
88	8677	1	Liver		Centrilobular hepatocellular hypertrophy, minimal	Concur RP
13	8678 I	1	Liver		NR	
96	8679	1	Liver	Tissue examined, no lesions found	NR	
9	8680	1	Liver		NR	
69	8681 I	1	Liver		NR	
91	8682	1	Liver	Tissue examined, no lesions found	NR	
84	8683 I	1	Liver		NR	

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PATHCO No. 90-128

Group I - Female

Code Number	Animal No.	No. of Slides	Organ	Study Pathologist's (SP) Diagnoses	Reviewing Pathologist's (RP) Coded Pathology Review	Chairperson's Diagnoses
20	8684 I	1	Liver		NR	
64	8685	1	Liver		NR	
28	8686 I	1	Liver		NR	

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Group II - Female

Code Number	Animal No.	No. of Slides	Organ	Study Pathologist's (SP) Diagnoses	Reviewing Pathologist's (RP) Coded Pathology Review	Chairperson's Diagnoses
70	8712 I	1	Liver		NR	
44	8713	1	Liver		NR	
24	8714	1	Liver		NR	
79	8715 I	1	Liver		NR	
7	8716	1	Liver		NR	
23	8717	1	Liver		NR	Agree
75	8718 I	1	Liver		NR	Agree
22	8719	1	Liver		NR	
67	8720	1	Liver		NR	
18	8721 I	1	Liver		NR	
15	8722 I	1	Liver		NR	
61	8723	1	Liver		NR	

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Group II - Female

Code Number	Animal No.	No. of Slides	Organ	Study Pathologist's (SP) Diagnoses	Reviewing Pathologist's (RP) Coded Pathology Review	Chairperson's Diagnoses
54	8724	1	Liver		NR	
62	8725	1	Liver		NR	
3	8726 I	1	Liver		NR	
87	8727 I	1	Liver		NR	
17	8728	1	Liver		NR	
47	8729	1	Liver		NR	
52	8730	1	Liver	Inflammation, multifocal, mild	NR	
85	8731	1	Liver		NR	
8	8732	1	Liver		NR	
95	8733 I	1	Liver		NR	
73	8734 I	1	Liver		NR	
46	8735 I	1	Liver		NR	

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PATHCO No. 90-128

Group II - Female

Code Number	Animal No.	No. of Slides Organ	Study Pathologist's (SP) Diagnoses	Reviewing Pathologist's (RP) Coded Pathology Review	Chairperson's Diagnoses
29	8736	1 Liver		NR	

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Group III - Female

Code Number	Animal No.	No. of Slides	Organ	Study Pathologist's (SP) Diagnoses	Reviewing Pathologist's (RP) Coded Pathology Review	Chairperson's Diagnoses
19	8762 I	1	Liver		Centrilobular hepatocellular hypertrophy, minimal	Concur RP
81	8763	1	Liver	Centrilobular cytomegaly, mild	Centrilobular hepatocellular hypertrophy, minimal	Agree
10	8764 I	1	Liver		NR	
71	8765	1	Liver	Centrilobular cytomegaly, mild	Centrilobular hepatocellular hypertrophy, minimal	Agree
41	8766	1	Liver	Centrilobular cytomegaly, mild	Centrilobular hepatocellular hypertrophy, minimal	Agree
42	8767	1	Liver		Centrilobular hepatocellular hypertrophy, minimal	Concur RP
26	8768	1	Liver		NR	
1	8769	1	Liver	Centrilobular cytomegaly, mild	NR	Concur SP
36	8770 I	1	Liver		NR	Agree

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PATHCO No. 90-128

Group III - Female

Code Number	Animal No.	No. of Slides	Organ	Study Pathologist's (SP) Diagnoses	Reviewing Pathologist's (RP) Coded Pathology Review	Chairperson's Diagnoses
21	8771	1	Liver	Centrilobular cytomegaly, mild	NR	Concur SP
60	8772 I	1	Liver	Focal ground-glass cytoplasmic change	NR	
31	8773 I	1	Liver		NR	Agree
77	8774 I	1	Liver		NR	
99	8775	1	Liver		NR	
66	8776	1	Liver	Centrilobular cytomegaly, mild	Centrilobular hepatocellular hypertrophy, minimal	Agree
97	8777 I	1	Liver		NR	
25	8778	1	Liver	Centrilobular cytomegaly, mild	Centrilobular hepatocellular hypertrophy, minimal	Agree
16	8779	1	Liver	Centrilobular cytomegaly, mild	Centrilobular hepatocellular hypertrophy, minimal	Agree
78	8780	1	Liver		Centrilobular hepatocellular hypertrophy, minimal	Concur RP

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Group IV - Female

Code Number	Animal No.	No. of Slides	Organ	Study Pathologist's (SP) Diagnoses	Reviewing Pathologist's (RP) Coded Pathology Review	Chairperson's Diagnoses
51	8836 I	1	Liver	Centrilobular cytomegaly, mild	Centrilobular hepatocellular hypertrophy, minimal	Agree

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Group IV - Female

Code Number	Animal No.	No. of Slides	Organ	Study Pathologist's (SP) Diagnoses	Reviewing Pathologist's (RP) Coded Pathology Review	Chairperson's Diagnoses
32	8828 I	1	Liver	Centrilobular cytomegaly, mild	Centrilobular hepatocellular hypertrophy, minimal	Agree
53	8829 I	1	Liver	Centrilobular cytomegaly, mild	Centrilobular hepatocellular hypertrophy, minimal	Agree
89	8830	1	Liver	Centrilobular cytomegaly, mild	Centrilobular hepatocellular hypertrophy, minimal	Agree
27	8831	1	Liver		Centrilobular hepatocellular hypertrophy, minimal	Concur RP
65	8832	1	Liver		Centrilobular hepatocellular hypertrophy, minimal	Concur RP
56	8833 I	1	Liver	Centrilobular cytomegaly, mild	Centrilobular hepatocellular hypertrophy, minimal	Agree
39	8834	1	Liver	Centrilobular cytomegaly, mild	Centrilobular hepatocellular hypertrophy, minimal	Agree
83	8835	1	Liver	Ground-glass cytoplasmic change	Focal fatty change, minimal	Tension lipidosis
				Centrilobular cytomegaly, mild	Centrilobular hepatocellular hypertrophy, minimal	Agree

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Subchronic Toxicity/Carcinogenicity Study
PATNCO No. 90-128

Group IV - Female

Code Number	Animal No.	No. of Slides	Organ	Study Pathologist's (SP) Diagnoses	Reviewing Pathologist's (RP) Coded Pathology Review	Chairperson's Diagnoses
48	8820	1	Liver	Centrilobular cytomegaly, mild	Centrilobular hepatocellular hypertrophy, minimal	Agree
68	8821	1	Liver	Centrilobular cytomegaly, mild		Concur SP
					Eosinophilic focus	Concur SP
72	8822	1	Liver	Centrilobular cytomegaly, mild	Centrilobular hepatocellular hypertrophy, minimal	Agree
14	8823	1	Liver	Centrilobular cytomegaly, mild	Centrilobular hepatocellular hypertrophy, minimal	Agree
100	8824 I	1	Liver	Centrilobular cytomegaly, mild	Centrilobular hepatocellular hypertrophy, minimal	Agree
93	8825 I	1	Liver	Hamatopoiesis, extramedullary, minimal		
				Centrilobular cytomegaly, mild	Centrilobular hepatocellular hypertrophy, minimal	Agree
33	8826	1	Liver	Centrilobular cytomegaly, mild	Centrilobular hepatocellular hypertrophy, minimal	Agree
58	8827 I	1	Liver	Centrilobular cytomegaly, mild	Centrilobular hepatocellular hypertrophy, minimal	Agree

Pathology Review Worksheets
Ciba-Geigy
Subchronic Toxicity/Carcinogenicity Study
PATNCO No. 90-128

Group IV - Female

Code Number	Animal No.	No. of Slides	Organ	Study Pathologist's (SP) Diagnoses	Reviewing Pathologist's (RP) Coded Pathology Review	Chairperson's Diagnoses
2	8812	1	Liver	Centrilobular cytomegaly, mild	Centrilobular hepatocellular hypertrophy, minimal	Agree
94	8813 I	1	Liver	Centrilobular cytomegaly, mild	Centrilobular hepatocellular hypertrophy, minimal	Agree
82	8814 I	1	Liver	Centrilobular cytomegaly, mild		Concur SP
				Focal metamorphosis, fatty, mild	Focal fatty change, minimal	Agree
5	8815	1	Liver	Centrilobular cytomegaly, mild	Centrilobular hepatocellular hypertrophy, minimal	Agree
11	8816	1	Liver	Centrilobular cytomegaly, mild	Centrilobular hepatocellular hypertrophy, minimal	Agree
55	8817	1	Liver	Centrilobular cytomegaly, mild	Centrilobular hepatocellular hypertrophy, minimal	Agree
86	8818	1	Liver	Centrilobular cytomegaly, mild	Centrilobular hepatocellular hypertrophy, minimal	Agree
17	8819 I	1	Liver	Centrilobular cytomegaly, mild	Centrilobular hepatocellular hypertrophy, minimal	Agree

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PATHCO No. 90-128

Group III - Female

Code Number	Animal No.	No. of Slides	Organ	Study Pathologist's (SP) Diagnoses	Reviewing Pathologist's (RP) Coded Pathology Review	Chairperson's Diagnoses
40	8781	1	Liver	Centrilobular cytomegaly, mild	Centrilobular hepatocellular hypertrophy, minimal	Agree
63	8782 I	1	Liver		NR	
4	8783	1	Liver	Ground-glass cytoplasmic change		Tension lipidosis
					Centrilobular hepatocellular hypertrophy, minimal	Concur RP
43	8784	1	Liver	Centrilobular cytomegaly, mild	Centrilobular hepatocellular hypertrophy, minimal	Agree
74	8785 I	1	Liver		Centrilobular hepatocellular hypertrophy, minimal	Concur RP
90	8786 I	1	Liver		NR	

APPENDIX C - C.V.s

D. G. Goodman, Chairperson

J. M. Cullen, Participant

P. M. Newberne, Participant

R. A. Squire, Participant

J. M. Ward, Participant

R. M. Sauer, Reviewing Pathologist

DAWN G. GOODMAN

EDUCATION:

Postdoctoral Fellowship Certificate in
Comparative Pathology, Johns Hopkins
University School of Medicine, 1972;
V.M.D. University of Pennsylvania, 1969;
B.S., George Washington University, 1965.

**BOARD
CERTIFICATION:**

Diplomate, American College of Veterinary
Pathologists, 1974.

EXPERIENCE:

1983 - Present	President and Senior Pathologist PATHCO, Inc. Gaithersburg, Maryland.
1983 - 1985	Consulting Pathologist.
1982 - 1989	Adjunct Assistant Professor, Department of Pathology, University of Maryland School of Medicine, Baltimore, Maryland.
1981 - 1983	Associate Scientist and Senior Pathologist, Clement Associates, Inc., Arlington, Virginia.
1980 - 1986	Lecturer, Neoplasms of Mice, Course on Pathology of Laboratory Animals, Armed Forces Institute of Pathology (AFIP), Washington, D.C.
1978 - Present	Visiting Lecturer in Comparative Medicine, Johns Hopkins University School of Medicine, Baltimore, Maryland.
1978 - 1986	Lecturer in Pathology, Johns Hopkins University School of Medicine, Baltimore, Maryland.
1978 - 1981	Director of Pathology, Clement Associates, Inc., Washington, D.C.
1978 - 1980	Lecturer, Graduate School, Foundation for Advanced Education in the Sciences, National Institutes of Health (NIH), Bethesda, Maryland.

Dawn G. Goodman, V.M.D.

1977 - 1978 Veterinary Pathologist, Tumor Pathology Branch,
Carcinogenesis Testing Program, Division of
Cancer Cause and Prevention (DCCP), National
Cancer Institute (NCI), NIH, Bethesda,
Maryland.

1976 - 1977 Acting Head, Tumor Pathology Section,
Experimental Pathology Branch (EPB),
Carcinogenesis Program (CP), DCCP, NCI,
Bethesda Maryland.

1975 - 1976 Veterinary Pathologist, Tumor Pathology
Section, EPB, CP, DCCP, NCI, NIH, Bethesda,
Maryland.

1974 - 1975 Director of Animal Disease Investigation
Services, Comparative Pathology Section,
Veterinary Resources Branch (VRB), Division of
Research Services (DRS), NIH, Bethesda,
Maryland.

1972 - 1975 Veterinary Pathologist, VRB, DRS, NIH,
Bethesda, Maryland.

1972 U.S. Public Health Service (USPHS), NIH Special
Research Fellow, Department of Pathology, Johns
Hopkins University School of Medicine,
Baltimore, Maryland.

1969 - 1972 USPHS Postdoctoral Fellow in Comparative
Pathology, Johns Hopkins University School of
Medicine, Baltimore, Maryland.

INDEPENDENT CONSULTATIONS:

Clement Associates, Inc., Arlington, Virginia
Gillette Medical Evaluations Laboratory, Rockville, Maryland
Environ Corporation, Washington, D.C.

MEMBERSHIPS:

American College of Veterinary Pathologists
American Association for the Advancement of Science
American Veterinary Medical Association
Association for Women Veterinarians
D.C. Academy of Veterinary Medicine

Dawn G. Goodman, V.M.D.



Memberships (continued)

United States and Canadian Academy of Pathology
Mid-Atlantic Comparative Pathology Colloque
Society of Toxicologic Pathologists
Society of Toxicology
Veterinary Cancer Society

HONORS AND AWARDS:

Society of Phi Zeta (Veterinary Honor Society) - University of Pennsylvania

USPHS, NIH Special Research Fellowship (Canine Mammary Tumors).

COMMITTEES AND PROFESSIONAL ADVISORY ACTIVITIES:

Chairman, Subcommittee on Liver, Standardized System of Nomenclature and Diagnostic Criteria Committee, Society of Toxicologic Pathologists, 1989-Present

Pathology Working Group, National Toxicology Program, National Institute of Environmental Health Sciences (NIEHS), 1980-Present

Expert witness on carcinogenicity of PCB's, 1988

Chairman, Liaison Committee on Federal Regulations, American College of Veterinary Pathologists, 1979-1985

Workshop on Proliferative Lesions of the Rat Liver, National Toxicology Program, NIEHS, 1983

Expert witness on Carcinogenicity of TCDD and Silvex, Environmental Protection Agency Hearing to ban use of pesticides TCDD and Silvex, 1979

Participant, Mouse Liver Workshop, Environmental Protection Agency, 1980

Head, Pathology Working Group, Carcinogenesis Testing Program (CTP), DCCP, NCI, 1976-1978

Data Evaluation Group, CTP, DCCP, NCI, 1976-1978

Experimental Design Group, CTP, DCCP, NCI, 1976-1978

Committees (continued)

PHS Career Development Committee for Veterinarians OAM/PHS, DHEW,
1977-1978

PUBLICATIONS:

Dunnick, J.K., Forbes, P.D., Eustis, S.L., Hardisty, J.F., and Goodman, D.G. Tumors of the Skin in the HRA/SKH Mouse after Treatment with 8-Methoxypsoralen and UVA Radiation. Fund. Appl. Toxicol. (In Press).

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Priester, W.A., Goodman, D.G., and Theilen, G.H. Nine simultaneous primary tumors in a boxer dog. *J. Am. Vet. Med. Assoc.* 170:823-826, (1977)

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Dawn G. Goodman, V.M.D.

Grubbs, C.J., Moon, R.C., Squire, R.A., Farrow, G.M., Stinson, S.F., Goodman, D.G., Brown, C.C., and Sporn, M.B. 13-cis-Retinoic acid: Inhibition of bladder carcinogenesis induced in rats by N-butyl-N-(4-hydroxybutyl) nitrosamine. *Science* 198:743-744, (1977)

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Carb, A.V., and Goodman, D.G. Oesophageal carcinoma in the dog. *J. Small Anim. Pract.* 14:91-99, (1973)

Goodman, D.G., and Garner, F.M. A comparison of methods for finding Nosema cuniculi in rabbit urine. *Lab. Anim. Sci.* 22:568-572, (1972)

Bush, M., Pieroni, D.R., Goodman, D.G., White, R.I., Thomas, J., and James, A.E. Tetrolology of Fallot in a cat. *J. Am. Vet. Med. Assoc.* 161:1679-1686, (1972)

ABSTRACTS:

Goodman, D.G. Animal models for cancer research. 105th Annual Meeting, American Public Health Association (1977)

Blitzer, B.L., Waggoner, J.G., Jones, E.A., Gralnick, H., Towne, D., Butler, J., Weise, V., Kopin, I., Walters, I., Teychenne, P., Goodman, D., and Berk, P. An animal model of fulminant hepatic failure (FHF). *Gastroenterology* (1977) (Abstract)

Dawn G. Goodman, V.M.D.

Grubbs, C.J., Moon, R.C., Sporn, M.B., and Goodman, D.G.
Suppression of NMU-induced mammary cancer by vitamin A acetate.
Am. Assoc. Cancer Res. (1977) (Abstract)

Altman, N.H., and Goodman, D.G. Spontaneous tumors in rats. J.
Am. Vet. Med. Assoc. (1976) (Abstract)

UNPUBLISHED DOCUMENTS IN THE PUBLIC DOMAIN:

Goodman, D.G. Pathology Working Group Report on Chlordane in F344
Rats. Pathology Review Participants: Goodman, D.G., Macklin,
A.W., Maronpot, R.R., Popp, J.A., Squire, R.A., Ward, J.M.,
Anver, M.R. Submitted to ICF-Clement. September 11, 1987.

Sauer, R.M. Pathology Working Group Report on 2,3,7,8-
Tetrachlorodibenzo-p-dioxin Chronic Toxicity/Carcinogenicity
Study in Sprague Dawley Rats. Pathology Review Participants:
Sauer, R.M., Brown, W.R., Maronpot, R.R., Newberne, P.M., Popp,
J.A., Ward, J.M., and Goodman, D.G. Submitted to the Maine
Scientific Advisory Panel. March 13, 1990.

Sauer, R.M., and Goodman, D.G., (1990). Hepatotoxicity in Female
Sprague Dawley Rats Treated with 2,3,7,8-Tetrachlorodibenzo-p-
dioxin (TCDD). April 27, 1990.

Sauer, R.M., and Goodman, D.G. Hepatotoxicity in Female Sprague
Dawley Rats Treated with 2,3,7,8-Tetrachlorodibenzo-p-dioxin
(TCDD). 13-Week Subchronic Toxicity Study, June 8, 1990.

STUDY SETS:

Goodman, D.G., Bates, R.R., Ward, J.M., Frith, C.H., Sauer, R.M.,
Jones, S.J., Strandberg, J.D., Squire, R.A., Montali, R.J., and
Parker, G.A. Common Lesions in Aged B6C3F1 (C57BL/6Nx -
C3H/HeN)F1 and BALB/cStCr1(FC3H/Nctr Mice. Registry of
Veterinary Pathology, AFIP (1981)

Goodman, D.G., Anver, M.R., Ward, J.M., Sauer, R.M., Boorman,
G.A., Bates, R.R., Strandberg, J.D., Squire, R.A., Ines, G.D.,
Reznik, G., Parker, G.A., and Jones, S.R. Chemically Induced and
Unusual Lesions in Rats. Registry of Veterinary Pathology, AFIP
(1984)

Dawn G. Goodman, V.M.D.

Goodman, D.G., Anver, M.R., Ward, J.M., Sauer, R.M., Strandberg, J.D., Imes, G.D., Parker, G.A., Seely, J.C. Hildebrandt, P.K. and Uriah, L., Experimentally Induced and Unusual Lesions in Mice. Registry of Veterinary Pathology, AFIP (In preparation).

PRESENTATIONS:

What a Toxicologic Pathologist Does. Division of Comparative Medicine Seminar, Johns Hopkins University School of Medicine (November 1988)

The Role of a Consultant in Safety Evaluation - Responsibility to Industry and Government. General Principles in Toxicology and Toxicologic Pathology. Sponsored by Department of Pathology. Boston University School of Medicine, (August 1988)

The Role of a Consultant in Toxicology - Responsibility to Industry and Government. General Principles in Toxicology and Toxicologic Pathology. Sponsored by Department of Pathology. Boston University School of Medicine, (August 1987)

Observer Bias in Histopathologic Evaluation. Interdisciplinary Discussion Group on Carcinogenicity Studies, Sponsored by International Life Sciences Institute-Nutrition Foundation (June 1986)

Principles of Carcinogenesis/Comparative Aspects of Mammary and Liver Neoplasms in Rodents. Division of Comparative Medicine, Johns Hopkins University School of Medicine (January 1986)

Design and Interpretation of Carcinogenesis Bioassays. U.S. Department of Agriculture Continuing Education Program on Risk Assessment (October 1983)

Neoplasms of the Female Reproductive Tract. Seminar on Neoplasms in Mice. Sponsored by Intox Laboratories (June 1982)

Fundamentals of Carcinogenesis. D.C. Academy of Veterinary Medicine (January 1980)

Neoplastic Diseases of Rats and Mice. Course in Pathology of Laboratory Animals (AFIP) (August 1979)

Mammary Lesions in F344 Rats and B6C3F1 Mice. NCI Carcinogenesis Testing Program Workshop (June 1978)


Dawn G. Goodman, V.M.D.

Adrenal Lesions in F344 Rats. NCI Carcinogenesis Testing Program Workshop (June 1978)

Mammary Carcinogenesis in Rodents--Viral and Chemical Etiology. Mid-Atlantic Comparative Pathology Colloquy (January 1978)

Animal Models for Cancer Research. 105th Annual Meeting of the American Public Health Association (October 1977)

Neoplastic Diseases of Mice. Course in Pathology of Laboratory Animals (AFIP) (September 1977)

Tumors of Rats and Mice. Veterinary Resources Branch Seminar, NIH (July 1977)

Animal Models in Cancer Research. USPHS Professional Association Annual Meeting, San Francisco (April 1977)

Bioassay Program. Division of Laboratory Animal Medicine, Johns Hopkins Hospital (January 1976)

New Zealand Mice as an Animal Model for Systemic Lupus Erythematosus. National Capital Area Branch Association for Laboratory Animal Science (September 1975)

Spontaneous Tumors in Mice. Interagency Collaborative Group on Environmental Carcinogenesis (September 1975)

Spontaneous Tumors in Mice and Rats. Course in Pathology of Laboratory Animals Course (AFIP) (September 1975)

Hepatic Nodule in a Rhesus Monkey. Primate Pathology Workshop (March 1975)

Spontaneous Tumors in Mice. Course in Pathology of Laboratory Animals (AFIP) (September 1974)

Uremic Myocarditis in a Rhesus Monkey. Primate Pathology Workshop (March 1974)

Simian Hemorrhagic Fever. Division of Laboratory Animal Medicine, Johns Hopkins University School of Medicine (January 1974)

Dawn G. Goodman, V.M.D.

NCI Chemicals Reviewed In
Pathology Working Group/Data Evaluation Group
National Cancer Institute/National Toxicology
Program Carcinogenesis Technical Report Series:

<u>TR NO.</u>	<u>CHEMICAL</u>	<u>TR NO.</u>	<u>CHEMICAL</u>
12	Endrin	5	Proflavine
13	Tetrachlorethylene	6	Nitrilotriacetic Acid (NTA) and Nitrilotriacetic Acid Trisodium Salt, Monohydrate (Na ₃ NTA.H ₂ O)
16	Phosphamidon	7	Phenformin
17	Photodieldrin	8	Chlordane
18	3,3'-Iminobis-1-Propanol Dimethanesulfonate (ester) Hydrochloride (IPD)	9	Hepatochlor
19	Procarbazine	39	Lasiocarpine
21,22	Dieldrin	40	Hexachlorophene
23	Picloram	41	Chlorothalonil
4	Malathion	42	5-Azacytidine
25	Chloramben	43	Emetine
27	1,1,2,2-Tetrachlorethane	45	Chlorpropamide
29	2-Methyl-1-Nitroanthraquinone	46	Ethionamide
30	Diarylanide Yellow	47	4,4'-Thiodianiline
31	Tolbutamide	48	Pyrazinamide
32	Isophosphamide	49	Acronycine
33	Tetrachlorvinphos	50	Acetohexamide
35	Methoxychlor	51	Tolazamide
36	Anthranilic Acid	52	3-Nitropropionic Acid
4	Dimethoate	53	2-Amino-5-Nitrothiazole
		54	2,4-Dinitrotoluene

<u>R NO.</u>	<u>CHEMICAL</u>	<u>TR NO.</u>	<u>CHEMICAL</u>
57	B-TGdR	82	N-Phenyl-p-Phenylenediamine
58	Thio-Tepa	83	Daminozide
59	Estradiol Mustard	84	2,4-Diaminoanisole Sulfate
60	Phenesterin	85	4-Chloro-m-Phenylenediamine
61	Pentachloronitrobenzene	88	1H-Benzotriazole
62	Endosulfan	89	o-Anisidine Hydrochloride
63	4-Chloro-o-Phenylenediamine	90	Dicofol
64	1-Nitronapthalene	91	Clonitralid
66	1,1-Dichloroethane	92	Hydrazobenzene
67	Aspirin, Phenacetin, Caffeine	93	3-Amino-9-Ethylcarbazole Hydrochloride
68	Hexachloroethane	94	4-Amino-2-Nitrophenol
69	Azinphosmethyl	95	3-(Chloromethyl) Pyridine Hydrochloride
70	Parathion	96	Coumaphos
71	L-Tryptophan	97	Titanium Dioxide
72	Phenoxybenzamine Hydrochloride	98	d1-Menthol
73	Allyl Chloride	99	Phenzopyridine Hydrochloride
74	1,1,2-Trichloroethane	100	Cupferron
75	Chlorobenzilate	101	Formulated Fenaminosulf
76	Tris (2,3-Dibromopropyl) Phosphate	102	3-Sulfolene
77	Pyrimethamine	103	Fenthione
78	ICRF-159	104	Anilazine
80	1,4-Dioxane	105	m-Cresidine
81	Trimethylphosphate		

<u>PR NO.</u>	<u>CHEMICAL</u>	<u>TR NO.</u>	<u>CHEMICAL</u>
106	Trichlorofluomethane	132	2,5-Dithiobiurea
107	5-Nitro-o-Toluidine	133	3-Nitro-p-Acetophenetide
108	Direct Blue 6, Direct Black 38, Direct Brown 95	139	Triphenyltin Hydroxide
109	4-Nitroanthianilic Acid	140	Pivalolactone
110	Iodoform	141	1-Phenyl-3-Methyl-5-Pyrazolone
111	1-Amino-2-Methylantraquinone	142	p-Cresidine
112	3-Amino-4-Ethoxyacetanilide	143	1,5-Napthalenediamine
113	2-Chloro-p-Phenylenediamine Sulfate	144	2-Aminoanthraquinone
114	2,3,5,6, Tetrachloro-4-Nitroanisole	145	3-Chloro-p-Toluidine
115	Sulfallate	146	Nithiazide
116	p-Anisidine Hydrochloride	147	Mexacarbate
117	6-Nitrobenzimidazole	148	1-Phenyl-2-Thiourea
118	5-Nitroacenaphthene	149	N,N'-Diethylthiourea
120	Piperonyl Butoxide	168	N-(1-Napthyl) Ethylenediamine
124	Piperonyl sulfoxide	171	2,4-Dimethoxyaniline Hydrochloride
125	Dioxathion	38	Arochlor 1254
126	2-5-Toluenediamine Sulfate		
127	5-Nitro-o-Anisidine		
128	3,3'-Dimethoxybenzidine-4,4'-Diisocyanate		
129	Trimethylthiourea		
130	Aniline Hydrochloride		
131	DDT, TDE and p,p'-DDE		

 Dawn G. Goodman, V.M.D.

**CHAIRPERSON FOR FWG'S
CONDUCTED FOR NTP**

Two Year Studies

Chlorendic Acid	Technical Report No. 304
4-vinylcyclohexene	Technical Report No. 303
Styrene Oxide	
t-Butanol	
Diallylpthalate	Technical Report No. 284
Nitrofurazone	Technical Report No. 337
Nalidixic Acid	Technical Report No. 368
Gamma-Butyrolactone	
Resorcinol (also 15 mo. Interim)	
Diphenylhydantoin	
C.I. Pigment Red 3	
2,4-Diaminophenol HCL	

90-Day Studies

Promethazine HCL
Methdilazine HCL
1-Amino-2,4-Dibromo-
Anthraquinone
4-Hydroxyacetanilide
t-Butanol
Acetone
6-Methoxy-2-
Benzothiazolamine
Pentachlorobenzene
Meta-Nitrobenzoic Acid
2-Hydroxy-4-Methoxybenzophenone
Antimony Potassium Tartarate
Psoralens (4 compounds)

Interim Sacrifice

t-Butanol
Ochratoxin A

CURRICULUM VITAE

John Michael Cullen, V.M.D., Ph.D.
Diplomate, American College of Veterinary Pathologists

Address:

611 East Olive Street
Apex, NC 27502
(919) 362-5675

Present Position:

Associate Professor
Department of Microbiology, Parasitology and Pathology
College of Veterinary Medicine
North Carolina State University
Raleigh, North Carolina 27606
(919) 829-4350

Birthdate: July 27, 1949

Education:

Ph.D., Comparative Pathology, University of California, Davis, 1985.
V.M.D., University of Pennsylvania, 1975.
A.B., Biology, University of Pennsylvania, 1971.

Experience:

1989 Associate Professor of Veterinary Pathology, College of
Veterinary Medicine, North Carolina State University
1984-89 Assistant Professor of Veterinary Pathology, College of
Veterinary Medicine, North Carolina State University
Additional Appointment:
1988- Toxicology Faculty, North State Carolina University
1983-84 Senior Resident in Anatomic Pathology, Veterinary Medical
Teaching Hospital, University of California, Davis
1979-83 Resident, Anatomic Pathology, School of Veterinary Medicine,
University of California, Davis
1976-79 Private practice, small animal clinician
1975-76 Intern, Angell Memorial Animal Hospital, Boston, Massachusetts

Teaching Experience

Veterinary Curriculum

- 1) General Pathology, VMM 831, 1984-present
- 2) Systemic Pathology, VMM 451, 1984-1986
- 3) Lab Animal Medicine, VMC 853, 1985-present

Graduate Curriculum

- 1) Advanced Histopathology, VMS 642, 1984-present, (Course Coordinator)
- 2) Systemic Pharmacology and Toxicology, VMS 562, 1984-present
- 3) Medical Virology, VMM 651, 1986-present

1981-83 Primary responsibility for Junior year clinic in Pathology.
Responsibilities included orientation, informal lecture, and
direct supervision of necropsy procedure.

CURRICULUM VITAE

John M. Cullen

Page 2

Professional Consultant Activities:

Consultant to National Toxicology Program at National Institute of Environmental Health Sciences, Research Triangle Park, North Carolina, 1984-present

Consultant to U.S. Environmental Protection Agency (HERL) UVB Health Effects Research Committee, July 1988.

Consultant to Stanford University Laboratory Animal Medicine Facility, 1987.

Short-Term Consultant, Pan American Health Organization, Suriname, South America, 1987.

Academic Responsibilities:

Graduate Student Committees:

PhD - Steven Holladay

MS - Doris Fultz (chairman)

- Derek Norford (chairman)

- Christopher Bowie

Residency Program in Veterinary Pathology at North Carolina State University, responsible for candidate recruitment and selection, as well as administration of the program.

Academic Committees: Admissions, Student conduct (Chairman), Committee on committees, Medical Records, Open House.

External Review, Ph.D. Thesis: Studies of the Pathogenesis, Toxicology and Pathology of lupinosis and associated conditions. Murdoch University, Western Australia, 1988.

Veterinary Licenses:

California, Massachusetts, North Carolina.

Board Certifications:

Diplomate, American College of Veterinary Pathology, 1982.

Society Memberships:

American Veterinary Medical Association
American College of Veterinary Pathologists
North Carolina Society of Toxicology
American Association for the Study of Liver Disease
North Carolina Veterinary Medical Society
American Association of Avian Pathologists

Academic Awards:

Phi Zeta Member, 1987

CURRICULUM VITAE
John M. Cullen
Page 3

Fields of Special Interest:

Hepatic Pathology
Animal models of viral hepatitis
Mycotoxicology

Grants Awarded:

Principal Investigator of "Combined effects of aflatoxin B₁ and chronic duck hepatitis B virus infection on the incidence of hepatocellular carcinoma in ducks." 1984, \$3,900, Faculty Research and Professional Development Fund.

Principal Investigator of "The role of cell cycle in aflatoxin B₁ induced hepatic carcinogenesis." 1985, \$22,300, North Carolina State Research Fund.

Principal Investigator of "Interactions of multiple concurrent naturally occurring mycotoxin administration on toxin metabolism, tissue residues, growth rates and toxicity of chickens." 1986, \$15,300, North Carolina State Research Fund.

Principal Investigator of "The role of cell cycle in aflatoxin-B₁ induced hepatic carcinogenesis." 1986, \$9,200, North Carolina State Research Fund.

Co-Investigator of "Ultrastructural and immunocytochemical studies on pituitary lesions induced by 2-mercaptobenzimidazole." 1986, \$14,106, NIH.

Co-Investigator of "Infant and adult rat susceptibility to aflatoxins B₁ and M₁." 1986, \$7,000, California Dairy Council.

Principal Investigator of "Cyclopaizonic Acid induced skeletal muscle injury in broiler chickens." 1987, \$14,300, North Carolina State Research Fund.

Principal Investigator of "Acute DHBV infection in geese. A model of HBV infection." 1987, \$4,000, United Way.

Principal Investigator of "An animal model of hepatitis B infection in geese." 1987, \$24,800, North Carolina Board of Science and Technology.

Principal Investigator of "Acute and chronic DHBV infection in geese." 1987, \$6,550, North Carolina State Research Fund.

Principal Investigator of "Delta hepatitis virus production in woodchuck hepatitis virus infected woodchucks." 1987, \$8,000, DuPont deNemours.

Principal Investigator of "Production of monoclonal antibodies to delta hepatitis virus, a human pathogen grown in woodchucks." 1988, \$24,800, North Carolina Biotechnology Center.

Principal Investigator of "Determination of tissue distribution of the human pathogen delta hepatitis virus in infected woodchuck (*Meomota monax*) by immunohistochemistry and in situ hybridization." 1988, \$19,600, North Carolina State Research Fund.

CURRICULUM VITAE
John M. Cullen
Page 4

Publications:

- 1989 Cullen, J.M., Marion, P. L., Newbold, J.N. A sequential histologic and immunohistochemical study of duck hepatitis B virus infection in Pekin ducks. Vet Path 26:164-172.
- 1989 Cullen, J.M., Levine J. Babesia microti Infection of Syrian Hamsters: An animal Model of Human disease. Comp Pathol Bull (Animal Models) 21:3-4.
- 1989 Bunch, S.E., Metcalf, M.R., Crane, S.W., Cullen, J.M. Idiopathic pulmonary thromboembolism and pleural effusion in a dog. J Am Vet Med Assoc (In press).
- 1989 Wilson, M.E., Hagler, W.M. Jr., Cullen, J.M., Ort, J.F., Cole, R.J. Acute toxicity of cyclopiazonic acid in selected avian species. In: Biodeterioration Research 2, G.C. Llewellyn and C.E. O'Rear (Eds.) Plenum Publishing Co., New York. 2:371-381.
- 1989 Bristol, D.G., Cullen, J.M. Use of a linear stapling device to construct an inverted, triangulated, end to end anastomosis of the equine jejunum. Cornell Vet 79:217-230.
- 1989 Corbett, W.T., Liew-A-Joe, R., Hunter, L., Grindem, C., Levy, M., Cullen, J. Epidemiologic survey of bovine diseases in Suriname, South America Bulletin of PAHO 106:314-320.
- 1989 Cullen, J.M., Marion, P. L., Sherman, G.J., Newbold, J. Hepatic neoplasms in aflatoxin B₁ treated, congenital duck hepatitis B virus-infected and virus free Pekin ducks (Cancer Research, accepted with revisions).
- 1988 MacLachlan N.J., Cullen J.M. The liver and pancreas In: Thompson, R.G. (ed.). Special Veterinary Pathology, B.C. Decker Inc. Toronto, Canada.
- 1988 Newbold, J., Cullen, J.M. Experimental transmission and subsequent replication of Duck Hepatitis B virus in domestic geese. In: Viral hepatitis and liver disease, A. Z. Zuckerman (Ed.) Alan R. Liss Inc., New York. pp. 513-516.
- 1988 Cullen, J.M., Wilson, M.S., Hagler, W.M., Ort, J.F., Cole, R.J. Histopathology of cyclopiazonic acid administration to broiler chickens. Am J Vet Res 49:728-732.
- 1988 Cullen, J.M., Newbold, J., Marion, P. Acute severe hepatic injury in DHBV infected geese. In: Viral Hepatitis and Liver Disease. A. Z. Zuckerman (Ed.) Alan R. Liss Inc., New York. pp. 517-522.
- 1988 Vaden, S.L., Bunch, S.E., Duncan, D.E., Cullen, J.M. Hepatotoxicity associated with heartworm preventive medication in a dog. J Am Vet Med Assoc 192:651-654.
- 1988 Bristol, D.G., Cullen, J.M. A comparison of three methods of end to end anastomosis in the equine small colon. Cornell Vet 78:325-337.

CURRICULUM VITAE

John M. Cullen

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Publications (continued):

- 1988 Cohn, L.A., Spaulding, K.A., Cullen, J.M., Hardie, E.M., MacLachlan, N.J., Breitschwerdt, E.B. Hepatic postsinusoidal venous obstruction in a dog. (Accepted, J Vet Int Med).
- 1988 Greene, R.T., Levine, J.F., Breitschwerdt, E.B., Walker, R.C., Berkhoff, H.A., Cullen, J.M., Nicholson, W.L. Clinical and serologic evaluations of induced Borrelia burgdorferi infection in dogs. J Am Vet Med Assoc 49:752-757.
- 1987 Cullen, J.M., Ruebner, B.H., Hsieh, L.S., Hyde, D.M., and Hsieh, D.P.H. Carcinogenicity of aflatoxin M₁ in male Fischer rats compared to aflatoxin B₁. Cancer Research 47:1913-1917.
- 1987 Cullen, J.M. and Levine, J.F. Pathology of experimental Babesia microti infection in the Syrian hamster (Mesocricetus auratus auratus). Lab Anim Sci 36:640-643.
- 1987 Cullen, J.M., Burkes, E.J., Ruebner, B. Oral neoplasms in Fischer rats. J Dental Res 16:210-214.
- 1987 Marion, P., Cullen, J.M., Robinson, W.S., Azcarraga, R., Van Davelaar, M.J. Experimental transmission of duck hepatitis B virus to Pekin ducks and to domestic geese. Hepatology 7:724-731.
- 1987 Brownie, C.F., Cullen, J.M. Characterization of experimentally induced equine leukoencephalomalacia (ELEM) in ponies (Equus caballus): Preliminary report. Vet Hum Toxicol 29:34-38.
- 1987 Ling, G., Lowenstine, L., Cullen, J., Ackerman, N., and Ruby, A. Chronic urinary tract infection in dogs: Induction by inoculation with bacteria via percutaneous nephropylotomy. Am J Vet Res 48:794-798.
- 1987 Tate, L.P., Newman, H.C., Cullen, J.M., Sweeney, C. Neodymium (Nd):YAG - Laser Surgery in the Equine Larynx: A Pilot Study. Lasers in Surgery and Medicine 6:470-472.
- 1987 Cullen, J.M., Whiteside, J., Umstead, J., Whitaker, M. A mixed germ cell-sex cord tumor in a horse. Vet Pathol 24:575-577.
- 1987 Ling, G., Lowenstine, L., Cullen, J., Ackerman, N., and Ruby, A. Experimentally induced chronic urinary tract infection in dogs, resulting from introduction of bacteria by percutaneous nephropylotomy. Am J Vet Res 48:851-854.
- 1986 Gregory, C.R., Cullen, J.M., Pool, R., Vasseur, P.B. The canine sacroiliac joint. Spine 11:1044-1048.
- 1986 Hsieh, D.P.H., Cullen, J.M., Hsieh, L.S., Shao, Y., Reuben B. Cancer risks poses by aflatoxin M₁. In: Diet Nutrition in Cancer. Y. Hayashi (ed) VNU Sci Press, Utrecht pp. 57-65

CURRICULUM VITAE

John M. Cullen

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Publications (continued):

- 1986 Kitchell, B., Strombeck, D., Cullen, J., and Harrold, D. Clinical and Pathological Changes in Experimentally Induced Acute Pancreatitis in Cats. *Am J Vet Res* 47:1170-1173.
- 1986 Gregory C.R., Gourley, I.M., Taylor, N.J., Cullen, J.M., Evans, A., Fsaas, C.D., Cowgill, L.D. Experience with cyclosporin A after renal allografting in two dogs. *Vet Surg* 17:441-443.
- 1985 Ling, G., Cullen, J., Kennedy, P., Ruby, A. and D. Brooks. Relationship of upper and lower urinary tract infection and bacterial invasion of uroepithelium to antibody coated bacteria test results in female dogs. *Am J Vet Res* 46:499-504.
- 1984 Hsieh, B.P.H., Cullen, J.M., Ruebner, B. Comparative hepatocarcinogenicity of Aflatoxins B₁ and M₁ in one rat. *Food Chem. Toxicol.* 22:1027-1028.
- 1984 Couto, G., Cullen, J., Pedroia, U. and J. Turrell. Central nervous system lymphosarcoma in dogs. *J Am Vet Med Assoc* 184:809-813.
- 1983 Wong, M., Pedersen, N. and J. Cullen. Dirofilariasis in cats. *JAAHA* 19:855-864.
- 1980 Ricklefs, R.E., White, S.C., and Cullen, J. Postnatal development of Leach's Storm Petrel. *Auk* 97:768-781.
- 1980 Ricklefs, R.E., White, S.C., and Cullen, J. Energetics of postnatal growth in Leach's Storm-Petrel. *Auk* 97:566-575.

Abstracts:

- 1987 Cullen, J.M., Burkes, E.J., Ruebner, B.H. Oral neoplasms in fischer rats. *J Dental Res* 66:644.
- 1987 Norford, D., Cullen, J.M., Meuten, D.J. Effects of 3-MBI in the pituitary of Fischer rats. American College Vet Pathol Annual Meeting. Monterey, California.
- 1987 Cullen, J.M., Newbold, J., Marion, P.L. Histopathology of acute severe liver injury in domestic geese infected with DHBV. *Med Virol* 96:475.
- 1987 Coffey, M.T., Hagler, W.M., Cullen, J.M., Jones, E.E. Effect of multiple mycotoxin contamination on the performance of swine. Annual Meeting of American Society of Animal Science. Utah State University July 1987.
- 1987 Coffey, M.T., Hagler, W.M., Cullen, J.M. The effect of L-Lysine and DL-methionine supplementation on the response of weanling pigs to mycotoxin contaminated corn. *J Anim Sci* 66(Suppl 1):45.
- 1986 Cullen, J.M., Wilson, M., Hagler, W., Ort, J., Cole, R.J. Histopathology of cyclopiazonic acid to broiler chicks. Poultry Science Assoc. Annual Meeting, August 1986, Raleigh, North Carolina.

PAUL MEDFORD NEWBERNE

BORN: November 4, 1920; Adel, Georgia

TITLE: Professor of Nutritional Pathology

Academic Degrees:

<u>D.V.M.</u>	Auburn University, Auburn, Alabama (Veterinary Medicine)	1950
<u>M.Sc.</u>	Auburn University, Auburn, Alabama (Veterinary Medicine)	1951
<u>Ph.D.</u>	Missouri University, Columbia, Missouri (Nutritional Biochemistry with minor in Human Pathology)	1958

APPOINTMENTS AND EXPERIENCE:

1950-1951	Instructor, Veterinary Pathology, Auburn University Auburn, Alabama
1951-1954	Director, Research and Diagnostic Laboratories, Jessa, Inc., Columbus, Georgia
1954-1956	Instructor, Veterinary Microbiology, School of Veterinary Medicine, Missouri University, Columbia, Missouri
1956-1958	Instructor, Agricultural Chemistry, Missouri University, Post-doctoral Fellowship, National Institute of Neurological Disease and Blindness, National Institutes of Health, Bethesda, Maryland
1958-1962	Animal Pathologist and Professor, Auburn University, Agricultural Experiment Station and School of Agriculture, Auburn, Alabama
1962-1965	Associate Professor, Nutritional Pathology, Department of Nutrition and Food Science, Massachusetts Institute of Technology, Cambridge, Massachusetts
1965-1984	Professor, Nutritional Pathology, Department of Applied Biological Sciences, Massachusetts Institute of Technology, Cambridge, Massachusetts
1984-	Professor Emeritus/Senior Lecturer, Department of Applied Biological Sciences, Massachusetts Institute of Technology, Cambridge, Massachusetts

APPOINTMENTS AND EXPERIENCE (CONT'D)

1984- Professor of Pathology, Boston University School of Medicine, Boston, Massachusetts

1985- Research Pathologist, Special Scientific Staff, Boston City Hospital and Mallory Institute of Pathology

MILITARY SERVICE:

1942-1945 (Navy) Naval aviator, discharged as Lieutenant

PROFESSIONAL AFFILIATIONS AND MEMBERSHIPS: PAST/PRESENT

Member, Board of Trustees, Forsyth Dental Center
New England Branch, American Association of Laboratory Animal Science
Teratology Society
American Academy of Clinical Toxicology
American Institute of Nutrition
American Society for Experimental Pathology
Society of Toxicology
New England Society of Pathologists
Massachusetts Pathology Society
American Veterinary Medical Association
American College of Veterinary Pathologists (Past President)
Editorial Board, Toxicology and Applied Pharmacology
Editorial Board, Cornell Veterinarian
Editorial Board, Journal of Environmental Pathology and Toxicology
Editorial Board, Cancer Detection and Prevention
Editorial Board, Nutrition Reports International
Editorial Board, American Journal of Veterinary Research
Editorial Board, Food and Chemical Toxicology
Editorial Board, Merck Veterinary Manual
Editorial Board, Drug-Nutrient Interactions
Editorial Board, Cancer Research (Associate Editor)
Editorial Board, Journal of Nutrition
Editorial Board, Fundamental and Applied Toxicology
Editorial Board, Journal Environmental Pathology, Toxicology, and Oncology
Editorial Board, Journal of Nutritional Biochemistry

Phi Kappa Phi
Omicron Delta Kappa
Gamma Sigma Delta
Phi Zeta
Cosmos Club

MEDICAL CERTIFICATION:

American College of Veterinary Pathologists, Diplomate, Former President
American Board of Toxicology, Certified Diplomate, Former Treasurer

HONORS AND AWARDS:

National Cancer Institute Research Career Award
E.A. Davis award for excellence in Clinical Small Animal Medicine
Cutler Fellowship for post-doctoral study in Animal Pathology
Post-doctoral Fellow, National Institute of Neurological Disease and Blindness
FAMA Award, Contributions to Livestock and Poultry Industry
Borden Award NIH/FASEB
Fellow American Institute of Nutrition

PUBLICATIONS:

See attached list

RESEARCH AND TEACHING INTERESTS:

Pathology and biochemistry of diseases of nutritional origin particularly liver and gastrointestinal tract; nutritional carcinogenesis; food safety evaluation; nutritionally induced congenital abnormalities; nutritional toxicology and immunology; environmental toxicology; drug nutrient interactions. Teaching interests in the field of nutritional pathology, comparative pathology, drug safety; toxicology and food-borne diseases. For the past twenty years, advisor to more than 40 graduate students and 100 undergraduate students at Auburn University and at Massachusetts Institute of Technology. In 1962 organized teaching and research program in general area of food, nutrition and disease and how these interact in biological systems. Formal courses or seminars are taught including Diseases of Nutrition and Metabolic Origin, Comparative and Toxicologic Pathology and Nutritional Carcinogenesis. Actively engaged in research in nutritional biochemistry, pathology and toxicology.

DEPARTMENTAL AND INSTITUTE RESPONSIBILITIES:

Departmental
Carcinogenesis Hazards Committee

Institute
Preprofessional Advisory Committee
Animal Care Committee
Mallory Institute of Pathology Animal Facilities, Director

CONSULTANT TO:

American Cancer Society,
National Committee, Cancer Detection and Prevention
Federation, American Societies Experimental Biology (FASEB)
Committee, Health Aspects of Sugar Alcohol and lactose
FASEB-Conference on Tricothecenes (Chairman National Institutes of Health)
National Institute of Environmental Health Sciences on
Environmental Carcinogenesis
National Institute of Environmental Health Sciences, Second Task

Force on Human Health and the Environment, Safety of Foods
and Food Additives
National Cancer Institute, Nutrition and Cancer
National Heart and Lung Institute, Primates in Cardiovascular
Research
Nutrition Study Section (Past)
Animal Resources Advisory Board (Past)
Pathology Training Committee (Past)
National Toxicology Program, Peer Review Panel
Science Advisory Board, NCTR/FDA

National Academy of Sciences/National Research Council
Committee to Overview National Center for Toxicological Research
(NCTR) (Past)
Subcommittee on Pathology, NCTR (Chairman) (Past)
Committee on Laboratory Animal Diets (Chairman) (Past)
Food Protection Committee (Chairman) (Past)
Subcommittee on Toxicology (Past)
Committee on Food Irradiation (Past)
Committee on Clean Drinking Water (Past)
Subcommittee on Metalloids (Past)
Subcommittee on Nutrition (Past)
Committee on Guide to Care and Use of Laboratory Animals (Past)
Committee, Drinking Water and Health (Past)
Subcommittee, Contribution of Water to Human Mineral Requirements
(Chairman) (Past)

World Health Organization
Committee on Evaluation of Mycotoxins
Committee on Pesticides
Pathology of Nutritional Diseases

International Union Against Cancer - Vol. Hepatocellular Cancer,
1982; Nutrition and Cancer

International Union of Nutritional Sciences
Committee on Toxicology

Other

Armed Forces Institute of Pathology Veterinary and Comparative
Pathology
American Academy of Pediatrics Committee on Nutrition
National Association of Broadcasters Medical Advisory Board
Food and Drug Administration
Committee on Gastrointestinal Drugs
Subcommittee on Hepatotoxins
EPA Science Advisory Board
Committee, Airborne Carcinogens
Canadian Task Force, Environment and Cancer
WHO Committee on Liver Cancer
Thailand Advisory Environmental Toxicology Committee, Royal Thai
Government
Association of Medical Schools, Istanbul, Advisor for Research
Advisor, Chulabhorn Research Institute, Bangkok, Thailand

Journal Publications:

1. Newberne, P.M. and Burnett, S.E.: Cestodiasis in the Chinchilla, Vet. Med. 46: 156-157, 1951.
2. Newberne, P.M.: An Introduction to the Chinchilla, The Auburn Veterinarian 7: 59-61, 1951.
3. Newberne, P.M.: Edema of the Glottis in the Chinchilla, Vet. Med. 47-51, 1951.
4. Newberne, P.M. Diseases and Treatments for the Chinchilla. The Auburn Veterinary Handbook, May, 1952.
5. Newberne, P.M.: Chinchilla Nutrition. The Auburn Veterinarian 8: 76-78, 1952.
6. Newberne, P.M.: Urinary Calculus in the Chinchilla. North American Veterinarian 33: 334, 1952.
7. Newberne, P.M.: Scrotal Hernia in the Chinchilla, North American Veterinarian 33: 631, 1952.
8. Newberne, P.M.: Use of Estradiol Cyclopentylate (ECP) in Slow or Nonbreeding Chinchillas. Vet. Med. 47, October, 1952.
9. Newberne, P.M.: A Preliminary Report on the Blood Picture of the South American Chinchillas. J. A.V.M.A. 122: 221-222, 1953.
10. Newberne, P.M.: An Outbreak of Bacterial Gastro-enteritis in the South American Chinchilla. North American Veterinarian 34: 187-188, 1953.
11. Newberne, P.M.: Treatment of Anomalies of the Eye of the South American Chinchilla. Vet. Med. 47: 126, 1953.
12. Newberne, P.M. and Siebold, H.R.: Malignant Lymphoma in a Chinchilla. North American Veterinarian, August, 1954.
13. Newberne, P.M. and Hayes, F.A.: Cesarean Section in the Chinchilla. Vet. Med. 49: 246-248, 1953.
14. Hayes, F.A. and Newberne, P.M.: Chinchilla Therapeutics: Dosage Interval and Administration. Auburn Veterinarian, August, 1954.
15. Newberne, P.M. and Newberne J.W.: Diverticulum of the Bladder in a Chinchilla. North American Veterinarian, August, 1954.
16. Newberne, P.M., Muher, M.E., Craghead, B.S. and O'Dell, B.L.: An Abnormality of the Proventriculus of the Chick. J. A.V.M.A. 128: 553-555, 1956.

17. Newberne, P.M. and Buck, W.V.: Studies on Drug Toxicity in Chicks. 1. The influence of Various Levels of Megasul on Growth and Development of Chicks. Poul. Sci. 45: 1044-1049, 1956.
18. Newberne, P.M. and McDougale, H.C.: Studies on Drug Toxicities in Chicks. 2. The Influence of Various Levels of Sulfaguinoxaline on Growth and Development of Chicks. Poul. Sci. 35: 1259-1264, 1956.
19. Newberne, P.M. and Buck, W.V.: Studies on Drug Toxicity in Chicks. 3. The Influence of Various Levels of Nicarbazin on Growth and Development of Chicks. Poul. Sci. 36: 304-312, 1957.
20. Newberne, P.M. and McEuen, G.L.: Studies on Drug Toxicities in Chicks. 4. The Influence of Various Levels of Nitrofurazone on Growth and Development of Chicks. Poul. Sci. 36: 739-743, 1957.
21. Newberne, P.M. and McEuen, G.L.: Studies on Drug Toxicities in Chicks. 5. The Influence of Various levels of DPPD on Growth and Development of Chicks. Poul. Sci. 35: 744-747, 1957.
22. Newberne, P.M., Laerdal, O.A., Savage, J. and O'Dell, B.L.: A Surgical Method for the Separation of Urine and Feces in Young Chicks. Poul. Sci. 36: 821-824, 1957.
23. Newberne, P.M., Laerdal, O.A., Savage, J. and O'Dell, B.L.: A Direct Method for Determination of Digestibility in Growing Chickens. Poul. Sci. 36: 815, 1957.
24. Newberne, P.M., and O'Dell, B.L.: The Histopathology of Hydrocephalus in Rats Due to Vitamin B₁₂ Deficiency. Proc. Soc. Exptl. Bio. Med. 97: 62, 1958.
25. Newberne, P.M., and Vosbrink, C.J.: A Review of the Literature on the Avian Leukosis Complex and a Report of Two Cases in Turkeys. Vet. Med. 50, February, 1959.
26. O'Dell, B.L., Newberne, P.M. and Savage, J.: Significance of Dietary Zinc for the Growing Chicken. J. Nutr. 65: 508, 1959.
27. Newberne, P.M., and Salmon, W.D.: Cardiovascular Disease in Rats Fed Edible Fats. Proc. Ala. Acad. Sci. 113, March, 1959.
28. Newberne, P.M., and O'Dell, B.L.: Pathology of Vitamin B₁₂ Deficiency in Rats. J. Nutr. 68: 343, 1959.
29. O'Dell, B.L., Newberne, P.M. and Savage, J.E.: An Abnormality of the Proventriculus Caused by Feed Texture. Poul. Sci. 38: 296, 1959.
30. Newberne, P.M., Savage, J.E. and O'Dell, B.L.: Pathology of Arginine Deficiency in the Chick. J. Nutr. 72: 347, 1960.

31. O'Dell, B.L., Erickson, A., Newberne, P.M. and Flynn, L.M.: State of Oxidation of Nonprotein Sulfhydryl Compounds and Vitamin B₁₂ Deficiency. *Am. J. Physiol.* 200: 99, 1961.
32. Newberne, P.M., Salmon, W.D. and Hare, W.V.: Chronic Murine Pneumonia in the Experimental Laboratory. *Arch. Path.* 72: 224, 1961.
33. Newberne, P.M. and Hare, W.V.: Axion Dystrophy in Clinically Normal Dogs. *Am. J. Vet. Res.* 23: 403, 1961.
34. Salmon, W.D. and Newberne, P.M.: Effects of Antibiotics, Sulfonamides, and a Nitrofurantoin on Development of Hepatic Cirrhosis in Choline-deficient Rats. *J. Nutr.* 76: 483-491, 1962.
35. Salmon, W.D. and Newberne, P.M.: Cardiovascular Disease in Choline Deficient Rats. *Arch. Path.* 73: 190, 1962.
36. Newberne, P.M.: The Subcommissural Organ of the Vitamin B₁₂ Deficient Rat. *J. Nutr.* 76: 393, 1962.
37. Newberne, P.M.: Effect of Vitamin B₁₂ Deficiency and Excess on the Embryonic Development of the Rat. *Am. J. Vet. Res.* 24: 1304, 1963.
38. Newberne, P.M. and Salmon, W.D.: Biochemical and Morphological Observations on Choline-deficient rats. Effects of Various Levels of Beef Fat and Cholesterol, and of Injections of Sulfamerazine and Parathyroid Hormone. *J. Nutr.* 79: 179, 1963.
39. Salmon, W.D. and Newberne, P.M.: Occurrence of Hepatomas in Rats Fed Diets Containing Peanut Meal as a Major Source of Protein. *Cancer Res.* 23: 571, 1963.
40. Newberne, P.M., Wogan, G.N., Carlton, W.W., and Abdel-Kader, M.M.: Histopathologic Lesions in Ducklings Caused by Aspergillus flavus Cultures, Culture Extracts and Crystalline Aflatoxins. *J. Toxicol. Appl. Pharmacol.* 6: 542, 1964.
41. Newberne, P.M., Carlton, W.W. and Wogan, G.H.: Hepatomas in Rats and Hepatorenal Injury in Ducklings Fed Peanut Meal or Aspergillus flavus Extract. *Path. Vet.* 1: 105, 1964.
42. Newberne, P.M.: Cardiorenal Lesions of Potassium Depletion or Steroid Therapy in the Rat. *Am. J. Vet. Res.* 25: 1256, 1964.
43. Carlton, W.W., Hunt, C.E. and Newberne, P.M.: Neural Lesions Induced in Ducklings by isonicotinic Acid Hydrazide and Semicarbazide Hydrochloride, *J. Exptl. Mol. Path.* 4: 438-448, 1965.

44. Newberne, P.M., Russo, R. and Wogan, G.N.: Acute Toxicity of Aflatoxin B₁ in the Dog. Path. Vet. 3: 331-340, 1966.
45. Woodard, J.C. and Newberne, P.M.: The Relation of Vitamin B₁₂ and One Carbon Metabolism to Hydrocephalus in the Rat. J. Nutr. 88: 375-381, 1966.
46. Newberne, P.M. and Young, V.: Effects of Diets Marginal in Methionine and Choline with and without Vitamin B₁₂ on Rat Liver and Kidney. J. Nutr. 89: 69-79, 1966.
47. Newberne, P.M., Harrington, D.H. and Wogan, G.N.: Effects of Cirrhosis and Other Liver Insults on Induction of Liver Tumors by Aflatoxin in Rats. Lab. Invest. 15: 962-969, 1966.
48. Newberne, P.M., Wogan, G.N. and Hall, A. III: Effects of Dietary Modifications on Response of the Duckling to Aflatoxin. J. Nutr. 90: 123-130, 1966.
49. Newberne, P.M.: Overnutrition on Resistance of Dogs to Distemper Virus. Fed. Proc. 25: 1701-1710, 1966.
50. Newberne, P.M., Hunt, C.E. and Wogan, G.N.: Neoplasms in the Rat Associated with Administration of Urethan and Aflatoxin. J. Expt. Molec. Path. 6: 285-299, 1967.
51. Woodward, J.C. and Newberne, P.M.: The Pathogenesis of Hydrocephalus in Newborn Rats Deficient in Vitamin B₁₂. J. Embryol. Exptl. Morph. 17: 177-0187, 1967.
52. Newberne, P.M. and Rogers, A.E.: Carcinoma, Thymidine Uptake, and Mitosis in the Livers of Rats Exposed to Aflatoxin. New Zealand Med. J. 67: 8-17, 1968.
53. Payne, B.J. and Newberne, P.M.: Mycotoxicoses, Proc. U.S. Livestock Sanitary Assoc., 70th Annual Meeting, Buffalo, N.Y., October 10-11, 1966.
54. Newberne, P.M.: Biological Activity of the Aflatoxins in Domestic and Laboratory Animals. Trout Hepatoma Research Conference Papers. U.S. Dept. of Interior Research Report 70: 130-144, 1967.
55. Newberne, J.W., Gibson, J.R. and Newberne, P.M.: Variation in Toxicologic Response of Animal Species to an Analgesic. Toxicol. Appl. Pharmacol. 10: 233-243, 1967.
56. Rogers, A.E. and Newberne, P.M.: Effects of Aflatoxin B₁ and Dimethylsulfoxide on Thymidine H³ Uptake and Mitosis in Rat Liver. Cancer Res. 27: 855-861, 1967.
57. Wogan, G.N. and Newberne, P.M.: Dose-Response Characteristics of Aflatoxin B₁ Carcinogenesis of the Rat. Cancer Res. 27: 2370-2376, 1967.

58. Newberne, P.M., Rogers, A.E. and Wogan, G.N.: Hepatorenal Lesions in Rats Fed a Low Lipotrope Diet and Exposed to Aflatoxin. J. Nutr. 94: 331-343, 1968.
59. McGuire, B.A., Young, V.R., Payne, B.J. and Newberne, P.M.: Effects of Salmonella typhimurium Infection in Rats Fed Varying Protein Intakes. Arch. Path. 86: 60-86, 1968.
60. Young, V.R., Chen, S.C. and Newberne, P.M.: Effects of Infection on Skeletal Muscle in Ribosomes in Rats Fed Adequate or Low Protein. J. Nutr. 94: 361-368, 1968.
61. Newberne, P.M. and Wogan, G.N.: Sequential Morphologic Changes in Aflatoxin B₁ Carcinogenesis in the Rat. Cancer Res. 28: 770-771, 1968.
62. Bresnahan, M.R. and Newberne, P.M.: Interaction of Diet and Distemper Virus Infection on Lipid Metabolism in the Dog. Brit. J. Exptl. Path. 49: 223-234, 1968.
63. Newberne, P.M., Hunt, C.E. and Young, V.R.: The Role of Diet and the Reticuloendothelial System on the Response of Rats to Salmonella typhimurium infection. Brit. J. Exptl. Path. 49: 448-457, 1968.
64. Newberne, P.M., Rogers, A.E. and Bailey, C.: The Induction of Liver Cirrhosis in Rats By Amino Acid Diet. Cancer Res. 29: 230-235, 1969.
65. Newberne, P.M.: Interaction of Nutrition and Disease. Proc. Am. Hosp. Assoc., Las Vegas, Nevada, April 22-25, 1968.
66. Newberne, P.M.: Research in Nutrition. Proc. Am. An. Hosp. Assoc., Las Vegas, Nevada, April 22-25, 1968.
67. Newberne, P.M. and Butler, W.H.: Acute and Chronic Effects of Aflatoxin on the Liver of Domestic and Laboratory Animals. A Review. Cancer. Res. 29: 236-250, 1969.
68. Newberne, P.M.: The Influence of a Low Lipotrope Diet on Response of Maternal and Fetal Rats to Lasiocarpine. Cancer Res. 28: 2327-2337, 1968.
69. Applendorf, H., Newberne, P.M. and Tannenbaum, S.: Influence of Altered Thyroid Status on the Food Intake and Growth of Rats Fed a Thiamine-Deficient diet. J. Nutr. 97: 271-278, 1969.
70. Newberne, P.M., Brisnahan, M.R., Kula, N.: Effects of Two Synthetic Antioxidants, Vitamin E, and Ascorbic Acid on the Choline-Deficient Rat. J. Nutr. 97: 219-231, 1969.
71. Newberne, P.M., Young, V.R., and Gravlee, J.F.: Effects of Caloric Intake and Infection on Some Aspects of Protein Metabolism in Dogs. Brit. J. Exptl. Path. 50: 172-180, 1969.

72. Hunt, C.E., Carlton, W.W. and Newberne, P.M.: Interrelationships Between Copper Deficiency and Dietary Ascorbic Acid in the Rabbit. *Brit. J. Nutr.* 24: 61-69, 1970.
73. Newberne, P.M. and Williams, G.: Inhibition of Aflatoxin Carcinogenesis by Diethylstilbestrol in Male Rats. *Arch. Environ. Hlth.* 19: 489-497, 1969.
74. Newberne, P.M. and Rogers, A.E.: Aflatoxin B₁ Carcinogenesis in Lipotrope Deficient Rats. *Cancer Res.* 29: 1965, 1969.
75. Tandon, B.N., Newberne, P.M. and Young, V.R.: A Histochemical Study of Enzyme Changes and Ultrastructure of the Jejunal Mucosa in Protein Depleted Rats. *J. Nutr.* 99: 519, 1969.
76. Hunt, C.E., Landesman, J., and Newberne, P.M.: Copper Deficiency in Chicks: Effects of Ascorbic Acid on Iron, Copper, Cytochrome Oxidase Activity and Aortic Mucopolysaccharides, *Brit. J. Nutr.* 24: 607, 1970.
77. Harrington, D.D. and Newberne, P.M.: Correlation of Maternal Blood Levels of Vitamin A at Conception and the Incidence of Hydrocephalus in Newborn Rabbits: An Experimental Animal Model. *Lab. Animal Care* 20: 675, 1970.
78. Newberne, P.M., Ahlstrom, A. and Rogers, A.E.: Effects of Maternal Diets Deficient and Marginal in Lipotropes on Pre- and Neonatal Rats. *J. Nutr.* 100: 1098, 1970.
79. Newberne, P.M., Wilson, R.B. and Williams, G.: Effects of Severe and Marginal Maternal Lipotrope Deficiency on Response of Postnatal Rats to Infection. *Brit. J. Exptl. Path.* 51: 229-235, 1970.
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82. Maurer, F., Poppensiek, G.C. and Newberne, P.M.: Protein For Tomorrow's Faces of Hunger. *Congressional Record*, Vol. 116, No. 169, Sept. 28, 1970, pp. 8650-8654.
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- Oncolog. Soc., Prague, April 14-15, 1970.
85. Goddard, K.M., Williams, G.D., Newberne, P.M. and Wilson, R.B.: A Comparison of All-Meat, Semimoist, and Dry-Type Dog Foods as Diets for Growing Beagles. J. A.V.M.A. 157: 1233-1236, 1970.
86. Newberne, P.M., Wilson, R.B. and Rogers, A.E.: Effect of a Low Lipotrope Diet on Response of Young Male Rats to the Pyrrolizidine Alkaloid, Monocrotaline, Toxicol. Appl. Pharmacol. 18: 387, 1971.
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88. Wilson, R.B., Martin, J.M., Kelly, H. and Newberne, P.M.: Plasma and Pancreatic Insulin Concentrations in Adult Squirrel and Rhesus Monkeys. Diabetes 20: 151-155, 1971.
89. Wilson, R.B., Hartroft, W.S., Conen, P.E., Anderson, D.E. and Newberne, P.M.: Early Changes in Myocardium of Rats Fed and Infarct-Producing Diet. Arch. Path. 91: 307-317, 1971.
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91. Glaser, O., Newberne, P.M., Gabliks, J. and Friedman, L.F.: Transplantable Malignant Cholangiocarcinoma from Hamster Liver. Arch. Environ. Hlth. 23: 137-141, 1971.
92. Rogers, A.E., Kula, N.S., and Newberne, P.M.: Absence of an Effect of Partial Hepatectomy on Aflatoxin B₁ Carcinogenesis. Cancer Res. 31: 491-495, 1971.
93. Wogan, G.N., Edwards, G.S. and Newberne, P.M.: Acute and Chronic Toxicity of Rubratoxin B₁. Toxicol. Appl. Pharmacol. 19: 712, 1971.
94. Rogers, A.E. and Newberne, P.M.: Diet and Aflatoxin B₁ Toxicity in Rats. Toxicol. Appl. Pharmacol. 20: 113-121, 1971.
95. Wogan, G.N., Edwards, G.S. and Newberne, P.M.: Structure-Activity Relationships in Toxicity and Carcinogenicity of Aflatoxins and Analogs. Cancer Res. 31: 1936-1942, 1971.
96. DiPaolo, R.V. and Newberne, P.M.: Copper Deficiency in the Newborn Rat with Special Reference to Phosphatidic Acid Synthesis. 5th Ann. Conf. on Tract Substances in Environmental Health. D.D. Hemphill, editor, University of Missouri Press, Columbia, Mo., 1972.
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98. Newberne, P.M.: Computers: Their Application to Veterinary Medical Research and Teaching. Am. J. Vet. Res. 33: 209-210, 1972.
99. Nelson, D.P. and Newberne, P.M.: Protein Deficiency and Mucosal Granulocytes. Nature, (New Biology) 236: 28-29, 1972.
100. Newberne, P.M., Glaser, O., Friedman, L.F. and Stillings, B.: Chronic Exposure of Rats to Methyl Mercury in Fish Protein. Nature 237: 40-41, 1972.
101. Sprinker, L.H., Harr, J.R., Newberne, P.M., Whanger, P.D. and Weswig, P.H.: Selenium Deficient Lesions in Rats Fed Vitamin E Supplemented Rations. Nutr. Reports Internatl. 4: 335-340, 1972.
102. Wilson, R.B., Hoppe, H. and Newberne, P.M.: Hemorrhagic Renal Necrosis in Young Adult Rats Fed a Cholesterol Supplemented Choline-Deficient Diet. Nutr. Reports Internatl. 6: 275-280, 1972.
103. Newberne, P.M.: Updating Knowledge of Nutrition. J. A.V.M.A. 160: 1177-1178, 1972.
104. DiPaolo, R.V. and Newberne, P.M.: Copper Deficiency and Myelination of the CNS: Histologic and Biochemical Studies. VII Ann. Conf. Trace Substances in Environ. Health, University of Missouri Press, Columbia, MO, 1974, p. 213-223.
105. Shank, R. and Newberne, P.M.: Nitrite-Morpholine Induced Hepatomas. Food Cosmet. Toxicol. 10: 887, 1982.
106. Newberne, P.M.: Natural Toxins in Food and Feeds. Clin. Toxicol. 5: 439-440, 1972.
107. Kroes, R.M., Sontag, J.M., Weisburger, J.H., Newberne, P.M. and Wogan, G.N.: Alpha-Fetoprotein in Rats with Hepatomas Induced by Aflatoxin B₁. Nature 240: 240-241, 1982.
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BOOKS EDITED

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2. Mouse Liver Neoplasia. W.H. Butler and P.M. Newberne, eds., Elsevier (New York, 1975).
3. Trace Substances and Health: A Handbook. Vol. 1. P.M. Newberne, ed., Marcel Dekker, Inc., New York, 1976.
4. Nutrition, Immunity and Infection: Mechanisms of Interactions. R.K. Chandra and P.M. Newberne, (Eds.), Plenum Press, New York, 1977.
5. Rat Liver Neoplasia. P.M. Newberne and W.H. Butler (Eds.), M.I.T. Press, Cambridge, MA, 1978.
6. Trace Substances and Health: A Handbook. Vol. 2. P.M. Newberne, (Ed.), Marcel Dekker, Inc., New York, 1982.
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BOOK CHAPTERS AND REVIEWS

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2. Newberne, P.M. and O'Dell, B.L.: Antimetabolites and Congenital Anomalies. In: Disorders of the Developing Nervous System. Chapter X, Charles C. Thomas, publisher, 1961.
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CHRONOLOGY OF EMPLOYMENT

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1976 - 1977 Chief, Carcinogen Bioassay and Program Resources Branch, Carcinogenesis Program, Division of Cancer Cause and Prevention, National Cancer Institute, Bethesda, Maryland.

1974 - 1976 Associate Chief, Experimental Pathology Branch, Carcinogenesis Program, Division of Cancer Cause and Prevention, National Cancer Institute, Bethesda, Maryland.

1973 - 1976 Head, Tumor Pathology Section, Carcinogenesis Program, Division of Cancer Cause and Prevention, National Cancer Institute, Bethesda, Maryland.

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- 1970 - 1975 Associate Professor of Pathobiology, The Johns Hopkins University, School of Hygiene and Public Health, Baltimore, Maryland.
- 1968 - 1984 Associate Professor of Comparative Medicine, Associate Professor of Pathology, The Johns Hopkins University School of Medicine, Baltimore, Maryland.
- 1968 - 1973 Director, Laboratory Animal and Comparative Pathology Training Program (USPHS-NIH), The Johns Hopkins University, School of Medicine, Baltimore, Maryland.
- 1966 - 1973 Head, Comparative Pathology Program, The Johns Hopkins University School of Medicine, Baltimore, Maryland.
- 1966 - 1973 Pathologist, Baltimore Zoo, Baltimore, Maryland.
- 1965 - 1973 Director, Animal Tumor Clinic, The Johns Hopkins University School of Medicine, Baltimore, Maryland.
- 1964 - 1968 Assistant Professor of Pathology, and Assistant Professor of Animal Medicine, The Johns Hopkins University School of Medicine, Baltimore, Maryland.
- 1962 - 1964 USPHS-NIH Postdoctoral Fellow, Cornell University, Ithaca, N.Y.
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- 1956 - 1960 Private Veterinary Practice, Fair Haven Animal Hospital, Fair, Haven, Vermont.

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1965	Special Task Force, Joint Committee on Veterinary Education, The American Veterinary Medical Association, Washington, D.C.
1968 - 1972	Chairman, Committee on Laboratory Animal Diseases, Institute of Laboratory Animal Resources, National Academy of Science, Washington, D.C.
1968 - 1978	Member, Advisory Committee to Registry of Comparative Pathology, Armed Forces Institute of Pathology (Universities Associated for Research and Education in Pathology), Washington, D.C.
1971 - 1972	Chairman, Statutory Advisory Committee, Food and Drug Administration, Washington, D.C.
1971 - 1974	Member, Scientific Advisory Council, Morris Animal Foundation, Denver, CO.
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1971 - 1973	Chairman, Medical Committee, Baltimore, Zoological Society.
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1974	Panel Member, National Cancer Program's Planning Conference, Washington, D.C.
1975 - 1976	Member, Advisory Council, New York State Veterinary College, Cornell University, Ithaca, N.Y.
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1975 - 1976	Leader, Pathology Working Group, Committee for the Review of Data on Carcinogenicity of Cyclamates, convened by the National Cancer Institute for the Food and Drug Administration.

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1976 - 1982	Consultant, Cancer Assessment Group, Environmental Protection Agency, Washington, D.C.
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1977 - 1982	Member, Scientific Committee, Food Safety Council, Washington, D.C.
1978 - 1984	Member, Advisory Council, New York State College of Veterinary Medicine, Cornell University, Ithaca, N.Y.
1978 - 1986	Director, Toxicology Forum, Washington, D.C.
1979 - date	Director-at-Large, Universities Associated for Research and Education in Pathology, Bethesda, Maryland.
1980 - 1982	Chairman, The Nutrition Foundation Expert Committee on the Safety of Lead and Lead Salts in Food, Washington, D.C.
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1980 - date	Member, Expert Committee on Pathology and Toxicology, International Life Sciences Institute, Washington, D.C.
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SCIENTIFIC AND ADVISORY COMMITTEES CONT'D.

- | | |
|-------------|--|
| 1982 - 1984 | Member, Committee on Chemical Environmental Mutagens, Board on Toxicology and Environmental Health Hazards, National Academy of Sciences, Washington, D.C. |
| 1982 - 1983 | Member, The Nutrition Foundation International Expert Advisory Group on the Relevance of Mouse Hepatoma to Human Carcinogenic Risk, Washington, D.C. |
| 1982 | Member, Four Nation Committee on the Evaluation of the Safety of BHA, Food and Drug Administration, Washington, D.C. |
| 1983 - 1984 | Member, American Industrial Health Council Committee on General Criteria for Assessing the Evidence for Carcinogenicity of Chemical Substances, Washington, D.C. |
| 1983 | Member, Panel of Experts, Rat Liver Tumor Workshop, National Toxicology Program, Research Triangle Park, North Carolina. |
| 1986 | Councilor, Carcinogenesis Specialty Section, Society of Toxicology. |
| 1986 - 1987 | Member, Expert Panel, Carcinogenicity of 2,4-D, Ontario Ministry of the Environment, Ontario, Canada. |
| 1987 | Consultant, Science Advisory Board, Environmental Protection Agency, Washington, D.C. |

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1971 - 1972 Supervisory Veterinary Medical Officer (Veterinary Pathologist), Division of Research and Monitoring, Radiation Programs, Environmental Protection Agency, Rockville, MD

1972 - 1974 Supervisory Veterinary Medical Officer (Veterinary Pathologist), Carcinogen Metabolism and Toxicology Branch, Carcinogenesis, Division of Cancer Cause and Prevention, (DCCP), National Cancer Institute (NCI), National Institutes of Health (NIH), Bethesda, MD

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Service on Boards or Committees:

- 1975 - 1981 Editorial Board, VETERINARY PATHOLOGY
- 1976 - 1978 Chairman and Organizer, Viral Specialty Group, American College of Veterinary Pathologists
- 1978 Member, Education Committee - Carcinogenesis Program, American College of Veterinary Pathologists
- 1979 - 1985 Co-Chairman, Infectious Disease Specialty Group, American College of Veterinary Pathologists
- 1981 - Editorial Board, PATHOLOGY OF LABORATORY ANIMALS (International Life Sciences Institute - ILSI)
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- 1988 - Editorial Board, EXPERIMENTAL PATHOLOGY

Professional Advisory and Consultant Activities:

Member, Discussion Group-Criteria for Tumor Diagnosis and Classification of Malignancy. Conference on Carcinogenesis Testing in the Development of New Drugs, May 23-25, 1973, Washington, D.C., National Academy of Sciences.

Member, FDA, FD&C Red No. 40 Second Interim Working Group, December, 1977-1981.

Consultant and Expert Witness, FDA Hearing on Denial of Petition for Listing of FD&C Red No. 4 for Use in Marishino Cherries and Ingested Drugs, April 12, 1978, Rockville, Maryland.

Member, FDA Interagency Committee on Nitrite Research, 1978-1980.

Member, Project Group on Standardization of Measurements and Tests, Task Force on Cancer and Heart and Lung Disease, Environmental Protection Agency, 1979.

Consultant, Scientific Advisory Board, National Center for Toxicological Research, Jefferson, Arkansas, 1979.

Member, Mouse Lymphoma Study Group, 1979. Sponsored by the Nutrition Foundation.

Consultant, Division of Pathology, Bureau of Foods, Food and Drug Administration, 1978-1982.

Member, Working Group on Evaluation of Carcinogenic Risk of Chemicals to Man. International Agency for Research in Cancer, Lyon, France, February 10-17, 1981.

Professional Advisory and Consultant Activities (cont.):

Consultant and Expert Witness, FDA Hearing on Proposal to Withdraw Approval of Certain New Animal Drug Applications: Furazolidone (NF-180), Nitrofurazone (NF-7), & Furaltadone (NF-260), 1978-1985.

Alternate Member, TSCA Interagency Testing Committee, 1981-1983.

Consultant, Carcinogen Identification and Risk Assessment Branch, Occupational, Safety and Health Administration, Dept. of Labor, Washington, D.C., 1979-1981.

Expert Witness, State of California, Department of Health, OSHA, Sacramento, California, November 12, 1981, Hearing on Standards for Occupational Exposure Levels to 1,2-Dibromoethane.

Consultant, Chemical Pathology Branch, National Toxicology Program, National Institute of Environmental Health Sciences, Research Triangle Park, North Carolina, 1982-1983.

Expert Witness, Occupational Safety and Health Administration, U.S. Department of Labor, Informal Public Hearing on Occupational Exposure to Ethylene Oxide, Washington, D.C., July 26, 1983.

Member, Consensus Workshop on Formaldehyde - Carcinogenicity, Histopathology, Genotoxicity Panel, Food and Drug Administration, National Center for Toxicological Research, Little Rock, Arkansas, October 3-6, 1983.

Expert Witness, Melvin D. Reuber v. United States of America, Washington, D.C., May 3, 1984.

Ad Hoc Consultant, National Toxicology Program, Peer Review Bioassay Panel, July 26, 1984.

Member, Committee on the Carcinogenicity of Cyclamates, 1984-1985, National Research Council, National Academy of Sciences.

Member, Color Additive Scientific Review Panel, FDA, 1985.

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Book Chapters, Books and Syllabuses

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2. Ward, J. M. and Grabin, M.: Intestinal Tumors of Mice. In: Altman, P. and Katz, D. (Eds.): Inbred and Genetically Defined Strains of Laboratory Animals, Part I. Mouse and Rat. Bethesda, Maryland, FASEB, 1979, pp. 208-210.
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11. Spangler, F. and Ward, J. M.: Skin Initiation/Promotion Study with Formaldehyde in SENCAR mice. In: Clary, J. J., Gibson, J. E., Waritz, R. S. (Eds.): Formaldehyde. New York: Marcel Dekker, Inc., 1983, pp. 141-158.

23. Reynolds, C. W. and Ward, J. M.: LGL Lymphoproliferative Diseases in Man and Experimental Animals. The Characteristics of These Cells and Their Potential Experimental Uses. In: Lotzova, E. and Herberman, R. B. (Eds.): Immunobiology of Natural Killer Cells. West Palm Beach, CRC Press, 1986, pp. 193-207.
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26. Frith, C. H. and Ward, J. M.: A Color Atlas of Neoplastic and Nonneoplastic Lesions in Aging Mice. Amsterdam, Elsevier, 1988, pp. 109.
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OTC Vol. No. 113

OTC Docket Number 75N-0183 (triclosan)

September 12, 1994

Ciba-Geigy Corporation
Chemicals Division
Greensboro, N.C. 27419

Brooker, P.C., Gray, V.M., Howell, A. Analysis of Metaphase Chromosomes Obtained from CHO Cells Cultured In Vitro and Treated with Triclosan. Huntington Research Centre Ltd., ULR 214/88731. Unilever Test No. KC 880171. August 11, 1988.

Study Summary

Triclosan was tested in vitro to determine whether it would cause chromosomal aberrations in a mammalian cell line derived from Chinese hamster ovary tissue. The cells were routinely grown and subcultured in tissue culture medium at 37°C in a humid atmosphere containing 5% carbon dioxide. They were incubated with the test compound both with and without supplementary metabolic activation (rat S-9 mix).

A preliminary toxicity test was carried out to assess the effect of the compound on the mitotic index of cultured CHO cells. The results of this test indicated that a top dose level of 1 µg/ml should be used for the metaphase analysis in the absence of metabolic activation and 38 µg/ml in its presence. Due to the steepness of the toxicity profile an additional high dose of 30 µg/ml was included in case undue toxicity should be observed in the metaphase analysis assay.

Triclosan did not cause a significant increase in chromosomal aberrations at any dose level in either the presence or absence of metabolic activation.

Both positive control compounds caused large, statistically highly significant increases in chromosomal aberrations thus demonstrating the sensitivity of the test system and the efficacy of the S-9 mix.

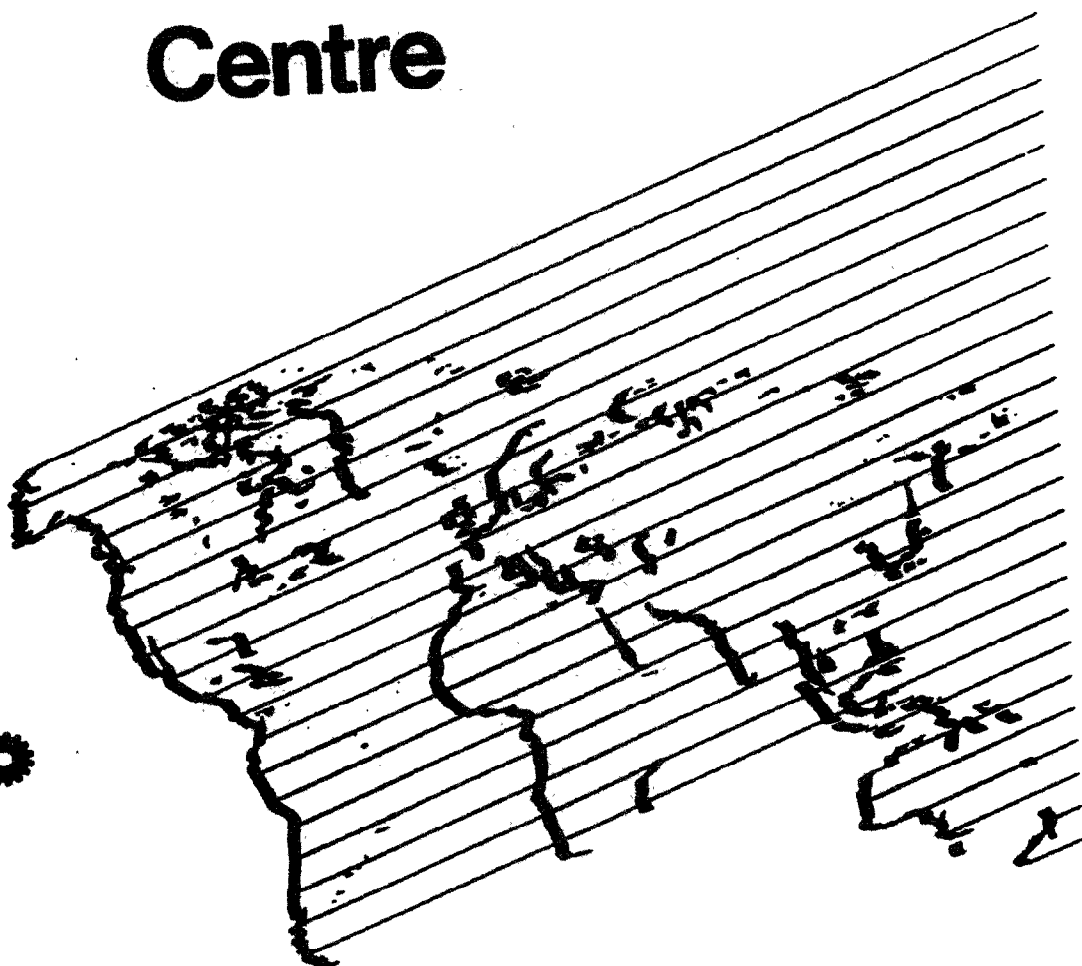
It is concluded that triclosan has shown no evidence of clastogenic activity in this in vitro cytogenetic assay.

HRC Report

TRICLOSAN

ANALYSIS OF METAPHASE CHROMOSOMES
OBTAINED FROM CHO CELLS
CULTURED IN VITRO

Huntingdon Research Centre



CONFIDENTIAL

ULR 214/88731
Unilever Test No.: KC 880171

ANALYSIS OF METAPHASE CHROMOSOMES
OBTAINED FROM CHO CELLS CULTURED
IN VITRO AND TREATED WITH
TRICLOSAN

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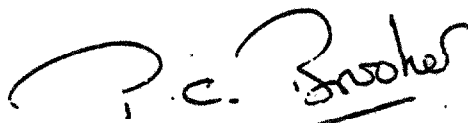
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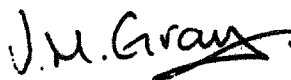
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We the undersigned, hereby declare that the work was performed under our supervision according to the procedures herein described, and that this report provides a correct and faithful record of the results obtained.



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HRC REPORT No. ULR 214/88731
Unilever Test No. 880171

COMPLIANCE WITH GOOD LABORATORY PRACTICE STANDARDS

To the best of my knowledge and belief the study described in this report was conducted in compliance with the following Good Laboratory Practice Standards:

United States Food and Drug Administration,
Title 21 Code of Federal Regulations Part 58,
Federal Register, 22 December 1978 and subsequent Amendments

Japan Ministry of Health and Welfare
Notification No. 313 Pharmaceutical Affairs Bureau
31 March 1982

Organization for Economic Co-operation and Development
ISBN 92-64-12367-9, Paris 1982

Good Laboratory Practice, The United Kingdom Compliance
Programme, Department of Health & Social Security 1986

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Study Director

11. 8. 88

Date

QUALITY ASSURANCE STATEMENT

Certain studies of short duration, such as that described in this report, are conducted at HRC in a setting which involves frequent repetition of similar or identical procedures. At or about the time the study described in this report was in progress, 'process-based' inspections were made by the Quality Assurance Department of critical procedures relevant to this study type. For the inspection of any given procedure, at least one study was selected without bias. The findings of these inspections were reported promptly to the Study Director and to HRC management.

This report has been audited by the HRC Quality Assurance Department. It is considered to be an accurate presentation of the procedures and practices employed during the course of the study and an accurate presentation of the findings.

P.H.C.V. Richold

Peter H.C.V. Richold, B.Sc.,
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4-8-88

Date

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SUMMARY

1. Triclosan was tested in vitro to determine whether it would cause chromosomal aberrations in a mammalian cell line derived from Chinese hamster ovary tissue. The cells were routinely grown and subcultured in tissue culture medium at 37°C in a humid atmosphere containing 5% carbon dioxide. They were incubated with the test compound both with and without supplementary metabolic activation (rat S-9 mix).
2. A preliminary toxicity test was carried out to assess the effect of the compound on the mitotic index of cultured CHO cells. The results of this test indicated that a top dose level of 1 µg/ml should be used for the metaphase analysis in the absence of metabolic activation and 38 µg/ml in its presence. Due to the steepness of the toxicity profile an additional high dose of 30 µg/ml was included in case undue toxicity should be observed in the metaphase analysis assay.
3. Triclosan did not cause a significant increase in chromosomal aberrations at any dose level in either the presence or absence of metabolic activation.
4. Both positive control compounds caused large, statistically highly significant increases in chromosomal aberrations thus demonstrating the sensitivity of the test system and the efficacy of the S-9 mix.
5. It is concluded that triclosan has shown no evidence of clastogenic activity in this in vitro cytogenetic assay.

INTRODUCTION

CHO-K₁ cells of the BH₁ subclone have an epithelial morphology with a modal chromosome number of 20 and grow as an adherent monolayer in vitro. They were originally derived from the ovary of a Chinese hamster and have frequently been used in this type of test system (6, 7, 8).

Division of the cells can be arrested at metaphase using the mitotic inhibitor colchicine (this prevents formation of the mitotic spindle). Chromosomes are examined in these metaphase cells for the presence of the following aberrations:

Gaps	} chromatid and isochromatid
Breaks	
Chromatid exchanges	
Dicentric chromosomes	
Acentric chromosome fragments	
Chromosome rings	
Complex rearrangements.	

A gap is defined as an achromatic region (occurring in one or both chromatids) which is smaller than the width of a single chromatid. The separated regions are still aligned. A break is defined as an achromatic region, occurring in one or both chromatids, that is greater than the width of a single chromatid. The accompanying fragment is usually displaced from the rest of the chromosome.

Many authors (1, 2, 3) believe that chromatid gaps are not examples of true chromosomal aberrations. In this study, therefore, the total numbers of cells with aberrations exclusive of gap damage have been calculated. The number of cells with aberrations including gap damage has also been tabulated.

Since many compounds do not exert their mutagenic effect until they have been converted by enzyme systems not present in cultured cells, one set of cultures was incubated with test compounds in the presence of a rat liver homogenate fraction (S-9 mix) taken from animals previously treated with a compound known to induce a high level of liver enzyme activity (4, 5, 9).

This report describes the experiments carried out between 8 April 1988 and 1 June 1988 to investigate the effects of triclosan on the chromosomes of a mammalian cell line cultured in vitro. The procedure followed the guidelines of the OECD (12).

Study Director and HRC management approval of the GLP protocol was obtained on 3 March 1988. Sponsor approval was given on 11 March 1988.

MATERIALS AND METHODS

(a) Test compound

Identity: Triclosan.

Chemical name: 2,4,4'-trichloro-2'-hydroxy diphenyl ether.

Unilever sample number: S15155 T01.

Expiry date: Later than March 1989.

Purity: >99%.

Stability: Stability data are the responsibility of the Sponsor.

Physical appearance: Off-white powder.

Solubility: Soluble in dimethylsulphoxide.

Storage: Room temperature in the dark.

Triclosan was dissolved in dimethylsulphoxide immediately before use. The test compound dissolved in the solvent at a concentration of approximately 289500 µg/ml, however at all final concentrations above 400 µg/ml a precipitate was formed in aqueous tissue culture medium. 400 µg/ml is considered to be the maximum achievable concentration in this test system.

(b) Positive control compounds

Mitomycin C from Sigma London Chemical Company Limited (batch number 96F-0547-1), was used as the positive control compound for the study in the absence of metabolic activation. It was prepared as a solution in sterile distilled water to give a final concentration of 0.4 µg/ml. Cyclophosphamide obtained from Sigma London Chemical Company Limited (batch number 123F-0283) was used as the positive control compound for the study in the presence of metabolic activation. It was prepared as a solution in sterile distilled water to give a final concentration of 20 µg/ml.

(c) Cell line and culture

Chinese hamster ovary (CHO) cells, strain K₁ -BH, were obtained from BIBRA and stored in polypropylene ampoules at -196°C in 90% foetal calf serum and 10% dimethylsulphoxide. The cells were routinely grown and subcultured in Hams F12 medium (Imperial) supplemented with 5% foetal calf serum (Gibco) at 37°C in a humid atmosphere containing 5% carbon dioxide in 175 cm² plastic tissue culture flasks (Nunc).

(d) Preliminary toxicity test

A 50 ml culture of CHO cells was harvested as follows: The supernatant medium was removed and the cells washed in 0.9% sterile saline; 20 ml of 0.25% trypsin was then added for 30 seconds. The trypsin solution was removed and the flask incubated at 37°C for 10 minutes. The cells were then resuspended in 20 ml Hams F12 + 5% FCS and diluted to give 8×10^4 cells/ml. Aliquots (5 ml) of cells were added to Nunc 25 cm² tissue culture flasks and the cultures incubated at 37°C in a humid atmosphere containing 5% carbon dioxide.

After 24 hours 500 µl of S-9 mix (see Appendix 1) was added to one set of cultures followed by 55 µl of various dilutions of the test compound and of the solvent. To the second set of cultures (i.e. without S-9 mix) 50 µl of the dilutions of test compound and of the solvent were added. Final concentrations of test compound in both sets were 6.3, 12.5, 25, 50, 100, 200 and 400 µg/ml with single flasks for each concentration and duplicate flasks for the solvent control. Duplicate flasks remained untreated in each case. The cultures without S-9 mix were incubated in the presence of the test compound for 24 hours.

Six hours after the addition of the test compound to those cultures treated with S-9 mix, the medium containing the S-9 mix and test compound was carefully removed and replaced with fresh Hams F12 + 5% FCS. The cultures were returned to the incubator for a further 18 hours.

(e) Harvesting, fixation and slide preparation

Two hours before the end of the 24-hour incubation period, mitotic activity was arrested by the addition of colchicine to each culture at a final concentration of 0.25 µg/ml. After the incubation period the medium was removed and discarded. 4 ml of 0.25% trypsin solution was then added. After 45 seconds this was removed and placed in a plastic conical centrifuge tube. The flasks were then incubated for 10 minutes at 37°C after which the cells were resuspended in Hams F12 + 5% FCS. The cell suspensions were placed with the trypsin solution in the centrifuge tubes. These cell suspensions were then centrifuged for 10 minutes at 200 x 'g'. The supernatant was discarded and the cells resuspended in 2.5 ml 0.07 M KCl. After a 10-minute incubation at room temperature the cell suspensions were centrifuged for 5 minutes at 110 x 'g'. The supernatant was discarded and 4 ml of freshly prepared fixative (3 parts methanol : 1 part glacial acetic acid v/v) added. The cells were left in fixative for 2 - 3 hours, then the pellets resuspended by repeated aspiration through a 20 gauge needle, centrifuged at 200 x 'g' for 10 minutes, the supernatant discarded, and the cell pellet resuspended in about 0.5 ml of fresh fixative by repeated aspiration through a Pasteur pipette.

Two drops of this cell suspension were dropped onto a cold, pre-cleaned microscope slide. The slides were left to air-dry at room temperature, then stained in 10% Giemsa. After air-drying they were mounted in DPX.

(f) Microscopical examination for mitotic index

The prepared slides were examined at a magnification of x160. The proportion of cells in mitosis in each culture was recorded. From these results the EC₅₀ was estimated (the EC₅₀ is that concentration of test substance expected to cause a 50% reduction in the mitotic index). Where possible, this concentration, or the maximum achievable concentration, was used as the top dose in the main study. Three other dose levels were selected at halving dilutions from the highest.

(g) Osmolality measurement

Following the exposure of the cells to the test compound in the preliminary toxicity test, a sample of the supernatants of the two highest doses and the control treatments were removed and measurement of osmolality made by conventional techniques.

(h) Metaphase analysis

Cultures were initiated and maintained as described in section (d). After 24 hours incubation 500 µl of S-9 mix was added to one set of cultures followed by 55 µl aliquots of various dilutions of the test compound giving final concentrations of 0.1, 0.3, 0.5 and 1 µg/ml. Two cultures were treated at each dose level. Four cultures were treated with 55 µl aliquots of the solvent control (dimethylsulphoxide), and two with 55 µl of the positive control compound, cyclophosphamide, at a final concentration of 20 µg/ml. Four cultures remained untreated. The cultures were then incubated at 37°C. To the remaining set of cultures (i.e. without S-9 mix) 50 µl aliquots of the test compound were added giving final concentrations of 4.8, 9.5, 19, 30 and 38 µg/ml. 50 µl aliquots of the solvent were added to four cultures and 50 µl aliquots of mitomycin C, which was used as the positive control compound at a final concentration of 0.4 µg/ml, were added to two cultures. Four cultures remained untreated. The cultures were then incubated at 37°C. Six hours after addition of test compound those cultures treated with S-9 mix had the medium carefully removed and replaced with fresh Hams F12 + 5% FCS. The cultures were then returned to the incubator for a further 18 hours.

All cultures were treated with colchicine, harvested, fixed and slides prepared as described in section (e). The slides were stained in 10% Giemsa, mounted in DPX and coded. Metaphase spreads were identified using a magnification of x160 and examined at a magnification of x1000 using an oil immersion objective. Approximately 100 metaphase figures were examined where possible from each culture, with normally a maximum of 25 from each slide.

(i) Analysis of dosing solutions

All dosing solutions were returned to the Sponsor for analysis of achieved concentration. Analysis confirmed the nominal concentrations. The raw data are retained by the Sponsor (Sponsor's analytical reference no. ANY 88.28).

(j) Storage of raw data

All slides and raw data, or exact copies thereof, together with a master copy of this final report are located in the Archives of Huntingdon Research Centre Ltd., Huntingdon, Cambridgeshire, England.

RESULTS

(a) Preliminary toxicity test

The mitotic indices of CHO cells treated with various concentrations of triclosan are shown in Table 1.

In the absence of metabolic activation, the cultures dosed with the four highest concentrations of triclosan yielded no live cells. Two of the remaining three cultures dosed contained no metaphase figures, while the lowest concentration dosed (6.3 µg/ml) caused a decline in mitotic index to approximately 29% of the solvent control value. 1 µg/ml was estimated to be the concentration of triclosan which would cause a 50% decline in mitotic index. This was selected as the highest concentration to be dosed in the main test, with intermediate and low dose levels of 0.5, 0.3 and 0.1 µg/ml.

In the presence of metabolic activation, cultures dosed with the three highest concentrations of the test compound contained no live cells. The fourth concentration (50 µg/ml) reduced the mitotic index to approximately 27% of the solvent control value and 25 µg/ml of the test compound caused a decline in mitotic index to approximately 77% of the solvent control value. The two lowest concentrations (6.3 and 12.5 µg/ml) yielded mitotic indices comparable to the solvent control value. The EC₅₀ value was estimated to be 38 µg/ml, and this was selected as the highest concentration to be dosed in the main test. Intermediate and low concentrations of triclosan were three serial halving dilutions from the highest (19, 9.5 and 4.8 µg/ml), together with an intermediate concentration (30 µg/ml) due to the steepness of the toxicity profile.

(b) Osmolality measurement

No difference was observed between triclosan and solvent control treated cultures, and so choice of dose levels for the main test was not affected.

(c) Metaphase analysis

The effects of triclosan on cultured CHO cells are shown in Table 2 in which the number and type of chromosomal aberrations are recorded.

Both positive control compounds, mitomycin C (0.4 µg/ml) and cyclophosphamide (20 µg/ml), caused statistically highly significant increases in the proportion of metaphase figures containing aberrations when compared with the relevant solvent controls.

In the presence of metabolic activation 38 µg/ml proved excessively toxic and was not analysed.

Triclosan did not cause a significant increase in chromosomal aberrations at any dose level in either the presence or absence of metabolic activation.

ULR 214/88731
Unilever Test No.: KC 880171

CONCLUSION

Triclosan has shown no evidence of clastogenic activity in this in vitro cytogenetic assay.

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TABLE 1

Preliminary toxicity test - mitotic indices of cultured
CHO cells treated with triclosan

(a) Without metabolic activation

Culture number	Test agent	Concentration (µg/ml)	Mitotic index		
			Slide a	Slide b	% Mean
1	Untreated	-	37/1000	32/1000	3.4
2			35/1000	30/1000	
3	Dimethylsulphoxide (solvent control)	10 µl/ml	28/1000	28/1000	2.8
4			31/1000	26/1000	
5	Triclosan	6.3	9/1000	6/1000	0.8
6		12.5	0/1000	0/1000	0.0
7		25.0	0/488	0/493	0.0
8		50.0	0/0	0/0	-
9		100.0	0/0	0/0	-
10		200.0	0/0	0/0	-
11		400.0	0/0	0/0	-

(b) With metabolic activation

Culture number	Test agent	Concentration (µg/ml)	Mitotic index		
			Slide a	Slide b	% Mean
12	Untreated	-	46/1000	53/1000	4.2
13			34/1000	33/1000	
14	Dimethylsulphoxide (solvent control)	10 µl/ml	39/1000	47/1000	3.0
15			11/1000	21/1000	
16	Triclosan	6.3	38/1000	42/1000	4.0
17		12.5	26/1000	25/1000	2.6
18		25.0	22/1000	23/1000	2.3
19		50.0	9/1000	7/1000	0.8
20		100.0	0/0	0/0	-
21		200.0	0/0	0/0	-
22		400.0	0/0	0/0	-

TABLE 2

Effect of triclosan on the chromosomes of cultured CHO cells

(a) Without metabolic activation

Culture no.	Test agent	Concentration $\mu\text{g/ml}$	No. cells examined	No. aberrations per 100 cells		Aberrations										Number of aberrant cells			
				Exc. gaps	Inc. gaps	BWF	I	R	D	SH	A	GT	CHR	Exc. gaps	% Mean	Inc. gaps	% Mean		
45	Untreated	-	100	0	0									0	0.25	0	0.25		
46			100	0	0									0		0			
47			100	0	0									0		0			
48			100	1	1	1								1		1			
49	Dimethylsulphoxide (solvent control)	=10 $\mu\text{l/ml}$	100	0	0									0	0.75	0	1.00		
50			100	1	1	1								1		1			
51			100	0	0									0		0			
52			100	4	5	3				1			1	2		3			
53	Triclosan	0.1	100	0	0									0	0.00	0	0.00		
54			100	0	0									0		0			
55		0.3	100	0	0									0	1.00	0	1.00		
56			100	4	4	3			1					2		2			
57		0.5	100	0	0									0	1.50	0	1.50		
58			100	3	3	3								3		3			
59		1.0	100	0	0									0	0.00	0	0.50		
60			100	0	1								1	0		1			
61	Mitomycin C	0.4	73	167.1	167.1	77	19	1		4	6	15		53	67.1***	53	67.1***		
62			76	132.9	134.2	57	20	3		7	1	13	1	47		47			

Statistical analysis used was Fisher's test

*** $P < 0.001$ Otherwise $P > 0.05$

BWF Chromatid break with fragment

I Interchange

R Ring

D Dicentric

SM Single minute

A Acentric fragment

GT Greater than 10 aberrations

CHR Chromatid gap

Unilever Test No.: KC 880171
ULR 214/88731

TABLE 2
(continued)

(b) With metabolic activation

Culture no.	Test agent	Concentration $\mu\text{g/ml}$	No. cells examined	No. aberrations per 100 cells		Aberrations										Number of aberrant cells			
				Exc. gaps	Inc. gaps	BWF	I	C	SM	R	A	GT	P	CHR	Exc. gaps	% Mean	Inc. gaps	% Mean	
63	Untreated	-	100	1	1	1									1	0.75	1	0.75	
64			100	1	1	1								1	1				
65			100	0	0									0	0				
66			100	1	1	1								1	1				
67	Dimethylsulphoxide (solvent control)	10 $\mu\text{l/ml}$	100	6	7	6							1	6	4.25	7	4.75		
68			100	4	5	2			1		1		1	4		5			
69			100	2	2	2								2		2			
70			100	7	7	5	1				1			5		5			
71	Triclosan	4.8	100	0	0									0	0.00	0	0.00		
72			100	0	0									0		0			
73		9.5	100	2	2	1					1			2	1.50	2	1.50		
74			100	2	2	1					1			1		1			
75		19.0	100	1	2	1							1	1	2.50	2	3.00		
76			100	4	4	4								4		4			
77		30.0	100	1	1		1							1	3.00	1	3.00		
78			100	5	5	4			1					5		5			
81	Cyclophosphamide	20.0	100	74	77	46	16		3	2	4	2	1	3	40	37.50***	40	37.50***	
82			100	67	68	40	10	1	5	1	8	2		1	35		35		

Statistical analysis used was Fisher's test
*** $P < 0.001$
Otherwise $P > 0.05$

BWF Chromatid break with fragment
I Interchange
C Complex rearrangement
SM Single minute
R Ring

A Acentric fragment
GT Greater than 10 aberrations
P Pulverised cell
CHR Chromatid gap

Unilever Test No.: KC 880171
ULR 214/88731

APPENDIX 1

Preparation of S-9 liver homogenate fraction

1. Animal used

Species: Rat.

Strain: CD rats of Sprague-Dawley origin.

Source: Charles River, UK Limited,
Manston Road, Margate, Kent, England.

Age range: 6 - 8 weeks.

Weight range: 180 - 220 g.

Diet: Labsure Rodent Diet LAD 1.

Number used: 10 males.

2. Stimulation of rat liver enzymes

Mixed-function oxidase systems in the rat liver were stimulated following a single i/p injection of Aroclor 1254 (diluted in Arachis oil to 200 mg/ml) at a dosage of 500 mg/kg. On the fifth day of induction, following an overnight starvation, the rats were killed and their livers aseptically removed.

3. Preparation of liver homogenate S-9

All steps were at 0 - 4°C using sterile solutions and glassware. The livers were placed in beakers containing 0.15 M KCl. After weighing, livers were transferred to a beaker containing 3 volumes of 0.15 M KCl and homogenised in an MSE top-drive homogeniser. This homogenate was centrifuged for 10 minutes at 9000 x 'g' and the supernatant divided into 5 ml aliquots. These were stored at -80°C and tested before use, with the carcinogen, 7,12-dimethylbenz(a)anthracene.

4. Preparation of S-9 mix

Each ml S-9 mix contained:

S-9 fraction	0.1 ml
Solution of 4.44 mM NADP and 27.78 mM glucose-6-phosphate	0.9 ml

All the above solutions were mixed and then filter-sterilised (apart from the S-9 fraction which was added after filter-sterilisation of the other S-9 mix components).

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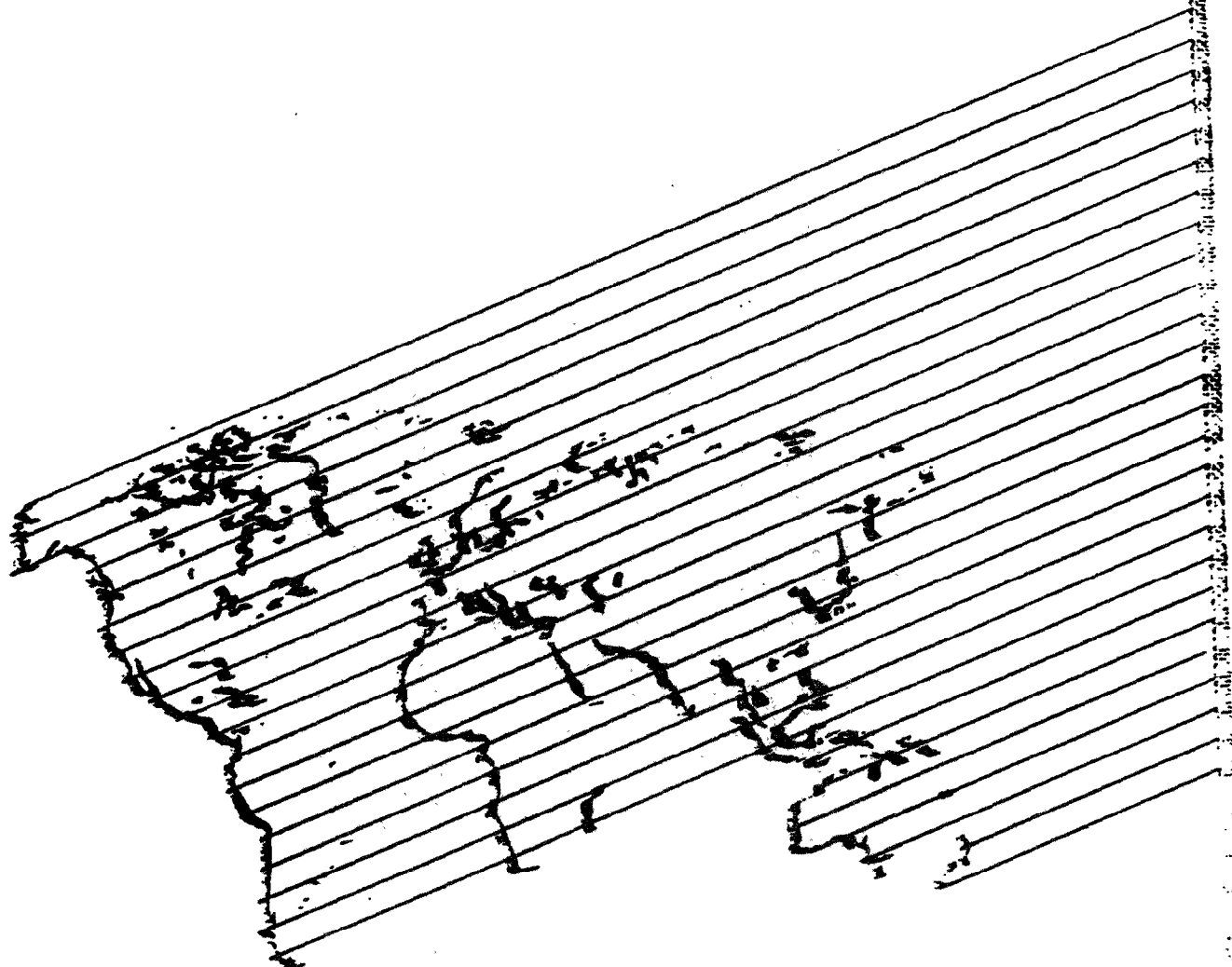
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OTC Vol. No. 114

OTC Docket Number 75N-0183 (triclosan)
September 12, 1994

Ciba-Geigy Corporation
Chemicals Division
Greensboro, N.C. 27419

Trutter, J.A. 13-Week Subchronic Oral Toxicity Study of Triclosan in CD-1® Mice.
Hazleton Washington, Inc. Lab. Project I.D. No. 483-287. January 28, 1993.

Summary

The toxicity of triclosan when fed daily in the diet to male and female CD-1® mice for at least 7 or 13 weeks was evaluated. The concentration dose of the test article in the diet was adjusted weekly to provide average daily doses of 0, 25, 75, 200, 350, 750, and 900 mg/kg for Groups 1-7 and 0, 25, 350, and 900 mg/kg for Groups 8-11. These latter groups (8-11) were representative low, mid and high-dose groups and treated for 7 weeks only. The animals were provided ad libitum access to the dosed diet until the day prior to sacrifice. Criteria evaluated for triclosan induced effects included survival, clinical observations, body weight, food consumption, auditory and ophthalmoscopic examinations, organ weights, and clinical (hematology and clinical chemistry), gross, and microscopic pathology.

In-life clinical signs, observed in only a small proportion of animals predominantly at the high dose (900 mg/kg), included hunched posture, hypoactivity, pale body, and few feces. Body weight and food consumption were consistent across all groups with the exception of the Group 7 (900 mg/kg/day) females where there was a significant decrease in body weight gain and food consumption. Negative responses to auditory stimuli were observed in 7 of 13 males in Group 7 (900 mg/kg). In the absence of similar findings in the females, the significance of this finding relative to the test material treatment is unclear. The ophthalmology findings were within those expected for mice of this age and strain.

Clinical pathology (hematology and clinical chemistry) studies at predose (Week -1), Week 7, and Week 14, were performed to assess the temporally-related health status of the animals. A significant dose-related trend toward decreased erythrocyte, hemoglobin, and hematocrit mean values was evident in both the males and females. Biochemical findings from the serum which were considered to be treatment related and biologically significant were increased aminotransferase, increased alkaline phosphatase, decreased total cholesterol, and increased gamma glutamyltransferase.

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Postmortem gross examinations of protocol-specified tissues were performed to evaluate the potential toxicity of triclosan as the result of the dietary exposure. The gross finding of dark enlarged liver was observed in the 75-900 mg/kg dose levels of both sexes at the Week 7 and Week 14 sacrifices and corresponded with the increase in liver weight which was also dose-related. The liver was evaluated histomorphologically from all dose groups (Groups 1-7). Other tissues which presented histomorphologic alterations at the highest dose level were examined at lower levels until no treatment-related changes could be found. The findings in the liver generally correlated with the clinical and gross pathology findings. Liver findings included centrilobular hepatocellular hypertrophy, vacuolization, pigment accumulations, necrosis, and/or inflammation (males at 75-900 mg/kg, females at 200-900 mg/kg). The severity of the various hepatic findings generally increased as a function of the dose. Increased extramedullary hematopoiesis was also observed in the spleen of 750 and 900 mg/kg/day mice of both sexes as well as some marginal increases at the 200 mg/kg/day level and higher of males only. This was considered related to the decreased erythrocyte count, hemoglobin, and hematocrit in these animals. Other histomorphologic findings were noted in the adrenals of males at the 75 mg/kg/day level and higher and females at the 200 mg/kg/day level and higher. Hyperplasia of the glandular stomach was noted in males at the 200 mg/kg/day and higher dose levels and in females at 350 mg/kg/day and higher. Inflammation in the kidneys (females only) of the 200 mg/kg/day dose level and higher and tubule regeneration in high dose (females only) were also attributed to exposure to the test article.

In summary, administration of triclosan in the diet for at least 13 weeks was associated with a significant trend toward increased liver weight in both sexes of animals in the absence of mortality. In addition, dose-related and significant depressions in total cholesterol were observed in males and females in Groups 2-7, in Group 9 males, and in males and females in Groups 10 and 11. Significant toxicity related to the administration of triclosan was manifested in both sexes at the 900 mg/kg/day dose level as evidenced by the organ weight changes and the clinical and histomorphologic pathology findings. The lowest dose level presenting histomorphologic alterations in males was 75 mg/kg/day and in females was 200 mg/kg/day. Based upon the dose-related trends in several of the hematology parameters (erythrocyte count, hemoglobin, and hematocrit), the significant trend for liver weight increase, and the significant depression in total cholesterol at 25 mg/kg/day (week 7, males only; Week 14 both sexes), a no adverse effect level cannot be definitively established from the dose levels administered in this study.

VOLUME 6 OF 10 OF SUBMISSION

STUDY TITLE

13-Week Subchronic Oral Toxicity Study of Triclosan in CD-1® Mice

EPA GUIDELINE NO. 82-1

AUTHOR

Janet A. Trutter, M.S., D.A.B.T.

STUDY COMPLETED ON: January 28, 1993

CONDUCTED BY

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LABORATORY PROJECT IDENTIFICATION NO. HWA 483-287

VOLUME 1 OF 2 OF STUDY

PAGE 1 OF 1113

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STATEMENT OF NO DATA CONFIDENTIALITY CLAIMS

NO CLAIM OF CONFIDENTIALITY IS MADE FOR ANY INFORMATION
CONTAINED IN THIS STUDY ON THE BASIS OF FALLING WITHIN THE SCOPE OF
FIFRA SECTION 10(d)(1)(A), (B) OR (C).

SUBMITTER/SPONSOR: CIBA-GEIGY CORPORATION
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COMPANY AGENT: Keith A. Hostetler, Ph.D., DABT
TITLE: Manager, Hazard Assessment
Product Stewardship Team

SIGNATURE: Keith A Hostetler DATE: 1-14-93

COMPLIANCE STATEMENT
13-Week Subchronic Oral Toxicity Study of Triclosan in CD-1[®] Mice

This study was conducted in compliance with the Good Laboratory Practice Regulations as set forth in Title 21 of the U.S. Code of Federal Regulations Part 58, issued December 22, 1978 (effective June 20, 1979), and with any applicable amendments; the Good Laboratory Practice Regulations as set forth in Title 40 of the U.S. Code of Federal Regulations Part 160, issued November 29, 1983 (effective May 2, 1984) and Part 792, issued November 29, 1983 (effective December 29, 1983), and in the Organisation for Economic Co-operation and Development Principles of Good Laboratory Practice C(81)30 (Final) Annex 2, issued 1979-1980 (effective 1981), and with any applicable amendments. All deviations from the protocol and/or GLPs are listed in Appendix 16. There were no deviations from the aforementioned regulations which affected the quality or integrity of the study or the interpretation of the results in the report.

Study Director:

Janet A. Trutter
Janet A. Trutter, M.S., D.A.B.T.
Department of Toxicology

Jan. 28, 1993
Date

Agent of Submitter/Sponsor: Carl D. D'Ruiz, MPH

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Date: 11-10-93

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FLAGGING STATEMENT

The criteria of 40 CFR 158.34 for flagging studies for potential adverse effects has been applied to the results of the attached study. This study neither meets nor exceeds any of the applicable criteria.

Agent of Submitter/Sponsor:

Carl D. D'Ruiz, MPH

Title:

Manager, Regulatory Compliance
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HWA 483-287

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HWA 483-287

QUALITY ASSURANCE STATEMENT

Study Title: 13-Week Subchronic Oral Toxicity Study in Triclosan in CD-1 Mice

Project No.: 483-287

Quality Assurance inspections and reviews of this study were conducted according to the standard operating procedures of the Quality Assurance Unit and according to the Good Laboratory Practice regulations of the Food and Drug Administration (FDA), Title 21 of the U.S. Code of Federal Regulations Part 58, issued December 22, 1978 (effective June 20, 1979); the Environmental Protection Agency (EPA - FIFRA), Title 40 of the U.S. Code of Federal Regulations Part 160, issued November 29, 1983 (effective May 2, 1984) and with any applicable amendments. These inspections and reviews were performed and findings were reported to the Study Director and management as follows:

Dates of Inspection/Review	Dates Findings Reported to Management	Inspector/Reviewer
Protocol Review: 7/26/91	7/26/91	D. Mullett
Inspection and/or Data Review: 8/9,27-30;9/3/91 11/5,6,11,14,15,20,22/91	9/17/91 12/3/91	D. Mullett J. Firreno
Report and Data Review: 5/6-8,11-15,18/92 1/25/93	5/26/92 1/25/93	K. Butler K. Butler

Karen E. Butler 1/28/93
Karen E. Butler Date Released
Quality Assurance Unit



HWA 483-287

STUDY IDENTIFICATION
13-Week Subchronic Oral Toxicity Study of Triclosan in CD-1[®] Mice

HWA Study Number: 483-287

Test Material: Triclosan (IRGASAN[®] DP 300)

Study Monitor/Sponsor: Keith Hostetler, Ph.D.
CIBA-GEIGY Corporation
Chemicals Division
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Study Directors: James L. Ivett, Ph.D.
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Study Timetable

Study Initiation:	July 1, 1991
Initiation of Dosing:	August 9, 1991
Completion of Necropsy:	November 14, 1991

STUDY PERSONNEL
13-Week Subchronic Oral Toxicity Study of Triclosan in CD-1[®] Mice

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Formulations Supervisor:	Gene Brown
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Laboratory Group Leader:	Nancy Centanni, M.S., L.A.T.G.
Laboratory Head Technician:	Sharon Taylor

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alkaline phosphatase, decreased total cholesterol, and increased gamma glutamyltransferase.

Postmortem gross examinations of protocol-specified tissues were performed to evaluate the potential toxicity of triclosan as the result of the dietary exposure. The gross finding of dark enlarged liver was observed in the 75-900 mg/kg dose levels of both sexes at the Week 7 and Week 14 sacrifices and corresponded with the increase in liver weight which was also dose-related. The liver was evaluated histomorphologically from all dose groups (Groups 1-7). Other tissues which presented histomorphologic alterations at the highest dose level were examined at lower levels until no treatment-related changes could be found. The findings in the liver generally correlated with the clinical and gross pathology findings. Liver findings included centrilobular hepatocellular hypertrophy, vacuolization, pigment accumulations, necrosis, and/or inflammation (males at 75-900 mg/kg, females at 200-900 mg/kg). The severity of the various hepatic findings generally increased as a function of the dose. Increased extramedullary hematopoiesis was also observed in the spleen of 750 and 900 mg/kg/day mice of both sexes as well as some marginal increases at the 200 mg/kg/day level and higher of males only. This was considered related to the decreased erythrocyte count, hemoglobin, and hematocrit in these animals. Other histomorphologic findings were noted in the adrenals of males at the 75 mg/kg/day level and higher and females at the 200 mg/kg/day level and higher. Hyperplasia of the glandular stomach was noted in males at the 200 mg/kg/day and higher dose levels and in females at 350 mg/kg/day and higher. Inflammation in the kidneys (females only) of the 200 mg/kg/day dose level and higher and tubule regeneration in high dose (females only) were also attributed to exposure to the test article.

In summary, administration of triclosan in the diet for at least 13 weeks was associated with a significant trend toward increased liver weight in both sexes of animals in the absence of mortality. In addition, dose-related and significant depressions in total cholesterol were observed in males and females in Groups 2-7, in Group 9 males, and in males and females in Groups 10 and 11. Significant toxicity related to the administration of triclosan was manifested in both sexes at the 900 mg/kg/day dose level as evidenced by the organ weight changes and the clinical and histomorphologic pathology findings. The lowest dose level presenting histomorphologic alterations in males was 75 mg/kg/day and in females was 200 mg/kg/day. Based upon the dose-related trends in several of the hematology parameters (erythrocyte count, hemoglobin, and hematocrit), the significant trend for liver weight increase, and the significant depression in total cholesterol at 25 mg/kg/day (Week 7, males only; Week 14 both sexes), a no adverse effect level cannot be definitively established from the dose levels administered in this study.

INTRODUCTION

This study was designed to characterize the potential subchronic toxicity of triclosan (IRGASAN[®] DP 300), when administered to mice for at least 6 weeks (Satellite Study, Groups 8-11) or 13 weeks (Main Study, Groups 1-7) in the diet. Dosing began on August 9, 1991, and terminal sacrifices were completed on November 14, 1991.

The protocol was designed in accordance with the OECD Development Guidelines for Testing Chemicals (ISBN 92-64-12221-4). The study was conducted in compliance with the Good Laboratory Practice Regulations of the Food and Drug Administration [21 CFR 58], the Environmental Protection Agency TSCA [40 CFR 792] and FIFRA [40 CFR 160] and in the Organisation for Economic Cooperation. Any deviations from protocol and/or GLPs are listed in Appendix 16.

TEST AND CONTROL MATERIALS

The test material, triclosan (IRGASAN[®] DP 300), Batch No. 5.2.0211.0, was received from Ciba-Geigy Corporation on July 9, 1991, and stored under ambient conditions. The test material was described as a white powder with a given purity of 99.7%. Information on the methods of synthesis and stability, as well as data on composition or other characteristics which define the test material, is on file with the originating company.

Purina[®] Certified Rodent Chow[®] served as the basal diet for the control animals and as the vehicle for the treated groups. It was stored at room temperature.

Reserve samples of the test and control materials (1 gram) were taken prior to initiation and were stored under ambient conditions. All remaining test material and reserve samples will be forwarded to the Sponsor upon issuance of the final report.

TEST ANIMALS AND HUSBANDRY

A total of 380 (190/sex) 28 day-old Cr1:CD-1[®] mice were received on July 23, 1991, from Charles River Laboratories, Inc., Raleigh, North Carolina.

Caging Conditions - Upon receipt, the animals were housed two per cage (except as noted in Appendix 16), in stainless-steel, hanging, wire-mesh cages. The animals were randomized following an acclimation period of 11 days, were assigned permanent identification numbers, and were individually housed for the duration of the study.

Feed and Water - Purina[®] Certified Rodent Chow[®] #5002 was available ad libitum during both the acclimation and study periods, unless otherwise noted. The feed was analyzed by the manufacturer for concentrations of specified heavy metals, aflatoxin, chlorinated hydrocarbons, organophosphates, and specified nutrients. Tap water, via an automatic watering system, was available ad libitum during both the acclimation and study periods. The water is retrospectively analyzed for specified pesticides and heavy metals. Results of feed and water analyses are on file at Hazleton Washington, Inc.

The Study Director and/or Sponsor considered the possibility of interfering substances potentially present in animal feed and water, including the test material itself or possible structurally related materials. None of these contaminants were expected to be present in animal feed or water at levels sufficient to interfere with this study.

Environmental Conditions - Temperature and humidity were monitored and recorded daily throughout the acclimation and dosing periods. Temperature and humidity were within protocol-specified ranges ($72 \pm 6^{\circ}\text{F}$ and $50 \pm 20\%$) except as noted in Appendix 16. A 12-hour light/12-hour dark diurnal cycle was maintained except as noted in Appendix 16. The room was ventilated at ten or more room air exchanges per hour.

Justification of Species - The mouse model was selected for safety testing on the basis of accumulated historical data and prior experience with this species. The use of the mouse conforms with the regulatory guidelines for testing in rodents.

METHODS

Group Assignment and Dosage Levels

Animals were initially accepted for potential study use based upon physical body weight, physical observations, auditory and ophthalmology examinations. Animals which exhibited abnormalities in these parameters were eliminated from the randomization pool except as noted in Appendix 16. A total of 310 mice were assigned to study by first eliminating the animals with extreme body weights and then selecting the random assignment which produced homogeneity of both the variance and the means by Bartlett's test (1937) and one-way analysis of variance (ANOVA). At the time of randomization, the weight variation of the animals selected did not exceed ± 2 standard deviations of the mean body weight for each sex, and the mean body weight for each group of each sex was not statistically different. Animals were assigned to groups as follows:

Text Table 1
 Group Assignment

Group	<u>Dosage Level</u>	<u>Concentration^a</u>	<u>Number of Animals</u>		<u>Animal Numbers</u>	
	mg/kg/day	ppm	Male	Female	Male	Female
Main Study						
1	0	0	15	15	37391-37405	37406-37420
2	25	25-100	15	15	37421-37435	37436-37550
3	75	75-300	15	15	37451-37465	37466-37480
4	200	200-800	15	15	37481-37495	37496-37510
5	350	350-1200	15	15	37511-37525	37526-37540
6	750	750-2000	15	15	37541-37555	37556-37570
7	900	900-3000	15	15	37571-37585	37586-37600
Satellite ^b						
8	0	0	20	20	37601-37620	37621-37640
9	25	25-100	10	10	37641-37650	37651-37660
10	350	350-1200	10	10	37661-37670	37671-37680
11	900	900-3000	10	10	37681-37690	37691-37700

^a Approximate concentration.

^b Last ten animals/sex/group were designated for blood collection for hematology and clinical chemistry at each of the specified intervals (Predose, Group 8; Day 45, Groups 8-11).

Dosage levels were selected by the Sponsor based upon previous 28-day studies.

Each animal was uniquely identified by a permanent identification number with an implanted microidentification device. At initiation of dosing, the animals were at least 6 weeks of age with body weights ranging from 22 to 31 grams for the males and 18 to 24 grams for the females.

Those animals not assigned to study groups were removed from the study room.

Compound Formulation and Administration

The test material triclosan was administered in the diet for at least 45 (Satellite Study, Groups 8-11) or 91 (Main Study, Groups 1-7) consecutive days. Control animals (Groups 1 and 8) received only the basal diet, Purina[®] Certified Rodent Chow[®] #5002.

Reserve samples of control and treated diet mixes were taken weekly and will be stored frozen at Hazleton Washington, Inc. until the final report has been issued.

The purity of triclosan was given as 99.7% and no adjustment was made for compound activity. Prior to weighing, the test material was ground into a fine powder with a mortar and pestle. For each dietary level, the test material and basal feed were weighed on an appropriate balance (mg or kg) in series with an Epson computer with printout tape. Each level was prepared in an appropriately sized glass beaker by placing the weighed test material into approximately 200 g of feed and pre-mixing in a Waring blender for approximately 2 minutes to ensure an apparent homogeneous mixture. The pre-mixes were added to approximately 3 kg of additional feed and mixed in a Hobart mixer for approximately 1 minute per kilogram for a minimum of 5 minutes.

Fresh diets were prepared weekly, delivered to the study room and administered the same day as mixed. The test diets were available to the animals 7 days/week (unless otherwise noted) for at least 91 days, and were available until the day prior to necropsy. The control animals were fed Purina[®] Certified Rodent Chow[®] #5002 in the same manner as the test animals.

The test material was administered via the diet because the intended human exposure is by the oral route.

Analysis of Prepared Formulations

Stability and Homogeneity - Prior to the initiation of dosing, samples from the low- and high-dose formulations (100 and 5100 ppm) were analyzed to assess 0-day stability. Also, 10-day room temperature stability and 30-day freezer stability were determined from these dose formulations.

Homogeneity - Evaluation for homogeneity was performed on the low- and high-dose formulations prior to the initiation of dosing. Duplicate samples from the top, middle, and bottom of the formulations were analyzed for the concentration of the test material.

Concentration Analyses - A sample of each dietary formulation was analyzed weekly for the concentration of the test material.

Analytical Method - The stability and routine concentration analyses were performed using a high performance liquid chromatography (HPLC) technique, which is detailed in Analytical Chemistry Method No. 147 (Appendix 1) with any modifications incorporated into Analytical Chemistry Method No. 480 (Appendix 1).

Observations and Records

Mortality and Clinical Observations - The mice were observed for mortality and moribundity twice daily. A careful cageside observation for obvious indications of toxic effects was performed once daily. A thorough physical examination was conducted at each weighing interval.

Body Weight and Food Consumption - Body weights were measured and recorded at randomization, prior to treatment (prior to dosing on Days -7 and 1), weekly thereafter, and prior to necropsy. Food consumption was measured and recorded once weekly starting one week prior to dosing.

Auditory Examinations - The acoustic startle reflex was determined for each animal prior to treatment and during Week 13 (Groups 1-7 only) using a Galton Whistle (set on 10.0).

Ophthalmoscopic Examinations - An indirect ophthalmoscopic examination was performed on each animal prior to treatment and during Week 13 (Groups 1-7 only), using 1% Mydriacyl[®] as the mydriatic agent.

Clinical Pathology

During the predose interval 10 animals/sex/group (Group 8 only), plus an additional 8 males and 7 females (extra animals that did not

qualify during weight randomization^a), and at approximately Day 45 of dosing (10 animals/sex/group, Groups 8-11 only), and at study termination (10 animals/sex/group, Groups 1-7 only), animals were sampled for evaluation of clinical pathology parameters. At the study termination all surviving animals were fasted overnight prior to clinical sampling. Samples for hematology were collected without anesthesia from the orbital sinus. Samples for serum chemistry were obtained via the abdominal vena cava of animals that were anesthetized with an injection of sodium pentobarbital. The following parameters were determined:

Hematology

cell morphology	hematocrit (HCT)
corrected leukocyte count (COR WBC)	hemoglobin (HGB)
erythrocyte count (RBC)	leukocyte count (WBC)
	leukocyte differential
	platelet (PLATELET)

Clinical Chemistry

alanine aminotransferase (ALT) ^a	glucose (GLUCOSE) ^a
albumin (ALBUMIN)	lactate dehydrogenase (LDH)
albumin/globulin ratio (A/G)	total bilirubin (T BILI) ^a
alkaline phosphatase (ALK P)	total cholesterol (T CHOL) ^a
aspartate aminotransferase (AST) ^a	total protein (T PROT)
blood urea nitrogen (BUN) ^a	triglycerides (TRIGLY) ^a
creatinine (CREAT) ^a	globulin (GLOBULIN)
gamma glutamyltransferase (GGT) ^a	

^a Also performed on extra un-assigned animals prior to initiation.

^a These animals were bled due to the incomplete clinical chemistry values obtained from the predose bleed of the satellite animals in Group 8 (low body weight produced insufficient sera for analysis).

Terminal Studies

Sacrifice and Gross Pathology - All animals in Groups 1-7 which were found dead or sacrificed in extremis during the study were subjected to a gross postmortem examination. A gross postmortem examination was performed on animals in Groups 8-11 which were sacrificed at the Day 45 clinical pathology bleeding. All other surviving animals were weighed on the day of scheduled necropsy and were sacrificed by sodium pentobarbital anesthesia (intraperitoneal injection). Necropsies were performed on all animals by appropriately trained personnel using procedures approved by board-certified pathologists. Necropsies included examination of the following:

all orifices	nasal cavity and paranasal
carcass	sinuses
cervical tissues and organs	thoracic, abdominal and pelvic
cranial cavity	cavities and their viscera
external surface of the body	
external surface of the brain (at necropsy); the external surface of the spinal cord and cut surfaces of the brain and spinal cord were examined at the time of tissue trimming, if histopathology was performed.	

Organ Weights - At the scheduled sacrifice the listed organs were weighed after careful dissection and following the trimming of fat and other contiguous tissue:

adrenals (postfixation) ^a	prostate
brain (including brainstem)	spleen
heart	submaxillary salivary glands
kidneys ^a	testes ^a
liver with gallbladder ^b	epididymides ^a
lung	thymus
ovaries (postfixation) ^a	uterus

^a Paired weight.

^b Also taken from animals in Groups 8-11 at the Day 45 sacrifice.

Organ-to-terminal-body-weight and organ-to-brain-weight ratios were calculated.

Tissue Preservation - The following tissues from each animal (Main Study, Groups 1-7) were preserved in 10% neutral-buffered formalin. Additionally, from the animals sacrificed at Day 45 (Satellite Study, Groups 8-11), a section of the left lateral lobe of the liver was taken and preserved in 100% methanol.

adrenals
aorta
sternum with bone marrow
brain with brainstem (medulla/
pons, cerebellar cortex, and
cerebral cortex)
colon, cecum, rectum
duodenum, jejunum, ileum
esophagus
eyes with optic nerves^a
femur with marrow and joint
heart
kidneys
lesions
lacrimal gland (extraorbital)
liver with gallbladder^b
lung
mammary region (females only)
mandibular lymph node^a

mesenteric lymph node^a
ovaries
pancreas
pituitary
prostate
salivary glands (submaxillary)
sciatic nerve
skeletal muscle (thigh)
skin (abdominal muscle)
spinal cord (cervical, lumbar,
thoracic)
spleen
stomach (cardia, fundus, pylorus)
testes with epididymides
thymus
thyroid/parathyroid^a
tongue
trachea
urinary bladder
uterus with vagina and cervix

^a At least one tissue section required.

^b The only organs preserved from animals in Groups 8-11.

Histopathology - All preserved tissues except for those sections preserved in 100% methanol were embedded in paraffin, sectioned, stained with hematoxylin and eosin and examined microscopically as follows:

- a) All gross lesions and tissue masses.
- b) All tissues from animals in Groups 1-7 which died or were sacrificed moribund.
- c) All tissues from all animals in Groups 1 and 7 necropsied at the terminal sacrifice.
- d) Liver from Groups 1-7.
- e) Spleen from Groups 1, and 3-7 ♂; Groups 1, 5-7 ♀
- f) Adrenal cortex from Groups 1-7 ♂ and Group 1, and 3-7 ♀
- g) Glandular stomach from Groups 1, 3-7 ♂; and Groups 1, and 4-7 ♀
- h) Kidney from Groups 1, and 3-7 ♀
- i) Mammary from Groups 1 and 5-7 ♀
- j) Uterus and cervix from Groups 1, and 3-7 ♀

Representative tissues (five/sex/group) were sent to the Sponsor-designated laboratory for cell proliferation assays and were not available for examination by HWA; however, there were adequate numbers of target tissues to assess the treatment-related effects.

Statistical Analyses

Mean absolute body weights (Weeks 6 and 13), mean body weight change (Weeks 0-6 and 0-13), mean absolute food consumption (Weeks 6 and 13), mean total food consumption (Weeks 1-6 and 1-13), clinical pathology data (except cell morphology gradings), and organ weight data of the control group were compared statistically to the data from the same sex of the treated groups. Statistical analyses were performed as diagrammed in Figure 1.

If the variances of the untransformed data were heterogeneous, a series of transformations were performed. When the series of

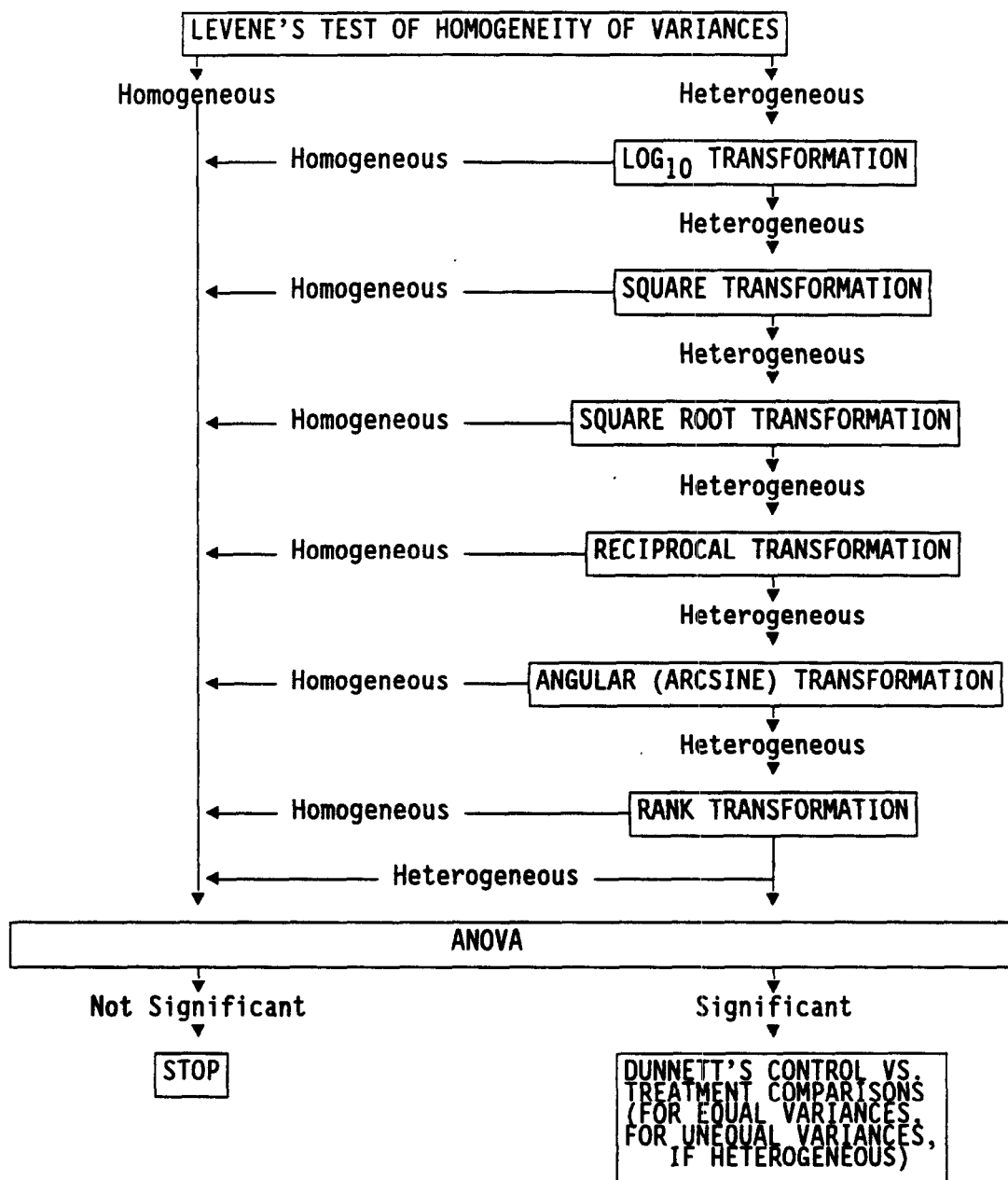
transformations was not successful in achieving variance homogeneity, analyses were performed on rank-transformed data. Group comparisons were routinely performed at the 5% two-tailed probability level.

Trend for hematology (red cell parameter only) and liver weights (absolute, relative to body and relative to brain) was evaluated by the Terpstra-Jonckheere test (monotone response) and simple linear regression (linear response) of both transformed and rank-transformed data. In the case where the Terpstra-Jonckheere test is significant, but none of the linear regressions are, indication is made by noting significant monotone trend ($p \leq 0.05$.) Otherwise, the notation is made as significant trend ($p \leq 0.05$.) Statistical significance is designated throughout the text of this report by the term significant. The data transformations which were used are presented in Appendix 14.

Specimen, Raw Data, and Final Report Storage

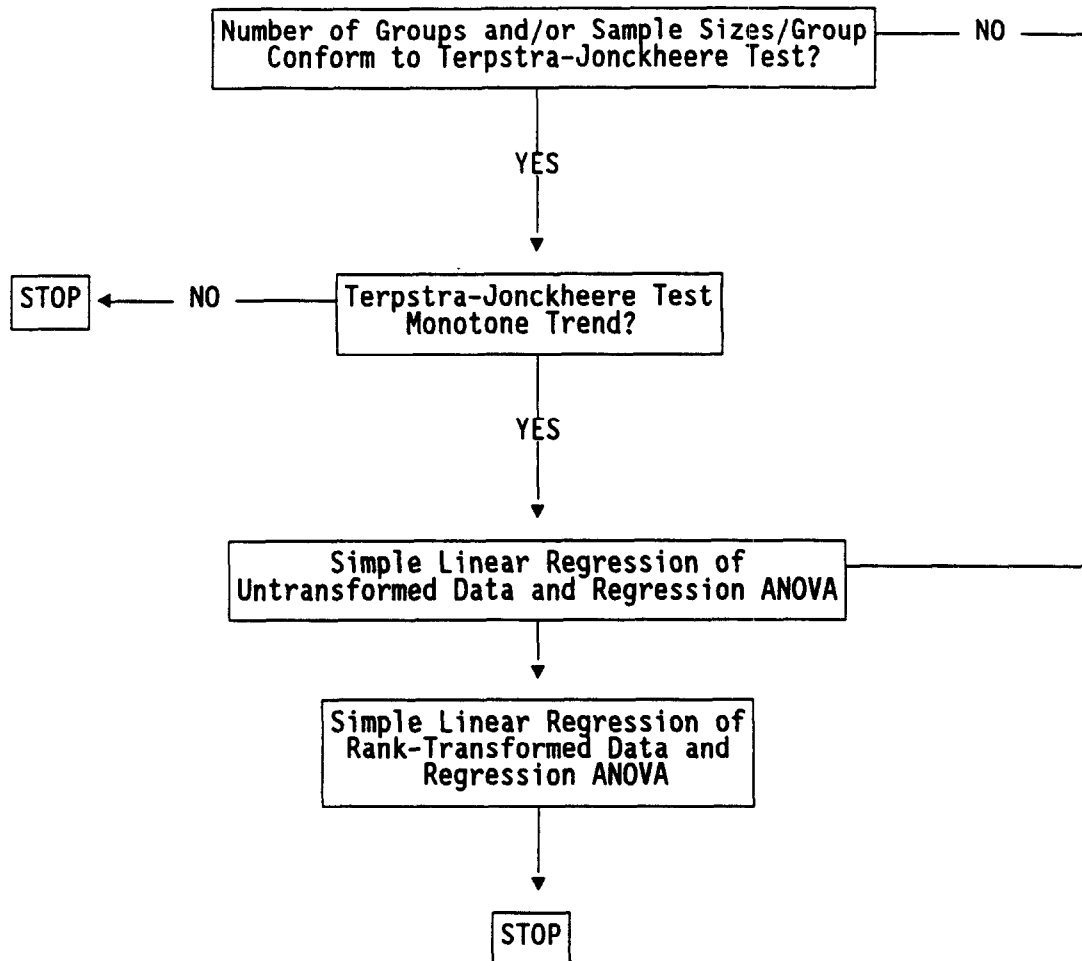
All tissue specimens, blocks and slides, raw data, and the final report will be retained by Hazleton Washington, Inc., in accordance with GLP requirements.

Figure 1
Flowchart of ANOVA and Related Methods



All parametric comparisons take variance homogeneity/heterogeneity into consideration. All transformations indicated in the flowchart are done on untransformed data.

Figure 2
Flowchart of Trend Statistical Methods



RESULTS

Analytical Chemistry

The analytical chemistry results are presented in Table 1. The analytical methodology is presented in Appendix 1.

Homogeneity was determined for triclosan in the basal diet prior to initiation of the study. The test material was stable in the diet under ambient conditions at Days 0 and 10 and when frozen for 30 days.

Weekly analyses indicated dose concentrations of triclosan to be within 10% of target except for the Group 4 males at Week 13. Reserve samples of Groups 4 and 5 males for Week 13 were subsequently analyzed and the target concentrations determined to be within 5% and 3%, respectively. Based upon the analysis of the reserve samples, the concentration of test article administered to Groups 4 and 5 was considered accurate. Additionally, the Study Director requested a concentration analysis for Week 14. This analysis revealed a target concentration of $\pm 10\%$ for all dose concentrations.

In-Life Observations

Mortality and Clinical Observations - The individual animal disposition data are presented in Appendices 2A (Main Study, Groups 1-7) and 2B (Satellite Study, Groups 8-11).

In the satellite study, all animals survived to the scheduled sacrifice at Day 45. In the main study, survival was comparable between the control and treated groups (unscheduled deaths: 2 Group 4 males and 1 Group 4 female, 2 Group 7 males and 1 Group 7 female). The unscheduled deaths were not considered attributable to the administration of the test material.

Summaries of the weekly clinical observations are presented in Tables 2A (Main Study, Groups 1-7) and 2B (Satellite Study, Groups 8-11). The individual data are presented in Appendices 3A (Main Study, Groups 1-7) and 3B (Satellite Study, Groups 8-11).

The clinical signs noted most often in the main study animals were alopecia and sores observed in various body areas and occurred primarily in the males. None of these signs were dose or test material related. Signs also sporadically observed in Group 7 animals included hypoactivity, hunched posture, and pale body. In the satellite study animals, there were very scattered observations of alopecia and sores and one incidence of hunched posture in one Group 11 male.

Summaries of the daily cageside observations are presented in Tables 3A (Main Study, Groups 1-7) and 3B (Satellite Study, Groups 8-11). The individual daily observations are presented in Appendices 4A (Main Study, Groups 1-7) and 4B (Satellite Study, Groups 8-11).

Most notable of the daily observations were hunched posture, hypoactivity, pale body, thin and few feces in various main study animals. Two Group 7 males that exhibited some of these signs were either sacrificed moribund or were found dead. Two other Group 7 animals had recovered from the reported clinical signs and were normal at the scheduled sacrifice. Cageside observations for the satellite study were one instance each of hunched posture and hypoactivity in the Group 11 females.

Body Weights - The mean body weight data are presented in Tables 4A (Main Study, Groups 1-7) and 4B (Satellite Study, Groups 8-11). The mean body weight change data including Weeks 1-6 and 1-13 (Main Study, Groups 1-7) and Weeks 1-6 (Satellite Study, Groups 8-11) are presented in Tables 5A and 5B, respectively. The individual body weights are presented in Appendices 5A (Main Study, Groups 1-7), and 5B (Satellite Study, Groups 8-11).

The mean absolute body weights were significantly decreased from the controls in the Group 7 females at Weeks 7 and 14. The mean body weight changes were significantly different from the controls at Weeks 1-6 (decreased Group 11 males; increased Group 5 animals), and Weeks 1-13 (decreased Group 6 males; increased in Groups 4 and 5 females and decreased in Group 7 females).

Food Consumption - The mean food and mean total food consumption data are presented in Tables 6A (Main Study, Groups 1-7) and 6B (Satellite Study, Groups 8-11). The individual data are presented in Appendices 6A (Main Study, Groups 1-7) and 6B (Satellite Study, Groups 8-11).

In the Main Study, Groups 1-7, the mean absolute food consumption was significantly different from the controls at Weeks 7 (decreased in Groups 3 and 6 males and in Group 7 males and females) and 13 (increased in Group 7 males). The mean total food consumption was significantly decreased in the Group 6 and 7 females during Weeks 1-13.

In the Satellite Study, Groups 8-11, the mean absolute food consumption was increased significantly in Group 10 males at Week 6 and mean total food consumption was significantly decreased in Group 11 females during Weeks 1-6.

Compound Consumption - The mean compound consumption values are presented in Tables 7A (Main Study, Groups 1-7) and 7B (Satellite Study, Groups 8-11). The individual data are presented in Appendices 7A (Main Study, Groups 1-7) and 7B (Satellite Study, Groups 8-11).

The mean compound consumption for the animals in the main study was within 10% of target levels with the exception of: 1) The Main Study, Group 7 males at Weeks 8 (113% of target) and 13 (123% of target) 2) The Main Study females of Group 4 at Week 10 (88% of target), Group 6 at Week 11 (85% of target), and Group 7 at Weeks 8 (111% of target) and 12 (113% of target) and 3) The Satellite Study, Group 11 females (88% of target) at Week 2.

Ophthalmology - The individual ophthalmology findings (Main Study, Groups 1-7) are presented in Appendix 10. The findings are further discussed in the examining veterinarian's Ophthalmology Report.

Animals which exhibited ocular abnormalities at the examination prior to study initiation were eliminated from randomization. The Week 13 examination revealed only sporadic corneal dystrophy observations and no lesions that were considered to be the result of the administration of the test material.

Auditory/Physical Examination - The individual auditory examination results (Main Study, Groups 1-7) are presented in Appendix 8. The individual physical examination (Main Study, Groups 1-7) results are presented in Appendix 9.

Animals which exhibited auditory or physical abnormalities at the examination prior to study initiation were eliminated from randomization, except as noted in Appendix 16. The Week 13 physical examination revealed primarily signs of alopecia and sores (generally in the males in Groups 1-5 and 7) and no abnormalities which were considered to be the result of administration of the test material. A summary of the negative auditory responses is presented by Group in Text Table 2:

Text Table 2
Auditory Response

SEX	Group 1	Group 2	Group 3	Group 4	Group 5	Group 6	Group 7
FEMALES	2/15	4/14	1/15	3/15	1/15	3/15	5/14
MALES	0/15	2/15	2/15	2/13	1/15	2/15	7/13

Clinical Pathology

The mean hematology values are presented in Tables 8A (Main Study, Groups 1-7) and 8B (Satellite Study, Groups 8-11) and the individual data are presented in Appendices 11A (Main Study, Groups 1-7) and 11B (Satellite Study, Groups 8-11). The mean serum chemistry values are presented in Tables 9A (Main Study, Groups 1-7), 9B (Satellite Study, Groups 8-11) and 9C (Extra Animals) and the individual data are presented in Appendices 12A (Main Study, Groups 1-7), 12B (Satellite Study, Groups 8-11) and 12C (Extra animals - No group assignment). These findings are further discussed in the Clinical Pathology Report.

Hematology - Main Study (Week 14) - There were dose-related decreases in mean values for erythrocyte count and hemoglobin in Group 2 males and Group 3-7 animals and hematocrit in Group 2 and 3 males and Group 5-7 animals. The mean values for segmented neutrophil count were significantly elevated for Group 6 and 7 females, but were not of a magnitude great enough to result in significant elevations in leukocyte counts. The incidence of polychromasia was slightly increased for Group 6 and 7 animals.

Hematology - Satellite Study (Week 7) - The mean values for erythrocyte count, hemoglobin (Group 9 females also), and hematocrit decreased significantly and in a dose-related manner for Group 10 and 11 animals. Mean values for total and corrected leukocyte counts increased due to significant elevations in segmented neutrophil and lymphocyte counts for Group 11 females. The cellular morphology was comparable between control and treated groups.

Serum Biochemistry - Main Study (Week 14) - Significant findings are presented in Text Table 3.

Text Table 3
 Week 14

Sex/Group	ALT	ALK P	T CHOL	GGT
M/2			↓	
F/2		↑	↓	
M/3			↓	
F/3		↑	↓	
M/4		↑	↓	
F/4		↑	↓	
M/5	↑	↑	↓	
F/5		↑	↓	
M/6	↑	↑	↓	(↑)
F/6	↑	↑	↓	(↑)
M/7	↑	↑	↓	(↑)
F/7	↑	↑	↓	(↑)

↑/↓ indicate significantly increased/decreased mean values compared to control
 () indicate a nonsignificant mean value that is biologically meaningful

Serum Biochemistry - Satellite Study (Week 7) - Statistically significant findings that are considered treatment related and evidence for hepatic involvement are listed in Text Table 4.

 Text Table 4
 Week 7

Sex/Group	ALT	ALK P	T CHOL	GGT
M/9			↓	
F/9		↑		
M/10	↑	↑	↓	
F/10	↑	(↑)	↓	
M/11	↑	↑	↓	↑
F/11	↑	↑	↓	(↑)

↑/↓ indicate significantly increased/decreased mean values compared to control
 () indicate a nonsignificant mean value that is biologically meaningful

Terminal Studies

Gross Pathology - The gross pathology findings are summarized in Tables 10A [Unscheduled Deaths - (Main Study, Groups 1-7)], 10B [Interim Sacrifice - (Satellite Study, Groups 8-11)] and 10C [Terminal Sacrifice - (Main Study, Groups 1-7)] and the individual data are presented in Appendices 13A - Unscheduled Deaths (Main Study, Groups 1-7), 13B - Terminal Sacrifice (Main Study, Groups 1-7) and 13C - Terminal Sacrifice (Satellite Study, Groups 8-11)

The only notable gross pathology findings in the study (either in the unscheduled deaths/terminal sacrifice of the main study animals or in the interim sacrifice of the satellite animals) were the occurrence of dose related lesions in the liver. Hepatic findings included pale areas, enlarged, dark, or thickened lobes, and masses were observed in both sexes.

Organ Weights - The mean absolute organ weights are presented in Tables 11A and Text Table 5 (Main Study, Groups 1-7) and 11B (Satellite Study, Groups 8-11) and Text Table 8. The organ-to-terminal-body-weight ratio data are presented in Table 12A and Text Table 6 (Main Study, Groups 1-7) and in Table 12B and Text Table 9 (Satellite Study, Groups 8-11). The organ-to-brain weight ratio data are presented in Table 13 and in Text Table 7 (Main Study, Groups 1-7). The individual organ weight data are presented in Appendices 13A - Unscheduled Deaths (Main Study, Groups 1-7), 13B - Terminal Sacrifice (Main Study, Groups 1-7), and 13C - Terminal Sacrifice (Satellite Study, Groups 8-11).

Text Table 5
 Absolute Organ Weight Means
 (Main Study, Groups 1-7)

ORGAN	Group 2	Group 3	Group 4	Group 5	Group 6	Group 7
TERMINAL BODY WT.			↑M	↑M		↓F
SALIVARY GL					↓M/F	↓M/F
LUNG						↓F
UTERUS					↓F	↓F
BRAIN w/STEM					↓F	↓F
HEART					↓M	
KIDNEY				↓M	↓M	↓M/F
LIVER w/ GALLBLADDER		↑M/F	↑M/F	↑M/F	↑M/F	↑M/F
ADRENAL					↑M	↑M
OVARY						↓F

KEY: ↓ = Significantly decreased, $p \leq 0.05$.
 ↑ = Significantly increased, $p \leq 0.05$.

Text Table 6
 Organ-to-Terminal Body Weight Ratio Means
 (Main Study, Groups 1-7)

ORGAN	Group 2	Group 3	Group 4	Group 5	Group 6	Group 7
SALIVARY GL				↓M	↓M/F	↓M/F
UTERUS					↓F	↓F
SPLEEN					↑M	
LIVER w/ GALLBLADDER		↑M/F	↑M/F	↑M/F	↑M/F	↑M/F
KIDNEY		↓M		↓M	↓M	↓M
ADRENAL					↑M	↑M

KEY: ↓ = Significantly decreased, $p \leq 0.05$.
 ↑ = Significantly increased, $p \leq 0.05$.

Text Table 7
 Organ-to-Brain Weight Ratio Means
 (Main Study, Groups 1-7)

ORGAN	Group 2	Group 3	Group 4	Group 5	Group 6	Group 7
SALIVARY GL					↓M	↓M
UTERUS					↓F	↓F
KIDNEY				↓M	↓M	↓M
LIVER w GALLBLADDER		↑M/F	↑M/F	↑M/F	↑M/F	↑M/F
HEART					↓M	
ADRENAL	↓M				↑M	↑M

KEY: ↓ = Significantly decreased, $p \leq 0.05$.
 ↑ = Significantly increased, $p \leq 0.05$.

Text Table 8
 Absolute Organ Weight Means
 (Satellite Study, Groups 8-11)

ORGAN	Group 9	Group 10	Group 11
TERMINAL BODY WT			↓M
LIVER w GALLBLADDER		↑M/F	↑M/F

KEY: ↓ = Significantly decreased, $p \leq 0.05$.
 ↑ = Significantly increased, $p \leq 0.05$.

Text Table 9
 Organ-to-Terminal Body Weight Ratio Means
 (Satellite Study, Groups 8-11)

ORGAN	Group 9	Group 10	Group 11
LIVER w GALLBLADDER		↑M/F	↑M/F

KEY: ↓ = Significantly decreased, $p \leq 0.05$.
 ↑ = Significantly increased, $p \leq 0.05$.

Histopathology - The microscopic findings are summarized in
 Tables 14A - Unscheduled Deaths (Main Study, Groups 1-7) and in 14B -

Terminal Sacrifice (Main Study, Groups 1-7). The individual histopathology findings are presented in Appendices 13A - Unscheduled Deaths (Main Study, Groups 1-7) and in 13B - Terminal Sacrifice (Main Study, Groups 1-7). The findings are further discussed in the Pathology Report.

Histomorphologic changes which could be related to the exposure to the test material were observed in the liver, spleen, adrenal cortex, glandular stomach, female kidney, female mammary gland, uterus, and cervix of mice that received 900 mg/kg/day triclosan as a dietary mixture for up to 14 weeks. Triclosan-related changes in the liver were also observed at the 75 (males only), 200, 350, and 750 mg/kg/day dose levels. Similar microscopic changes were observed in the liver of some of the females at 25 and 75 mg/kg/day triclosan; however, neither the incidences nor the average severities were sufficiently increased to definitively ascribe the changes to test material administration. Increased extramedullary hematopoiesis was also observed in the spleens of 750 and 900 mg/kg/day mice of both sexes as well as some marginal increases at the 200 mg/kg/day level and higher of males only. Decreases in incidence and severity of pigment accumulation were noted in the adrenal cortices of males at the 75 mg/kg/day level and higher and females at the 200 mg/kg/day level and higher. Hyperplasia of the glandular stomach was noted in males at the 200 mg/kg/day and higher dose levels and in females at 350 mg/kg/day and higher. Inflammation in the kidneys (females only) of the 200 mg/kg/day dose level and higher and tubule regeneration in highest dose (900 mg/kg/day) females only were also attributed to exposure to the test article. In the female reproductive organs, mammary gland (750 and 900 mg/kg/day), uterus (350 mg/kg/day and higher) and cervix (900 mg/kg/day), histomorphologic alterations observed were associated with delayed onset of maturity. The no-observable effect levels for these microscopic changes was 75 mg/kg/day in males and 200 mg/kg/day in females.

DISCUSSION AND CONCLUSION

The toxicity of triclosan when fed daily in the diet to male and female CD-1[®] mice for at least 7 or 13 weeks was evaluated. The test material was added to the diet to provide doses of 0, 25, 75, 200, 350, 750, and 900 mg/kg for Groups 1-7 and 0, 25, 350, and 900 mg/kg for Groups 8-11. The animals were provided ad libitum access to the dosed diet until the day prior to sacrifice. Criteria evaluated for triclosan induced effects included survival, clinical observations, body weight, food consumption, auditory and ophthalmoscopic examinations, organ weights, and clinical (hematology and clinical chemistry), gross, and microscopic pathology.

In-life clinical observations which may be related to the test material administration included hunched posture, hypoactivity, pale body, and few feces. These observations were observed predominantly in the high-dose (900 mg/kg) animals although only a small proportion of animals exhibited these signs. A significant decrease in body weight gain was observed in the 900 mg/kg females (Group 7) at the 1-6 week and 1-13 week intervals. However, significant increases in liver/gallbladder weight may have obscured effects on body weight. A concurrent significant decrease in food consumption (Weeks 1-13) was also observed in this group. At the terminal sacrifice an increase in negative responses to auditory stimuli was observed in the 900 mg/kg males. The significance of this finding relative to the test material treatment is unclear since a similar finding was not observed in the 900 mg/kg females. The ophthalmology findings were within those expected for mice of this age and strain.

Clinical pathology (hematology and clinical chemistry) studies at predose (Week -1), Week 7, and Week 14, were performed to assess the temporally-related health status of the animals. A significant dose-related trend toward decreased erythrocyte, hemoglobin, and hematocrit mean values was evident in both the males and females in Groups 1-7 (0-900 mg/kg). All groups were not, however, significantly different from

the respective controls. Similar trends were observed in the satellite animals (Groups 8-11; 0, 25, 350, and 900 mg/kg). Biochemical findings from the blood serum which were considered to be treatment related and biologically significant were:

- 1) Increased alanine aminotransferase in the Group 5-7 (350, 750, and 900 mg/kg) and Group 10 and 11 (350 and 900 mg/kg) males and Group 6 and 7 (750 and 900 mg/kg) and Group 10 and 11 (350 and 900 mg/kg) females.
- 2) Increased alkaline phosphatase in the Group 4-7 (200, 350, 750, and 900 mg/kg) and Group 10 and 11 (350 and 900 mg/kg) males.
- 3) Increased alkaline phosphatase in the Groups 2-7 (25, 75, 200, 350, 750 and 900 mg/kg) and in Group 9 and 11 females (25 and 900 mg/kg). A nonsignificant increase in alkaline phosphatase was evident in the Group 10 females (350 mg/kg).
- 4) Indication of decreased total cholesterol in Groups 2-7 (25, 75, 200, 350, 750, and 900 mg/kg) and in Groups 9 (males only), 10 and 11 (250, 350 and 900 mg/kg), although there were limited numbers (as few as two and no more than seven) of samples analyzed in each group.
- 5) Non-significant increases in gamma glutamyltransferase (GGT) in the Group 6 and 7 animals (750 and 900 mg/kg) and in Group 11 females (900 mg/kg). GGT was significantly increased in the Group 11 males (900 mg/kg).

Postmortem gross examinations of protocol-specified tissues were performed to evaluate the potential toxicity of triclosan as the result of the dietary exposure. Dark enlarged livers were observed in a dose-related manner in the 75-900 mg/kg dose levels at both the Week 7 and Week 14 sacrifices. Liver lesions were also observed grossly in 4 of 5 unscheduled death animals (from Groups 1-7) which were examined prior to the Week 7 sacrifices (Days 9, 16, 33 and 38). The liver weight was also significantly elevated in a dose-related manner (absolute weight, liver-to-terminal body weight, or liver-to-brain weight) in the 75-900 mg/kg dose groups of both sexes. A significant trend in liver weight increase was also observed.

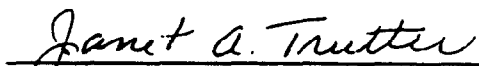
The histopathological evaluation of the tissues in the Group 1 and 7 animals as well as those animals in the other groups in which gross lesions had been identified resulted in the identification of the liver as potential target tissue for further analysis. The liver was evaluated histomorphologically from all dose groups. Other tissues which were examined until a no-effect level was established were spleen (males and females), adrenal cortex (males and females), glandular stomach (males and females), kidney (females), mammary gland (females), and uterus and cervix (females). Histomorphologic findings in the liver were observed at the 75 (males only), 200, 350, 750, and 900 mg/kg dose levels and generally correlated with the clinical and gross pathology findings. Liver findings included centrilobular hepatocellular hypertrophy, vacuolization, pigment accumulations, necrosis, and/or inflammation. The severity of the various hepatic findings generally increased as a function of the dose. Increased extramedullary hematopoiesis was observed in the spleens of male mice receiving the 200 mg/kg/day dose level and higher and the females of the 750 and 900 mg/kg/day groups. This response was considered in part due to the significantly decreased erythrocyte count, hemoglobin, and hematocrit in these animals.

Histomorphologic findings included decreased incidence and severity of pigment near the juncture of the adrenal medulla in males of the 75 mg/kg/day dose and higher and in females of the 200 mg/kg/day dose and higher. Slight to minimal cellular hyperplasia of the zona fasciculata was observed in the males and corresponded to a significant increase in adrenal weight. A significant effect on adrenal weight was also observed in the 750 mg/kg males. Subcapsular hyperplasia and vacuolization of the X-zone in the 200 mg/kg/day and higher male dose groups and the 750 and 900 mg/kg females was less than that observed in the sex-matched controls. Alterations of the glandular stomach were noted in male mice at 200 mg/kg/day and in female mice at 350 mg/kg/day. Marginal increases in inflammation and tubular regeneration were observed in the high-dose females along with a significant decrease in the absolute

kidney weight. A significant dose-related trend in decreased kidney weight (absolute and relative to body) was observed in the males and females of the Main Study, without any corresponding histomorphologic findings.

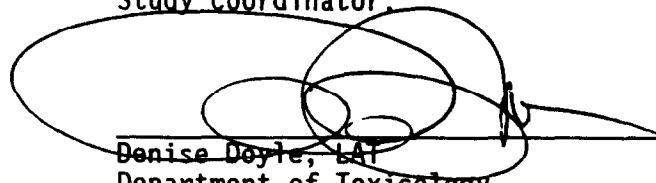
In conclusion, administration of triclosan in the diet for at least 13 weeks was associated with a significant trend toward increased liver weight in both sexes in the absence of mortality. In addition, dose-related and significant depressions in total cholesterol (an indicator of altered hepatic function) were observed at all dose levels (25-900 mg/kg/day). Significant toxicity related to the administration of triclosan was manifested in both sexes at the 900 mg/kg/day dose level as evidenced by the organ weight changes and the clinical and histomorphologic pathology findings. The lowest observable effect level for histomorphologic alterations was 75 mg/kg/day in males and 200 mg/kg/day in females. Based upon the dose-related trends in several of the hematology parameters (erythrocyte count, hemoglobin, and hematocrit), the significant trend for increased liver weight, and the significant depression in total cholesterol at 25 mg/kg/day (Week 7 males only; Week 14 both sexes), a no adverse effect level cannot be definitively established from the dose levels administered in this study.

Study Director:


Janet A. Trutter M.S., D.A.B.T.
Department of Toxicology

5/10/93
Date

Study Coordinator:

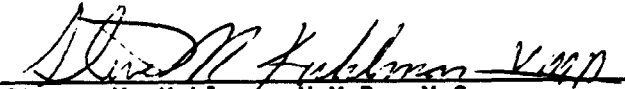

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Department of Toxicology

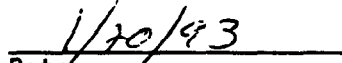
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OPHTHALMOLOGY REPORT

The animals observed prior to test material administration that displayed ophthalmoscopic lesions were rejected from study. At the termination of this study, there did not appear to be any ophthalmoscopic abnormalities related to the compound or dose level. The ophthalmoscopic observations noted are considered to be incidental findings.

Veterinarian:


Steven M. Kuhlman, V.M.D., M.S.
Department of Laboratory Animal Medicine


Date 1/20/93

CLINICAL PATHOLOGY REPORT

Summary

The test material, triclosan, was administered in the diet to mice at dose levels of 0, 25, 75, 200, 350, 750, and 900 mg/kg/day (Groups 1-7, respectively) and at dose levels of 0, 25, 350, and 900 mg/kg/day (satellite Groups 8-11, respectively). Blood was collected from Group 8 at Week -1, Groups 8-11 at Week 7, and Groups 1-7 at Week 14 for hematologic and biochemical evaluation. Prior to initiation, additional blood was collected from extra animals for several biochemical tests due to insufficient volumes of sera obtained from animals in Group 8. Treatment-related changes observed in the clinical pathology data included decreased red cell mass and elevated hepatic enzyme activity of animals treated with 350 mg/kg/day or greater.

Results

Hematology - Main Study (Week 14) - There were dose-related decreases in mean values for erythrocyte count and hemoglobin in Group 2 males and Group 3-7 animals and hematocrit in Group 2 and 3 males and Group 5-7 animals. The mean values for segmented neutrophil count were significantly elevated for Group 6 and 7 females, but were not of a magnitude great enough to result in significant elevations in leukocyte counts. The incidence of polychromasia was slightly increased for Group 6 and 7 animals.

Hematology - Satellite Study (Week 7) - The mean values for erythrocyte count, hemoglobin (Group 9 females also), and hematocrit decreased significantly and in a dose-related manner for Group 10 and 11 animals. Mean values for total and corrected leukocyte counts increased due to significant elevations in segmented neutrophil and lymphocyte counts for Group 11 females. The cellular morphology was comparable between control and treated groups.



Serum Biochemistry - Main Study (Week 14) - The incidence of insufficient-volume (quantity not sufficient [QNS]) samples was a factor for several analytes, including glucose, cholesterol, triglycerides, total protein, albumin, globulin, and albumin/globulin ratio, and most likely affected the statistical significance of these parameters to various degrees. Significant changes in the biochemistry data from the main study that are judged to be treatment-related effects are illustrated in Text Table 1. The mean values for gamma glutamyltransferase activity were elevated for Group 6 and 7 animals, but were not statistically significant. The mean values for aspartate aminotransferase activity were increased for Group 5 and 7 males. Although tissue origin of this enzyme is not liver-specific, its activity frequently parallels that of liver-specific enzymes. The aforementioned changes correspond to the histologic evidence of hepatocellular injury and cholestasis. In contrast to the suspected bile pigment observed microscopically, the mean values for total bilirubin concentration were significantly, but slightly, decreased for Group 6 males. It is not clear why the total bilirubin concentration was not elevated in light of the histologic findings.

The following statistically significant findings in the biochemical data are considered incidental to the administration of the test material: The urea nitrogen concentration was increased for Group 7 females. Creatinine concentration, rather than increasing as the urea nitrogen concentration, decreased significantly for Group 4, 6, and 7 males. The mean values for globulin concentration were significantly decreased for Group 2-7 males, with no changes observed for total protein or albumin concentrations or albumin/globulin ratios. The decrease in globulin concentration, although mild, appears to be dose related; the mechanism of this decrease is not readily apparent. Mean values for glucose concentration were significantly decreased for Group 6 and 7 males.

Text Table 1
 Week 14

Sex/Group	ALT	ALK P	T CHOL	GGT
M/2			↓	
F/2		↑	↓	
M/3			↓	
F/3		↑	↓	
M/4		↑	↓	
F/4		↑	↓	
M/5	↑	↑	↓	
F/5		↑	↓	
M/6	↑	↑	↓	(↑)
F/6	↑	↑	↓	(↑)
M/7	↑	↑	↓	(↑)
F/7	↑	↑	↓	(↑)

↑/↓ indicate significantly increased/decreased mean values compared to control
 () indicate a nonsignificant mean value that is biologically meaningful

Serum Biochemistry - Satellite Study (Week 7) - Statistically significant findings that are considered treatment related and evidence for hepatic involvement are listed in Text Table 2. These significant findings in the biochemical data were considered incidental to the administration of the test material. The mean value for total bilirubin concentration was significantly decreased for Group 11 males. The mean value for urea nitrogen concentration was increased for Group 11 males. The total protein concentration was significantly decreased due to a significant decrease in globulin concentration for Group 10 males without concurrent changes in the albumin concentration or albumin/globulin ratio. The mean value for globulin concentration was significantly decreased for Group 11 males, which resulted in a significant increase in the albumin/globulin ratio but not a significant decrease in total protein

concentration. The mean value for glucose concentration was significantly decreased for Group 11 males.

Text Table 2
Week 7

Sex/Group	ALT	ALK P	T CHOL	GGT
M/9			↓	
F/9		↑		
M/10	↑	↑	↓	
F/10	↑	(↑)	↓	
M/11	↑	↑	↓	↑
F/11	↑	↑	↓	(↑)

↑/↓ indicate significantly increased/decreased mean values compared to control
 () indicate a nonsignificant mean value that is biologically meaningful

Clinical Pathologist:

Renée C. Pearson
 Renée C. Pearson, M.S., D.V.M.
 Diplomate American College of Veterinary
 Pathologists
 Department of Toxicology

Jan. 20, 1993
 Date

PATHOLOGY REPORT

Design Summary

One hundred five CD-1[®] mice of each sex were divided into seven groups and dosed with triclosan as follows:

Group	Number of Mice		Dose Level mg/kg/day
	Males	Females	
1	15	15	0
2	15	15	25
3	15	15	75
4	15	15	200
5	15	15	350
6	15	15	750
7	15	15	900

At sacrifice or unscheduled death, each animal was subjected to a complete necropsy and representative samples of protocol-designated tissues were preserved. A broad spectrum of tissues was examined from all 0 and 900 mg/kg/day animals and from all animals that died or were sacrificed before scheduled study termination. Liver was evaluated for all animals from all groups. Special techniques consisting of PAS, Pearls' Iron, Hall's bile, AFIP method for lipofuscin, and Fontana-Masson stains were used on selected liver sections to define the nature of the observed pigment. Target tissues identified from evaluation of tissues from 900 mg/kg/day animals were evaluated at progressively lower dose levels until a no-effect level was identified. Tissues representing macroscopic changes were examined for all animals.

An additional 50 CD-1[®] mice of each sex were divided into 4 groups and used for collateral studies. These mice were necropsied at death or sacrifice; however, tissues were not examined microscopically.

Results

Test-compound-related changes were observed in the liver, spleen, adrenal cortex, glandular stomach, female kidney, female mammary gland, uterus, and cervix of CD-1[®] mice that received 900 mg/kg/day triclosan as a dietary mixture for up to 14 weeks. Test-compound-related liver changes were observed at the 75 (males only), 200, 350, 750, or 900 mg/kg/day levels. Similar microscopic changes were observed in some livers at 25 and 75 (females) mg/kg/day triclosan; however, neither the incidences nor the average severities were sufficiently increased to definitively ascribe them to test-compound administration. In the spleen, adrenal cortex, glandular stomach, female kidney, female mammary gland, uterus, and cervix, test-compound-related microscopic changes were observed at 900 mg/kg/day triclosan. None of these effects were observed below 75 mg/kg/day in males or 200 mg/kg/day in females.

In the liver, centrilobular hepatocellular hypertrophy, vacuolization, pigment accumulations, necrosis, and/or inflammation were observed in a dose-related fashion from 75 to 900 mg/kg/day triclosan in males and from 200 to 900 mg/kg/day in females (see Text Table 1). In the more severe cases of hepatocellular hypertrophy, hepatocytes were individualized, although the overall hepatic architecture was still intact. Vacuolization varied in type and location from animal to animal. Generally, in the lower-dose groups, a less-severe vacuolization presented as fine cytoplasmic vacuoles in individual hepatocytes; while in the higher-dose groups, a more-severe vacuolization presented as single large cytoplasmic vacuoles in individual hepatocytes. Also, the pattern of vacuolization in the lower-dose groups was generally centrilobular, although an occasional periportal pattern was observed; while in the higher-dose groups, a random or midzonal pattern was generally observed. Pigment accumulations were considered to represent either bile stasis (bile pigment) or a combination of phagocytosed bile and cellular remnants resulting from hepatocellular necrosis (Kupffer cell/macrophage pigment). Reactions of these pigments using special staining techniques were

consistent with iron containing pigment, lipofuscin, and bile. Necrosis, whether involving individual cells or discrete foci of multiple cells, was more common and severe in the higher-dose groups. It was accompanied by collateral changes, such as the described pigment accumulations and inflammation. A number of macroscopic changes generally corresponded to one or more microscopic changes: enlarged liver to hepatocellular hypertrophy, dark liver to various pigment accumulations, and pale areas to foci of vacuolization. Liver weights (absolute, relative to brain, and relative to terminal body weight) were statistically different from sex-matched controls and increased in a dose-related fashion from 75 to 900 mg/kg/day. As described in detail in the Clinical Pathology Report, alterations in alanine aminotransferase, alkaline phosphatase, gamma glutamyltransferase, and total cholesterol, all evidence of hepatocellular injury, were observed at various time points at various levels of triclosan administration; however, total bilirubin concentrations did not reflect the bile pigment (bile stasis) observed microscopically. Similar microscopic changes were observed in some 25 and 75 (females) mg/kg/day livers; however, neither the incidences nor the average severities were sufficiently increased to definitively ascribe them to test-compound administration.

Text Table 1
Liver Changes With Average Severity^a in Affected Animals

Group	1	3	4	5	6	7	1	4	5	6	7
Sex	Male						Female				
Number Examined	15	15	14	15	15	15	15	15	15	14	15
Hypertrophy, centrolobular Severity	3 1.3	12 1.4	13 2.0	15 2.5	15 3.4	15 3.7	0 -	15 1.3	14 2.1	14 2.0	15 3.0
Vacuolization Severity	0 -	7 1.3	11 1.7	14 1.7	13 1.5	13 1.1	0 -	8 2.0	7 2.3	13 1.2	14 1.5
Pigment, bile Severity	0 -	1 1.0	7 1.0	12 1.0	15 1.4	13 1.8	0 -	1 1.0	7 1.0	14 1.0	14 1.1
Pigment, Kupffer cell/ macrophage Severity	0 -	5 1.0	13 1.2	15 1.1	15 1.3	13 1.8	2 1.0	8 1.3	14 1.3	14 1.7	15 1.2
Pigment, hepatocyte Severity	0 -	0 -	12 1.5	14 1.2	15 1.8	13 1.8	0 -	12 1.1	14 1.3	14 2.1	13 1.9
Necrosis Severity	0 -	1 1.0	5 1.4	10 1.7	7 2.0	8 3.0	1 1.0	3 1.0	5 1.4	3 2.7	7 1.9
Necrosis, individual cell Severity	0 -	4 1.0	12 1.3	14 1.3	15 1.7	15 1.7	0 -	8 1.0	11 1.0	14 1.2	13 1.4
Inflammation, chronic/chronic active Severity	1 1.0	5 1.0	13 1.2	14 1.5	12 1.3	9 2.2	7 1.0	10 1.1	12 1.3	11 1.4	7 1.6
Bile duct, inflammation, chronic Severity	0 -	0 -	2 1.0	10 1.0	8 1.6	6 1.2	2 1.0	2 1.0	4 1.0	12 1.1	10 1.2

^a1 = minimal, 2 = slight, 3 = moderate, 4 = moderately severe, and 5 = severe.

Note: Average severity based on number of livers in which change was observed, not number of livers examined.

An increased incidence and/or severity of splenic extramedullary hematopoiesis was observed in 750 and 900 mg/kg/day mice of both sexes. At 200 and 350 mg/kg/day, a marginal increase in splenic extramedullary hematopoiesis was observed in males. This was considered part of the response to decreased erythrocyte count, hemoglobin, and hematocrit, as

described in the Clinical Pathology Report. There were no corresponding macroscopic or organ weight changes.

Several changes were observed in the adrenal cortex. In both sexes, there was a decreased incidence and severity of pigment accumulation near the juncture with the adrenal medulla. This change was evident at dose levels of 75 mg/kg/day and higher in males and 200 mg/kg/day and higher in females. This pigment represents the accumulation of lipofuscin (wear and tear) pigment and is a normal age-related change. In males, there was a slight to minimal hypertrophy of the zona fasciculata at dose levels of 350 mg/kg/day and higher. Similar hypertrophy was also observed in two 200 mg/kg/day males. This corresponded to an increase in the total number of cells (cellular hyperplasia) rather than to an increase in the size of individual cells (cellular hypertrophy) in this zone. A similar change was not observed in females. Adrenal weights (absolute, relative to brain, and relative to terminal body weight) in the 750 and 900 mg/kg/day groups were statistically different from sex-matched controls in males, but not females. In females, there was a decreased incidence of subcapsular cell hyperplasia in both the 750 and 900 mg/kg/day groups and decreased vacuolization of the X-zone at 200 mg/kg/day and higher when compared to sex-matched controls. As with the pigment accumulation and in contrast to the findings observed in this study, subcapsular hyperplasia and vacuolization of the X-zone normally increase with age. There were no macroscopic changes observed in the adrenal of any animal.

Hyperplasia, cystic or noncystic, of the glandular stomach was observed in male mice at 200 mg/kg/day and higher and in female mice at 350 mg/kg/day and higher. Macroscopic observations of a thickened mucosa and/or dark area were frequently made at 900 mg/kg/day.

In the kidney of female mice, increased incidences of inflammation (chronic and/or subacute; 200 mg/kg/day and higher) and tubular regeneration (900 mg/kg/day) were observed. Urea nitrogen concentration was increased at 900 mg/kg/day at Week 14; however,

creatinine concentration was decreased. These differences were not observed in 900 mg/kg/day males. Statistically decreased absolute kidney weight, but not relative to brain or relative to terminal body weight, was noted in 900 mg/kg/day females. Statistically decreased male kidney weights (absolute, relative to brain, and relative to terminal body weight) were observed in the 900 mg/kg/day group and in several lower-dose groups. The elevation in urea nitrogen concentration in 900 mg/kg/day females was considered related to the marginal tissue damage evidenced by the microscopic changes noted; no correlation between changes in morphology and either the decreased creatinine concentration or decreased organ weights could be made.

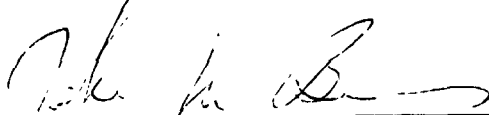
Changes observed in the female mammary gland (epithelial hypoplasia and cystic dilatation; 750 and 900 mg/kg/day), uterus (hypoplasia; 350 mg/kg/day and higher), and cervix (hypoplasia; 900 mg/kg/day) were considered to represent a delay in onset of maturation rather than a direct effect of triclosan. No corresponding macroscopic changes were observed; however, uterine weights (absolute, relative to brain, and relative to terminal body weight) in the 750 and 900 mg/kg/day groups were statistically different (lower) from sex-matched controls. Delayed maturation is a normal biological response in animals undergoing challenges unrelated to the reproductive system.

Five animals died before scheduled terminal sacrifice. An underlying cause of death or morbidity could not be determined for any of them.

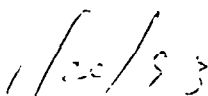
No neoplastic changes were observed.

Miscellaneous microscopic changes observed in animals that received up to 900 mg/kg/day triclosan were considered consistent with commonly occurring spontaneous processes in the mouse.

Pathologist:



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Department of Pathology


Date

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Corrected Leukocyte Count (COR WBC)

$(\text{WBC} \times 100) \div (\text{NRBC} + 100) = \text{COR WBC (Calculated)}$.

Coulter Counter® Model S+IV System

Product Reference Manual 4235328B (1983, November). Coulter Electronics, Inc., Hialeah, FL.

Data Terminal with Data Handling PN4235456D (1986, January). Coulter Electronics, Inc., Hialeah, FL.

Erythrocyte Count (RBC)
 Hematocrit (HCT)
 Hemoglobin (HGB)
 Leukocyte Count (WBC)
 Platelet (PLATELET)

Clinical Chemistry
Albumin/Globulin Ratio (A/G)

Albumin ÷ Globulin = A/G RATIO (Calculated).

BMD/Hitachi® 737 Chemistry Analyzer

Boehringer Mannheim Diagnostics, Indianapolis, IN.

	Insert #
Alanine Aminotransferase (ALT)	1127760 (R1), 1127799 (R2)
Albumin (ALBUMIN)	1127447
Alkaline Phosphatase (ALK P)	1127489 (R1), 1127620 (R2)
Aspartate Aminotransferase (AST)	1127740 (R1), 1127764 (R2)
Blood Urea Nitrogen (BUN)	1127292 (R1), 1127306 (R2)
Creatinine (CREAT)	1127632 (R1), 1127659 (R2)
Gamma Glutamyltransferase (GGT)	1127853 (R1), 1127720 (R2)
Glucose (GLUCOSE)	1127233 (R1), 1127241 (R2)
Lactate Dehydrogenase (LDH) - Effective 12/6/90	749045
Total Bilirubin (T BILI)	1127097
Total Cholesterol (T CHOL)	816302
Total Protein	1127706 (R1), 1127714 (R2)
Triglycerides (TRIGLY)	1128027

Globulin (GLOBULIN)

Total Protein - Albumin = Globulin (Calculated).

Statistical Analyses/Laboratory ProceduresDunnett's t-Test for Control vs. Treatment Comparisons

DUNNETT, C. W. (1955). A multiple comparison procedure for comparing several treatments with a control. J. Am. Stat. Assoc. 50, pp. 1096-1121.

DUNNETT, C. W. (1964). New tables for multiple comparisons with a control. Biometrics 20, pp. 482-491.

Levene's Test

DRAPER, N. R., AND HUNTER, W. G. (1969). Transformations: some examples revisited. Technometrics 11, pp. 23-40.

LEVENE, H. (1960). Robust tests for equality of variances. In Contributions to Probability and Statistics (I. Olkin, ed.). Stanford University Press, Palo Alto, pp. 278-292.

Bartlett's Test

BARTLETT, M. S. (1937). Some examples of statistical methods of research in agriculture and applied biology. J. Royal Statist. Soc. Suppl. IV, pp. 137-170.

Terpstra-Jonckheere Test

THAKUR, A. K. (1984). A FORTRAN program to perform the nonparametric Terpstra-Jonckheere test. Comp. Progr. Biomed. 18, pp. 235-240.

Linear Regression

DRAPER, N., AND SMITH, H. (1966). Applied regression analysis. Wiley, NY.

Table 1
Results of Dietary Analyses
13-Week Subchronic Oral Toxicity Study of Triclosan in CD-1[®] Mice

Table 1
Results of Dietary Analyses
13-Week Subchronic Oral Toxicity Study of Triclosan in CD-1^a Mice

Dose Level (mg/kg/day):	Group:	Target Concentration						Corrected Assayed Level (ppm)						Percent of Target						
		2	3	4	5	6	7	2	3	4	5	6	7	2	3	4	5	6	7	
		25	75	200	350	750	900	25	75	200	350	750	900	25	75	200	350	750	900	
Homogeneity and Day 0 Stability																				
Top		100	-	-	-	-	5100	A	108.0	-	-	-	-	5143	108	-	-	-	-	101
								B	104.0	-	-	-	-	5171	104	-	-	-	-	-
Middle		100	-	-	-	-	5100	A	109.2	-	-	-	-	5329	109	-	-	-	-	104
								B	101.2	-	-	-	-	5131	101	-	-	-	-	-
Bottom		100	-	-	-	-	5100	A	104.4	-	-	-	-	5123	104	-	-	-	-	100
								B	100.3	-	-	-	-	5139	100	-	-	-	-	-
													\bar{x}						101	
													S.D.						1.37	
													%RSD						1.36	
Stability																				
Day 10 (Room Temperature)		100	-	-	-	-	5100	A	98.18	-	-	-	-	5204	98.2	-	-	-	-	102
								B	103.4	-	-	-	-	5281	103	-	-	-	-	-
Day 30 (Frozen)		100	-	-	-	-	5100	A	106.5	-	-	-	-	5169	107	-	-	-	-	101
								B	104.4	-	-	-	-	5205	104	-	-	-	-	-
Week 1 (Males)		110.4	334.5	955.4	1695.3	3701.4	4259.5	A	117.8	334.8	952.3	1891	3812	4447	107	100	99.7	112	103	104
								B	114.7	336.0	975.2	1810	3764	4249	104	100	102	107	102	99.8
Week 1 (Females)		106.6	317.8	829.0	1318.2	2760.1	3672.4	A	102.6	324.5 ^a	848.3	1370	2892	3671	96.2	102	102	104	105	100
								B	102.9	320.5 ^a	832.8	1392	2726	3764	96.5	101	100	106	98.8	102
Week 2 (Males)		120.7	370.3	1006.7	1818.7	3598.7	4195.8	A	121.1	385.8	1007	1883	3532	4253	100	104	100	104	98.1	101
								B	117.9	369.0	1002	1883	3496	4310	97.7	99.6	99.5	104	97.1	103
Week 2 (Females)		112.6	323.6	835.8	1619.0	3074.2	3619.5	A	105.0	309.9	828.6	1676	2913	3643	94.0	95.8	99.1	104	94.8	101
								B	106.0	316.4	833.1	1700	2934	3649	94.1	97.8	99.7	105	95.4	101

^a Results of a re-extraction and re-dilution.

KEY: - = No analysis necessary.

NOTE: No test material was detected in control (Group 1) diet samples.

Table 1 - Continued
Results of Dietary Analyses
13-Week Subchronic Oral Toxicity Study of Triclosan in CD-1[®] Mice

Dose Level (mg/kg/day):	Group:	Target Concentration							Corrected Assayed Level (ppm)						Percent of Target					
		2	3	4	5	6	7		2	3	4	5	6	7	2	3	4	5	6	7
		25	75	200	350	750	900		25	75	200	350	750	900	25	75	200	350	750	900
Week 3 (Males)		121.4	362.6	1015.6	1752.0	3598.7	4194.2	A	123.7	385.7	1050	1794	3656	4252	102	106	103	102	102	101
								B	123.3	379.2	1061	1737	3742	4300	102	105	104	99.1	104	103
Week 3 (Females)		109.3	334.9	877.9	1502.7	3180.3	3758.6	A	108.2	358.0	911.7	1526	3227	3755	99.0	107	104	102	101	99.9
								B	111.9	356.2	904.5	1553	3283	3806	102	106	103	103	103	101
Week 4 (Males)		136.8	411.9	1033.9	1920.1	3454.4	4194.3	A	139.3	434.0	1066	1970	3533	4265	102	105	103	103	102	102
								B	137.7	434.2	1041	1931	3590	4204	101	105	101	101	104	100
Week 4 (Females)		111.7	339.9	922.9	1557.8	3344.7	3738.1	A	108.9	361.0	915.0	1564	3449	3679	97.5	106	99.1	100	103	98.4
								B	111.6	355.9	936.9	1595	3336	3747	99.9	105	102	102	99.7	100
Week 5 (Males)		126.8	374.7	1041.3	1762.5	3667.5	4341.4	A	133.8	371.8	1045	1768	3764	4292	106	99.2	100	100	103	98.9
								B	133.3	383.1	1027	1790	3728	4284	105	102	98.6	102	102	98.7
Week 5 (Females)		105.4	333.4	914.7	1601.3	3127.5	3510.9	A	109.9	351.1	901.5	1589	3068	3378	104	105	98.6	99.2	98.1	96.2
								B	106.8	336.5	940.6	1586	3162	3410	101	101	103	99.0	101	97.1
Week 6 (Males)		135.8	420.6	1109.2	1867.2	3691.5	4325.6	A	125.1	398.5	1155	1957	3997	4543	92.1	94.7	104	105	108	105
								B	133.6	393.3	1138	1931	3857	4444	98.4	93.5	103	103	104	103
Week 6 (Females)		110.9	332.4	918.8	1561.2	3359.4	3994.1	A	106.0	321.2	920.8	1672	3371	4265	95.6	96.6	100	107	100	107
								B	107.1	325.0	926.9	1626	3530	4093	96.6	97.8	101	104	105	103
Week 7 (Males)		136.4	432.3	1140.9	2012.2	4243.8	4763.9	A	129.1	430.9	1172	1994	4378	4812	94.6	99.7	103	99.1	103	101
								B	129.6	442.0	1150	1984	4440	4852	95.0	102	101	98.6	105	102
Week 7 (Females)		114.5	351.9	930.1	1625.9	3381.5	4158.4	A	111.4	322.0	942.7	1616	3546	4121	97.3	91.5	101	99.4	105	99.1
								B	108.3	356.6	929.0	1633	3490	4161	94.6	101	99.9	100.4	103	100
Week 8 (Males)		134.8	426.9	1124.1	2010.5	4147.2	5060.5	A	144.3	421.9	1117	2061	4184	5228	107	98.8	99.4	103	101	103
								B	136.2	421.2	1134	2028	4064	5240	101	98.7	101	101	98.0	104
Week 8 (Females)		127.9	359.5	966.8	1702.4	3512.7	4247.7	A	129.0	354.6	988.3	1758	3499	4252	101	98.6	102	103	99.6	100
								B	130.8	356.2	962.6	1784	3538	4280	102	99.1	99.6	105	101	101

NOTE: No test material was detected in control (Group 1) diet samples.

Table 1 - Continued
Results of Dietary Analyses
13-Week Subchronic Oral Toxicity Study of Triclosan in CD-1^a Mice

Group: Dose Level (mg/kg/day):	Target Concentration							Corrected Assayed Level (ppm)						Percent of Target					
	2	3	4	5	6	7		2	3	4	5	6	7	2	3	4	5	6	7
	25	75	200	350	750	900		25	75	200	350	750	900	25	75	200	350	750	900
Week 9 (Males)	140.2	439.3	1210.8	2107.3	4169.1	4228.4	A	139.2	435.0	1260	2223	4315	4580	99.3	99.0	104	105	103	108
							B	137.5	466.9	1250	2137	4434	4409	98.1	106	103	101	106	104
Week 9 (Females)	121.9	370.0	1052.2	1765.8	3631.7	3666.8	A	117.9	393.8	1063	1751	3645	3694	96.7	106	101	99.2	100	101
							B	121.5	382.1	1064	1818	3822	3789	99.7	103	101	103	105	103
Week 10 (Males)	168.8	498.4	1339.4	2259.3	4652.4	5173.1	A	182.6	527.1	1354	2307	4581	5661	108	106	101	102	98.5	109
							B	179.7	513.4	1378	2271	4824	5585	106	103	103	101	104	108
Week 10 (Females)	124.6	372.8	1034.7	1805.7	3912.9	4467.2	A	126.1	337.4	1005	1772	4020	4613	101	90.5	97.1	98.1	103	103
							B	120.0	346.9	1029	1743	4138	4617	96.3	93.1	99.4	96.5	106	103
Week 11 (Males)	158.8	492.8	1310.3	2426.2	4601.4	5589.8	A	165.8	491.9	1325	2354	4740	5457	104	99.8	101	97.0	103	97.6
							B	164.4	487.5	1319	2420	4679	5683	104	98.9	101	99.7	102	102
Week 11 (Females)	126.1	410.6	1202.5	2081.3	3880.6	4890.6	A	123.7	412.0	1208	2094	3886	4954	98.1	100	100	101	100	101
							B	129.2	410.8	1239	2074	3896	4935	102	100	103	99.6	100	101
Week 12 (Males)	167.2	536.5	1394.2	2539.1	4772.1	5798.2	A	171.1	539.9	1369	2630	4715	5482	102	101	98.2	104	98.8	94.5
							B	169.1	533.3	1374	2570	4755	5559	101	99.4	98.6	101	98.6	95.9
Week 12 (Females)	134.3	429.3	1139.8	2085.4	4621.8	5690.3	A	125.9	428.8	1101	2113	4673	5840	93.7	99.9	96.6	101	101	103
							B	129.0	434.9	1116	2105	4611	5533	96.1	101	97.9	101	99.8	97.2
Week 13 (Males) ^a	150.7	487.9	1329.6	2355.2	4557.9	5577.8	A	145.4	475.6	2754	2424	4645	5579	96.5	97.5	207	103	102	100
							B	156.4	488.9	2701	2344	4617	5639	104	100	203	99.5	101	101
Week 13 (Males) ^b	-	-	1329.6	2355.2	-	-	A	-	-	1377	2338	-	-	-	-	104	99.3	-	-
							B	-	-	1324	2314	-	-	-	-	99.6	98.3	-	-

^a Group 4 male results were from a re-extraction. This group and Group 5 male reserves were analyzed to prove that there was no mix-up between these groups.

^b Reserve.

NOTE: No test material was detected in control (Group 1) diet samples.

Table 1 - Continued
Results of Dietary Analyses
13-Week Subchronic Oral Toxicity Study of Triclosan in CD-1^a Mice

Dose Level (mg/kg/day):	Group:	Target Concentration							Corrected Assayed Level (ppm)						Percent of Target					
		2	3	4	5	6	7		2	3	4	5	6	7	2	3	4	5	6	7
		25	75	200	350	750	900		25	75	200	350	750	900	25	75	200	350	750	900
Week 13 (Females)		137.7	399.2	1052.2	1941.0	4300.2	4922.3	A	136.6	400.5	1058	1886	4270	4948	99.2	100	101	97.2	99.3	101
								B	136.3	387.9	1060	1911	4306	4906	99.0	97.2	101	98.5	100	99.7
Week 14 (Males)		163.4	501.1	1327.2	2430.8	4158.5	4573.1	A	167.6	477.8	1445	2558	4040	4364	103	95.4	109	105	97.2	95.4
								B	162.6	493.0	1420	2584	4204	4479	99.5	98.4	107	106	101	97.9
Week 14 (Females)		132.8	391.7	1202.2	2012.5	4098.7	4862.1	A	119.5	414.0	1250	2159	4012	4570	90.0	106	104	107	97.9	94.0
								B	121.1	410.8	1292	2173	4132	4653	91.2	105	107	108	101	95.7

Key: - = No analysis necessary.

NOTE: No test material was detected in control (Group 1) diet samples.

Table 2A
Summary Incidence of Clinical Observations - Weekly
Clinical Observations (Main Study)
13-Week Subchronic Oral Toxicity Study of Triclosan in CD-1[®] Mice

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

TABLE 2A

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)

SUMMARY INCIDENCE OF CLINICAL OBSERVATIONS

STUDY NUMBER: 483287

WEEKS 1-14		NUMBER OF ANIMALS AFFECTED						
CATEGORY KEYWORD QUALIFIER	SEX:	MALE						
	GROUP:	1	2	3	4	5	6	7
	DOSE:	0	25	75	200	350	750	900
	NUMBER:	15	15	15	15	15	15	15
*** TOP OF LIST ***								
APPEARANCE								
HUNCHED POSTURE		0	0	0	0	0	0	1
PALE								
ENTIRE BODY		0	0	0	0	0	0	2
THIN		0	0	0	0	0	0	0
BEHAVIOR								
HYPOACTIVE		0	0	0	0	0	0	1
RESPIRATION								
DYSPNEA		0	0	0	0	0	0	0
SKIN/PELAGE								
ALOPECIA								
DORSAL-CERVICAL		1	0	0	0	1	0	0
SACRAL-LEFT		1	0	0	0	0	0	1
PERINEAL AREA		0	0	0	0	0	0	1
SHOULDER-LEFT		0	0	0	0	1	0	0
SORE(S)								
DORSAL-CERVICAL		1	0	0	1	1	0	0
SACRAL-LEFT		1	0	0	0	0	0	0
PERINEAL AREA		0	0	0	0	0	0	1
SHOULDER-LEFT		0	0	0	0	1	0	0
TAIL-DISTAL		0	0	0	0	0	0	0
EARS-BOTH		1	0	0	1	1	0	0
EAR-RIGHT		1	0	0	2	2	0	0
EAR-LEFT		3	1	1	0	2	0	0
URINE STAINS		0	0	0	0	0	0	1
*** END OF LIST ***								

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

TABLE 2A

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
SUMMARY INCIDENCE OF CLINICAL OBSERVATIONS

STUDY NUMBER: 483287

		NUMBER OF ANIMALS AFFECTED						
WEEKS 1-14								
CATEGORY KEYWORD QUALIFIER	SEX:	-----FEMALE-----						
	GROUP:	1	2	3	4	5	6	7
	DOSE:	0	25	75	200	350	750	900
	NUMBER:	15	15	15	15	15	15	15
*** TOP OF LIST ***								
APPEARANCE								
HUNCHED POSTURE		0	0	0	0	0	1	2
PALE								
ENTIRE BODY		0	0	0	0	0	0	2
THIN		0	0	0	0	0	0	1
BEHAVIOR								
HYPOACTIVE		0	0	0	0	0	1	4
RESPIRATION								
DYSPNEA		0	0	0	0	0	0	1
SKIN/PELAGE								
ALOPECIA								
DORSAL-CERVICAL		0	0	0	0	0	0	0
SACRAL-LEFT		0	0	0	0	0	0	0
PERINEAL AREA		0	0	0	0	0	0	0
SHOULDER-LEFT		0	0	0	0	0	0	0
SORE(S)								
DORSAL-CERVICAL		0	0	0	0	0	0	0
SACRAL-LEFT		0	0	0	0	0	0	0
PERINEAL AREA		0	0	0	0	0	0	0
SHOULDER-LEFT		0	0	0	0	0	0	0
TAIL-DISTAL		0	0	0	0	0	0	1
EARS-BOTH		0	0	0	0	0	0	0
EAR-RIGHT		0	0	0	1	0	0	0
EAR-LEFT		0	0	0	0	0	0	0
URINE STAINS		0	0	0	0	0	0	0
*** END OF LIST ***								

Table 2B
Summary Incidence of Clinical Observations - Weekly
Clinical Observations (Satellite Study)
13-Week Subchronic Oral Toxicity Study of Triclosan in CD-1[®] Mice

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

TABLE 2B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY IN TRICLOSAN IN CD-1
MICE. (SATELLITE-GROUPS 8-11)
SUMMARY INCIDENCE OF CLINICAL OBSERVATIONS

STUDY NUMBER: 483287

WEEKS 1-7

NUMBER OF ANIMALS AFFECTED

CATEGORY KEYWORD QUALIFIER	SEX: -----MALE-----				-----FEMALE-----				
	GROUP:	8	9	10	11	8	9	10	11
	DOSE:	0	25	350	900	0	25	350	900
	NUMBER:	20	10	10	10	20	10	10	10

*** TOP OF LIST ***

APPEARANCE

HUNCHED POSTURE

0 0 0 1 0 0 0 0

SKIN/PELAGE

ALOPECIA

SHOULDER-RIGHT

0 0 0 0 0 0 1 0

SORE(S)

EAR-RIGHT

1 0 0 0 0 0 0 0

EAR-LEFT

0 0 1 0 0 0 0 0

*** END OF LIST ***

Table 3A
Summary Incidence of Clinical Observations - Daily
Cageside Observations (Main Study)
13-Week Subchronic Oral Toxicity Study of Triclosan in CD-1[®] Mice

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

TABLE 3A
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
SUMMARY INCIDENCE OF CLINICAL OBSERVATIONS

STUDY NUMBER: 483287

		NUMBER OF ANIMALS AFFECTED						
WEEKS 1-14								
CATEGORY	SEX:	-----MALE-----						
	GROUP:	1	2	3	4	5	6	7
	DOSE:	0	25	75	200	350	750	900
	NUMBER:	15	15	15	15	15	15	15
QUALIFIER								

*** TOP OF LIST ***

APPEARANCE

COLD TO TOUCH	0	0	0	0	0	0	0
HUNCHED POSTURE	0	0	0	0	0	1	2
LIMITED USE							
LIMBS-HIND	0	0	0	0	0	0	0
PALE							
ENTIRE BODY	0	0	0	0	0	0	3
THIN	0	0	0	0	0	1	2

BEHAVIOR

HYPOACTIVE	0	0	0	0	0	1	2
------------	---	---	---	---	---	---	---

EXCRETION

FEW FECES	0	0	0	0	0	0	0
-----------	---	---	---	---	---	---	---

SKIN/PELAGE

ALOPECIA							
SACRAL-LEFT	0	0	0	0	0	0	1
URINE STAINS	0	0	0	0	0	0	1

*** END OF LIST ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

TABLE 3A
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
SUMMARY INCIDENCE OF CLINICAL OBSERVATIONS

STUDY NUMBER: 483287

		NUMBER OF ANIMALS AFFECTED						
WEEKS 1-14								
CATEGORY KEYWORD QUALIFIER	SEX:	-----FEMALE-----						
	GROUP:	1	2	3	4	5	6	7
	DOSE:	0	25	75	200	350	750	900
	NUMBER:	15	15	15	15	15	15	15

*** TOP OF LIST ***								
APPEARANCE								
COLD TO TOUCH		0	0	0	0	0	0	1
HUNCHED POSTURE		0	0	0	0	0	1	1
LIMITED USE								
LIMBS-HIND		0	0	0	1	0	0	0
PALE								
ENTIRE BODY		0	0	0	0	0	0	1
THIN		0	0	0	0	0	0	1
- 70 -								
BEHAVIOR								
HYPOACTIVE		0	0	0	0	0	1	4
EXCRETION								
FEW FECES		0	0	0	0	0	0	1
SKIN/PELAGE								
ALOPECIA								
SACRAL-LEFT		0	0	0	0	0	0	0
URINE STAINS		0	0	0	1	0	0	0
*** END OF LIST ***								

Table 3B
Summary Incidence of Clinical Observations - Daily
Cageside Observations (Satellite Study)
13-Week Subchronic Oral Toxicity Study of Triclosan in CD-1[®] Mice

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

TABLE 3B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY IN TRICLOSAN IN CD-1
MICE. (SATELLITE-GROUPS 8-11)

SUMMARY INCIDENCE OF CLINICAL OBSERVATIONS

STUDY NUMBER: 483287

WEEK 7

NUMBER OF ANIMALS AFFECTED

	SEX:	-----MALE-----				-----FEMALE-----			
CATEGORY	GROUP:	8	9	10	11	8	9	10	11
KEYWORD	DOSE:	0	25	350	900	0	25	350	900
QUALIFIER	NUMBER:	20	10	10	10	20	10	10	10

*** TOP OF LIST ***

APPEARANCE

HUNCHED POSTURE

0 0 0 0 0 0 0 0 1

BEHAVIOR

HYPOACTIVE

0 0 0 0 0 0 0 0 1

*** END OF LIST ***

Table 4A
Body Weight Means and Standard Deviations - Main Study
13-Week Subchronic Oral Toxicity Study of Triclosan in CD-1[®] Mice

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

TABLE 4A

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
BODY WEIGHT MEANS AND STANDARD DEVIATIONS (G)

STUDY NUMBER: 483287

WEEK	SEX:	MALE-						
	GROUP: DOSE:	1 0	2 25	3 75	4 200	5 350	6 750	7 900
74	-1	N MEAN S.D.	15 25 1.2	15 24 1.8	15 25 1.4	15 25 1.0	15 25 1.2	15 25 1.4
	1	N MEAN S.D.	15 26 1.5	15 26 1.8	15 26 1.9	15 27 1.7	15 26 1.2	15 27 1.6
	2	N MEAN S.D.	15 27 2.1	15 28 1.9	15 28 1.8	15 29 1.9	15 28 1.5	15 25 2.7
	3	N MEAN S.D.	15 28 1.6	15 29 1.9	15 29 1.9	15 30 1.8	15 29 1.7	14 26 2.2
	4	N MEAN S.D.	15 29 1.8	15 30 1.8	15 30 2.2	15 31 1.9	15 31 1.9	15 28 2.4
	5	N MEAN S.D.	15 30 1.5	15 30 1.6	15 31 2.0	15 32 1.9	15 31 1.8	15 29 2.6
	6	N MEAN S.D.	15 30 1.8	15 30 1.6	15 31 2.5	15 32 1.9	15 32 2.2	15 29 2.3
	7	N MEAN S.D.	15 31 1.4	15 30 1.6	15 31 2.3	14 33 1.9	15 33 2.5	15 30 3.0
	8	N MEAN S.D.	15 31 1.7	15 31 1.5	15 31 2.3	14 33 1.8	15 33 1.9	15 30 2.6
	9	N MEAN S.D.	15 31 2.1	15 32 1.7	15 32 2.2	14 34 2.1	15 33 1.9	15 30 2.6

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

TABLE 4A

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
BODY WEIGHT MEANS AND STANDARD DEVIATIONS (G)

STUDY NUMBER: 483287

WEEK	SEX:	-----MALE-----						
	GROUP: DOSE:	1 0	2 25	3 75	4 200	5 350	6 750	7 900
10	N	15	15	15	14	15	15	13
	MEAN	31	33	33	34	34	30	31
	S.D.	1.9	2.1	2.7	2.1	2.0	2.7	2.5
11	N	15	15	15	14	15	15	13
	MEAN	31	32	32	33	34	30	31
	S.D.	2.0	1.5	2.5	1.8	2.1	2.6	2.5
12	N	15	15	15	14	15	15	13
	MEAN	32	33	34	34	34	30	31
	S.D.	2.1	1.8	2.7	2.0	1.9	2.6	2.8
13	N	15	15	15	13	15	15	13
	MEAN	32	33	33	34	34	31	31
	S.D.	1.8	1.7	2.8	2.2	1.9	2.4	2.5
14	N	15	15	15	13	15	15	13
	MEAN	32	33	33	33	34	31	31
	S.D.	2.0	1.6	2.8	2.5	2.0	2.4	2.9

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HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

TABLE 4A

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)

BODY WEIGHT MEANS AND STANDARD DEVIATIONS (G)

STUDY NUMBER: 483287

WEEK	SEX:	FEMALE						
	GROUP: DOSE:	1 0	2 25	3 75	4 200	5 350	6 750	7 900
-1	N	15	15	15	15	15	15	15
	MEAN	20	20	20	20	20	20	20
	S.D.	0.9	1.4	0.9	1.1	1.2	1.0	1.0
1	N	15	15	15	15	15	15	15
	MEAN	22	22	22	22	21	21	22
	S.D.	1.0	1.2	0.8	1.3	1.6	1.0	1.4
2	N	15	15	15	15	15	15	15
	MEAN	24	24	23	23	24	22	20
	S.D.	1.1	1.5	0.9	1.4	1.7	1.8	1.4
3	N	15	15	15	15	15	15	15
	MEAN	24	25	24	25	25	23	22
	S.D.	1.1	1.6	1.1	1.5	1.9	1.6	1.6
4	N	15	15	15	15	15	15	15
	MEAN	25	25	25	26	26	24	23
	S.D.	1.5	1.5	1.2	1.6	1.8	1.8	1.7
5	N	15	15	15	15	15	15	15
	MEAN	25	26	26	27	28	24	23
	S.D.	1.8	1.8	1.1	1.9	2.7	2.1	1.9
6	N	15	15	15	14	15	15	15
	MEAN	27	26	26	27	27	25	24
	S.D.	1.7	1.9	1.3	1.9	1.4	2.2	1.7
7	N	15	15	15	14	15	15	15 *
	MEAN	27	27	27	28	28	26	25
	S.D.	1.9	2.0	1.1	1.6	1.9	2.0	2.0
8	N	15	15	15	14	15	15	15
	MEAN	27	27	27	28	29	26	24
	S.D.	1.9	1.9	1.5	1.9	2.3	1.7	1.9
9	N	15	15	15	14	15	15	14
	MEAN	28	27	28	29	29	27	25
	S.D.	2.5	1.8	1.7	1.8	2.5	1.6	1.8

* Significantly different from control value, $p \leq 0.05$.

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

TABLE 4A

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
BODY WEIGHT MEANS AND STANDARD DEVIATIONS (G)

STUDY NUMBER: 483287

WEEK	SEX: -----		-----FEMALE-----					
	GROUP:	1	2	3	4	5	6	7
	DOSE:	0	25	75	200	350	750	900
10	N	15	15	15	14	15	15	14
	MEAN	27	28	27	28	29	27	25
	S.D.	2.1	2.1	1.5	1.3	2.0	2.0	1.9
11	N	15	15	15	14	15	15	14
	MEAN	28	28	28	29	29	27	25
	S.D.	1.9	2.0	1.4	1.6	2.3	2.3	1.7
12	N	15	15	15	14	15	15	14
	MEAN	28	27	28	28	30	27	25
	S.D.	1.7	2.0	1.4	2.8	2.1	2.3	2.3
13	N	15	15	15	14	15	15	14
	MEAN	28	28	28	29	30	27	25
	S.D.	1.6	2.1	1.2	2.1	2.3	2.5	2.2
14	N	15	15	15	14	15	15	14 *
	MEAN	28	28	29	30	30	27	26
	S.D.	2.1	2.0	1.5	1.4	2.4	2.2	2.2

* Significantly different from control value, $p \leq 0.05$.

Table 4B
Body Weight Means and Standard Deviations - Satellite Study
13-Week Subchronic Oral Toxicity Study of Triclosan in CD-1[®] Mice

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

TABLE 4B
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY IN TRICLOSAN IN CD-1
MICE. (SATELLITE-GROUPS 8-11)
BODY WEIGHT MEANS AND STANDARD DEVIATIONS (G)

STUDY NUMBER: 483287

SEX:		MALE				FEMALE			
WEEK	GROUP: DOSE:	8 0	9 25	10 350	11 900	8 0	9 25	10 350	11 900
-1	N	20	10	10	10	20	10	10	10
	MEAN	25	25	25	25	21	20	20	20
	S.D.	1.5	1.7	1.8	1.6	1.2	1.1	1.3	1.0
1	N	11	10	10	10	10	10	10	10
	MEAN	26	26	26	26	21	21	22	21
	S.D.	2.1	1.4	1.1	1.4	1.2	1.4	1.2	1.6
2	N	10	10	10	10	10	10	10	10
	MEAN	28	28	28	23	23	23	24	21
	S.D.	1.9	1.9	1.4	1.9	1.2	1.4	1.0	1.7
3	N	10	10	10	10	10	10	10	10
	MEAN	29	29	29	25	23	22	24	22
	S.D.	1.8	1.8	2.8	2.1	1.0	1.2	1.1	1.4
4	N	10	10	10	10	10	10	10	10
	MEAN	30	29	30	26	25	25	26	24
	S.D.	1.8	2.2	2.2	2.2	1.3	1.0	0.9	1.6
5	N	10	10	10	10	10	10	10	10
	MEAN	30	30	30	26	26	25	26	24
	S.D.	1.9	1.8	2.0	2.1	1.2	1.3	1.1	2.0
6	N	10	10	10	10	10	10	10	10
	MEAN	31	31	31	28	26	25	27	26
	S.D.	1.9	2.2	1.8	1.9	1.5	1.7	1.8	1.9
7	N	10	10	10	10	10	10	10	10
	MEAN	31	31	32	29	27	26	28	26
	S.D.	1.8	2.3	1.8	2.2	1.4	1.2	1.4	1.9

Table 5A
Body Weight Change Means and Standard Deviations - Main Study
13-Week Subchronic Oral Toxicity Study of Triclosan in CD-1[®] Mice

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

TABLE 5A

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
BODY WEIGHT CHANGES MEANS AND STANDARD DEVIATIONS (G)

STUDY NUMBER: 483287

WEEK	SEX: GROUP: DOSE:	-----MALE-----						
		1 0	2 25	3 75	4 200	5 350	6 750	7 900
1	N	15	15	15	15	15	15	15
	MEAN	1	3	2	2	2	-3	-2
	S.D.	1.5	0.7	0.9	0.9	1.0	2.6	1.4
2	N	15	15	15	15	15	15	14
	MEAN	1	1	1	1	1	1	1
	S.D.	1.0	0.5	0.8	1.0	1.2	1.6	1.1
3	N	15	15	15	15	15	15	13
	MEAN	1	1	1	1	2	2	2
	S.D.	0.9	0.9	0.9	0.8	1.4	1.7	1.5
4	N	15	15	15	15	15	15	13
	MEAN	0	0	0	1	0	1	1
	S.D.	0.6	0.9	1.2	0.9	1.2	1.0	1.3
5	N	15	15	15	15	15	15	13
	MEAN	1	0	1	1	1	1	1
	S.D.	0.9	1.0	0.6	0.8	0.9	0.8	1.1
6	N	15	15	15	14	15	15	13
	MEAN	1	0	0	0	1	1	1
	S.D.	1.4	1.0	1.0	0.8	1.2	1.3	1.0
7	N	15	15	15	14	15	15	13
	MEAN	0	1	0	0	0	-1	0
	S.D.	1.3	0.8	0.8	0.7	1.3	0.9	1.7
8	N	15	15	15	14	15	15	13
	MEAN	1	1	1	1	1	0	1
	S.D.	0.6	0.6	0.6	0.8	0.8	0.9	1.1
9	N	15	15	15	14	15	15	13
	MEAN	0	0	1	0	0	0	0
	S.D.	0.7	1.1	1.1	1.2	0.9	0.8	1.8

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

TABLE 5A
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
BODY WEIGHT CHANGES MEANS AND STANDARD DEVIATIONS (G)

STUDY NUMBER: 483287

SEX: -----		MALE-----						
WEEK	GROUP: DOSE:	1 0	2 25	3 75	4 200	5 350	6 750	7 900
10	N	15	15	15	14	15	15	13
	MEAN	0	-1	0	-1	0	0	0
	S.D.	1.0	0.9	1.2	1.2	1.0	1.6	1.0
11	N	15	15	15	14	15	15	13
	MEAN	1	1	1	1	0	0	0
	S.D.	0.5	0.7	0.8	0.9	0.6	1.1	1.0
12	N	15	15	15	13	15	15	13
	MEAN	0	0	0	0	0	0	0
	S.D.	0.9	0.6	0.5	0.8	1.0	0.8	1.2
13	N	15	15	15	13	15	15	13
	MEAN	1	0	0	-1	0	0	0
	S.D.	1.0	0.7	0.9	1.1	1.1	0.6	0.9
1-6	N	15	15	15	14	15*	15	13
	MEAN	5	5	5	6	7*	3	4
	S.D.	1.8	1.2	1.7	1.6	1.8	2.8	1.9
1-13	N	15	15	15	13	15	15*	13
	MEAN	6	7	7	6	8	4*	5
	S.D.	2.0	1.2	2.1	2.8	1.6	2.0	2.8

* significantly different from control value, $p \leq 0.05$.

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

TABLE 5A

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
BODY WEIGHT CHANGES MEANS AND STANDARD DEVIATIONS (G)

STUDY NUMBER: 483287

SEX: -----FEMALE-----								
WEEK	GROUP: DOSE:	1 0	2 25	3 75	4 200	5 350	6 750	7 900
1	N	15	15	15	15	15	15	15
	MEAN	1	2	1	1	3	1	-2
	S.D.	0.9	0.9	0.6	1.1	0.6	1.6	0.8
2	N	15	15	15	15	15	15	15
	MEAN	0	0	1	1	1	1	1
	S.D.	0.9	0.8	0.8	1.0	0.8	0.8	0.9
3	N	15	15	15	15	15	15	15
	MEAN	1	1	1	1	1	1	1
	S.D.	0.8	0.8	0.5	0.6	0.8	0.8	1.0
4	N	15	15	15	15	15	15	15
	MEAN	0	1	1	1	2	0	0
	S.D.	1.8	0.8	0.9	1.5	1.8	1.5	0.7
5	N	15	15	15	14	15	15	15
	MEAN	2	0	0	0	0	1	1
	S.D.	1.4	0.8	1.4	1.6	1.7	1.5	0.7
6	N	15	15	15	14	15	15	15
	MEAN	0	1	1	1	1	1	0
	S.D.	1.2	0.8	1.1	0.7	1.0	0.9	0.5
7	N	15	15	15	14	15	15	15
	MEAN	0	1	0	0	0	-1	-1
	S.D.	1.2	1.4	1.0	1.5	1.2	0.9	0.7
8	N	15	15	15	14	15	15	14
	MEAN	1	0	1	1	0	1	1
	S.D.	1.7	1.1	1.3	1.9	1.0	0.5	1.7
9	N	15	15	15	14	15	15	14
	MEAN	-1	0	-1	-1	0	0	1
	S.D.	1.4	0.9	1.2	0.9	1.2	0.8	1.6

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

TABLE 5A

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)

BODY WEIGHT CHANGES MEANS AND STANDARD DEVIATIONS (G)

STUDY NUMBER: 483287

SEX: ----- FEMALE -----								
WEEK	GROUP: DOSE:	1 0	2 25	3 75	4 200	5 350	6 750	7 900
10	N	15	15	15	14	15	15	14
	MEAN	0	0	1	1	1	0	0
	S.D.	0.9	0.8	0.7	0.9	0.7	1.0	1.0
11	N	15	15	15	14	15	15	14
	MEAN	0	0	0	0	0	0	0
	S.D.	1.0	0.5	0.7	2.2	0.8	0.6	1.1
12	N	15	15	15	14	15	15	14
	MEAN	0	0	0	1	1	0	-1
	S.D.	1.4	1.0	0.7	2.2	1.1	0.7	1.2
13	N	15	15	15	14	15	15	14
	MEAN	0	1	1	0	0	0	1
	S.D.	1.2	1.1	0.8	0.9	0.9	0.8	1.3
1-6	N	15	15	15	14	15*	15	15*
	MEAN	5	4	5	6	7	5	2*
	S.D.	1.4	1.6	1.2	1.3	1.5	1.9	1.4
1-13	N	15	15	15	14 *	15 *	15	14 *
	MEAN	6	6	7	8 *	9 *	6	4 *
	S.D.	1.9	1.5	1.7	1.4	1.8	2.0	1.8

* Significantly different from control value, $p \leq 0.05$.

Table 5B
Body Weight Change Means and Standard Deviations - Satellite Study
13-Week Subchronic Oral Toxicity Study of Triclosan in CD-1[®] Mice

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

TABLE 5B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY IN TRICLOSAN IN CD-1
MICE. (SATELLITE-GROUPS 8-11)
BODY WEIGHT CHANGES MEANS AND STANDARD DEVIATIONS (G)

STUDY NUMBER: 483287

WEEK	SEX:	MALE				FEMALE			
	GROUP: DOSE:	8 0	9 25	10 350	11 900	8 0	9 25	10 350	11 900
1	N	10	10	10	10	10	10	10	10
	MEAN	1	2	2	-3	2	2	2	0
	S.D.	0.8	0.8	0.7	1.5	1.2	1.3	0.8	1.9
2	N	10	10	10	10	10	10	10	10
	MEAN	1	1	1	1	0	0	1	1
	S.D.	0.4	0.4	1.6	1.0	0.7	0.9	0.7	0.8
3	N	10	10	10	10	10	10	10	10
	MEAN	1	1	1	2	1	3	2	2
	S.D.	0.7	0.7	1.1	1.1	0.7	0.5	0.9	0.9
4	N	10	10	10	10	10	10	10	10
	MEAN	1	1	1	0	1	0	0	0
	S.D.	0.7	0.9	1.0	1.2	1.0	0.8	0.9	0.9
5	N	10	10	10	10	10	10	10	10
	MEAN	1	0	0	1	1	1	0	1
	S.D.	0.7	0.8	1.2	0.8	1.2	1.0	1.4	0.7
6	N	10	10	10	10	10	10	10	10
	MEAN	1	1	1	2	1	1	1	1
	S.D.	0.7	0.9	0.8	0.7	0.7	0.9	0.9	0.7
1-6	N	10	10	10	10*	10	10	10	10
	MEAN	5	5	6	3*	6	5	6	5
	S.D.	0.9	1.5	1.0	1.5	1.0	1.5	1.1	2.2

* Significantly different from control value, $p \leq 0.05$.

Table 6A
Food Consumption Means and Standard Deviations - Main Study
13-Week Subchronic Oral Toxicity Study of Triclosan in CD-1[®] Mice

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

TABLE 6A

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
FOOD CONSUMPTION MEANS AND STANDARD DEVIATIONS (G)

STUDY NUMBER: 483287

WEEK	SEX: GROUP: DOSE:	MALE						
		1 0	2 25	3 75	4 200	5 350	6 750	7 900
1	N	12	13	12	11	13	13	14
	MEAN	41	43	42	42	40	35	36
	S.D.	3.0	3.3	4.0	3.5	3.1	4.3	8.1
2	N	14	15	15	15	15	15	14
	MEAN	41	42	43	41	42	39	39
	S.D.	4.5	2.7	5.4	3.6	2.9	5.1	5.8
3	N	14	15	15	15	15	15	13
	MEAN	38	39	39	42	41	43	42
	S.D.	7.0	2.8	3.1	2.5	2.7	4.7	5.2
4	N	15	15	15	15	14	15	13
	MEAN	42	42	43	43	43	42	42
	S.D.	3.0	4.0	4.8	3.5	7.8	8.9	3.2
5	N	14	15	15	14	15	15	13
	MEAN	40	39	39	41	43	42	43
	S.D.	4.1	3.2	4.2	2.6	4.0	2.6	2.1
6	N	15	15	15	14	15	15	13
	MEAN	39	39	38	40	41	39	40
	S.D.	3.8	3.5	3.3	2.9	3.3	2.6	3.5
7	N	15	15	15	14	15	12 *	9 *
	MEAN	42	41	39 *	41	40	38 *	38 *
	S.D.	3.4	3.8	2.9	3.2	3.2	2.8	3.4
8	N	15	15	15	13	15	14	11
	MEAN	39	41	39	39	39	39	42
	S.D.	4.0	4.4	2.0	2.6	2.9	3.2	3.7

* Significantly different from control value, $p \leq 0.05$.

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

TABLE 6A

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
FOOD CONSUMPTION MEANS AND STANDARD DEVIATIONS (G)

STUDY NUMBER: 483287

WEEK	SEX: GROUP: DOSE:	1	2	3	4	5	6	7
		0	25	75	200	350	750	900
9	N	15	14	15	14	15	10	12
	MEAN	35	34	35	36	36	35	39
	S.D.	4.0	2.3	2.1	3.0	4.2	2.1	4.1
10	N	15	15	15	14	15	15	13
	MEAN	35	34	34	35	34	35	34
	S.D.	2.8	2.0	2.2	2.5	2.8	5.0	2.4
11	N	15	15	15	14	15	11	10
	MEAN	35	35	33	35	33	33	34
	S.D.	3.7	2.3	2.2	2.4	3.7	3.2	1.7
12	N	15	15	15	13	15	15	13
	MEAN	38	38	36	36	35	35	35
	S.D.	4.8	2.1	2.4	2.2	2.7	2.9	3.2
13	N	15	15	15	13	15	15	13
	MEAN	35	35	34	35	34	39	43 *
	S.D.	3.6	2.4	2.9	3.2	2.9	4.8	5.6
1-13	N	9	13	12	10	13	5	6
	MEAN	490	503	495	503	502	494	500
	S.D.	36.4	27.5	36.7	25.0	29.4	7.8	28.0

* Significantly different from control value, $p \leq 0.05$.

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

TABLE 6A

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
FOOD CONSUMPTION MEANS AND STANDARD DEVIATIONS (G)

STUDY NUMBER: 483287

WEEK	SEX:	FEMALE						
	GROUP: DOSE:	1 0	2 25	3 75	4 200	5 350	6 750	7 900
1	N	14	11	13	11	12	10	6
	MEAN	37	38	39	40	38	37	35
	S.D.	2.5	3.3	3.5	4.4	4.3	4.6	2.3
2	N	15	14	15	15	15	15	15
	MEAN	38	40	39	40	41	38	37
	S.D.	2.5	4.9	2.4	3.6	4.2	4.3	5.6
3	N	15	15	15	14	15	15	14
	MEAN	40	40	40	40	41	38	39
	S.D.	3.6	3.4	3.4	3.7	4.5	4.1	4.8
4	N	15	15	15	15	15	15	15
	MEAN	47	44	41	42	43	40	41
	S.D.	3.5	5.3	3.0	4.3	4.6	4.6	4.3
5	N	15	15	14	14	15	13	13
	MEAN	42	41	42	41	42	41	40
	S.D.	3.4	5.0	4.4	4.1	4.1	6.0	4.9
6	N	14	15	15	14	14	14	14
	MEAN	42	41	41	42	43	40	37
	S.D.	3.8	2.7	2.8	3.0	3.9	4.0	4.1
7	N	14	14	13	14	14	11	15
	MEAN	40	38	40	41	42	38	35*
	S.D.	2.8	4.4	3.1	3.8	4.1	2.2	5.3
8	N	15	14	15	14	15	12	11
	MEAN	39	40	40	40	42	39	40
	S.D.	9.2	7.3	4.2	2.8	5.1	3.7	6.8

* Significantly different from control value, $p \leq 0.05$.

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

TABLE 6A

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
FOOD CONSUMPTION MEANS AND STANDARD DEVIATIONS (G)

STUDY NUMBER: 483287

WEEK	SEX: GROUP: DOSE:	FEMALE						
		1 0	2 25	3 75	4 200	5 350	6 750	7 900
9	N	15	15	15	14	15	15	14
	MEAN	40	39	38	38	39	36	36
	S.D.	3.9	3.8	4.9	2.5	5.9	3.8	4.2
10	N	15	15	15	14	15	15	14
	MEAN	42	39	36	34	35	37	32
	S.D.	4.5	4.0	2.8	2.8	2.7	2.7	4.5
11	N	13	13	12	13	13	11	4
	MEAN	37	36	35	35	35	32	31
	S.D.	2.4	2.9	2.4	2.5	2.6	2.9	4.1
12	N	15	14	15	12	13	15	14
	MEAN	36	35	37	40	38	34	31
	S.D.	2.6	2.4	3.5	9.3	3.1	3.6	5.2
13	N	15	15	15	13	15	15	14
	MEAN	37	38	39	34	36	34	34
	S.D.	4.4	3.2	3.5	3.7	5.7	4.3	4.5
1-13	N	11	8	9	9	8	4	2
	MEAN	516	490	487	494	495	458 *	435 *
	S.D.	23.2	33.5	17.5	27.9	41.1	26.1	12.0

* Significantly different from control value, $p \leq 0.05$.

Table 6B
Food Consumption Means and Standard Deviations - Satellite Study
13-Week Subchronic Oral Toxicity Study of Triclosan in CD-1[®] Mice

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

TABLE 6B
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY IN TRICLOSAN IN CD-1
MICE. (SATELLITE-GROUPS 8-11)
FOOD CONSUMPTION MEANS AND STANDARD DEVIATIONS (G)

STUDY NUMBER: 483287

WEEK	SEX: GROUP: DOSE:	MALE				FEMALE			
		8 0	9 25	10 350	11 900	8 0	9 25	10 350	11 900
1	N	9	10	9	8	7	7	9	7
	MEAN	41	41	39	33	37	41	38	35
	S.D.	2.6	2.5	4.9	7.6	2.1	5.3	5.7	3.8
2	N	10	10	10	10	9	10	10	9
	MEAN	39	37	39	36	36	39	40	33
	S.D.	2.5	6.4	3.8	2.7	6.5	2.5	4.6	4.7
3	N	9	10	10	10	10	10	10	10
	MEAN	38	41	41	41	41	40	40	36
	S.D.	2.9	2.8	5.0	4.0	4.2	3.0	3.8	5.0
4	N	10	10	10	10	10	10	10	10
	MEAN	40	41	41	40	44	41	43	37
	S.D.	3.4	2.9	3.6	4.7	6.4	2.3	3.4	6.3
5	N	10	10	10	9	7	10	10	10
	MEAN	39	42	42	39	48	46	45	38
	S.D.	2.9	2.7	2.0	2.2	5.2	3.2	3.7	5.2
6	N	10	10	10	8	10	10	10	9
	MEAN	40	42	45 *	43	47	46	44	40
	S.D.	2.4	3.1	3.1	2.4	4.2	2.9	3.8	6.1
1-6	N	8	10	9	5	4	7	9	6 *
	MEAN	238	242	246	237	248	253	248	218 *
	S.D.	13.7	16.3	18.5	13.8	19.1	10.0	18.0	16.1

* Significantly different from control value, $p \leq 0.05$.

Table 7A
Compound Consumption Means and Standard Deviations - Main Study
13-Week Subchronic Oral Toxicity Study of Triclosan in CD-1[®] Mice

Compound Consumption Calculation:

$$\frac{(\text{mg/kg})(\text{Individual Food Consumption})}{7 \text{ Days}} + \frac{\text{Body Weight} + \frac{(\text{BW Change})}{2}}{1000}$$

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

TABLE 7A

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
COMPOUND CONSUMPTION MEANS AND STANDARD DEVIATIONS (MG/KG/DAY)

STUDY NUMBER: 483287

WEEK	SEX: GROUP: DOSE:	MALE						
		1 0	2 25	3 75	4 200	5 350	6 750	7 900
1	N	12	13	12	11	13	13	14
	MEAN	0.0	25.0	72.8	203.0	352.5	713.5	861.1
	S.D.	0.0	1.7	6.4	18.8	33.2	84.9	191.0
2	N	14	15	15	15	15	15	14
	MEAN	0.0	25.4	79.0	203.2	374.9	796.6	923.1
	S.D.	0.0	1.6	11.1	12.7	29.0	103.2	111.5
3	N	14	15	15	15	15	15	13
	MEAN	0.0	23.2	69.0	202.7	337.6	840.2	954.8
	S.D.	0.0	1.4	6.1	15.1	23.2	144.9	87.1
4	N	15	15	15	15	14	15	13
	MEAN	0.0	27.4	83.6	205.6	381.5	747.2	897.9
	S.D.	0.0	2.5	10.3	20.6	60.0	206.3	59.4
5	N	14	15	15	14	15	15	13
	MEAN	0.0	23.1	68.4	192.4	340.8	765.5	933.1
	S.D.	0.0	1.8	8.8	14.5	33.5	80.0	64.7
6	N	15	15	15	14	15	15	13
	MEAN	0.0	25.1	74.1	197.5	335.2	689.4	838.9
	S.D.	0.0	2.2	7.0	17.4	30.9	79.3	80.7
7	N	15	15	15	14	15	12	9
	MEAN	0.0	26.1	76.1	205.9	351.8	753.3	851.7
	S.D.	0.0	2.1	5.6	20.6	37.3	64.3	51.5
8	N	15	15	15	13	15	14	11
	MEAN	0.0	24.8	75.1	190.2	341.8	792.2	1020.5
	S.D.	0.0	2.8	5.3	17.6	31.2	96.1	110.3

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

TABLE 7A

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
COMPOUND CONSUMPTION MEANS AND STANDARD DEVIATIONS (MG/KG/DAY)

STUDY NUMBER: 483287

WEEK	SEX:	-MALE-						
	GROUP: DOSE:	1 0	2 25	3 75	4 200	5 350	6 750	7 900
9	N	15	14	15	14	15	10	12
	MEAN	0.0	21.2	67.7	182.2	328.1	682.9	745.8
	S.D.	0.0	1.6	6.6	14.0	42.3	71.0	80.5
10	N	15	15	15	14	15	15	13
	MEAN	0.0	25.7	75.1	198.7	329.5	768.4	825.0
	S.D.	0.0	1.7	6.6	15.9	32.2	134.9	56.2
11	N	15	15	15	14	15	11	10
	MEAN	0.0	24.7	71.7	194.1	337.7	733.5	885.0
	S.D.	0.0	1.6	6.1	16.1	40.2	116.5	83.0
12	N	15	15	15	13	15	15	13
	MEAN	0.0	27.7	82.5	212.0	377.3	802.1	939.6
	S.D.	0.0	1.7	7.3	20.2	30.9	106.9	66.1
13	N	15	15	15	13	15	15	13
	MEAN	0.0	22.9	72.6	196.7	338.1	833.9	1107.3
	S.D.	0.0	1.4	6.5	19.3	26.4	147.7	167.0
1-13	MEAN	0.0	24.8	74.5	198.8	348.0	766.4	907.6

HAZLETON WASHINGTON, INC.
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TABLE 7A

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
COMPOUND CONSUMPTION MEANS AND STANDARD DEVIATIONS (MG/KG/DAY)

STUDY NUMBER: 483287

WEEK	SEX:	FEMALE						
	GROUP: DOSE:	1 0	2 25	3 75	4 200	5 350	6 750	7 900
1	N	14	11	13	11	12	10	6
	MEAN	0.0	25.4	78.3	208.6	320.9	686.8	841.4
	S.D.	0.0	2.7	9.2	18.3	26.9	85.4	96.5
2	N	15	14	15	15	15	15	15
	MEAN	0.0	26.3	75.6	201.0	395.0	753.8	927.2
	S.D.	0.0	2.6	5.1	20.6	34.2	69.1	145.1
3	N	15	15	15	14	15	15	14
	MEAN	0.0	25.3	76.7	199.6	351.4	745.8	945.9
	S.D.	0.0	1.6	8.3	16.1	35.4	79.8	145.8
4	N	15	15	15	15	15	15	15
	MEAN	0.0	27.3	78.6	211.1	362.9	814.3	967.3
	S.D.	0.0	2.9	6.8	28.4	41.4	102.9	131.0
5	N	15	15	14	14	15	13	13
	MEAN	0.0	23.7	76.6	200.5	353.9	737.0	844.1
	S.D.	0.0	2.8	8.7	19.2	26.0	106.8	123.4
6	N	14	15	15	14	14	14	14
	MEAN	0.0	24.9	72.5	203.6	351.2	741.9	862.9
	S.D.	0.0	2.2	5.4	15.8	30.5	89.3	120.6
7	N	14	14	13	14	14	11	15
	MEAN	0.0	23.2	73.8	196.1	340.8	712.9	864.5
	S.D.	0.0	3.4	5.0	22.9	32.3	50.8	135.7
8	N	15	14	15	14	15	12	11
	MEAN	0.0	26.5	74.4	194.3	356.2	743.9	1002.6
	S.D.	0.0	5.2	8.0	21.0	44.4	73.5	179.1

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HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

TABLE 7A

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
COMPOUND CONSUMPTION MEANS AND STANDARD DEVIATIONS (MG/KG/DAY)

STUDY NUMBER: 483287

SEX: -----FEMALE-----								
WEEK	GROUP: DOSE:	1 0	2 25	3 75	4 200	5 350	6 750	7 900
9	N	15	15	15	14	15	15	14
	MEAN	0.0	24.7	73.0	198.8	340.5	693.6	754.7
	S.D.	0.0	2.2	8.6	17.4	57.3	70.2	85.2
10	N	15	15	15	14	15	15	14
	MEAN	0.0	24.8	69.6	176.8	312.8	767.7	811.3
	S.D.	0.0	2.1	5.0	18.1	23.7	78.2	123.3
11	N	13	13	12	13	13	11	4
	MEAN	0.0	23.1	73.1	208.0	354.1	639.3	801.9
	S.D.	0.0	1.8	4.9	13.4	29.4	56.9	89.9
12	N	15	14	15	12	13	15	14
	MEAN	0.0	24.8	80.9	225.3	381.3	813.6	1016.7
	S.D.	0.0	2.4	7.5	47.6	37.7	95.5	127.1
13	N	15	15	15	13	15	15	14
	MEAN	0.0	26.5	78.0	177.2	336.4	777.1	942.9
	S.D.	0.0	2.5	7.5	21.0	53.6	106.1	126.9
1-13	MEAN	0.0	25.1	75.5	199.8	350.7	745.0	897.7

Table 7B
Compound Consumption Means and Standard Deviations - Satellite Study
13-Week Subchronic Oral Toxicity Study of Triclosan in CD-1[®] Mice

Compound Consumption Calculation:

$$\frac{(\text{mg/kg})(\text{Individual Food Consumption})}{7 \text{ Days}} + \frac{\text{Body Weight} + \frac{(\text{BW Change})}{2}}{1000}$$

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

TABLE 7B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY IN TRICLOSAN IN CD-1
MICE. (SATELLITE-GROUPS 8-11)
COMPOUND CONSUMPTION MEANS AND STANDARD DEVIATIONS

STUDY NUMBER: 483287

WEEK	SEX: GROUP: DOSE:	MALE				FEMALE			
		8 0	9 25	10 350	11 900	8 0	9 25	10 350	11 900
1	N	9	10	9	8	7	7	9	7
	MEAN	0.0	23.9	347.1	819.6	0.0	28.8	318.4	868.0
	S.D.	0.0	1.2	34.9	183.5	0.0	4.5	48.3	90.8
2	N	10	10	10	10	9	10	10	9
	MEAN	0.0	22.6	360.3	914.1	0.0	28.1	379.6	790.0
	S.D.	0.0	3.0	25.5	71.2	0.0	1.6	46.5	134.2
3	N	9	10	10	10	10	10	10	10
	MEAN	0.0	24.4	353.2	965.4	0.0	26.8	338.9	821.3
	S.D.	0.0	1.6	37.0	80.5	0.0	2.1	31.9	107.1
4	N	10	10	10	10	10	10	10	10
	MEAN	0.0	26.5	375.7	920.8	0.0	26.8	365.5	809.5
	S.D.	0.0	1.6	34.5	117.8	0.0	1.6	25.2	126.0
5	N	10	10	10	9	7	10	10	10
	MEAN	0.0	26.7	379.0	863.8	0.0	29.2	376.8	815.0
	S.D.	0.0	1.5	19.1	55.2	0.0	1.4	35.0	78.4
6	N	10	10	10	8	10	10	10	9
	MEAN	0.0	26.4	394.0	883.8	0.0	28.4	361.5	817.3
	S.D.	0.0	1.7	35.3	71.0	0.0	1.3	32.8	113.3

Table 8A
Summary of Clinical Hematology Data - Main Study
13-Week Subchronic Oral Toxicity Study of Triclosan in CD-1[®] Mice

TABLE 8A
SUMMARY OF CLINICAL HEMATOLOGY DATA
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1 MICE
MALES

HWA 483287

GROUP	RBC - MI/UL	HGB - G/DL	HCT - %	PLATELET - TH/UL	WBC - TH/UL	NRBC - /100 WBC
	WEEK	WEEK	WEEK	WEEK	WEEK	WEEK
	14 ^a	14 ^a	14 ^a	14	14	14
1 (0 MG/KG)						
MEAN	10.64	17.2	50.3	1623	3.9	0
S.D.	.615	.85	3.05	113.8	.80	.0
N	10	10	10	10	10	10
2 (25 MG/KG)						
MEAN	9.77 *	15.8 *	45.5 *	1614	5.6	0
S.D.	.322	.31	1.47	160.2	1.82	.0
N	10	10	10	10	10	10
3 (75 MG/KG)						
MEAN	9.78 *	15.9 *	46.4 *	1679	5.1	0
S.D.	.558	.46	1.94	229.4	1.52	.0
N	10	10	10	10	10	10
4 (200 MG/KG)						
MEAN	9.05 *	14.5 *	43.4	1589	5.3	0
S.D.	1.289	2.27	6.84	112.3	2.93	.0
N	9	9	9	9	9	9
5 (350 MG/KG)						
MEAN	9.04 *	14.6 *	43.5 *	1615	6.4	0
S.D.	.616	1.02	2.85	187.6	2.71	.0
N	10	10	10	10	10	10
6 (750 MG/KG)						
MEAN	8.65 *	13.6 *	41.1 *	1419	5.6	0
S.D.	.701	1.05	2.89	281.0	2.85	.0
N	10	10	10	10	10	10
7 (900 MG/KG)						
MEAN	7.40 *	11.7 *	35.9 *	1464	4.7	0
S.D.	1.188	1.59	4.72	211.0	2.98	.0
N	10	10	10	10	10	10

* Significantly different from control value, $p \leq 0.05$.

^a A significant trend at $p \leq 0.05$.

TABLE 8A
SUMMARY OF CLINICAL HEMATOLOGY DATA
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1 MICE
MALES

HWA 483287

GROUP	COR WBC - TH/UL		BLAST - TH/UL		PRO/MYEL - TH/UL		META - TH/UL		BAND - TH/UL		SEG - TH/UL	
	WEEK		WEEK		WEEK		WEEK		WEEK		WEEK	
	14		14		14		14		14		14	
1 (0 MG/KG)												
MEAN	3.9		.0		.0		.0		.0		1.0	
S.D.	.80		.00		.00		.00		.00		.42	
N	10		10		10		10		10		10	
2 (25 MG/KG)												
MEAN	5.6		.0		.0		.0		.0		1.8	
S.D.	1.82		.00		.00		.00		.00		.95	
N	10		10		10		10		10		10	
3 (75 MG/KG)												
MEAN	5.1		.0		.0		.0		.0		1.4	
S.D.	1.52		.00		.00		.00		.00		.65	
N	10		10		10		10		10		10	
4 (200 MG/KG)												
MEAN	5.3		.0		.0		.0		.0		1.6	
S.D.	2.93		.00		.00		.00		.00		.64	
N	9		9		9		9		9		9	
5 (350 MG/KG)												
MEAN	6.4		.0		.0		.0		.0		2.4	
S.D.	2.71		.00		.00		.00		.00		2.42	
N	10		10		10		10		10		10	
6 (750 MG/KG)												
MEAN	5.6		.0		.0		.0		.0		2.3	
S.D.	2.85		.00		.00		.00		.00		1.61	
N	10		10		10		10		10		10	
7 (900 MG/KG)												
MEAN	4.7		.0		.0		.0		.0		2.3	
S.D.	2.98		.00		.00		.00		.00		1.39	
N	10		10		10		10		10		10	

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TABLE 8A
SUMMARY OF CLINICAL HEMATOLOGY DATA
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1 MICE
MALES

HWA 483287

GROUP	LYMPH - TH/UL	MONO - TH/UL	EOSIN - TH/UL	BASO - TH/UL
	WEEK	WEEK	WEEK	WEEK
	14	14	14	14
1 (0 MG/KG)				
MEAN	2.8	.0	.0	.0
S.D.	.96	.03	.07	.00
N	10	10	10	10
2 (25 MG/KG)				
MEAN	3.8	.0	.1	.0
S.D.	1.18	.03	.07	.00
N	10	10	10	10
3 (75 MG/KG)				
MEAN	3.6	.0	.0	.0
S.D.	1.16	.07	.03	.00
N	10	10	10	10
4 (200 MG/KG)				
MEAN	3.6	.0	.1	.0
S.D.	2.29	.04	.26	.00
N	9	9	9	9
5 (350 MG/KG)				
MEAN	3.9	.0	.0	.0
S.D.	.97	.00	.07	.03
N	10	10	10	10
6 (750 MG/KG)				
MEAN	3.2	.0	.0	.0
S.D.	1.74	.04	.03	.00
N	10	10	10	10
7 (900 MG/KG)				
MEAN	2.4	.0	.0	.0
S.D.	1.83	.03	.04	.00
N	10	10	10	10

TABLE 8A
SUMMARY OF CLINICAL HEMATOLOGY DATA
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1 MICE
FEMALES

HWA 483287

GROUP	RBC - MI/UL		HGB - G/DL		HCT - %		PLATELET - TH/UL		WBC - TH/UL		NRBC - /100 WBC	
	WEEK		WEEK		WEEK		WEEK		WEEK		WEEK	
	14 ^a		14 ^a		14 ^a		14		14		14	
1 (0 MG/KG)												
MEAN	10.30		17.0		48.4		1484		3.1		0	
S.D.	.487		.77		2.55		180.2		1.75		.0	
N	9		9		9		9		9		9	
2 (25 MG/KG)												
MEAN	9.87		16.4		47.7		1499		4.0		0	
S.D.	.502		.55		1.63		191.4		1.93		.0	
N	10		10		10		10		10		10	
3 (75 MG/KG)												
MEAN	9.36 *		15.2 *		45.1		1505		4.1		0	
S.D.	.439		.90		2.63		182.6		2.87		.0	
N	10		10		10		10		10		10	
4 (200 MG/KG)												
MEAN	9.02 *		15.0 *		45.1		1463		5.2		0	
S.D.	.422		.75		2.80		179.9		1.56		.0	
N	10		10		10		10		10		10	
5 (350 MG/KG)												
MEAN	8.72 *		14.3 *		41.9 *		1422		5.0		0	
S.D.	1.036		1.60		4.60		318.8		3.39		.0	
N	10		10		10		10		10		10	
6 (750 MG/KG)												
MEAN	8.42 *		13.9 *		41.2 *		1433		5.4		0	
S.D.	1.070		1.85		5.15		167.5		2.59		.0	
N	9		9		9		9		9		9	
7 (900 MG/KG)												
MEAN	7.69 *		12.4 *		36.9 *		1432		9.1		0	
S.D.	1.700		2.68		7.12		382.0		9.27		.0	
N	9		9		9		9		9		9	

* Significantly different from control value, $p \leq 0.05$.

^a A significant trend at $p \leq 0.05$.

TABLE 8A
SUMMARY OF CLINICAL HEMATOLOGY DATA
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1 MICE
FEMALES

HWA 483287

GROUP	COR WBC - TH/UL		BLAST - TH/UL		PRO/MYEL - TH/UL		META - TH/UL		BAND - TH/UL		SEG - TH/UL	
	WEEK		WEEK		WEEK		WEEK		WEEK		WEEK	
	14		14		14		14		14		14	
1 (0 MG/KG)												
MEAN	3.1		.0		.0		.0		.0		.8	
S.D.	1.75		.00		.00		.00		.00		.53	
N	9		9		9		9		9		9	
2 (25 MG/KG)												
MEAN	4.0		.0		.0		.0		.0		1.7	
S.D.	1.93		.00		.00		.00		.00		1.04	
N	10		10		10		10		10		10	
3 (75 MG/KG)												
MEAN	4.1		.0		.0		.0		.0		1.9	
S.D.	2.87		.00		.00		.00		.00		1.85	
N	10		10		10		10		10		10	
4 (200 MG/KG)												
MEAN	5.2		.0		.0		.0		.0		1.8	
S.D.	1.56		.00		.00		.00		.00		.65	
N	10		10		10		10		10		10	
5 (350 MG/KG)												
MEAN	5.0		.0		.0		.0		.0		1.8	
S.D.	3.39		.00		.00		.00		.00		1.55	
N	10		10		10		10		10		10	
6 (750 MG/KG)												
MEAN	5.4		.0		.0		.0		.0		3.4*	
S.D.	2.59		.00		.00		.00		.00		2.36	
N	9		9		9		9		9		9	
7 (900 MG/KG)												
MEAN	9.1		.0		.0		.0		.0		6.1*	
S.D.	9.27		.00		.00		.00		.00		7.28	
N	9		9		9		9		9		9	

* Significantly different from control value, $p \leq 0.05$.

TABLE 8A
SUMMARY OF CLINICAL HEMATOLOGY DATA
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1 MICE
FEMALES

HWA 483287

GROUP	LYMPH - TH/UL	MONO - TH/UL	EOSIN - TH/UL	BASO - TH/UL
	WEEK	WEEK	WEEK	WEEK
	14	14	14	14
1 (0 MG/KG)				
MEAN	2.3	.0	.0	.0
S.D.	1.29	.03	.03	.00
N	9	9	9	9
2 (25 MG/KG)				
MEAN	2.3	.0	.0	.0
S.D.	.97	.00	.00	.00
N	10	10	10	10
3 (75 MG/KG)				
MEAN	2.2	.0	.0	.0
S.D.	1.38	.03	.04	.00
N	10	10	10	10
4 (200 MG/KG)				
MEAN	3.4	.0	.0	.0
S.D.	1.18	.00	.05	.00
N	10	10	10	10
5 (350 MG/KG)				
MEAN	3.1	.0	.0	.0
S.D.	2.33	.00	.07	.00
N	10	10	10	10
6 (750 MG/KG)				
MEAN	2.0	.0	.0	.0
S.D.	.72	.03	.00	.00
N	9	9	9	9
7 (900 MG/KG)				
MEAN	3.0	.0	.0	.0
S.D.	2.28	.00	.07	.00
N	9	9	9	9

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Table 8B
Summary of Clinical Hematology Data - Satellite Study
13-Week Subchronic Oral Toxicity Study of Triclosan in CD-1[®] Mice

TABLE 8B
SUMMARY OF CLINICAL HEMATOLOGY DATA
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1 MICE

HWA 483287S

GROUP	RBC - MI/UL		HGB - G/DL		HCT - %		PLATELET - TH/UL		WBC - TH/UL		NRBC - /100 WBC	
	WEEK		WEEK		WEEK		WEEK		WEEK		WEEK	
	-1	7 ^a	-1	7 ^a	-1	7 ^a	-1	7	-1	7	-1	7
MALES												
8 (0 MG/KG)												
MEAN	10.29	10.55	17.8	17.4	51.5	50.1	1763	1536	3.3	4.0	0	0
S.D.	.651	.360	.77	.47	2.73	1.92	281.0	133.0	1.30	1.71	.0	.0
N	10	10	10	10	10	10	10	10	10	10	10	10
9 (25 MG/KG)												
MEAN		10.35		17.2		50.5		1576		3.4		0
S.D.		.487		.76		3.11		177.0		1.67		.0
N		10		10		10		10		10		10
10 (350 MG/KG)												
MEAN		9.52*		15.0*		44.5*		1645		5.7		0
S.D.		.428		.70		2.05		172.6		3.25		.0
N		10		10		10		10		10		10
11 (900 MG/KG)												
MEAN		8.94*		14.2*		43.3*		1579		4.0		0
S.D.		1.195		1.79		5.37		215.3		1.20		.0
N		10		10		10		10		10		10
FEMALES												
8 (0 MG/KG)												
MEAN	10.46	10.47	17.8	18.0	51.0	51.7	1526	1399	3.6	2.4	0	0
S.D.	.639	.418	.80	.78	2.50	3.00	92.6	156.6	1.59	.99	.0	.0
N	7	10	7	10	7	10	7	10	7	10	10	10
9 (25 MG/KG)												
MEAN		10.12		17.0*		49.1		1447		2.7		0
S.D.		.501		.87		2.48		116.1		1.30		.0
N		10		10		10		10		10		10
10 (350 MG/KG)												
MEAN		9.38*		15.5*		45.6*		1509		4.3		0
S.D.		.372		.65		2.05		122.7		3.32		.0
N		10		10		10		10		10		10
11 (900 MG/KG)												
MEAN		9.60*		15.7*		45.8*		1269		7.2*		0
S.D.		.401		.83		2.80		123.1		3.18		.0
N		10		10		10		10		10		10

^a A significant trend at $p \leq 0.05$.

* Significantly different from control value, $p \leq 0.05$.

TABLE 8B
SUMMARY OF CLINICAL HEMATOLOGY DATA
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1 MICE

HWA 483287S

GROUP	COR WBC - TH/UL		BLAST - TH/UL		PRO/MYEL - TH/UL		META - TH/UL		BAND - TH/UL		SEG - TH/UL	
	WEEK		WEEK		WEEK		WEEK		WEEK		WEEK	
	-1	7	-1	7	-1	7	-1	7	-1	7	-1	7
MALES												
8 (0 MG/KG)												
MEAN	3.3	4.0	.0	.0	.0	.0	.0	.0	.0	.0	.6	1.1
S.D.	1.30	1.71	.00	.00	.00	.00	.00	.00	.03	.00	.49	.51
N	10	10	10	10	10	10	10	10	10	10	10	10
9 (25 MG/KG)												
MEAN		3.4		.0		.0		.0		.0		1.3
S.D.		1.67		.00		.00		.00		.00		.93
N		10		10		10		10		10		10
10 (350 MG/KG)												
MEAN		5.7		.0		.0		.0		.0		2.6
S.D.		3.25		.00		.00		.00		.00		2.80
N		10		10		10		10		10		10
11 (900 MG/KG)												
MEAN		4.0		.0		.0		.0		.0		2.3
S.D.		1.20		.00		.00		.00		.00		1.13
N		10		10		10		10		10		10
FEMALES												
8 (0 MG/KG)												
MEAN	3.6	2.4	.0	.0	.0	.0	.0	.0	.0	.0	.8	.9
S.D.	1.59	.99	.00	.00	.00	.00	.00	.00	.00	.00	.54	.68
N	7	10	7	10	7	10	7	10	7	10	7	10
9 (25 MG/KG)												
MEAN		2.7		.0		.0		.0		.0		1.1
S.D.		1.30		.00		.00		.00		.00		.68
N		10		10		10		10		10		10
10 (350 MG/KG)												
MEAN		4.3		.0		.0		.0		.0		1.7
S.D.		3.32		.00		.00		.00		.00		1.63
N		10		10		10		10		10		10
11 (900 MG/KG)												
MEAN		7.2 *		.0		.0		.0		.0		4.3 *
S.D.		3.18		.00		.00		.00		.00		2.78
N		10		10		10		10		10		10

* Significantly different from control value, $p \leq 0.05$.

TABLE 8B
SUMMARY OF CLINICAL HEMATOLOGY DATA
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1 MICE

HWA 483287S

GROUP	LYMPH - TH/UL		MONO - TH/UL		EOSIN - TH/UL		BASO - TH/UL	
	WEEK		WEEK		WEEK		WEEK	
	-1	7	-1	7	-1	7	-1	7
MALES								
8 (0 MG/KG)								
MEAN	2.7	2.8	.0	.0	.0	.1	.0	.0
S.D.	1.06	1.56	.00	.00	.00	.05	.00	.00
N	10	10	10	10	10	10	10	10
9 (25 MG/KG)								
MEAN		2.0		.0		.0		.0
S.D.		.94		.03		.07		.00
N		10		10		10		10
10 (350 MG/KG)								
MEAN		3.0		.0		.1		.0
S.D.		1.24		.04		.09		.00
N		10		10		10		10
11 (900 MG/KG)								
MEAN		1.6		.0		.0		.0
S.D.		.44		.03		.04		.00
N		10		10		10		10
FEMALES								
8 (0 MG/KG)								
MEAN	2.7	1.5	.0	.0	.0	.0	.0	.0
S.D.	1.28	.54	.05	.00	.00	.03	.00	.00
N	7	10	7	10	7	10	7	10
9 (25 MG/KG)								
MEAN		1.6		.0		.0		.0
S.D.		1.00		.00		.06		.00
N		10		10		10		10
10 (350 MG/KG)								
MEAN		2.6		.0		.0		.0
S.D.		1.76		.03		.05		.00
N		10		10		10		10
11 (900 MG/KG)								
MEAN		2.8*		.0		.1		.0
S.D.		.82		.07		.09		.00
N		10		10		10		10

* Significantly different from control value, $p \leq 0.05$.

Table 9A
Summary of Clinical Chemistry Data - Main Study
13-Week Subchronic Oral Toxicity Study of Triclosan in CD-1® Mice

TABLE 9A
SUMMARY OF CLINICAL CHEMISTRY DATA
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1 MICE
MALES

HWA 483287

GROUP	GLUCOSE - MG/DL		BUN - MG/DL		CREAT - MG/DL		T CHOL - MG/DL		AST - U/L		ALT - U/L	
	WEEK		WEEK		WEEK		WEEK		WEEK		WEEK	
	14		14		14		14		14		14	
1 (0 MG/KG)												
MEAN	239		42		.5		113		142		66	
S.D.	63.2		14.8		.11		30.5		27.0		17.8	
N	3		7		5		3		9		9	
2 (25 MG/KG)												
MEAN	210		40		.4		19 *		155		64	
S.D.	53.8		10.0		.08		17.7		60.4		32.7	
N	6		8		8		2		10		10	
3 (75 MG/KG)												
MEAN	195		42		.4		7 *		155		65	
S.D.	34.5		11.3		.10		.0		56.5		33.0	
N	3		4		3		2		8		8	
4 (200 MG/KG)												
MEAN	178		42		.4 *		17 *		210		114	
S.D.	37.7		9.6		.07		11.9		98.5		64.2	
N	9		10		10		7		10		10	
5 (350 MG/KG)												
MEAN	166		36		.4		13 *		271 *		219 *	
S.D.	34.9		6.0		.09		7.1		114.4		169.4	
N	5		7		7		5		9		9	
6 (750 MG/KG)												
MEAN	109 *		42		.4 *		20 *		317		408 *	
S.D.	47.9		10.1		.05		9.4		327.8		753.3	
N	8		10		10		7		10		10	
7 (900 MG/KG)												
MEAN	137 *		52		.3 *		21 *		333 *		226 *	
S.D.	51.1		22.4		.08		13.4		220.0		148.4	
N	5		8		8		4		9		9	

* Significantly different from control value, $p \leq 0.05$.

TABLE 9A
SUMMARY OF CLINICAL CHEMISTRY DATA
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1 MICE
MALES

HWA 483287

GROUP	LDH - U/L		ALK P - U/L		T PROT - G/DL		ALBUMIN - G/DL		GLOBULIN - G/DL		A/G - RATIO	
	WEEK		WEEK		WEEK		WEEK		WEEK		WEEK	
	14		14		14		14		14		14	
1 (0 MG/KG)												
MEAN	1076		59		5.3		3.4		1.9		1.84	
S.D.	188.9		25.5		.15		.26		.15		.298	
N	9		9		3		3		3		3	
2 (25 MG/KG)												
MEAN	1005		83		4.7		3.2		1.5 *		2.16	
S.D.	120.6		46.8		.26		.23		.20		.342	
N	10		10		7		8		7		7	
3 (75 MG/KG)												
MEAN	1052		87		4.8		3.4		1.5 *		2.30	
S.D.	281.9		19.0		.25		.21		.06		.100	
N	8		8		3		3		3		3	
4 (200 MG/KG)												
MEAN	1130		211 *		4.3		2.9		1.5 *		1.95	
S.D.	384.0		190.1		.52		.39		.15		.203	
N	10		10		9		10		9		9	
5 (350 MG/KG)												
MEAN	1290		192 *		4.2		2.9		1.3 *		2.30	
S.D.	206.5		145.3		.53		.60		.12		.630	
N	9		9		5		5		5		5	
6 (750 MG/KG)												
MEAN	1447		258 *		4.6		3.4		1.4 *		2.44	
S.D.	871.1		236.5		.52		.61		.24		.565	
N	10		10		8		9		8		8	
7 (900 MG/KG)												
MEAN	1300		170 *		4.5		3.2		1.4 *		2.23	
S.D.	414.8		75.6		.63		.53		.16		.198	
N	9		9		5		6		5		5	

* Significantly different from control value, $p \leq 0.05$.

TABLE 9A
SUMMARY OF CLINICAL CHEMISTRY DATA
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1 MICE
MALES

HWA 483287

GROUP	T BILI - MG/DL		TRIGLY - MG/DL		GGT - U/L	
	WEEK		WEEK		WEEK	
	14		14		14	
1 (0 MG/KG)						
MEAN	.2		44		0	
S.D.	.05		5.1		.4	
N	7		3		7	
2 (25 MG/KG)						
MEAN	.1		24		0	
S.D.	.05		.0		.0	
N	9		1		9	
3 (75 MG/KG)						
MEAN	.2		42		0	
S.D.	.05		3.5		.0	
N	6		2		5	
4 (200 MG/KG)						
MEAN	.1		43		0	
S.D.	.06		12.0		.0	
N	10		6		10	
5 (350 MG/KG)						
MEAN	.1		42		0	
S.D.	.08		11.2		.0	
N	8		5		7	
6 (750 MG/KG)						
MEAN	.1 *		50		1	
S.D.	.05		30.0		1.0	
N	10		6		10	
7 (900 MG/KG)						
MEAN	.1		64		1	
S.D.	.06		33.9		1.4	
N	8		3		8	

* Significantly different from control value, $p \leq 0.05$.

TABLE 9A
SUMMARY OF CLINICAL CHEMISTRY DATA
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1 MICE
FEMALES

HWA 483287

GROUP	GLUCOSE - MG/DL		BUN - MG/DL		CREAT - MG/DL		T CHOL - MG/DL		AST - U/L		ALT - U/L	
	WEEK		WEEK		WEEK		WEEK		WEEK		WEEK	
	14		14		14		14		14		14	
1 (0 MG/KG)												
MEAN	204		32		.4		93		365		79	
S.D.	67.9		7.8		.10		31.8		454.7		43.6	
N	3		6		5		2		10		10	
2 (25 MG/KG)												
MEAN	196		33		.4		11 *		257		63	
S.D.	19.8		9.7		.04		3.2		116.2		16.8	
N	4		8		7		3		9		9	
3 (75 MG/KG)												
MEAN	157		33		.3		13 *		235		83	
S.D.	33.4		8.6		.08		9.2		134.8		46.5	
N	6		9		7		2		9		9	
4 (200 MG/KG)												
MEAN	156		39		.3		12 *		246		105	
S.D.	48.3		9.3		.08		6.1		128.8		56.3	
N	5		6		6		3		10		10	
5 (350 MG/KG)												
MEAN	163		37		.3		15 *		203		99	
S.D.	22.9		8.5		.05		7.1		60.0		42.8	
N	6		6		6		5		8		8	
6 (750 MG/KG)												
MEAN	148		48		.3		14 *		559		247 *	
S.D.	27.1		13.2		.05		6.5		521.4		118.1	
N	4		6		6		3		9		9	
7 (900 MG/KG)												
MEAN	127		59 *		.3		26 *		550		216 *	
S.D.	80.9		16.0		.10		14.2		753.2		116.4	
N	4		8		8		4		10		10	

* Significantly different from control value, $p \leq 0.05$.

TABLE 9A
SUMMARY OF CLINICAL CHEMISTRY DATA
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1 MICE
FEMALES

HWA 483287

GROUP	LDH - U/L	ALK P - U/L	T PROT - G/DL	ALBUMIN - G/DL	GLOBULIN - G/DL	A/G - RATIO
	WEEK	WEEK	WEEK	WEEK	WEEK	WEEK
	14	14	14	14	14	14
1 (0 MG/KG)						
MEAN	1242	71	5.0	3.4	1.5	2.24
S.D.	973.3	15.1	.50	.36	.13	.137
N	10	10	4	5	4	4
2 (25 MG/KG)						
MEAN	1157	112*	4.5	3.3	1.3	2.42
S.D.	426.6	35.2	.29	.31	.05	.234
N	9	9	4	6	4	4
3 (75 MG/KG)						
MEAN	1019	127*	4.5	3.2	1.3	2.41
S.D.	387.5	36.2	.47	.37	.20	.403
N	9	9	7	8	7	7
4 (200 MG/KG)						
MEAN	1096	122*	4.2	3.0	1.2	2.65
S.D.	358.1	27.2	.21	.19	.15	.409
N	10	10	6	6	6	6
5 (350 MG/KG)						
MEAN	1027	131*	4.4	3.2	1.3	2.55
S.D.	387.8	22.9	.35	.22	.27	.526
N	8	8	6	6	6	6
6 (750 MG/KG)						
MEAN	1894	119*	3.9	2.9	1.0	2.77
S.D.	1616.3	36.3	.74	.45	.24	.475
N	9	9	4	6	4	4
7 (900 MG/KG)						
MEAN	2633	176*	4.3	3.1	1.3	2.34
S.D.	3765.7	93.6	.78	.57	.28	.533
N	10	10	5	7	5	5

* Significantly different from control value, $p \leq 0.05$.

TABLE 9A
SUMMARY OF CLINICAL CHEMISTRY DATA
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1 MICE
FEMALES

HWA 483287

GROUP	T BILI - MG/DL		TRIGLY - MG/DL		GGT - U/L	
	WEEK		WEEK		WEEK	
	14		14		14	
1 (0 MG/KG)						
MEAN	.2		43		0	
S.D.	.07		10.6		.4	
N	9		2		8	
2 (25 MG/KG)						
MEAN	.2		45		0	
S.D.	.05		20.7		.0	
N	9		3		8	
3 (75 MG/KG)						
MEAN	.1		21		0	
S.D.	.07		4.6		.0	
N	9		3		9	
4 (200 MG/KG)						
MEAN	.1		44		0	
S.D.	.08		19.9		.5	
N	8		3		7	
5 (350 MG/KG)						
MEAN	.1		53		0	
S.D.	.05		46.8		.0	
N	6		5		6	
6 (750 MG/KG)						
MEAN	.1		33		4	
S.D.	.06		12.9		10.5	
N	7		3		7	
7 (900 MG/KG)						
MEAN	.1		38		2	
S.D.	.07		45.6		2.3	
N	10		4		9	

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Table 9B
Summary of Clinical Chemistry Data - Satellite Study
13-Week Subchronic Oral Toxicity Study of Triclosan in CD-1® Mice

TABLE 9B
SUMMARY OF CLINICAL CHEMISTRY DATA
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1 MICE

HWA 483287S

GROUP	GLUCOSE - MG/DL		BUN - MG/DL		CREAT - MG/DL		T CHOL - MG/DL		AST - U/L		ALT - U/L	
	WEEK		WEEK		WEEK		WEEK		WEEK		WEEK	
	-1	7	-1	7	-1	7	-1	7	-1	7	-1	7
MALES												
8 (0 MG/KG)												
MEAN	96	273	49	40	.5	.4	173	103	223	209	53	49
S.D.	30.4	46.6	39.1	8.7	.05	.05	1.4	17.1	181.9	65.6	28.1	12.9
N	2	7	4	7	4	7	2	5	9	8	9	8
9 (25 MG/KG)												
MEAN		273		44		.4		47 *		195		49
S.D.		83.7		8.8		.08		27.1		60.2		11.6
N		5		7		6		4		8		8
10 (350 MG/KG)												
MEAN		212		40		.4		15 *		204		111 *
S.D.		47.0		7.1		.00		5.4		79.5		43.1
N		8		9		9		6		10		10
11 (900 MG/KG)												
MEAN		155 *		61 *		.4		15 *		356		334 *
S.D.		73.1		15.1		.05		8.5		351.7		446.5
N		5		8		8		2		10		9
FEMALES												
8 (0 MG/KG)												
MEAN	0	233	0	35	.0	.4	0	48	330	266	60	53
S.D.	.0	27.9	.0	6.9	.00	.04	.0	13.4	150.6	81.4	20.7	6.6
N	0	4	0	6	0	6	0	4	9	9	5	9
9 (25 MG/KG)												
MEAN		242		44		.4		15		256		58
S.D.		39.5		23.2		.06		.0		71.4		21.0
N		3		4		3		1		9		9
10 (350 MG/KG)												
MEAN		222		41		.4		19 *		258		93 *
S.D.		59.1		19.0		.04		9.2		91.7		32.4
N		7		7		7		7		10		10
11 (900 MG/KG)												
MEAN		182		52		.4		22 *		329		214 *
S.D.		55.5		11.3		.00		10.0		163.5		206.2
N		4		6		5		3		10		10

* Significantly different from control value, $p \leq 0.05$.

TABLE 9B
SUMMARY OF CLINICAL CHEMISTRY DATA
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1 MICE

HWA 483287S

GROUP	LDH - U/L		ALK P - U/L		T PROT - G/DL		ALBUMIN - G/DL		GLOBULIN - G/DL		A/G - RATIO	
	WEEK		WEEK		WEEK		WEEK		WEEK		WEEK	
	-1	7	-1	7	-1	7	-1	7	-1	7	-1	7
MALES												
8 (0 MG/KG)												
MEAN	822	937	170	72	6.1	5.2	4.3	3.3	1.8	1.8	2.40	1.84
S.D.	414.0	402.6	26.2	15.4	.07	.21	.35	.20	.20	.14	.573	.197
N	9	8	9	8	2	7	2	7	2	7	2	7
9 (25 MG/KG)												
MEAN		792		71		4.9		3.2		1.7		1.92
S.D.		207.2		12.3		.50		.35		.22		.219
N		8		8		6		6		6		6
10 (350 MG/KG)												
MEAN		1124		227 *		4.3 *		2.8		1.4 *		2.01
S.D.		643.3		223.5		.63		.44		.23		.229
N		10		9		9		9		9		9
11 (900 MG/KG)												
MEAN		1464		213 *		5.3		3.8		1.4 *		2.79 *
S.D.		1070.8		111.3		.56		.61		.22		.371
N		9		9		5		8		5		5
FEMALES												
8 (0 MG/KG)												
MEAN	651	1208	180	104	.0	4.9	.0	3.6	.0	1.5	.00	2.43
S.D.	191.7	306.0	79.9	4.5	.00	.37	.00	.29	.00	.17	.000	.203
N	3	8	2	6	0	4	0	6	0	4	0	4
9 (25 MG/KG)												
MEAN		1157		145 *		4.7		3.5		1.2		2.82
S.D.		426.9		27.3		.10		.15		.06		.246
N		8		7		3		3		3		3
10 (350 MG/KG)												
MEAN		1081		150		4.3		3.1		1.1		2.95
S.D.		614.0		83.3		.53		.29		.29		.642
N		9		9		7		7		7		7
11 (900 MG/KG)												
MEAN		1383		236 *		4.4		3.4		1.1		2.91
S.D.		427.7		140.5		.55		.52		.05		.464
N		10		10		4		5		4		4

* Significantly different from control value, $p \leq 0.05$.

TABLE 9B
SUMMARY OF CLINICAL CHEMISTRY DATA
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1 MICE

HWA 483287S

GROUP	T BILI - MG/DL		TRIGLY - MG/DL		GGT - U/L	
	WEEK		WEEK		WEEK	
	-1	7	-1	7	-1	7
MALES						
8 (0 MG/KG)						
MEAN	.2	.2	52	48	0	0
S.D.	.05	.04	.0	7.9	.0	.5
N	8	8	1	5	8	8
9 (25 MG/KG)						
MEAN		.1		65		0
S.D.		.05		24.5		.5
N		7		3		7
10 (350 MG/KG)						
MEAN		.1		42		0
S.D.		.05		11.3		.3
N		9		5		9
11 (900 MG/KG)						
MEAN		.1 *		30		3 *
S.D.		.05		.0		2.9
N		8		1		8
FEMALES						
8 (0 MG/KG)						
MEAN	.3	.2	0	28	0	0
S.D.	.00	.05	.0	8.5	.0	.4
N	1	6	0	3	1	6
9 (25 MG/KG)						
MEAN		.1		17		0
S.D.		.05		.0		.4
N		6		1		6
10 (350 MG/KG)						
MEAN		.1		44		0
S.D.		.03		24.7		.5
N		9		7		9
11 (900 MG/KG)						
MEAN		.1		35		2
S.D.		.05		4.4		4.2
N		9		3		9

* Significantly different from control value, $p \leq 0.05$.

Table 9C
Summary of Clinical Chemistry Data - Extra Animals
13-Week Subchronic Oral Toxicity Study of Triclosan in CD-1[®] Mice

TABLE 9C
SUMMARY OF CLINICAL CHEMISTRY DATA
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1 MICE

HWA 483287A

	GLUCOSE - MG/DL	BUN - MG/DL	CREAT - MG/DL	T CHOL - MG/DL	AST - U/L	ALT - U/L
	WEEK	WEEK	WEEK	WEEK	WEEK	WEEK
	-1	-1	-1	-1	-1	-1
MALES						
MEAN	194	33	.5	133	114	34
S.D.	78.7	8.6	.07	30.4	53.3	9.9
N	7	8	7	6	8	8
FEMALES						
MEAN	190	39	.5	94	178	39
S.D.	9.2	7.4	.05	2.8	46.3	8.6
N	2	7	7	2	7	7

TABLE 9C
SUMMARY OF CLINICAL CHEMISTRY DATA
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1 MICE

HWA 483287A

	T BILI - MG/DL	TRIGLY - MG/DL	GCT - U/L
	WEEK	WEEK	WEEK
	-1	-1	-1
MALES			
MEAN	.1	31	0
S.D.	.05	12.9	.0
N	8	5	8
FEMALES			
MEAN	.2	26	0
S.D.	.05	.0	.0
N	7	1	7

TABLE 9C
SUMMARY OF CLINICAL CHEMISTRY DATA
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1 MICE

HWA 483287A

	LDH - U/L	ALK P - U/L	T PROT - G/DL	ALBUMIN - G/DL	GLOBULIN - G/DL	A/G - RATIO
	WEEK	WEEK	WEEK	WEEK	WEEK	WEEK
	-1	-1	-1	-1	-1	-1
MALES						
MEAN	925	153	5.2	3.5	1.7	2.03
S.D.	562.4	48.4	.17	.16	.10	.165
N	8	8	7	7	7	7
FEMALES						
MEAN	1273	151	5.4	4.0	1.5	2.71
S.D.	623.8	28.4	.33	.17	.17	.231
N	7	7	4	5	4	4

Table 10A
Gross Pathology Incidence Summary - Main Study (Unscheduled Deaths)
13-Week Subchronic Oral Toxicity Study of Triclosan in CD-1[®] Mice

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

TABLE 10A
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
GROSS PATHOLOGY INCIDENCE SUMMARY

STUDY NUMBER: 483287

TABLE INCLUDES:
SEX=ALL;GROUP=ALL;WEEKS=ALL
DEATH=UNSCHEG;SUBSET=T

--- NUMBER - OF - ANIMALS - AFFECTED ---

SEX=ALL;GROUP=ALL;WEEKS=ALL DEATH=UNSCHEG;SUBSET=T		SEX: -----MALE-----						
		GROUP: -1-	-2-	-3-	-4-	-5-	-6-	-7-
ORGAN AND KEYWORD(S) OR PHRASE	NUMBER:	0	0	0	2	0	0	2
-----		==	==	==	==	==	==	==
** TOP OF LIST **								
BRAIN W/STEM (BR)	NUMBER EXAMINED:	0	0	0	2	0	0	2
	NOT REMARKABLE:	0	0	0	2	0	0	2
CORD, CERVICAL (CS)	NUMBER EXAMINED:	0	0	0	2	0	0	2
	NOT REMARKABLE:	0	0	0	2	0	0	2
CORD, THORACIC (TC)	NUMBER EXAMINED:	0	0	0	2	0	0	2
	NOT REMARKABLE:	0	0	0	2	0	0	2
CORD, LUMBAR (LC)	NUMBER EXAMINED:	0	0	0	2	0	0	2
	NOT REMARKABLE:	0	0	0	2	0	0	2
PITUITARY (PI)	NUMBER EXAMINED:	0	0	0	2	0	0	2
	NOT REMARKABLE:	0	0	0	2	0	0	2
ADRENAL, CORTEX (AC)	NUMBER EXAMINED:	0	0	0	2	0	0	2
	NOT REMARKABLE:	0	0	0	2	0	0	2
ADRENAL, MEDULLA (AM)	NUMBER EXAMINED:	0	0	0	2	0	0	2
	NOT REMARKABLE:	0	0	0	2	0	0	2
THYROID (TY)	NUMBER EXAMINED:	0	0	0	2	0	0	2
	NOT REMARKABLE:	0	0	0	2	0	0	2

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)

GROSS PATHOLOGY INCIDENCE SUMMARY

STUDY NUMBER: 483287

TABLE INCLUDES:

SEX=ALL; GROUP=ALL; WEEKS=ALL
DEATH=UNSCHED; SUBSET=T

--- NUMBER - OF - ANIMALS - AFFECTED ---

SEX: -----MALE-----

GROUP: -1- -2- -3- -4- -5- -6- -7-

ORGAN AND KEYWORD(S) OR PHRASE	NUMBER:	0	0	0	2	0	0	2
		-=-	-=-	-=-	-=-	-=-	-=-	-=-
PARATHYROID (PT)	NUMBER EXAMINED:	0	0	0	2	0	0	2
	NOT REMARKABLE:	0	0	0	2	0	0	2
ESOPHAGUS (ES)	NUMBER EXAMINED:	0	0	0	2	0	0	2
	NOT REMARKABLE:	0	0	0	2	0	0	2
TRACHEA (TR)	NUMBER EXAMINED:	0	0	0	2	0	0	2
	NOT REMARKABLE:	0	0	0	2	0	0	2
LUNG (LU)	NUMBER EXAMINED:	0	0	0	2	0	0	2
	NOT REMARKABLE:	0	0	0	2	0	0	2
HEART (HT)	NUMBER EXAMINED:	0	0	0	2	0	0	2
	NOT REMARKABLE:	0	0	0	2	0	0	2
SPLEEN (SP)	NUMBER EXAMINED:	0	0	0	2	0	0	2
	NOT REMARKABLE:	0	0	0	2	0	0	1
PALE		0	0	0	0	0	0	1
LIVER (LI)	NUMBER EXAMINED:	0	0	0	2	0	0	2
	NOT REMARKABLE:	0	0	0	1	0	0	0
PALE AREA		0	0	0	0	0	0	2
LOBE, THICKENED		0	0	0	0	0	0	1
ENLARGED		0	0	0	1	0	0	0

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

TABLE 10A
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
GROSS PATHOLOGY INCIDENCE SUMMARY

STUDY NUMBER: 483287

TABLE INCLUDES:
SEX=ALL;GROUP=ALL;WEEKS=ALL
DEATH=UNSCHEG;SUBSET=T

--- NUMBER - OF - ANIMALS - AFFECTED ---

SEX: -----MALE-----

GROUP: -1- -2- -3- -4- -5- -6- -7-

ORGAN AND KEYWORD(S) OR PHRASE	NUMBER:	0	0	0	2	0	0	2
		--	--	--	--	--	--	--
GALLBLADDER (GB)	NUMBER EXAMINED:	0	0	0	2	0	0	2
	NOT REMARKABLE:	0	0	0	2	0	0	2
KIDNEY (KD)	NUMBER EXAMINED:	0	0	0	2	0	0	2
	NOT REMARKABLE:	0	0	0	2	0	0	2
STOMACH, NONGL (SU)	NUMBER EXAMINED:	0	0	0	2	0	0	2
	NOT REMARKABLE:	0	0	0	2	0	0	2
STOMACH, GL (ST)	NUMBER EXAMINED:	0	0	0	2	0	0	2
	NOT REMARKABLE:	0	0	0	2	0	0	1
DARK AREA		0	0	0	0	0	0	1
DUODENUM (DU)	NUMBER EXAMINED:	0	0	0	2	0	0	2
	NOT REMARKABLE:	0	0	0	2	0	0	2
JEJUNUM (JE)	NUMBER EXAMINED:	0	0	0	2	0	0	2
	NOT REMARKABLE:	0	0	0	2	0	0	2
ILEUM (IL)	NUMBER EXAMINED:	0	0	0	2	0	0	2
	NOT REMARKABLE:	0	0	0	2	0	0	2
PANCREAS (PA)	NUMBER EXAMINED:	0	0	0	2	0	0	2
	NOT REMARKABLE:	0	0	0	2	0	0	2

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HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

TABLE 10A
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
GROSS PATHOLOGY INCIDENCE SUMMARY

STUDY NUMBER: 483287

TABLE INCLUDES:
SEX=ALL;GROUP=ALL;WEEKS=ALL
DEATH=UNSCHED;SUBSET=T

--- NUMBER - OF - ANIMALS - AFFECTED ---

SEX: -----MALE-----

GROUP: -1- -2- -3- -4- -5- -6- -7-

ORGAN AND KEYWORD(S) OR PHRASE	NUMBER:	0	0	0	2	0	0	2
		--	--	--	--	--	--	--
CECUM (CE)	NUMBER EXAMINED:	0	0	0	2	0	0	2
	NOT REMARKABLE:	0	0	0	2	0	0	2
COLON (CO)	NUMBER EXAMINED:	0	0	0	2	0	0	2
	NOT REMARKABLE:	0	0	0	2	0	0	2
RECTUM (RE)	NUMBER EXAMINED:	0	0	0	2	0	0	2
	NOT REMARKABLE:	0	0	0	2	0	0	2
LN, MESENTERIC (MS)	NUMBER EXAMINED:	0	0	0	2	0	0	2
	NOT REMARKABLE:	0	0	0	2	0	0	2
TESTIS (TE)	NUMBER EXAMINED:	0	0	0	2	0	0	2
	NOT REMARKABLE:	0	0	0	2	0	0	2
EPIDIDYMIS (EP)	NUMBER EXAMINED:	0	0	0	2	0	0	2
	NOT REMARKABLE:	0	0	0	2	0	0	2
PROSTATE (PR)	NUMBER EXAMINED:	0	0	0	2	0	0	2
	NOT REMARKABLE:	0	0	0	2	0	0	2
URINARY BLADDER (UB)	NUMBER EXAMINED:	0	0	0	2	0	0	2
	NOT REMARKABLE:	0	0	0	2	0	0	2

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

TABLE 10A
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
GROSS PATHOLOGY INCIDENCE SUMMARY

STUDY NUMBER: 483287

TABLE INCLUDES:
SEX=ALL;GROUP=ALL;WEEKS=ALL
DEATH=UNSCHED;SUBSET=T

--- NUMBER - OF - ANIMALS - AFFECTED ---

SEX: -----MALE-----

GROUP: -1- -2- -3- -4- -5- -6- -7-

ORGAN AND KEYWORD(S) OR PHRASE	NUMBER:	0	0	0	2	0	0	2
		--	--	--	--	--	--	--
OVARY (OV)	NUMBER EXAMINED:	0	0	0	0	0	0	0
	NOT REMARKABLE:	0	0	0	0	0	0	0
UTERUS (UT)	NUMBER EXAMINED:	0	0	0	0	0	0	0
	NOT REMARKABLE:	0	0	0	0	0	0	0
UTERUS, CERVIX (CV)	NUMBER EXAMINED:	0	0	0	0	0	0	0
	NOT REMARKABLE:	0	0	0	0	0	0	0
VAGINA (VA)	NUMBER EXAMINED:	0	0	0	0	0	0	0
	NOT REMARKABLE:	0	0	0	0	0	0	0
LN, MANDIBULAR (MN)	NUMBER EXAMINED:	0	0	0	2	0	0	2
	NOT REMARKABLE:	0	0	0	2	0	0	2
MAND SALIVARY GL (SG)	NUMBER EXAMINED:	0	0	0	2	0	0	2
	NOT REMARKABLE:	0	0	0	2	0	0	2
THYMUS (TH)	NUMBER EXAMINED:	0	0	0	2	0	0	2
	NOT REMARKABLE:	0	0	0	2	0	0	2
AORTA, THORACIC (AO)	NUMBER EXAMINED:	0	0	0	2	0	0	2
	NOT REMARKABLE:	0	0	0	2	0	0	2

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HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

TABLE 10A

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)

GROSS PATHOLOGY INCIDENCE SUMMARY

STUDY NUMBER: 483287

TABLE INCLUDES:

SEX=ALL; GROUP=ALL; WEEKS=ALL
DEATH=UNSCHED; SUBSET=T

--- NUMBER - OF - ANIMALS - AFFECTED ---

SEX: -----MALE-----

GROUP: -1- -2- -3- -4- -5- -6- -7-

ORGAN AND KEYWORD(S) OR PHRASE

NUMBER: 0 0 0 2 0 0 2

EYE (EY)	NUMBER EXAMINED:	0	0	0	2	0	0	2
	NOT REMARKABLE:	0	0	0	1	0	0	2
EXOPHTHALMUS		0	0	0	1	0	0	0
NERVE, OPTIC (ON)	NUMBER EXAMINED:	0	0	0	2	0	0	2
	NOT REMARKABLE:	0	0	0	2	0	0	2
LACRIMAL GL, EX (EO)	NUMBER EXAMINED:	0	0	0	2	0	0	2
	NOT REMARKABLE:	0	0	0	2	0	0	2
MUSCLE, SKELETAL (SM)	NUMBER EXAMINED:	0	0	0	2	0	0	2
	NOT REMARKABLE:	0	0	0	2	0	0	2
NERVE, SCIATIC (SN)	NUMBER EXAMINED:	0	0	0	2	0	0	2
	NOT REMARKABLE:	0	0	0	2	0	0	2
SKIN (SK)	NUMBER EXAMINED:	0	0	0	2	0	0	2
	NOT REMARKABLE:	0	0	0	2	0	0	2
MAMMARY, FEMALE (MF)	NUMBER EXAMINED:	0	0	0	0	0	0	0
	NOT REMARKABLE:	0	0	0	0	0	0	0
MARROW, STERNUM (SE)	NUMBER EXAMINED:	0	0	0	2	0	0	2
	NOT REMARKABLE:	0	0	0	2	0	0	2

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HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

TABLE 10A

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)

GROSS PATHOLOGY INCIDENCE SUMMARY

STUDY NUMBER: 483287

TABLE INCLUDES:

SEX=ALL;GROUP=ALL;WEEKS=ALL
DEATH=UNSCHED;SUBSET=T

--- NUMBER - OF - ANIMALS - AFFECTED ---

SEX: -----MALE-----

GROUP: -1- -2- -3- -4- -5- -6- -7-

ORGAN AND KEYWORD(S) OR PHRASE

NUMBER: 0 0 0 2 0 0 2

MARROW, FEMUR (FM) NUMBER EXAMINED: 0 0 0 2 0 0 2
NOT REMARKABLE: 0 0 0 2 0 0 2

BONE, FEMUR (FE) NUMBER EXAMINED: 0 0 0 2 0 0 2
NOT REMARKABLE: 0 0 0 2 0 0 2

TONGUE (TO) NUMBER EXAMINED: 0 0 0 2 0 0 2
NOT REMARKABLE: 0 0 0 2 0 0 2

SKIN, OTHER (SS) NUMBER EXAMINED: 0 0 0 2 0 0 2
NOT REMARKABLE: 0 0 0 2 0 0 1

ALOPECIA 0 0 0 0 0 0 1

BONE, OTHER (OB) NUMBER EXAMINED: 0 0 0 2 0 0 2
NOT REMARKABLE: 0 0 0 1 0 0 2

FRACTURED 0 0 0 1 0 0 0
** END OF LIST **

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HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

TABLE 10A
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
GROSS PATHOLOGY INCIDENCE SUMMARY

STUDY NUMBER: 483287

TABLE INCLUDES:
SEX=ALL; GROUP=ALL; WEEKS=ALL
DEATH=UNSCHED; SUBSET=T

--- NUMBER - OF - ANIMALS - AFFECTED ---

SEX: ----- FEMALE -----

GROUP: -1- -2- -3- -4- -5- -6- -7-

ORGAN AND KEYWORD(S) OR PHRASE	NUMBER:	0	0	0	1	0	0	1
		--	--	--	--	--	--	--
** TOP OF LIST **								
BRAIN W/STEM (BR)	NUMBER EXAMINED:	0	0	0	1	0	0	1
	NOT REMARKABLE:	0	0	0	1	0	0	1
CORD, CERVICAL (CS)	NUMBER EXAMINED:	0	0	0	1	0	0	1
	NOT REMARKABLE:	0	0	0	1	0	0	1
CORD, THORACIC (TC)	NUMBER EXAMINED:	0	0	0	1	0	0	1
	NOT REMARKABLE:	0	0	0	1	0	0	1
CORD, LUMBAR (LC)	NUMBER EXAMINED:	0	0	0	1	0	0	1
	NOT REMARKABLE:	0	0	0	1	0	0	1
PITUITARY (PI)	NUMBER EXAMINED:	0	0	0	1	0	0	1
	NOT REMARKABLE:	0	0	0	1	0	0	1
ADRENAL, CORTEX (AC)	NUMBER EXAMINED:	0	0	0	1	0	0	1
	NOT REMARKABLE:	0	0	0	1	0	0	1
ADRENAL, MEDULLA (AM)	NUMBER EXAMINED:	0	0	0	1	0	0	1
	NOT REMARKABLE:	0	0	0	1	0	0	1
THYROID (TY)	NUMBER EXAMINED:	0	0	0	1	0	0	1
	NOT REMARKABLE:	0	0	0	1	0	0	1

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HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

TABLE 10A
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
GROSS PATHOLOGY INCIDENCE SUMMARY

STUDY NUMBER: 483287

TABLE INCLUDES:
SEX=ALL;GROUP=ALL;WEEKS=ALL
DEATH=UNSCHED;SUBSET=T

--- NUMBER - OF - ANIMALS - AFFECTED ---

SEX: -----FEMALE-----

GROUP: -1- -2- -3- -4- -5- -6- -7-

ORGAN AND KEYWORD(S) OR PHRASE

NUMBER: 0 0 0 1 0 0 1

PARATHYROID (PT) NUMBER EXAMINED: 0 0 0 1 0 0 1
NOT REMARKABLE: 0 0 0 1 0 0 1

ESOPHAGUS (ES) NUMBER EXAMINED: 0 0 0 1 0 0 1
NOT REMARKABLE: 0 0 0 1 0 0 1

TRACHEA (TR) NUMBER EXAMINED: 0 0 0 1 0 0 1
NOT REMARKABLE: 0 0 0 1 0 0 1

LUNG (LU) NUMBER EXAMINED: 0 0 0 1 0 0 1
NOT REMARKABLE: 0 0 0 1 0 0 1

HEART (HT) NUMBER EXAMINED: 0 0 0 1 0 0 1
NOT REMARKABLE: 0 0 0 1 0 0 1

SPLEEN (SP) NUMBER EXAMINED: 0 0 0 1 0 0 1
NOT REMARKABLE: 0 0 0 1 0 0 1

LIVER (LI) NUMBER EXAMINED: 0 0 0 1 0 0 1
NOT REMARKABLE: 0 0 0 0 0 0 1

ENLARGED 0 0 0 1 0 0 0

GALLBLADDER (GB) NUMBER EXAMINED: 0 0 0 1 0 0 1
NOT REMARKABLE: 0 0 0 1 0 0 1

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

TABLE 10A
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
GROSS PATHOLOGY INCIDENCE SUMMARY

STUDY NUMBER: 483287

TABLE INCLUDES:

SEX=ALL;GROUP=ALL;WEEKS=ALL
DEATH=UNSCHED;SUBSET=T

--- NUMBER - OF - ANIMALS - AFFECTED ---

SEX: -----FEMALE-----

GROUP: -1- -2- -3- -4- -5- -6- -7-

ORGAN AND KEYWORD(S) OR PHRASE

NUMBER: 0 0 0 1 0 0 1

KIDNEY (KD) NUMBER EXAMINED: 0 0 0 1 0 0 1
NOT REMARKABLE: 0 0 0 1 0 0 1

STOMACH, NONGL (SU) NUMBER EXAMINED: 0 0 0 1 0 0 1
NOT REMARKABLE: 0 0 0 1 0 0 1

STOMACH, GL (ST) NUMBER EXAMINED: 0 0 0 1 0 0 1
NOT REMARKABLE: 0 0 0 1 0 0 0

MUCOSA, SMOOTH 0 0 0 0 0 0 1

DUODENUM (DU) NUMBER EXAMINED: 0 0 0 1 0 0 1
NOT REMARKABLE: 0 0 0 1 0 0 1

JEJUNUM (JE) NUMBER EXAMINED: 0 0 0 1 0 0 1
NOT REMARKABLE: 0 0 0 1 0 0 1

ILEUM (IL) NUMBER EXAMINED: 0 0 0 1 0 0 1
NOT REMARKABLE: 0 0 0 1 0 0 1

PANCREAS (PA) NUMBER EXAMINED: 0 0 0 1 0 0 1
NOT REMARKABLE: 0 0 0 1 0 0 1

CECUM (CE) NUMBER EXAMINED: 0 0 0 1 0 0 1
NOT REMARKABLE: 0 0 0 1 0 0 1

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

TABLE 10A

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)

GROSS PATHOLOGY INCIDENCE SUMMARY

STUDY NUMBER: 483287

TABLE INCLUDES:

SEX=ALL;GROUP=ALL;WEEKS=ALL
DEATH=UNSCHEDED;SUBSET=T

--- NUMBER - OF - ANIMALS - AFFECTED ---

SEX: -----FEMALE-----

GROUP: -1- -2- -3- -4- -5- -6- -7-

ORGAN AND KEYWORD(S) OR PHRASE

NUMBER: 0 0 0 1 0 0 1

COLON (CO) NUMBER EXAMINED: 0 0 0 1 0 0 1
NOT REMARKABLE: 0 0 0 1 0 0 1

RECTUM (RE) NUMBER EXAMINED: 0 0 0 1 0 0 1
NOT REMARKABLE: 0 0 0 1 0 0 1

LN, MESENTERIC (MS) NUMBER EXAMINED: 0 0 0 1 0 0 1
NOT REMARKABLE: 0 0 0 1 0 0 1

TESTIS (TE) NUMBER EXAMINED: 0 0 0 0 0 0 0
NOT REMARKABLE: 0 0 0 0 0 0 0

EPIDIDYMIS (EP) NUMBER EXAMINED: 0 0 0 0 0 0 0
NOT REMARKABLE: 0 0 0 0 0 0 0

PROSTATE (PR) NUMBER EXAMINED: 0 0 0 0 0 0 0
NOT REMARKABLE: 0 0 0 0 0 0 0

URINARY BLADDER (UB) NUMBER EXAMINED: 0 0 0 1 0 0 1
NOT REMARKABLE: 0 0 0 1 0 0 1

OVARY (OV) NUMBER EXAMINED: 0 0 0 1 0 0 1
NOT REMARKABLE: 0 0 0 1 0 0 1

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

TABLE 10A

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)

GROSS PATHOLOGY INCIDENCE SUMMARY

STUDY NUMBER: 483287

TABLE INCLUDES:

SEX=ALL;GROUP=ALL;WEEKS=ALL
DEATH=UNSCHED;SUBSET=T

--- NUMBER - OF - ANIMALS - AFFECTED ---

SEX: -----FEMALE-----

GROUP: -1- -2- -3- -4- -5- -6- -7-

ORGAN AND KEYWORD(S) OR PHRASE

NUMBER: 0 0 0 1 0 0 1

UTERUS (UT) NUMBER EXAMINED: 0 0 0 1 0 0 1
NOT REMARKABLE: 0 0 0 1 0 0 1

UTERUS, CERVIX (CV) NUMBER EXAMINED: 0 0 0 1 0 0 1
NOT REMARKABLE: 0 0 0 1 0 0 1

VAGINA (VA) NUMBER EXAMINED: 0 0 0 1 0 0 1
NOT REMARKABLE: 0 0 0 1 0 0 1

LN, MANDIBULAR (MN) NUMBER EXAMINED: 0 0 0 1 0 0 1
NOT REMARKABLE: 0 0 0 1 0 0 1

MAND SALIVARY GL (SG) NUMBER EXAMINED: 0 0 0 1 0 0 1
NOT REMARKABLE: 0 0 0 1 0 0 1

THYMUS (TH) NUMBER EXAMINED: 0 0 0 1 0 0 1
NOT REMARKABLE: 0 0 0 1 0 0 1

AORTA, THORACIC (AO) NUMBER EXAMINED: 0 0 0 1 0 0 1
NOT REMARKABLE: 0 0 0 1 0 0 1

EYE (EY) NUMBER EXAMINED: 0 0 0 1 0 0 1
NOT REMARKABLE: 0 0 0 1 0 0 1

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

TABLE 10A
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
GROSS PATHOLOGY INCIDENCE SUMMARY

STUDY NUMBER: 483287

TABLE INCLUDES:
SEX=ALL;GROUP=ALL;WEEKS=ALL
DEATH=UNSCHED;SUBSET=T

--- NUMBER - OF - ANIMALS - AFFECTED ---

SEX: -----FEMALE-----

GROUP: -1- -2- -3- -4- -5- -6- -7-

ORGAN AND KEYWORD(S) OR PHRASE

NUMBER: 0 0 0 1 0 0 1

NERVE, OPTIC (ON) NUMBER EXAMINED: 0 0 0 1 0 0 1
NOT REMARKABLE: 0 0 0 1 0 0 1

LACRIMAL GL, EX (EO) NUMBER EXAMINED: 0 0 0 1 0 0 1
NOT REMARKABLE: 0 0 0 1 0 0 1

MUSCLE, SKELETAL (SM) NUMBER EXAMINED: 0 0 0 1 0 0 1
NOT REMARKABLE: 0 0 0 1 0 0 1

NERVE, SCIATIC (SN) NUMBER EXAMINED: 0 0 0 1 0 0 1
NOT REMARKABLE: 0 0 0 1 0 0 1

SKIN (SK) NUMBER EXAMINED: 0 0 0 1 0 0 1
NOT REMARKABLE: 0 0 0 1 0 0 1

MAMMARY, FEMALE (MF) NUMBER EXAMINED: 0 0 0 1 0 0 1
NOT REMARKABLE: 0 0 0 1 0 0 1

MARROW, STERNUM (SE) NUMBER EXAMINED: 0 0 0 1 0 0 1
NOT REMARKABLE: 0 0 0 1 0 0 1

MARROW, FEMUR (FM) NUMBER EXAMINED: 0 0 0 1 0 0 1
NOT REMARKABLE: 0 0 0 1 0 0 1

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HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

TABLE 10A

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)

GROSS PATHOLOGY INCIDENCE SUMMARY

STUDY NUMBER: 483287

TABLE INCLUDES:

SEX=ALL;GROUP=ALL;WEEKS=ALL
DEATH=UNSCHED;SUBSET=T

--- NUMBER - OF - ANIMALS - AFFECTED ---

SEX: -----FEMALE-----

GROUP: -1- -2- -3- -4- -5- -6- -7-

ORGAN AND KEYWORD(S) OR PHRASE

NUMBER: 0 0 0 1 0 0 1

BONE, FEMUR (FE) NUMBER EXAMINED: 0 0 0 1 0 0 1
NOT REMARKABLE: 0 0 0 1 0 0 1

TONGUE (TO) NUMBER EXAMINED: 0 0 0 1 0 0 1
NOT REMARKABLE: 0 0 0 1 0 0 1

SKIN, OTHER (SS) NUMBER EXAMINED: 0 0 0 1 0 0 1
NOT REMARKABLE: 0 0 0 1 0 0 1

BONE, OTHER (OB) NUMBER EXAMINED: 0 0 0 1 0 0 1
NOT REMARKABLE: 0 0 0 1 0 0 1

** END OF LIST **

Table 10B

Gross Pathology Incidence Summary - Satellite Study (Interim Sacrifice)
13-Week Subchronic Oral Toxicity Study of Triclosan in CD-1[®] Mice

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

TABLE 10B
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY IN TRICLOSAN IN CD-1
MICE. (SATELLITE-GROUPS 8-11)
GROSS PATHOLOGY INCIDENCE SUMMARY

STUDY NUMBER: 483287

TABLE INCLUDES:

SEX=ALL;GROUP=ALL;WEEKS=ALL
DEATH=1;SUBSET=ALL

--- NUMBER - OF - ANIMALS - AFFECTED ---

SEX=ALL;GROUP=ALL;WEEKS=ALL DEATH=1;SUBSET=ALL		SEX: -----MALE-----				-----FEMALE-----				
		GROUP:	-8-	-9-	-10-	-11-	-8-	-9-	-10-	-11-
ORGAN AND KEYWORD(S) OR PHRASE		NUMBER:	10	10	10	10	10	10	10	10
-----		-----	-----	-----	-----	-----	-----	-----	-----	-----
** TOP OF LIST **										
LIVER (LI)	NUMBER EXAMINED:	10	10	10	10	10	10	10	10	10
	NOT REMARKABLE:	9	10	1	0	10	9	1	1	1
PALE AREA		1	0	7	10	0	1	8	9	
DARK		0	0	5	9	0	0	7	5	
ENLARGED		0	0	3	8	0	0	4	4	
SKIN, OTHER (SS)	NUMBER EXAMINED:	10	10	10	10	10	10	10	10	10
	NOT REMARKABLE:	9	10	9	10	10	10	10	10	10
EAR, SORE		1	0	1	0	0	0	0	0	
KIDNEY (KD)	NUMBER EXAMINED:	10	10	10	10	10	10	10	10	10
	NOT REMARKABLE:	10	10	9	10	10	10	9	10	
DARK		0	0	1	0	0	0	0	0	
PALE AREA		0	0	1	0	0	0	0	0	
CYST		0	0	0	0	0	0	1	0	
STOMACH, GL (ST)	NUMBER EXAMINED:	10	10	10	10	10	10	10	10	10
	NOT REMARKABLE:	10	10	9	8	10	10	10	10	10
DARK AREA		0	0	1	2	0	0	0	0	
OVARY (OV)	NUMBER EXAMINED:	0	0	0	0	10	10	10	10	10
	NOT REMARKABLE:	0	0	0	0	8	9	10	10	
CYST		0	0	0	0	2	1	0	0	
** END OF LIST **										

Table 10C
Gross Pathology Incidence Summary - Main Study (Terminal Sacrifice)
13-Week Subchronic Oral Toxicity Study of Triclosan in CD-1[®] Mice

Standard Key to Gross Pathology Incidence Summary

LOCATIONS OF TISSUE MASSES OBSERVED GROSSLY

DFL = Dorsal-Front-Left
DFR = Dorsal-Front-Right
DHL = Dorsal-Hind-Left
DHR = Dorsal-Hind-Right
DFM = Dorsal-Front-Mid
DHM = Dorsal-Hind-Mid
VFL = Ventral-Front-Left
VFR = Ventral-Front-Right
VHL = Ventral-Hind-Left
VHR = Ventral-Hind-Right
VFM = Ventral-Front-Mid
VHM = Ventral-Hind-Mid

OTHER SYMBOLS AND NOTATIONS

H- = Finding noted during processing of tissues in histology (precedes keyword).

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

TABLE 10C
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
GROSS PATHOLOGY INCIDENCE SUMMARY

STUDY NUMBER: 483287

TABLE INCLUDES:

SEX=ALL;GROUP=ALL;WEEKS=ALL
DEATH=T;SUBSET=T

--- NUMBER - OF - ANIMALS - AFFECTED ---

SEX: -----MALE-----

GROUP: -1- -2- -3- -4- -5- -6- -7-

ORGAN AND KEYWORD(S) OR PHRASE

NUMBER: 15 15 15 13 15 15 13

** TOP OF LIST **

BRAIN W/STEM (BR) NUMBER EXAMINED: 15 15 15 13 15 15 13
NOT REMARKABLE: 15 15 15 13 15 15 13

CORD, CERVICAL (CS) NUMBER EXAMINED: 15 15 15 13 15 15 13
NOT REMARKABLE: 15 15 15 13 15 15 13

CORD, THORACIC (TC) NUMBER EXAMINED: 15 15 15 13 15 15 13
NOT REMARKABLE: 15 15 15 13 15 15 13

CORD, LUMBAR (LC) NUMBER EXAMINED: 15 15 15 13 15 15 13
NOT REMARKABLE: 15 15 15 13 15 15 13

PITUITARY (PI) NUMBER EXAMINED: 15 15 15 13 15 15 13
NOT REMARKABLE: 15 15 15 12 15 15 13

PALE AREA 0 0 0 1 0 0 0

ADRENAL, CORTEX (AC) NUMBER EXAMINED: 15 15 15 13 15 15 13
NOT REMARKABLE: 15 15 15 13 15 15 13

ADRENAL, MEDULLA (AM) NUMBER EXAMINED: 15 15 15 13 15 15 13
NOT REMARKABLE: 15 15 15 13 15 15 13

THYROID (TY) NUMBER EXAMINED: 15 15 15 13 15 15 13
NOT REMARKABLE: 15 15 15 13 15 15 13

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HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

TABLE 10C

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)

GROSS PATHOLOGY INCIDENCE SUMMARY

STUDY NUMBER: 483287

TABLE INCLUDES:

SEX=ALL;GROUP=ALL;WEEKS=ALL
DEATH=T;SUBSET=T

--- NUMBER - OF - ANIMALS - AFFECTED ---

SEX: -----MALE-----

GROUP: -1- -2- -3- -4- -5- -6- -7-

ORGAN AND KEYWORD(S) OR PHRASE

NUMBER: 15 15 15 13 15 15 13

PARATHYROID (PT) NUMBER EXAMINED: 15 15 15 13 15 15 13
NOT REMARKABLE: 15 15 15 13 15 15 13

ESOPHAGUS (ES) NUMBER EXAMINED: 15 15 15 13 15 15 13
NOT REMARKABLE: 15 15 15 13 15 15 13

TRACHEA (TR) NUMBER EXAMINED: 15 15 15 13 15 15 13
NOT REMARKABLE: 15 15 15 13 15 15 13

LUNG (LU) NUMBER EXAMINED: 15 15 15 13 15 15 13
NOT REMARKABLE: 15 15 15 13 15 15 13

HEART (HT) NUMBER EXAMINED: 15 15 15 13 15 15 13
NOT REMARKABLE: 15 15 15 13 15 15 13

SPLEEN (SP) NUMBER EXAMINED: 15 15 15 13 15 15 13
NOT REMARKABLE: 15 15 15 13 15 15 13

LIVER (LI) NUMBER EXAMINED: 15 15 15 13 15 15 13
NOT REMARKABLE: 15 14 13 2 1 0 0

PALE AREA 0 0 0 4 8 9 11
ENLARGED 0 0 1 5 13 15 12
DARK 0 1 2 11 14 15 13
MASS 0 0 1 0 0 0 0

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HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

TABLE 10C

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
GROSS PATHOLOGY INCIDENCE SUMMARY

STUDY NUMBER: 483287

TABLE INCLUDES:
SEX=ALL;GROUP=ALL;WEEKS=ALL
DEATH=T;SUBSET=T

--- NUMBER - OF - ANIMALS - AFFECTED ---

SEX: -----MALE-----

GROUP: -1- -2- -3- -4- -5- -6- -7-

ORGAN AND KEYWORD(S) OR PHRASE

NUMBER: 15 15 15 13 15 15 13

GALLBLADDER (GB) NUMBER EXAMINED: 15 15 15 13 15 15 13
NOT REMARKABLE: 15 15 15 13 15 15 13

KIDNEY (KD) NUMBER EXAMINED: 15 15 15 13 15 15 13
NOT REMARKABLE: 15 15 15 13 14 15 13

CYST 0 0 0 0 1 0 0
H-CYST 0 0 0 0 1 0 0

STOMACH, NONGL (SU) NUMBER EXAMINED: 15 15 15 13 15 15 13
NOT REMARKABLE: 15 15 15 13 15 15 13

STOMACH, GL (ST) NUMBER EXAMINED: 15 15 15 13 15 15 13
NOT REMARKABLE: 15 15 15 13 14 12 10

DARK AREA 0 0 0 0 0 3 3
MUCOSA, THICKENED 0 0 0 0 1 1 0

DUODENUM (DU) NUMBER EXAMINED: 15 15 15 13 15 15 13
NOT REMARKABLE: 15 15 15 13 15 15 13

JEJUNUM (JE) NUMBER EXAMINED: 15 15 15 13 15 15 13
NOT REMARKABLE: 15 15 15 13 15 15 13

ILEUM (IL) NUMBER EXAMINED: 15 15 15 13 15 15 13
NOT REMARKABLE: 15 15 15 13 15 15 13

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

TABLE 10C
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
GROSS PATHOLOGY INCIDENCE SUMMARY

STUDY NUMBER: 483287

TABLE INCLUDES:

SEX=ALL;GROUP=ALL;WEEKS=ALL
DEATH=T;SUBSET=T

--- NUMBER - OF - ANIMALS - AFFECTED ---

SEX: -----MALE-----

GROUP: -1- -2- -3- -4- -5- -6- -7-

ORGAN AND KEYWORD(S) OR PHRASE

NUMBER: 15 15 15 13 15 15 13

PANCREAS (PA) NUMBER EXAMINED: 15 15 15 13 15 15 13
NOT REMARKABLE: 15 15 15 13 15 15 13

CECUM (CE) NUMBER EXAMINED: 15 15 15 13 15 15 13
NOT REMARKABLE: 15 15 15 13 15 15 13

COLON (CO) NUMBER EXAMINED: 15 15 15 13 15 15 13
NOT REMARKABLE: 15 15 15 13 15 15 13

RECTUM (RE) NUMBER EXAMINED: 15 15 15 13 15 15 13
NOT REMARKABLE: 15 15 15 13 15 15 13

LN, MESENTERIC (MS) NUMBER EXAMINED: 15 15 15 13 15 15 13
NOT REMARKABLE: 15 14 15 13 15 15 13

DARK 0 1 0 0 0 0 0

TESTIS (TE) NUMBER EXAMINED: 15 15 15 13 15 15 13
NOT REMARKABLE: 15 15 14 13 15 15 13

DARK AREA 0 0 1 0 0 0 0

EPIDIDYMIS (EP) NUMBER EXAMINED: 15 15 15 13 15 15 13
NOT REMARKABLE: 15 15 15 13 15 15 13

PROSTATE (PR) NUMBER EXAMINED: 15 15 15 13 15 15 13
NOT REMARKABLE: 15 15 15 13 15 15 13

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

TABLE 10C

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)

GROSS PATHOLOGY INCIDENCE SUMMARY

STUDY NUMBER: 483287

TABLE INCLUDES:
SEX=ALL;GROUP=ALL;WEEKS=ALL
DEATH=T;SUBSET=T

--- NUMBER - OF - ANIMALS - AFFECTED ---

SEX: -----MALE-----

GROUP: -1- -2- -3- -4- -5- -6- -7-

ORGAN AND KEYWORD(S) OR PHRASE

NUMBER: 15 15 15 13 15 15 13

URINARY BLADDER (UB) NUMBER EXAMINED: 15 15 15 13 15 15 13
NOT REMARKABLE: 15 15 15 13 15 15 13

OVARY (OV) NUMBER EXAMINED: 0 0 0 0 0 0 0
NOT REMARKABLE: 0 0 0 0 0 0 0

UTERUS (UT) NUMBER EXAMINED: 0 0 0 0 0 0 0
NOT REMARKABLE: 0 0 0 0 0 0 0

UTERUS, CERVIX (CV) NUMBER EXAMINED: 0 0 0 0 0 0 0
NOT REMARKABLE: 0 0 0 0 0 0 0

VAGINA (VA) NUMBER EXAMINED: 0 0 0 0 0 0 0
NOT REMARKABLE: 0 0 0 0 0 0 0

LN, MANDIBULAR (MN) NUMBER EXAMINED: 15 15 15 13 15 15 13
NOT REMARKABLE: 15 15 15 12 15 15 13

ENLARGED 0 0 0 1 0 0 0

MAND SALIVARY GL (SG) NUMBER EXAMINED: 15 15 15 13 15 15 13
NOT REMARKABLE: 15 15 15 13 15 15 13

THYMUS (TH) NUMBER EXAMINED: 15 15 15 13 15 15 13
NOT REMARKABLE: 15 15 15 13 15 15 13

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HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

TABLE 10C

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
GROSS PATHOLOGY INCIDENCE SUMMARY

STUDY NUMBER: 483287

TABLE INCLUDES:

SEX=ALL;GROUP=ALL;WEEKS=ALL
DEATH=T;SUBSET=T

--- NUMBER - OF - ANIMALS - AFFECTED ---

SEX: -----MALE-----

GROUP: -1- -2- -3- -4- -5- -6- -7-

ORGAN AND KEYWORD(S) OR PHRASE

NUMBER: 15 15 15 13 15 15 13

AORTA, THORACIC (AO) NUMBER EXAMINED: 15 15 15 13 15 15 13
NOT REMARKABLE: 15 15 15 13 15 15 13

EYE (EY) NUMBER EXAMINED: 15 15 15 13 15 15 13
NOT REMARKABLE: 15 15 15 13 15 15 13

NERVE, OPTIC (ON) NUMBER EXAMINED: 15 15 15 13 15 15 13
NOT REMARKABLE: 15 15 15 13 15 15 13

LACRIMAL GL, EX (EO) NUMBER EXAMINED: 15 15 15 13 15 15 13
NOT REMARKABLE: 15 15 15 13 15 15 13

MUSCLE, SKELETAL (SM) NUMBER EXAMINED: 15 15 15 13 15 15 13
NOT REMARKABLE: 15 15 15 13 15 15 13

NERVE, SCIATIC (SN) NUMBER EXAMINED: 15 15 15 13 15 15 13
NOT REMARKABLE: 15 15 15 13 15 15 13

SKIN (SK) NUMBER EXAMINED: 15 15 15 13 15 15 13
NOT REMARKABLE: 15 15 15 13 15 15 13

MAMMARY, FEMALE (MF) NUMBER EXAMINED: 0 0 0 0 0 0 0
NOT REMARKABLE: 0 0 0 0 0 0 0

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HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

TABLE 10C

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)

GROSS PATHOLOGY INCIDENCE SUMMARY

STUDY NUMBER: 483287

TABLE INCLUDES:

SEX=ALL;GROUP=ALL;WEEKS=ALL
DEATH=T;SUBSET=T

--- NUMBER - OF - ANIMALS - AFFECTED ---

SEX: -----MALE-----

GROUP: -1- -2- -3- -4- -5- -6- -7-

ORGAN AND KEYWORD(S) OR PHRASE

NUMBER: 15 15 15 13 15 15 13

MARROW, STERNUM (SE) NUMBER EXAMINED: 15 15 15 13 15 15 13
NOT REMARKABLE: 15 15 15 13 15 15 13

MARROW, FEMUR (FM) NUMBER EXAMINED: 15 15 15 13 15 15 13
NOT REMARKABLE: 15 15 15 13 15 15 13

BONE, FEMUR (FE) NUMBER EXAMINED: 15 15 15 13 15 15 13
NOT REMARKABLE: 15 15 15 13 15 15 13

TONGUE (TO) NUMBER EXAMINED: 15 15 15 13 15 15 13
NOT REMARKABLE: 15 15 15 13 15 15 13

SKIN, OTHER (SS) NUMBER EXAMINED: 15 15 15 13 15 15 13
NOT REMARKABLE: 13 14 15 12 14 15 13

ALOPECIA 1 0 0 0 0 0 0
EAR, SORE 2 1 0 1 1 0 0
SORE 0 0 0 1 0 0 0

BONE, OTHER (OB) NUMBER EXAMINED: 15 15 15 13 15 15 13
NOT REMARKABLE: 15 15 15 13 15 15 13

** END OF LIST **

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HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

TABLE 10C
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
GROSS PATHOLOGY INCIDENCE SUMMARY

STUDY NUMBER: 483287

TABLE INCLUDES:
SEX=ALL; GROUP=ALL; WEEKS=ALL
DEATH=T; SUBSET=T

--- NUMBER - OF - ANIMALS - AFFECTED ---

SEX: -----FEMALE-----

GROUP: -1- -2- -3- -4- -5- -6- -7-

ORGAN AND KEYWORD(S) OR PHRASE	NUMBER:	15	15	15	14	15	15	14
** TOP OF LIST **								
BRAIN W/STEM (BR)	NUMBER EXAMINED:	15	15	15	14	15	15	14
	NOT REMARKABLE:	15	15	15	14	15	15	14
CORD, CERVICAL (CS)	NUMBER EXAMINED:	15	15	15	14	15	15	14
	NOT REMARKABLE:	15	15	15	14	15	15	14
CORD, THORACIC (TC)	NUMBER EXAMINED:	15	15	15	14	15	15	14
	NOT REMARKABLE:	15	15	15	14	15	15	14
CORD, LUMBAR (LC)	NUMBER EXAMINED:	15	15	15	14	15	15	14
	NOT REMARKABLE:	15	15	15	14	15	15	14
PITUITARY (PI)	NUMBER EXAMINED:	15	15	15	14	15	15	14
	NOT REMARKABLE:	15	15	15	14	15	15	14
ADRENAL, CORTEX (AC)	NUMBER EXAMINED:	15	15	15	14	15	15	14
	NOT REMARKABLE:	15	15	15	14	15	15	14
ADRENAL, MEDULLA (AM)	NUMBER EXAMINED:	15	15	15	14	15	15	14
	NOT REMARKABLE:	15	15	15	14	15	15	14
THYROID (TY)	NUMBER EXAMINED:	15	15	15	14	15	15	14
	NOT REMARKABLE:	15	15	15	14	15	15	14

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HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

TABLE 10C
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
GROSS PATHOLOGY INCIDENCE SUMMARY

STUDY NUMBER: 483287

TABLE INCLUDES:

SEX=ALL;GROUP=ALL;WEEKS=ALL
DEATH=T;SUBSET=T

--- NUMBER - OF - ANIMALS - AFFECTED ---

SEX: -----FEMALE-----

GROUP: -1- -2- -3- -4- -5- -6- -7-

ORGAN AND KEYWORD(S) OR PHRASE

NUMBER: 15 15 15 14 15 15 14

PARATHYROID (PT) NUMBER EXAMINED: 15 15 15 14 15 15 14
NOT REMARKABLE: 15 15 15 14 15 15 14

ESOPHAGUS (ES) NUMBER EXAMINED: 15 15 15 14 15 15 14
NOT REMARKABLE: 15 15 15 14 15 15 14

TRACHEA (TR) NUMBER EXAMINED: 15 15 15 14 15 15 14
NOT REMARKABLE: 15 15 15 14 15 15 14

LUNG (LU) NUMBER EXAMINED: 15 15 15 14 15 15 14
NOT REMARKABLE: 15 15 15 14 15 15 14

HEART (HT) NUMBER EXAMINED: 15 15 15 14 15 15 14
NOT REMARKABLE: 15 15 15 14 15 15 14

SPLEEN (SP) NUMBER EXAMINED: 15 15 15 14 15 15 14
NOT REMARKABLE: 15 15 15 14 15 15 14

LIVER (LI) NUMBER EXAMINED: 15 15 15 14 15 15 14
NOT REMARKABLE: 15 15 11 4 2 1 0

PALE AREA 0 0 2 3 5 5 11
ENLARGED 0 0 1 6 12 14 13
DARK 0 0 2 10 13 14 14
MASS 0 0 1 0 0 0 0
DARK AREA 0 0 1 0 0 0 0

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

TABLE 10C
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
NICE. (MAIN-GROUPS 1-7)
GROSS PATHOLOGY INCIDENCE SUMMARY

STUDY NUMBER: 483287

TABLE INCLUDES:

SEX=ALL;GROUP=ALL;WEEKS=ALL
DEATH=T;SUBSET=T

--- NUMBER - OF - ANIMALS - AFFECTED ---

SEX: -----FEMALE-----

GROUP: -1- -2- -3- -4- -5- -6- -7-

ORGAN AND KEYWORD(S) OR PHRASE

NUMBER: 15 15 15 14 15 15 14

GALLBLADDER (GB) NUMBER EXAMINED: 15 15 15 14 15 15 14
NOT REMARKABLE: 15 15 15 14 15 15 14

KIDNEY (KD) NUMBER EXAMINED: 15 15 15 14 15 15 14
NOT REMARKABLE: 15 15 15 14 14 15 13

MASS 0 0 0 0 1 0 0
IRREGULARLY SHAPED 0 0 0 0 0 0 1

STOMACH, NONGL (SU) NUMBER EXAMINED: 15 15 15 14 15 15 14
NOT REMARKABLE: 15 15 15 14 15 15 14

STOMACH, GL (ST) NUMBER EXAMINED: 15 15 15 14 15 15 14
NOT REMARKABLE: 15 14 13 14 13 15 11

DARK AREA 0 1 2 0 2 0 2
MUCOSA, THICKENED 0 0 0 0 0 0 1

DUODENUM (DU) NUMBER EXAMINED: 15 15 15 14 15 15 14
NOT REMARKABLE: 15 15 15 14 15 15 14

JEJUNUM (JE) NUMBER EXAMINED: 15 15 15 14 15 15 14
NOT REMARKABLE: 15 15 15 14 15 15 14

ILEUM (IL) NUMBER EXAMINED: 15 15 15 14 15 15 14
NOT REMARKABLE: 15 15 15 14 15 15 14

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HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

TABLE 10C
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
GROSS PATHOLOGY INCIDENCE SUMMARY

STUDY NUMBER: 483287

TABLE INCLUDES:
SEX=ALL;GROUP=ALL;WEEKS=ALL
DEATH=T;SUBSET=T

--- NUMBER - OF - ANIMALS - AFFECTED ---

SEX: -----FEMALE-----

GROUP: -1- -2- -3- -4- -5- -6- -7-

ORGAN AND KEYWORD(S) OR PHRASE	NUMBER:	15	15	15	14	15	15	14
		-2-	-2-	-2-	-2-	-2-	-2-	-2-
PANCREAS (PA)	NUMBER EXAMINED:	15	15	15	14	15	15	14
	NOT REMARKABLE:	15	15	15	14	15	15	13
DARK		0	0	0	0	0	0	1
CECUM (CE)	NUMBER EXAMINED:	15	15	15	14	15	15	14
	NOT REMARKABLE:	15	15	15	14	15	15	14
COLON (CO)	NUMBER EXAMINED:	15	15	15	14	15	15	14
	NOT REMARKABLE:	15	15	15	14	15	15	14
RECTUM (RE)	NUMBER EXAMINED:	15	15	15	14	15	15	14
	NOT REMARKABLE:	15	15	15	14	15	15	14
LN, MESENTERIC (MS)	NUMBER EXAMINED:	15	15	15	14	15	15	14
	NOT REMARKABLE:	15	15	15	14	15	15	14
TESTIS (TE)	NUMBER EXAMINED:	0	0	0	0	0	0	0
	NOT REMARKABLE:	0	0	0	0	0	0	0
EPIDIDYMIS (EP)	NUMBER EXAMINED:	0	0	0	0	0	0	0
	NOT REMARKABLE:	0	0	0	0	0	0	0
PROSTATE (PR)	NUMBER EXAMINED:	0	0	0	0	0	0	0
	NOT REMARKABLE:	0	0	0	0	0	0	0

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HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

TABLE 10C

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)

GROSS PATHOLOGY INCIDENCE SUMMARY

STUDY NUMBER: 483287

TABLE INCLUDES:
SEX=ALL;GROUP=ALL;WEEKS=ALL
DEATH=T;SUBSET=T

--- NUMBER - OF - ANIMALS - AFFECTED ---

SEX: -----FEMALE-----

GROUP: -1- -2- -3- -4- -5- -6- -7-

ORGAN AND KEYWORD(S) OR PHRASE

NUMBER: 15 15 15 14 15 15 14

URINARY BLADDER (UB) NUMBER EXAMINED: 15 15 15 14 15 15 14
NOT REMARKABLE: 15 15 15 14 15 15 14

OVARY (OV) NUMBER EXAMINED: 15 15 15 14 15 15 14
NOT REMARKABLE: 15 11 10 10 12 12 14

CYST 0 4 5 4 3 3 0

UTERUS (UT) NUMBER EXAMINED: 15 15 15 14 15 15 14
NOT REMARKABLE: 15 13 12 14 14 15 14

LUMEN, FLUID 0 1 0 0 0 0 0
DARK 0 1 1 0 0 0 0
DISTENDED 0 2 1 0 0 0 0
WALL, THICKENED 0 0 2 0 1 0 0

UTERUS, CERVIX (CV) NUMBER EXAMINED: 15 15 15 14 15 15 14
NOT REMARKABLE: 15 15 15 14 15 15 14

VAGINA (VA) NUMBER EXAMINED: 15 15 15 14 15 15 14
NOT REMARKABLE: 15 15 15 14 15 15 14

LN, MANDIBULAR (MN) NUMBER EXAMINED: 15 15 15 14 15 15 14
NOT REMARKABLE: 15 15 15 14 15 15 14

MAND SALIVARY GL (SG) NUMBER EXAMINED: 15 15 15 14 15 15 14
NOT REMARKABLE: 15 15 15 14 15 15 14

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HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

TABLE 10C
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
GROSS PATHOLOGY INCIDENCE SUMMARY

STUDY NUMBER: 483287

TABLE INCLUDES:
SEX=ALL;GROUP=ALL;WEEKS=ALL
DEATH=T;SUBSET=T

--- NUMBER - OF - ANIMALS - AFFECTED ---

ORGAN AND KEYWORD(S) OR PHRASE	NUMBER:	SEX: ----- FEMALE -----						
		GROUP: -1- -2- -3- -4- -5- -6- -7-						
		15	15	15	14	15	15	14
THYMUS (TH)	NUMBER EXAMINED:	15	15	15	14	15	15	14
	NOT REMARKABLE:	15	15	15	14	15	15	14
AORTA, THORACIC (AO)	NUMBER EXAMINED:	15	15	15	14	15	15	14
	NOT REMARKABLE:	15	15	15	14	15	15	14
EYE (EY)	NUMBER EXAMINED:	15	15	15	14	15	15	14
	NOT REMARKABLE:	15	15	15	14	15	15	14
NERVE, OPTIC (ON)	NUMBER EXAMINED:	15	15	15	14	15	15	14
	NOT REMARKABLE:	15	15	15	14	15	15	14
LACRIMAL GL, EX (EO)	NUMBER EXAMINED:	15	15	15	14	15	15	14
	NOT REMARKABLE:	15	15	15	14	15	15	14
MUSCLE, SKELETAL (SM)	NUMBER EXAMINED:	15	15	15	14	15	15	14
	NOT REMARKABLE:	15	15	15	14	15	15	14
NERVE, SCIATIC (SN)	NUMBER EXAMINED:	15	15	15	14	15	15	14
	NOT REMARKABLE:	15	15	15	14	15	15	14
SKIN (SK)	NUMBER EXAMINED:	15	15	15	14	15	15	14
	NOT REMARKABLE:	15	15	15	14	15	15	14

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HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

GROSS PATHOLOGY INCIDENCE SUMMARY

STUDY NUMBER: 483287

--- NUMBER - OF - ANIMALS - AFFECTED ---

SEX: -----FEMALE-----

GROUP: -1- -2- -3- -4- -5- -6- -7-

ORGAN AND KEYWORD(S) OR PHRASE

NUMBER: 15 15 15 14 15 15 14

MAMMARY, FEMALE (MF)	NUMBER EXAMINED:	15	15	15	14	15	15	14
	NOT REMARKABLE:	15	15	15	14	15	15	14

MARROW, STERNUM (SE)	NUMBER EXAMINED:	15	15	15	14	15	15	14
	NOT REMARKABLE:	15	15	15	14	15	15	14

MARROW, FEMUR (FM)	NUMBER EXAMINED:	15	15	15	14	15	15	14
	NOT REMARKABLE:	15	15	15	14	15	15	14

BONE, FEMUR (FE)	NUMBER EXAMINED:	15	15	15	14	15	15	14
	NOT REMARKABLE:	15	15	15	14	15	15	14

TONGUE (TO)	NUMBER EXAMINED:	15	15	15	14	15	15	14
	NOT REMARKABLE:	15	15	15	14	15	15	14

SKIN, OTHER (SS)	NUMBER EXAMINED:	15	15	15	14	15	15	14
	NOT REMARKABLE:	15	15	15	13	15	15	13

EAR, SORE	0	0	0	1	0	0	0
TAIL, SORE	0	0	0	0	0	0	1

BONE, OTHER (OB)	NUMBER EXAMINED:	15	15	15	14	15	15	14
	NOT REMARKABLE:	15	15	15	14	15	15	14

** END OF LIST **

Table 11A
Absolute Organ Weight Means - Main Study (Terminal Sacrifice)
13-Week Subchronic Oral Toxicity Study of Triclosan in CD-1 Mice

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

TABLE 11A

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
ABSOLUTE ORGAN WEIGHT MEANS (g)

STUDY NUMBER: 483287

TABLE INCLUDES:

SEX=ALL; GROUP=ALL; WEEKS=ALL
DEATH=T; SUBSET=ALL

SEX:	MALE						
GROUP:	1	2	3	4	5	6	7
NUMBER:	15	15	15	13	15	15	13

TERMINAL BODY WEIGHT (g)

# IN GRP :	15	15	15	13	15	15	13
M E A N :	26.8	27.7	28.4	29.1*	29.1*	26.8	26.9
STAND DEV:	1.6	1.7	2.3	1.7	1.6	2.1	2.4

SG - MAND SALIVARY GL

# IN GRP :	15	15	15	13	15	15	13
M E A N :	0.22	0.21	0.21	0.21	0.20	0.16*	0.16*
STAND DEV:	0.04	0.04	0.03	0.02	0.04	0.03	0.04

LU - LUNG

# IN GRP :	15	15	15	13	15	15	13
M E A N :	0.19	0.19	0.18	0.19	0.18	0.18	0.18
STAND DEV:	0.02	0.02	0.02	0.01	0.02	0.01	0.03

PR - PROSTATE

# IN GRP :	15	15	15	13	15	15	13
M E A N :	0.051	0.053	0.056	0.049	0.042	0.045	0.044
STAND DEV:	0.020	0.019	0.026	0.022	0.014	0.015	0.018

UT - UTERUS

# IN GRP :	0	0	0	0	0	0	0
M E A N :							
STAND DEV:							

* Significantly different from control value, $p \leq 0.05$.

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

TABLE 11A

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
ABSOLUTE ORGAN WEIGHT MEANS (g)

STUDY NUMBER: 483287

TABLE INCLUDES:
SEX=ALL;GROUP=ALL;WEEKS=ALL
DEATH=T;SUBSET=ALL

SEX:	MALE						
GROUP:	1	2	3	4	5	6	7
NUMBER:	15	15	15	13	15	15	13

BR - BRAIN W/STEM

# IN GRP :	15	15	15	13	15	15	13
M E A N :	0.47	0.50	0.49	0.49	0.49	0.49	0.48
STAND DEV:	0.02	0.04	0.04	0.04	0.04	0.04	0.04

HT - HEART

# IN GRP :	15	15	15	13	15	15	13
M E A N :	0.16	0.16	0.17	0.16	0.16	0.14*	0.15
STAND DEV:	0.02	0.02	0.02	0.02	0.03	0.02	0.02

SP - SPLEEN

# IN GRP :	15	15	15	13	15	15	13
M E A N :	0.06	0.06	0.07	0.07	0.07	0.08	0.08
STAND DEV:	0.01	0.01	0.01	0.02	0.01	0.03	0.02

KD - KIDNEY*

# IN GRP :	15	15	15	13	15	15	13
M E A N :	0.53	0.51	0.49	0.49	0.47*	0.43*	0.45*
STAND DEV:	0.07	0.06	0.08	0.04	0.03	0.04	0.05

LL - LIVER/GALLBLADD*

# IN GRP :	15	15	15	13	15	15	13
M E A N :	1.25	1.32	1.63*	2.08*	2.61*	3.52*	3.70*
STAND DEV:	0.12	0.12	0.15	0.29	0.32	0.42	0.68

* Significantly different from control value, $p \leq 0.05$.

* A significant trend at $p \leq 0.05$.

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

TABLE 11A

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
ABSOLUTE ORGAN WEIGHT MEANS (g)

STUDY NUMBER: 483287

TABLE INCLUDES:

SEX=ALL;GROUP=ALL;WEEKS=ALL
DEATH=T;SUBSET=ALL

SEX:	MALE						
GROUP:	1	2	3	4	5	6	7
NUMBER:	15	15	15	13	15	15	13

TE - TESTIS							
# IN GRP :	15	15	15	13	15	15	13
M E A N :	0.22	0.24	0.23	0.25	0.24	0.21	0.21
STAND DEV:	0.04	0.04	0.04	0.03	0.03	0.04	0.04

EP - EPIDIDYMISS							
# IN GRP :	15	15	15	13	15	15	13
M E A N :	0.11	0.12	0.13	0.12	0.12	0.10	0.10
STAND DEV:	0.02	0.02	0.02	0.03	0.02	0.02	0.01

AD - ADRENAL							
# IN GRP :	15	14	14	13	14	15	13
M E A N :	0.009	0.007	0.007	0.009	0.011	0.012*	0.012*
STAND DEV:	0.002	0.003	0.002	0.002	0.003	0.003	0.002

OV - OVARY							
# IN GRP :	0	0	0	0	0	0	0
M E A N :							
STAND DEV:							

TH - THYMUS							
# IN GRP :	15	15	15	13	14	15	13
M E A N :	0.03	0.02	0.03	0.03	0.03	0.02	0.02
STAND DEV:	0.01	0.01	0.01	0.01	0.01	0.01	0.01

* Significantly different from control value, $p \leq 0.05$.

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

TABLE 11A
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
ABSOLUTE ORGAN WEIGHT MEANS (g)

STUDY NUMBER: 483287

TABLE INCLUDES:
SEX=ALL; GROUP=ALL; WEEKS=ALL
DEATH=T; SUBSET=ALL

SEX:	FEMALE						
GROUP:	1	2	3	4	5	6	7
NUMBER:	15	15	15	14	15	15	14

TERMINAL BODY WEIGHT (g)

# IN GRP :	15	15	15	14	15	15	14
M E A N :	24.0	23.6	24.3	24.7	25.0	23.4	22.1*
STAND DEV:	1.7	1.6	1.5	1.2	2.4	1.6	1.6

SG - MAND SALIVARY GL

# IN GRP :	15	15	15	14	15	15	14
M E A N :	0.15	0.14	0.16	0.13	0.14	0.12*	0.11*
STAND DEV:	0.02	0.03	0.03	0.02	0.02	0.03	0.02

LU - LUNG

# IN GRP :	15	15	15	14	15	15	14
M E A N :	0.19	0.18	0.18	0.18	0.18	0.17	0.16*
STAND DEV:	0.02	0.01	0.02	0.03	0.02	0.02	0.02

PR - PROSTATE

# IN GRP :	0	0	0	0	0	0	0
M E A N :							
STAND DEV:							

UT - UTERUS

# IN GRP :	15	15	15	14	15	15	14
M E A N :	0.22	0.25	0.22	0.19	0.18	0.12*	0.13*
STAND DEV:	0.06	0.09	0.10	0.06	0.07	0.05	0.06

* significantly different from control value, $p \leq 0.05$.

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

TABLE 11A
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
ABSOLUTE ORGAN WEIGHT MEANS (g)

STUDY NUMBER: 483287

TABLE INCLUDES:
SEX=ALL;GROUP=ALL;WEEKS=ALL
DEATH=T;SUBSET=ALL

SEX:	FEMALE						
GROUP:	1	2	3	4	5	6	7
NUMBER:	15	15	15	14	15	15	14

BR - BRAIN W/STEM

# IN GRP :	15	15	15	14	15	15	14
M E A N :	0.53	0.52	0.51	0.52	0.52	0.49*	0.48*
STAND DEV:	0.03	0.02	0.03	0.03	0.03	0.04	0.02

HT - HEART

# IN GRP :	15	15	15	14	15	15	14
M E A N :	0.14	0.14	0.15	0.14	0.15	0.13	0.13
STAND DEV:	0.01	0.01	0.02	0.02	0.02	0.01	0.01

SP - SPLEEN

# IN GRP :	15	15	15	14	15	15	14
M E A N :	0.07	0.08	0.08	0.08	0.08	0.07	0.07
STAND DEV:	0.02	0.01	0.02	0.01	0.01	0.01	0.02

KD - KIDNEY*

# IN GRP :	15	15	15	14	15	15	14
M E A N :	0.38	0.38	0.37	0.38	0.38	0.35	0.33*
STAND DEV:	0.03	0.04	0.04	0.04	0.05	0.05	0.04

LL - LIVER/GALLBLADD*

# IN GRP :	15	15	15	14	15	15	14
M E A N :	1.08	1.16	1.40*	1.94*	2.41*	3.03*	3.04*
STAND DEV:	0.13	0.12	0.23	0.25	0.44	0.36	0.44

* Significantly different from control value, $p \leq 0.05$.

* A significant trend at $p \leq 0.05$.

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

TABLE 11A
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
ABSOLUTE ORGAN WEIGHT MEANS (g)

STUDY NUMBER: 483287

TABLE INCLUDES:
SEX=ALL;GROUP=ALL;WEEKS=ALL
DEATH=T;SUBSET=ALL

SEX: -----FEMALE-----
GROUP: ---1--- ---2--- ---3--- ---4--- ---5--- ---6--- ---7---
NUMBER: 15 15 15 14 15 15 14

TE - TESTIS

IN GRP : 0 0 0 0 0 0 0
M E A N :
STAND DEV:

EP - EPIDIDYMS

IN GRP : 0 0 0 0 0 0 0
M E A N :
STAND DEV:

AD - ADRENAL

IN GRP : 15 15 15 14 15 15 14
M E A N : 0.013 0.011 0.013 0.013 0.012 0.013 0.011
STAND DEV: 0.002 0.003 0.003 0.003 0.003 0.003 0.002

OV - OVARY

IN GRP : 15 15 15 14 15 15 14
M E A N : 0.044 0.049 0.043 0.042 0.045 0.035 0.029*
STAND DEV: 0.019 0.013 0.012 0.016 0.016 0.010 0.009

TH - THYMUS

IN GRP : 15 15 15 14 15 15 14
M E A N : 0.03 0.03 0.03 0.03 0.03 0.03 0.03
STAND DEV: 0.01 0.01 0.01 0.01 0.01 0.01 0.01

* Significantly different from control value, $p \leq 0.05$.

Table 11B
Absolute Organ Weight Means - Satellite Study (Interim Sacrifice)
13-Week Subchronic Oral Toxicity Study of Triclosan in CD-1[®] Mice

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

TABLE 11B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY IN TRICLOSAN IN CD-1
MICE. (SATELLITE-GROUPS 8-11)
ABSOLUTE ORGAN WEIGHT MEANS (g)

STUDY NUMBER: 483287

TABLE INCLUDES:

SEX=ALL;GROUP=ALL;WEEKS=ALL
DEATH=1;SUBSET=ALL

SEX:	MALE				FEMALE			
GROUP:	8	9	10	11	8	9	10	11
NUMBER:	10	10	10	10	10	10	10	10
TERMINAL BODY WEIGHT (g)								
# IN GRP :	10	10	10	10	10	10	10	10
M E A N :	26.3	25.9	26.9	24.0*	22.0	21.4	23.2	21.9
STAND DEV:	1.4	1.8	1.6	2.2	1.4	1.1	1.1	1.6
LI - LIVER/GALLBLADD ^a								
# IN GRP :	10	10	10	10	10	10	10	10
M E A N :	1.24	1.36	2.51*	3.50*	1.05	1.10	2.08*	2.96*
STAND DEV:	0.08	0.14	0.29	0.56	0.10	0.10	0.13	0.47

* Significantly different from control value, $p \leq 0.05$.

^a A significant trend at $p \leq 0.05$.

Table 12A
Organ-to-Terminal Body Weight Ratio Means - Main
Study (Terminal Sacrifice)
13-Week Subchronic Oral Toxicity Study of Triclosan in CD-1[®] Mice

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

TABLE 12A
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
ORGAN TO TERMINAL BODY WEIGHT RATIO MEANS (%)

STUDY NUMBER: 483207

TABLE INCLUDES:
SEX=ALL; GROUP=ALL; WEEKS=ALL
DEATH=ALL; SUBSET=ALL

SEX:	MALE						
GROUP:	1	2	3	4	5	6	7
NUMBER:	15	15	15	15	15	15	15

SG - MAND SALIVARY GL

# IN GRP :	15	15	15	13	15	15	13
M E A N :	0.819	0.783	0.751	0.738	0.685*	0.602*	0.606*
STAND DEV:	0.148	0.164	0.114	0.064	0.115	0.109	0.159

LU - LUNG

# IN GRP :	15	15	15	13	15	15	13
M E A N :	0.701	0.688	0.641	0.664	0.631	0.667	0.654
STAND DEV:	0.065	0.086	0.053	0.053	0.054	0.068	0.078

PR - PROSTATE

# IN GRP :	15	15	15	13	15	15	13
M E A N :	0.1902	0.1887	0.1938	0.1707	0.1447	0.1693	0.1638
STAND DEV:	0.0704	0.0655	0.0789	0.0834	0.0484	0.0569	0.0693

UT - UTERUS

# IN GRP :	0	0	0	0	0	0	0
M E A N :							
STAND DEV:							

BR - BRAIN W/STEM

# IN GRP :	15	15	15	13	15	15	13
M E A N :	1.769	1.809	1.733	1.685	1.685	1.836	1.802
STAND DEV:	0.128	0.158	0.145	0.173	0.139	0.128	0.133

* Significantly different from control value, $p \leq 0.05$.

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

TABLE 12A
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
ORGAN TO TERMINAL BODY WEIGHT RATIO MEANS (%)

STUDY NUMBER: 483287

TABLE INCLUDES:
SEX=ALL;GROUP=ALL;WEEKS=ALL
DEATH=ALL;SUBSET=ALL

SEX:	MALE						
GROUP:	1	2	3	4	5	6	7
NUMBER:	15	15	15	15	15	15	15

HT - HEART

# IN GRP :	15	15	15	13	15	15	13
M E A N :	0.614	0.578	0.585	0.557	0.552	0.538	0.560
STAND DEV:	0.064	0.067	0.058	0.084	0.087	0.049	0.063

SP - SPLEEN

# IN GRP :	15	15	15	13	15	15	13
M E A N :	0.235	0.220	0.234	0.253	0.238	0.298*	0.283
STAND DEV:	0.049	0.048	0.040	0.062	0.036	0.104	0.080

KD - KIDNEY ^a

# IN GRP :	15	15	15	13	15	15	13
M E A N :	1.963	1.829	1.741*	1.700	1.619*	1.615*	1.660*
STAND DEV:	0.282	0.190	0.274	0.175	0.141	0.132	0.118

LL - LIVER/GALLBLADD ^a

# IN GRP :	15	15	15	13	15	15	13
M E A N :	4.682	4.774	5.752*	7.157*	8.970*	13.137*	13.724*
STAND DEV:	0.558	0.307	0.473	0.853	0.954	1.431	1.714

TE - TESTIS

# IN GRP :	15	15	15	13	15	15	13
M E A N :	0.836	0.866	0.807	0.854	0.826	0.779	0.794
STAND DEV:	0.116	0.163	0.164	0.095	0.130	0.133	0.116

* Significantly different from control value, $p \leq 0.05$.

^a A significant trend at $p \leq 0.05$.

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

TABLE 12A
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
ORGAN TO TERMINAL BODY WEIGHT RATIO MEANS (%)

STUDY NUMBER: 483287

TABLE INCLUDES:
SEX=ALL;GROUP=ALL;WEEKS=ALL
DEATH=ALL;SUBSET=ALL

SEX:	MALE						
GROUP:	1	2	3	4	5	6	7
NUMBER:	15	15	15	15	15	15	15

EP - EPIDIDYMS

# IN GRP :	15	15	15	13	15	15	13
M E A N :	0.426	0.428	0.446	0.406	0.405	0.373	0.377
STAND DEV:	0.076	0.065	0.052	0.099	0.077	0.063	0.045

AD - ADRENAL

# IN GRP :	15	14	14	13	14	15	13
M E A N :	0.0335	0.0243	0.0261	0.0292	0.0387	0.0453*	0.0456*
STAND DEV:	0.0096	0.0107	0.0090	0.0070	0.0107	0.0124	0.0083

OV - OVARY

# IN GRP :	0	0	0	0	0	0	0
M E A N :							
STAND DEV:							

TH - THYMUS

# IN GRP :	15	15	15	13	14	15	13
M E A N :	0.102	0.086	0.096	0.103	0.100	0.087	0.084
STAND DEV:	0.038	0.022	0.028	0.027	0.030	0.021	0.027

* Significantly different from control value, $p \leq 0.05$.

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

TABLE 12A
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
ORGAN TO TERMINAL BODY WEIGHT RATIO MEANS (%)

STUDY NUMBER: 483287

TABLE INCLUDES:
SEX=ALL;GROUP=ALL;WEEKS=ALL
DEATH=ALL;SUBSET=ALL

SEX:	FEMALE						
GROUP:	1	2	3	4	5	6	7
NUMBER:	15	15	15	15	15	15	15

SG - MAND SALIVARY GL

# IN GRP :	15	15	15	14	15	15	14
M E A N :	0.625	0.597	0.660	0.542	0.575	0.506*	0.515*
STAND DEV:	0.091	0.109	0.105	0.077	0.088	0.120	0.104

LU - LUNG

# IN GRP :	15	15	15	14	15	15	14
M E A N :	0.775	0.777	0.754	0.747	0.731	0.736	0.731
STAND DEV:	0.073	0.066	0.080	0.092	0.090	0.054	0.061

PR - PROSTATE

# IN GRP :	0	0	0	0	0	0	0
M E A N :							
STAND DEV:							

UT - UTERUS

# IN GRP :	15	15	15	14	15	15	14
M E A N :	0.912	1.067	0.919	0.755	0.711	0.501*	0.567*
STAND DEV:	0.270	0.347	0.411	0.230	0.270	0.207	0.277

BR - BRAIN W/STEM

# IN GRP :	15	15	15	14	15	15	14
M E A N :	2.206	2.213	2.105	2.115	2.097	2.083	2.168
STAND DEV:	0.180	0.173	0.201	0.156	0.241	0.164	0.154

* Significantly different from control value, $p \leq 0.05$.

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

TABLE 12A
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
ORGAN TO TERMINAL BODY WEIGHT RATIO MEANS (%)

STUDY NUMBER: 483287

TABLE INCLUDES:
SEX=ALL; GROUP=ALL; WEEKS=ALL
DEATH=ALL; SUBSET=ALL

SEX:	FEMALE						
GROUP:	1	2	3	4	5	6	7
NUMBER:	15	15	15	15	15	15	15

HT - HEART

# IN GRP :	15	15	15	14	15	15	14
M E A N :	0.570	0.597	0.616	0.568	0.585	0.570	0.586
STAND DEV:	0.055	0.055	0.081	0.065	0.072	0.057	0.053

SP - SPLEEN

# IN GRP :	15	15	15	14	15	15	14
M E A N :	0.291	0.320	0.318	0.327	0.299	0.296	0.335
STAND DEV:	0.061	0.050	0.064	0.040	0.049	0.042	0.122

KD - KIDNEY ^a

# IN GRP :	15	15	15	14	15	15	14
M E A N :	1.580	1.600	1.538	1.529	1.514	1.496	1.490
STAND DEV:	0.104	0.155	0.154	0.160	0.145	0.150	0.173

LL - LIVER/GALLBLADD ^a

# IN GRP :	15	15	15	14	15	15	14
M E A N :	4.506	4.911	5.733*	7.870*	9.608*	12.957*	13.756*
STAND DEV:	0.322	0.350	0.658	0.923	1.374	1.419	1.623

TE - TESTIS

# IN GRP :	0	0	0	0	0	0	0
M E A N :							
STAND DEV:							

* Significantly different from control value, $p \leq 0.05$.

^a A significant trend at $p \leq 0.05$.

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

TABLE 12A
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
NICE. (MAIN-GROUPS 1-7)
ORGAN TO TERMINAL BODY WEIGHT RATIO MEANS (%)

STUDY NUMBER: 483287

TABLE INCLUDES:
SEX=ALL;GROUP=ALL;WEEKS=ALL
DEATH=ALL;SUBSET=ALL

SEX:	FEMALE						
GROUP:	1	2	3	4	5	6	7
NUMBER:	15	15	15	15	15	15	15

EP - EPIDIDYMIS

# IN GRP :	0	0	0	0	0	0	0
M E A N :							
STAND DEV:							

AD - ADRENAL

# IN GRP :	15	15	15	14	15	15	14
M E A N :	0.0550	0.0476	0.0558	0.0542	0.0476	0.0561	0.0512
STAND DEV:	0.0075	0.0117	0.0145	0.0132	0.0131	0.0115	0.0087

OV - OVARY

# IN GRP :	15	15	15	14	15	15	14
M E A N :	0.1825	0.2093	0.1791	0.1710	0.1802	0.1513	0.1304
STAND DEV:	0.0717	0.0539	0.0504	0.0648	0.0579	0.0426	0.0394

TN - THYMUS

# IN GRP :	15	15	15	14	15	15	14
M E A N :	0.130	0.126	0.129	0.127	0.139	0.128	0.140
STAND DEV:	0.034	0.045	0.034	0.035	0.044	0.040	0.039

Table 12B
Organ-to-Terminal Body Weight Ratio Means - Satellite
Study (Interim Sacrifice)
13-Week Subchronic Oral Toxicity Study of Triclosan in CD-1[®] Mice

TABLE 12B

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY IN TRICLOSAN IN CD-1
MICE. (SATELLITE-GROUPS 8-11)
ORGAN TO TERMINAL BODY WEIGHT RATIO MEANS (%)

STUDY NUMBER: 483287

TABLE INCLUDES:

SEX=ALL; GROUP=ALL; WEEKS=ALL
DEATH=1; SUBSET=ALL

SEX:	-----MALE-----				-----FEMALE-----			
GROUP:	---8---	---9---	---10---	---11---	---8---	---9---	---10---	---11---
NUMBER:	10	10	10	10	10	10	10	10

	LI - LIVER/GALLBLADD ^a							
# IN GRP :	10	10	10	10	10	10	10	10
M E A N :	4.711	5.257	9.302*	14.546*	4.776	5.153	9.006*	13.540*
STAND DEV:	0.265	0.745	0.654	1.355	0.250	0.383	0.377	2.045

* Significantly different from control value, $p \leq 0.05$.

^a A significant trend at $p \leq 0.05$.

Table 13
Organ-to-Brain Weight Ratio Means - Main Study (Terminal Sacrifice)
13-Week Subchronic Oral Toxicity Study of Triclosan in CD-1[®] Mice

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

TABLE 13
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
ORGAN-TO-BRAIN WEIGHT RATIO MEANS

STUDY NUMBER: 483287

TABLE INCLUDES:
SEX=ALL; GROUP=ALL; WEEKS=ALL
DEATH=ALL; SUBSET=ALL

SEX:	-----MALE-----						
GROUP:	---1---	---2---	---3---	---4---	---5---	---6---	---7---
NUMBER:	15	15	15	15	15	15	15

SG - MAND SALIVARY GL

# IN GRP :	15	15	15	13	15	15	13
M E A N :	0.464	0.435	0.435	0.442	0.410	0.331*	0.339*
STAND DEV:	0.078	0.101	0.068	0.059	0.083	0.071	0.092

LU - LUNG

# IN GRP :	15	15	15	13	15	15	13
M E A N :	0.398	0.382	0.372	0.397	0.376	0.364	0.364
STAND DEV:	0.040	0.050	0.036	0.041	0.037	0.034	0.046

PR - PROSTATE

# IN GRP :	15	15	15	13	15	15	13
M E A N :	0.1088	0.1045	0.1137	0.0993	0.0859	0.0922	0.0897
STAND DEV:	0.0436	0.0363	0.0516	0.0430	0.0283	0.0311	0.0343

UT - UTERUS

# IN GRP :	0	0	0	0	0	0	0
M E A N :							
STAND DEV:							

* Significantly different from control value, $p \leq 0.05$.

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

TABLE 13
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
ORGAN-TO-BRAIN WEIGHT RATIO MEANS

STUDY NUMBER: 483287

TABLE INCLUDES:
SEX=ALL; GROUP=ALL; WEEKS=ALL
DEATH=ALL; SUBSET=ALL

SEX:	MALE						
GROUP:	1	2	3	4	5	6	7
NUMBER:	15	15	15	15	15	15	15

HT - HEART

# IN GRP :	15	15	15	13	15	15	13
M E A N :	0.348	0.321	0.339	0.333	0.330	0.294*	0.312
STAND DEV:	0.035	0.042	0.036	0.056	0.061	0.030	0.046

SP - SPLEEN

# IN GRP :	15	15	15	13	15	15	13
M E A N :	0.133	0.122	0.135	0.153	0.142	0.163	0.158
STAND DEV:	0.026	0.029	0.019	0.044	0.026	0.058	0.045

KD - KIDNEY

# IN GRP :	15	15	15	13	15	15	13
M E A N :	1.110	1.013	1.011	1.016	0.964*	0.884*	0.927*
STAND DEV:	0.150	0.092	0.179	0.131	0.087	0.098	0.108

LL - LIVER/GALLBLADD^a

# IN GRP :	15	15	15	13	15	15	13
M E A N :	2.651	2.661	3.345*	4.312*	5.364*	7.220*	7.695*
STAND DEV:	0.265	0.320	0.429	0.860	0.760	1.177	1.407

TE - TESTIS

# IN GRP :	15	15	15	13	15	15	13
M E A N :	0.476	0.481	0.466	0.511	0.491	0.426	0.444
STAND DEV:	0.084	0.091	0.087	0.069	0.071	0.080	0.078

* Significantly different from control value, $p \leq 0.05$.

^a A significant trend at $p \leq 0.05$.

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

TABLE 13
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
ORGAN-TO-BRAIN WEIGHT RATIO MEANS

STUDY NUMBER: 483287

TABLE INCLUDES:
SEX=ALL;GROUP=ALL;WEEKS=ALL
DEATH=ALL;SUBSET=ALL

SEX:	MALE						
GROUP:	1	2	3	4	5	6	7
NUMBER:	15	15	15	15	15	15	15

EP - EPIDIDYMIS

# IN GRP :	15	15	15	13	15	15	13
M E A N :	0.242	0.238	0.259	0.241	0.243	0.205	0.211
STAND DEV:	0.051	0.040	0.037	0.053	0.056	0.042	0.029

AD - ADRENAL

# IN GRP :	15	14	14	13	14	15	13
M E A N :	0.0190	0.0133*	0.0153	0.0177	0.0230	0.0247*	0.0253*
STAND DEV:	0.0053	0.0057	0.0055	0.0054	0.0060	0.0067	0.0042

OV - OVARY

# IN GRP :	0	0	0	0	0	0	0
M E A N :							
STAND DEV:							

TH - THYMUS

# IN GRP :	15	15	15	13	14	15	13
M E A N :	0.058	0.048	0.056	0.063	0.060	0.048	0.047
STAND DEV:	0.022	0.012	0.017	0.021	0.017	0.013	0.015

* Significantly different from control value, $p \leq 0.05$.

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TABLE 13
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
ORGAN-TO-BRAIN WEIGHT RATIO MEANS

STUDY NUMBER: 483287

TABLE INCLUDES:
SEX=ALL;GROUP=ALL;WEEKS=ALL
DEATH=ALL;SUBSET=ALL

SEX:	FEMALE						
GROUP:	1	2	3	4	5	6	7
NUMBER:	15	15	15	15	15	15	15

SG - MAND SALIVARY GL

# IN GRP :	15	15	15	14	15	15	14
M E A N :	0.285	0.271	0.317	0.257	0.277	0.243	0.239
STAND DEV:	0.048	0.055	0.065	0.038	0.052	0.056	0.055

LU - LUNG

# IN GRP :	15	15	15	14	15	15	14
M E A N :	0.353	0.353	0.360	0.354	0.350	0.356	0.339
STAND DEV:	0.042	0.036	0.042	0.041	0.031	0.043	0.042

PR - PROSTATE

# IN GRP :	0	0	0	0	0	0	0
M E A N :							
STAND DEV:							

UT - UTERUS

# IN GRP :	15	15	15	14	15	15	14
M E A N :	0.415	0.488	0.431	0.359	0.341	0.240*	0.264*
STAND DEV:	0.123	0.178	0.172	0.115	0.127	0.091	0.130

* Significantly different from control value, $p \leq 0.05$.

HAZLETON WASHINGTON, INC.
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TABLE 13
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
ORGAN-TO-BRAIN WEIGHT RATIO MEANS

STUDY NUMBER: 483287

TABLE INCLUDES:
SEX=ALL; GROUP=ALL; WEEKS=ALL
DEATH=ALL; SUBSET=ALL

SEX:	FEMALE						
GROUP:	1	2	3	4	5	6	7
NUMBER:	15	15	15	15	15	15	15

HT - HEART

# IN GRP :	15	15	15	14	15	15	14
M E A N :	0.259	0.270	0.293	0.269	0.281	0.274	0.271
STAND DEV:	0.022	0.023	0.031	0.033	0.035	0.026	0.027

SP - SPLEEN

# IN GRP :	15	15	15	14	15	15	14
M E A N :	0.134	0.146	0.152	0.155	0.145	0.143	0.154
STAND DEV:	0.035	0.030	0.032	0.020	0.030	0.021	0.053

KD - KIDNEY

# IN GRP :	15	15	15	14	15	15	14
M E A N :	0.719	0.727	0.735	0.725	0.728	0.723	0.689
STAND DEV:	0.050	0.092	0.092	0.082	0.087	0.101	0.081

LL - LIVER/GALLBLADD^a

# IN GRP :	15	15	15	14	15	15	14
M E A N :	2.059	2.235	2.768*	3.739*	4.644*	6.263*	6.390*
STAND DEV:	0.270	0.263	0.577	0.487	0.897	0.853	0.985

TE - TESTIS

# IN GRP :	0	0	0	0	0	0	0
M E A N :							
STAND DEV:							

* significantly different from control value, $p \leq 0.05$.

^a A significant trend at $p \leq 0.05$.

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

TABLE 13
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
ORGAN-TO-BRAIN WEIGHT RATIO MEANS

STUDY NUMBER: 483287

TABLE INCLUDES:
SEX=ALL; GROUP=ALL; WEEKS=ALL
DEATH=ALL; SUBSET=ALL

SEX:	FEMALE						
GROUP:	1	2	3	4	5	6	7
NUMBER:	15	15	15	15	15	15	15

EP - EPIDIDYMNIS

# IN GRP :	0	0	0	0	0	0	0
MEAN :							
STAND DEV:							

AD - ADRENAL

# IN GRP :	15	15	15	14	15	15	14
MEAN :	0.0250	0.0215	0.0264	0.0258	0.0230	0.0270	0.0238
STAND DEV:	0.0033	0.0051	0.0057	0.0067	0.0068	0.0054	0.0046

OV - OVARY

# IN GRP :	15	15	15	14	15	15	14
MEAN :	0.0828	0.0949	0.0850	0.0807	0.0862	0.0724	0.0607
STAND DEV:	0.0333	0.0241	0.0229	0.0284	0.0268	0.0180	0.0195

TN - THYMUS

# IN GRP :	15	15	15	14	15	15	14
MEAN :	0.059	0.058	0.063	0.060	0.067	0.062	0.065
STAND DEV:	0.018	0.023	0.020	0.018	0.021	0.020	0.018

Table 14A
Expanded Histopathology Incidence Summary
Main Study (Unscheduled Deaths)
13-Week Subchronic Oral Toxicity Study of Triclosan in CD-1[®] Mice

Standard Key to Expanded Histopathology Incidence Summary

SYMBOLS PREFACING NEOPLASTIC FINDINGS

B- = Primary, Benign Neoplasm
M- = Primary, Malignant Neoplasm
N- = Metastatic Neoplasm
I- = Locally Invasive Neoplasm
X- = Other Neoplasm

SYMBOLS USED IN EXPANDED TABLE

-> = Finding Not Present
P> = Finding Present
+> = Neoplastic Finding Present
1> = Minimal
2> = Slight
3> = Moderate
4> = Moderately Severe
5> = Severe
TL> = Total
MN> = Mean of Graded Findings

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TABLE 14A
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
EXPANDED HISTOPATHOLOGY INCIDENCE SUMMARY

PRINTED: 20-JAN-93
PAGE: 187

STUDY NUMBER: 483287

TABLE INCLUDES:

SEX=ALL; GROUP=ALL; WEEKS=ALL
DEATH=UNSCHED; FIND=ALL; SUBSET=ALL

--- NUMBER - OF - ANIMALS - AFFECTED ---

SEX: -----MALE-----

GROUP: -1- -2- -3- -4- -5- -6- -7-

ORGAN/TISSUE EXAMINED

NUMBER: 0 0 0 2 0 0 2

** TOP OF LIST **

SPLEEN (SP) NUMBER EXAMINED: 0 0 0 2 0 0 2
NOT REMARKABLE: 0 0 0 1 0 0 0

--EXTRAMEDULLARY HEMATOPOIESIS, INCREASED

-> 0 0 0 2 0 0 1
4> 0 0 0 0 0 0 1
TL> 0 0 0 2 0 0 2
MN> 0.0 0.0 0.0 0.0 0.0 0.0 2.0

--PIGMENT

-> 0 0 0 2 0 0 1
1> 0 0 0 0 0 0 1
2> 0 0 0 0 0 0 0
TL> 0 0 0 2 0 0 2
MN> 0.0 0.0 0.0 0.0 0.0 0.0 0.5

--AMYLOIDOSIS

-> 0 0 0 2 0 0 2
TL> 0 0 0 2 0 0 2
MN> 0.0 0.0 0.0 0.0 0.0 0.0 0.0

--DEPLETION, LYMPHOID

-> 0 0 0 1 0 0 1
2> 0 0 0 1 0 0 1
4> 0 0 0 0 0 0 0
TL> 0 0 0 2 0 0 2
MN> 0.0 0.0 0.0 1.0 0.0 0.0 1.0

--NECROSIS, LYMPHOID

-> 0 0 0 2 0 0 2
TL> 0 0 0 2 0 0 2
MN> 0.0 0.0 0.0 0.0 0.0 0.0 0.0

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TABLE 14A
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE, (MAIN-GROUPS 1-7)
EXPANDED HISTOPATHOLOGY INCIDENCE SUMMARY

PRINTED: 20-JAN-93
PAGE: 188

STUDY NUMBER: 483287

TABLE INCLUDES:

SEX=ALL; GROUP=ALL; WEEKS=ALL
DEATH=UNSCHED; FIND=ALL; SUBSET=ALL

--- NUMBER - OF - ANIMALS - AFFECTED ---

ORGAN/TISSUE EXAMINED	NUMBER:	SEX: -----MALE-----						
		GROUP: -1-	-2-	-3-	-4-	-5-	-6-	-7-
		0	0	0	2	0	0	2
STOMACH, NONGL (SU)	NUMBER EXAMINED:	0	0	0	2	0	0	2
	NOT REMARKABLE:	0	0	0	2	0	0	2
--INFLAMMATION, CHRONIC	->	0	0	0	2	0	0	2
	TL>	0	0	0	2	0	0	2
	MN>	0.0	0.0	0.0	0.0	0.0	0.0	0.0
STOMACH, GL (ST)	NUMBER EXAMINED:	0	0	0	1	0	0	2
	NOT REMARKABLE:	0	0	0	1	0	0	1
--HYPERPLASIA	->	0	0	0	1	0	0	2
	TL>	0	0	0	1	0	0	2
	MN>	0.0	0.0	0.0	0.0	0.0	0.0	0.0
--HYPERPLASIA, CYSTIC	->	0	0	0	1	0	0	2
	TL>	0	0	0	1	0	0	2
	MN>	0.0	0.0	0.0	0.0	0.0	0.0	0.0
--INFLAMMATION, CHRONIC	->	0	0	0	1	0	0	2
	TL>	0	0	0	1	0	0	2
	MN>	0.0	0.0	0.0	0.0	0.0	0.0	0.0
--MUCOSA, NECROSIS	->	0	0	0	1	0	0	1
	1>	0	0	0	0	0	0	1
	TL>	0	0	0	1	0	0	2
	MN>	0.0	0.0	0.0	0.0	0.0	0.0	0.5
--INFLAMMATION, ACUTE	->	0	0	0	1	0	0	2
	TL>	0	0	0	1	0	0	2
	MN>	0.0	0.0	0.0	0.0	0.0	0.0	0.0

** CONTINUED ON NEXT PAGE **

HAZLETON WASHINGTON, INC.
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TABLE 14A
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
EXPANDED HISTOPATHOLOGY INCIDENCE SUMMARY

PRINTED: 20-JAN-93
PAGE: 189

STUDY NUMBER: 483287

TABLE INCLUDES:

SEX=ALL;GROUP=ALL;WEEKS=ALL
DEATH=UNSCHED;FIND=ALL;SUBSET=ALL

--- NUMBER - OF - ANIMALS - AFFECTED ---

SEX: -----MALE-----								
GROUP: -1- -2- -3- -4- -5- -6- -7-								
NUMBER:		0	0	0	2	0	0	2
-----		---	---	---	---	---	---	---
ORGAN/TISSUE EXAMINED								
** FROM PREVIOUS PAGE **								
STOMACH, GL (ST)		NUMBER EXAMINED:	0	0	0	1	0	0
		NOT REMARKABLE:	0	0	0	1	0	0
--AMYLOIDOSIS		->	0	0	0	1	0	0
		TL>	0	0	0	1	0	0
ADRENAL, CORTEX (AC)		NUMBER EXAMINED:	0	0	0	2	0	0
		NOT REMARKABLE:	0	0	0	2	0	0
--PIGMENT		->	0	0	0	2	0	0
		TL>	0	0	0	2	0	0
		MN>	0.0	0.0	0.0	0.0	0.0	0.0
--HYPERTROPHY, ZONA FASCICULATA		->	0	0	0	2	0	0
		2>	0	0	0	0	0	1
		TL>	0	0	0	2	0	0
		MN>	0.0	0.0	0.0	0.0	0.0	1.0
--VACUOLIZATION, X-ZONE		->	0	0	0	2	0	0
		TL>	0	0	0	2	0	0
		MN>	0.0	0.0	0.0	0.0	0.0	0.0
--HYPERPLASIA, SUBCAPSULAR CELL		->	0	0	0	2	0	0
		TL>	0	0	0	2	0	0
		MN>	0.0	0.0	0.0	0.0	0.0	0.0
--UNILATERALLY EXAMINED		->	0	0	0	2	0	0
		TL>	0	0	0	2	0	0

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TABLE 14A
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
EXPANDED HISTOPATHOLOGY INCIDENCE SUMMARY

PRINTED: 20-JAN-93
PAGE: 190

STUDY NUMBER: 483287

TABLE INCLUDES:

SEX=ALL; GROUP=ALL; WEEKS=ALL
DEATH=UNSCHED; FIND=ALL; SUBSET=ALL

--- NUMBER - OF - ANIMALS - AFFECTED ---

TABLE INCLUDED: SEX=ALL; GROUP=ALL; WEEKS=ALL DEATH=UNSCHED; FIND=ALL; SUBSET=ALL		SEX: -----MALE-----							
		GROUP: -1- -2- -3- -4- -5- -6- -7-							
ORGAN/TISSUE EXAMINED		NUMBER:	0	0	0	2	0	0	2
			--	--	--	--	--	--	--
ADRENAL, MEDULLA (AM)		NUMBER EXAMINED:	0	0	0	2	0	0	2
		NOT REMARKABLE:	0	0	0	1	0	0	2
--UNILATERALLY EXAMINED		->	0	0	0	1	0	0	2
		P>	0	0	0	1	0	0	0
		TL>	0	0	0	2	0	0	2
KIDNEY (KD)		NUMBER EXAMINED:	0	0	0	2	0	0	2
		NOT REMARKABLE:	0	0	0	2	0	0	1
--INFLAMMATION, CHRONIC		->	0	0	0	2	0	0	2
		I>	0	0	0	0	0	0	0
		TL>	0	0	0	2	0	0	2
		MN>	0.0	0.0	0.0	0.0	0.0	0.0	0.0
--TUBULE, MINERALIZATION		->	0	0	0	2	0	0	2
		TL>	0	0	0	2	0	0	2
		MN>	0.0	0.0	0.0	0.0	0.0	0.0	0.0
--TUBULE, REGENERATION		->	0	0	0	2	0	0	1
		I>	0	0	0	0	0	0	1
		TL>	0	0	0	2	0	0	2
		MN>	0.0	0.0	0.0	0.0	0.0	0.0	0.5
--HYPERPLASIA, LYMPHOID		->	0	0	0	2	0	0	2
		TL>	0	0	0	2	0	0	2
		MN>	0.0	0.0	0.0	0.0	0.0	0.0	0.0
--TUBULE, DILATATION		->	0	0	0	2	0	0	2
		TL>	0	0	0	2	0	0	2
		MN>	0.0	0.0	0.0	0.0	0.0	0.0	0.0

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HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

TABLE 14A
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
EXPANDED HISTOPATHOLOGY INCIDENCE SUMMARY

PRINTED: 20-JAN-93
PAGE: 191

STUDY NUMBER: 483287

TABLE INCLUDES:

SEX=ALL;GROUP=ALL;WEEKS=ALL
DEATH=UNSCHED;FIND=ALL;SUBSET=ALL

--- NUMBER - OF - ANIMALS - AFFECTED ---

SEX=ALL; GROUP=ALL; WEEKS=ALL DEATH=UNSCHEd; FIND=ALL; SUBSET=ALL		SEX: -----MALE-----							
		GROUP:	-1-	-2-	-3-	-4-	-5-	-6-	-7-
ORGAN/TISSUE EXAMINED		NUMBER:	0	0	0	2	0	0	2

** FROM PREVIOUS PAGE **									
KIDNEY (KD)		NUMBER EXAMINED:	0	0	0	2	0	0	2
		NOT REMARKABLE:	0	0	0	2	0	0	1
--AMYLOIDOSIS		->	0	0	0	2	0	0	2
		TL>	0	0	0	2	0	0	2
		MN>	0.0	0.0	0.0	0.0	0.0	0.0	0.0
--PIGMENT		->	0	0	0	2	0	0	2
		TL>	0	0	0	2	0	0	2
		MN>	0.0	0.0	0.0	0.0	0.0	0.0	0.0
--INFLAMMATION, GRANULOMATOUS		->	0	0	0	2	0	0	2
		TL>	0	0	0	2	0	0	2
		MN>	0.0	0.0	0.0	0.0	0.0	0.0	0.0
--CYST		->	0	0	0	2	0	0	2
		P>	0	0	0	0	0	0	0
		TL>	0	0	0	2	0	0	2
--INFLAMMATION, SUBACUTE		->	0	0	0	2	0	0	2
		TL>	0	0	0	2	0	0	2
		MN>	0.0	0.0	0.0	0.0	0.0	0.0	0.0
--PELVIS, DILATATION		->	0	0	0	2	0	0	2
		TL>	0	0	0	2	0	0	2
UTERUS (UT)		NUMBER EXAMINED:	0	0	0	0	0	0	0
		NOT REMARKABLE:	0	0	0	0	0	0	0
--HYPERPLASIA, CYSTIC ENDOMETRIAL		->	0	0	0	0	0	0	0
		TL>	0	0	0	0	0	0	0
		MN>	0.0	0.0	0.0	0.0	0.0	0.0	0.0

** CONTINUED ON NEXT PAGE **

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

TABLE 14A
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
EXPANDED HISTOPATHOLOGY INCIDENCE SUMMARY

PRINTED: 20-JAN-93
PAGE: 192

STUDY NUMBER: 483287

TABLE INCLUDES:

SEX=ALL; GROUP=ALL; WEEKS=ALL
DEATH=UNSCHED; FIND=ALL; SUBSET=ALL

--- NUMBER - OF - ANIMALS - AFFECTED ---

TABLE INCLUDES:		SEX: -----MALE-----							
SEX=ALL; GROUP=ALL; WEEKS=ALL		GROUP: -1- -2- -3- -4- -5- -6- -7-							
DEATH=UNSCHED; FIND=ALL; SUBSET=ALL									
ORGAN/TISSUE EXAMINED		NUMBER:	0	0	0	2	0	0	2
-----		----	----	----	----	----	----	----	----
** FROM PREVIOUS PAGE **									
UTERUS (UT)		NUMBER EXAMINED:	0	0	0	0	0	0	0
		NOT REMARKABLE:	0	0	0	0	0	0	0
--DILATATION		->	0	0	0	0	0	0	0
		TL>	0	0	0	0	0	0	0
--HYPOPLASIA		4>	0	0	0	0	0	0	0
		5>	0	0	0	0	0	0	0
		TL>	0	0	0	0	0	0	0
		MN>	0.0	0.0	0.0	0.0	0.0	0.0	0.0
UTERUS, CERVIX (CV)		NUMBER EXAMINED:	0	0	0	0	0	0	0
		NOT REMARKABLE:	0	0	0	0	0	0	0
--HYPOPLASIA		->	0	0	0	0	0	0	0
		4>	0	0	0	0	0	0	0
		TL>	0	0	0	0	0	0	0
		MN>	0.0	0.0	0.0	0.0	0.0	0.0	0.0
VAGINA (VA)		NUMBER EXAMINED:	0	0	0	0	0	0	0
		NOT REMARKABLE:	0	0	0	0	0	0	0
--CYST, KERATIN		->	0	0	0	0	0	0	0
		TL>	0	0	0	0	0	0	0
--HYPOPLASIA		->	0	0	0	0	0	0	0
		TL>	0	0	0	0	0	0	0

HAZLETON WASHINGTON, INC.
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TABLE 14A
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
EXPANDED HISTOPATHOLOGY INCIDENCE SUMMARY

PRINTED: 20-JAN-93
PAGE: 193

STUDY NUMBER: 483287

TABLE INCLUDES:

SEX=ALL; GROUP=ALL; WEEKS=ALL
DEATH=UNSCHED; FIND=ALL; SUBSET=ALL

--- NUMBER OF ANIMALS AFFECTED ---

ORGAN/TISSUE EXAMINED	NUMBER:	SEX: -----MALE-----						
		GROUP: -1- -2- -3- -4- -5- -6- -7-						
		0	0	0	2	0	0	2
MAMMARY, FEMALE (MF)	NUMBER EXAMINED:	0	0	0	0	0	0	0
	NOT REMARKABLE:	0	0	0	0	0	0	0
--DILATATION, CYSTIC	->	0	0	0	0	0	0	0
	TL>	0	0	0	0	0	0	0
	MN>	0.0	0.0	0.0	0.0	0.0	0.0	0.0
--HYPOPLASIA, EPITHELIAL	->	0	0	0	0	0	0	0
	TL>	0	0	0	0	0	0	0
SKIN (SK)	NUMBER EXAMINED:	0	0	0	2	0	0	2
	NOT REMARKABLE:	0	0	0	2	0	0	2
LIVER (LI)	NUMBER EXAMINED:	0	0	0	1	0	0	2
	NOT REMARKABLE:	0	0	0	0	0	0	0
--HEPATOCYTE, HYPERTROPHY, CENTROLOBULAR	->	0	0	0	1	0	0	0
	1>	0	0	0	0	0	0	1
	2>	0	0	0	0	0	0	0
	3>	0	0	0	0	0	0	0
	4>	0	0	0	0	0	0	1
	TL>	0	0	0	1	0	0	2
	MN>	0.0	0.0	0.0	0.0	0.0	0.0	2.5
--VACUOLIZATION	->	0	0	0	0	0	0	2
	1>	0	0	0	1	0	0	0
	TL>	0	0	0	1	0	0	2
	MN>	0.0	0.0	0.0	1.0	0.0	0.0	0.0
--PIGMENT, BILE	->	0	0	0	1	0	0	2
	TL>	0	0	0	1	0	0	2
	MN>	0.0	0.0	0.0	0.0	0.0	0.0	0.0

** CONTINUED ON NEXT PAGE **

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

TABLE 14A
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
EXPANDED HISTOPATHOLOGY INCIDENCE SUMMARY

PRINTED: 20-JAN-93
PAGE: 194

STUDY NUMBER: 483287

TABLE INCLUDES:

SEX=ALL; GROUP=ALL; WEEKS=ALL
DEATH=UNSCHED; FIND=ALL; SUBSET=ALL

--- NUMBER - OF - ANIMALS - AFFECTED ---

SEX: -----MALE-----

GROUP: -1- -2- -3- -4- -5- -6- -7-

ORGAN/TISSUE EXAMINED

NUMBER: 0 0 0 2 0 0 2

** FROM PREVIOUS PAGE **

LIVER (LI) NUMBER EXAMINED: 0 0 0 1 0 0 2
NOT REMARKABLE: 0 0 0 0 0 0 0

--KUPFFER CELL/MACROPHAGE, PIGMENT

-> 0 0 0 1 0 0 2
1> 0 0 0 0 0 0 0
TL> 0 0 0 1 0 0 2
MN> 0.0 0.0 0.0 0.0 0.0 0.0 0.0

--HEPATOCYTE, PIGMENT

-> 0 0 0 1 0 0 2
TL> 0 0 0 1 0 0 2
MN> 0.0 0.0 0.0 0.0 0.0 0.0 0.0

--NECROSIS

-> 0 0 0 1 0 0 0
3> 0 0 0 0 0 0 1
4> 0 0 0 0 0 0 1
TL> 0 0 0 1 0 0 2
MN> 0.0 0.0 0.0 0.0 0.0 0.0 3.5

--NECROSIS, INDIVIDUAL CELL

-> 0 0 0 1 0 0 0
1> 0 0 0 0 0 0 1
3> 0 0 0 0 0 0 1
TL> 0 0 0 1 0 0 2
MN> 0.0 0.0 0.0 0.0 0.0 0.0 2.0

--INFLAMMATION, CHRONIC/CHRONIC ACTIVE

-> 0 0 0 1 0 0 1
3> 0 0 0 0 0 0 1
TL> 0 0 0 1 0 0 2
MN> 0.0 0.0 0.0 0.0 0.0 0.0 1.5

** CONTINUED ON NEXT PAGE **

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

TABLE 14A
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
EXPANDED HISTOPATHOLOGY INCIDENCE SUMMARY

PRINTED: 20-JAN-93
PAGE: 195
STUDY NUMBER: 483287

TABLE INCLUDES:
SEX=ALL; GROUP=ALL; WEEKS=ALL
DEATH=UNSCHED; FIND=ALL; SUBSET=ALL

		--- N U M B E R - O F - A N I M A L S - A F F E C T E D ---							
		SEX: -----MALE-----							
		GROUP:	-1-	-2-	-3-	-4-	-5-	-6-	-7-
ORGAN/TISSUE EXAMINED	NUMBER:	0	0	0	2	0	0	0	2

** FROM PREVIOUS PAGE **									
LIVER (LI)	NUMBER EXAMINED:	0	0	0	1	0	0	0	2
	NOT REMARKABLE:	0	0	0	0	0	0	0	0
--BILE DUCT, INFLAMMATION, CHRONIC									
	->	0	0	0	1	0	0	0	2
	1>	0	0	0	0	0	0	0	0
	TL>	0	0	0	1	0	0	0	2
	MN>	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
--MINERALIZATION									
	->	0	0	0	1	0	0	0	1
	2>	0	0	0	0	0	0	0	1
	TL>	0	0	0	1	0	0	0	2
	MN>	0.0	0.0	0.0	0.0	0.0	0.0	0.0	1.0
--INFARCT									
	->	0	0	0	1	0	0	0	2
	TL>	0	0	0	1	0	0	0	2
--EXTRAMEDULLARY HEMATOPOIESIS, INCREASED									
	->	0	0	0	1	0	0	0	2
	TL>	0	0	0	1	0	0	0	2
	MN>	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
BRAIN W/STEM (BR)	NUMBER EXAMINED:	0	0	0	2	0	0	0	2
	NOT REMARKABLE:	0	0	0	1	0	0	0	2
--HEMORRHAGE									
	->	0	0	0	1	0	0	0	2
	P>	0	0	0	1	0	0	0	0
	TL>	0	0	0	2	0	0	0	2

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

TABLE 14A
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
EXPANDED HISTOPATHOLOGY INCIDENCE SUMMARY

PRINTED: 20-JAN-93
PAGE: 196

STUDY NUMBER: 483287

TABLE INCLUDES:
SEX=ALL; GROUP=ALL; WEEKS=ALL
DEATH=UNSCHEG; FIND=ALL; SUBSET=ALL

		--- N U M B E R - O F - A N I M A L S - A F F E C T E D ---							
TABLE INCLUDES: SEX=ALL;GROUP=ALL;WEEKS=ALL DEATH=UNSCHED;FIND=ALL;SUBSET=ALL		SEX:	-----MALE-----						
		GROUP:	-1-	-2-	-3-	-4-	-5-	-6-	-7-
ORGAN/TISSUE EXAMINED		NUMBER:	0	0	0	2	0	0	2
			-	-	-	-	-	-	-
CORD, CERVICAL (CS)	NUMBER EXAMINED:	0	0	0	2	0	0	0	2
	NOT REMARKABLE:	0	0	0	1	0	0	0	2
	--HEMORRHAGE								
	->	0	0	0	1	0	0	0	2
CORD, THORACIC (TC)	P>	0	0	0	1	0	0	0	0
	TL>	0	0	0	2	0	0	0	2
	NUMBER EXAMINED:	0	0	0	2	0	0	0	2
	NOT REMARKABLE:	0	0	0	1	0	0	0	2
CORD, LUMBAR (LC)	--HEMORRHAGE								
	->	0	0	0	1	0	0	0	2
	P>	0	0	0	1	0	0	0	0
	TL>	0	0	0	2	0	0	0	2
PITUITARY (PI)	NUMBER EXAMINED:	0	0	0	2	0	0	0	2
	NOT REMARKABLE:	0	0	0	2	0	0	0	2
	--CYST								
	->	0	0	0	1	0	0	0	1
THYROID (TY)	TL>	0	0	0	1	0	0	0	1
	NUMBER EXAMINED:	0	0	0	2	0	0	0	2
	NOT REMARKABLE:	0	0	0	1	0	0	0	2
	--FOLLICLE, CYST								
--UNILATERALLY EXAMINED	->	0	0	0	2	0	0	0	2
	P>	0	0	0	2	0	0	0	2
	TL>	0	0	0	2	0	0	0	2

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TABLE 14A
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
EXPANDED HISTOPATHOLOGY INCIDENCE SUMMARY

PRINTED: 20-JAN-93
PAGE: 197

STUDY NUMBER: 483287

		--- NUMBER - OF - ANIMALS - AFFECTED ---						
		SEX: -----MALE-----						
		GROUP: -1- -2- -3- -4- -5- -6- -7-						
ORGAN/TISSUE EXAMINED	NUMBER:	0	0	0	2	0	0	2

PARATHYROID (PT)	NUMBER EXAMINED:	0	0	0	1	0	0	2
	NOT REMARKABLE:	0	0	0	0	0	0	1
--UNILATERALLY EXAMINED								
	->	0	0	0	0	0	0	1
	P>	0	0	0	1	0	0	1
	TL>	0	0	0	1	0	0	2
ESOPHAGUS (ES)	NUMBER EXAMINED:	0	0	0	2	0	0	2
	NOT REMARKABLE:	0	0	0	2	0	0	2
--INFLAMMATION, CHRONIC								
	->	0	0	0	2	0	0	2
	TL>	0	0	0	2	0	0	2
	MN>	0.0	0.0	0.0	0.0	0.0	0.0	0.0
TRACHEA (TR)	NUMBER EXAMINED:	0	0	0	2	0	0	2
	NOT REMARKABLE:	0	0	0	2	0	0	2
LUNG (LU)	NUMBER EXAMINED:	0	0	0	2	0	0	2
	NOT REMARKABLE:	0	0	0	2	0	0	2
--PERIBRONCHIAL/PERIVASCULAR, INFILTRATION, LYMPHOID								
	->	0	0	0	2	0	0	2
	TL>	0	0	0	2	0	0	2
	MN>	0.0	0.0	0.0	0.0	0.0	0.0	0.0
--INFLAMMATION, CHRONIC								
	->	0	0	0	2	0	0	2
	TL>	0	0	0	2	0	0	2
	MN>	0.0	0.0	0.0	0.0	0.0	0.0	0.0
--VESSEL, MINERALIZATION								
	->	0	0	0	2	0	0	2
	TL>	0	0	0	2	0	0	2
	MN>	0.0	0.0	0.0	0.0	0.0	0.0	0.0

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HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

TABLE 14A
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
EXPANDED HISTOPATHOLOGY INCIDENCE SUMMARY

PRINTED: 20-JAN-93
PAGE: 198

STUDY NUMBER: 483287

TABLE INCLUDES:

SEX=ALL; GROUP=ALL; WEEKS=ALL
DEATH=UNSCHED; FIND=ALL; SUBSET=ALL

--- NUMBER - OF - ANIMALS - AFFECTED ---

		SEX: -----MALE-----						
		GROUP: -1- -2- -3- -4- -5- -6- -7-						
ORGAN/TISSUE EXAMINED		NUMBER: 0 0 0 2 0 0 2						
** FROM PREVIOUS PAGE **								
LUNG (LU)	NUMBER EXAMINED:	0	0	0	2	0	0	2
	NOT REMARKABLE:	0	0	0	2	0	0	2
--HEMORRHAGE	->	0	0	0	2	0	0	2
	TL>	0	0	0	2	0	0	2
	MN>	0.0	0.0	0.0	0.0	0.0	0.0	0.0
HEART (HT)	NUMBER EXAMINED:	0	0	0	2	0	0	2
	NOT REMARKABLE:	0	0	0	2	0	0	1
--INFLAMMATION, CHRONIC	->	0	0	0	2	0	0	1
	1>	0	0	0	0	0	0	1
	TL>	0	0	0	2	0	0	2
	MN>	0.0	0.0	0.0	0.0	0.0	0.0	0.5
--MINERALIZATION	->	0	0	0	2	0	0	1
	1>	0	0	0	0	0	0	1
	TL>	0	0	0	2	0	0	2
	MN>	0.0	0.0	0.0	0.0	0.0	0.0	0.5
--DEGENERATION	->	0	0	0	2	0	0	1
	1>	0	0	0	0	0	0	1
	TL>	0	0	0	2	0	0	2
	MN>	0.0	0.0	0.0	0.0	0.0	0.0	0.5
GALLBLADDER (GB)	NUMBER EXAMINED:	0	0	0	0	0	0	1
	NOT REMARKABLE:	0	0	0	0	0	0	1
--INFLAMMATION, CHRONIC	->	0	0	0	0	0	0	1
	TL>	0	0	0	0	0	0	1
	MN>	0.0	0.0	0.0	0.0	0.0	0.0	0.0

HAZLETON WASHINGTON, INC.
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TABLE 14A
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
EXPANDED HISTOPATHOLOGY INCIDENCE SUMMARY

PRINTED: 20-JAN-93
PAGE: 199

STUDY NUMBER: 483287

TABLE INCLUDES:

SEX=ALL; GROUP=ALL; WEEKS=ALL
DEATH=UNSCHED; FIND=ALL; SUBSET=ALL

--- NUMBER - OF - ANIMALS - AFFECTED ---

TABLE INCLUDES:		SEX: -----MALE-----							
SEX=ALL; GROUP=ALL; WEEKS=ALL		GROUP: -1- -2- -3- -4- -5- -6- -7-							
DEATH=UNSCHED; FIND=ALL; SUBSET=ALL									
ORGAN/TISSUE EXAMINED		NUMBER:	0	0	0	2	0	0	2
-----		-----	-----	-----	-----	-----	-----	-----	-----
DUODENUM (DU)		NUMBER EXAMINED:	0	0	0	1	0	0	2
		NOT REMARKABLE:	0	0	0	1	0	0	2
JEJUNUM (JE)		NUMBER EXAMINED:	0	0	0	1	0	0	2
		NOT REMARKABLE:	0	0	0	1	0	0	2
--HYPERPLASIA, LYMPHOID		->	0	0	0	1	0	0	2
		P>	0	0	0	0	0	0	0
		TL>	0	0	0	1	0	0	2
--AMYLOIDOSIS		->	0	0	0	1	0	0	2
		TL>	0	0	0	1	0	0	2
		MN>	0.0	0.0	0.0	0.0	0.0	0.0	0.0
ILEUM (IL)		NUMBER EXAMINED:	0	0	0	0	0	0	2
		NOT REMARKABLE:	0	0	0	0	0	0	2
--HYPERPLASIA, LYMPHOID		->	0	0	0	0	0	0	2
		TL>	0	0	0	0	0	0	2
--AMYLOIDOSIS		->	0	0	0	0	0	0	2
		TL>	0	0	0	0	0	0	2
		MN>	0.0	0.0	0.0	0.0	0.0	0.0	0.0
PANCREAS (PA)		NUMBER EXAMINED:	0	0	0	2	0	0	2
		NOT REMARKABLE:	0	0	0	2	0	0	1
--INFLAMMATION, CHRONIC		->	0	0	0	2	0	0	1
		1>	0	0	0	0	0	0	1
		TL>	0	0	0	2	0	0	2
		MN>	0.0	0.0	0.0	0.0	0.0	0.0	0.5

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HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

TABLE 14A
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
EXPANDED HISTOPATHOLOGY INCIDENCE SUMMARY

PRINTED: 20-JAN-93
PAGE: 200

STUDY NUMBER: 483287

TABLE INCLUDES:

SEX=ALL; GROUP=ALL; WEEKS=ALL
DEATH=UNSCHED; FIND=ALL; SUBSET=ALL

--- NUMBER - OF - ANIMALS - AFFECTED ---

SEX=ALL;GROUP=ALL;WEEKS=ALL DEATH=UNSCHED;FIND=ALL;SUBSET=ALL		SEX: -----MALE-----							
		GROUP:	-1-	-2-	-3-	-4-	-5-	-6-	-7-
		NUMBER:	0	0	0	2	0	0	2
ORGAN/TISSUE EXAMINED			--	--	--	--	--	--	--
** FROM PREVIOUS PAGE **									
PANCREAS (PA)		NUMBER EXAMINED:	0	0	0	2	0	0	2
		NOT REMARKABLE:	0	0	0	2	0	0	1
--AMYLOIDOSIS		->	0	0	0	2	0	0	2
		TL>	0	0	0	2	0	0	2
		MN>	0.0	0.0	0.0	0.0	0.0	0.0	0.0
--ISLET CELL, HYPERPLASIA		->	0	0	0	2	0	0	2
		TL>	0	0	0	2	0	0	2
		MN>	0.0	0.0	0.0	0.0	0.0	0.0	0.0
CECUM (CE)		NUMBER EXAMINED:	0	0	0	1	0	0	2
		NOT REMARKABLE:	0	0	0	0	0	0	2
--HYPERPLASIA, LYMPHOID		->	0	0	0	0	0	0	2
		P>	0	0	0	1	0	0	0
		TL>	0	0	0	1	0	0	2
COLON (CO)		NUMBER EXAMINED:	0	0	0	1	0	0	2
		NOT REMARKABLE:	0	0	0	1	0	0	2
--HYPERPLASIA, LYMPHOID		->	0	0	0	1	0	0	2
		TL>	0	0	0	1	0	0	2
RECTUM (RE)		NUMBER EXAMINED:	0	0	0	0	0	0	2
		NOT REMARKABLE:	0	0	0	0	0	0	1
--HYPERPLASIA, LYMPHOID		->	0	0	0	0	0	0	1
		P>	0	0	0	0	0	0	1
		TL>	0	0	0	0	0	0	2

** CONTINUED ON NEXT PAGE **

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

TABLE 14A
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
EXPANDED HISTOPATHOLOGY INCIDENCE SUMMARY

PRINTED: 20-JAN-93
PAGE: 201

STUDY NUMBER: 483287

TABLE INCLUDES:

SEX=ALL; GROUP=ALL; WEEKS=ALL
DEATH=UNSCHED; FIND=ALL; SUBSET=ALL

--- NUMBER - OF - ANIMALS - AFFECTED ---

SEX: -----MALE-----

GROUP: -1- -2- -3- -4- -5- -6- -7-

ORGAN/TISSUE EXAMINED

NUMBER: 0 0 0 2 0 0 2

** FROM PREVIOUS PAGE **

RECTUM (RE) NUMBER EXAMINED: 0 0 0 0 0 0 2
NOT REMARKABLE: 0 0 0 0 0 0 1

--AMYLOIDOSIS

-> 0 0 0 0 0 0 2
TL> 0 0 0 0 0 0 2
MN> 0.0 0.0 0.0 0.0 0.0 0.0 0.0

LN, MESENTERIC (MS) NUMBER EXAMINED: 0 0 0 1 0 0 0
NOT REMARKABLE: 0 0 0 1 0 0 0

--MACROPHAGES, PIGMENTED

-> 0 0 0 1 0 0 0
1> 0 0 0 0 0 0 0
TL> 0 0 0 1 0 0 0
MN> 0.0 0.0 0.0 0.0 0.0 0.0 0.0

--HYPERPLASIA, LYMPHOID

-> 0 0 0 1 0 0 0
TL> 0 0 0 1 0 0 0
MN> 0.0 0.0 0.0 0.0 0.0 0.0 0.0

--INFLAMMATION, GRANULOMATOUS

-> 0 0 0 1 0 0 0
TL> 0 0 0 1 0 0 0
MN> 0.0 0.0 0.0 0.0 0.0 0.0 0.0

--AMYLOIDOSIS

-> 0 0 0 1 0 0 0
TL> 0 0 0 1 0 0 0
MN> 0.0 0.0 0.0 0.0 0.0 0.0 0.0

--HEMORRHAGE

-> 0 0 0 1 0 0 0
TL> 0 0 0 1 0 0 0

** CONTINUED ON NEXT PAGE **

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WASHINGTON, D.C. U.S.A.

TABLE 14A
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
EXPANDED HISTOPATHOLOGY INCIDENCE SUMMARY

PRINTED: 20-JAN-93
PAGE: 202

STUDY NUMBER: 483287

TABLE INCLUDES:

SEX=ALL; GROUP=ALL; WEEKS=ALL
DEATH=UNSCHED; FIND=ALL; SUBSET=ALL

--- NUMBER - OF - ANIMALS - AFFECTED ---

SEX=ALL;GROUP=ALL;WEEKS=ALL DEATH=UNSCHED;FIND=ALL;SUBSET=ALL		SEX: -----MALE-----							
		GROUP:	-1-	-2-	-3-	-4-	-5-	-6-	-7-
ORGAN/TISSUE EXAMINED		NUMBER:	0	0	0	2	0	0	2
-----		---	---	---	---	---	---	---	---
** FROM PREVIOUS PAGE **									
LN, MESENTERIC (MS)	NUMBER EXAMINED:	0	0	0	1	0	0	0	0
	NOT REMARKABLE:	0	0	0	1	0	0	0	0
--NECROSIS, LYMPHOID									
	->	0	0	0	1	0	0	0	0
	TL>	0	0	0	1	0	0	0	0
	MN>	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
TESTIS (TE)	NUMBER EXAMINED:	0	0	0	2	0	0	2	2
	NOT REMARKABLE:	0	0	0	2	0	0	2	2
--MINERALIZATION									
	->	0	0	0	2	0	0	2	2
	TL>	0	0	0	2	0	0	2	2
	MN>	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
--HEMORRHAGE									
	->	0	0	0	2	0	0	2	2
	TL>	0	0	0	2	0	0	2	2
EPIDIDYMIS (EP)	NUMBER EXAMINED:	0	0	0	2	0	0	2	0
	NOT REMARKABLE:	0	0	0	2	0	0	0	0
--INFLAMMATION, CHRONIC									
	->	0	0	0	2	0	0	2	2
	TL>	0	0	0	2	0	0	2	2
	MN>	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
--LUMEN, DEBRIS, CELLULAR									
	->	0	0	0	2	0	0	0	0
	P>	0	0	0	0	0	0	2	2
	TL>	0	0	0	2	0	0		

HAZLETON WASHINGTON, INC.
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TABLE 14A

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
EXPANDED HISTOPATHOLOGY INCIDENCE SUMMARY

PRINTED: 20-JAN-93
PAGE: 203

STUDY NUMBER: 483287

TABLE INCLUDES:

SEX=ALL; GROUP=ALL; WEEKS=ALL
DEATH=UNSCHED; FIND=ALL; SUBSET=ALL

--- NUMBER - OF - ANIMALS - AFFECTED ---

SEX=ALL;GROUP=ALL;WEEKS=ALL DEATH=UNSCHED;FIND=ALL;SUBSET=ALL		SEX: -----MALE-----							
		GROUP:	-1-	-2-	-3-	-4-	-5-	-6-	-7-
ORGAN/TISSUE EXAMINED		NUMBER:	0	0	0	2	0	0	2

PROSTATE (PR)	NUMBER EXAMINED:	0	0	0	2	0	0	2	
	NOT REMARKABLE:	0	0	0	2	0	0	2	
--INFLAMMATION, CHRONIC	->	0	0	0	2	0	0	2	
	TL>	0	0	0	2	0	0	2	
	MN>	0.0	0.0	0.0	0.0	0.0	0.0	0.0	
URINARY BLADDER (UB)	NUMBER EXAMINED:	0	0	0	2	0	0	2	
	NOT REMARKABLE:	0	0	0	2	0	0	2	
--INFLAMMATION, CHRONIC	->	0	0	0	2	0	0	2	
	TL>	0	0	0	2	0	0	2	
	MN>	0.0	0.0	0.0	0.0	0.0	0.0	0.0	
OVARY (OV)	NUMBER EXAMINED:	0	0	0	0	0	0	0	
	NOT REMARKABLE:	0	0	0	0	0	0	0	
--FOLLICLE, CYST	->	0	0	0	0	0	0	0	
	P>	0	0	0	0	0	0	0	
	TL>	0	0	0	0	0	0	0	
--MINERALIZATION	->	0	0	0	0	0	0	0	
	I>	0	0	0	0	0	0	0	
	TL>	0	0	0	0	0	0	0	
	MN>	0.0	0.0	0.0	0.0	0.0	0.0	0.0	
--BURSA, CYST	->	0	0	0	0	0	0	0	
	TL>	0	0	0	0	0	0	0	
--UNILATERALLY EXAMINED	->	0	0	0	0	0	0	0	
	TL>	0	0	0	0	0	0	0	

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

TABLE 14A
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
EXPANDED HISTOPATHOLOGY INCIDENCE SUMMARY

PRINTED: 20-JAN-93
PAGE: 204

STUDY NUMBER: 483287

TABLE INCLUDES:

SEX=ALL; GROUP=ALL; WEEKS=ALL
DEATH=UNSCHED; FIND=ALL; SUBSET=ALL

--- NUMBER - OF - ANIMALS - AFFECTED ---

TABLE INCLUDED: SEX=ALL;GROUP=ALL;WEEKS=ALL DEATH=UNSCHED;FIND=ALL;SUBSET=ALL		SEX: -----MALE-----							
		GROUP:	-1-	-2-	-3-	-4-	-5-	-6-	-7-
ORGAN/TISSUE EXAMINED		NUMBER:	0	0	0	2	0	0	2
			-----	-----	-----	-----	-----	-----	-----
OVIDUCT (OD)	NUMBER EXAMINED:	0	0	0	0	0	0	0	0
	NOT REMARKABLE:	0	0	0	0	0	0	0	0
LN, MANDIBULAR (MN)	NUMBER EXAMINED:	0	0	0	1	0	0	0	2
	NOT REMARKABLE:	0	0	0	1	0	0	0	2
--MACROPHAGES, PIGMENTED	->	0	0	0	1	0	0	0	2
	1>	0	0	0	0	0	0	0	0
	TL>	0	0	0	1	0	0	0	2
	MN>	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
--AMYLOIDOSIS	->	0	0	0	1	0	0	0	2
	TL>	0	0	0	1	0	0	0	2
	MN>	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
--HYPERPLASIA, LYMPHOID	->	0	0	0	1	0	0	0	2
	TL>	0	0	0	1	0	0	0	2
MAND SALIVARY GL (SG)	NUMBER EXAMINED:	0	0	0	2	0	0	0	2
	NOT REMARKABLE:	0	0	0	2	0	0	0	2
--INFLAMMATION, CHRONIC	->	0	0	0	2	0	0	0	2
	TL>	0	0	0	2	0	0	0	2
	MN>	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
SALIVARY, OTHER (OS)	NUMBER EXAMINED:	0	0	0	2	0	0	0	2
	NOT REMARKABLE:	0	0	0	2	0	0	0	2

HAZLETON WASHINGTON, INC.
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TABLE 14A
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
EXPANDED HISTOPATHOLOGY INCIDENCE SUMMARY

PRINTED: 20-JAN-93
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STUDY NUMBER: 483287

		--- N U M B E R - O F - A N I M A L S - A F F E C T E D ---							
TABLE INCLUDES:		SEX: -----MALE-----							
SEX=ALL;GROUP=ALL;WEEKS=ALL									
DEATH=UNSCHED;FIND=ALL;SUBSET=ALL									
		GROUP:	-1-	-2-	-3-	-4-	-5-	-6-	-7-
ORGAN/TISSUE EXAMINED	NUMBER:	0	0	0	2	0	0	2	
-----		-----	-----	-----	-----	-----	-----	-----	
THYMUS (TH)	NUMBER EXAMINED:	0	0	0	2	0	0	0	
	NOT REMARKABLE:	0	0	0	1	0	0	0	
--CYST	->	0	0	0	1	0	0	0	
	P>	0	0	0	1	0	0	0	
	TL>	0	0	0	2	0	0	0	
--ECTOPIC THYROID	->	0	0	0	2	0	0	0	
	TL>	0	0	0	2	0	0	0	
--NECROSIS, LYMPHOID	->	0	0	0	2	0	0	0	
	1>	0	0	0	0	0	0	0	
	TL>	0	0	0	2	0	0	0	
	MN>	0.0	0.0	0.0	0.0	0.0	0.0	0.0	
--ATROPHY	->	0	0	0	2	0	0	0	
	4>	0	0	0	0	0	0	0	
	TL>	0	0	0	2	0	0	0	
	MN>	0.0	0.0	0.0	0.0	0.0	0.0	0.0	
AORTA, THORACIC (AO)	NUMBER EXAMINED:	0	0	0	2	0	0	1	
	NOT REMARKABLE:	0	0	0	2	0	0	1	
EYE (EY)	NUMBER EXAMINED:	0	0	0	2	0	0	2	
	NOT REMARKABLE:	0	0	0	1	0	0	2	
--UNILATERALLY EXAMINED	->	0	0	0	1	0	0	2	
	P>	0	0	0	1	0	0	0	
	TL>	0	0	0	2	0	0	2	

** CONTINUED ON NEXT PAGE **

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TABLE 14A
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
EXPANDED HISTOPATHOLOGY INCIDENCE SUMMARY

PRINTED: 20-JAN-93
PAGE: 206

STUDY NUMBER: 483287

TABLE INCLUDES:

SEX=ALL; GROUP=ALL; WEEKS=ALL
DEATH=UNSCHED; FIND=ALL; SUBSET=ALL

--- NUMBER - OF - ANIMALS - AFFECTED ---

TABLE INCLUDES:		SEX: -----MALE-----							
SEX=ALL; GROUP=ALL; WEEKS=ALL		GROUP:	-1-	-2-	-3-	-4-	-5-	-6-	-7-
DEATH=UNSCHED; FINO=ALL; SUBSET=ALL		NUMBER:	0	0	0	2	0	0	2
ORGAN/TISSUE EXAMINED		---	---	---	---	---	---	---	---
** FROM PREVIOUS PAGE **									
EYE (EY)	NUMBER EXAMINED:	0	0	0	2	0	0	0	2
	NOT REMARKABLE:	0	0	0	1	0	0	0	2
--CORNEA, MINERALIZATION									
	->	0	0	0	2	0	0	0	2
	TL>	0	0	0	2	0	0	0	2
	MN>	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
HARDERIAN GLAND (HG)	NUMBER EXAMINED:	0	0	0	2	0	0	0	2
	NOT REMARKABLE:	0	0	0	2	0	0	0	2
--INFLAMMATION, CHRONIC									
	->	0	0	0	2	0	0	0	2
	P>	0	0	0	0	0	0	0	0
	TL>	0	0	0	2	0	0	0	2
NERVE, OPTIC (ON)	NUMBER EXAMINED:	0	0	0	0	0	0	0	2
	NOT REMARKABLE:	0	0	0	0	0	0	0	0
--UNILATERALLY EXAMINED									
	->	0	0	0	0	0	0	0	0
	P>	0	0	0	0	0	0	0	2
	TL>	0	0	0	0	0	0	0	2
LACRIMAL GL, EX (EO)	NUMBER EXAMINED:	0	0	0	2	0	0	0	2
	NOT REMARKABLE:	0	0	0	2	0	0	0	1
--INFLAMMATION, CHRONIC									
	->	0	0	0	2	0	0	0	1
	1>	0	0	0	0	0	0	0	1
	TL>	0	0	0	2	0	0	0	2
	MN>	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.5
--UNILATERALLY EXAMINED									
	->	0	0	0	2	0	0	0	2
	P>	0	0	0	0	0	0	0	0
	TL>	0	0	0	2	0	0	0	2

HAZLETON WASHINGTON, INC.
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TABLE 14A
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
EXPANDED HISTOPATHOLOGY INCIDENCE SUMMARY

PRINTED: 20-JAN-93
PAGE: 207

STUDY NUMBER: 483287

TABLE INCLUDES:

SEX=ALL; GROUP=ALL; WEEKS=ALL
DEATH=UNSCHED; FIND=ALL; SUBSET=ALL

--- NUMBER - OF - ANIMALS - AFFECTED ---

TABLE INCLUDED: SEX=ALL; GROUP=ALL; WEEKS=ALL DEATH=UNSCHED; FIND=ALL; SUBSET=ALL		SEX: -----	MALE-----						
		GROUP:	-1-	-2-	-3-	-4-	-5-	-6-	-7-
ORGAN/TISSUE EXAMINED		NUMBER:	0	0	0	2	0	0	2

TONGUE (TO)	NUMBER EXAMINED:	0	0	0	2	0	0	0	2
	NOT REMARKABLE:	0	0	0	2	0	0	0	2
MUSCLE, SKELETAL (SM)	NUMBER EXAMINED:	0	0	0	2	0	0	0	2
	NOT REMARKABLE:	0	0	0	2	0	0	0	2
NERVE, SCIATIC (SN)	NUMBER EXAMINED:	0	0	0	2	0	0	0	2
	NOT REMARKABLE:	0	0	0	2	0	0	0	2
MUSCLE, ABDOM (MA)	NUMBER EXAMINED:	0	0	0	0	0	0	0	2
	NOT REMARKABLE:	0	0	0	0	0	0	0	2
MARROW, STERNUM (SE)	NUMBER EXAMINED:	0	0	0	2	0	0	0	2
	NOT REMARKABLE:	0	0	0	2	0	0	0	2
BONE, STERNUM (SB)	NUMBER EXAMINED:	0	0	0	2	0	0	0	2
	NOT REMARKABLE:	0	0	0	2	0	0	0	2
MARROW, FEMUR (FM)	NUMBER EXAMINED:	0	0	0	2	0	0	0	2
	NOT REMARKABLE:	0	0	0	2	0	0	0	1
--HYPERCELLULAR		->	0	0	0	2	0	0	1
		P>	0	0	0	0	0	0	1
		TL>	0	0	0	2	0	0	2
BONE, FEMUR (FE)	NUMBER EXAMINED:	0	0	0	2	0	0	0	2
	NOT REMARKABLE:	0	0	0	2	0	0	0	2
HEMATO NEOPLASIA (HN)	NUMBER EXAMINED:	0	0	0	2	0	0	0	2
	NOT REMARKABLE:	0	0	0	2	0	0	0	2

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TABLE 14A
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
EXPANDED HISTOPATHOLOGY INCIDENCE SUMMARY

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PAGE: 208

STUDY NUMBER: 483287

TABLE INCLUDES:

SEX-ALL; GROUP-ALL; WEEKS-ALL
DEATH-UNSCHED; FIND-ALL; SUBSET-ALL

--- NUMBER - OF - ANIMALS - AFFECTED ---

		SEX: -----MALE-----						
		GROUP: -1-	-2-	-3-	-4-	-5-	-6-	-7-
ORGAN/TISSUE EXAMINED	NUMBER:	0	0	0	2	0	0	2
<hr/>								
^DEATH COMMENT (DC)		NUMBER EXAMINED:	0	0	0	2	0	0
		NOT REMARKABLE:	0	0	0	0	0	0
--SCHEDULED SACRIFICE		->	0	0	0	2	0	0
		P>	0	0	0	0	0	0
		TL>	0	0	0	2	0	0
--UNDETERMINED		->	0	0	0	1	0	0
		P>	0	0	0	1	0	0
		TL>	0	0	0	2	0	0
--ACCIDENTAL		->	0	0	0	1	0	0
		P>	0	0	0	1	0	0
		TL>	0	0	0	2	0	0
LN, OTHER (LN)		NUMBER EXAMINED:	0	0	0	0	0	0
		NOT REMARKABLE:	0	0	0	0	0	0
--MACROPHAGES, PIGMENTED		->	0	0	0	0	0	0
		P>	0	0	0	0	0	0
		TL>	0	0	0	0	0	0
--HYPERPLASIA, LYMPHOID		->	0	0	0	0	0	0
		TL>	0	0	0	0	0	0
SKIN, OTHER (SS)		NUMBER EXAMINED:	0	0	0	0	0	1
		NOT REMARKABLE:	0	0	0	0	0	1
--DERMATITIS, CHRONIC		->	0	0	0	0	0	1
		TL>	0	0	0	0	0	1

** CONTINUED ON NEXT PAGE **

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

TABLE 14A

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
EXPANDED HISTOPATHOLOGY INCIDENCE SUMMARY

PRINTED: 20-JAN-93
PAGE: 209

STUDY NUMBER: 483287

TABLE INCLUDES:

SEX=ALL; GROUP=ALL; WEEKS=ALL
DEATH=UNSCHED; FIND=ALL; SUBSET=ALL

--- NUMBER - OF - ANIMALS - AFFECTED ---

SEX: -----MALE-----								
GROUP: -1- -2- -3- -4- -5- -6- -7-								
NUMBER: 0 0 0 2 0 0 2								
ORGAN/TISSUE EXAMINED								
** FROM PREVIOUS PAGE **								
SKIN, OTHER (SS)		NUMBER EXAMINED:	0	0	0	0	0	1
		NOT REMARKABLE:	0	0	0	0	0	1
--DERMATITIS, ULCERATIVE								
		TL>	0	0	0	0	0	1
BONE, OTHER (OB)		NUMBER EXAMINED:	0	0	0	1	0	0
		NOT REMARKABLE:	0	0	0	1	0	0
CAVITY, ABDOM (PC)		NUMBER EXAMINED:	0	0	0	0	0	0
		NOT REMARKABLE:	0	0	0	0	0	0
--ADHESION								
		TL>	0	0	0	0	0	0
LI, INTRAHEPATIC (LIO)		NUMBER EXAMINED:	0	0	0	0	0	0
		NOT REMARKABLE:	0	0	0	0	0	0
--PIGMENT, PAS POSITIVE								
		TL>	0	0	0	0	0	0
		MN>	0.0	0.0	0.0	0.0	0.0	0.0
--PIGMENT, IRON POSITIVE								
		TL>	0	0	0	0	0	0
		MN>	0.0	0.0	0.0	0.0	0.0	0.0
--PIGMENT, BILE POSITIVE								
		TL>	0	0	0	0	0	0
		MN>	0.0	0.0	0.0	0.0	0.0	0.0
--PIGMENT, LIPOFUSCIN POSITIVE								
		TL>	0	0	0	0	0	0
		MN>	0.0	0.0	0.0	0.0	0.0	0.0
--PIGMENT, FONTANA MASSON POSITIVE								
		TL>	0	0	0	0	0	0
		MN>	0.0	0.0	0.0	0.0	0.0	0.0

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TABLE 14A
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
EXPANDED HISTOPATHOLOGY INCIDENCE SUMMARY

PRINTED: 20-JAN-93
PAGE: 210

STUDY NUMBER: 483287

TABLE INCLUDES:
SEX=ALL;GROUP=ALL;WEEKS=ALL
DEATH=UNSCHED;FIND=ALL;SUBSET=ALL

		--- NUMBER - OF - ANIMALS - AFFECTED ---							
TABLE INCLUDES: SEX=ALL;GROUP=ALL;WEEKS=ALL DEATH=UNSCHED;FIND=ALL;SUBSET=ALL		SEX:	-----MALE-----						
		GROUP:	-1-	-2-	-3-	-4-	-5-	-6-	-7-
ORGAN/TISSUE EXAMINED		NUMBER:	0	0	0	2	0	0	2
			--	--	--	--	--	--	--
LI, EXTRAHEPATIC (LI1)	NUMBER EXAMINED:	0	0	0	0	0	0	0	0
	NOT REMARKABLE:	0	0	0	0	0	0	0	0
--PIGMENT, PAS POSITIVE	TL>	0	0	0	0	0	0	0	0
	MN>	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
--PIGMENT, IRON POSITIVE	TL>	0	0	0	0	0	0	0	0
	MN>	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
--PIGMENT, BILE POSITIVE	TL>	0	0	0	0	0	0	0	0
	MN>	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
--PIGMENT, LIPOFUSCIN POSITIVE	TL>	0	0	0	0	0	0	0	0
	MN>	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
--PIGMENT, FONTANA MASSON POSITIVE	TL>	0	0	0	0	0	0	0	0
	MN>	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
** END OF LIST **									

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TABLE 14A
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
EXPANDED HISTOPATHOLOGY INCIDENCE SUMMARY

PRINTED: 20-JAN-93
PAGE: 211

STUDY NUMBER: 483287

TABLE INCLUDES:

SEX=ALL; GROUP=ALL; WEEKS=ALL
DEATH=UNSCHED; FIND=ALL; SUBSET=ALL

--- NUMBER OF ANIMALS AFFECTED ---

SEX: -----FEMALE-----

GROUP: -1- -2- -3- -4- -5- -6- -7-

ORGAN/TISSUE EXAMINED

NUMBER: 0 0 0 1 0 0 1

** TOP OF LIST **

SPLEEN (SP) NUMBER EXAMINED: 0 0 0 0 0 0 1
NOT REMARKABLE: 0 0 0 0 0 0 0

--EXTRAMEDULLARY HEMATOPOIESIS, INCREASED

-> 0 0 0 0 0 0 1
4> 0 0 0 0 0 0 0
TL> 0 0 0 0 0 0 1
MN> 0.0 0.0 0.0 0.0 0.0 0.0 0.0

--PIGMENT

-> 0 0 0 0 0 0 0
1> 0 0 0 0 0 0 0
2> 0 0 0 0 0 0 1
TL> 0 0 0 0 0 0 1
MN> 0.0 0.0 0.0 0.0 0.0 0.0 2.0

--AMYLOIDOSIS

-> 0 0 0 0 0 0 1
TL> 0 0 0 0 0 0 1
MN> 0.0 0.0 0.0 0.0 0.0 0.0 0.0

--DEPLETION, LYMPHOID

-> 0 0 0 0 0 0 0
2> 0 0 0 0 0 0 0
4> 0 0 0 0 0 0 1
TL> 0 0 0 0 0 0 1
MN> 0.0 0.0 0.0 0.0 0.0 0.0 4.0

--NECROSIS, LYMPHOID

-> 0 0 0 0 0 0 1
TL> 0 0 0 0 0 0 1
MN> 0.0 0.0 0.0 0.0 0.0 0.0 0.0

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TABLE 14A
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
EXPANDED HISTOPATHOLOGY INCIDENCE SUMMARY

PRINTED: 20-JAN-93
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STUDY NUMBER: 483287

TABLE INCLUDES:

SEX=ALL; GROUP=ALL; WEEKS=ALL
DEATH=UNSCHED; FIND=ALL; SUBSET=ALL

--- NUMBER - OF - ANIMALS - AFFECTED ---

TABLE INCLUDES:		SEX: -----FEMALE-----							
SEX=ALL; GROUP=ALL; WEEKS=ALL		GROUP: -1- -2- -3- -4- -5- -6- -7-							
DEATH=UNCHED; FIND=ALL; SUBSET=ALL									
ORGAN/TISSUE EXAMINED		NUMBER:	0	0	0	1	0	0	1
			==	==	==	==	==	==	==
STOMACH, NONGL (SU)	NUMBER EXAMINED:	0	0	0	1	0	0	0	1
	NOT REMARKABLE:	0	0	0	1	0	0	0	1
--INFLAMMATION, CHRONIC									
	->	0	0	0	1	0	0	0	1
	TL>	0	0	0	1	0	0	0	1
	MN>	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
STOMACH, GL (ST)	NUMBER EXAMINED:	0	0	0	1	0	0	0	1
	NOT REMARKABLE:	0	0	0	1	0	0	0	1
--HYPERPLASIA									
	->	0	0	0	1	0	0	0	1
	TL>	0	0	0	1	0	0	0	1
	MN>	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
--HYPERPLASIA, CYSTIC									
	->	0	0	0	1	0	0	0	1
	TL>	0	0	0	1	0	0	0	1
	MN>	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
--INFLAMMATION, CHRONIC									
	->	0	0	0	1	0	0	0	1
	TL>	0	0	0	1	0	0	0	1
	MN>	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
--MUCOSA, NECROSIS									
	->	0	0	0	1	0	0	0	1
	1>	0	0	0	0	0	0	0	0
	TL>	0	0	0	1	0	0	0	1
	MN>	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
--INFLAMMATION, ACUTE									
	->	0	0	0	1	0	0	0	1
	TL>	0	0	0	1	0	0	0	1
	MN>	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0

** CONTINUED ON NEXT PAGE **

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TABLE 14A
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE, (MAIN-GROUPS 1-7)
EXPANDED HISTOPATHOLOGY INCIDENCE SUMMARY

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STUDY NUMBER: 483287

		--- NUMBER - OF - ANIMALS - AFFECTED ---						
		SEX: -----FEMALE-----						
		GROUP: -1- -2- -3- -4- -5- -6- -7-						
ORGAN/TISSUE EXAMINED	NUMBER:	0	0	0	1	0	0	1

** FROM PREVIOUS PAGE **								
STOMACH, GL (ST)	NUMBER EXAMINED:	0	0	0	1	0	0	1
	NOT REMARKABLE:	0	0	0	1	0	0	1
--AMYLOIDOSIS								
	->	0	0	0	1	0	0	1
	TL>	0	0	0	1	0	0	1
ADRENAL, CORTEX (AC)	NUMBER EXAMINED:	0	0	0	1	0	0	1
	NOT REMARKABLE:	0	0	0	1	0	0	1
--PIGMENT								
	->	0	0	0	1	0	0	1
	TL>	0	0	0	1	0	0	1
	MN>	0.0	0.0	0.0	0.0	0.0	0.0	0.0
--HYPERTROPHY, ZONA FASCICULATA								
	->	0	0	0	1	0	0	1
	2>	0	0	0	0	0	0	0
	TL>	0	0	0	1	0	0	1
	MN>	0.0	0.0	0.0	0.0	0.0	0.0	0.0
--VACUOLIZATION, X-ZONE								
	->	0	0	0	1	0	0	1
	TL>	0	0	0	1	0	0	1
	MN>	0.0	0.0	0.0	0.0	0.0	0.0	0.0
--HYPERPLASIA, SUBCAPSULAR CELL								
	->	0	0	0	1	0	0	1
	TL>	0	0	0	1	0	0	1
	MN>	0.0	0.0	0.0	0.0	0.0	0.0	0.0
--UNILATERALLY EXAMINED								
	->	0	0	0	1	0	0	1
	TL>	0	0	0	1	0	0	1

HAZLETON WASHINGTON, INC.
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TABLE 14A
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
EXPANDED HISTOPATHOLOGY INCIDENCE SUMMARY

PRINTED: 20-JAN-93
PAGE: 214

STUDY NUMBER: 483287

TABLE INCLUDES:

SEX=ALL; GROUP=ALL; WEEKS=ALL
DEATH=UNSCHED; FIND=ALL; SUBSET=ALL

--- NUMBER OF ANIMALS AFFECTED ---

SEX=ALL; GROUP=ALL; WEEKS=ALL DEATH=UNSCHED; FIND=ALL; SUBSET=ALL		SEX: -----FEMALE-----							
		GROUP: -1- -2- -3- -4- -5- -6- -7-							
ORGAN/TISSUE EXAMINED		NUMBER:	0	0	0	1	0	0	1
			---	---	---	---	---	---	---
ADRENAL, MEDULLA (AM)	NUMBER EXAMINED:	0	0	0	1	0	0	1	1
	NOT REMARKABLE:	0	0	0	1	0	0	1	1
	--UNILATERALLY EXAMINED								
	->	0	0	0	1	0	0	1	1
	P>	0	0	0	0	0	0	0	0
	TL>	0	0	0	1	0	0	1	1
KIDNEY (KD)	NUMBER EXAMINED:	0	0	0	1	0	0	1	1
	NOT REMARKABLE:	0	0	0	0	0	0	0	0
	--INFLAMMATION, CHRONIC								
	->	0	0	0	0	0	0	1	1
	I>	0	0	0	1	0	0	0	0
	TL>	0	0	0	1	0	0	1	1
	MN>	0.0	0.0	0.0	1.0	0.0	0.0	0.0	0.0
--TUBULE, MINERALIZATION	->	0	0	0	1	0	0	1	1
	TL>	0	0	0	1	0	0	1	1
	MN>	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
--TUBULE, REGENERATION	->	0	0	0	0	0	0	0	0
	I>	0	0	0	1	0	0	1	1
	TL>	0	0	0	1	0	0	1	1
	MN>	0.0	0.0	0.0	1.0	0.0	0.0	1.0	1.0
--HYPERPLASIA, LYMPHOID	->	0	0	0	1	0	0	1	1
	TL>	0	0	0	1	0	0	1	1
	MN>	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
--TUBULE, DILATATION	->	0	0	0	1	0	0	1	1
	TL>	0	0	0	1	0	0	1	1
	MN>	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0

** CONTINUED ON NEXT PAGE **

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

TABLE 14A
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
EXPANDED HISTOPATHOLOGY INCIDENCE SUMMARY

PRINTED: 20-JAN-93
PAGE: 215

STUDY NUMBER: 483287

TABLE INCLUDES:

SEX=ALL;GROUP=ALL;WEEKS=ALL
DEATH=UNSCHED;FIND=ALL;SUBSET=ALL

--- NUMBER OF ANIMALS AFFECTED ---

TABLE INCLUDES:		SEX: -----FEMALE-----							
SEX=ALL; GROUP=ALL; WEEKS=ALL									
DEATH=UNSCHED; FIND=ALL; SUBSET=ALL									
		GROUP: -1- -2- -3- -4- -5- -6- -7-							
ORGAN/TISSUE EXAMINED		NUMBER:	0	0	0	1	0	0	1
			--	--	--	--	--	--	--
** FROM PREVIOUS PAGE **									
KIDNEY (KD)	NUMBER EXAMINED:	0	0	0	1	0	0	1	
	NOT REMARKABLE:	0	0	0	0	0	0	0	0
--AMYLOIDOSIS	->	0	0	0	1	0	0	1	
	TL>	0	0	0	1	0	0	1	
	MN>	0.0	0.0	0.0	0.0	0.0	0.0	0.0	
--PIGMENT	->	0	0	0	1	0	0	1	
	TL>	0	0	0	1	0	0	1	
	MN>	0.0	0.0	0.0	0.0	0.0	0.0	0.0	
--INFLAMMATION, GRANULOMATOUS	->	0	0	0	1	0	0	1	
	TL>	0	0	0	1	0	0	1	
	MN>	0.0	0.0	0.0	0.0	0.0	0.0	0.0	
--CYST	->	0	0	0	0	0	0	1	
	P>	0	0	0	1	0	0	0	
	TL>	0	0	0	1	0	0	1	
--INFLAMMATION, SUBACUTE	->	0	0	0	1	0	0	1	
	TL>	0	0	0	1	0	0	1	
	MN>	0.0	0.0	0.0	0.0	0.0	0.0	0.0	
--PELVIS, DILATATION	->	0	0	0	1	0	0	1	
	TL>	0	0	0	1	0	0	1	
UTERUS (UT)	NUMBER EXAMINED:	0	0	0	1	0	0	1	
	NOT REMARKABLE:	0	0	0	0	0	0	0	
--HYPERPLASIA, CYSTIC ENDOMETRIAL	->	0	0	0	1	0	0	1	
	TL>	0	0	0	1	0	0	1	
	MN>	0.0	0.0	0.0	0.0	0.0	0.0	0.0	

** CONTINUED ON NEXT PAGE **

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TABLE 14A
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
EXPANDED HISTOPATHOLOGY INCIDENCE SUMMARY

PRINTED: 20-JAN-93
PAGE: 216

STUDY NUMBER: 483287

TABLE INCLUDES:		--- N U M B E R - O F - A N I M A L S - A F F E C T E D ---						
SEX=ALL;GROUP=ALL;WEEKS=ALL		SEX: -----FEMALE-----						
DEATH=UNSCHED;FIND=ALL;SUBSET=ALL		GROUP: -1- -2- -3- -4- -5- -6- -7-						
ORGAN/TISSUE EXAMINED	NUMBER:	0	0	0	1	0	0	1

** FROM PREVIOUS PAGE **								
UTERUS (UT)	NUMBER EXAMINED:	0	0	0	1	0	0	1
	NOT REMARKABLE:	0	0	0	0	0	0	0
--DILATATION	->	0	0	0	1	0	0	1
	TL>	0	0	0	1	0	0	1
--HYPOPLASIA	4>	0	0	0	1	0	0	0
	5>	0	0	0	0	0	0	1
	TL>	0	0	0	1	0	0	1
	MN>	0.0	0.0	0.0	4.0	0.0	0.0	5.0
UTERUS, CERVIX (CV)	NUMBER EXAMINED:	0	0	0	1	0	0	1
	NOT REMARKABLE:	0	0	0	0	0	0	1
--HYPOPLASIA	->	0	0	0	0	0	0	1
	4>	0	0	0	1	0	0	0
	TL>	0	0	0	1	0	0	1
	MN>	0.0	0.0	0.0	4.0	0.0	0.0	0.0
VAGINA (VA)	NUMBER EXAMINED:	0	0	0	1	0	0	1
	NOT REMARKABLE:	0	0	0	1	0	0	1
--CYST, KERATIN	->	0	0	0	1	0	0	1
	TL>	0	0	0	1	0	0	1
--HYPOPLASIA	->	0	0	0	1	0	0	1
	TL>	0	0	0	1	0	0	1

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TABLE 14A

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
EXPANDED HISTOPATHOLOGY INCIDENCE SUMMARY

PRINTED: 20-JAN-93
PAGE: 217

STUDY NUMBER: 483287

TABLE INCLUDES:
SEX=ALL; GROUP=ALL; WEEKS=ALL
DEATH=UNSCHED; FIND=ALL; SUBSET=ALL

		--- NUMBER - OF - ANIMALS - AFFECTED ---						
		SEX: -----FEMALE-----						
		GROUP: -1-	-2-	-3-	-4-	-5-	-6-	-7-
ORGAN/TISSUE EXAMINED	NUMBER:	0	0	0	1	0	0	1
MAMMARY, FEMALE (MF)	NUMBER EXAMINED:	0	0	0	0	0	0	1
	NOT REMARKABLE:	0	0	0	0	0	0	1
--DILATATION, CYSTIC	->	0	0	0	0	0	0	1
	TL>	0	0	0	0	0	0	1
	MN>	0.0	0.0	0.0	0.0	0.0	0.0	0.0
--HYPOPLASIA, EPITHELIAL	->	0	0	0	0	0	0	1
	TL>	0	0	0	0	0	0	1
SKIN (SK)	NUMBER EXAMINED:	0	0	0	0	0	0	1
	NOT REMARKABLE:	0	0	0	0	0	0	1
LIVER (LI)	NUMBER EXAMINED:	0	0	0	1	0	0	1
	NOT REMARKABLE:	0	0	0	0	0	0	0
--HEPATOCYTE, HYPERTROPHY, CENTROLOBULAR	->	0	0	0	0	0	0	0
	1>	0	0	0	0	0	0	0
	2>	0	0	0	1	0	0	0
	3>	0	0	0	0	0	0	1
	4>	0	0	0	0	0	0	0
	TL>	0	0	0	1	0	0	1
	MN>	0.0	0.0	0.0	2.0	0.0	0.0	3.0
--VACUOLIZATION	->	0	0	0	1	0	0	0
	1>	0	0	0	0	0	0	1
	TL>	0	0	0	1	0	0	1
	MN>	0.0	0.0	0.0	0.0	0.0	0.0	1.0
--PIGMENT, BILE	->	0	0	0	1	0	0	1
	TL>	0	0	0	1	0	0	1
	MN>	0.0	0.0	0.0	0.0	0.0	0.0	0.0

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HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

TABLE 14A
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
EXPANDED HISTOPATHOLOGY INCIDENCE SUMMARY

PRINTED: 20-JAN-93
PAGE: 218

STUDY NUMBER: 483287

TABLE INCLUDES:
SEX=ALL; GROUP=ALL; WEEKS=ALL
DEATH=UNSCHED; FIND=ALL; SUBSET=ALL

		--- NUMBER - OF - ANIMALS - AFFECTED ---						
		SEX: -----FEMALE-----						
		GROUP:	-1-	-2-	-3-	-4-	-5-	-6- -7-
ORGAN/TISSUE EXAMINED		NUMBER:	0	0	0	1	0	0 1
-----		---	---	---	---	---	---	---
** FROM PREVIOUS PAGE **								
LIVER (LI)	NUMBER EXAMINED:	0	0	0	1	0	0	1
	NOT REMARKABLE:	0	0	0	0	0	0	0
--KUPFFER CELL/MACROPHAGE, PIGMENT	->	0	0	0	1	0	0	0
	1>	0	0	0	0	0	0	1
	TL>	0	0	0	1	0	0	1
	MN>	0.0	0.0	0.0	0.0	0.0	0.0	1.0
--HEPATOCYTE, PIGMENT	->	0	0	0	1	0	0	1
	TL>	0	0	0	1	0	0	1
	MN>	0.0	0.0	0.0	0.0	0.0	0.0	0.0
--NECROSIS	->	0	0	0	1	0	0	1
	3>	0	0	0	0	0	0	0
	4>	0	0	0	0	0	0	0
	TL>	0	0	0	1	0	0	1
	MN>	0.0	0.0	0.0	0.0	0.0	0.0	0.0
--NECROSIS, INDIVIDUAL CELL	->	0	0	0	0	0	0	1
	1>	0	0	0	1	0	0	0
	3>	0	0	0	0	0	0	0
	TL>	0	0	0	1	0	0	1
	MN>	0.0	0.0	0.0	1.0	0.0	0.0	0.0
--INFLAMMATION, CHRONIC/CHRONIC ACTIVE	->	0	0	0	1	0	0	1
	3>	0	0	0	0	0	0	0
	TL>	0	0	0	1	0	0	1
	MN>	0.0	0.0	0.0	0.0	0.0	0.0	0.0

** CONTINUED ON NEXT PAGE **

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

TABLE 14A
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
EXPANDED HISTOPATHOLOGY INCIDENCE SUMMARY

PRINTED: 20-JAN-93
PAGE: 219

STUDY NUMBER: 483287

TABLE INCLUDES:

SEX=ALL; GROUP=ALL; WEEKS=ALL
DEATH=UNSCHED; FIND=ALL; SUBSET=ALL

--- NUMBER OF ANIMALS AFFECTED ---

SEX: -----FEMALE-----

GROUP: -1- -2- -3- -4- -5- -6- -7-

NUMBER: 0 0 0 1 0 0 1

ORGAN/TISSUE EXAMINED

** FROM PREVIOUS PAGE **

LIVER (LI) NUMBER EXAMINED: 0 0 0 1 0 0 1
NOT REMARKABLE: 0 0 0 0 0 0 0

--BILE DUCT, INFLAMMATION, CHRONIC

-> 0 0 0 1 0 0 0
1> 0 0 0 0 0 0 1
TL> 0 0 0 1 0 0 1
MN> 0.0 0.0 0.0 0.0 0.0 0.0 1.0

--MINERALIZATION

-> 0 0 0 1 0 0 1
2> 0 0 0 0 0 0 0
TL> 0 0 0 1 0 0 1
MN> 0.0 0.0 0.0 0.0 0.0 0.0 0.0

--INFARCT

-> 0 0 0 1 0 0 1
TL> 0 0 0 1 0 0 1

--EXTRAMEDULLARY HEMATOPOIESIS, INCREASED

-> 0 0 0 1 0 0 1
TL> 0 0 0 1 0 0 1
MN> 0.0 0.0 0.0 0.0 0.0 0.0 0.0

BRAIN W/STEM (BR) NUMBER EXAMINED: 0 0 0 1 0 0 1
NOT REMARKABLE: 0 0 0 1 0 0 1

--HEMORRHAGE

-> 0 0 0 1 0 0 1
P> 0 0 0 0 0 0 0
TL> 0 0 0 1 0 0 1

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TABLE 14A
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
EXPANDED HISTOPATHOLOGY INCIDENCE SUMMARY

PRINTED: 20-JAN-93
PAGE: 220

STUDY NUMBER: 483287

TABLE INCLUDES:

SEX=ALL; GROUP=ALL; WEEKS=ALL
DEATH=UNSCHED; FIND=ALL; SUBSET=ALL

--- NUMBER - OF - ANIMALS - AFFECTED ---

SEX=ALL; GROUP=ALL; WEEKS=ALL DEATH=UNSCHED; FIND=ALL; SUBSET=ALL		SEX: -----FEMALE-----							
		GROUP:	-1-	-2-	-3-	-4-	-5-	-6-	-7-
ORGAN/TISSUE EXAMINED		NUMBER:	0	0	0	1	0	0	1
CORD, CERVICAL (CS)		NUMBER EXAMINED:	0	0	0	1	0	0	1
		NOT REMARKABLE:	0	0	0	1	0	0	1
--HEMORRHAGE		->	0	0	0	1	0	0	1
		P>	0	0	0	0	0	0	0
		TL>	0	0	0	1	0	0	1
CORD, THORACIC (TC)		NUMBER EXAMINED:	0	0	0	1	0	0	1
		NOT REMARKABLE:	0	0	0	1	0	0	1
--HEMORRHAGE		->	0	0	0	1	0	0	1
		P>	0	0	0	0	0	0	0
		TL>	0	0	0	1	0	0	1
CORD, LUMBAR (LC)		NUMBER EXAMINED:	0	0	0	1	0	0	1
		NOT REMARKABLE:	0	0	0	1	0	0	1
PITUITARY (PI)		NUMBER EXAMINED:	0	0	0	1	0	0	1
		NOT REMARKABLE:	0	0	0	1	0	0	1
--CYST		->	0	0	0	1	0	0	1
		TL>	0	0	0	1	0	0	1
THYROID (TY)		NUMBER EXAMINED:	0	0	0	1	0	0	1
		NOT REMARKABLE:	0	0	0	1	0	0	1
--FOLLICLE, CYST		->	0	0	0	1	0	0	1
		TL>	0	0	0	1	0	0	1
--UNILATERALLY EXAMINED		->	0	0	0	1	0	0	1
		P>	0	0	0	0	0	0	0
		TL>	0	0	0	1	0	0	1

HAZLETON WASHINGTON, INC.
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TABLE 14A
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
EXPANDED HISTOPATHOLOGY INCIDENCE SUMMARY

PRINTED: 20-JAN-93
PAGE: 221

STUDY NUMBER: 483287

TABLE INCLUDES:

SEX=ALL; GROUP=ALL; WEEKS=ALL
DEATH=UNSCHED; FIND=ALL; SUBSET=ALL

--- NUMBER - OF - ANIMALS - AFFECTED ---

SEX=ALL; GROUP=ALL; WEEKS=ALL DEATH=UNSCHED; FIND=ALL; SUBSET=ALL		SEX: -----FEMALE-----							
		GROUP:	-1-	-2-	-3-	-4-	-5-	-6-	-7-
ORGAN/TISSUE EXAMINED		NUMBER:	0	0	0	1	0	0	1
-----		---	---	---	---	---	---	---	---
PARATHYROID (PT)		NUMBER EXAMINED:	0	0	0	1	0	0	1
		NOT REMARKABLE:	0	0	0	0	0	0	1
--UNILATERALLY EXAMINED		->	0	0	0	0	0	0	1
		P>	0	0	0	1	0	0	0
		TL>	0	0	0	1	0	0	1
ESOPHAGUS (ES)		NUMBER EXAMINED:	0	0	0	1	0	0	1
		NOT REMARKABLE:	0	0	0	1	0	0	1
--INFLAMMATION, CHRONIC		->	0	0	0	1	0	0	1
		TL>	0	0	0	1	0	0	1
		MN>	0.0	0.0	0.0	0.0	0.0	0.0	0.0
TRACHEA (TR)		NUMBER EXAMINED:	0	0	0	1	0	0	1
		NOT REMARKABLE:	0	0	0	1	0	0	1
LUNG (LU)		NUMBER EXAMINED:	0	0	0	1	0	0	1
		NOT REMARKABLE:	0	0	0	1	0	0	1
--PERIBRONCHIAL/PERIVASCULAR, INFILTRATION, LYMPHOID		->	0	0	0	1	0	0	1
		TL>	0	0	0	1	0	0	1
		MN>	0.0	0.0	0.0	0.0	0.0	0.0	0.0
--INFLAMMATION, CHRONIC		->	0	0	0	1	0	0	1
		TL>	0	0	0	1	0	0	1
		MN>	0.0	0.0	0.0	0.0	0.0	0.0	0.0
--VESSEL, MINERALIZATION		->	0	0	0	1	0	0	1
		TL>	0	0	0	1	0	0	1
		MN>	0.0	0.0	0.0	0.0	0.0	0.0	0.0

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TABLE 14A
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
EXPANDED HISTOPATHOLOGY INCIDENCE SUMMARY

PRINTED: 20-JAN-93
PAGE: 222

STUDY NUMBER: 483287

TABLE INCLUDES:

SEX=ALL; GROUP=ALL; WEEKS=ALL
DEATH=UNSCHED; FIND=ALL; SUBSET=ALL

--- NUMBER - OF - ANIMALS - AFFECTED ---

SEX=ALL; GROUP=ALL; WEEKS=ALL		SEX: -----FEMALE-----							
DEATH=UNSCHED; FIND=ALL; SUBSET=ALL		GROUP: -1- -2- -3- -4- -5- -6- -7-							
ORGAN/TISSUE EXAMINED		NUMBER:	0	0	0	1	0	0	1
-----		---	---	---	---	---	---	---	---
** FROM PREVIOUS PAGE **									
LUNG (LU)	NUMBER EXAMINED:	0	0	0	1	0	0	0	1
	NOT REMARKABLE:	0	0	0	1	0	0	0	1
--HEMORRHAGE									
	->	0	0	0	1	0	0	0	1
	TL>	0	0	0	1	0	0	0	1
	MN>	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
HEART (HT)	NUMBER EXAMINED:	0	0	0	1	0	0	0	1
	NOT REMARKABLE:	0	0	0	1	0	0	0	1
--INFLAMMATION, CHRONIC									
	->	0	0	0	1	0	0	0	1
	1>	0	0	0	0	0	0	0	0
	TL>	0	0	0	1	0	0	0	1
	MN>	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
--MINERALIZATION									
	->	0	0	0	1	0	0	0	1
	1>	0	0	0	0	0	0	0	0
	TL>	0	0	0	1	0	0	0	1
	MN>	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
--DEGENERATION									
	->	0	0	0	1	0	0	0	1
	1>	0	0	0	0	0	0	0	0
	TL>	0	0	0	1	0	0	0	1
	MN>	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
GALLBLADDER (GB)	NUMBER EXAMINED:	0	0	0	1	0	0	0	0
	NOT REMARKABLE:	0	0	0	1	0	0	0	0
--INFLAMMATION, CHRONIC									
	->	0	0	0	1	0	0	0	0
	TL>	0	0	0	1	0	0	0	0
	MN>	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

TABLE 14A
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
EXPANDED HISTOPATHOLOGY INCIDENCE SUMMARY

PRINTED: 20-JAN-93
PAGE: 223

STUDY NUMBER: 483287

TABLE INCLUDES:

SEX=ALL; GROUP=ALL; WEEKS=ALL
DEATH=UNSCHED; FIND=ALL; SUBSET=ALL

--- NUMBER - OF - ANIMALS - AFFECTED ---

TABLE INCLUDES:		SEX: -----FEMALE-----							
SEX=ALL; GROUP=ALL; WEEKS=ALL		GROUP: -1- -2- -3- -4- -5- -6- -7-							
DEATH=UNCHED; FIND=ALL; SUBSET=ALL									
ORGAN/TISSUE EXAMINED		NUMBER:	0	0	0	1	0	0	1
			--	--	--	--	--	--	--
DUODENUM (DU)		NUMBER EXAMINED:	0	0	0	1	0	0	0
		NOT REMARKABLE:	0	0	0	1	0	0	0
JEJUNUM (JE)		NUMBER EXAMINED:	0	0	0	1	0	0	1
		NOT REMARKABLE:	0	0	0	0	0	0	1
--HYPERPLASIA, LYMPHOID		->	0	0	0	0	0	0	1
		P>	0	0	0	1	0	0	0
		TL>	0	0	0	1	0	0	1
--AMYLOIDOSIS		->	0	0	0	1	0	0	1
		TL>	0	0	0	1	0	0	1
		MN>	0.0	0.0	0.0	0.0	0.0	0.0	0.0
ILEUM (IL)		NUMBER EXAMINED:	0	0	0	1	0	0	1
		NOT REMARKABLE:	0	0	0	1	0	0	1
--HYPERPLASIA, LYMPHOID		->	0	0	0	1	0	0	1
		TL>	0	0	0	1	0	0	1
--AMYLOIDOSIS		->	0	0	0	1	0	0	1
		TL>	0	0	0	1	0	0	1
		MN>	0.0	0.0	0.0	0.0	0.0	0.0	0.0
PANCREAS (PA)		NUMBER EXAMINED:	0	0	0	1	0	0	1
		NOT REMARKABLE:	0	0	0	1	0	0	1
--INFLAMMATION, CHRONIC		->	0	0	0	1	0	0	1
		I>	0	0	0	0	0	0	0
		TL>	0	0	0	1	0	0	1
		MN>	0.0	0.0	0.0	0.0	0.0	0.0	0.0

** CONTINUED ON NEXT PAGE **

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

TABLE 14A

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
EXPANDED HISTOPATHOLOGY INCIDENCE SUMMARY

PRINTED: 20-JAN-93
PAGE: 224

STUDY NUMBER: 483287

TABLE INCLUDES:

SEX=ALL;GROUP=ALL;WEEKS=ALL
DEATH=UNSCHED;FIND=ALL;SUBSET=ALL

--- NUMBER - OF - ANIMALS - AFFECTED ---

SEX=ALL;GROUP=ALL;WEEKS=ALL DEATH=UNSCHED;FIND=ALL;SUBSET=ALL		SEX: -----FEMALE-----							
		GROUP: -1- -2- -3- -4- -5- -6- -7-							
ORGAN/TISSUE EXAMINED		NUMBER:	0	0	0	1	0	0	1
-----		---	---	---	---	---	---	---	---
** FROM PREVIOUS PAGE **									
PANCREAS (PA)	NUMBER EXAMINED:	0	0	0	1	0	0	0	1
	NOT REMARKABLE:	0	0	0	1	0	0	0	1
--AMYLOIDOSIS	->	0	0	0	1	0	0	0	1
	TL>	0	0	0	1	0	0	0	1
	MN>	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
--ISLET CELL, HYPERPLASIA	->	0	0	0	1	0	0	0	1
	TL>	0	0	0	1	0	0	0	1
	MN>	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
CECUM (CE)	NUMBER EXAMINED:	0	0	0	1	0	0	0	1
	NOT REMARKABLE:	0	0	0	1	0	0	0	1
--HYPERPLASIA, LYMPHOID	->	0	0	0	1	0	0	0	1
	P>	0	0	0	0	0	0	0	0
	TL>	0	0	0	1	0	0	0	1
COLON (CO)	NUMBER EXAMINED:	0	0	0	1	0	0	0	1
	NOT REMARKABLE:	0	0	0	1	0	0	0	1
--HYPERPLASIA, LYMPHOID	->	0	0	0	1	0	0	0	1
	TL>	0	0	0	1	0	0	0	1
RECTUM (RE)	NUMBER EXAMINED:	0	0	0	1	0	0	0	1
	NOT REMARKABLE:	0	0	0	0	0	0	0	1
--HYPERPLASIA, LYMPHOID	->	0	0	0	0	0	0	0	1
	P>	0	0	0	1	0	0	0	0
	TL>	0	0	0	1	0	0	0	0
** CONTINUED ON NEXT PAGE **									

** CONTINUED ON NEXT PAGE **

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WASHINGTON, D.C. U.S.A.

TABLE 14A
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
EXPANDED HISTOPATHOLOGY INCIDENCE SUMMARY

PRINTED: 20-JAN-93
PAGE: 225

STUDY NUMBER: 483287

TABLE INCLUDES:

SEX=ALL; GROUP=ALL; WEEKS=ALL
DEATH=UNSCHED; FIND=ALL; SUBSET=ALL

--- NUMBER - OF - ANIMALS - AFFECTED ---

SEX: -----FEMALE-----								
GROUP: -1- -2- -3- -4- -5- -6- -7-								
NUMBER:		0	0	0	1	0	0	1
ORGAN/TISSUE EXAMINED		---	---	---	---	---	---	---
** FROM PREVIOUS PAGE **								
RECTUM (RE)		NUMBER EXAMINED:	0	0	0	1	0	0
		NOT REMARKABLE:	0	0	0	0	0	1
--AMYLOIDOSIS		->	0	0	0	1	0	0
		TL>	0	0	0	1	0	0
		MN>	0.0	0.0	0.0	0.0	0.0	0.0
LN, MESENTERIC (MS)		NUMBER EXAMINED:	0	0	0	1	0	0
		NOT REMARKABLE:	0	0	0	0	0	0
--MACROPHAGES, PIGMENTED		->	0	0	0	0	0	0
		1>	0	0	0	1	0	0
		TL>	0	0	0	1	0	0
		MN>	0.0	0.0	0.0	1.0	0.0	0.0
--HYPERPLASIA, LYMPHOID		->	0	0	0	1	0	0
		TL>	0	0	0	1	0	0
		MN>	0.0	0.0	0.0	0.0	0.0	0.0
--INFLAMMATION, GRANULOMATOUS		->	0	0	0	1	0	0
		TL>	0	0	0	1	0	0
		MN>	0.0	0.0	0.0	0.0	0.0	0.0
--AMYLOIDOSIS		->	0	0	0	1	0	0
		TL>	0	0	0	1	0	0
		MN>	0.0	0.0	0.0	0.0	0.0	0.0
--HEMORRHAGE		->	0	0	0	1	0	0
		TL>	0	0	0	1	0	0

** CONTINUED ON NEXT PAGE **

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TABLE 14A
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
EXPANDED HISTOPATHOLOGY INCIDENCE SUMMARY

PRINTED: 20-JAN-93
PAGE: 226

STUDY NUMBER: 483287

TABLE INCLUDES:

SEX=ALL; GROUP=ALL; WEEKS=ALL
DEATH=UNSCHED; FIND=ALL; SUBSET=ALL

--- NUMBER - OF - ANIMALS - AFFECTED ---

TABLE INCLUDED: SEX=ALL; GROUP=ALL; WEEKS=ALL DEATH=UNSCHED; FIND=ALL; SUBSET=ALL		SEX: -----FEMALE-----							
		GROUP:	-1-	-2-	-3-	-4-	-5-	-6-	-7-
ORGAN/TISSUE EXAMINED		NUMBER:	0	0	0	1	0	0	1
-----		----	----	----	----	----	----	----	----
** FROM PREVIOUS PAGE **									
LN, MESENTERIC (MS)	NUMBER EXAMINED:	0	0	0	1	0	0	0	0
	NOT REMARKABLE:	0	0	0	0	0	0	0	0
--NECROSIS, LYMPHOID									
	->	0	0	0	1	0	0	0	0
	TL>	0	0	0	1	0	0	0	0
	MN>	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
TESTIS (TE)	NUMBER EXAMINED:	0	0	0	0	0	0	0	0
	NOT REMARKABLE:	0	0	0	0	0	0	0	0
--MINERALIZATION									
	->	0	0	0	0	0	0	0	0
	TL>	0	0	0	0	0	0	0	0
	MN>	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
--HEMORRHAGE									
	->	0	0	0	0	0	0	0	0
	TL>	0	0	0	0	0	0	0	0
EPIDIDYMIS (EP)	NUMBER EXAMINED:	0	0	0	0	0	0	0	0
	NOT REMARKABLE:	0	0	0	0	0	0	0	0
--INFLAMMATION, CHRONIC									
	->	0	0	0	0	0	0	0	0
	TL>	0	0	0	0	0	0	0	0
	MN>	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
--LUMEN, DEBRIS, CELLULAR									
	->	0	0	0	0	0	0	0	0
	P>	0	0	0	0	0	0	0	0
	TL>	0	0	0	0	0	0	0	0

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TABLE 14A
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
EXPANDED HISTOPATHOLOGY INCIDENCE SUMMARY

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STUDY NUMBER: 483287

		--- N U M B E R - O F - A N I M A L S - A F F E C T E D ---						
		SEX: -----FEMALE-----						
		GROUP: -1-	-2-	-3-	-4-	-5-	-6-	-7-
ORGAN/TISSUE EXAMINED	NUMBER:	0	0	0	1	0	0	1
PROSTATE (PR)	NUMBER EXAMINED:	0	0	0	0	0	0	0
	NOT REMARKABLE:	0	0	0	0	0	0	0
--INFLAMMATION, CHRONIC	->	0	0	0	0	0	0	0
	TL>	0	0	0	0	0	0	0
	MN>	0.0	0.0	0.0	0.0	0.0	0.0	0.0
URINARY BLADDER (UB)	NUMBER EXAMINED:	0	0	0	1	0	0	1
	NOT REMARKABLE:	0	0	0	1	0	0	1
--INFLAMMATION, CHRONIC	->	0	0	0	1	0	0	1
	TL>	0	0	0	1	0	0	1
	MN>	0.0	0.0	0.0	0.0	0.0	0.0	0.0
OVARY (OV)	NUMBER EXAMINED:	0	0	0	1	0	0	1
	NOT REMARKABLE:	0	0	0	0	0	0	1
--FOLLICLE, CYST	->	0	0	0	0	0	0	1
	P>	0	0	0	1	0	0	0
	TL>	0	0	0	1	0	0	1
--MINERALIZATION	->	0	0	0	0	0	0	1
	1>	0	0	0	1	0	0	0
	TL>	0	0	0	1	0	0	1
	MN>	0.0	0.0	0.0	1.0	0.0	0.0	0.0
--BURSA, CYST	->	0	0	0	1	0	0	1
	TL>	0	0	0	1	0	0	1
--UNILATERALLY EXAMINED	->	0	0	0	1	0	0	1
	TL>	0	0	0	1	0	0	1

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

TABLE 14A
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
EXPANDED HISTOPATHOLOGY INCIDENCE SUMMARY

PRINTED: 20-JAN-93
PAGE: 228

STUDY NUMBER: 483287

TABLE INCLUDES:

SEX=ALL; GROUP=ALL; WEEKS=ALL
DEATH=UNCHED; FIND=ALL; SUBSET=ALL

--- NUMBER - OF - ANIMALS - AFFECTED ---

SEX=ALL; GROUP=ALL; WEEKS=ALL DEATH=UNSCHED; FIND=ALL; SUBSET=ALL		SEX: -----FEMALE-----							
		GROUP:	-1-	-2-	-3-	-4-	-5-	-6-	-7-
ORGAN/TISSUE EXAMINED		NUMBER:	0	0	0	1	0	0	1
OVIDUCT (OD)		NUMBER EXAMINED:	0	0	0	1	0	0	1
		NOT REMARKABLE:	0	0	0	1	0	0	1
LN, MANDIBULAR (MN)		NUMBER EXAMINED:	0	0	0	1	0	0	1
		NOT REMARKABLE:	0	0	0	1	0	0	0
--MACROPHAGES, PIGMENTED		->	0	0	0	1	0	0	0
		1>	0	0	0	0	0	0	1
		TL>	0	0	0	1	0	0	1
		MN>	0.0	0.0	0.0	0.0	0.0	0.0	1.0
--AMYLÓIDOSIS		->	0	0	0	1	0	0	1
		TL>	0	0	0	1	0	0	1
		MN>	0.0	0.0	0.0	0.0	0.0	0.0	0.0
--HYPERPLASIA, LYMPHOID		->	0	0	0	1	0	0	1
		TL>	0	0	0	1	0	0	1
MAND SALIVARY GL (SG)		NUMBER EXAMINED:	0	0	0	1	0	0	1
		NOT REMARKABLE:	0	0	0	1	0	0	1
--INFLAMMATION, CHRONIC		->	0	0	0	1	0	0	1
		TL>	0	0	0	1	0	0	1
		MN>	0.0	0.0	0.0	0.0	0.0	0.0	0.0
SALIVARY, OTHER (OS)		NUMBER EXAMINED:	0	0	0	0	0	0	1
		NOT REMARKABLE:	0	0	0	0	0	0	1

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TABLE 14A
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
EXPANDED HISTOPATHOLOGY INCIDENCE SUMMARY

PRINTED: 20-JAN-93
PAGE: 229

STUDY NUMBER: 483287

TABLE INCLUDES:

SEX=ALL; GROUP=ALL; WEEKS=ALL
DEATH=UNSCHED; FIND=ALL; SUBSET=ALL

--- NUMBER - OF - ANIMALS - AFFECTED ---

SEX: -----FEMALE-----

GROUP: -1- -2- -3- -4- -5- -6- -7-

ORGAN/TISSUE EXAMINED

NUMBER: 0 0 0 1 0 0 1

THYMUS (TH)	NUMBER EXAMINED:	0	0	0	1	0	0	1
	NOT REMARKABLE:	0	0	0	0	0	0	0
--CYST	-->	0	0	0	0	0	0	1
	P>	0	0	0	1	0	0	0
	TL>	0	0	0	1	0	0	1
--ECTOPIC THYROID	-->	0	0	0	1	0	0	1
	TL>	0	0	0	1	0	0	1
--NECROSIS, LYMPHOID	-->	0	0	0	1	0	0	0
	1>	0	0	0	0	0	0	1
	TL>	0	0	0	1	0	0	1
	MN>	0.0	0.0	0.0	0.0	0.0	0.0	1.0
--ATROPHY	-->	0	0	0	0	0	0	1
	4>	0	0	0	1	0	0	0
	TL>	0	0	0	1	0	0	1
	MN>	0.0	0.0	0.0	4.0	0.0	0.0	0.0
AORTA, THORACIC (AO)	NUMBER EXAMINED:	0	0	0	1	0	0	1
	NOT REMARKABLE:	0	0	0	1	0	0	1
EYE (EY)	NUMBER EXAMINED:	0	0	0	1	0	0	1
	NOT REMARKABLE:	0	0	0	1	0	0	1
--UNILATERALLY EXAMINED	-->	0	0	0	1	0	0	1
	P>	0	0	0	0	0	0	0
	TL>	0	0	0	1	0	0	1

** CONTINUED ON NEXT PAGE **

HAZLETON WASHINGTON, INC:
WASHINGTON, D.C. U.S.A.

TABLE 14A
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
EXPANDED HISTOPATHOLOGY INCIDENCE SUMMARY

PRINTED: 20-JAN-93
PAGE: 230

STUDY NUMBER: 483287

TABLE INCLUDES:

SEX=ALL; GROUP=ALL; WEEKS=ALL
DEATH=UNSCHED; FIND=ALL; SUBSET=ALL

--- NUMBER - OF - ANIMALS - AFFECTED ---

SEX: -----FEMALE-----

GROUP: -1- -2- -3- -4- -5- -6- -7-

ORGAN/TISSUE EXAMINED

NUMBER: 0 0 0 1 0 0 1

** FROM PREVIOUS PAGE **

EYE (EY) NUMBER EXAMINED: 0 0 0 1 0 0 1
NOT REMARKABLE: 0 0 0 1 0 0 1

--CORNEA, MINERALIZATION

-> 0 0 0 1 0 0 1
TL> 0 0 0 1 0 0 1
MN> 0.0 0.0 0.0 0.0 0.0 0.0 0.0

HARDERIAN GLAND (HG) NUMBER EXAMINED: 0 0 0 1 0 0 1
NOT REMARKABLE: 0 0 0 1 0 0 0

--INFLAMMATION, CHRONIC

-> 0 0 0 1 0 0 0
P> 0 0 0 0 0 0 1
TL> 0 0 0 1 0 0 1

NERVE, OPTIC (ON) NUMBER EXAMINED: 0 0 0 1 0 0 1
NOT REMARKABLE: 0 0 0 1 0 0 1

--UNILATERALLY EXAMINED

-> 0 0 0 1 0 0 1
P> 0 0 0 0 0 0 0
TL> 0 0 0 1 0 0 1

LACRIMAL GL, EX (EO) NUMBER EXAMINED: 0 0 0 1 0 0 1
NOT REMARKABLE: 0 0 0 0 0 0 1

--INFLAMMATION, CHRONIC

-> 0 0 0 1 0 0 1
I> 0 0 0 0 0 0 0
TL> 0 0 0 1 0 0 1
MN> 0.0 0.0 0.0 0.0 0.0 0.0 0.0

--UNILATERALLY EXAMINED

-> 0 0 0 0 0 0 1
P> 0 0 0 1 0 0 0
TL> 0 0 0 1 0 0 1

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TABLE 14A
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
EXPANDED HISTOPATHOLOGY INCIDENCE SUMMARY

PRINTED: 20-JAN-93
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STUDY NUMBER: 483287

		--- NUMBER - OF - ANIMALS - AFFECTED ---						
		SEX: -----FEMALE-----						
		GROUP: -1-	-2-	-3-	-4-	-5-	-6-	-7-
ORGAN/TISSUE EXAMINED	NUMBER:	0	0	0	1	0	0	1
TONGUE (TO)	NUMBER EXAMINED:	0	0	0	1	0	0	1
	NOT REMARKABLE:	0	0	0	1	0	0	1
MUSCLE, SKELETAL (SM)	NUMBER EXAMINED:	0	0	0	1	0	0	1
	NOT REMARKABLE:	0	0	0	1	0	0	1
NERVE, SCIATIC (SN)	NUMBER EXAMINED:	0	0	0	1	0	0	1
	NOT REMARKABLE:	0	0	0	1	0	0	1
MUSCLE, ABDOM (MA)	NUMBER EXAMINED:	0	0	0	0	0	0	1
	NOT REMARKABLE:	0	0	0	0	0	0	1
MARROW, STERNUM (SE)	NUMBER EXAMINED:	0	0	0	1	0	0	1
	NOT REMARKABLE:	0	0	0	1	0	0	1
BONE, STERNUM (SB)	NUMBER EXAMINED:	0	0	0	1	0	0	1
	NOT REMARKABLE:	0	0	0	1	0	0	1
MARROW, FEMUR (FM)	NUMBER EXAMINED:	0	0	0	1	0	0	1
	NOT REMARKABLE:	0	0	0	1	0	0	1
--HYPERCELLULAR	-->	0	0	0	1	0	0	1
	P>	0	0	0	0	0	0	0
	TL>	0	0	0	1	0	0	1
BONE, FEMUR (FE)	NUMBER EXAMINED:	0	0	0	1	0	0	1
	NOT REMARKABLE:	0	0	0	1	0	0	1
HEMATO NEOPLASIA (HN)	NUMBER EXAMINED:	0	0	0	1	0	0	1
	NOT REMARKABLE:	0	0	0	1	0	0	1

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TABLE 14A
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
EXPANDED HISTOPATHOLOGY INCIDENCE SUMMARY

PRINTED: 20-JAN-93
PAGE: 232

STUDY NUMBER: 483287

TABLE INCLUDES:

SEX=ALL; GROUP=ALL; WEEKS=ALL
DEATH=UNSCHED; FIND=ALL; SUBSET=ALL

--- NUMBER - OF - ANIMALS - AFFECTED ---

SEX=ALL; GROUP=ALL; WEEKS=ALL		SEX: -----FEMALE-----							
DEATH=UNSCHED; FIND=ALL; SUBSET=ALL		GROUP: -1- -2- -3- -4- -5- -6- -7-							
ORGAN/TISSUE EXAMINED		NUMBER:	0	0	0	1	0	0	1
-----		-----	-----	-----	-----	-----	-----	-----	-----
^DEATH COMMENT (DC)		NUMBER EXAMINED:	0	0	0	1	0	0	1
		NOT REMARKABLE:	0	0	0	0	0	0	0
--SCHEDULED SACRIFICE		->	0	0	0	0	0	0	1
		P>	0	0	0	1	0	0	0
		TL>	0	0	0	1	0	0	1
--UNDETERMINED		->	0	0	0	1	0	0	0
		P>	0	0	0	0	0	0	1
		TL>	0	0	0	1	0	0	1
--ACCIDENTAL		->	0	0	0	1	0	0	1
		P>	0	0	0	0	0	0	0
		TL>	0	0	0	1	0	0	1
LN, OTHER (LN)		NUMBER EXAMINED:	0	0	0	1	0	0	1
		NOT REMARKABLE:	0	0	0	0	0	0	1
--MACROPHAGES, PIGMENTED		->	0	0	0	0	0	0	1
		P>	0	0	0	1	0	0	0
		TL>	0	0	0	1	0	0	1
--HYPERPLASIA, LYMPHOID		->	0	0	0	1	0	0	1
		TL>	0	0	0	1	0	0	1
SKIN, OTHER (SS)		NUMBER EXAMINED:	0	0	0	0	0	0	0
		NOT REMARKABLE:	0	0	0	0	0	0	0
--DERMATITIS, CHRONIC		->	0	0	0	0	0	0	0
		TL>	0	0	0	0	0	0	0

** CONTINUED ON NEXT PAGE **

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

TABLE 14A
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
EXPANDED HISTOPATHOLOGY INCIDENCE SUMMARY

PRINTED: 20-JAN-93
PAGE: 233

STUDY NUMBER: 483287

TABLE INCLUDES:

SEX=ALL;GROUP=ALL;WEEKS=ALL
DEATH=UNSCHED;FIND=ALL;SUBSET=ALL

--- NUMBER - OF - ANIMALS - AFFECTED ---

TABLE INCLUDES:		SEX: -----FEMALE-----							
SEX=ALL;GROUP=ALL;WEEKS=ALL									
DEATH=UNSCHED;FIND=ALL;SUBSET=ALL									
		GROUP:	-1-	-2-	-3-	-4-	-5-	-6-	-7-
ORGAN/TISSUE EXAMINED		NUMBER:	0	0	0	1	0	0	1

** FROM PREVIOUS PAGE **									
SKIN, OTHER (SS)		NUMBER EXAMINED:	0	0	0	0	0	0	0
		NOT REMARKABLE:	0	0	0	0	0	0	0
--DERMATITIS, ULCERATIVE		->	0	0	0	0	0	0	0
		TL>	0	0	0	0	0	0	0
BONE, OTHER (OB)		NUMBER EXAMINED:	0	0	0	0	0	0	0
		NOT REMARKABLE:	0	0	0	0	0	0	0
CAVITY, ABDOM (PC)		NUMBER EXAMINED:	0	0	0	0	0	0	0
		NOT REMARKABLE:	0	0	0	0	0	0	0
--ADHESION		TL>	0	0	0	0	0	0	0
LI, INTRAHEPATIC (LIO)		NUMBER EXAMINED:	0	0	0	0	0	0	0
		NOT REMARKABLE:	0	0	0	0	0	0	0
--PIGMENT, PAS POSITIVE		TL>	0	0	0	0	0	0	0
		MN>	0.0	0.0	0.0	0.0	0.0	0.0	0.0
--PIGMENT, IRON POSITIVE		TL>	0	0	0	0	0	0	0
		MN>	0.0	0.0	0.0	0.0	0.0	0.0	0.0
--PIGMENT, BILE POSITIVE		TL>	0	0	0	0	0	0	0
		MN>	0.0	0.0	0.0	0.0	0.0	0.0	0.0
--PIGMENT, LIPOFUSCIN POSITIVE		TL>	0	0	0	0	0	0	0
		MN>	0.0	0.0	0.0	0.0	0.0	0.0	0.0
--PIGMENT, FONTANA MASSON POSITIVE		TL>	0	0	0	0	0	0	0
		MN>	0.0	0.0	0.0	0.0	0.0	0.0	0.0

HAZLETON WASHINGTON, INC.
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TABLE 14A
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
EXPANDED HISTOPATHOLOGY INCIDENCE SUMMARY

PRINTED: 20-JAN-93
PAGE: 234

STUDY NUMBER: 483287

TABLE INCLUDES:

SEX=ALL; GROUP=ALL; WEEKS=ALL
DEATH=UNSCHED; FIND=ALL; SUBSET=ALL

--- NUMBER - OF - ANIMALS - AFFECTED ---

SEX: -----FEMALE-----

GROUP: -1- -2- -3- -4- -5- -6- -7-

ORGAN/TISSUE EXAMINED

NUMBER: 0 0 0 1 0 0 1

LI, EXTRAHEPATIC (LI1)	NUMBER EXAMINED:	0	0	0	0	0	0	0
	NOT REMARKABLE:	0	0	0	0	0	0	0
--PIGMENT, PAS POSITIVE	TL>	0	0	0	0	0	0	0
	MN>	0.0	0.0	0.0	0.0	0.0	0.0	0.0
--PIGMENT, IRON POSITIVE	TL>	0	0	0	0	0	0	0
	MN>	0.0	0.0	0.0	0.0	0.0	0.0	0.0
--PIGMENT, BILE POSITIVE	TL>	0	0	0	0	0	0	0
	MN>	0.0	0.0	0.0	0.0	0.0	0.0	0.0
--PIGMENT, LIPOFUSCIN POSITIVE	TL>	0	0	0	0	0	0	0
	MN>	0.0	0.0	0.0	0.0	0.0	0.0	0.0
--PIGMENT, FONTANA MASSON POSITIVE	TL>	0	0	0	0	0	0	0
	MN>	0.0	0.0	0.0	0.0	0.0	0.0	0.0
** END OF LIST **								

Table 14B
Expanded Histopathology Incidence Summary
Main Study (Terminal Sacrifice)
13-Week Subchronic Oral Toxicity Study of Triclosan in CD-1[®] Mice

Standard Key to Expanded Histopathology Incidence Summary

SYMBOLS PREFACING NEOPLASTIC FINDINGS

B- = Primary, Benign Neoplasm
M- = Primary, Malignant Neoplasm
N- = Metastatic Neoplasm
I- = Locally Invasive Neoplasm
X- = Other Neoplasm

SYMBOLS USED IN EXPANDED TABLE

-> = Finding Not Present
P> = Finding Present
+> = Neoplastic Finding Present
1> = Minimal
2> = Slight
3> = Moderate
4> = Moderately Severe
5> = Severe
TL> = Total
MN> = Mean of Graded Findings

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TABLE 14B
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
EXPANDED HISTOPATHOLOGY INCIDENCE SUMMARY

PRINTED: 20-JAN-93
PAGE: 237

STUDY NUMBER: 483287

TABLE INCLUDES:

SEX=ALL;GROUP=ALL;WEEKS=ALL
DEATH=T;FIND=ALL;SUBSET=ALL

--- NUMBER - OF - ANIMALS - AFFECTED ---

ORGAN/TISSUE EXAMINED	SEX: -----MALE-----						
	GROUP: -1-	-2-	-3-	-4-	-5-	-6-	-7-
NUMBER:	15	15	15	13	15	15	13
** TOP OF LIST **							
SPLEEN (SP)	NUMBER EXAMINED: 15 0 10 8 15 15 13						
	NOT REMARKABLE: 0 0 0 0 0 0 0						
--EXTRAMEDULLARY HEMATOPOIESIS, INCREASED							
->	2	0	2	0	1	0	0
1>	5	0	3	0	3	2	2
2>	6	0	5	5	8	7	3
3>	2	0	0	3	3	4	6
4>	0	0	0	0	0	2	2
TL>	15	0	10	8	15	15	13
MN>	1.5	0.0	1.3	2.4	1.9	2.4	2.6
--PIGMENT							
->	0	0	0	0	0	2	4
1>	15	0	10	8	15	13	9
2>	0	0	0	0	0	0	0
3>	0	0	0	0	0	0	0
TL>	15	0	10	8	15	15	13
MN>	1.0	0.0	1.0	1.0	1.0	0.9	0.7
--AMYLOIDOSIS							
->	15	0	10	8	14	15	12
1>	0	0	0	0	1	0	1
TL>	15	0	10	8	15	15	13
MN>	0.0	0.0	0.0	0.0	0.1	0.0	0.1
--DEPLETION, LYMPHOID							
->	15	0	10	8	15	15	13
TL>	15	0	10	8	15	15	13
MN>	0.0	0.0	0.0	0.0	0.0	0.0	0.0
--NECROSIS, LYMPHOID							
->	15	0	10	8	15	15	13
1>	0	0	0	0	0	0	0
TL>	15	0	10	8	15	15	13
MN>	0.0	0.0	0.0	0.0	0.0	0.0	0.0

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TABLE 14B
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE, (MAIN-GROUPS 1-7)
EXPANDED HISTOPATHOLOGY INCIDENCE SUMMARY

PRINTED: 20-JAN-93
PAGE: 238

STUDY NUMBER: 483287

TABLE INCLUDES:

SEX=ALL; GROUP=ALL; WEEKS=ALL
DEATH=T; FIND=ALL; SUBSET=ALL

--- NUMBER OF ANIMALS AFFECTED ---

ORGAN/TISSUE EXAMINED	NUMBER	SEX: -----MALE-----					
		GROUP: -1-	-2-	-3-	-4-	-5-	-6- -7-
		15	15	15	13	15	15 13
STOMACH, NONGL (SU)	NUMBER EXAMINED:	14	0	10	8	15	14 13
	NOT REMARKABLE:	14	0	10	8	14	14 13
--INFLAMMATION, CHRONIC	->	14	0	10	8	14	14 13
	1>	0	0	0	0	1	0 0
	TL>	14	0	10	8	15	14 13
	MN>	0.0	0.0	0.0	0.0	0.1	0.0 0.0
STOMACH, GL (ST)	NUMBER EXAMINED:	14	0	10	8	15	15 13
	NOT REMARKABLE:	9	0	6	2	7	5 4
--HYPERPLASIA	->	14	0	10	8	15	14 10
	1>	0	0	0	0	0	0 1
	2>	0	0	0	0	0	1 2
	TL>	14	0	10	8	15	15 13
	MN>	0.0	0.0	0.0	0.0	0.0	0.1 0.4
--HYPERPLASIA, CYSTIC	->	13	0	9	2	8	8 8
	1>	1	0	1	5	6	7 3
	2>	0	0	0	1	1	0 1
	3>	0	0	0	0	0	0 1
	TL>	14	0	10	8	15	15 13
	MN>	0.1	0.0	0.1	0.9	0.5	0.5 0.6
--INFLAMMATION, CHRONIC	->	10	0	6	4	11	11 8
	1>	4	0	4	3	4	4 5
	2>	0	0	0	1	0	0 0
	TL>	14	0	10	8	15	15 13
	MN>	0.3	0.0	0.4	0.6	0.3	0.3 0.4

** CONTINUED ON NEXT PAGE **

HAZLETON WASHINGTON, INC.
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TABLE 14B
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
EXPANDED HISTOPATHOLOGY INCIDENCE SUMMARY

PRINTED: 20-JAN-93
PAGE: 239

STUDY NUMBER: 483287

TABLE INCLUDES:

SEX=ALL;GROUP=ALL;WEEKS=ALL
DEATH=T;FIND=ALL;SUBSET=ALL

--- NUMBER - OF - ANIMALS - AFFECTED ---

		SEX: -----MALE-----						
		GROUP: -1-	-2-	-3-	-4-	-5-	-6-	-7-
		NUMBER:	15	15	13	15	15	13
ORGAN/TISSUE EXAMINED								
** FROM PREVIOUS PAGE **								
STOMACH, GL (ST)		NUMBER EXAMINED:	14	0	10	8	15	13
		NOT REMARKABLE:	9	0	6	2	7	4
--MUCOSA, NECROSIS		->	14	0	10	8	15	13
		1>	0	0	0	0	0	0
		2>	0	0	0	0	0	0
		3>	0	0	0	0	0	0
		TL>	14	0	10	8	15	13
		MN>	0.0	0.0	0.0	0.0	0.1	0.0
--INFLAMMATION, ACUTE		->	14	0	10	8	15	13
		1>	0	0	0	0	0	0
		TL>	14	0	10	8	15	13
		MN>	0.0	0.0	0.0	0.0	0.0	0.0
--AMYLOIDOSIS		->	14	0	10	8	15	13
		P>	0	0	0	0	1	0
		TL>	14	0	10	8	15	13
ADRENAL, CORTEX (AC)		NUMBER EXAMINED:	15	15	10	8	15	13
		NOT REMARKABLE:	3	2	7	4	4	2
--PIGMENT		->	4	3	9	5	14	12
		1>	9	11	1	3	1	2
		2>	2	1	0	0	0	0
		TL>	15	15	10	8	15	13
		MN>	0.9	0.9	0.1	0.4	0.1	0.1

** CONTINUED ON NEXT PAGE **

HAZLETON WASHINGTON, INC.
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TABLE 14B
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
EXPANDED HISTOPATHOLOGY INCIDENCE SUMMARY

PRINTED: 20-JAN-93
PAGE: 240
STUDY NUMBER: 483287

TABLE INCLUDES:

SEX=ALL;GROUP=ALL;WEEKS=ALL
DEATH=T;FIND=ALL;SUBSET=ALL

--- NUMBER - OF - ANIMALS - AFFECTED ---

SEX=ALL;GROUP=ALL;WEEKS=ALL DEATH=T;FIND=ALL;SUBSET=ALL		SEX: -----MALE-----							
GROUP:		-1-	-2-	-3-	-4-	-5-	-6-	-7-	
ORGAN/TISSUE EXAMINED		NUMBER:	15	15	15	13	15	15	13
-----		---	---	---	---	---	---	---	
** FROM PREVIOUS PAGE **									
ADRENAL, CORTEX (AC)		NUMBER EXAMINED:	15	15	10	8	15	15	13
		NOT REMARKABLE:	3	2	7	4	4	5	2
--HYPERTROPHY, ZONA FASCICULATA		-->	15	15	10	6	4	6	2
		1>	0	0	0	2	11	9	7
		2>	0	0	0	0	0	0	4
		TL>	15	15	10	8	15	15	13
		MN>	0.0	0.0	0.0	0.3	0.7	0.6	1.2
--VACUOLIZATION, X-ZONE		-->	15	15	10	8	15	15	13
		1>	0	0	0	0	0	0	0
		2>	0	0	0	0	0	0	0
		3>	0	0	0	0	0	0	0
		4>	0	0	0	0	0	0	0
		TL>	15	15	10	8	15	15	13
		MN>	0.0	0.0	0.0	0.0	0.0	0.0	0.0
--HYPERPLASIA, SUBCAPSULAR CELL		-->	12	12	8	7	13	15	13
		1>	3	3	2	1	2	0	0
		2>	0	0	0	0	0	0	0
		TL>	15	15	10	8	15	15	13
		MN>	0.2	0.2	0.2	0.1	0.1	0.0	0.0
--UNILATERALLY EXAMINED		-->	14	11	8	7	14	15	13
		P>	1	4	2	1	1	0	0
		TL>	15	15	10	8	15	15	13

HAZLETON WASHINGTON, INC.
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TABLE 14B
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
EXPANDED HISTOPATHOLOGY INCIDENCE SUMMARY

PRINTED: 20-JAN-93
PAGE: 241

STUDY NUMBER: 483287

TABLE INCLUDES:

SEX=ALL; GROUP=ALL; WEEKS=ALL
DEATH=T; FIND=ALL; SUBSET=ALL

--- NUMBER - OF - ANIMALS - AFFECTED ---

TABLE INCLUDES:		SEX: -----MALE-----							
SEX=ALL; GROUP=ALL; WEEKS=ALL		GROUP: -1- -2- -3- -4- -5- -6- -7-							
DEATH=T; FIND=ALL; SUBSET=ALL									
ORGAN/TISSUE EXAMINED		NUMBER:	15	15	15	13	15	15	13
		----	----	----	----	----	----	----	----
ADRENAL, MEDULLA (AM)		NUMBER EXAMINED:	15	15	9	8	14	15	13
		NOT REMARKABLE:	14	11	7	7	12	12	13
--UNILATERALLY EXAMINED		->	14	11	7	7	12	12	13
		P>	1	4	2	1	2	3	0
		TL>	15	15	9	8	14	15	13
KIDNEY (KD)		NUMBER EXAMINED:	15	0	0	0	1	0	13
		NOT REMARKABLE:	3	0	0	0	0	0	0
--INFLAMMATION, CHRONIC		->	6	0	0	0	0	0	3
		1>	9	0	0	0	0	0	10
		2>	0	0	0	0	1	0	0
		4>	0	0	0	0	0	0	0
		5>	0	0	0	0	0	0	0
		TL>	15	0	0	0	1	0	13
		MN>	0.6	0.0	0.0	0.0	2.0	0.0	0.8
--TUBULE, MINERALIZATION		->	15	0	0	0	0	0	11
		1>	0	0	0	0	1	0	2
		TL>	15	0	0	0	1	0	13
		MN>	0.0	0.0	0.0	0.0	1.0	0.0	0.2
--TUBULE, REGENERATION		->	9	0	0	0	0	0	4
		1>	6	0	0	0	0	0	6
		2>	0	0	0	0	1	0	2
		3>	0	0	0	0	0	0	1
		TL>	15	0	0	0	1	0	13
		MN>	0.4	0.0	0.0	0.0	2.0	0.0	1.0

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HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

TABLE 14B
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
EXPANDED HISTOPATHOLOGY INCIDENCE SUMMARY

PRINTED: 20-JAN-93
PAGE: 242

STUDY NUMBER: 483287

TABLE INCLUDES:

SEX=ALL; GROUP=ALL; WEEKS=ALL
DEATH=T; FIND=ALL; SUBSET=ALL

--- NUMBER - OF - ANIMALS - AFFECTED ---

SEX: -----MALE-----

GROUP: -1- -2- -3- -4- -5- -6- -7-

NUMBER: 15 15 15 13 15 15 13

ORGAN/TISSUE EXAMINED

** FROM PREVIOUS PAGE **

KIDNEY (KD) NUMBER EXAMINED: 15 0 0 0 1 0 13
NOT REMARKABLE: 3 0 0 0 0 0 0

--HYPERPLASIA, LYMPHOID

-> 10 0 0 0 0 0 5
1> 5 0 0 0 1 0 8
TL> 15 0 0 0 1 0 13
MN> 0.3 0.0 0.0 0.0 1.0 0.0 0.6

--TUBULE, DILATATION

-> 15 0 0 0 1 0 12
2> 0 0 0 0 0 0 1
TL> 15 0 0 0 1 0 13
MN> 0.0 0.0 0.0 0.0 0.0 0.0 0.2

--AMYLOIDOSIS

-> 15 0 0 0 1 0 12
1> 0 0 0 0 0 0 1
TL> 15 0 0 0 1 0 13
MN> 0.0 0.0 0.0 0.0 0.0 0.0 0.1

--PIGMENT

-> 13 0 0 0 0 0 12
1> 2 0 0 0 1 0 1
TL> 15 0 0 0 1 0 13
MN> 0.1 0.0 0.0 0.0 1.0 0.0 0.1

--INFLAMMATION, GRANULOMATOUS

-> 14 0 0 0 1 0 13
1> 1 0 0 0 0 0 0
TL> 15 0 0 0 1 0 13
MN> 0.1 0.0 0.0 0.0 0.0 0.0 0.0

--CYST

-> 14 0 0 0 0 0 12
P> 1 0 0 0 1 0 1
TL> 15 0 0 0 1 0 13

** CONTINUED ON NEXT PAGE **

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

TABLE 14B
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
EXPANDED HISTOPATHOLOGY INCIDENCE SUMMARY

PRINTED: 20-JAN-93
PAGE: 243

STUDY NUMBER: 483287

TABLE INCLUDES:

SEX=ALL; GROUP=ALL; WEEKS=ALL
DEATH=T; FIND=ALL; SUBSET=ALL

--- NUMBER - OF - ANIMALS - AFFECTED ---

SEX: -----MALE-----								
GROUP: -1- -2- -3- -4- -5- -6- -7-								
NUMBER:		15	15	15	13	15	15	13
ORGAN/TISSUE EXAMINED								
** FROM PREVIOUS PAGE **								
KIDNEY (KD)	NUMBER EXAMINED:	15	0	0	0	1	0	13
	NOT REMARKABLE:	3	0	0	0	0	0	0
--INFLAMMATION, SUBACUTE								
	->	15	0	0	0	1	0	13
	1>	0	0	0	0	0	0	0
	2>	0	0	0	0	0	0	0
	TL>	15	0	0	0	1	0	13
	MN>	0.0	0.0	0.0	0.0	0.0	0.0	0.0
--PELVIS, DILATATION								
	->	15	0	0	0	1	0	13
	P>	0	0	0	0	0	0	0
	TL>	15	0	0	0	1	0	13
UTERUS (UT)	NUMBER EXAMINED:	0	0	0	0	0	0	0
	NOT REMARKABLE:	0	0	0	0	0	0	0
--HYPERPLASIA, CYSTIC ENDOMETRIAL								
	->	0	0	0	0	0	0	0
	1>	0	0	0	0	0	0	0
	2>	0	0	0	0	0	0	0
	3>	0	0	0	0	0	0	0
	TL>	0	0	0	0	0	0	0
	MN>	0.0	0.0	0.0	0.0	0.0	0.0	0.0
--DILATATION								
	->	0	0	0	0	0	0	0
	P>	0	0	0	0	0	0	0
	TL>	0	0	0	0	0	0	0

** CONTINUED ON NEXT PAGE **

HAZLETON WASHINGTON, INC.
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TABLE 14B
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
EXPANDED HISTOPATHOLOGY INCIDENCE SUMMARY

PRINTED: 20-JAN-93
PAGE: 244

STUDY NUMBER: 483287

TABLE INCLUDES:
SEX=ALL;GROUP=ALL;WEEKS=ALL
DEATH=T;FIND=ALL;SUBSET=ALL

		--- N U M B E R - O F - A N I M A L S - A F F E C T E D ---						
		SEX: -----MALE-----						
		GROUP:	-1-	-2-	-3-	-4-	-5-	-6- -7-
		NUMBER:	15	15	15	13	15	15 13
ORGAN/TISSUE EXAMINED			---	---	---	---	---	---
** FROM PREVIOUS PAGE **								
UTERUS (UT)		NUMBER EXAMINED:	0	0	0	0	0	0
		NOT REMARKABLE:	0	0	0	0	0	0
--HYPOPLASIA		->	0	0	0	0	0	0
		1>	0	0	0	0	0	0
		2>	0	0	0	0	0	0
		3>	0	0	0	0	0	0
		4>	0	0	0	0	0	0
		5>	0	0	0	0	0	0
		TL>	0	0	0	0	0	0
		MN>	0.0	0.0	0.0	0.0	0.0	0.0
UTERUS, CERVIX (CV)		NUMBER EXAMINED:	0	0	0	0	0	0
		NOT REMARKABLE:	0	0	0	0	0	0
--HYPOPLASIA		->	0	0	0	0	0	0
		1>	0	0	0	0	0	0
		2>	0	0	0	0	0	0
		3>	0	0	0	0	0	0
		4>	0	0	0	0	0	0
		5>	0	0	0	0	0	0
		TL>	0	0	0	0	0	0
		MN>	0.0	0.0	0.0	0.0	0.0	0.0
VAGINA (VA)		NUMBER EXAMINED:	0	0	0	0	0	0
		NOT REMARKABLE:	0	0	0	0	0	0
--CYST, KERATIN		->	0	0	0	0	0	0
		P>	0	0	0	0	0	0
		TL>	0	0	0	0	0	0

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HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

TABLE 14B
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
EXPANDED HISTOPATHOLOGY INCIDENCE SUMMARY

PRINTED: 20-JAN-93
PAGE: 245

STUDY NUMBER: 483287

TABLE INCLUDES:

SEX=ALL;GROUP=ALL;WEEKS=ALL
DEATH=T;FIND=ALL;SUBSET=ALL

--- NUMBER - O F - A N I M A L S - A F F E C T E D ---

SEX=ALL; GROUP=ALL; WEEKS=ALL DEATH=T; FIND=ALL; SUBSET=ALL		SEX: -----MALE-----							
		GROUP:	-1-	-2-	-3-	-4-	-5-	-6-	-7-
ORGAN/TISSUE EXAMINED	NUMBER:	15	15	15	13	15	15	13	

** FROM PREVIOUS PAGE **									
VAGINA (VA)	NUMBER EXAMINED:	0	0	0	0	0	0	0	0
	NOT REMARKABLE:	0	0	0	0	0	0	0	0
--HYPOPLASIA	->	0	0	0	0	0	0	0	0
	P>	0	0	0	0	0	0	0	0
	TL>	0	0	0	0	0	0	0	0
MAMMARY, FEMALE (MF)	NUMBER EXAMINED:	0	0	0	0	0	0	0	0
	NOT REMARKABLE:	0	0	0	0	0	0	0	0
--DILATATION, CYSTIC	->	0	0	0	0	0	0	0	0
	1>	0	0	0	0	0	0	0	0
	2>	0	0	0	0	0	0	0	0
	TL>	0	0	0	0	0	0	0	0
	MN>	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
--HYPOPLASIA, EPITHELIAL	->	0	0	0	0	0	0	0	0
	P>	0	0	0	0	0	0	0	0
	TL>	0	0	0	0	0	0	0	0
SKIN (SK)	NUMBER EXAMINED:	15	0	0	0	0	0	0	13
	NOT REMARKABLE:	15	0	0	0	0	0	0	13

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

TABLE 14B
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
EXPANDED HISTOPATHOLOGY INCIDENCE SUMMARY

PRINTED: 20-JAN-93
PAGE: 246

STUDY NUMBER: 483287

TABLE INCLUDES:

SEX=ALL;GROUP=ALL;WEEKS=ALL
DEATH=T;FIND=ALL;SUBSET=ALL

--- NUMBER - OF - ANIMALS - AFFECTED ---

SEX: -----MALE-----								
GROUP: -1- -2- -3- -4- -5- -6- -7-								
NUMBER: 15 15 15 13 15 15 13								
ORGAN/TISSUE EXAMINED								
LIVER (LI)		NUMBER EXAMINED: 15 15 15 13 15 15 13						
		NOT REMARKABLE: 12 7 1 0 0 0 0						
--HEPATOCYTE, HYPERTROPHY, CENTROLOBULAR								
		-> 12 9 3 0 0 0 0						
		1> 2 6 7 1 0 0 0						
		2> 1 0 5 11 9 0 0						
		3> 0 0 0 1 5 9 2						
		4> 0 0 0 0 1 6 11						
		TL> 15 15 15 13 15 15 13						
		MN> 0.3 0.4 1.1 2.0 2.5 3.4 3.8						
--VACUOLIZATION								
		-> 15 13 8 3 1 2 0						
		1> 0 2 5 3 7 8 12						
		2> 0 0 2 6 4 4 1						
		3> 0 0 0 1 3 1 0						
		4> 0 0 0 0 0 0 0						
		TL> 15 15 15 13 15 15 13						
		MN> 0.0 0.1 0.6 1.4 1.6 1.3 1.1						
--PIGMENT, BILE								
		-> 15 15 14 6 3 0 0						
		1> 0 0 1 7 12 9 5						
		2> 0 0 0 0 0 6 5						
		3> 0 0 0 0 0 0 3						
		TL> 15 15 15 13 15 15 13						
		MN> 0.0 0.0 0.1 0.5 0.8 1.4 1.8						

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HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

TABLE 14B
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
EXPANDED HISTOPATHOLOGY INCIDENCE SUMMARY

PRINTED: 20-JAN-93
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STUDY NUMBER: 483287

TABLE INCLUDES:

SEX=ALL;GROUP=ALL;WEEKS=ALL
DEATH=T;FIND=ALL;SUBSET=ALL

--- NUMBER - OF - ANIMALS - AFFECTED ---

SEX: -----MALE-----

GROUP: -1- -2- -3- -4- -5- -6- -7-

ORGAN/TISSUE EXAMINED

NUMBER: 15 15 15 13 15 15 13

** FROM PREVIOUS PAGE **

LIVER (LI) NUMBER EXAMINED: 15 15 15 13 15 15 13
NOT REMARKABLE: 12 7 1 0 0 0 0

--KUPFFER CELL/MACROPHAGE, PIGMENT

-> 15 15 10 0 0 0 0
1> 0 0 5 11 14 10 4
2> 0 0 0 2 1 5 8
3> 0 0 0 0 0 0 1
4> 0 0 0 0 0 0 0
TL> 15 15 15 13 15 15 13
MN> 0.0 0.0 0.3 1.2 1.1 1.3 1.8

--HEPATOCYTE, PIGMENT

-> 15 15 15 1 1 0 0
1> 0 0 0 6 12 6 3
2> 0 0 0 6 1 6 9
3> 0 0 0 0 1 3 1
TL> 15 15 15 13 15 15 13
MN> 0.0 0.0 0.0 1.4 1.1 1.8 1.8

--NECROSIS

-> 15 15 14 8 5 8 7
1> 0 0 1 3 5 2 1
2> 0 0 0 2 3 3 2
3> 0 0 0 0 2 2 1
4> 0 0 0 0 0 0 1
5> 0 0 0 0 0 0 1
TL> 15 15 15 13 15 15 13
MN> 0.0 0.0 0.1 0.5 1.1 0.9 1.3

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HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

TABLE 14B
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
EXPANDED HISTOPATHOLOGY INCIDENCE SUMMARY

PRINTED: 20-JAN-93
PAGE: 248

STUDY NUMBER: 483287

TABLE INCLUDES:
SEX=ALL;GROUP=ALL;WEEKS=ALL
DEATH=T;FIND=ALL;SUBSET=ALL

--- NUMBER - OF - ANIMALS - AFFECTED ---								
SEX: -----MALE-----								
GROUP:	-1-	-2-	-3-	-4-	-5-	-6-	-7-	
NUMBER:	15	15	15	13	15	15	13	
ORGAN/TISSUE EXAMINED								
** FROM PREVIOUS PAGE **								
LIVER (LI)								
	NUMBER EXAMINED:	15	15	15	13	15	15	13
	NOT REMARKABLE:	12	7	1	0	0	0	0
--NECROSIS, INDIVIDUAL CELL	-->	15	14	11	1	1	0	0
	1>	0	1	4	9	10	6	6
	2>	0	0	0	3	4	8	5
	3>	0	0	0	0	0	1	2
	TL>	15	15	15	13	15	15	13
	MN>	0.0	0.1	0.3	1.2	1.2	1.7	1.7
--INFLAMMATION, CHRONIC/CHRONIC ACTIVE	-->	14	11	10	0	1	3	5
	1>	1	4	5	11	8	8	3
	2>	0	0	0	2	6	4	2
	3>	0	0	0	0	0	0	2
	4>	0	0	0	0	0	0	1
	TL>	15	15	15	13	15	15	13
	MN>	0.1	0.3	0.3	1.2	1.3	1.1	1.3
--BILE DUCT, INFLAMMATION, CHRONIC	-->	15	15	15	11	5	7	7
	1>	0	0	0	2	10	5	5
	2>	0	0	0	0	0	2	1
	4>	0	0	0	0	0	1	0
	TL>	15	15	15	13	15	15	13
	MN>	0.0	0.0	0.0	0.2	0.7	0.9	0.5
--MINERALIZATION	-->	15	15	15	12	12	12	9
	1>	0	0	0	1	3	3	3
	2>	0	0	0	0	0	0	1
	TL>	15	15	15	13	15	15	13
	MN>	0.0	0.0	0.0	0.1	0.2	0.2	0.4

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HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

TABLE 14B
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
EXPANDED HISTOPATHOLOGY INCIDENCE SUMMARY

PRINTED: 20-JAN-93
PAGE: 249

STUDY NUMBER: 483287

TABLE INCLUDES:

SEX=ALL;GROUP=ALL;WEEKS=ALL
DEATH=T;FIND=ALL;SUBSET=ALL

--- NUMBER - OF - ANIMALS - AFFECTED ---

ORGAN/TISSUE EXAMINED	NUMBER	SEX: ---MALE---						
		GROUP: -1-	-2-	-3-	-4-	-5-	-6-	-7-
		15	15	15	13	15	15	13
--- --								
** FROM PREVIOUS PAGE **								
LIVER (LI)	NUMBER EXAMINED:	15	15	15	13	15	15	13
	NOT REMARKABLE:	12	7	1	0	0	0	0
--INFARCT	->	15	15	14	13	15	15	13
	P>	0	0	1	0	0	0	0
	TL>	15	15	15	13	15	15	13
--EXTRAMEDULLARY HEMATOPOIESIS, INCREASED	->	15	15	15	11	15	15	13
	1>	0	0	0	1	0	0	0
	2>	0	0	0	1	0	0	0
	TL>	15	15	15	13	15	15	13
	MN>	0.0	0.0	0.0	0.2	0.0	0.0	0.0
BRAIN W/STEM (BR)	NUMBER EXAMINED:	15	0	0	0	0	0	13
	NOT REMARKABLE:	15	0	0	0	0	0	13
--HEMORRHAGE	->	15	0	0	0	0	0	13
	TL>	15	0	0	0	0	0	13
CORD, CERVICAL (CS)	NUMBER EXAMINED:	15	0	0	0	0	0	13
	NOT REMARKABLE:	15	0	0	0	0	0	13
--HEMORRHAGE	->	15	0	0	0	0	0	13
	TL>	15	0	0	0	0	0	13
CORD, THORACIC (TC)	NUMBER EXAMINED:	15	0	0	0	0	0	13
	NOT REMARKABLE:	15	0	0	0	0	0	13
--HEMORRHAGE	->	15	0	0	0	0	0	13
	TL>	15	0	0	0	0	0	13

HAZLETON WASHINGTON, INC..
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TABLE 14B
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE, (MAIN-GROUPS 1-7)
EXPANDED HISTOPATHOLOGY INCIDENCE SUMMARY

PRINTED: 20-JAN-93
PAGE: 250

STUDY NUMBER: 483287

TABLE INCLUDES:

SEX=ALL;GROUP=ALL;WEEKS=ALL
DEATH=T;FIND=ALL;SUBSET=ALL

--- NUMBER - OF - ANIMALS - AFFECTED ---

TABLES INCLUDED:		SEX: -----MALE-----							
SEX=ALL;GROUP=ALL;WEEKS=ALL		GROUP: -1- -2- -3- -4- -5- -6- -7-							
DEATH=T;FIND=ALL;SUBSET=ALL		NUMBER: 15 15 15 13 15 15 13							
ORGAN/TISSUE EXAMINED		-----							
CORD, LUMBAR (LC)		NUMBER EXAMINED:	15	0	0	0	0	0	13
		NOT REMARKABLE:	15	0	0	0	0	0	13
PITUITARY (PI)		NUMBER EXAMINED:	15	0	0	1	0	0	13
		NOT REMARKABLE:	14	0	0	1	0	0	13
--CYST		-->	14	0	0	1	0	0	13
		P>	1	0	0	0	0	0	0
		TL>	15	0	0	1	0	0	13
THYROID (TY)		NUMBER EXAMINED:	15	0	0	0	0	0	13
		NOT REMARKABLE:	15	0	0	0	0	0	12
--FOLLICLE, CYST		-->	15	0	0	0	0	0	12
		P>	0	0	0	0	0	0	1
		TL>	15	0	0	0	0	0	13
--UNILATERALLY EXAMINED		-->	15	0	0	0	0	0	13
		P>	0	0	0	0	0	0	0
		TL>	15	0	0	0	0	0	13
PARATHYROID (PT)		NUMBER EXAMINED:	14	0	0	0	0	0	12
		NOT REMARKABLE:	7	0	0	0	0	0	4
--UNILATERALLY EXAMINED		-->	7	0	0	0	0	0	4
		P>	7	0	0	0	0	0	8
		TL>	14	0	0	0	0	0	12

HAZLETON WASHINGTON, INC.
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TABLE 14B
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
EXPANDED HISTOPATHOLOGY INCIDENCE SUMMARY

PRINTED: 20-JAN-93
PAGE: 251

STUDY NUMBER: 483287

TABLE INCLUDES:

SEX=ALL;GROUP=ALL;WEEKS=ALL
DEATH=T;FIND=ALL;SUBSET=ALL

--- NUMBER - OF - ANIMALS - AFFECTED ---

		SEX: -----MALE-----						
		GROUP: -1- -2- -3- -4- -5- -6- -7-						
ORGAN/TISSUE EXAMINED		NUMBER:	15	15	15	13	15	15 13
			---	---	---	---	---	---
ESOPHAGUS (ES)		NUMBER EXAMINED:	15	0	0	0	0	0 13
		NOT REMARKABLE:	14	0	0	0	0	0 13
--INFLAMMATION, CHRONIC		->	14	0	0	0	0	0 13
		1>	1	0	0	0	0	0 0
		TL>	15	0	0	0	0	0 13
		MN>	0.1	0.0	0.0	0.0	0.0	0.0 0.0
TRACHEA (TR)		NUMBER EXAMINED:	15	0	0	0	0	0 13
		NOT REMARKABLE:	15	0	0	0	0	0 13
LUNG (LU)		NUMBER EXAMINED:	15	0	0	0	0	0 13
		NOT REMARKABLE:	2	0	0	0	0	0 6
--PERIBRONCHIAL/PERIVASCULAR, INFILTRATION, LYMPHOID		->	4	0	0	0	0	0 6
		1>	11	0	0	0	0	0 7
		TL>	15	0	0	0	0	0 13
		MN>	0.7	0.0	0.0	0.0	0.0	0.0 0.5
--INFLAMMATION, CHRONIC		->	14	0	0	0	0	0 13
		1>	1	0	0	0	0	0 0
		TL>	15	0	0	0	0	0 13
		MN>	0.1	0.0	0.0	0.0	0.0	0.0 0.0
--VESSEL, MINERALIZATION		->	14	0	0	0	0	0 13
		1>	1	0	0	0	0	0 0
		TL>	15	0	0	0	0	0 13
		MN>	0.1	0.0	0.0	0.0	0.0	0.0 0.0

** CONTINUED ON NEXT PAGE **

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

TABLE 14B
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
EXPANDED HISTOPATHOLOGY INCIDENCE SUMMARY

PRINTED: 20-JAN-93
PAGE: 252

STUDY NUMBER: 483287

TABLE INCLUDES:
SEX=ALL; GROUP=ALL; WEEKS=ALL
DEATH=T; FIND=ALL; SUBSET=ALL

--- NUMBER - O F - A N I M A L S - A F F E C T E D ---

SEX=ALL;GROUP=ALL;WEEKS=ALL DEATH=T;FIND=ALL;SUBSET=ALL		SEX: -----MALE-----							
		GROUP:	-1-	-2-	-3-	-4-	-5-	-6-	-7-
ORGAN/TISSUE EXAMINED		NUMBER:	15	15	15	13	15	15	13
** FROM PREVIOUS PAGE **			--	--	--	--	--	--	--
LUNG (LU)	NUMBER EXAMINED:	15	0	0	0	0	0	0	13
	NOT REMARKABLE:	2	0	0	0	0	0	0	6
--HEMORRHAGE	->	14	0	0	0	0	0	0	13
	1>	1	0	0	0	0	0	0	0
	TL>	15	0	0	0	0	0	0	13
	MN>	0.1	0.0	0.0	0.0	0.0	0.0	0.0	0.0
HEART (HT)	NUMBER EXAMINED:	15	0	0	0	0	0	0	13
	NOT REMARKABLE:	11	0	0	0	0	0	0	10
--INFLAMMATION, CHRONIC	->	11	0	0	0	0	0	0	10
	1>	4	0	0	0	0	0	0	3
	TL>	15	0	0	0	0	0	0	13
	MN>	0.3	0.0	0.0	0.0	0.0	0.0	0.0	0.2
--MINERALIZATION	->	15	0	0	0	0	0	0	13
	TL>	15	0	0	0	0	0	0	13
	MN>	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
--DEGENERATION	->	15	0	0	0	0	0	0	13
	TL>	15	0	0	0	0	0	0	13
	MN>	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
GALLBLADDER (GB)	NUMBER EXAMINED:	15	0	0	0	0	0	0	13
	NOT REMARKABLE:	15	0	0	0	0	0	0	12
--INFLAMMATION, CHRONIC	->	15	0	0	0	0	0	0	12
	1>	0	0	0	0	0	0	0	1
	TL>	15	0	0	0	0	0	0	13
	MN>	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0

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TABLE 14B
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
EXPANDED HISTOPATHOLOGY INCIDENCE SUMMARY

PRINTED: 20-JAN-93
PAGE: 253

STUDY NUMBER: 483287

TABLE INCLUDES:

SEX=ALL;GROUP=ALL;WEEKS=ALL
DEATH=T;FIND=ALL;SUBSET=ALL

--- NUMBER - OF - ANIMALS - AFFECTED ---

		SEX: -----MALE-----						
		GROUP: -1-	-2-	-3-	-4-	-5-	-6-	-7-
ORGAN/TISSUE EXAMINED		NUMBER:	15	15	13	15	15	13
DUODENUM (DU)		NUMBER EXAMINED:	14	0	0	0	0	12
		NOT REMARKABLE:	14	0	0	0	0	12
JEJUNUM (JE)		NUMBER EXAMINED:	15	0	0	0	0	13
		NOT REMARKABLE:	13	0	0	0	0	11
--HYPERPLASIA, LYMPHOID		->	13	0	0	0	0	12
		P>	2	0	0	0	0	1
		TL>	15	0	0	0	0	13
--AMYLOIDOSIS		->	15	0	0	0	0	12
		2>	0	0	0	0	0	0
		3>	0	0	0	0	0	1
		TL>	15	0	0	0	0	13
		MN>	0.0	0.0	0.0	0.0	0.0	0.2
ILEUM (IL)		NUMBER EXAMINED:	15	0	0	0	0	13
		NOT REMARKABLE:	13	0	0	0	0	8
--HYPERPLASIA, LYMPHOID		->	14	0	0	0	0	11
		P>	1	0	0	0	0	2
		TL>	15	0	0	0	0	13
--AMYLOIDOSIS		->	14	0	0	0	0	10
		2>	1	0	0	0	0	1
		3>	0	0	0	0	0	2
		5>	0	0	0	0	0	0
		TL>	15	0	0	0	0	13
		MN>	0.1	0.0	0.0	0.0	0.0	0.6

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TABLE 14B
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
EXPANDED HISTOPATHOLOGY INCIDENCE SUMMARY

PRINTED: 20-JAN-93
PAGE: 254

STUDY NUMBER: 483287

TABLE INCLUDES:

SEX=ALL;GROUP=ALL;WEEKS=ALL
DEATH=T;FIND=ALL;SUBSET=ALL

--- NUMBER - OF - ANIMALS - AFFECTED ---

SEX: ALL; GROUP: ALL; WEEKS: ALL DEATH=T; FIND=ALL; SUBSET=ALL		SEX: -----MALE-----							
GROUP:		-1-	-2-	-3-	-4-	-5-	-6-	-7-	
ORGAN/TISSUE EXAMINED		NUMBER:	15	15	15	13	15	15	13
			--	--	--	--	--	--	--
PANCREAS (PA)		NUMBER EXAMINED:	15	0	2	0	1	2	13
		NOT REMARKABLE:	14	0	2	0	1	2	12
--INFLAMMATION, CHRONIC		->	14	0	2	0	1	2	13
		1>	1	0	0	0	0	0	0
		TL>	15	0	2	0	1	2	13
		MN>	0.1	0.0	0.0	0.0	0.0	0.0	0.0
--AMYLOIDOSIS		->	15	0	2	0	1	2	12
		1>	0	0	0	0	0	0	1
		TL>	15	0	2	0	1	2	13
		MN>	0.0	0.0	0.0	0.0	0.0	0.0	0.1
--ISLET CELL, HYPERPLASIA		->	15	0	2	0	1	2	13
		1>	0	0	0	0	0	0	0
		TL>	15	0	2	0	1	2	13
		MN>	0.0	0.0	0.0	0.0	0.0	0.0	0.0
CECUM (CE)		NUMBER EXAMINED:	15	0	0	0	0	0	13
		NOT REMARKABLE:	6	0	0	0	0	0	7
--HYPERPLASIA, LYMPHOID		->	6	0	0	0	0	0	7
		P>	9	0	0	0	0	0	6
		TL>	15	0	0	0	0	0	13
COLON (CO)		NUMBER EXAMINED:	15	0	0	0	0	0	13
		NOT REMARKABLE:	15	0	0	0	0	0	13
--HYPERPLASIA, LYMPHOID		->	15	0	0	0	0	0	13
		P>	0	0	0	0	0	0	0
		TL>	15	0	0	0	0	0	13

HAZLETON WASHINGTON, INC..
WASHINGTON, D.C. U.S.A.

TABLE 14B
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
EXPANDED HISTOPATHOLOGY INCIDENCE SUMMARY

PRINTED: 20-JAN-93
PAGE: 255

STUDY NUMBER: 483287

TABLE INCLUDES:

SEX=ALL;GROUP=ALL;WEEKS=ALL
DEATH=T;FIND=ALL;SUBSET=ALL

--- NUMBER - OF - ANIMALS - AFFECTED ---

CASE INCLUDED:		SEX: -----MALE-----							
SEX=ALL;GROUP=ALL;WEEKS=ALL		GROUP: -1- -2- -3- -4- -5- -6- -7-							
DEATH=T;FIND=ALL;SUBSET=ALL									
ORGAN/TISSUE EXAMINED		NUMBER:	15	15	15	13	15	15	13
			---	---	---	---	---	---	---
RECTUM (RE)		NUMBER EXAMINED:	15	0	0	0	0	0	13
		NOT REMARKABLE:	8	0	0	0	0	0	10
--HYPERPLASIA, LYMPHOID		->	8	0	0	0	0	0	10
		P>	7	0	0	0	0	0	3
		TL>	15	0	0	0	0	0	13
--AMYLOIDOSIS		->	15	0	0	0	0	0	12
		3>	0	0	0	0	0	0	1
		TL>	15	0	0	0	0	0	13
		MN>	0.0	0.0	0.0	0.0	0.0	0.0	0.2
LN, MESENTERIC (MS)		NUMBER EXAMINED:	15	1	0	0	0	0	12
		NOT REMARKABLE:	10	0	0	0	0	0	5
--MACROPHAGES, PIGMENTED		->	13	0	0	0	0	0	9
		1>	2	1	0	0	0	0	3
		TL>	15	1	0	0	0	0	12
		MN>	0.1	1.0	0.0	0.0	0.0	0.0	0.3
--HYPERPLASIA, LYMPHOID		->	12	1	0	0	0	0	9
		1>	1	0	0	0	0	0	2
		2>	2	0	0	0	0	0	1
		TL>	15	1	0	0	0	0	12
		MN>	0.3	0.0	0.0	0.0	0.0	0.0	0.3
--INFLAMMATION, GRANULOMATOUS		->	15	1	0	0	0	0	11
		2>	0	0	0	0	0	0	1
		TL>	15	1	0	0	0	0	12
		MN>	0.0	0.0	0.0	0.0	0.0	0.0	0.2

** CONTINUED ON NEXT PAGE **

HAZLETON WASHINGTON, INC.
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TABLE 14B
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
EXPANDED HISTOPATHOLOGY INCIDENCE SUMMARY

PRINTED: 20-JAN-93
PAGE: 256

STUDY NUMBER: 483287

TABLE INCLUDES:
SEX=ALL;GROUP=ALL;WEEKS=ALL
DEATH=T;FIND=ALL;SUBSET=ALL

--- NUMBER - OF - ANIMALS - AFFECTED ---								
SEX: -----MALE-----								
GROUP:	-1-	-2-	-3-	-4-	-5-	-6-	-7-	
NUMBER:	15	15	15	13	15	15	13	
ORGAN/TISSUE EXAMINED								
** FROM PREVIOUS PAGE **								
LN, MESENTERIC (MS)	NUMBER EXAMINED:	15	1	0	0	0	0	12
	NOT REMARKABLE:	10	0	0	0	0	0	5
--AMYLOIDOSIS	->	15	1	0	0	0	0	11
	1>	0	0	0	0	0	0	1
	2>	0	0	0	0	0	0	0
	TL>	15	1	0	0	0	0	12
	MN>	0.0	0.0	0.0	0.0	0.0	0.0	0.1
--HEMORRHAGE	->	15	0	0	0	0	0	12
	P>	0	1	0	0	0	0	0
	TL>	15	1	0	0	0	0	12
--NECROSIS, LYMPHOID	->	15	1	0	0	0	0	12
	1>	0	0	0	0	0	0	0
	TL>	15	1	0	0	0	0	12
	MN>	0.0	0.0	0.0	0.0	0.0	0.0	0.0
TESTIS (TE)	NUMBER EXAMINED:	15	0	1	0	0	0	13
	NOT REMARKABLE:	15	0	0	0	0	0	12
--MINERALIZATION	->	15	0	1	0	0	0	12
	1>	0	0	0	0	0	0	1
	TL>	15	0	1	0	0	0	13
	MN>	0.0	0.0	0.0	0.0	0.0	0.0	0.1
--HEMORRHAGE	->	15	0	0	0	0	0	13
	P>	0	0	1	0	0	0	0
	TL>	15	0	1	0	0	0	13

HAZLETON WASHINGTON, INC.
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TABLE 14B
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE, (MAIN-GROUPS 1-7)
EXPANDED HISTOPATHOLOGY INCIDENCE SUMMARY

PRINTED: 20-JAN-93
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STUDY NUMBER: 483287

		--- NUMBER - OF - ANIMALS - AFFECTED ---							
		SEX: -----MALE-----							
		GROUP:	-1-	-2-	-3-	-4-	-5-	-6-	-7-
ORGAN/TISSUE EXAMINED	NUMBER:	15	15	15	13	15	15	13	
-----		==	==	==	==	==	==	==	
EPIDIDYMIS (EP)	NUMBER EXAMINED:	15	0	0	0	0	0	0	13
	NOT REMARKABLE:	8	0	0	0	0	0	0	3
--INFLAMMATION, CHRONIC		->	15	0	0	0	0	0	12
	1>	0	0	0	0	0	0	0	1
	TL>	15	0	0	0	0	0	0	13
	MN>	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.1
--LUMEN, DEBRIS, CELLULAR		->	8	0	0	0	0	0	3
	P>	7	0	0	0	0	0	0	10
	TL>	15	0	0	0	0	0	0	13
PROSTATE (PR)	NUMBER EXAMINED:	13	0	0	0	0	0	0	12
	NOT REMARKABLE:	9	0	0	0	0	0	0	11
--INFLAMMATION, CHRONIC		->	9	0	0	0	0	0	11
	1>	4	0	0	0	0	0	0	1
	TL>	13	0	0	0	0	0	0	12
	MN>	0.3	0.0	0.0	0.0	0.0	0.0	0.0	0.1
URINARY BLADDER (UB)	NUMBER EXAMINED:	14	0	0	0	0	0	0	13
	NOT REMARKABLE:	12	0	0	0	0	0	0	12
--INFLAMMATION, CHRONIC		->	12	0	0	0	0	0	12
	1>	2	0	0	0	0	0	0	1
	TL>	14	0	0	0	0	0	0	13
	MN>	0.1	0.0	0.0	0.0	0.0	0.0	0.0	0.1

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TABLE 14B
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
EXPANDED HISTOPATHOLOGY INCIDENCE SUMMARY

PRINTED: 20-JAN-93
PAGE: 258

STUDY NUMBER: 483287

TABLE INCLUDES:

SEX=ALL; GROUP=ALL; WEEKS=ALL
DEATH=T; FIND=ALL; SUBSET=ALL

--- NUMBER - OF - ANIMALS - AFFECTED ---

SEX: -----MALE-----

GROUP: -1- -2- -3- -4- -5- -6- -7-

ORGAN/TISSUE EXAMINED

NUMBER: 15 15 15 13 15 15 13

OVARY (OV)	NUMBER EXAMINED:	0	0	0	0	0	0	0
	NOT REMARKABLE:	0	0	0	0	0	0	0
--FOLLICLE, CYST	-->	0	0	0	0	0	0	0
	P>	0	0	0	0	0	0	0
	TL>	0	0	0	0	0	0	0
--MINERALIZATION	-->	0	0	0	0	0	0	0
	TL>	0	0	0	0	0	0	0
	MN>	0.0	0.0	0.0	0.0	0.0	0.0	0.0
--BURSA, CYST	-->	0	0	0	0	0	0	0
	P>	0	0	0	0	0	0	0
	TL>	0	0	0	0	0	0	0
--UNILATERALLY EXAMINED	-->	0	0	0	0	0	0	0
	P>	0	0	0	0	0	0	0
	TL>	0	0	0	0	0	0	0
OVIDUCT (OD)	NUMBER EXAMINED:	0	0	0	0	0	0	0
	NOT REMARKABLE:	0	0	0	0	0	0	0
LN, MANDIBULAR (MN)	NUMBER EXAMINED:	13	0	0	1	0	0	13
	NOT REMARKABLE:	10	0	0	0	0	0	4
--MACROPHAGES, PIGMENTED	-->	10	0	0	1	0	0	5
	1>	3	0	0	0	0	0	8
	TL>	13	0	0	1	0	0	13
	MN>	0.2	0.0	0.0	0.0	0.0	0.0	0.6

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TABLE 14B
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
EXPANDED HISTOPATHOLOGY INCIDENCE SUMMARY

PRINTED: 20-JAN-93
PAGE: 259

STUDY NUMBER: 483287

TABLE INCLUDES:

SEX=ALL; GROUP=ALL; WEEKS=ALL
DEATH=T; FIND=ALL; SUBSET=ALL

--- NUMBER - OF - ANIMALS - AFFECTED ---

SEX=ALL;GROUP=ALL;WEEKS=ALL DEATH=T;FIND=ALL;SUBSET=ALL		SEX: -----MALE-----							
		GROUP:	-1-	-2-	-3-	-4-	-5-	-6-	-7-
ORGAN/TISSUE EXAMINED	NUMBER:	15	15	15	13	15	15	13	
-----		---	---	---	---	---	---	---	
** FROM PREVIOUS PAGE **									
LN, MANDIBULAR (MN)	NUMBER EXAMINED:	13	0	0	1	0	0	13	
	NOT REMARKABLE:	10	0	0	0	0	0	4	
--AMYLOIDOSIS									
	->	13	0	0	1	0	0	12	
	1>	0	0	0	0	0	0	1	
	TL>	13	0	0	1	0	0	13	
	MN>	0.0	0.0	0.0	0.0	0.0	0.0	0.1	
--HYPERPLASIA, LYMPHOID									
	->	13	0	0	0	0	0	13	
	P>	0	0	0	1	0	0	0	
	TL>	13	0	0	1	0	0	13	
MAND SALIVARY GL (SG)	NUMBER EXAMINED:	15	0	0	0	0	0	13	
	NOT REMARKABLE:	10	0	0	0	0	0	13	
--INFLAMMATION, CHRONIC									
	->	10	0	0	0	0	0	13	
	1>	5	0	0	0	0	0	0	
	TL>	15	0	0	0	0	0	13	
	MN>	0.3	0.0	0.0	0.0	0.0	0.0	0.0	
SALIVARY, OTHER (OS)	NUMBER EXAMINED:	15	0	0	1	0	0	13	
	NOT REMARKABLE:	15	0	0	1	0	0	13	
THYMUS (TH)	NUMBER EXAMINED:	15	0	0	0	0	0	12	
	NOT REMARKABLE:	12	0	0	0	0	0	11	
--CYST									
	->	12	0	0	0	0	0	11	
	P>	3	0	0	0	0	0	1	
	TL>	15	0	0	0	0	0	12	

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TABLE 14B
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
EXPANDED HISTOPATHOLOGY INCIDENCE SUMMARY

PRINTED: 20-JAN-93
PAGE: 260

STUDY NUMBER: 483287

TABLE INCLUDES:

SEX=ALL; GROUP=ALL; WEEKS=ALL
DEATH=T; FIND=ALL; SUBSET=ALL

--- NUMBER - OF - ANIMALS - AFFECTED ---							
SEX: -----MALE-----							
GROUP:	-1-	-2-	-3-	-4-	-5-	-6-	-7-
NUMBER:	15	15	15	13	15	15	13
ORGAN/TISSUE EXAMINED	---	---	---	---	---	---	---
** FROM PREVIOUS PAGE **							
THYMUS (TH)	NUMBER EXAMINED:	15	0	0	0	0	12
	NOT REMARKABLE:	12	0	0	0	0	11
--ECTOPIC THYROID							
	->	14	0	0	0	0	12
	P>	1	0	0	0	0	0
	TL>	15	0	0	0	0	12
--NECROSIS, LYMPHOID							
	->	15	0	0	0	0	12
	1>	0	0	0	0	0	0
	2>	0	0	0	0	0	0
	3>	0	0	0	0	0	0
	TL>	15	0	0	0	0	12
	MN>	0.0	0.0	0.0	0.0	0.0	0.0
--ATROPHY							
	->	15	0	0	0	0	12
	TL>	15	0	0	0	0	12
	MN>	0.0	0.0	0.0	0.0	0.0	0.0
AORTA, THORACIC (AO)	NUMBER EXAMINED:	15	0	0	0	0	13
	NOT REMARKABLE:	15	0	0	0	0	13
EYE (EY)	NUMBER EXAMINED:	15	0	0	0	0	13
	NOT REMARKABLE:	15	0	0	0	0	12
--UNILATERALLY EXAMINED							
	->	15	0	0	0	0	12
	P>	0	0	0	0	0	1
	TL>	15	0	0	0	0	13
--CORNEA, MINERALIZATION							
	->	15	0	0	0	0	13
	2>	0	0	0	0	0	0
	TL>	15	0	0	0	0	13
	MN>	0.0	0.0	0.0	0.0	0.0	0.0

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TABLE 14B
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
EXPANDED HISTOPATHOLOGY INCIDENCE SUMMARY

PRINTED: 20-JAN-93
PAGE: 261

STUDY NUMBER: 483287

TABLE INCLUDES:

SEX=ALL; GROUP=ALL; WEEKS=ALL
DEATH=T; FIND=ALL; SUBSET=ALL

--- NUMBER - OF - ANIMALS - AFFECTED ---

SEX: -----MALE-----

GROUP: -1- -2- -3- -4- -5- -6- -7-

ORGAN/TISSUE EXAMINED

NUMBER: 15 15 15 13 15 15 13

HARDERIAN GLAND (HG) NUMBER EXAMINED: 15 0 0 0 0 0 13
NOT REMARKABLE: 14 0 0 0 0 0 13

--INFLAMMATION, CHRONIC

-> 14 0 0 0 0 0 13
P> 1 0 0 0 0 0 0
TL> 15 0 0 0 0 0 13

NERVE, OPTIC (ON) NUMBER EXAMINED: 14 0 0 0 0 0 10
NOT REMARKABLE: 7 0 0 0 0 0 3

--UNILATERALLY EXAMINED

-> 7 0 0 0 0 0 3
P> 7 0 0 0 0 0 7
TL> 14 0 0 0 0 0 10

LACRIMAL GL, EX (EO) NUMBER EXAMINED: 15 0 0 0 0 0 11
NOT REMARKABLE: 9 0 0 0 0 0 8

--INFLAMMATION, CHRONIC

-> 10 0 0 0 0 0 9
1> 5 0 0 0 0 0 2
TL> 15 0 0 0 0 0 11
MN> 0.3 0.0 0.0 0.0 0.0 0.0 0.2

--UNILATERALLY EXAMINED

-> 14 0 0 0 0 0 9
P> 1 0 0 0 0 0 2
TL> 15 0 0 0 0 0 11

TONGUE (TO) NUMBER EXAMINED: 15 0 0 0 0 0 13
NOT REMARKABLE: 15 0 0 0 0 0 13

MUSCLE, SKELETAL (SM) NUMBER EXAMINED: 15 0 0 0 0 0 13
NOT REMARKABLE: 15 0 0 0 0 0 13

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TABLE 14B
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
EXPANDED HISTOPATHOLOGY INCIDENCE SUMMARY

PRINTED: 20-JAN-93
PAGE: 262

STUDY NUMBER: 483287

TABLE INCLUDES:

SEX=ALL; GROUP=ALL; WEEKS=ALL
DEATH=T; FIND=ALL; SUBSET=ALL

--- NUMBER - OF - ANIMALS - AFFECTED ---

SEX: -----MALE-----								
GROUP: -1- -2- -3- -4- -5- -6- -7-								
ORGAN/TISSUE EXAMINED	NUMBER:	15	15	15	13	15	15	13

NERVE, SCIATIC (SN)	NUMBER EXAMINED:	15	0	0	0	0	0	13
	NOT REMARKABLE:	15	0	0	0	0	0	13
MUSCLE, ABDOM (MA)	NUMBER EXAMINED:	15	0	0	0	0	0	13
	NOT REMARKABLE:	15	0	0	0	0	0	13
MARROW, STERNUM (SE)	NUMBER EXAMINED:	15	0	0	0	0	0	13
	NOT REMARKABLE:	15	0	0	0	0	0	13
BONE, STERNUM (SB)	NUMBER EXAMINED:	15	0	0	0	0	0	13
	NOT REMARKABLE:	15	0	0	0	0	0	13
MARROW, FEMUR (FM)	NUMBER EXAMINED:	15	0	0	0	0	0	13
	NOT REMARKABLE:	15	0	0	0	0	0	10
--HYPERCELLULAR								
	->	15	0	0	0	0	0	10
	P>	0	0	0	0	0	0	3
	TL>	15	0	0	0	0	0	13
BONE, FEMUR (FE)	NUMBER EXAMINED:	15	0	0	0	0	0	13
	NOT REMARKABLE:	15	0	0	0	0	0	13
HEMATO NEOPLASIA (HN)	NUMBER EXAMINED:	15	0	0	0	0	0	13
	NOT REMARKABLE:	15	0	0	0	0	0	13
^DEATH COMMENT (DC)	NUMBER EXAMINED:	15	0	0	0	0	0	13
	NOT REMARKABLE:	0	0	0	0	0	0	0
--SCHEDULED SACRIFICE								
	P>	15	0	0	0	0	0	13
	TL>	15	0	0	0	0	0	13

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TABLE 14B
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
EXPANDED HISTOPATHOLOGY INCIDENCE SUMMARY

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STUDY NUMBER: 483287

		--- NUMBER OF ANIMALS AFFECTED ---						
		SEX: -----MALE-----						
		GROUP: -1-	-2-	-3-	-4-	-5-	-6-	-7-
ORGAN/TISSUE EXAMINED	NUMBER:	15	15	15	13	15	15	13

** FROM PREVIOUS PAGE **								
DEATH COMMENT (DC)	NUMBER EXAMINED:	15	0	0	0	0	0	13
	NOT REMARKABLE:	0	0	0	0	0	0	0
--UNDETERMINED								
	->	15	0	0	0	0	0	13
	TL>	15	0	0	0	0	0	13
--ACCIDENTAL								
	->	15	0	0	0	0	0	13
	TL>	15	0	0	0	0	0	13
LN, OTHER (LN)	NUMBER EXAMINED:	3	0	0	0	0	0	2
	NOT REMARKABLE:	2	0	0	0	0	0	1
--MACROPHAGES, PIGMENTED								
	->	2	0	0	0	0	0	1
	P>	1	0	0	0	0	0	1
	TL>	3	0	0	0	0	0	2
--HYPERPLASIA, LYMPHOID								
	->	3	0	0	0	0	0	2
	P>	0	0	0	0	0	0	0
	TL>	3	0	0	0	0	0	2
SKIN, OTHER (SS)	NUMBER EXAMINED:	2	1	0	1	1	0	0
	NOT REMARKABLE:	0	0	0	0	0	0	0
--DERMATITIS, CHRONIC								
	->	1	1	0	1	1	0	0
	P>	1	0	0	0	0	0	0
	TL>	2	1	0	1	1	0	0
--DERMATITIS, ULCERATIVE								
	P>	2	1	0	1	1	0	0
	TL>	2	1	0	1	1	0	0
BONE, OTHER (OB)	NUMBER EXAMINED:	0	0	0	0	0	0	0
	NOT REMARKABLE:	0	0	0	0	0	0	0

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TABLE 14B
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE, (MAIN-GROUPS 1-7)
EXPANDED HISTOPATHOLOGY INCIDENCE SUMMARY

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STUDY NUMBER: 483287

		--- N U M B E R - O F - A N I M A L S - A F F E C T E D ---						
TABLE INCLUDES:		SEX: -----MALE-----						
SEX=ALL;GROUP=ALL;WEEKS=ALL		GROUP: -1- -2- -3- -4- -5- -6- -7-						
DEATH=T;FIND=ALL;SUBSET=ALL		NUMBER: 15 15 15 13 15 15 13						
ORGAN/TISSUE EXAMINED		-----						
CAVITY, ABDOM (PC)		NUMBER EXAMINED:	0	0	0	0	0	0
		NOT REMARKABLE:	0	0	0	0	0	0
--ADHESION		P>	0	0	0	0	0	0
		TL>	0	0	0	0	0	0
LI, INTRAHEPATIC (LIO)		NUMBER EXAMINED:	0	0	0	0	0	3
		NOT REMARKABLE:	0	0	0	0	0	0
--PIGMENT, PAS POSITIVE		5>	0	0	0	0	0	3
		TL>	0	0	0	0	0	3
		MN>	0.0	0.0	0.0	0.0	0.0	5.0
--PIGMENT, IRON POSITIVE		2>	0	0	0	0	0	1
		3>	0	0	0	0	0	1
		4>	0	0	0	0	0	1
		TL>	0	0	0	0	0	3
		MN>	0.0	0.0	0.0	0.0	0.0	3.0
--PIGMENT, BILE POSITIVE		1>	0	0	0	0	0	3
		TL>	0	0	0	0	0	3
		MN>	0.0	0.0	0.0	0.0	0.0	1.0
--PIGMENT, LIPOFUSCIN POSITIVE		2>	0	0	0	0	0	1
		3>	0	0	0	0	0	2
		TL>	0	0	0	0	0	3
		MN>	0.0	0.0	0.0	0.0	0.0	2.7
--PIGMENT, FONTANA MASSON POSITIVE		->	0	0	0	0	0	3
		TL>	0	0	0	0	0	3
		MN>	0.0	0.0	0.0	0.0	0.0	0.0

HAZLETON WASHINGTON, INC..
WASHINGTON, D.C. U.S.A.

TABLE 14B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
EXPANDED HISTOPATHOLOGY INCIDENCE SUMMARY

PRINTED: 20-JAN-93
PAGE: 265

STUDY NUMBER: 483287

TABLE INCLUDES:

SEX=ALL;GROUP=ALL;WEEKS=ALL
DEATH=T;FIND=ALL;SUBSET=ALL

--- NUMBER - OF - ANIMALS - AFFECTED ---

TABLE INCLUDES:		SEX: -----MALE-----						
SEX=ALL;GROUP=ALL;WEEKS=ALL		GROUP: -1- -2- -3- -4- -5- -6- -7-						
DEATH=T;FIND=ALL;SUBSET=ALL								
ORGAN/TISSUE EXAMINED	NUMBER:	15	15	15	13	15	15	13
-----		---	---	---	---	---	---	---
LI, EXTRAHEPATIC (LI1)	NUMBER EXAMINED:	0	0	0	0	0	0	3
	NOT REMARKABLE:	0	0	0	0	0	0	0
--PIGMENT, PAS POSITIVE	3>	0	0	0	0	0	0	1
	4>	0	0	0	0	0	0	1
	5>	0	0	0	0	0	0	1
	TL>	0	0	0	0	0	0	3
	MN>	0.0	0.0	0.0	0.0	0.0	0.0	4.0
--PIGMENT, IRON POSITIVE	2>	0	0	0	0	0	0	2
	3>	0	0	0	0	0	0	1
	TL>	0	0	0	0	0	0	3
	MN>	0.0	0.0	0.0	0.0	0.0	0.0	2.3
--PIGMENT, BILE POSITIVE	->	0	0	0	0	0	0	3
	TL>	0	0	0	0	0	0	3
	MN>	0.0	0.0	0.0	0.0	0.0	0.0	0.0
--PIGMENT, LIPOFUSCIN POSITIVE	1>	0	0	0	0	0	0	1
	2>	0	0	0	0	0	0	0
	3>	0	0	0	0	0	0	2
	TL>	0	0	0	0	0	0	3
	MN>	0.0	0.0	0.0	0.0	0.0	0.0	2.3
--PIGMENT, FONTANA MASSON POSITIVE	->	0	0	0	0	0	0	3
	TL>	0	0	0	0	0	0	3
	MN>	0.0	0.0	0.0	0.0	0.0	0.0	0.0

** END OF LIST **

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

TABLE 14B
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
EXPANDED HISTOPATHOLOGY INCIDENCE SUMMARY

PRINTED: 20-JAN-93
PAGE: 266

STUDY NUMBER: 483287

TABLE INCLUDES:

SEX=ALL;GROUP=ALL;WEEKS=ALL
DEATH=T;FIND=ALL;SUBSET=ALL

--- NUMBER - OF - ANIMALS - AFFECTED ---

ORGAN/TISSUE EXAMINED	SEX: -----FEMALE-----						
	GROUP: -1-	-2-	-3-	-4-	-5-	-6-	-7-
NUMBER:	15	15	15	14	15	15	14

** TOP OF LIST **							
SPLEEN (SP)	NUMBER EXAMINED: 15	0	0	0	15	14	14
	NOT REMARKABLE: 0	0	0	0	0	0	0
--EXTRAMEDULLARY HEMATOPOIESIS, INCREASED							
	-> 3	0	0	0	4	0	0
	1> 4	0	0	0	9	2	0
	2> 7	0	0	0	2	8	7
	3> 1	0	0	0	0	3	6
	4> 0	0	0	0	0	1	1
	TL> 15	0	0	0	15	14	14
	MN> 1.4	0.0	0.0	0.0	0.9	2.2	2.6
--PIGMENT							
	-> 0	0	0	0	0	0	0
	1> 3	0	0	0	8	8	9
	2> 12	0	0	0	7	6	4
	3> 0	0	0	0	0	0	1
	TL> 15	0	0	0	15	14	14
	MN> 1.8	0.0	0.0	0.0	1.5	1.4	1.4
--AMYLOIDOSIS							
	-> 15	0	0	0	15	13	14
	1> 0	0	0	0	0	1	0
	TL> 15	0	0	0	15	14	14
	MN> 0.0	0.0	0.0	0.0	0.0	0.1	0.0
--DEPLETION, LYMPHOID							
	-> 15	0	0	0	15	14	14
	TL> 15	0	0	0	15	14	14
	MN> 0.0	0.0	0.0	0.0	0.0	0.0	0.0
--NECROSIS, LYMPHOID							
	-> 15	0	0	0	14	14	14
	1> 0	0	0	0	1	0	0
	TL> 15	0	0	0	15	14	14
	MN> 0.0	0.0	0.0	0.0	0.1	0.0	0.0

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

TABLE 14B
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
EXPANDED HISTOPATHOLOGY INCIDENCE SUMMARY

PRINTED: 20-JAN-93
PAGE: 267

STUDY NUMBER: 483287

TABLE INCLUDES:
SEX=ALL;GROUP=ALL;WEEKS=ALL
DEATH-T;FIND-ALL;SUBSET=ALL

--- NUMBER - O F - A N I M A L S - A F F E C T E D ---

SEX: -----FEMALE-----								
GROUP: -1- -2- -3- -4- -5- -6- -7-								
NUMBER:		15	15	15	14	15	15	14
ORGAN/TISSUE EXAMINED								
STOMACH, NONGL (SU)								
NUMBER EXAMINED:		15	1	2	9	15	15	14
NOT REMARKABLE:		15	1	2	9	15	15	14
--INFLAMMATION, CHRONIC								
->		15	1	2	9	15	15	14
1>		0	0	0	0	0	0	0
TL>		15	1	2	9	15	15	14
MN>		0.0	0.0	0.0	0.0	0.0	0.0	0.0
STOMACH, GL (ST)								
NUMBER EXAMINED:		15	1	2	9	15	15	14
NOT REMARKABLE:		9	0	0	5	6	3	4
--HYPERPLASIA								
->		15	1	1	9	14	15	12
1>		0	0	1	0	0	0	2
2>		0	0	0	0	1	0	0
TL>		15	1	2	9	15	15	14
MN>		0.0	0.0	0.5	0.0	0.1	0.0	0.1
--HYPERPLASIA, CYSTIC								
->		13	1	1	6	10	5	10
1>		2	0	0	3	4	9	1
2>		0	0	1	0	1	1	3
3>		0	0	0	0	0	0	0
TL>		15	1	2	9	15	15	14
MN>		0.1	0.0	1.0	0.3	0.4	0.7	0.5
--INFLAMMATION, CHRONIC								
->		11	1	1	8	9	9	7
1>		4	0	1	1	6	6	7
2>		0	0	0	0	0	0	0
TL>		15	1	2	9	15	15	14
MN>		0.3	0.0	0.5	0.1	0.4	0.4	0.5

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HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

TABLE 14B
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
EXPANDED HISTOPATHOLOGY INCIDENCE SUMMARY

PRINTED: 20-JAN-93
PAGE: 268

STUDY NUMBER: 483287

TABLE INCLUDES:
SEX=ALL; GROUP=ALL; WEEKS=ALL
DEATH=T; FIND=ALL; SUBSET=ALL

--- NUMBER - OF - ANIMALS - AFFECTED ---

TABLE INCLUDES:		SEX: -----		FEMALE-----				
SEX=ALL;GROUP=ALL;WEEKS=ALL		GROUP: -1- -2- -3- -4- -5- -6- -7-						
DEATH=T;FIND=ALL;SUBSET=ALL		NUMBER: 15 15 15 14 15 15 14						
ORGAN/TISSUE EXAMINED		NUMBER: 15 15 15 14 15 15 14						
** FROM PREVIOUS PAGE **		NUMBER EXAMINED: 15 1 2 9 15 15 14						
STOMACH, GL (ST)		NOT REMARKABLE: 9 0 0 5 6 3 4						
--MUCOSA, NECROSIS		-> 15 0 1 9 15 15 14						
		1> 0 0 0 0 0 0 0						
		2> 0 1 0 0 0 0 0						
		3> 0 0 1 0 0 0 0						
		TL> 15 1 2 9 15 15 14						
		MN> 0.0 2.0 1.5 0.0 0.0 0.0 0.0						
--INFLAMMATION, ACUTE		-> 15 1 2 9 15 14 14						
		1> 0 0 0 0 0 1 0						
		TL> 15 1 2 9 15 15 14						
		MN> 0.0 0.0 0.0 0.0 0.0 0.1 0.0						
--AMYLOIDOSIS		-> 15 1 2 9 15 14 14						
		P> 0 0 0 0 0 1 0						
		TL> 15 1 2 9 15 15 14						
ADRENAL, CORTEX (AC)		NUMBER EXAMINED: 15 0 9 9 15 15 14						
		NOT REMARKABLE: 0 0 0 3 2 6 11						
--PIGMENT		-> 6 0 5 8 11 11 12						
		1> 8 0 4 1 4 4 2						
		2> 1 0 0 0 0 0 0						
		TL> 15 0 9 9 15 15 14						
		MN> 0.7 0.0 0.4 0.1 0.3 0.3 0.1						

** CONTINUED ON NEXT PAGE **

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TABLE 14B
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
EXPANDED HISTOPATHOLOGY INCIDENCE SUMMARY

PRINTED: 20-JAN-93
PAGE: 269

STUDY NUMBER: 483287

TABLE INCLUDES:
SEX=ALL; GROUP=ALL; WEEKS=ALL
DEATH=T; FIND=ALL; SUBSET=ALL

--- NUMBER - OF - ANIMALS - AFFECTED ---

SEX: -----FEMALE-----

GROUP: -1- -2- -3- -4- -5- -6- -7-

ORGAN/TISSUE EXAMINED

NUMBER: 15 15 15 14 15 15 14

** FROM PREVIOUS PAGE **

ADRENAL, CORTEX (AC) NUMBER EXAMINED: 15 0 9 9 15 15 14
NOT REMARKABLE: 0 0 0 3 2 6 11

--HYPERTROPHY, ZONA FASCICULATA

-> 15 0 9 9 15 15 14
1> 0 0 0 0 0 0 0
2> 0 0 0 0 0 0 0
TL> 15 0 9 9 15 15 14
MN> 0.0 0.0 0.0 0.0 0.0 0.0 0.0

--VACUOLIZATION, X-ZONE

-> 1 0 1 4 4 11 12
1> 7 0 2 3 8 3 2
2> 3 0 4 1 2 1 0
3> 3 0 2 1 1 0 0
4> 1 0 0 0 0 0 0
TL> 15 0 9 9 15 15 14
MN> 1.7 0.0 1.8 0.9 1.0 0.3 0.1

--HYPERPLASIA, SUBCAPSULAR CELL

-> 3 0 5 5 8 11 13
1> 12 0 4 4 6 4 1
2> 0 0 0 0 1 0 0
TL> 15 0 9 9 15 15 14
MN> 0.8 0.0 0.4 0.4 0.5 0.3 0.1

--UNILATERALLY EXAMINED

-> 15 0 9 9 13 14 14
P> 0 0 0 0 2 1 0
TL> 15 0 9 9 15 15 14

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TABLE 14B
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
EXPANDED HISTOPATHOLOGY INCIDENCE SUMMARY

PRINTED: 20-JAN-93
PAGE: 270

STUDY NUMBER: 483287

TABLE INCLUDES:

SEX=ALL;GROUP=ALL;WEEKS=ALL
DEATH=T;FIND=ALL;SUBSET=ALL

--- NUMBER - OF - ANIMALS - AFFECTED ---

		SEX: -----FEMALE-----						
		GROUP: -1-	-2-	-3-	-4-	-5-	-6-	-7-
ORGAN/TISSUE EXAMINED		NUMBER:	15	15	15	14	15	14
ADRENAL, MEDULLA (AM)		NUMBER EXAMINED:	15	0	9	9	15	14
		NOT REMARKABLE:	15	0	5	7	13	14
--UNILATERALLY EXAMINED		-->	15	0	5	7	13	14
		P>	0	0	4	2	2	1
		TL>	15	0	9	9	15	14
KIDNEY (KD)		NUMBER EXAMINED:	15	0	9	9	15	14
		NOT REMARKABLE:	10	0	5	3	2	4
--INFLAMMATION, CHRONIC		-->	10	0	6	8	9	5
		1>	5	0	3	1	4	6
		2>	0	0	0	0	1	3
		4>	0	0	0	0	0	1
		5>	0	0	0	0	1	0
		TL>	15	0	9	9	15	14
		MN>	0.3	0.0	0.3	0.1	0.7	0.9
--TUBULE, MINERALIZATION		-->	14	0	9	9	13	13
		1>	1	0	0	0	2	1
		TL>	15	0	9	9	15	14
		MN>	0.1	0.0	0.0	0.0	0.1	0.1
--TUBULE, REGENERATION		-->	15	0	8	9	10	13
		1>	0	0	1	0	5	1
		2>	0	0	0	0	0	0
		3>	0	0	0	0	0	1
		TL>	15	0	9	9	15	14
		MN>	0.0	0.0	0.1	0.0	0.3	0.1

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HAZLETON WASHINGTON, INC.
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TABLE 14B
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
EXPANDED HISTOPATHOLOGY INCIDENCE SUMMARY

PRINTED: 20-JAN-93
PAGE: 271

STUDY NUMBER: 483287

TABLE INCLUDES:
SEX=ALL; GROUP=ALL; WEEKS=ALL
DEATH=T; FIND=ALL; SUBSET=ALL

--- NUMBER - OF - ANIMALS - AFFECTED ---								
SEX: -----FEMALE-----								
GROUP:	-1-	-2-	-3-	-4-	-5-	-6-	-7-	
NUMBER:	15	15	15	14	15	15	14	
ORGAN/TISSUE EXAMINED	---	---	---	---	---	---	---	---
** FROM PREVIOUS PAGE **								
KIDNEY (KD)	NUMBER EXAMINED: 15	0	9	9	15	14	14	
	NOT REMARKABLE: 10	0	5	3	2	4	1	
--HYPERPLASIA, LYMPHOID	-> 14	0	9	9	15	14	9	
	1> 1	0	0	0	0	0	5	
	TL> 15	0	9	9	15	14	14	
	MN> 0.1	0.0	0.0	0.0	0.0	0.0	0.4	
--TUBULE, DILATATION	-> 15	0	9	9	15	14	14	
	2> 0	0	0	0	0	0	0	
	TL> 15	0	9	9	15	14	14	
	MN> 0.0	0.0	0.0	0.0	0.0	0.0	0.0	
--AMYLOIDOSIS	-> 15	0	9	9	15	14	14	
	1> 0	0	0	0	0	0	0	
	TL> 15	0	9	9	15	14	14	
	MN> 0.0	0.0	0.0	0.0	0.0	0.0	0.0	
--PIGMENT	-> 13	0	9	9	15	13	13	
	1> 2	0	0	0	0	1	1	
	TL> 15	0	9	9	15	14	14	
	MN> 0.1	0.0	0.0	0.0	0.0	0.1	0.1	
--INFLAMMATION, GRANULOMATOUS	-> 15	0	9	9	15	14	14	
	1> 0	0	0	0	0	0	0	
	TL> 15	0	9	9	15	14	14	
	MN> 0.0	0.0	0.0	0.0	0.0	0.0	0.0	
--CYST	-> 14	0	9	9	14	10	11	
	P> 1	0	0	0	1	4	3	
	TL> 15	0	9	9	15	14	14	

** CONTINUED ON NEXT PAGE **

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

TABLE 14B
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
EXPANDED HISTOPATHOLOGY INCIDENCE SUMMARY

PRINTED: 20-JAN-93
PAGE: 272

STUDY NUMBER: 483287

TABLE INCLUDES:

SEX=ALL;GROUP=ALL;WEEKS=ALL
DEATH=T;FIND=ALL;SUBSET=ALL

--- NUMBER - O F - A N I M A L S - A F F E C T E D ---

TABLE INCLUDED:		SEX: -----		FEMALE-----				
SEX=ALL; GROUP=ALL; WEEKS=ALL		GROUP: -1- -2- -3- -4- -5- -6- -7-						
DEATH=T; FIND=ALL; SUBSET=ALL		NUMBER: 15 15 15 14 15 15 14						
ORGAN/TISSUE EXAMINED		-----		-----				
** FROM PREVIOUS PAGE **								
KIDNEY (KD)		NUMBER EXAMINED: 15 0 9 9 15 14 14						
		NOT REMARKABLE: 10 0 5 3 2 4 1						
--INFLAMMATION, SUBACUTE		-> 15 0 9 4 7 10 10						
		1> 0 0 0 4 8 4 4						
		2> 0 0 0 1 0 0 0						
		TL> 15 0 9 9 15 14 14						
		MN> 0.0 0.0 0.0 0.7 0.5 0.3 0.3						
--PELVIS, DILATATION		-> 15 0 9 9 14 13 14						
		P> 0 0 0 0 1 1 0						
		TL> 15 0 9 9 15 14 14						
UTERUS (UT)		NUMBER EXAMINED: 15 2 9 9 14 13 14						
		NOT REMARKABLE: 5 0 0 3 2 0 0						
--HYPERPLASIA, CYSTIC ENDOMETRIAL		-> 7 0 2 5 8 13 11						
		1> 8 1 3 2 3 0 3						
		2> 0 1 3 2 3 0 0						
		3> 0 0 1 0 0 0 0						
		TL> 15 2 9 9 14 13 14						
		MN> 0.5 1.5 1.3 0.7 0.6 0.0 0.2						
--DILATATION		-> 15 2 9 9 14 12 13						
		P> 0 0 0 0 0 1 1						
		TL> 15 2 9 9 14 13 14						

** CONTINUED ON NEXT PAGE **

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TABLE 14B
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
EXPANDED HISTOPATHOLOGY INCIDENCE SUMMARY

PRINTED: 20-JAN-93
PAGE: 273

STUDY NUMBER: 483287

TABLE INCLUDES:

SEX=ALL; GROUP=ALL; WEEKS=ALL
DEATH=T; FIND=ALL; SUBSET=ALL

--- NUMBER OF ANIMALS AFFECTED ---

TABLE INCLUDES:		SEX: -----FEMALE-----							
SEX=ALL; GROUP=ALL; WEEKS=ALL									
DEATH=T; FIND=ALL; SUBSET=ALL									
		GROUP:	-1-	-2-	-3-	-4-	-5-	-6-	-7-
ORGAN/TISSUE EXAMINED		NUMBER:	15	15	15	14	15	15	14

** FROM PREVIOUS PAGE **									
UTERUS (UT)		NUMBER EXAMINED:	15	2	9	9	14	13	14
		NOT REMARKABLE:	5	0	0	3	2	0	0
--HYPOPLASIA		->	12	2	7	7	5	0	2
		1>	2	0	2	0	3	2	0
		2>	0	0	0	0	1	0	1
		3>	1	0	0	2	2	5	2
		4>	0	0	0	0	3	3	7
		5>	0	0	0	0	0	3	2
		TL>	15	2	9	9	14	13	14
		MN>	0.3	0.0	0.2	0.7	1.6	3.4	3.3
UTERUS, CERVIX (CV)		NUMBER EXAMINED:	14	0	8	8	14	11	14
		NOT REMARKABLE:	13	0	8	8	12	9	7
--HYPOPLASIA		->	13	0	8	8	12	9	7
		1>	1	0	0	0	1	0	1
		2>	0	0	0	0	0	0	1
		3>	0	0	0	0	1	1	2
		4>	0	0	0	0	0	0	1
		5>	0	0	0	0	0	1	2
		TL>	14	0	8	8	14	11	14
		MN>	0.1	0.0	0.0	0.0	0.3	0.7	1.6
VAGINA (VA)		NUMBER EXAMINED:	15	0	0	0	0	0	14
		NOT REMARKABLE:	14	0	0	0	0	0	11
--CYST, KERATIN		->	14	0	0	0	0	0	14
		P>	1	0	0	0	0	0	0
		TL>	15	0	0	0	0	0	14

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WASHINGTON, D.C. U.S.A.

TABLE 14B
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
EXPANDED HISTOPATHOLOGY INCIDENCE SUMMARY

PRINTED: 20-JAN-93
PAGE: 274

STUDY NUMBER: 483287

TABLE INCLUDES:

SEX=ALL;GROUP=ALL;WEEKS=ALL
DEATH=T;FIND=ALL;SUBSET=ALL

--- NUMBER - OF - ANIMALS - AFFECTED ---

ORGAN/TISSUE EXAMINED	SEX:	FEMALE						
		GROUP: -1-	-2-	-3-	-4-	-5-	-6-	-7-
	NUMBER:	15	15	15	14	15	15	14

** FROM PREVIOUS PAGE **								
VAGINA (VA)	NUMBER EXAMINED:	15	0	0	0	0	0	14
	NOT REMARKABLE:	14	0	0	0	0	0	11
--HYPOPLASIA								
	->	15	0	0	0	0	0	11
	P>	0	0	0	0	0	0	3
	TL>	15	0	0	0	0	0	14
MAMMARY, FEMALE (MF)	NUMBER EXAMINED:	15	0	0	0	12	14	14
	NOT REMARKABLE:	15	0	0	0	12	9	5
--DILATATION, CYSTIC								
	->	15	0	0	0	12	9	6
	1>	0	0	0	0	0	3	7
	2>	0	0	0	0	0	2	1
	TL>	15	0	0	0	12	14	14
	MN>	0.0	0.0	0.0	0.0	0.0	0.5	0.6
--HYPOPLASIA, EPITHELIAL								
	->	15	0	0	0	12	10	6
	P>	0	0	0	0	0	4	8
	TL>	15	0	0	0	12	14	14
SKIN (SK)	NUMBER EXAMINED:	15	0	0	0	15	15	14
	NOT REMARKABLE:	15	0	0	0	15	15	14

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13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
EXPANDED HISTOPATHOLOGY INCIDENCE SUMMARY

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PAGE: 275

STUDY NUMBER: 483287

TABLE INCLUDES:

SEX=ALL; GROUP=ALL; WEEKS=ALL
DEATH=T; FIND=ALL; SUBSET=ALL

--- NUMBER - OF - ANIMALS - AFFECTED ---

SEX: -----FEMALE-----								
GROUP: -1- -2- -3- -4- -5- -6- -7-								
NUMBER:		15	15	15	14	15	15	14
ORGAN/TISSUE EXAMINED		---	---	---	---	---	---	---
LIVER (LI)		NUMBER EXAMINED:	15	15	15	14	15	14
		NOT REMARKABLE:	6	6	3	0	0	0
--HEPATOCYTE, HYPERTROPHY, CENTROLOBULAR		->	15	13	12	0	1	0
		1>	0	2	3	11	4	3
		2>	0	0	0	2	5	8
		3>	0	0	0	1	4	3
		4>	0	0	0	0	1	0
		TL>	15	15	15	14	15	14
		MN>	0.0	0.1	0.2	1.3	2.0	3.0
--VACUOLIZATION		->	15	14	13	6	8	1
		1>	0	1	1	3	2	11
		2>	0	0	1	3	3	1
		3>	0	0	0	1	0	1
		4>	0	0	0	1	2	0
		TL>	15	15	15	14	15	14
		MN>	0.0	0.1	0.2	1.1	1.1	1.1
--PIGMENT, BILE		->	15	15	15	13	8	0
		1>	0	0	0	1	7	14
		2>	0	0	0	0	0	0
		3>	0	0	0	0	0	0
		TL>	15	15	15	14	15	14
		MN>	0.0	0.0	0.0	0.1	0.5	1.0

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HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

TABLE 14B
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
EXPANDED HISTOPATHOLOGY INCIDENCE SUMMARY

PRINTED: 20-JAN-93
PAGE: 276

STUDY NUMBER: 483287

TABLE INCLUDES:

SEX=ALL; GROUP=ALL; WEEKS=ALL
DEATH=T; FIND=ALL; SUBSET=ALL

--- NUMBER - OF - ANIMALS - AFFECTED ---

SEX: -----FEMALE-----

GROUP: -1- -2- -3- -4- -5- -6- -7-

ORGAN/TISSUE EXAMINED

NUMBER: 15 15 15 14 15 15 14

** FROM PREVIOUS PAGE **

LIVER (LI) NUMBER EXAMINED: 15 15 15 14 15 14 14
NOT REMARKABLE: 6 6 3 0 0 0 0

--KUPFFER CELL/MACROPHAGE, PIGMENT

-> 13 15 13 6 1 0 0
1> 2 0 2 6 12 5 11
2> 0 0 0 2 1 8 3
3> 0 0 0 0 0 1 0
4> 0 0 0 0 1 0 0
TL> 15 15 15 14 15 14 14
MN> 0.1 0.0 0.1 0.7 1.2 1.7 1.2

--HEPATOCYTE, PIGMENT

-> 15 15 15 2 1 0 1
1> 0 0 0 11 10 2 4
2> 0 0 0 1 4 9 6
3> 0 0 0 0 0 3 3
TL> 15 15 15 14 15 14 14
MN> 0.0 0.0 0.0 0.9 1.2 2.1 1.8

--NECROSIS

-> 14 15 12 11 10 11 7
1> 1 0 3 3 4 0 2
2> 0 0 0 0 0 1 4
3> 0 0 0 0 1 2 1
4> 0 0 0 0 0 0 0
5> 0 0 0 0 0 0 0
TL> 15 15 15 14 15 14 14
MN> 0.1 0.0 0.2 0.2 0.5 0.6 0.9

** CONTINUED ON NEXT PAGE **

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

TABLE 14B
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
EXPANDED HISTOPATHOLOGY INCIDENCE SUMMARY

PRINTED: 20-JAN-93
PAGE: 277

STUDY NUMBER: 483287

TABLE INCLUDES:

SEX=ALL;GROUP=ALL;WEEKS=ALL
DEATH=T;FIND=ALL;SUBSET=ALL

--- NUMBER - OF - ANIMALS - AFFECTED ---

ORGAN/TISSUE EXAMINED	SEX: -----FEMALE-----						
	GROUP: -1-	-2-	-3-	-4-	-5-	-6-	-7-
NUMBER:	15	15	15	14	15	15	14

** FROM PREVIOUS PAGE **							
LIVER (LI)	NUMBER EXAMINED: 15	15	15	14	15	14	14
	NOT REMARKABLE: 6	6	3	0	0	0	0

--NECROSIS, INDIVIDUAL CELL	-> 15	12	13	7	4	0	1
	1> 0	3	2	7	11	11	8
	2> 0	0	0	0	0	3	5
	3> 0	0	0	0	0	0	0
	TL> 15	15	15	14	15	14	14
	MN> 0.0	0.2	0.1	0.5	0.7	1.2	1.3

--INFLAMMATION, CHRONIC/CHRONIC ACTIVE	-> 8	8	6	4	3	3	7
	1> 7	7	9	9	10	7	3
	2> 0	0	0	1	1	4	4
	3> 0	0	0	0	1	0	0
	4> 0	0	0	0	0	0	0
	TL> 15	15	15	14	15	14	14
	MN> 0.5	0.5	0.6	0.8	1.0	1.1	0.8

--BILE DUCT, INFLAMMATION, CHRONIC	-> 13	15	15	12	11	2	5
	1> 2	0	0	2	4	11	7
	2> 0	0	0	0	0	1	2
	4> 0	0	0	0	0	0	0
	TL> 15	15	15	14	15	14	14
	MN> 0.1	0.0	0.0	0.1	0.3	0.9	0.8

--MINERALIZATION	-> 15	15	15	14	15	14	14
	1> 0	0	0	0	0	0	0
	2> 0	0	0	0	0	0	0
	TL> 15	15	15	14	15	14	14
	MN> 0.0	0.0	0.0	0.0	0.0	0.0	0.0

** CONTINUED ON NEXT PAGE **

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

TABLE 14B
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
EXPANDED HISTOPATHOLOGY INCIDENCE SUMMARY

PRINTED: 20-JAN-93
PAGE: 278

STUDY NUMBER: 483287

TABLE INCLUDES:

SEX=ALL; GROUP=ALL; WEEKS=ALL
DEATH=T; FIND=ALL; SUBSET=ALL

--- NUMBER - OF - ANIMALS - AFFECTED ---

SEX: -----FEMALE-----								
GROUP: -1- -2- -3- -4- -5- -6- -7-								
NUMBER:		15	15	15	14	15	15	14
ORGAN/TISSUE EXAMINED								
** FROM PREVIOUS PAGE **								
LIVER (LI)		NUMBER EXAMINED:	15	15	15	14	15	14
		NOT REMARKABLE:	6	6	3	0	0	0
--INFARCT		->	15	15	14	14	15	14
		P>	0	0	1	0	0	0
		TL>	15	15	15	14	15	14
--EXTRAMEDULLARY HEMATOPOIESIS, INCREASED		->	14	15	15	14	15	11
		1>	1	0	0	0	0	3
		2>	0	0	0	0	0	0
		TL>	15	15	15	14	15	14
		MN>	0.1	0.0	0.0	0.0	0.0	0.2
BRAIN W/STEM (BR)		NUMBER EXAMINED:	15	0	0	0	0	0
		NOT REMARKABLE:	15	0	0	0	0	0
--HEMORRHAGE		->	15	0	0	0	0	0
		TL>	15	0	0	0	0	0
CORD, CERVICAL (CS)		NUMBER EXAMINED:	14	0	0	0	0	0
		NOT REMARKABLE:	14	0	0	0	0	0
--HEMORRHAGE		->	14	0	0	0	0	0
		TL>	14	0	0	0	0	0
CORD, THORACIC (TC)		NUMBER EXAMINED:	14	0	0	0	0	0
		NOT REMARKABLE:	14	0	0	0	0	0
--HEMORRHAGE		->	14	0	0	0	0	0
		TL>	14	0	0	0	0	0

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TABLE 14B
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
EXPANDED HISTOPATHOLOGY INCIDENCE SUMMARY

PRINTED: 20-JAN-93
PAGE: 279

STUDY NUMBER: 483287

TABLE INCLUDES:

SEX=ALL;GROUP=ALL;WEEKS=ALL
DEATH=T;FIND=ALL;SUBSET=ALL

--- NUMBER - OF - ANIMALS - AFFECTED ---

TABLE 1. INCLUDED:		SEX: -----FEMALE-----							
SEX=ALL; GROUP=ALL; WEEKS=ALL		GROUP:	-1-	-2-	-3-	-4-	-5-	-6-	-7-
DEATH=T; FIND=ALL; SUBSET=ALL		NUMBER:	15	15	15	14	15	15	14
ORGAN/TISSUE EXAMINED			---	---	---	---	---	---	---
CORD, LUMBAR (LC)	NUMBER EXAMINED:	14	0	0	0	0	0	0	14
	NOT REMARKABLE:	14	0	0	0	0	0	0	14
PITUITARY (PI)	NUMBER EXAMINED:	12	0	0	0	0	0	0	14
	NOT REMARKABLE:	11	0	0	0	0	0	0	14
--CYST	->	11	0	0	0	0	0	0	14
	P>	1	0	0	0	0	0	0	0
	TL>	12	0	0	0	0	0	0	14
THYROID (TY)	NUMBER EXAMINED:	15	0	0	0	0	0	0	14
	NOT REMARKABLE:	15	0	0	0	0	0	0	13
--FOLLICLE, CYST	->	15	0	0	0	0	0	0	14
	P>	0	0	0	0	0	0	0	0
	TL>	15	0	0	0	0	0	0	14
--UNILATERALLY EXAMINED	->	15	0	0	0	0	0	0	13
	P>	0	0	0	0	0	0	0	1
	TL>	15	0	0	0	0	0	0	14
PARATHYROID (PT)	NUMBER EXAMINED:	15	0	0	0	0	0	0	13
	NOT REMARKABLE:	9	0	0	0	0	0	0	6
--UNILATERALLY EXAMINED	->	9	0	0	0	0	0	0	6
	P>	6	0	0	0	0	0	0	7
	TL>	15	0	0	0	0	0	0	13

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TABLE 14B
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
EXPANDED HISTOPATHOLOGY INCIDENCE SUMMARY

PRINTED: 20-JAN-93
PAGE: 280

STUDY NUMBER: 483287

TABLE INCLUDES:

SEX=ALL; GROUP=ALL; WEEKS=ALL
DEATH=T; FIND=ALL; SUBSET=ALL

--- NUMBER - OF - ANIMALS - AFFECTED ---

SEX=ALL;GROUP=ALL;WEEKS=ALL DEATH=T;FIND=ALL;SUBSET=ALL		SEX: -----FEMALE-----							
		GROUP:	-1-	-2-	-3-	-4-	-5-	-6-	-7-
ORGAN/TISSUE EXAMINED		NUMBER:	15	15	15	14	15	15	14
-----		-----	-----	-----	-----	-----	-----	-----	-----
ESOPHAGUS (ES)	NUMBER EXAMINED:	15	0	0	0	0	0	0	14
	NOT REMARKABLE:	15	0	0	0	0	0	0	14
--INFLAMMATION, CHRONIC									
	->	15	0	0	0	0	0	0	14
	1>	0	0	0	0	0	0	0	0
	TL>	15	0	0	0	0	0	0	14
	MN>	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
TRACHEA (TR)	NUMBER EXAMINED:	15	0	0	0	0	0	0	14
	NOT REMARKABLE:	15	0	0	0	0	0	0	14
LUNG (LU)	NUMBER EXAMINED:	15	0	0	0	0	0	0	14
	NOT REMARKABLE:	9	0	0	0	0	0	0	9
--PERIBRONCHIAL/PERIVASCULAR, INFILTRATION, LYMPHOID									
	->	9	0	0	0	0	0	0	9
	1>	6	0	0	0	0	0	0	5
	TL>	15	0	0	0	0	0	0	14
	MN>	0.4	0.0	0.0	0.0	0.0	0.0	0.0	0.4
--INFLAMMATION, CHRONIC									
	->	14	0	0	0	0	0	0	14
	1>	1	0	0	0	0	0	0	0
	TL>	15	0	0	0	0	0	0	14
	MN>	0.1	0.0	0.0	0.0	0.0	0.0	0.0	0.0
--VESSEL, MINERALIZATION									
	->	15	0	0	0	0	0	0	14
	1>	0	0	0	0	0	0	0	0
	TL>	15	0	0	0	0	0	0	14
	MN>	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
** CONTINUED ON NEXT PAGE **									

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HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

TABLE 14B
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
EXPANDED HISTOPATHOLOGY INCIDENCE SUMMARY

PRINTED: 20-JAN-93
PAGE: 281

STUDY NUMBER: 483287

TABLE INCLUDES:

SEX=ALL; GROUP=ALL; WEEKS=ALL
DEATH=T; FIND=ALL; SUBSET=ALL

--- NUMBER - OF - ANIMALS - AFFECTED ---

SEX: -----FEMALE-----								
GROUP: -1- -2- -3- -4- -5- -6- -7-								
ORGAN/TISSUE EXAMINED	NUMBER:	15	15	15	14	15	15	14

** FROM PREVIOUS PAGE **								
LUNG (LU)	NUMBER EXAMINED:	15	0	0	0	0	0	14
	NOT REMARKABLE:	9	0	0	0	0	0	9
--HEMORRHAGE	-->	15	0	0	0	0	0	14
	1>	0	0	0	0	0	0	0
	TL>	15	0	0	0	0	0	14
	MN>	0.0	0.0	0.0	0.0	0.0	0.0	0.0
HEART (HT)	NUMBER EXAMINED:	15	0	0	0	0	0	14
	NOT REMARKABLE:	14	0	0	0	0	0	8
--INFLAMMATION, CHRONIC	-->	14	0	0	0	0	0	8
	1>	1	0	0	0	0	0	6
	TL>	15	0	0	0	0	0	14
	MN>	0.1	0.0	0.0	0.0	0.0	0.0	0.4
--MINERALIZATION	-->	15	0	0	0	0	0	14
	TL>	15	0	0	0	0	0	14
	MN>	0.0	0.0	0.0	0.0	0.0	0.0	0.0
--DEGENERATION	-->	15	0	0	0	0	0	14
	TL>	15	0	0	0	0	0	14
	MN>	0.0	0.0	0.0	0.0	0.0	0.0	0.0
GALLBLADDER (GB)	NUMBER EXAMINED:	15	0	0	0	0	0	14
	NOT REMARKABLE:	15	0	0	0	0	0	13
--INFLAMMATION, CHRONIC	-->	15	0	0	0	0	0	13
	1>	0	0	0	0	0	0	1
	TL>	15	0	0	0	0	0	14
	MN>	0.0	0.0	0.0	0.0	0.0	0.0	0.1

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TABLE 14B
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
EXPANDED HISTOPATHOLOGY INCIDENCE SUMMARY

PRINTED: 20-JAN-93
PAGE: 282

STUDY NUMBER: 483287

TABLE INCLUDES:

SEX=ALL; GROUP=ALL; WEEKS=ALL
DEATH-T; FIND=ALL; SUBSET=ALL

--- NUMBER - OF - ANIMALS - AFFECTED ---

TABLE INCLUDED:		SEX: -----FEMALE-----							
SEX=ALL; GROUP=ALL; WEEKS=ALL		GROUP: -1- -2- -3- -4- -5- -6- -7-							
DEATH=T; FIND=ALL; SUBSET=ALL									
ORGAN/TISSUE EXAMINED		NUMBER:	15	15	15	14	15	15	14
-----		-----	-----	-----	-----	-----	-----	-----	-----
DUODENUM (DU)		NUMBER EXAMINED:	15	0	0	0	0	0	14
		NOT REMARKABLE:	15	0	0	0	0	0	14
JEJUNUM (JE)		NUMBER EXAMINED:	15	0	0	0	0	0	14
		NOT REMARKABLE:	15	0	0	0	0	0	11
--HYPERPLASIA, LYMPHOID		->	15	0	0	0	0	0	12
		P>	0	0	0	0	0	0	2
		TL>	15	0	0	0	0	0	14
--AMYLOIDOSIS		->	15	0	0	0	0	0	12
		2>	0	0	0	0	0	0	2
		3>	0	0	0	0	0	0	0
		TL>	15	0	0	0	0	0	14
		MN>	0.0	0.0	0.0	0.0	0.0	0.0	0.3
ILEUM (IL)		NUMBER EXAMINED:	15	0	0	0	0	0	14
		NOT REMARKABLE:	15	0	0	0	0	0	11
--HYPERPLASIA, LYMPHOID		->	15	0	0	0	0	0	13
		P>	0	0	0	0	0	0	1
		TL>	15	0	0	0	0	0	14
--AMYLOIDOSIS		->	15	0	0	0	0	0	11
		2>	0	0	0	0	0	0	0
		3>	0	0	0	0	0	0	2
		5>	0	0	0	0	0	0	1
		TL>	15	0	0	0	0	0	14
		MN>	0.0	0.0	0.0	0.0	0.0	0.0	0.8

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TABLE 14B
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
EXPANDED HISTOPATHOLOGY INCIDENCE SUMMARY

PRINTED: 20-JAN-93
PAGE: 283

STUDY NUMBER: 483287

TABLE INCLUDES:

SEX=ALL; GROUP=ALL; WEEKS=ALL
DEATH=T; FIND=ALL; SUBSET=ALL

--- NUMBER - OF - ANIMALS - AFFECTED ---

TABLE INCLUDES:		SEX: -----FEMALE-----							
SEX=ALL; GROUP=ALL; WEEKS=ALL		GROUP: -1- -2- -3- -4- -5- -6- -7-							
DEATH=T; FIND=ALL; SUBSET=ALL									
ORGAN/TISSUE EXAMINED		NUMBER:	15	15	15	14	15	15	14
-----		-----	-----	-----	-----	-----	-----	-----	-----
PANCREAS (PA)	NUMBER EXAMINED:	15	0	0	1	0	4	14	
	NOT REMARKABLE:	12	0	0	1	0	4	12	
--INFLAMMATION, CHRONIC	->	13	0	0	1	0	4	13	
	1>	2	0	0	0	0	0	1	
	TL>	15	0	0	1	0	4	14	
	MN>	0.1	0.0	0.0	0.0	0.0	0.0	0.1	
--AMYLOIDOSIS	->	15	0	0	1	0	4	13	
	1>	0	0	0	0	0	0	1	
	TL>	15	0	0	1	0	4	14	
	MN>	0.0	0.0	0.0	0.0	0.0	0.0	0.1	
--ISLET CELL, HYPERPLASIA	->	14	0	0	1	0	4	14	
	1>	1	0	0	0	0	0	0	
	TL>	15	0	0	1	0	4	14	
	MN>	0.1	0.0	0.0	0.0	0.0	0.0	0.0	
CECUM (CE)	NUMBER EXAMINED:	15	0	0	0	0	0	14	
	NOT REMARKABLE:	15	0	0	0	0	0	6	
--HYPERPLASIA, LYMPHOID	->	15	0	0	0	0	0	6	
	P>	0	0	0	0	0	0	8	
	TL>	15	0	0	0	0	0	14	
COLON (CO)	NUMBER EXAMINED:	15	0	0	0	0	0	14	
	NOT REMARKABLE:	14	0	0	0	0	0	14	
--HYPERPLASIA, LYMPHOID	->	14	0	0	0	0	0	14	
	P>	1	0	0	0	0	0	0	
	TL>	15	0	0	0	0	0	14	

HAZLETON WASHINGTON, INC.
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TABLE 14B
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
EXPANDED HISTOPATHOLOGY INCIDENCE SUMMARY

PRINTED: 20-JAN-93
PAGE: 284

STUDY NUMBER: 483287

TABLE INCLUDES:

SEX=ALL;GROUP=ALL;WEEKS=ALL
DEATH=T;FIND=ALL;SUBSET=ALL

--- NUMBER OF ANIMALS AFFECTED ---

SEX=ALL;GROUP=ALL;WEEKS=ALL DEATH=T;FIND=ALL;SUBSET=ALL		SEX: -----FEMALE-----							
		GROUP:	-1-	-2-	-3-	-4-	-5-	-6-	-7-
ORGAN/TISSUE EXAMINED		NUMBER:	15	15	15	14	15	15	14
			--	--	--	--	--	--	--
RECTUM (RE)		NUMBER EXAMINED:	15	0	0	0	0	0	14
		NOT REMARKABLE:	13	0	0	0	0	0	12
--HYPERPLASIA, LYMPHOID		->	13	0	0	0	0	0	12
		P>	2	0	0	0	0	0	2
		TL>	15	0	0	0	0	0	14
--AMYLOIDOSIS		->	15	0	0	0	0	0	14
		3>	0	0	0	0	0	0	0
		TL>	15	0	0	0	0	0	14
		MN>	0.0	0.0	0.0	0.0	0.0	0.0	0.0
LN, MESENTERIC (MS)		NUMBER EXAMINED:	14	0	0	0	0	0	14
		NOT REMARKABLE:	6	0	0	0	0	0	5
--MACROPHAGES, PIGMENTED		->	7	0	0	0	0	0	7
		1>	7	0	0	0	0	0	7
		TL>	14	0	0	0	0	0	14
		MN>	0.5	0.0	0.0	0.0	0.0	0.0	0.5
--HYPERPLASIA, LYMPHOID		->	14	0	0	0	0	0	12
		1>	0	0	0	0	0	0	0
		2>	0	0	0	0	0	0	2
		TL>	14	0	0	0	0	0	14
		MN>	0.0	0.0	0.0	0.0	0.0	0.0	0.3
--INFLAMMATION, GRANULOMATOUS		->	14	0	0	0	0	0	14
		2>	0	0	0	0	0	0	0
		TL>	14	0	0	0	0	0	14
		MN>	0.0	0.0	0.0	0.0	0.0	0.0	0.0
** CONTINUED ON NEXT PAGE **									

** CONTINUED ON NEXT PAGE **

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TABLE 14B
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
EXPANDED HISTOPATHOLOGY INCIDENCE SUMMARY

PRINTED: 20-JAN-93
PAGE: 285

STUDY NUMBER: 483287

TABLE INCLUDES:

SEX=ALL; GROUP=ALL; WEEKS=ALL
DEATH=T; FIND=ALL; SUBSET=ALL

--- NUMBER - OF - ANIMALS - AFFECTED ---

SEX: -----FEMALE-----

GROUP: -1- -2- -3- -4- -5- -6- -7-

ORGAN/TISSUE EXAMINED

NUMBER: 15 15 15 14 15 15 14

** FROM PREVIOUS PAGE **

LN, MESENTERIC (MS) NUMBER EXAMINED: 14 0 0 0 0 0 14
NOT REMARKABLE: 6 0 0 0 0 0 5

--AMYLOIDOSIS

-> 14 0 0 0 0 0 11
1> 0 0 0 0 0 0 2
2> 0 0 0 0 0 0 1
TL> 14 0 0 0 0 0 14
MN> 0.0 0.0 0.0 0.0 0.0 0.0 0.3

--HEMORRHAGE

-> 14 0 0 0 0 0 14
P> 0 0 0 0 0 0 0
TL> 14 0 0 0 0 0 14

--NECROSIS, LYMPHOID

-> 13 0 0 0 0 0 14
1> 1 0 0 0 0 0 0
TL> 14 0 0 0 0 0 14
MN> 0.1 0.0 0.0 0.0 0.0 0.0 0.0

TESTIS (TE) NUMBER EXAMINED: 0 0 0 0 0 0 0
NOT REMARKABLE: 0 0 0 0 0 0 0

--MINERALIZATION

-> 0 0 0 0 0 0 0
1> 0 0 0 0 0 0 0
TL> 0 0 0 0 0 0 0
MN> 0.0 0.0 0.0 0.0 0.0 0.0 0.0

--HEMORRHAGE

-> 0 0 0 0 0 0 0
P> 0 0 0 0 0 0 0
TL> 0 0 0 0 0 0 0

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TABLE 14B
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
EXPANDED HISTOPATHOLOGY INCIDENCE SUMMARY

PRINTED: 20-JAN-93
PAGE: 286

STUDY NUMBER: 483287

TABLE INCLUDES:

SEX-ALL; GROUP-ALL; WEEKS-ALL
DEATH-T; FIND-ALL; SUBSET-ALL

--- NUMBER - OF - ANIMALS - AFFECTED ---

SEX: -----FEMALE-----								
GROUP: -1- -2- -3- -4- -5- -6- -7-								
NUMBER: 15 15 15 14 15 15 14								
ORGAN/TISSUE EXAMINED								
EPIDIDYMIS (EP)		NUMBER EXAMINED:	0	0	0	0	0	0
		NOT REMARKABLE:	0	0	0	0	0	0
--INFLAMMATION, CHRONIC		->	0	0	0	0	0	0
		1>	0	0	0	0	0	0
		TL>	0	0	0	0	0	0
		MN>	0.0	0.0	0.0	0.0	0.0	0.0
--LUMEN, DEBRIS, CELLULAR		->	0	0	0	0	0	0
		P>	0	0	0	0	0	0
		TL>	0	0	0	0	0	0
PROSTATE (PR)		NUMBER EXAMINED:	0	0	0	0	0	0
		NOT REMARKABLE:	0	0	0	0	0	0
--INFLAMMATION, CHRONIC		->	0	0	0	0	0	0
		1>	0	0	0	0	0	0
		TL>	0	0	0	0	0	0
		MN>	0.0	0.0	0.0	0.0	0.0	0.0
URINARY BLADDER (UB)		NUMBER EXAMINED:	14	0	0	0	0	14
		NOT REMARKABLE:	12	0	0	0	0	12
--INFLAMMATION, CHRONIC		->	12	0	0	0	0	12
		1>	2	0	0	0	0	2
		TL>	14	0	0	0	0	14
		MN>	0.1	0.0	0.0	0.0	0.0	0.1

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TABLE 14B
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
EXPANDED HISTOPATHOLOGY INCIDENCE SUMMARY

PRINTED: 20-JAN-93
PAGE: 287

STUDY NUMBER: 483287

TABLE INCLUDES:

SEX=ALL; GROUP=ALL; WEEKS=ALL
DEATH=T; FIND=ALL; SUBSET=ALL

--- NUMBER - OF - ANIMALS - AFFECTED ---

TABLE INCLUDED:		SEX: -----FEMALE-----							
SEX=ALL; GROUP=ALL; WEEKS=ALL		GROUP:	-1-	-2-	-3-	-4-	-5-	-6-	-7-
DEATH=T; FIND=ALL; SUBSET=ALL		NUMBER:	15	15	15	14	15	15	14
ORGAN/TISSUE EXAMINED									
OVARY (OV)		NUMBER EXAMINED:	15	4	5	4	3	3	14
		NOT REMARKABLE:	14	1	1	0	0	0	12
--FOLLICLE, CYST		->	14	3	3	2	1	1	12
		P>	1	1	2	2	2	2	2
		TL>	15	4	5	4	3	3	14
--MINERALIZATION		->	15	4	5	4	3	3	14
		TL>	15	4	5	4	3	3	14
		MN>	0.0	0.0	0.0	0.0	0.0	0.0	0.0
--BURSA, CYST		->	15	2	3	2	2	2	14
		P>	0	2	2	2	1	1	0
		TL>	15	4	5	4	3	3	14
--UNILATERALLY EXAMINED		->	15	4	5	3	3	3	14
		P>	0	0	0	1	0	0	0
		TL>	15	4	5	4	3	3	14
OVIDUCT (OD)		NUMBER EXAMINED:	15	4	5	4	3	3	14
		NOT REMARKABLE:	15	4	5	4	3	3	14
LN, MANDIBULAR (MN)		NUMBER EXAMINED:	14	0	0	0	0	0	12
		NOT REMARKABLE:	4	0	0	0	0	0	0
--MACROPHAGES, PIGMENTED		->	4	0	0	0	0	0	0
		1>	10	0	0	0	0	0	12
		TL>	14	0	0	0	0	0	12
		MN>	0.7	0.0	0.0	0.0	0.0	0.0	1.0

** CONTINUED ON NEXT PAGE **

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TABLE 14B
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
EXPANDED HISTOPATHOLOGY INCIDENCE SUMMARY

PRINTED: 20-JAN-93
PAGE: 288

STUDY NUMBER: 483287

TABLE INCLUDES:

SEX=ALL; GROUP=ALL; WEEKS=ALL
DEATH=T; FIND=ALL; SUBSET=ALL

--- NUMBER - OF - ANIMALS - AFFECTED ---

SEX: -----FEMALE-----								
GROUP: -1- -2- -3- -4- -5- -6- -7-								
NUMBER:		15	15	15	14	15	15	14
ORGAN/TISSUE EXAMINED								
** FROM PREVIOUS PAGE **								
LN, MANDIBULAR (MN)		NUMBER EXAMINED:	14	0	0	0	0	12
		NOT REMARKABLE:	4	0	0	0	0	0
--AMYLOIDOSIS		->	14	0	0	0	0	12
		1>	0	0	0	0	0	0
		TL>	14	0	0	0	0	12
		MN>	0.0	0.0	0.0	0.0	0.0	0.0
--HYPERPLASIA, LYMPHOID		->	14	0	0	0	0	12
		P>	0	0	0	0	0	0
		TL>	14	0	0	0	0	12
MAND SALIVARY GL (SG)		NUMBER EXAMINED:	15	0	0	0	0	14
		NOT REMARKABLE:	15	0	0	0	0	13
--INFLAMMATION, CHRONIC		->	15	0	0	0	0	13
		1>	0	0	0	0	0	1
		TL>	15	0	0	0	0	14
		MN>	0.0	0.0	0.0	0.0	0.0	0.1
SALIVARY, OTHER (OS)		NUMBER EXAMINED:	14	0	0	0	0	14
		NOT REMARKABLE:	14	0	0	0	0	14
THYMUS (TH)		NUMBER EXAMINED:	15	0	0	0	0	14
		NOT REMARKABLE:	12	0	0	0	0	12
--CYST		->	14	0	0	0	0	13
		P>	1	0	0	0	0	1
		TL>	15	0	0	0	0	14

** CONTINUED ON NEXT PAGE **

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TABLE 14B
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
EXPANDED HISTOPATHOLOGY INCIDENCE SUMMARY

PRINTED: 20-JAN-93
PAGE: 289

STUDY NUMBER: 483287

TABLE INCLUDES:
SEX=ALL; GROUP=ALL; WEEKS=ALL
DEATH=T; FIND=ALL; SUBSET=ALL

		--- NUMBER - OF - ANIMALS - AFFECTED ---						
		SEX: -----FEMALE-----						
		GROUP: -1-	-2-	-3-	-4-	-5-	-6-	-7-
ORGAN/TISSUE EXAMINED	NUMBER:	15	15	15	14	15	15	14

** FROM PREVIOUS PAGE **								
THYRUS (TH)	NUMBER EXAMINED:	15	0	0	0	0	0	14
	NOT REMARKABLE:	12	0	0	0	0	0	12
--ECTOPIC THYROID								
	->	15	0	0	0	0	0	14
	P>	0	0	0	0	0	0	0
	TL>	15	0	0	0	0	0	14
--NECROSIS, LYMPHOID								
	->	13	0	0	0	0	0	13
	1>	0	0	0	0	0	0	1
	2>	1	0	0	0	0	0	0
	3>	1	0	0	0	0	0	0
	TL>	15	0	0	0	0	0	14
	MN>	0.3	0.0	0.0	0.0	0.0	0.0	0.1
--ATROPHY								
	->	15	0	0	0	0	0	14
	TL>	15	0	0	0	0	0	14
	MN>	0.0	0.0	0.0	0.0	0.0	0.0	0.0
AORTA, THORACIC (AO)	NUMBER EXAMINED:	15	0	0	0	0	0	14
	NOT REMARKABLE:	15	0	0	0	0	0	14
EYE (EY)	NUMBER EXAMINED:	13	0	0	0	0	0	14
	NOT REMARKABLE:	12	0	0	0	0	0	14
--UNILATERALLY EXAMINED								
	->	13	0	0	0	0	0	14
	P>	0	0	0	0	0	0	0
	TL>	13	0	0	0	0	0	14
--CORNEA, MINERALIZATION								
	->	12	0	0	0	0	0	14
	2>	1	0	0	0	0	0	0
	TL>	13	0	0	0	0	0	14
	MN>	0.2	0.0	0.0	0.0	0.0	0.0	0.0

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TABLE 14B
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
EXPANDED HISTOPATHOLOGY INCIDENCE SUMMARY

PRINTED: 20-JAN-93
PAGE: 290

STUDY NUMBER: 483287

TABLE INCLUDES:

SEX-ALL; GROUP-ALL; WEEKS-ALL
DEATH-T; FIND-ALL; SUBSET-ALL

--- NUMBER - OF - ANIMALS - AFFECTED ---

SEX: -----FEMALE-----								
GROUP: -1- -2- -3- -4- -5- -6- -7-								
NUMBER:		15	15	15	14	15	15	14
ORGAN/TISSUE EXAMINED								
HARDERIAN GLAND (HG)		NUMBER EXAMINED:	13	0	0	0	0	14
		NOT REMARKABLE:	11	0	0	0	0	11
--INFLAMMATION, CHRONIC		->	11	0	0	0	0	11
		P>	2	0	0	0	0	3
		TL>	13	0	0	0	0	14
NERVE, OPTIC (ON)		NUMBER EXAMINED:	12	0	0	0	0	12
		NOT REMARKABLE:	7	0	0	0	0	8
--UNILATERALLY EXAMINED		->	7	0	0	0	0	8
		P>	5	0	0	0	0	4
		TL>	12	0	0	0	0	12
LACRIMAL GL, EX (EO)		NUMBER EXAMINED:	14	0	0	0	0	11
		NOT REMARKABLE:	11	0	0	0	0	5
--INFLAMMATION, CHRONIC		->	13	0	0	0	0	11
		I>	1	0	0	0	0	0
		TL>	14	0	0	0	0	11
		MN>	0.1	0.0	0.0	0.0	0.0	0.0
--UNILATERALLY EXAMINED		->	12	0	0	0	0	5
		P>	2	0	0	0	0	6
		TL>	14	0	0	0	0	11
TONGUE (TO)		NUMBER EXAMINED:	14	0	0	0	0	14
		NOT REMARKABLE:	14	0	0	0	0	14
MUSCLE, SKELETAL (SM)		NUMBER EXAMINED:	14	0	0	0	0	14
		NOT REMARKABLE:	14	0	0	0	0	14

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TABLE 14B
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
EXPANDED HISTOPATHOLOGY INCIDENCE SUMMARY

PRINTED: 20-JAN-93
PAGE: 291

STUDY NUMBER: 483287

TABLE INCLUDES:

SEX=ALL;GROUP=ALL;WEEKS=ALL
DEATH=T;FIND=ALL;SUBSET=ALL

--- NUMBER - OF - ANIMALS - AFFECTED ---

SEX: -----FEMALE-----

GROUP: -1- -2- -3- -4- -5- -6- -7-

ORGAN/TISSUE EXAMINED	NUMBER:	15	15	15	14	15	15	14
NERVE, SCIATIC (SN)	NUMBER EXAMINED:	14	0	0	0	0	0	14
	NOT REMARKABLE:	14	0	0	0	0	0	14
MUSCLE, ABDOM (MA)	NUMBER EXAMINED:	15	0	0	0	0	0	14
	NOT REMARKABLE:	15	0	0	0	0	0	14
MARROW, STERNUM (SE)	NUMBER EXAMINED:	15	0	0	0	0	0	14
	NOT REMARKABLE:	15	0	0	0	0	0	14
BONE, STERNUM (SB)	NUMBER EXAMINED:	15	0	0	0	0	0	14
	NOT REMARKABLE:	15	0	0	0	0	0	14
MARROW, FEMUR (FM)	NUMBER EXAMINED:	14	0	0	0	0	0	14
	NOT REMARKABLE:	14	0	0	0	0	0	13
--HYPERCELLULAR	->	14	0	0	0	0	0	13
	P>	0	0	0	0	0	0	1
	TL>	14	0	0	0	0	0	14
BONE, FEMUR (FE)	NUMBER EXAMINED:	14	0	0	0	0	0	14
	NOT REMARKABLE:	14	0	0	0	0	0	14
HEMATO NEOPLASIA (HN)	NUMBER EXAMINED:	15	0	0	0	0	0	14
	NOT REMARKABLE:	15	0	0	0	0	0	14
^DEATH COMMENT (DC)	NUMBER EXAMINED:	15	0	0	0	0	0	14
	NOT REMARKABLE:	0	0	0	0	0	0	0
--SCHEDULED SACRIFICE	P>	15	0	0	0	0	0	14
	TL>	15	0	0	0	0	0	14

** CONTINUED ON NEXT PAGE **

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TABLE 14B
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
EXPANDED HISTOPATHOLOGY INCIDENCE SUMMARY

PRINTED: 20-JAN-93
PAGE: 292

STUDY NUMBER: 483287

		--- NUMBER - OF - ANIMALS - AFFECTED ---						
		SEX: -----FEMALE-----						
		GROUP:	-1-	-2-	-3-	-4-	-5-	-6- -7-
ORGAN/TISSUE EXAMINED		NUMBER:	15	15	15	14	15	15 14
** FROM PREVIOUS PAGE **								
^DEATH COMMENT (DC)		NUMBER EXAMINED:	15	0	0	0	0	0 14
		NOT REMARKABLE:	0	0	0	0	0	0 0
--UNDETERMINED		->	15	0	0	0	0	0 14
		TL>	15	0	0	0	0	0 14
--ACCIDENTAL		->	15	0	0	0	0	0 14
		TL>	15	0	0	0	0	0 14
LN, OTHER (LN)		NUMBER EXAMINED:	7	0	0	0	0	1 1
		NOT REMARKABLE:	7	0	0	0	0	1 0
--MACROPHAGES, PIGMENTED		->	7	0	0	0	0	1 1
		P>	0	0	0	0	0	0 0
		TL>	7	0	0	0	0	1 1
--HYPERPLASIA, LYMPHOID		->	7	0	0	0	0	1 0
		P>	0	0	0	0	0	0 1
		TL>	7	0	0	0	0	1 1
SKIN, OTHER (SS)		NUMBER EXAMINED:	0	0	0	1	0	0 1
		NOT REMARKABLE:	0	0	0	0	0	0 0
--DERMATITIS, CHRONIC		->	0	0	0	1	0	0 1
		P>	0	0	0	0	0	0 0
		TL>	0	0	0	1	0	0 1
--DERMATITIS, ULCERATIVE		P>	0	0	0	1	0	0 1
		TL>	0	0	0	1	0	0 1
BONE, OTHER (OB)		NUMBER EXAMINED:	0	0	0	0	0	0 0
		NOT REMARKABLE:	0	0	0	0	0	0 0

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TABLE 14B
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
EXPANDED HISTOPATHOLOGY INCIDENCE SUMMARY

PRINTED: 20-JAN-93
PAGE: 293

STUDY NUMBER: 483287

TABLE INCLUDES:

SEX=ALL;GROUP=ALL;WEEKS=ALL
DEATH=T;FIND=ALL;SUBSET=ALL

--- NUMBER - OF - ANIMALS - AFFECTED ---

ORGAN/TISSUE EXAMINED	SEX: -----FEMALE-----						
	GROUP: -1-	-2-	-3-	-4-	-5-	-6-	-7-
	NUMBER: 15	15	15	14	15	15	14
CAVITY, ABDOM (PC)	NUMBER EXAMINED:	2	0	0	0	0	0
	NOT REMARKABLE:	0	0	0	0	0	0
--ADHESION	P>	2	0	0	0	0	0
	TL>	2	0	0	0	0	0
LI, INTRAHEPATIC (LI0)	NUMBER EXAMINED:	0	0	0	0	0	1
	NOT REMARKABLE:	0	0	0	0	0	0
--PIGMENT, PAS POSITIVE	5>	0	0	0	0	0	1
	TL>	0	0	0	0	0	1
	MN>	0.0	0.0	0.0	0.0	0.0	5.0
--PIGMENT, IRON POSITIVE	2>	0	0	0	0	0	0
	3>	0	0	0	0	0	0
	4>	0	0	0	0	0	1
	TL>	0	0	0	0	0	1
	MN>	0.0	0.0	0.0	0.0	0.0	4.0
--PIGMENT, BILE POSITIVE	1>	0	0	0	0	0	1
	TL>	0	0	0	0	0	1
	MN>	0.0	0.0	0.0	0.0	0.0	1.0
--PIGMENT, LIPOFUSCIN POSITIVE	2>	0	0	0	0	0	0
	3>	0	0	0	0	0	1
	TL>	0	0	0	0	0	1
	MN>	0.0	0.0	0.0	0.0	0.0	3.0
--PIGMENT, FONTANA MASSON POSITIVE	->	0	0	0	0	0	1
	TL>	0	0	0	0	0	1
	MN>	0.0	0.0	0.0	0.0	0.0	0.0

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TABLE 14B
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EXPANDED HISTOPATHOLOGY INCIDENCE SUMMARY

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PAGE: 294

STUDY NUMBER: 483287

TABLE INCLUDES:

SEX=ALL; GROUP=ALL; WEEKS=ALL
DEATH=T; FIND=ALL; SUBSET=ALL

--- NUMBER OF ANIMALS AFFECTED ---

SEX: -----FEMALE-----

GROUP: -1- -2- -3- -4- -5- -6- -7-

NUMBER: 15 15 15 14 15 15 14

ORGAN/TISSUE EXAMINED

LI, EXTRAHEPATIC (LI1)	NUMBER EXAMINED:	0	0	0	0	0	0	1
	NOT REMARKABLE:	0	0	0	0	0	0	0
--PIGMENT, PAS POSITIVE								
	3>	0	0	0	0	0	0	0
	4>	0	0	0	0	0	0	0
	5>	0	0	0	0	0	0	1
	TL>	0	0	0	0	0	0	1
	MN>	0.0	0.0	0.0	0.0	0.0	0.0	5.0
--PIGMENT, IRON POSITIVE								
	2>	0	0	0	0	0	0	1
	3>	0	0	0	0	0	0	0
	TL>	0	0	0	0	0	0	1
	MN>	0.0	0.0	0.0	0.0	0.0	0.0	2.0
--PIGMENT, BILE POSITIVE								
	->	0	0	0	0	0	0	1
	TL>	0	0	0	0	0	0	1
	MN>	0.0	0.0	0.0	0.0	0.0	0.0	0.0
--PIGMENT, LIPOFUSCIN POSITIVE								
	1>	0	0	0	0	0	0	0
	2>	0	0	0	0	0	0	1
	3>	0	0	0	0	0	0	0
	TL>	0	0	0	0	0	0	1
	MN>	0.0	0.0	0.0	0.0	0.0	0.0	2.0
--PIGMENT, FONTANA MASSON POSITIVE								
	->	0	0	0	0	0	0	1
	TL>	0	0	0	0	0	0	1
	MN>	0.0	0.0	0.0	0.0	0.0	0.0	0.0

** END OF LIST **

Appendix 1
Analytical Chemistry Methods
13-Week Subchronic Oral Toxicity Study of Triclosan in CD-1[®] Mice

ANALYTICAL CHEMISTRY METHOD

METHOD NO. 480

AMENDMENT NO. 1
DATE EFFECTIVE: August 19, 1991 .
APPROVAL: Lee Hohing
Lee Hohing

TITLE: Determination of Triclosan in Rodent Feed

Amendment

Following are the changes to the analytical method:

1. Section 4.4 Mobile Phase
82.5% Methanol/2.5% Tetrahydrofuran/15% Water

ANALYTICAL CHEMISTRY LABORATORY

METHOD NO. 480

DATE: July 1, 1997
APPROVAL: *T. Lee Hohng*

TITLE: Determination of Triclosan in Rodent Feed

STRUCTURE: On file with sponsor.

DEVELOPED BY: Hazleton Washington, Inc.; developed from methods supplied by Ciba-Geigy and Litton Bionetics

1.0 SCOPE

This method describes the determination of Triclosan in rodent feed at concentrations ranging from 100 ppm to 5100 ppm.

2.0 PRINCIPLE

Triclosan is extracted with methanol from a weighed amount of rodent feed for at least 6 hours in a soxhlet apparatus. An aliquot of the extract is filtered using 0.45 micron filters and analyzed against standards by reverse phase high performance liquid chromatography (HPLC).

3.0 EQUIPMENT

- 3.1 High performance liquid chromatography apparatus consisting of a Waters Data Module 730, a Waters WISP 710B autosampler, a Waters pump 510 and a Kratos UV-Vis variable wavelength detector, or equivalent.
- 3.2 Column: Dupont Zorbax ODS, 25 cm x 4.6 mm ID and RP-8 guard column and holder (Brownlee Laboratories).
- 3.3 Top loading balance accurate to ± 0.01 g.
- 3.4 Round bottom flasks: 250 mL and 500 mL capacity.
- 3.5 Soxhlet extraction equipment suitable for Whatman extraction thimbles size 25 x 80 mm and 33 x 94 mm.
- 3.6 Heating mantles equipped with transformers.

- 3.7 Millipore® 0.45 micron filters.
- 3.8 Wisp vials with teflon septa.
- 3.9 General laboratory glassware and equipment.

4.0 REAGENTS

- 4.1 Methanol: HPLC grade.
- 4.2 Deionized water: HPLC quality.
- 4.3 Triclosan reference standard (supplied by Sponsor).
- 4.4 Mobile phase: 85% methanol in water.

5.0 PROCEDURE

5.1 Standards

5.1.1 Stock Standard A

Prepare a stock standard containing 1000 µg/mL of Triclosan in methanol

5.1.2 Intermediate Standards

Dilute 1 mL of the stock standard to 100 mL with methanol.

5.1.3 Dilute to obtain the following working standards.

<u>Target</u> µg/mL	<u>Volume of</u> <u>Intermediate Standard</u> mL	<u>Final Volume</u> <u>in Methanol</u> mL
1.00	1.0	10
2.00	2.0	10
4.00	4.0	10
8.00	8.0	10

5.2 FORTIFICATION (spikes)

5.2.1 Stock Spike A

Prepare a stock spiking solution containing 1000 µg/mL of Triclosan in methanol.

5.2.2 Intermediate Spike B

Dilute 10 mL of stock spiking solution to 100 mL with methanol (equal to approx 100 µg/mL).

5.2.3 Analytical spike preparations will vary weekly because dose levels are based on mg/kg/day.

Sample calculation:

conc of spike B x $\frac{\text{mL of spike B}}{\text{wt. of control feed}}$ = actual conc.

$$\frac{100 \mu\text{g}}{\text{mL}} \times \frac{2 \text{ mL}}{2\text{g}} = 100 \text{ ppm}$$

5.3 Preparation of Samples

5.3.1 Weigh out 2 g feed ± 0.01 g and place in appropriate soxhlet thimbles.

5.3.2 Assemble soxhlet apparatus; apply heat and reflux gently for at least 6 hours according to the following:

<u>Dose</u> mg/kg	<u>Thimble Size</u> mm	<u>Flask Size</u> mL	<u>Methanol</u> mL
0	25 x 80	250	80
25	25 x 80	250	80
75	25 x 80	250	80
200	33 x 94	500	150
350	33 x 94	500	150
750	33 x 94	500	150
900	33 x 94	500	150

5.3.3 Switch off heat; allow apparatus to cool and quantitatively transfer the methanol to volumetric flask according to the following:

<u>Dose</u> mg/kg	<u>Volumetric Flask</u> mL
0	100
25	100
75	100
200	200
350	200
750	200
900	200

Dilute to volume with methanol and mix well.

5.3.4 Dilution scheme will vary weekly because dose levels are based on mg/kg/day. Dilutions are made so that the concentrations of the samples will fall within the middle range of the standard curve.

Sample Calculations:

$$\text{dose conc (ppm)} \times \frac{\text{wt. of feed (g)}}{\text{total extraction volume (mL)}} \times \frac{\text{aliquot for dilution (mL)}}{\text{final vol of dilution (mL)}} = \text{final conc. } \frac{\mu\text{g}}{\text{mL}}$$

$$4000 \text{ ppm} \times \frac{2 \text{ g}}{200 \text{ mL}} \times \frac{1 \text{ mL}}{10 \text{ mL}} = \frac{4 \mu\text{g}}{\text{mL}}$$

5.3.5 Using a Millipore 0.45 micron filter attached to a syringe, filter required aliquots into WISP vials and close with Teflon® lined caps. Samples are ready for analysis by HPLC.

6.0 CALCULATIONS

The nanograms detected may be determined by linear regression or by calibrating the instrument on a standard injection close to the theoretical concentration of the samples.

ppm = ng detected x calculation factor (cal factor)

$$\text{cal factor} = \frac{1}{\mu\text{L injected}} \times \frac{\text{extraction volume (mL)}}{\text{weight of feed (g)}} \times \frac{\text{final volume (mL)}}{\text{aliquot taken for dilution (mL)}}$$

$$\text{spike \% target} = \frac{\text{ppm found}}{\text{target ppm}} \times 100$$

$$\text{corrected ppm} = \frac{\text{ppm found}}{\text{spike \% target}} \times 100$$

$$\% \text{ target} = \frac{\text{corrected ppm}}{\text{target ppm}} \times 100$$

7.0 INSTRUMENT PARAMETERS

High Performance Liquid	:	1. Waters Model 510 pump 2. Kratos UV-Vis Variable Wavelength detector 3. Waters WISP 710B auto-sampler 4. Waters 730 Data Module (or equivalent)
Column	:	Dupont Zorbax ODS, 25 cm x 4.6 mm ID, equipped with RP-8 guard column (Brownlee Lab), or equivalent
Mobile Flow Rate	:	1.3 ml/min
Detector	:	0.02 AUFS
Wavelength	:	280 nm
Chart Speed	:	0.25 cm/min
Injection Volume	:	25 μ l
Run Time	:	12 min.
Peak Width	:	14
Noise Rejection	:	20
Area Rejection	:	100
Quantitation	:	Area or height

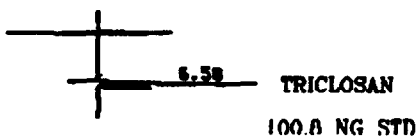
Note: Instrument parameters may be adjusted to optimize chromatography and/or response.

8.0 LIST OF FIGURES

- Figure 1. Typical chromatogram, standard.
- Figure 2. Typical standard curve.
- Figure 3. Typical chromatogram, sample.
- Figure 4. Typical chromatogram, control.

Figure 1. Typical chromatogram, standard

INJECT



SAMPLE POSITION	14	AUTO MODE	MISS REPORT
INJECTION VOLUME	0025		
NUMBER OF INJECTIONS	1	INJECTIONS REMAINING	0
RUN TIME	00:10	EQUILIBRIUM DELAY	00:00
NON-DEFAULT SYS MSG'S: 6500-0030 P01.7000			
MISS CODES GENERATED:			
AUG. 9, 1991 02:30:54		CHUNK 4.25 CR/MIN	
COLUMN		NON 000	UNCL 00
		SOLVENT	UPK 10' 6
EXTERNAL STANDARD QUANTIFICATION			
PLATE	AREA	K1	EXP K1
1	101.11000	6.58	
TOTAL	101.11000		
			27.0000 0.34000000

Figure 2. Typical standard curve.

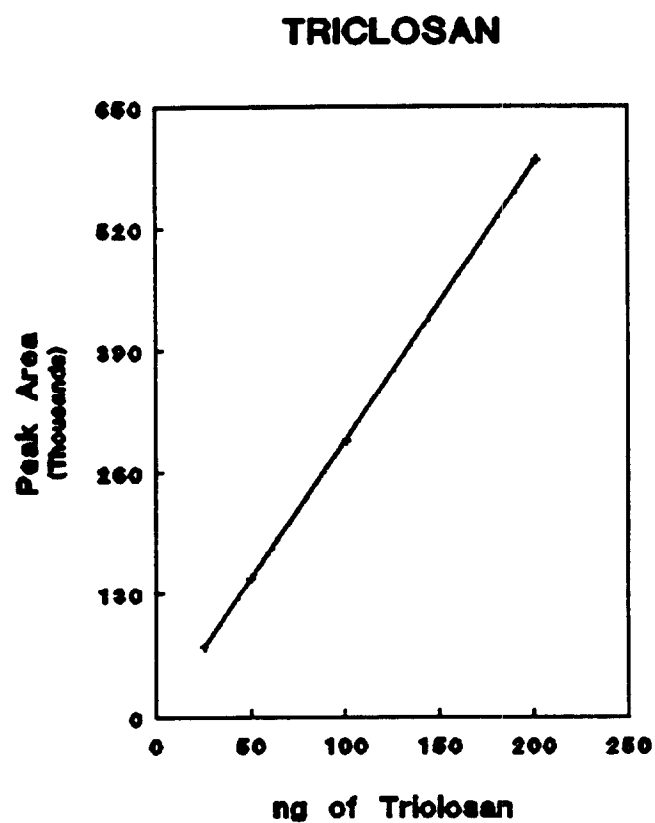


Figure 3. Typical chromatogram, sample

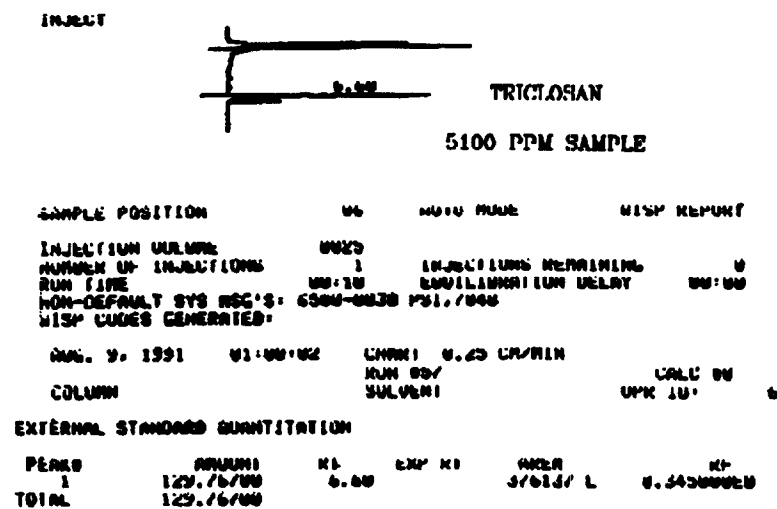


Figure 4. Typical chromatogram, control



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SAMPLE POSITION      13      AUTO PAUSE      HWP REPORT
INJECTION VOLUME    0.025
NUMBER OF INJECTIONS 1      INJECTION RETENTION 0
RUN TIME           00:10      ELUTION DELAY       00:00
NON-DEFAULT SYS PLS'S: 0000-0030 PLS/000
HWP CURS GENERATED:

AUG. 9, 1991      02:19:42      CHART 0.25 CM/IN
COLUMNS          RUN 004      CALC ON
SOLVENT          UPK 10'      6

EXTERNAL STANDARD QUANTIFICATION
PEAKS      AREA      RI      SRT RI      AREA      RT
1          16.00010      3.30      46.677 L      0.44000000
TOTAL          16.00010

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Appendix 2A
Individual Animal Disposition - Main Study
13-Week Subchronic Oral Toxicity Study of Triclosan in CD-1® Mice

Key to Animal Death Codes

The following animal death codes are used in conjunction with gross pathology findings, organ weight data, and histopathology findings:

- T = Terminal Sacrifice
- A = Accidental Death
- D = Found Dead
- M = Moribund Sacrifice

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APPENDIX 2A

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL DISPOSITION

STUDY NUMBER: 483287

ANIMAL NUMBER	DOSE GROUP	SEX	TERMINAL BODY WEIGHT	DEATH CODE	TYPE OF DEATH	DESCRIPTION OF DEATH	DATE OF DEATH	DAY OF STUDY	WEEK OF STUDY
A37391	1	MALE	24.4	T	SCHEDULED	TERMINAL SACRIFICE	11/11/91	95	14
A37392	1	MALE	25.8	T	SCHEDULED	TERMINAL SACRIFICE	11/11/91	95	14
A37393	1	MALE	28.6	T	SCHEDULED	TERMINAL SACRIFICE	11/11/91	95	14
A37394	1	MALE	26.8	T	SCHEDULED	TERMINAL SACRIFICE	11/11/91	95	14
A37395	1	MALE	28.4	T	SCHEDULED	TERMINAL SACRIFICE	11/12/91	96	14
A37396	1	MALE	27.0	T	SCHEDULED	TERMINAL SACRIFICE	11/12/91	96	14
A37397	1	MALE	29.9	T	SCHEDULED	TERMINAL SACRIFICE	11/12/91	96	14
A37398	1	MALE	26.4	T	SCHEDULED	TERMINAL SACRIFICE	11/12/91	96	14
A37399	1	MALE	26.6	T	SCHEDULED	TERMINAL SACRIFICE	11/13/91	97	14
A37400	1	MALE	25.7	T	SCHEDULED	TERMINAL SACRIFICE	11/13/91	97	14
A37401	1	MALE	28.7	T	SCHEDULED	TERMINAL SACRIFICE	11/13/91	97	14
A37402	1	MALE	27.2	T	SCHEDULED	TERMINAL SACRIFICE	11/13/91	97	14
A37403	1	MALE	27.0	T	SCHEDULED	TERMINAL SACRIFICE	11/14/91	98	14
A37404	1	MALE	24.1	T	SCHEDULED	TERMINAL SACRIFICE	11/14/91	98	14
A37405	1	MALE	26.0	T	SCHEDULED	TERMINAL SACRIFICE	11/14/91	98	14
A37421	2	MALE	29.8	T	SCHEDULED	TERMINAL SACRIFICE	11/11/91	95	14
A37422	2	MALE	26.0	T	SCHEDULED	TERMINAL SACRIFICE	11/11/91	95	14
A37423	2	MALE	27.3	T	SCHEDULED	TERMINAL SACRIFICE	11/11/91	95	14
A37424	2	MALE	30.4	T	SCHEDULED	TERMINAL SACRIFICE	11/11/91	95	14
A37425	2	MALE	29.1	T	SCHEDULED	TERMINAL SACRIFICE	11/12/91	96	14
A37426	2	MALE	26.9	T	SCHEDULED	TERMINAL SACRIFICE	11/12/91	96	14
A37427	2	MALE	26.5	T	SCHEDULED	TERMINAL SACRIFICE	11/12/91	96	14
A37428	2	MALE	27.7	T	SCHEDULED	TERMINAL SACRIFICE	11/12/91	96	14
A37429	2	MALE	30.2	T	SCHEDULED	TERMINAL SACRIFICE	11/13/91	97	14
A37430	2	MALE	27.1	T	SCHEDULED	TERMINAL SACRIFICE	11/13/91	97	14
A37431	2	MALE	28.7	T	SCHEDULED	TERMINAL SACRIFICE	11/13/91	97	14
A37432	2	MALE	26.1	T	SCHEDULED	TERMINAL SACRIFICE	11/13/91	97	14
A37433	2	MALE	28.2	T	SCHEDULED	TERMINAL SACRIFICE	11/14/91	98	14
A37434	2	MALE	25.0	T	SCHEDULED	TERMINAL SACRIFICE	11/14/91	98	14
A37435	2	MALE	26.2	T	SCHEDULED	TERMINAL SACRIFICE	11/14/91	98	14
A37451	3	MALE	28.3	T	SCHEDULED	TERMINAL SACRIFICE	11/11/91	95	14
A37452	3	MALE	27.8	T	SCHEDULED	TERMINAL SACRIFICE	11/11/91	95	14
A37453	3	MALE	29.2	T	SCHEDULED	TERMINAL SACRIFICE	11/11/91	95	14
A37454	3	MALE	26.4	T	SCHEDULED	TERMINAL SACRIFICE	11/11/91	95	14
A37455	3	MALE	26.1	T	SCHEDULED	TERMINAL SACRIFICE	11/12/91	96	14
A37456	3	MALE	32.9	T	SCHEDULED	TERMINAL SACRIFICE	11/12/91	96	14
A37457	3	MALE	31.8	T	SCHEDULED	TERMINAL SACRIFICE	11/12/91	96	14
A37458	3	MALE	29.6	T	SCHEDULED	TERMINAL SACRIFICE	11/12/91	96	14
A37459	3	MALE	26.4	T	SCHEDULED	TERMINAL SACRIFICE	11/13/91	97	14

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APPENDIX 2A

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL DISPOSITION

STUDY NUMBER: 483287

ANIMAL NUMBER	DOSE GROUP	SEX	TERMINAL BODY WEIGHT	DEATH CODE	TYPE OF DEATH	DESCRIPTION OF DEATH	DATE OF DEATH	DAY OF STUDY	WEEK OF STUDY
A37460	3	MALE	30.7	T	SCHEDULED	TERMINAL SACRIFICE	11/13/91	97	14
A37461	3	MALE	29.6	T	SCHEDULED	TERMINAL SACRIFICE	11/13/91	97	14
A37462	3	MALE	27.3	T	SCHEDULED	TERMINAL SACRIFICE	11/13/91	97	14
A37463	3	MALE	25.5	T	SCHEDULED	TERMINAL SACRIFICE	11/14/91	98	14
A37464	3	MALE	28.3	T	SCHEDULED	TERMINAL SACRIFICE	11/14/91	98	14
A37465	3	MALE	25.4	T	SCHEDULED	TERMINAL SACRIFICE	11/14/91	98	14
A37481	4	MALE	28.2	T	SCHEDULED	TERMINAL SACRIFICE	11/11/91	95	14
A37482	4	MALE	27.6	T	SCHEDULED	TERMINAL SACRIFICE	11/11/91	95	14
A37483	4	MALE	28.0	T	SCHEDULED	TERMINAL SACRIFICE	11/11/91	95	14
A37484	4	MALE	29.0	D	UNSCHEDULED	UNSCHEDULED DEATH	11/01/91	85	13
A37485	4	MALE	26.2	T	SCHEDULED	TERMINAL SACRIFICE	11/11/91	95	14
A37486	4	MALE	28.6	T	SCHEDULED	TERMINAL SACRIFICE	11/12/91	96	14
A37487	4	MALE	31.5	T	SCHEDULED	TERMINAL SACRIFICE	11/12/91	96	14
A37488	4	MALE	28.9	T	SCHEDULED	TERMINAL SACRIFICE	11/12/91	96	14
A37489	4	MALE	31.4	T	SCHEDULED	TERMINAL SACRIFICE	11/12/91	96	14
A37490	4	MALE	28.8	T	SCHEDULED	TERMINAL SACRIFICE	11/13/91	97	14
A37491	4	MALE	28.0	T	SCHEDULED	TERMINAL SACRIFICE	11/13/91	97	14
A37492	4	MALE	31.0	T	SCHEDULED	TERMINAL SACRIFICE	11/13/91	97	14
A37493	4	MALE	28.2	T	SCHEDULED	TERMINAL SACRIFICE	11/13/91	97	14
A37494	4	MALE	33.0	A	UNSCHEDULED	UNSCHEDULED DEATH	09/15/91	38	6
A37495	4	MALE	31.7	T	SCHEDULED	TERMINAL SACRIFICE	11/14/91	98	14
A37511	5	MALE	27.5	T	SCHEDULED	TERMINAL SACRIFICE	11/11/91	95	14
A37512	5	MALE	24.7	T	SCHEDULED	TERMINAL SACRIFICE	11/11/91	95	14
A37513	5	MALE	28.8	T	SCHEDULED	TERMINAL SACRIFICE	11/11/91	95	14
A37514	5	MALE	30.3	T	SCHEDULED	TERMINAL SACRIFICE	11/11/91	95	14
A37515	5	MALE	29.4	T	SCHEDULED	TERMINAL SACRIFICE	11/12/91	96	14
A37516	5	MALE	29.4	T	SCHEDULED	TERMINAL SACRIFICE	11/12/91	96	14
A37517	5	MALE	27.9	T	SCHEDULED	TERMINAL SACRIFICE	11/12/91	96	14
A37518	5	MALE	31.6	T	SCHEDULED	TERMINAL SACRIFICE	11/12/91	96	14
A37519	5	MALE	29.5	T	SCHEDULED	TERMINAL SACRIFICE	11/13/91	97	14
A37520	5	MALE	31.2	T	SCHEDULED	TERMINAL SACRIFICE	11/13/91	97	14
A37521	5	MALE	29.5	T	SCHEDULED	TERMINAL SACRIFICE	11/13/91	97	14
A37522	5	MALE	28.6	T	SCHEDULED	TERMINAL SACRIFICE	11/13/91	97	14
A37523	5	MALE	28.3	T	SCHEDULED	TERMINAL SACRIFICE	11/14/91	98	14
A37524	5	MALE	29.1	T	SCHEDULED	TERMINAL SACRIFICE	11/14/91	98	14
A37525	5	MALE	30.1	T	SCHEDULED	TERMINAL SACRIFICE	11/14/91	98	14
A37541	6	MALE	28.8	T	SCHEDULED	TERMINAL SACRIFICE	11/11/91	95	14
A37542	6	MALE	26.5	T	SCHEDULED	TERMINAL SACRIFICE	11/11/91	95	14
A37543	6	MALE	29.9	T	SCHEDULED	TERMINAL SACRIFICE	11/11/91	95	14

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APPENDIX 2A

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL DISPOSITION

STUDY NUMBER: 483287

ANIMAL NUMBER	DOSE GROUP	SEX	TERMINAL BODY WEIGHT	DEATH CODE	TYPE OF DEATH	DESCRIPTION OF DEATH	DATE OF DEATH	DAY OF STUDY	WEEK OF STUDY
A37544	6	MALE	27.5	T	SCHEDULED	TERMINAL SACRIFICE	11/11/91	95	14
A37545	6	MALE	28.4	T	SCHEDULED	TERMINAL SACRIFICE	11/12/91	96	14
A37546	6	MALE	26.1	T	SCHEDULED	TERMINAL SACRIFICE	11/12/91	96	14
A37547	6	MALE	29.6	T	SCHEDULED	TERMINAL SACRIFICE	11/12/91	96	14
A37548	6	MALE	27.9	T	SCHEDULED	TERMINAL SACRIFICE	11/12/91	96	14
A37549	6	MALE	26.5	T	SCHEDULED	TERMINAL SACRIFICE	11/13/91	97	14
A37550	6	MALE	22.0	T	SCHEDULED	TERMINAL SACRIFICE	11/13/91	97	14
A37551	6	MALE	27.0	T	SCHEDULED	TERMINAL SACRIFICE	11/13/91	97	14
A37552	6	MALE	24.1	T	SCHEDULED	TERMINAL SACRIFICE	11/13/91	97	14
A37553	6	MALE	27.6	T	SCHEDULED	TERMINAL SACRIFICE	11/14/91	98	14
A37554	6	MALE	24.7	T	SCHEDULED	TERMINAL SACRIFICE	11/14/91	98	14
A37555	6	MALE	25.5	T	SCHEDULED	TERMINAL SACRIFICE	11/14/91	98	14
A37571	7	MALE	25.8	T	SCHEDULED	TERMINAL SACRIFICE	11/11/91	95	14
A37572	7	MALE	26.4	T	SCHEDULED	TERMINAL SACRIFICE	11/11/91	95	14
A37573	7	MALE	23.2	T	SCHEDULED	TERMINAL SACRIFICE	11/11/91	95	14
A37574	7	MALE	24.6	T	SCHEDULED	TERMINAL SACRIFICE	11/11/91	95	14
A37575	7	MALE	28.4	T	SCHEDULED	TERMINAL SACRIFICE	11/12/91	96	14
A37576	7	MALE	30.3	T	SCHEDULED	TERMINAL SACRIFICE	11/12/91	96	14
A37577	7	MALE	14.0	D	UNSCHEDULED	UNSCHEDULED DEATH	08/17/91	9	2
A37578	7	MALE	27.8	T	SCHEDULED	TERMINAL SACRIFICE	11/12/91	96	14
A37579	7	MALE	20.0	M	UNSCHEDULED	UNSCHEDULED DEATH	08/24/91	16	3
A37580	7	MALE	26.3	T	SCHEDULED	TERMINAL SACRIFICE	11/12/91	96	14
A37581	7	MALE	23.0	T	SCHEDULED	TERMINAL SACRIFICE	11/13/91	97	14
A37582	7	MALE	26.9	T	SCHEDULED	TERMINAL SACRIFICE	11/13/91	97	14
A37583	7	MALE	30.4	T	SCHEDULED	TERMINAL SACRIFICE	11/13/91	97	14
A37584	7	MALE	27.2	T	SCHEDULED	TERMINAL SACRIFICE	11/13/91	97	14
A37585	7	MALE	29.1	T	SCHEDULED	TERMINAL SACRIFICE	11/14/91	98	14
A37406	1	FEMALE	23.6	T	SCHEDULED	TERMINAL SACRIFICE	11/11/91	95	14
A37407	1	FEMALE	24.5	T	SCHEDULED	TERMINAL SACRIFICE	11/11/91	95	14
A37408	1	FEMALE	25.9	T	SCHEDULED	TERMINAL SACRIFICE	11/11/91	95	14
A37409	1	FEMALE	21.8	T	SCHEDULED	TERMINAL SACRIFICE	11/11/91	95	14
A37410	1	FEMALE	25.4	T	SCHEDULED	TERMINAL SACRIFICE	11/12/91	96	14
A37411	1	FEMALE	24.1	T	SCHEDULED	TERMINAL SACRIFICE	11/12/91	96	14
A37412	1	FEMALE	23.2	T	SCHEDULED	TERMINAL SACRIFICE	11/12/91	96	14
A37413	1	FEMALE	23.7	T	SCHEDULED	TERMINAL SACRIFICE	11/12/91	96	14
A37414	1	FEMALE	20.4	T	SCHEDULED	TERMINAL SACRIFICE	11/13/91	97	14
A37415	1	FEMALE	25.5	T	SCHEDULED	TERMINAL SACRIFICE	11/13/91	97	14
A37416	1	FEMALE	25.5	T	SCHEDULED	TERMINAL SACRIFICE	11/13/91	97	14
A37417	1	FEMALE	22.5	T	SCHEDULED	TERMINAL SACRIFICE	11/13/91	97	14

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APPENDIX 2A

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL DISPOSITION

STUDY NUMBER: 483287

ANIMAL NUMBER	DOSE GROUP	SEX	TERMINAL BODY WEIGHT	DEATH CODE	TYPE OF DEATH	DESCRIPTION OF DEATH	DATE OF DEATH	DAY OF STUDY	WEEK OF STUDY
A37418	1	FEMALE	24.6	T	SCHEDULED	TERMINAL SACRIFICE	11/14/91	98	14
A37419	1	FEMALE	26.5	T	SCHEDULED	TERMINAL SACRIFICE	11/14/91	98	14
A37420	1	FEMALE	22.5	T	SCHEDULED	TERMINAL SACRIFICE	11/14/91	98	14
A37436	2	FEMALE	22.2	T	SCHEDULED	TERMINAL SACRIFICE	11/11/91	95	14
A37437	2	FEMALE	25.4	T	SCHEDULED	TERMINAL SACRIFICE	11/11/91	95	14
A37438	2	FEMALE	21.8	T	SCHEDULED	TERMINAL SACRIFICE	11/11/91	95	14
A37439	2	FEMALE	25.9	T	SCHEDULED	TERMINAL SACRIFICE	11/11/91	95	14
A37440	2	FEMALE	25.1	T	SCHEDULED	TERMINAL SACRIFICE	11/12/91	96	14
A37441	2	FEMALE	25.6	T	SCHEDULED	TERMINAL SACRIFICE	11/12/91	96	14
A37442	2	FEMALE	23.7	T	SCHEDULED	TERMINAL SACRIFICE	11/12/91	96	14
A37443	2	FEMALE	23.1	T	SCHEDULED	TERMINAL SACRIFICE	11/12/91	96	14
A37444	2	FEMALE	21.8	T	SCHEDULED	TERMINAL SACRIFICE	11/13/91	97	14
A37445	2	FEMALE	25.0	T	SCHEDULED	TERMINAL SACRIFICE	11/13/91	97	14
A37446	2	FEMALE	22.0	T	SCHEDULED	TERMINAL SACRIFICE	11/13/91	97	14
A37447	2	FEMALE	24.6	T	SCHEDULED	TERMINAL SACRIFICE	11/13/91	97	14
A37448	2	FEMALE	21.6	T	SCHEDULED	TERMINAL SACRIFICE	11/14/91	98	14
A37449	2	FEMALE	24.2	T	SCHEDULED	TERMINAL SACRIFICE	11/14/91	98	14
A37450	2	FEMALE	22.3	T	SCHEDULED	TERMINAL SACRIFICE	11/14/91	98	14
A37466	3	FEMALE	25.5	T	SCHEDULED	TERMINAL SACRIFICE	11/11/91	95	14
A37467	3	FEMALE	21.6	T	SCHEDULED	TERMINAL SACRIFICE	11/11/91	95	14
A37468	3	FEMALE	22.3	T	SCHEDULED	TERMINAL SACRIFICE	11/11/91	95	14
A37469	3	FEMALE	26.0	T	SCHEDULED	TERMINAL SACRIFICE	11/11/91	95	14
A37470	3	FEMALE	23.9	T	SCHEDULED	TERMINAL SACRIFICE	11/12/91	96	14
A37471	3	FEMALE	24.6	T	SCHEDULED	TERMINAL SACRIFICE	11/12/91	96	14
A37472	3	FEMALE	22.2	T	SCHEDULED	TERMINAL SACRIFICE	11/12/91	96	14
A37473	3	FEMALE	26.0	T	SCHEDULED	TERMINAL SACRIFICE	11/12/91	96	14
A37474	3	FEMALE	24.9	T	SCHEDULED	TERMINAL SACRIFICE	11/13/91	97	14
A37475	3	FEMALE	22.9	T	SCHEDULED	TERMINAL SACRIFICE	11/13/91	97	14
A37476	3	FEMALE	26.8	T	SCHEDULED	TERMINAL SACRIFICE	11/13/91	97	14
A37477	3	FEMALE	24.7	T	SCHEDULED	TERMINAL SACRIFICE	11/13/91	97	14
A37478	3	FEMALE	24.9	T	SCHEDULED	TERMINAL SACRIFICE	11/14/91	98	14
A37479	3	FEMALE	23.9	T	SCHEDULED	TERMINAL SACRIFICE	11/14/91	98	14
A37480	3	FEMALE	23.4	T	SCHEDULED	TERMINAL SACRIFICE	11/14/91	98	14
A37496	4	FEMALE	22.0	M	UNSCHEDULED	UNSCHEDULED DEATH	09/10/91	33	5
A37497	4	FEMALE	24.0	T	SCHEDULED	TERMINAL SACRIFICE	11/11/91	95	14
A37498	4	FEMALE	25.5	T	SCHEDULED	TERMINAL SACRIFICE	11/11/91	95	14
A37499	4	FEMALE	24.7	T	SCHEDULED	TERMINAL SACRIFICE	11/11/91	95	14
A37500	4	FEMALE	25.3	T	SCHEDULED	TERMINAL SACRIFICE	11/11/91	95	14
A37501	4	FEMALE	24.7	T	SCHEDULED	TERMINAL SACRIFICE	11/12/91	96	14

HAZLETON WASHINGTON, INC.
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APPENDIX 2A

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL DISPOSITION

STUDY NUMBER: 483287

ANIMAL NUMBER	DOSE GROUP	SEX	TERMINAL BODY WEIGHT	DEATH CODE	TYPE OF DEATH	DESCRIPTION OF DEATH	DATE OF DEATH	DAY OF STUDY	WEEK OF STUDY
A37502	4	FEMALE	23.8	T	SCHEDULED	TERMINAL SACRIFICE	11/12/91	96	14
A37503	4	FEMALE	24.7	T	SCHEDULED	TERMINAL SACRIFICE	11/12/91	96	14
A37504	4	FEMALE	23.0	T	SCHEDULED	TERMINAL SACRIFICE	11/12/91	96	14
A37505	4	FEMALE	23.1	T	SCHEDULED	TERMINAL SACRIFICE	11/13/91	97	14
A37506	4	FEMALE	24.6	T	SCHEDULED	TERMINAL SACRIFICE	11/13/91	97	14
A37507	4	FEMALE	27.9	T	SCHEDULED	TERMINAL SACRIFICE	11/13/91	97	14
A37508	4	FEMALE	25.0	T	SCHEDULED	TERMINAL SACRIFICE	11/13/91	97	14
A37509	4	FEMALE	24.1	T	SCHEDULED	TERMINAL SACRIFICE	11/14/91	98	14
A37510	4	FEMALE	24.8	T	SCHEDULED	TERMINAL SACRIFICE	11/14/91	98	14
A37526	5	FEMALE	22.0	T	SCHEDULED	TERMINAL SACRIFICE	11/11/91	95	14
A37527	5	FEMALE	28.2	T	SCHEDULED	TERMINAL SACRIFICE	11/11/91	95	14
A37528	5	FEMALE	27.8	T	SCHEDULED	TERMINAL SACRIFICE	11/11/91	95	14
A37529	5	FEMALE	24.0	T	SCHEDULED	TERMINAL SACRIFICE	11/11/91	95	14
A37530	5	FEMALE	26.9	T	SCHEDULED	TERMINAL SACRIFICE	11/12/91	96	14
A37531	5	FEMALE	26.5	T	SCHEDULED	TERMINAL SACRIFICE	11/12/91	96	14
A37532	5	FEMALE	23.4	T	SCHEDULED	TERMINAL SACRIFICE	11/12/91	96	14
A37533	5	FEMALE	20.3	T	SCHEDULED	TERMINAL SACRIFICE	11/12/91	96	14
A37534	5	FEMALE	27.7	T	SCHEDULED	TERMINAL SACRIFICE	11/13/91	97	14
A37535	5	FEMALE	24.1	T	SCHEDULED	TERMINAL SACRIFICE	11/13/91	97	14
A37536	5	FEMALE	25.6	T	SCHEDULED	TERMINAL SACRIFICE	11/13/91	97	14
A37537	5	FEMALE	24.7	T	SCHEDULED	TERMINAL SACRIFICE	11/13/91	97	14
A37538	5	FEMALE	26.7	T	SCHEDULED	TERMINAL SACRIFICE	11/14/91	98	14
A37539	5	FEMALE	25.5	T	SCHEDULED	TERMINAL SACRIFICE	11/14/91	98	14
A37540	5	FEMALE	22.0	T	SCHEDULED	TERMINAL SACRIFICE	11/14/91	98	14
A37556	6	FEMALE	22.5	T	SCHEDULED	TERMINAL SACRIFICE	11/11/91	95	14
A37557	6	FEMALE	24.6	T	SCHEDULED	TERMINAL SACRIFICE	11/11/91	95	14
A37558	6	FEMALE	22.3	T	SCHEDULED	TERMINAL SACRIFICE	11/11/91	95	14
A37559	6	FEMALE	21.4	T	SCHEDULED	TERMINAL SACRIFICE	11/11/91	95	14
A37560	6	FEMALE	22.4	T	SCHEDULED	TERMINAL SACRIFICE	11/12/91	96	14
A37561	6	FEMALE	22.2	T	SCHEDULED	TERMINAL SACRIFICE	11/12/91	96	14
A37562	6	FEMALE	24.6	T	SCHEDULED	TERMINAL SACRIFICE	11/12/91	96	14
A37563	6	FEMALE	22.8	T	SCHEDULED	TERMINAL SACRIFICE	11/12/91	96	14
A37564	6	FEMALE	25.1	T	SCHEDULED	TERMINAL SACRIFICE	11/13/91	97	14
A37565	6	FEMALE	23.8	T	SCHEDULED	TERMINAL SACRIFICE	11/13/91	97	14
A37566	6	FEMALE	23.5	T	SCHEDULED	TERMINAL SACRIFICE	11/13/91	97	14
A37567	6	FEMALE	27.6	T	SCHEDULED	TERMINAL SACRIFICE	11/13/91	97	14
A37568	6	FEMALE	23.7	T	SCHEDULED	TERMINAL SACRIFICE	11/14/91	98	14
A37569	6	FEMALE	22.7	T	SCHEDULED	TERMINAL SACRIFICE	11/14/91	98	14
A37570	6	FEMALE	21.6	T	SCHEDULED	TERMINAL SACRIFICE	11/14/91	98	14

HAZLETON WASHINGTON, INC.
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APPENDIX 2A

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL DISPOSITION

STUDY NUMBER: 483287

ANIMAL NUMBER	DOSE GROUP	SEX	TERMINAL BODY WEIGHT	DEATH CODE	TYPE OF DEATH	DESCRIPTION OF DEATH	DATE OF DEATH	DAY OF STUDY	WEEK OF STUDY
A37586	7	FEMALE	20.0	D	UNSCHEDULED	UNSCHEDULED DEATH	09/30/91	53	8
A37587	7	FEMALE	21.4	T	SCHEDULED	TERMINAL SACRIFICE	11/11/91	95	14
A37588	7	FEMALE	23.0	T	SCHEDULED	TERMINAL SACRIFICE	11/11/91	95	14
A37589	7	FEMALE	23.3	T	SCHEDULED	TERMINAL SACRIFICE	11/11/91	95	14
A37590	7	FEMALE	18.8	T	SCHEDULED	TERMINAL SACRIFICE	11/11/91	95	14
A37591	7	FEMALE	23.1	T	SCHEDULED	TERMINAL SACRIFICE	11/12/91	96	14
A37592	7	FEMALE	23.2	T	SCHEDULED	TERMINAL SACRIFICE	11/12/91	96	14
A37593	7	FEMALE	21.3	T	SCHEDULED	TERMINAL SACRIFICE	11/12/91	96	14
A37594	7	FEMALE	22.9	T	SCHEDULED	TERMINAL SACRIFICE	11/12/91	96	14
A37595	7	FEMALE	22.1	T	SCHEDULED	TERMINAL SACRIFICE	11/13/91	97	14
A37596	7	FEMALE	18.8	T	SCHEDULED	TERMINAL SACRIFICE	11/13/91	97	14
A37597	7	FEMALE	23.9	T	SCHEDULED	TERMINAL SACRIFICE	11/13/91	97	14
A37598	7	FEMALE	21.4	T	SCHEDULED	TERMINAL SACRIFICE	11/13/91	97	14
A37599	7	FEMALE	23.8	T	SCHEDULED	TERMINAL SACRIFICE	11/14/91	98	14
A37600	7	FEMALE	22.0	T	SCHEDULED	TERMINAL SACRIFICE	11/14/91	98	14

Appendix 2B
Individual Animal Disposition - Satellite Study
13-Week Subchronic Oral Toxicity Study of Triclosan in CD-1[®] Mice

NOTE: Due to computer limitations, Groups 1-4 correspond to Groups 8-11, respectively.

KEY: P = Animals sacrificed after the pre-initiation bleed.
1 = Scheduled sacrifice for the Satellite Study animals.

HAZLETON WASHINGTON, INC.
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APPENDIX 28

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY IN TRICLOSAM IN CD-1
MICE. (SATELLITE-GROUPS 8-11)
INDIVIDUAL ANIMAL DISPOSITION

STUDY NUMBER: 483287

ANIMAL NUMBER	DOSE GROUP	SEX	TERMINAL BODY WEIGHT	DEATH CODE	TYPE OF DEATH	DESCRIPTION OF DEATH	DATE OF DEATH	DAY OF STUDY	WEEK OF STUDY
A37601	1	MALE	24.9	1	SCHEDULED	FIRST INTERIM SACRIFICE	09/23/91	46	7
A37602	1	MALE	25.3	1	SCHEDULED	FIRST INTERIM SACRIFICE	09/23/91	46	7
A37603	1	MALE	25.3	1	SCHEDULED	FIRST INTERIM SACRIFICE	09/23/91	46	7
A37604	1	MALE	26.4	1	SCHEDULED	FIRST INTERIM SACRIFICE	09/23/91	46	7
A37605	1	MALE	25.5	1	SCHEDULED	FIRST INTERIM SACRIFICE	09/23/91	46	7
A37606	1	MALE	26.1	1	SCHEDULED	FIRST INTERIM SACRIFICE	09/24/91	47	7
A37607	1	MALE	29.8	1	SCHEDULED	FIRST INTERIM SACRIFICE	09/24/91	47	7
A37608	1	MALE	25.9	1	SCHEDULED	FIRST INTERIM SACRIFICE	09/24/91	47	7
A37609	1	MALE	26.6	1	SCHEDULED	FIRST INTERIM SACRIFICE	09/24/91	47	7
A37610	1	MALE	27.2	1	SCHEDULED	FIRST INTERIM SACRIFICE	09/24/91	47	7
A37611	1	MALE	22.0	P	UNSCHEDULED	UNSCHEDULED DEATH	08/09/91	1	1
A37612	1	MALE	25.0	P	UNSCHEDULED	UNSCHEDULED DEATH	08/09/91	1	1
A37613	1	MALE	25.0	P	UNSCHEDULED	UNSCHEDULED DEATH	08/09/91	1	1
A37614	1	MALE	23.0	P	UNSCHEDULED	UNSCHEDULED DEATH	08/09/91	1	1
A37615	1	MALE	27.0	P	UNSCHEDULED	UNSCHEDULED DEATH	08/09/91	1	1
A37616	1	MALE	26.0	P	UNSCHEDULED	UNSCHEDULED DEATH	08/09/91	1	1
A37617	1	MALE	27.0	P	UNSCHEDULED	UNSCHEDULED DEATH	08/09/91	1	1
A37618	1	MALE	25.0	P	UNSCHEDULED	UNSCHEDULED DEATH	08/09/91	1	1
A37619	1	MALE	27.0	P	UNSCHEDULED	UNSCHEDULED DEATH	08/09/91	1	1
A37620	1	MALE	25.0	P	UNSCHEDULED	UNSCHEDULED DEATH	08/09/91	1	1
A37641	2	MALE	26.5	1	SCHEDULED	FIRST INTERIM SACRIFICE	09/23/91	46	7
A37642	2	MALE	25.2	1	SCHEDULED	FIRST INTERIM SACRIFICE	09/23/91	46	7
A37643	2	MALE	24.1	1	SCHEDULED	FIRST INTERIM SACRIFICE	09/23/91	46	7
A37644	2	MALE	28.8	1	SCHEDULED	FIRST INTERIM SACRIFICE	09/23/91	46	7
A37645	2	MALE	22.2	1	SCHEDULED	FIRST INTERIM SACRIFICE	09/23/91	46	7
A37646	2	MALE	27.1	1	SCHEDULED	FIRST INTERIM SACRIFICE	09/24/91	47	7
A37647	2	MALE	25.4	1	SCHEDULED	FIRST INTERIM SACRIFICE	09/24/91	47	7
A37648	2	MALE	26.6	1	SCHEDULED	FIRST INTERIM SACRIFICE	09/24/91	47	7
A37649	2	MALE	27.0	1	SCHEDULED	FIRST INTERIM SACRIFICE	09/24/91	47	7
A37650	2	MALE	26.4	1	SCHEDULED	FIRST INTERIM SACRIFICE	09/24/91	47	7
A37661	3	MALE	27.0	1	SCHEDULED	FIRST INTERIM SACRIFICE	09/23/91	46	7
A37662	3	MALE	27.1	1	SCHEDULED	FIRST INTERIM SACRIFICE	09/23/91	46	7
A37663	3	MALE	27.7	1	SCHEDULED	FIRST INTERIM SACRIFICE	09/23/91	46	7
A37664	3	MALE	25.8	1	SCHEDULED	FIRST INTERIM SACRIFICE	09/23/91	46	7
A37665	3	MALE	29.0	1	SCHEDULED	FIRST INTERIM SACRIFICE	09/23/91	46	7
A37666	3	MALE	27.1	1	SCHEDULED	FIRST INTERIM SACRIFICE	09/24/91	47	7
A37667	3	MALE	27.6	1	SCHEDULED	FIRST INTERIM SACRIFICE	09/24/91	47	7
A37668	3	MALE	28.5	1	SCHEDULED	FIRST INTERIM SACRIFICE	09/24/91	47	7
A37669	3	MALE	23.6	1	SCHEDULED	FIRST INTERIM SACRIFICE	09/24/91	47	7

HAZLETON WASHINGTON, INC.
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APPENDIX 2B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY IN TRICLOSAN IN CD-1
MICE. (SATELLITE-GROUPS 8-11)
INDIVIDUAL ANIMAL DISPOSITION

STUDY NUMBER: 483287

ANIMAL NUMBER	DOSE GROUP	SEX	TERMINAL BODY WEIGHT	DEATH CODE	TYPE OF DEATH	DESCRIPTION OF DEATH	DATE OF DEATH	DAY OF STUDY	WEEK OF STUDY
A37670	3	MALE	25.4	1	SCHEDULED	FIRST INTERIM SACRIFICE	09/24/91	47	7
A37681	4	MALE	22.2	1	SCHEDULED	FIRST INTERIM SACRIFICE	09/23/91	46	7
A37682	4	MALE	21.4	1	SCHEDULED	FIRST INTERIM SACRIFICE	09/23/91	46	7
A37683	4	MALE	24.4	1	SCHEDULED	FIRST INTERIM SACRIFICE	09/23/91	46	7
A37684	4	MALE	22.5	1	SCHEDULED	FIRST INTERIM SACRIFICE	09/23/91	46	7
A37685	4	MALE	22.2	1	SCHEDULED	FIRST INTERIM SACRIFICE	09/23/91	46	7
A37686	4	MALE	27.6	1	SCHEDULED	FIRST INTERIM SACRIFICE	09/24/91	47	7
A37687	4	MALE	25.2	1	SCHEDULED	FIRST INTERIM SACRIFICE	09/24/91	47	7
A37688	4	MALE	23.8	1	SCHEDULED	FIRST INTERIM SACRIFICE	09/24/91	47	7
A37689	4	MALE	23.5	1	SCHEDULED	FIRST INTERIM SACRIFICE	09/24/91	47	7
A37690	4	MALE	27.4	1	SCHEDULED	FIRST INTERIM SACRIFICE	09/24/91	47	7
A37621	1	FEMALE	22.3	1	SCHEDULED	FIRST INTERIM SACRIFICE	09/23/91	46	7
A37622	1	FEMALE	19.2	1	SCHEDULED	FIRST INTERIM SACRIFICE	09/23/91	46	7
A37623	1	FEMALE	22.4	1	SCHEDULED	FIRST INTERIM SACRIFICE	09/23/91	46	7
A37624	1	FEMALE	23.6	1	SCHEDULED	FIRST INTERIM SACRIFICE	09/23/91	46	7
A37625	1	FEMALE	19.7	1	SCHEDULED	FIRST INTERIM SACRIFICE	09/23/91	46	7
A37626	1	FEMALE	22.0	1	SCHEDULED	FIRST INTERIM SACRIFICE	09/24/91	47	7
A37627	1	FEMALE	21.9	1	SCHEDULED	FIRST INTERIM SACRIFICE	09/24/91	47	7
A37628	1	FEMALE	22.2	1	SCHEDULED	FIRST INTERIM SACRIFICE	09/24/91	47	7
A37629	1	FEMALE	22.6	1	SCHEDULED	FIRST INTERIM SACRIFICE	09/24/91	47	7
A37630	1	FEMALE	23.6	1	SCHEDULED	FIRST INTERIM SACRIFICE	09/24/91	47	7
A37631	1	FEMALE	22.0	P	UNSCHEDULED	UNSCHEDULED DEATH	08/09/91	1	1
A37632	1	FEMALE	20.0	P	UNSCHEDULED	UNSCHEDULED DEATH	08/09/91	1	1
A37633	1	FEMALE	22.0	P	UNSCHEDULED	UNSCHEDULED DEATH	08/09/91	1	1
A37634	1	FEMALE	20.0	P	UNSCHEDULED	UNSCHEDULED DEATH	08/09/91	1	1
A37635	1	FEMALE	20.0	P	UNSCHEDULED	UNSCHEDULED DEATH	08/09/91	1	1
A37636	1	FEMALE	21.0	P	UNSCHEDULED	UNSCHEDULED DEATH	08/09/91	1	1
A37637	1	FEMALE	18.0	P	UNSCHEDULED	UNSCHEDULED DEATH	08/09/91	1	1
A37638	1	FEMALE	22.0	P	UNSCHEDULED	UNSCHEDULED DEATH	08/09/91	1	1
A37639	1	FEMALE	21.0	P	UNSCHEDULED	UNSCHEDULED DEATH	08/09/91	1	1
A37640	1	FEMALE	20.0	P	UNSCHEDULED	UNSCHEDULED DEATH	08/09/91	1	1
A37651	2	FEMALE	22.5	1	SCHEDULED	FIRST INTERIM SACRIFICE	09/23/91	46	7
A37652	2	FEMALE	21.1	1	SCHEDULED	FIRST INTERIM SACRIFICE	09/23/91	46	7
A37653	2	FEMALE	21.8	1	SCHEDULED	FIRST INTERIM SACRIFICE	09/23/91	46	7
A37654	2	FEMALE	21.3	1	SCHEDULED	FIRST INTERIM SACRIFICE	09/23/91	46	7
A37655	2	FEMALE	23.3	1	SCHEDULED	FIRST INTERIM SACRIFICE	09/23/91	46	7
A37656	2	FEMALE	19.9	1	SCHEDULED	FIRST INTERIM SACRIFICE	09/24/91	47	7
A37657	2	FEMALE	19.9	1	SCHEDULED	FIRST INTERIM SACRIFICE	09/24/91	47	7
A37658	2	FEMALE	22.0	1	SCHEDULED	FIRST INTERIM SACRIFICE	09/24/91	47	7

HAZLETON WASHINGTON, INC.
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APPENDIX 28

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY IN TRICLOSAN IN CD-1
MICE. (SATELLITE-GROUPS 8-11)
INDIVIDUAL ANIMAL DISPOSITION

STUDY NUMBER: 483287

ANIMAL NUMBER	DOSE GROUP	SEX	TERMINAL BODY WEIGHT	DEATH CODE	TYPE OF DEATH	DESCRIPTION OF DEATH	DATE OF DEATH	DAY OF STUDY	WEEK OF STUDY
A37659	2	FEMALE	20.6	1	SCHEDULED	FIRST INTERIM SACRIFICE	09/24/91	47	7
A37660	2	FEMALE	21.4	1	SCHEDULED	FIRST INTERIM SACRIFICE	09/24/91	47	7
A37671	3	FEMALE	21.2	1	SCHEDULED	FIRST INTERIM SACRIFICE	09/23/91	46	7
A37672	3	FEMALE	23.4	1	SCHEDULED	FIRST INTERIM SACRIFICE	09/23/91	46	7
A37673	3	FEMALE	23.0	1	SCHEDULED	FIRST INTERIM SACRIFICE	09/23/91	46	7
A37674	3	FEMALE	23.7	1	SCHEDULED	FIRST INTERIM SACRIFICE	09/23/91	46	7
A37675	3	FEMALE	22.2	1	SCHEDULED	FIRST INTERIM SACRIFICE	09/23/91	46	7
A37676	3	FEMALE	23.5	1	SCHEDULED	FIRST INTERIM SACRIFICE	09/24/91	47	7
A37677	3	FEMALE	22.2	1	SCHEDULED	FIRST INTERIM SACRIFICE	09/24/91	47	7
A37678	3	FEMALE	23.3	1	SCHEDULED	FIRST INTERIM SACRIFICE	09/24/91	47	7
A37679	3	FEMALE	25.0	1	SCHEDULED	FIRST INTERIM SACRIFICE	09/24/91	47	7
A37680	3	FEMALE	24.0	1	SCHEDULED	FIRST INTERIM SACRIFICE	09/24/91	47	7
A37691	4	FEMALE	21.0	1	SCHEDULED	FIRST INTERIM SACRIFICE	09/23/91	46	7
A37692	4	FEMALE	21.2	1	SCHEDULED	FIRST INTERIM SACRIFICE	09/23/91	46	7
A37693	4	FEMALE	20.3	1	SCHEDULED	FIRST INTERIM SACRIFICE	09/23/91	46	7
A37694	4	FEMALE	21.2	1	SCHEDULED	FIRST INTERIM SACRIFICE	09/23/91	46	7
A37695	4	FEMALE	22.2	1	SCHEDULED	FIRST INTERIM SACRIFICE	09/23/91	46	7
A37696	4	FEMALE	23.3	1	SCHEDULED	FIRST INTERIM SACRIFICE	09/24/91	47	7
A37697	4	FEMALE	21.6	1	SCHEDULED	FIRST INTERIM SACRIFICE	09/24/91	47	7
A37698	4	FEMALE	24.9	1	SCHEDULED	FIRST INTERIM SACRIFICE	09/24/91	47	7
A37699	4	FEMALE	23.4	1	SCHEDULED	FIRST INTERIM SACRIFICE	09/24/91	47	7
A37700	4	FEMALE	19.9	1	SCHEDULED	FIRST INTERIM SACRIFICE	09/24/91	47	7

Appendix 3A
Individual Clinical Observations - Weekly
Clinical Observations (Main Study)
13-Week Subchronic Oral Toxicity Study of Triclosan in CD-1[®] Mice

Key to Animal Death Codes

T = Terminal Sacrifice
M = Moribund Sacrifice

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 3A

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL CLINICAL OBSERVATIONS

STUDY NUMBER: 483287

ANIMAL DEATH WK OF CATEGORY GROUP: M1 DOSE: 0 MG/KG/DAY
NUMBER CODE DEATH KEYWORD WEEKS 1-14 - OBSERVED DURING EACH SCHEDULED WEEK
QUALIFIER

A37391	T	14	SKIN/PELAGE	
			ALOPECIA	
			SACRAL-LEFT	7-14
			SORE(S)	
			SACRAL-LEFT	13-14
			EARS-BOTH	13-14
			EAR-LEFT	7-12
A37392	T	14	SKIN/PELAGE	
			SORE(S)	
			EAR-LEFT	8
A37401	T	14	SKIN/PELAGE	
			SORE(S)	
			EAR-LEFT	10-11
A37404	T	14	SKIN/PELAGE	
			ALOPECIA	
			DORSAL-CERVICAL	5-10
			SORE(S)	
			DORSAL-CERVICAL	5-11
			EAR-RIGHT	8-14

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HAZLETON WASHINGTON, INC.
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APPENDIX 3A

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL CLINICAL OBSERVATIONS

STUDY NUMBER: 483287

ANIMAL NUMBER	DEATH CODE	WK OF DEATH	CATEGORY KEYWORD QUALIFIER	GROUP: M2	DOSE: 25 MG/KG/DAY	WEEKS 1-14 - OBSERVED DURING EACH SCHEDULED WEEK
A37430	T	14	SKIN/PELAGE SORE(S) EAR-LEFT			12-14

HAZLETON WASHINGTON, INC.
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APPENDIX 3A

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL CLINICAL OBSERVATIONS

STUDY NUMBER: 483287

ANIMAL NUMBER	DEATH CODE	WK OF DEATH	CATEGORY KEYWORD QUALIFIER	GROUP: M3	DOSE: 75 MG/KG/DAY	WEEKS 1-14 - OBSERVED DURING EACH SCHEDULED WEEK
A37454	T	14	SKIN/PELAGE SORE(S) EAR-LEFT			5-7

PATLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 3A

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL CLINICAL OBSERVATIONS

STUDY NUMBER: 483287

ANIMAL NUMBER	DEATH CODE	WK OF DEATH	CATEGORY KEYWORD QUALIFIER	GROUP: M4	DOSE: 200 MG/KG/DAY	WEEKS 1-14 - OBSERVED DURING EACH SCHEDULED WEEK
A37485	T	14	SKIN/PELAGE SORE(S) EAR-RIGHT			6-10
A37491	T	14	SKIN/PELAGE SORE(S) DORSAL-CERVICAL EARS-BOTH EAR-RIGHT			12-14 8-14 5-7

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HAZLETON WASHINGTON, INC.
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APPENDIX 3A

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL CLINICAL OBSERVATIONS

STUDY NUMBER: 483287

ANIMAL NUMBER	DEATH CODE	WK OF DEATH	CATEGORY KEYWORD QUALIFIER	GROUP: M5	DOSE: 350 MG/KG/DAY	WEEKS 1-14 - OBSERVED DURING EACH SCHEDULED WEEK
A37513	T	14	SKIN/PELAGE SORE(S) EAR-RIGHT			13-14
A37517	T	14	SKIN/PELAGE ALOPECIA DORSAL-CERVICAL SHOULDER-LEFT SORE(S) DORSAL-CERVICAL SHOULDER-LEFT EARS-BOTH EAR-LEFT			5-11 8 5-11 8-10 6-8 5
A37518	T	14	SKIN/PELAGE SORE(S) EAR-RIGHT			5-7, 10-12
A37523	T	14	SKIN/PELAGE SORE(S) EAR-LEFT			10-12

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HAZLETON WASHINGTON, INC.
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APPENDIX 3A

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL CLINICAL OBSERVATIONS

STUDY NUMBER: 483287

ANIMAL NUMBER	DEATH CODE	WK OF DEATH	CATEGORY KEYWORD QUALIFIER	GROUP: M7	DOSE: 900 MG/KG/DAY	WEEKS 1-14 - OBSERVED DURING EACH SCHEDULED WEEK
A37573	T	14	SKIN/PELAGE ALOPECIA PERINEAL AREA SORE(S) PERINEAL AREA			10 10-11
A37579	M	3	APPEARANCE PALE ENTIRE BODY			3
			SKIN/PELAGE ALOPECIA SACRAL-LEFT URINE STAINS			3 3
A37582	T	14	APPEARANCE HUNCHED POSTURE PALE ENTIRE BODY BEHAVIOR HYPOACTIVE			3-4 3-4 3

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HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 3A

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL CLINICAL OBSERVATIONS

STUDY NUMBER: 483287

ANIMAL DEATH WK OF NUMBER CODE DEATH	CATEGORY KEYWORD QUALIFIER	GROUP: F4	DOSE: 200 MG/KG/DAY	WEEKS 1-14 - OBSERVED DURING EACH SCHEDULED WEEK
A37501 T 14	SKIN/PELAGE SORE(S) EAR-RIGHT			12-14

HAZLETON WASHINGTON, INC.
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APPENDIX 3A

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL CLINICAL OBSERVATIONS

STUDY NUMBER: 483287

ANIMAL DEATH WK OF	CATEGORY	GROUP: F6	DOSE: 750 MG/KG/DAY	WEEKS 1-14 - OBSERVED DURING EACH SCHEDULED WEEK
NUMBER CODE DEATH	KEYWORD QUALIFIER			
A37559 T 14	APPEARANCE			
	HUNCHED POSTURE			4-6
	BEHAVIOR			
	HYPOACTIVE			4-6

HAZLETON WASHINGTON, INC.
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APPENDIX 3A

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL CLINICAL OBSERVATIONS

STUDY NUMBER: 483287

ANIMAL NUMBER	DEATH CODE	WK OF DEATH	CATEGORY KEYWORD QUALIFIER	GROUP: F7	DOSE: 900 MG/KG/DAY	WEEKS 1-14 - OBSERVED DURING EACH SCHEDULED WEEK
A37590	T	14	BEHAVIOR HYPOACTIVE			13
A37592	T	14	APPEARANCE HUNCHED POSTURE PALE ENTIRE BODY THIN			3 3 3
			BEHAVIOR HYPOACTIVE			3, 5-6, 14
			RESPIRATION DYSPNEA			3
A37596	T	14	APPEARANCE PALE ENTIRE BODY			14
			BEHAVIOR HYPOACTIVE			12, 14
A37597	T	14	APPEARANCE HUNCHED POSTURE			5-6
			BEHAVIOR HYPOACTIVE			5-6
A37600	T	14	SKIN/PELAGE SORE(S) TAIL-DISTAL			14

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Appendix 3B
Individual Clinical Observations - Weekly
Clinical Observations (Satellite Study)
13-Week Subchronic Oral Toxicity Study of Triclosan in CD-1[®] Mice

NOTE: Due to computer limitations, Groups 1-4 correspond to Groups 8-11, respectively.

Key to Animal Death Codes

1 = Interim Sacrifice

HAZLETON WASHINGTON, INC.
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APPENDIX 3B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY IN TRICLOSAN IN CD-1
MICE. (SATELLITE-GROUPS 8-11)
INDIVIDUAL CLINICAL OBSERVATIONS

STUDY NUMBER: 483287

ANIMAL NUMBER	DEATH CODE	WK OF DEATH	CATEGORY KEYWORD QUALIFIER	GROUP: M1	DOSE: 0 MG/KG/DAY	WEEKS 1-7 - OBSERVED DURING EACH SCHEDULED WEEK
A37608	1	7	SKIN/PELAGE SCORE(S) EAR-RIGHT			7

HAZLETON WASHINGTON, INC.
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APPENDIX 3B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY IN TRICLOSAN IN CD-1
MICE. (SATELLITE-GROUPS 8-11)
INDIVIDUAL CLINICAL OBSERVATIONS

STUDY NUMBER: 483287

ANIMAL NUMBER	DEATH CODE	WK OF DEATH	CATEGORY KEYWORD QUALIFIER	GROUP: M3	DOSE: 350 MG/KG/DAY	WEEKS 1-7 - OBSERVED DURING EACH SCHEDULED WEEK
A37661	1	7	SKIN/PELAGE SORE(S) EAR-LEFT			7

HAZLETON WASHINGTON, INC.
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APPENDIX 3B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY IN TRICLOSAN IN CD-1
MICE. (SATELLITE-GROUPS 8-11)
INDIVIDUAL CLINICAL OBSERVATIONS

STUDY NUMBER: 483287

ANIMAL NUMBER	DEATH CODE	WK OF DEATH	CATEGORY KEYWORD QUALIFIER	GROUP: M4	DOSE: 900 MG/KG/DAY	WEEKS 1-7 - OBSERVED DURING EACH SCHEDULED WEEK
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A37682	1	7	APPEARANCE HUNCHED POSTURE			
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HAZLETON WASHINGTON, INC.
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APPENDIX 3B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY IN TRICLOSAN IN CD-1
MICE. (SATELLITE-GROUPS 8-11)
INDIVIDUAL CLINICAL OBSERVATIONS

STUDY NUMBER: 483287

ANIMAL NUMBER	DEATH CODE	WK OF DEATH	CATEGORY KEYWORD QUALIFIER	GROUP: F3	DOSE: 350 MG/KG/DAY	WEEKS 1-7 - OBSERVED DURING EACH SCHEDULED WEEK
A37678	1	7	SKIN/PELAGE ALOPECIA SHOULDER-RIGHT			

2

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Appendix 4A
Individual Clinical Observations - Daily
Cageside Observations (Main Study)
13-Week Subchronic Oral Toxicity Study of Triclosan in CD-1[®] Mice

Key to Animal Death Codes

T = Terminal Sacrifice
M = Moribund Sacrifice
D = Found Dead

HAZLETON WASHINGTON, INC.
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APPENDIX 4A

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL CLINICAL OBSERVATIONS

STUDY NUMBER: 483287

ANIMAL NUMBER	DEATH CODE	WK OF DEATH	CATEGORY KEYWORD QUALIFIER	GROUP: M4	DOSE: 200 MG/KG/DAY	WEEKS 1-14 - OBSERVED DURING EACH SCHEDULED WEEK
A37489	T	14	APPEARANCE HUNCHED POSTURE			2
			BEHAVIOR HYPOACTIVE			2
			EXCRETION FEW FECES			2

HAZLETON WASHINGTON, INC.
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APPENDIX 4A

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL CLINICAL OBSERVATIONS

STUDY NUMBER: 483287

ANIMAL NUMBER	DEATH CODE	WK OF DEATH	CATEGORY KEYWORD QUALIFIER	GROUP: M6	DOSE: 750 MG/KG/DAY	WEEKS 1-14 - OBSERVED DURING EACH SCHEDULED WEEK
A37555	T	14	APPEARANCE			
			HUNCHED POSTURE			2
			THIN			2
			BEHAVIOR			
			HYPOACTIVE			2

HAZLETON WASHINGTON, INC.
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APPENDIX 4A

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL CLINICAL OBSERVATIONS

STUDY NUMBER: 483287

ANIMAL NUMBER	DEATH CODE	WK OF DEATH	CATEGORY KEYWORD QUALIFIER	GROUP: M7	DOSE: 900 MG/KG/DAY	WEEKS 1-14 - OBSERVED DURING EACH SCHEDULED WEEK
A37577	D	2	APPEARANCE HUNCHED POSTURE PALE ENTIRE BODY THIN			2 2 2
			BEHAVIOR HYPOACTIVE			2
A37579	M	3	APPEARANCE PALE ENTIRE BODY THIN			2-3 2
			BEHAVIOR PROSTRATE			3
			RESPIRATION DYSPNEA			3
			SKIN/PELAGE ALOPECIA SACRAL-LEFT URINE STAINS			2-3 2-3
A37582	T	14	APPEARANCE HUNCHED POSTURE PALE ENTIRE BODY THIN			2-3 2-3 2-3
			BEHAVIOR HYPOACTIVE			2-3

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HAZLETON WASHINGTON, INC.
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APPENDIX 4A

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL CLINICAL OBSERVATIONS

STUDY NUMBER: 483287

ANIMAL DEATH WK OF CATEGORY GROUP: F4 DOSE: 200 MG/KG/DAY
NUMBER CODE DEATH KEYWORD QUALIFIER WEEKS 1-14 - OBSERVED DURING EACH SCHEDULED WEEK

A37496 M 5 APPEARANCE
LIMITED USE
LIMBS-HIND
SKIN/PELAGE
URINE STAINS

5

5

HAZLETON WASHINGTON, INC.
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APPENDIX 4A

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL CLINICAL OBSERVATIONS

STUDY NUMBER: 483287

ANIMAL NUMBER	DEATH CODE	WK OF DEATH	CATEGORY KEYWORD QUALIFIER	GROUP: F6	DOSE: 750 MG/KG/DAY	WEEKS 1-14 - OBSERVED DURING EACH SCHEDULED WEEK
A37559	T	14	APPEARANCE HUNCHED POSTURE			4
			BEHAVIOR HYPOACTIVE			4

HAZLETON WASHINGTON, INC.
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APPENDIX 4A

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL CLINICAL OBSERVATIONS

STUDY NUMBER: 483287

ANIMAL NUMBER	DEATH CODE	WK OF DEATH	CATEGORY KEYWORD QUALIFIER	GROUP: F7	DOSE: 900 MG/KG/DAY	WEEKS 1-14 - OBSERVED DURING EACH SCHEDULED WEEK
A37590	T	14	BEHAVIOR HYPOACTIVE			12-13
			EXCRETION FEW FECES			12-13
A37592	T	14	APPEARANCE HUNCHED POSTURE			2-3
			PALE			2-3
			ENTIRE BODY			2-3
			THIN			2-3
			BEHAVIOR HYPOACTIVE			2-3, 13-14
			EXCRETION FEW FECES			3
A37596	T	14	APPEARANCE PALE			14
			ENTIRE BODY			14
			BEHAVIOR HYPOACTIVE			13-14
A37597	T	14	APPEARANCE HUNCHED POSTURE			4
			BEHAVIOR HYPOACTIVE			4

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HAZLETON WASHINGTON, INC.
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APPENDIX 4A

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL CLINICAL OBSERVATIONS

STUDY NUMBER: 483287

ANIMAL NUMBER	DEATH CODE	WK OF DEATH	CATEGORY KEYWORD QUALIFIER	GROUP: F7	DOSE: 900 MG/KG/DAY	WEEKS 1-14 - OBSERVED DURING EACH SCHEDULED WEEK
A37598	T	14	APPEARANCE COLD TO TOUCH			12
			BEHAVIOR HYPOACTIVE			12

Appendix 4B
Individual Clinical Observations - Daily
Cageside Observations (Satellite Study)
13-Week Subchronic Oral Toxicity Study of Triclosan in CD-1[®] Mice

NOTE: Due to computer limitations, Groups 1-4 correspond to Groups 8-11, respectively.

Key to Animal Death Codes

1 = Interim Sacrifice

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 4B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY IN TRICLOSAN IN CD-1
MICE. (SATELLITE-GROUPS 8-11)
INDIVIDUAL CLINICAL OBSERVATIONS

STUDY NUMBER: 483287

ANIMAL NUMBER	DEATH CODE	WK OF DEATH	CATEGORY KEYWORD QUALIFIER	GROUP: F4	DOSE: 900 MG/KG/DAY	WEEK 7 - OBSERVED DURING EACH SCHEDULED WEEK
A37695	1	7	APPEARANCE			
			HUNCHED POSTURE			7
			BEHAVIOR			
			HYPOACTIVE			7

Appendix 5A
Individual Body Weights - Main Study
13-Week Subchronic Oral Toxicity Study of Triclosan in CD-1[®] Mice

NOTE: Due to computer limitations, pretreatment values actually represent Week -1.

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 5A

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (PRETREATMENT-GROUPS 1-7)
INDIVIDUAL BODY WEIGHTS (G)

STUDY NUMBER: 483287A

ANIMAL
NUMBER

WEEK
1

GROUP: MALE 1 - 0 MG/KG/DAY

A37391	25
A37392	24
A37393	25
A37394	25
A37395	23
A37396	23
A37397	26
A37398	27
A37399	24
A37400	24
A37401	26
A37402	24
A37403	26
A37404	24
A37405	24

GROUP: MALE 2 - 25 MG/KG/DAY

A37421	27
A37422	23
A37423	23
A37424	26
A37425	25
A37426	23
A37427	23
A37428	24
A37429	26
A37430	23
A37431	27
A37432	23
A37433	23
A37434	22
A37435	27

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HAZLETON WASHINGTON, INC.
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APPENDIX 5A

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (PRETREATMENT-GROUPS 1-7)
INDIVIDUAL BODY WEIGHTS (G)

STUDY NUMBER: 483287A

ANIMAL
NUMBER

WEEK
1

GROUP: MALE 3 - 75 MG/KG/DAY

A37451	23
A37452	26
A37453	25
A37454	23
A37455	23
A37456	27
A37457	25
A37458	26
A37459	25
A37460	24
A37461	27
A37462	25
A37463	23
A37464	24
A37465	26

GROUP: MALE 4 - 200 MG/KG/DAY

A37481	25
A37482	25
A37483	25
A37484	26
A37485	24
A37486	24
A37487	26
A37488	24
A37489	25
A37490	26
A37491	24
A37492	25
A37493	25
A37494	27
A37495	27

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HAZLETON WASHINGTON, INC.
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APPENDIX 5A

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (PRETREATMENT-GROUPS 1-7)
INDIVIDUAL BODY WEIGHTS (G)

STUDY NUMBER: 483287A

ANIMAL
NUMBER

WEEK
1

GROUP: MALE 5 - 350 MG/KG/DAY

A37511	25
A37512	23
A37513	25
A37514	26
A37515	26
A37516	26
A37517	24
A37518	25
A37519	23
A37520	26
A37521	26
A37522	26
A37523	23
A37524	25
A37525	25

GROUP: MALE 6 - 750 MG/KG/DAY

A37541	25
A37542	26
A37543	26
A37544	25
A37545	23
A37546	27
A37547	28
A37548	25
A37549	25
A37550	25
A37551	25
A37552	24
A37553	25
A37554	24
A37555	25

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APPENDIX 5A

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (PRETREATMENT-GROUPS 1-7)
INDIVIDUAL BODY WEIGHTS (G)

STUDY NUMBER: 483287A

ANIMAL WEEK
NUMBER 1

GROUP: MALE 7 - 900 MG/KG/DAY

A37571	23
A37572	24
A37573	24
A37574	26
A37575	25
A37576	24
A37577	23
A37578	28
A37579	24
A37580	25
A37581	24
A37582	24
A37583	26
A37584	26
A37585	26

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GROUP: FEMALE 1 - 0 MG/KG/DAY

A37406	20
A37407	21
A37408	21
A37409	19
A37410	21
A37411	20
A37412	21
A37413	20
A37414	18
A37415	21
A37416	20
A37417	21
A37418	19
A37419	21
A37420	20

HAZLETON WASHINGTON, INC.
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APPENDIX 5A

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (PRETREATMENT-GROUPS 1-7)
INDIVIDUAL BODY WEIGHTS (G)

STUDY NUMBER: 483287A

ANIMAL
NUMBER

WEEK
1

GROUP: FEMALE 2 - 25 MG/KG/DAY

A37436	20
A37437	21
A37438	20
A37439	21
A37440	20
A37441	22
A37442	22
A37443	22
A37444	18
A37445	21
A37446	19
A37447	20
A37448	20
A37449	22
A37450	18

GROUP: FEMALE 3 - 75 MG/KG/DAY

A37466	20
A37467	21
A37468	19
A37469	21
A37470	20
A37471	19
A37472	20
A37473	22
A37474	20
A37475	20
A37476	19
A37477	20
A37478	21
A37479	21
A37480	20

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HAZLETON WASHINGTON, INC.
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APPENDIX 5A

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (PRETREATMENT-GROUPS 1-7)
INDIVIDUAL BODY WEIGHTS (G)

STUDY NUMBER: 483287A

ANIMAL
NUMBER

WEEK
1

GROUP: FEMALE 4 - 200 MG/KG/DAY

A37496	19
A37497	20
A37498	22
A37499	19
A37500	21
A37501	21
A37502	19
A37503	20
A37504	19
A37505	19
A37506	21
A37507	22
A37508	20
A37509	19
A37510	19

GROUP: FEMALE 5 - 350 MG/KG/DAY

A37526	19
A37527	22
A37528	22
A37529	20
A37530	20
A37531	22
A37532	21
A37533	19
A37534	22
A37535	20
A37536	21
A37537	21
A37538	19
A37539	19
A37540	19

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HAZLETON WASHINGTON, INC.
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APPENDIX 5A

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (PRETREATMENT-GROUPS 1-7)
INDIVIDUAL BODY WEIGHTS (G)

STUDY NUMBER: 483287A

ANIMAL
NUMBER

WEEK
1

GROUP: FEMALE 6 - 750 MG/KG/DAY

A37556	20
A37557	20
A37558	20
A37559	21
A37560	21
A37561	19
A37562	22
A37563	20
A37564	20
A37565	20
A37566	18
A37567	21
A37568	19
A37569	19
A37570	19

GROUP: FEMALE 7 - 900 MG/KG/DAY

A37586	21
A37587	19
A37588	21
A37589	19
A37590	19
A37591	21
A37592	21
A37593	19
A37594	20
A37595	18
A37596	20
A37597	20
A37598	20
A37599	21
A37600	21

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HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 5A

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL BODY WEIGHTS (G)

STUDY NUMBER: 483287

ANIMAL NUMBER	WEEK 1	WEEK 2	WEEK 3	WEEK 4	WEEK 5	WEEK 6	WEEK 7	WEEK 8	WEEK 9	WEEK 10
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GROUP: MALE 1 - 0 MG/KG/DAY

A37391	26	28	29	29	30	29	31	30	30	30
A37392	26	27	28	29	28	28	29	30	31	30
A37393	28	30	30	32	32	33	33	34	35	35
A37394	23	27	29	31	31	31	31	31	32	32
A37395	26	27	28	30	30	30	30	32	32	32
A37396	25	27	26	29	30	30	30	30	30	31
A37397	28	29	30	31	31	31	31	33	34	33
A37398	27	27	27	27	28	28	29	29	29	29
A37399	25	22	25	27	28	30	32	30	29	29
A37400	24	25	26	27	27	27	31	28	29	30
A37401	28	30	30	32	32	33	33	33	34	34
A37402	25	27	28	29	30	31	32	32	33	34
A37403	28	30	30	31	31	32	32	32	33	32
A37404	26	27	28	28	29	31	29	29	29	30
A37405	26	27	27	28	29	31	30	30	31	31

GROUP: MALE 2 - 25 MG/KG/DAY

A37421	29	31	32	33	32	32	33	33	35	36
A37422	25	28	28	30	29	29	29	30	30	31
A37423	25	28	29	30	31	32	31	32	33	32
A37424	27	30	30	32	32	32	33	33	34	36
A37425	26	28	29	29	30	29	30	32	33	33
A37426	24	26	27	29	30	28	29	30	31	32
A37427	24	28	28	29	29	30	30	30	31	33
A37428	25	26	27	29	29	29	31	31	31	32
A37429	27	30	31	32	32	33	32	34	35	37
A37430	24	26	27	29	30	29	29	30	31	30
A37431	29	32	32	33	33	32	31	33	34	33
A37432	24	27	28	28	30	30	29	30	32	31
A37433	25	28	28	31	31	30	30	32	32	33
A37434	24	26	26	27	27	28	27	29	30	30
A37435	27	29	30	30	32	30	31	31	32	32

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HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 5A

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL BODY WEIGHTS (G)

STUDY NUMBER: 483287

ANIMAL NUMBER	WEEK 1	WEEK 2	WEEK 3	WEEK 4	WEEK 5	WEEK 6	WEEK 7	WEEK 8	WEEK 9	WEEK 10
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GROUP: MALE 3 - 75 MG/KG/DAY

A37451	23	27	28	30	30	30	30	31	32	33
A37452	27	29	30	30	30	31	31	32	32	33
A37453	26	29	30	32	32	33	34	33	34	35
A37454	24	26	27	27	29	29	29	29	29	31
A37455	23	26	27	27	28	28	28	28	29	31
A37456	29	32	33	34	34	35	35	35	36	38
A37457	26	29	29	31	32	34	33	33	34	36
A37458	28	30	31	32	32	32	33	33	33	34
A37459	26	28	28	29	30	30	30	30	31	31
A37460	27	29	29	31	32	33	33	33	34	34
A37461	28	29	32	33	34	35	33	34	35	35
A37462	28	30	30	32	30	31	30	31	33	32
A37463	24	25	26	27	27	27	27	27	29	28
A37464	26	27	28	29	31	32	33	31	32	32
A37465	27	28	28	31	29	29	31	30	30	29

GROUP: MALE 4 - 200 MG/KG/DAY

A37481	25	28	27	28	30	31	32	32	32	31
A37482	27	28	28	29	31	32	33	32	32	31
A37483	26	28	29	30	30	31	31	31	32	32
A37484	28	30	31	32	33	33	34	35	37	37
A37485	26	28	28	29	30	30	31	31	31	32
A37486	26	28	30	30	31	33	32	33	33	36
A37487	29	31	32	33	32	34	35	35	35	36
A37488	27	30	30	30	31	32	32	33	34	35
A37489	25	25	28	30	32	32	33	34	35	35
A37490	30	31	32	33	34	34	35	35	35	35
A37491	25	27	28	30	32	31	30	32	34	34
A37492	28	28	28	27	27	28	29	29	30	31
A37493	27	29	30	32	32	33	33	33	34	34
A37494	30	32	33	33	34	35				
A37495	28	31	31	32	34	35	35	35	37	35

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HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 5A

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)

INDIVIDUAL BODY WEIGHTS (G)

STUDY NUMBER: 483287

ANIMAL NUMBER	WEEK 1	WEEK 2	WEEK 3	WEEK 4	WEEK 5	WEEK 6	WEEK 7	WEEK 8	WEEK 9	WEEK 10
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GROUP: MALE 5 - 350 MG/KG/DAY

A37511	27	28	28	29	29	29	32	31	32	31
A37512	24	26	26	27	27	28	28	28	29	29
A37513	26	28	29	30	32	33	33	33	34	35
A37514	28	30	31	32	33	35	36	34	36	36
A37515	27	29	29	31	31	34	35	34	34	33
A37516	27	28	30	31	32	32	33	33	34	33
A37517	24	25	28	29	28	28	28	31	32	32
A37518	26	30	32	33	33	33	34	34	35	36
A37519	25	29	27	32	31	32	34	34	34	33
A37520	28	30	30	35	32	34	37	36	37	36
A37521	27	30	32	32	33	34	35	35	34	35
A37522	27	28	30	31	31	32	31	33	32	32
A37523	26	28	29	31	31	31	33	32	32	33
A37524	26	28	29	30	31	32	32	32	33	34
A37525	27	29	29	31	32	33	33	34	34	35

GROUP: MALE 6 - 750 MG/KG/DAY

A37541	28	25	26	28	31	32	33	30	31	33
A37542	29	25	25	25	27	28	27	27	28	28
A37543	28	27	29	31	33	33	36	35	35	36
A37544	28	27	28	28	28	30	30	31	31	31
A37545	26	23	25	27	28	28	28	28	28	29
A37546	28	25	28	30	30	30	31	30	31	30
A37547	30	28	29	31	32	31	33	32	32	33
A37548	25	26	26	29	31	32	33	32	31	31
A37549	27	26	28	28	28	29	29	29	29	29
A37550	24	22	23	24	25	25	24	24	24	25
A37551	27	24	26	29	29	30	29	29	30	30
A37552	26	23	22	24	24	26	28	28	26	27
A37553	27	26	27	29	31	31	33	32	31	31
A37554	26	24	25	24	26	27	29	28	29	28
A37555	28	17	23	29	30	30	29	29	30	30

APPENDIX 5A

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL BODY WEIGHTS (G)

STUDY NUMBER: 483287

ANIMAL NUMBER	WEEK 1	WEEK 2	WEEK 3	WEEK 4	WEEK 5	WEEK 6	WEEK 7	WEEK 8	WEEK 9	WEEK 10
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GROUP: MALE 7 - 900 MG/KG/DAY

A37571	26	23	23	28	27	28	28	29	29	29
A37572	25	24	26	26	28	29	31	32	32	33
A37573	25	23	24	27	25	26	28	25	26	28
A37574	28	25	26	25	28	28	28	28	28	31
A37575	28	27	27	28	29	31	31	32	32	32
A37576	25	23	25	28	29	30	32	31	32	33
A37577	20	16								
A37578	31	30	31	33	33	33	34	34	35	31
A37579	26	24	23							
A37580	27	28	28	29	29	29	31	31	30	32
A37581	24	24	23	24	26	26	27	26	26	26
A37582	25	22	22	24	25	28	29	27	29	29
A37583	28	25	27	28	29	31	30	34	34	35
A37584	26	25	27	28	29	30	32	32	34	33
A37585	27	27	27	29	31	30	31	31	34	33

GROUP: FEMALE 1 - 0 MG/KG/DAY

A37406	22	24	22	24	23	27	27	28	28	27
A37407	24	25	25	27	28	28	29	27	30	29
A37408	24	25	26	28	26	29	32	32	34	33
A37409	21	23	23	24	23	24	25	26	27	26
A37410	23	25	24	26	24	27	27	26	27	28
A37411	22	24	24	26	25	27	28	27	32	28
A37412	22	24	24	24	24	26	26	27	29	26
A37413	23	23	23	24	23	26	26	27	27	26
A37414	21	21	22	23	24	24	24	25	24	24
A37415	23	24	25	26	26	26	28	26	28	28
A37416	21	24	24	25	25	28	27	27	28	28
A37417	23	23	24	25	24	26	26	26	26	26
A37418	21	22	23	23	24	26	25	26	27	27
A37419	22	23	24	24	29	30	28	30	28	29
A37420	22	23	24	24	26	25	26	25	25	26

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APPENDIX 5A

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL BODY WEIGHTS (G)

STUDY NUMBER: 483287

ANIMAL NUMBER	WEEK 1	WEEK 2	WEEK 3	WEEK 4	WEEK 5	WEEK 6	WEEK 7	WEEK 8	WEEK 9	WEEK 10
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GROUP: FEMALE 2 - 25 MG/KG/DAY

A37436	20	22	23	24	25	24	26	25	26	26
A37437	24	25	26	26	27	27	27	29	29	30
A37438	22	23	23	24	25	25	25	28	27	27
A37439	23	26	26	27	29	29	29	29	28	31
A37440	23	24	26	26	27	27	28	29	29	29
A37441	23	25	26	28	28	29	30	29	30	30
A37442	23	26	25	26	26	27	28	29	28	28
A37443	23	25	26	26	26	26	28	27	27	27
A37444	21	21	22	23	22	22	22	24	24	23
A37445	22	25	25	26	27	27	28	27	28	28
A37446	22	23	24	24	25	25	26	27	26	26
A37447	22	25	25	27	28	27	27	30	29	29
A37448	22	24	23	23	24	25	26	26	26	27
A37449	24	25	26	26	27	27	26	27	30	29
A37450	20	22	22	24	26	24	24	24	25	25

GROUP: FEMALE 3 - 75 MG/KG/DAY

A37466	23	24	25	27	26	29	28	29	30	29
A37467	22	23	24	24	25	25	25	25	24	25
A37468	22	23	24	25	26	27	26	27	26	25
A37469	22	24	25	26	26	27	29	29	29	28
A37470	21	23	24	25	24	25	27	26	28	27
A37471	20	22	23	24	25	26	27	26	29	27
A37472	22	22	24	24	25	26	26	27	27	26
A37473	23	24	24	25	27	27	27	29	28	27
A37474	22	23	23	24	25	26	26	26	28	29
A37475	22	23	24	25	26	25	27	26	25	26
A37476	22	24	27	28	28	28	28	28	29	30
A37477	22	24	25	26	26	28	28	28	28	28
A37478	23	25	25	26	27	27	28	28	28	28
A37479	23	25	26	26	27	25	27	29	30	27
A37480	22	23	24	25	27	25	26	25	27	26

APPENDIX 5A

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL BODY WEIGHTS (G)

STUDY NUMBER: 483287

ANIMAL NUMBER	WEEK 1	WEEK 2	WEEK 3	WEEK 4	WEEK 5	WEEK 6	WEEK 7	WEEK 8	WEEK 9	WEEK 10
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GROUP: FEMALE 4 - 200 MG/KG/DAY

A37496	22	23	25	25	24					
A37497	22	24	25	26	26	27	27	27	27	28
A37498	23	24	26	27	28	29	29	28	31	30
A37499	21	21	24	25	24	27	27	26	30	28
A37500	23	23	26	27	25	27	27	27	30	29
A37501	23	25	26	27	28	29	29	28	29	28
A37502	21	21	21	22	25	23	25	29	27	26
A37503	22	23	25	26	28	27	27	28	29	28
A37504	22	23	23	23	24	25	26	25	25	26
A37505	20	22	23	25	27	25	26	28	29	28
A37506	23	25	26	27	28	28	29	30	28	28
A37507	24	26	26	28	30	31	31	33	32	31
A37508	20	22	23	25	27	27	27	27	29	27
A37509	21	23	24	25	28	27	28	27	29	28
A37510	20	24	25	27	29	27	28	29	28	28

GROUP: FEMALE 5 - 350 MG/KG/DAY

A37526	19	21	22	23	26	26	25	26	25	26
A37527	23	25	26	28	33	30	31	32	34	31
A37528	23	26	28	27	30	28	29	29	30	30
A37529	21	24	25	26	29	27	28	29	30	28
A37530	23	26	26	27	29	29	29	29	29	30
A37531	23	26	28	30	30	29	31	31	31	31
A37532	21	24	25	26	26	26	27	26	26	27
A37533	21	24	24	25	26	26	26	26	26	25
A37534	21	24	25	26	27	28	31	31	30	31
A37535	20	23	24	25	27	27	29	29	28	28
A37536	21	24	25	25	29	26	28	32	31	30
A37537	22	24	26	27	28	27	28	28	28	28
A37538	19	21	24	25	27	27	29	30	31	30
A37539	19	23	24	25	24	26	27	28	27	27
A37540	19	21	21	23	22	25	26	25	26	26

APPENDIX 5A

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL BODY WEIGHTS (G)

STUDY NUMBER: 483287

ANIMAL NUMBER	WEEK 1	WEEK 2	WEEK 3	WEEK 4	WEEK 5	WEEK 6	WEEK 7	WEEK 8	WEEK 9	WEEK 10
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GROUP: FEMALE 6 - 750 MG/KG/DAY

A37556	20	18	20	21	22	22	24	24	26	25
A37557	21	24	24	26	25	27	29	28	28	29
A37558	22	21	23	23	23	25	26	25	26	25
A37559	22	21	22	23	23	23	25	24	25	24
A37560	22	23	23	24	22	25	26	26	27	26
A37561	19	21	23	23	25	24	26	25	26	27
A37562	23	23	25	25	25	26	27	27	27	28
A37563	21	22	23	25	26	26	27	25	26	26
A37564	22	23	23	25	24	26	28	27	28	29
A37565	21	22	22	23	25	27	27	26	27	27
A37566	21	22	22	24	23	25	26	26	27	26
A37567	22	25	26	27	29	31	31	30	31	31
A37568	21	22	23	24	23	26	25	25	26	26
A37569	21	19	20	21	20	24	24	26	27	26
A37570	21	21	21	21	24	23	24	23	24	24

GROUP: FEMALE 7 - 900 MG/KG/DAY

A37586	23	22	24	25	26	27	27	26		
A37587	21	19	22	22	22	23	24	23	23	24
A37588	23	21	22	23	22	24	24	24	27	27
A37589	22	19	20	21	22	24	25	24	26	26
A37590	20	18	18	19	19	21	21	20	22	22
A37591	23	20	21	22	21	24	24	23	25	26
A37592	22	19	20	24	25	26	27	26	25	26
A37593	21	20	22	23	23	24	25	24	28	25
A37594	22	20	22	23	23	23	23	22	25	24
A37595	20	19	22	23	22	23	23	23	25	26
A37596	22	21	22	23	23	24	24	24	24	23
A37597	24	22	23	22	23	24	25	24	23	27
A37598	22	20	20	21	21	23	23	24	23	24
A37599	25	23	24	26	26	28	29	28	27	29
A37600	22	19	21	22	22	24	24	25	26	27

APPENDIX 5A

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL BODY WEIGHTS (G)

STUDY NUMBER: 483287

ANIMAL NUMBER	WEEK 11	WEEK 12	WEEK 13	WEEK 14
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GROUP: MALE 1 - 0 MG/KG/DAY

A37391	29	29	29	30
A37392	30	30	31	31
A37393	35	36	33	36
A37394	32	33	32	33
A37395	32	33	33	33
A37396	32	33	32	33
A37397	34	35	35	36
A37398	29	30	30	31
A37399	30	31	30	32
A37400	29	30	30	30
A37401	33	34	34	33
A37402	32	33	33	33
A37403	32	33	33	33
A37404	28	30	29	29
A37405	30	31	31	31

GROUP: MALE 2 - 25 MG/KG/DAY

A37421	33	36	36	35
A37422	30	31	31	31
A37423	32	34	34	33
A37424	34	35	34	35
A37425	31	33	32	33
A37426	31	32	32	32
A37427	31	32	32	31
A37428	31	32	33	33
A37429	35	36	36	35
A37430	30	31	32	31
A37431	33	34	33	33
A37432	30	32	31	31
A37433	32	33	33	33
A37434	30	30	30	30
A37435	31	32	32	32

APPENDIX 5A

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL BODY WEIGHTS (G)

STUDY NUMBER: 483287

ANIMAL NUMBER	WEEK 11	WEEK 12	WEEK 13	WEEK 14
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GROUP: MALE 3 - 75 MG/KG/DAY

A37451	31	33	33	32
A37452	31	33	33	33
A37453	35	36	37	35
A37454	30	32	32	31
A37455	29	30	30	29
A37456	37	38	38	37
A37457	34	37	37	36
A37458	33	34	33	34
A37459	31	32	31	30
A37460	35	36	35	36
A37461	35	36	36	37
A37462	32	33	33	33
A37463	29	29	29	29
A37464	33	34	34	34
A37465	30	30	30	30

GROUP: MALE 4 - 200 MG/KG/DAY

A37481	32	34	32	33
A37482	32	33	34	32
A37483	31	33	33	32
A37484	34	35		
A37485	31	31	31	32
A37486	34	35	35	35
A37487	35	36	36	35
A37488	34	34	35	34
A37489	33	36	36	36
A37490	34	35	35	35
A37491	32	32	33	32
A37492	29	30	30	27
A37493	33	33	34	33
A37495	36	37	38	37

APPENDIX 5A

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL BODY WEIGHTS (G)

STUDY NUMBER: 483287

ANIMAL NUMBER	WEEK 11	WEEK 12	WEEK 13	WEEK 14
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GROUP: MALE 5 - 350 MG/KG/DAY

A37511	31	32	33	31
A37512	29	29	30	29
A37513	35	35	35	33
A37514	35	36	35	35
A37515	34	34	34	34
A37516	35	35	35	35
A37517	32	32	32	33
A37518	37	36	38	37
A37519	34	34	32	34
A37520	36	36	36	36
A37521	35	36	35	35
A37522	34	34	34	35
A37523	32	33	33	33
A37524	33	34	34	33
A37525	35	35	34	35

GROUP: MALE 6 - 750 MG/KG/DAY

A37541	31	30	32	33
A37542	28	28	29	30
A37543	34	35	35	35
A37544	33	31	31	32
A37545	31	29	29	29
A37546	31	31	30	30
A37547	30	32	33	33
A37548	33	33	33	33
A37549	30	30	31	31
A37550	24	24	25	26
A37551	31	30	31	31
A37552	26	27	28	27
A37553	31	32	31	31
A37554	29	29	29	29
A37555	31	31	31	30

APPENDIX 5A

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL BODY WEIGHTS (G)

STUDY NUMBER: 483287

ANIMAL NUMBER	WEEK 11	WEEK 12	WEEK 13	WEEK 14
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GROUP: MALE 7 - 900 MG/KG/DAY

A37571	30	30	30	30
A37572	33	32	32	32
A37573	28	28	29	27
A37574	29	28	29	29
A37575	31	32	32	31
A37576	33	33	34	35
A37578	32	34	32	33
A37580	31	32	30	31
A37581	25	25	25	25
A37582	30	30	32	32
A37583	34	35	34	35
A37584	31	33	33	33
A37585	33	32	33	33

GROUP: FEMALE 1 - 0 MG/KG/DAY

A37406	28	29	29	28
A37407	29	30	29	31
A37408	31	30	33	32
A37409	27	26	27	28
A37410	28	29	27	27
A37411	29	29	28	29
A37412	26	26	27	25
A37413	26	28	28	27
A37414	24	25	27	25
A37415	28	30	29	29
A37416	30	30	29	30
A37417	26	26	27	26
A37418	27	28	28	28
A37419	30	29	30	30
A37420	27	27	29	27

GROUP: FEMALE 2 - 25 MG/KG/DAY

A37436	28	27	27	28
A37437	29	29	30	31

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 5A

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL BODY WEIGHTS (G)

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STUDY NUMBER: 483287

ANIMAL NUMBER	WEEK 11	WEEK 12	WEEK 13	WEEK 14
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GROUP: FEMALE 2 - 25 MG/KG/DAY

A37438	27	26	26	28
A37439	32	31	32	32
A37440	29	29	29	28
A37441	30	30	31	30
A37442	28	28	28	29
A37443	28	27	27	28
A37444	24	24	27	26
A37445	28	28	28	29
A37446	26	26	26	26
A37447	28	28	27	30
A37448	26	26	25	26
A37449	29	28	28	29
A37450	25	24	25	25

GROUP: FEMALE 3 - 75 MG/KG/DAY

A37466	29	29	29	29
A37467	25	26	26	26
A37468	27	28	28	27
A37469	30	30	29	31
A37470	27	28	27	28
A37471	28	27	28	29
A37472	27	26	27	27
A37473	28	28	28	28
A37474	29	30	29	31
A37475	27	27	27	28
A37476	30	30	30	31
A37477	28	28	29	29
A37478	29	30	30	30
A37479	27	28	29	29
A37480	26	27	27	28

GROUP: FEMALE 4 - 200 MG/KG/DAY

A37497	27	28	27	29
A37498	30	31	31	31

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APPENDIX 5A

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL BODY WEIGHTS (G)

STUDY NUMBER: 483287

ANIMAL NUMBER	WEEK 11	WEEK 12	WEEK 13	WEEK 14
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GROUP: FEMALE 4 - 200 MG/KG/DAY

A37499	28	29	29	30
A37500	30	30	30	30
A37501	28	28	30	30
A37502	27	27	27	28
A37503	29	29	30	30
A37504	26	26	27	27
A37505	28	20	28	29
A37506	30	30	30	29
A37507	32	32	35	33
A37508	29	29	30	30
A37509	30	29	29	29
A37510	29	29	29	29

GROUP: FEMALE 5 - 350 MG/KG/DAY

A37526	28	27	28	27
A37527	33	32	34	34
A37528	31	30	33	33
A37529	29	30	30	30
A37530	30	31	31	32
A37531	32	33	32	31
A37532	28	28	28	28
A37533	25	26	26	27
A37534	32	32	33	33
A37535	29	29	31	30
A37536	30	30	30	30
A37537	28	29	29	30
A37538	31	32	32	31
A37539	28	29	28	28
A37540	26	27	28	26

GROUP: FEMALE 6 - 750 MG/KG/DAY

A37556	26	26	27	26
A37557	30	31	30	30
A37558	24	26	25	25

APPENDIX 5A

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL BODY WEIGHTS (G)

STUDY NUMBER: 483287

ANIMAL NUMBER	WEEK 11	WEEK 12	WEEK 13	WEEK 14
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GROUP: FEMALE 6 - 750 MG/KG/DAY

A37559	24	24	24	24
A37560	27	27	27	27
A37561	26	27	27	25
A37562	28	29	29	29
A37563	26	27	28	27
A37564	29	29	29	29
A37565	28	28	28	27
A37566	27	27	28	28
A37567	32	32	33	31
A37568	27	27	28	27
A37569	24	24	24	25
A37570	25	25	24	24

GROUP: FEMALE 7 - 900 MG/KG/DAY

A37587	23	23	24	26
A37588	26	27	27	27
A37589	27	29	29	28
A37590	22	22	21	22
A37591	25	25	24	25
A37592	27	27	25	26
A37593	25	26	26	25
A37594	25	24	25	26
A37595	26	25	25	26
A37596	23	23	23	21
A37597	26	26	26	28
A37598	23	23	22	24
A37599	27	30	27	29
A37600	25	25	23	25

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Appendix 5B
Individual Body Weights - Satellite Study
13-Week Subchronic Oral Toxicity Study of Triclosan in CD-1[®] Mice

NOTES: Due to computer limitations, Groups 1-4 correspond to Groups 8-11, respectively; pretreatment values actually represent Week -1.

APPENDIX 5B

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (PRETREATMENT-GROUPS 8-11)
INDIVIDUAL BODY WEIGHTS (G)

STUDY NUMBER: 483287B

ANIMAL WEEK
NUMBER 1

GROUP: MALE 1 - 0 MG/KG/DAY

A37601	22
A37602	24
A37603	24
A37604	25
A37605	25
A37606	26
A37607	27
A37608	24
A37609	24
A37610	26
A37611	22
A37612	25
A37613	25
A37614	23
A37615	27
A37616	26
A37617	27
A37618	25
A37619	27
A37620	25

GROUP: MALE 2 - 25 MG/KG/DAY

A37641	25
A37642	25
A37643	24
A37644	24
A37645	22
A37646	27
A37647	23
A37648	26
A37649	27
A37650	26

APPENDIX 5B

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (PRETREATMENT-GROUPS 8-11)
INDIVIDUAL BODY WEIGHTS (G)

STUDY NUMBER: 483287B

ANIMAL
NUMBER

WEEK
1

GROUP: MALE 3 - 350 MG/KG/DAY

A37661	23
A37662	23
A37663	25
A37664	23
A37665	27
A37666	25
A37667	27
A37668	26
A37669	22
A37670	25

GROUP: MALE 4 - 900 MG/KG/DAY

A37681	24
A37682	24
A37683	24
A37684	23
A37685	26
A37686	27
A37687	25
A37688	25
A37689	24
A37690	28

GROUP: FEMALE 1 - 0 MG/KG/DAY

A37621	22
A37622	19
A37623	22
A37624	21
A37625	19
A37626	19
A37627	20
A37628	21
A37629	20
A37630	22

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APPENDIX 5B

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (PRETREATMENT-GROUPS 8-11)
INDIVIDUAL BODY WEIGHTS (G)

STUDY NUMBER: 483287B

ANIMAL WEEK
NUMBER 1

GROUP: FEMALE 1 - 0 MG/KG/DAY

A37631	22
A37632	20
A37633	22
A37634	20
A37635	20
A37636	21
A37637	18
A37638	22
A37639	21
A37640	20

GROUP: FEMALE 2 - 25 MG/KG/DAY

A37651	20
A37652	19
A37653	20
A37654	20
A37655	21
A37656	21
A37657	20
A37658	22
A37659	19
A37660	22

GROUP: FEMALE 3 - 350 MG/KG/DAY

A37671	19
A37672	20
A37673	22
A37674	20
A37675	19
A37676	19
A37677	20
A37678	19
A37679	22
A37680	22

APPENDIX 5B

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (PRETREATMENT-GROUPS 8-11)
INDIVIDUAL BODY WEIGHTS (G)

STUDY NUMBER: 483287B

ANIMAL WEEK
NUMBER 1

GROUP: FEMALE 4 - 900 MG/KG/DAY

A37691	21
A37692	19
A37693	20
A37694	21
A37695	20
A37696	20
A37697	22
A37698	20
A37699	19
A37700	19

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APPENDIX 5B

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.13-WEEK SUBCHRONIC ORAL TOXICITY STUDY IN TRICLOSAN IN CD-1
MICE. (SATELLITE-GROUPS 8-11)
INDIVIDUAL BODY WEIGHTS (G)

STUDY NUMBER: 483287

ANIMAL NUMBER	WEEK 1	WEEK 2	WEEK 3	WEEK 4	WEEK 5	WEEK 6	WEEK 7
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GROUP: MALE 1 - 0 MG/KG/DAY

A37601	24	25	26	27	28	28	29
A37602	27	27	27	29	29	29	31
A37603	26	27	28	28	29	29	29
A37604	26	27	28	29	30	32	32
A37605	27	28	29	30	30	31	31
A37606	26	27	28	29	29	30	31
A37607	30	31	32	32	34	34	35
A37608	26	28	29	30	30	30	31
A37609	25	27	28	29	30	31	31
A37610	28	31	31	33	33	33	33
A37611	22						

GROUP: MALE 2 - 25 MG/KG/DAY

A37641	26	27	28	29	31	32	32
A37642	25	27	28	30	30	30	29
A37643	26	27	28	29	30	29	30
A37644	28	30	31	32	33	33	35
A37645	24	24	25	25	27	26	27
A37646	27	28	29	30	31	32	33
A37647	24	26	27	27	28	29	31
A37648	26	29	29	31	32	33	33
A37649	28	30	31	32	31	32	33
A37650	27	29	29	29	30	30	31

GROUP: MALE 3 - 350 MG/KG/DAY

A37661	26	28	29	30	31	30	31
A37662	26	27	28	29	30	32	33
A37663	26	29	31	31	30	31	32
A37664	26	27	26	27	29	31	31
A37665	28	30	32	34	35	34	35
A37666	26	28	26	29	30	30	30
A37667	27	30	32	32	31	31	33
A37668	26	28	30	30	31	31	33
A37669	24	26	24	27	28	27	29

APPENDIX 58

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.13-WEEK SUBCHRONIC ORAL TOXICITY STUDY IN TRICLOSAN IN CD-1
MICE. (SATELLITE-GROUPS 8-11)
INDIVIDUAL BODY WEIGHTS (G)

STUDY NUMBER: 483287

ANIMAL NUMBER	WEEK 1	WEEK 2	WEEK 3	WEEK 4	WEEK 5	WEEK 6	WEEK 7
GROUP: MALE 3 - 350 MG/KG/DAY							
A37670	25	26	27	28	28	29	31
GROUP: MALE 4 - 900 MG/KG/DAY							
A37681	25	22	24	25	25	25	27
A37682	25	21	21	23	24	25	26
A37683	25	22	23	25	27	28	30
A37684	26	23	24	25	26	28	29
A37685	26	22	22	25	24	27	27
A37686	28	24	27	29	29	30	32
A37687	25	26	27	29	28	29	30
A37688	25	23	25	26	25	27	29
A37689	26	24	25	24	26	28	30
A37690	29	27	27	29	30	31	33
GROUP: FEMALE 1 - 0 MG/KG/DAY							
A37621	22	24	24	27	26	28	28
A37622	20	21	21	22	24	23	24
A37623	23	24	24	25	26	27	28
A37624	22	23	24	25	27	28	29
A37625	20	22	23	24	25	26	27
A37626	21	23	24	25	26	26	28
A37627	20	25	24	25	27	26	27
A37628	20	22	23	24	24	27	27
A37629	21	22	23	24	24	25	27
A37630	23	24	24	26	26	27	29
GROUP: FEMALE 2 - 25 MG/KG/DAY							
A37651	21	24	22	25	25	26	26
A37652	21	22	22	24	24	25	25
A37653	21	23	23	25	26	26	28
A37654	20	23	22	25	24	25	26
A37655	21	25	24	26	27	29	28
A37656	19	21	21	23	23	23	24

APPENDIX 58

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY IN TRICLOSAN IN CD-1
MICE. (SATELLITE-GROUPS 8-11)
INDIVIDUAL BODY WEIGHTS (G)

STUDY NUMBER: 483287

ANIMAL NUMBER	WEEK 1	WEEK 2	WEEK 3	WEEK 4	WEEK 5	WEEK 6	WEEK 7
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GROUP: FEMALE 2 - 25 MG/KG/DAY

A37657	20	22	21	24	24	23	25
A37658	23	23	23	26	25	25	26
A37659	19	20	21	24	23	25	26
A37660	23	23	24	26	25	25	26

GROUP: FEMALE 3 - 350 MG/KG/DAY

A37671	21	22	23	25	25	25	27
A37672	22	25	26	27	28	26	29
A37673	22	24	23	27	27	27	28
A37674	22	24	25	26	26	28	28
A37675	22	23	24	26	25	24	25
A37676	21	23	24	25	26	25	27
A37677	20	23	24	26	26	26	27
A37678	23	25	26	28	26	28	29
A37679	24	25	25	27	28	30	30
A37680	23	24	24	26	26	27	28

GROUP: FEMALE 4 - 900 MG/KG/DAY

A37691	23	21	23	23	23	24	25
A37692	18	20	21	23	23	24	25
A37693	21	21	21	23	22	24	24
A37694	22	18	21	24	25	25	27
A37695	22	21	22	24	24	26	27
A37696	21	23	24	27	27	28	28
A37697	23	22	23	25	23	25	25
A37698	23	24	25	27	28	29	30
A37699	20	21	22	25	26	28	28
A37700	21	20	21	23	23	24	25

Appendix 6A
Individual Food Consumption - Main Study
13-Week Subchronic Oral Toxicity Study of Triclosan in CD-1[®] Mice

NOTE: Due to computer limitations, pretreatment values actually represent Week -1.

APPENDIX 6A

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (PRETREATMENT-GROUPS 1-7)
INDIVIDUAL FOOD CONSUMPTION (G)

STUDY NUMBER: 483287A

ANIMAL
NUMBER

WEEK
1

GROUP: MALE 1 - 0 MG/KG/DAY

A37391	36
A37392	34
A37393	40
A37394	SPILLED
A37395	30
A37396	43
A37397	SPILLED
A37398	33
A37399	34
A37400	37
A37401	40
A37402	39
A37403	42
A37404	39
A37405	37

GROUP: MALE 2 - 25 MG/KG/DAY

A37421	44
A37422	40
A37423	46
A37424	42
A37425	46
A37426	39
A37427	40
A37428	41
A37429	44
A37430	43
A37431	43
A37432	39
A37433	39
A37434	37
A37435	43

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HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 6A

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (PRETREATMENT-GROUPS 1-7)
INDIVIDUAL FOOD CONSUMPTION (G)

STUDY NUMBER: 483287A

ANIMAL WEEK
NUMBER 1

GROUP: MALE 3 - 75 MG/KG/DAY

A37451	40
A37452	41
A37453	42
A37454	44
A37455	35
A37456	46
A37457	40
A37458	44
A37459	46
A37460	44
A37461	44
A37462	44
A37463	37
A37464	41
A37465	43

GROUP: MALE 4 - 200 MG/KG/DAY

A37481	40
A37482	43
A37483	42
A37484	43
A37485	43
A37486	39
A37487	41
A37488	40
A37489	SPILLED
A37490	40
A37491	38
A37492	43
A37493	43
A37494	44
A37495	42

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 6A

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (PRETREATMENT-GROUPS 1-7)
INDIVIDUAL FOOD CONSUMPTION (G)

STUDY NUMBER: 483287A

ANIMAL
NUMBER

WEEK
1

GROUP: MALE 5 - 350 MG/KG/DAY

A37511 39
A37512 35
A37513 38
A37514 41
A37515 39
A37516 41
A37517 38
A37518 39
A37519 41
A37520 41
A37521 40
A37522 40
A37523 34
A37524 41
A37525 39

GROUP: MALE 6 - 750 MG/KG/DAY

A37541 39
A37542 41
A37543 41
A37544 42
A37545 40
A37546 38
A37547 40
A37548 35
A37549 41
A37550 39
A37551 43
A37552 40
A37553 38
A37554 39
A37555 SPILLED

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HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 6A

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (PRETREATMENT-GROUPS 1-7)
INDIVIDUAL FOOD CONSUMPTION (G)

STUDY NUMBER: 483287A

ANIMAL WEEK
NUMBER 1

GROUP: MALE 7 - 900 MG/KG/DAY

A37571 39
A37572 40
A37573 36
A37574 39
A37575 40
A37576 38
A37577 SPILLED
A37578 44
A37579 39
A37580 40
A37581 41
A37582 38
A37583 47
A37584 41
A37585 43

GROUP: FEMALE 1 - 0 MG/KG/DAY

A37406 42
A37407 48
A37408 41
A37409 43
A37410 38
A37411 33
A37412 39
A37413 39
A37414 32
A37415 37
A37416 SPILLED
A37417 37
A37418 35
A37419 36
A37420 42

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APPENDIX 6A

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (PRETREATMENT-GROUPS 1-7)
INDIVIDUAL FOOD CONSUMPTION (G)

STUDY NUMBER: 483287A

ANIMAL WEEK
NUMBER 1

GROUP: FEMALE 2 - 25 MG/KG/DAY

A37436	34
A37437	40
A37438	35
A37439	38
A37440	36
A37441	43
A37442	42
A37443	37
A37444	38
A37445	36
A37446	37
A37447	43
A37448	37
A37449	40
A37450	33

GROUP: FEMALE 3 - 75 MG/KG/DAY

A37466	39
A37467	33
A37468	35
A37469	37
A37470	36
A37471	43
A37472	40
A37473	38
A37474	48
A37475	40
A37476	38
A37477	35
A37478	36
A37479	38
A37480	34

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HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 6A

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (PRETREATMENT-GROUPS 1-7)
INDIVIDUAL FOOD CONSUMPTION (G)

STUDY NUMBER: 483287A

ANIMAL
NUMBER

WEEK
1

ANIMAL
NUMBER

WEEK
1

GROUP: FEMALE 4 - 200 MG/KG/DAY

A37496 39
A37497 37
A37498 40
A37499 35
A37500 38
A37501 39
A37502 38
A37503 43
A37504 47
A37505 34
A37506 39
A37507 41
A37508 34
A37509 38
A37510 33

GROUP: FEMALE 5 - 350 MG/KG/DAY

A37526 35
A37527 42
A37528 39
A37529 46
A37530 43
A37531 43
A37532 36
A37533 43
A37534 37
A37535 40
A37536 37
A37537 SPILLED
A37538 37
A37539 33
A37540 41

GROUP: FEMALE 6 - 750 MG/KG/DAY

A37556 39
A37557 54
A37558 43
A37559 48
A37560 39
A37561 44
A37562 41
A37563 36
A37564 39
A37565 41
A37566 40
A37567 SPILLED
A37568 36
A37569 46
A37570 37

GROUP: FEMALE 7 - 900 MG/KG/DAY

A37586 36
A37587 44
A37588 40
A37589 39
A37590 32
A37591 46
A37592 42
A37593 42
A37594 40
A37595 38
A37596 46
A37597 38
A37598 37
A37599 42
A37600 35

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 6A
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL FOOD CONSUMPTION (G)

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STUDY NUMBER: 483287

ANIMAL NUMBER	WEEK 1	WEEK 2	WEEK 3	WEEK 4	WEEK 5	WEEK 6	WEEK 7	WEEK 8	WEEK 9	WEEK 10
GROUP: MALE 1 - 0 MG/KG/DAY										
A37391	42	41	34	39	37	38	41	37	41	38
A37392	38	36	SPILLED	38	37	34	37	33	30	32
A37393	SPILLED	48	43	44	45	46	49	41	41	39
A37394	38	44	41	44	41	40	43	41	36	36
A37395	41	43	42	45	41	39	43	42	35	36
A37396	42	40	41	43	SPILLED	40	43	39	37	35
A37397	40	38	42	42	34	35	43	35	33	36
A37398	41	39	24	36	36	34	37	34	32	32
A37399	SPILLED	47	53	47	49	42	44	45	41	39
A37400	38	34	30	38	35	34	38	37	31	31
A37401	SPILLED	49	34	41	41	37	41	41	32	33
A37402	41	SPILLED	41	42	40	41	46	41	38	36
A37403	49	42	39	44	42	44	42	40	35	37
A37404	38	38	36	42	41	42	45	47	39	39
A37405	41	40	33	40	36	37	39	35	30	32
GROUP: MALE 2 - 25 MG/KG/DAY										
A37421	46	46	43	42	39	40	40	43	36	36
A37422	46	43	41	42	38	39	41	41	36	33
A37423	SPILLED	42	39	41	40	41	48	43	SPILLED	36
A37424	47	41	41	40	36	37	39	40	33	32
A37425	42	42	37	40	33	34	45	40	30	32
A37426	SPILLED	42	40	43	37	35	37	38	33	35
A37427	46	39	37	37	37	37	37	39	34	33
A37428	39	41	36	42	37	37	40	37	38	33
A37429	44	44	43	50	44	42	48	44	36	38
A37430	42	40	40	50	41	38	40	54	32	34
A37431	43	42	39	43	40	42	47	42	36	35
A37432	42	44	40	43	46	48	42	41	36	37
A37433	40	37	35	38	38	38	38	39	34	32
A37434	36	39	35	37	36	37	38	35	31	32
A37435	46	47	43	47	39	41	40	37	35	35

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 6A

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL FOOD CONSUMPTION (G)

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STUDY NUMBER: 483287

ANIMAL NUMBER	WEEK 1	WEEK 2	WEEK 3	WEEK 4	WEEK 5	WEEK 6	WEEK 7	WEEK 8	WEEK 9	WEEK 10
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GROUP: MALE 3 - 75 MG/KG/DAY

A37451	42	42	43	44	40	41	40	40	37	33
A37452	46	39	34	37	35	35	40	37	32	31
A37453	SPILLED	42	42	44	41	38	39	40	34	37
A37454	SPILLED	44	41	52	37	38	39	38	34	34
A37455	35	39	36	39	35	32	34	36	33	32
A37456	43	45	42	45	43	43	42	41	36	37
A37457	SPILLED	38	37	42	38	36	38	38	33	34
A37458	43	43	39	41	36	41	41	39	34	35
A37459	48	60	43	52	51	42	42	42	39	35
A37460	40	39	37	43	37	38	37	40	33	33
A37461	42	44	43	48	42	39	40	42	37	35
A37462	39	39	38	40	36	38	35	36	34	32
A37463	36	39	37	36	43	35	33	38	33	32
A37464	39	44	37	40	38	37	36	37	36	34
A37465	46	43	43	45	39	44	42	41	38	39

GROUP: MALE 4 - 200 MG/KG/DAY

A37481	SPILLED	40	44	49	39	40	45	42	33	35
A37482	SPILLED	38	41	42	39	40	40	39	35	34
A37483	41	41	40	45	39	38	40	39	34	36
A37484	48	48	45	48	45	43	46	SPILLED	40	40
A37485	47	44	44	47	43	46	44	42	35	36
A37486	42	43	44	46	45	42	43	40	39	38
A37487	40	40	39	39	41	38	37	36	33	33
A37488	41	41	43	41	43	39	38	36	32	33
A37489	SPILLED	35	38	43	37	34	37	37	33	31
A37490	39	42	41	42	39	41	38	37	35	33
A37491	36	37	40	40	40	39	45	44	41	32
A37492	40	39	40	37	40	39	39	36	33	32
A37493	44	41	41	41	39	40	40	39	35	36
A37494	SPILLED	48	47	41	SPILLED	NOT TAKEN				
A37495	43	44	42	45	44	43	44	40	39	35

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 6A

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL FOOD CONSUMPTION (G)

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STUDY NUMBER: 483287

ANIMAL NUMBER	WEEK 1	WEEK 2	WEEK 3	WEEK 4	WEEK 5	WEEK 6	WEEK 7	WEEK 8	WEEK 9	WEEK 10
GROUP: MALE 5 - 350 MG/KG/DAY										
A37511	41	40	37	39	37	37	37	37	31	33
A37512	SPILLED	38	38	40	39	40	36	37	34	31
A37513	37	38	38	39	39	38	35	36	31	32
A37514	44	44	43	48	46	45	44	42	34	34
A37515	37	42	41	40	44	43	39	39	36	34
A37516	SPILLED	40	39	SPILLED	49	43	41	41	39	38
A37517	43	42	41	30	47	42	46	47	46	40
A37518	39	42	40	58	40	39	38	37	39	36
A37519	38	40	41	54	41	43	40	40	40	35
A37520	37	37	39	40	42	42	38	38	35	31
A37521	39	42	44	47	50	44	41	41	40	35
A37522	42	42	42	49	44	41	44	41	39	38
A37523	41	45	38	32	40	37	39	37	33	32
A37524	36	48	40	46	38	33	41	37	32	31
A37525	46	43	47	42	43	43	43	41	37	34
GROUP: MALE 6 - 750 MG/KG/DAY										
A37541	36	34	46	28	42	40	38	40	36	40
A37542	40	31	41	38	44	36	SPILLED	40	32	35
A37543	31	46	42	47	41	41	40	42	35	31
A37544	33	39	42	39	44	40	41	42	36	28
A37545	35	44	49	55	47	42	39	43	SPILLED	48
A37546	43	38	43	36	46	42	37	38	35	39
A37547	34	41	44	39	44	38	36	40	36	32
A37548	35	35	38	34	39	35	36	32	SPILLED	32
A37549	43	40	44	36	39	38	38	SPILLED	35	33
A37550	SPILLED	41	55	53	40	40	SPILLED	38	SPILLED	33
A37551	34	37	43	45	41	37	34	43	SPILLED	35
A37552	29	41	49	46	43	38	SPILLED	38	38	37
A37553	36	49	39	32	45	39	44	37	32	31
A37554	32	38	40	59	41	41	39	43	32	34
A37555	SPILLED	31	37	45	39	33	35	36	SPILLED	30

HAZLETON WASHINGTON, INC.
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APPENDIX 6A

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
NICE. (MAIN-GROUPS 1-7)
INDIVIDUAL FOOD CONSUMPTION (G)

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STUDY NUMBER: 483287

ANIMAL NUMBER	WEEK 1	WEEK 2	WEEK 3	WEEK 4	WEEK 5	WEEK 6	WEEK 7	WEEK 8	WEEK 9	WEEK 10
GROUP: MALE 7 - 900 MG/KG/DAY										
A37571	28	37	44	43	40	37	40	39	36	32
A37572	37	43	40	44	43	37	SPILLED	45	42	37
A37573	37	41	40	38	39	35	31	38	38	32
A37574	27	34	36	44	41	37	36	39	39	32
A37575	33	38	45	45	42	37	37	SPILLED	36	37
A37576	51	42	38	38	44	42	40	43	38	33
A37577	30	NOT TAKEN								
A37578	47	49	45	45	45	41	40	SPILLED	29	35
A37579	40	27	NOT TAKEN							
A37580	36	43	45	43	44	46	SPILLED	45	40	34
A37581	21	42	37	37	44	44	34	45	SPILLED	32
A37582	SPILLED	30	36	38	46	39	SPILLED	41	37	36
A37583	38	37	53	41	43	41	41	42	43	36
A37584	32	40	44	40	44	41	39	49	44	33
A37585	43	43	49	46	45	45	SPILLED	37	42	39
GROUP: FEMALE 1 - 0 MG/KG/DAY										
A37406	44	43	38	43	42	48	40	36	37	42
A37407	38	41	39	50	41	40	39	39	39	41
A37408	38	39	45	47	48	45	43	39	48	40
A37409	40	40	48	53	48	SPILLED	43	56	48	53
A37410	39	37	45	49	44	41	41	32	41	44
A37411	35	37	40	53	43	42	39	40	39	41
A37412	36	36	37	47	42	47	37	40	39	37
A37413	37	39	40	46	40	37	41	35	39	41
A37414	35	33	35	42	37	35	35	34	38	37
A37415	39	36	42	49	43	47	36	60	41	41
A37416	37	38	43	46	42	42	44	21	41	50
A37417	36	36	39	45	41	43	SPILLED	39	39	41
A37418	35	35	37	44	38	38	37	36	34	38
A37419	35	36	38	50	47	41	38	36	36	38
A37420	SPILLED	38	40	43	39	42	41	41	37	39

HAZLETON WASHINGTON, INC.
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APPENDIX 6A
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL FOOD CONSUMPTION (G)

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STUDY NUMBER: 483287

ANIMAL NUMBER	WEEK 1	WEEK 2	WEEK 3	WEEK 4	WEEK 5	WEEK 6	WEEK 7	WEEK 8	WEEK 9	WEEK 10
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GROUP: FEMALE 2 - 25 MG/KG/DAY

A37436	33	34	34	39	37	39	39	35	36	30
A37437	37	37	40	55	39	41	34	38	39	41
A37438	33	32	36	34	35	36	30	35	34	35
A37439	41	49	42	44	43	42	38	38	40	46
A37440	38	39	40	42	40	40	33	35	38	37
A37441	SPILLED	42	46	50	43	46	SPILLED	47	46	42
A37442	SPILLED	40	42	43	39	41	38	37	36	37
A37443	38	39	40	40	39	40	35	SPILLED	35	36
A37444	44	38	41	43	43	44	44	49	39	37
A37445	38	SPILLED	40	44	43	43	39	39	39	41
A37446	SPILLED	43	39	47	42	43	40	45	42	39
A37447	SPILLED	48	47	52	56	45	46	55	45	43
A37448	41	37	39	41	35	39	35	40	36	39
A37449	40	42	42	44	43	43	42	26	44	42
A37450	38	35	37	43	39	38	36	35	36	35

GROUP: FEMALE 3 - 75 MG/KG/DAY

A37466	40	34	41	44	45	42	SPILLED	49	45	39
A37467	33	35	34	39	36	36	36	34	35	35
A37468	38	40	41	43	42	38	36	38	26	33
A37469	38	38	37	40	39	37	38	39	35	36
A37470	SPILLED	42	43	46	44	42	41	39	42	40
A37471	48	37	45	47	42	44	36	44	40	30
A37472	38	41	39	38	39	37	38	36	35	32
A37473	38	40	38	44	41	41	41	39	37	37
A37474	43	41	45	41	45	43	SPILLED	43	42	39
A37475	SPILLED	39	44	42	53	45	44	47	44	36
A37476	37	43	39	43	SPILLED	43	44	39	43	39
A37477	42	39	39	39	45	41	39	38	38	36
A37478	38	40	39	39	37	40	43	36	35	35
A37479	39	40	38	40	40	43	43	39	38	36
A37480	39	38	35	37	38	39	38	36	34	36

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 6A

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL FOOD CONSUMPTION (G)

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STUDY NUMBER: 483287

ANIMAL NUMBER	WEEK 1	WEEK 2	WEEK 3	WEEK 4	WEEK 5	WEEK 6	WEEK 7	WEEK 8	WEEK 9	WEEK 10
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GROUP: FEMALE 4 - 200 MG/KG/DAY

A37496	42	43	SPILLED	48	NOT TAKEN					
A37497	39	39	39	43	41	43	42	39	38	34
A37498	36	39	37	41	40	42	37	39	36	31
A37499	41	45	43	38	40	42	47	39	38	35
A37500	40	43	41	40	42	45	41	39	38	37
A37501	SPILLED	43	43	48	50	46	45	43	39	33
A37502	34	35	33	46	37	38	41	38	34	31
A37503	44	38	43	40	46	40	42	39	39	32
A37504	SPILLED	44	40	46	44	48	46	47	42	40
A37505	33	34	35	37	36	39	36	36	34	31
A37506	47	40	39	42	42	43	40	40	39	36
A37507	44	41	47	46	46	45	44	42	41	36
A37508	SPILLED	45	43	37	41	40	40	38	37	35
A37509	38	37	37	39	39	43	36	41	36	34
A37510	SPILLED	36	39	35	35	38	35	37	34	30

GROUP: FEMALE 5 - 350 MG/KG/DAY

A37526	36	32	35	32	34	33	32	31	28	28
A37527	41	44	42	45	46	44	44	41	39	34
A37528	37	40	38	41	44	45	44	43	37	37
A37529	37	38	40	42	43	44	43	39	36	35
A37530	46	45	46	46	50	SPILLED	46	49	53	38
A37531	SPILLED	47	49	50	44	46	43	53	38	39
A37532	40	44	48	40	39	40	44	47	38	36
A37533	39	45	47	39	42	46	44	41	47	33
A37534	37	44	40	47	43	46	45	42	40	38
A37535	41	43	38	44	47	47	37	42	37	35
A37536	39	39	41	43	43	46	45	41	37	33
A37537	SPILLED	46	44	50	44	47	SPILLED	44	44	36
A37538	28	38	35	42	38	39	41	40	34	35
A37539	36	36	37	43	38	41	36	37	33	33
A37540	SPILLED	41	42	47	39	44	41	40	37	35

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 6A

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL FOOD CONSUMPTION (G)

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STUDY NUMBER: 483287

ANIMAL NUMBER	WEEK 1	WEEK 2	WEEK 3	WEEK 4	WEEK 5	WEEK 6	WEEK 7	WEEK 8	WEEK 9	WEEK 10
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GROUP: FEMALE 6 - 750 MG/KG/DAY

A37556	SPILLED	34	34	37	37	38	35	38	36	39
A37557	SPILLED	44	41	42	45	44	SPILLED	SPILLED	38	40
A37558	SPILLED	31	45	38	41	38	38	35	34	34
A37559	34	37	43	39	38	43	35	43	33	40
A37560	33	41	36	38	38	40	41	39	31	38
A37561	32	35	33	38	35	36	39	38	36	36
A37562	34	33	33	29	34	35	37	35	32	31
A37563	42	38	35	47	SPILLED	45	SPILLED	SPILLED	37	35
A37564	40	40	37	42	39	32	38	SPILLED	37	39
A37565	SPILLED	40	37	41	38	41	36	40	32	33
A37566	38	42	43	43	42	43	40	32	33	34
A37567	SPILLED	44	43	47	46	40	SPILLED	46	43	39
A37568	46	42	39	41	57	46	SPILLED	41	44	36
A37569	35	32	35	46	SPILLED	39	35	38	33	37
A37570	40	39	35	38	39	SPILLED	40	38	35	37

GROUP: FEMALE 7 - 900 MG/KG/DAY

A37586	32	38	35	40	38	36	32	NOT TAKEN		
A37587	SPILLED	37	41	42	38	38	36	53	39	37
A37588	SPILLED	29	42	41	36	37	40	SPILLED	39	37
A37589	SPILLED	49	47	48	53	SPILLED	45	SPILLED	33	40
A37590	SPILLED	32	35	37	SPILLED	33	25	29	30	27
A37591	SPILLED	39	38	47	37	32	35	38	34	33
A37592	38	26	SPILLED	43	39	35	35	39	35	30
A37593	SPILLED	42	37	45	45	41	33	39	45	33
A37594	36	40	40	41	41	39	37	48	39	38
A37595	33	36	41	44	39	45	43	SPILLED	39	31
A37596	SPILLED	35	36	37	SPILLED	42	30	42	31	29
A37597	36	43	31	35	33	33	28	31	32	29
A37598	SPILLED	37	34	41	40	30	37	39	40	30
A37599	33	38	36	35	38	35	37	39	36	25
A37600	SPILLED	38	48	35	38	36	35	43	35	28

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 6A

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL FOOD CONSUMPTION (G)

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STUDY NUMBER: 483287

ANIMAL NUMBER	WEEK 11	WEEK 12	WEEK 13
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GROUP: MALE 1 - 0 MG/KG/DAY

A37391	38	38	35
A37392	30	32	30
A37393	41	40	41
A37394	37	38	36
A37395	39	39	35
A37396	36	37	35
A37397	33	33	34
A37398	32	32	34
A37399	38	43	43
A37400	28	33	31
A37401	35	38	33
A37402	36	47	35
A37403	36	43	35
A37404	39	45	40
A37405	31	35	32

GROUP: MALE 2 - 25 MG/KG/DAY

A37421	39	40	39
A37422	36	38	35
A37423	37	40	37
A37424	32	33	33
A37425	34	38	34
A37426	34	37	32
A37427	35	36	32
A37428	33	37	37
A37429	37	42	37
A37430	32	38	32
A37431	38	39	34
A37432	37	39	38
A37433	33	36	34
A37434	33	37	32
A37435	36	39	35

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 6A

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL FOOD CONSUMPTION (G)

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STUDY NUMBER: 483287

ANIMAL NUMBER	WEEK 11	WEEK 12	WEEK 13
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GROUP: MALE 3 - 75 MG/KG/DAY

A37451	36	35	35
A37452	31	33	31
A37453	34	37	32
A37454	35	37	34
A37455	31	32	32
A37456	36	39	39
A37457	35	35	35
A37458	33	36	38
A37459	35	38	34
A37460	32	36	37
A37461	35	38	37
A37462	30	34	31
A37463	30	32	30
A37464	32	36	34
A37465	36	40	38

GROUP: MALE 4 - 200 MG/KG/DAY

A37481	37	37	39
A37482	33	35	32
A37483	34	36	35
A37484	39	NOT TAKEN	
A37485	36	40	38
A37486	36	37	35
A37487	32	33	34
A37488	32	34	33
A37489	32	34	35
A37490	33	34	33
A37491	37	38	38
A37492	31	34	27
A37493	35	36	37
A37495	36	39	36

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 6A

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL FOOD CONSUMPTION (G)

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STUDY NUMBER: 483287

ANIMAL NUMBER	WEEK 11	WEEK 12	WEEK 13
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GROUP: MALE 5 - 350 MG/KG/DAY

A37511	31	33	30
A37512	30	31	29
A37513	30	35	33
A37514	35	34	33
A37515	34	36	33
A37516	36	41	38
A37517	41	39	35
A37518	33	37	34
A37519	32	36	38
A37520	33	33	33
A37521	34	34	35
A37522	37	39	39
A37523	26	34	34
A37524	28	33	31
A37525	35	35	36

GROUP: MALE 6 - 750 MG/KG/DAY

A37541	29	38	44
A37542	SPIILLED	34	45
A37543	37	37	37
A37544	SPIILLED	40	37
A37545	37	38	49
A37546	33	31	34
A37547	37	36	36
A37548	29	30	30
A37549	SPIILLED	38	36
A37550	35	37	44
A37551	30	34	39
A37552	36	38	38
A37553	32	32	38
A37554	SPIILLED	34	38
A37555	33	34	37

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 6A

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL FOOD CONSUMPTION (G)

PRINTED: 20-JAN-93
PAGE: 391

STUDY NUMBER: 483287

ANIMAL NUMBER	WEEK 11	WEEK 12	WEEK 13
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GROUP: MALE 7 - 900 MG/KG/DAY

A37571	34	36	48
A37572	34	38	41
A37573	32	30	33
A37574	33	32	42
A37575	37	39	49
A37576	31	38	38
A37578	35	33	41
A37580	SPILLED	33	54
A37581	33	32	42
A37582	SPILLED	33	38
A37583	35	39	46
A37584	35	36	41
A37585	SPILLED	39	47

GROUP: FEMALE 1 - 0 MG/KG/DAY

A37406	40	43	32
A37407	38	36	36
A37408	38	40	41
A37409	36	37	39
A37410	39	37	41
A37411	37	36	36
A37412	33	38	45
A37413	36	37	37
A37414	38	37	37
A37415	37	34	36
A37416	40	36	34
A37417	SPILLED	33	36
A37418	32	34	43
A37419	SPILLED	33	27
A37420	35	35	36

GROUP: FEMALE 2 - 25 MG/KG/DAY

A37436	36	33	33
A37437	34	35	39

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 6A

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL FOOD CONSUMPTION (G)

PRINTED: 20-JAN-93
PAGE: 392

STUDY NUMBER: 483287

ANIMAL NUMBER	WEEK 11	WEEK 12	WEEK 13
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GROUP: FEMALE 2 - 25 MG/KG/DAY

A37438	32	32	33
A37439	39	37	41
A37440	33	33	35
A37441	41	38	39
A37442	34	34	36
A37443	33	33	35
A37444	SPILLED	39	41
A37445	38	36	39
A37446	33	SPILLED	37
A37447	SPILLED	40	45
A37448	37	36	37
A37449	39	37	38
A37450	35	36	38

GROUP: FEMALE 3 - 75 MG/KG/DAY

A37466	38	45	45
A37467	34	34	39
A37468	33	36	35
A37469	33	34	36
A37470	36	38	38
A37471	SPILLED	33	42
A37472	32	35	31
A37473	36	38	39
A37474	39	38	40
A37475	SPILLED	39	43
A37476	SPILLED	38	40
A37477	31	31	37
A37478	35	38	36
A37479	36	41	42
A37480	34	39	40

GROUP: FEMALE 4 - 200 MG/KG/DAY

A37497	34	28	37
A37498	34	33	32

APPENDIX 6A

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL FOOD CONSUMPTION (G)PRINTED: 20-JAN-93
PAGE: 393

STUDY NUMBER: 483287

ANIMAL NUMBER	WEEK 11	WEEK 12	WEEK 13
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GROUP: FEMALE 4 - 200 MG/KG/DAY

A37499	35	61	33
A37500	37	38	35
A37501	38	42	39
A37502	31	35	31
A37503	33	37	32
A37504	SPILLED	SPILLED	40
A37505	31	38	30
A37506	36	39	35
A37507	37	56	SPILLED
A37508	38	38	40
A37509	36	38	32
A37510	32	SPILLED	30

GROUP: FEMALE 5 - 350 MG/KG/DAY

A37526	31	30	28
A37527	36	37	33
A37528	35	SPILLED	40
A37529	31	36	32
A37530	39	40	48
A37531	37	38	32
A37532	37	40	41
A37533	36	37	38
A37534	38	SPILLED	39
A37535	SPILLED	43	40
A37536	36	38	27
A37537	SPILLED	39	39
A37538	35	38	39
A37539	35	35	39
A37540	31	40	31

GROUP: FEMALE 6 - 750 MG/KG/DAY

A37556	32	36	36
A37557	37	39	39
A37558	SPILLED	31	34

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 6A

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL FOOD CONSUMPTION (G)

PRINTED: 20-JAN-93
PAGE: 394

STUDY NUMBER: 483287

ANIMAL NUMBER	WEEK 11	WEEK 12	WEEK 13
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GROUP: FEMALE 6 - 750 MG/KG/DAY

A37559	SPILLED	34	31
A37560	30	31	28
A37561	30	33	32
A37562	30	31	31
A37563	27	40	44
A37564	34	33	40
A37565	SPILLED	26	30
A37566	30	35	33
A37567	33	35	34
A37568	36	36	31
A37569	SPILLED	29	33
A37570	32	34	37

GROUP: FEMALE 7 - 900 MG/KG/DAY

A37587	SPILLED	33	41
A37588	SPILLED	29	38
A37589	37	48	31
A37590	SPILLED	28	33
A37591	SPILLED	33	34
A37592	SPILLED	31	37
A37593	SPILLED	30	37
A37594	SPILLED	33	39
A37595	28	31	26
A37596	SPILLED	28	27
A37597	30	30	35
A37598	SPILLED	28	31
A37599	29	30	32
A37600	SPILLED	27	30

Appendix 6B
Individual Food Consumption - Satellite Study
13-Week Subchronic Oral Toxicity Study of Triclosan in CD-1[®] Mice

NOTES: Due to computer limitations, Groups 1-4 correspond to Groups 8-11, respectively; pretreatment values actually represent Week -1.

APPENDIX 6B

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (PRETREATMENT-GROUPS 8-11)
INDIVIDUAL FOOD CONSUMPTION (G)

STUDY NUMBER: 483287B

ANIMAL WEEK
NUMBER 1

GROUP: MALE 1 - 0 MG/KG/DAY

A37601	39
A37602	40
A37603	36
A37604	39
A37605	38
A37606	44
A37607	45
A37608	40
A37609	37
A37610	43

GROUP: MALE 2 - 25 MG/KG/DAY

A37641	42
A37642	38
A37643	36
A37644	42
A37645	40
A37646	42
A37647	38
A37648	38
A37649	40
A37650	43

GROUP: MALE 3 - 350 MG/KG/DAY

A37661	38
A37662	41
A37663	39
A37664	44
A37665	43
A37666	37
A37667	43
A37668	41
A37669	43
A37670	37

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HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 6B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (PRETREATMENT-GROUPS 8-11)
INDIVIDUAL FOOD CONSUMPTION (G)

STUDY NUMBER: 4832878

ANIMAL
NUMBER

WEEK
1

GROUP: MALE 4 - 900 MG/KG/DAY

A37681	46
A37682	40
A37683	38
A37684	45
A37685	39
A37686	44
A37687	41
A37688	40
A37689	38
A37690	46

GROUP: FEMALE 1 - 0 MG/KG/DAY

A37621	41
A37622	37
A37623	38
A37624	36
A37625	37
A37626	37
A37627	45
A37628	37
A37629	36
A37630	40
A37638	32

GROUP: FEMALE 2 - 25 MG/KG/DAY

A37651	SPILLED
A37652	SPILLED
A37653	45
A37654	37
A37655	39
A37656	33
A37657	44
A37658	41
A37659	39

APPENDIX 6B

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (PRETREATMENT-GROUPS 8-11)
INDIVIDUAL FOOD CONSUMPTION (G)

STUDY NUMBER: 4832878

ANIMAL WEEK
NUMBER 1

GROUP: FEMALE 2 - 25 MG/KG/DAY

A37660 41

GROUP: FEMALE 3 - 350 MG/KG/DAY

A37671 38
A37672 55
A37673 42
A37674 49
A37675 51
A37676 36
A37677 32
A37678 41
A37679 39
A37680 34

GROUP: FEMALE 4 - 900 MG/KG/DAY

A37691 40
A37692 SPILLED
A37693 42
A37694 43
A37695 39
A37696 38
A37697 38
A37698 37
A37699 37
A37700 38

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HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 6B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY IN TRICLOSAN IN CD-1
MICE. (SATELLITE-GROUPS 8-11)
DRAFT INDIVIDUAL FOOD CONSUMPTION (G)

PRINTED: 15-MAR-92
PAGE: 1

STUDY NUMBER: 483287

ANIMAL NUMBER	WEEK 1	WEEK 2	WEEK 3	WEEK 4	WEEK 5	WEEK 6	WEEK 7
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GROUP: MALE 1 - 0 MG/KG/DAY

A37601	39	39	37	44	41	41	
A37602	39	35	36	36	34	38	
A37603	SPILLED	36	34	35	35	36	
A37604	42	42	40	45	41	43	
A37605	44	41	43	41	42	42	
A37606	37	36	36	36	37	36	
A37607	43	41	40	41	38	41	
A37608	40	39	38	40	42	41	
A37609	38	39	41	39	37	40	
A37610	44	41	SPILLED	41	39	41	

GROUP: MALE 2 - 25 MG/KG/DAY

A37641	42	38	39	40	47	42	
A37642	41	40	42	38	40	37	
A37643	39	39	41	39	42	43	
A37644	42	41	42	45	41	44	
A37645	39	21	40	39	38	39	
A37646	40	39	40	39	41	42	
A37647	36	31	35	36	38	39	
A37648	40	39	39	42	42	43	
A37649	43	42	46	43	44	48	
A37650	45	40	42	44	43	41	

GROUP: MALE 3 - 350 MG/KG/DAY

A37661	42	41	43	38	41	44	
A37662	35	36	37	37	43	44	
A37663	37	39	40	38	40	41	
A37664	40	35	37	42	41	45	
A37665	44	42	53	48	46	48	
A37666	33	33	38	42	39	40	
A37667	48	46	43	41	43	49	
A37668	36	42	38	42	43	44	
A37669	SPILLED	38	44	45	41	49	
A37670	36	39	37	37	43	43	

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 6B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY IN TRICLOSAN IN CD-1
MICE. (SATELLITE-GROUPS 8-11)
INDIVIDUAL FOOD CONSUMPTION (G)

STUDY NUMBER: 483287

ANIMAL NUMBER	WEEK 1	WEEK 2	WEEK 3	WEEK 4	WEEK 5	WEEK 6	WEEK 7
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GROUP: MALE 4 - 900 MG/KG/DAY

A37681	SPILLED	37	45	43	41	41	
A37682	34	32	36	35	35	SPILLED	
A37683	31	36	38	35	38	42	
A37684	45	36	40	37	41	44	
A37685	21	35	40	37	SPILLED	41	
A37686	SPILLED	38	43	45	40	42	
A37687	31	34	38	43	39	41	
A37688	27	36	40	45	37	SPILLED	
A37689	41	42	37	46	40	48	
A37690	36	38	49	35	42	42	

GROUP: FEMALE 1 - 0 MG/KG/DAY

A37621	39	39	42	43	50	48	
A37622	33	31	36	40	SPILLED	41	
A37623	SPILLED	38	50	44	45	47	
A37624	39	37	39	43	57	47	
A37625	36	20	43	59	SPILLED	55	
A37626	37	40	40	40	46	46	
A37627	SPILLED	SPILLED	44	42	52	51	
A37628	SPILLED	40	41	46	48	46	
A37629	35	35	35	34	41	41	
A37630	37	40	40	44	SPILLED	49	

GROUP: FEMALE 2 - 25 MG/KG/DAY

A37651	41	40	43	45	48	49	
A37652	38	39	40	39	47	44	
A37653	SPILLED	44	44	41	45	49	
A37654	40	39	37	41	47	47	
A37655	37	43	42	44	52	46	
A37656	50	38	36	41	42	41	
A37657	35	37	44	38	43	41	
A37658	46	37	37	43	46	48	
A37659	SPILLED	38	40	43	44	45	
A37660	SPILLED	37	41	39	41	45	

APPENDIX 6B

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.13-WEEK SUBCHRONIC ORAL TOXICITY STUDY IN TRICLOSAN IN CD-1
MICE. (SATELLITE-GROUPS 8-11)
INDIVIDUAL FOOD CONSUMPTION (G)

STUDY NUMBER: 483287

ANIMAL NUMBER	WEEK 1	WEEK 2	WEEK 3	WEEK 4	WEEK 5	WEEK 6	WEEK 7
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GROUP: FEMALE 3 - 350 MG/KG/DAY

A37671	36	46	37	40	46	42
A37672	41	48	40	47	41	43
A37673	39	39	47	44	50	52
A37674	43	39	45	45	44	48
A37675	49	40	41	45	44	43
A37676	38	38	39	42	46	44
A37677	34	35	36	38	39	38
A37678	SPILLED	41	42	49	51	46
A37679	37	34	37	42	44	42
A37680	29	35	36	40	42	43

GROUP: FEMALE 4 - 900 MG/KG/DAY

A37691	SPILLED	36	30	32	30	30
A37692	32	30	31	37	37	39
A37693	39	37	33	30	33	38
A37694	SPILLED	35	42	41	40	44
A37695	SPILLED	22	41	49	46	SPILLED
A37696	39	33	38	44	43	42
A37697	30	35	29	30	37	48
A37698	38	32	42	36	43	47
A37699	32	SPILLED	37	39	41	37
A37700	36	37	34	32	33	33

Appendix 7A
Individual Compound Consumption - Main Study
13-Week Subchronic Oral Toxicity Study of Triclosan in CD-1[®] Mice

Compound Consumption Calculation:

$$\frac{(\text{mg/kg})(\text{Individual Food Consumption})}{7 \text{ Days}} + \frac{\text{Body Weight} + \frac{(\text{BW Change})}{2}}{1000}$$

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 7A

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL COMPOUND CONSUMPTION (MG/KG)

STUDY NUMBER: 483287

ANIMAL NUMBER	WEEK 1	WEEK 2	WEEK 3	WEEK 4	WEEK 5	WEEK 6	WEEK 7	WEEK 8	WEEK 9	WEEK 10
GROUP: MALE 1 - 0 MG/KG/DAY										
A37391	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
A37392	0.0	0.0	SPILLED	0.0	0.0	0.0	0.0	0.0	0.0	0.0
A37393	SPILLED	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
A37394	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
A37395	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
A37396	0.0	0.0	0.0	0.0	SPILLED	0.0	0.0	0.0	0.0	0.0
A37397	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
A37398	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
A37399	SPILLED	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
A37400	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
A37401	SPILLED	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
A37402	0.0	SPILLED	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
A37403	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
A37404	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
A37405	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
GROUP: MALE 2 - 25 MG/KG/DAY										
A37421	24.2	25.2	23.0	25.3	22.1	23.9	23.6	24.4	20.3	25.2
A37422	27.4	26.5	24.5	27.8	23.7	26.1	27.1	26.3	23.6	26.1
A37423	SPILLED	25.4	22.9	26.3	23.0	25.3	29.7	25.5	SPILLED	27.1
A37424	26.0	23.6	22.9	24.4	20.4	22.1	23.0	23.0	18.9	22.0
A37425	24.5	25.4	22.1	26.5	20.3	22.4	28.3	23.7	18.2	24.1
A37426	SPILLED	27.3	24.8	28.5	23.1	23.8	24.4	24.0	21.0	26.8
A37427	27.9	24.0	22.5	24.9	22.7	23.9	24.0	24.6	21.3	24.9
A37428	24.1	26.7	22.3	28.3	23.1	23.9	25.1	23.0	24.2	25.3
A37429	24.3	24.9	23.7	30.5	24.5	25.1	28.3	24.6	20.0	25.5
A37430	26.5	26.0	24.8	33.1	25.2	25.4	26.4	34.1	21.0	27.3
A37431	22.2	22.6	20.8	25.5	22.3	25.9	28.6	24.1	21.5	25.6
A37432	26.0	27.6	24.8	29.0	27.8	31.6	27.7	25.5	22.9	29.3
A37433	23.8	22.8	20.6	24.0	22.6	24.6	23.9	23.5	20.9	23.7
A37434	22.7	25.9	22.9	26.8	23.7	26.1	26.4	22.8	20.7	25.7
A37435	25.9	27.5	24.9	29.6	22.8	26.1	25.1	22.6	21.9	26.8

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HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 7A

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL COMPOUND CONSUMPTION (MG/KG)

STUDY NUMBER: 483287

ANIMAL NUMBER	WEEK 1	WEEK 2	WEEK 3	WEEK 4	WEEK 5	WEEK 6	WEEK 7	WEEK 8	WEEK 9	WEEK 10
GROUP: MALE 3 - 75 MG/KG/DAY										
A37451	80.3	80.8	76.8	86.3	71.4	82.1	81.0	77.4	71.4	73.4
A37452	78.5	69.9	58.7	72.6	61.4	67.8	78.4	70.5	61.8	69.0
A37453	SPIILLED	75.3	70.2	80.9	67.5	68.2	71.9	72.8	61.8	75.3
A37454	SPIILLED	87.8	78.7	109.3	68.3	78.7	83.0	79.9	71.1	79.4
A37455	68.3	77.9	69.1	83.5	66.9	68.7	75.0	77.0	69.0	75.9
A37456	67.4	73.3	64.9	77.9	66.7	73.8	74.1	70.4	61.1	70.3
A37457	SPIILLED	69.3	63.9	78.5	61.6	64.6	71.1	69.2	59.2	69.2
A37458	70.9	74.6	64.1	75.4	60.2	75.8	76.7	72.1	63.7	74.4
A37459	85.0	113.4	78.1	103.7	91.0	84.1	86.5	84.0	79.0	80.4
A37460	68.3	71.1	63.9	80.3	60.9	69.2	69.2	72.8	60.9	68.1
A37461	70.4	76.3	68.5	84.3	65.2	68.9	73.7	74.2	66.3	71.2
A37462	64.3	68.8	63.5	75.9	63.2	74.9	70.9	68.6	65.7	71.2
A37463	70.2	80.9	72.3	78.5	85.3	77.9	75.5	82.8	72.7	79.9
A37464	70.3	84.6	67.2	78.5	64.6	68.4	69.5	71.6	70.6	74.5
A37465	79.9	81.2	75.5	88.3	72.0	88.1	85.0	83.3	80.8	94.1
GROUP: MALE 4 - 200 MG/KG/DAY										
A37481	SPIILLED	209.2	232.1	249.6	190.2	201.2	229.2	210.8	181.2	212.6
A37482	SPIILLED	195.2	208.7	206.8	184.2	195.0	200.6	195.7	192.2	206.5
A37483	207.3	206.9	196.7	221.5	190.2	194.2	210.3	198.8	183.8	218.7
A37484	225.9	226.3	207.3	218.1	202.9	203.4	217.3	SPIILLED	187.0	215.6
A37485	237.6	226.0	224.0	235.3	213.2	239.0	231.3	217.6	192.2	218.7
A37486	212.3	213.2	212.8	222.8	209.2	204.8	215.6	194.7	195.5	207.7
A37487	182.0	182.6	174.1	177.2	184.8	174.5	172.3	165.2	160.8	177.9
A37488	196.3	196.6	208.0	198.5	203.1	193.1	190.6	172.6	160.4	183.0
A37489	SPIILLED	189.9	190.1	204.9	172.0	165.8	180.0	172.2	163.1	174.5
A37490	174.5	191.8	183.0	185.2	170.6	188.3	177.0	169.8	173.0	183.0
A37491	189.0	193.5	200.1	190.6	188.9	202.6	236.6	214.1	208.6	185.5
A37492	195.0	200.3	211.0	202.4	216.4	216.8	219.2	196.0	187.2	204.1
A37493	214.5	199.9	191.9	189.2	178.5	192.1	197.6	187.0	178.1	205.6
A37494	SPIILLED	212.4	206.6	180.8	SPIILLED	NOT TAKEN	NOT TAKEN	NOT TAKEN	NOT TAKEN	NOT TAKEN
A37495	198.9	204.1	193.5	201.4	189.7	194.7	204.9	178.4	187.4	188.7

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 7A

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL COMPOUND CONSUMPTION (MG/KG)

STUDY NUMBER: 483287

ANIMAL NUMBER	WEEK 1	WEEK 2	WEEK 3	WEEK 4	WEEK 5	WEEK 6	WEEK 7	WEEK 8	WEEK 9	WEEK 10
GROUP: MALE 5 - 350 MG/KG/DAY										
A37511	361.1	371.2	324.9	368.9	321.2	323.6	337.7	337.4	296.3	343.6
A37512	SPILLED	379.7	358.9	406.4	357.1	381.1	369.6	372.9	352.9	345.0
A37513	331.9	346.4	322.4	345.1	302.1	307.2	304.9	308.6	270.5	295.1
A37514	367.5	374.8	341.7	405.1	340.6	338.1	361.4	344.7	284.3	309.1
A37515	320.0	376.3	342.1	353.9	340.9	332.5	325.0	329.4	323.5	327.6
A37516	SPILLED	358.4	320.0	SPILLED	385.5	352.9	357.1	351.5	350.5	360.7
A37517	425.1	411.8	360.1	288.7	422.6	400.1	448.2	428.5	432.7	403.4
A37518	337.3	352.0	308.0	482.1	305.2	310.5	321.3	308.0	330.7	318.3
A37519	340.9	371.2	347.8	470.2	327.7	347.6	338.2	337.9	359.4	337.2
A37520	309.0	320.4	300.3	327.5	320.4	315.6	299.3	299.0	288.7	277.9
A37521	331.4	352.0	344.1	396.7	375.8	340.2	336.7	341.3	349.0	322.8
A37522	369.9	376.3	344.6	433.6	351.7	347.2	395.3	362.3	366.9	371.7
A37523	367.8	410.2	317.0	283.1	324.9	308.4	345.0	332.1	305.7	317.8
A37524	322.9	437.6	339.4	413.7	303.7	275.1	368.3	327.0	287.6	298.7
A37525	397.9	385.2	392.1	365.7	333.1	347.6	369.0	346.3	322.9	313.5
GROUP: MALE 6 - 750 MG/KG/DAY										
A37541	718.3	685.5	875.9	468.4	698.6	649.1	731.3	777.0	670.0	830.8
A37542	783.4	637.5	843.1	721.2	838.3	690.4	SPILLED	861.7	680.7	830.8
A37543	596.1	844.6	719.7	724.8	650.9	626.7	683.1	710.9	587.2	588.7
A37544	634.5	729.1	771.2	687.3	794.9	703.1	815.0	802.7	691.7	581.5
A37545	755.4	942.5	968.9	987.0	879.5	791.0	844.4	909.8	SPILLED	1063.4
A37546	858.0	737.2	762.3	592.2	803.4	726.2	735.5	738.1	683.5	849.8
A37547	619.9	739.6	754.0	611.0	731.8	626.2	671.5	740.6	659.7	675.2
A37548	725.8	692.1	710.4	559.3	648.7	567.9	671.5	601.9	SPILLED	664.6
A37549	858.0	761.6	807.9	634.5	717.0	691.0	794.4	SPILLED	718.8	743.5
A37550	SPILLED	936.8	1203.2	1067.5	838.3	861.0	SPILLED	938.0	SPILLED	895.2
A37551	705.0	760.9	803.9	765.7	728.2	661.4	710.8	863.6	SPILLED	762.7
A37552	625.9	936.8	1095.3	945.8	901.2	742.2	SPILLED	833.8	854.1	928.0
A37553	718.3	950.6	716.1	526.4	760.5	642.7	820.8	695.9	614.8	664.6
A37554	676.8	797.4	839.4	1164.6	810.6	772.2	829.6	893.9	658.7	792.9
A37555	SPILLED	796.9	731.6	752.8	681.1	589.9	731.7	723.0	SPILLED	653.7

APPENDIX 7A

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)

INDIVIDUAL COMPOUND CONSUMPTION (MG/KG)

STUDY NUMBER: 483287

ANIMAL NUMBER	WEEK 1	WEEK 2	WEEK 3	WEEK 4	WEEK 5	WEEK 6	WEEK 7	WEEK 8	WEEK 9	WEEK 10
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GROUP: MALE 7 - 900 MG/KG/DAY

A37571	695.4	964.3	1033.9	936.9	902.1	816.6	955.2	972.2	749.9	801.6
A37572	919.0	1031.0	921.8	976.4	935.7	762.1	SPILLED	1016.6	780.6	828.6
A37573	938.1	1045.8	939.9	875.7	948.5	801.0	796.1	1077.3	850.2	844.6
A37574	620.0	799.2	845.9	994.9	908.2	816.6	875.0	1006.9	798.6	788.3
A37575	730.2	843.6	980.5	946.1	868.3	737.5	799.4	SPILLED	679.6	868.0
A37576	1293.1	1048.9	859.2	798.9	925.0	837.2	864.2	986.9	706.3	739.0
A37577	1014.2		NOT TAKEN	NOT TAKEN	NOT TAKEN	NOT TAKEN	NOT TAKEN	NOT TAKEN	NOT TAKEN	NOT TAKEN
A37578	937.7	963.0	842.6	817.1	845.7	756.3	800.7	SPILLED	530.8	821.1
A37579	973.6	688.7		NOT TAKEN	NOT TAKEN	NOT TAKEN	NOT TAKEN	NOT TAKEN	NOT TAKEN	NOT TAKEN
A37580	796.6	920.5	946.1	888.4	941.0	947.5	SPILLED	1066.6	779.4	797.7
A37581	532.4	1071.3	943.4	886.8	1049.6	1026.0	873.2	1251.2	SPILLED	927.4
A37582	SPILLED	817.4	937.8	929.3	1076.6	845.6	SPILLED	1058.6	770.7	901.8
A37583	872.6	853.0	1154.8	862.0	889.0	830.7	872.0	893.0	752.9	771.1
A37584	763.6	922.2	958.7	841.0	925.0	817.3	829.4	1073.4	793.4	762.1
A37585	969.1	954.6	1048.6	918.8	915.1	911.7	SPILLED	823.0	757.3	873.4

GROUP: FEMALE 1 - 0 MG/KG/DAY

A37406	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
A37407	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
A37408	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
A37409	0.0	0.0	0.0	0.0	0.0	SPILLED	0.0	0.0	0.0	0.0
A37410	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
A37411	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
A37412	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
A37413	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
A37414	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
A37415	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
A37416	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
A37417	0.0	0.0	0.0	0.0	0.0	0.0	SPILLED	0.0	0.0	0.0
A37418	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
A37419	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
A37420	SPILLED	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 7A

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL COMPOUND CONSUMPTION (MG/KG)

STUDY NUMBER: 483287

ANIMAL NUMBER	WEEK 1	WEEK 2	WEEK 3	WEEK 4	WEEK 5	WEEK 6	WEEK 7	WEEK 8	WEEK 9	WEEK 10
GROUP: FEMALE 2 - 25 MG/KG/DAY										
A37436	23.9	24.3	22.6	25.4	22.7	24.7	25.0	25.1	24.1	19.8
A37437	23.0	23.4	24.0	33.1	21.7	24.1	19.9	23.9	23.0	24.7
A37438	22.3	22.4	23.9	22.1	21.1	22.8	18.5	23.2	21.9	23.1
A37439	25.5	30.3	24.7	25.1	22.3	23.0	21.4	24.4	23.6	26.0
A37440	24.6	25.1	24.0	25.3	22.3	23.1	18.9	22.0	22.8	22.7
A37441	SPILLED	26.5	26.6	28.5	22.7	24.7	SPILLED	29.1	26.7	24.9
A37442	SPILLED	25.2	25.7	26.4	22.2	23.6	21.8	23.7	22.4	23.5
A37443	24.1	24.6	24.0	24.5	22.6	23.5	20.8	SPILLED	22.6	23.3
A37444	31.9	28.4	28.4	30.5	29.4	31.7	31.3	37.3	28.9	28.0
A37445	24.6	SPILLED	24.5	26.5	24.0	24.8	23.2	25.9	24.3	26.1
A37446	SPILLED	29.4	25.4	30.6	25.3	26.7	24.7	31.0	28.1	26.7
A37447	SPILLED	30.9	28.2	30.2	30.7	26.4	26.4	34.1	27.0	26.9
A37448	27.1	25.3	26.5	27.8	21.5	24.2	22.0	28.1	23.7	26.2
A37449	24.9	26.5	25.2	26.5	24.0	25.7	25.9	16.7	26.0	25.8
A37450	27.6	25.6	25.1	27.4	23.5	25.1	24.5	26.1	25.1	24.9
GROUP: FEMALE 3 - 75 MG/KG/DAY										
A37466	77.3	64.2	75.5	80.6	77.9	70.0	SPILLED	85.3	80.6	71.6
A37467	66.6	68.9	67.8	77.3	68.6	68.4	72.4	71.3	75.5	74.6
A37468	76.7	78.7	80.1	81.9	75.5	68.1	68.3	73.6	53.9	67.6
A37469	75.0	71.7	69.4	74.7	70.1	62.7	65.9	69.1	64.9	66.1
A37470	SPILLED	82.6	84.0	91.2	85.5	76.7	77.8	74.2	80.7	78.9
A37471	103.8	76.0	91.6	93.1	78.4	78.8	68.3	82.2	75.5	58.1
A37472	78.4	82.4	77.8	75.3	72.8	67.6	72.1	68.5	69.8	64.3
A37473	73.4	77.1	74.2	82.2	72.3	72.1	73.6	70.3	71.1	71.6
A37474	86.8	82.4	91.6	81.3	84.1	78.5	SPILLED	81.8	77.9	71.6
A37475	SPILLED	76.7	85.9	80.0	99.0	82.2	83.5	94.7	91.2	72.3
A37476	73.0	78.0	67.9	74.6	SPILLED	72.9	79.0	70.3	77.0	69.2
A37477	82.9	73.6	73.2	72.8	79.4	69.5	70.0	69.7	71.7	68.5
A37478	71.9	74.0	73.2	71.5	65.3	69.1	77.2	66.0	66.1	65.4
A37479	73.8	72.5	69.9	73.3	73.3	78.5	77.2	67.9	70.5	71.0
A37480	78.7	74.8	68.4	69.1	69.6	72.6	74.9	71.1	67.8	73.7

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HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 7A
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL COMPOUND CONSUMPTION (MG/KG)

STUDY NUMBER: 483287

ANIMAL NUMBER	WEEK 1	WEEK 2	WEEK 3	WEEK 4	WEEK 5	WEEK 6	WEEK 7	WEEK 8	WEEK 9	WEEK 10
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GROUP: FEMALE 4 - 200 MG/KG/DAY

A37496	221.1	213.9	SPILLED	258.3		NOT TAKEN	NOT TAKEN	NOT TAKEN	NOT TAKEN	NOT TAKEN
A37497	200.8	190.1	191.8	218.0	202.2	209.0	206.7	199.5	207.7	182.7
A37498	181.4	186.3	175.1	196.6	183.4	190.1	172.5	182.6	177.4	152.7
A37499	231.2	238.8	220.1	204.5	205.0	204.2	235.7	192.4	197.0	184.8
A37500	206.0	209.6	194.0	202.8	211.1	218.8	201.8	189.0	193.6	185.4
A37501	SPILLED	201.4	203.5	230.1	229.2	208.2	209.8	208.4	205.7	174.2
A37502	191.7	199.0	192.5	258.1	201.5	207.8	201.8	187.4	192.9	172.9
A37503	231.6	189.1	211.5	195.3	218.6	194.5	202.9	189.0	205.7	166.0
A37504	SPILLED	228.4	218.1	258.1	234.7	247.1	239.7	259.7	247.6	227.4
A37505	186.1	180.4	182.9	187.6	180.9	200.8	177.2	174.5	179.3	163.6
A37506	231.9	187.3	184.6	201.4	196.0	198.0	180.2	190.5	209.4	183.5
A37507	208.4	188.3	218.3	209.1	197.1	190.5	182.7	178.5	195.7	168.9
A37508	SPILLED	238.8	224.7	187.6	198.4	194.5	196.8	187.4	198.6	184.8
A37509	204.6	188.0	189.4	194.0	185.3	205.2	173.9	202.2	189.9	173.3
A37510	SPILLED	175.5	188.1	164.8	163.3	181.4	163.2	179.3	182.5	155.6

GROUP: FEMALE 5 - 350 MG/KG/DAY

A37526	339.0	344.2	333.9	290.7	299.2	288.6	291.5	295.7	277.0	267.5
A37527	321.7	399.1	333.9	328.3	334.1	321.7	324.5	302.2	302.7	274.1
A37528	284.4	342.7	296.6	320.2	347.1	352.2	352.4	354.5	311.1	312.9
A37529	309.7	358.7	336.7	339.9	351.3	356.8	350.5	321.5	313.1	316.8
A37530	353.6	400.3	372.6	365.6	394.4	SPILLED	368.4	410.9	453.2	326.7
A37531	SPILLED	402.6	362.7	370.9	341.2	342.0	322.2	415.8	309.2	319.4
A37532	334.8	415.4	404.1	342.4	343.1	336.6	385.7	439.6	361.7	337.7
A37533	326.4	433.7	411.8	340.4	369.5	394.6	393.1	383.5	464.9	340.5
A37534	309.7	415.4	336.7	394.7	357.7	347.8	337.2	334.9	330.8	311.2
A37535	359.1	423.2	333.0	376.6	398.2	374.4	296.4	358.4	333.3	316.8
A37536	326.4	368.2	352.1	354.4	357.7	380.0	348.4	316.6	306.0	283.8
A37537	SPILLED	425.6	356.4	404.6	366.0	381.2	SPILLED	382.2	396.4	331.7
A37538	263.6	390.6	306.7	359.5	322.0	310.6	322.8	319.0	281.2	296.0
A37539	322.8	354.3	324.2	390.6	347.7	345.1	304.1	327.2	308.3	309.6
A37540	SPILLED	451.6	409.8	464.9	379.6	384.8	373.5	381.5	359.0	347.3

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 7A

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL COMPOUND CONSUMPTION (MG/KG)

STUDY NUMBER: 483287

ANIMAL NUMBER	WEEK 1	WEEK 2	WEEK 3	WEEK 4	WEEK 5	WEEK 6	WEEK 7	WEEK 8	WEEK 9	WEEK 10
GROUP: FEMALE 6 - 750 MG/KG/DAY										
A37556	SPILLED	785.9	753.5	822.3	751.4	792.9	704.5	762.8	732.4	854.9
A37557	SPILLED	805.1	745.1	787.0	773.3	754.2	SPILLED	SPILLED	691.8	758.0
A37558	SPILLED	618.8	888.9	789.4	763.3	715.2	719.9	688.8	691.8	775.7
A37559	623.5	755.8	868.3	810.2	738.2	859.8	690.1	880.7	698.8	931.6
A37560	578.3	782.9	696.0	789.4	722.5	752.8	761.8	738.5	606.9	801.6
A37561	630.9	698.7	651.9	756.5	638.3	691.1	738.8	747.8	704.8	759.4
A37562	582.9	603.9	599.7	554.3	595.7	633.8	662.0	650.5	603.7	618.9
A37563	770.3	741.7	662.6	880.7	SPILLED	814.9	SPILLED	SPILLED	738.3	752.5
A37564	701.0	763.8	700.4	819.1	697.0	568.8	667.5	SPILLED	673.6	751.7
A37565	SPILLED	798.5	747.1	816.3	653.0	728.8	656.2	757.5	614.9	670.8
A37566	696.9	838.4	849.4	874.3	781.9	809.3	743.2	606.0	646.1	717.2
A37567	SPILLED	757.8	737.2	802.0	685.1	619.2	SPILLED	756.8	719.6	692.1
A37568	843.6	819.8	754.0	833.6	1039.5	865.7	SPILLED	806.8	878.0	759.4
A37569	690.0	720.7	775.7	1072.2	SPILLED	779.9	676.3	719.6	646.1	827.3
A37570	751.0	815.6	757.2	807.0	741.5	SPILLED	822.2	811.4	756.6	844.2
GROUP: FEMALE 7 - 900 MG/KG/DAY										
A37586	746.1	854.3	767.1	837.7	719.2	760.8	717.4		NOT TAKEN	NOT TAKEN
A37587	SPILLED	933.2	1000.7	1019.5	847.1	922.6	910.0	1398.3	869.3	1004.8
A37588	SPILLED	697.4	1002.3	973.1	785.0	879.6	990.1	SPILLED	756.6	891.0
A37589	SPILLED	1299.3	1231.0	1192.2	1155.8	SPILLED	1091.1	SPILLED	664.9	963.3
A37590	SPILLED	919.2	1015.8	1039.9	SPILLED	896.6	724.5	838.0	714.3	783.2
A37591	SPILLED	983.7	949.0	1167.4	824.8	760.8	884.8	960.8	698.4	825.9
A37592	972.5	689.4	SPILLED	937.2	767.1	753.6	784.6	928.1	719.0	722.5
A37593	SPILLED	1034.1	883.0	1044.8	960.4	954.9	800.2	910.2	889.5	842.4
A37594	899.4	984.9	954.6	951.9	894.1	967.5	976.9	1239.5	833.8	989.8
A37595	887.8	908.0	978.4	1044.3	869.4	1116.4	1110.6	SPILLED	801.1	760.9
A37596	SPILLED	841.7	859.1	859.1	SPILLED	998.5	742.6	1061.9	691.0	804.6
A37597	821.2	988.2	739.8	830.7	704.3	768.5	678.9	800.5	670.5	698.4
A37598	SPILLED	956.6	890.5	1042.6	911.9	744.2	935.3	1007.1	891.6	814.7
A37599	721.4	836.1	773.2	718.9	705.9	700.7	771.2	860.6	673.5	569.8
A37600	SPILLED	982.4	1198.8	849.6	828.7	855.9	848.7	1023.3	691.8	687.3

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 7A

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL COMPOUND CONSUMPTION (MG/KG)

STUDY NUMBER: 483287

ANIMAL NUMBER	WEEK 11	WEEK 12	WEEK 13
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GROUP: MALE 1 - 0 MG/KG/DAY

A37391	0.0	0.0	0.0
A37392	0.0	0.0	0.0
A37393	0.0	0.0	0.0
A37394	0.0	0.0	0.0
A37395	0.0	0.0	0.0
A37396	0.0	0.0	0.0
A37397	0.0	0.0	0.0
A37398	0.0	0.0	0.0
A37399	0.0	0.0	0.0
A37400	0.0	0.0	0.0
A37401	0.0	0.0	0.0
A37402	0.0	0.0	0.0
A37403	0.0	0.0	0.0
A37404	0.0	0.0	0.0
A37405	0.0	0.0	0.0

GROUP: MALE 2 - 25 MG/KG/DAY

A37421	25.6	26.5	23.7
A37422	26.8	29.3	24.3
A37423	25.4	28.1	23.8
A37424	21.0	22.8	20.6
A37425	24.1	27.9	22.5
A37426	24.5	27.6	21.5
A37427	25.2	26.9	21.9
A37428	23.8	27.2	24.1
A37429	23.6	27.9	22.4
A37430	23.8	28.8	21.9
A37431	25.7	27.8	22.2
A37432	27.1	29.6	26.4
A37433	23.0	26.1	22.2
A37434	25.0	29.5	23.0
A37435	25.9	29.1	23.5

HAZLETON WASHINGTON, INC.
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APPENDIX 7A

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL COMPOUND CONSUMPTION (MG/KG)

STUDY NUMBER: 483287

ANIMAL
NUMBER

WEEK
11

WEEK
12

WEEK
13

GROUP: MALE 3 - 75 MG/KG/DAY

A37451	79.2	81.3	75.1
A37452	68.2	76.6	65.5
A37453	67.4	77.7	62.0
A37454	79.5	88.6	75.2
A37455	74.0	81.8	75.6
A37456	67.6	78.7	72.5
A37457	69.4	72.5	66.8
A37458	69.3	82.4	79.1
A37459	78.2	92.5	77.7
A37460	63.5	77.7	72.6
A37461	69.4	80.9	70.7
A37462	65.0	79.0	65.5
A37463	72.8	84.6	72.1
A37464	67.2	81.2	69.7
A37465	84.5	102.2	88.3

GROUP: MALE 4 - 200 MG/KG/DAY

A37481	209.9	223.3	227.9
A37482	190.1	208.1	184.2
A37483	198.9	217.3	204.5
A37484	211.6		NOT TAKEN
A37485	217.4	257.0	229.1
A37486	195.3	210.6	189.9
A37487	168.7	182.6	181.9
A37488	176.2	196.3	181.7
A37489	173.6	188.1	184.7
A37490	179.1	193.5	179.1
A37491	216.4	232.9	222.1
A37492	196.7	225.7	179.9
A37493	198.5	214.0	209.8
A37494	NOT TAKEN	NOT TAKEN	NOT TAKEN
A37495	184.6	207.1	182.3

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 7A

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)

INDIVIDUAL COMPOUND CONSUMPTION (MG/KG)

STUDY NUMBER: 483287

ANIMAL
NUMBER

WEEK
11

WEEK
12

WEEK
13

GROUP: MALE 5 - 350 MG/KG/DAY

A37511	341.1	368.3	315.4
A37512	358.5	381.2	330.8
A37513	297.1	362.7	326.6
A37514	341.7	347.4	317.2
A37515	346.6	384.1	326.6
A37516	356.5	424.9	365.3
A37517	444.1	442.1	362.3
A37518	313.4	362.7	305.1
A37519	326.2	395.7	387.4
A37520	317.7	332.5	308.4
A37521	332.0	347.4	336.5
A37522	377.2	416.1	380.3
A37523	277.3	373.7	346.7
A37524	289.7	352.1	311.4
A37525	346.6	368.0	351.1

GROUP: MALE 6 - 750 MG/KG/DAY

A37541	625.0	835.7	881.5
A37542	SPILLED	813.3	993.2
A37543	705.0	720.7	688.3
A37544	SPILLED	879.6	764.8
A37545	810.7	893.3	1100.2
A37546	699.7	692.9	737.9
A37547	784.6	755.1	710.3
A37548	577.7	619.8	591.9
A37549	SPILLED	849.4	756.2
A37550	958.6	1029.5	1123.5
A37551	646.6	760.0	819.2
A37552	893.0	942.0	899.7
A37553	667.8	692.5	798.2
A37554	SPILLED	799.3	853.2
A37555	699.7	747.7	789.9

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HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 7A

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL COMPOUND CONSUMPTION (MG/KG)

STUDY NUMBER: 483287

ANIMAL NUMBER	WEEK 11	WEEK 12	WEEK 13
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GROUP: MALE 7 - 900 MG/KG/DAY

A37571	905.0	994.0	1274.9
A37572	835.4	983.6	1020.9
A37573	912.6	871.9	939.1
A37574	924.6	930.0	1154.0
A37575	938.0	1009.5	1239.5
A37576	750.2	939.6	877.7
A37577	NOT TAKEN	NOT TAKEN	NOT TAKEN
A37578	846.9	828.3	1005.2
A37579	NOT TAKEN	NOT TAKEN	NOT TAKEN
A37580	SPILLED	881.8	1410.8
A37581	1054.1	1060.2	1338.7
A37582	SPILLED	881.8	946.2
A37583	810.1	936.4	1062.4
A37584	873.4	903.6	990.0
A37585	SPILLED	994.0	1134.9

GROUP: FEMALE 1 - 0 MG/KG/DAY

A37406	0.0	0.0	0.0
A37407	0.0	0.0	0.0
A37408	0.0	0.0	0.0
A37409	0.0	0.0	0.0
A37410	0.0	0.0	0.0
A37411	0.0	0.0	0.0
A37412	0.0	0.0	0.0
A37413	0.0	0.0	0.0
A37414	0.0	0.0	0.0
A37415	0.0	0.0	0.0
A37416	0.0	0.0	0.0
A37417	SPILLED	0.0	0.0
A37418	0.0	0.0	0.0
A37419	SPILLED	0.0	0.0
A37420	0.0	0.0	0.0

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 7A

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL COMPOUND CONSUMPTION (MG/KG)

STUDY NUMBER: 483287

ANIMAL NUMBER	WEEK 11	WEEK 12	WEEK 13
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GROUP: FEMALE 2 - 25 MG/KG/DAY

A37436	23.6	23.4	23.6
A37437	21.1	22.8	25.1
A37438	21.8	23.6	24.0
A37439	22.3	22.5	25.2
A37440	20.5	21.8	24.1
A37441	24.6	23.9	25.1
A37442	21.9	23.3	24.8
A37443	21.6	23.4	25.0
A37444	SPILLED	29.3	30.4
A37445	24.5	24.7	26.9
A37446	22.9	SPILLED	28.0
A37447	SPILLED	27.9	31.0
A37448	25.6	27.1	28.5
A37449	24.7	25.3	26.2
A37450	25.7	28.2	29.9

GROUP: FEMALE 3 - 75 MG/KG/DAY

A37466	76.9	95.2	88.5
A37467	78.2	80.2	85.5
A37468	70.4	78.9	72.6
A37469	64.5	70.7	68.4
A37470	76.8	84.7	78.8
A37471	SPILLED	73.6	84.0
A37472	70.8	81.0	65.5
A37473	75.4	83.2	79.4
A37474	77.5	79.0	76.0
A37475	SPILLED	88.6	89.2
A37476	SPILLED	77.7	74.8
A37477	64.9	66.7	72.8
A37478	69.6	77.7	68.4
A37479	76.8	88.2	82.6
A37480	75.2	88.6	82.9

HAZLETON WASHINGTON, INC.
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APPENDIX 7A

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL COMPOUND CONSUMPTION (MG/KG)

STUDY NUMBER: 483287

ANIMAL NUMBER	WEEK 11	WEEK 12	WEEK 13
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GROUP: FEMALE 4 - 200 MG/KG/DAY

A37496	NOT TAKEN	NOT TAKEN	NOT TAKEN
A37497	212.4	165.8	198.6
A37498	191.5	173.3	155.2
A37499	211.0	342.5	168.1
A37500	211.9	206.3	175.4
A37501	233.1	235.8	195.4
A37502	197.2	211.1	169.4
A37503	195.5	204.2	160.3
A37504	SPILLED	SPILLED	222.7
A37505	221.9	257.8	158.2
A37506	206.1	211.7	178.3
A37507	198.6	272.2	SPILLED
A37508	225.1	209.7	200.4
A37509	209.6	213.4	165.9
A37510	189.6	SPILLED	155.5

GROUP: FEMALE 5 - 350 MG/KG/DAY

A37526	335.2	325.0	282.3
A37527	329.4	334.0	269.1
A37528	341.2	SPILLED	336.1
A37529	312.5	357.5	295.8
A37530	380.2	384.4	422.5
A37531	338.5	348.3	281.7
A37532	392.9	425.6	406.0
A37533	419.8	424.0	397.6
A37534	353.1	SPILLED	327.7
A37535	SPILLED	427.0	363.7
A37536	356.8	377.4	249.6
A37537	SPILLED	400.7	366.6
A37538	330.4	353.8	343.3
A37539	365.1	365.9	386.2
A37540	347.8	433.3	318.4

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 7A

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL COMPOUND CONSUMPTION (MG/KG)

STUDY NUMBER: 483287

ANIMAL NUMBER	WEEK 11	WEEK 12	WEEK 13
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GROUP: FEMALE 6 - 750 MG/KG/DAY

A37556	682.2	897.0	834.5
A37557	672.4	844.3	798.6
A37558	SPILLED	802.7	835.5
A37559	SPILLED	935.4	793.5
A37560	615.9	758.1	637.1
A37561	627.5	807.0	756.1
A37562	583.5	705.8	656.7
A37563	564.7	960.4	982.9
A37564	649.9	751.3	847.3
A37565	SPILLED	613.1	670.2
A37566	615.9	840.3	724.0
A37567	571.6	711.0	652.7
A37568	739.1	864.3	692.5
A37569	SPILLED	797.8	827.4
A37570	709.5	916.3	947.1

GROUP: FEMALE 7 - 900 MG/KG/DAY

A37586	NOT TAKEN	NOT TAKEN	NOT TAKEN
A37587	SPILLED	1141.5	1153.2
A37588	SPILLED	873.1	989.7
A37589	923.2	1345.5	764.9
A37590	SPILLED	1058.7	1079.3
A37591	SPILLED	1094.9	975.9
A37592	SPILLED	969.2	1020.3
A37593	SPILLED	938.0	1020.3
A37594	SPILLED	1094.9	1075.5
A37595	767.2	1008.0	717.0
A37596	SPILLED	989.6	863.0
A37597	806.1	938.0	911.5
A37598	SPILLED	1011.6	947.8
A37599	710.9	855.7	803.6
A37600	SPILLED	914.5	879.0

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Appendix 7B
Individual Compound Consumption - Satellite Study
13-Week Subchronic Oral Toxicity Study of Triclosan in CD-1[®] Mice

NOTE: Due to computer limitations, Groups 1-4 correspond to Groups 8-11, respectively.

Compound Consumption Calculation:

$$\frac{(\text{mg/kg})(\text{Individual Food Consumption})}{7 \text{ Days}} + \frac{\text{Body Weight} + \frac{(\text{BW Change})}{2}}{1000}$$

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 7B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY IN TRICLOSAN IN CD-1
MICE. (SATELLITE-GROUPS 8-11)
INDIVIDUAL COMPOUND CONSUMPTION (MG/KG)

STUDY NUMBER: 483287

ANIMAL NUMBER	WEEK 1	WEEK 2	WEEK 3	WEEK 4	WEEK 5	WEEK 6
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GROUP: MALE 1 - 0 MG/KG/DAY

A37601	0.0	0.0	0.0	0.0	0.0	0.0
A37602	0.0	0.0	0.0	0.0	0.0	0.0
A37603	SPILLED	0.0	0.0	0.0	0.0	0.0
A37604	0.0	0.0	0.0	0.0	0.0	0.0
A37605	0.0	0.0	0.0	0.0	0.0	0.0
A37606	0.0	0.0	0.0	0.0	0.0	0.0
A37607	0.0	0.0	0.0	0.0	0.0	0.0
A37608	0.0	0.0	0.0	0.0	0.0	0.0
A37609	0.0	0.0	0.0	0.0	0.0	0.0
A37610	0.0	0.0	SPILLED	0.0	0.0	0.0

GROUP: MALE 2 - 25 MG/KG/DAY

A37641	25.0	23.8	23.7	26.1	29.2	25.6
A37642	24.9	25.1	25.1	24.8	26.1	24.5
A37643	23.2	24.5	24.9	25.8	27.8	28.5
A37644	22.8	23.2	23.1	27.1	24.3	25.3
A37645	25.6	14.8	27.7	29.3	28.0	28.8
A37646	22.9	23.6	23.5	25.0	25.4	25.3
A37647	22.7	20.2	22.5	25.6	26.1	25.4
A37648	22.9	23.2	22.5	26.1	25.3	25.5
A37649	23.4	23.7	25.3	26.7	27.3	28.9
A37650	25.3	23.8	25.1	29.1	28.0	26.3

GROUP: MALE 3 - 350 MG/KG/DAY

A37661	376.7	373.8	364.8	341.8	368.7	395.7
A37662	319.9	340.1	324.9	344.0	380.5	371.4
A37663	325.8	337.8	322.9	341.8	359.7	357.0
A37664	365.6	343.2	349.5	411.5	374.9	398.2
A37665	367.5	352.0	402.0	381.6	365.7	381.6
A37666	296.0	317.6	345.8	390.5	356.6	365.7
A37667	407.9	385.5	336.3	357.0	380.5	420.0
A37668	322.9	376.3	317.0	377.7	380.5	377.2
A37669	SPILLED	394.9	431.9	448.9	409.0	480.0

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APPENDIX 78

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.13-WEEK SUBCHRONIC ORAL TOXICITY STUDY IN TRICLOSAM IN CD-1
MICE. (SATELLITE-GROUPS 8-11)
INDIVIDUAL COMPOUND CONSUMPTION (MG/KG)

STUDY NUMBER: 483287

ANIMAL NUMBER	WEEK 1	WEEK 2	WEEK 3	WEEK 4	WEEK 5	WEEK 6
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GROUP: MALE 3 - 350 MG/KG/DAY

A37670	341.9	382.4	336.7	362.5	413.9	393.2
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GROUP: MALE 4 - 900 MG/KG/DAY

A37681	SPILLED	964.3	1100.5	1030.6	982.7	944.9
A37682	899.5	913.4	980.5	892.4	856.0	SPILLED
A37683	802.7	959.0	948.7	806.6	828.0	867.8
A37684	1117.7	918.2	978.2	869.4	909.9	925.1
A37685	532.4	953.6	1019.9	904.9	SPILLED	909.9
A37686	SPILLED	893.2	920.2	929.8	812.5	811.8
A37687	739.7	769.0	813.2	904.0	819.9	832.8
A37688	684.6	899.1	939.9	1057.4	852.7	SPILLED
A37689	997.9	1027.5	904.9	1102.5	887.7	991.8
A37690	782.4	843.6	1048.6	710.9	825.1	786.4

GROUP: FEMALE 1 - 0 MG/KG/DAY

A37621	0.0	0.0	0.0	0.0	0.0	0.0
A37622	0.0	0.0	0.0	0.0	SPILLED	0.0
A37623	SPILLED	0.0	0.0	0.0	0.0	0.0
A37624	0.0	0.0	0.0	0.0	0.0	0.0
A37625	0.0	0.0	0.0	0.0	SPILLED	0.0
A37626	0.0	0.0	0.0	0.0	0.0	0.0
A37627	SPILLED	SPILLED	0.0	0.0	0.0	0.0
A37628	SPILLED	0.0	0.0	0.0	0.0	0.0
A37629	0.0	0.0	0.0	0.0	0.0	0.0
A37630	0.0	0.0	0.0	0.0	SPILLED	0.0

GROUP: FEMALE 2 - 25 MG/KG/DAY

A37651	27.7	28.0	28.6	28.7	30.0	30.1
A37652	26.9	28.5	27.2	25.9	30.6	28.1
A37653	SPILLED	30.8	28.6	25.7	27.6	29.0
A37654	28.3	27.9	24.6	26.7	30.6	29.4
A37655	24.5	28.2	26.2	26.5	29.6	25.8

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 7B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY IN TRICLOSAN IN CD-1
MICE. (SATELLITE-GROUPS 8-11)
INDIVIDUAL COMPOUND CONSUMPTION (MG/KG)

STUDY NUMBER: 483287

ANIMAL NUMBER	WEEK 1	WEEK 2	WEEK 3	WEEK 4	WEEK 5	WEEK 6
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GROUP: FEMALE 2 - 25 MG/KG/DAY

A37656	38.1	29.1	25.6	28.4	29.1	27.8
A37657	25.4	27.7	30.5	25.3	29.2	27.3
A37658	30.5	25.9	23.6	26.9	29.4	30.0
A37659	SPILLED	29.8	27.8	29.2	29.3	28.2
A37660	SPILLED	25.3	25.6	24.4	26.2	28.2

GROUP: FEMALE 3 - 350 MG/KG/DAY

A37671	315.3	472.9	331.0	356.1	409.5	359.5
A37672	328.5	435.4	324.0	380.3	337.9	348.0
A37673	319.3	383.8	403.6	362.7	412.1	420.8
A37674	352.1	368.2	378.8	385.2	362.7	381.5
A37675	410.1	393.7	352.1	392.7	399.7	390.6
A37676	325.3	374.0	341.7	366.5	401.4	376.6
A37677	297.8	344.5	309.1	325.3	333.8	319.1
A37678	SPILLED	371.9	333.9	403.9	420.4	359.2
A37679	284.4	314.5	305.5	339.9	337.7	311.6
A37680	232.4	337.3	309.1	342.4	352.7	348.0

GROUP: FEMALE 4 - 900 MG/KG/DAY

A37691	SPILLED	846.1	700.4	743.0	681.7	653.9
A37692	883.6	756.7	756.6	859.1	840.8	850.1
A37693	974.3	911.0	805.4	712.0	766.2	845.5
A37694	SPILLED	928.1	1002.3	893.7	854.4	903.7
A37695	SPILLED	529.1	957.2	1090.3	982.6	SPILLED
A37696	930.0	726.1	800.2	870.2	835.0	801.0
A37697	699.5	804.3	648.8	667.5	823.3	1025.3
A37698	848.3	675.4	867.4	699.1	805.7	850.8
A37699	818.9	SPILLED	845.4	816.7	810.9	705.7
A37700	921.3	933.3	829.8	743.0	749.9	719.3

Appendix 8
Individual Auditory Examinations - Main Study
13-Week Subchronic Oral Toxicity Study of Triclosan in CD-1® Mice
Week 13

Appendix 8
Individual Auditory Examinations - Main Study
13-Week Subchronic Oral Toxicity Study of Triclosan in CD-1® Mice
Week 13

NOTE: Auditory responses are presented by exception, i.e. those having a negative response. All other animals tested were normal.

<u>Animal Number</u>	<u>Group/ Sex</u>
37432	2M
37434	2M
37458	3M
37464	3M
37491	4M
37492	4M
37514	5M
37541	6M
37553	6M
37571	7M
37574	7M
37575	7M
37580	7M
37582	7M
37583	7M
37585	7M
37409	1F
37418	1F
37436	2F
37437	2F
37444	2F
37446	2F
37479	3F
37499	4F
37502	4F
37507	4F
37529	5F
37556	6F
37563	6F
37569	6F
37589	7F
37592	7F
37596	7F
37599	7F
37600	7F

Appendix 9
Individual Physical Examinations - Main Study
13-Week Subchronic Oral Toxicity Study of Triclosan in CD-1[®] Mice

Appendix 9
Individual Physical Examinations - Main Study
13-Week Subchronic Oral Toxicity Study of Triclosan in CD-1® Mice

NOTE: Physical examination results are presented by exception. All other animals were normal.

<u>Animal Number</u>	<u>Group/ Sex</u>	<u>Finding</u>	<u>Location</u>
<u>Week 13</u>			
37391	1M	ALOPECIA/SORES	BACK/EARS
37393	1M	SORES	RT. EAR
37404	1M	SORES/ALOPECIA	RT EAR/HEAD
37429	2M	ALOPECIA	BACK
37430	2M	SORES	LT. EAR
37451	3M	SORES	RT. EAR
37455	3M	SORES	RT. EAR
37482	4M	SORES	RT. EAR
37491	4M	SORES/SWOLLEN	EARS, NECK/RT. EAR
37513	5M	SORES	RT. EAR, NECK
37518	5M	SORES	RT. EAR
37523	5M	SORES	LT. EAR
37583	7M	ALOPECIA	ABDOMEN
37501	4F	SORES	RT. EAR
37532	5F	SMALL MOVEABLE TISSUE MASS	VENTRAL HIND RIGHT
37570	6F	SMALL MOVEABLE TISSUE MASS	VENTRAL HIND RIGHT
37600	7F	SMALL MOVEABLE TISSUE MASS	VENTRAL HIND RIGHT

Appendix 10
Individual Ophthalmoscopic Findings - Main Study
13-Week Subchronic Oral Toxicity Study of Triclosan in CD-1[®] Mice

Appendix 10
 Individual Ophthalmoscopic Findings - Main Study
 13-Week Subchronic Oral Toxicity Study of Triclosan in CD-1® Mice

<u>Animal Number</u>	<u>Group/ Sex</u>	<u>Finding</u>	<u>Location</u>
<u>Week 13</u>			
37455	3M	Corneal dystrophy	Both eyes
37459	3M	Corneal dystrophy	Right eye
37487	4M	Corneal dystrophy	Right eye
37492	4M	Corneal dystrophy	Right eye
37523	5M	Corneal dystrophy	Both eyes
37551	6M	Corneal dystrophy	Right eye
37552	6M	Corneal dystrophy	Both eyes
37444	2F	Corneal dystrophy	Both eyes
37540	5F	Corneal dystrophy	Both eyes
37600	7F	Corneal dystrophy	Both eyes

KEY: M = Male.
 F = Female.

Appendix 11A
Individual Clinical Hematology Values - Main Study
13-Week Subchronic Oral Toxicity Study of Triclosan in CD-1[®] Mice

Standard Key to Hematology for Rodent Studies

LEUKOCYTE DIFFERENTIALS		CELL MORPHOLOGY	
Blast Cells	BLAST	Reactive Lymphocytes*	REACTLYM
Metamyelocytes	META	Anisocytes	ANISO
Band Neutrophils	BAND	Polychromatophilic Cells	POLY
Segmented Neutrophils	SEG	Echinocytes	ECHINO
Lymphocytes	LYMPH	Acanthocytes	ACANTH
Monocytes	MONO	Hypochromic Cells	HYPO
Eosinophils	EOSIN	Target Cells	TARGET
Basophils	BASO	Schistocytes	SCHISTO
Promyelocyte/Myelocyte	PRO/MYEL	Poikilocytes	POIK
		Howell-Jolly Bodies	HJBODY
		Microcytes	MICRO
		Nucleated RBCs*	NRBC

Cell morphology findings are graded by one of the following two methods, unless footnoted otherwise.

- = None Present
 T = Trace Numbers Present
 1 = Slight Numbers Present
 2 = Moderate Numbers Present
 3 = Marked Numbers Present
 4 = Severe Numbers Present

or

- = None Present
 F = Few Cells Present
 M = Many Cells Present

* Expressed as a percentage of 100 white blood cells counted.

Key to Hematology for Rodent Studies

Week 14 (Main Study, Groups 1-7)

The following animals had indications of stomatocytes (STOMAT) during cell morphology evaluation:

STOMAT 1: 37571, 37556, 37543, 37500, 37470, 37530, 37591, 37516, 37576, 37593, 37595, 37582, and 37535.

STOMAT 2: 37544, 37574, 37559, 37592, 37547, 37578, 37549, and 37491.

STOMAT 3: 37581

STOMAT T: 37572, 37483, 37499, 37528, 37558, 37514, 37529, 37590, 37515, 37545, 37575, 37560, 37546, 37471, 37502, 37531, 37561, 37517, 37472, 37503, 37518, 37548, 37580, 37533, 37459, 37519, 37444, 37564, 37460, 37520, 37550, 37445, 37456, 37473, 37475, 37506, 37565, and 37596.

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APPENDIX 11A
INDIVIDUAL CLINICAL HEMATOLOGY VALUES
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1 MICE
WEEK 14 MALES

ANIMAL NUMBER	RBC MI/UL	HGB G/DL	HCT %	PLATELET TH/UL

GROUP: 1	DOSE LEVEL: 0		DOSAGE UNIT: MG/KG	
37391	9.49	15.9	45.3	1599
37392	10.70	17.3	50.2	1683
37393	11.71	18.6	54.3	1693
37394	11.11	18.5	54.3	1737
37395	10.65	16.9	48.9	1460
37396	10.52	16.5	52.0	1482
37397	11.20	17.5	51.9	1797
37398	10.43	17.1	47.8	1665
37399	10.46	16.8	51.7	1615
37400	10.09	16.7	47.0	1497
GROUP: 2	DOSE LEVEL: 25		DOSAGE UNIT: MG/KG	
37421	9.69	15.6	43.8	1658
37422	9.38	16.2	46.1	1390
37423	9.91	15.9	45.5	1642
37424	9.59	15.5	43.3	1782
37425	10.37	16.0	48.0	1554
37426	10.07	16.2	47.1	1509
37427	9.91	15.9	45.8	1891
37428	9.37	15.2	44.4	1504
37429	9.49	15.9	46.5	1757
37430	9.88	15.9	44.9	1453

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APPENDIX 11A
INDIVIDUAL CLINICAL HEMATOLOGY VALUES
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1 MICE
WEEK 14 MALES

ANIMAL NUMBER	RBC MI/UL	HGB G/DL	HCT %	PLATELET TH/UL

GROUP: 3	DOSE LEVEL: 75		DOSAGE UNIT: MG/KG	
37451	9.51	16.2	45.9	1705
37452	8.46	15.2	43.1	1532
37453	9.81	15.9	47.8	1923
37454	9.77	15.8	45.0	1644
37455	10.06	16.0	45.5	1837
37456	9.88	16.3	49.2	1658
37457	10.29	16.6	47.5	1212
37458	9.54	15.1	44.5	1828
37459	10.51	15.9	47.5	1970
37460	9.99	15.7	48.4	1478
GROUP: 4	DOSE LEVEL: 200		DOSAGE UNIT: MG/KG	
37481	6.39	10.2	30.2	1543
37482	10.00	16.3	46.7	1760
37483	8.87	14.6	42.1	1409
37485	9.04	14.5	45.0	1573
37486	9.78	15.6	45.1	1643
37487	10.15	16.8	50.8	1524
37488	10.13	16.2	49.8	1716
37489	CLOT	CLOT	CLOT	CLOT
37490	9.54	15.2	46.1	1647
37491	7.59	11.4	34.5	1488

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APPENDIX 11A
INDIVIDUAL CLINICAL HEMATOLOGY VALUES
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1 MICE
WEEK 14 MALES

ANIMAL NUMBER	RBC MI/UL	HGB G/DL	HCT %	PLATELET TH/UL

GROUP: 5	DOSE LEVEL: 350		DOSAGE UNIT: MG/KG	
37511	9.55	15.9	45.8	1589
37512	8.72	14.2	41.9	1401
37513	8.16	13.3	41.3	1773
37514	9.10	14.8	43.0	1636
37515	8.79	14.2	41.8	1796
37516	9.71	16.2	47.9	1744
37517	8.93	14.3	42.1	1629
37518	8.18	13.0	39.0	1303
37519	9.27	14.7	45.7	1861
37520	10.02	15.2	46.8	1422
GROUP: 6	DOSE LEVEL: 750		DOSAGE UNIT: MG/KG	
37541	8.87	14.3	42.0	1403
37542	9.69	14.4	43.6	1854
37543	7.92	12.8	38.7	1543
37544	7.90	12.3	38.2	1762
37545	9.60	15.4	46.5	1463
37546	7.91	12.1	36.9	1012
37547	9.04	14.2	42.5	1077
37548	8.99	14.1	42.8	1111
37549	7.96	13.0	39.6	1457
37550	8.65	13.7	40.7	1505

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APPENDIX 11A
INDIVIDUAL CLINICAL HEMATOLOGY VALUES
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1 MICE
WEEK 14 MALES

ANIMAL NUMBER	RBC MI/UL	HGB G/DL	HCT %	PLATELET TH/UL
GROUP: 7	DOSE LEVEL: 900		DOSAGE UNIT: MG/KG	
37571	6.41	10.3	30.7	1370
37572	8.14	13.3	39.6	1432
37573	7.94	12.8	40.4	1532
37574	7.57	11.5	37.1	1375
37575	5.59	10.0	31.3	1924
37576	8.50	13.3	40.2	1408
37578	6.14	9.7	30.4	1103
37580	6.27	9.8	29.9	1637
37581	8.88	13.0	39.7	1406
37582	8.55	13.2	40.1	1455

APPENDIX 11A
INDIVIDUAL CLINICAL HEMATOLOGY VALUES
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1 MICE
WEEK 14 MALES

ANIMAL NUMBER	WBC TH/UL	NRBC /100 WBC	COR WBC TH/UL	BLAST TH/UL(%)	PRO/MYEL TH/UL(%)	META TH/UL(%)	BAND TH/UL(%)	SEG TH/UL(%)	LYMPH TH/UL(%)	MONO TH/UL(%)	EOSIN TH/UL(%)	BASO TH/UL(%)
GROUP: 1	DOSE LEVEL: 0		DOSAGE UNIT: MG/KG									
37391	4.3	0	4.3	.0(0)	.0(0)	.0(0)	.0(0)	1.5(34)	2.8(66)	.0(0)	.0(0)	.0(0)
37392	4.6	0	4.6	.0(0)	.0(0)	.0(0)	.0(0)	1.1(24)	3.4(73)	.1(2)	.0(1)	.0(0)
37393	4.2	0	4.2	.0(0)	.0(0)	.0(0)	.0(0)	1.4(34)	2.8(66)	.0(0)	.0(0)	.0(0)
37394	2.3	0	2.3	.0(0)	.0(0)	.0(0)	.0(0)	1.6(68)	.7(32)	.0(0)	.0(0)	.0(0)
37395	4.5	0	4.5	.0(0)	.0(0)	.0(0)	.0(0)	.9(21)	3.4(76)	.0(0)	.1(3)	.0(0)
37396	3.5	0	3.5	.0(0)	.0(0)	.0(0)	.0(0)	.4(12)	3.1(88)	.0(0)	.0(0)	.0(0)
37397	4.2	0	4.2	.0(0)	.0(0)	.0(0)	.0(0)	.4(9)	3.8(90)	.0(1)	.0(0)	.0(0)
37398	4.1	0	4.1	.0(0)	.0(0)	.0(0)	.0(0)	.9(22)	3.0(73)	.0(0)	.2(5)	.0(0)
37399	2.7	0	2.7	.0(0)	.0(0)	.0(0)	.0(0)	1.1(42)	1.6(58)	.0(0)	.0(0)	.0(0)
37400	4.5	0	4.5	.0(0)	.0(0)	.0(0)	.0(0)	.8(17)	3.6(81)	.0(0)	.1(2)	.0(0)
GROUP: 2	DOSE LEVEL: 25		DOSAGE UNIT: MG/KG									
37421	5.3	0	5.3	.0(0)	.0(0)	.0(0)	.0(0)	2.9(54)	2.4(45)	.0(0)	.1(1)	.0(0)
37422	5.9	0	5.9	.0(0)	.0(0)	.0(0)	.0(0)	1.6(27)	4.2(72)	.1(1)	.0(0)	.0(0)
37423	5.9	0	5.9	.0(0)	.0(0)	.0(0)	.0(0)	1.8(30)	4.1(70)	.0(0)	.0(0)	.0(0)
37424	9.8	0	9.8	.0(0)	.0(0)	.0(0)	.0(0)	4.1(42)	5.5(56)	.0(0)	.2(2)	.0(0)
37425	4.9	0	4.9	.0(0)	.0(0)	.0(0)	.0(0)	1.1(22)	3.8(77)	.0(0)	.0(1)	.0(0)
37426	4.9	0	4.9	.0(0)	.0(0)	.0(0)	.0(0)	1.1(23)	3.7(75)	.0(0)	.1(2)	.0(0)
37427	5.0	0	5.0	.0(0)	.0(0)	.0(0)	.0(0)	1.4(28)	3.6(72)	.0(0)	.0(0)	.0(0)
37428	7.2	0	7.2	.0(0)	.0(0)	.0(0)	.0(0)	1.7(23)	5.4(75)	.0(0)	.1(2)	.0(0)
37429	3.0	0	3.0	.0(0)	.0(0)	.0(0)	.0(0)	1.3(43)	1.7(57)	.0(0)	.0(0)	.0(0)
37430	4.5	0	4.5	.0(0)	.0(0)	.0(0)	.0(0)	1.3(28)	3.2(70)	.0(0)	.1(2)	.0(0)

APPENDIX 11A
INDIVIDUAL CLINICAL HEMATOLOGY VALUES
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1 MICE
WEEK 14 MALES

ANIMAL NUMBER	WBC TH/UL	NRBC /100 WBC	COR WBC TH/UL	BLAST TH/UL(%)	PRO/MYEL TH/UL(%)	META TH/UL(%)	BAND TH/UL(%)	SEG TH/UL(%)	LYMPH TH/UL(%)	MONO TH/UL(%)	EOSIN TH/UL(%)	BASO TH/UL(%)
GROUP: 3	DOSE LEVEL: 75		DOSAGE UNIT: MG/KG									
37451	4.2	0	4.2	.0(0)	.0(0)	.0(0)	.0(0)	1.0(24)	3.2(75)	.0(1)	.0(0)	.0(0)
37452	4.6	0	4.6	.0(0)	.0(0)	.0(0)	.0(0)	2.0(44)	2.6(56)	.0(0)	.0(0)	.0(0)
37453	5.9	0	5.9	.0(0)	.0(0)	.0(0)	.0(0)	1.2(20)	4.7(80)	.0(0)	.0(0)	.0(0)
37454	6.6	0	6.6	.0(0)	.0(0)	.0(0)	.0(0)	2.1(32)	4.2(64)	.1(2)	.1(2)	.0(0)
37455	3.2	0	3.2	.0(0)	.0(0)	.0(0)	.0(0)	1.3(40)	1.9(60)	.0(0)	.0(0)	.0(0)
37456	7.6	0	7.6	.0(0)	.0(0)	.0(0)	.0(0)	2.5(33)	4.9(65)	.2(2)	.0(0)	.0(0)
37457	5.3	0	5.3	.0(0)	.0(0)	.0(0)	.0(0)	1.4(27)	3.9(73)	.0(0)	.0(0)	.0(0)
37458	6.0	0	6.0	.0(0)	.0(0)	.0(0)	.0(0)	.7(12)	5.3(88)	.0(0)	.0(0)	.0(0)
37459	4.6	0	4.6	.0(0)	.0(0)	.0(0)	.0(0)	1.4(31)	3.2(69)	.0(0)	.0(0)	.0(0)
37460	2.7	0	2.7	.0(0)	.0(0)	.0(0)	.0(0)	.4(15)	2.3(85)	.0(0)	.0(0)	.0(0)
GROUP: 4	DOSE LEVEL: 200		DOSAGE UNIT: MG/KG									
37481	7.0	0	7.0	.0(0)	.0(0)	.0(0)	.0(0)	2.2(32)	4.6(66)	.1(1)	.1(1)	.0(0)
37482	4.8	0	4.8	.0(0)	.0(0)	.0(0)	.0(0)	1.2(25)	3.6(75)	.0(0)	.0(0)	.0(0)
37483	11.3	0	11.3	.0(0)	.0(0)	.0(0)	.0(0)	2.4(21)	8.0(71)	.1(1)	.8(7)	.0(0)
37485	1.8	0	1.8	.0(0)	.0(0)	.0(0)	.0(0)	1.1(62)	.7(38)	.0(0)	.0(0)	.0(0)
37486	3.0	0	3.0	.0(0)	.0(0)	.0(0)	.0(0)	1.0(34)	2.0(66)	.0(0)	.0(0)	.0(0)
37487	7.5	0	7.5	.0(0)	.0(0)	.0(0)	.0(0)	1.8(24)	5.7(76)	.0(0)	.0(0)	.0(0)
37488	4.9	0	4.9	.0(0)	.0(0)	.0(0)	.0(0)	1.0(21)	3.9(79)	.0(0)	.0(0)	.0(0)
37489	CLOT	CLOT	CLOT	CLOT	CLOT	CLOT	CLOT	CLOT	CLOT	CLOT	CLOT	CLOT
37490	2.9	0	2.9	.0(0)	.0(0)	.0(0)	.0(0)	.9(32)	1.9(67)	.0(0)	.0(1)	.0(0)
37491	4.2	0	4.2	.0(0)	.0(0)	.0(0)	.0(0)	2.4(57)	1.8(43)	.0(0)	.0(0)	.0(0)

APPENDIX 11A
INDIVIDUAL CLINICAL HEMATOLOGY VALUES
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1 MICE
WEEK 14 MALES

ANIMAL NUMBER	WBC TH/UL	NRBC /100 WBC	COR WBC TH/UL	BLAST TH/UL(%)	PRO/MYEL TH/UL(%)	META TH/UL(%)	BAND TH/UL(%)	SEG TH/UL(%)	LYMPH TH/UL(%)	MONO TH/UL(%)	EOSIN TH/UL(%)	BASO TH/UL(%)
GROUP: 5	DOSE LEVEL: 350		DOSAGE UNIT: MG/KG									
37511	6.9	0	6.9	.0(0)	.0(0)	.0(0)	.0(0)	1.9(27)	5.0(73)	.0(0)	.0(0)	.0(0)
37512	5.0	0	5.0	.0(0)	.0(0)	.0(0)	.0(0)	1.5(29)	3.4(68)	.0(1)	.1(2)	.0(0)
37513	6.3	0	6.3	.0(0)	.0(0)	.0(0)	.0(0)	2.0(32)	4.3(68)	.0(0)	.0(0)	.0(0)
37514	7.3	0	7.3	.0(0)	.0(0)	.0(0)	.0(0)	2.2(30)	5.0(69)	.0(0)	.1(1)	.0(0)
37515	3.6	0	3.6	.0(0)	.0(0)	.0(0)	.0(0)	1.1(30)	2.5(70)	.0(0)	.0(0)	.0(0)
37516	13.0	0	13.0	.0(0)	.0(0)	.0(0)	.0(0)	9.2(71)	3.8(29)	.0(0)	.0(0)	.0(0)
37517	4.6	0	4.6	.0(0)	.0(0)	.0(0)	.0(0)	1.0(21)	3.6(79)	.0(0)	.0(0)	.0(0)
37518	5.8	0	5.8	.0(0)	.0(0)	.0(0)	.0(0)	1.7(29)	4.1(70)	.0(0)	.1(1)	.0(0)
37519	7.5	0	7.5	.0(0)	.0(0)	.0(0)	.0(0)	2.2(29)	5.0(67)	.0(0)	.2(3)	.1(1)
37520	3.8	0	3.8	.0(0)	.0(0)	.0(0)	.0(0)	1.4(36)	2.4(64)	.0(0)	.0(0)	.0(0)
GROUP: 6	DOSE LEVEL: 750		DOSAGE UNIT: MG/KG									
37541	3.2	0	3.2	.0(0)	.0(0)	.0(0)	.0(0)	.9(27)	2.3(73)	.0(0)	.0(0)	.0(0)
37542	4.5	0	4.5	.0(0)	.0(0)	.0(0)	.0(0)	3.2(72)	1.2(27)	.0(1)	.0(0)	.0(0)
37543	4.6	0	4.6	.0(0)	.0(0)	.0(0)	.0(0)	1.5(33)	3.0(66)	.0(1)	.0(0)	.0(0)
37544	2.9	0	2.9	.0(0)	.0(0)	.0(0)	.0(0)	.6(20)	2.3(80)	.0(0)	.0(0)	.0(0)
37545	6.0	0	6.0	.0(0)	.0(0)	.0(0)	.0(0)	1.5(25)	4.4(74)	.1(1)	.0(0)	.0(0)
37546	11.9	0	11.9	.0(0)	.0(0)	.0(0)	.0(0)	5.7(48)	6.1(51)	.0(0)	.1(1)	.0(0)
37547	4.5	0	4.5	.0(0)	.0(0)	.0(0)	.0(0)	1.3(28)	3.2(72)	.0(0)	.0(0)	.0(0)
37548	9.3	0	9.3	.0(0)	.0(0)	.0(0)	.0(0)	3.4(37)	5.8(62)	.1(1)	.0(0)	.0(0)
37549	4.2	0	4.2	.0(0)	.0(0)	.0(0)	.0(0)	1.4(33)	2.8(66)	.0(0)	.0(1)	.0(0)
37550	4.6	0	4.6	.0(0)	.0(0)	.0(0)	.0(0)	3.6(79)	1.0(21)	.0(0)	.0(0)	.0(0)

APPENDIX 11A
 INDIVIDUAL CLINICAL HEMATOLOGY VALUES
 13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1 MICE
 WEEK 14 MALES

ANIMAL NUMBER	WBC TH/UL	NRBC /100 WBC	COR WBC TH/UL	BLAST TH/UL(%)	PRO/MYEL TH/UL(%)	META TH/UL(%)	BAND TH/UL(%)	SEG TH/UL(%)	LYMPH TH/UL(%)	MONO TH/UL(%)	EOSIN TH/UL(%)	BASO TH/UL(%)
GROUP: 7	DOSE LEVEL: 900			DOSAGE UNIT: MG/KG								
37571	3.2	0	3.2	.0(0)	.0(0)	.0(0)	.0(0)	1.8(57)	1.3(41)	.0(1)	.0(1)	.0(0)
37572	6.0	0	6.0	.0(0)	.0(0)	.0(0)	.0(0)	2.3(39)	3.6(60)	.0(0)	.1(1)	.0(0)
37573	7.2	0	7.2	.0(0)	.0(0)	.0(0)	.0(0)	4.5(63)	2.6(36)	.1(1)	.0(0)	.0(0)
37574	2.9	0	2.9	.0(0)	.0(0)	.0(0)	.0(0)	1.0(34)	1.9(64)	.0(0)	.1(2)	.0(0)
37575	11.2	0	11.2	.0(0)	.0(0)	.0(0)	.0(0)	4.4(39)	6.8(61)	.0(0)	.0(0)	.0(0)
37576	6.5	0	6.5	.0(0)	.0(0)	.0(0)	.0(0)	3.2(49)	3.3(51)	.0(0)	.0(0)	.0(0)
37578	3.8	0	3.8	.0(0)	.0(0)	.0(0)	.0(0)	2.4(62)	1.4(38)	.0(0)	.0(0)	.0(0)
37580	2.4	0	2.4	.0(0)	.0(0)	.0(0)	.0(0)	1.0(41)	1.4(59)	.0(0)	.0(0)	.0(0)
37581	2.5	0	2.5	.0(0)	.0(0)	.0(0)	.0(0)	1.9(75)	.6(25)	.0(0)	.0(0)	.0(0)
37582	1.5	0	1.5	.0(0)	.0(0)	.0(0)	.0(0)	.4(26)	1.1(74)	.0(0)	.0(0)	.0(0)

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13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1 MICE
WEEK 14 MALES

ANIMAL NUMBER	REACTLYM	ANISO	POLY	ECHINO	ACANTH	HYPO	TARGET	SCHISTO	POIK	HJBODY	MICRO
<hr/>											
GROUP: 1	DOSE LEVEL: 0		DOSAGE UNIT: MG/KG								
37391	1	-	2	-	-	-	-	-	-	-	-
37392	0	-	T	-	-	-	-	-	-	-	-
37393	0	-	1	-	-	-	-	-	-	-	-
37394	0	-	1	-	-	-	-	-	-	-	-
37395	0	T	1	1	-	-	-	-	-	-	-
37396	0	-	1	-	-	-	-	-	-	-	-
37397	0	-	1	-	-	-	-	-	-	-	-
37398	0	-	1	-	-	-	-	-	-	-	-
37399	0	T	1	-	-	-	-	-	-	F	-
37400	0	-	1	-	-	-	-	-	-	-	-
GROUP: 2	DOSE LEVEL: 25		DOSAGE UNIT: MG/KG								
37421	0	-	1	-	-	-	-	-	-	-	-
37422	0	-	2	-	-	-	-	-	-	-	-
37423	0	-	1	-	-	-	-	-	-	F	-
37424	0	-	1	-	-	-	-	-	-	F	-
37425	0	T	1	-	-	-	-	-	-	-	-
37426	0	-	2	-	-	-	-	-	-	-	-
37427	0	-	1	-	-	-	-	-	-	F	-
37428	0	-	2	-	-	-	-	-	-	-	-
37429	0	-	1	-	-	-	-	-	-	F	-
37430	0	T	1	-	-	-	-	-	-	-	-

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INDIVIDUAL CLINICAL HEMATOLOGY VALUES
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1 MICE
WEEK 14 MALES

ANIMAL NUMBER	REACTLYM	ANISO	POLY	ECHINO	ACANTH	HYPO	TARGET	SCHISTO	POIK	HJBODY	MICRO
<hr/>											
GROUP: 3	DOSE LEVEL: 75		DOSAGE UNIT: MG/KG								
37451	0	-	2	-	-	-	-	-	-	F	-
37452	0	-	1	-	-	-	-	-	-	-	-
37453	0	-	2	-	-	-	-	-	-	-	-
37454	0	-	2	-	-	-	-	-	-	-	-
37455	0	-	1	-	-	T	-	-	-	F	-
37456	0	-	2	-	-	-	-	-	-	-	-
37457	0	-	2	-	-	-	-	-	-	F	-
37458	0	T	1	-	-	-	-	-	-	-	-
37459	0	-	1	-	-	-	-	-	-	F	-
37460	0	-	1	-	-	-	-	-	-	-	-
GROUP: 4	DOSE LEVEL: 200		DOSAGE UNIT: MG/KG								
37481	0	-	1	-	-	-	-	-	-	-	-
37482	0	-	1	-	-	-	-	-	-	-	-
37483	0	-	1	-	-	-	-	-	-	-	-
37485	0	-	1	-	-	-	-	-	-	-	-
37486	0	-	1	-	-	T	T	-	-	F	-
37487	0	-	1	-	-	-	-	-	-	-	-
37488	0	-	1	-	-	-	-	-	-	-	-
37489	CLOT	CLOT	CLOT	CLOT	CLOT	CLOT	CLOT	CLOT	CLOT	CLOT	CLOT
37490	0	-	1	-	-	-	-	-	-	-	-
37491	0	T	1	-	-	2	-	-	-	-	-

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APPENDIX 11A
 INDIVIDUAL CLINICAL HEMATOLOGY VALUES
 13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1 MICE
 WEEK 14 MALES

ANIMAL NUMBER	REACTLYM	ANISO	POLY	ECHINO	ACANTH	HYP0	TARGET	SCHISTO	POIK	HJBODY	MICRO
<hr/>											
GROUP: 5	DOSE LEVEL: 350		DOSAGE UNIT: MG/KG								
37511	0	-	1	-	-	-	-	-	-	-	-
37512	0	-	2	-	-	-	-	-	-	-	-
37513	0	T	2	-	-	-	T	-	-	-	-
37514	0	-	1	-	-	-	-	-	-	-	-
37515	0	-	2	-	-	T	-	-	-	-	-
37516	0	-	1	-	-	-	-	-	-	F	-
37517	0	-	1	-	-	-	-	-	-	F	-
37518	0	T	2	-	-	-	-	-	-	F	-
37519	0	-	1	-	-	T	-	-	-	-	-
37520	0	1	1	-	-	-	-	-	-	-	-
GROUP: 6	DOSE LEVEL: 750		DOSAGE UNIT: MG/KG								
37541	0	-	1	-	-	-	-	-	-	-	-
37542	0	-	2	-	-	T	-	-	-	F	-
37543	0	-	1	-	-	-	-	-	-	F	-
37544	0	T	2	-	-	-	-	-	-	F	-
37545	0	-	2	-	-	T	-	-	-	-	-
37546	0	1	2	-	-	-	-	-	-	-	-
37547	0	1	2	-	-	-	-	-	-	F	-
37548	0	1	2	-	-	-	-	-	-	F	-
37549	0	2	2	-	-	-	-	-	-	-	-
37550	0	T	1	-	-	-	-	-	-	-	-

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 INDIVIDUAL CLINICAL HEMATOLOGY VALUES
 13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1 MICE
 WEEK 14 MALES

ANIMAL NUMBER	REACTLYM	ANISO	POLY	ECHINO	ACANTH	HYPO	TARGET	SCHISTO	POIK	HJBODY	MICRO

GROUP: 7	DOSE LEVEL: 900		DOSAGE UNIT: MG/KG								
37571	0	-	2	-	-	-	-	-	-	-	-
37572	0	-	2	-	-	T	T	-	-	-	-
37573	0	T	1	-	-	-	-	-	-	-	-
37574	0	2	2	-	-	T	-	-	-	F	2
37575	0	2	4	-	-	T	T	-	-	F	-
37576	0	1	2	-	-	-	-	-	-	-	-
37578	0	2	2	-	-	-	-	-	-	F	-
37580	0	1	3	-	-	-	-	-	-	F	-
37581	0	1	2	-	-	1	-	-	-	F	-
37582	0	1	1	-	-	-	-	-	-	-	-

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APPENDIX 11A
INDIVIDUAL CLINICAL HEMATOLOGY VALUES
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1 MICE
WEEK 14 FEMALES

ANIMAL NUMBER	RBC MI/UL	HGB G/DL	HCT %	PLATELET TH/UL
GROUP: 1 DOSE LEVEL: 0 DOSAGE UNIT: MG/KG				
37406	10.87	17.8	49.5	1546
37407	10.56	17.6	48.0	1346
37408	10.74	17.7	49.0	1435
37409	10.65	16.3	49.5	1512
37410	9.93	16.0	44.8	1406
37411	CLOT	CLOT	CLOT	CLOT
37412	10.38	17.7	52.4	1558
37413	10.34	17.2	50.7	1463
37414	9.88	16.9	47.1	1872
37415	9.37	15.9	44.8	1217
GROUP: 2 DOSE LEVEL: 25 DOSAGE UNIT: MG/KG				
37436	9.69	15.9	46.1	1430
37437	9.31	16.1	46.0	1498
37438	10.03	16.2	47.1	1408
37439	10.72	17.6	49.8	1696
37440	10.53	17.1	47.9	1337
37441	9.50	15.9	46.1	1914
37442	9.53	16.6	47.4	1467
37443	10.27	16.6	46.6	1498
37444	9.30	16.1	49.6	1220
37445	9.83	16.3	50.2	1524

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INDIVIDUAL CLINICAL HEMATOLOGY VALUES
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1 MICE
WEEK 14 FEMALES

ANIMAL NUMBER	RBC MI/UL	HGB G/DL	HCT %	PLATELET TH/UL

GROUP: 3	DOSE LEVEL: 75	DOSAGE UNIT: MG/KG		
37466	10.15	15.4	45.9	1694
37467	9.42	15.1	47.0	1537
37468	9.55	16.2	46.9	1295
37469	9.82	16.6	50.3	1503
37470	8.98	14.1	42.6	1474
37471	8.71	14.1	41.5	1767
37472	9.46	15.7	45.4	1283
37473	8.86	15.3	43.9	1251
37474	9.46	15.6	45.2	1564
37475	9.21	14.0	42.5	1685
GROUP: 4	DOSE LEVEL: 200	DOSAGE UNIT: MG/KG		
37497	9.43	15.5	43.6	1287
37498	9.68	16.6	49.9	1679
37499	8.92	15.1	43.2	1551
37500	8.29	13.8	42.5	1356
37501	8.72	14.6	45.3	1752
37502	9.07	14.9	43.6	1550
37503	9.10	14.8	43.9	1260
37504	8.99	15.5	49.9	1218
37505	9.40	14.7	46.7	1473
37506	8.56	14.5	42.7	1507

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INDIVIDUAL CLINICAL HEMATOLOGY VALUES
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1 MICE
WEEK 14 FEMALES

ANIMAL NUMBER	RBC MI/UL	HGB G/DL	HCT %	PLATELET TH/UL

GROUP: 5	DOSE LEVEL: 350	DOSAGE UNIT: MG/KG		
37526	9.19	14.0	41.4	1762
37527	8.81	14.9	42.6	1811
37528	8.28	14.4	40.9	1492
37529	9.72	16.3	47.4	1555
37530	9.58	15.2	45.1	1269
37531	9.27	15.4	45.0	1550
37532	9.13	15.1	44.1	1376
37533	6.12	10.4	30.5	958
37534	8.84	14.1	41.9	1606
37535	8.22	13.5	39.9	844
GROUP: 6	DOSE LEVEL: 750	DOSAGE UNIT: MG/KG		
37556	7.00	11.9	34.9	1240
37557	9.16	15.9	45.2	1353
37558	8.89	14.3	41.6	1698
37559	7.30	12.4	36.6	1452
37560	7.15	11.1	33.9	1681
37561	9.16	15.4	45.2	1237
37562	10.09	16.4	47.3	1454
37563	CLOT	CLOT	CLOT	CLOT
37564	8.80	14.6	46.4	1447
37565	8.24	13.4	39.9	1335

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INDIVIDUAL CLINICAL HEMATOLOGY VALUES
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1 MICE
WEEK 14 FEMALES

ANIMAL NUMBER	RBC MI/UL	HGB G/DL	HCT %	PLATELET TH/UL
GROUP: 7	DOSE LEVEL: 900		DOSAGE UNIT: MG/KG	
37587	8.96	14.2	40.8	1741
37588	6.79	10.3	32.9	1428
37589	8.41	13.7	39.0	1048
37590	10.32	16.0	47.2	1463
37591	9.07	14.6	43.0	1446
37592	5.41	8.7	26.4	1076
37593	7.52	12.9	38.4	1101
37594	CLOT	CLOT	CLOT	CLOT
37595	7.51	12.9	38.1	1327
37596	5.22	8.4	26.3	2254

APPENDIX 11A
INDIVIDUAL CLINICAL HEMATOLOGY VALUES
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1 MICE
WEEK 14 FEMALES

ANIMAL NUMBER	WBC TH/UL	NRBC /100 WBC	COR WBC TH/UL	BLAST TH/UL(%)	PRO/MYEL TH/UL(%)	META TH/UL(%)	BAND TH/UL(%)	SEG TH/UL(%)	LYMPH TH/UL(%)	MONO TH/UL(%)	EOSIN TH/UL(%)	BASO TH/UL(%)
GROUP: 1	DOSE LEVEL: 0		DOSAGE UNIT: MG/KG									
37406	6.4	0	6.4	.0(0)	.0(0)	.0(0)	.0(0)	1.8(28)	4.5(70)	.1(1)	.1(1)	.0(0)
37407	4.0	0	4.0	.0(0)	.0(0)	.0(0)	.0(0)	1.4(36)	2.6(64)	.0(0)	.0(0)	.0(0)
37408	3.8	0	3.8	.0(0)	.0(0)	.0(0)	.0(0)	.8(21)	3.0(79)	.0(0)	.0(0)	.0(0)
37409	1.6	0	1.6	.0(0)	.0(0)	.0(0)	.0(0)	.5(31)	1.1(69)	.0(0)	.0(0)	.0(0)
37410	1.1	0	1.1	.0(0)	.0(0)	.0(0)	.0(0)	.1(5)	1.0(93)	.0(0)	.0(2)	.0(0)
37411	CLOT	CLOT	CLOT	CLOT	CLOT	CLOT	CLOT	CLOT	CLOT	CLOT	CLOT	CLOT
37412	4.6	0	4.6	.0(0)	.0(0)	.0(0)	.0(0)	.7(16)	3.9(84)	.0(0)	.0(0)	.0(0)
37413	2.2	0	2.2	.0(0)	.0(0)	.0(0)	.0(0)	.5(22)	1.7(78)	.0(0)	.0(0)	.0(0)
37414	1.4	0	1.4	.0(0)	.0(0)	.0(0)	.0(0)	.4(27)	1.0(73)	.0(0)	.0(0)	.0(0)
37415	3.0	0	3.0	.0(0)	.0(0)	.0(0)	.0(0)	1.0(33)	2.0(67)	.0(0)	.0(0)	.0(0)
GROUP: 2	DOSE LEVEL: 25		DOSAGE UNIT: MG/KG									
37436	2.0	0	2.0	.0(0)	.0(0)	.0(0)	.0(0)	1.0(49)	1.0(51)	.0(0)	.0(0)	.0(0)
37437	2.5	0	2.5	.0(0)	.0(0)	.0(0)	.0(0)	1.0(39)	1.5(59)	.0(0)	.0(2)	.0(0)
37438	3.0	0	3.0	.0(0)	.0(0)	.0(0)	.0(0)	1.3(44)	1.6(54)	.0(1)	.0(1)	.0(0)
37439	7.4	0	7.4	.0(0)	.0(0)	.0(0)	.0(0)	3.6(48)	3.8(52)	.0(0)	.0(0)	.0(0)
37440	2.8	0	2.8	.0(0)	.0(0)	.0(0)	.0(0)	.8(30)	2.0(70)	.0(0)	.0(0)	.0(0)
37441	4.2	0	4.2	.0(0)	.0(0)	.0(0)	.0(0)	1.3(31)	2.9(68)	.0(0)	.0(1)	.0(0)
37442	4.2	0	4.2	.0(0)	.0(0)	.0(0)	.0(0)	1.8(43)	2.4(56)	.0(1)	.0(0)	.0(0)
37443	2.9	0	2.9	.0(0)	.0(0)	.0(0)	.0(0)	1.4(47)	1.5(53)	.0(0)	.0(0)	.0(0)
37444	7.4	0	7.4	.0(0)	.0(0)	.0(0)	.0(0)	3.6(49)	3.8(51)	.0(0)	.0(0)	.0(0)
37445	3.4	0	3.4	.0(0)	.0(0)	.0(0)	.0(0)	1.1(33)	2.2(66)	.0(0)	.0(1)	.0(0)

APPENDIX 11A
INDIVIDUAL CLINICAL HEMATOLOGY VALUES
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1 MICE
WEEK 14 FEMALES

ANIMAL NUMBER	WBC TH/UL	NRBC /100 WBC	COR WBC TH/UL	BLAST TH/UL(%)	PRO/MYEL TH/UL(%)	META TH/UL(%)	BAND TH/UL(%)	SEG TH/UL(%)	LYMPH TH/UL(%)	MONO TH/UL(%)	EOSIN TH/UL(%)	BASO TH/UL(%)
GROUP: 3	DOSE LEVEL: 75		DOSAGE UNIT: MG/KG									
37466	8.7	0	8.7	.0(0)	.0(0)	.0(0)	.0(0)	3.6(41)	5.0(57)	.1(1)	.1(1)	.0(0)
37467	1.5	0	1.5	.0(0)	.0(0)	.0(0)	.0(0)	.8(55)	.7(45)	.0(0)	.0(0)	.0(0)
37468	2.8	0	2.8	.0(0)	.0(0)	.0(0)	.0(0)	1.4(50)	1.4(50)	.0(0)	.0(0)	.0(0)
37469	3.5	0	3.5	.0(0)	.0(0)	.0(0)	.0(0)	1.5(43)	2.0(56)	.0(0)	.0(1)	.0(0)
37470	1.5	0	1.5	.0(0)	.0(0)	.0(0)	.0(0)	.5(33)	1.0(67)	.0(0)	.0(0)	.0(0)
37471	9.7	0	9.7	.0(0)	.0(0)	.0(0)	.0(0)	6.5(67)	3.2(33)	.0(0)	.0(0)	.0(0)
37472	4.9	0	4.9	.0(0)	.0(0)	.0(0)	.0(0)	1.0(21)	3.9(79)	.0(0)	.0(0)	.0(0)
37473	3.8	0	3.8	.0(0)	.0(0)	.0(0)	.0(0)	2.1(54)	1.7(44)	.0(0)	.1(2)	.0(0)
37474	2.0	0	2.0	.0(0)	.0(0)	.0(0)	.0(0)	.6(31)	1.3(67)	.0(2)	.0(0)	.0(0)
37475	3.1	0	3.1	.0(0)	.0(0)	.0(0)	.0(0)	1.1(35)	2.0(65)	.0(0)	.0(0)	.0(0)
GROUP: 4	DOSE LEVEL: 200		DOSAGE UNIT: MG/KG									
37497	3.4	0	3.4	.0(0)	.0(0)	.0(0)	.0(0)	1.6(47)	1.8(53)	.0(0)	.0(0)	.0(0)
37498	6.7	0	6.7	.0(0)	.0(0)	.0(0)	.0(0)	1.6(24)	5.1(76)	.0(0)	.0(0)	.0(0)
37499	5.7	0	5.7	.0(0)	.0(0)	.0(0)	.0(0)	1.7(29)	4.0(70)	.0(0)	.1(1)	.0(0)
37500	8.0	0	8.0	.0(0)	.0(0)	.0(0)	.0(0)	3.4(43)	4.5(56)	.0(0)	.1(1)	.0(0)
37501	4.1	0	4.1	.0(0)	.0(0)	.0(0)	.0(0)	1.8(44)	2.3(55)	.0(0)	.0(1)	.0(0)
37502	5.6	0	5.6	.0(0)	.0(0)	.0(0)	.0(0)	1.6(28)	4.0(72)	.0(0)	.0(0)	.0(0)
37503	5.8	0	5.8	.0(0)	.0(0)	.0(0)	.0(0)	1.9(32)	3.8(66)	.0(0)	.1(2)	.0(0)
37504	3.3	0	3.3	.0(0)	.0(0)	.0(0)	.0(0)	.8(23)	2.5(76)	.0(0)	.0(1)	.0(0)
37505	5.6	0	5.6	.0(0)	.0(0)	.0(0)	.0(0)	1.5(26)	4.1(74)	.0(0)	.0(0)	.0(0)
37506	3.5	0	3.5	.0(0)	.0(0)	.0(0)	.0(0)	1.7(49)	1.8(50)	.0(0)	.0(1)	.0(0)

APPENDIX 11A
INDIVIDUAL CLINICAL HEMATOLOGY VALUES
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1 MICE
WEEK 14 FEMALES

ANIMAL NUMBER	WBC TH/UL	NRBC /100 WBC	COR WBC TH/UL	BLAST TH/UL(%)	PRO/MYEL TH/UL(%)	META TH/UL(%)	BAND TH/UL(%)	SEG TH/UL(%)	LYMPH TH/UL(%)	MONO TH/UL(%)	EOSIN TH/UL(%)	BASO TH/UL(%)
GROUP: 5	DOSE LEVEL: 350		DOSAGE UNIT: MG/KG									
37526	2.9	0	2.9	.0(0)	.0(0)	.0(0)	.0(0)	.9(32)	1.9(67)	.0(1)	.0(0)	.0(0)
37527	6.8	0	6.8	.0(0)	.0(0)	.0(0)	.0(0)	1.6(23)	5.2(76)	.0(0)	.1(1)	.0(0)
37528	4.7	0	4.7	.0(0)	.0(0)	.0(0)	.0(1)	2.0(43)	2.6(56)	.0(0)	.0(0)	.0(0)
37529	9.4	0	9.4	.0(0)	.0(0)	.0(0)	.0(0)	1.6(17)	7.6(81)	.0(0)	.2(2)	.0(0)
37530	2.4	0	2.4	.0(0)	.0(0)	.0(0)	.0(0)	1.1(45)	1.2(51)	.0(1)	.1(3)	.0(0)
37531	12.0	0	12.0	.0(0)	.0(0)	.0(0)	.0(0)	6.0(50)	6.0(50)	.0(0)	.0(0)	.0(0)
37532	2.6	0	2.6	.0(0)	.0(0)	.0(0)	.0(0)	1.4(55)	1.1(44)	.0(1)	.0(0)	.0(0)
37533	2.0	0	2.0	.0(0)	.0(0)	.0(0)	.0(0)	.3(17)	1.6(82)	.0(0)	.0(1)	.0(0)
37534	4.4	0	4.4	.0(0)	.0(0)	.0(0)	.0(0)	1.9(43)	2.5(57)	.0(0)	.0(0)	.0(0)
37535	2.7	0	2.7	.0(0)	.0(0)	.0(0)	.0(0)	1.6(58)	1.1(42)	.0(0)	.0(0)	.0(0)
GROUP: 6	DOSE LEVEL: 750		DOSAGE UNIT: MG/KG									
37556	4.0	0	4.0	.0(0)	.0(0)	.0(0)	.0(0)	1.9(48)	2.0(51)	.0(0)	.0(1)	.0(0)
37557	4.2	0	4.2	.0(0)	.0(0)	.0(0)	.0(0)	2.1(50)	2.1(50)	.0(0)	.0(0)	.0(0)
37558	10.7	0	10.7	.0(0)	.0(0)	.0(0)	.0(0)	8.5(79)	2.1(20)	.1(1)	.0(0)	.0(0)
37559	8.0	0	8.0	.0(0)	.0(0)	.0(0)	.0(0)	5.4(67)	2.6(33)	.0(0)	.0(0)	.0(0)
37560	6.2	0	6.2	.0(0)	.0(0)	.0(0)	.0(0)	4.8(78)	1.4(22)	.0(0)	.0(0)	.0(0)
37561	2.9	0	2.9	.0(0)	.0(0)	.0(0)	.0(0)	1.7(60)	1.2(40)	.0(0)	.0(0)	.0(0)
37562	5.9	0	5.9	.0(0)	.0(0)	.0(0)	.0(0)	2.5(43)	3.4(57)	.0(0)	.0(0)	.0(0)
37563	CLOT	CLOT	CLOT	CLOT	CLOT	CLOT	CLOT	CLOT	CLOT	CLOT	CLOT	CLOT
37564	3.2	0	3.2	.0(0)	.0(0)	.0(0)	.0(0)	1.4(44)	1.8(56)	.0(0)	.0(0)	.0(0)
37565	3.6	0	3.6	.0(0)	.0(0)	.0(0)	.0(0)	2.5(70)	1.1(30)	.0(0)	.0(0)	.0(0)

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 13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1 MICE
 WEEK 14 FEMALES

ANIMAL NUMBER	WBC TH/UL	NRBC /100 WBC	COR WBC TH/UL	BLAST TH/UL(%)	PRO/MYEL TH/UL(%)	META TH/UL(%)	BAND TH/UL(%)	SEG TH/UL(%)	LYMPH TH/UL(%)	MONO TH/UL(%)	EOSIN TH/UL(%)	BASO TH/UL(%)
GROUP: 7	DOSE LEVEL: 900		DOSAGE UNIT: MG/KG									
37587	7.1	0	7.1	.0(0)	.0(0)	.0(0)	.0(0)	5.0(71)	2.1(29)	.0(0)	.0(0)	.0(0)
37588	5.3	0	5.3	.0(0)	.0(0)	.0(0)	.0(0)	3.3(62)	2.0(38)	.0(0)	.0(0)	.0(0)
37589	8.2	0	8.2	.0(0)	.0(0)	.0(0)	.0(0)	5.7(70)	2.5(30)	.0(0)	.0(0)	.0(0)
37590	8.5	0	8.5	.0(0)	.0(0)	.0(0)	.0(0)	6.2(73)	2.3(27)	.0(0)	.0(0)	.0(0)
37591	7.6	0	7.6	.0(0)	.0(0)	.0(0)	.0(0)	2.2(29)	5.2(68)	.0(0)	.2(3)	.0(0)
37592	3.5	0	3.5	.0(0)	.0(0)	.0(0)	.0(0)	2.2(63)	1.3(37)	.0(0)	.0(0)	.0(0)
37593	3.4	0	3.4	.0(0)	.0(0)	.0(0)	.0(0)	1.8(52)	1.6(48)	.0(0)	.0(0)	.0(0)
37594	CLOT	CLOT	CLOT	CLOT	CLOT	CLOT	CLOT	CLOT	CLOT	CLOT	CLOT	CLOT
37595	5.1	0	5.1	.0(0)	.0(0)	.0(0)	.0(0)	3.2(62)	1.8(36)	.0(0)	.1(2)	.0(0)
37596	33.3	0	33.3	.0(0)	.0(0)	.0(0)	.0(0)	25.0(75)	8.3(25)	.0(0)	.0(0)	.0(0)

APPENDIX 11A
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 13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1 MICE
 WEEK 14 FEMALES

ANIMAL NUMBER	REACTLYM	ANISO	POLY	ECHINO	ACANTH	HYPO	TARGET	SCHISTO	POIK	HJBODY	MICRO

GROUP: 1	DOSE LEVEL: 0		DOSAGE UNIT: MG/KG								
37406	0	-	1	-	-	-	-	-	-	-	-
37407	0	-	1	-	-	-	-	-	-	-	-
37408	0	-	1	-	-	-	-	-	-	-	-
37409	0	-	1	-	-	-	-	-	-	F	-
37410	0	-	2	-	-	-	-	-	-	-	-
37411	CLOT	CLOT	CLOT	CLOT	CLOT	CLOT	CLOT	CLOT	CLOT	CLOT	CLOT
37412	0	-	1	-	-	-	-	-	-	-	-
37413	0	-	1	-	-	-	-	-	-	-	-
37414	0	-	1	-	-	-	-	-	-	-	-
37415	0	-	1	-	-	-	-	-	-	-	-
GROUP: 2	DOSE LEVEL: 25		DOSAGE UNIT: MG/KG								
37436	0	-	1	-	-	-	-	-	-	-	-
37437	0	-	2	-	-	-	-	-	-	-	-
37438	0	-	1	-	-	-	-	-	-	-	-
37439	0	-	1	-	-	-	-	-	-	-	-
37440	0	-	1	-	-	-	-	-	-	-	-
37441	0	-	1	-	-	-	-	-	-	F	-
37442	0	-	1	-	-	-	-	-	-	F	-
37443	0	-	1	-	-	-	-	-	-	-	-
37444	0	-	1	-	-	-	-	-	-	F	-
37445	0	-	1	-	-	-	-	-	-	F	-

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INDIVIDUAL CLINICAL HEMATOLOGY VALUES
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1 MICE
WEEK 14 FEMALES

ANIMAL NUMBER	REACTLYM	ANISO	POLY	ECHINO	ACANTH	HYP0	TARGET	SCHISTO	POIK	HJBODY	MICRO
<hr/>											
GROUP: 3	DOSE LEVEL: 75		DOSAGE UNIT: MG/KG								
37466	0	-	1	-	-	-	-	-	-	-	-
37467	0	-	1	-	-	-	-	-	-	F	-
37468	0	-	1	-	-	-	-	-	-	F	-
37469	0	-	1	-	-	-	-	-	-	-	-
37470	0	1	2	-	-	-	-	-	-	-	-
37471	0	-	2	-	-	-	T	-	-	-	-
37472	0	-	2	-	-	-	-	-	-	F	-
37473	0	T	2	-	-	-	-	-	-	F	-
37474	0	-	1	-	-	-	-	-	-	-	-
37475	0	T	1	-	-	-	-	-	-	-	-
GROUP: 4	DOSE LEVEL: 200		DOSAGE UNIT: MG/KG								
37497	0	-	1	-	-	-	-	-	-	-	-
37498	0	-	1	-	-	-	T	-	-	F	-
37499	1	-	1	-	-	-	-	-	-	-	-
37500	0	T	1	-	-	-	-	-	-	F	-
37501	0	-	2	-	-	-	-	-	-	-	-
37502	0	T	2	-	-	-	T	-	-	-	-
37503	0	T	1	-	-	-	T	-	-	-	-
37504	0	T	1	-	-	-	-	-	-	F	-
37505	0	T	1	-	-	-	-	-	-	F	-
37506	0	T	2	-	-	-	-	-	-	F	-

APPENDIX 11A
INDIVIDUAL CLINICAL HEMATOLOGY VALUES
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1 MICE
WEEK 14 FEMALES

ANIMAL NUMBER	REACTLYM	ANISO	POLY	ECHINO	ACANTH	HYPO	TARGET	SCHISTO	POIK	HJBODY	MICRO
<hr/>											
GROUP: 5	DOSE LEVEL: 350		DOSAGE UNIT: MG/KG								
37526	0	-	1	-	-	-	-	-	-	-	-
37527	0	-	1	-	-	-	-	-	-	-	-
37528	0	-	2	-	-	-	T	-	-	-	-
37529	0	-	2	-	-	-	-	-	-	-	-
37530	0	1	2	-	-	-	T	-	-	-	-
37531	0	T	1	-	-	-	-	-	-	-	-
37532	0	-	1	-	-	-	-	-	-	-	-
37533	0	T	1	-	-	-	-	-	-	-	-
37534	0	-	1	-	-	-	T	-	-	F	-
37535	0	T	1	-	-	-	-	-	-	-	-
GROUP: 6	DOSE LEVEL: 750		DOSAGE UNIT: MG/KG								
37556	0	1	2	-	-	-	-	-	-	F	-
37557	0	-	1	-	-	-	T	-	-	F	-
37558	0	-	2	-	-	-	T	-	-	F	-
37559	0	2	3	-	-	2	-	-	-	-	-
37560	0	1	3	-	-	T	-	-	-	F	-
37561	0	-	2	-	-	-	-	-	-	-	-
37562	0	-	1	-	-	-	-	-	-	F	-
37563	CLOT	CLOT	CLOT	CLOT	CLOT	CLOT	CLOT	CLOT	CLOT	CLOT	CLOT
37564	0	-	1	-	-	-	-	-	-	F	-
37565	0	T	2	-	-	-	-	-	-	-	-

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 13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1 MICE
 WEEK 14 FEMALES

ANIMAL NUMBER	REACTLYM	ANISO	POLY	ECHINO	ACANTH	HYPO	TARGET	SCHISTO	POIK	HJBODY	MICRO

GROUP: 7	DOSE LEVEL: 900		DOSAGE UNIT: MG/KG								
37587	0	-	1	-	-	-	-	-	-	F	-
37588	0	1	2	-	-	-	-	-	-	-	-
37589	0	1	2	-	-	-	-	-	-	-	-
37590	0	-	1	-	-	T	T	-	-	-	-
37591	0	-	2	-	-	-	T	-	-	-	-
37592	0	1	2	-	-	-	-	-	-	-	-
37593	0	1	2	-	-	-	-	-	-	-	-
37594	CLOT	CLOT	CLOT	CLOT	CLOT	CLOT	CLOT	CLOT	CLOT	CLOT	CLOT
37595	0	1	1	-	-	-	T	-	-	F	-
37596	0	3	4	-	-	-	-	-	-	-	-

Appendix 11B
Individual Clinical Hematology Values - Satellite Study
13-Week Subchronic Oral Toxicity Study of Triclosan in CD-1 Mice

NOTE: Due to computer limitations, Groups 1-4 correspond to Groups 8-11, respectively.

Key to Hematology for Rodent Studies

<u>LEUKOCYTE DIFFERENTIALS</u>		<u>CELL MORPHOLOGY</u>	
Blast Cells	BLAST	Reactive Lymphocytes ^a	REACTLYM
Metamyelocytes	META	Anisocytes	ANISO
Band Neutrophils	BAND	Polychromatophilic Cells	POLY
Segmented Neutrophils	SEG	Echinocytes	ECHINO
Lymphocytes	LYMPH	Acanthocytes	ACANTH
Monocytes	MONO	Hypochromic Cells	HYPO
Eosinophils	EOSIN	Target Cells	TARGET
Basophils	BASO	Schistocytes	SCHISTO
Promyelocyte/Myelocyte	PRO/MYEL	Poikilocytes	POIK
		Howell-Jolly Bodies	HJBODY
		Microcytes	MICRO
		Nucleated RBCs ^a	NRBC

Cell morphology findings are graded by one of the following two methods, unless footnoted otherwise.

- = None Present
 T = Trace Numbers Present
 1 = Slight Numbers Present
 2 = Moderate Numbers Present
 3 = Marked Numbers Present
 4 = Severe Numbers Present

or

- = None Present
 F = Few Cells Present
 M = Many Cells Present

^a Expressed as a percentage of 100 white blood cells counted.

OTHER NOTATIONS

QNS = Quantity Not Sufficient

Week 7 (Satellite Study, Groups 8-11)

The following animals had indications of stomatocytes (STOMAT) during cell morphology evaluation:

STOMAT T: 37681

The following animals had indications of few neutrophils containing large numbers of chromatin projection, many with filament:

37691, 37602, 37662, 37643, 37673, 37644, 37694, 37695, 37666, 37696, 37627, and 37698.

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APPENDIX 11B
INDIVIDUAL CLINICAL HEMATOLOGY VALUES
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1 MICE
WEEK -1 MALES

ANIMAL NUMBER	RBC MI/UL	HGB G/DL	HCT %	PLATELET TH/UL
GROUP: 1	DOSE LEVEL: 0		DOSAGE UNIT: MG/KG	
37611	11.10	18.3	55.3	1573
37612	10.15	18.1	50.5	1755
37613	10.38	18.5	54.6	1997
37614	10.45	17.7	50.6	1080
37615	9.92	17.7	50.7	1954
37616	9.66	17.4	50.2	2055
37617	10.01	18.0	53.4	1782
37618	9.17	15.8	45.7	1688
37619	10.69	18.3	52.8	1902
37620	11.33	18.1	51.5	1842

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 13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1 MICE
 WEEK -1 MALES

ANIMAL NUMBER	WBC TH/UL	NRBC /100 WBC	COR WBC TH/UL	BLAST TH/UL(%)	PRO/MYEL TH/UL(%)	META TH/UL(%)	BAND TH/UL(%)	SEG TH/UL(%)	LYMPH TH/UL(%)	MONO TH/UL(%)	EOSIN TH/UL(%)	BASO TH/UL(%)
GROUP: 1	DOSE LEVEL: 0											
37611	3.2	0	3.2	.0(0)	.0(0)	.0(0)	.0(0)	.5(17)	2.7(83)	.0(0)	.0(0)	.0(0)
37612	5.1	0	5.1	.0(0)	.0(0)	.0(0)	.0(0)	1.9(37)	3.2(63)	.0(0)	.0(0)	.0(0)
37613	3.5	0	3.5	.0(0)	.0(0)	.0(0)	.0(0)	.5(15)	3.0(85)	.0(0)	.0(0)	.0(0)
37614	4.4	0	4.4	.0(0)	.0(0)	.0(0)	.0(0)	.4(9)	4.0(91)	.0(0)	.0(0)	.0(0)
37615	1.4	0	1.4	.0(0)	.0(0)	.0(0)	.0(0)	.2(12)	1.2(87)	.0(1)	.0(0)	.0(0)
37616	3.3	0	3.3	.0(0)	.0(0)	.0(0)	.1(3)	.4(12)	2.8(85)	.0(0)	.0(0)	.0(0)
37617	2.0	0	2.0	.0(0)	.0(0)	.0(0)	.0(0)	.1(4)	1.9(96)	.0(0)	.0(0)	.0(0)
37618	4.9	0	4.9	.0(0)	.0(0)	.0(0)	.0(0)	.6(13)	4.2(86)	.0(1)	.0(0)	.0(0)
37619	1.7	0	1.7	.0(0)	.0(0)	.0(0)	.0(0)	.6(35)	1.1(65)	.0(0)	.0(0)	.0(0)
37620	3.9	0	3.9	.0(0)	.0(0)	.0(0)	.0(0)	.6(15)	3.3(85)	.0(0)	.0(0)	.0(0)

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 INDIVIDUAL CLINICAL HEMATOLOGY VALUES
 13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1 MICE
 WEEK -1 MALES

ANIMAL NUMBER	REACTLYM	ANISO	POLY	ECHINO	ACANTH	HYP0	TARGET	SCHISTO	POIK	HJBODY	MICRO
GROUP: 1	DOSE LEVEL: 0										
37611	0	-	2	-	-	-	-	-	-	F	-
37612	0	T	2	T	-	-	-	-	-	F	-
37613	0	-	2	-	-	-	-	-	-	F	-
37614	0	-	2	-	-	-	-	-	-	F	-
37615	0	-	1	T	-	-	-	-	-	F	-
37616	0	-	1	-	-	-	-	-	-	F	-
37617	0	-	1	T	-	-	-	-	-	-	-
37618	0	-	1	T	-	-	-	-	-	F	-
37619	0	T	1	-	-	-	-	-	-	F	-
37620	0	T	2	T	-	-	-	-	-	F	-

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APPENDIX 11B
INDIVIDUAL CLINICAL HEMATOLOGY VALUES
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1 MICE
WEEK -1 FEMALES

ANIMAL NUMBER	RBC MI/UL	HGB G/DL	HCT %	PLATELET TH/UL
GROUP: 1	DOSE LEVEL: 0		DOSAGE UNIT: MG/KG	
37631	QNS	QNS	QNS	QNS
37632	10.92	18.6	53.4	1437
37633	10.15	17.1	48.1	1633
37634	11.65	18.9	53.4	1439
37635	9.69	17.2	49.1	1550
37636	10.39	18.4	54.0	1448
37637	10.29	17.8	49.8	1513
37638	10.15	16.9	49.1	1659
37639	QNS	QNS	QNS	QNS
37640	QNS	QNS	QNS	QNS

APPENDIX 11B
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13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1 MICE
WEEK -1 FEMALES

ANIMAL NUMBER	WBC TH/UL	NRBC /100 WBC	COR WBC TH/UL	BLAST TH/UL(%)	PRO/MYEL TH/UL(%)	META TH/UL(%)	BAND TH/UL(%)	SEG TH/UL(%)	LYMPH TH/UL(%)	MONO TH/UL(%)	EOSIN TH/UL(%)	BASO TH/UL(%)
GROUP: 1	DOSE LEVEL: 0		DOSAGE UNIT: MG/KG									
37631	QNS	0	QNS	QNS (0)	QNS (0)	QNS (0)	QNS (0)	QNS (18)	QNS (82)	QNS (0)	QNS (0)	QNS (0)
37632	3.8	0	3.8	.0(0)	.0(0)	.0(0)	.0(0)	.6(17)	3.1(82)	.0(1)	.0(0)	.0(0)
37633	2.8	0	2.8	.0(0)	.0(0)	.0(0)	.0(0)	.7(26)	2.1(74)	.0(0)	.0(0)	.0(0)
37634	4.2	0	4.2	.0(0)	.0(0)	.0(0)	.0(0)	.4(10)	3.8(90)	.0(0)	.0(0)	.0(0)
37635	1.5	0	1.5	.0(0)	.0(0)	.0(0)	.0(0)	.2(16)	1.3(84)	.0(0)	.0(0)	.0(0)
37636	1.9	0	1.9	.0(0)	.0(0)	.0(0)	.0(0)	1.0(52)	.9(45)	.1(3)	.0(0)	.0(0)
37637	5.4	0	5.4	.0(0)	.0(0)	.0(0)	.0(0)	1.2(23)	4.1(76)	.1(1)	.0(0)	.0(0)
37638	5.5	0	5.5	.0(0)	.0(0)	.0(0)	.0(0)	1.8(32)	3.7(67)	.1(1)	.0(0)	.0(0)
37639	QNS	0	QNS	QNS (0)	QNS (0)	QNS (0)	QNS (0)	QNS (12)	QNS (88)	QNS (0)	QNS (0)	QNS (0)
37640	QNS	0	QNS	QNS (0)	QNS (0)	QNS (0)	QNS (0)	QNS (74)	QNS (26)	QNS (0)	QNS (0)	QNS (0)

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 WEEK -1 FEMALES

ANIMAL NUMBER	REACTLYM	ANISO	POLY	ECHINO	ACANTH	HYP0	TARGET	SCHISTO	POIK	HJBODY	MICRO
GROUP: 1	DOSE LEVEL: 0										
37631	0	-	T	1	-	-	-	-	-	F	-
37632	0	-	1	T	-	-	-	-	-	F	-
37633	0	T	1	T	-	-	-	-	-	F	-
37634	0	-	1	T	-	-	-	-	-	F	-
37635	0	-	1	-	-	-	-	-	-	F	-
37636	0	-	2	-	-	-	-	-	-	F	-
37637	0	-	1	T	-	-	-	-	-	-	-
37638	0	-	1	-	-	-	-	-	-	F	-
37639	0	-	1	-	-	-	-	-	-	F	-
37640	0	-	1	T	-	-	-	-	-	F	-

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APPENDIX 11B
INDIVIDUAL CLINICAL HEMATOLOGY VALUES
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1 MICE
WEEK 7 MALES

ANIMAL NUMBER	RBC MI/UL	HGB G/DL	HCT %	PLATELET TH/UL
GROUP: 1 DOSE LEVEL: 0 DOSAGE UNIT: MG/KG				
37601	10.01	17.0	48.6	1462
37602	11.02	17.9	50.7	1585
37603	10.11	17.2	47.6	1557
37604	10.56	17.3	49.0	1515
37605	10.16	16.8	47.8	1591
37606	10.57	16.9	52.0	1539
37607	10.70	17.5	50.0	1198
37608	11.03	18.1	53.7	1637
37609	10.51	17.7	50.1	1609
37610	10.78	18.0	51.2	1669
GROUP: 2 DOSE LEVEL: 25 DOSAGE UNIT: MG/KG				
37641	11.20	18.2	55.3	1547
37642	10.39	17.2	49.1	1706
37643	10.05	16.6	49.1	1403
37644	10.57	18.0	53.2	1736
37645	10.26	17.8	54.0	1492
37646	9.78	16.2	46.9	1559
37647	9.69	16.0	46.3	1499
37648	11.05	17.8	53.0	1768
37649	10.22	17.0	48.8	1246
37650	10.34	17.1	49.6	1799

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INDIVIDUAL CLINICAL HEMATOLOGY VALUES
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1 MICE
WEEK 7 MALES

ANIMAL NUMBER	RBC MI/UL	HGB G/DL	HCT %	PLATELET TH/UL

GROUP: 3	DOSE LEVEL: 350	DOSAGE UNIT: MG/KG		
37661	9.58	14.8	43.4	1825
37662	9.90	15.7	48.7	1907
37663	9.57	14.9	43.1	1429
37664	9.42	15.6	45.8	1597
37665	9.70	15.6	45.9	1648
37666	9.06	14.4	43.3	1574
37667	9.13	13.8	41.8	1705
37668	9.72	15.2	44.6	1821
37669	8.82	14.4	42.9	1375
37670	10.27	16.0	45.9	1571
GROUP: 4	DOSE LEVEL: 900	DOSAGE UNIT: MG/KG		
37681	10.18	15.7	47.7	1607
37682	8.75	14.2	43.6	1648
37683	7.16	11.5	34.7	1169
37684	6.90	11.2	34.6	1601
37685	9.11	14.5	43.5	1690
37686	9.78	15.3	45.8	1590
37687	9.77	15.5	46.4	1911
37688	8.10	13.0	39.3	1796
37689	10.15	16.5	49.5	1397
37690	9.53	14.9	47.8	1379

APPENDIX 11B
INDIVIDUAL CLINICAL HEMATOLOGY VALUES
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1 MICE
WEEK 7 MALES

ANIMAL NUMBER	WBC TH/UL	NRBC /100 WBC	COR WBC TH/UL	BLAST TH/UL(%)	PRO/MYEL TH/UL(%)	META TH/UL(%)	BAND TH/UL(%)	SEG TH/UL(%)	LYMPH TH/UL(%)	MONO TH/UL(%)	EOSIN TH/UL(%)	BASO TH/UL(%)
GROUP: 1	DOSE LEVEL: 0		DOSAGE UNIT: MG/KG									
37601	3.0	0	3.0	.0(0)	.0(0)	.0(0)	.0(0)	.7(22)	2.3(75)	.0(0)	.1(3)	.0(0)
37602	3.4	0	3.4	.0(0)	.0(0)	.0(0)	.0(0)	1.8(54)	1.5(43)	.0(1)	.1(2)	.0(0)
37603	2.9	0	2.9	.0(0)	.0(0)	.0(0)	.0(0)	1.2(42)	1.5(53)	.0(1)	.1(4)	.0(0)
37604	1.2	0	1.2	.0(0)	.0(0)	.0(0)	.0(0)	.3(22)	.9(78)	.0(0)	.0(0)	.0(0)
37605	6.3	0	6.3	.0(0)	.0(0)	.0(0)	.0(0)	.9(14)	5.4(86)	.0(0)	.0(0)	.0(0)
37606	5.8	0	5.8	.0(0)	.0(0)	.0(0)	.0(0)	1.0(17)	4.7(81)	.0(0)	.1(2)	.0(0)
37607	5.7	0	5.7	.0(0)	.0(0)	.0(0)	.0(0)	1.8(31)	3.8(67)	.0(0)	.1(2)	.0(0)
37608	3.4	0	3.4	.0(0)	.0(0)	.0(0)	.0(0)	1.4(42)	1.9(56)	.0(1)	.0(1)	.0(0)
37609	2.5	0	2.5	.0(0)	.0(0)	.0(0)	.0(0)	.5(19)	2.0(78)	.0(0)	.1(3)	.0(0)
37610	5.4	0	5.4	.0(0)	.0(0)	.0(0)	.0(0)	1.2(23)	4.2(77)	.0(0)	.0(0)	.0(0)
GROUP: 2	DOSE LEVEL: 25		DOSAGE UNIT: MG/KG									
37641	2.8	0	2.8	.0(0)	.0(0)	.0(0)	.0(0)	1.0(37)	1.7(62)	.0(0)	.0(1)	.0(0)
37642	3.4	0	3.4	.0(0)	.0(0)	.0(0)	.0(0)	.8(23)	2.6(76)	.0(0)	.0(1)	.0(0)
37643	2.5	0	2.5	.0(0)	.0(0)	.0(0)	.0(0)	1.3(50)	1.2(49)	.0(0)	.0(1)	.0(0)
37644	3.8	0	3.8	.0(0)	.0(0)	.0(0)	.0(0)	.6(15)	3.2(83)	.0(0)	.1(2)	.0(0)
37645	2.3	0	2.3	.0(0)	.0(0)	.0(0)	.0(0)	.8(34)	1.5(66)	.0(0)	.0(0)	.0(0)
37646	7.9	0	7.9	.0(0)	.0(0)	.0(0)	.0(0)	3.6(46)	3.9(50)	.1(1)	.2(3)	.0(0)
37647	3.2	0	3.2	.0(0)	.0(0)	.0(0)	.0(0)	1.6(51)	1.5(48)	.0(0)	.0(1)	.0(0)
37648	3.0	0	3.0	.0(0)	.0(0)	.0(0)	.0(0)	.8(26)	2.2(73)	.0(1)	.0(0)	.0(0)
37649	2.9	0	2.9	.0(0)	.0(0)	.0(0)	.0(0)	1.9(66)	1.0(34)	.0(0)	.0(0)	.0(0)
37650	2.0	0	2.0	.0(0)	.0(0)	.0(0)	.0(0)	.5(25)	1.4(68)	.0(1)	.1(6)	.0(0)

APPENDIX 11B
INDIVIDUAL CLINICAL HEMATOLOGY VALUES
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1 MICE
WEEK 7 MALES

ANIMAL NUMBER	WBC TH/UL	NRBC /100 WBC	COR WBC TH/UL	BLAST TH/UL(%)	PRO/MYEL TH/UL(%)	META TH/UL(%)	BAND TH/UL(%)	SEG TH/UL(%)	LYMPH TH/UL(%)	MONO TH/UL(%)	EOSIN TH/UL(%)	BASO TH/UL(%)
GROUP: 3	DOSE LEVEL: 350		DOSAGE UNIT: MG/KG									
37661	5.6	0	5.6	.0(0)	.0(0)	.0(0)	.0(0)	.6(11)	4.7(84)	.1(1)	.2(4)	.0(0)
37662	5.2	0	5.2	.0(0)	.0(0)	.0(0)	.0(0)	1.2(23)	3.8(74)	.0(0)	.2(3)	.0(0)
37663	2.5	0	2.5	.0(0)	.0(0)	.0(0)	.0(0)	1.4(56)	1.0(41)	.0(1)	.0(2)	.0(0)
37664	2.1	0	2.1	.0(0)	.0(0)	.0(0)	.0(0)	.7(31)	1.4(69)	.0(0)	.0(0)	.0(0)
37665	5.4	0	5.4	.0(0)	.0(0)	.0(0)	.0(0)	1.2(23)	3.9(73)	.1(1)	.2(3)	.0(0)
37666	13.8	0	13.8	.0(0)	.0(0)	.0(0)	.0(0)	10.1(73)	3.7(27)	.0(0)	.0(0)	.0(0)
37667	4.1	0	4.1	.0(0)	.0(0)	.0(0)	.0(0)	2.4(58)	1.7(41)	.0(1)	.0(0)	.0(0)
37668	5.1	0	5.1	.0(0)	.0(0)	.0(0)	.0(0)	2.3(45)	2.7(53)	.0(0)	.1(2)	.0(0)
37669	5.5	0	5.5	.0(0)	.0(0)	.0(0)	.0(0)	2.2(40)	3.3(60)	.0(0)	.0(0)	.0(0)
37670	7.4	0	7.4	.0(0)	.0(0)	.0(0)	.0(0)	3.7(50)	3.7(50)	.0(0)	.0(0)	.0(0)
GROUP: 4	DOSE LEVEL: 900		DOSAGE UNIT: MG/KG									
37681	3.2	0	3.2	.0(0)	.0(0)	.0(0)	.0(0)	1.3(41)	1.9(59)	.0(0)	.0(0)	.0(0)
37682	5.8	0	5.8	.0(0)	.0(0)	.0(0)	.0(0)	4.4(76)	1.4(24)	.0(0)	.0(0)	.0(0)
37683	2.1	0	2.1	.0(0)	.0(0)	.0(0)	.0(0)	.9(42)	1.2(58)	.0(0)	.0(0)	.0(0)
37684	5.3	0	5.3	.0(0)	.0(0)	.0(0)	.0(0)	3.8(71)	1.5(29)	.0(0)	.0(0)	.0(0)
37685	5.0	0	5.0	.0(0)	.0(0)	.0(0)	.0(0)	2.9(57)	2.1(41)	.0(0)	.1(2)	.0(0)
37686	4.2	0	4.2	.0(0)	.0(0)	.0(0)	.0(0)	2.1(51)	2.1(49)	.0(0)	.0(0)	.0(0)
37687	2.8	0	2.8	.0(0)	.0(0)	.0(0)	.0(0)	1.1(40)	1.5(55)	.1(3)	.1(2)	.0(0)
37688	3.9	0	3.9	.0(0)	.0(0)	.0(0)	.0(0)	2.5(64)	1.4(36)	.0(0)	.0(0)	.0(0)
37689	4.4	0	4.4	.0(0)	.0(0)	.0(0)	.0(0)	2.3(53)	2.1(47)	.0(0)	.0(0)	.0(0)
37690	2.9	0	2.9	.0(0)	.0(0)	.0(0)	.0(0)	2.1(74)	.8(26)	.0(0)	.0(0)	.0(0)

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APPENDIX 11B
 INDIVIDUAL CLINICAL HEMATOLOGY VALUES
 13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1 MICE
 WEEK 7 MALES

ANIMAL NUMBER	REACTLYM	ANISO	POLY	ECHINO	ACANTH	HYPO	TARGET	SCHISTO	POIK	HJBODY	MICRO
<hr/>											
GROUP: 1	DOSE LEVEL: 0	DOSAGE UNIT: MG/KG									
37601	0	-	1	-	-	-	-	-	-	-	-
37602	0	-	1	-	-	-	-	-	-	-	-
37603	0	-	1	-	-	-	-	-	-	-	-
37604	0	-	1	-	-	-	-	-	-	F	-
37605	0	-	1	-	-	-	-	-	-	-	-
37606	0	-	1	-	-	-	-	-	-	-	-
37607	1	-	1	-	-	-	-	-	-	-	-
37608	0	-	1	-	-	-	-	-	-	-	-
37609	0	-	1	-	-	-	-	-	-	-	-
37610	0	-	1	-	-	-	-	-	-	-	-
GROUP: 2	DOSE LEVEL: 25	DOSAGE UNIT: MG/KG									
37641	0	-	1	-	-	-	-	-	-	F	-
37642	0	-	1	-	-	-	-	-	-	-	-
37643	0	-	1	-	-	-	-	-	-	F	-
37644	0	-	1	-	-	-	-	-	-	F	-
37645	0	-	1	-	-	-	-	-	-	-	-
37646	0	-	1	-	-	-	-	-	-	-	-
37647	0	-	1	-	-	-	-	-	-	-	-
37648	0	-	1	-	-	-	-	-	-	-	-
37649	0	-	T	-	-	-	-	-	-	F	-
37650	0	-	T	-	-	-	-	-	-	F	-

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13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1 MICE
WEEK 7 MALES

ANIMAL NUMBER	REACTLYM	ANISO	POLY	ECHINO	ACANTH	HYP0	TARGET	SCHISTO	POIK	HJBODY	MICRO
<hr/>											
GROUP: 3	DOSE LEVEL: 350		DOSAGE UNIT: MG/KG								
37661	0	-	1	-	-	-	-	-	-	-	-
37662	0	-	1	-	-	-	-	-	-	-	-
37663	0	1	2	-	-	-	-	-	-	-	-
37664	0	-	2	-	-	-	-	-	-	F	-
37665	0	-	1	-	-	-	-	-	-	-	-
37666	0	-	1	-	-	-	-	-	-	-	-
37667	0	-	1	-	-	-	-	-	-	-	-
37668	0	-	1	-	-	-	-	-	-	-	-
37669	0	-	1	-	-	-	-	-	-	-	-
37670	0	-	1	-	-	-	-	-	-	F	-
GROUP: 4	DOSE LEVEL: 900		DOSAGE UNIT: MG/KG								
37681	0	-	2	-	-	-	-	-	-	F	-
37682	0	1	1	-	-	-	-	-	-	-	-
37683	0	-	1	-	-	-	-	-	-	F	-
37684	0	2	-	-	-	-	-	-	-	F	-
37685	0	-	1	-	-	-	-	-	-	-	-
37686	0	-	1	-	-	-	-	-	-	-	-
37687	0	-	1	-	-	-	-	-	-	-	-
37688	0	-	1	-	-	-	-	-	-	-	-
37689	0	-	1	-	-	-	-	-	-	-	-
37690	0	-	1	-	-	-	-	-	-	F	-

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13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1 MICE
WEEK 7 FEMALES

ANIMAL NUMBER	RBC MI/UL	HGB G/DL	HCT %	PLATELET TH/UL

GROUP: 1	DOSE LEVEL: 0	DOSAGE UNIT: MG/KG		
37621	9.85	18.2	53.8	1248
37622	11.09	19.0	54.9	1260
37623	10.59	18.6	55.4	1328
37624	10.19	17.6	48.5	1523
37625	9.90	16.4	46.1	1268
37626	10.48	17.6	52.4	1614
37627	10.62	17.9	53.0	1578
37628	10.70	18.4	50.9	1547
37629	10.25	17.7	49.1	1422
37630	10.98	19.0	53.0	1198
GROUP: 2	DOSE LEVEL: 25	DOSAGE UNIT: MG/KG		
37651	10.37	17.3	49.7	1408
37652	9.42	16.6	47.5	1305
37653	9.33	15.5	43.8	1636
37654	10.24	17.8	50.4	1447
37655	10.39	17.3	52.5	1480
37656	10.22	16.5	48.6	1402
37657	10.48	17.2	48.8	1633
37658	10.65	18.0	51.3	1358
37659	9.52	16.1	47.6	1317
37660	10.58	18.2	51.0	1484

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13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1 MICE
WEEK 7 FEMALES

ANIMAL NUMBER	RBC MI/UL	HGB G/DL	HCT %	PLATELET TH/UL
GROUP: 3 DOSE LEVEL: 350 DOSAGE UNIT: MG/KG				
37671	9.28	15.2	47.4	1501
37672	9.82	15.7	46.0	1587
37673	9.54	16.9	47.7	1357
37674	10.09	16.0	47.4	1401
37675	9.24	14.7	43.5	1434
37676	9.35	14.9	44.5	1635
37677	9.34	16.0	48.8	1398
37678	9.06	15.2	43.3	1755
37679	9.35	15.1	43.8	1500
37680	8.76	15.5	44.0	1524
GROUP: 4 DOSE LEVEL: 900 DOSAGE UNIT: MG/KG				
37691	9.06	15.2	43.5	1213
37692	10.07	16.0	47.0	1184
37693	10.07	16.0	45.9	1434
37694	9.54	14.3	42.7	1066
37695	9.10	14.9	42.9	1344
37696	9.39	15.8	45.3	1373
37697	9.40	14.9	44.2	1396
37698	9.35	15.9	46.2	1226
37699	10.05	16.6	48.8	1324
37700	9.93	17.0	51.6	1127

APPENDIX 11B
INDIVIDUAL CLINICAL HEMATOLOGY VALUES
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1 MICE
WEEK 7 FEMALES

ANIMAL NUMBER	WBC TH/UL	NRBC /100 WBC	COR WBC TH/UL	BLAST TH/UL(%)	PRO/MYEL TH/UL(%)	META TH/UL(%)	BAND TH/UL(%)	SEG TH/UL(%)	LYMPH TH/UL(%)	MONO TH/UL(%)	EOSIN TH/UL(%)	BASO TH/UL(%)
GROUP: 1	DOSE LEVEL: 0		DOSAGE UNIT: MG/KG									
37621	1.2	0	1.2	.0(0)	.0(0)	.0(0)	.0(0)	.2(20)	1.0(80)	.0(0)	.0(0)	.0(0)
37622	3.5	0	3.5	.0(0)	.0(0)	.0(0)	.0(0)	2.1(61)	1.3(37)	.0(0)	.1(2)	.0(0)
37623	1.8	0	1.8	.0(0)	.0(0)	.0(0)	.0(0)	.9(49)	.9(51)	.0(0)	.0(0)	.0(0)
37624	1.2	0	1.2	.0(0)	.0(0)	.0(0)	.0(0)	.3(29)	.9(71)	.0(0)	.0(0)	.0(0)
37625	2.9	0	2.9	.0(0)	.0(0)	.0(0)	.0(0)	.7(25)	2.2(75)	.0(0)	.0(0)	.0(0)
37626	1.9	0	1.9	.0(0)	.0(0)	.0(0)	.0(0)	.6(33)	1.3(67)	.0(0)	.0(0)	.0(0)
37627	4.2	0	4.2	.0(0)	.0(0)	.0(0)	.0(0)	2.1(51)	2.1(49)	.0(0)	.0(0)	.0(0)
37628	1.8	0	1.8	.0(0)	.0(0)	.0(0)	.0(0)	.5(26)	1.3(74)	.0(0)	.0(0)	.0(0)
37629	2.9	0	2.9	.0(0)	.0(0)	.0(0)	.0(0)	.6(22)	2.2(77)	.0(1)	.0(0)	.0(0)
37630	2.5	0	2.5	.0(0)	.0(0)	.0(0)	.0(0)	.6(23)	1.9(77)	.0(0)	.0(0)	.0(0)
GROUP: 2	DOSE LEVEL: 25		DOSAGE UNIT: MG/KG									
37651	1.7	0	1.7	.0(0)	.0(0)	.0(0)	.0(0)	.6(35)	1.1(64)	.0(0)	.0(1)	.0(0)
37652	3.9	0	3.9	.0(0)	.0(0)	.0(0)	.0(0)	2.5(65)	1.3(34)	.0(1)	.0(0)	.0(0)
37653	3.0	0	3.0	.0(0)	.0(0)	.0(0)	.0(0)	1.7(58)	1.3(42)	.0(0)	.0(0)	.0(0)
37654	5.3	0	5.3	.0(0)	.0(0)	.0(0)	.0(0)	1.0(18)	4.2(79)	.0(0)	.2(3)	.0(0)
37655	1.9	0	1.9	.0(0)	.0(0)	.0(0)	.0(0)	1.0(51)	.9(49)	.0(0)	.0(0)	.0(0)
37656	1.7	0	1.7	.0(0)	.0(0)	.0(0)	.0(0)	.4(22)	1.3(78)	.0(0)	.0(0)	.0(0)
37657	2.8	0	2.8	.0(0)	.0(0)	.0(0)	.0(0)	.8(27)	2.0(72)	.0(0)	.0(1)	.0(0)
37658	1.7	0	1.7	.0(0)	.0(0)	.0(0)	.0(0)	.6(37)	1.1(63)	.0(0)	.0(0)	.0(0)
37659	1.3	0	1.3	.0(0)	.0(0)	.0(0)	.0(0)	.4(29)	.9(68)	.0(2)	.0(1)	.0(0)
37660	3.8	0	3.8	.0(0)	.0(0)	.0(0)	.0(0)	1.6(41)	2.2(58)	.0(1)	.0(0)	.0(0)

APPENDIX 11B
INDIVIDUAL CLINICAL HEMATOLOGY VALUES
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1 MICE
WEEK 7 FEMALES

ANIMAL NUMBER	WBC TH/UL	NRBC /100 WBC	COR WBC TH/UL	BLAST TH/UL(%)	PRO/MYEL TH/UL(%)	META TH/UL(%)	BAND TH/UL(%)	SEG TH/UL(%)	LYMPH TH/UL(%)	MONO TH/UL(%)	EOSIN TH/UL(%)	BASO TH/UL(%)
GROUP: 3	DOSE LEVEL: 350		DOSAGE UNIT: MG/KG									
37671	2.3	0	2.3	.0(0)	.0(0)	.0(0)	.0(0)	.9(40)	1.3(58)	.0(0)	.0(2)	.0(0)
37672	4.2	0	4.2	.0(0)	.0(0)	.0(0)	.0(0)	1.8(44)	2.3(55)	.0(0)	.0(1)	.0(0)
37673	2.5	0	2.5	.0(0)	.0(0)	.0(0)	.0(0)	1.1(46)	1.3(54)	.0(0)	.0(0)	.0(0)
37674	4.1	0	4.1	.0(0)	.0(0)	.0(0)	.0(0)	1.4(33)	2.7(66)	.0(1)	.0(0)	.0(0)
37675	3.2	0	3.2	.0(0)	.0(0)	.0(0)	.0(0)	1.7(53)	1.5(47)	.0(0)	.0(0)	.0(0)
37676	2.0	0	2.0	.0(0)	.0(0)	.0(0)	.0(0)	.8(40)	1.2(59)	.0(0)	.0(1)	.0(0)
37677	13.0	0	13.0	.0(0)	.0(0)	.0(0)	.0(0)	6.2(48)	6.6(51)	.0(0)	.1(1)	.0(0)
37678	2.8	0	2.8	.0(0)	.0(0)	.0(0)	.0(0)	.8(30)	2.0(70)	.0(0)	.0(0)	.0(0)
37679	2.8	0	2.8	.0(0)	.0(0)	.0(0)	.0(0)	.8(28)	2.0(70)	.0(0)	.1(2)	.0(0)
37680	6.6	0	6.6	.0(0)	.0(0)	.0(0)	.0(0)	1.8(27)	4.7(71)	.1(1)	.1(1)	.0(0)
GROUP: 4	DOSE LEVEL: 900		DOSAGE UNIT: MG/KG									
37691	13.7	0	13.7	.0(0)	.0(0)	.0(0)	.0(0)	10.8(79)	2.6(19)	.1(1)	.1(1)	.0(0)
37692	7.5	0	7.5	.0(0)	.0(0)	.0(0)	.0(0)	3.8(50)	3.7(49)	.0(0)	.1(1)	.0(0)
37693	5.3	0	5.3	.0(0)	.0(0)	.0(0)	.0(0)	3.0(56)	2.3(43)	.0(0)	.1(1)	.0(0)
37694	7.1	0	7.1	.0(0)	.0(0)	.0(0)	.0(0)	4.4(62)	2.6(37)	.1(1)	.0(0)	.0(0)
37695	6.0	0	6.0	.0(0)	.0(0)	.0(0)	.0(0)	3.4(57)	2.5(42)	.0(0)	.1(1)	.0(0)
37696	10.8	0	10.8	.0(0)	.0(0)	.0(0)	.0(0)	7.0(65)	3.6(33)	.2(2)	.0(0)	.0(0)
37697	3.0	0	3.0	.0(0)	.0(0)	.0(0)	.0(0)	1.9(62)	1.1(37)	.0(1)	.0(0)	.0(0)
37698	5.5	0	5.5	.0(0)	.0(0)	.0(0)	.0(0)	1.9(35)	3.2(59)	.1(1)	.3(5)	.0(0)
37699	4.5	0	4.5	.0(0)	.0(0)	.0(0)	.0(0)	2.0(44)	2.5(56)	.0(0)	.0(0)	.0(0)
37700	8.9	0	8.9	.0(0)	.0(0)	.0(0)	.0(0)	5.1(57)	3.8(43)	.0(0)	.0(0)	.0(0)

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APPENDIX 11B
 INDIVIDUAL CLINICAL HEMATOLOGY VALUES
 13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1 MICE
 WEEK 7 FEMALES

ANIMAL NUMBER	REACTLYM	ANISO	POLY	ECHINO	ACANTH	HYP0	TARGET	SCHISTO	POIK	HJBODY	MICRO
<hr/>											
GROUP: 1	DOSE LEVEL: 0		DOSAGE UNIT: MG/KG								
37621	0	-	1	-	-	-	-	-	-	-	-
37622	0	-	1	-	-	-	-	-	-	F	-
37623	0	-	1	-	-	-	-	-	-	-	-
37624	0	-	1	-	-	-	-	-	-	F	-
37625	0	-	1	-	-	-	-	-	-	-	-
37626	0	-	1	-	-	-	-	-	-	-	-
37627	0	-	1	-	-	-	-	-	-	-	-
37628	0	-	T	-	-	-	-	-	-	-	-
37629	0	-	1	-	-	-	-	-	-	F	-
37630	0	-	1	-	-	-	-	-	-	-	-
GROUP: 2	DOSE LEVEL: 25		DOSAGE UNIT: MG/KG								
37651	0	-	1	-	-	-	-	-	-	-	-
37652	1	-	1	-	-	-	-	-	-	-	-
37653	1	-	1	-	-	-	-	-	-	F	-
37654	0	-	T	-	-	-	-	-	-	F	-
37655	0	-	1	-	-	-	-	-	-	F	-
37656	0	-	1	-	-	-	-	-	-	-	-
37657	0	-	T	-	-	-	-	-	-	-	-
37658	0	-	1	-	-	-	-	-	-	-	-
37659	0	-	1	-	-	-	-	-	-	F	-
37660	0	-	1	-	-	-	-	-	-	-	-

APPENDIX 11B
 INDIVIDUAL CLINICAL HEMATOLOGY VALUES
 13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1 MICE
 WEEK 7 FEMALES

ANIMAL NUMBER	REACTLYM	ANISO	POLY	ECHINO	ACANTH	HYPO	TARGET	SCHISTO	POIK	HJBODY	MICRO
<hr/>											
GROUP: 3	DOSE LEVEL: 350		DOSAGE UNIT: MG/KG								
37671	0	-	1	-	-	-	-	-	-	F	-
37672	0	-	1	-	-	-	-	-	-	-	-
37673	0	-	2	-	-	-	-	-	-	F	-
37674	0	-	1	-	-	-	-	-	-	-	-
37675	0	-	1	-	-	-	-	-	-	-	-
37676	0	-	1	-	-	-	-	-	-	-	-
37677	0	-	1	-	-	-	-	-	-	-	-
37678	0	-	1	-	-	-	-	-	-	-	-
37679	0	-	1	-	-	-	-	-	-	-	-
37680	0	1	2	-	-	-	-	-	-	-	-
GROUP: 4	DOSE LEVEL: 900		DOSAGE UNIT: MG/KG								
37691	0	-	2	-	-	-	-	-	-	-	-
37692	0	T	2	-	-	-	-	-	-	-	-
37693	0	-	2	-	-	-	-	-	-	-	-
37694	0	-	2	-	-	-	-	-	-	-	-
37695	0	-	1	-	-	-	-	-	-	-	-
37696	0	-	1	-	-	-	-	-	-	-	-
37697	0	-	1	-	-	-	-	-	-	-	-
37698	1	-	1	-	-	-	-	-	-	-	-
37699	0	1	1	-	-	-	-	-	-	-	-
37700	0	-	1	-	-	-	-	-	-	-	-

Appendix 12A
Individual Clinical Chemistry Values - Main Study
13-Week Subchronic Oral Toxicity Study of Triclosan in CD-1[®] Mice

Key to Clinical Chemistry

Serum Hemolysis (SERUMHEM)

- 0 = No Hemolysis
- 1 = Trace Hemolysis
- 2 = Slight Hemolysis
- 3 = Moderate Hemolysis
- 4 = Marked Hemolysis
- 5 = Severe Hemolysis

OTHER NOTATIONS

QNS = Quantity Not Sufficient
NSR = No Sample Received

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APPENDIX 12A
INDIVIDUAL CLINICAL CHEMISTRY VALUES
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1 MICE
WEEK 14 MALES

ANIMAL NUMBER	SERUMHEM	GLUCOSE MG/DL	BUN MG/DL	CREAT MG/DL	T CHOL MG/DL	AST U/L	ALT U/L	LDH U/L	ALK P U/L
<hr/>									
GROUP: 1	DOSE LEVEL: 0	DOSAGE UNIT: MG/KG							
37391	0	QNS	36	.5	QNS	158	43	1060	119
37392	2	QNS	43	.5	QNS	166	73	1308	35
37393	0	QNS	QNS	QNS	QNS	167	57	1229	47
37394	1	218	73	.5	147	169	64	1179	53
37395	NSR	NSR	NSR	NSR	NSR	NSR	NSR	NSR	NSR
37396	0	189	35	.3	104	114	65	894	47
37397	0	310	46	.6	88	97	92	831	54
37398	2	QNS	QNS	QNS	QNS	153	96	1045	48
37399	1	QNS	29	QNS	QNS	143	53	1295	80
37400	0	QNS	33	QNS	QNS	115	55	841	49
<hr/>									
GROUP: 2	DOSE LEVEL: 25	DOSAGE UNIT: MG/KG							
37421	1	176	30	.5	QNS	166	66	1006	56
37422	0	180	41	.3	QNS	183	43	1046	59
37423	0	QNS	QNS	QNS	QNS	133	32	969	70
37424	1	162	35	.4	31	282	81	966	75
37425	1	QNS	35	.5	QNS	85	39	885	213
37426	0	QNS	QNS	QNS	QNS	182	124	874	85
37427	0	199	62	.4	QNS	191	41	1210	73
37428	1	QNS	35	.3	QNS	149	116	1048	60
37429	0	238	46	.5	6	82	46	1181	85
37430	0	306	37	.4	QNS	100	54	864	58

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APPENDIX 12A
INDIVIDUAL CLINICAL CHEMISTRY VALUES
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1 MICE
WEEK 14 MALES

ANIMAL NUMBER	SERUMHEM	GLUCOSE MG/DL	BUN MG/DL	CREAT MG/DL	T CHOL MG/DL	AST U/L	ALT U/L	LDH U/L	ALK P U/L

GROUP: 3	DOSE LEVEL: 75	DOSAGE UNIT: MG/KG							
37451	1	QNS	QNS	QNS	QNS	116	49	1289	83
37452	0	QNS	QNS	QNS	QNS	203	68	1136	100
37453	1	QNS	QNS	QNS	QNS	179	64	1065	80
37454	2	QNS	QNS	QNS	QNS	QNS	QNS	QNS	QNS
37455	2	QNS	QNS	QNS	QNS	QNS	QNS	QNS	QNS
37456	0	161	31	.3	7	90	52	758	77
37457	1	230	43	.4	QNS	262	141	1188	75
37458	0	QNS	57	QNS	QNS	127	28	666	76
37459	1	QNS	QNS	QNS	QNS	146	58	1485	74
37460	0	194	36	.5	7	118	61	825	129

GROUP: 4	DOSE LEVEL: 200	DOSAGE UNIT: MG/KG							
37481	1	207	31	.4	QNS	192	50	971	54
37482	2	QNS	29	.4	QNS	168	92	917	93
37483	0	157	36	.4	29	139	68	963	502
37485	0	164	42	.3	16	335	68	1248	234
37486	0	231	38	.5	QNS	156	124	1770	112
37487	0	129	59	.3	6	85	69	547	244
37488	0	171	47	.3	29	223	259	948	134
37489	0	138	44	.3	3	311	142	1715	594
37490	1	233	37	.4	28	115	90	900	70
37491	0	174	54	.3	6	373	175	1322	77

APPENDIX 12A
INDIVIDUAL CLINICAL CHEMISTRY VALUES
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1 MICE
WEEK 14 MALES

ANIMAL NUMBER	SERUMHEM	GLUCOSE MG/DL	BUN MG/DL	CREAT MG/DL	T CHOL MG/DL	AST U/L	ALT U/L	LDH U/L	ALK P U/L
<hr/>									
GROUP: 5	DOSE LEVEL: 350		DOSAGE UNIT: MG/KG						
37511	1	QNS	35	.5	QNS	180	119	1316	147
37512	2	QNS	46	.4	QNS	162	66	1208	84
37513	0	QNS	QNS	QNS	QNS	185	118	1700	125
37514	1	QNS	QNS	QNS	QNS	344	286	1401	129
37515	0	190	39	.3	19	204	121	1115	192
37516	1	QNS	QNS	QNS	QNS	QNS	QNS	QNS	QNS
37517	0	203	33	.3	10	352	158	1350	464
37518	0	124	28	.3	22	162	107	945	83
37519	0	134	39	.5	6	447	515	1294	417
37520	0	178	31	.4	8	405	480	1280	91
<hr/>									
GROUP: 6	DOSE LEVEL: 750		DOSAGE UNIT: MG/KG						
37541	0	QNS	38	.4	QNS	148	115	625	127
37542	0	QNS	60	.4	QNS	332	333	1313	281
37543	1	121	35	.4	21	158	75	1112	112
37544	0	45	43	.4	QNS	316	238	1675	218
37545	0	113	39	.4	12	133	150	1520	135
37546	0	101	38	.3	33	352	101	1262	338
37547	0	150	38	.3	25	144	167	967	896
37548	0	126	34	.3	27	1215	2540	3780	138
37549	0	179	37	.4	15	128	119	991	211
37550	0	39	62	.3	6	239	239	1223	126

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APPENDIX 12A
 INDIVIDUAL CLINICAL CHEMISTRY VALUES
 13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1 MICE
 WEEK 14 MALES

ANIMAL NUMBER	SERUMHEM	GLUCOSE MG/DL	BUN MG/DL	CREAT MG/DL	T CHOL MG/DL	AST U/L	ALT U/L	LDH U/L	ALK P U/L

GROUP: 7	DOSE LEVEL: 900	DOSAGE UNIT: MG/KG							
37571	0	QNS	45	.4	QNS	391	179	1266	114
37572	0	143	43	.4	26	315	341	990	141
37573	0	QNS	QNS	QNS	QNS	319	233	1382	213
37574	0	50	84	.3	QNS	604	575	1715	279
37575	0	146	30	.3	15	123	93	1145	286
37576	0	175	36	.2	36	99	155	659	70
37578	1	QNS	QNS	QNS	QNS	QNS	QNS	QNS	QNS
37580	0	QNS	91	.3	QNS	751	163	2085	103
37581	1	QNS	44	.2	QNS	212	158	1367	168
37582	0	173	45	.4	5	186	139	1088	160

APPENDIX 12A
INDIVIDUAL CLINICAL CHEMISTRY VALUES
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1 MICE
WEEK 14 MALES

ANIMAL NUMBER	T PROT G/DL	ALBUMIN G/DL	GLOBULIN G/DL	A/G RATIO	T BILI MG/DL	TRIGLY MG/DL	GGT U/L
GROUP: 1 DOSE LEVEL: 0 DOSAGE UNIT: MG/KG							
37391	QNS	QNS	QNS	QNS	.1	QNS	0
37392	QNS	QNS	QNS	QNS	.2	QNS	0
37393	QNS	QNS	QNS	QNS	QNS	QNS	QNS
37394	5.3	3.3	2.0	1.65	.2	48	0
37395	NSR	NSR	NSR	NSR	NSR	NSR	NSR
37396	5.1	3.2	1.9	1.68	.2	45	0
37397	5.4	3.7	1.7	2.18	.1	38	1
37398	QNS	QNS	QNS	QNS	QNS	QNS	QNS
37399	QNS	QNS	QNS	QNS	.2	QNS	0
37400	QNS	QNS	QNS	QNS	.1	QNS	0
GROUP: 2 DOSE LEVEL: 25 DOSAGE UNIT: MG/KG							
37421	4.5	3.2	1.3	2.46	.2	QNS	0
37422	4.5	2.9	1.6	1.81	.1	QNS	0
37423	QNS	QNS	QNS	QNS	QNS	QNS	QNS
37424	5.1	3.2	1.9	1.68	.2	QNS	0
37425	5.1	3.7	1.4	2.64	.2	QNS	0
37426	QNS	QNS	QNS	QNS	.1	QNS	0
37427	4.6	3.1	1.5	2.07	.1	QNS	0
37428	QNS	3.2	QNS	QNS	.2	QNS	0
37429	4.8	3.3	1.5	2.20	.1	24	0
37430	4.6	3.2	1.4	2.29	.1	QNS	0

APPENDIX 12A
INDIVIDUAL CLINICAL CHEMISTRY VALUES
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1 MICE
WEEK 14 MALES

ANIMAL NUMBER	T PROT G/DL	ALBUMIN G/DL	GLOBULIN G/DL	A/G RATIO	T BILI MG/DL	TRIGLY MG/DL	GGT U/L
GROUP: 3 DOSE LEVEL: 75 DOSAGE UNIT: MG/KG							
37451	QNS	QNS	QNS	QNS	.2	QNS	0
37452	QNS	QNS	QNS	QNS	QNS	QNS	QNS
37453	QNS	QNS	QNS	QNS	.2	QNS	QNS
37454	QNS	QNS	QNS	QNS	QNS	QNS	QNS
37455	QNS	QNS	QNS	QNS	QNS	QNS	QNS
37456	4.8	3.3	1.5	2.20	.1	39	0
37457	5.1	3.6	1.5	2.40	.2	QNS	0
37458	QNS	QNS	QNS	QNS	.2	QNS	0
37459	QNS	QNS	QNS	QNS	QNS	QNS	QNS
37460	4.6	3.2	1.4	2.29	.1	44	0
GROUP: 4 DOSE LEVEL: 200 DOSAGE UNIT: MG/KG							
37481	3.8	2.4	1.4	1.71	.1	QNS	0
37482	QNS	3.2	QNS	QNS	.1	QNS	0
37483	4.6	3.0	1.6	1.87	.1	51	0
37485	4.4	2.9	1.5	1.93	.1	41	0
37486	5.1	3.4	1.7	2.00	.1	QNS	0
37487	4.6	3.1	1.5	2.07	.1	37	0
37488	4.2	2.7	1.5	1.80	.0	47	0
37489	4.5	3.0	1.5	2.00	.0	23	0
37490	4.4	3.1	1.3	2.38	.2	57	0
37491	3.3	2.1	1.2	1.75	.1	QNS	0

APPENDIX 12A
INDIVIDUAL CLINICAL CHEMISTRY VALUES
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1 MICE
WEEK 14 MALES

ANIMAL NUMBER	T PROT G/DL	ALBUMIN G/DL	GLOBULIN G/DL	A/G RATIO	T BILI MG/DL	TRIGLY MG/DL	GGT U/L
<hr/>							
GROUP: 5	DOSE LEVEL: 350		DOSAGE UNIT: MG/KG				
37511	QNS	QNS	QNS	QNS	.1	QNS	0
37512	QNS	QNS	QNS	QNS	.3	QNS	0
37513	QNS	QNS	QNS	QNS	.1	QNS	QNS
37514	QNS	QNS	QNS	QNS	QNS	QNS	QNS
37515	3.6	2.2	1.4	1.57	.1	41	0
37516	QNS	QNS	QNS	QNS	QNS	QNS	QNS
37517	3.9	2.5	1.4	1.79	.0	25	0
37518	4.3	3.0	1.3	2.31	.1	52	0
37519	5.0	3.7	1.3	2.85	.1	52	0
37520	4.4	3.3	1.1	3.00	.1	38	0
GROUP: 6	DOSE LEVEL: 750		DOSAGE UNIT: MG/KG				
37541	QNS	QNS	QNS	QNS	.1	QNS	0
37542	QNS	4.5	QNS	QNS	.1	QNS	0
37543	4.6	3.1	1.5	2.07	.1	44	0
37544	4.2	2.9	1.3	2.23	.1	QNS	0
37545	4.9	3.5	1.4	2.50	.1	29	0
37546	4.8	3.0	1.8	1.67	.0	17	0
37547	5.0	3.5	1.5	2.33	.0	97	3
37548	3.5	2.4	1.1	2.18	.0	75	0
37549	5.0	3.8	1.2	3.17	.1	40	1
37550	4.8	3.7	1.1	3.36	.1	QNS	1

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 INDIVIDUAL CLINICAL CHEMISTRY VALUES
 13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1 MICE
 WEEK 14 MALES

ANIMAL NUMBER	T PROT G/DL	ALBUMIN G/DL	GLOBULIN G/DL	A/G RATIO	T BILI MG/DL	TRIGLY MG/DL	GGT U/L

GROUP: 7	DOSE LEVEL: 900		DOSAGE UNIT: MG/KG				
37571	QNS	QNS	QNS	QNS	.1	QNS	0
37572	4.8	3.3	1.5	2.20	.1	QNS	0
37573	QNS	QNS	QNS	QNS	QNS	QNS	QNS
37574	4.5	3.2	1.3	2.46	.1	QNS	4
37575	4.3	3.0	1.3	2.31	.1	70	0
37576	3.5	2.3	1.2	1.92	.0	94	1
37578	QNS	QNS	QNS	QNS	QNS	QNS	QNS
37580	QNS	QNS	QNS	QNS	.0	QNS	0
37581	QNS	3.8	QNS	QNS	.2	QNS	0
37582	5.2	3.6	1.6	2.25	.1	27	0

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APPENDIX 12A
INDIVIDUAL CLINICAL CHEMISTRY VALUES
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1 MICE
WEEK 14 FEMALES

ANIMAL NUMBER	SERUMHEM	GLUCOSE MG/DL	BUN MG/DL	CREAT MG/DL	T CHOL MG/DL	AST U/L	ALT U/L	LDH U/L	ALK P U/L
GROUP: 1 DOSE LEVEL: 0 DOSAGE UNIT: MG/KG									
37406	0	QNS	35	.5	QNS	187	65	661	76
37407	0	QNS	QNS	QNS	QNS	199	39	934	56
37408	0	QNS	35	QNS	QNS	132	39	508	79
37409	1	QNS	QNS	QNS	QNS	1620	182	3670	101
37410	0	172	23	.3	70	93	42	541	72
37411	1	282	42	.4	115	288	86	1284	60
37412	0	QNS	QNS	QNS	QNS	475	77	2130	70
37413	0	158	22	.3	QNS	317	117	799	50
37414	1	QNS	QNS	QNS	QNS	152	82	899	83
37415	1	QNS	35	.5	QNS	184	64	991	60
GROUP: 2 DOSE LEVEL: 25 DOSAGE UNIT: MG/KG									
37436	1	QNS	55	.4	QNS	290	61	1900	80
37437	0	197	32	.4	QNS	291	56	1650	115
37438	NSR	NSR	NSR	NSR	NSR	NSR	NSR	NSR	NSR
37439	1	QNS	32	.5	QNS	358	82	1130	89
37440	1	QNS	31	QNS	QNS	104	32	702	192
37441	2	209	29	.4	13	256	76	1349	96
37442	0	QNS	27	.4	QNS	483	65	1020	138
37443	2	QNS	QNS	QNS	QNS	151	46	821	89
37444	0	211	37	.4	7	201	82	1218	116
37445	0	168	23	.4	12	175	71	627	90

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INDIVIDUAL CLINICAL CHEMISTRY VALUES
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1 MICE
WEEK 14 FEMALES

ANIMAL NUMBER	SERUMHEM	GLUCOSE MG/DL	BUN MG/DL	CREAT MG/DL	T CHOL MG/DL	AST U/L	ALT U/L	LDH U/L	ALK P U/L
GROUP: 3 DOSE LEVEL: 75 DOSAGE UNIT: MG/KG									
37466	1	220	33	.4	QNS	224	60	1381	171
37467	0	QNS	49	QNS	QNS	529	85	1394	98
37468	0	146	44	.3	QNS	264	60	1635	104
37469	0	143	29	.4	QNS	340	169	797	133
37470	0	139	26	.3	QNS	85	42	606	156
37471	0	168	33	.4	19	149	53	742	63
37472	0	QNS	QNS	QNS	QNS	QNS	QNS	QNS	QNS
37473	0	128	22	.2	6	230	152	582	157
37474	2	QNS	29	.4	QNS	176	78	1194	156
37475	0	QNS	30	QNS	QNS	119	45	841	106
GROUP: 4 DOSE LEVEL: 200 DOSAGE UNIT: MG/KG									
37497	0	209	46	.4	QNS	124	47	1133	121
37498	0	QNS	QNS	QNS	QNS	244	92	986	97
37499	0	QNS	QNS	QNS	QNS	226	97	963	106
37500	0	150	30	.4	19	154	49	769	129
37501	0	179	39	.3	8	139	72	762	164
37502	0	QNS	QNS	QNS	QNS	286	114	1112	121
37503	1	QNS	QNS	QNS	QNS	325	107	1750	155
37504	1	79	50	.2	QNS	555	245	1635	81
37505	1	QNS	42	.4	QNS	144	90	1173	97
37506	0	161	26	.4	9	267	133	672	146

APPENDIX 12A
INDIVIDUAL CLINICAL CHEMISTRY VALUES
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1 MICE
WEEK 14 FEMALES

ANIMAL NUMBER	SERUMHEM	GLUCOSE MG/DL	BUN MG/DL	CREAT MG/DL	T CHOL MG/DL	AST U/L	ALT U/L	LDH U/L	ALK P U/L
<hr/>									
GROUP: 5	DOSE LEVEL: 350	DOSAGE UNIT: MG/KG							
37526	1	203	44	.4	QNS	178	77	1146	163
37527	0	159	29	.3	26	126	43	480	116
37528	0	QNS	QNS	QNS	QNS	174	79	1010	152
37529	0	145	25	.4	14	195	139	562	143
37530	0	148	45	.4	16	183	75	1525	132
37531	1	QNS	QNS	QNS	QNS	287	176	1535	91
37532	0	176	43	.3	11	302	119	1055	116
37533	NSR	NSR	NSR	NSR	NSR	NSR	NSR	NSR	NSR
37534	0	146	36	.3	7	181	81	901	133
37535	NSR	NSR	NSR	NSR	NSR	NSR	NSR	NSR	NSR
<hr/>									
GROUP: 6	DOSE LEVEL: 750	DOSAGE UNIT: MG/KG							
37556	1	QNS	QNS	QNS	QNS	441	137	1382	123
37557	1	QNS	QNS	QNS	QNS	QNS	QNS	QNS	QNS
37558	1	QNS	QNS	QNS	QNS	444	104	1940	54
37559	0	QNS	74	.3	QNS	646	346	1960	111
37560	0	171	41	.3	14	222	138	1103	136
37561	0	111	47	.3	QNS	244	223	699	127
37562	0	QNS	QNS	QNS	QNS	382	393	1217	123
37563	0	QNS	48	.4	QNS	1910	425	6035	189
37564	1	144	39	.4	8	378	189	1795	88
37565	0	165	40	.3	21	364	269	913	118

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 INDIVIDUAL CLINICAL CHEMISTRY VALUES
 13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1 MICE
 WEEK 14 FEMALES

ANIMAL NUMBER	SERUMHEM	GLUCOSE MG/DL	BUN MG/DL	CREAT MG/DL	T CHOL MG/DL	AST U/L	ALT U/L	LDH U/L	ALK P U/L

GROUP: 7	DOSE LEVEL: 900	DOSAGE UNIT: MG/KG							
37587	0	QNS	46	.4	QNS	247	118	1313	151
37588	0	56	80	.3	10	358	359	808	348
37589	0	QNS	QNS	QNS	QNS	467	162	971	333
37590	2	QNS	70	.5	QNS	365	261	2300	118
37591	0	173	44	.4	39	139	146	1515	178
37592	0	217	40	.2	17	242	164	982	103
37593	0	61	51	.2	36	644	193	2555	108
37594	0	QNS	62	.3	QNS	2650	475	13230	163
37595	2	QNS	QNS	QNS	QNS	178	127	1377	184
37596	0	QNS	79	.3	QNS	211	155	1283	74

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 INDIVIDUAL CLINICAL CHEMISTRY VALUES
 13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1 MICE
 WEEK 14 FEMALES

ANIMAL NUMBER	T PROT G/DL	ALBUMIN G/DL	GLOBULIN G/DL	A/G RATIO	T BILI MG/DL	TRIGLY MG/DL	GGT U/L
<hr/>							
GROUP: 1	DOSE LEVEL: 0		DOSAGE UNIT: MG/KG				
37406	5.5	3.9	1.6	2.44	.1	QNS	0
37407	QNS	QNS	QNS	QNS	.1	QNS	QNS
37408	QNS	QNS	QNS	QNS	.1	QNS	0
37409	QNS	QNS	QNS	QNS	.3	QNS	0
37410	4.5	3.1	1.4	2.21	.1	35	0
37411	5.4	3.7	1.7	2.18	.2	50	0
37412	QNS	QNS	QNS	QNS	QNS	QNS	QNS
37413	4.7	3.2	1.5	2.13	.1	QNS	1
37414	QNS	QNS	QNS	QNS	.2	QNS	0
37415	QNS	3.2	QNS	QNS	.2	QNS	0
GROUP: 2	DOSE LEVEL: 25		DOSAGE UNIT: MG/KG				
37436	QNS	QNS	QNS	QNS	.2	QNS	0
37437	4.6	3.2	1.4	2.29	.1	QNS	0
37438	NSR	NSR	NSR	NSR	NSR	NSR	NSR
37439	QNS	3.7	QNS	QNS	.2	QNS	0
37440	QNS	QNS	QNS	QNS	.2	QNS	0
37441	4.9	3.6	1.3	2.77	.2	67	0
37442	QNS	3.5	QNS	QNS	.1	QNS	0
37443	QNS	QNS	QNS	QNS	.2	QNS	QNS
37444	4.3	3.0	1.3	2.31	.1	26	0
37445	4.3	3.0	1.3	2.31	.1	42	0

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INDIVIDUAL CLINICAL CHEMISTRY VALUES
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1 MICE
WEEK 14 FEMALES

ANIMAL NUMBER	T PROT G/DL	ALBUMIN G/DL	GLOBULIN G/DL	A/G RATIO	T BILI MG/DL	TRIGLY MG/DL	GGT U/L
<hr/>							
GROUP: 3	DOSE LEVEL: 75		DOSAGE UNIT: MG/KG				
37466	4.6	3.3	1.3	2.54	.2	QNS	0
37467	QNS	3.2	QNS	QNS	.1	QNS	0
37468	4.5	3.2	1.3	2.46	.1	QNS	0
37469	5.0	3.4	1.6	2.13	.1	QNS	0
37470	4.5	3.3	1.2	2.75	.1	20	0
37471	4.5	2.9	1.6	1.81	.0	26	0
37472	QNS	QNS	QNS	QNS	QNS	QNS	QNS
37473	3.5	2.4	1.1	2.18	.0	17	0
37474	4.8	3.6	1.2	3.00	.2	QNS	0
37475	QNS	QNS	QNS	QNS	.1	QNS	0
GROUP: 4	DOSE LEVEL: 200		DOSAGE UNIT: MG/KG				
37497	4.6	3.2	1.4	2.29	.1	QNS	0
37498	QNS	QNS	QNS	QNS	QNS	QNS	QNS
37499	QNS	QNS	QNS	QNS	.1	QNS	QNS
37500	4.1	2.8	1.3	2.15	.1	66	0
37501	4.2	3.1	1.1	2.82	.0	27	1
37502	QNS	QNS	QNS	QNS	.1	QNS	0
37503	QNS	QNS	QNS	QNS	QNS	QNS	QNS
37504	4.0	2.9	1.1	2.64	.2	QNS	0
37505	4.3	3.3	1.0	3.30	.2	QNS	0
37506	4.1	3.0	1.1	2.73	.0	40	1

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INDIVIDUAL CLINICAL CHEMISTRY VALUES
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1 MICE
WEEK 14 FEMALES

ANIMAL NUMBER	T PROT G/DL	ALBUMIN G/DL	GLOBULIN G/DL	A/G RATIO	T BILI MG/DL	TRIGLY MG/DL	GGT U/L
<hr/>							
GROUP: 5	DOSE LEVEL: 350		DOSAGE UNIT: MG/KG				
37526	5.0	3.3	1.7	1.94	.1	QNS	0
37527	4.4	2.9	1.5	1.93	.0	135	0
37528	QNS	QNS	QNS	QNS	QNS	QNS	QNS
37529	4.4	3.3	1.1	3.00	.1	34	0
37530	4.5	3.2	1.3	2.46	.0	44	0
37531	QNS	QNS	QNS	QNS	QNS	QNS	QNS
37532	4.5	3.4	1.1	3.09	.1	29	0
37533	NSR	NSR	NSR	NSR	NSR	NSR	NSR
37534	3.9	2.9	1.0	2.90	.1	21	0
37535	NSR	NSR	NSR	NSR	NSR	NSR	NSR
<hr/>							
GROUP: 6	DOSE LEVEL: 750		DOSAGE UNIT: MG/KG				
37556	QNS	QNS	QNS	QNS	.2	QNS	0
37557	QNS	QNS	QNS	QNS	QNS	QNS	QNS
37558	QNS	QNS	QNS	QNS	QNS	QNS	QNS
37559	QNS	2.8	QNS	QNS	.1	QNS	28
37560	3.0	2.1	.9	2.33	.0	22	0
37561	4.8	3.4	1.4	2.43	.1	QNS	1
37562	QNS	QNS	QNS	QNS	QNS	QNS	QNS
37563	QNS	3.2	QNS	QNS	.1	QNS	1
37564	3.9	3.0	.9	3.33	.1	29	0
37565	4.0	3.0	1.0	3.00	.1	47	0

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 INDIVIDUAL CLINICAL CHEMISTRY VALUES
 13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1 MICE
 WEEK 14 FEMALES

ANIMAL NUMBER	T PROT G/DL	ALBUMIN G/DL	GLOBULIN G/DL	A/G RATIO	T BILI MG/DL	TRIGLY MG/DL	GGT U/L

GROUP: 7	DOSE LEVEL: 900		DOSAGE UNIT: MG/KG				
37587	QNS	3.2	QNS	QNS	.1	QNS	1
37588	4.2	2.8	1.4	2.00	.1	6	7
37589	QNS	QNS	QNS	QNS	.1	QNS	0
37590	QNS	3.5	QNS	QNS	.3	QNS	0
37591	5.6	4.1	1.5	2.73	.1	105	1
37592	3.7	2.7	1.0	2.70	.1	26	3
37593	3.7	2.7	1.0	2.70	.1	14	1
37594	QNS	QNS	QNS	QNS	.2	QNS	0
37595	QNS	QNS	QNS	QNS	.2	QNS	QNS
37596	4.1	2.5	1.6	1.56	.1	QNS	3

Appendix 12B
Individual Clinical Chemistry Values - Satellite Study
13-Week Subchronic Oral Toxicity Study of Triclosan in CD-1[®] Mice

NOTE: Due to computer limitations, Groups 1-4 correspond to Groups 8-11, respectively.

Key to Clinical Chemistry

Serum Hemolysis (SERUMHEM)

- 0 = No Hemolysis
- 1 = Trace Hemolysis
- 2 = Slight Hemolysis
- 3 = Moderate Hemolysis
- 4 = Marked Hemolysis
- 5 = Severe Hemolysis

OTHER NOTATIONS

- QNS = Quantity Not Sufficient
- NSR = No Sample Received
- NT = No Test

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APPENDIX 12B
 INDIVIDUAL CLINICAL CHEMISTRY VALUES
 13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1 MICE
 WEEK -1 MALES

ANIMAL NUMBER	SERUMHEM	GLUCOSE MG/DL	BUN MG/DL	CREAT MG/DL	T CHOL MG/DL	AST U/L	ALT U/L	LDH U/L

GROUP: 1	DOSE LEVEL: 0	DOSAGE UNIT: MG/KG						
37611	0	QNS	32	.5	QNS	218	48	782
37612	1	QNS	26	.5	QNS	248	69	1083
37613	0	QNS	QNS	QNS	QNS	150	55	628
37614	2	QNS	QNS	QNS	QNS	QNS	QNS	QNS
37615	0	QNS	QNS	QNS	QNS	692	118	1835
37616	0	74	29	.4	174	113	31	513
37617	0	QNS	QNS	QNS	QNS	152	34	703
37618	0	QNS	QNS	QNS	QNS	96	22	625
37619	0	117	107	.5	172	171	50	666
37620	0	QNS	QNS	QNS	QNS	170	52	567

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APPENDIX 12B
 INDIVIDUAL CLINICAL CHEMISTRY VALUES
 13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1 MICE
 WEEK -1 MALES

ANIMAL NUMBER	ALK P U/L	T PROT G/DL	ALBUMIN G/DL	GLOBULIN G/DL	A/G RATIO	T BILI MG/DL	TRIGLY MG/DL	GGT U/L
<hr/>								
GROUP: 1	DOSE LEVEL: 0		DOSAGE UNIT: MG/KG					
37611	143	QNS	QNS	QNS	QNS	.2	QNS	0
37612	123	QNS	QNS	QNS	QNS	.2	QNS	0
37613	177	QNS	QNS	QNS	QNS	.2	QNS	0
37614	QNS	QNS	QNS	QNS	QNS	QNS	QNS	QNS
37615	189	QNS	QNS	QNS	QNS	QNS	QNS	QNS
37616	166	6.1	4.5	1.6	2.81	.2	52	0
37617	210	QNS	QNS	QNS	QNS	.2	QNS	0
37618	157	QNS	QNS	QNS	QNS	.3	QNS	0
37619	181	6.0	4.0	2.0	2.00	.3	QNS	0
37620	185	QNS	QNS	QNS	QNS	.2	QNS	0

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APPENDIX 12B
INDIVIDUAL CLINICAL CHEMISTRY VALUES
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1 MICE
WEEK -1 FEMALES

ANIMAL NUMBER	SERUMHEM	GLUCOSE MG/DL	BUN MG/DL	CREAT MG/DL	T CHOL MG/DL	AST U/L	ALT U/L	LDH U/L
<hr/>								
GROUP: 1	DOSE LEVEL: 0	DOSAGE UNIT: MG/KG						
37631	2	QNS	QNS	QNS	QNS	354	QNS	QNS
37632	0	QNS	QNS	QNS	QNS	243	58	819
37633	1	QNS	QNS	QNS	QNS	592	QNS	QNS
37634	1	QNS	QNS	QNS	QNS	424	83	QNS
37635	1	QNS	QNS	QNS	QNS	359	78	QNS
37636	0	QNS	QNS	QNS	QNS	198	37	691
37637	0	QNS	QNS	QNS	QNS	209	QNS	QNS
37638	0	QNS	QNS	QNS	QNS	120	42	442
37639	2	QNS	QNS	QNS	QNS	QNS	QNS	QNS
37640	0	QNS	QNS	QNS	QNS	467	QNS	QNS

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APPENDIX 12B
 INDIVIDUAL CLINICAL CHEMISTRY VALUES
 13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1 MICE
 WEEK -1 FEMALES

ANIMAL NUMBER	ALK P U/L	T PROT G/DL	ALBUMIN G/DL	GLOBULIN G/DL	A/G RATIO	T BILI MG/DL	TRIGLY MG/DL	GGT U/L

GROUP: 1	DOSE LEVEL: 0		DOSAGE UNIT: MG/KG					
37631	QNS	QNS	QNS	QNS	QNS	QNS	QNS	QNS
37632	QNS	QNS	QNS	QNS	QNS	QNS	QNS	QNS
37633	QNS	QNS	QNS	QNS	QNS	QNS	QNS	QNS
37634	QNS	QNS	QNS	QNS	QNS	QNS	QNS	QNS
37635	QNS	QNS	QNS	QNS	QNS	QNS	QNS	QNS
37636	236	QNS	QNS	QNS	QNS	.3	QNS	0
37637	QNS	QNS	QNS	QNS	QNS	QNS	QNS	QNS
37638	123	QNS	QNS	QNS	QNS	QNS	QNS	QNS
37639	QNS	QNS	QNS	QNS	QNS	QNS	QNS	QNS
37640	QNS	QNS	QNS	QNS	QNS	QNS	QNS	QNS

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APPENDIX 12B
INDIVIDUAL CLINICAL CHEMISTRY VALUES
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1 MICE
WEEK 7 MALES

ANIMAL NUMBER	SERUMHEM	GLUCOSE MG/DL	BUN MG/DL	CREAT MG/DL	T CHOL MG/DL	AST U/L	ALT U/L	LDH U/L
<hr/>								
GROUP: 1	DOSE LEVEL: 0	DOSAGE UNIT: MG/KG						
37601	0	365	33	.5	QNS	160	32	702
37602	0	272	27	.4	110	209	53	502
37603	NSR	NSR	NSR	NSR	NSR	NSR	NSR	NSR
37604	1	257	42	.5	94	299	65	1670
37605	1	QNS	QNS	QNS	QNS	169	54	1216
37606	NSR	NSR	NSR	NSR	NSR	NSR	NSR	NSR
37607	0	276	40	.4	110	152	31	611
37608	0	247	54	.5	QNS	220	44	838
37609	0	280	37	.4	122	147	64	698
37610	1	213	45	.4	78	313	47	1256
<hr/>								
GROUP: 2	DOSE LEVEL: 25	DOSAGE UNIT: MG/KG						
37641	0	416	36	.5	60	127	30	574
37642	1	QNS	42	QNS	QNS	122	50	598
37643	1	261	51	.4	QNS	248	44	826
37644	1	QNS	QNS	QNS	QNS	161	69	1118
37645	1	QNS	QNS	QNS	NT	QNS	QNS	QNS
37646	NSR	NSR	NSR	NSR	NSR	NSR	NSR	NSR
37647	0	214	58	.5	11	157	46	535
37648	1	263	46	.3	74	276	51	952
37649	0	211	45	.4	44	250	58	812
37650	0	QNS	32	.5	QNS	215	41	918

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APPENDIX 12B
INDIVIDUAL CLINICAL CHEMISTRY VALUES
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1 MICE
WEEK 7 MALES

ANIMAL NUMBER	SERUMHEM	GLUCOSE MG/DL	BUN MG/DL	CREAT MG/DL	T CHOL MG/DL	AST U/L	ALT U/L	LDH U/L
<hr/>								
GROUP: 3	DOSE LEVEL: 350	DOSAGE UNIT: MG/KG						
37661	1	182	33	.4	QNS	155	93	884
37662	0	279	38	.4	9	217	120	877
37663	1	261	29	.4	15	130	80	604
37664	0	171	41	.4	24	245	156	975
37665	1	154	52	.4	13	332	125	1183
37666	1	QNS	42	.4	QNS	150	57	1142
37667	0	183	47	.4	12	114	65	1256
37668	0	254	36	.4	19	225	156	901
37669	0	210	44	.4	QNS	145	77	578
37670	2	QNS	QNS	QNS	QNS	330	181	2840
<hr/>								
GROUP: 4	DOSE LEVEL: 900	DOSAGE UNIT: MG/KG						
37681	0	QNS	57	.5	QNS	143	81	1056
37682	0	145	72	.4	9	163	198	1197
37683	0	226	63	.4	21	222	115	610
37684	0	QNS	74	.3	QNS	1320	1505	4035
37685	0	QNS	39	.4	QNS	262	210	1213
37686	1	235	40	.4	QNS	113	78	1089
37687	2	QNS	QNS	QNS	QNS	388	QNS	QNS
37688	0	95	62	.4	QNS	396	244	837
37689	0	QNS	QNS	QNS	QNS	287	277	873
37690	0	76	80	.4	QNS	267	300	2270

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APPENDIX 12B
INDIVIDUAL CLINICAL CHEMISTRY VALUES
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1 MICE
WEEK 7 MALES

ANIMAL NUMBER	ALK P U/L	T PROT G/DL	ALBUMIN G/DL	GLOBULIN G/DL	A/G RATIO	T BILI MG/DL	TRIGLY MG/DL	GCT U/L
<hr/>								
GROUP: 1	DOSE LEVEL: 0		DOSAGE UNIT: MG/KG					
37601	58	5.1	3.1	2.0	1.55	.2	QNS	0
37602	103	5.1	3.4	1.7	2.00	.1	59	0
37603	NSR	NSR	NSR	NSR	NSR	NSR	NSR	NSR
37604	61	5.0	3.2	1.8	1.78	.2	46	0
37605	84	QNS	QNS	QNS	QNS	.2	QNS	0
37606	NSR	NSR	NSR	NSR	NSR	NSR	NSR	NSR
37607	62	4.9	3.2	1.7	1.88	.2	49	1
37608	68	5.5	3.6	1.9	1.89	.2	QNS	0
37609	62	5.3	3.3	2.0	1.65	.2	37	1
37610	77	5.3	3.6	1.7	2.12	.2	48	0
<hr/>								
GROUP: 2	DOSE LEVEL: 25		DOSAGE UNIT: MG/KG					
37641	65	5.5	3.4	2.1	1.62	.1	QNS	0
37642	73	QNS	QNS	QNS	QNS	.2	QNS	0
37643	73	4.5	3.0	1.5	2.00	.2	QNS	0
37644	67	QNS	QNS	QNS	QNS	QNS	QNS	QNS
37645	QNS	QNS	QNS	QNS	QNS	QNS	QNS	QNS
37646	NSR	NSR	NSR	NSR	NSR	NSR	NSR	NSR
37647	97	4.6	3.1	1.5	2.07	.1	40	0
37648	57	5.0	3.3	1.7	1.94	.2	89	0
37649	61	4.3	2.7	1.6	1.69	.1	67	1
37650	77	5.4	3.7	1.7	2.18	.1	QNS	1

APPENDIX 12B
 INDIVIDUAL CLINICAL CHEMISTRY VALUES
 13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1 MICE
 WEEK 7 MALES

ANIMAL NUMBER	ALK P U/L	T PROT G/DL	ALBUMIN G/DL	GLOBULIN G/DL	A/G RATIO	T BILI MG/DL	TRIGLY MG/DL	GGT U/L
<hr/>								
GROUP: 3	DOSE LEVEL: 350		DOSAGE UNIT: MG/KG					
37661	116	5.1	3.3	1.8	1.83	.1	QNS	0
37662	147	4.7	3.1	1.6	1.94	.1	QNS	0
37663	89	4.2	3.0	1.2	2.50	.2	47	0
37664	534	4.4	3.0	1.4	2.14	.1	43	0
37665	164	4.5	2.9	1.6	1.81	.2	51	0
37666	80	3.1	2.0	1.1	1.82	.2	QNS	0
37667	133	4.1	2.7	1.4	1.93	.1	22	0
37668	691	3.5	2.3	1.2	1.92	.2	45	0
37669	93	4.8	3.3	1.5	2.20	.1	QNS	1
37670	QNS	QNS	QNS	QNS	QNS	QNS	QNS	QNS
<hr/>								
GROUP: 4	DOSE LEVEL: 900		DOSAGE UNIT: MG/KG					
37681	357	QNS	4.4	QNS	QNS	.2	QNS	0
37682	373	5.3	3.8	1.5	2.53	.1	QNS	3
37683	87	4.3	3.2	1.1	2.91	.1	30	1
37684	111	QNS	2.7	QNS	QNS	.0	QNS	4
37685	240	QNS	4.4	QNS	QNS	.1	QNS	1
37686	120	5.7	4.0	1.7	2.35	.1	QNS	0
37687	QNS	QNS	QNS	QNS	QNS	QNS	QNS	QNS
37688	154	5.6	4.3	1.3	3.31	.1	QNS	6
37689	157	QNS	QNS	QNS	QNS	QNS	QNS	QNS
37690	315	5.4	4.0	1.4	2.86	.1	QNS	8

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APPENDIX 12B
INDIVIDUAL CLINICAL CHEMISTRY VALUES
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1 MICE
WEEK 7 FEMALES

ANIMAL NUMBER	SERUMHEM	GLUCOSE MG/DL	BUN MG/DL	CREAT MG/DL	T CHOL MG/DL	AST U/L	ALT U/L	LDH U/L
<hr/>								
GROUP: 1	DOSE LEVEL: 0	DOSAGE UNIT: MG/KG						
37621	0	236	40	.4	64	186	38	959
37622	0	QNS	QNS	QNS	QNS	235	59	1191
37623	0	QNS	37	.4	QNS	259	53	1219
37624	0	232	32	.5	32	460	59	1360
37625	NSR	NSR	NSR	NSR	NSR	NSR	NSR	NSR
37626	0	QNS	QNS	QNS	QNS	205	50	1800
37627	0	265	45	.4	45	208	53	1268
37628	1	QNS	QNS	QNS	QNS	274	54	QNS
37629	0	QNS	25	.4	QNS	276	52	754
37630	1	197	33	.4	52	292	59	1109
<hr/>								
GROUP: 2	DOSE LEVEL: 25	DOSAGE UNIT: MG/KG						
37651	0	281	36	.4	QNS	145	45	813
37652	0	QNS	21	QNS	QNS	201	48	827
37653	1	QNS	QNS	QNS	QNS	331	109	QNS
37654	1	QNS	QNS	QNS	QNS	190	59	807
37655	0	202	76	.5	15	352	68	1099
37656	0	QNS	QNS	QNS	QNS	325	57	1870
37657	0	244	43	.4	QNS	221	42	1095
37658	0	QNS	QNS	QNS	QNS	268	56	971
37659	NSR	NSR	NSR	NSR	NSR	NSR	NSR	NSR
37660	0	NT	NT	NT	QNS	267	41	1770

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APPENDIX 12B
 INDIVIDUAL CLINICAL CHEMISTRY VALUES
 13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1 MICE
 WEEK 7 FEMALES

ANIMAL NUMBER	SERUMHEM	GLUCOSE MG/DL	BUN MG/DL	CREAT MG/DL	T CHOL MG/DL	AST U/L	ALT U/L	LDH U/L
<hr/>								
GROUP: 3	DOSE LEVEL: 350	DOSAGE UNIT: MG/KG						
37671	0	347	40	.4	17	129	58	696
37672	0	188	29	.4	10	209	80	468
37673	0	216	25	.4	34	211	106	841
37674	0	160	27	.4	13	344	127	2100
37675	0	211	39	.3	18	308	85	810
37676	0	209	80	.4	28	182	62	439
37677	2	QNS	QNS	QNS	QNS	345	91	QNS
37678	0	226	48	.4	10	241	98	899
37679	1	QNS	QNS	QNS	QNS	419	162	1805
37680	0	QNS	QNS	QNS	QNS	188	63	1675
<hr/>								
GROUP: 4	DOSE LEVEL: 900	DOSAGE UNIT: MG/KG						
37691	0	QNS	68	.4	QNS	565	775	1333
37692	1	QNS	QNS	QNS	QNS	294	235	975
37693	1	QNS	QNS	QNS	QNS	261	115	1227
37694	0	QNS	57	QNS	QNS	267	75	1775
37695	0	QNS	QNS	QNS	QNS	683	131	2335
37696	0	163	55	.4	21	247	196	1187
37697	0	149	44	.4	12	305	224	1069
37698	0	265	51	.4	QNS	248	121	946
37699	0	152	35	.4	32	148	65	1344
37700	0	QNS	QNS	QNS	QNS	273	203	1635

APPENDIX 12B
 INDIVIDUAL CLINICAL CHEMISTRY VALUES
 13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1 MICE
 WEEK 7 FEMALES

ANIMAL NUMBER	ALK P U/L	T PROT G/DL	ALBUMIN G/DL	GLOBULIN G/DL	A/G RATIO	T BILI MG/DL	TRIGLY MG/DL	GGT U/L
<hr/>								
GROUP: 1	DOSE LEVEL: 0		DOSAGE UNIT: MG/KG					
37621	109	5.4	3.7	1.7	2.18	.2	QNS	0
37622	QNS	QNS	QNS	QNS	QNS	QNS	QNS	QNS
37623	97	QNS	3.9	QNS	QNS	.1	QNS	0
37624	106	4.7	3.3	1.4	2.36	.2	22	0
37625	NSR	NSR	NSR	NSR	NSR	NSR	NSR	NSR
37626	QNS	QNS	QNS	QNS	QNS	QNS	QNS	QNS
37627	108	4.6	3.3	1.3	2.54	.1	25	1
37628	QNS	QNS	QNS	QNS	QNS	QNS	QNS	QNS
37629	101	QNS	4.0	QNS	QNS	.2	QNS	0
37630	105	5.1	3.7	1.4	2.64	.2	38	0
<hr/>								
GROUP: 2	DOSE LEVEL: 25		DOSAGE UNIT: MG/KG					
37651	127	4.6	3.3	1.3	2.54	.1	QNS	0
37652	169	QNS	QNS	QNS	QNS	.1	QNS	0
37653	QNS	QNS	QNS	QNS	QNS	QNS	QNS	QNS
37654	QNS	QNS	QNS	QNS	QNS	QNS	QNS	QNS
37655	188	4.7	3.5	1.2	2.92	.2	17	0
37656	134	QNS	QNS	QNS	QNS	QNS	QNS	QNS
37657	159	4.8	3.6	1.2	3.00	.1	QNS	0
37658	118	QNS	QNS	QNS	QNS	.2	QNS	1
37659	NSR	NSR	NSR	NSR	NSR	NSR	NSR	NSR
37660	119	QNS	QNS	QNS	QNS	.1	QNS	0

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APPENDIX 12B
 INDIVIDUAL CLINICAL CHEMISTRY VALUES
 13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1 MICE
 WEEK 7 FEMALES

ANIMAL NUMBER	ALK P U/L	T PROT G/DL	ALBUMIN G/DL	GLOBULIN G/DL	A/G RATIO	T BILI MG/DL	TRIGLY MG/DL	GGT U/L
<hr/>								
GROUP: 3	DOSE LEVEL: 350		DOSAGE UNIT: MG/KG					
37671	96	4.4	3.2	1.2	2.67	.1	47	0
37672	365	4.5	3.5	1.0	3.50	.1	17	0
37673	117	5.1	3.5	1.6	2.19	.1	67	0
37674	152	3.8	2.9	.9	3.22	.1	27	0
37675	102	3.5	2.8	.7	4.00	.1	81	0
37676	124	4.5	3.2	1.3	2.46	.1	51	1
37677	QNS	QNS	QNS	QNS	QNS	QNS	QNS	QNS
37678	135	4.0	2.9	1.1	2.64	.1	18	1
37679	158	QNS	QNS	QNS	QNS	.2	QNS	0
37680	105	QNS	QNS	QNS	QNS	.1	QNS	1
<hr/>								
GROUP: 4	DOSE LEVEL: 900		DOSAGE UNIT: MG/KG					
37691	282	QNS	3.8	QNS	QNS	.1	QNS	13
37692	112	QNS	QNS	QNS	QNS	.2	QNS	0
37693	198	QNS	QNS	QNS	QNS	.2	QNS	0
37694	133	QNS	QNS	QNS	QNS	.2	QNS	0
37695	126	QNS	QNS	QNS	QNS	.1	QNS	0
37696	257	3.6	2.5	1.1	2.27	.1	40	1
37697	459	4.5	3.4	1.1	3.09	.1	33	2
37698	135	4.7	3.5	1.2	2.92	.1	QNS	1
37699	499	4.8	3.7	1.1	3.36	.1	32	1
37700	156	QNS	QNS	QNS	QNS	QNS	QNS	QNS

Appendix 12C
Individual Clinical Chemistry Values - Extra Animals
13-Week Subchronic Oral Toxicity Study of Triclosan in CD-1® Mice

Key to Clinical Chemistry

Serum Hemolysis (SERUMHEM)

- 0 = No Hemolysis
- 1 = Trace Hemolysis
- 2 = Slight Hemolysis
- 3 = Moderate Hemolysis
- 4 = Marked Hemolysis
- 5 = Severe Hemolysis

OTHER NOTATIONS

QNS = Quantity Not Sufficient

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ANIMAL NUMBER	SERUMHEM	GLUCOSE MG/DL	BUN MG/DL	CREAT MG/DL	T CHOL MG/DL	AST U/L	ALT U/L	LDH U/L
	DISEASE LEVEL:			DOSAGE UNIT:				
00024	0	266	27	.6	121	65	22	518
00081	0	239	49	QNS	176	50	24	231
00087	0	166	26	.4	117	161	45	460
00121	0	33	30	.5	QNS	182	47	1720
00134	1	QNS	29	.5	QNS	152	32	1635
00138	0	232	26	.5	159	66	33	974
00165	1	188	31	.5	130	155	42	1258
00169	0	236	43	.4	92	80	25	607

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APPENDIX 12C
INDIVIDUAL CLINICAL CHEMISTRY VALUES
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1 MICE
WEEK -1 MALES

ANIMAL NUMBER	ALK P U/L	T PROT G/DL	ALBUMIN G/DL	GLOBULIN G/DL	A/G RATIO	T BILI MG/DL	TRIGLY MG/DL	GGT U/L
-----	-----	-----	-----	-----	-----	-----	-----	-----
	DOSE LEVEL:		DOSAGE UNIT:					
00024	131	5.4	3.6	1.8	2.00	.1	43	0
00081	266	5.4	3.7	1.7	2.18	.1	QNS	0
00087	144	5.1	3.3	1.8	1.83	.1	38	0
00121	167	5.1	3.3	1.8	1.83	.1	QNS	0
00134	132	QNS	QNS	QNS	QNS	.2	QNS	0
00138	110	5.4	3.6	1.8	2.00	.1	18	0
00165	136	5.2	3.6	1.6	2.25	.2	40	0
00169	136	5.0	3.4	1.6	2.13	.1	16	0

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APPENDIX 12 C
INDIVIDUAL CLINICAL CHEMISTRY VALUES
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1 MICE
WEEK -1 FEMALES

ANIMAL NUMBER	SERUMHEM	GLUCOSE MG/DL	BUN MG/DL	CREAT MG/DL	T CHOL MG/DL	AST U/L	ALT U/L	LDH U/L
	DOSE LEVEL:		DOSAGE UNIT:					
00195	1	QNS	34	.5	QNS	124	35	506
00209	1	183	38	.5	96	110	24	883
00211	0	QNS	41	.5	QNS	231	49	1560
00215	0	196	41	.4	92	188	42	973
00274	1	QNS	36	.4	QNS	220	41	1287
00313	0	QNS	31	.5	QNS	173	34	2465
00368	0	QNS	54	.5	QNS	203	47	1237

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APPENDIX 12C
INDIVIDUAL CLINICAL CHEMISTRY VALUES
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1 MICE
WEEK -1 FEMALES

ANIMAL NUMBER	ALK P U/L	T PROT G/DL	ALBUMIN G/DL	GLOBULIN G/DL	A/G RATIO	T BILI MG/DL	TRIGLY MG/DL	GGT U/L
DOSE LEVEL:		DOSAGE UNIT:						
00195	180	QNS	QNS	QNS	QNS	.2	QNS	0
00209	185	5.8	4.1	1.7	2.41	.2	QNS	0
00211	173	QNS	QNS	QNS	QNS	.2	QNS	0
00215	148	5.5	4.1	1.4	2.93	.1	26	0
00274	127	5.0	3.7	1.3	2.85	.2	QNS	0
00313	135	5.5	4.0	1.5	2.67	.1	QNS	0
00368	112	QNS	4.1	QNS	QNS	.2	QNS	0

OTC Vol. No. 115

OTC Docket Number 75N-0183 (triclosan)
September 12, 1994

Ciba-Geigy Corporation
Chemicals Division
Greensboro, N.C. 27419

Trutter, J.A. 13-Week Subchronic Oral Toxicity Study of Triclosan in CD-1® Mice (Volume 2). Hazleton Washington, Inc. Lab. Project I.D. No. 483-287. January 28, 1993.

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VOLUME 7 OF 10 OF SUBMISSION

STUDY TITLE

13-Week Subchronic Oral Toxicity Study of Triclosan in CD-1® Mice

EPA GUIDELINE NO. 82-1

AUTHOR

Janet A. Trutter, M.S., D.A.B.T.

STUDY COMPLETED ON: January 28, 1993

CONDUCTED BY

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Vienna, Virginia 22182

LABORATORY PROJECT IDENTIFICATION NO. HWA 483-287

VOLUME 2 OF 2 OF STUDY

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SPONSOR

Chemicals Division
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410 Swaing Road
Greensboro, NC 27419-8300

Appendix 13A

Individual Animal Summary Report - Main Study (Unscheduled Deaths)
13-Week Subchronic Oral Toxicity Study of Triclosan in CD-1[®] Mice

Standard Key to Individual Animal Summary Data

ORGAN WEIGHING STATUSES

NOT TAKEN = Organ Weight Not Taken; No Explanation Given
MISSING = Organ Missing Or Lost
UNSUITABLE = Organ Technically Unsuitable For Weighing
AUTOLYTIC = Organ Autolytic And Could Not Be Weighed
EXCLUDE = Weight Has Been Taken, But Will Be Excluded From All Calculations

OTHER SYMBOLS AND NOTATIONS

H- = Finding Noted During Processing Of Tissues In Histology (Precedes Keyword).

LOCATIONS OF TISSUE MASSES
OBSERVED GROSSLY

DFL = Dorsal-Front-Left
DFR = Dorsal-Front-Right
DHL = Dorsal-Hind-Left
DHR = Dorsal-Hind-Right
DFM = Dorsal-Front-Mid
DHM = Dorsal-Hind-Mid
VFL = Ventral-Front-Left
VFR = Ventral-Front-Right
VHL = Ventral-Hind-Left
VHR = Ventral-Hind-Right
VFM = Ventral-Front-Mid
VHM = Ventral-Hind-Mid

SYMBOLS PREFACING NEOPLASTIC FINDINGS

B- = Primary, Benign Neoplasm
M- = Primary, Malignant Neoplasm
N- = Metastatic Neoplasm
I- = Locally Invasive Neoplasm
X- = Other Neoplasm

APPENDIX 13A

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 20-JAN-93
PAGE: 515

STUDY NUMBER: 483287

ANIMAL NUMBER: A37484 SEX: MALE DOSE GROUP: 4 SACRIFICE STATUS: UNSCHEDULED (D)
DATE OF DEATH: 11/01/91 STUDY DAY OF DEATH: 85 STUDY WEEK OF DEATH: 13 TERMINAL BODY WEIGHT: 29.0 GRAMS
DATE AND TIME OF NECROPSY: 11/01/91 9:30 PROSECTOR: ADEFOLAHAN AKINSOLA RECORDER: ADEFOLAHAN AKINSOLA
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: NOT REQUIRED BY PROTOCOL

*** ANIMAL HAS NO ORGAN WEIGHTS RECORDED ***

CLINICAL OBSERVATIONS	PATHOLOGY OBSERVATIONS NECROPSY	HISTOPATHOLOGY
-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS		CECUM (CE) : -HYPERPLASIA, LYMPHOID,-PRESENT DUODENUM (DU) : >AUTOLYTIC GALLBLADDER (GB) : >AUTOLYTIC ILEUM (IL) : >AUTOLYTIC JEJUNUM (JE) : >AUTOLYTIC LIVER (LI) : >AUTOLYTIC LN, MANDIBULAR (MN) : >TISSUE MISSING LN, MESENTERIC (MS) : >TISSUE MISSING NERVE, OPTIC (ON) : >TISSUE MISSING PARATHYROID (PT) : -UNILATERALLY EXAMINED,-PRESENT PITUITARY (PI) : >TISSUE MISSING RECTUM (RE) : >AUTOLYTIC SPLEEN (SP) : -DEPLETION, LYMPHOID,-SLIGHT THYMUS (TH) : -CYST,-PRESENT THYROID (TY) : -UNILATERALLY EXAMINED,-PRESENT

HAZLETON WASHINGTON, INC.
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DATE AND TIME OF NECROPSY: 11/01/91 9:30 PROSECTOR: ADEFOLAHAN AKINSOLA RECORDER: ADEFOLAHAN AKINSOLA
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: NOT REQUIRED BY PROTOCOL

CLINICAL OBSERVATIONS

P A T H O L O G Y O B S E R V A T I O N S (CONTINUED)
NECROPSY

HISTOPATHOLOGY

^COLLECTED/TAKEN (XW) :
-NO SPECIAL REQUIREMENT

^DEATH COMMENT (DC) :
-UNDETERMINED,-PRESENT

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), EPIDIDYMIS (EP), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE),
KIDNEY (KD), LACRIMAL GL, EX (EO), LIVER (LI), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU),
MAND SALIVARY GL (SG), MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON),
NERVE, SCIATIC (SN), PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), PROSTATE (PR), RECTUM (RE), SKIN (SK),
SKIN, OTHER (SS), SPLEEN (SP), STOMACH, GL (ST), STOMACH, NONGL (SU), TESTIS (TE), THYMUS (TH), THYROID (TY),
TONGUE (TO), TRACHEA (TR), URINARY BLADDER (UB)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, STERNUM (SB),
BRAIN W/STEM (BR), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC), EPIDIDYMIS (EP),
ESOPHAGUS (ES), EYE (EY), HARDERIAN GLAND (HG), HEART (HT), HEMATO NEOPLASIA (HN), KIDNEY (KD), LACRIMAL GL, EX (EO),
LUNG (LU), MAND SALIVARY GL (SG), MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM),
NERVE, SCIATIC (SN), PANCREAS (PA), PROSTATE (PR), SALIVARY, OTHER (OS), SKIN (SK), STOMACH, GL (ST),
STOMACH, NONGL (SU), TESTIS (TE), TONGUE (TO), TRACHEA (TR), URINARY BLADDER (UB)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

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MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 20-JAN-93
PAGE: 517

STUDY NUMBER: 483287

ANIMAL NUMBER: A37494 SEX: MALE DOSE GROUP: 4 SACRIFICE STATUS: UNSCHEDULED (A)
DATE OF DEATH: 09/15/91 STUDY DAY OF DEATH: 38 STUDY WEEK OF DEATH: 6 TERMINAL BODY WEIGHT: 33.0 GRAMS
DATE AND TIME OF NECROPSY: 09/15/91 11:55 PROSECTOR: LINDA RUMBLE RECORDER: LINDA RUMBLE
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: NOT REQUIRED BY PROTOCOL

*** ANIMAL HAS NO ORGAN WEIGHTS RECORDED ***

CLINICAL OBSERVATIONS	P A T H O L O G Y O B S E R V A T I O N S NECROPSY	HISTOPATHOLOGY
-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS	BONE, OTHER (OB) : -FRACTURED; SKULL CAP	ADRENAL, MEDULLA (AM) : -UNILATERALLY EXAMINED,-PRESENT BONE, OTHER (OB) : >UNREMARKABLE BRAIN W/STEM (BR) : -HEMORRHAGE,-PRESENT CECUM (CE) : >AUTOLYTIC COLON (CO) : >AUTOLYTIC CORD, CERVICAL (CS) : -HEMORRHAGE,-PRESENT CORD, THORACIC (TC) : -HEMORRHAGE,-PRESENT EYE (EY) : -UNILATERALLY EXAMINED,-PRESENT GALLBLADDER (GB) : >AUTOLYTIC ILEUM (IL) : >AUTOLYTIC LIVER (LI) : -VACUOLIZATION,-MINIMAL NERVE, OPTIC (ON) : >TISSUE MISSING PARATHYROID (PT) : >SECTION EXAMINED; TISSUE NOT PRESENT RECTUM (RE) : >AUTOLYTIC STOMACH, GL (ST) : >AUTOLYTIC
	EYE (EY) : -EXOPHTHALMUS; BOTH	
	LIVER (LI) : -ENLARGED, MODERATE; ALL LOBES	

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DATE AND TIME OF NECROPSY: 09/15/91 11:55 PROSECTOR: LINDA RUMBLE RECORDER: LINDA RUMBLE
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: NOT REQUIRED BY PROTOCOL

CLINICAL OBSERVATIONS

P A T H O L O G Y O B S E R V A T I O N S (CONTINUED)
NECROPSY

HISTOPATHOLOGY

^COLLECTED/TAKEN (XW) :
-NO SPECIAL REQUIREMENT

^DEATH COMMENT (DC) :
-ACCIDENTAL, -PRESENT

GENERAL INFORMATION (XX) :
>NOTE:>ANIMAL'S HEAD CRUSHED IN LIXIT
OPENING OF CAGE

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BRAIN W/STEM (BR), CECUM (CE),
COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC), DUODENUM (DU), EPIDIDYMIS (EP),
ESOPHAGUS (ES), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE), KIDNEY (KD), LACRIMAL GL, EX (EO),
LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU), MAND SALIVARY GL (SG), MARROW, FEMUR (FM), MARROW, STERNUM (SE),
MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON), NERVE, SCIATIC (SN), PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI),
PROSTATE (PR), RECTUM (RE), SKIN (SK), SKIN, OTHER (SS), SPLEEN (SP), STOMACH, GL (ST), STOMACH, NONGL (SU),
TESTIS (TE), THYMUS (TH), THYROID (TY), TONGUE (TO), TRACHEA (TR), URINARY BLADDER (UB)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:

ADRENAL, CORTEX (AC), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, STERNUM (SB), CORD, LUMBAR (LC), DUODENUM (DU),
EPIDIDYMIS (EP), ESOPHAGUS (ES), HARDERIAN GLAND (HG), HEART (HT), HEMATO NEOPLASIA (HN), JEJUNUM (JE), KIDNEY (KD),
LACRIMAL GL, EX (EO), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU), MAND SALIVARY GL (SG), MARROW, FEMUR (FM),
MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, SCIATIC (SN), PANCREAS (PA), PITUITARY (PI), PROSTATE (PR),
SALIVARY, OTHER (OS), SKIN (SK), SPLEEN (SP), STOMACH, NONGL (SU), TESTIS (TE), THYMUS (TH), THYROID (TY),
TONGUE (TO), TRACHEA (TR), URINARY BLADDER (UB)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
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13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)

INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 20-JAN-93
PAGE: 519

STUDY NUMBER: 483287

ANIMAL NUMBER: A37577 SEX: MALE DOSE GROUP: 7 SACRIFICE STATUS: UNSCHEDULED (D)
DATE OF DEATH: 08/17/91 STUDY DAY OF DEATH: 9 STUDY WEEK OF DEATH: 2 TERMINAL BODY WEIGHT: 14.0 GRAMS
DATE AND TIME OF NECROPSY: 08/17/91 13:25 PROSECTOR: ADEPOLAHAN AKINSOLA RECORDER: ADEPOLAHAN AKINSOLA
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: NOT REQUIRED BY PROTOCOL

*** ANIMAL HAS NO ORGAN WEIGHTS RECORDED ***

P A T H O L O G Y O B S E R V A T I O N S
NECROPSY

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE
OBSERVATIONS. LAST CAGESIDE
OBSERVATIONS:THIN; HUNCHED POSTURE;
PALE; HYPOACTIVE

LIVER (LI) :
-PALE AREA; ALL LOBES, FEW, TAN,
WHITE, PINPOINT TO 3 X 3 MM

HISTOPATHOLOGY

ADRENAL, CORTEX (AC) :
-HYPERTROPHY, ZONA FASCICULATA,-SLIGHT

EPIDIDYMIS (EP) :
-LUMEN, DEBRIS, CELLULAR,-PRESENT
LIVER (LI) :
-HEPATOCTYE, HYPERTROPHY,
CENTROLOBULAR,-MINIMAL
-NECROSIS,-MODERATE, MULTI-FOCAL
-NECROSIS, INDIVIDUAL CELL,-MINIMAL
LN, MESENTERIC (MS) :

>TISSUE MISSING
NERVE, OPTIC (ON) :
-UNILATERALLY EXAMINED,-PRESENT
PANCREAS (PA) :
-INFLAMMATION, CHRONIC,-MINIMAL
PARATHYROID (PT) :
-UNILATERALLY EXAMINED,-PRESENT
PITUITARY (PI) :
>TISSUE MISSING

RECTUM (RE) :
-HYPERPLASIA, LYMPHOID,-PRESENT
SPLEEN (SP) :
-PIGMENT,-MINIMAL
-DEPLETION, LYMPHOID,-SLIGHT
THYMUS (TH) :

>SECTION EXAMINED; TISSUE NOT PRESENT

^COLLECTED/TAKEN (XW) :
-NO SPECIAL REQUIREMENT

HAZLETON WASHINGTON, INC.
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APPENDIX 13A

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MICE. (MAIN-GROUPS 1-7)

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DATE AND TIME OF NECROPSY: 08/17/91 13:25 PROSECTOR: ADEPOLAHAN AKINSOLA RECORDER: ADEPOLAHAN AKINSOLA
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: NOT REQUIRED BY PROTOCOL

CLINICAL OBSERVATIONS

P A T H O L O G Y O B S E R V A T I O N S (CONTINUED)
NECROPSY

HISTOPATHOLOGY

^DEATH COMMENT (DC) :
-UNDETERMINED, -PRESENT

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), EPIDIDYMIS (EP), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE),
KIDNEY (KD), LACRIMAL GL, EX (EO), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU), MAND SALIVARY GL (SG),
MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON), NERVE, SCIATIC (SN),
PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), PROSTATE (PR), RECTUM (RE), SKIN (SK), SKIN, OTHER (SS),
SPLEEN (SP), STOMACH, GL (ST), STOMACH, NONGL (SU), TESTIS (TE), THYMUS (TH), THYROID (TY), TONGUE (TO),
TRACHEA (TR), URINARY BLADDER (UB)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:

ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, STERNUM (SB), BRAIN W/STEM (BR), CECUM (CE),
COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC), DUODENUM (DU), ESOPHAGUS (ES), EYE (EY),
GALLBLADDER (GB), HARDERIAN GLAND (HG), HEART (HT), HEMATO NEOPLASIA (HN), ILEUM (IL), JEJUNUM (JE), KIDNEY (KD),
LACRIMAL GL, EX (EO), LN, MANDIBULAR (MN), LUNG (LU), MAND SALIVARY GL (SG), MARROW, FEMUR (FM), MARROW, STERNUM (SE),
MUSCLE, ABDOM (MA), MUSCLE, SKELETAL (SM), NERVE, SCIATIC (SN), PROSTATE (PR), SALIVARY, OTHER (OS), SKIN (SK),
STOMACH, GL (ST), STOMACH, NONGL (SU), TESTIS (TE), THYROID (TY), TONGUE (TO), TRACHEA (TR), URINARY BLADDER (UB)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

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MICE. (MAIN-GROUPS 1-7)
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STUDY NUMBER: 483287

ANIMAL NUMBER: A37579 SEX: MALE DOSE GROUP: 7 SACRIFICE STATUS: UNSCHEDULED (M)
DATE OF DEATH: 08/24/91 STUDY DAY OF DEATH: 16 STUDY WEEK OF DEATH: 3 TERMINAL BODY WEIGHT: 20.0 GRAMS
DATE AND TIME OF NECROPSY: 08/24/91 9:50 PROSECTOR: JANE EARHARDT RECORDER: JANE EARHARDT
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: NOT REQUIRED BY PROTOCOL

*** ANIMAL HAS NO ORGAN WEIGHTS RECORDED ***

CLINICAL OBSERVATIONS	P A T H O L O G Y O B S E R V A T I O N S NECROPSY	HISTOPATHOLOGY
-CURRENT OBSERVATIONS: PROSTRATE; SEVERE DYSPNEA; PALE; URINE STAINS; SACRAL AREA- ALOPECIA;	LIVER (LI) : -PALE AREA; ALL LOBES, BOTH SURFACES, TAN, DIFFUSE, LINEAR, PINPOINT TO 5 X 2 MM -LOBE, THICKENED, SLIGHT; ALL	AORTA, THORACIC (AO) : >TISSUE MISSING EPIDIDYMIS (EP) : -LUMEN, DEBRIS, CELLULAR, -PRESENT GALLBLADDER (GB) : >AUTOLYTIC HEART (HT) : -INFLAMMATION, CHRONIC, -MINIMAL -MINERALIZATION, -MINIMAL -DEGENERATION, -MINIMAL KIDNEY (KD) : -TUBULE, REGENERATION, -MINIMAL LACRIMAL GL, EX (EO) : -INFLAMMATION, CHRONIC, -MINIMAL LIVER (LI) : -HEPATOCYTE, HYPERTROPHY, CENTROLOBULAR, -MODERATELY SEVERE -NECROSIS, -MODERATELY SEVERE, MULTI- FOCAL -NECROSIS, INDIVIDUAL CELL, -MODERATE -INFLAMMATION, CHRONIC/CHRONIC ACTIVE, - MODERATE -MINERALIZATION, -SLIGHT LN, MESENTERIC (MS) : >TISSUE MISSING MARROW, FEMUR (FM) : -HYPERCELLULAR, -PRESENT NERVE, OPTIC (ON) : -UNILATERALLY EXAMINED, -PRESENT

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POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: NOT REQUIRED BY PROTOCOL

CLINICAL OBSERVATIONS

P A T H O L O G Y O B S E R V A T I O N S (CONTINUED)
NECROPSY

HISTOPATHOLOGY

SKIN, OTHER (SS) :
-ALOPECIA; LEFT HIP
SPLEEN (SP) :
-PALE; PINK
STOMACH, GL (ST) :
-DARK AREA; MUCOSA, FEW, BLACK,
PINPOINT

^COLLECTED/TAKEN (XW) :
-NO SPECIAL REQUIREMENT

GENERAL INFORMATION (XX) :
>NOTE:>REASON FOR SACRIFICE:PROSTRATE;
SEVERE DYSPNEA. ANIMAL DIED
PRIOR TO EUTHANASIA

SKIN, OTHER (SS) :
>UNREMARKABLE
SPLEEN (SP) :
-EXTRAMEDULLARY HEMATOPOIESIS,
INCREASED,-MODERATELY SEVERE
STOMACH, GL (ST) :
-MUCOSA, NECROSIS,-MINIMAL
THYMUS (TH) :
>SECTION EXAMINED; TISSUE NOT PRESENT
^DEATH COMMENT (DC) :
-UNDETERMINED,-PRESENT

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MICE. (MAIN-GROUPS 1-7)

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POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: NOT REQUIRED BY PROTOCOL

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), EPIDIDYMIS (EP), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE),
KIDNEY (KD), LACRIMAL GL, EX (EO), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU), MAND SALIVARY GL (SG),
MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON), NERVE, SCIATIC (SN),
PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), PROSTATE (PR), RECTUM (RE), SKIN (SK), STOMACH, NONGL (SU),
TESTIS (TE), THYMUS (TH), THYROID (TY), TONGUE (TO), TRACHEA (TR), URINARY BLADDER (UB)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), BONE, FEMUR (FE), BONE, STERNUM (SB), BRAIN W/STEM (BR), CECUM (CE),
COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC), DUODENUM (DU), ESOPHAGUS (ES), EYE (EY),
HARDERIAN GLAND (HG), HEMATO NEOPLASIA (HN), ILEUM (IL), JEJUNUM (JE), LN, MANDIBULAR (MN), LUNG (LU),
MAND SALIVARY GL (SG), MARROW, STERNUM (SE), MUSCLE, ABDOM (MA), MUSCLE, SKELETAL (SM), NERVE, SCIATIC (SN),
PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), PROSTATE (PR), RECTUM (RE), SALIVARY, OTHER (OS), SKIN (SK),
STOMACH, NONGL (SU), TESTIS (TE), THYROID (TY), TONGUE (TO), TRACHEA (TR), URINARY BLADDER (UB)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

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APPENDIX 13A

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 20-JAN-93
PAGE: 524

STUDY NUMBER: 483287

ANIMAL NUMBER: A37496 SEX: FEMALE DOSE GROUP: 4 SACRIFICE STATUS: UNSCHEDULED (M)
DATE OF DEATH: 09/10/91 STUDY DAY OF DEATH: 33 STUDY WEEK OF DEATH: 5 TERMINAL BODY WEIGHT: 22.0 GRAMS
DATE AND TIME OF NECROPSY: 09/10/91 10:25 PROSECTOR: LINDA RUMBLE RECORDER: LINDA RUMBLE
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: NOT REQUIRED BY PROTOCOL

*** ANIMAL HAS NO ORGAN WEIGHTS RECORDED ***

CLINICAL OBSERVATIONS	PATHOLOGY OBSERVATIONS NECROPSY	HISTOPATHOLOGY
-CURRENT OBSERVATIONS:HIND LIMBS-LIMITED USE; URINE STAINS	LIVER (LI) : -ENLARGED, MODERATE; ALL LOBES	JEJUNUM (JE) : -HYPERPLASIA, LYMPHOID,-PRESENT KIDNEY (KD) : -INFLAMMATION, CHRONIC,-MINIMAL -TUBULE, REGENERATION,-MINIMAL -CYST,-PRESENT LACRIMAL GL, EX (EO) : -UNILATERALLY EXAMINED,-PRESENT LIVER (LI) : -HEPATOCYTE, HYPERTROPHY, CENTROLOBULAR,-SLIGHT -NECROSIS, INDIVIDUAL CELL,-MINIMAL LN, MESENTERIC (MS) : -MACROPHAGES, PIGMENTED,-MINIMAL LN, OTHER (LN) : -MACROPHAGES, PIGMENTED,-PRESENT >NOTE:>THORACIC. OVARY (OV) : -FOLLICLE, CYST,-PRESENT -MINERALIZATION,-MINIMAL PARATHYROID (PT) : -UNILATERALLY EXAMINED,-PRESENT RECTUM (RE) : -HYPERPLASIA, LYMPHOID,-PRESENT THYMUS (TH) : -CYST,-PRESENT -ATROPHY,-MODERATELY SEVERE UTERUS (UT) : -HYPOPLASIA,-MODERATELY SEVERE

HAZLETON WASHINGTON, INC.
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APPENDIX 13A

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 20-JAN-93
PAGE: 525

STUDY NUMBER: 483287

ANIMAL NUMBER: A37496 SEX: FEMALE DOSE GROUP: 4 SACRIFICE STATUS: UNSCHEDULED (M)
DATE OF DEATH: 09/10/91 STUDY DAY OF DEATH: 33 STUDY WEEK OF DEATH: 5 TERMINAL BODY WEIGHT: 22.0 GRAMS
DATE AND TIME OF NECROPSY: 09/10/91 10:25 PROSECTOR: LINDA RUMBLE RECORDER: LINDA RUMBLE
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: NOT REQUIRED BY PROTOCOL

CLINICAL OBSERVATIONS	P A T H O L O G Y O B S E R V A T I O N S (CONTINUED) NECROPSY	HISTOPATHOLOGY
	^COLLECTED/TAKEN (XW) : -NO SPECIAL REQUIREMENT	UTERUS, CERVIX (CV) : -HYPOPLASIA, -MODERATELY SEVERE
	GENERAL INFORMATION (XX) : >NOTE: >REASON FOR SACRIFICE: HIND LIMBS- LIMITED USE; URINE STAINS	^DEATH COMMENT (DC) : -SCHEDULED SACRIFICE, -PRESENT
THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY: ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB), BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC), DUODENUM (DU), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE), KIDNEY (KD), LACRIMAL GL, EX (EO), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU), MAMMARY, FEMALE (MF), MAND SALIVARY GL (SG), MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON), NERVE, SCIATIC (SN), OVARY (OV), PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), RECTUM (RE), SKIN (SK), SKIN, OTHER (SS), SPLEEN (SP), STOMACH, GL (ST), STOMACH, NONGL (SU), THYMUS (TH), THYROID (TY), TONGUE (TO), TRACHEA (TR), URINARY BLADDER (UB), UTERUS (UT), UTERUS, CERVIX (CV), VAGINA (VA)		
THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION: ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, STERNUM (SB), BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC), DUODENUM (DU), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HARDERIAN GLAND (HG), HEART (HT), HEMATO NEOPLASIA (HN), ILEUM (IL), LN, MANDIBULAR (MN), LUNG (LU), MAND SALIVARY GL (SG), MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON), NERVE, SCIATIC (SN), OVIDUCT (OD), PANCREAS (PA), PITUITARY (PI), STOMACH, GL (ST), STOMACH, NONGL (SU), THYROID (TY), TONGUE (TO), TRACHEA (TR), URINARY BLADDER (UB), VAGINA (VA)		

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
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APPENDIX 13A

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 20-JAN-93
PAGE: 526

STUDY NUMBER: 483287

ANIMAL NUMBER: A37586 SEX: FEMALE DOSE GROUP: 7 SACRIFICE STATUS: UNSCHEDULED (D)
DATE OF DEATH: 09/30/91 STUDY DAY OF DEATH: 53 STUDY WEEK OF DEATH: 8 TERMINAL BODY WEIGHT: 20.0 GRAMS
DATE AND TIME OF NECROPSY: 10/01/91 8:40 PROSECTOR: SONNY DIKES RECORDER: RICHARD KAGYARE
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: NOT REQUIRED BY PROTOCOL

*** ANIMAL HAS NO ORGAN WEIGHTS RECORDED ***

CLINICAL OBSERVATIONS	PATHOLOGY OBSERVATIONS NECROPSY	HISTOPATHOLOGY
-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS		DUODENUM (DU) : >AUTOLYTIC EYE (EY) : >UNREMARKABLE >NOTE:>ONE CORNEA EXAMINED. GALLBLADDER (GB) : >AUTOLYTIC HARDERIAN GLAND (HG) : -INFLAMMATION, CHRONIC,-PRESENT KIDNEY (KD) : -TUBULE, REGENERATION,-MINIMAL LIVER (LI) : -HEPATOCTYE, HYPERTROPHY, CENTROLOBULAR,-MODERATE -VACUOLIZATION,-MINIMAL -KUPFFER CELL/MACROPHAGE, PIGMENT,- MINIMAL -BILE DUCT, INFLAMMATION, CHRONIC,- MINIMAL LN, MANDIBULAR (MN) : -MACROPHAGES, PIGMENTED,-MINIMAL LN, MESENTERIC (MS) : >AUTOLYTIC LN, OTHER (LN) : >UNREMARKABLE >NOTE:>SUBCUTANEOUS. SPLEEN (SP) : -PIGMENT,-SLIGHT -DEPLETION, LYMPHOID,-MODERATELY SEVERE

HAZLETON WASHINGTON, INC.
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APPENDIX 13A

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

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PAGE: 527

STUDY NUMBER: 483287

ANIMAL NUMBER: A37586 SEX: FEMALE DOSE GROUP: 7 SACRIFICE STATUS: UNSCHEDULED (D)
DATE OF DEATH: 09/30/91 STUDY DAY OF DEATH: 53 STUDY WEEK OF DEATH: 8 TERMINAL BODY WEIGHT: 20.0 GRAMS
DATE AND TIME OF NECROPSY: 10/01/91 8:40 PROSECTOR: SONNY DIKES RECORDER: RICHARD KAGYARE
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: NOT REQUIRED BY PROTOCOL

CLINICAL OBSERVATIONS

P A T H O L O G Y O B S E R V A T I O N S (CONTINUED)
NECROPSY

HISTOPATHOLOGY

STOMACH, GL (ST) :
-MUCOSA, SMOOTH

STOMACH, GL (ST) :
>UNREMARKABLE
THYMUS (TH) :
-NECROSIS, LYMPHOID, -MINIMAL
UTERUS (UT) :
-HYPOPLASIA, -SEVERE

^COLLECTED/TAKEN (XW) :
-NO SPECIAL REQUIREMENT

^DEATH COMMENT (DC) :
-UNDETERMINED, -PRESENT

GENERAL INFORMATION (XX) :
>NOTE: >FOUND DEAD AFTER WORKING HOURS

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APPENDIX 13A

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
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INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 20-JAN-93
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STUDY NUMBER: 483287

ANIMAL NUMBER: A37586 SEX: FEMALE DOSE GROUP: 7 SACRIFICE STATUS: UNSCHEDULED (D)
DATE OF DEATH: 09/30/91 STUDY DAY OF DEATH: 53 STUDY WEEK OF DEATH: 8 TERMINAL BODY WEIGHT: 20.0 GRAMS
DATE AND TIME OF NECROPSY: 10/01/91 8:40 PROSECTOR: SONNY DIKES RECORDER: RICHARD KAGYARE
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: NOT REQUIRED BY PROTOCOL

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE), KIDNEY (KD),
LACRIMAL GL, EX (EO), LIVER (LI), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU), MAMMARY, FEMALE (MF),
MAND SALIVARY GL (SG), MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON),
NERVE, SCIATIC (SN), OVARY (OV), PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), RECTUM (RE), SKIN (SK),
SKIN, OTHER (SS), SPLEEN (SP), STOMACH, NONGL (SU), THYMUS (TH), THYROID (TY), TONGUE (TO), TRACHEA (TR),
URINARY BLADDER (UB), UTERUS (UT), UTERUS, CERVIX (CV), VAGINA (VA)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, STERNUM (SB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
ESOPHAGUS (ES), HEART (HT), HEMATO NEOPLASIA (HN), ILEUM (IL), JEJUNUM (JE), LACRIMAL GL, EX (EO), LUNG (LU),
MAMMARY, FEMALE (MF), MAND SALIVARY GL (SG), MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, ABDOM (MA),
MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON), NERVE, SCIATIC (SN), OVARY (OV), OVIDUCT (OD), PANCREAS (PA),
PARATHYROID (PT), PITUITARY (PI), RECTUM (RE), SALIVARY, OTHER (OS), SKIN (SK), STOMACH, NONGL (SU), THYROID (TY),
TONGUE (TO), TRACHEA (TR), URINARY BLADDER (UB), UTERUS, CERVIX (CV), VAGINA (VA)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

Appendix 13B

Individual Animal Summary Report - Main Study (Terminal Sacrifice)
13-Week Subchronic Oral Toxicity Study of Triclosan in CD-1[®] Mice

Standard Key to Individual Animal Summary Data

ORGAN WEIGHING STATUSES

NOT TAKEN = Organ Weight Not Taken; No Explanation Given
MISSING = Organ Missing Or Lost
UNSUITABLE = Organ Technically Unsuitable For Weighing
AUTOLYTIC = Organ Autolytic And Could Not Be Weighed
EXCLUDE = Weight Has Been Taken, But Will Be Excluded From All Calculations

OTHER SYMBOLS AND NOTATIONS

H- = Finding Noted During Processing Of Tissues In Histology (Precedes Keyword).

LOCATIONS OF TISSUE MASSES
OBSERVED GROSSLY

DFL = Dorsal-Front-Left
DFR = Dorsal-Front-Right
DHL = Dorsal-Hind-Left
DHR = Dorsal-Hind-Right
DFM = Dorsal-Front-Mid
DHM = Dorsal-Hind-Mid
VFL = Ventral-Front-Left
VFR = Ventral-Front-Right
VHL = Ventral-Hind-Left
VHR = Ventral-Hind-Right
VFM = Ventral-Front-Mid
VHM = Ventral-Hind-Mid

SYMBOLS PREFACING NEOPLASTIC FINDINGS

B- = Primary, Benign Neoplasm
M- = Primary, Malignant Neoplasm
N- = Metastatic Neoplasm
I- = Locally Invasive Neoplasm
X- = Other Neoplasm

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APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 531

STUDY NUMBER: 483287

ANIMAL NUMBER: A37391 SEX: MALE DOSE GROUP: 1 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/11/91 STUDY DAY OF DEATH: 95 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 24.4 GRAMS
DATE AND TIME OF NECROPSY: 11/11/91 8:45 PROSECTOR: JANE EARHARDT RECORDER: JANE EARHARDT
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.16	.670 %	.383	WEIGHT TAKEN
LUNG (LU)	.18	.748 %	.428	WEIGHT TAKEN
PROSTATE (PR)	.038	.1549 %	.0886	WEIGHT TAKEN
BRAIN W/STEM (BR)	.43	1.749 %	1.000	WEIGHT TAKEN
HEART (HT)	.14	.586 %	.335	WEIGHT TAKEN
SPLEEN (SP)	.07	.289 %	.165	WEIGHT TAKEN
KIDNEY (KD)	.52	2.114 %	1.209	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	1.07	4.386 %	2.508	WEIGHT TAKEN
TESTIS (TE)	.22	.885 %	.506	WEIGHT TAKEN
EPIDIDYMIS (EP)	.13	.518 %	.296	WEIGHT TAKEN
ADRENAL (AD)	.010	.0406 %	.0232	WEIGHT TAKEN
THYMUS (TH)	.04	.154 %	.088	WEIGHT TAKEN

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:BOTH EARS, LEFT
SACRAL-SORES; LEFT SACRAL-ALOPECIA

PATHOLOGY OBSERVATIONS
NECROPSY

HISTOPATHOLOGY

EPIDIDYMIS (EP) :
-LUMEN, DEBRIS, CELLULAR, -PRESENT
EYE (EY) :
>UNREMARKABLE
>NOTE:>CORNEA NOT EXAMINED.
KIDNEY (KD) :
-INFLAMMATION, CHRONIC, -MINIMAL
-TUBULE, REGENERATION, -MINIMAL
LN, OTHER (LN) :
>UNREMARKABLE
>NOTE:>THORACIC.
LUNG (LU) :
-PERIBRONCHIAL/PERIVASCULAR,
INFILTRATION, LYMPHOID, -MINIMAL
MAND SALIVARY GL (SG) :
-INFLAMMATION, CHRONIC, -MINIMAL
NERVE, OPTIC (ON) :
>TISSUE MISSING

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APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 532

STUDY NUMBER: 483287

ANIMAL NUMBER: A37391 SEX: MALE DOSE GROUP: 1 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/11/91 STUDY DAY OF DEATH: 95 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 24.4 GRAMS
DATE AND TIME OF NECROPSY: 11/11/91 8:45 PROSECTOR: JANE EARHARDT RECORDER: JANE EARHARDT
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

CLINICAL OBSERVATIONS	P A T H O L O G Y O B S E R V A T I O N S (CONTINUED) NECROPSY	HISTOPATHOLOGY
	SKIN, OTHER (SS) : -ALOPECIA; LEFT SACRAL REGION -EAR, SORE; BOTH, FEW, CRUSTY, BROWN, PINPOINT TO 3 X 2 MM	SKIN, OTHER (SS) : -DERMATITIS, CHRONIC, -PRESENT -DERMATITIS, ULCERATIVE, -PRESENT
	^COLLECTED/TAKEN (XW) : -LIVER SECTIONS, IN METHANOL	SPLEEN (SP) : -EXTRAMEDULLARY HEMATOPOIESIS, INCREASED, -MINIMAL -PIGMENT, -MINIMAL STOMACH, GL (ST) : -HYPERPLASIA, CYSTIC, -MINIMAL
	GENERAL INFORMATION (XX) : >NOTE:>LEFT SACRAL-SORES, NOT EVIDENT AT NECROPSY	^DEATH COMMENT (DC) : -SCHEDULED SACRIFICE, -PRESENT

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APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

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PAGE: 533

STUDY NUMBER: 483287

ANIMAL NUMBER: A37391 SEX: MALE DOSE GROUP: 1 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/11/91 STUDY DAY OF DEATH: 95 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 24.4 GRAMS
DATE AND TIME OF NECROPSY: 11/11/91 8:45 PROSECTOR: JANE EARHARDT RECORDER: JANE EARHARDT
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), EPIDIDYMIS (EP), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE),
KIDNEY (KD), LACRIMAL GL, EX (EO), LIVER (LI), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU),
MAND SALIVARY GL (SG), MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON),
NERVE, SCIATIC (SN), PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), PROSTATE (PR), RECTUM (RE), SKIN (SK),
SPLEEN (SP), STOMACH, GL (ST), STOMACH, NONGL (SU), TESTIS (TE), THYMUS (TH), THYROID (TY), TONGUE (TO),
TRACHEA (TR), URINARY BLADDER (UB)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, STERNUM (SB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), ESOPHAGUS (ES), GALLBLADDER (GB), HARDERIAN GLAND (HG), HEART (HT), HEMATO NEOPLASIA (HN), ILEUM (IL),
JEJUNUM (JE), LACRIMAL GL, EX (EO), LIVER (LI), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), MARROW, FEMUR (FM),
MARROW, STERNUM (SE), MUSCLE, ABDOM (MA), MUSCLE, SKELETAL (SM), NERVE, SCIATIC (SN), PANCREAS (PA),
PARATHYROID (PT), PITUITARY (PI), PROSTATE (PR), RECTUM (RE), SALIVARY, OTHER (OS), SKIN (SK), STOMACH, NONGL (SU),
TESTIS (TE), THYMUS (TH), THYROID (TY), TONGUE (TO), TRACHEA (TR), URINARY BLADDER (UB)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
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APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 534

STUDY NUMBER: 483287

ANIMAL NUMBER: A37392 SEX: MALE DOSE GROUP: 1 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/11/91 STUDY DAY OF DEATH: 95 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 25.8 GRAMS
DATE AND TIME OF NECROPSY: 11/11/91 10:05 PROSECTOR: SCOTT BELL RECORDER: SCOTT BELL
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.24	.933 %	.503	WEIGHT TAKEN
LUNG (LU)	.16	.616 %	.332	WEIGHT TAKEN
PROSTATE (PR)	.062	.2399 %	.1295	WEIGHT TAKEN
BRAIN W/STEM (BR)	.48	1.853 %	1.000	WEIGHT TAKEN
HEART (HT)	.19	.720 %	.389	WEIGHT TAKEN
SPLEEN (SP)	.05	.201 %	.109	WEIGHT TAKEN
KIDNEY (KD)	.51	1.986 %	1.072	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	1.34	5.178 %	2.794	WEIGHT TAKEN
TESTIS (TE)	.20	.763 %	.412	WEIGHT TAKEN
EPIDIDYMIS (EP)	.10	.377 %	.203	WEIGHT TAKEN
ADRENAL (AD)	.006	.0248 %	.0134	WEIGHT TAKEN
THYMUS (TH)	.02	.072 %	.039	WEIGHT TAKEN

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE
OBSERVATIONS

PATHOLOGY OBSERVATIONS
NECROPSY

HISTOPATHOLOGY

ADRENAL, CORTEX (AC) :
-PIGMENT,-MINIMAL
EPIDIDYMIS (EP) :
-LUMEN, DEBRIS, CELLULAR,-PRESENT
LUNG (LU) :
-PERIBRONCHIAL/PERIVASCULAR,
INFILTRATION, LYMPHOID,-MINIMAL
-INFLAMMATION, CHRONIC,-MINIMAL
PARATHYROID (PT) :
-UNILATERALLY EXAMINED,-PRESENT
PROSTATE (PR) :
-INFLAMMATION, CHRONIC,-MINIMAL
SPLEEN (SP) :
-EXTRAMEDULLARY HEMATOPOIESIS,
INCREASED,-SLIGHT
-PIGMENT,-MINIMAL

^COLLECTED/TAKEN (XW) :
-LIVER SECTIONS, IN METHANOL

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APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 535

STUDY NUMBER: 483287

ANIMAL NUMBER: A37392 SEX: MALE DOSE GROUP: 1 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
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DATE AND TIME OF NECROPSY: 11/11/91 10:05 PROSECTOR: SCOTT BELL RECORDER: SCOTT BELL
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

P A T H O L O G Y O B S E R V A T I O N S (CONTINUED)
NECROPSY

CLINICAL OBSERVATIONS

HISTOPATHOLOGY

^DEATH COMMENT (DC) :
-SCHEDULED SACRIFICE, -PRESENT

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), EPIDIDYMIS (EP), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE),
KIDNEY (KD), LACRIMAL GL, EX (EO), LIVER (LI), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU),
MAND SALIVARY GL (SG), MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON),
NERVE, SCIATIC (SN), PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), PROSTATE (PR), RECTUM (RE), SKIN (SK),
SKIN, OTHER (SS), SPLEEN (SP), STOMACH, GL (ST), STOMACH, NONGL (SU), TESTIS (TE), THYMUS (TH), THYROID (TY),
TONGUE (TO), TRACHEA (TR), URINARY BLADDER (UB)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:

ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, STERNUM (SB), BRAIN W/STEM (BR), CECUM (CE),
COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC), DUODENUM (DU), ESOPHAGUS (ES), EYE (EY),
GALLBLADDER (GB), HARDERIAN GLAND (HG), HEART (HT), HEMATO NEOPLASIA (HN), ILEUM (IL), JEJUNUM (JE), KIDNEY (KD),
LACRIMAL GL, EX (EO), LIVER (LI), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), MAND SALIVARY GL (SG),
MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, ABDOM (MA), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON),
NERVE, SCIATIC (SN), PANCREAS (PA), PITUITARY (PI), RECTUM (RE), SALIVARY, OTHER (OS), SKIN (SK), STOMACH, GL (ST),
STOMACH, NONGL (SU), TESTIS (TE), THYMUS (TH), THYROID (TY), TONGUE (TO), TRACHEA (TR), URINARY BLADDER (UB)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 536

STUDY NUMBER: 483287

ANIMAL NUMBER: A37393 SEX: MALE DOSE GROUP: 1 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/11/91 STUDY DAY OF DEATH: 95 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 28.6 GRAMS
DATE AND TIME OF NECROPSY: 11/11/91 10:57 PROSECTOR: FRED AGEY RECORDER: FRED AGEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.27	.951 %	.578	WEIGHT TAKEN
LUNG (LU)	.19	.678 %	.412	WEIGHT TAKEN
PROSTATE (PR)	.087	.3049 %	.1854	WEIGHT TAKEN
BRAIN W/STEM (BR)	.47	1.645 %	1.000	WEIGHT TAKEN
HEART (HT)	.18	.634 %	.385	WEIGHT TAKEN
SPLEEN (SP)	.05	.173 %	.105	WEIGHT TAKEN
KIDNEY (KD)	.70	2.446 %	1.487	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	1.40	4.886 %	2.971	WEIGHT TAKEN
TESTIS (TE)	.22	.780 %	.474	WEIGHT TAKEN
EPIDIDYMIS (EP)	.18	.626 %	.380	WEIGHT TAKEN
ADRENAL (AD)	.010	.0353 %	.0215	WEIGHT TAKEN
THYMUS (TH)	.02	.069 %	.042	WEIGHT TAKEN

CLINICAL OBSERVATIONS	PATHOLOGY OBSERVATIONS NECROPSY	HISTOPATHOLOGY
-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS		ADRENAL, CORTEX (AC) : -PIGMENT, -MINIMAL -HYPERPLASIA, SUBCAPSULAR CELL, -MINIMAL CECUM (CE) : -HYPERPLASIA, LYMPHOID, -PRESENT EPIDIDYMIS (EP) : -LUMEN, DEBRIS, CELLULAR, -PRESENT KIDNEY (KD) : -INFLAMMATION, CHRONIC, -MINIMAL -TUBULE, REGENERATION, -MINIMAL LN, MANDIBULAR (MN) : -MACROPHAGES, PIGMENTED, -MINIMAL LN, MESENTERIC (MS) : -MACROPHAGES, PIGMENTED, -MINIMAL LUNG (LU) : -PERIBRONCHIAL/PERIVASCULAR, INFILTRATION, LYMPHOID, -MINIMAL

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE, (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 537

STUDY NUMBER: 483287

ANIMAL NUMBER: A37393 SEX: MALE DOSE GROUP: 1 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/11/91 STUDY DAY OF DEATH: 95 STUDY WEEK OF DEATH: 14. TERMINAL BODY WEIGHT: 28.6 GRAMS
DATE AND TIME OF NECROPSY: 11/11/91 10:57 PROSECTOR: FRED AGEY RECORDER: FRED AGEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

CLINICAL OBSERVATIONS

P A T H O L O G Y O B S E R V A T I O N S (CONTINUED)
NECROPSY

HISTOPATHOLOGY

PROSTATE (PR) :
-INFLAMMATION, CHRONIC, -MINIMAL
SPLEEN (SP) :
-EXTRAMEDULLARY HEMATOPOIESIS,
INCREASED, -SLIGHT
-PIGMENT, -MINIMAL
THYMUS (TH) :
-CYST, -PRESENT
-ECTOPIC THYROID, -PRESENT

^COLLECTED/TAKEN (XW) :
-LIVER SECTIONS, IN METHANOL

^DEATH COMMENT (DC) :
-SCHEDULED SACRIFICE, -PRESENT

HAZLETON WASHINGTON, INC.
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APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
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INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
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STUDY NUMBER: 483287

ANIMAL NUMBER: A37393 SEX: MALE DOSE GROUP: 1 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/11/91 STUDY DAY OF DEATH: 95 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 28.6 GRAMS
DATE AND TIME OF NECROPSY: 11/11/91 10:57 PROSECTOR: FRED AGEY RECORDER: FRED AGEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), EPIDIDYMIS (EP), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE),
KIDNEY (KD), LACRIMAL GL, EX (EO), LIVER (LI), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU),
MAND SALIVARY GL (SG), MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON),
NERVE, SCIATIC (SN), PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), PROSTATE (PR), RECTUM (RE), SKIN (SK),
SKIN, OTHER (SS), SPLEEN (SP), STOMACH, GL (ST), STOMACH, NONGL (SU), TESTIS (TE), THYMUS (TH), THYROID (TY),
TONGUE (TO), TRACHEA (TR), URINARY BLADDER (UB)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:

ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, STERNUM (SB), BRAIN W/STEM (BR), COLON (CO),
CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC), DUODENUM (DU), ESOPHAGUS (ES), EYE (EY),
GALLBLADDER (GB), HARDERIAN GLAND (HG), HEART (HT), HEMATO NEOPLASIA (HN), ILEUM (IL), JEJUNUM (JE),
LACRIMAL GL, EX (EO), LIVER (LI), MAND SALIVARY GL (SG), MARROW, FEMUR (FM), MARROW, STERNUM (SE),
MUSCLE, ABDOM (MA), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON), NERVE, SCIATIC (SN), PANCREAS (PA), PARATHYROID (PT),
PITUITARY (PI), RECTUM (RE), SALIVARY, OTHER (OS), SKIN (SK), STOMACH, GL (ST), STOMACH, NONGL (SU), TESTIS (TE),
THYROID (TY), TONGUE (TO), TRACHEA (TR), URINARY BLADDER (UB)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 539

STUDY NUMBER: 483287

ANIMAL NUMBER: A37394 SEX: MALE DOSE GROUP: 1 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/11/91 STUDY DAY OF DEATH: 95 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 26.8 GRAMS
DATE AND TIME OF NECROPSY: 11/11/91 13:11 PROSECTOR: FRED AGEY RECORDER: FRED AGEY
POST-FIX WEAHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEAHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.21	.797 %	.464	WEIGHT TAKEN
LUNG (LU)	.21	.768 %	.448	WEIGHT TAKEN
PROSTATE (PR)	.018	.0683 %	.0398	WEIGHT TAKEN
BRAIN W/STEM (BR)	.46	1.717 %	1.000	WEIGHT TAKEN
HEART (HT)	.17	.616 %	.359	WEIGHT TAKEN
SPLEEN (SP)	.05	.183 %	.106	WEIGHT TAKEN
KIDNEY (KD)	.54	2.021 %	1.177	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	1.24	4.629 %	2.697	WEIGHT TAKEN
TESTIS (TE)	.18	.668 %	.389	WEIGHT TAKEN
EPIDIDYMIS (EP)	.10	.386 %	.225	WEIGHT TAKEN
ADRENAL (AD)	.008	.0306 %	.0178	WEIGHT TAKEN
THYMUS (TH)	.03	.108 %	.063	WEIGHT TAKEN

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE
OBSERVATIONS

PATHOLOGY OBSERVATIONS
NECROPSY

HISTOPATHOLOGY

ADRENAL, CORTEX (AC) :
-PIGMENT,-MINIMAL
EPIDIDYMIS (EP) :
-LUMEN, DEBRIS, CELLULAR,-PRESENT
ILEUM (IL) :
-HYPERPLASIA, LYMPHOID,-PRESENT
KIDNEY (KD) :
-TUBULE, REGENERATION,-MINIMAL
PARATHYROID (PT) :
-UNILATERALLY EXAMINED,-PRESENT
PROSTATE (PR) :
>TISSUE MISSING
RECTUM (RE) :
-HYPERPLASIA, LYMPHOID,-PRESENT
SPLEEN (SP) :
-EXTRAMEDULLARY HEMATOPOIESIS,
INCREASED,-MODERATE
-PIGMENT,-MINIMAL

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 540

STUDY NUMBER: 483287

ANIMAL NUMBER: A37394 SEX: MALE DOSE GROUP: 1 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/11/91 STUDY DAY OF DEATH: 95 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 26.8 GRAMS
DATE AND TIME OF NECROPSY: 11/11/91 13:11 PROSECTOR: FRED AGEY RECORDER: FRED AGEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

P A T H O L O G Y O B S E R V A T I O N S (CONTINUED)
NECROPSY

CLINICAL OBSERVATIONS

HISTOPATHOLOGY

^COLLECTED/TAKEN (XW) :
-LIVER SECTIONS, IN METHANOL

THYMUS (TH) :
-CYST, -PRESENT

^DEATH COMMENT (DC) :
-SCHEDULED SACRIFICE, -PRESENT

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), EPIDIDYMIS (EP), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE),
KIDNEY (KD), LACRIMAL GL, EX (EO), LIVER (LI), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU),
MAND SALIVARY GL (SG), MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON),
NERVE, SCIATIC (SN), PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), PROSTATE (PR), RECTUM (RE), SKIN (SK),
SKIN, OTHER (SS), SPLEEN (SP), STOMACH, GL (ST), STOMACH, NONGL (SU), TESTIS (TE), THYMUS (TH), THYROID (TY),
TONGUE (TO), TRACHEA (TR), URINARY BLADDER (UB)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:

ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, STERNUM (SB), BRAIN W/STEM (BR), CECUM (CE),
COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC), DUODENUM (DU), ESOPHAGUS (ES), EYE (EY),
GALLBLADDER (GB), HARDERIAN GLAND (HG), HEART (HT), HEMATO NEOPLASIA (HN), JEJUNUM (JE), LACRIMAL GL, EX (EO),
LIVER (LI), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU), MAND SALIVARY GL (SG), MARROW, FEMUR (FM),
MARROW, STERNUM (SE), MUSCLE, ABDOM (MA), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON), NERVE, SCIATIC (SN),
PANCREAS (PA), PITUITARY (PI), SALIVARY, OTHER (OS), SKIN (SK), STOMACH, GL (ST), STOMACH, NONGL (SU), TESTIS (TE),
THYROID (TY), TONGUE (TO), TRACHEA (TR), URINARY BLADDER (UB)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 541

STUDY NUMBER: 483287

ANIMAL NUMBER: A37395 SEX: MALE DOSE GROUP: 1 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/12/91 STUDY DAY OF DEATH: 96 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 28.4 GRAMS
DATE AND TIME OF NECROPSY: 11/12/91 8:45 PROSECTOR: SCOTT BELL RECORDER: SCOTT BELL
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.25	.876 %	.502	WEIGHT TAKEN
LUNG (LU)	.18	.651 %	.373	WEIGHT TAKEN
PROSTATE (PR)	.051	.1806 %	.1036	WEIGHT TAKEN
BRAIN W/STEM (BR)	.50	1.743 %	1.000	WEIGHT TAKEN
HEART (HT)	.18	.641 %	.368	WEIGHT TAKEN
SPLEEN (SP)	.06	.224 %	.128	WEIGHT TAKEN
KIDNEY (KD)	.55	1.938 %	1.112	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	1.28	4.498 %	2.580	WEIGHT TAKEN
TESTIS (TE)	.20	.715 %	.410	WEIGHT TAKEN
EPIDIDYMIS (EP)	.09	.333 %	.191	WEIGHT TAKEN
ADRENAL (AD)	.004	.0151 %	.0087	WEIGHT TAKEN
THYMUS (TH)	.03	.097 %	.056	WEIGHT TAKEN

CLINICAL OBSERVATIONS	PATHOLOGY OBSERVATIONS NECROPSY	HISTOPATHOLOGY
-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS		ADRENAL, CORTEX (AC) : -HYPERPLASIA, SUBCAPSULAR CELL,-MINIMAL CECUM (CE) : -HYPERPLASIA, LYMPHOID,-PRESENT EPIDIDYMIS (EP) : -LUMEN, DEBRIS, CELLULAR,-PRESENT EYE (EY) : >UNREMARKABLE >NOTE:>ONE CORNEA EXAMINED. JEJUNUM (JE) : -HYPERPLASIA, LYMPHOID,-PRESENT LN, MESENTERIC (MS) : -HYPERPLASIA, LYMPHOID,-SLIGHT LUNG (LU) : -PERIBRONCHIAL/PERIVASCULAR, INFILTRATION, LYMPHOID,-MINIMAL NERVE, OPTIC (ON) : -UNILATERALLY EXAMINED,-PRESENT

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
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DATE OF DEATH: 11/12/91 STUDY DAY OF DEATH: 96 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 28.4 GRAMS
DATE AND TIME OF NECROPSY: 11/12/91 8:45 PROSECTOR: SCOTT BELL RECORDER: SCOTT BELL
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

CLINICAL OBSERVATIONS	P A T H O L O G Y O B S E R V A T I O N S (CONTINUED) NECROPSY	HISTOPATHOLOGY
		PROSTATE (PR) : -INFLAMMATION, CHRONIC, -MINIMAL RECTUM (RE) : -HYPERPLASIA, LYMPHOID, -PRESENT SPLEEN (SP) : -EXTRAMEDULLARY HEMATOPOIESIS, INCREASED, -MODERATE -PIGMENT, -MINIMAL
	^COLLECTED/TAKEN (XW) : -LIVER SECTIONS, IN METHANOL	
		^DEATH COMMENT (DC) : -SCHEDULED SACRIFICE, -PRESENT

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

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13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
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POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), EPIDIDYMIS (EP), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE),
KIDNEY (KD), LACRIMAL GL, EX (EO), LIVER (LI), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU),
MAND SALIVARY GL (SG), MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON),
NERVE, SCIATIC (SN), PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), PROSTATE (PR), RECTUM (RE), SKIN (SK),
SKIN, OTHER (SS), SPLEEN (SP), STOMACH, GL (ST), STOMACH, NONGL (SU), TESTIS (TE), THYMUS (TH), THYROID (TY),
TONGUE (TO), TRACHEA (TR), URINARY BLADDER (UB)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:

ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, STERNUM (SB), BRAIN W/STEM (BR), COLON (CO),
CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC), DUODENUM (DU), ESOPHAGUS (ES), GALLBLADDER (GB),
HARDERIAN GLAND (HG), HEART (HT), HEMATO NEOPLASIA (HN), ILEUM (IL), KIDNEY (KD), LACRIMAL GL, EX (EO), LIVER (LI),
LN, MANDIBULAR (MN), MAND SALIVARY GL (SG), MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, ABDOM (MA),
MUSCLE, SKELETAL (SM), NERVE, SCIATIC (SN), PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), SALIVARY, OTHER (OS),
SKIN (SK), STOMACH, GL (ST), STOMACH, NONGL (SU), TESTIS (TE), THYMUS (TH), THYROID (TY), TONGUE (TO), TRACHEA (TR),
URINARY BLADDER (UB)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
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APPENDIX 13B

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MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

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STUDY NUMBER: 483287

ANIMAL NUMBER: A37396 SEX: MALE DOSE GROUP: 1 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/12/91 STUDY DAY OF DEATH: 96 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 27.0 GRAMS
DATE AND TIME OF NECROPSY: 11/12/91 9:32 PROSECTOR: SONNY DIKES RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.17	.641 %	.367	WEIGHT TAKEN
LUNG (LU)	.17	.623 %	.356	WEIGHT TAKEN
PROSTATE (PR)	.039	.1463 %	.0837	WEIGHT TAKEN
BRAIN W/STEM (BR)	.47	1.749 %	1.000	WEIGHT TAKEN
HEART (HT)	.17	.619 %	.354	WEIGHT TAKEN
SPLEEN (SP)	.08	.286 %	.163	WEIGHT TAKEN
KIDNEY (KD)	.60	2.226 %	1.273	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	1.18	4.356 %	2.491	WEIGHT TAKEN
TESTIS (TE)	.26	.953 %	.545	WEIGHT TAKEN
EPIDIDYMIS (EP)	.13	.464 %	.266	WEIGHT TAKEN
ADRENAL (AD)	.009	.0319 %	.0182	WEIGHT TAKEN
THYMUS (TH)	.01	.051 %	.029	WEIGHT TAKEN

CLINICAL OBSERVATIONS

PATHOLOGY OBSERVATIONS
NECROPSY

HISTOPATHOLOGY

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE
OBSERVATIONS

ADRENAL, CORTEX (AC) :
-PIGMENT, -MINIMAL
-HYPERPLASIA, SUBCAPSULAR CELL, -MINIMAL
CECUM (CE) :
-HYPERPLASIA, LYMPHOID, -PRESENT
HARDERIAN GLAND (HG) :
-INFLAMMATION, CHRONIC, -PRESENT
KIDNEY (KD) :
-HYPERPLASIA, LYMPHOID, -MINIMAL
LACRIMAL GL, EX (EO) :
-INFLAMMATION, CHRONIC, -MINIMAL
LUNG (LU) :
-PERIBRONCHIAL/PERIVASCULAR,
INFILTRATION, LYMPHOID, -MINIMAL
MAND SALIVARY GL (SG) :
-INFLAMMATION, CHRONIC, -MINIMAL
NERVE, OPTIC (ON) :
-UNILATERALLY EXAMINED, -PRESENT

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 545

STUDY NUMBER: 483287

ANIMAL NUMBER: A37396 SEX: MALE DOSE GROUP: 1 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/12/91 STUDY DAY OF DEATH: 96 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 27.0 GRAMS
DATE AND TIME OF NECROPSY: 11/12/91 9:32 PROSECTOR: SONNY DIKES RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

P A T H O L O G Y O B S E R V A T I O N S (CONTINUED)
NECROPSY

CLINICAL OBSERVATIONS

HISTOPATHOLOGY

^COLLECTED/TAKEN (XW) :
-LIVER SECTIONS, IN METHANOL

PARATHYROID (PT) :
-UNILATERALLY EXAMINED, -PRESENT
SPLEEN (SP) :
-EXTRAMEDULLARY HEMATOPOIESIS,
INCREASED, -MINIMAL
-PIGMENT, -MINIMAL
URINARY BLADDER (UB) :
-INFLAMMATION, CHRONIC, -MINIMAL

^DEATH COMMENT (DC) :
-SCHEDULED SACRIFICE, -PRESENT

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
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STUDY NUMBER: 483287

ANIMAL NUMBER: A37396 SEX: MALE DOSE GROUP: 1 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/12/91 STUDY DAY OF DEATH: 96 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 27.0 GRAMS
DATE AND TIME OF NECROPSY: 11/12/91 9:32 PROSECTOR: SONNY DIKES RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), EPIDIDYMIS (EP), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE),
KIDNEY (KD), LACRIMAL GL, EX (EO), LIVER (LI), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU),
MAND SALIVARY GL (SG), MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON),
NERVE, SCIATIC (SN), PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), PROSTATE (PR), RECTUM (RE), SKIN (SK),
SKIN, OTHER (SS), SPLEEN (SP), STOMACH, GL (ST), STOMACH, NONGL (SU), TESTIS (TE), THYMUS (TH), THYROID (TY),
TONGUE (TO), TRACHEA (TR), URINARY BLADDER (UB)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:

ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, STERNUM (SB), BRAIN W/STEM (BR), COLON (CO),
CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC), DUODENUM (DU), EPIDIDYMIS (EP), ESOPHAGUS (ES),
EYE (EY), GALLBLADDER (GB), HEART (HT), HEMATO NEOPLASIA (HN), ILEUM (IL), JEJUNUM (JE), LIVER (LI),
LN, MANDIBULAR (MN), LN, MESENTERIC (MS), MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, ABDOM (MA),
MUSCLE, SKELETAL (SM), NERVE, SCIATIC (SN), PANCREAS (PA), PITUITARY (PI), PROSTATE (PR), RECTUM (RE),
SALIVARY, OTHER (OS), SKIN (SK), STOMACH, GL (ST), STOMACH, NONGL (SU), TESTIS (TE), THYMUS (TH), THYROID (TY),
TONGUE (TO), TRACHEA (TR)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 547

STUDY NUMBER: 483287

ANIMAL NUMBER: A37397 SEX: MALE DOSE GROUP: 1 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/12/91 STUDY DAY OF DEATH: 96 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 29.9 GRAMS
DATE AND TIME OF NECROPSY: 11/12/91 10:20 PROSECTOR: FRED AGEY RECORDER: FRED AGEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.24	.812 %	.547	WEIGHT TAKEN
LUNG (LU)	.19	.632 %	.426	WEIGHT TAKEN
PROSTATE (PR)	.082	.2759 %	.1859	WEIGHT TAKEN
BRAIN W/STEM (BR)	.44	1.484 %	1.000	WEIGHT TAKEN
HEART (HT)	.15	.494 %	.333	WEIGHT TAKEN
SPLEEN (SP)	.06	.199 %	.134	WEIGHT TAKEN
KIDNEY (KD)	.46	1.533 %	1.033	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	1.31	4.370 %	2.944	WEIGHT TAKEN
TESTIS (TE)	.27	.895 %	.603	WEIGHT TAKEN
EPIDIDYMIS (EP)	.11	.377 %	.254	WEIGHT TAKEN
ADRENAL (AD)	.010	.0318 %	.0214	WEIGHT TAKEN
THYMUS (TH)	.04	.129 %	.087	WEIGHT TAKEN

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE
OBSERVATIONS

PATHOLOGY OBSERVATIONS
NECROPSY

HISTOPATHOLOGY

ADRENAL, CORTEX (AC) :
-PIGMENT, -MINIMAL
HEART (HT) :
-INFLAMMATION, CHRONIC, -MINIMAL
KIDNEY (KD) :
-INFLAMMATION, CHRONIC, -MINIMAL
LACRIMAL GL, EX (EO) :
-INFLAMMATION, CHRONIC, -MINIMAL
LN, MANDIBULAR (MN) :
-MACROPHAGES, PIGMENTED, -MINIMAL
LUNG (LU) :
-PERIBRONCHIAL/PERIVASCULAR,
INFILTRATION, LYMPHOID, -MINIMAL
PARATHYROID (PT) :
-UNILATERALLY EXAMINED, -PRESENT
PROSTATE (PR) :
>TISSUE MISSING

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

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STUDY NUMBER: 483287

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DATE OF DEATH: 11/12/91 STUDY DAY OF DEATH: 96 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 29.9 GRAMS
DATE AND TIME OF NECROPSY: 11/12/91 10:20 PROSECTOR: FRED AGEY RECORDER: FRED AGEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

CLINICAL OBSERVATIONS

P A T H O L O G Y O B S E R V A T I O N S (CONTINUED)
NECROPSY

HISTOPATHOLOGY

SPLEEN (SP) :
-EXTRAMEDULLARY HEMATOPOIESIS,
INCREASED, -SLIGHT
-PIGMENT, -MINIMAL
URINARY BLADDER (UB) :
->TISSUE MISSING

^COLLECTED/TAKEN (XW) :
-LIVER SECTIONS, IN METHANOL

^DEATH COMMENT (DC) :
-SCHEDULED SACRIFICE, -PRESENT

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), EPIDIDYMIS (EP), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE),
KIDNEY (KD), LACRIMAL GL, EX (EO), LIVER (LI), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU),
MAND SALIVARY GL (SG), MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON),
NERVE, SCIATIC (SN), PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), PROSTATE (PR), RECTUM (RE), SKIN (SK),
SKIN, OTHER (SS), SPLEEN (SP), STOMACH, GL (ST), STOMACH, NONGL (SU), TESTIS (TE), THYMUS (TH), THYROID (TY),
TONGUE (TO), TRACHEA (TR), URINARY BLADDER (UB)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:

ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, STERNUM (SB), BRAIN W/STEM (BR), CECUM (CE),
COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC), DUODENUM (DU), EPIDIDYMIS (EP),
ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HARDERIAN GLAND (HG), HEMATO NEOPLASIA (HN), ILEUM (IL), JEJUNUM (JE),
LIVER (LI), LN, MESENTERIC (MS), MAND SALIVARY GL (SG), MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, ABDOM (MA),
MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON), NERVE, SCIATIC (SN), PANCREAS (PA), PITUITARY (PI), RECTUM (RE),
SALIVARY, OTHER (OS), SKIN (SK), STOMACH, GL (ST), STOMACH, NONGL (SU), TESTIS (TE), THYMUS (TH), THYROID (TY),
TONGUE (TO), TRACHEA (TR)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 549

STUDY NUMBER: 483287

ANIMAL NUMBER: A37398 SEX: MALE DOSE GROUP: 1 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/12/91 STUDY DAY OF DEATH: 96 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 26.4 GRAMS
DATE AND TIME OF NECROPSY: 11/12/91 12:51 PROSECTOR: DOUGLAS HERNDON RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.18	.664 %	.360	WEIGHT TAKEN
LUNG (LU)	.22	.814 %	.441	WEIGHT TAKEN
PROSTATE (PR)	.049	.1864 %	.1010	WEIGHT TAKEN
BRAIN W/STEM (BR)	.49	1.845 %	1.000	WEIGHT TAKEN
HEART (HT)	.13	.506 %	.274	WEIGHT TAKEN
SPLEEN (SP)	.06	.215 %	.117	WEIGHT TAKEN
KIDNEY (KD)	.47	1.798 %	.975	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	1.16	4.380 %	2.374	WEIGHT TAKEN
TESTIS (TE)	.24	.901 %	.488	WEIGHT TAKEN
EPIDIDYMIS (EP)	.11	.405 %	.220	WEIGHT TAKEN
ADRENAL (AD)	.014	.0534 %	.0290	WEIGHT TAKEN
THYMUS (TH)	.03	.098 %	.053	WEIGHT TAKEN

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE
OBSERVATIONS

PATHOLOGY OBSERVATIONS
NECROPSY

HISTOPATHOLOGY

DUODENUM (DU) :
-TISSUE MISSING
ILEUM (IL) :
-AMYLOIDOSIS,-SLIGHT
KIDNEY (KD) :
-INFLAMMATION, CHRONIC,-MINIMAL
-HYPERPLASIA, LYMPHOID,-MINIMAL
LUNG (LU) :
-PERIBRONCHIAL/PERIVASCULAR,
INFILTRATION, LYMPHOID,-MINIMAL
PARATHYROID (PT) :
-UNILATERALLY EXAMINED,-PRESENT
PITUITARY (PI) :
-CYST,-PRESENT
SPLEEN (SP) :
-EXTRAMEDULLARY HEMATOPOIESIS,
INCREASED,-SLIGHT
-PIGMENT,-MINIMAL

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 550

STUDY NUMBER: 483287

ANIMAL NUMBER: A37398 SEX: MALE DOSE GROUP: 1 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/12/91 STUDY DAY OF DEATH: 96 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 26.4 GRAMS
DATE AND TIME OF NECROPSY: 11/12/91 12:51 PROSECTOR: DOUGLAS HERNDON RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

CLINICAL OBSERVATIONS P A T H O L O G Y O B S E R V A T I O N S (CONTINUED)
NECROPSY HISTOPATHOLOGY

^COLLECTED/TAKEN (XW) :
-LIVER SECTIONS, IN METHANOL

STOMACH, GL (ST) :
>TISSUE MISSING
STOMACH, NONGL (SU) :
>TISSUE MISSING

^DEATH COMMENT (DC) :
-SCHEDULED SACRIFICE, -PRESENT

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), EPIDIDYMIS (EP), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE),
KIDNEY (KD), LACRIMAL GL, EX (EO), LIVER (LI), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU),
MAND SALIVARY GL (SG), MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON),
NERVE, SCIATIC (SN), PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), PROSTATE (PR), RECTUM (RE), SKIN (SK),
SKIN, OTHER (SS), SPLEEN (SP), STOMACH, GL (ST), STOMACH, NONGL (SU), TESTIS (TE), THYMUS (TH), THYROID (TY),
TONGUE (TO), TRACHEA (TR), URINARY BLADDER (UB)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, STERNUM (SB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
EPIDIDYMIS (EP), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HARDERIAN GLAND (HG), HEART (HT), HEMATO NEOPLASIA (HN),
JEJUNUM (JE), LACRIMAL GL, EX (EO), LIVER (LI), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), MAND SALIVARY GL (SG),
MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, ABDOM (MA), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON),
NERVE, SCIATIC (SN), PANCREAS (PA), PROSTATE (PR), RECTUM (RE), SALIVARY, OTHER (OS), SKIN (SK), TESTIS (TE),
THYMUS (TH), THYROID (TY), TONGUE (TO), TRACHEA (TR), URINARY BLADDER (UB)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 551

STUDY NUMBER: 483287

ANIMAL NUMBER: A37399 SEX: MALE DOSE GROUP: 1 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/13/91 STUDY DAY OF DEATH: 97 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 26.6 GRAMS
DATE AND TIME OF NECROPSY: 11/13/91 8:27 PROSECTOR: LINDA RUMBLE RECORDER: LINDA RUMBLE
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.23	.879 %	.482	WEIGHT TAKEN
LUNG (LU)	.20	.763 %	.418	WEIGHT TAKEN
PROSTATE (PR)	.040	.1504 %	.0825	WEIGHT TAKEN
BRAIN W/STEM (BR)	.49	1.824 %	1.000	WEIGHT TAKEN
HEART (HT)	.19	.730 %	.400	WEIGHT TAKEN
SPLEEN (SP)	.06	.241 %	.132	WEIGHT TAKEN
KIDNEY (KD)	.53	2.000 %	1.097	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	1.27	4.779 %	2.620	WEIGHT TAKEN
TESTIS (TE)	.18	.683 %	.374	WEIGHT TAKEN
EPIDIDYMIS (EP)	.13	.485 %	.266	WEIGHT TAKEN
ADRENAL (AD)	.009	.0350 %	.0192	WEIGHT TAKEN
THYMUS (TH)	.05	.175 %	.096	WEIGHT TAKEN

CLINICAL OBSERVATIONS	PATHOLOGY OBSERVATIONS NECROPSY	HISTOPATHOLOGY
-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS		CECUM (CE) : -HYPERPLASIA, LYMPHOID,-PRESENT EPIDIDYMIS (EP) : -LUMEN, DEBRIS, CELLULAR,-PRESENT EYE (EY) : >UNREMARKABLE >NOTE:>ONE LENS EXAMINED. HEART (HT) : -INFLAMMATION, CHRONIC,-MINIMAL KIDNEY (KD) : -HYPERPLASIA, LYMPHOID,-MINIMAL LIVER (LI) : -HEPATOCYTE, HYPERTROPHY, CENTROLOBULAR,-SLIGHT -INFLAMMATION, CHRONIC/CHRONIC ACTIVE,- MINIMAL LN, MANDIBULAR (MN) : >TISSUE MISSING

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
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POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

CLINICAL OBSERVATIONS P A T H O L O G Y O B S E R V A T I O N S (CONTINUED)
NECROPSY HISTOPATHOLOGY

LN, OTHER (LN) :
-MACROPHAGES, PIGMENTED, -PRESENT
LUNG (LU) :
-VESSEL, MINERALIZATION, -MINIMAL
MAND SALIVARY GL (SG) :
-INFLAMMATION, CHRONIC, -MINIMAL
NERVE, OPTIC (ON) :
-UNILATERALLY EXAMINED, -PRESENT
PARATHYROID (PT) :
-UNILATERALLY EXAMINED, -PRESENT
RECTUM (RE) :
-HYPERPLASIA, LYMPHOID, -PRESENT
SPLEEN (SP) :
-EXTRAMEDULLARY HEMATOPOIESIS,
INCREASED, -SLIGHT
-PIGMENT, -MINIMAL

^COLLECTED/TAKEN (XW) :
-LIVER SECTIONS, IN METHANOL

^DEATH COMMENT (DC) :
-SCHEDULED SACRIFICE, -PRESENT

APPENDIX 13B

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
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DATE AND TIME OF NECROPSY: 11/13/91 8:27 PROSECTOR: LINDA RUMBLE RECORDER: LINDA RUMBLE
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), EPIDIDYMIS (EP), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE),
KIDNEY (KD), LACRIMAL GL, EX (EO), LIVER (LI), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU),
MAND SALIVARY GL (SG), MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON),
NERVE, SCIATIC (SN), PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), PROSTATE (PR), RECTUM (RE), SKIN (SK),
SKIN, OTHER (SS), SPLEEN (SP), STOMACH, GL (ST), STOMACH, NONGL (SU), TESTIS (TE), THYMUS (TH), THYROID (TY),
TONGUE (TO), TRACHEA (TR), URINARY BLADDER (UB)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, STERNUM (SB),
BRAIN W/STEM (BR), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC), DUODENUM (DU),
ESOPHAGUS (ES), GALLBLADDER (GB), HARDERIAN GLAND (HG), HEMATO NEOPLASIA (HN), ILEUM (IL), JEJUNUM (JE),
LACRIMAL GL, EX (EO), LN, MESENTERIC (MS), MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, ABDOM (MA),
MUSCLE, SKELETAL (SM), NERVE, SCIATIC (SN), PANCREAS (PA), PITUITARY (PI), PROSTATE (PR), SALIVARY, OTHER (OS),
SKIN (SK), STOMACH, GL (ST), STOMACH, NONGL (SU), TESTIS (TE), THYMUS (TH), THYROID (TY), TONGUE (TO), TRACHEA (TR),
URINARY BLADDER (UB)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 554

STUDY NUMBER: 483287

ANIMAL NUMBER: A37400 SEX: MALE DOSE GROUP: 1 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/13/91 STUDY DAY OF DEATH: 97 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 25.7 GRAMS
DATE AND TIME OF NECROPSY: 11/13/91 9:25 PROSECTOR: SCOTT BELL RECORDER: SCOTT BELL
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.20	.777 %	.424	WEIGHT TAKEN
LUNG (LU)	.19	.736 %	.402	WEIGHT TAKEN
PROSTATE (PR)	.057	.2222 %	.1212	WEIGHT TAKEN
BRAIN W/STEM (BR)	.47	1.833 %	1.000	WEIGHT TAKEN
HEART (HT)	.16	.628 %	.343	WEIGHT TAKEN
SPLEEN (SP)	.07	.269 %	.147	WEIGHT TAKEN
KIDNEY (KD)	.41	1.593 %	.869	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	1.11	4.313 %	2.353	WEIGHT TAKEN
TESTIS (TE)	.23	.902 %	.492	WEIGHT TAKEN
EPIDIDYMIS (EP)	.10	.404 %	.220	WEIGHT TAKEN
ADRENAL (AD)	.008	.0296 %	.0161	WEIGHT TAKEN
THYMUS (TH)	.02	.075 %	.041	WEIGHT TAKEN

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE
OBSERVATIONS

PATHOLOGY OBSERVATIONS
NECROPSY

HISTOPATHOLOGY

ADRENAL, CORTEX (AC) :
-PIGMENT, -MINIMAL
CECUM (CE) :
-HYPERPLASIA, LYMPHOID, -PRESENT
JEJUNUM (JE) :
-HYPERPLASIA, LYMPHOID, -PRESENT
LACRIMAL GL, EX (EO) :
-INFLAMMATION, CHRONIC, -MINIMAL
LN, MANDIBULAR (MN) :
-MACROPHAGES, PIGMENTED, -MINIMAL
LUNG (LU) :
-PERIBRONCHIAL/PERIVASCULAR,
INFILTRATION, LYMPHOID, -MINIMAL
NERVE, OPTIC (ON) :
-UNILATERALLY EXAMINED, -PRESENT
RECTUM (RE) :
-HYPERPLASIA, LYMPHOID, -PRESENT

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 555

STUDY NUMBER: 483287

ANIMAL NUMBER: A37400 SEX: MALE DOSE GROUP: 1 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/13/91 STUDY DAY OF DEATH: 97 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 25.7 GRAMS
DATE AND TIME OF NECROPSY: 11/13/91 9:25 PROSECTOR: SCOTT BELL RECORDER: SCOTT BELL
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

CLINICAL OBSERVATIONS P A T H O L O G Y O B S E R V A T I O N S (CONTINUED)
NECROPSY HISTOPATHOLOGY

^COLLECTED/TAKEN (XW) :
-LIVER SECTIONS, IN METHANOL

SPLEEN (SP) :
-EXTRAMEDULLARY HEMATOPOIESIS,
INCREASED, -SLIGHT
-PIGMENT, -MINIMAL

^DEATH COMMENT (DC) :
-SCHEDULED SACRIFICE, -PRESENT

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), EPIDIDYMIS (EP), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE),
KIDNEY (KD), LACRIMAL GL, EX (EO), LIVER (LI), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU),
MAND SALIVARY GL (SG), MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON),
NERVE, SCIATIC (SN), PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), PROSTATE (PR), RECTUM (RE), SKIN (SK),
SKIN, OTHER (SS), SPLEEN (SP), STOMACH, GL (ST), STOMACH, NONGL (SU), TESTIS (TE), THYMUS (TH), THYROID (TY),
TONGUE (TO), TRACHEA (TR), URINARY BLADDER (UB)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:

ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, STERNUM (SB), BRAIN W/STEM (BR), COLON (CO),
CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC), DUODENUM (DU), EPIDIDYMIS (EP), ESOPHAGUS (ES),
EYE (EY), GALLBLADDER (GB), HARDERIAN GLAND (HG), HEART (HT), HEMATO NEOPLASIA (HN), ILEUM (IL), KIDNEY (KD),
LIVER (LI), LN, MESENTERIC (MS), MAND SALIVARY GL (SG), MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, ABDOM (MA),
MUSCLE, SKELETAL (SM), NERVE, SCIATIC (SN), PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), PROSTATE (PR),
SALIVARY, OTHER (OS), SKIN (SK), STOMACH, GL (ST), STOMACH, NONGL (SU), TESTIS (TE), THYMUS (TH), THYROID (TY),
TONGUE (TO), TRACHEA (TR), URINARY BLADDER (UB)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 556

STUDY NUMBER: 483287

ANIMAL NUMBER: A37401 SEX: MALE DOSE GROUP: 1 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/13/91 STUDY DAY OF DEATH: 97 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 28.7 GRAMS
DATE AND TIME OF NECROPSY: 11/13/91 10:50 PROSECTOR: LINDA RUMBLE RECORDER: LINDA RUMBLE
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.16	.551 %	.346	WEIGHT TAKEN
LUNG (LU)	.19	.660 %	.415	WEIGHT TAKEN
PROSTATE (PR)	.042	.1449 %	.0910	WEIGHT TAKEN
BRAIN W/STEM (BR)	.46	1.592 %	1.000	WEIGHT TAKEN
HEART (HT)	.18	.620 %	.389	WEIGHT TAKEN
SPLEEN (SP)	.08	.275 %	.173	WEIGHT TAKEN
KIDNEY (KD)	.44	1.529 %	.960	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	1.21	4.213 %	2.646	WEIGHT TAKEN
TESTIS (TE)	.30	1.033 %	.649	WEIGHT TAKEN
EPIDIDYMIS (EP)	.13	.444 %	.279	WEIGHT TAKEN
ADRENAL (AD)	.011	.0397 %	.0250	WEIGHT TAKEN
THYMUS (TH)	.03	.111 %	.070	WEIGHT TAKEN

CLINICAL OBSERVATIONS	PATHOLOGY OBSERVATIONS NECROPSY	HISTOPATHOLOGY
-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS		ADRENAL, CORTEX (AC) : -PIGMENT,-MINIMAL CECUM (CE) : -HYPERPLASIA, LYMPHOID,-PRESENT ESOPHAGUS (ES) : -INFLAMMATION, CHRONIC,-MINIMAL KIDNEY (KD) : -INFLAMMATION, CHRONIC,-MINIMAL -TUBULE, REGENERATION,-MINIMAL -HYPERPLASIA, LYMPHOID,-MINIMAL LACRIMAL GL, EX (EO) : -INFLAMMATION, CHRONIC,-MINIMAL LIVER (LI) : -HEPATOCYTE, HYPERTROPHY, CENTROLOBULAR,-MINIMAL PANCREAS (PA) : -INFLAMMATION, CHRONIC,-MINIMAL

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 557

STUDY NUMBER: 483287

ANIMAL NUMBER: A37401 SEX: MALE DOSE GROUP: 1 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/13/91 STUDY DAY OF DEATH: 97 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 28.7 GRAMS
DATE AND TIME OF NECROPSY: 11/13/91 10:50 PROSECTOR: LINDA RUMBLE RECORDER: LINDA RUMBLE
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

CLINICAL OBSERVATIONS P A T H O L O G Y O B S E R V A T I O N S (CONTINUED)
NECROPSY HISTOPATHOLOGY

^COLLECTED/TAKEN (XW) :
-LIVER SECTIONS, IN METHANOL

PARATHYROID (PT) :
-UNILATERALLY EXAMINED, -PRESENT
PROSTATE (PR) :
-INFLAMMATION, CHRONIC, -MINIMAL
SPLEEN (SP) :
-EXTRAMEDULLARY HEMATOPOIESIS,
INCREASED, -MINIMAL
-PIGMENT, -MINIMAL

^DEATH COMMENT (DC) :
-SCHEDULED SACRIFICE, -PRESENT

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 558

STUDY NUMBER: 483287

ANIMAL NUMBER: A37401 SEX: MALE DOSE GROUP: 1 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/13/91 STUDY DAY OF DEATH: 97 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 28.7 GRAMS
DATE AND TIME OF NECROPSY: 11/13/91 10:50 PROSECTOR: LINDA RUMBLE RECORDER: LINDA RUMBLE
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), EPIDIDYMIS (EP), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE),
KIDNEY (KD), LACRIMAL GL, EX (EO), LIVER (LI), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU),
MAND SALIVARY GL (SG), MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON),
NERVE, SCIATIC (SN), PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), PROSTATE (PR), RECTUM (RE), SKIN (SK),
SKIN, OTHER (SS), SPLEEN (SP), STOMACH, GL (ST), STOMACH, NONGL (SU), TESTIS (TE), THYMUS (TH), THYROID (TY),
TONGUE (TO), TRACHEA (TR), URINARY BLADDER (UB)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:

ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, STERNUM (SB), BRAIN W/STEM (BR), COLON (CO),
CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC), DUODENUM (DU), EPIDIDYMIS (EP), EYE (EY),
GALLBLADDER (GB), HARDERIAN GLAND (HG), HEART (HT), HEMATO NEOPLASIA (HN), ILEUM (IL), JEJUNUM (JE),
LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU), MAND SALIVARY GL (SG), MARROW, FEMUR (FM), MARROW, STERNUM (SE),
MUSCLE, ABDOM (MA), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON), NERVE, SCIATIC (SN), PITUITARY (PI), RECTUM (RE),
SALIVARY, OTHER (OS), SKIN (SK), STOMACH, GL (ST), STOMACH, NONGL (SU), TESTIS (TE), THYMUS (TH), THYROID (TY),
TONGUE (TO), TRACHEA (TR), URINARY BLADDER (UB)

*** ALL ORGANS/ISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 559

STUDY NUMBER: 483287

ANIMAL NUMBER: A37402 SEX: MALE DOSE GROUP: 1 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/13/91 STUDY DAY OF DEATH: 97 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 27.2 GRAMS
DATE AND TIME OF NECROPSY: 11/13/91 11:31 PROSECTOR: SCOTT BELL RECORDER: SCOTT BELL
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.24	.886 %	.484	WEIGHT TAKEN
LUNG (LU)	.21	.764 %	.417	WEIGHT TAKEN
PROSTATE (PR)	.069	.2548 %	.1391	WEIGHT TAKEN
BRAIN W/STEM (BR)	.50	1.832 %	1.000	WEIGHT TAKEN
HEART (HT)	.16	.570 %	.311	WEIGHT TAKEN
SPLEEN (SP)	.05	.182 %	.100	WEIGHT TAKEN
KIDNEY (KD)	.48	1.780 %	.972	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	1.20	4.414 %	2.409	WEIGHT TAKEN
TESTIS (TE)	.26	.957 %	.522	WEIGHT TAKEN
EPIDIDYMISS (EP)	.09	.328 %	.179	WEIGHT TAKEN
ADRENAL (AD)	.008	.0309 %	.0169	WEIGHT TAKEN
THYMUS (TH)	.03	.126 %	.069	WEIGHT TAKEN

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE
OBSERVATIONS

PATHOLOGY OBSERVATIONS
NECROPSY

HISTOPATHOLOGY

ADRENAL, CORTEX (AC) :
-PIGMENT, -MINIMAL
-UNILATERALLY EXAMINED, -PRESENT
ADRENAL, MEDULLA (AM) :
-UNILATERALLY EXAMINED, -PRESENT
CECUM (CE) :
-HYPERPLASIA, LYMPHOID, -PRESENT
KIDNEY (KD) :
-INFLAMMATION, CHRONIC, -MINIMAL
-TUBULE, REGENERATION, -MINIMAL
-PIGMENT, -MINIMAL
LACRIMAL GL, EX (EO) :
-INFLAMMATION, CHRONIC, -MINIMAL
LIVER (LI) :
-HEPATOCYTE, HYPERTROPHY,
CENTROLOBULAR, -MINIMAL
LN, MANDIBULAR (MN) :
*TISSUE MISSING

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 560

STUDY NUMBER: 483287

ANIMAL NUMBER: A37402 SEX: MALE DOSE GROUP: 1 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
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DATE AND TIME OF NECROPSY: 11/13/91 11:31 PROSECTOR: SCOTT BELL RECORDER: SCOTT BELL
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

CLINICAL OBSERVATIONS	P A T H O L O G Y O B S E R V A T I O N S (CONTINUED) NECROPSY	HISTOPATHOLOGY
		LN, MESENTERIC (MS) : -HYPERPLASIA, LYMPHOID, -SLIGHT LN, OTHER (LN) : UNREMARKABLE NOTE: PANCREATIC. LUNG (LU) : -HEMORRHAGE, -MINIMAL RECTUM (RE) : -HYPERPLASIA, LYMPHOID, -PRESENT SPLEEN (SP) : -PIGMENT, -MINIMAL STOMACH, GL (ST) : -INFLAMMATION, CHRONIC, -MINIMAL THYMUS (TH) : -CYST, -PRESENT URINARY BLADDER (UB) : -INFLAMMATION, CHRONIC, -MINIMAL
	^COLLECTED/TAKEN (XW) : -LIVER SECTIONS, IN METHANOL	^DEATH COMMENT (DC) : -SCHEDULED SACRIFICE, -PRESENT

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

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PAGE: 561

STUDY NUMBER: 483287

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DATE AND TIME OF NECROPSY: 11/13/91 11:31 PROSECTOR: SCOTT BELL RECORDER: SCOTT BELL
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), EPIDIDYMIS (EP), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE),
KIDNEY (KD), LACRIMAL GL, EX (EO), LIVER (LI), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU),
MAND SALIVARY GL (SG), MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON),
NERVE, SCIATIC (SN), PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), PROSTATE (PR), RECTUM (RE), SKIN (SK),
SKIN, OTHER (SS), SPLEEN (SP), STOMACH, GL (ST), STOMACH, NONGL (SU), TESTIS (TE), THYMUS (TH), THYROID (TY),
TONGUE (TO), TRACHEA (TR), URINARY BLADDER (UB)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:

AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, STERNUM (SB), BRAIN W/STEM (BR), COLON (CO), CORD, CERVICAL (CS),
CORD, LUMBAR (LC), CORD, THORACIC (TC), DUODENUM (DU), EPIDIDYMIS (EP), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB),
HARDERIAN GLAND (HG), HEART (HT), HEMATO NEOPLASIA (HN), ILEUM (IL), JEJUNUM (JE), MAND SALIVARY GL (SG),
MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, ABDOM (MA), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON),
NERVE, SCIATIC (SN), PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), PROSTATE (PR), SALIVARY, OTHER (OS), SKIN (SK),
STOMACH, NONGL (SU), TESTIS (TE), THYROID (TY), TONGUE (TO), TRACHEA (TR)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 562

STUDY NUMBER: 483287

ANIMAL NUMBER: A37403 SEX: MALE DOSE GROUP: 1 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/14/91 STUDY DAY OF DEATH: 98 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 27.0 GRAMS
DATE AND TIME OF NECROPSY: 11/14/91 7:50 PROSECTOR: SCOTT BELL RECORDER: SCOTT BELL
POST-FIX WEAHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEAHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.25	.910 %	.521	WEIGHT TAKEN
LUNG (LU)	.20	.742 %	.425	WEIGHT TAKEN
PROSTATE (PR)	.062	.2285 %	.1308	WEIGHT TAKEN
BRAIN W/STEM (BR)	.47	1.747 %	1.000	WEIGHT TAKEN
HEART (HT)	.16	.593 %	.340	WEIGHT TAKEN
SPLEEN (SP)	.05	.180 %	.103	WEIGHT TAKEN
KIDNEY (KD)	.51	1.905 %	1.091	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	1.28	4.747 %	2.717	WEIGHT TAKEN
TESTIS (TE)	.22	.828 %	.474	WEIGHT TAKEN
EPIDIDYMIS (EP)	.11	.406 %	.232	WEIGHT TAKEN
ADRENAL (AD)	.006	.0226 %	.0129	WEIGHT TAKEN
THYMUS (TH)	.03	.102 %	.059	WEIGHT TAKEN

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE
OBSERVATIONS

PATHOLOGY OBSERVATIONS
NECROPSY

HISTOPATHOLOGY

ADRENAL, CORTEX (AC) :
-PIGMENT,-SLIGHT
CECUM (CE) :
-HYPERPLASIA, LYMPHOID,-PRESENT
HEART (HT) :
-INFLAMMATION, CHRONIC,-MINIMAL
KIDNEY (KD) :
-INFLAMMATION, CHRONIC,-MINIMAL
-INFLAMMATION, GRANULOMATOUS,-MINIMAL,
FOCAL
LN, MESENTERIC (MS) :
-MACROPHAGES, PIGMENTED,-MINIMAL
LUNG (LU) :
-PERIBRONCHIAL/PERIVASCULAR,
INFILTRATION, LYMPHOID,-MINIMAL
NERVE, OPTIC (ON) :
-UNILATERALLY EXAMINED,-PRESENT

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 563

STUDY NUMBER: 483287

ANIMAL NUMBER: A37403 SEX: MALE DOSE GROUP: 1 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/14/91 STUDY DAY OF DEATH: 98 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 27.0 GRAMS
DATE AND TIME OF NECROPSY: 11/14/91 7:50 PROSECTOR: SCOTT BELL RECORDER: SCOTT BELL
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

CLINICAL OBSERVATIONS	PATHOLOGY OBSERVATIONS (CONTINUED) NECROPSY	HISTOPATHOLOGY
		RECTUM (RE) : -HYPERPLASIA, LYMPHOID, -PRESENT SPLEEN (SP) : -EXTRAMEDULLARY HEMATOPOIESIS, INCREASED, -MINIMAL -PIGMENT, -MINIMAL STOMACH, GL (ST) : -INFLAMMATION, CHRONIC, -MINIMAL
	^COLLECTED/TAKEN (XW) : -LIVER SECTIONS, IN METHANOL	^DEATH COMMENT (DC) : -SCHEDULED SACRIFICE, -PRESENT

APPENDIX 13B

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 564

STUDY NUMBER: 483287

ANIMAL NUMBER: A37403 SEX: MALE DOSE GROUP: 1 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/14/91 STUDY DAY OF DEATH: 98 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 27.0 GRAMS
DATE AND TIME OF NECROPSY: 11/14/91 7:50 PROSECTOR: SCOTT BELL RECORDER: SCOTT BELL
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), EPIDIDYMIS (EP), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE),
KIDNEY (KD), LACRIMAL GL, EX (EO), LIVER (LI), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU),
MAND SALIVARY GL (SG), MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON),
NERVE, SCIATIC (SN), PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), PROSTATE (PR), RECTUM (RE), SKIN (SK),
SKIN, OTHER (SS), SPLEEN (SP), STOMACH, GL (ST), STOMACH, NONGL (SU), TESTIS (TE), THYMUS (TH), THYROID (TY),
TONGUE (TO), TRACHEA (TR), URINARY BLADDER (UB)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:

ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, STERNUM (SB), BRAIN W/STEM (BR), COLON (CO),
CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC), DUODENUM (DU), EPIDIDYMIS (EP), ESOPHAGUS (ES),
EYE (EY), GALLBLADDER (GB), HARDERIAN GLAND (HG), HEMATO NEOPLASIA (HN), ILEUM (IL), JEJUNUM (JE), LACRIMAL GL, EX (EO),
LIVER (LI), LN, MANDIBULAR (MN), MAND SALIVARY GL (SG), MARROW, FEMUR (FM), MARROW, STERNUM (SE),
MUSCLE, ABDOM (MA), MUSCLE, SKELETAL (SM), NERVE, SCIATIC (SN), PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI),
PROSTATE (PR), SALIVARY, OTHER (OS), SKIN (SK), STOMACH, NONGL (SU), TESTIS (TE), THYMUS (TH), THYROID (TY),
TONGUE (TO), TRACHEA (TR), URINARY BLADDER (UB)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 565

STUDY NUMBER: 483287

ANIMAL NUMBER: A37404 SEX: MALE DOSE GROUP: 1 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/14/91 STUDY DAY OF DEATH: 98 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 24.1 GRAMS
DATE AND TIME OF NECROPSY: 11/14/91 8:45 PROSECTOR: SONNY DIKES RECORDER: SONNY DIKES
POST-FIX WEAHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEAHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.28	1.145 %	.582	WEIGHT TAKEN
LUNG (LU)	.17	.692 %	.352	WEIGHT TAKEN
PROSTATE (PR)	.056	.2315 %	.1177	WEIGHT TAKEN
BRAIN W/STEM (BR)	.47	1.968 %	1.000	WEIGHT TAKEN
HEART (HT)	.16	.649 %	.330	WEIGHT TAKEN
SPLEEN (SP)	.07	.300 %	.152	WEIGHT TAKEN
KIDNEY (KD)	.56	2.308 %	1.173	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	1.56	6.471 %	3.289	WEIGHT TAKEN
TESTIS (TE)	.22	.910 %	.462	WEIGHT TAKEN
EPIDIDYMIS (EP)	.10	.406 %	.206	WEIGHT TAKEN
ADRENAL (AD)	.012	.0485 %	.0247	WEIGHT TAKEN
THYMUS (TH)	.03	.133 %	.067	WEIGHT TAKEN

CLINICAL OBSERVATIONS	PATHOLOGY OBSERVATIONS NECROPSY	HISTOPATHOLOGY
-LAST PHYSICAL EXAM:RIGHT EAR-SORES		ADRENAL, CORTEX (AC) : -PIGMENT,-MINIMAL CECUM (CE) : -HYPERPLASIA, LYMPHOID,-PRESENT KIDNEY (KD) : -INFLAMMATION, CHRONIC,-MINIMAL -TUBULE, REGENERATION,-MINIMAL LUNG (LU) : -PERIBRONCHIAL/PERIVASCULAR, INFILTRATION, LYMPHOID,-MINIMAL MAND SALIVARY GL (SG) : -INFLAMMATION, CHRONIC,-MINIMAL NERVE, OPTIC (ON) : -UNILATERALLY EXAMINED,-PRESENT PARATHYROID (PT) : >SECTION EXAMINED; TISSUE NOT PRESENT RECTUM (RE) : -HYPERPLASIA, LYMPHOID,-PRESENT

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 566

STUDY NUMBER: 483287

ANIMAL NUMBER: A37404 SEX: MALE DOSE GROUP: 1 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/14/91 STUDY DAY OF DEATH: 98 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 24.1 GRAMS
DATE AND TIME OF NECROPSY: 11/14/91 8:45 PROSECTOR: SONNY DIKES RECORDER: SONNY DIKES
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

CLINICAL OBSERVATIONS

P A T H O L O G Y O B S E R V A T I O N S (CONTINUED)
NECROPSY

HISTOPATHOLOGY

SKIN, OTHER (SS) :
-EAR, SORE; RIGHT, FEW, CRUSTY, RED,
PINPOINT TO 3 X 3 MM

SKIN, OTHER (SS) :
-DERMATITIS, ULCERATIVE, -PRESENT

SPLEEN (SP) :
-EXTRAMEDULLARY HEMATOPOIESIS,
INCREASED, -MINIMAL
-PIGMENT, -MINIMAL

STOMACH, GL (ST) :
-INFLAMMATION, CHRONIC, -MINIMAL

^COLLECTED/TAKEN (XW) :
-LIVER SECTIONS, IN METHANOL

^DEATH COMMENT (DC) :
-SCHEDULED SACRIFICE, -PRESENT

APPENDIX 13B

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORTPRINTED: 21-JAN-93
PAGE: 567

STUDY NUMBER: 483287

ANIMAL NUMBER: A37404 SEX: MALE DOSE GROUP: 1 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/14/91 STUDY DAY OF DEATH: 98 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 24.1 GRAMS
DATE AND TIME OF NECROPSY: 11/14/91 8:45 PROSECTOR: SONNY DIKES RECORDER: SONNY DIKES
POST-FIX WEAHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEAHER: RICHARD KAGYARE

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), EPIDIDYMIS (EP), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE),
KIDNEY (KD), LACRIMAL GL, EX (EO), LIVER (LI), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU),
MAND SALIVARY GL (SG), MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON),
NERVE, SCIATIC (SN), PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), PROSTATE (PR), RECTUM (RE), SKIN (SK),
SPLEEN (SP), STOMACH, GL (ST), STOMACH, NONGL (SU), TESTIS (TE), THYMUS (TH), THYROID (TY), TONGUE (TO),
TRACHEA (TR), URINARY BLADDER (UB)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:

ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, STERNUM (SB), BRAIN W/STEM (BR), COLON (CO),
CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC), DUODENUM (DU), EPIDIDYMIS (EP), ESOPHAGUS (ES),
EYE (EY), GALLBLADDER (GB), HARDERIAN GLAND (HG), HEART (HT), HEMATO NEOPLASIA (HN), ILEUM (IL), JEJUNUM (JE),
LACRIMAL GL, EX (EO), LIVER (LI), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), MARROW, FEMUR (FM), MARROW, STERNUM (SE),
MUSCLE, ABDOM (MA), MUSCLE, SKELETAL (SM), NERVE, SCIATIC (SN), PANCREAS (PA), PITUITARY (PI), PROSTATE (PR),
SALIVARY, OTHER (OS), SKIN (SK), STOMACH, NONGL (SU), TESTIS (TE), THYMUS (TH), THYROID (TY), TONGUE (TO),
TRACHEA (TR), URINARY BLADDER (UB)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 568

STUDY NUMBER: 483287

ANIMAL NUMBER: A37405 SEX: MALE DOSE GROUP: 1 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/14/91 STUDY DAY OF DEATH: 98 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 26.0 GRAMS
DATE AND TIME OF NECROPSY: 11/14/91 9:40 PROSECTOR: ADEPOLAHAN AKINSOLA RECORDER: ADEPOLAHAN AKINSOLA
POST-FIX WEAHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEAHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.21	.800 %	.410	WEIGHT TAKEN
LUNG (LU)	.16	.627 %	.321	WEIGHT TAKEN
PROSTATE (PR)	.016	.0627 %	.0321	WEIGHT TAKEN
BRAIN W/STEM (BR)	.51	1.953 %	1.000	WEIGHT TAKEN
HEART (HT)	.16	.602 %	.308	WEIGHT TAKEN
SPLEEN (SP)	.08	.312 %	.160	WEIGHT TAKEN
KIDNEY (KD)	.59	2.262 %	1.158	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	1.20	4.617 %	2.364	WEIGHT TAKEN
TESTIS (TE)	.17	.672 %	.344	WEIGHT TAKEN
EPIDIDYMIS (EP)	.11	.428 %	.219	WEIGHT TAKEN
ADRENAL (AD)	.009	.0327 %	.0167	WEIGHT TAKEN
THYMUS (TH)	.01	.036 %	.019	WEIGHT TAKEN

CLINICAL OBSERVATIONS	PATHOLOGY OBSERVATIONS NECROPSY	HISTOPATHOLOGY
-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS		ADRENAL, CORTEX (AC) : -PIGMENT,-SLIGHT EPIDIDYMIS (EP) : -LUMEN, DEBRIS, CELLULAR,-PRESENT HEART (HT) : -INFLAMMATION, CHRONIC,-MINIMAL KIDNEY (KD) : -INFLAMMATION, CHRONIC,-MINIMAL -HYPERPLASIA, LYMPHOID,-MINIMAL -PIGMENT,-MINIMAL -CYST,-PRESENT LACRIMAL GL, EX (EO) : -UNILATERALLY EXAMINED,-PRESENT LN, MESENTERIC (MS) : -HYPERPLASIA, LYMPHOID,-MINIMAL LUNG (LU) : -PERIBRONCHIAL/PERIVASCULAR, INFILTRATION, LYMPHOID,-MINIMAL

APPENDIX 13B

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 569

STUDY NUMBER: 483287

ANIMAL NUMBER: A37405 SEX: MALE DOSE GROUP: 1 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/14/91 STUDY DAY OF DEATH: 98 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 26.0 GRAMS
DATE AND TIME OF NECROPSY: 11/14/91 9:40 PROSECTOR: ADEFOLAHAN AKINSOLA RECORDER: ADEFOLAHAN AKINSOLA
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

P A T H O L O G Y O B S E R V A T I O N S (CONTINUED)
NECROPSY

CLINICAL OBSERVATIONS

HISTOPATHOLOGY

^COLLECTED/TAKEN (XW) :
-LIVER SECTIONS, IN METHANOL

MAND SALIVARY GL (SG) :
-INFLAMMATION, CHRONIC, -MINIMAL
NERVE, OPTIC (ON) :
-UNILATERALLY EXAMINED, -PRESENT
SPLEEN (SP) :
-PIGMENT, -MINIMAL
STOMACH, GL (ST) :
-INFLAMMATION, CHRONIC, -MINIMAL

^DEATH COMMENT (DC) :
-SCHEDULED SACRIFICE, -PRESENT

APPENDIX 13B

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 570

STUDY NUMBER: 483287

ANIMAL NUMBER: A37405 SEX: MALE DOSE GROUP: 1 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/14/91 STUDY DAY OF DEATH: 98 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 26.0 GRAMS
DATE AND TIME OF NECROPSY: 11/14/91 9:40 PROSECTOR: ADEFOLAHAN AKINSOLA RECORDER: ADEFOLAHAN AKINSOLA
POST-FIX WEAHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEAHER: RICHARD KAGYARE

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), EPIDIDYMIS (EP), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE),
KIDNEY (KD), LACRIMAL GL, EX (EO), LIVER (LI), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU),
MAND SALIVARY GL (SG), MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON),
NERVE, SCIATIC (SN), PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), PROSTATE (PR), RECTUM (RE), SKIN (SK),
SKIN, OTHER (SS), SPLEEN (SP), STOMACH, GL (ST), STOMACH, NONGL (SU), TESTIS (TE), THYMUS (TH), THYROID (TY),
TONGUE (TO), TRACHEA (TR), URINARY BLADDER (UB)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:

ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, STERNUM (SB), BRAIN W/STEM (BR), CECUM (CE),
COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC), DUODENUM (DU), ESOPHAGUS (ES), EYE (EY),
GALLBLADDER (GB), HARDERIAN GLAND (HG), HEMATO NEOPLASIA (HN), ILEUM (IL), JEJUNUM (JE), LIVER (LI),
LN, MANDIBULAR (MN), MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, ABDOM (MA), MUSCLE, SKELETAL (SM),
NERVE, SCIATIC (SN), PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), PROSTATE (PR), RECTUM (RE), SALIVARY, OTHER (OS),
SKIN (SK), STOMACH, NONGL (SU), TESTIS (TE), THYMUS (TH), THYROID (TY), TONGUE (TO), TRACHEA (TR),
URINARY BLADDER (UB)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 571

STUDY NUMBER: 483287

ANIMAL NUMBER: A37421 SEX: MALE DOSE GROUP: 2 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/11/91 STUDY DAY OF DEATH: 95 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 29.8 GRAMS
DATE AND TIME OF NECROPSY: 11/11/91 8:50 PROSECTOR: SCOTT BELL RECORDER: SCOTT BELL
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	O R G A N S T A T U S
MAND SALIVARY GL (SG)	.16	.524 %	.302	WEIGHT TAKEN
LUNG (LU)	.19	.621 %	.358	WEIGHT TAKEN
PROSTATE (PR)	.038	.1282 %	.0739	WEIGHT TAKEN
BRAIN W/STEM (BR)	.52	1.736 %	1.000	WEIGHT TAKEN
HEART (HT)	.16	.533 %	.307	WEIGHT TAKEN
SPLEEN (SP)	.05	.153 %	.088	WEIGHT TAKEN
KIDNEY (KD)	.52	1.752 %	1.009	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	1.37	4.581 %	2.639	WEIGHT TAKEN
TESTIS (TE)	.26	.859 %	.495	WEIGHT TAKEN
EPIDIDYMIS (EP)	.10	.346 %	.200	WEIGHT TAKEN
ADRENAL (AD)	.005	.0158 %	.0091	WEIGHT TAKEN
THYMUS (TH)	.02	.053 %	.030	WEIGHT TAKEN

P A T H O L O G Y O B S E R V A T I O N S
NECROPSY

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE
OBSERVATIONS

HISTOPATHOLOGY

ADRENAL, CORTEX (AC) :
-PIGMENT,-MINIMAL

^COLLECTED/TAKEN (XW) :
-LIVER SECTIONS, IN METHANOL

APPENDIX 13B

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 572

STUDY NUMBER: 483287

ANIMAL NUMBER: A37421 SEX: MALE DOSE GROUP: 2 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/11/91 STUDY DAY OF DEATH: 95 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 29.8 GRAMS
DATE AND TIME OF NECROPSY: 11/11/91 8:50 PROSECTOR: SCOTT BELL RECORDER: SCOTT BELL
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), EPIDIDYMIS (EP), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE),
KIDNEY (KD), LACRIMAL GL, EX (EO), LIVER (LI), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU),
MAND SALIVARY GL (SG), MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON),
NERVE, SCIATIC (SN), PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), PROSTATE (PR), RECTUM (RE), SKIN (SK),
SKIN, OTHER (SS), SPLEEN (SP), STOMACH, GL (ST), STOMACH, NONGL (SU), TESTIS (TE), THYMUS (TH), THYROID (TY),
TONGUE (TO), TRACHEA (TR), URINARY BLADDER (UB)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:

ADRENAL, MEDULLA (AM), LIVER (LI)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 573

STUDY NUMBER: 483287

ANIMAL NUMBER: A37422 SEX: MALE DOSE GROUP: 2 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/11/91 STUDY DAY OF DEATH: 95 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 26.0 GRAMS
DATE AND TIME OF NECROPSY: 11/11/91 10:05 PROSECTOR: FRED AGEY RECORDER: FRED AGEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.29	1.125 %	.677	WEIGHT TAKEN
LUNG (LU)	.15	.594 %	.357	WEIGHT TAKEN
PROSTATE (PR)	.033	.1281 %	.0771	WEIGHT TAKEN
BRAIN W/STEM (BR)	.43	1.661 %	1.000	WEIGHT TAKEN
HEART (HT)	.14	.549 %	.330	WEIGHT TAKEN
SPLEEN (SP)	.08	.305 %	.184	WEIGHT TAKEN
KIDNEY (KD)	.42	1.620 %	.975	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	1.29	4.977 %	2.996	WEIGHT TAKEN
TESTIS (TE)	.23	.899 %	.541	WEIGHT TAKEN
EPIDIDYMIS (EP)	.11	.415 %	.250	WEIGHT TAKEN
ADRENAL (AD)	.004	.0154 %	.0093	WEIGHT TAKEN
THYMUS (TH)	.02	.086 %	.052	WEIGHT TAKEN

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE
OBSERVATIONS

PATHOLOGY OBSERVATIONS
NECROPSY

HISTOPATHOLOGY

ADRENAL, CORTEX (AC) :
-UNILATERALLY EXAMINED,-PRESENT
ADRENAL, MEDULLA (AM) :
-UNILATERALLY EXAMINED,-PRESENT
LIVER (LI) :
-HEPATOCYTE, HYPERTROPHY,
CENTROLOBULAR,-MINIMAL
-INFLAMMATION, CHRONIC/CHRONIC ACTIVE,-
MINIMAL

^COLLECTED/TAKEN (XW) :
-LIVER SECTIONS, IN METHANOL

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 574

STUDY NUMBER: 483287

ANIMAL NUMBER: A37422 SEX: MALE DOSE GROUP: 2 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/11/91 STUDY DAY OF DEATH: 95 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 26.0 GRAMS
DATE AND TIME OF NECROPSY: 11/11/91 10:05 PROSECTOR: FRED AGEY RECORDER: FRED AGEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), EPIDIDYMIS (EP), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE),
KIDNEY (KD), LACRIMAL GL, EX (EO), LIVER (LI), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU),
MAND SALIVARY GL (SG), MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON),
NERVE, SCIATIC (SN), PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), PROSTATE (PR), RECTUM (RE), SKIN (SK),
SKIN, OTHER (SS), SPLEEN (SP), STOMACH, GL (ST), STOMACH, NONGL (SU), TESTIS (TE), THYMUS (TH), THYROID (TY),
TONGUE (TO), TRACHEA (TR), URINARY BLADDER (UB)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 575

STUDY NUMBER: 483287

ANIMAL NUMBER: A37423 SEX: MALE DOSE GROUP: 2 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/11/91 STUDY DAY OF DEATH: 95 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 27.3 GRAMS
DATE AND TIME OF NECROPSY: 11/11/91 11:00 PROSECTOR: DOUGLAS HERNDON RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	O R G A N S T A T U S
MAND SALIVARY GL (SG)	.22	.793 %	.400	WEIGHT TAKEN
LUNG (LU)	.18	.657 %	.331	WEIGHT TAKEN
PROSTATE (PR)	.057	.2099 %	.1058	WEIGHT TAKEN
BRAIN W/STEM (BR)	.54	1.983 %	1.000	WEIGHT TAKEN
HEART (HT)	.16	.573 %	.289	WEIGHT TAKEN
SPLEEN (SP)	.07	.250 %	.126	WEIGHT TAKEN
KIDNEY (KD)	.63	2.298 %	1.159	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	1.41	5.154 %	2.599	WEIGHT TAKEN
TESTIS (TE)	.21	.758 %	.382	WEIGHT TAKEN
EPIDIDYMIS (EP)	.11	.398 %	.201	WEIGHT TAKEN
ADRENAL (AD)	.012	.0447 %	.0225	WEIGHT TAKEN
THYMUS (TH)	.02	.057 %	.029	WEIGHT TAKEN

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE
OBSERVATIONS

P A T H O L O G Y O B S E R V A T I O N S
NECROPSY

^COLLECTED/TAKEN (XW) :
-LIVER SECTIONS, IN METHANOL

HISTOPATHOLOGY

ADRENAL, CORTEX (AC) :
-PIGMENT, -MINIMAL
-HYPERPLASIA, SUBCAPSULAR CELL, -MINIMAL

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 576

STUDY NUMBER: 483287

ANIMAL NUMBER: A37423 SEX: MALE DOSE GROUP: 2 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/11/91 STUDY DAY OF DEATH: 95 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 27.3 GRAMS
DATE AND TIME OF NECROPSY: 11/11/91 11:00 PROSECTOR: DOUGLAS HERNDON RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: JANE EARNHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), EPIDIDYMIS (EP), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE),
KIDNEY (KD), LACRIMAL GL, EX (EO), LIVER (LI), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU),
MAND SALIVARY GL (SG), MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON),
NERVE, SCIATIC (SN), PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), PROSTATE (PR), RECTUM (RE), SKIN (SK),
SKIN, OTHER (SS), SPLEEN (SP), STOMACH, GL (ST), STOMACH, NONGL (SU), TESTIS (TE), THYMUS (TH), THYROID (TY),
TONGUE (TO), TRACHEA (TR), URINARY BLADDER (UB)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:

ADRENAL, MEDULLA (AM), LIVER (LI)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 577

STUDY NUMBER: 483287

ANIMAL NUMBER: A37424 SEX: MALE DOSE GROUP: 2 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/11/91 STUDY DAY OF DEATH: 95 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 30.4 GRAMS
DATE AND TIME OF NECROPSY: 11/11/91 13:23 PROSECTOR: SONNY DIKES RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.21	.695 %	.388	WEIGHT TAKEN
LUNG (LU)	.16	.514 %	.287	WEIGHT TAKEN
PROSTATE (PR)	.074	.2424 %	.1354	WEIGHT TAKEN
BRAIN W/STEM (BR)	.54	1.791 %	1.000	WEIGHT TAKEN
HEART (HT)	.14	.460 %	.257	WEIGHT TAKEN
SPLEEN (SP)	.05	.148 %	.083	WEIGHT TAKEN
KIDNEY (KD)	.52	1.715 %	.958	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	1.36	4.486 %	2.505	WEIGHT TAKEN
TESTIS (TE)	.26	.847 %	.473	WEIGHT TAKEN
EPIDIDYMIS (EP)	.12	.396 %	.221	WEIGHT TAKEN
ADRENAL (AD)	.005	.0161 %	.0090	WEIGHT TAKEN
THYMUS (TH)	.03	.112 %	.062	WEIGHT TAKEN

CLINICAL OBSERVATIONS

PATHOLOGY OBSERVATIONS
NECROPSY

HISTOPATHOLOGY

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE
OBSERVATIONS

ADRENAL, CORTEX (AC) :
-PIGMENT,-MINIMAL
-UNILATERALLY EXAMINED,-PRESENT
ADRENAL, MEDULLA (AM) :
-UNILATERALLY EXAMINED,-PRESENT
LIVER (LI) :
-INFLAMMATION, CHRONIC/CHRONIC ACTIVE,-
MINIMAL

^COLLECTED/TAKEN (XW) :
-LIVER SECTIONS, IN METHANOL

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 578

STUDY NUMBER: 483287

ANIMAL NUMBER: A37424 SEX: MALE DOSE GROUP: 2 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/11/91 STUDY DAY OF DEATH: 95 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 30.4 GRAMS
DATE AND TIME OF NECROPSY: 11/11/91 13:23 PROSECTOR: SONNY DIKES RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), EPIDIDYMIS (EP), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE),
KIDNEY (KD), LACRIMAL GL, EX (EO), LIVER (LI), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU),
MAND SALIVARY GL (SG), MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON),
NERVE, SCIATIC (SN), PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), PROSTATE (PR), RECTUM (RE), SKIN (SK),
SKIN, OTHER (SS), SPLEEN (SP), STOMACH, GL (ST), STOMACH, NONGL (SU), TESTIS (TE), THYMUS (TH), THYROID (TY),
TONGUE (TO), TRACHEA (TR), URINARY BLADDER (UB)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 579

STUDY NUMBER: 483287

ANIMAL NUMBER: A37425 SEX: MALE DOSE GROUP: 2 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/12/91 STUDY DAY OF DEATH: 96 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 29.1 GRAMS
DATE AND TIME OF NECROPSY: 11/12/91 8:46 PROSECTOR: DOUGLAS HERNDON RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: JANE EARMHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.16	.556 %	.326	WEIGHT TAKEN
LUNG (LU)	.18	.621 %	.364	WEIGHT TAKEN
PROSTATE (PR)	.055	.1887 %	.1107	WEIGHT TAKEN
BRAIN W/STEM (BR)	.50	1.704 %	1.000	WEIGHT TAKEN
HEART (HT)	.16	.564 %	.331	WEIGHT TAKEN
SPLEEN (SP)	.06	.204 %	.120	WEIGHT TAKEN
KIDNEY (KD)	.51	1.759 %	1.032	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	1.43	4.897 %	2.873	WEIGHT TAKEN
TESTIS (TE)	.27	.934 %	.548	WEIGHT TAKEN
EPIDIDYMIS (EP)	.13	.449 %	.263	WEIGHT TAKEN
ADRENAL (AD)	.004	.0120 %	.0071	WEIGHT TAKEN
THYMUS (TH)	.02	.053 %	.031	WEIGHT TAKEN

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE
OBSERVATIONS

PATHOLOGY OBSERVATIONS
NECROPSY

^COLLECTED/TAKEN (XW) :
-LIVER SECTIONS, IN METHANOL

HISTOPATHOLOGY

ADRENAL, CORTEX (AC) :
-PIGMENT, -MINIMAL
LIVER (LI) :
-HEPATOCYTE, HYPERTROPHY,
CENTROLOBULAR, -MINIMAL
-VACUOLIZATION, -MINIMAL

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 580

STUDY NUMBER: 483287

ANIMAL NUMBER: A37425 SEX: MALE DOSE GROUP: 2 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/12/91 STUDY DAY OF DEATH: 96 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 29.1 GRAMS
DATE AND TIME OF NECROPSY: 11/12/91 8:46 PROSECTOR: DOUGLAS HERNDON RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), EPIDIDYMIS (EP), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE),
KIDNEY (KD), LACRIMAL GL, EX (EO), LIVER (LI), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU),
MAND SALIVARY GL (SG), MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON),
NERVE, SCIATIC (SN), PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), PROSTATE (PR), RECTUM (RE), SKIN (SK),
SKIN, OTHER (SS), SPLEEN (SP), STOMACH, GL (ST), STOMACH, NONGL (SU), TESTIS (TE), THYMUS (TH), THYROID (TY),
TONGUE (TO), TRACHEA (TR), URINARY BLADDER (UB)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:

ADRENAL, MEDULLA (AM)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 581

STUDY NUMBER: 483287

ANIMAL NUMBER: A37426 SEX: MALE DOSE GROUP: 2 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/12/91 STUDY DAY OF DEATH: 96 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 26.9 GRAMS
DATE AND TIME OF NECROPSY: 11/12/91 9:35 PROSECTOR: FRED AGEY RECORDER: FRED AGEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.23	.847 %	.548	WEIGHT TAKEN
LUNG (LU)	.17	.636 %	.412	WEIGHT TAKEN
PROSTATE (PR)	.024	.0877 %	.0568	WEIGHT TAKEN
BRAIN W/STEM (BR)	.42	1.546 %	1.000	WEIGHT TAKEN
HEART (HT)	.16	.578 %	.374	WEIGHT TAKEN
SPLEEN (SP)	.07	.273 %	.177	WEIGHT TAKEN
KIDNEY (KD)	.40	1.504 %	.973	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	1.29	4.804 %	3.108	WEIGHT TAKEN
TESTIS (TE)	.22	.821 %	.531	WEIGHT TAKEN
EPIDIDYMIS (EP)	.10	.385 %	.249	WEIGHT TAKEN
ADRENAL (AD)	.002	.0078 %	.0051	EXCLUDE
THYMUS (TH)	.02	.093 %	.060	WEIGHT TAKEN

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE
OBSERVATIONS

PATHOLOGY OBSERVATIONS
NECROPSY

LIVER (LI) :
-DARK; ALL LOBES, DARK BROWN
^COLLECTED/TAKEN (XW) :
-LIVER SECTIONS, IN METHANOL

HISTOPATHOLOGY

ADRENAL, CORTEX (AC) :
-PIGMENT, -MINIMAL
-UNILATERALLY EXAMINED, -PRESENT
ADRENAL, MEDULLA (AM) :
-UNILATERALLY EXAMINED, -PRESENT
LIVER (LI) :
-HEPATOCYTE, HYPERTROPHY,
CENTROLOBULAR, -MINIMAL

APPENDIX 13B

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 582

STUDY NUMBER: 483287

ANIMAL NUMBER: A37426 SEX: MALE DOSE GROUP: 2 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/12/91 STUDY DAY OF DEATH: 96 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 26.9 GRAMS
DATE AND TIME OF NECROPSY: 11/12/91 9:35 PROSECTOR: FRED AGEY RECORDER: FRED AGEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), EPIDIDYMIS (EP), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE),
KIDNEY (KD), LACRIMAL GL, EX (EO), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU), MAND SALIVARY GL (SG),
MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON), NERVE, SCIATIC (SN),
PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), PROSTATE (PR), RECTUM (RE), SKIN (SK), SKIN, OTHER (SS),
SPLEEN (SP), STOMACH, GL (ST), STOMACH, NONGL (SU), TESTIS (TE), THYMUS (TH), THYROID (TY), TONGUE (TO),
TRACHEA (TR), URINARY BLADDER (UB)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 583

STUDY NUMBER: 483287

ANIMAL NUMBER: A37427 SEX: MALE DOSE GROUP: 2 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/12/91 STUDY DAY OF DEATH: 96 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 26.5 GRAMS
DATE AND TIME OF NECROPSY: 11/12/91 10:47 PROSECTOR: DOUGLAS HERNDON RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: JANE. EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.20	.757 %	.406	WEIGHT TAKEN
LUNG (LU)	.20	.772 %	.415	WEIGHT TAKEN
PROSTATE (PR)	.048	.1819 %	.0977	WEIGHT TAKEN
BRAIN W/STEM (BR)	.49	1.862 %	1.000	WEIGHT TAKEN
HEART (HT)	.15	.579 %	.311	WEIGHT TAKEN
SPLEEN (SP)	.05	.202 %	.109	WEIGHT TAKEN
KIDNEY (KD)	.49	1.832 %	.984	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	1.23	4.653 %	2.499	WEIGHT TAKEN
TESTIS (TE)	.23	.883 %	.474	WEIGHT TAKEN
EPIDIDYMIS (EP)	.12	.452 %	.243	WEIGHT TAKEN
ADRENAL (AD)	.009	.0321 %	.0172	WEIGHT TAKEN
THYMUS (TH)	.02	.061 %	.033	WEIGHT TAKEN

CLINICAL OBSERVATIONS	PATHOLOGY OBSERVATIONS NECROPSY	HISTOPATHOLOGY
-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS	^COLLECTED/TAKEN (XW) : -LIVER SECTIONS, IN METHANOL	ADRENAL, CORTEX (AC) : -PIGMENT,-MINIMAL

APPENDIX 13B

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 584

STUDY NUMBER: 483287

ANIMAL NUMBER: A37427 SEX: MALE DOSE GROUP: 2 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/12/91 STUDY DAY OF DEATH: 96 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 26.5 GRAMS
DATE AND TIME OF NECROPSY: 11/12/91 10:47 PROSECTOR: DOUGLAS HERNDON RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), EPIDIDYMIS (EP), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE),
KIDNEY (KD), LACRIMAL GL, EX (EO), LIVER (LI), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU),
MAND SALIVARY GL (SG), MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON),
NERVE, SCIATIC (SN), PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), PROSTATE (PR), RECTUM (RE), SKIN (SK),
SKIN, OTHER (SS), SPLEEN (SP), STOMACH, GL (ST), STOMACH, NONGL (SU), TESTIS (TE), THYMUS (TH), THYROID (TY),
TONGUE (TO), TRACHEA (TR), URINARY BLADDER (UB)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:

ADRENAL, MEDULLA (AM), LIVER (LI)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 585

STUDY NUMBER: 483287

ANIMAL NUMBER: A37428 SEX: MALE DOSE GROUP: 2 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/12/91 STUDY DAY OF DEATH: 96 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 27.7 GRAMS
DATE AND TIME OF NECROPSY: 11/12/91 12:59 PROSECTOR: SONNY DIKES RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.17	.607 %	.320	WEIGHT TAKEN
LUNG (LU)	.17	.614 %	.324	WEIGHT TAKEN
PROSTATE (PR)	.076	.2755 %	.1453	WEIGHT TAKEN
BRAIN W/STEM (BR)	.52	1.895 %	1.000	WEIGHT TAKEN
HEART (HT)	.21	.742 %	.392	WEIGHT TAKEN
SPLEEN (SP)	.07	.257 %	.136	WEIGHT TAKEN
KIDNEY (KD)	.50	1.790 %	.944	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	1.22	4.406 %	2.325	WEIGHT TAKEN
TESTIS (TE)	.29	1.060 %	.559	WEIGHT TAKEN
EPIDIDYMIS (EP)	.14	.508 %	.268	WEIGHT TAKEN
ADRENAL (AD)	.008	.0303 %	.0160	WEIGHT TAKEN
THYMUS (TH)	.03	.091 %	.048	WEIGHT TAKEN

CLINICAL OBSERVATIONS

PATHOLOGY OBSERVATIONS
NECROPSY

HISTOPATHOLOGY

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE
OBSERVATIONS

LIVER (LI) :
-HEPATOCYTE, HYPERTROPHY,
CENTROLOBULAR, -MINIMAL
-VACUOLIZATION, -MINIMAL

^COLLECTED/TAKEN (XW) :
-LIVER SECTIONS, IN METHANOL

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 586

STUDY NUMBER: 483287

ANIMAL NUMBER: A37428 SEX: MALE DOSE GROUP: 2 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/12/91 STUDY DAY OF DEATH: 96 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 27.7 GRAMS
DATE AND TIME OF NECROPSY: 11/12/91 12:59 PROSECTOR: SONNY DIKES RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), EPIDIDYMIS (EP), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE),
KIDNEY (KD), LACRIMAL GL, EX (EO), LIVER (LI), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU),
MAND SALIVARY GL (SG), MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON),
NERVE, SCIATIC (SN), PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), PROSTATE (PR), RECTUM (RE), SKIN (SK),
SKIN, OTHER (SS), SPLEEN (SP), STOMACH, GL (ST), STOMACH, NONGL (SU), TESTIS (TE), THYMUS (TH), THYROID (TY),
TONGUE (TO), TRACHEA (TR), URINARY BLADDER (UB)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 587

STUDY NUMBER: 483287

ANIMAL NUMBER: A37429 SEX: MALE DOSE GROUP: 2 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/13/91 STUDY DAY OF DEATH: 97 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 30.2 GRAMS
DATE AND TIME OF NECROPSY: 11/13/91 8:24 PROSECTOR: DOUGLAS HERNDON RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.21	.704 %	.443	WEIGHT TAKEN
LUNG (LU)	.23	.772 %	.485	WEIGHT TAKEN
PROSTATE (PR)	.081	.2692 %	.1692	WEIGHT TAKEN
BRAIN W/STEM (BR)	.48	1.591 %	1.000	WEIGHT TAKEN
HEART (HT)	.17	.561 %	.352	WEIGHT TAKEN
SPLEEN (SP)	.05	.178 %	.112	WEIGHT TAKEN
KIDNEY (KD)	.61	2.016 %	1.267	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	1.56	5.150 %	3.238	WEIGHT TAKEN
TESTIS (TE)	.22	.729 %	.458	WEIGHT TAKEN
EPIDIDYMIS (EP)	.11	.379 %	.239	WEIGHT TAKEN
ADRENAL (AD)	.011	.0368 %	.0231	WEIGHT TAKEN
THYMUS (TH)	.02	.074 %	.046	WEIGHT TAKEN

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE
OBSERVATIONS

PATHOLOGY OBSERVATIONS
NECROPSY

^COLLECTED/TAKEN (XW) :
-LIVER SECTIONS, IN METHANOL

HISTOPATHOLOGY

ADRENAL, CORTEX (AC) :
-PIGMENT, -MINIMAL
LIVER (LI) :
-INFLAMMATION, CHRONIC/CHRONIC ACTIVE, -
MINIMAL

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

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13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
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STUDY NUMBER: 483287

ANIMAL NUMBER: A37429 SEX: MALE DOSE GROUP: 2 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/13/91 STUDY DAY OF DEATH: 97 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 30.2 GRAMS
DATE AND TIME OF NECROPSY: 11/13/91 8:24 PROSECTOR: DOUGLAS HERNDON RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), EPIDIDYMIS (EP), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE),
KIDNEY (KD), LACRIMAL GL, EX (EO), LIVER (LI), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU),
MAND SALIVARY GL (SG), MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON),
NERVE, SCIATIC (SN), PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), PROSTATE (PR), RECTUM (RE), SKIN (SK),
SKIN, OTHER (SS), SPLEEN (SP), STOMACH, GL (ST), STOMACH, NONGL (SU), TESTIS (TE), THYMUS (TH), THYROID (TY),
TONGUE (TO), TRACHEA (TR), URINARY BLADDER (UB)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:
ADRENAL, MEDULLA (AM)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 589

STUDY NUMBER: 483287

ANIMAL NUMBER: A37430 SEX: MALE DOSE GROUP: 2 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/13/91 STUDY DAY OF DEATH: 97 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 27.1 GRAMS
DATE AND TIME OF NECROPSY: 11/13/91 9:19 PROSECTOR: DOUGLAS HERNDON RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.19	.685 %	.361	WEIGHT TAKEN
LUNG (LU)	.21	.789 %	.416	WEIGHT TAKEN
PROSTATE (PR)	.079	.2923 %	.1541	WEIGHT TAKEN
BRAIN W/STEM (BR)	.51	1.896 %	1.000	WEIGHT TAKEN
HEART (HT)	.14	.508 %	.268	WEIGHT TAKEN
SPLEEN (SP)	.07	.251 %	.133	WEIGHT TAKEN
KIDNEY (KD)	.55	2.028 %	1.069	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	1.31	4.842 %	2.554	WEIGHT TAKEN
TESTIS (TE)	.32	1.173 %	.619	WEIGHT TAKEN
EPIDIDYMIS (EP)	.12	.450 %	.237	WEIGHT TAKEN
ADRENAL (AD)	.010	.0373 %	.0197	WEIGHT TAKEN
THYMUS (TH)	.03	.104 %	.055	WEIGHT TAKEN

CLINICAL OBSERVATIONS	PATHOLOGY OBSERVATIONS NECROPSY	HISTOPATHOLOGY
-LAST PHYSICAL EXAM: LEFT EAR-SORE	SKIN, OTHER (SS) : -EAR, SORE; LEFT, ONE, CRUSTY, BROWN, 5 X 5 MM ^COLLECTED/TAKEN (XW) : -LIVER SECTIONS, IN METHANOL	SKIN, OTHER (SS) : -DERMATITIS, ULCERATIVE, -PRESENT

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

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STUDY NUMBER: 483287

ANIMAL NUMBER: A37430 SEX: MALE DOSE GROUP: 2 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/13/91 STUDY DAY OF DEATH: 97 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 27.1 GRAMS
DATE AND TIME OF NECROPSY: 11/13/91 9:19 PROSECTOR: DOUGLAS HERNDON RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), EPIDIDYMIS (EP), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE),
KIDNEY (KD), LACRIMAL GL, EX (EO), LIVER (LI), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU),
MAND SALIVARY GL (SG), MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON),
NERVE, SCIATIC (SN), PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), PROSTATE (PR), RECTUM (RE), SKIN (SK),
SPLEEN (SP), STOMACH, GL (ST), STOMACH, NONGL (SU), TESTIS (TE), THYMUS (TH), THYROID (TY), TONGUE (TO),
TRACHEA (TR), URINARY BLADDER (UB)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), LIVER (LI)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 591

STUDY NUMBER: 483287

ANIMAL NUMBER: A37431 SEX: MALE DOSE GROUP: 2 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/13/91 STUDY DAY OF DEATH: 97 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 28.7 GRAMS
DATE AND TIME OF NECROPSY: 11/13/91 10:40 PROSECTOR: SCOTT BELL RECORDER: SCOTT BELL
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.23	.798 %	.426	WEIGHT TAKEN
LUNG (LU)	.22	.756 %	.404	WEIGHT TAKEN
PROSTATE (PR)	.043	.1505 %	.0804	WEIGHT TAKEN
BRAIN W/STEM (BR)	.54	1.873 %	1.000	WEIGHT TAKEN
HEART (HT)	.17	.592 %	.316	WEIGHT TAKEN
SPLEEN (SP)	.06	.197 %	.105	WEIGHT TAKEN
KIDNEY (KD)	.51	1.771 %	.946	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	1.37	4.771 %	2.548	WEIGHT TAKEN
TESTIS (TE)	.21	.716 %	.382	WEIGHT TAKEN
EPIDIDYMIS (EP)	.09	.327 %	.175	WEIGHT TAKEN
ADRENAL (AD)	.003	.0101 %	.0054	WEIGHT TAKEN
THYMUS (TH)	.03	.121 %	.065	WEIGHT TAKEN

CLINICAL OBSERVATIONS	PATHOLOGY OBSERVATIONS NECROPSY	HISTOPATHOLOGY
-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS	^COLLECTED/TAKEN (XW) : -LIVER SECTIONS, IN METHANOL	ADRENAL, CORTEX (AC) : -PIGMENT,-MINIMAL -HYPERPLASIA, SUBCAPSULAR CELL,-MINIMAL

APPENDIX 13B

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
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ANIMAL NUMBER: A37431 SEX: MALE DOSE GROUP: 2 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
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DATE AND TIME OF NECROPSY: 11/13/91 10:40 PROSECTOR: SCOTT BELL RECORDER: SCOTT BELL
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), EPIDIDYMIS (EP), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE),
KIDNEY (KD), LACRIMAL GL, EX (EO), LIVER (LI), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU),
MAND SALIVARY GL (SG), MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON),
NERVE, SCIATIC (SN), PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), PROSTATE (PR), RECTUM (RE), SKIN (SK),
SKIN, OTHER (SS), SPLEEN (SP), STOMACH, GL (ST), STOMACH, NONGL (SU), TESTIS (TE), THYMUS (TH), THYROID (TY),
TONGUE (TO), TRACHEA (TR), URINARY BLADDER (UB)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:

ADRENAL, MEDULLA (AM), LIVER (LI)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

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PAGE: 593

STUDY NUMBER: 483287

ANIMAL NUMBER: A37432 SEX: MALE DOSE GROUP: 2 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/13/91 STUDY DAY OF DEATH: 97 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 26.1 GRAMS
DATE AND TIME OF NECROPSY: 11/13/91 12:49 PROSECTOR: ADEFOLAHAN AKINSOLA RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.26	1.005 %	.553	WEIGHT TAKEN
LUNG (LU)	.20	.748 %	.411	WEIGHT TAKEN
PROSTATE (PR)	.032	.1241 %	.0683	WEIGHT TAKEN
BRAIN W/STEM (BR)	.47	1.818 %	1.000	WEIGHT TAKEN
HEART (HT)	.16	.615 %	.338	WEIGHT TAKEN
SPLEEN (SP)	.07	.254 %	.140	WEIGHT TAKEN
KIDNEY (KD)	.46	1.757 %	.967	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	1.20	4.614 %	2.539	WEIGHT TAKEN
TESTIS (TE)	.28	1.090 %	.600	WEIGHT TAKEN
EPIDIDYMIS (EP)	.12	.467 %	.257	WEIGHT TAKEN
ADRENAL (AD)	.006	.0241 %	.0133	WEIGHT TAKEN
THYMUS (TH)	.02	.094 %	.052	WEIGHT TAKEN

CLINICAL OBSERVATIONS	PATHOLOGY OBSERVATIONS NECROPSY	HISTOPATHOLOGY
-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS		ADRENAL, CORTEX (AC) : -PIGMENT -MINIMAL LIVER (LI) : -HEPATOCYTE, HYPERTROPHY, CENTROLOBULAR, -MINIMAL -NECROSIS, INDIVIDUAL CELL, -MINIMAL -INFLAMMATION, CHRONIC/CHRONIC ACTIVE, - MINIMAL
	^COLLECTED/TAKEN (XW) : -LIVER SECTIONS, IN METHANOL	

APPENDIX 13B

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 594

STUDY NUMBER: 483287

ANIMAL NUMBER: A37432 SEX: MALE DOSE GROUP: 2 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/13/91 STUDY DAY OF DEATH: 97 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 26.1 GRAMS
DATE AND TIME OF NECROPSY: 11/13/91 12:49 PROSECTOR: ADEFOLAHAN AKINSOLA RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), EPIDIDYMI (EP), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE),
KIDNEY (KD), LACRIMAL GL, EX (EO), LIVER (LI), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU),
MAND SALIVARY GL (SG), MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON),
NERVE, SCIATIC (SN), PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), PROSTATE (PR), RECTUM (RE), SKIN (SK),
SKIN, OTHER (SS), SPLEEN (SP), STOMACH, GL (ST), STOMACH, NONGL (SU), TESTIS (TE), THYMUS (TH), THYROID (TY),
TONGUE (TO), TRACHEA (TR), URINARY BLADDER (UB)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:

ADRENAL, MEDULLA (AM)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 595

STUDY NUMBER: 483287

ANIMAL NUMBER: A37433 SEX: MALE DOSE GROUP: 2 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/14/91 STUDY DAY OF DEATH: 98 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 28.2 GRAMS
DATE AND TIME OF NECROPSY: 11/14/91 7:50 PROSECTOR: JANE EARHARDT RECORDER: JANE EARHARDT
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.24	.866 %	.507	WEIGHT TAKEN
LUNG (LU)	.21	.746 %	.437	WEIGHT TAKEN
PROSTATE (PR)	.054	.1933 %	.1132	WEIGHT TAKEN
BRAIN W/STEM (BR)	.48	1.708 %	1.000	WEIGHT TAKEN
HEART (HT)	.19	.662 %	.388	WEIGHT TAKEN
SPLEEN (SP)	.04	.154 %	.090	WEIGHT TAKEN
KIDNEY (KD)	.50	1.763 %	1.033	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	1.34	4.749 %	2.781	WEIGHT TAKEN
TESTIS (TE)	.22	.762 %	.446	WEIGHT TAKEN
EPIDIDYMIS (EP)	.17	.591 %	.346	WEIGHT TAKEN
ADRENAL (AD)	.007	.0245 %	.0143	WEIGHT TAKEN
THYMUS (TH)	.03	.097 %	.057	WEIGHT TAKEN

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE
OBSERVATIONS

PATHOLOGY OBSERVATIONS
NECROPSY

^COLLECTED/TAKEN (XW) :
-LIVER SECTIONS, IN METHANOL

HISTOPATHOLOGY

ADRENAL, CORTEX (AC) :
-PIGMENT, -MINIMAL
-HYPERPLASIA, SUBCAPSULAR CELL, -MINIMAL
LIVER (LI) :
-HEPATOCYTE, HYPERTROPHY,
CENTROLOBULAR, -MINIMAL

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93

PAGE: 596

STUDY NUMBER: 483287

ANIMAL NUMBER: A37433 SEX: MALE DOSE GROUP: 2 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/14/91 STUDY DAY OF DEATH: 98 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 28.2 GRAMS
DATE AND TIME OF NECROPSY: 11/14/91 7:50 PROSECTOR: JANE EARHARDT RECORDER: JANE EARHARDT
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), EPIDIDYMIS (EP), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE),
KIDNEY (KD), LACRIMAL GL, EX (EO), LIVER (LI), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU),
MAND SALIVARY GL (SG), MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON),
NERVE, SCIATIC (SN), PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), PROSTATE (PR), RECTUM (RE), SKIN (SK),
SKIN, OTHER (SS), SPLEEN (SP), STOMACH, GL (ST), STOMACH, NONGL (SU), TESTIS (TE), THYMUS (TH), THYROID (TY),
TONGUE (TO), TRACHEA (TR), URINARY BLADDER (UB)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:

ADRENAL, MEDULLA (AM)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 597

STUDY NUMBER: 483287

ANIMAL NUMBER: A37434 SEX: MALE DOSE GROUP: 2 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/14/91 STUDY DAY OF DEATH: 98 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 25.0 GRAMS
DATE AND TIME OF NECROPSY: 11/14/91 8:58 PROSECTOR: SCOTT BELL RECORDER: SCOTT BELL
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.23	.915 %	.426	WEIGHT TAKEN
LUNG (LU)	.20	.792 %	.369	WEIGHT TAKEN
PROSTATE (PR)	.028	.1136 %	.0529	WEIGHT TAKEN
BRAIN W/STEM (BR)	.54	2.149 %	1.000	WEIGHT TAKEN
HEART (HT)	.16	.632 %	.294	WEIGHT TAKEN
SPLEEN (SP)	.06	.250 %	.116	WEIGHT TAKEN
KIDNEY (KD)	.49	1.972 %	.918	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	1.05	4.182 %	1.946	WEIGHT TAKEN
TESTIS (TE)	.23	.929 %	.432	WEIGHT TAKEN
EPIDIDYMIS (EP)	.11	.430 %	.200	WEIGHT TAKEN
ADRENAL (AD)	.006	.0256 %	.0119	WEIGHT TAKEN
THYMUS (TH)	.02	.097 %	.045	WEIGHT TAKEN

CLINICAL OBSERVATIONS

PATHOLOGY OBSERVATIONS
NECROPSY

HISTOPATHOLOGY

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE
OBSERVATIONS

LN, MESENTERIC (MS) :
-DARK; DARK RED
^COLLECTED/TAKEN (XW) :
-LIVER SECTIONS, IN METHANOL

ADRENAL, CORTEX (AC) :
-PIGMENT,-MINIMAL
-UNILATERALLY EXAMINED,-PRESENT
ADRENAL, MEDULLA (AM) :
-UNILATERALLY EXAMINED,-PRESENT
LN, MESENTERIC (MS) :
-MACROPHAGES, PIGMENTED,-MINIMAL
-HEMORRHAGE,-PRESENT

APPENDIX 13B

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 598

STUDY NUMBER: 483287

ANIMAL NUMBER: A37434 SEX: MALE DOSE GROUP: 2 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/14/91 STUDY DAY OF DEATH: 98 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 25.0 GRAMS
DATE AND TIME OF NECROPSY: 11/14/91 8:58 PROSECTOR: SCOTT BELL RECORDER: SCOTT BELL
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), EPIDIDYMIS (EP), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE),
KIDNEY (KD), LACRIMAL GL, EX (EO), LIVER (LI), LN, MANDIBULAR (MN), LUNG (LU), MAND SALIVARY GL (SG),
MARKOW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON), NERVE, SCIATIC (SN),
PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), PROSTATE (PR), RECTUM (RE), SKIN (SK), SKIN, OTHER (SS),
SPLEEN (SP), STOMACH, GL (ST), STOMACH, NONGL (SU), TESTIS (TE), THYMUS (TH), THYROID (TY), TONGUE (TO),
TRACHEA (TR), URINARY BLADDER (UB)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:
LIVER (LI)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 599

STUDY NUMBER: 483287

ANIMAL NUMBER: A37435 SEX: MALE DOSE GROUP: 2 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/14/91 STUDY DAY OF DEATH: 98 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 26.2 GRAMS
DATE AND TIME OF NECROPSY: 11/14/91 9:41 PROSECTOR: JANE EARHARDT RECORDER: JANE EARHARDT
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.23	.865 %	.448	WEIGHT TAKEN
LUNG (LU)	.18	.683 %	.354	WEIGHT TAKEN
PROSTATE (PR)	.064	.2450 %	.1270	WEIGHT TAKEN
BRAIN W/STEM (BR)	.51	1.929 %	1.000	WEIGHT TAKEN
HEART (HT)	.14	.531 %	.275	WEIGHT TAKEN
SPLEEN (SP)	.06	.229 %	.119	WEIGHT TAKEN
KIDNEY (KD)	.49	1.858 %	.963	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	1.40	5.341 %	2.768	WEIGHT TAKEN
TESTIS (TE)	.14	.526 %	.273	WEIGHT TAKEN
EPIDIDYMIS (EP)	.11	.426 %	.221	WEIGHT TAKEN
ADRENAL (AD)	.004	.0160 %	.0083	WEIGHT TAKEN
THYMUS (TH)	.02	.095 %	.049	WEIGHT TAKEN

CLINICAL OBSERVATIONS

PATHOLOGY OBSERVATIONS
NECROPSY

HISTOPATHOLOGY

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE
OBSERVATIONS

^COLLECTED/TAKEN (XW) :
-LIVER SECTIONS, IN METHANOL

ADRENAL, CORTEX (AC) :
-PIGMENT,-SLIGHT

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 600

STUDY NUMBER: 483287

ANIMAL NUMBER: A37435 SEX: MALE DOSE GROUP: 2 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/14/91 STUDY DAY OF DEATH: 98 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 26.2 GRAMS
DATE AND TIME OF NECROPSY: 11/14/91 9:41 PROSECTOR: JANE EARHARDT RECORDER: JANE EARHARDT
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), EPIDIDYMIS (EP), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE),
KIDNEY (KD), LACRIMAL GL, EX (EO), LIVER (LI), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU),
MAND SALIVARY GL (SG), MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON),
NERVE, SCIATIC (SN), PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), PROSTATE (PR), RECTUM (RE), SKIN (SK),
SKIN, OTHER (SS), SPLEEN (SP), STOMACH, GL (ST), STOMACH, NONGL (SU), TESTIS (TE), THYMUS (TH), THYROID (TY),
TONGUE (TO), TRACHEA (TR), URINARY BLADDER (UB)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:

ADRENAL, MEDULLA (AM), LIVER (LI)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 601

STUDY NUMBER: 483287

ANIMAL NUMBER: A37451 SEX: MALE DOSE GROUP: 3 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/11/91 STUDY DAY OF DEATH: 95 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 28.3 GRAMS
DATE AND TIME OF NECROPSY: 11/11/91 8:50 PROSECTOR: ADEFOLAHAN AKINSOLA RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.20	.700 %	.416	WEIGHT TAKEN
LUNG (LU)	.17	.593 %	.352	WEIGHT TAKEN
PROSTATE (PR)	.056	.1979 %	.1175	WEIGHT TAKEN
BRAIN W/STEM (BR)	.48	1.684 %	1.000	WEIGHT TAKEN
HEART (HT)	.15	.535 %	.318	WEIGHT TAKEN
SPLEEN (SP)	.06	.221 %	.131	WEIGHT TAKEN
KIDNEY (KD)	.55	1.949 %	1.157	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	1.78	6.275 %	3.725	WEIGHT TAKEN
TESTIS (TE)	.19	.667 %	.396	WEIGHT TAKEN
EPIDIDYMIS (EP)	.12	.435 %	.258	WEIGHT TAKEN
ADRENAL (AD)	.010	.0353 %	.0210	WEIGHT TAKEN
THYMUS (TH)	.02	.088 %	.052	WEIGHT TAKEN

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE
OBSERVATIONS

PATHOLOGY OBSERVATIONS
NECROPSY

^COLLECTED/TAKEN (XW) :
-LIVER SECTIONS, IN METHANOL

HISTOPATHOLOGY

LIVER (LI) :
-HEPATOCYTE, HYPERTROPHY,
CENTROLOBULAR, -SLIGHT
-VACUOLIZATION, -MINIMAL
-KUPFFER CELL/MACROPHAGE, PIGMENT, -
MINIMAL
-NECROSIS, -MINIMAL, FOCAL
-NECROSIS, INDIVIDUAL CELL, -MINIMAL
-INFLAMMATION, CHRONIC/CHRONIC ACTIVE, -
MINIMAL

HAZLETON WASHINGTON, INC.
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APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 602

STUDY NUMBER: 483287

ANIMAL NUMBER: A37451 SEX: MALE DOSE GROUP: 3 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/11/91 STUDY DAY OF DEATH: 95 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 28.3 GRAMS
DATE AND TIME OF NECROPSY: 11/11/91 8:50 PROSECTOR: ADEFOLAHAN AKINSOLA RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), EPIDIDYMIS (EP), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE),
KIDNEY (KD), LACRIMAL GL, EX (EO), LIVER (LI), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU),
MAND SALIVARY GL (SG), MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON),
NERVE, SCIATIC (SN), PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), PROSTATE (PR), RECTUM (RE), SKIN (SK),
SKIN, OTHER (SS), SPLEEN (SP), STOMACH, GL (ST), STOMACH, NONGL (SU), TESTIS (TE), THYMUS (TH), THYROID (TY),
TONGUE (TO), TRACHEA (TR), URINARY BLADDER (UB)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 603

STUDY NUMBER: 483287

ANIMAL NUMBER: A37452 SEX: MALE DOSE GROUP: 3 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/11/91 STUDY DAY OF DEATH: 95 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 27.8 GRAMS
DATE AND TIME OF NECROPSY: 11/11/91 10:05 PROSECTOR: DOUGLAS HERNDON RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: JANE EARNHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.20	.717 %	.406	WEIGHT TAKEN
LUNG (LU)	.16	.592 %	.335	WEIGHT TAKEN
PROSTATE (PR)	.052	.1853 %	.1049	WEIGHT TAKEN
BRAIN W/STEM (BR)	.49	1.766 %	1.000	WEIGHT TAKEN
HEART (HT)	.15	.547 %	.310	WEIGHT TAKEN
SPLEEN (SP)	.06	.220 %	.125	WEIGHT TAKEN
KIDNEY (KD)	.50	1.781 %	1.008	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	1.58	5.700 %	3.228	WEIGHT TAKEN
TESTIS (TE)	.25	.882 %	.499	WEIGHT TAKEN
EPIDIDYMIS (EP)	.11	.403 %	.228	WEIGHT TAKEN
ADRENAL (AD)	.007	.0245 %	.0139	WEIGHT TAKEN
THYMUS (TH)	.02	.074 %	.042	WEIGHT TAKEN

CLINICAL OBSERVATIONS	PATHOLOGY OBSERVATIONS NECROPSY	HISTOPATHOLOGY
-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS		LIVER (LI) : -HEPATOCYTE, HYPERTROPHY, CENTROLOBULAR, -MINIMAL -KUPFFER CELL/MACROPHAGE, PIGMENT, - MINIMAL SPLEEN (SP) : -EXTRAMEDULLARY HEMATOPOIESIS, INCREASED, -SLIGHT -PIGMENT, -MINIMAL
	^COLLECTED/TAKEN (XW) : -LIVER SECTIONS, IN METHANOL	

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 604

STUDY NUMBER: 483287

ANIMAL NUMBER: A37452 SEX: MALE DOSE GROUP: 3 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/11/91 STUDY DAY OF DEATH: 95 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 27.8 GRAMS
DATE AND TIME OF NECROPSY: 11/11/91 10:05 PROSECTOR: DOUGLAS HERNDON RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), EPIDIDYMIS (EP), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE),
KIDNEY (KD), LACRIMAL GL, EX (EO), LIVER (LI), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU),
MAND SALIVARY GL (SG), MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON),
NERVE, SCIATIC (SN), PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), PROSTATE (PR), RECTUM (RE), SKIN (SK),
SKIN, OTHER (SS), SPLEEN (SP), STOMACH, GL (ST), STOMACH, NONGL (SU), TESTIS (TE), THYMUS (TH), THYROID (TY),
TONGUE (TO), TRACHEA (TR), URINARY BLADDER (UB)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), PANCREAS (PA), STOMACH, GL (ST), STOMACH, NONGL (SU)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 605

STUDY NUMBER: 483287

ANIMAL NUMBER: A37453 SEX: MALE DOSE GROUP: 3 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/11/91 STUDY DAY OF DEATH: 95 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 29.2 GRAMS
DATE AND TIME OF NECROPSY: 11/11/91 11:08 PROSECTOR: SCOTT BELL RECORDER: SCOTT BELL
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.17	.598 %	.343	WEIGHT TAKEN
LUNG (LU)	.17	.584 %	.334	WEIGHT TAKEN
PROSTATE (PR)	.063	.2168 %	.1242	WEIGHT TAKEN
BRAIN W/STEM (BR)	.51	1.745 %	1.000	WEIGHT TAKEN
HEART (HT)	.18	.606 %	.347	WEIGHT TAKEN
SPLEEN (SP)	.07	.243 %	.140	WEIGHT TAKEN
KIDNEY (KD)	.46	1.581 %	.906	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	1.60	5.473 %	3.136	WEIGHT TAKEN
TESTIS (TE)	.22	.745 %	.427	WEIGHT TAKEN
EPIDIDYMIS (EP)	.10	.339 %	.195	WEIGHT TAKEN
ADRENAL (AD)	.007	.0247 %	.0141	WEIGHT TAKEN
THYMUS (TH)	.03	.105 %	.060	WEIGHT TAKEN

CLINICAL OBSERVATIONS	PATHOLOGY OBSERVATIONS NECROPSY	HISTOPATHOLOGY
-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS		LIVER (LI) : -HEPATOCYTE, HYPERTROPHY, CENTROLOBULAR,-MINIMAL -NECROSIS, INDIVIDUAL CELL,-MINIMAL -INFLAMMATION, CHRONIC/CHRONIC ACTIVE,- MINIMAL

^COLLECTED/TAKEN (XW) :
-LIVER SECTIONS, IN METHANOL

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), EPIDIDYMIS (EP), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE),
KIDNEY (KD), LACRIMAL GL, EX (EO), LIVER (LI), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU),
MAND SALIVARY GL (SG), MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON),
NERVE, SCIATIC (SN), PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), PROSTATE (PR), RECTUM (RE), SKIN (SK),
SKIN, OTHER (SS), SPLEEN (SP), STOMACH, GL (ST), STOMACH, NONGL (SU), TESTIS (TE), THYMUS (TH), THYROID (TY),
TONGUE (TO), TRACHEA (TR), URINARY BLADDER (UB)

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

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STUDY NUMBER: 483287

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DATE OF DEATH: 11/11/91 STUDY DAY OF DEATH: 95 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 29.2 GRAMS
DATE AND TIME OF NECROPSY: 11/11/91 11:08 PROSECTOR: SCOTT BELL RECORDER: SCOTT BELL
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 607

STUDY NUMBER: 483287

ANIMAL NUMBER: A37454 SEX: MALE DOSE GROUP: 3 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/11/91 STUDY DAY OF DEATH: 95 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 26.4 GRAMS
DATE AND TIME OF NECROPSY: 11/11/91 13:27 PROSECTOR: ADEFOLAHAN AKINSOLA RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.20	.758 %	.406	WEIGHT TAKEN
LUNG (LU)	.18	.670 %	.359	WEIGHT TAKEN
PROSTATE (PR)	.044	.1674 %	.0897	WEIGHT TAKEN
BRAIN W/STEM (BR)	.49	1.867 %	1.000	WEIGHT TAKEN
HEART (HT)	.15	.583 %	.312	WEIGHT TAKEN
SPLEEN (SP)	.06	.239 %	.128	WEIGHT TAKEN
KIDNEY (KD)	.45	1.697 %	.909	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	1.45	5.483 %	2.936	WEIGHT TAKEN
TESTIS (TE)	.17	.642 %	.344	WEIGHT TAKEN
EPIDIDYMIS (EP)	.12	.438 %	.235	WEIGHT TAKEN
ADRENAL (AD)	.002	.0057 %	.0030	EXCLUDE
THYMUS (TH)	.03	.102 %	.055	WEIGHT TAKEN

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE
OBSERVATIONS

PATHOLOGY OBSERVATIONS
NECROPSY

HISTOPATHOLOGY

ADRENAL, CORTEX (AC) :
-UNILATERALLY EXAMINED,-PRESENT
LIVER (LI) :
-HEPATOCYTE, HYPERTROPHY,
CENTROLOBULAR,-MINIMAL
-VACUOLIZATION,-MINIMAL
SPLEEN (SP) :
-EXTRAMEDULLARY HEMATOPOIESIS,
INCREASED,-MINIMAL
-PIGMENT,-MINIMAL

^COLLECTED/TAKEN (XW) :
-LIVER SECTIONS, IN METHANOL

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
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DATE OF DEATH: 11/11/91 STUDY DAY OF DEATH: 95 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 26.4 GRAMS
DATE AND TIME OF NECROPSY: 11/11/91 13:27 PROSECTOR: ADEFOLAHAN AKINSOLA RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), EPIDIDYMIS (EP), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE),
KIDNEY (KD), LACRIMAL GL, EX (EO), LIVER (LI), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU),
MAND SALIVARY GL (SG), MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON),
NERVE, SCIATIC (SN), PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), PROSTATE (PR), RECTUM (RE), SKIN (SK),
SKIN, OTHER (SS), SPLEEN (SP), STOMACH, GL (ST), STOMACH, NONGL (SU), TESTIS (TE), THYMUS (TH), THYROID (TY),
TONGUE (TO), TRACHEA (TR), URINARY BLADDER (UB)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:

STOMACH, GL (ST), STOMACH, NONGL (SU)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
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STUDY NUMBER: 483287

ANIMAL NUMBER: A37455 SEX: MALE DOSE GROUP: 3 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/12/91 STUDY DAY OF DEATH: 96 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 26.1 GRAMS
DATE AND TIME OF NECROPSY: 11/12/91 8:47 PROSECTOR: JANE EARHARDT RECORDER: JANE EARHARDT
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	O R G A N S T A T U S
MAND SALIVARY GL (SG)	.20	.767 %	.379	WEIGHT TAKEN
LUNG (LU)	.19	.713 %	.352	WEIGHT TAKEN
PROSTATE (PR)	.060	.2284 %	.1128	WEIGHT TAKEN
BRAIN W/STEM (BR)	.53	2.025 %	1.000	WEIGHT TAKEN
HEART (HT)	.15	.562 %	.277	WEIGHT TAKEN
SPLEEN (SP)	.09	.346 %	.171	WEIGHT TAKEN
KIDNEY (KD)	.46	1.747 %	.863	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	1.33	5.093 %	2.515	WEIGHT TAKEN
TESTIS (TE)	.19	.737 %	.364	WEIGHT TAKEN
EPIDIDYMIS (EP)	.11	.415 %	.205	WEIGHT TAKEN
ADRENAL (AD)	.004	.0153 %	.0076	WEIGHT TAKEN
THYMUS (TH)	.03	.134 %	.066	WEIGHT TAKEN

P A T H O L O G Y O B S E R V A T I O N S
NECROPSY

CLINICAL OBSERVATIONS

HISTOPATHOLOGY

-LAST PHYSICAL EXAM: NORMAL-NO REMARKABLE
OBSERVATIONS

^COLLECTED/TAKEN (XW) :
-LIVER SECTIONS, IN METHANOL

APPENDIX 13B

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
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DATE OF DEATH: 11/12/91 STUDY DAY OF DEATH: 96 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 26.1 GRAMS
DATE AND TIME OF NECROPSY: 11/12/91 8:47 PROSECTOR: JANE EARHARDT RECORDER: JANE EARHARDT
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), EPIDIDYMIS (EP), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE),
KIDNEY (KD), LACRIMAL GL, EX (EO), LIVER (LI), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU),
MAND SALIVARY GL (SG), MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON),
NERVE, SCIATIC (SN), PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), PROSTATE (PR), RECTUM (RE), SKIN (SK),
SKIN, OTHER (SS), SPLEEN (SP), STOMACH, GL (ST), STOMACH, NONGL (SU), TESTIS (TE), THYMUS (TH), THYROID (TY),
TONGUE (TO), TRACHEA (TR), URINARY BLADDER (UB)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:
LIVER (LI)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

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PAGE: 611

STUDY NUMBER: 483287

ANIMAL NUMBER: A37456 SEX: MALE DOSE GROUP: 3 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/12/91 STUDY DAY OF DEATH: 96 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 32.9 GRAMS
DATE AND TIME OF NECROPSY: 11/12/91 9:35 PROSECTOR: JANE EARHARDT RECORDER: JANE EARHARDT
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.24	.729 %	.461	WEIGHT TAKEN
LUNG (LU)	.21	.630 %	.399	WEIGHT TAKEN
PROSTATE (PR)	.102	.3112 %	.1971	WEIGHT TAKEN
BRAIN W/STEM (BR)	.52	1.579 %	1.000	WEIGHT TAKEN
HEART (HT)	.18	.548 %	.347	WEIGHT TAKEN
SPLEEN (SP)	.07	.198 %	.126	WEIGHT TAKEN
KIDNEY (KD)	.52	1.572 %	.996	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	1.75	5.326 %	3.373	WEIGHT TAKEN
TESTIS (TE)	.23	.702 %	.444	WEIGHT TAKEN
EPIDIDYMIS (EP)	.17	.508 %	.322	WEIGHT TAKEN
ADRENAL (AD)	.008	.0237 %	.0150	WEIGHT TAKEN
THYMUS (TH)	.04	.133 %	.084	WEIGHT TAKEN

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE
OBSERVATIONS

PATHOLOGY OBSERVATIONS
NECROPSY

HISTOPATHOLOGY

LIVER (LI) :
-HEPATOCYTE, HYPERTROPHY,
CENTROLOBULAR,-SLIGHT
-VACUOLIZATION,-SLIGHT
-NECROSIS, INDIVIDUAL CELL,-MINIMAL
SPLEEN (SP) :
-EXTRAMEDULLARY HEMATOPOIESIS,
INCREASED,-SLIGHT
-PIGMENT,-MINIMAL

^COLLECTED/TAKEN (XW) :
-LIVER SECTIONS, IN METHANOL

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
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DATE AND TIME OF NECROPSY: 11/12/91 9:35 PROSECTOR: JANE EARHARDT RECORDER: JANE EARHARDT
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), EPIDIDYMIS (EP), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE),
KIDNEY (KD), LACRIMAL GL, EX (EO), LIVER (LI), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU),
MAND SALIVARY GL (SG), MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON),
NERVE, SCIATIC (SN), PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), PROSTATE (PR), RECTUM (RE), SKIN (SK),
SKIN, OTHER (SS), SPLEEN (SP), STOMACH, GL (ST), STOMACH, NONGL (SU), TESTIS (TE), THYMUS (TH), THYROID (TY),
TONGUE (TO), TRACHEA (TR), URINARY BLADDER (UB)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), STOMACH, GL (ST), STOMACH, NONGL (SU)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
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STUDY NUMBER: 483287

ANIMAL NUMBER: A37457 SEX: MALE DOSE GROUP: 3 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/12/91 STUDY DAY OF DEATH: 96 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 31.8 GRAMS
DATE AND TIME OF NECROPSY: 11/12/91 10:50 PROSECTOR: JANE EARHARDT RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.22	.691 %	.470	WEIGHT TAKEN
LUNG (LU)	.19	.608 %	.413	WEIGHT TAKEN
PROSTATE (PR)	.096	.3019 %	.2051	WEIGHT TAKEN
BRAIN W/STEM (BR)	.47	1.472 %	1.000	WEIGHT TAKEN
HEART (HT)	.15	.480 %	.326	WEIGHT TAKEN
SPLEEN (SP)	.06	.189 %	.128	WEIGHT TAKEN
KIDNEY (KD)	.44	1.374 %	.933	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	1.69	5.330 %	3.622	WEIGHT TAKEN
TESTIS (TE)	.22	.700 %	.476	WEIGHT TAKEN
EPIDIDYMIS (EP)	.12	.367 %	.250	WEIGHT TAKEN
ADRENAL (AD)	.006	.0186 %	.0126	WEIGHT TAKEN
THYMUS (TH)	.03	.092 %	.063	WEIGHT TAKEN

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE
OBSERVATIONS

PATHOLOGY OBSERVATIONS
NECROPSY

^COLLECTED/TAKEN (XW) :
-LIVER SECTIONS, IN METHANOL

HISTOPATHOLOGY

LIVER (LI) :
-HEPATOCTYE, HYPERTROPHY,
CENTROLOBULAR,-SLIGHT
-VACUOLIZATION,-SLIGHT
-NECROSIS, INDIVIDUAL CELL,-MINIMAL
-INFLAMMATION, CHRONIC/CHRONIC ACTIVE,-
MINIMAL

HAZLETON WASHINGTON, INC.
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13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
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ANIMAL NUMBER: A37457 SEX: MALE DOSE GROUP: 3 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/12/91 STUDY DAY OF DEATH: 96 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 31.8 GRAMS
DATE AND TIME OF NECROPSY: 11/12/91 10:50 PROSECTOR: JANE EARHARDT RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), EPIDIDYMIS (EP), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE),
KIDNEY (KD), LACRIMAL GL, EX (EO), LIVER (LI), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU),
MAND SALIVARY GL (SG), MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON),
NERVE, SCIATIC (SN), PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), PROSTATE (PR), RECTUM (RE), SKIN (SK),
SKIN, OTHER (SS), SPLEEN (SP), STOMACH, GL (ST), STOMACH, NONGL (SU), TESTIS (TE), THYMUS (TH), THYROID (TY),
TONGUE (TO), TRACHEA (TR), URINARY BLADDER (UB)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 615

STUDY NUMBER: 483287

ANIMAL NUMBER: A37458 SEX: MALE DOSE GROUP: 3 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/12/91 STUDY DAY OF DEATH: 96 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 29.6 GRAMS
DATE AND TIME OF NECROPSY: 11/12/91 13:01 PROSECTOR: JANE EARHARDT RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.27	.914 %	.509	WEIGHT TAKEN
LUNG (LU)	.21	.701 %	.391	WEIGHT TAKEN
PROSTATE (PR)	.075	.2544 %	.1418	WEIGHT TAKEN
BRAIN W/STEM (BR)	.53	1.794 %	1.000	WEIGHT TAKEN
HEART (HT)	.17	.558 %	.311	WEIGHT TAKEN
SPLEEN (SP)	.08	.255 %	.142	WEIGHT TAKEN
KIDNEY (KD)	.44	1.477 %	.823	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	1.59	5.370 %	2.993	WEIGHT TAKEN
TESTIS (TE)	.25	.836 %	.466	WEIGHT TAKEN
EPIDIDYMIS (EP)	.14	.463 %	.258	WEIGHT TAKEN
ADRENAL (AD)	.005	.0186 %	.0104	WEIGHT TAKEN
THYMUS (TH)	.03	.094 %	.053	WEIGHT TAKEN

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE
OBSERVATIONS

PATHOLOGY OBSERVATIONS
NECROPSY

HISTOPATHOLOGY

LIVER (LI) :
-HEPATOCYTE, HYPERTROPHY,
CENTROLOBULAR, -MINIMAL
-VACUOLIZATION, -MINIMAL
SPLEEN (SP) :
-EXTRAMEDULLARY HEMATOPOIESIS,
INCREASED, -SLIGHT
-PIGMENT, -MINIMAL
STOMACH, GL (ST) :
-INFLAMMATION, CHRONIC, -MINIMAL

^COLLECTED/TAKEN (XW) :
-LIVER SECTIONS, IN METHANOL

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 616

STUDY NUMBER: 483287

ANIMAL NUMBER: A37458 SEX: MALE DOSE GROUP: 3 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/12/91 STUDY DAY OF DEATH: 96 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 29.6 GRAMS
DATE AND TIME OF NECROPSY: 11/12/91 13:01 PROSECTOR: JANE EARHARDT RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), EPIDIDYMIS (EP), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE),
KIDNEY (KD), LACRIMAL GL, EX (EO), LIVER (LI), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU),
MAND SALIVARY GL (SG), MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON),
NERVE, SCIATIC (SN), PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), PROSTATE (PR), RECTUM (RE), SKIN (SK),
SKIN, OTHER (SS), SPLEEN (SP), STOMACH, GL (ST), STOMACH, NONGL (SU), TESTIS (TE), THYMUS (TH), THYROID (TY),
TONGUE (TO), TRACHEA (TR), URINARY BLADDER (UB)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), STOMACH, NONGL (SU)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 617

STUDY NUMBER: 483287

ANIMAL NUMBER: A37459 SEX: MALE DOSE GROUP: 3 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/13/91 STUDY DAY OF DEATH: 97 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 26.4 GRAMS
DATE AND TIME OF NECROPSY: 11/13/91 8:30 PROSECTOR: FRED AGEY RECORDER: FRED AGEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.22	.817 %	.547	WEIGHT TAKEN
LUNG (LU)	.16	.598 %	.400	WEIGHT TAKEN
PROSTATE (PR)	.039	.1489 %	.0996	WEIGHT TAKEN
BRAIN W/STEM (BR)	.39	1.495 %	1.000	WEIGHT TAKEN
HEART (HT)	.15	.586 %	.392	WEIGHT TAKEN
SPLEEN (SP)	.07	.252 %	.169	WEIGHT TAKEN
KIDNEY (KD)	.48	1.822 %	1.219	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	1.60	6.045 %	4.044	WEIGHT TAKEN
TESTIS (TE)	.22	.815 %	.545	WEIGHT TAKEN
EPIDIDYMIS (EP)	.13	.478 %	.320	WEIGHT TAKEN
ADRENAL (AD)	.008	.0311 %	.0208	WEIGHT TAKEN
THYMUS (TH)	.03	.128 %	.085	WEIGHT TAKEN

CLINICAL OBSERVATIONS	PATHOLOGY OBSERVATIONS NECROPSY	HISTOPATHOLOGY
-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS	LIVER (LI) : -DARK; ALL LOBES, DARK BROWN -MASS; PAPILLARY PROCESS, ONE, FIRM, TAN, RED, 7 X 5 MM, CUT SURFACE:SAME	LIVER (LI) : -HEPATOCYTE, HYPERTROPHY, CENTROLOBULAR,-MINIMAL -INFARCT,-PRESENT >NOTE:>INFARCTED LOBE CORRESPONDS TO MASS. SPLEEN (SP) : -EXTRAMEDULLARY HEMATOPOIESIS, INCREASED,-SLIGHT -PIGMENT,-MINIMAL
	^COLLECTED/TAKEN (XW) : -LIVER SECTIONS, IN METHANOL	

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 618

STUDY NUMBER: 483287

ANIMAL NUMBER: A37459 SEX: MALE DOSE GROUP: 3 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/13/91 STUDY DAY OF DEATH: 97 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 26.4 GRAMS
DATE AND TIME OF NECROPSY: 11/13/91 8:30 PROSECTOR: FRED AGEY RECORDER: FRED AGEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), EPIDIDYMIS (EP), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE),
KIDNEY (KD), LACRIMAL GL, EX (EO), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU), MAND SALIVARY GL (SG),
MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON), NERVE, SCIATIC (SN),
PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), PROSTATE (PR), RECTUM (RE), SKIN (SK), SKIN, OTHER (SS),
SPLEEN (SP), STOMACH, GL (ST), STOMACH, NONGL (SU), TESTIS (TE), THYMUS (TH), THYROID (TY), TONGUE (TO),
TRACHEA (TR), URINARY BLADDER (UB)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), STOMACH, GL (ST), STOMACH, NONGL (SU)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 619

STUDY NUMBER: 483287

ANIMAL NUMBER: A37460 SEX: MALE DOSE GROUP: 3 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/13/91 STUDY DAY OF DEATH: 97 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 30.7 GRAMS
DATE AND TIME OF NECROPSY: 11/13/91 9:25 PROSECTOR: LINDA RUMBLE RECORDER: LINDA RUMBLE
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.17	.545 %	.311	WEIGHT TAKEN
LUNG (LU)	.18	.596 %	.340	WEIGHT TAKEN
PROSTATE (PR)	.027	.0893 %	.0509	WEIGHT TAKEN
BRAIN W/STEM (BR)	.54	1.753 %	1.000	WEIGHT TAKEN
HEART (HT)	.21	.674 %	.384	WEIGHT TAKEN
SPLEEN (SP)	.06	.185 %	.106	WEIGHT TAKEN
KIDNEY (KD)	.45	1.472 %	.839	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	1.84	5.998 %	3.421	WEIGHT TAKEN
TESTIS (TE)	.23	.745 %	.425	WEIGHT TAKEN
EPIDIDYMIS (EP)	.15	.496 %	.283	WEIGHT TAKEN
ADRENAL (AD)	.006	.0186 %	.0106	WEIGHT TAKEN
THYMUS (TH)	.03	.107 %	.061	WEIGHT TAKEN

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE
OBSERVATIONS

PATHOLOGY OBSERVATIONS
NECROPSY

HISTOPATHOLOGY

LIVER (LI) :
-HEPATOCYTE, HYPERTROPHY,
CENTROLOBULAR,-SLIGHT
-VACUOLIZATION,-MINIMAL
SPLEEN (SP) :
-EXTRAMEDULLARY HEMATOPOIESIS,
INCREASED,-MINIMAL
-PIGMENT,-MINIMAL
STOMACH, GL (ST) :
-HYPERPLASIA, CYSTIC,-MINIMAL
-INFLAMMATION, CHRONIC,-MINIMAL

^COLLECTED/TAKEN (XW) :
-LIVER SECTIONS, IN METHANOL

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 620

STUDY NUMBER: 483287

ANIMAL NUMBER: A37460 SEX: MALE DOSE GROUP: 3 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/13/91 STUDY DAY OF DEATH: 97 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 30.7 GRAMS
DATE AND TIME OF NECROPSY: 11/13/91 9:25 PROSECTOR: LINDA RUMBLE RECORDER: LINDA RUMBLE
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), EPIDIDYMIS (EP), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE),
KIDNEY (KD), LACRIMAL GL, EX (EO), LIVER (LI), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU),
MAND SALIVARY GL (SG), MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON),
NERVE, SCIATIC (SN), PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), PROSTATE (PR), RECTUM (RE), SKIN (SK),
SKIN, OTHER (SS), SPLEEN (SP), STOMACH, GL (ST), STOMACH, NONGL (SU), TESTIS (TE), THYMUS (TH), THYROID (TY),
TONGUE (TO), TRACHEA (TR), URINARY BLADDER (UB)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), STOMACH, NONGL (SU)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 621

STUDY NUMBER: 483287

ANIMAL NUMBER: A37461 SEX: MALE DOSE GROUP: 3 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/13/91 STUDY DAY OF DEATH: 97 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 29.6 GRAMS
DATE AND TIME OF NECROPSY: 11/13/91 10:45 PROSECTOR: DOUGLAS HERNDON RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.20	.673 %	.404	WEIGHT TAKEN
LUNG (LU)	.22	.740 %	.444	WEIGHT TAKEN
PROSTATE (PR)	.096	.3233 %	.1940	WEIGHT TAKEN
BRAIN W/STEM (BR)	.49	1.666 %	1.000	WEIGHT TAKEN
HEART (HT)	.20	.675 %	.405	WEIGHT TAKEN
SPLEEN (SP)	.08	.273 %	.164	WEIGHT TAKEN
KIDNEY (KD)	.69	2.336 %	1.402	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	1.72	5.811 %	3.488	WEIGHT TAKEN
TESTIS (TE)	.25	.850 %	.510	WEIGHT TAKEN
EPIDIDYMIS (EP)	.14	.457 %	.274	WEIGHT TAKEN
ADRENAL (AD)	.008	.0277 %	.0166	WEIGHT TAKEN
THYMUS (TH)	.03	.086 %	.052	WEIGHT TAKEN

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE
OBSERVATIONS

PATHOLOGY OBSERVATIONS
NECROPSY

HISTOPATHOLOGY

LIVER (LI) :
-HEPATOCYTE, HYPERTROPHY,
CENTROLOBULAR,-MINIMAL
-KUPFFER CELL/MACROPHAGE, PIGMENT,-
MINIMAL

^COLLECTED/TAKEN (XW) :
-LIVER SECTIONS, IN METHANOL

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), EPIDIDYMIS (EP), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE),
KIDNEY (KD), LACRIMAL GL, EX (EO), LIVER (LI), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU),
MAND SALIVARY GL (SG), MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON),
NERVE, SCIATIC (SN), PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), PROSTATE (PR), RECTUM (RE), SKIN (SK),
SKIN, OTHER (SS), SPLEEN (SP), STOMACH, GL (ST), STOMACH, NONGL (SU), TESTIS (TE), THYMUS (TH), THYROID (TY),
TONGUE (TO), TRACHEA (TR), URINARY BLADDER (UB)

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 622

STUDY NUMBER: 483287

ANIMAL NUMBER: A37461 SEX: MALE DOSE GROUP: 3 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/13/91 STUDY DAY OF DEATH: 97 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 29.6 GRAMS
DATE AND TIME OF NECROPSY: 11/13/91 10:45 PROSECTOR: DOUGLAS HERNDON RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 623

STUDY NUMBER: 483287

ANIMAL NUMBER: A37462 SEX: MALE DOSE GROUP: 3 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/13/91 STUDY DAY OF DEATH: 97 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 27.3 GRAMS
DATE AND TIME OF NECROPSY: 11/13/91 12:50 PROSECTOR: LINDA RUMBLE RECORDER: LINDA RUMBLE
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.21	.778 %	.417	WEIGHT TAKEN
LUNG (LU)	.18	.659 %	.353	WEIGHT TAKEN
PROSTATE (PR)	.030	.1110 %	.0594	WEIGHT TAKEN
BRAIN W/STEM (BR)	.51	1.868 %	1.000	WEIGHT TAKEN
HEART (HT)	.17	.607 %	.325	WEIGHT TAKEN
SPLEEN (SP)	.07	.240 %	.129	WEIGHT TAKEN
KIDNEY (KD)	.42	1.526 %	.817	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	1.52	5.568 %	2.981	WEIGHT TAKEN
TESTIS (TE)	.36	1.335 %	.715	WEIGHT TAKEN
EPIIDIDYMIS (EP)	.15	.535 %	.286	WEIGHT TAKEN
ADRENAL (AD)	.006	.0231 %	.0124	WEIGHT TAKEN
THYMUS (TH)	.01	.046 %	.025	WEIGHT TAKEN

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE
OBSERVATIONS

PATHOLOGY OBSERVATIONS
NECROPSY

LIVER (LI) :
-ENLARGED, MODERATE; ALL LOBES
-DARK; ALL LOBES, DARK BROWN

TESTIS (TE) :
-DARK AREA; RIGHT, ONE, DARK RED, 5 X
4 MM
^COLLECTED/TAKEN (XW) :
-LIVER SECTIONS, IN METHANOL

HISTOPATHOLOGY

LIVER (LI) :
-HEPATOCYTE, HYPERTROPHY,
CENTROLOBULAR,-SLIGHT
SPLEEN (SP) :
-EXTRAMEDULLARY HEMATOPOIESIS,
INCREASED,-SLIGHT
-PIGMENT,-MINIMAL
STOMACH, GL (ST) :
-INFLAMMATION, CHRONIC,-MINIMAL
TESTIS (TE) :
-HEMORRHAGE,-PRESENT

APPENDIX 13B

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 624

STUDY NUMBER: 483287

ANIMAL NUMBER: A37462 SEX: MALE DOSE GROUP: 3 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/13/91 STUDY DAY OF DEATH: 97 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 27.3 GRAMS
DATE AND TIME OF NECROPSY: 11/13/91 12:50 PROSECTOR: LINDA RUMBLE RECORDER: LINDA RUMBLE
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), EPIDIDYMIS (EP), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE),
KIDNEY (KD), LACRIMAL GL, EX (EO), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU), MAND SALIVARY GL (SG),
MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON), NERVE, SCIATIC (SN),
PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), PROSTATE (PR), RECTUM (RE), SKIN (SK), SKIN, OTHER (SS),
SPLEEN (SP), STOMACH, GL (ST), STOMACH, NONGL (SU), THYMUS (TH), THYROID (TY), TONGUE (TO), TRACHEA (TR),
URINARY BLADDER (UB)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), STOMACH, NONGL (SU)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 625

STUDY NUMBER: 483287

ANIMAL NUMBER: A37463 SEX: MALE DOSE GROUP: 3 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/14/91 STUDY DAY OF DEATH: 98 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 25.5 GRAMS
DATE AND TIME OF NECROPSY: 11/14/91 7:55 PROSECTOR: ADEFOLOHAN AKINSOLA RECORDER: ADEFOLOHAN AKINSOLA
POST-FIX WEIGHER: JOHN CROWLEY PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.19	.756 %	.450	WEIGHT TAKEN
LUNG (LU)	.18	.692 %	.411	WEIGHT TAKEN
PROSTATE (PR)	.023	.0910 %	.0541	WEIGHT TAKEN
BRAIN W/STEM (BR)	.43	1.682 %	1.000	WEIGHT TAKEN
HEART (HT)	.13	.518 %	.308	WEIGHT TAKEN
SPLEEN (SP)	.05	.208 %	.124	WEIGHT TAKEN
KIDNEY (KD)	.48	1.873 %	1.114	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	1.77	6.924 %	4.118	WEIGHT TAKEN
TESTIS (TE)	.20	.765 %	.455	WEIGHT TAKEN
EPIDIDYMIS (EP)	.12	.487 %	.289	WEIGHT TAKEN
ADRENAL (AD)	.011	.0443 %	.0264	WEIGHT TAKEN
THYMUS (TH)	.01	.038 %	.023	WEIGHT TAKEN

CLINICAL OBSERVATIONS	PATHOLOGY OBSERVATIONS NECROPSY	HISTOPATHOLOGY
-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS	^COLLECTED/TAKEN (XW) : -LIVER SECTIONS, IN METHANOL	ADRENAL, CORTEX (AC) : -PIGMENT,-MINIMAL -HYPERPLASIA, SUBCAPSULAR CELL,-MINIMAL LIVER (LI) : -VACUOLIZATION,-MINIMAL -KUPFFER CELL/MACROPHAGE, PIGMENT,- MINIMAL SPLEEN (SP) : -PIGMENT,-MINIMAL

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 626

STUDY NUMBER: 483287

ANIMAL NUMBER: A37463 SEX: MALE DOSE GROUP: 3 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/14/91 STUDY DAY OF DEATH: 98 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 25.5 GRAMS
DATE AND TIME OF NECROPSY: 11/14/91 7:55 PROSECTOR: ADEFOLAHAN AKINSOLA RECORDER: ADEFOLAHAN AKINSOLA
POST-FIX WEIGHER: JOHN CROWLEY PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), EPIDIDYMIS (EP), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE),
KIDNEY (KD), LACRIMAL GL, EX (EO), LIVER (LI), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU),
MAND SALIVARY GL (SG), MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON),
NERVE, SCIATIC (SN), PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), PROSTATE (PR), RECTUM (RE), SKIN (SK),
SKIN, OTHER (SS), SPLEEN (SP), STOMACH, GL (ST), STOMACH, NONGL (SU), TESTIS (TE), THYMUS (TH), THYROID (TY),
TONGUE (TO), TRACHEA (TR), URINARY BLADDER (UB)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:

ADRENAL, MEDULLA (AM), STOMACH, GL (ST), STOMACH, NONGL (SU)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 627

STUDY NUMBER: 483287

ANIMAL NUMBER: A37464 SEX: MALE DOSE GROUP: 3 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/14/91 STUDY DAY OF DEATH: 98 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 28.3 GRAMS
DATE AND TIME OF NECROPSY: 11/14/91 9:00 PROSECTOR: ADEFOLAHAN AKINSOLA RECORDER: ADEFOLAHAN AKINSOLA
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.23	.810 %	.455	WEIGHT TAKEN
LUNG (LU)	.16	.578 %	.324	WEIGHT TAKEN
PROSTATE (PR)	.030	.1042 %	.0585	WEIGHT TAKEN
BRAIN W/STEM (BR)	.50	1.781 %	1.000	WEIGHT TAKEN
HEART (HT)	.19	.656 %	.368	WEIGHT TAKEN
SPLEEN (SP)	.07	.231 %	.130	WEIGHT TAKEN
KIDNEY (KD)	.63	2.232 %	1.253	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	1.76	6.206 %	3.484	WEIGHT TAKEN
TESTIS (TE)	.23	.803 %	.451	WEIGHT TAKEN
EPIDIDYMIS (EP)	.12	.431 %	.242	WEIGHT TAKEN
ADRENAL (AD)	.005	.0187 %	.0105	WEIGHT TAKEN
THYMUS (TH)	.03	.116 %	.065	WEIGHT TAKEN

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE
OBSERVATIONS

PATHOLOGY OBSERVATIONS
NECROPSY

HISTOPATHOLOGY

ADRENAL, CORTEX (AC) :
-HYPERPLASIA, SUBCAPSULAR CELL,-MINIMAL
-UNILATERALLY EXAMINED,-PRESENT
ADRENAL, MEDULLA (AM) :
-UNILATERALLY EXAMINED,-PRESENT
LIVER (LI) :
-HEPATOCYTE, HYPERTROPHY,
CENTROLOBULAR,-MINIMAL
-INFLAMMATION, CHRONIC/CHRONIC ACTIVE,-
MINIMAL
SPLEEN (SP) :
-PIGMENT,-MINIMAL
STOMACH, GL (ST) :
-INFLAMMATION, CHRONIC,-MINIMAL

^COLLECTED/TAKEN (XW) :
-LIVER SECTIONS, IN METHANOL

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 628

STUDY NUMBER: 483287

ANIMAL NUMBER: A37464 SEX: MALE DOSE GROUP: 3 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/14/91 STUDY DAY OF DEATH: 98 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 28.3 GRAMS
DATE AND TIME OF NECROPSY: 11/14/91 9:00 PROSECTOR: ADEFOLAHAN AKINSOLA RECORDER: ADEFOLAHAN AKINSOLA
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), EPIDIDYMIS (EP), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE),
KIDNEY (KD), LACRIMAL GL, EX (EO), LIVER (LI), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU),
MAND SALIVARY GL (SG), MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON),
NERVE, SCIATIC (SN), PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), PROSTATE (PR), RECTUM (RE), SKIN (SK),
SKIN, OTHER (SS), SPLEEN (SP), STOMACH, GL (ST), STOMACH, NONGL (SU), TESTIS (TE), THYMUS (TH), THYROID (TY),
TONGUE (TO), TRACHEA (TR), URINARY BLADDER (UB)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:

PANCREAS (PA), STOMACH, NONGL (SU)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 629

STUDY NUMBER: 483287

ANIMAL NUMBER: A37465 SEX: MALE DOSE GROUP: 3 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/14/91 STUDY DAY OF DEATH: 98 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 25.4 GRAMS
DATE AND TIME OF NECROPSY: 11/14/91 9:50 PROSECTOR: FRED AGEY RECORDER: FRED AGEY
POST-FIX WEIGHER: DANIEL JACK PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KACYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.26	1.012 %	.555	WEIGHT TAKEN
LUNG (LU)	.17	.668 %	.366	WEIGHT TAKEN
PROSTATE (PR)	.045	.1756 %	.0963	WEIGHT TAKEN
BRAIN W/STEM (BR)	.46	1.822 %	1.000	WEIGHT TAKEN
HEART (HT)	.16	.644 %	.353	WEIGHT TAKEN
SPLEEN (SP)	.05	.206 %	.113	WEIGHT TAKEN
KIDNEY (KD)	.43	1.682 %	.923	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	1.44	5.672 %	3.112	WEIGHT TAKEN
TESTIS (TE)	.22	.874 %	.480	WEIGHT TAKEN
EPIDIDYMIS (EP)	.11	.439 %	.241	WEIGHT TAKEN
ADRENAL (AD)	.011	.0417 %	.0229	WEIGHT TAKEN
THYMUS (TH)	.02	.096 %	.053	WEIGHT TAKEN

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE
OBSERVATIONS

PATHOLOGY OBSERVATIONS
NECROPSY

HISTOPATHOLOGY

ADRENAL, MEDULLA (AM) :
-UNILATERALLY EXAMINED,-PRESENT
LIVER (LI) :
-PIGMENT, BILE,-MINIMAL
-KUPFFER CELL/MACROPHAGE, PIGMENT,-
MINIMAL
-INFLAMMATION, CHRONIC/CHRONIC ACTIVE,-
MINIMAL
SPLEEN (SP) :
-EXTRAMEDULLARY HEMATOPOIESIS,
INCREASED,-MINIMAL
-PIGMENT,-MINIMAL

^COLLECTED/TAKEN (XW) :
-LIVER SECTIONS, IN METHANOL

APPENDIX 13B

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 630

STUDY NUMBER: 483287

ANIMAL NUMBER: A37465 SEX: MALE DOSE GROUP: 3 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/14/91 STUDY DAY OF DEATH: 98 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 25.4 GRAMS
DATE AND TIME OF NECROPSY: 11/14/91 9:50 PROSECTOR: FRED AGEY RECORDER: FRED AGEY
POST-FIX WEIGHER: DANIEL JACK PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), EPIDIDYMIS (EP), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE),
KIDNEY (KD), LACRIMAL GL, EX (EO), LIVER (LI), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU),
MAND SALIVARY GL (SG), MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON),
NERVE, SCIATIC (SN), PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), PROSTATE (PR), RECTUM (RE), SKIN (SK),
SKIN, OTHER (SS), SPLEEN (SP), STOMACH, GL (ST), STOMACH, NONGL (SU), TESTIS (TE), THYMUS (TH), THYROID (TY),
TONGUE (TO), TRACHEA (TR), URINARY BLADDER (UB)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:

ADRENAL, CORTEX (AC), STOMACH, GL (ST), STOMACH, NONGL (SU)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE, (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 631

STUDY NUMBER: 483287

ANIMAL NUMBER: A37481 SEX: MALE DOSE GROUP: 4 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/11/91 STUDY DAY OF DEATH: 95 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 28.2 GRAMS
DATE AND TIME OF NECROPSY: 11/11/91 8:54 PROSECTOR: FRED AGEY RECORDER: FRED AGEY
POST-FIX WEAIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEAIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.19	.672 %	.403	WEIGHT TAKEN
LUNG (LU)	.19	.671 %	.403	WEIGHT TAKEN
PROSTATE (PR)	.022	.0784 %	.0471	WEIGHT TAKEN
BRAIN W/STEM (BR)	.47	1.666 %	1.000	WEIGHT TAKEN
HEART (HT)	.15	.517 %	.311	WEIGHT TAKEN
SPLEEN (SP)	.06	.202 %	.121	WEIGHT TAKEN
KIDNEY (KD)	.52	1.831 %	1.099	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	1.74	6.170 %	3.704	WEIGHT TAKEN
TESTIS (TE)	.28	.983 %	.590	WEIGHT TAKEN
EPIDIDYMIS (EP)	.12	.435 %	.261	WEIGHT TAKEN
ADRENAL (AD)	.007	.0255 %	.0153	WEIGHT TAKEN
THYMUS (TH)	.03	.089 %	.054	WEIGHT TAKEN

CLINICAL OBSERVATIONS	PATHOLOGY OBSERVATIONS NECROPSY	HISTOPATHOLOGY
-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS	LIVER (LI) : -DARK; ALL LOBES, DARK BROWN	LIVER (LI) : -HEPATOCYTE, HYPERTROPHY, CENTROLOBULAR,-MINIMAL -VACUOLIZATION,-MINIMAL -KUPFFER CELL/MACROPHAGE, PIGMENT,- MINIMAL -NECROSIS, INDIVIDUAL CELL,-MINIMAL -INFLAMMATION, CHRONIC/CHRONIC ACTIVE,- MINIMAL
	^COLLECTED/TAKEN (XW) : -LIVER SECTIONS, IN METHANOL	

APPENDIX 13B

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 632

STUDY NUMBER: 483287

ANIMAL NUMBER: A37481 SEX: MALE DOSE GROUP: 4 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/11/91 STUDY DAY OF DEATH: 95 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 28.2 GRAMS
DATE AND TIME OF NECROPSY: 11/11/91 8:54 PROSECTOR: FRED AGEY RECORDER: FRED AGEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KACYARE

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), EPIDIDYMIS (EP), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE),
KIDNEY (KD), LACRIMAL GL, EX (EO), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU), MAND SALIVARY GL (SG),
MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON), NERVE, SCIATIC (SN),
PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), PROSTATE (PR), RECTUM (RE), SKIN (SK), SKIN, OTHER (SS),
SPLEEN (SP), STOMACH, GL (ST), STOMACH, NONGL (SU), TESTIS (TE), THYMUS (TH), THYROID (TY), TONGUE (TO),
TRACHEA (TR), URINARY BLADDER (UB)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 633

STUDY NUMBER: 483287

ANIMAL NUMBER: A37482 SEX: MALE DOSE GROUP: 4 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/11/91 STUDY DAY OF DEATH: 95 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 27.6 GRAMS
DATE AND TIME OF NECROPSY: 11/11/91 10:10 PROSECTOR: JANE EARHARDT RECORDER: JANE EARHARDT
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.21	.764 %	.420	WEIGHT TAKEN
LUNG (LU)	.21	.758 %	.417	WEIGHT TAKEN
PROSTATE (PR)	.066	.2373 %	.1306	WEIGHT TAKEN
BRAIN W/STEM (BR)	.50	1.817 %	1.000	WEIGHT TAKEN
HEART (HT)	.14	.507 %	.279	WEIGHT TAKEN
SPLEEN (SP)	.07	.236 %	.130	WEIGHT TAKEN
KIDNEY (KD)	.47	1.692 %	.931	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	2.06	7.458 %	4.105	WEIGHT TAKEN
TESTIS (TE)	.27	.961 %	.529	WEIGHT TAKEN
EPIDIDYMIS (EP)	.16	.577 %	.317	WEIGHT TAKEN
ADRENAL (AD)	.007	.0236 %	.0130	WEIGHT TAKEN
THYMUS (TH)	.03	.096 %	.053	WEIGHT TAKEN

CLINICAL OBSERVATIONS	PATHOLOGY OBSERVATIONS NECROPSY	HISTOPATHOLOGY
-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS		ADRENAL, CORTEX (AC) : -HYPERTROPHY, ZONA FASCICULATA,-MINIMAL LIVER (LI) : -HEPATOCTYE, HYPERTROPHY, CENTROLOBULAR,-MODERATE -VACUOLIZATION,-MODERATE -PIGMENT, BILE,-MINIMAL -KUPFFER CELL/MACROPHAGE, PIGMENT,- MINIMAL -HEPATOCTYE, PIGMENT,-MINIMAL -NECROSIS, INDIVIDUAL CELL,-MINIMAL -INFLAMMATION, CHRONIC/CHRONIC ACTIVE,- MINIMAL SPLEEN (SP) : -EXTRAMEDULLARY HEMATOPOIESIS, INCREASED,-SLIGHT -PIGMENT,-MINIMAL

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 634

STUDY NUMBER: 483287

ANIMAL NUMBER: A37482 SEX: MALE DOSE GROUP: 4 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/11/91 STUDY DAY OF DEATH: 95 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 27.6 GRAMS
DATE AND TIME OF NECROPSY: 11/11/91 10:10 PROSECTOR: JANE EARHARDT RECORDER: JANE EARHARDT
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

CLINICAL OBSERVATIONS PATHOLOGY OBSERVATIONS (CONTINUED) HISTOPATHOLOGY
NECROPSY

STOMACH, GL (ST) :
-HYPERPLASIA, CYSTIC, -MINIMAL

^COLLECTED/TAKEN (XW) :
-LIVER SECTIONS, IN METHANOL

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), EPIDIDYMIS (EP), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE),
KIDNEY (KD), LACRIMAL GL, EX (EO), LIVER (LI), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU),
MAND SALIVARY GL (SG), MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON),
NERVE, SCIATIC (SN), PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), PROSTATE (PR), RECTUM (RE), SKIN (SK),
SKIN, OTHER (SS), SPLEEN (SP), STOMACH, GL (ST), STOMACH, NONGL (SU), TESTIS (TE), THYMUS (TH), THYROID (TY),
TONGUE (TO), TRACHEA (TR), URINARY BLADDER (UB)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:
ADRENAL, MEDULLA (AM), STOMACH, NONGL (SU)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

PRINTED: 21-JAN-93
PAGE: 635

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

STUDY NUMBER: 483287

ANIMAL NUMBER: A37483 SEX: MALE DOSE GROUP: 4 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/11/91 STUDY DAY OF DEATH: 95 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 28.0 GRAMS
DATE AND TIME OF NECROPSY: 11/11/91 11:05 PROSECTOR: JANE EARHARDT RECORDER: JANE EARHARDT
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.19	.681 %	.364	WEIGHT TAKEN
LUNG (LU)	.20	.704 %	.376	WEIGHT TAKEN
PROSTATE (PR)	.095	.3382 %	.1808	WEIGHT TAKEN
BRAIN W/STEM (BR)	.52	1.871 %	1.000	WEIGHT TAKEN
HEART (HT)	.21	.765 %	.409	WEIGHT TAKEN
SPLEEN (SP)	.07	.245 %	.131	WEIGHT TAKEN
KIDNEY (KD)	.51	1.814 %	.969	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	1.85	6.619 %	3.538	WEIGHT TAKEN
TESTIS (TE)	.26	.934 %	.499	WEIGHT TAKEN
EPIDIDYMIS (EP)	.16	.558 %	.298	WEIGHT TAKEN
ADRENAL (AD)	.007	.0250 %	.0134	WEIGHT TAKEN
THYMUS (TH)	.03	.108 %	.058	WEIGHT TAKEN

CLINICAL OBSERVATIONS	PATHOLOGY OBSERVATIONS NECROPSY	HISTOPATHOLOGY
-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS		LIVER (LI) : -HEPATOCTE, HYPERTROPHY, CENTROLOBULAR,-SLIGHT -KUPFFER CELL/MACROPHAGE, PIGMENT,- MINIMAL -HEPATOCTE, PIGMENT,-SLIGHT -NECROSIS,-MINIMAL, MULTI-FOCAL -NECROSIS, INDIVIDUAL CELL,-MINIMAL -INFLAMMATION, CHRONIC/CHRONIC ACTIVE,- MINIMAL
	^COLLECTED/TAKEN (XW) : -LIVER SECTIONS, IN METHANOL	

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 636

STUDY NUMBER: 483287

ANIMAL NUMBER: A37483 SEX: MALE DOSE GROUP: 4 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/11/91 STUDY DAY OF DEATH: 95 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 28.0 GRAMS
DATE AND TIME OF NECROPSY: 11/11/91 11:05 PROSECTOR: JANE EARHARDT RECORDER: JANE EARHARDT
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), EPIDIDYMIS (EP), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE),
KIDNEY (KD), LACRIMAL GL, EX (EO), LIVER (LI), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU),
MAND SALIVARY GL (SG), MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON),
NERVE, SCIATIC (SN), PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), PROSTATE (PR), RECTUM (RE), SKIN (SK),
SKIN, OTHER (SS), SPLEEN (SP), STOMACH, GL (ST), STOMACH, NONGL (SU), TESTIS (TE), THYMUS (TH), THYROID (TY),
TONGUE (TO), TRACHEA (TR), URINARY BLADDER (UB)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 637

STUDY NUMBER: 483287

ANIMAL NUMBER: A37485 SEX: MALE DOSE GROUP: 4 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/11/91 STUDY DAY OF DEATH: 95 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 26.2 GRAMS
DATE AND TIME OF NECROPSY: 11/11/91 13:30 PROSECTOR: JANE EARHARDT RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.21	.806 %	.414	WEIGHT TAKEN
LUNG (LU)	.18	.701 %	.359	WEIGHT TAKEN
PROSTATE (PR)	.064	.2443 %	.1252	WEIGHT TAKEN
BRAIN W/STEM (BR)	.51	1.950 %	1.000	WEIGHT TAKEN
HEART (HT)	.16	.597 %	.306	WEIGHT TAKEN
SPLEEN (SP)	.05	.173 %	.089	WEIGHT TAKEN
KIDNEY (KD)	.46	1.747 %	.896	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	1.68	6.422 %	3.293	WEIGHT TAKEN
TESTIS (TE)	.20	.752 %	.386	WEIGHT TAKEN
EPIDIDYMIS (EP)	.11	.416 %	.213	WEIGHT TAKEN
ADRENAL (AD)	.009	.0355 %	.0182	WEIGHT TAKEN
THYMUS (TH)	.02	.094 %	.048	WEIGHT TAKEN

CLINICAL OBSERVATIONS	PATHOLOGY OBSERVATIONS NECROPSY	HISTOPATHOLOGY
-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS	LIVER (LI) : -DARK; ALL LOBES, DARK BROWN	LIVER (LI) : -HEPATOCYTE, HYPERTROPHY, CENTROLOBULAR,-SLIGHT -VACUOLIZATION,-SLIGHT -PIGMENT, BILE,-MINIMAL -KUPFFER CELL/MACROPHAGE, PIGMENT,- MINIMAL -HEPATOCYTE, PIGMENT,-MINIMAL -INFLAMMATION, CHRONIC/CHRONIC ACTIVE,- MINIMAL
	^COLLECTED/TAKEN (XW) : -LIVER SECTIONS, IN METHANOL	

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 638

STUDY NUMBER: 483287

ANIMAL NUMBER: A37485 SEX: MALE DOSE GROUP: 4 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/11/91 STUDY DAY OF DEATH: 95 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 26.2 GRAMS
DATE AND TIME OF NECROPSY: 11/11/91 13:30 PROSECTOR: JANE EARHARDT RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), EPIDIDYMIS (EP), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE),
KIDNEY (KD), LACRIMAL GL, EX (EO), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU), MAND SALIVARY GL (SG),
MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON), NERVE, SCIATIC (SN),
PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), PROSTATE (PR), RECTUM (RE), SKIN (SK), SKIN, OTHER (SS),
SPLEEN (SP), STOMACH, GL (ST), STOMACH, NONGL (SU), TESTIS (TE), THYMUS (TH), THYROID (TY), TONGUE (TO),
TRACHEA (TR), URINARY BLADDER (UB)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 639

STUDY NUMBER: 483287

ANIMAL NUMBER: A37486 SEX: MALE DOSE GROUP: 4 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/12/91 STUDY DAY OF DEATH: 96 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 28.6 GRAMS
DATE AND TIME OF NECROPSY: 11/12/91 8:52 PROSECTOR: FRED AGEY RECORDER: FRED AGEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.25	.864 %	.560	WEIGHT TAKEN
LUNG (LU)	.18	.645 %	.418	WEIGHT TAKEN
PROSTATE (PR)	.035	.1231 %	.0797	WEIGHT TAKEN
BRAIN W/STEM (BR)	.44	1.543 %	1.000	WEIGHT TAKEN
HEART (HT)	.16	.576 %	.373	WEIGHT TAKEN
SPLEEN (SP)	.09	.320 %	.207	WEIGHT TAKEN
KIDNEY (KD)	.49	1.709 %	1.107	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	2.08	7.266 %	4.708	WEIGHT TAKEN
TESTIS (TE)	.26	.923 %	.598	WEIGHT TAKEN
EPIDIDYMIS (EP)	.12	.429 %	.278	WEIGHT TAKEN
ADRENAL (AD)	.009	.0315 %	.0204	WEIGHT TAKEN
THYMUS (TH)	.03	.088 %	.057	WEIGHT TAKEN

CLINICAL OBSERVATIONS	PATHOLOGY OBSERVATIONS NECROPSY	HISTOPATHOLOGY
-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS	LIVER (LI) : -PALE AREA; ALL LOBES, FEW, TAN, PINPOINT -DARK; ALL LOBES, DARK BROWN	LIVER (LI) : -HEPATOCYTE, HYPERTROPHY, CENTROLOBULAR,-SLIGHT -VACUOLIZATION,-MINIMAL -PIGMENT, BILE,-MINIMAL -KUPFFER CELL/MACROPHAGE, PIGMENT,- MINIMAL -HEPATOCYTE, PIGMENT,-MINIMAL -NECROSIS, INDIVIDUAL CELL,-SLIGHT -INFLAMMATION, CHRONIC/CHRONIC ACTIVE,- MINIMAL -BILE DUCT, INFLAMMATION, CHRONIC,- MINIMAL SPLEEN (SP) : -EXTRAMEDULLARY HEMATOPOIESIS, INCREASED,-MODERATE -PIGMENT,-MINIMAL

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 640

STUDY NUMBER: 483287

ANIMAL NUMBER: A37486 SEX: MALE DOSE GROUP: 4 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/12/91 STUDY DAY OF DEATH: 96 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 28.6 GRAMS
DATE AND TIME OF NECROPSY: 11/12/91 8:52 PROSECTOR: FRED AGEY RECORDER: FRED AGEY
POST-FIX WEIGHER: JANE EARNHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

CLINICAL OBSERVATIONS P A T H O L O G Y O B S E R V A T I O N S (CONTINUED)
NECROPSY HISTOPATHOLOGY

STOMACH, GL (ST) :
-HYPERPLASIA, CYSTIC, -SLIGHT
-INFLAMMATION, CHRONIC, -SLIGHT

^COLLECTED/TAKEN (XW) :
-LIVER SECTIONS, IN METHANOL

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), EPIDIDYMIS (EP), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE),
KIDNEY (KD), LACRIMAL GL, EX (EO), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU), MAND SALIVARY GL (SG),
MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON), NERVE, SCIATIC (SN),
PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), PROSTATE (PR), RECTUM (RE), SKIN (SK), SKIN, OTHER (SS),
SPLEEN (SP), STOMACH, GL (ST), STOMACH, NONGL (SU), TESTIS (TE), THYMUS (TH), THYROID (TY), TONGUE (TO),
TRACHEA (TR), URINARY BLADDER (UB)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), STOMACH, NONGL (SU)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

PRINTED: 21-JAN-93
PAGE: 641

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

STUDY NUMBER: 483287

ANIMAL NUMBER: A37487 SEX: MALE DOSE GROUP: 4 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/12/91 STUDY DAY OF DEATH: 96 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 31.5 GRAMS
DATE AND TIME OF NECROPSY: 11/12/91 9:41 PROSECTOR: DOUGLAS HERNDON RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.24	.754 %	.463	WEIGHT TAKEN
LUNG (LU)	.19	.599 %	.367	WEIGHT TAKEN
PROSTATE (PR)	.052	.1654 %	.1015	WEIGHT TAKEN
BRAIN W/STEM (BR)	.51	1.630 %	1.000	WEIGHT TAKEN
HEART (HT)	.15	.471 %	.289	WEIGHT TAKEN
SPLEEN (SP)	.06	.186 %	.114	WEIGHT TAKEN
KIDNEY (KD)	.49	1.566 %	.961	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	2.24	7.127 %	4.372	WEIGHT TAKEN
TESTIS (TE)	.23	.718 %	.440	WEIGHT TAKEN
EPIDIDYMIS (EP)	.11	.345 %	.211	WEIGHT TAKEN
ADRENAL (AD)	.006	.0184 %	.0113	WEIGHT TAKEN
THYMUS (TH)	.02	.078 %	.048	WEIGHT TAKEN

CLINICAL OBSERVATIONS	PATHOLOGY OBSERVATIONS NECROPSY	HISTOPATHOLOGY
-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS	LIVER (LI) : -ENLARGED, MODERATE; ALL LOBES -DARK; ALL LOBES, DARK BROWN	LIVER (LI) : -HEPATOCYTE, HYPERTROPHY, CENTROLOBULAR,-SLIGHT -VACUOLIZATION,-SLIGHT -KUPFFER CELL/MACROPHAGE, PIGMENT,- MINIMAL -HEPATOCYTE, PIGMENT,-MINIMAL -NECROSIS, INDIVIDUAL CELL,-MINIMAL -INFLAMMATION, CHRONIC/CHRONIC ACTIVE,- MINIMAL -BILE DUCT, INFLAMMATION, CHRONIC,- MINIMAL
	^COLLECTED/TAKEN (XW) : -LIVER SECTIONS, IN METHANOL	

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 642

STUDY NUMBER: 483287

ANIMAL NUMBER: A37487 SEX: MALE DOSE GROUP: 4 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/12/91 STUDY DAY OF DEATH: 96 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 31.5 GRAMS
DATE AND TIME OF NECROPSY: 11/12/91 9:41 PROSECTOR: DOUGLAS HERNDON RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: JANE EARNHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), EPIDIDYMIS (EP), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE),
KIDNEY (KD), LACRIMAL GL, EX (EO), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU), MAND SALIVARY GL (SG),
MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON), NERVE, SCIATIC (SN),
PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), PROSTATE (PR), RECTUM (RE), SKIN (SK), SKIN, OTHER (SS),
SPLEEN (SP), STOMACH, GL (ST), STOMACH, NONGL (SU), TESTIS (TE), THYMUS (TH), THYROID (TY), TONGUE (TO),
TRACHEA (TR), URINARY BLADDER (UB)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 643

STUDY NUMBER: 483287

ANIMAL NUMBER: A37488 SEX: MALE DOSE GROUP: 4 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/12/91 STUDY DAY OF DEATH: 96 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 28.9 GRAMS
DATE AND TIME OF NECROPSY: 11/12/91 10:54 PROSECTOR: FRED AGEY RECORDER: FRED AGEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.22	.778 %	.542	WEIGHT TAKEN
LUNG (LU)	.19	.669 %	.466	WEIGHT TAKEN
PROSTATE (PR)	.050	.1720 %	.1198	WEIGHT TAKEN
BRAIN W/STEM (BR)	.41	1.435 %	1.000	WEIGHT TAKEN
HEART (HT)	.19	.651 %	.454	WEIGHT TAKEN
SPLEEN (SP)	.07	.244 %	.170	WEIGHT TAKEN
KIDNEY (KD)	.56	1.951 %	1.359	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	2.76	9.558 %	6.659	WEIGHT TAKEN
TESTIS (TE)	.22	.749 %	.522	WEIGHT TAKEN
EPIDIDYMIS (EP)	.12	.402 %	.280	WEIGHT TAKEN
ADRENAL (AD)	.010	.0332 %	.0231	WEIGHT TAKEN
THYMUS (TH)	.04	.142 %	.099	WEIGHT TAKEN

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE
OBSERVATIONS

PATHOLOGY OBSERVATIONS
NECROPSY

LIVER (LI) :
-PALE AREA; ALL LOBES, SEVERAL, TAN,
PINPOINT TO 3 X 3 MM
-ENLARGED, MODERATE; ALL LOBES
-DARK; ALL LOBES, DARK BROWN

HISTOPATHOLOGY

LIVER (LI) :
-HEPATOCTE, HYPERTROPHY,
CENTROLOBULAR, -SLIGHT
-VACUOLIZATION, -SLIGHT
-PIGMENT, BILE, -MINIMAL
-KUPFFER CELL/MACROPHAGE, PIGMENT, -
SLIGHT
-HEPATOCTE, PIGMENT, -SLIGHT
-NECROSIS, -SLIGHT, MULTI-FOCAL
-NECROSIS, INDIVIDUAL CELL, -MINIMAL
-INFLAMMATION, CHRONIC/CHRONIC ACTIVE, -
MINIMAL
-MINERALIZATION, -MINIMAL
SPLEEN (SP) :
-EXTRAMEDULLARY HEMATOPOIESIS,
INCREASED, -MODERATE
-PIGMENT, -MINIMAL

APPENDIX 13B

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORTPRINTED: 21-JAN-93
PAGE: 644

STUDY NUMBER: 483287

ANIMAL NUMBER: A37488 SEX: MALE DOSE GROUP: 4 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/12/91 STUDY DAY OF DEATH: 96 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 28.9 GRAMS
DATE AND TIME OF NECROPSY: 11/12/91 10:54 PROSECTOR: FRED AGEY RECORDER: FRED AGEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

P A T H O L O G Y O B S E R V A T I O N S (CONTINUED)

CLINICAL OBSERVATIONS

NECROPSY

HISTOPATHOLOGY

STOMACH, GL (ST) :
-HYPERPLASIA, CYSTIC, -MINIMAL
-INFLAMMATION, CHRONIC, -MINIMAL

^COLLECTED/TAKEN (XW) :
-LIVER SECTIONS, IN METHANOL

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), EPIDIDYMIS (EP), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE),
KIDNEY (KD), LACRIMAL GL, EX (EO), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU), MAND SALIVARY GL (SG),
MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON), NERVE, SCIATIC (SN),
PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), PROSTATE (PR), RECTUM (RE), SKIN (SK), SKIN, OTHER (SS),
SPLEEN (SP), STOMACH, GL (ST), STOMACH, NONGL (SU), TESTIS (TE), THYMUS (TH), THYROID (TY), TONGUE (TO),
TRACHEA (TR), URINARY BLADDER (UB)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), STOMACH, NONGL (SU)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 645

STUDY NUMBER: 483287

ANIMAL NUMBER: A37489 SEX: MALE DOSE GROUP: 4 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/12/91 STUDY DAY OF DEATH: 96 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 31.4 GRAMS
DATE AND TIME OF NECROPSY: 11/12/91 13:04 PROSECTOR: FRED AGEY RECORDER: FRED AGEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.20	.638 %	.425	WEIGHT TAKEN
LUNG (LU)	.19	.605 %	.403	WEIGHT TAKEN
PROSTATE (PR)	.032	.1010 %	.0672	WEIGHT TAKEN
BRAIN W/STEM (BR)	.47	1.501 %	1.000	WEIGHT TAKEN
HEART (HT)	.18	.558 %	.371	WEIGHT TAKEN
SPLEEN (SP)	.08	.269 %	.179	WEIGHT TAKEN
KIDNEY (KD)	.52	1.654 %	1.102	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	2.18	6.935 %	4.619	WEIGHT TAKEN
TESTIS (TE)	.28	.887 %	.591	WEIGHT TAKEN
EPIDIDYMIS (EP)	.13	.417 %	.277	WEIGHT TAKEN
ADRENAL (AD)	.009	.0277 %	.0185	WEIGHT TAKEN
THYMUS (TH)	.05	.173 %	.115	WEIGHT TAKEN

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE
OBSERVATIONS

PATHOLOGY OBSERVATIONS
NECROPSY

LIVER (LI) :
-DARK; ALL LOBES, DARK BROWN

^COLLECTED/TAKEN (XW) :
-LIVER SECTIONS, IN METHANOL

HISTOPATHOLOGY

LIVER (LI) :
-HEPATOCTE, HYPERTROPHY,
CENTROLOBULAR, -SLIGHT
-VACUOLIZATION, -SLIGHT
-PIGMENT, BILE, -MINIMAL
-KUPFFER CELL/MACROPHAGE, PIGMENT, -
MINIMAL
-HEPATOCTE, PIGMENT, -MINIMAL
-NECROSIS, INDIVIDUAL CELL, -MINIMAL
-INFLAMMATION, CHRONIC/CHRONIC ACTIVE, -
MINIMAL

APPENDIX 13B

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 646

STUDY NUMBER: 483287

ANIMAL NUMBER: A37489 SEX: MALE DOSE GROUP: 4 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/12/91 STUDY DAY OF DEATH: 96 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 31.4 GRAMS
DATE AND TIME OF NECROPSY: 11/12/91 13:04 PROSECTOR: FRED AGEY RECORDER: FRED AGEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), EPIDIDYMIS (EP), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE),
KIDNEY (KD), LACRIMAL GL, EX (EO), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU), MAND SALIVARY GL (SG),
MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON), NERVE, SCIATIC (SN),
PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), PROSTATE (PR), RECTUM (RE), SKIN (SK), SKIN, OTHER (SS),
SPLEEN (SP), STOMACH, GL (ST), STOMACH, NONGL (SU), TESTIS (TE), THYMUS (TH), THYROID (TY), TONGUE (TO),
TRACHEA (TR), URINARY BLADDER (UB)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 647

STUDY NUMBER: 483287

ANIMAL NUMBER: A37490 SEX: MALE DOSE GROUP: 4 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/13/91 STUDY DAY OF DEATH: 97 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 28.8 GRAMS
DATE AND TIME OF NECROPSY: 11/13/91 8:35 PROSECTOR: SCOTT BELL RECORDER: SCOTT BELL
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.22	.777 %	.418	WEIGHT TAKEN
LUNG (LU)	.20	.680 %	.366	WEIGHT TAKEN
PROSTATE (PR)	.063	.2194 %	.1181	WEIGHT TAKEN
BRAIN W/STEM (BR)	.54	1.858 %	1.000	WEIGHT TAKEN
HEART (HT)	.15	.503 %	.271	WEIGHT TAKEN
SPLEEN (SP)	.06	.217 %	.117	WEIGHT TAKEN
KIDNEY (KD)	.47	1.644 %	.885	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	1.99	6.919 %	3.723	WEIGHT TAKEN
TESTIS (TE)	.22	.753 %	.405	WEIGHT TAKEN
EPIDIDYMIS (EP)	.11	.370 %	.199	WEIGHT TAKEN
ADRENAL (AD)	.008	.0264 %	.0142	WEIGHT TAKEN
THYMUS (TH)	.03	.117 %	.063	WEIGHT TAKEN

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE
OBSERVATIONS

PATHOLOGY OBSERVATIONS
NECROPSY

LIVER (LI) :
-DARK; ALL LOBES, DARK BROWN

HISTOPATHOLOGY

ADRENAL, CORTEX (AC) :
-PIGMENT,-MINIMAL
-UNILATERALLY EXAMINED,-PRESENT
ADRENAL, MEDULLA (AM) :
-UNILATERALLY EXAMINED,-PRESENT
LIVER (LI) :
-HEPATOCYTE, HYPERTROPHY,
CENTROLOBULAR,-SLIGHT
-VACUOLIZATION,-SLIGHT
-PIGMENT, BILE,-MINIMAL
-KUPFFER CELL/MACROPHAGE, PIGMENT,-
SLIGHT
-HEPATOCYTE, PIGMENT,-SLIGHT
-NECROSIS,-MINIMAL, MULTI-FOCAL
-NECROSIS, INDIVIDUAL CELL,-MINIMAL
-INFLAMMATION, CHRONIC/CHRONIC ACTIVE,-
SLIGHT

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 648

STUDY NUMBER: 483287

ANIMAL NUMBER: A37490 SEX: MALE DOSE GROUP: 4 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/13/91 STUDY DAY OF DEATH: 97 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 28.8 GRAMS
DATE AND TIME OF NECROPSY: 11/13/91 8:35 PROSECTOR: SCOTT BELL RECORDER: SCOTT BELL
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

CLINICAL OBSERVATIONS

PATHOLOGY OBSERVATIONS (CONTINUED)
NECROPSY

HISTOPATHOLOGY

PITUITARY (PI) :
-PALE AREA; FEW, WHITE, 1 X 1 MM

^COLLECTED/TAKEN (XW) :
-LIVER SECTIONS, IN METHANOL

LIVER (LI) :
-EXTRAMEDULLARY HEMATOPOIESIS,
INCREASED, -MINIMAL
PITUITARY (PI) :
UNREMARKABLE
SPLEEN (SP) :
-EXTRAMEDULLARY HEMATOPOIESIS,
INCREASED, -SLIGHT
-PIGMENT, -MINIMAL

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), EPIDIDYMIS (EP), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE),
KIDNEY (KD), LACRIMAL GL, EX (EO), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU), MAND SALIVARY GL (SG),
MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON), NERVE, SCIATIC (SN),
PANCREAS (PA), PARATHYROID (PT), PROSTATE (PR), RECTUM (RE), SKIN (SK), SKIN, OTHER (SS), SPLEEN (SP),
STOMACH, GL (ST), STOMACH, NONGL (SU), TESTIS (TE), THYMUS (TH), THYROID (TY), TONGUE (TO), TRACHEA (TR),
URINARY BLADDER (UB)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:

STOMACH, GL (ST), STOMACH, NONGL (SU)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 649

STUDY NUMBER: 483287

ANIMAL NUMBER: A37491 SEX: MALE DOSE GROUP: 4 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/13/91 STUDY DAY OF DEATH: 97 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 28.0 GRAMS
DATE AND TIME OF NECROPSY: 11/13/91 9:21 PROSECTOR: ADEFOLAHAN AKINSOLA RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.19	.675 %	.358	WEIGHT TAKEN
LUNG (LU)	.16	.588 %	.312	WEIGHT TAKEN
PROSTATE (PR)	.042	.1482 %	.0786	WEIGHT TAKEN
BRAIN W/STEM (BR)	.53	1.886 %	1.000	WEIGHT TAKEN
HEART (HT)	.15	.533 %	.283	WEIGHT TAKEN
SPLEEN (SP)	.09	.334 %	.177	WEIGHT TAKEN
KIDNEY (KD)	.55	1.958 %	1.038	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	2.06	7.347 %	3.895	WEIGHT TAKEN
TESTIS (TE)	.26	.944 %	.501	WEIGHT TAKEN
EPIDIDYMIS (EP)	.12	.414 %	.219	WEIGHT TAKEN
ADRENAL (AD)	.007	.0261 %	.0138	WEIGHT TAKEN
THYMUS (TH)	.02	.081 %	.043	WEIGHT TAKEN

CLINICAL OBSERVATIONS	PATHOLOGY OBSERVATIONS NECROPSY	HISTOPATHOLOGY
-LAST PHYSICAL EXAM:BOTH EARS, DORSAL CERVICAL-SORES	LIVER (LI) : -PALE AREA; ALL LOBES, FEW, TAN, PINPOINT TO 1 X 1 MM -ENLARGED, MODERATE; ALL LOBES -DARK; ALL LOBES, DARK BROWN LN, MANDIBULAR (MN) : -ENLARGED, SEVERE SKIN, OTHER (SS) : -EAR, SORE; BOTH, FEW, CRUSTY, TAN, BROWN, PINPOINT TO 3 X 3 MM -SORE; HEAD, ONE, CRUSTY, TAN, 4 X 4 MM; CORRESPONDS TO DORSAL CERVICAL- SORES	LIVER (LI) : -HEPATOCYTE, HYPERTROPHY, CENTROLOBULAR,-SLIGHT -KUPFFER CELL/MACROPHAGE, PIGMENT,- MINIMAL -HEPATOCYTE, PIGMENT,-SLIGHT -NECROSIS, INDIVIDUAL CELL,-SLIGHT -INFLAMMATION, CHRONIC/CHRONIC ACTIVE,- MINIMAL LN, MANDIBULAR (MN) : -HYPERPLASIA, LYMPHOID,-PRESENT SKIN, OTHER (SS) : -DERMATITIS, ULCERATIVE,-PRESENT

APPENDIX 13B

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 650

STUDY NUMBER: 483287

ANIMAL NUMBER: A37491 SEX: MALE DOSE GROUP: 4 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/13/91 STUDY DAY OF DEATH: 97 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 28.0 GRAMS
DATE AND TIME OF NECROPSY: 11/13/91 9:21 PROSECTOR: ADEFOLAHAN AKINSOLA RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

P A T H O L O G Y O B S E R V A T I O N S (CONTINUED)

CLINICAL OBSERVATIONS

NECROPSY

HISTOPATHOLOGY

SPLEEN (SP) :
-EXTRAMEDULLARY HEMATOPOIESIS,
INCREASED, -SLIGHT
-PIGMENT, -MINIMAL
STOMACH, GL (ST) :
-HYPERPLASIA, CYSTIC, -MINIMAL

^COLLECTED/TAKEN (XW) :
-LIVER SECTIONS, IN METHANOL

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), EPIDIDYMIS (EP), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE),
KIDNEY (KD), LACRIMAL GL, EX (EO), LN, MESENTERIC (MS), LUNG (LU), MAND SALIVARY GL (SG), MARROW, FEMUR (FM),
MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON), NERVE, SCIATIC (SN), PANCREAS (PA), PARATHYROID (PT),
PITUITARY (PI), PROSTATE (PR), RECTUM (RE), SKIN (SK), SPLEEN (SP), STOMACH, GL (ST), STOMACH, NONGL (SU),
TESTIS (TE), THYMUS (TH), THYROID (TY), TONGUE (TO), TRACHEA (TR), URINARY BLADDER (UB)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), SALIVARY, OTHER (OS), STOMACH, NONGL (SU)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 651

STUDY NUMBER: 483287

ANIMAL NUMBER: A37492 SEX: MALE DOSE GROUP: 4 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/13/91 STUDY DAY OF DEATH: 97 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 31.0 GRAMS
DATE AND TIME OF NECROPSY: 11/13/91 10:44 PROSECTOR: FRED AGEY RECORDER: FRED AGEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.22	.701 %	.470	WEIGHT TAKEN
LUNG (LU)	.20	.646 %	.433	WEIGHT TAKEN
PROSTATE (PR)	.022	.0716 %	.0480	WEIGHT TAKEN
BRAIN W/STEM (BR)	.46	1.493 %	1.000	WEIGHT TAKEN
HEART (HT)	.13	.433 %	.290	WEIGHT TAKEN
SPLEEN (SP)	.08	.250 %	.167	WEIGHT TAKEN
KIDNEY (KD)	.41	1.333 %	.893	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	2.08	6.724 %	4.503	WEIGHT TAKEN
TESTIS (TE)	.25	.798 %	.534	WEIGHT TAKEN
EPIDIDYMIS (EP)	.05	.170 %	.114	WEIGHT TAKEN
ADRENAL (AD)	.015	.0474 %	.0318	WEIGHT TAKEN
THYMUS (TH)	.03	.092 %	.062	WEIGHT TAKEN

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE
OBSERVATIONS

PATHOLOGY OBSERVATIONS
NECROPSY

LIVER (LI) :
-PALE AREA; ALL LOBES, FEW, TAN,
PINPOINT TO 2 X 2 MM
-ENLARGED, MODERATE; ALL LOBES
-DARK; ALL LOBES, DARK BROWN

HISTOPATHOLOGY

LIVER (LI) :
-HEPATOCYTE, HYPERTROPHY,
CENTROLOBULAR,-SLIGHT
-KUPFFER CELL/MACROPHAGE, PIGMENT,-
MINIMAL
-HEPATOCYTE, PIGMENT,-SLIGHT
-NECROSIS,-SLIGHT, MULTI-FOCAL
-NECROSIS, INDIVIDUAL CELL,-SLIGHT
-INFLAMMATION, CHRONIC/CHRONIC ACTIVE,-
SLIGHT
SPLEEN (SP) :
-EXTRAMEDULLARY HEMATOPOIESIS,
INCREASED,-SLIGHT
-PIGMENT,-MINIMAL
STOMACH, GL (ST) :
-HYPERPLASIA, CYSTIC,-MINIMAL
-INFLAMMATION, CHRONIC,-MINIMAL

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 652

STUDY NUMBER: 483287

ANIMAL NUMBER: A37492 SEX: MALE DOSE GROUP: 4 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/13/91 STUDY DAY OF DEATH: 97 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 31.0 GRAMS
DATE AND TIME OF NECROPSY: 11/13/91 10:44 PROSECTOR: FRED AGEY RECORDER: FRED AGEY
POST-FIX WEIGHER: JANE EARMHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

CLINICAL OBSERVATIONS P A T H O L O G Y O B S E R V A T I O N S (CONTINUED)
NECROPSY HISTOPATHOLOGY

^COLLECTED/TAKEN (XW) :
-LIVER SECTIONS, IN METHANOL

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), EPIDIDYMIS (EP), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE),
KIDNEY (KD), LACRIMAL GL, EX (EO), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU), MAND SALIVARY GL (SG),
MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON), NERVE, SCIATIC (SN),
PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), PROSTATE (PR), RECTUM (RE), SKIN (SK), SKIN, OTHER (SS),
SPLEEN (SP), STOMACH, GL (ST), STOMACH, NONGL (SU), TESTIS (TE), THYMUS (TH), THYROID (TY), TONGUE (TO),
TRACHEA (TR), URINARY BLADDER (UB)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), STOMACH, NONGL (SU)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 653

STUDY NUMBER: 483287

ANIMAL NUMBER: A37493 SEX: MALE DOSE GROUP: 4 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/13/91 STUDY DAY OF DEATH: 97 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 28.2 GRAMS
DATE AND TIME OF NECROPSY: 11/13/91 12:48 PROSECTOR: DOUGLAS HERNDON RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.21	.761 %	.456	WEIGHT TAKEN
LUNG (LU)	.21	.740 %	.444	WEIGHT TAKEN
PROSTATE (PR)	.071	.2521 %	.1510	WEIGHT TAKEN
BRAIN W/STEM (BR)	.47	1.670 %	1.000	WEIGHT TAKEN
HEART (HT)	.16	.571 %	.342	WEIGHT TAKEN
SPLEEN (SP)	.06	.225 %	.135	WEIGHT TAKEN
KIDNEY (KD)	.49	1.723 %	1.032	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	1.88	6.654 %	3.985	WEIGHT TAKEN
TESTIS (TE)	.22	.796 %	.477	WEIGHT TAKEN
EPIDIDYMIS (EP)	.11	.373 %	.223	WEIGHT TAKEN
ADRENAL (AD)	.009	.0312 %	.0187	WEIGHT TAKEN
THYMUS (TH)	.03	.089 %	.054	WEIGHT TAKEN

CLINICAL OBSERVATIONS	PATHOLOGY OBSERVATIONS NECROPSY	HISTOPATHOLOGY
-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS	LIVER (LI) : -ENLARGED, MODERATE; ALL LOBES -DARK; ALL LOBES, DARK BROWN	ADRENAL, CORTEX (AC) : -PIGMENT, -MINIMAL LIVER (LI) : -HEPATOCTYE, HYPERTROPHY, CENTROLOBULAR, -SLIGHT -VACUOLIZATION, -MINIMAL -PIGMENT, BILE, -MINIMAL -KUPFFER CELL/MACROPHAGE, PIGMENT, - MINIMAL -HEPATOCTYE, PIGMENT, -SLIGHT -NECROSIS, -MINIMAL, FOCAL -NECROSIS, INDIVIDUAL CELL, -MINIMAL -INFLAMMATION, CHRONIC/CHRONIC ACTIVE, - MINIMAL SPLEEN (SP) : -EXTRAMEDULLARY HEMATOPOIESIS, INCREASED, -MODERATE -PIGMENT, -MINIMAL

HAZLETON WASHINGTON, INC.
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APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 654

STUDY NUMBER: 483287

ANIMAL NUMBER: A37493 SEX: MALE DOSE GROUP: 4 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/13/91 STUDY DAY OF DEATH: 97 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 28.2 GRAMS
DATE AND TIME OF NECROPSY: 11/13/91 12:48 PROSECTOR: DOUGLAS HERNDON RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

CLINICAL OBSERVATIONS P A T H O L O G Y O B S E R V A T I O N S (CONTINUED)
NECROPSY HISTOPATHOLOGY

^COLLECTED/TAKEN (XW) :
-LIVER SECTIONS, IN METHANOL

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), EPIDIDYMIS (EP), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE),
KIDNEY (KD), LACRIMAL GL, EX (EO), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU), MAND SALIVARY GL (SG),
MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON), NERVE, SCIATIC (SN),
PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), PROSTATE (PR), RECTUM (RE), SKIN (SK), SKIN, OTHER (SS),
SPLEEN (SP), STOMACH, GL (ST), STOMACH, NONGL (SU), TESTIS (TE), THYMUS (TH), THYROID (TY), TONGUE (TO),
TRACHEA (TR), URINARY BLADDER (UB)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:

ADRENAL, MEDULLA (AM), STOMACH, GL (ST), STOMACH, NONGL (SU)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE, (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 655

STUDY NUMBER: 483287

ANIMAL NUMBER: A37495 SEX: MALE DOSE GROUP: 4 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/14/91 STUDY DAY OF DEATH: 98 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 31.7 GRAMS
DATE AND TIME OF NECROPSY: 11/14/91 7:52 PROSECTOR: FRED AGEY RECORDER: FRED AGEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.23	.719 %	.453	WEIGHT TAKEN
LUNG (LU)	.20	.629 %	.397	WEIGHT TAKEN
PROSTATE (PR)	.021	.0678 %	.0428	WEIGHT TAKEN
BRAIN W/STEM (BR)	.50	1.586 %	1.000	WEIGHT TAKEN
HEART (HT)	.18	.555 %	.350	WEIGHT TAKEN
SPLEEN (SP)	.12	.392 %	.247	WEIGHT TAKEN
KIDNEY (KD)	.47	1.479 %	.933	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	2.49	7.849 %	4.950	WEIGHT TAKEN
TESTIS (TE)	.29	.900 %	.568	WEIGHT TAKEN
EPIDIDYMIS (EP)	.12	.373 %	.235	WEIGHT TAKEN
ADRENAL (AD)	.009	.0287 %	.0181	WEIGHT TAKEN
THYMUS (TH)	.03	.099 %	.062	WEIGHT TAKEN

CLINICAL OBSERVATIONS	PATHOLOGY OBSERVATIONS NECROPSY	HISTOPATHOLOGY
-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS	LIVER (LI) : -DARK; ALL LOBES, DARK BROWN	ADRENAL, CORTEX (AC) : -PIGMENT,-MINIMAL -HYPERTROPHY, ZONA FASCICULATA,-MINIMAL -HYPERPLASIA, SUBCAPSULAR CELL,-MINIMAL LIVER (LI) : -HEPATOCTYE, HYPERTROPHY, CENTROLOBULAR,-SLIGHT -VACUOLIZATION,-SLIGHT -KUPFFER CELL/MACROPHAGE, PIGMENT,- MINIMAL -HEPATOCTYE, PIGMENT,-MINIMAL -NECROSIS, INDIVIDUAL CELL,-MINIMAL -INFLAMMATION, CHRONIC/CHRONIC ACTIVE,- MINIMAL -EXTRAMEDULLARY HEMATOPOIESIS, INCREASED,-SLIGHT

HAZLETON WASHINGTON, INC.
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13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 656

STUDY NUMBER: 483287

ANIMAL NUMBER: A37495 SEX: MALE DOSE GROUP: 4 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/14/91 STUDY DAY OF DEATH: 98 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 31.7 GRAMS
DATE AND TIME OF NECROPSY: 11/14/91 7:52 PROSECTOR: FRED AGEY RECORDER: FRED AGEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

CLINICAL OBSERVATIONS PATHOLOGY OBSERVATIONS (CONTINUED) HISTOPATHOLOGY
NECROPSY

SPLEEN (SP) :
-EXTRAMEDULLARY HEMATOPOIESIS,
INCREASED, -SLIGHT
-PIGMENT, -MINIMAL
STOMACH, GL (ST) :
-HYPERPLASIA, CYSTIC, -MINIMAL
-INFLAMMATION, CHRONIC, -MINIMAL

^COLLECTED/TAKEN (XW) :
-LIVER SECTIONS, IN METHANOL

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), EPIDIDYMIS (EP), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE),
KIDNEY (KD), LACRIMAL GL, EX (EO), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU), MAND SALIVARY GL (SG),
MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON), NERVE, SCIATIC (SN),
PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), PROSTATE (PR), RECTUM (RE), SKIN (SK), SKIN, OTHER (SS),
SPLEEN (SP), STOMACH, GL (ST), STOMACH, NONGL (SU), TESTIS (TE), THYMUS (TH), THYROID (TY), TONGUE (TO),
TRACHEA (TR), URINARY BLADDER (UB)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:

ADRENAL, MEDULLA (AM), STOMACH, NONGL (SU)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
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APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 657

STUDY NUMBER: 483287

ANIMAL NUMBER: A37511 SEX: MALE DOSE GROUP: 5 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/11/91 STUDY DAY OF DEATH: 95 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 27.5 GRAMS
DATE AND TIME OF NECROPSY: 11/11/91 8:55 PROSECTOR: DOUGLAS HERNDON RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.19	.703 %	.412	WEIGHT TAKEN
LUNG (LU)	.18	.657 %	.385	WEIGHT TAKEN
PROSTATE (PR)	.056	.2018 %	.1183	WEIGHT TAKEN
BRAIN W/STEM (BR)	.47	1.706 %	1.000	WEIGHT TAKEN
HEART (HT)	.14	.503 %	.295	WEIGHT TAKEN
SPLEEN (SP)	.08	.299 %	.175	WEIGHT TAKEN
KIDNEY (KD)	.48	1.756 %	1.029	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	2.56	9.326 %	5.466	WEIGHT TAKEN
TESTIS (TE)	.20	.719 %	.421	WEIGHT TAKEN
EPIDIDYMIS (EP)	.12	.449 %	.263	WEIGHT TAKEN
ADRENAL (AD)	.005	.0193 %	.0113	EXCLUDE
THYMUS (TH)	.03	.105 %	.061	WEIGHT TAKEN

CLINICAL OBSERVATIONS	PATHOLOGY OBSERVATIONS NECROPSY	HISTOPATHOLOGY
-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS	LIVER (LI) : -ENLARGED, SEVERE; ALL LOBES -DARK; ALL LOBES, DARK BROWN	ADRENAL, CORTEX (AC) : -HYPERTROPHY, ZONA FASCICULATA,-MINIMAL -UNILATERALLY EXAMINED,-PRESENT LIVER (LI) : -HEPATOCYTE, HYPERTROPHY, CENTROLOBULAR,-MODERATE -VACUOLIZATION,-MODERATE -PIGMENT, BILE,-MINIMAL -KUPFFER CELL/MACROPHAGE, PIGMENT,- MINIMAL -HEPATOCYTE, PIGMENT,-MINIMAL -NECROSIS, INDIVIDUAL CELL,-SLIGHT -INFLAMMATION, CHRONIC/CHRONIC ACTIVE,- MINIMAL -BILE DUCT, INFLAMMATION, CHRONIC,- MINIMAL

HAZLETON WASHINGTON, INC.
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APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 658

STUDY NUMBER: 483287

ANIMAL NUMBER: A37511 SEX: MALE DOSE GROUP: 5 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/11/91 STUDY DAY OF DEATH: 95 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 27.5 GRAMS
DATE AND TIME OF NECROPSY: 11/11/91 8:55 PROSECTOR: DOUGLAS HERNDON RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

CLINICAL OBSERVATIONS

P A T H O L O G Y O B S E R V A T I O N S (CONTINUED)
NECROPSY

HISTOPATHOLOGY

SPLEEN (SP) :
-EXTRAMEDULLARY HEMATOPOIESIS,
INCREASED, -MINIMAL
-PIGMENT, -MINIMAL

^COLLECTED/TAKEN (XW) :
-LIVER SECTIONS, IN METHANOL

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), EPIDIDYMIS (EP), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE),
KIDNEY (KD), LACRIMAL GL, EX (EO), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU), MAND SALIVARY GL (SG),
MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON), NERVE, SCIATIC (SN),
PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), PROSTATE (PR), RECTUM (RE), SKIN (SK), SKIN, OTHER (SS),
SPLEEN (SP), STOMACH, GL (ST), STOMACH, NONGL (SU), TESTIS (TE), THYMUS (TH), THYROID (TY), TONGUE (TO),
TRACHEA (TR), URINARY BLADDER (UB)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:

STOMACH, GL (ST), STOMACH, NONGL (SU)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 659

STUDY NUMBER: 483287

ANIMAL NUMBER: A37512 SEX: MALE DOSE GROUP: 5 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/11/91 STUDY DAY OF DEATH: 95 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 24.7 GRAMS
DATE AND TIME OF NECROPSY: 11/11/91 10:18 PROSECTOR: ADEPOLAHAN AKINSOLA RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.18	.722 %	.367	WEIGHT TAKEN
LUNG (LU)	.15	.615 %	.313	WEIGHT TAKEN
PROSTATE (PR)	.037	.1482 %	.0754	WEIGHT TAKEN
BRAIN W/STEM (BR)	.49	1.966 %	1.000	WEIGHT TAKEN
HEART (HT)	.14	.581 %	.295	WEIGHT TAKEN
SPLEEN (SP)	.06	.230 %	.117	WEIGHT TAKEN
KIDNEY (KD)	.50	2.028 %	1.031	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	2.09	8.464 %	4.305	WEIGHT TAKEN
TESTIS (TE)	.27	1.111 %	.565	WEIGHT TAKEN
EPIDIDYMIS (EP)	.12	.487 %	.248	WEIGHT TAKEN
ADRENAL (AD)	.013	.0518 %	.0264	WEIGHT TAKEN
THYMUS (TH)	.04	.146 %	.074	WEIGHT TAKEN

CLINICAL OBSERVATIONS	PATHOLOGY OBSERVATIONS NECROPSY	HISTOPATHOLOGY
-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS	LIVER (LI) : -PALE AREA; ALL LOBES, FEW, TAN, 1 X 1 MM -ENLARGED, MODERATE; ALL LOBES -DARK; ALL LOBES, DARK BROWN	ADRENAL, CORTEX (AC) : -HYPERTROPHY, ZONA FASCICULATA,-MINIMAL -HYPERPLASIA, SUBCAPSULAR CELL,-MINIMAL LIVER (LI) : -HEPATOCYTE, HYPERTROPHY, CENTROLOBULAR,-SLIGHT -VACUOLIZATION,-MINIMAL -PIGMENT, BILE,-MINIMAL -KUPFFER CELL/MACROPHAGE, PIGMENT,- MINIMAL -HEPATOCYTE, PIGMENT,-SLIGHT -NECROSIS,-SLIGHT, MULTI-FOCAL -NECROSIS, INDIVIDUAL CELL,-MINIMAL -INFLAMMATION, CHRONIC/CHRONIC ACTIVE,- SLIGHT -MINERALIZATION,-MINIMAL

HAZLETON WASHINGTON, INC.
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APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 660

STUDY NUMBER: 483287

ANIMAL NUMBER: A37512 SEX: MALE DOSE GROUP: 5 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/11/91 STUDY DAY OF DEATH: 95 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 24.7 GRAMS
DATE AND TIME OF NECROPSY: 11/11/91 10:18 PROSECTOR: ADEFOLAHAN AKINSOLA RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

CLINICAL OBSERVATIONS P A T H O L O G Y O B S E R V A T I O N S (CONTINUED)
NECROPSY HISTOPATHOLOGY

SPLEEN (SP) :
-EXTRAMEDULLARY HEMATOPOIESIS,
INCREASED, -SLIGHT
-PIGMENT, -MINIMAL
STOMACH, GL (ST) :
-HYPERPLASIA, CYSTIC, -MINIMAL
-INFLAMMATION, CHRONIC, -MINIMAL

^COLLECTED/TAKEN (XW) :
-LIVER SECTIONS, IN METHANOL

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), EPIDIDYMIS (EP), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE),
KIDNEY (KO), LACRIMAL GL, EX (EO), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU), MAND SALIVARY GL (SG),
MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON), NERVE, SCIATIC (SN),
PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), PROSTATE (PR), RECTUM (RE), SKIN (SK), SKIN, OTHER (SS),
SPLEEN (SP), STOMACH, GL (ST), STOMACH, NONGL (SU), TESTIS (TE), THYMUS (TH), THYROID (TY), TONGUE (TO),
TRACHEA (TR), URINARY BLADDER (UB)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:

ADRENAL, MEDULLA (AM), STOMACH, NONGL (SU)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 661

STUDY NUMBER: 483287

ANIMAL NUMBER: A37513 SEX: MALE DOSE GROUP: 5 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/11/91 STUDY DAY OF DEATH: 95 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 28.8 GRAMS
DATE AND TIME OF NECROPSY: 11/11/91 11:12 PROSECTOR: ADEPOLAHAN AKINSOLA RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.24	.819 %	.507	WEIGHT TAKEN
LUNG (LU)	.17	.584 %	.361	WEIGHT TAKEN
PROSTATE (PR)	.024	.0837 %	.0517	WEIGHT TAKEN
BRAIN W/STEM (BR)	.47	1.617 %	1.000	WEIGHT TAKEN
HEART (HT)	.15	.516 %	.319	WEIGHT TAKEN
SPLEEN (SP)	.08	.287 %	.177	WEIGHT TAKEN
KIDNEY (KD)	.45	1.558 %	.963	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	2.43	8.420 %	5.206	WEIGHT TAKEN
TESTIS (TE)	.22	.768 %	.475	WEIGHT TAKEN
EPIDIDYMIS (EP)	.12	.415 %	.256	WEIGHT TAKEN
ADRENAL (AD)	.005	.0184 %	.0114	WEIGHT TAKEN
THYMUS (TH)	.02	.078 %	.049	WEIGHT TAKEN

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM: RIGHT EAR-SORE

PATHOLOGY OBSERVATIONS
NECROPSY

LIVER (LI) :
-PALE AREA; ALL LOBES, FEW, TAN,
PINPOINT
-ENLARGED, MODERATE; ALL LOBES
-DARK; ALL LOBES, DARK BROWN

SKIN, OTHER (SS) :
-EAR, SORE; BOTH EARS, FEW, CRUSTY,
TAN, BROWN, 2 X 2 MM TO 5 X 5 MM

HISTOPATHOLOGY

ADRENAL, MEDULLA (AM) :
-UNILATERALLY EXAMINED, -PRESENT
LIVER (LI) :
-HEPATOCTE, HYPERTROPHY,
CENTROLOBULAR, -MODERATE
-VACUOLIZATION, -MINIMAL
-PIGMENT, BILE, -MINIMAL
-KUPFFER CELL/MACROPHAGE, PIGMENT, -
MINIMAL
-HEPATOCTE, PIGMENT, -MINIMAL
-NECROSIS, -MINIMAL, MULTI-FOCAL
-NECROSIS, INDIVIDUAL CELL, -MINIMAL
-INFLAMMATION, CHRONIC/CHRONIC ACTIVE, -
SLIGHT
SKIN, OTHER (SS) :
-DERMATITIS, ULCERATIVE, -PRESENT

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APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
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STUDY NUMBER: 483287

ANIMAL NUMBER: A37513 SEX: MALE DOSE GROUP: 5 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/11/91 STUDY DAY OF DEATH: 95 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 28.8 GRAMS
DATE AND TIME OF NECROPSY: 11/11/91 11:12 PROSECTOR: ADEFOLAHAN AKINSOLA RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

CLINICAL OBSERVATIONS PATHOLOGY OBSERVATIONS (CONTINUED) HISTOPATHOLOGY
NECROPSY

SPLEEN (SP) :
-EXTRAMEDULLARY HEMATOPOIESIS,
INCREASED, -MODERATE
-PIGMENT, -MINIMAL
STOMACH, GL (ST) :
-HYPERPLASIA, CYSTIC, -MINIMAL

^COLLECTED/TAKEN (XW) :
-LIVER SECTIONS, IN METHANOL

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), EPIDIDYMIS (EP), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE),
KIDNEY (KD), LACRIMAL GL, EX (EO), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU), MAND SALIVARY GL (SG),
MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON), NERVE, SCIATIC (SN),
PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), PROSTATE (PR), RECTUM (RE), SKIN (SK), SPLEEN (SP),
STOMACH, GL (ST), STOMACH, NONGL (SU), TESTIS (TE), THYMUS (TH), THYROID (TY), TONGUE (TO), TRACHEA (TR),
URINARY BLADDER (UB)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:
ADRENAL, CORTEX (AC), STOMACH, NONGL (SU)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 663

STUDY NUMBER: 483287

ANIMAL NUMBER: A37514 SEX: MALE DOSE GROUP: 5 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/11/91 STUDY DAY OF DEATH: 95 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 30.3 GRAMS
DATE AND TIME OF NECROPSY: 11/11/91 13:35 PROSECTOR: FRED AGEY RECORDER: FRED AGEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.24	.789 %	.594	WEIGHT TAKEN
LUNG (LU)	.18	.580 %	.436	WEIGHT TAKEN
PROSTATE (PR)	.035	.1162 %	.0875	WEIGHT TAKEN
BRAIN W/STEM (BR)	.40	1.328 %	1.000	WEIGHT TAKEN
HEART (HT)	.17	.565 %	.426	WEIGHT TAKEN
SPLEEN (SP)	.06	.204 %	.153	WEIGHT TAKEN
KIDNEY (KD)	.48	1.579 %	1.189	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	2.54	8.389 %	6.318	WEIGHT TAKEN
TESTIS (TE)	.23	.762 %	.574	WEIGHT TAKEN
EPIDIDYMS (EP)	.13	.420 %	.316	WEIGHT TAKEN
ADRENAL (AD)	.010	.0314 %	.0236	WEIGHT TAKEN
THYMUS (TH)	.02	.078 %	.059	WEIGHT TAKEN

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE
OBSERVATIONS

PATHOLOGY OBSERVATIONS
NECROPSY

LIVER (LI) :
-PALE AREA; ALL LOBES, SEVERAL, TAN,
PINPOINT TO 4 X 4 MM
-DARK; ALL LOBES, DARK BROWN

HISTOPATHOLOGY

ADRENAL, CORTEX (AC) :
-HYPERTROPHY, ZONA FASCICULATA,-MINIMAL
LIVER (LI) :
-HEPATOCYTE, HYPERTROPHY,
CENTROLOBULAR,-SLIGHT
-VACUOLIZATION,-MODERATE
-PIGMENT, BILE,-MINIMAL
-KUPFFER CELL/MACROPHAGE, PIGMENT,-
MINIMAL
-HEPATOCYTE, PIGMENT,-MINIMAL
-NECROSIS,-SLIGHT, MULTI-FOCAL
-NECROSIS, INDIVIDUAL CELL,-SLIGHT
-INFLAMMATION, CHRONIC/CHRONIC ACTIVE,-
SLIGHT
-BILE DUCT, INFLAMMATION, CHRONIC,-
MINIMAL
SPLEEN (SP) :
-PIGMENT,-MINIMAL

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 664

STUDY NUMBER: 483287

ANIMAL NUMBER: A37514 SEX: MALE DOSE GROUP: 5 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/11/91 STUDY DAY OF DEATH: 95 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 30.3 GRAMS
DATE AND TIME OF NECROPSY: 11/11/91 13:35 PROSECTOR: FRED AGEY RECORDER: FRED AGEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

CLINICAL OBSERVATIONS P A T H O L O G Y O B S E R V A T I O N S (CONTINUED)
NECROPSY HISTOPATHOLOGY

^COLLECTED/TAKEN (XW) :
-LIVER SECTIONS, IN METHANOL

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), EPIDIDYMIS (EP), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE),
KIDNEY (KD), LACRIMAL GL, EX (EO), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU), MAND SALIVARY GL (SG),
MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON), NERVE, SCIATIC (SN),
PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), PROSTATE (PR), RECTUM (RE), SKIN (SK), SKIN, OTHER (SS),
SPLEEN (SP), STOMACH, GL (ST), STOMACH, NONGL (SU), TESTIS (TE), THYMUS (TH), THYROID (TY), TONGUE (TO),
TRACHEA (TR), URINARY BLADDER (UB)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:

ADRENAL, MEDULLA (AM), STOMACH, GL (ST), STOMACH, NONGL (SU)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 665

STUDY NUMBER: 483287

ANIMAL NUMBER: A37515 SEX: MALE DOSE GROUP: 5 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/12/91 STUDY DAY OF DEATH: 96 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 29.4 GRAMS
DATE AND TIME OF NECROPSY: 11/12/91 9:00 PROSECTOR: SCOTT BELL RECORDER: SCOTT BELL
POST-FIX WEAHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEAHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.22	.733 %	.422	WEIGHT TAKEN
LUNG (LU)	.18	.601 %	.346	WEIGHT TAKEN
PROSTATE (PR)	.056	.1908 %	.1099	WEIGHT TAKEN
BRAIN W/STEM (BR)	.51	1.737 %	1.000	WEIGHT TAKEN
HEART (HT)	.15	.526 %	.303	WEIGHT TAKEN
SPLEEN (SP)	.06	.208 %	.120	WEIGHT TAKEN
KIDNEY (KD)	.48	1.618 %	.931	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	2.27	7.728 %	4.450	WEIGHT TAKEN
TESTIS (TE)	.30	1.015 %	.584	WEIGHT TAKEN
EPIDIDYMIS (EP)	.10	.344 %	.198	WEIGHT TAKEN
ADRENAL (AD)	.009	.0289 %	.0166	WEIGHT TAKEN
THYMUS (TH)	.03	.092 %	.053	WEIGHT TAKEN

CLINICAL OBSERVATIONS	PATHOLOGY OBSERVATIONS NECROPSY	HISTOPATHOLOGY
-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS	LIVER (LI) : -ENLARGED, MODERATE; ALL LOBES -DARK; ALL LOBES, DARK BROWN	ADRENAL, CORTEX (AC) : -HYPERTROPHY, ZONA FASCICULATA,-MINIMAL LIVER (LI) : -HEPATOCYTE, HYPERTROPHY, CENTROLOBULAR,-SLIGHT -VACUOLIZATION,-SLIGHT -PIGMENT, BILE,-MINIMAL -KUPFFER CELL/MACROPHAGE, PIGMENT,- SLIGHT -HEPATOCYTE, PIGMENT,-MINIMAL -NECROSIS, INDIVIDUAL CELL,-MINIMAL -INFLAMMATION, CHRONIC/CHRONIC ACTIVE,- SLIGHT -BILE DUCT, INFLAMMATION, CHRONIC,- MINIMAL SPLEEN (SP) : -EXTRAMEDULLARY HEMATOPOIESIS, INCREASED,-MINIMAL

HAZLETON WASHINGTON, INC.
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APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 666

STUDY NUMBER: 483287

ANIMAL NUMBER: A37515 SEX: MALE DOSE GROUP: 5 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/12/91 STUDY DAY OF DEATH: 96 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 29.4 GRAMS
DATE AND TIME OF NECROPSY: 11/12/91 9:00 PROSECTOR: SCOTT BELL RECORDER: SCOTT BELL
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

CLINICAL OBSERVATIONS P A T H O L O G Y O B S E R V A T I O N S (CONTINUED)
NECROPSY HISTOPATHOLOGY

STOMACH, GL (ST) :
-MUCOSA, THICKENED, MODERATE
^COLLECTED/TAKEN (XW) :
-LIVER SECTIONS, IN METHANOL

SPLEEN (SP) :
-PIGMENT, -MINIMAL
-AMYLOIDOSIS, -MINIMAL
STOMACH, GL (ST) :
-HYPERPLASIA, CYSTIC, -SLIGHT

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), EPIDIDYMIS (EP), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE),
KIDNEY (KD), LACRIMAL GL, EX (EO), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU), MAND SALIVARY GL (SG),
MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON), NERVE, SCIATIC (SN),
PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), PROSTATE (PR), RECTUM (RE), SKIN (SK), SKIN, OTHER (SS),
SPLEEN (SP), STOMACH, NONGL (SU), TESTIS (TE), THYMUS (TH), THYROID (TY), TONGUE (TO), TRACHEA (TR),
URINARY BLADDER (UB)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:

ADRENAL, MEDULLA (AM), STOMACH, NONGL (SU)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 667

STUDY NUMBER: 483287

ANIMAL NUMBER: A37516 SEX: MALE DOSE GROUP: 5 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/12/91 STUDY DAY OF DEATH: 96 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 29.4 GRAMS
DATE AND TIME OF NECROPSY: 11/12/91 9:50 PROSECTOR: SCOTT BELL RECORDER: SCOTT BELL
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.23	.783 %	.429	WEIGHT TAKEN
LUNG (LU)	.21	.699 %	.383	WEIGHT TAKEN
PROSTATE (PR)	.035	.1187 %	.0651	WEIGHT TAKEN
BRAIN W/STEM (BR)	.54	1.824 %	1.000	WEIGHT TAKEN
HEART (HT)	.17	.571 %	.313	WEIGHT TAKEN
SPLEEN (SP)	.07	.239 %	.131	WEIGHT TAKEN
KIDNEY (KD)	.47	1.587 %	.870	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	2.37	8.067 %	4.421	WEIGHT TAKEN
TESTIS (TE)	.17	.587 %	.322	WEIGHT TAKEN
EPIDIDYMIS (EP)	.09	.320 %	.175	WEIGHT TAKEN
ADRENAL (AD)	.010	.0333 %	.0183	WEIGHT TAKEN
THYMUS (TH)	.02	.079 %	.043	WEIGHT TAKEN

CLINICAL OBSERVATIONS	PATHOLOGY OBSERVATIONS NECROPSY	HISTOPATHOLOGY
-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS	LIVER (LI) : -PALE AREA; ALL LOBES, FEW, TAN, PINPOINT TO 3 X 2 MM -ENLARGED, SEVERE; ALL LOBES -DARK; ALL LOBES, DARK BROWN	ADRENAL, CORTEX (AC) : -HYPERTROPHY, ZONA FASCICULATA,-MINIMAL LIVER (LI) : -HEPATOCYTE, HYPERTROPHY, CENTROLOBULAR,-MODERATE -VACUOLIZATION,-MINIMAL -PIGMENT, BILE,-MINIMAL -KUPFFER CELL/MACROPHAGE, PIGMENT,- MINIMAL -HEPATOCYTE, PIGMENT,-MINIMAL -NECROSIS,-MINIMAL, MULTI-FOCAL -NECROSIS, INDIVIDUAL CELL,-MINIMAL -INFLAMMATION, CHRONIC/CHRONIC ACTIVE,- SLIGHT SPLEEN (SP) : -EXTRAMEDULLARY HEMATOPOIESIS, INCREASED,-SLIGHT -PIGMENT,-MINIMAL

HAZLETON WASHINGTON, INC.
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APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 668

STUDY NUMBER: 483287

ANIMAL NUMBER: A37516 SEX: MALE DOSE GROUP: 5 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/12/91 STUDY DAY OF DEATH: 96 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 29.4 GRAMS
DATE AND TIME OF NECROPSY: 11/12/91 9:50 PROSECTOR: SCOTT BELL RECORDER: SCOTT BELL
POST-PIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

P A T H O L O G Y O B S E R V A T I O N S (CONTINUED)
NECROPSY

CLINICAL OBSERVATIONS

HISTOPATHOLOGY

STOMACH, GL (ST) :
-HYPERPLASIA, CYSTIC, -MINIMAL

^COLLECTED/TAKEN (XW) :
-LIVER SECTIONS, IN METHANOL

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), EPIDIDYMIS (EP), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE),
KIDNEY (KD), LACRIMAL GL, EX (EO), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU), MAND SALIVARY GL (SG),
MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON), NERVE, SCIATIC (SN),
PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), PROSTATE (PR), RECTUM (RE), SKIN (SK), SKIN, OTHER (SS),
SPLEEN (SP), STOMACH, GL (ST), STOMACH, NONGL (SU), TESTIS (TE), THYMUS (TH), THYROID (TY), TONGUE (TO),
TRACHEA (TR), URINARY BLADDER (UB)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:

ADRENAL, MEDULLA (AM), STOMACH, NONGL (SU)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 669

STUDY NUMBER: 483287

ANIMAL NUMBER: A37517 SEX: MALE DOSE GROUP: 5 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/12/91 STUDY DAY OF DEATH: 96 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 27.9 GRAMS
DATE AND TIME OF NECROPSY: 11/12/91 10:54 PROSECTOR: SONNY DIKES RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.15	.553 %	.351	WEIGHT TAKEN
LUNG (LU)	.15	.538 %	.341	WEIGHT TAKEN
PROSTATE (PR)	.046	.1645 %	.1043	WEIGHT TAKEN
BRAIN W/STEM (BR)	.44	1.578 %	1.000	WEIGHT TAKEN
HEART (HT)	.15	.521 %	.330	WEIGHT TAKEN
SPLEEN (SP)	.09	.314 %	.199	WEIGHT TAKEN
KIDNEY (KD)	.39	1.411 %	.894	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	2.34	8.405 %	5.327	WEIGHT TAKEN
TESTIS (TE)	.21	.764 %	.484	WEIGHT TAKEN
EPIDIDYMIS (EP)	.16	.586 %	.371	WEIGHT TAKEN
ADRENAL (AD)	.011	.0405 %	.0257	WEIGHT TAKEN
THYMUS (TH)	.03	.100 %	.064	WEIGHT TAKEN

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE
OBSERVATIONS

PATHOLOGY OBSERVATIONS
NECROPSY

LIVER (LI) :
-ENLARGED, MODERATE; ALL LOBES
-DARK; ALL LOBES, DARK BROWN

HISTOPATHOLOGY

ADRENAL, CORTEX (AC) :
-HYPERTROPHY, ZONA FASCICULATA,-MINIMAL
LIVER (LI) :
-HEPATOCYTE, HYPERTROPHY,
CENTROLOBULAR,-SLIGHT
-VACUOLIZATION,-MINIMAL
-PIGMENT, BILE,-MINIMAL
-KUPFFER CELL/MACROPHAGE, PIGMENT,-
MINIMAL
-HEPATOCYTE, PIGMENT,-MINIMAL
-NECROSIS,-MINIMAL, MULTI-FOCAL
-NECROSIS, INDIVIDUAL CELL,-MINIMAL
-INFLAMMATION, CHRONIC/CHRONIC ACTIVE,-
MINIMAL
-BILE DUCT, INFLAMMATION, CHRONIC,-
MINIMAL

HAZLETON WASHINGTON, INC.
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APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 670

STUDY NUMBER: 483287

ANIMAL NUMBER: A37517 SEX: MALE DOSE GROUP: 5 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/12/91 STUDY DAY OF DEATH: 96 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 27.9 GRAMS
DATE AND TIME OF NECROPSY: 11/12/91 10:54 PROSECTOR: SONNY DIKES RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

CLINICAL OBSERVATIONS P A T H O L O G Y O B S E R V A T I O N S (CONTINUED)
NECROPSY HISTOPATHOLOGY

SPLEEN (SP) :
-EXTRAMEDULLARY HEMATOPOIESIS,
INCREASED, -MODERATE
-PIGMENT, -MINIMAL

^COLLECTED/TAKEN (XW) :
-LIVER SECTIONS, IN METHANOL

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), EPIDIDYMIS (EP), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE),
KIDNEY (KD), LACRIMAL GL, EX (EO), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU), MAND SALIVARY GL (SG),
MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON), NERVE, SCIATIC (SN),
PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), PROSTATE (PR), RECTUM (RE), SKIN (SK), SKIN, OTHER (SS),
SPLEEN (SP), STOMACH, GL (ST), STOMACH, NONGL (SU), TESTIS (TE), THYMUS (TH), THYROID (TY), TONGUE (TO),
TRACHEA (TR), URINARY BLADDER (UB)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:
ADRENAL, MEDULLA (AM), STOMACH, GL (ST), STOMACH, NONGL (SU)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
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STUDY NUMBER: 483287

ANIMAL NUMBER: A37518 SEX: MALE DOSE GROUP: 5 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/12/91 STUDY DAY OF DEATH: 96 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 31.6 GRAMS
DATE AND TIME OF NECROPSY: 11/12/91 13:15 PROSECTOR: SCOTT BELL RECORDER: SCOTT BELL
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.23	.738 %	.421	WEIGHT TAKEN
LUNG (LU)	.19	.606 %	.346	WEIGHT TAKEN
PROSTATE (PR)	.056	.1775 %	.1014	WEIGHT TAKEN
BRAIN W/STEM (BR)	.55	1.751 %	1.000	WEIGHT TAKEN
HEART (HT)	.15	.487 %	.278	WEIGHT TAKEN
SPLEEN (SP)	.07	.237 %	.135	WEIGHT TAKEN
KIDNEY (KD)	.49	1.544 %	.882	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	2.56	8.105 %	4.629	WEIGHT TAKEN
TESTIS (TE)	.25	.785 %	.448	WEIGHT TAKEN
EPIDIDYMIS (EP)	.11	.350 %	.200	WEIGHT TAKEN
ADRENAL (AD)	.013	.0418 %	.0239	WEIGHT TAKEN
THYMUS (TH)	.02	.079 %	.045	WEIGHT TAKEN

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE
OBSERVATIONS

PATHOLOGY OBSERVATIONS
NECROPSY

HISTOPATHOLOGY

LIVER (LI) :
-HEPATOCYTE, HYPERTROPHY,
CENTROLOBULAR,-MODERATE
-VACUOLIZATION,-SLIGHT
-PIGMENT, BILE,-MINIMAL
-KUPFFER CELL/MACROPHAGE, PIGMENT,-
MINIMAL
-HEPATOCYTE, PIGMENT,-MODERATE
-NECROSIS,-MINIMAL, MULTI-FOCAL
-NECROSIS, INDIVIDUAL CELL,-MINIMAL
-INFLAMMATION, CHRONIC/CHRONIC ACTIVE,-
MINIMAL
-BILE DUCT, INFLAMMATION, CHRONIC,-
MINIMAL
SPLEEN (SP) :
-EXTRAMEDULLARY HEMATOPOIESIS,
INCREASED,-SLIGHT
-PIGMENT,-MINIMAL

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 672

STUDY NUMBER: 483287

ANIMAL NUMBER: A37518 SEX: MALE DOSE GROUP: 5 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/12/91 STUDY DAY OF DEATH: 96 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 31.6 GRAMS
DATE AND TIME OF NECROPSY: 11/12/91 13:15 PROSECTOR: SCOTT BELL RECORDER: SCOTT BELL
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

CLINICAL OBSERVATIONS PATHOLOGY OBSERVATIONS (CONTINUED) HISTOPATHOLOGY
NECROPSY

STOMACH, GL (ST) :
-HYPERPLASIA, CYSTIC, -MINIMAL

^COLLECTED/TAKEN (XW) :
-LIVER SECTIONS, IN METHANOL

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), EPIDIDYMIS (EP), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE),
KIDNEY (KD), LACRIMAL GL, EX (EO), LIVER (LI), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU),
MAND SALIVARY GL (SG), MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON),
NERVE, SCIATIC (SN), PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), PROSTATE (PR), RECTUM (RE), SKIN (SK),
SKIN, OTHER (SS), SPLEEN (SP), STOMACH, GL (ST), STOMACH, NONGL (SU), TESTIS (TE), THYMUS (TH), THYROID (TY),
TONGUE (TO), TRACHEA (TR), URINARY BLADDER (UB)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), STOMACH, NONGL (SU)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 673

STUDY NUMBER: 483287

ANIMAL NUMBER: A37519 SEX: MALE DOSE GROUP: 5 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/13/91 STUDY DAY OF DEATH: 97 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 29.5 GRAMS
DATE AND TIME OF NECROPSY: 11/13/91 8:37 PROSECTOR: ADEPOLAHAN AKINSOLA RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.19	.632 %	.401	WEIGHT TAKEN
LUNG (LU)	.18	.607 %	.385	WEIGHT TAKEN
PROSTATE (PR)	.013	.0441 %	.0279	WEIGHT TAKEN
BRAIN W/STEM (BR)	.47	1.578 %	1.000	WEIGHT TAKEN
HEART (HT)	.19	.646 %	.410	WEIGHT TAKEN
SPLEEN (SP)	.08	.255 %	.162	WEIGHT TAKEN
KIDNEY (KD)	.49	1.653 %	1.047	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	3.16	10.725 %	6.795	WEIGHT TAKEN
TESTIS (TE)	.26	.892 %	.565	WEIGHT TAKEN
EPIDIDYMIS (EP)	.14	.487 %	.309	WEIGHT TAKEN
ADRENAL (AD)	.013	.0434 %	.0275	WEIGHT TAKEN
THYMUS (TH)	.03	.094 %	.060	WEIGHT TAKEN

CLINICAL OBSERVATIONS	PATHOLOGY OBSERVATIONS NECROPSY	HISTOPATHOLOGY
-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS	LIVER (LI) : -PALE AREA; ALL LOBES, SEVERAL, TAN, PINPOINT -ENLARGED, MODERATE; ALL LOBES -DARK; ALL LOBES, DARK BROWN	ADRENAL, CORTEX (AC) : -HYPERTROPHY, ZONA FASCICULATA,-MINIMAL LIVER (LI) : -HEPATOCYTE, HYPERTROPHY, CENTROLOBULAR,-SLIGHT -VACUOLIZATION,-SLIGHT -PIGMENT, BILE,-MINIMAL -KUPFFER CELL/MACROPHAGE, PIGMENT,- MINIMAL -HEPATOCYTE, PIGMENT,-MINIMAL -NECROSIS,-MODERATE, MULTI-FOCAL -NECROSIS, INDIVIDUAL CELL,-MINIMAL -INFLAMMATION, CHRONIC/CHRONIC ACTIVE,- MINIMAL SPLEEN (SP) : -EXTRAMEDULLARY HEMATOPOIESIS, INCREASED,-MODERATE -PIGMENT,-MINIMAL

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 674

STUDY NUMBER: 483287

ANIMAL NUMBER: A37519 SEX: MALE DOSE GROUP: 5 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/13/91 STUDY DAY OF DEATH: 97 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 29.5 GRAMS
DATE AND TIME OF NECROPSY: 11/13/91 8:37 PROSECTOR: ADEPOLAHAN AKINSOLA RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

CLINICAL OBSERVATIONS P A T H O L O G Y O B S E R V A T I O N S (CONTINUED)
NECROPSY HISTOPATHOLOGY

STOMACH, GL (ST) :
-HYPERPLASIA, CYSTIC, -MINIMAL
-INFLAMMATION, CHRONIC, -MINIMAL
STOMACH, NONGL (SU) :
-INFLAMMATION, CHRONIC, -MINIMAL

^COLLECTED/TAKEN (XW) :
-LIVER SECTIONS, IN METHANOL

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), EPIDIDYMIS (EP), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE),
KIDNEY (KD), LACRIMAL GL, EX (EO), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU), MAND SALIVARY GL (SG),
MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON), NERVE, SCIATIC (SN),
PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), PROSTATE (PR), RECTUM (RE), SKIN (SK), SKIN, OTHER (SS),
SPLEEN (SP), STOMACH, GL (ST), STOMACH, NONGL (SU), TESTIS (TE), THYMUS (TH), THYROID (TY), TONGUE (TO),
TRACHEA (TR), URINARY BLADDER (UB)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:
ADRENAL, MEDULLA (AM)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 675

STUDY NUMBER: 483287

ANIMAL NUMBER: A37520 SEX: MALE DOSE GROUP: 5 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/13/91 STUDY DAY OF DEATH: 97 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 31.2 GRAMS
DATE AND TIME OF NECROPSY: 11/13/91 9:40 PROSECTOR: DOUGLAS HERNDON RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.21	.666 %	.405	WEIGHT TAKEN
LUNG (LU)	.20	.632 %	.384	WEIGHT TAKEN
PROSTATE (PR)	.061	.1946 %	.1183	WEIGHT TAKEN
BRAIN W/STEM (BR)	.51	1.644 %	1.000	WEIGHT TAKEN
HEART (HT)	.18	.574 %	.349	WEIGHT TAKEN
SPLEEN (SP)	.07	.213 %	.129	WEIGHT TAKEN
KIDNEY (KD)	.49	1.586 %	.965	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	2.81	9.013 %	5.483	WEIGHT TAKEN
TESTIS (TE)	.23	.753 %	.458	WEIGHT TAKEN
EPIDIDYMIS (EP)	.10	.328 %	.199	WEIGHT TAKEN
ADRENAL (AD)	.009	.0272 %	.0166	WEIGHT TAKEN
THYMUS (TH)	.05	.144 %	.088	WEIGHT TAKEN

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE
OBSERVATIONS

PATHOLOGY OBSERVATIONS
NECROPSY

LIVER (LI) :
-ENLARGED, SEVERE; ALL LOBES
-DARK; ALL LOBES, DARK BROWN

HISTOPATHOLOGY

ADRENAL, CORTEX (AC) :
-HYPERTROPHY, ZONA FASCICULATA,-MINIMAL
LIVER (LI) :
-HEPATOCYTE, HYPERTROPHY,
CENTROLOBULAR,-SLIGHT
-VACUOLIZATION,-MODERATE
-PIGMENT, BILE,-MINIMAL
-KUPFFER CELL/MACROPHAGE, PIGMENT,-
MINIMAL
-HEPATOCYTE, PIGMENT,-MINIMAL
-NECROSIS,-SLIGHT, MULTI-FOCAL
-NECROSIS, INDIVIDUAL CELL,-MINIMAL
-INFLAMMATION, CHRONIC/CHRONIC ACTIVE,-
MINIMAL
-BILE DUCT, INFLAMMATION, CHRONIC,-
MINIMAL

HAZLETON WASHINGTON, INC.
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APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 676

STUDY NUMBER: 483287

ANIMAL NUMBER: A37520 SEX: MALE DOSE GROUP: 5 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/13/91 STUDY DAY OF DEATH: 97 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 31.2 GRAMS
DATE AND TIME OF NECROPSY: 11/13/91 9:40 PROSECTOR: DOUGLAS HERNDON RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

P A T H O L O G Y O B S E R V A T I O N S (CONTINUED)
NECROPSY

CLINICAL OBSERVATIONS

HISTOPATHOLOGY

SPLEEN (SP) :
-EXTRAMEDULLARY HEMATOPOIESIS,
INCREASED, -MINIMAL
-PIGMENT, -MINIMAL

^COLLECTED/TAKEN (XW) :
-LIVER SECTIONS, IN METHANOL

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), EPIDIDYMIS (EP), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE),
KIDNEY (KD), LACRIMAL GL, EX (EO), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU), MAND SALIVARY GL (SG),
MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON), NERVE, SCIATIC (SN),
PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), PROSTATE (PR), RECTUM (RE), SKIN (SK), SKIN, OTHER (SS),
SPLEEN (SP), STOMACH, GL (ST), STOMACH, NONGL (SU), TESTIS (TE), THYMUS (TH), THYROID (TY), TONGUE (TO),
TRACHEA (TR), URINARY BLADDER (UB)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:

ADRENAL, MEDULLA (AM), STOMACH, GL (ST), STOMACH, NONGL (SU)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 677

STUDY NUMBER: 483287

ANIMAL NUMBER: A37521 SEX: MALE DOSE GROUP: 5 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/13/91 STUDY DAY OF DEATH: 97 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 29.5 GRAMS
DATE AND TIME OF NECROPSY: 11/13/91 10:45 PROSECTOR: ADEPOLAHAN AKINSOLA RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.23	.767 %	.448	WEIGHT TAKEN
LUNG (LU)	.19	.636 %	.371	WEIGHT TAKEN
PROSTATE (PR)	.023	.0773 %	.0451	WEIGHT TAKEN
BRAIN W/STEM (BR)	.51	1.715 %	1.000	WEIGHT TAKEN
HEART (HT)	.24	.817 %	.477	WEIGHT TAKEN
SPLEEN (SP)	.07	.229 %	.133	WEIGHT TAKEN
KIDNEY (KD)	.48	1.634 %	.953	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	2.69	9.113 %	5.314	WEIGHT TAKEN
TESTIS (TE)	.24	.817 %	.477	WEIGHT TAKEN
EPIDIDYMIS (EP)	.13	.448 %	.261	WEIGHT TAKEN
ADRENAL (AD)	.011	.0356 %	.0208	WEIGHT TAKEN
THYMUS (TH)				MISSING

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM: NORMAL-NO REMARKABLE
OBSERVATIONS

PATHOLOGY OBSERVATIONS
NECROPSY

LIVER (LI) :
-ENLARGED, MODERATE; ALL LOBES
-DARK; ALL LOBES, DARK BROWN

HISTOPATHOLOGY

ADRENAL, CORTEX (AC) :
-PIGMENT, -MINIMAL
-HYPERTROPHY, ZONA FASCICULATA, -MINIMAL
LIVER (LI) :
-HEPATOCYTE, HYPERTROPHY,
CENTROLOBULAR, -SLIGHT
-VACUOLIZATION, -MINIMAL
-KUPFFER CELL/MACROPHAGE, PIGMENT, -
MINIMAL
-HEPATOCYTE, PIGMENT, -MINIMAL
-NECROSIS, INDIVIDUAL CELL, -MINIMAL
-INFLAMMATION, CHRONIC/CHRONIC ACTIVE, -
MINIMAL
-BILE DUCT, INFLAMMATION, CHRONIC, -
MINIMAL
SPLEEN (SP) :
-EXTRAMEDULLARY HEMATOPOIESIS,
INCREASED, -SLIGHT

HAZLETON WASHINGTON, INC.
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APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 678

STUDY NUMBER: 483287

ANIMAL NUMBER: A37521 SEX: MALE DOSE GROUP: 5 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/13/91 STUDY DAY OF DEATH: 97 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 29.5 GRAMS
DATE AND TIME OF NECROPSY: 11/13/91 10:45 PROSECTOR: ADEFOLAHAN AKINSOLA RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

CLINICAL OBSERVATIONS P A T H O L O G Y O B S E R V A T I O N S (CONTINUED)
NECROPSY HISTOPATHOLOGY

SPLEEN (SP) :
-PIGMENT, -MINIMAL

^COLLECTED/TAKEN (XW) :
-LIVER SECTIONS, IN METHANOL

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), EPIDIDYMIS (EP), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE),
KIDNEY (KD), LACRIMAL GL, EX (EO), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU), MAND SALIVARY GL (SG),
MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON), NERVE, SCIATIC (SN),
PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), PROSTATE (PR), RECTUM (RE), SKIN (SK), SKIN, OTHER (SS),
SPLEEN (SP), STOMACH, GL (ST), STOMACH, NONGL (SU), TESTIS (TE), THYMUS (TH), THYROID (TY), TONGUE (TO),
TRACHEA (TR), URINARY BLADDER (UB)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:

ADRENAL, MEDULLA (AM), STOMACH, GL (ST), STOMACH, NONGL (SU)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 679

STUDY NUMBER: 483287

ANIMAL NUMBER: A37522 SEX: MALE DOSE GROUP: 5 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/13/91 STUDY DAY OF DEATH: 97 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 28.6 GRAMS
DATE AND TIME OF NECROPSY: 11/13/91 13:07 PROSECTOR: DOUGLAS HERNDON RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.15	.533 %	.316	WEIGHT TAKEN
LUNG (LU)	.21	.747 %	.443	WEIGHT TAKEN
PROSTATE (PR)	.039	.1378 %	.0818	WEIGHT TAKEN
BRAIN W/STEM (BR)	.48	1.684 %	1.000	WEIGHT TAKEN
HEART (HT)	.14	.487 %	.289	WEIGHT TAKEN
SPLEEN (SP)	.06	.207 %	.123	WEIGHT TAKEN
KIDNEY (KD)	.49	1.703 %	1.011	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	2.45	8.562 %	5.085	WEIGHT TAKEN
TESTIS (TE)	.26	.912 %	.542	WEIGHT TAKEN
EPIDIDYMIS (EP)	.12	.410 %	.244	WEIGHT TAKEN
ADRENAL (AD)	.011	.0385 %	.0228	WEIGHT TAKEN
THYMUS (TH)	.03	.106 %	.063	WEIGHT TAKEN

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE
OBSERVATIONS

PATHOLOGY OBSERVATIONS
NECROPSY

LIVER (LI) :
-ENLARGED, MODERATE; ALL LOBES
-DARK; ALL LOBES, DARK BROWN

^COLLECTED/TAKEN (XW) :
-LIVER SECTIONS, IN METHANOL

HISTOPATHOLOGY

ADRENAL, CORTEX (AC) :
-HYPERTROPHY, ZONA FASCICULATA,-MINIMAL
-HYPERPLASIA, SUBCAPSULAR CELL,-MINIMAL
LIVER (LI) :
-HEPATOCYTE, HYPERTROPHY,
CENTROLOBULAR,-SLIGHT
-VACUOLIZATION,-SLIGHT
-KUPFFER CELL/MACROPHAGE, PIGMENT,-
MINIMAL
-HEPATOCYTE, PIGMENT,-MINIMAL
SPLEEN (SP) :
-EXTRAMEDULLARY HEMATOPOIESIS,
INCREASED,-SLIGHT
-PIGMENT,-MINIMAL
STOMACH, GL (ST) :
-INFLAMMATION, CHRONIC,-MINIMAL

APPENDIX 13B

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 680

STUDY NUMBER: 483287

ANIMAL NUMBER: A37522 SEX: MALE DOSE GROUP: 5 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/13/91 STUDY DAY OF DEATH: 97 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 28.6 GRAMS
DATE AND TIME OF NECROPSY: 11/13/91 13:07 PROSECTOR: DOUGLAS HERNDON RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), EPIDIDYMIS (EP), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE),
KIDNEY (KD), LACRIMAL GL, EX (EO), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU), MAND SALIVARY GL (SG),
MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON), NERVE, SCIATIC (SN),
PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), PROSTATE (PR), RECTUM (RE), SKIN (SK), SKIN, OTHER (SS),
SPLEEN (SP), STOMACH, GL (ST), STOMACH, NONGL (SU), TESTIS (TE), THYMUS (TH), THYROID (TY), TONGUE (TO),
TRACHEA (TR), URINARY BLADDER (UB)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:

ADRENAL, MEDULLA (AM), PANCREAS (PA), STOMACH, NONGL (SU)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 681

STUDY NUMBER: 483287

ANIMAL NUMBER: A37523 SEX: MALE DOSE GROUP: 5 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/14/91 STUDY DAY OF DEATH: 98 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 28.3 GRAMS
DATE AND TIME OF NECROPSY: 11/14/91 8:08 PROSECTOR: SCOTT BELL RECORDER: SCOTT BELL
POST-FIX WEIGHER: JOHN CROWLEY PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.21	.727 %	.428	WEIGHT TAKEN
LUNG (LU)	.19	.688 %	.405	WEIGHT TAKEN
PROSTATE (PR)	.054	.1919 %	.1130	WEIGHT TAKEN
BRAIN W/STEM (BR)	.48	1.698 %	1.000	WEIGHT TAKEN
HEART (HT)	.15	.519 %	.306	WEIGHT TAKEN
SPLEEN (SP)	.07	.236 %	.139	WEIGHT TAKEN
KIDNEY (KD)	.41	1.454 %	.856	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	3.00	10.592 %	6.237	WEIGHT TAKEN
TESTIS (TE)	.21	.747 %	.440	WEIGHT TAKEN
EPIDIDYMIS (EP)	.09	.327 %	.192	WEIGHT TAKEN
ADRENAL (AD)	.014	.0498 %	.0293	WEIGHT TAKEN
THYMUS (TH)	.04	.152 %	.090	WEIGHT TAKEN

CLINICAL OBSERVATIONS	PATHOLOGY OBSERVATIONS NECROPSY	HISTOPATHOLOGY
-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS	KIDNEY (KD) : -CYST; RIGHT CORTEX, ONE, CLEAR, PINPOINT -H-CYST; LEFT, SEVERAL, CLEAR, 2 X 1 MM LIVER (LI) : -PALE AREA; ALL LOBES, FEW, TAN, PINPOINT TO 3 X 3 MM -ENLARGED, SEVERE; ALL LOBES -DARK; ALL LOBES, DARK BROWN	ADRENAL, CORTEX (AC) : -HYPERTROPHY, ZONA FASCICULATA,-MINIMAL KIDNEY (KD) : -INFLAMMATION, CHRONIC,-SLIGHT -TUBULE, MINERALIZATION,-MINIMAL -TUBULE, REGENERATION,-SLIGHT -HYPERPLASIA, LYMPHOID,-MINIMAL -PIGMENT,-MINIMAL -CYST,-PRESENT LIVER (LI) : -HEPATOCYTE, HYPERTROPHY, CENTROLOBULAR,-MODERATE -VACUOLIZATION,-MINIMAL -KUPFFER CELL/MACROPHAGE, PIGMENT,- MINIMAL -HEPATOCYTE, PIGMENT,-MINIMAL -NECROSIS, INDIVIDUAL CELL,-SLIGHT

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 682

STUDY NUMBER: 483287

ANIMAL NUMBER: A37523 SEX: MALE DOSE GROUP: 5 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/14/91 STUDY DAY OF DEATH: 98 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 28.3 GRAMS
DATE AND TIME OF NECROPSY: 11/14/91 8:08 PROSECTOR: SCOTT BELL RECORDER: SCOTT BELL
POST-FIX WEIGHER: JOHN CROWLEY PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

CLINICAL OBSERVATIONS P A T H O L O G Y O B S E R V A T I O N S (CONTINUED)
NECROPSY HISTOPATHOLOGY

LIVER (LI) :
-INFLAMMATION, CHRONIC/CHRONIC ACTIVE,-
MINIMAL
-BILE DUCT, INFLAMMATION, CHRONIC,-
MINIMAL
SPLEEN (SP) :
-EXTRAMEDULLARY HEMATOPOIESIS,
INCREASED,-SLIGHT
-PIGMENT,-MINIMAL
STOMACH, GL (ST) :
-HYPERPLASIA, CYSTIC,-MINIMAL
-INFLAMMATION, CHRONIC,-MINIMAL

^COLLECTED/TAKEN (XW) :
-LIVER SECTIONS, IN METHANOL

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), EPIDIDYMIS (EP), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE),
LACRIMAL GL, EX (EO), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU), MAND SALIVARY GL (SG), MARROW, FEMUR (FM),
MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON), NERVE, SCIATIC (SN), PANCREAS (PA), PARATHYROID (PT),
PITUITARY (PI), PROSTATE (PR), RECTUM (RE), SKIN (SK), SKIN, OTHER (SS), SPLEEN (SP), STOMACH, GL (ST),
STOMACH, NONGL (SU), TESTIS (TE), THYMUS (TH), THYROID (TY), TONGUE (TO), TRACHEA (TR), URINARY BLADDER (UB)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:

ADRENAL, MEDULLA (AM), STOMACH, NONGL (SU)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 683

STUDY NUMBER: 483287

ANIMAL NUMBER: A37524 SEX: MALE DOSE GROUP: 5 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/14/91 STUDY DAY OF DEATH: 98 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 29.1 GRAMS
DATE AND TIME OF NECROPSY: 11/14/91 9:05 PROSECTOR: SONNY DIKES RECORDER: SONNY DIKES
POST-FIX WEIGHER: JOHN CROWLEY PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.11	.390 %	.220	WEIGHT TAKEN
LUNG (LU)	.17	.599 %	.338	WEIGHT TAKEN
PROSTATE (PR)	.042	.1443 %	.0814	WEIGHT TAKEN
BRAIN W/STEM (BR)	.52	1.773 %	1.000	WEIGHT TAKEN
HEART (HT)	.14	.485 %	.274	WEIGHT TAKEN
SPLEEN (SP)	.06	.195 %	.110	WEIGHT TAKEN
KIDNEY (KD)	.47	1.600 %	.902	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	2.66	9.133 %	5.153	WEIGHT TAKEN
TESTIS (TE)	.27	.941 %	.531	WEIGHT TAKEN
EPIDIDYMIS (EP)	.09	.322 %	.181	WEIGHT TAKEN
ADRENAL (AD)	.012	.0426 %	.0240	WEIGHT TAKEN
THYMUS (TH)	.03	.102 %	.058	WEIGHT TAKEN

CLINICAL OBSERVATIONS	PATHOLOGY OBSERVATIONS NECROPSY	HISTOPATHOLOGY
-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS	LIVER (LI) : -PALE AREA; ALL LOBES, SEVERAL, TAN, PINPOINT TO 2 X 2 MM -ENLARGED, MODERATE; ALL LOBES -DARK; ALL LOBES, DARK BROWN	LIVER (LI) : -HEPATOCYTE, HYPERTROPHY, CENTROLOBULAR,-SLIGHT -VACUOLIZATION,-MINIMAL -PIGMENT, BILE,-MINIMAL -KUPFFER CELL/MACROPHAGE, PIGMENT,- MINIMAL -NECROSIS,-MODERATE, MULTI-FOCAL -NECROSIS, INDIVIDUAL CELL,-SLIGHT -INFLAMMATION, CHRONIC/CHRONIC ACTIVE,- SLIGHT -BILE DUCT, INFLAMMATION, CHRONIC,- MINIMAL -MINERALIZATION,-MINIMAL SPLEEN (SP) : -EXTRAMEDULLARY HEMATOPOIESIS, INCREASED,-SLIGHT -PIGMENT,-MINIMAL

APPENDIX 13B

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORTPRINTED: 21-JAN-93
PAGE: 684

STUDY NUMBER: 483287

ANIMAL NUMBER: A37524 SEX: MALE DOSE GROUP: 5 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/14/91 STUDY DAY OF DEATH: 98 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 29.1 GRAMS
DATE AND TIME OF NECROPSY: 11/14/91 9:05 PROSECTOR: SONNY DIKES RECORDER: SONNY DIKES
POST-FIX WEIGHER: JOHN CROWLEY PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

CLINICAL OBSERVATIONS P A T H O L O G Y O B S E R V A T I O N S (CONTINUED)
NECROPSY HISTOPATHOLOGY

^COLLECTED/TAKEN (XW) :
-LIVER SECTIONS, IN METHANOL

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), EPIDIDYMIS (EP), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE),
KIDNEY (KD), LACRIMAL GL, EX (EO), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU), MAND SALIVARY GL (SG),
MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON), NERVE, SCIATIC (SN),
PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), PROSTATE (PR), RECTUM (RE), SKIN (SK), SKIN, OTHER (SS),
SPLEEN (SP), STOMACH, GL (ST), STOMACH, NONGL (SU), TESTIS (TE), THYMUS (TH), THYROID (TY), TONGUE (TO),
TRACHEA (TR), URINARY BLADDER (UB)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), STOMACH, GL (ST), STOMACH, NONGL (SU)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 685

STUDY NUMBER: 483287

ANIMAL NUMBER: A37525 SEX: MALE DOSE GROUP: 5 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/14/91 STUDY DAY OF DEATH: 98 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 30.1 GRAMS
DATE AND TIME OF NECROPSY: 11/14/91 9:52 PROSECTOR: SCOTT BELL RECORDER: SCOTT BELL
POST-FIX WEAHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEAHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.21	.713 %	.425	WEIGHT TAKEN
LUNG (LU)	.21	.682 %	.407	WEIGHT TAKEN
PROSTATE (PR)	.054	.1797 %	.1071	WEIGHT TAKEN
BRAIN W/STEM (BR)	.50	1.678 %	1.000	WEIGHT TAKEN
HEART (HT)	.14	.475 %	.283	WEIGHT TAKEN
SPLEEN (SP)	.07	.219 %	.131	WEIGHT TAKEN
KIDNEY (KD)	.47	1.577 %	.940	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	3.16	10.512 %	6.265	WEIGHT TAKEN
TESTIS (TE)	.24	.813 %	.485	WEIGHT TAKEN
EPIDIDYMIS (EP)	.12	.385 %	.230	WEIGHT TAKEN
ADRENAL (AD)	.018	.0591 %	.0352	WEIGHT TAKEN
THYMUS (TH)	.01	.048 %	.028	WEIGHT TAKEN

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE
OBSERVATIONS

PATHOLOGY OBSERVATIONS
NECROPSY

LIVER (LI) :
-PALE AREA; ALL LOBES, FEW, TAN,
PINPOINT TO 2 X 2 MM
-ENLARGED, SEVERE; ALL LOBES
-DARK; ALL LOBES, DARK BROWN

HISTOPATHOLOGY

ADRENAL, MEDULLA (AM) :
-UNILATERALLY EXAMINED,-PRESENT
LIVER (LI) :
-HEPATOCYTE, HYPERTROPHY,
CENTROLOBULAR,-MODERATELY SEVERE
-PIGMENT, BILE,-MINIMAL
-KUPFFER CELL/MACROPHAGE, PIGMENT,-
MINIMAL
-HEPATOCYTE, PIGMENT,-MINIMAL
-NECROSIS,-MINIMAL, MULTI-FOCAL
-NECROSIS, INDIVIDUAL CELL,-MINIMAL
-INFLAMMATION, CHRONIC/CHRONIC ACTIVE,-
MINIMAL
-BILE DUCT, INFLAMMATION, CHRONIC,-
MINIMAL
-MINERALIZATION,-MINIMAL

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 686

STUDY NUMBER: 483287

ANIMAL NUMBER: A37525 SEX: MALE DOSE GROUP: 5 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/14/91 STUDY DAY OF DEATH: 98 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 30.1 GRAMS
DATE AND TIME OF NECROPSY: 11/14/91 9:52 PROSECTOR: SCOTT BELL RECORDER: SCOTT BELL
POST-FIX WEIGHER: JANE EARNHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

CLINICAL OBSERVATIONS

P A T H O L O G Y O B S E R V A T I O N S (CONTINUED)
NECROPSY

HISTOPATHOLOGY

SPLEEN (SP) :
-EXTRAMEDULLARY HEMATOPOIESIS,
INCREASED, -SLIGHT
-PIGMENT, -MINIMAL

^COLLECTED/TAKEN (XW) :
-LIVER SECTIONS, IN METHANOL

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), EPIDIDYMIS (EP), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE),
KIDNEY (KD), LACRIMAL GL, EX (EO), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU), MAND SALIVARY GL (SG),
MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON), NERVE, SCIATIC (SN),
PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), PROSTATE (PR), RECTUM (RE), SKIN (SK), SKIN, OTHER (SS),
SPLEEN (SP), STOMACH, GL (ST), STOMACH, NONGL (SU), TESTIS (TE), THYMUS (TH), THYROID (TY), TONGUE (TO),
TRACHEA (TR), URINARY BLADDER (UB)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:

ADRENAL, CORTEX (AC), STOMACH, GL (ST), STOMACH, NONGL (SU)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 687

STUDY NUMBER: 483287

ANIMAL NUMBER: A37541 SEX: MALE DOSE GROUP: 6 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/11/91 STUDY DAY OF DEATH: 95 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 28.8 GRAMS
DATE AND TIME OF NECROPSY: 11/11/91 9:10 PROSECTOR: SCOTT BELL RECORDER: SCOTT BELL
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.18	.622 %	.351	WEIGHT TAKEN
LUNG (LU)	.17	.589 %	.333	WEIGHT TAKEN
PROSTATE (PR)	.049	.1708 %	.0965	WEIGHT TAKEN
BRAIN W/STEM (BR)	.51	1.770 %	1.000	WEIGHT TAKEN
HEART (HT)	.16	.566 %	.320	WEIGHT TAKEN
SPLEEN (SP)	.10	.338 %	.191	WEIGHT TAKEN
KIDNEY (KD)	.50	1.737 %	.982	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	3.49	12.125 %	6.851	WEIGHT TAKEN
TESTIS (TE)	.19	.649 %	.366	WEIGHT TAKEN
EPIDIDYMIS (EP)	.10	.335 %	.189	WEIGHT TAKEN
ADRENAL (AD)	.009	.0306 %	.0173	WEIGHT TAKEN
THYMUS (TH)	.03	.091 %	.052	WEIGHT TAKEN

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE
OBSERVATIONS

PATHOLOGY OBSERVATIONS
NECROPSY

LIVER (LI) :
-PALE AREA; ALL LOBES, FEW, WHITE,
PINPOINT TO 3 X 3 MM
-ENLARGED, SEVERE; ALL LOBES
-DARK; ALL LOBES, DARK BROWN

HISTOPATHOLOGY

LIVER (LI) :
-HEPATOCYTE, HYPERTROPHY,
CENTROLOBULAR,-MODERATELY SEVERE
-VACUOLIZATION,-SLIGHT
-PIGMENT, BILE,-SLIGHT
-KUPFFER CELL/MACROPHAGE, PIGMENT,-
SLIGHT
-HEPATOCYTE, PIGMENT,-MINIMAL
-NECROSIS,-SLIGHT, MULTI-FOCAL
-NECROSIS, INDIVIDUAL CELL,-MINIMAL
-INFLAMMATION, CHRONIC/CHRONIC ACTIVE,-
SLIGHT
SPLEEN (SP) :
-EXTRAMEDULLARY HEMATOPOIESIS,
INCREASED,-MODERATE
-PIGMENT,-MINIMAL
STOMACH, GL (ST) :
-HYPERPLASIA,-SLIGHT

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 688

STUDY NUMBER: 483287

ANIMAL NUMBER: A37541 SEX: MALE DOSE GROUP: 6 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/11/91 STUDY DAY OF DEATH: 95 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 28.8 GRAMS
DATE AND TIME OF NECROPSY: 11/11/91 9:10 PROSECTOR: SCOTT BELL RECORDER: SCOTT BELL
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

CLINICAL OBSERVATIONS P A T H O L O G Y O B S E R V A T I O N S (CONTINUED)
NECROPSY HISTOPATHOLOGY

STOMACH, GL (ST) :
-DARK AREA; MUCOSA, FEW, BROWN, 3 X 3
MM
-MUCOSA, THICKENED, MODERATE
^COLLECTED/TAKEN (XW) :
-LIVER SECTIONS, IN METHANOL

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), EPIDIDYMIS (EP), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE),
KIDNEY (KD), LACRIMAL GL, EX (EO), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU), MAND SALIVARY GL (SG),
MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON), NERVE, SCIATIC (SN),
PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), PROSTATE (PR), RECTUM (RE), SKIN (SK), SKIN, OTHER (SS),
SPLEEN (SP), STOMACH, NONGL (SU), TESTIS (TE), THYMUS (TH), THYROID (TY), TONGUE (TO), TRACHEA (TR),
URINARY BLADDER (UB)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:
ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), STOMACH, NONGL (SU)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 689

STUDY NUMBER: 483287

ANIMAL NUMBER: A37542 SEX: MALE DOSE GROUP: 6 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/11/91 STUDY DAY OF DEATH: 95 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 26.5 GRAMS
DATE AND TIME OF NECROPSY: 11/11/91 10:25 PROSECTOR: SCOTT BELL RECORDER: SCOTT BELL
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.19	.717 %	.399	WEIGHT TAKEN
LUNG (LU)	.16	.603 %	.336	WEIGHT TAKEN
PROSTATE (PR)	.050	.1875 %	.1043	WEIGHT TAKEN
BRAIN W/STEM (BR)	.48	1.797 %	1.000	WEIGHT TAKEN
HEART (HT)	.17	.641 %	.357	WEIGHT TAKEN
SPLEEN (SP)	.06	.238 %	.132	WEIGHT TAKEN
KIDNEY (KD)	.47	1.765 %	.982	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	4.06	15.331 %	8.530	WEIGHT TAKEN
TESTIS (TE)	.21	.780 %	.434	WEIGHT TAKEN
EPIDIDYMIS (EP)	.09	.353 %	.197	WEIGHT TAKEN
ADRENAL (AD)	.009	.0332 %	.0185	WEIGHT TAKEN
THYMUS (TH)	.04	.144 %	.080	WEIGHT TAKEN

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE
OBSERVATIONS

PATHOLOGY OBSERVATIONS
NECROPSY

LIVER (LI) :
-PALE AREA; ALL LOBES, FEW, WHITE,
PINPOINT TO 1 X 1 MM
-ENLARGED, SEVERE; ALL LOBES
-DARK; ALL LOBES, DARK BROWN

HISTOPATHOLOGY

ADRENAL, CORTEX (AC) :
-HYPERTROPHY, ZONA FASCICULATA,-MINIMAL
ADRENAL, MEDULLA (AM) :
-UNILATERALLY EXAMINED,-PRESENT
LIVER (LI) :
-HEPATOCYTE, HYPERTROPHY,
CENTROLOBULAR,-MODERATELY SEVERE
-VACUOLIZATION,-MINIMAL
-PIGMENT, BILE,-SLIGHT
-KUPFFER CELL/MACROPHAGE, PIGMENT,-
SLIGHT
-HEPATOCYTE, PIGMENT,-SLIGHT
-NECROSIS,-MINIMAL, MULTI-FOCAL
-NECROSIS, INDIVIDUAL CELL,-SLIGHT
-INFLAMMATION, CHRONIC/CHRONIC ACTIVE,-
SLIGHT
-BILE DUCT, INFLAMMATION, CHRONIC,-
MINIMAL

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 690

STUDY NUMBER: 483287

ANIMAL NUMBER: A37542 SEX: MALE DOSE GROUP: 6 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/11/91 STUDY DAY OF DEATH: 95 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 26.5 GRAMS
DATE AND TIME OF NECROPSY: 11/11/91 10:25 PROSECTOR: SCOTT BELL RECORDER: SCOTT BELL
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

CLINICAL OBSERVATIONS P A T H O L O G Y O B S E R V A T I O N S (CONTINUED)
NECROPSY HISTOPATHOLOGY

LIVER (LI) :
-MINERALIZATION, -MINIMAL
SPLEEN (SP) :
-EXTRAMEDULLARY HEMATOPOIESIS,
INCREASED, -SLIGHT

^COLLECTED/TAKEN (XW) :
-LIVER SECTIONS, IN METHANOL

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), EPIDIDYMIS (EP), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE),
KIDNEY (KD), LACRIMAL GL, EX (EO), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU), MAND SALIVARY GL (SG),
MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON), NERVE, SCIATIC (SN),
PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), PROSTATE (PR), RECTUM (RE), SKIN (SK), SKIN, OTHER (SS),
SPLEEN (SP), STOMACH, GL (ST), STOMACH, NONGL (SU), TESTIS (TE), THYMUS (TH), THYROID (TY), TONGUE (TO),
TRACHEA (TR), URINARY BLADDER (UB)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:

STOMACH, GL (ST), STOMACH, NONGL (SU)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 691

STUDY NUMBER: 483287

ANIMAL NUMBER: A37543 SEX: MALE DOSE GROUP: 6 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/11/91 STUDY DAY OF DEATH: 95 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 29.9 GRAMS
DATE AND TIME OF NECROPSY: 11/11/91 11:25 PROSECTOR: SCOTT BELL RECORDER: SCOTT BELL
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.18	.605 %	.323	WEIGHT TAKEN
LUNG (LU)	.18	.617 %	.329	WEIGHT TAKEN
PROSTATE (PR)	.032	.1087 %	.0580	WEIGHT TAKEN
BRAIN W/STEM (BR)	.56	1.875 %	1.000	WEIGHT TAKEN
HEART (HT)	.16	.551 %	.294	WEIGHT TAKEN
SPLEEN (SP)	.07	.237 %	.126	WEIGHT TAKEN
KIDNEY (KD)	.43	1.429 %	.762	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	3.68	12.323 %	6.573	WEIGHT TAKEN
TESTIS (TE)	.25	.843 %	.450	WEIGHT TAKEN
EPIDIDYMIS (EP)	.11	.364 %	.194	WEIGHT TAKEN
ADRENAL (AD)	.015	.0488 %	.0260	WEIGHT TAKEN
THYMUS (TH)	.03	.087 %	.046	WEIGHT TAKEN

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE
OBSERVATIONS

PATHOLOGY OBSERVATIONS
NECROPSY

LIVER (LI) :
-PALE AREA; ALL LOBES, FEW, WHITE,
PINPOINT
-ENLARGED, SEVERE; ALL LOBES
-DARK; ALL LOBES, DARK BROWN

HISTOPATHOLOGY

ADRENAL, CORTEX (AC) :
-HYPERTROPHY, ZONA FASCICULATA,-MINIMAL
LIVER (LI) :
-HEPATOCYTE, HYPERTROPHY,
CENTROLOBULAR,-MODERATE
-VACUOLIZATION,-MINIMAL
-PIGMENT, BILE,-MINIMAL
-KUPFFER CELL/MACROPHAGE, PIGMENT,-
MINIMAL
-HEPATOCYTE, PIGMENT,-MODERATE
-NECROSIS, INDIVIDUAL CELL,-SLIGHT
-INFLAMMATION, CHRONIC/CHRONIC ACTIVE,-
MINIMAL
SPLEEN (SP) :
-EXTRAMEDULLARY HEMATOPOIESIS,
INCREASED,-SLIGHT
-PIGMENT,-MINIMAL

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 692

STUDY NUMBER: 483287

ANIMAL NUMBER: A37543 SEX: MALE DOSE GROUP: 6 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/11/91 STUDY DAY OF DEATH: 95 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 29.9 GRAMS
DATE AND TIME OF NECROPSY: 11/11/91 11:25 PROSECTOR: SCOTT BELL RECORDER: SCOTT BELL
POST-FIX WEAHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEAHER: RICHARD KAGYARE

CLINICAL OBSERVATIONS P A T H O L O G Y O B S E R V A T I O N S (CONTINUED)
NECROPSY HISTOPATHOLOGY

STOMACH, GL (ST) :
-AMYLOIDOSIS, -PRESENT

^COLLECTED/TAKEN (XW) :
-LIVER SECTIONS, IN METHANOL

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), EPIDIDYMIS (EP), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE),
KIDNEY (KD), LACRIMAL GL, EX (EO), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU), MAND SALIVARY GL (SG),
MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON), NERVE, SCIATIC (SN),
PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), PROSTATE (PR), RECTUM (RE), SKIN (SK), SKIN, OTHER (SS),
SPLEEN (SP), STOMACH, GL (ST), STOMACH, NONGL (SU), TESTIS (TE), THYMUS (TH), THYROID (TY), TONGUE (TO),
TRACHEA (TR), URINARY BLADDER (UB)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:

ADRENAL, MEDULLA (AM), PANCREAS (PA), STOMACH, NONGL (SU)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 693

STUDY NUMBER: 483287

ANIMAL NUMBER: A37544 SEX: MALE DOSE GROUP: 6 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/11/91 STUDY DAY OF DEATH: 95 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 27.5 GRAMS
DATE AND TIME OF NECROPSY: 11/11/91 13:40 PROSECTOR: SCOTT BELL RECORDER: SCOTT BELL
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.15	.548 %	.279	WEIGHT TAKEN
LUNG (LU)	.16	.580 %	.295	WEIGHT TAKEN
PROSTATE (PR)	.045	.1633 %	.0830	WEIGHT TAKEN
BRAIN W/STEM (BR)	.54	1.967 %	1.000	WEIGHT TAKEN
HEART (HT)	.16	.572 %	.291	WEIGHT TAKEN
SPLEEN (SP)	.06	.217 %	.111	WEIGHT TAKEN
KIDNEY (KD)	.42	1.535 %	.781	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	3.12	11.336 %	5.764	WEIGHT TAKEN
TESTIS (TE)	.18	.641 %	.326	WEIGHT TAKEN
EPIDIDYMIS (EP)	.09	.310 %	.158	WEIGHT TAKEN
ADRENAL (AD)	.013	.0458 %	.0233	WEIGHT TAKEN
THYMUS (TH)	.03	.103 %	.052	WEIGHT TAKEN

CLINICAL OBSERVATIONS	PATHOLOGY OBSERVATIONS NECROPSY	HISTOPATHOLOGY
-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS	LIVER (LI) : -ENLARGED, SEVERE; ALL LOBES -DARK; ALL LOBES, DARK BROWN	ADRENAL, CORTEX (AC) : -PIGMENT,-MINIMAL -HYPERTROPHY, ZONA FASCICULATA,-MINIMAL LIVER (LI) : -HEPATOCYTE, HYPERTROPHY, CENTROLOBULAR,-MODERATE -VACUOLIZATION,-SLIGHT -PIGMENT, BILE,-MINIMAL -KUPFFER CELL/MACROPHAGE, PIGMENT,- SLIGHT -HEPATOCYTE, PIGMENT,-SLIGHT -NECROSIS,-SLIGHT, FOCAL -NECROSIS, INDIVIDUAL CELL,-SLIGHT -INFLAMMATION, CHRONIC/CHRONIC ACTIVE,- MINIMAL -BILE DUCT, INFLAMMATION, CHRONIC,- SLIGHT

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 694

STUDY NUMBER: 483287

ANIMAL NUMBER: A37544 SEX: MALE DOSE GROUP: 6 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/11/91 STUDY DAY OF DEATH: 95 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 27.5 GRAMS
DATE AND TIME OF NECROPSY: 11/11/91 13:40 PROSECTOR: SCOTT BELL RECORDER: SCOTT BELL
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

CLINICAL OBSERVATIONS

P A T H O L O G Y O B S E R V A T I O N S (CONTINUED)
NECROPSY

HISTOPATHOLOGY

SPLEEN (SP) :
-EXTRAMEDULLARY HEMATOPOIESIS,
INCREASED, -SLIGHT
-PIGMENT, -MINIMAL
STOMACH, GL (ST) :
-HYPERPLASIA, CYSTIC, -MINIMAL

^COLLECTED/TAKEN (XW) :
-LIVER SECTIONS, IN METHANOL

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), EPIDIDYMIS (EP), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE),
KIDNEY (KD), LACRIMAL GL, EX (EO), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU), MAND SALIVARY GL (SG),
MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON), NERVE, SCIATIC (SN),
PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), PROSTATE (PR), RECTUM (RE), SKIN (SK), SKIN, OTHER (SS),
SPLEEN (SP), STOMACH, GL (ST), STOMACH, NONGL (SU), TESTIS (TE), THYMUS (TH), THYROID (TY), TONGUE (TO),
TRACHEA (TR), URINARY BLADDER (UB)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:

ADRENAL, MEDULLA (AM), STOMACH, NONGL (SU)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 695

STUDY NUMBER: 483287

ANIMAL NUMBER: A37545 SEX: MALE DOSE GROUP: 6 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/12/91 STUDY DAY OF DEATH: 96 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 28.4 GRAMS
DATE AND TIME OF NECROPSY: 11/12/91 9:00 PROSECTOR: SONNY DIKES RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.13	.466 %	.263	WEIGHT TAKEN
LUNG (LU)	.17	.612 %	.346	WEIGHT TAKEN
PROSTATE (PR)	.042	.1482 %	.0838	WEIGHT TAKEN
BRAIN W/STEM (BR)	.50	1.769 %	1.000	WEIGHT TAKEN
HEART (HT)	.16	.560 %	.317	WEIGHT TAKEN
SPLEEN (SP)	.07	.232 %	.131	WEIGHT TAKEN
KIDNEY (KD)	.45	1.599 %	.904	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	3.95	13.913 %	7.866	WEIGHT TAKEN
TESTIS (TE)	.25	.891 %	.504	WEIGHT TAKEN
EPIDIDYMIS (EP)	.12	.407 %	.230	WEIGHT TAKEN
ADRENAL (AD)	.012	.0437 %	.0247	WEIGHT TAKEN
THYMUS (TH)	.03	.096 %	.055	WEIGHT TAKEN

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE
OBSERVATIONS

PATHOLOGY OBSERVATIONS
NECROPSY

LIVER (LI) :
-ENLARGED, MODERATE; ALL LOBES
-DARK; ALL LOBES, DARK BROWN

HISTOPATHOLOGY

ADRENAL, CORTEX (AC) :
-HYPERTROPHY, ZONA FASCICULATA,-MINIMAL
LIVER (LI) :
-HEPATOCYTE, HYPERTROPHY,
CENTROLOBULAR,-MODERATELY SEVERE
-VACUOLIZATION,-MINIMAL
-PIGMENT, BILE,-MINIMAL
-KUPFFER CELL/MACROPHAGE, PIGMENT,-
MINIMAL
-HEPATOCYTE, PIGMENT,-MINIMAL
-NECROSIS, INDIVIDUAL CELL,-MINIMAL
-INFLAMMATION, CHRONIC/CHRONIC ACTIVE,-
SLIGHT
-MINERALIZATION,-MINIMAL
SPLEEN (SP) :
-EXTRAMEDULLARY HEMATOPOIESIS,
INCREASED,-SLIGHT
-PIGMENT,-MINIMAL

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 696

STUDY NUMBER: 483287

ANIMAL NUMBER: A37545 SEX: MALE DOSE GROUP: 6 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/12/91 STUDY DAY OF DEATH: 96 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 28.4 GRAMS
DATE AND TIME OF NECROPSY: 11/12/91 9:00 PROSECTOR: SONNY DIKES RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

CLINICAL OBSERVATIONS P A T H O L O G Y O B S E R V A T I O N S (CONTINUED)
NECROPSY HISTOPATHOLOGY

STOMACH, GL (ST) :
-INFLAMMATION, CHRONIC, -MINIMAL

^COLLECTED/TAKEN (XW) :
-LIVER SECTIONS, IN METHANOL

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), EPIDIDYMIS (EP), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE),
KIDNEY (KD), LACRIMAL GL, EX (EO), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU), MAND SALIVARY GL (SG),
MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON), NERVE, SCIATIC (SN),
PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), PROSTATE (PR), RECTUM (RE), SKIN (SK), SKIN, OTHER (SS),
SPLEEN (SP), STOMACH, GL (ST), STOMACH, NONGL (SU), TESTIS (TE), THYMUS (TH), THYROID (TY), TONGUE (TO),
TRACHEA (TR), URINARY BLADDER (UB)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:

ADRENAL, MEDULLA (AM), STOMACH, NONGL (SU)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 697

STUDY NUMBER: 483287

ANIMAL NUMBER: A37546 SEX: MALE DOSE GROUP: 6 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/12/91 STUDY DAY OF DEATH: 96 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 26.1 GRAMS
DATE AND TIME OF NECROPSY: 11/12/91 9:49 PROSECTOR: SONNY DIKES RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.13	.485 %	.249	WEIGHT TAKEN
LUNG (LU)	.20	.769 %	.395	WEIGHT TAKEN
PROSTATE (PR)	.045	.1724 %	.0885	WEIGHT TAKEN
BRAIN W/STEM (BR)	.51	1.949 %	1.000	WEIGHT TAKEN
HEART (HT)	.14	.548 %	.281	WEIGHT TAKEN
SPLEEN (SP)	.14	.533 %	.273	WEIGHT TAKEN
KIDNEY (KD)	.40	1.533 %	.787	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	3.26	12.507 %	6.417	WEIGHT TAKEN
TESTIS (TE)	.20	.768 %	.394	WEIGHT TAKEN
EPIDIDYMIS (EP)	.09	.347 %	.178	WEIGHT TAKEN
ADRENAL (AD)	.013	.0517 %	.0265	WEIGHT TAKEN
THYMUS (TH)	.02	.067 %	.034	WEIGHT TAKEN

CLINICAL OBSERVATIONS	PATHOLOGY OBSERVATIONS NECROPSY	HISTOPATHOLOGY
-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS	LIVER (LI) : -ENLARGED, MODERATE; ALL LOBES -DARK; ALL LOBES, DARK BROWN	LIVER (LI) : -HEPATOCYTE, HYPERTROPHY, CENTROLOBULAR,-MODERATELY SEVERE -PIGMENT, BILE,-SLIGHT -KUPFFER CELL/MACROPHAGE, PIGMENT,- MINIMAL -HEPATOCYTE, PIGMENT,-MINIMAL -NECROSIS, INDIVIDUAL CELL,-SLIGHT -INFLAMMATION, CHRONIC/CHRONIC ACTIVE,- MINIMAL -BILE DUCT, INFLAMMATION, CHRONIC,- MODERATELY SEVERE SPLEEN (SP) : -EXTRAMEDULLARY HEMATOPOIESIS, INCREASED,-MODERATE -PIGMENT,-MINIMAL STOMACH, GL (ST) : -HYPERPLASIA, CYSTIC,-MINIMAL

HAZLETON WASHINGTON, INC.
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APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 698

STUDY NUMBER: 483287

ANIMAL NUMBER: A37546 SEX: MALE DOSE GROUP: 6 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/12/91 STUDY DAY OF DEATH: 96 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 26.1 GRAMS
DATE AND TIME OF NECROPSY: 11/12/91 9:49 PROSECTOR: SONNY DIKES RECORDER: JOHN CROWLEY
POST-FIX WEAIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEAIGHER: RICHARD KAGYARE

CLINICAL OBSERVATIONS P A T H O L O G Y O B S E R V A T I O N S (CONTINUED)
NECROPSY HISTOPATHOLOGY

STOMACH, GL (ST) :
-INFLAMMATION, CHRONIC, -MINIMAL

^COLLECTED/TAKEN (XW) :
-LIVER SECTIONS, IN METHANOL

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), EPIDIDYMIS (EP), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE),
KIDNEY (KD), LACRIMAL GL, EX (EO), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU), MAND SALIVARY GL (SG),
MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON), NERVE, SCIATIC (SN),
PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), PROSTATE (PR), RECTUM (RE), SKIN (SK), SKIN, OTHER (SS),
SPLEEN (SP), STOMACH, GL (ST), STOMACH, NONGL (SU), TESTIS (TE), THYMUS (TH), THYROID (TY), TONGUE (TO),
TRACHEA (TR), URINARY BLADDER (UB)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), PANCREAS (PA), STOMACH, NONGL (SU)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 699

STUDY NUMBER: 483287

ANIMAL NUMBER: A37547 SEX: MALE DOSE GROUP: 6 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/12/91 STUDY DAY OF DEATH: 96 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 29.6 GRAMS
DATE AND TIME OF NECROPSY: 11/12/91 11:05 PROSECTOR: JANE EARHARDT RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.19	.643 %	.407	WEIGHT TAKEN
LUNG (LU)	.19	.630 %	.399	WEIGHT TAKEN
PROSTATE (PR)	.075	.2527 %	.1598	WEIGHT TAKEN
BRAIN W/STEM (BR)	.47	1.582 %	1.000	WEIGHT TAKEN
HEART (HT)	.16	.526 %	.332	WEIGHT TAKEN
SPLEEN (SP)	.06	.205 %	.130	WEIGHT TAKEN
KIDNEY (KD)	.49	1.655 %	1.046	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	4.14	13.989 %	8.844	WEIGHT TAKEN
TESTIS (TE)	.27	.897 %	.567	WEIGHT TAKEN
EPIDIDYMIS (EP)	.15	.498 %	.315	WEIGHT TAKEN
ADRENAL (AD)	.015	.0520 %	.0329	WEIGHT TAKEN
THYMUS (TH)	.03	.095 %	.060	WEIGHT TAKEN

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE
OBSERVATIONS

PATHOLOGY OBSERVATIONS
NECROPSY

LIVER (LI) :
-ENLARGED, SEVERE; ALL LOBES
-DARK; ALL LOBES, DARK BROWN

HISTOPATHOLOGY

ADRENAL, CORTEX (AC) :
-HYPERTROPHY, ZONA FASCICULATA,-MINIMAL
LIVER (LI) :
-HEPATOCYTE, HYPERTROPHY,
CENTROLOBULAR,-MODERATE
-VACUOLIZATION,-SLIGHT
-PIGMENT, BILE,-MINIMAL
-KUPFFER CELL/MACROPHAGE, PIGMENT,-
SLIGHT
-HEPATOCYTE, PIGMENT,-SLIGHT
-NECROSIS,-MINIMAL, MULTI-FOCAL
-NECROSIS, INDIVIDUAL CELL,-SLIGHT
-INFLAMMATION, CHRONIC/CHRONIC ACTIVE,-
MINIMAL
-BILE DUCT, INFLAMMATION, CHRONIC,-
SLIGHT
-MINERALIZATION,-MINIMAL

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 700

STUDY NUMBER: 483287

ANIMAL NUMBER: A37547 SEX: MALE DOSE GROUP: 6 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/12/91 STUDY DAY OF DEATH: 96 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 29.6 GRAMS
DATE AND TIME OF NECROPSY: 11/12/91 11:05 PROSECTOR: JANE EARHARDT RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

CLINICAL OBSERVATIONS

P A T H O L O G Y O B S E R V A T I O N S (CONTINUED)
NECROPSY

HISTOPATHOLOGY

SPLEEN (SP) :
-EXTRAMEDULLARY HEMATOPOIESIS,
INCREASED, -MINIMAL
-PIGMENT, -MINIMAL

^COLLECTED/TAKEN (XW) :
-LIVER SECTIONS, IN METHANOL

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), EPIDIDYMIS (EP), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE),
KIDNEY (KD), LACRIMAL GL, EX (EO), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU), MAND SALIVARY GL (SG),
MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON), NERVE, SCIATIC (SN),
PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), PROSTATE (PR), RECTUM (RE), SKIN (SK), SKIN, OTHER (SS),
SPLEEN (SP), STOMACH, GL (ST), STOMACH, NONGL (SU), TESTIS (TE), THYMUS (TH), THYROID (TY), TONGUE (TO),
TRACHEA (TR), URINARY BLADDER (UB)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:

ADRENAL, MEDULLA (AM), STOMACH, GL (ST), STOMACH, NONGL (SU)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE, (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 701

STUDY NUMBER: 483287

ANIMAL NUMBER: A37548 SEX: MALE DOSE GROUP: 6 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/12/91 STUDY DAY OF DEATH: 96 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 27.9 GRAMS
DATE AND TIME OF NECROPSY: 11/12/91 13:12 PROSECTOR: DOUGLAS HERNDON RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.16	.556 %	.307	WEIGHT TAKEN
LUNG (LU)	.19	.669 %	.369	WEIGHT TAKEN
PROSTATE (PR)	.047	.1685 %	.0929	WEIGHT TAKEN
BRAIN W/STEM (BR)	.51	1.813 %	1.000	WEIGHT TAKEN
HEART (HT)	.13	.464 %	.256	WEIGHT TAKEN
SPLEEN (SP)	.07	.239 %	.132	WEIGHT TAKEN
KIDNEY (KD)	.42	1.510 %	.833	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	3.59	12.851 %	7.087	WEIGHT TAKEN
TESTIS (TE)	.20	.731 %	.403	WEIGHT TAKEN
EPIDIDYMIS (EP)	.09	.310 %	.171	WEIGHT TAKEN
ADRENAL (AD)	.011	.0401 %	.0221	WEIGHT TAKEN
THYMUS (TH)	.02	.089 %	.049	WEIGHT TAKEN

CLINICAL OBSERVATIONS	PATHOLOGY OBSERVATIONS NECROPSY	HISTOPATHOLOGY
-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS	LIVER (LI) : -PALE AREA; ALL LOBES, SEVERAL, TAN, PINPOINT TO 3 X 3 MM -ENLARGED, SEVERE; ALL LOBES -DARK; ALL LOBES, DARK BROWN	ADRENAL, CORTEX (AC) : -HYPERTROPHY, ZONA FASCICULATA,-MINIMAL LIVER (LI) : -HEPATOCYTE, HYPERTROPHY, CENTROLOBULAR,-MODERATE -VACUOLIZATION,-MINIMAL -PIGMENT, BILE,-MINIMAL -KUPFFER CELL/MACROPHAGE, PIGMENT,- MINIMAL -HEPATOCYTE, PIGMENT,-MINIMAL -NECROSIS, INDIVIDUAL CELL,-MINIMAL -INFLAMMATION, CHRONIC/CHRONIC ACTIVE,- MINIMAL -BILE DUCT, INFLAMMATION, CHRONIC,- MINIMAL SPLEEN (SP) : -EXTRAMEDULLARY HEMATOPOIESIS, INCREASED,-MINIMAL

HAZLETON WASHINGTON, INC.
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APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 702

STUDY NUMBER: 483287

ANIMAL NUMBER: A37548 SEX: MALE DOSE GROUP: 6 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/12/91 STUDY DAY OF DEATH: 96 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 27.9 GRAMS
DATE AND TIME OF NECROPSY: 11/12/91 13:12 PROSECTOR: DOUGLAS HERNDON RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

CLINICAL OBSERVATIONS P A T H O L O G Y O B S E R V A T I O N S (CONTINUED)
NECROPSY HISTOPATHOLOGY

SPLEEN (SP) :
-PIGMENT, -MINIMAL
STOMACH, GL (ST) :
-HYPERPLASIA, CYSTIC, -MINIMAL

^COLLECTED/TAKEN (XW) :
-LIVER SECTIONS, IN METHANOL

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), EPIDIDYMIS (EP), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE),
KIDNEY (KD), LACRIMAL GL, EX (EO), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU), MAND SALIVARY GL (SG),
MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON), NERVE, SCIATIC (SN),
PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), PROSTATE (PR), RECTUM (RE), SKIN (SK), SKIN, OTHER (SS),
SPLEEN (SP), STOMACH, GL (ST), STOMACH, NONGL (SU), TESTIS (TE), THYMUS (TH), THYROID (TY), TONGUE (TO),
TRACHEA (TR), URINARY BLADDER (UB)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:
ADRENAL, MEDULLA (AM), STOMACH, NONGL (SU)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 703

STUDY NUMBER: 483287

ANIMAL NUMBER: A37549 SEX: MALE DOSE GROUP: 6 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/13/91 STUDY DAY OF DEATH: 97 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 26.5 GRAMS
DATE AND TIME OF NECROPSY: 11/13/91 8:42 PROSECTOR: DOUGLAS HERNDON RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.18	.695 %	.368	WEIGHT TAKEN
LUNG (LU)	.18	.695 %	.368	WEIGHT TAKEN
PROSTATE (PR)	.071	.2679 %	.1418	WEIGHT TAKEN
BRAIN W/STEM (BR)	.50	1.889 %	1.000	WEIGHT TAKEN
HEART (HT)	.14	.544 %	.288	WEIGHT TAKEN
SPLEEN (SP)	.08	.311 %	.165	WEIGHT TAKEN
KIDNEY (KD)	.50	1.877 %	.993	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	3.11	11.755 %	6.221	WEIGHT TAKEN
TESTIS (TE)	.14	.520 %	.275	WEIGHT TAKEN
EPIDIDYMIS (EP)	.10	.378 %	.200	WEIGHT TAKEN
ADRENAL (AD)	.010	.0392 %	.0208	WEIGHT TAKEN
THYMUS (TH)	.02	.080 %	.043	WEIGHT TAKEN

CLINICAL OBSERVATIONS	PATHOLOGY OBSERVATIONS NECROPSY	HISTOPATHOLOGY
-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS	LIVER (LI) : -ENLARGED, SEVERE; ALL LOBES -DARK; ALL LOBES, DARK BROWN	LIVER (LI) : -HEPATOCYTE, HYPERTROPHY, CENTROLOBULAR,-MODERATE -PIGMENT, BILE,-MINIMAL -KUPFFER CELL/MACROPHAGE, PIGMENT,- MINIMAL -HEPATOCYTE, PIGMENT,-MODERATE -NECROSIS, INDIVIDUAL CELL,-MINIMAL SPLEEN (SP) : -EXTRAMEDULLARY HEMATOPOIESIS, INCREASED,-MODERATELY SEVERE -PIGMENT,-MINIMAL STOMACH, GL (ST) : -HYPERPLASIA, CYSTIC,-MINIMAL -INFLAMMATION, CHRONIC,-MINIMAL

^COLLECTED/TAKEN (XW) :
-LIVER SECTIONS, IN METHANOL

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 704

STUDY NUMBER: 483287

ANIMAL NUMBER: A37549 SEX: MALE DOSE GROUP: 6 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/13/91 STUDY DAY OF DEATH: 97 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 26.5 GRAMS
DATE AND TIME OF NECROPSY: 11/13/91 8:42 PROSECTOR: DOUGLAS HERNDON RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), EPIDIDYMIS (EP), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE),
KIDNEY (KD), LACRIMAL GL, EX (EO), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU), MAND SALIVARY GL (SG),
MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON), NERVE, SCIATIC (SN),
PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), PROSTATE (PR), RECTUM (RE), SKIN (SK), SKIN, OTHER (SS),
SPLEEN (SP), STOMACH, GL (ST), STOMACH, NONGL (SU), TESTIS (TE), THYMUS (TH), THYROID (TY), TONGUE (TO),
TRACHEA (TR), URINARY BLADDER (UB)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), STOMACH, NONGL (SU)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 705

STUDY NUMBER: 483287

ANIMAL NUMBER: A37550 SEX: MALE DOSE GROUP: 6 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/13/91 STUDY DAY OF DEATH: 97 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 22.0 GRAMS
DATE AND TIME OF NECROPSY: 11/13/91 9:40 PROSECTOR: SCOTT BELL RECORDER: SCOTT BELL
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.16	.708 %	.342	WEIGHT TAKEN
LUNG (LU)	.18	.818 %	.395	WEIGHT TAKEN
PROSTATE (PR)	.059	.2700 %	.1304	WEIGHT TAKEN
BRAIN W/STEM (BR)	.46	2.070 %	1.000	WEIGHT TAKEN
HEART (HT)	.13	.590 %	.285	WEIGHT TAKEN
SPLEEN (SP)	.04	.204 %	.098	WEIGHT TAKEN
KIDNEY (KD)	.39	1.750 %	.845	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	2.83	12.856 %	6.209	WEIGHT TAKEN
TESTIS (TE)	.20	.899 %	.434	WEIGHT TAKEN
EPIDIDYMIS (EP)	.08	.351 %	.169	WEIGHT TAKEN
ADRENAL (AD)	.016	.0727 %	.0351	WEIGHT TAKEN
THYMUS (TH)	.02	.074 %	.036	WEIGHT TAKEN

CLINICAL OBSERVATIONS	PATHOLOGY OBSERVATIONS NECROPSY	HISTOPATHOLOGY
-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS	LIVER (LI) : -PALE AREA; ALL LOBES, FEW, TAN, PINPOINT TO 1 X 1 MM -ENLARGED, SEVERE; ALL LOBES -DARK; ALL LOBES, DARK BROWN	ADRENAL, CORTEX (AC) : -HYPERTROPHY, ZONA FASCICULATA,-MINIMAL ADRENAL, MEDULLA (AM) : -UNILATERALLY EXAMINED,-PRESENT LIVER (LI) : -HEPATOCYTE, HYPERTROPHY, CENTROLOBULAR,-MODERATELY SEVERE -VACUOLIZATION,-MINIMAL -PIGMENT, BILE,-SLIGHT -KUPFFER CELL/MACROPHAGE, PIGMENT,- MINIMAL -HEPATOCYTE, PIGMENT,-SLIGHT -NECROSIS,-SLIGHT, MULTI-FOCAL -NECROSIS, INDIVIDUAL CELL,-SLIGHT SPLEEN (SP) : -EXTRAMEDULLARY HEMATOPOIESIS, INCREASED,-SLIGHT -PIGMENT,-MINIMAL

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 706

STUDY NUMBER: 483287

ANIMAL NUMBER: A37550 SEX: MALE DOSE GROUP: 6 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/13/91 STUDY DAY OF DEATH: 97 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 22.0 GRAMS
DATE AND TIME OF NECROPSY: 11/13/91 9:40 PROSECTOR: SCOTT BELL RECORDER: SCOTT BELL
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

CLINICAL OBSERVATIONS P A T H O L O G Y O B S E R V A T I O N S (CONTINUED)
NECROPSY HISTOPATHOLOGY

STOMACH, GL (ST) :
-DARK AREA: MUCOSA, SEVERAL, TAN,
PINPOINT TO 1 X 1 MM
^COLLECTED/TAKEN (XW) :
-LIVER SECTIONS, IN METHANOL

STOMACH, GL (ST) :
-HYPERPLASIA, CYSTIC, -MINIMAL
-MUCOSA, NECROSIS, -MINIMAL

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), EPIDIDYMIS (EP), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE),
KIDNEY (KD), LACRIMAL GL, EX (EO), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU), MAND SALIVARY GL (SG),
MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON), NERVE, SCIATIC (SN),
PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), PROSTATE (PR), RECTUM (RE), SKIN (SK), SKIN, OTHER (SS),
SPLEEN (SP), STOMACH, NONGL (SU), TESTIS (TE), THYMUS (TH), THYROID (TY), TONGUE (TO), TRACHEA (TR),
URINARY BLADDER (UB)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:

STOMACH, NONGL (SU)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 707

STUDY NUMBER: 483287

ANIMAL NUMBER: A37551 SEX: MALE DOSE GROUP: 6 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/13/91 STUDY DAY OF DEATH: 97 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 27.0 GRAMS
DATE AND TIME OF NECROPSY: 11/13/91 11:01 PROSECTOR: ADEPOLAHAN AKINSOLA RECORDER: JOHN CROWLEY
POST-FIX WEAIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEAIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.19	.712 %	.413	WEIGHT TAKEN
LUNG (LU)	.17	.642 %	.373	WEIGHT TAKEN
PROSTATE (PR)	.031	.1141 %	.0662	WEIGHT TAKEN
BRAIN W/STEM (BR)	.47	1.723 %	1.000	WEIGHT TAKEN
HEART (HT)	.13	.475 %	.276	WEIGHT TAKEN
SPLEEN (SP)	.07	.271 %	.157	WEIGHT TAKEN
KIDNEY (KD)	.45	1.656 %	.961	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	4.04	14.961 %	8.685	WEIGHT TAKEN
TESTIS (TE)	.17	.647 %	.376	WEIGHT TAKEN
EPIIDIDYMIS (EP)	.10	.383 %	.222	WEIGHT TAKEN
ADRENAL (AD)	.009	.0341 %	.0198	WEIGHT TAKEN
THYMUS (TH)	.02	.089 %	.052	WEIGHT TAKEN

CLINICAL OBSERVATIONS	PATHOLOGY OBSERVATIONS NECROPSY	HISTOPATHOLOGY
-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS	LIVER (LI) : -PALE AREA; ALL LOBES, SEVERAL, TAN, PINPOINT TO 2 X 2 MM -ENLARGED, SEVERE; ALL LOBES -DARK; ALL LOBES, DARK BROWN	ADRENAL, CORTEX (AC) : -HYPERTROPHY, ZONA FASCICULATA,-MINIMAL LIVER (LI) : -HEPATOCYTE, HYPERTROPHY, CENTROLOBULAR,-MODERATE -VACUOLIZATION,-MODERATE -PIGMENT, BILE,-SLIGHT -KUPFFER CELL/MACROPHAGE, PIGMENT,- MINIMAL -HEPATOCYTE, PIGMENT,-MINIMAL -NECROSIS, INDIVIDUAL CELL,-SLIGHT -INFLAMMATION, CHRONIC/CHRONIC ACTIVE,- MINIMAL SPLEEN (SP) : -EXTRAMEDULLARY HEMATOPOIESIS, INCREASED,-SLIGHT -PIGMENT,-MINIMAL

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 708

STUDY NUMBER: 483287

ANIMAL NUMBER: A37551 SEX: MALE DOSE GROUP: 6 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/13/91 STUDY DAY OF DEATH: 97 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 27.0 GRAMS
DATE AND TIME OF NECROPSY: 11/13/91 11:01 PROSECTOR: ADEFOLAHAN AKINSOLA RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

CLINICAL OBSERVATIONS P A T H O L O G Y O B S E R V A T I O N S (CONTINUED)
NECROPSY HISTOPATHOLOGY

^COLLECTED/TAKEN (XW) :
-LIVER SECTIONS, IN METHANOL

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), EPIDIDYMIS (EP), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE),
KIDNEY (KD), LACRIMAL GL, EX (EO), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU), MAND SALIVARY GL (SG),
MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON), NERVE, SCIATIC (SN),
PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), PROSTATE (PR), RECTUM (RE), SKIN (SK), SKIN, OTHER (SS),
SPLEEN (SP), STOMACH, GL (ST), STOMACH, NONGL (SU), TESTIS (TE), THYMUS (TH), THYROID (TY), TONGUE (TO),
TRACHEA (TR), URINARY BLADDER (UB)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:

ADRENAL, MEDULLA (AM), STOMACH, GL (ST), STOMACH, NONGL (SU)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 709

STUDY NUMBER: 483287

ANIMAL NUMBER: A37552 SEX: MALE DOSE GROUP: 6 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/13/91 STUDY DAY OF DEATH: 97 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 24.1 GRAMS
DATE AND TIME OF NECROPSY: 11/13/91 13:08 PROSECTOR: LINDA RUMBLE RECORDER: LINDA RUMBLE
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.17	.696 %	.407	WEIGHT TAKEN
LUNG (LU)	.17	.694 %	.405	WEIGHT TAKEN
PROSTATE (PR)	.021	.0863 %	.0504	WEIGHT TAKEN
BRAIN W/STEM (BR)	.41	1.711 %	1.000	WEIGHT TAKEN
HEART (HT)	.13	.560 %	.327	WEIGHT TAKEN
SPLEEN (SP)	.13	.531 %	.310	WEIGHT TAKEN
KIDNEY (KD)	.35	1.469 %	.858	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	3.83	15.910 %	9.298	WEIGHT TAKEN
TESTIS (TE)	.16	.658 %	.384	WEIGHT TAKEN
EPIDIDYMIS (EP)	.07	.287 %	.168	WEIGHT TAKEN
ADRENAL (AD)	.017	.0689 %	.0403	WEIGHT TAKEN
THYMUS (TH)	.01	.043 %	.025	WEIGHT TAKEN

CLINICAL OBSERVATIONS	PATHOLOGY OBSERVATIONS NECROPSY	HISTOPATHOLOGY
-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS	LIVER (LI) : -PALE AREA; ALL LOBES, SEVERAL, TAN, PINPOINT TO 5 X 5 MM -ENLARGED, MODERATE; ALL LOBES -DARK; ALL LOBES, DARK BROWN STOMACH, GL (ST) : -DARK AREA; MUCOSA, SEVERAL, BLACK, PINPOINT TO 4 X 3 MM	LIVER (LI) : -HEPATOCYTE, HYPERTROPHY, CENTROLOBULAR,-MODERATELY SEVERE -VACUOLIZATION,-MINIMAL -PIGMENT, BILE,-SLIGHT -KUPFFER CELL/MACROPHAGE, PIGMENT,- MINIMAL -HEPATOCYTE, PIGMENT,-MODERATE -NECROSIS,-MODERATE, MULTI-FOCAL -NECROSIS, INDIVIDUAL CELL,-MODERATE -INFLAMMATION, CHRONIC/CHRONIC ACTIVE,- SLIGHT SPLEEN (SP) : -EXTRAMEDULLARY HEMATOPOIESIS, INCREASED,-MODERATELY SEVERE STOMACH, GL (ST) : -HYPERPLASIA, CYSTIC,-MINIMAL -MUCOSA, NECROSIS,-MINIMAL

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 710

STUDY NUMBER: 483287

ANIMAL NUMBER: A37552 SEX: MALE DOSE GROUP: 6 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/13/91 STUDY DAY OF DEATH: 97 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 24.1 GRAMS
DATE AND TIME OF NECROPSY: 11/13/91 13:08 PROSECTOR: LINDA RUMBLE RECORDER: LINDA RUMBLE
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

CLINICAL OBSERVATIONS PATHOLOGY OBSERVATIONS (CONTINUED)
NECROPSY HISTOPATHOLOGY

^COLLECTED/TAKEN (XW) :
-LIVER SECTIONS, IN METHANOL

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), EPIDIDYMIS (EP), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE),
KIDNEY (KD), LACRIMAL GL, EX (EO), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU), MAND SALIVARY GL (SG),
MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON), NERVE, SCIATIC (SN),
PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), PROSTATE (PR), RECTUM (RE), SKIN (SK), SKIN, OTHER (SS),
SPLEEN (SP), STOMACH, NONGL (SU), TESTIS (TE), THYMUS (TH), THYROID (TY), TONGUE (TO), TRACHEA (TR),
URINARY BLADDER (UB)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), STOMACH, NONGL (SU)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 711

STUDY NUMBER: 483287

ANIMAL NUMBER: A37553 SEX: MALE DOSE GROUP: 6 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/14/91 STUDY DAY OF DEATH: 98 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 27.6 GRAMS
DATE AND TIME OF NECROPSY: 11/14/91 8:15 PROSECTOR: SONNY DIKES RECORDER: SONNY DIKES
POST-FIX WEAHER: DANIEL JACK PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEAHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.13	.475 %	.241	WEIGHT TAKEN
LUNG (LU)	.19	.703 %	.356	WEIGHT TAKEN
PROSTATE (PR)	.048	.1739 %	.0881	WEIGHT TAKEN
BRAIN W/STEM (BR)	.54	1.974 %	1.000	WEIGHT TAKEN
HEART (HT)	.14	.491 %	.249	WEIGHT TAKEN
SPLEEN (SP)	.08	.304 %	.154	WEIGHT TAKEN
KIDNEY (KD)	.40	1.432 %	.726	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	3.07	11.113 %	5.630	WEIGHT TAKEN
TESTIS (TE)	.25	.911 %	.462	WEIGHT TAKEN
EPIDIDYMIS (EP)	.14	.491 %	.249	WEIGHT TAKEN
ADRENAL (AD)	.011	.0388 %	.0196	WEIGHT TAKEN
THYMUS (TH)	.02	.088 %	.045	WEIGHT TAKEN

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE
OBSERVATIONS

PATHOLOGY OBSERVATIONS
NECROPSY

LIVER (LI) :
-ENLARGED, MODERATE; ALL LOBES
-DARK; ALL LOBES, DARK BROWN

HISTOPATHOLOGY

ADRENAL, CORTEX (AC) :
-HYPERTROPHY, ZONA FASCICULATA,-MINIMAL
LIVER (LI) :
-HEPATOCYTE, HYPERTROPHY,
CENTROLOBULAR,-MODERATE
-VACUOLIZATION,-SLIGHT
-PIGMENT, BILE,-MINIMAL
-KUPFFER CELL/MACROPHAGE, PIGMENT,-
MINIMAL
-HEPATOCYTE, PIGMENT,-SLIGHT
-NECROSIS, INDIVIDUAL CELL,-SLIGHT
-BILE DUCT, INFLAMMATION, CHRONIC,-
MINIMAL
SPLEEN (SP) :
-EXTRAMEDULLARY HEMATOPOIESIS,
INCREASED,-MODERATE
-PIGMENT,-MINIMAL

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 712

STUDY NUMBER: 483287

ANIMAL NUMBER: A37553 SEX: MALE DOSE GROUP: 6 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/14/91 STUDY DAY OF DEATH: 98 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 27.6 GRAMS
DATE AND TIME OF NECROPSY: 11/14/91 8:15 PROSECTOR: SONNY DIKES RECORDER: SONNY DIKES
POST-FIX WEIGHER: DANIEL JACK PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

CLINICAL OBSERVATIONS P A T H O L O G Y O B S E R V A T I O N S (CONTINUED)
NECROPSY HISTOPATHOLOGY

^COLLECTED/TAKEN (XW) :
-LIVER SECTIONS, IN METHANOL

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), EPIDIDYMIS (EP), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE),
KIDNEY (KD), LACRIMAL GL, EX (EO), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU), MAND SALIVARY GL (SG),
MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON), NERVE, SCIATIC (SN),
PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), PROSTATE (PR), RECTUM (RE), SKIN (SK), SKIN, OTHER (SS),
SPLEEN (SP), STOMACH, GL (ST), STOMACH, NONGL (SU), TESTIS (TE), THYMUS (TH), THYROID (TY), TONGUE (TO),
TRACHEA (TR), URINARY BLADDER (UB)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:

ADRENAL, MEDULLA (AM), STOMACH, GL (ST), STOMACH, NONGL (SU)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 713

STUDY NUMBER: 483287

ANIMAL NUMBER: A37554 SEX: MALE DOSE GROUP: 6 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/14/91 STUDY DAY OF DEATH: 98 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 24.7 GRAMS
DATE AND TIME OF NECROPSY: 11/14/91 9:06 PROSECTOR: FRED AGEY RECORDER: FRED AGEY
POST-FIX WEAHER: DANIEL JACK PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEAHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.18	.712 %	.409	WEIGHT TAKEN
LUNG (LU)	.18	.726 %	.417	WEIGHT TAKEN
PROSTATE (PR)	.028	.1126 %	.0647	WEIGHT TAKEN
BRAIN W/STEM (BR)	.43	1.739 %	1.000	WEIGHT TAKEN
HEART (HT)	.12	.470 %	.270	WEIGHT TAKEN
SPLEEN (SP)	.07	.283 %	.163	WEIGHT TAKEN
KIDNEY (KD)	.41	1.653 %	.950	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	3.23	13.083 %	7.522	WEIGHT TAKEN
TESTIS (TE)	.24	.972 %	.559	WEIGHT TAKEN
EPIDIDYMIS (EP)	.11	.442 %	.254	WEIGHT TAKEN
ADRENAL (AD)	.008	.0336 %	.0193	WEIGHT TAKEN
THYMUS (TH)	.02	.085 %	.049	WEIGHT TAKEN

P A T H O L O G Y O B S E R V A T I O N S
NECROPSY

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM: NORMAL-NO REMARKABLE
OBSERVATIONS

LIVER (LI) :
-PALE AREA; ALL LOBES, SEVERAL, TAN,
PINPOINT TO 2 X 2 MM
-ENLARGED, SEVERE; ALL LOBES
-DARK; ALL LOBES, DARK BROWN

HISTOPATHOLOGY

ADRENAL, MEDULLA (AM) :
-UNILATERALLY EXAMINED, -PRESENT
LIVER (LI) :
-HEPATOCTE, HYPERTROPHY,
CENTROLOBULAR, -MODERATE
-VACUOLIZATION, -MINIMAL
-PIGMENT, BILE, -MINIMAL
-KUPFFER CELL/MACROPHAGE, PIGMENT, -
SLIGHT
-HEPATOCTE, PIGMENT, -MINIMAL
-NECROSIS, INDIVIDUAL CELL, -MINIMAL
-INFLAMMATION, CHRONIC/CHRONIC ACTIVE, -
MINIMAL
-BILE DUCT, INFLAMMATION, CHRONIC, -
MINIMAL
SPLEEN (SP) :
-EXTRAMEDULLARY HEMATOPOIESIS,
INCREASED, -MODERATE

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 714

STUDY NUMBER: 483287

ANIMAL NUMBER: A37554 SEX: MALE DOSE GROUP: 6 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/14/91 STUDY DAY OF DEATH: 98 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 24.7 GRAMS
DATE AND TIME OF NECROPSY: 11/14/91 9:06 PROSECTOR: FRED AGEY RECORDER: FRED AGEY
POST-FIX WEIGHER: DANIEL JACK PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

CLINICAL OBSERVATIONS P A T H O L O G Y O B S E R V A T I O N S (CONTINUED)
NECROPSY HISTOPATHOLOGY

SPLEEN (SP) :
-PIGMENT, -MINIMAL

^COLLECTED/TAKEN (XW) :
-LIVER SECTIONS, IN METHANOL

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), EPIDIDYMIS (EP), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE),
KIDNEY (KD), LACRIMAL GL, EX (EO), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU), MAND SALIVARY GL (SG),
MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON), NERVE, SCIATIC (SN),
PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), PROSTATE (PR), RECTUM (RE), SKIN (SK), SKIN, OTHER (SS),
SPLEEN (SP), STOMACH, GL (ST), STOMACH, NONGL (SU), TESTIS (TE), THYMUS (TH), THYROID (TY), TONGUE (TO),
TRACHEA (TR), URINARY BLADDER (UB)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:

ADRENAL, CORTEX (AC), STOMACH, GL (ST), STOMACH, NONGL (SU)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 715

STUDY NUMBER: 483287

ANIMAL NUMBER: A37555 SEX: MALE DOSE GROUP: 6 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/14/91 STUDY DAY OF DEATH: 98 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 25.5 GRAMS
DATE AND TIME OF NECROPSY: 11/14/91 10:00 PROSECTOR: SONNY DIKES RECORDER: SONNY DIKES
POST-FIX WEIGHER: JOHN CROWLEY PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.10	.393 %	.205	WEIGHT TAKEN
LUNG (LU)	.17	.652 %	.341	WEIGHT TAKEN
PROSTATE (PR)	.036	.1420 %	.0742	WEIGHT TAKEN
BRAIN W/STEM (BR)	.49	1.914 %	1.000	WEIGHT TAKEN
HEART (HT)	.13	.518 %	.271	WEIGHT TAKEN
SPLEEN (SP)	.08	.332 %	.174	WEIGHT TAKEN
KIDNEY (KD)	.42	1.629 %	.851	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	3.32	13.009 %	6.796	WEIGHT TAKEN
TESTIS (TE)	.23	.883 %	.461	WEIGHT TAKEN
EPIDIDYMIS (EP)	.09	.342 %	.179	WEIGHT TAKEN
ADRENAL (AD)	.012	.0459 %	.0240	WEIGHT TAKEN
THYMUS (TH)	.02	.075 %	.039	WEIGHT TAKEN

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE
OBSERVATIONS

PATHOLOGY OBSERVATIONS
NECROPSY

LIVER (LI) :
-PALE AREA; ALL LOBES, SEVERAL, TAN,
PINPOINT TO 4 X 2 MM
-ENLARGED, SEVERE; ALL LOBES
-DARK; ALL LOBES, DARK BROWN

HISTOPATHOLOGY

ADRENAL, CORTEX (AC) :
-PIGMENT,-MINIMAL
LIVER (LI) :
-HEPATOCYTE, HYPERTROPHY,
CENTROLOBULAR,-MODERATE
-VACUOLIZATION,-MINIMAL
-PIGMENT, BILE,-MINIMAL
-KUPFFER CELL/MACROPHAGE, PIGMENT,-
MINIMAL
-HEPATOCYTE, PIGMENT,-SLIGHT
-NECROSIS,-MODERATE, MULTI-FOCAL
-NECROSIS, INDIVIDUAL CELL,-MINIMAL
-INFLAMMATION, CHRONIC/CHRONIC ACTIVE,-
MINIMAL
-BILE DUCT, INFLAMMATION, CHRONIC,-
MINIMAL

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 716

STUDY NUMBER: 483287

ANIMAL NUMBER: A37555 SEX: MALE DOSE GROUP: 6 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/14/91 STUDY DAY OF DEATH: 98 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 25.5 GRAMS
DATE AND TIME OF NECROPSY: 11/14/91 10:00 PROSECTOR: SONNY DIKES RECORDER: SONNY DIKES
POST-FIX WEIGHER: JOHN CROWLEY PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

CLINICAL OBSERVATIONS

P A T H O L O G Y O B S E R V A T I O N S (CONTINUED)
NECROPSY

HISTOPATHOLOGY

SPLEEN (SP) :
-EXTRAMEDULLARY HEMATOPOIESIS,
INCREASED, -SLIGHT
-PIGMENT, -MINIMAL
STOMACH, GL (ST) :
-HYPERPLASIA, CYSTIC, -MINIMAL
-INFLAMMATION, CHRONIC, -MINIMAL

^COLLECTED/TAKEN (XW) :
-LIVER SECTIONS, IN METHANOL

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), EPIDIDYMIS (EP), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE),
KIDNEY (KD), LACRIMAL GL, EX (EO), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU), MAND SALIVARY GL (SG),
MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON), NERVE, SCIATIC (SN),
PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), PROSTATE (PR), RECTUM (RE), SKIN (SK), SKIN, OTHER (SS),
SPLEEN (SP), STOMACH, GL (ST), STOMACH, NONGL (SU), TESTIS (TE), THYMUS (TH), THYROID (TY), TONGUE (TO),
TRACHEA (TR), URINARY BLADDER (UB)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:
ADRENAL, MEDULLA (AM)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 717

STUDY NUMBER: 483287

ANIMAL NUMBER: A37571 SEX: MALE DOSE GROUP: 7 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/11/91 STUDY DAY OF DEATH: 95 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 25.8 GRAMS
DATE AND TIME OF NECROPSY: 11/11/91 9:11 PROSECTOR: ADEFOLAHAN AKINSOLA RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.14	.534 %	.306	WEIGHT TAKEN
LUNG (LU)	.16	.613 %	.351	WEIGHT TAKEN
PROSTATE (PR)	.019	.0725 %	.0415	WEIGHT TAKEN
BRAIN W/STEM (BR)	.45	1.745 %	1.000	WEIGHT TAKEN
HEART (HT)	.13	.517 %	.296	WEIGHT TAKEN
SPLEEN (SP)	.07	.265 %	.152	WEIGHT TAKEN
KIDNEY (KD)	.45	1.741 %	.998	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	3.69	14.305 %	8.198	WEIGHT TAKEN
TESTIS (TE)	.19	.735 %	.421	WEIGHT TAKEN
EPIDIDYMIS (EP)	.09	.334 %	.192	WEIGHT TAKEN
ADRENAL (AD)	.011	.0411 %	.0235	WEIGHT TAKEN
THYMUS (TH)	.02	.072 %	.041	WEIGHT TAKEN

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE
OBSERVATIONS

PATHOLOGY OBSERVATIONS
NECROPSY

LIVER (LI) :
-PALE AREA; ALL LOBES, FEW, TAN,
PINPOINT TO 3 X 3 MM
-ENLARGED, SEVERE; ALL LOBES

HISTOPATHOLOGY

ADRENAL, CORTEX (AC) :
-HYPERTROPHY, ZONA FASCICULATA, -SLIGHT
EPIDIDYMIS (EP) :
-LUMEN, DEBRIS, CELLULAR, -PRESENT
ILEUM (IL) :
-AMYLOIDOSIS, -SLIGHT
KIDNEY (KD) :
-INFLAMMATION, CHRONIC, -MINIMAL
-TUBULE, REGENERATION, -SLIGHT
-TUBULE, DILATATION, -SLIGHT
-AMYLOIDOSIS, -MINIMAL
LACRIMAL GL, EX (EO) :
-INFLAMMATION, CHRONIC, -MINIMAL
-UNILATERALLY EXAMINED, -PRESENT
LIVER (LI) :
-HEPATOCYTE, HYPERTROPHY,
CENTROLOBULAR, -MODERATELY SEVERE
-VACUOLIZATION, -MINIMAL

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 718

STUDY NUMBER: 483287

ANIMAL NUMBER: A37571 SEX: MALE DOSE GROUP: 7 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/11/91 STUDY DAY OF DEATH: 95 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 25.8 GRAMS
DATE AND TIME OF NECROPSY: 11/11/91 9:11 PROSECTOR: ADEFOLAHAN AKINSOLA RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

CLINICAL OBSERVATIONS

P A T H O L O G Y O B S E R V A T I O N S (CONTINUED)
NECROPSY

HISTOPATHOLOGY

LIVER (LI) :
-DARK; ALL LOBES, DARK BROWN

LIVER (LI) :
-PIGMENT, BILE, -SLIGHT
-KUPFFER CELL/MACROPHAGE, PIGMENT, -
SLIGHT
-HEPATOCYTE, PIGMENT, -SLIGHT
-NECROSIS, INDIVIDUAL CELL, -SLIGHT
-INFLAMMATION, CHRONIC/CHRONIC ACTIVE, -
MINIMAL
LN, MANDIBULAR (MN) :
-MACROPHAGES, PIGMENTED, -MINIMAL
NERVE, OPTIC (ON) :
-UNILATERALLY EXAMINED, -PRESENT
PARATHYROID (PT) :
-UNILATERALLY EXAMINED, -PRESENT
SPLEEN (SP) :
-EXTRAMEDULLARY HEMATOPOIESIS,
INCREASED, -MODERATE
-PIGMENT, -MINIMAL
STOMACH, GL (ST) :
>UNREMARKABLE

STOMACH, GL (ST) :
-DARK AREA; MUCOSA, SEVERAL, BLACK,
PINPOINT
^COLLECTED/TAKEN (XW) :
-LIVER SECTIONS, IN METHANOL

^DEATH COMMENT (DC) :
-SCHEDULED SACRIFICE, -PRESENT

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 719

STUDY NUMBER: 483287

ANIMAL NUMBER: A37571 SEX: MALE DOSE GROUP: 7 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/11/91 STUDY DAY OF DEATH: 95 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 25.8 GRAMS
DATE AND TIME OF NECROPSY: 11/11/91 9:11 PROSECTOR: ADEFOLAHAN AKINSOLA RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), EPIDIDYMIS (EP), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE),
KIDNEY (KD), LACRIMAL GL, EX (EO), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU), MAND SALIVARY GL (SG),
MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON), NERVE, SCIATIC (SN),
PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), PROSTATE (PR), RECTUM (RE), SKIN (SK), SKIN, OTHER (SS),
SPLEEN (SP), STOMACH, NONGL (SU), TESTIS (TE), THYMUS (TH), THYROID (TY), TONGUE (TO), TRACHEA (TR),
URINARY BLADDER (UB)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:

ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, STERNUM (SB), BRAIN W/STEM (BR), CECUM (CE),
COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC), DUODENUM (DU), ESOPHAGUS (ES), EYE (EY),
GALLBLADDER (GB), HARDERIAN GLAND (HG), HEART (HT), HEMATO NEOPLASIA (HN), JEJUNUM (JE), LN, MESENTERIC (MS),
LUNG (LU), MAND SALIVARY GL (SG), MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, ABDOM (MA), MUSCLE, SKELETAL (SM),
NERVE, SCIATIC (SN), PANCREAS (PA), PITUITARY (PI), PROSTATE (PR), RECTUM (RE), SALIVARY, OTHER (OS), SKIN (SK),
STOMACH, NONGL (SU), TESTIS (TE), THYMUS (TH), THYROID (TY), TONGUE (TO), TRACHEA (TR), URINARY BLADDER (UB)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 720

STUDY NUMBER: 483287

ANIMAL NUMBER: A37572 SEX: MALE DOSE GROUP: 7 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/11/91 STUDY DAY OF DEATH: 95 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 26.4 GRAMS
DATE AND TIME OF NECROPSY: 11/11/91 10:27 PROSECTOR: JANE EARHARDT RECORDER: JANE EARHARDT
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.10	.394 %	.192	WEIGHT TAKEN
LUNG (LU)	.18	.698 %	.341	WEIGHT TAKEN
PROSTATE (PR)	.081	.3053 %	.1488	WEIGHT TAKEN
BRAIN W/STEM (BR)	.54	2.051 %	1.000	WEIGHT TAKEN
HEART (HT)	.15	.572 %	.279	WEIGHT TAKEN
SPLEEN (SP)	.09	.350 %	.170	WEIGHT TAKEN
KIDNEY (KD)	.41	1.569 %	.765	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	3.18	12.042 %	5.871	WEIGHT TAKEN
TESTIS (TE)	.22	.822 %	.401	WEIGHT TAKEN
EPIDIDYMIS (EP)	.09	.335 %	.163	WEIGHT TAKEN
ADRENAL (AD)	.011	.0413 %	.0201	WEIGHT TAKEN
THYMUS (TH)	.03	.103 %	.050	WEIGHT TAKEN

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE
OBSERVATIONS

PATHOLOGY OBSERVATIONS
NECROPSY

HISTOPATHOLOGY

ADRENAL, CORTEX (AC) :
-HYPERTROPHY, ZONA FASCICULATA,-SLIGHT
DUODENUM (DU) :
-TISSUE MISSING
EPIDIDYMIS (EP) :
-LUMEN, DEBRIS, CELLULAR,-PRESENT
HEART (HT) :
-INFLAMMATION, CHRONIC,-MINIMAL
KIDNEY (KD) :
-INFLAMMATION, CHRONIC,-MINIMAL
-TUBULE, MINERALIZATION,-MINIMAL
-TUBULE, REGENERATION,-MODERATE
-HYPERPLASIA, LYMPHOID,-MINIMAL
LI, EXTRAHEPATIC (LI) :
-PIGMENT, PAS POSITIVE,-SEVERE
-PIGMENT, IRON POSITIVE,-SLIGHT
-PIGMENT, LIPOFUSCIN POSITIVE,-MODERATE

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 721

STUDY NUMBER: 483287

ANIMAL NUMBER: A37572 SEX: MALE DOSE GROUP: 7 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/11/91 STUDY DAY OF DEATH: 95 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 26.4 GRAMS
DATE AND TIME OF NECROPSY: 11/11/91 10:27 PROSECTOR: JANE EARHARDT RECORDER: JANE EARHARDT
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

CLINICAL OBSERVATIONS

P A T H O L O G Y O B S E R V A T I O N S (CONTINUED)
NECROPSY

HISTOPATHOLOGY

LIVER (LI) :
-PALE AREA; ALL LOBES, SEVERAL, TAN, 6
X 5 MM
-DARK; ALL LOBES, BROWN

LI, INTRAHEPATIC (LIO) :
-PIGMENT, PAS POSITIVE, -SEVERE
-PIGMENT, IRON POSITIVE, -SLIGHT
-PIGMENT, BILE POSITIVE, -MINIMAL
-PIGMENT, LIPOFUSCIN POSITIVE, -SLIGHT
LIVER (LI) :
-HEPATOCYTE, HYPERTROPHY,
CENTROLOBULAR, -MODERATELY SEVERE
-VACUOLIZATION, -MINIMAL
-PIGMENT, BILE, -SLIGHT
-KUPFFER CELL/MACROPHAGE, PIGMENT, -
MINIMAL
-HEPATOCYTE, PIGMENT, -MINIMAL
-NECROSIS, -SEVERE, MULTI-FOCAL
-NECROSIS, INDIVIDUAL CELL, -MINIMAL
-INFLAMMATION, CHRONIC/CHRONIC ACTIVE, -
MODERATELY SEVERE
-MINERALIZATION, -MINIMAL
LN, MANDIBULAR (MN) :
-MACROPHAGES, PIGMENTED, -MINIMAL
LN, MESENTERIC (MS) :
-HYPERPLASIA, LYMPHOID, -SLIGHT
MARROW, FEMUR (FM) :
-HYPERCELLULAR, -PRESENT
NERVE, OPTIC (ON) :
>TISSUE MISSING
SPLEEN (SP) :
-EXTRAMEDULLARY HEMATOPOIESIS,
INCREASED, -MODERATE
-PIGMENT, -MINIMAL

^COLLECTED/TAKEN (XW) :
-LIVER SECTIONS, IN METHANOL

^DEATH COMMENT (DC) :
-SCHEDULED SACRIFICE, -PRESENT

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 722

STUDY NUMBER: 483287

ANIMAL NUMBER: A37572 SEX: MALE DOSE GROUP: 7 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/11/91 STUDY DAY OF DEATH: 95 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 26.4 GRAMS
DATE AND TIME OF NECROPSY: 11/11/91 10:27 PROSECTOR: JANE EARHARDT RECORDER: JANE EARHARDT
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), EPIDIDYMIS (EP), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE),
KIDNEY (KD), LACRIMAL GL, EX (EO), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU), MAND SALIVARY GL (SG),
MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON), NERVE, SCIATIC (SN),
PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), PROSTATE (PR), RECTUM (RE), SKIN (SK), SKIN, OTHER (SS),
SPLEEN (SP), STOMACH, GL (ST), STOMACH, NONGL (SU), TESTIS (TE), THYMUS (TH), THYROID (TY), TONGUE (TO),
TRACHEA (TR), URINARY BLADDER (UB)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:

ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, STERNUM (SB), BRAIN W/STEM (BR), CECUM (CE),
COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB),
HARDERIAN GLAND (HG), HEMATO NEOPLASIA (HN), ILEUM (IL), JEJUNUM (JE), LACRIMAL GL, EX (EO), LUNG (LU),
MAND SALIVARY GL (SG), MARROW, STERNUM (SE), MUSCLE, ABDOM (MA), MUSCLE, SKELETAL (SM), NERVE, SCIATIC (SN),
PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), PROSTATE (PR), RECTUM (RE), SALIVARY, OTHER (OS), SKIN (SK),
STOMACH, GL (ST), STOMACH, NONGL (SU), TESTIS (TE), THYMUS (TH), THYROID (TY), TONGUE (TO), TRACHEA (TR),
URINARY BLADDER (UB)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 723

STUDY NUMBER: 483287

ANIMAL NUMBER: A37573 SEX: MALE DOSE GROUP: 7 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/11/91 STUDY DAY OF DEATH: 95 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 23.2 GRAMS
DATE AND TIME OF NECROPSY: 11/11/91 11:21 PROSECTOR: FRED AGEY RECORDER: FRED AGEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.16	.700 %	.398	WEIGHT TAKEN
LUNG (LU)	.15	.656 %	.373	WEIGHT TAKEN
PROSTATE (PR)	.046	.2000 %	.1137	WEIGHT TAKEN
BRAIN W/STEM (BR)	.41	1.759 %	1.000	WEIGHT TAKEN
HEART (HT)	.15	.632 %	.360	WEIGHT TAKEN
SPLEEN (SP)	.06	.269 %	.153	WEIGHT TAKEN
KIDNEY (KD)	.43	1.866 %	1.061	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	3.18	13.703 %	7.792	WEIGHT TAKEN
TESTIS (TE)	.17	.741 %	.422	WEIGHT TAKEN
EPIIDIDYMIS (EP)	.10	.413 %	.235	WEIGHT TAKEN
ADRENAL (AD)	.009	.0392 %	.0223	WEIGHT TAKEN
THYMUS (TH)	.01	.050 %	.029	WEIGHT TAKEN

CLINICAL OBSERVATIONS	PATHOLOGY OBSERVATIONS NECROPSY	HISTOPATHOLOGY
-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS	LIVER (LI) : -PALE AREA; ALL LOBES, SEVERAL, TAN, PINPOINT TO 7 X 5 MM -ENLARGED, SEVERE; ALL LOBES -DARK; ALL LOBES, DARK BROWN	CECUM (CE) : -HYPERPLASIA, LYMPHOID,-PRESENT KIDNEY (KD) : -INFLAMMATION, CHRONIC,-MINIMAL -TUBULE, REGENERATION,-MINIMAL -HYPERPLASIA, LYMPHOID,-MINIMAL LACRIMAL GL, EX (EO) : >TISSUE MISSING LIVER (LI) : -HEPATOCYTE, HYPERTROPHY, CENTROLOBULAR,-MODERATELY SEVERE -VACUOLIZATION,-MINIMAL -PIGMENT, BILE,-SLIGHT -KUPFFER CELL/MACROPHAGE, PIGMENT,- SLIGHT -HEPATOCYTE, PIGMENT,-SLIGHT -NECROSIS,-MODERATELY SEVERE, MULTI- FOCAL

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 724

STUDY NUMBER: 483287

ANIMAL NUMBER: A37573 SEX: MALE DOSE GROUP: 7 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/11/91 STUDY DAY OF DEATH: 95 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 23.2 GRAMS
DATE AND TIME OF NECROPSY: 11/11/91 11:21 PROSECTOR: FRED AGEY RECORDER: FRED AGEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

P A T H O L O G Y O B S E R V A T I O N S (CONTINUED)
NECROPSY

CLINICAL OBSERVATIONS

HISTOPATHOLOGY

LIVER (LI) :
-NECROSIS, INDIVIDUAL CELL, -SLIGHT
-INFLAMMATION, CHRONIC/CHRONIC ACTIVE, -
MODERATE
LN, MANDIBULAR (MN) :
-MACROPHAGES, PIGMENTED, -MINIMAL
LN, MESENTERIC (MS) :
>TISSUE MISSING
LUNG (LU) :
-PERIBRONCHIAL/PERIVASCULAR,
INFILTRATION, LYMPHOID, -MINIMAL
NERVE, OPTIC (ON) :
>TISSUE MISSING
SPLEEN (SP) :
-EXTRAMEDULLARY HEMATOPOIESIS,
INCREASED, -SLIGHT
-PIGMENT, -MINIMAL
STOMACH, GL (ST) :
-HYPERPLASIA, CYSTIC, -SLIGHT
THYMUS (TH) :
>SECTION EXAMINED; TISSUE NOT PRESENT

^COLLECTED/TAKEN (XW) :
-LIVER SECTIONS, IN METHANOL

^DEATH COMMENT (DC) :
-SCHEDULED SACRIFICE, -PRESENT

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 725

STUDY NUMBER: 483287

ANIMAL NUMBER: A37573 SEX: MALE DOSE GROUP: 7 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/11/91 STUDY DAY OF DEATH: 95 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 23.2 GRAMS
DATE AND TIME OF NECROPSY: 11/11/91 11:21 PROSECTOR: FRED AGEY RECORDER: FRED AGEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), EPIDIDYMIS (EP), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE),
KIDNEY (KD), LACRIMAL GL, EX (EO), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU), MAND SALIVARY GL (SG),
MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON), NERVE, SCIATIC (SN),
PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), PROSTATE (PR), RECTUM (RE), SKIN (SK), SKIN, OTHER (SS),
SPLEEN (SP), STOMACH, GL (ST), STOMACH, NONGL (SU), TESTIS (TE), THYMUS (TH), THYROID (TY), TONGUE (TO),
TRACHEA (TR), URINARY BLADDER (UB)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, STERNUM (SB),
BRAIN W/STEM (BR), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC), DUODENUM (DU),
EPIDIDYMIS (EP), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HARDERIAN GLAND (HG), HEART (HT), HEMATO NEOPLASIA (HN),
ILEUM (IL), JEJUNUM (JE), MAND SALIVARY GL (SG), MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, ABDOM (MA),
MUSCLE, SKELETAL (SM), NERVE, SCIATIC (SN), PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), PROSTATE (PR),
RECTUM (RE), SALIVARY, OTHER (OS), SKIN (SK), STOMACH, NONGL (SU), TESTIS (TE), THYROID (TY), TONGUE (TO),
TRACHEA (TR), URINARY BLADDER (UB)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 726

STUDY NUMBER: 483287

ANIMAL NUMBER: A37574 SEX: MALE DOSE GROUP: 7 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/11/91 STUDY DAY OF DEATH: 95 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 24.6 GRAMS
DATE AND TIME OF NECROPSY: 11/11/91 13:44 PROSECTOR: SONNY DIKES RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.10	.411 %	.211	WEIGHT TAKEN
LUNG (LU)	.16	.630 %	.324	WEIGHT TAKEN
PROSTATE (PR)	.046	.1874 %	.0964	WEIGHT TAKEN
BRAIN W/STEM (BR)	.48	1.945 %	1.000	WEIGHT TAKEN
HEART (HT)	.13	.512 %	.263	WEIGHT TAKEN
SPLEEN (SP)	.06	.225 %	.116	WEIGHT TAKEN
KIDNEY (KD)	.40	1.640 %	.843	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	3.35	13.626 %	7.007	WEIGHT TAKEN
TESTIS (TE)	.14	.583 %	.300	WEIGHT TAKEN
EPIDIDYMIS (EP)	.08	.325 %	.167	WEIGHT TAKEN
ADRENAL (AD)	.011	.0451 %	.0232	WEIGHT TAKEN
THYMUS (TH)	.02	.083 %	.043	WEIGHT TAKEN

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE
OBSERVATIONS

PATHOLOGY OBSERVATIONS
NECROPSY

LIVER (LI) :
-PALE AREA; ALL LOBES, FEW, TAN,
PINPOINT TO 3 X 1 MM
-ENLARGED, MODERATE; ALL LOBES
-DARK; ALL LOBES, DARK BROWN

HISTOPATHOLOGY

ADRENAL, CORTEX (AC) :
-HYPERTROPHY, ZONA FASCICULATA,-SLIGHT
CECUM (CE) :
-HYPERPLASIA, LYMPHOID,-PRESENT
EPIDIDYMIS (EP) :
-LUMEN, DEBRIS, CELLULAR,-PRESENT
GALLBLADDER (GB) :
-INFLAMMATION, CHRONIC,-MINIMAL
KIDNEY (KD) :
-HYPERPLASIA, LYMPHOID,-MINIMAL
LACRIMAL GL, EX (EO) :
>TISSUE MISSING
LIVER (LI) :
-HEPATOCYTE, HYPERTROPHY,
CENTROLOBULAR,-MODERATELY SEVERE
-VACUOLIZATION,-SLIGHT
-PIGMENT, BILE,-SLIGHT

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 727

STUDY NUMBER: 483287

ANIMAL NUMBER: A37574 SEX: MALE DOSE GROUP: 7 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/11/91 STUDY DAY OF DEATH: 95 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 24.6 GRAMS
DATE AND TIME OF NECROPSY: 11/11/91 13:44 PROSECTOR: SONNY DIKES RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

CLINICAL OBSERVATIONS

P A T H O L O G Y O B S E R V A T I O N S (CONTINUED)
NECROPSY

HISTOPATHOLOGY

LIVER (LI) :
-KUPFFER CELL/MACROPHAGE, PIGMENT, -
SLIGHT
-HEPATOCYTE, PIGMENT, -SLIGHT
-NECROSIS, INDIVIDUAL CELL, -SLIGHT
-BILE DUCT, INFLAMMATION, CHRONIC, -
SLIGHT
-MINERALIZATION, -MINIMAL
LN, MANDIBULAR (MN) :
-MACROPHAGES, PIGMENTED, -MINIMAL
LN, MESENTERIC (MS) :
-MACROPHAGES, PIGMENTED, -MINIMAL
LN, OTHER (LN) :
>UNREMARKABLE
>NOTE:>SUBCUTANEOUS.
PARATHYROID (PT) :
-UNILATERALLY EXAMINED, -PRESENT
RECTUM (RE) :
-HYPERPLASIA, LYMPHOID, -PRESENT
SPLEEN (SP) :
-EXTRAMEDULLARY HEMATOPOIESIS,
INCREASED, -MINIMAL
STOMACH, GL (ST) :
-HYPERPLASIA, CYSTIC, -MINIMAL
-INFLAMMATION, CHRONIC, -MINIMAL

^COLLECTED/TAKEN (XW) :
-LIVER SECTIONS, IN METHANOL

^DEATH COMMENT (DC) :
-SCHEDULED SACRIFICE, -PRESENT

APPENDIX 13B

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 728

STUDY NUMBER: 483287

ANIMAL NUMBER: A37574 SEX: MALE DOSE GROUP: 7 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/11/91 STUDY DAY OF DEATH: 95 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 24.6 GRAMS
DATE AND TIME OF NECROPSY: 11/11/91 13:44 PROSECTOR: SONNY DIKES RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), EPIDIDYMIS (EP), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE),
KIDNEY (KD), LACRIMAL GL, EX (EO), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU), MAND SALIVARY GL (SG),
MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON), NERVE, SCIATIC (SN),
PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), PROSTATE (PR), RECTUM (RE), SKIN (SK), SKIN, OTHER (SS),
SPLEEN (SP), STOMACH, GL (ST), STOMACH, NONGL (SU), TESTIS (TE), THYMUS (TH), THYROID (TY), TONGUE (TO),
TRACHEA (TR), URINARY BLADDER (UB)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:

ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, STERNUM (SB), BRAIN W/STEM (BR), COLON (CO),
CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC), DUODENUM (DU), ESOPHAGUS (ES), EYE (EY),
HARDERIAN GLAND (HG), HEART (HT), HEMATO NEOPLASIA (HN), ILEUM (IL), JEJUNUM (JE), LUNG (LU), MAND SALIVARY GL (SG),
MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, ABDOM (MA), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON),
NERVE, SCIATIC (SN), PANCREAS (PA), PITUITARY (PI), PROSTATE (PR), SALIVARY, OTHER (OS), SKIN (SK),
STOMACH, NONGL (SU), TESTIS (TE), THYMUS (TH), THYROID (TY), TONGUE (TO), TRACHEA (TR), URINARY BLADDER (UB)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 729

STUDY NUMBER: 483287

ANIMAL NUMBER: A37575 SEX: MALE DOSE GROUP: 7 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/12/91 STUDY DAY OF DEATH: 96 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 28.4 GRAMS
DATE AND TIME OF NECROPSY: 11/12/91 9:04 PROSECTOR: DOUGLAS HERNDON RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: NOT AVAILABLE PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.17	.584 %	.325	WEIGHT TAKEN
LUNG (LU)	.19	.663 %	.369	WEIGHT TAKEN
PROSTATE (PR)	.059	.2070 %	.1152	WEIGHT TAKEN
BRAIN W/STEM (BR)	.51	1.796 %	1.000	WEIGHT TAKEN
HEART (HT)	.15	.515 %	.287	WEIGHT TAKEN
SPLEEN (SP)	.14	.496 %	.276	WEIGHT TAKEN
KIDNEY (KD)	.48	1.673 %	.931	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	3.42	12.029 %	6.696	WEIGHT TAKEN
TESTIS (TE)	.27	.953 %	.531	WEIGHT TAKEN
EPIDIDYMIS (EP)	.11	.392 %	.218	WEIGHT TAKEN
ADRENAL (AD)	.013	.0465 %	.0259	WEIGHT TAKEN
THYMUS (TH)	.02	.060 %	.033	WEIGHT TAKEN

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE
OBSERVATIONS

PATHOLOGY OBSERVATIONS
NECROPSY

LIVER (LI) :
-ENLARGED, SEVERE; ALL LOBES
-DARK; ALL LOBES, DARK BROWN

HISTOPATHOLOGY

ADRENAL, CORTEX (AC) :
-HYPERTROPHY, ZONA FASCICULATA, -MINIMAL
EPIDIDYMIS (EP) :
-LUMEN, DEBRIS, CELLULAR, -PRESENT
HEART (HT) :
-INFLAMMATION, CHRONIC, -MINIMAL
ILEUM (IL) :
-AMYLOIDOSIS, -MODERATE
KIDNEY (KD) :
-INFLAMMATION, CHRONIC, -MINIMAL
-TUBULE, REGENERATION, -MINIMAL
LIVER (LI) :
-HEPATOCYTE, HYPERTROPHY,
CENTROLOBULAR, -MODERATE
-VACUOLIZATION, -MINIMAL
-PIGMENT, BILE, -MINIMAL
-KUPFFER CELL/MACROPHAGE, PIGMENT, -
MINIMAL

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 730

STUDY NUMBER: 483287

ANIMAL NUMBER: A37575 SEX: MALE DOSE GROUP: 7 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/12/91 STUDY DAY OF DEATH: 96 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 28.4 GRAMS
DATE AND TIME OF NECROPSY: 11/12/91 9:04 PROSECTOR: DOUGLAS HERNDON RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: NOT AVAILABLE PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KACYARE

CLINICAL OBSERVATIONS P A T H O L O G Y O B S E R V A T I O N S (CONTINUED)
NECROPSY

HISTOPATHOLOGY

LIVER (LI) :
-HEPATOCYTE, PIGMENT, -MINIMAL
-NECROSIS, INDIVIDUAL CELL, -MINIMAL
-BILE DUCT, INFLAMMATION, CHRONIC, -
MINIMAL
LN, MANDIBULAR (MN) :
-MACROPHAGES, PIGMENTED, -MINIMAL
LN, MESENTERIC (MS) :
-MACROPHAGES, PIGMENTED, -MINIMAL
-INFLAMMATION, GRANULOMATOUS, -SLIGHT,
FOCAL
LUNG (LU) :
-PERIBRONCHIAL/PERIVASCULAR,
INFILTRATION, LYMPHOID, -MINIMAL
NERVE, OPTIC (ON) :
>TISSUE MISSING
SPLEEN (SP) :
-EXTRAMEDULLARY HEMATOPOIESIS,
INCREASED, -MODERATELY SEVERE
-PIGMENT, -MINIMAL
-AMYLOIDOSIS, -MINIMAL
STOMACH, GL (ST) :
-HYPERPLASIA, -SLIGHT

^COLLECTED/TAKEN (XW) :
-LIVER SECTIONS, IN METHANOL

^DEATH COMMENT (DC) :
-SCHEDULED SACRIFICE, -PRESENT

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 731

STUDY NUMBER: 483287

ANIMAL NUMBER: A37575 SEX: MALE DOSE GROUP: 7 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/12/91 STUDY DAY OF DEATH: 96 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 28.4 GRAMS
DATE AND TIME OF NECROPSY: 11/12/91 9:04 PROSECTOR: DOUGLAS HERNDON RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: NOT AVAILABLE PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), EPIDIDYMIS (EP), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE),
KIDNEY (KD), LACRIMAL GL, EX (EO), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU), MAND SALIVARY GL (SG),
MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON), NERVE, SCIATIC (SN),
PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), PROSTATE (PR), RECTUM (RE), SKIN (SK), SKIN, OTHER (SS),
SPLEEN (SP), STOMACH, GL (ST), STOMACH, NONGL (SU), TESTIS (TE), THYMUS (TH), THYROID (TY), TONGUE (TO),
TRACHEA (TR), URINARY BLADDER (UB)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:

ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, STERNUM (SB), BRAIN W/STEM (BR), CECUM (CE),
COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC), DUODENUM (DU), ESOPHAGUS (ES), EYE (EY),
GALLBLADDER (GB), HARDERIAN GLAND (HG), HEMATO NEOPLASIA (HN), JEJUNUM (JE), LACRIMAL GL, EX (EO),
MAND SALIVARY GL (SG), MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, ABDOM (MA), MUSCLE, SKELETAL (SM),
NERVE, SCIATIC (SN), PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), PROSTATE (PR), RECTUM (RE), SALIVARY, OTHER (OS),
SKIN (SK), STOMACH, NONGL (SU), TESTIS (TE), THYMUS (TH), THYROID (TY), TONGUE (TO), TRACHEA (TR),
URINARY BLADDER (UB)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 732

STUDY NUMBER: 483287

ANIMAL NUMBER: A37576 SEX: MALE DOSE GROUP: 7 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/12/91 STUDY DAY OF DEATH: 96 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 30.3 GRAMS
DATE AND TIME OF NECROPSY: 11/12/91 9:56 PROSECTOR: FRED AGEY RECORDER: FRED AGEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.11	.379 %	.231	WEIGHT TAKEN
LUNG (LU)	.20	.662 %	.403	WEIGHT TAKEN
PROSTATE (PR)	.034	.1129 %	.0687	WEIGHT TAKEN
BRAIN W/STEM (BR)	.50	1.642 %	1.000	WEIGHT TAKEN
HEART (HT)	.16	.520 %	.317	WEIGHT TAKEN
SPLEEN (SP)	.08	.270 %	.165	WEIGHT TAKEN
KIDNEY (KD)	.55	1.818 %	1.107	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	4.75	15.686 %	9.552	WEIGHT TAKEN
TESTIS (TE)	.29	.953 %	.580	WEIGHT TAKEN
EPIDIDYMIS (EP)	.12	.394 %	.240	WEIGHT TAKEN
ADRENAL (AD)	.011	.0347 %	.0211	WEIGHT TAKEN
THYMUS (TH)	.02	.073 %	.045	WEIGHT TAKEN

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE
OBSERVATIONS

PATHOLOGY OBSERVATIONS
NECROPSY

LIVER (LI) :
-PALE AREA; ALL LOBES, SEVERAL, TAN,
PINPOINT TO 3 X 2 MM
-ENLARGED, SEVERE; ALL LOBES
-DARK; ALL LOBES, DARK BROWN

HISTOPATHOLOGY

ADRENAL, CORTEX (AC) :
-HYPERTROPHY, ZONA FASCICULATA,-MINIMAL
HEART (HT) :
-INFLAMMATION, CHRONIC,-MINIMAL
KIDNEY (KD) :
-INFLAMMATION, CHRONIC,-MINIMAL
-TUBULE, REGENERATION,-SLIGHT
-HYPERPLASIA, LYMPHOID,-MINIMAL
LIVER (LI) :
-HEPATOCYTE, HYPERTROPHY,
CENTROLOBULAR,-MODERATELY SEVERE
-VACUOLIZATION,-MINIMAL
-PIGMENT, BILE,-MINIMAL
-KUPFFER CELL/MACROPHAGE, PIGMENT,-
SLIGHT
-HEPATOCYTE, PIGMENT,-SLIGHT
-NECROSIS, INDIVIDUAL CELL,-MINIMAL

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 733

STUDY NUMBER: 483287

ANIMAL NUMBER: A37576 SEX: MALE DOSE GROUP: 7 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/12/91 STUDY DAY OF DEATH: 96 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 30.3 GRAMS
DATE AND TIME OF NECROPSY: 11/12/91 9:56 PROSECTOR: FRED AGEY RECORDER: FRED AGEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

CLINICAL OBSERVATIONS

P A T H O L O G Y O B S E R V A T I O N S (CONTINUED)
NECROPSY

HISTOPATHOLOGY

LIVER (LI) :
-INFLAMMATION, CHRONIC/CHRONIC ACTIVE, -
MINIMAL
LN, MANDIBULAR (MN) :
-MACROPHAGES, PIGMENTED, -MINIMAL
LN, MESENTERIC (MS) :
-HYPERPLASIA, LYMPHOID, -MINIMAL
LUNG (LU) :
-PERIBRONCHIAL/PERIVASCULAR,
INFILTRATION, LYMPHOID, -MINIMAL
NERVE, OPTIC (ON) :
-UNILATERALLY EXAMINED, -PRESENT
PARATHYROID (PT) :
-UNILATERALLY EXAMINED, -PRESENT
RECTUM (RE) :
-HYPERPLASIA, LYMPHOID, -PRESENT
SPLEEN (SP) :
-EXTRAMEDULLARY HEMATOPOIESIS,
INCREASED, -MODERATE
STOMACH, GL (ST) :
-HYPERPLASIA, CYSTIC, -MODERATE
THYMUS (TH) :
-CYST, -PRESENT

^COLLECTED/TAKEN (XW) :
-LIVER SECTIONS, IN METHANOL

^DEATH COMMENT (DC) :
-SCHEDULED SACRIFICE, -PRESENT

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 734

STUDY NUMBER: 483287

ANIMAL NUMBER: A37576 SEX: MALE DOSE GROUP: 7 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/12/91 STUDY DAY OF DEATH: 96 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 30.3 GRAMS
DATE AND TIME OF NECROPSY: 11/12/91 9:56 PROSECTOR: FRED AGEY RECORDER: FRED AGEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), EPIDIDYMIS (EP), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE),
KIDNEY (KD), LACRIMAL GL, EX (EO), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU), MAND SALIVARY GL (SG),
MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON), NERVE, SCIATIC (SN),
PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), PROSTATE (PR), RECTUM (RE), SKIN (SK), SKIN, OTHER (SS),
SPLEEN (SP), STOMACH, GL (ST), STOMACH, NONGL (SU), TESTIS (TE), THYMUS (TH), THYROID (TY), TONGUE (TO),
TRACHEA (TR), URINARY BLADDER (UB)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:

ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, STERNUM (SB), BRAIN W/STEM (BR), CECUM (CE),
COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC), DUODENUM (DU), EPIDIDYMIS (EP),
ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HARDERIAN GLAND (HG), HEMATO NEOPLASIA (HN), ILEUM (IL), JEJUNUM (JE),
LACRIMAL GL, EX (EO), MAND SALIVARY GL (SG), MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, ABDOM (MA),
MUSCLE, SKELETAL (SM), NERVE, SCIATIC (SN), PANCREAS (PA), PITUITARY (PI), PROSTATE (PR), SALIVARY, OTHER (OS),
SKIN (SK), STOMACH, NONGL (SU), TESTIS (TE), THYROID (TY), TONGUE (TO), TRACHEA (TR), URINARY BLADDER (UB)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 735

STUDY NUMBER: 483287

ANIMAL NUMBER: A37578 SEX: MALE DOSE GROUP: 7 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/12/91 STUDY DAY OF DEATH: 96 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 27.8 GRAMS
DATE AND TIME OF NECROPSY: 11/12/91 10:59 PROSECTOR: SCOTT BELL RECORDER: SCOTT BELL
POST-PIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.21	.764 %	.421	WEIGHT TAKEN
LUNG (LU)	.23	.836 %	.461	WEIGHT TAKEN
PROSTATE (PR)	.049	.1770 %	.0975	WEIGHT TAKEN
BRAIN W/STEM (BR)	.50	1.814 %	1.000	WEIGHT TAKEN
HEART (HT)	.14	.499 %	.275	WEIGHT TAKEN
SPLEEN (SP)	.08	.276 %	.152	WEIGHT TAKEN
KIDNEY (KD)	.44	1.585 %	.874	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	3.63	13.053 %	7.194	WEIGHT TAKEN
TESTIS (TE)	.24	.849 %	.468	WEIGHT TAKEN
EPIDIDYMIS (EP)	.10	.367 %	.202	WEIGHT TAKEN
ADRENAL (AD)	.013	.0475 %	.0262	WEIGHT TAKEN
THYMUS (TH)	.02	.062 %	.034	WEIGHT TAKEN

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE
OBSERVATIONS

PATHOLOGY OBSERVATIONS
NECROPSY

HISTOPATHOLOGY

ADRENAL, CORTEX (AC) :
-HYPERTROPHY, ZONA FASCICULATA, -MINIMAL
CECUM (CE) :
-HYPERPLASIA, LYMPHOID, -PRESENT
EPIDIDYMIS (EP) :
-LUMEN, DEBRIS, CELLULAR, -PRESENT
EYE (EY) :
-UNILATERALLY EXAMINED, -PRESENT
KIDNEY (KD) :
-INFLAMMATION, CHRONIC, -MINIMAL
-TUBULE, REGENERATION, -MINIMAL
-HYPERPLASIA, LYMPHOID, -MINIMAL
LI, EXTRAHEPATIC (LI1) :
-PIGMENT, PAS POSITIVE, -MODERATELY
SEVERE
-PIGMENT, IRON POSITIVE, -MODERATE
-PIGMENT, LIPOFUSCIN POSITIVE, -MODERATE

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 736

STUDY NUMBER: 483287

ANIMAL NUMBER: A37578 SEX: MALE DOSE GROUP: 7 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/12/91 STUDY DAY OF DEATH: 96 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 27.8 GRAMS
DATE AND TIME OF NECROPSY: 11/12/91 10:59 PROSECTOR: SCOTT BELL RECORDER: SCOTT BELL
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

CLINICAL OBSERVATIONS

P A T H O L O G Y O B S E R V A T I O N S (CONTINUED)
NECROPSY

HISTOPATHOLOGY

LIVER (LI) :
-PALE AREA; ALL LOBES, FEW, TAN,
PINPOINT TO 5 X 4 MM
-ENLARGED, SEVERE; ALL LOBES
-DARK; ALL LOBES, DARK BROWN

STOMACH, GL (ST) :
-DARK AREA; MUCOSA, FEW, BLACK,
PINPOINT
^COLLECTED/TAKEN (XW) :
-LIVER SECTIONS, IN METHANOL

LI, INTRAHEPATIC (LIO) :
-PIGMENT, PAS POSITIVE, -SEVERE
-PIGMENT, IRON POSITIVE, -MODERATELY
SEVERE
-PIGMENT, BILE POSITIVE, -MINIMAL
-PIGMENT, LIPOFUSCIN POSITIVE, -MODERATE
LIVER (LI) :
-HEPATOCTE, HYPERTROPHY,
CENTROLOBULAR, -MODERATELY SEVERE
-VACUOLIZATION, -MINIMAL
-PIGMENT, BILE, -MINIMAL
-KUPFFER CELL/MACROPHAGE, PIGMENT, -
MODERATE
-HEPATOCTE, PIGMENT, -MODERATE
-NECROSIS, -SLIGHT, MULTI-FOCAL
-NECROSIS, INDIVIDUAL CELL, -MINIMAL
-INFLAMMATION, CHRONIC/CHRONIC ACTIVE, -
MODERATE
LUNG (LU) :
-PERIBRONCHIAL/PERIVASCULAR,
INFILTRATION, LYMPHOID, -MINIMAL
NERVE, OPTIC (ON) :
-UNILATERALLY EXAMINED, -PRESENT
PARATHYROID (PT) :
-UNILATERALLY EXAMINED, -PRESENT
SPLEEN (SP) :
-EXTRAMEDULLARY HEMATOPOIESIS,
INCREASED, -MODERATE
STOMACH, GL (ST) :
-INFLAMMATION, CHRONIC, -MINIMAL

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 737

STUDY NUMBER: 483287

ANIMAL NUMBER: A37578 SEX: MALE DOSE GROUP: 7 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/12/91 STUDY DAY OF DEATH: 96 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 27.8 GRAMS
DATE AND TIME OF NECROPSY: 11/12/91 10:59 PROSECTOR: SCOTT BELL RECORDER: SCOTT BELL
POST-FIX WEIGHER: JANE FARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

CLINICAL OBSERVATIONS

P A T H O L O G Y O B S E R V A T I O N S (CONTINUED)
NECROPSY

HISTOPATHOLOGY

^DEATH COMMENT (DC) :
-SCHEDULED SACRIFICE, -PRESENT

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), EPIDIDYMIS (EP), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE),
KIDNEY (KD), LACRIMAL GL, EX (EO), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU), MAND SALIVARY GL (SG),
MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON), NERVE, SCIATIC (SN),
PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), PROSTATE (PR), RECTUM (RE), SKIN (SK), SKIN, OTHER (SS),
SPLEEN (SP), STOMACH, NONGL (SU), TESTIS (TE), THYMUS (TH), THYROID (TY), TONGUE (TO), TRACHEA (TR),
URINARY BLADDER (UB)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:

ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, STERNUM (SB), BRAIN W/STEM (BR), COLON (CO),
CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC), DUODENUM (DU), ESOPHAGUS (ES), GALLBLADDER (GB),
HARDERIAN GLAND (HG), HEART (HT), HEMATO NEOPLASIA (HN), ILEUM (IL), JEJUNUM (JE), LACRIMAL GL, EX (EO),
LN, MANDIBULAR (MN), LN, MESENTERIC (MS), MAND SALIVARY GL (SG), MARROW, FEMUR (FM), MARROW, STERNUM (SE),
MUSCLE, ABDOM (MA), MUSCLE, SKELETAL (SM), NERVE, SCIATIC (SN), PANCREAS (PA), PITUITARY (PI), PROSTATE (PR),
RECTUM (RE), SALIVARY, OTHER (OS), SKIN (SK), STOMACH, NONGL (SU), TESTIS (TE), THYMUS (TH), THYROID (TY),
TONGUE (TO), TRACHEA (TR), URINARY BLADDER (UB)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 738

STUDY NUMBER: 483287

ANIMAL NUMBER: A37580 SEX: MALE DOSE GROUP: 7 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/12/91 STUDY DAY OF DEATH: 96 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 26.3 GRAMS
DATE AND TIME OF NECROPSY: 11/12/91 13:15 PROSECTOR: SONNY DIKES RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.15	.587 %	.316	WEIGHT TAKEN
LUNG (LU)	.16	.591 %	.318	WEIGHT TAKEN
PROSTATE (PR)	.044	.1677 %	.0903	WEIGHT TAKEN
BRAIN W/STEM (BR)	.49	1.858 %	1.000	WEIGHT TAKEN
HEART (HT)	.14	.538 %	.289	WEIGHT TAKEN
SPLEEN (SP)	.07	.249 %	.134	WEIGHT TAKEN
KIDNEY (KD)	.39	1.489 %	.801	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	2.86	10.890 %	5.862	WEIGHT TAKEN
TESTIS (TE)	.24	.895 %	.482	WEIGHT TAKEN
EPIDIDYMIS (EP)	.11	.436 %	.235	WEIGHT TAKEN
ADRENAL (AD)	.010	.0388 %	.0209	WEIGHT TAKEN
THYMUS (TH)	.03	.106 %	.057	WEIGHT TAKEN

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE
OBSERVATIONS

PATHOLOGY OBSERVATIONS
NECROPSY

LIVER (LI) :
-PALE AREA; ALL LOBES, SEVERAL, TAN,
PINPOINT TO 2 X 2 MM
-ENLARGED, MODERATE; ALL LOBES
-DARK; ALL LOBES, DARK BROWN

HISTOPATHOLOGY

CECUM (CE) :
-HYPERPLASIA, LYMPHOID, -PRESENT
EPIDIDYMIS (EP) :
-LUMEN, DEBRIS, CELLULAR, -PRESENT
ILEUM (IL) :
-AMYLOIDOSIS, -MODERATE
JEJUNUM (JE) :
-AMYLOIDOSIS, -MODERATE
KIDNEY (KD) :
-INFLAMMATION, CHRONIC, -MINIMAL
-TUBULE, REGENERATION, -MINIMAL
-PIGMENT, -MINIMAL
-CYST, -PRESENT
LIVER (LI) :
-HEPATOCYTE, HYPERTROPHY,
CENTROLOBULAR, -MODERATE
-VACUOLIZATION, -MINIMAL
-PIGMENT, BILE, -MINIMAL

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

PRINTED: 21-JAN-93
PAGE: 739

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

STUDY NUMBER: 483287

ANIMAL NUMBER: A37580 SEX: MALE DOSE GROUP: 7 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/12/91 STUDY DAY OF DEATH: 96 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 26.3 GRAMS
DATE AND TIME OF NECROPSY: 11/12/91 13:15 PROSECTOR: SONNY DIKES RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

CLINICAL OBSERVATIONS

P A T H O L O G Y O B S E R V A T I O N S (CONTINUED)
NECROPSY

HISTOPATHOLOGY

LIVER (LI) :
-KUPFFER CELL/MACROPHAGE, PIGMENT, -
SLIGHT
-HEPATOCYTE, PIGMENT, -SLIGHT
-NECROSIS, INDIVIDUAL CELL, -MINIMAL
-INFLAMMATION, CHRONIC/CHRONIC ACTIVE, -
SLIGHT
LN, MANDIBULAR (MN) :
-AMYLOIDOSIS, -MINIMAL
LN, MESENTERIC (MS) :
-AMYLOIDOSIS, -MINIMAL
NERVE, OPTIC (ON) :
-UNILATERALLY EXAMINED, -PRESENT
PANCREAS (PA) :
-AMYLOIDOSIS, -MINIMAL
PARATHYROID (PT) :
-SECTION EXAMINED; TISSUE NOT PRESENT
RECTUM (RE) :
-HYPERPLASIA, LYMPHOID, -PRESENT
-AMYLOIDOSIS, -MODERATE
SPLEEN (SP) :
-EXTRAMEDULLARY HEMATOPOIESIS,
INCREASED, -MODERATELY SEVERE
-PIGMENT, -MINIMAL
STOMACH, GL (ST) :
-HYPERPLASIA, CYSTIC, -MINIMAL
-INFLAMMATION, CHRONIC, -MINIMAL

^COLLECTED/TAKEN (XW) :
-LIVER SECTIONS, IN METHANOL

^DEATH COMMENT (DC) :
-SCHEDULED SACRIFICE, -PRESENT

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 740

STUDY NUMBER: 483287

ANIMAL NUMBER: A37580 SEX: MALE DOSE GROUP: 7 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/12/91 STUDY DAY OF DEATH: 96 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 26.3 GRAMS
DATE AND TIME OF NECROPSY: 11/12/91 13:15 PROSECTOR: SONNY DIKES RECORDER: JOHN CROWLEY
POST-FIX WEAHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEAHER: RICHARD KAGYARE

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), EPIDIDYMIS (EP), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE),
KIDNEY (KD), LACRIMAL GL, EX (EO), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU), MAND SALIVARY GL (SG),
MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON), NERVE, SCIATIC (SN),
PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), PROSTATE (PR), RECTUM (RE), SKIN (SK), SKIN, OTHER (SS),
SPLEEN (SP), STOMACH, GL (ST), STOMACH, NONGL (SU), TESTIS (TE), THYMUS (TH), THYROID (TY), TONGUE (TO),
TRACHEA (TR), URINARY BLADDER (UB)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, STERNUM (SB),
BRAIN W/STEM (BR), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC), DUODENUM (DU),
ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HARDERIAN GLAND (HG), HEART (HT), HEMATO NEOPLASIA (HN),
LACRIMAL GL, EX (EO), LUNG (LU), MAND SALIVARY GL (SG), MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, ABDOM (MA),
MUSCLE, SKELETAL (SM), NERVE, SCIATIC (SN), PITUITARY (PI), PROSTATE (PR), SALIVARY, OTHER (OS), SKIN (SK),
STOMACH, NONGL (SU), TESTIS (TE), THYMUS (TH), THYROID (TY), TONGUE (TO), TRACHEA (TR), URINARY BLADDER (UB)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 741

STUDY NUMBER: 483287

ANIMAL NUMBER: A37581 SEX: MALE DOSE GROUP: 7 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/13/91 STUDY DAY OF DEATH: 97 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 23.0 GRAMS
DATE AND TIME OF NECROPSY: 11/13/91 8:42 PROSECTOR: LINDA RUMBLE RECORDER: LINDA RUMBLE
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.19	.830 %	.414	WEIGHT TAKEN
LUNG (LU)	.15	.667 %	.333	WEIGHT TAKEN
PROSTATE (PR)	.048	.2083 %	.1039	WEIGHT TAKEN
BRAIN W/STEM (BR)	.46	2.004 %	1.000	WEIGHT TAKEN
HEART (HT)	.14	.590 %	.294	WEIGHT TAKEN
SPLEEN (SP)	.05	.223 %	.111	WEIGHT TAKEN
KIDNEY (KD)	.39	1.683 %	.840	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	3.18	13.811 %	6.892	WEIGHT TAKEN
TESTIS (TE)	.17	.720 %	.359	WEIGHT TAKEN
EPIDIDYMIS (EP)	.09	.403 %	.201	WEIGHT TAKEN
ADRENAL (AD)	.015	.0665 %	.0332	WEIGHT TAKEN
THYMUS (TH)	.02	.091 %	.045	WEIGHT TAKEN

CLINICAL OBSERVATIONS	PATHOLOGY OBSERVATIONS NECROPSY	HISTOPATHOLOGY
-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS	LIVER (LI) : -ENLARGED, MODERATE; ALL LOBES -DARK; ALL LOBES, DARK BROWN	ADRENAL, CORTEX (AC) : -HYPERTROPHY, ZONA FASCICULATA,-MINIMAL EPIDIDYMIS (EP) : -LUMEN, DEBRIS, CELLULAR,-PRESENT JEJUNUM (JE) : -HYPERPLASIA, LYMPHOID,-PRESENT KIDNEY (KD) : -INFLAMMATION, CHRONIC,-MINIMAL -HYPERPLASIA, LYMPHOID,-MINIMAL LIVER (LI) : -HEPATOCYTE, HYPERTROPHY, CENTROLOBULAR,-MODERATELY SEVERE -VACUOLIZATION,-MINIMAL -PIGMENT, BILE,-MODERATE -KUPFFER CELL/MACROPHAGE, PIGMENT,- SLIGHT -HEPATOCYTE, PIGMENT,-SLIGHT -NECROSIS, INDIVIDUAL CELL,-SLIGHT

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 742

STUDY NUMBER: 483287

ANIMAL NUMBER: A37581 SEX: MALE DOSE GROUP: 7 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/13/91 STUDY DAY OF DEATH: 97 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 23.0 GRAMS
DATE AND TIME OF NECROPSY: 11/13/91 8:42 PROSECTOR: LINDA RUMBLE RECORDER: LINDA RUMBLE
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

CLINICAL OBSERVATIONS	P A T H O L O G Y O B S E R V A T I O N S (CONTINUED)	HISTOPATHOLOGY
	NECROPSY	
		LIVER (LI) : -BILE DUCT, INFLAMMATION, CHRONIC,- MINIMAL LN, MANDIBULAR (MN) : -MACROPHAGES, PIGMENTED,-MINIMAL LN, MESENTERIC (MS) : -MACROPHAGES, PIGMENTED,-MINIMAL LUNG (LU) : -PERIBRONCHIAL/PERIVASCULAR, INFILTRATION, LYMPHOID,-MINIMAL PARATHYROID (PT) : -UNILATERALLY EXAMINED,-PRESENT SPLEEN (SP) : -EXTRAMEDULLARY HEMATOPOIESIS, INCREASED,-MINIMAL -PIGMENT,-MINIMAL STOMACH, GL (ST) : -HYPERPLASIA,-SLIGHT -INFLAMMATION, CHRONIC,-MINIMAL ^DEATH COMMENT (DC) : -SCHEDULED SACRIFICE,-PRESENT
	STOMACH, GL (ST) : -DARK AREA; MUCOSA, SEVERAL, BROWN, PINPOINT TO 1 X 1 MM ^COLLECTED/TAKEN (XW) : -LIVER SECTIONS, IN METHANOL	

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 743

STUDY NUMBER: 483287

ANIMAL NUMBER: A37581 SEX: MALE DOSE GROUP: 7 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/13/91 STUDY DAY OF DEATH: 97 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 23.0 GRAMS
DATE AND TIME OF NECROPSY: 11/13/91 8:42 PROSECTOR: LINDA RUMBLE RECORDER: LINDA RUMBLE
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), EPIDIDYMIS (EP), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE),
KIDNEY (KD), LACRIMAL GL, EX (EO), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU), MAND SALIVARY GL (SG),
MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON), NERVE, SCIATIC (SN),
PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), PROSTATE (PR), RECTUM (RE), SKIN (SK), SKIN, OTHER (SS),
SPLEEN (SP), STOMACH, NONGL (SU), TESTIS (TE), THYMUS (TH), THYROID (TY), TONGUE (TO), TRACHEA (TR),
URINARY BLADDER (UB)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:

ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, STERNUM (SB), BRAIN W/STEM (BR), CECUM (CE),
COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC), DUODENUM (DU), ESOPHAGUS (ES), EYE (EY),
GALLBLADDER (GB), HARDERIAN GLAND (HG), HEART (HT), HEMATO NEOPLASIA (HN), ILEUM (IL), LACRIMAL GL, EX (EO),
MAND SALIVARY GL (SG), MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, ABDOM (MA), MUSCLE, SKELETAL (SM),
NERVE, OPTIC (ON), NERVE, SCIATIC (SN), PANCREAS (PA), PITUITARY (PI), PROSTATE (PR), RECTUM (RE),
SALIVARY, OTHER (OS), SKIN (SK), STOMACH, NONGL (SU), TESTIS (TE), THYMUS (TH), THYROID (TY), TONGUE (TO),
TRACHEA (TR), URINARY BLADDER (UB)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 744

STUDY NUMBER: 483287

ANIMAL NUMBER: A37582 SEX: MALE DOSE GROUP: 7 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/13/91 STUDY DAY OF DEATH: 97 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 26.9 GRAMS
DATE AND TIME OF NECROPSY: 11/13/91 9:40 PROSECTOR: FRED AGEY RECORDER: FRED AGEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.22	.818 %	.474	WEIGHT TAKEN
LUNG (LU)	.20	.735 %	.425	WEIGHT TAKEN
PROSTATE (PR)	.016	.0602 %	.0349	WEIGHT TAKEN
BRAIN W/STEM (BR)	.46	1.727 %	1.000	WEIGHT TAKEN
HEART (HT)	.18	.686 %	.397	WEIGHT TAKEN
SPLEEN (SP)	.10	.362 %	.209	WEIGHT TAKEN
KIDNEY (KD)	.48	1.784 %	1.033	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	3.51	13.033 %	7.546	WEIGHT TAKEN
TESTIS (TE)	.24	.875 %	.507	WEIGHT TAKEN
EPIDIDYMIS (EP)	.12	.464 %	.268	WEIGHT TAKEN
ADRENAL (AD)	.012	.0431 %	.0250	WEIGHT TAKEN
THYMUS (TH)	.03	.125 %	.073	WEIGHT TAKEN

CLINICAL OBSERVATIONS

PATHOLOGY OBSERVATIONS
NECROPSY

HISTOPATHOLOGY

LIVER (LI) :
-PALE AREA; ALL LOBES, SEVERAL, TAN,
PINPOINT TO 3 X 3 MM
-ENLARGED, SEVERE; ALL LOBES
-DARK; ALL LOBES, DARK BROWN

ADRENAL, CORTEX (AC) :
-HYPERTROPHY, ZONA FASCICULATA, -MINIMAL
EPIDIDYMIS (EP) :
-LUMEN, DEBRIS, CELLULAR, -PRESENT
EYE (EY) :
>UNREMARKABLE
>NOTE: >ONE CORNEA EXAMINED.
KIDNEY (KD) :
-INFLAMMATION, CHRONIC, -MINIMAL
-TUBULE, REGENERATION, -MINIMAL
-HYPERPLASIA, LYMPHOID, -MINIMAL
LACRIMAL GL, EX (EO) :
-INFLAMMATION, CHRONIC, -MINIMAL
LIVER (LI) :
-HEPATOCYTE, HYPERTROPHY,
CENTROLOBULAR, -MODERATELY SEVERE
-VACUOLIZATION, -MINIMAL
-PIGMENT, BILE, -MINIMAL

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 745

STUDY NUMBER: 483287

ANIMAL NUMBER: A37582 SEX: MALE DOSE GROUP: 7 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/13/91 STUDY DAY OF DEATH: 97 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 26.9 GRAMS
DATE AND TIME OF NECROPSY: 11/13/91 9:40 PROSECTOR: FRED AGEY RECORDER: FRED AGEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

CLINICAL OBSERVATIONS	P A T H O L O G Y O B S E R V A T I O N S (CONTINUED) NECROPSY	HISTOPATHOLOGY
		LIVER (LI) : -KUPFFER CELL/MACROPHAGE, PIGMENT, - SLIGHT -HEPATOCYTE, PIGMENT, -SLIGHT -NECROSIS, -MINIMAL, FOCAL -NECROSIS, INDIVIDUAL CELL, -MINIMAL -MINERALIZATION, -SLIGHT LN, MANDIBULAR (MN) : -MACROPHAGES, PIGMENTED, -MINIMAL LUNG (LU) : -PERIBRONCHIAL/PERIVASCULAR, INFILTRATION, LYMPHOID, -MINIMAL NERVE, OPTIC (ON) : -UNILATERALLY EXAMINED, -PRESENT PARATHYROID (PT) : -UNILATERALLY EXAMINED, -PRESENT PROSTATE (PR) : >TISSUE MISSING SPLEEN (SP) : -EXTRAMEDULLARY HEMATOPOIESIS, INCREASED, -MODERATE -PIGMENT, -MINIMAL STOMACH, GL (ST) : -HYPERPLASIA, CYSTIC, -MINIMAL -INFLAMMATION, CHRONIC, -MINIMAL TESTIS (TE) : -MINERALIZATION, -MINIMAL
	^COLLECTED/TAKEN (XW) : -LIVER SECTIONS, IN METHANOL	^DEATH COMMENT (DC) : -SCHEDULED SACRIFICE, -PRESENT

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 746

STUDY NUMBER: 483287

ANIMAL NUMBER: A37582 SEX: MALE DOSE GROUP: 7 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/13/91 STUDY DAY OF DEATH: 97 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 26.9 GRAMS
DATE AND TIME OF NECROPSY: 11/13/91 9:40 PROSECTOR: FRED AGEY RECORDER: FRED AGEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), EPIDIDYMIS (EP), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE),
KIDNEY (KD), LACRIMAL GL, EX (EO), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU), MAND SALIVARY GL (SG),
MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON), NERVE, SCIATIC (SN),
PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), PROSTATE (PR), RECTUM (RE), SKIN (SK), SKIN, OTHER (SS),
SPLEEN (SP), STOMACH, GL (ST), STOMACH, NONGL (SU), TESTIS (TE), THYMUS (TH), THYROID (TY), TONGUE (TO),
TRACHEA (TR), URINARY BLADDER (UB)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:

ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, STERNUM (SB), BRAIN W/STEM (BR), CECUM (CE),
COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC), DUODENUM (DU), ESOPHAGUS (ES),
GALLBLADDER (GB), HARDERIAN GLAND (HG), HEART (HT), HEMATO NEOPLASIA (HN), ILEUM (IL), JEJUNUM (JE),
LN, MESENTERIC (MS), MAND SALIVARY GL (SG), MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, ABDOM (MA),
MUSCLE, SKELETAL (SM), NERVE, SCIATIC (SN), PANCREAS (PA), PITUITARY (PI), RECTUM (RE), SALIVARY, OTHER (OS),
SKIN (SK), STOMACH, NONGL (SU), THYMUS (TH), THYROID (TY), TONGUE (TO), TRACHEA (TR), URINARY BLADDER (UB)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 747

STUDY NUMBER: 483287

ANIMAL NUMBER: A37583 SEX: MALE DOSE GROUP: 7 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/13/91 STUDY DAY OF DEATH: 97 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 30.4 GRAMS
DATE AND TIME OF NECROPSY: 11/13/91 11:01 PROSECTOR: DOUGLAS HERNDON RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.15	.500 %	.299	WEIGHT TAKEN
LUNG (LU)	.20	.672 %	.402	WEIGHT TAKEN
PROSTATE (PR)	.066	.2184 %	.1308	WEIGHT TAKEN
BRAIN W/STEM (BR)	.51	1.670 %	1.000	WEIGHT TAKEN
HEART (HT)	.15	.504 %	.302	WEIGHT TAKEN
SPLEEN (SP)	.06	.205 %	.123	WEIGHT TAKEN
KIDNEY (KD)	.50	1.640 %	.982	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	5.18	17.025 %	10.192	WEIGHT TAKEN
TESTIS (TE)	.26	.855 %	.512	WEIGHT TAKEN
EPIDIDYMIS (EP)	.11	.358 %	.214	WEIGHT TAKEN
ADRENAL (AD)	.017	.0553 %	.0331	WEIGHT TAKEN
THYMUS (TH)	.03	.090 %	.054	WEIGHT TAKEN

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE
OBSERVATIONS

PATHOLOGY OBSERVATIONS
NECROPSY

LIVER (LI) :
-PALE AREA; ALL LOBES, MULTIPLE, TAN,
PINPOINT TO 1 X 1 MM
-ENLARGED, SEVERE; ALL LOBES

HISTOPATHOLOGY

ADRENAL, CORTEX (AC) :
-HYPERTROPHY, ZONA FASCICULATA,-SLIGHT
CECUM (CE) :
-HYPERPLASIA, LYMPHOID,-PRESENT
EPIDIDYMIS (EP) :
-LUMEN, DEBRIS, CELLULAR,-PRESENT
EYE (EY) :
>UNREMARKABLE
>NOTE:>ONE CORNEA EXAMINED.
ILEUM (IL) :
-HYPERPLASIA, LYMPHOID,-PRESENT
KIDNEY (KD) :
-INFLAMMATION, CHRONIC,-MINIMAL
-TUBULE, REGENERATION,-MINIMAL
LIVER (LI) :
-HEPATOCYTE, HYPERTROPHY,
CENTROLOBULAR,-MODERATELY SEVERE
-VACUOLIZATION,-MINIMAL

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 748

STUDY NUMBER: 483287

ANIMAL NUMBER: A37583 SEX: MALE DOSE GROUP: 7 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/13/91 STUDY DAY OF DEATH: 97 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 30.4 GRAMS
DATE AND TIME OF NECROPSY: 11/13/91 11:01 PROSECTOR: DOUGLAS HERNDON RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

CLINICAL OBSERVATIONS

P A T H O L O G Y O B S E R V A T I O N S (CONTINUED)
NECROPSY

HISTOPATHOLOGY

LIVER (LI) :
-DARK; ALL LOBES, DARK BROWN

LIVER (LI) :
-PIGMENT, BILE, -SLIGHT
-KUPFFER CELL/MACROPHAGE, PIGMENT, -
MINIMAL
-HEPATOCYTE, PIGMENT, -SLIGHT
-NECROSIS, INDIVIDUAL CELL, -SLIGHT
-INFLAMMATION, CHRONIC/CHRONIC ACTIVE, -
SLIGHT
-BILE DUCT, INFLAMMATION, CHRONIC, -
MINIMAL
-MINERALIZATION, -MINIMAL
LN, MESENTERIC (MS) :
-HYPERPLASIA, LYMPHOID, -MINIMAL
MARROW, FEMUR (FM) :
-HYPERCELLULAR, -PRESENT
NERVE, OPTIC (ON) :
-UNILATERALLY EXAMINED, -PRESENT
SPLEEN (SP) :
-EXTRAMEDULLARY HEMATOPOIESIS,
INCREASED, -SLIGHT
THYROID (TY) :
-FOLLICLE, CYST, -PRESENT

^COLLECTED/TAKEN (XW) :
-LIVER SECTIONS, IN METHANOL

^DEATH COMMENT (DC) :
-SCHEDULED SACRIFICE, -PRESENT

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 749

STUDY NUMBER: 483287

ANIMAL NUMBER: A37583 SEX: MALE DOSE GROUP: 7 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/13/91 STUDY DAY OF DEATH: 97 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 30.4 GRAMS
DATE AND TIME OF NECROPSY: 11/13/91 11:01 PROSECTOR: DOUGLAS HERNDON RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), EPIDIDYMIS (EP), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE),
KIDNEY (KD), LACRIMAL GL, EX (EO), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU), MAND SALIVARY GL (SG),
MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON), NERVE, SCIATIC (SN),
PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), PROSTATE (PR), RECTUM (RE), SKIN (SK), SKIN, OTHER (SS),
SPLEEN (SP), STOMACH, GL (ST), STOMACH, NONGL (SU), TESTIS (TE), THYMUS (TH), THYROID (TY), TONGUE (TO),
TRACHEA (TR), URINARY BLADDER (UB)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:

ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, STERNUM (SB), BRAIN W/STEM (BR), COLON (CO),
CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC), DUODENUM (DU), ESOPHAGUS (ES), GALLBLADDER (GB),
HARDERIAN GLAND (HG), HEART (HT), HEMATO NEOPLASIA (HN), JEJUNUM (JE), LACRIMAL GL, EX (EO), LN, MANDIBULAR (MN),
LUNG (LU), MAND SALIVARY GL (SG), MARROW, STERNUM (SE), MUSCLE, ABDOM (MA), MUSCLE, SKELETAL (SM),
NERVE, SCIATIC (SN), PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), PROSTATE (PR), RECTUM (RE), SALIVARY, OTHER (OS),
SKIN (SK), STOMACH, GL (ST), STOMACH, NONGL (SU), TESTIS (TE), THYMUS (TH), TONGUE (TO), TRACHEA (TR),
URINARY BLADDER (UB)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 750

STUDY NUMBER: 483287

ANIMAL NUMBER: A37584 SEX: MALE DOSE GROUP: 7 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/13/91 STUDY DAY OF DEATH: 97 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 27.2 GRAMS
DATE AND TIME OF NECROPSY: 11/13/91 13:08 PROSECTOR: ADEPOLAHAN AKINSOLA RECORDER: JOHN CROWLEY
POST-FIX WEAIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEAIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.20	.750 %	.461	WEIGHT TAKEN
LUNG (LU)	.15	.533 %	.328	WEIGHT TAKEN
PROSTATE (PR)	.025	.0912 %	.0561	WEIGHT TAKEN
BRAIN W/STEM (BR)	.44	1.625 %	1.000	WEIGHT TAKEN
HEART (HT)	.18	.656 %	.404	WEIGHT TAKEN
SPLEEN (SP)	.08	.276 %	.170	WEIGHT TAKEN
KIDNEY (KD)	.43	1.594 %	.981	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	4.35	16.007 %	9.850	WEIGHT TAKEN
TESTIS (TE)	.18	.675 %	.415	WEIGHT TAKEN
EPIDIDYMIS (EP)	.09	.313 %	.193	WEIGHT TAKEN
ADRENAL (AD)	.012	.0434 %	.0267	WEIGHT TAKEN
THYMUS (TH)	.01	.046 %	.028	WEIGHT TAKEN

CLINICAL OBSERVATIONS	PATHOLOGY OBSERVATIONS NECROPSY	HISTOPATHOLOGY
-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS	LIVER (LI) : -PALE AREA; ALL LOBES, SEVERAL, TAN, PINPOINT TO 1 X 1 MM -ENLARGED, SEVERE; ALL LOBES -DARK; ALL LOBES, DARK BROWN	ADRENAL, CORTEX (AC) : -PIGMENT, -MINIMAL -HYPERTROPHY, ZONA FASCICULATA, -MINIMAL CECUM (CE) : -HYPERPLASIA, LYMPHOID, -PRESENT KIDNEY (KD) : -TUBULE, MINERALIZATION, -MINIMAL LIVER (LI) : -HEPATOCYTE, HYPERTROPHY, CENTROLOBULAR, -MODERATELY SEVERE -VACUOLIZATION, -MINIMAL -PIGMENT, BILE, -MODERATE -KUPFFER CELL/MACROPHAGE, PIGMENT, - MINIMAL -HEPATOCYTE, PIGMENT, -SLIGHT -NECROSIS, -SLIGHT, MULTI-FOCAL -NECROSIS, INDIVIDUAL CELL, -MODERATE

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 751

STUDY NUMBER: 483287

ANIMAL NUMBER: A37584 SEX: MALE DOSE GROUP: 7 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/13/91 STUDY DAY OF DEATH: 97 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 27.2 GRAMS
DATE AND TIME OF NECROPSY: 11/13/91 13:08 PROSECTOR: ADEFOLAHAN AKINSOLA RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

CLINICAL OBSERVATIONS P A T H O L O G Y O B S E R V A T I O N S (CONTINUED)
NECROPSY HISTOPATHOLOGY

LIVER (LI) :
-INFLAMMATION, CHRONIC/CHRONIC ACTIVE,-
MINIMAL
-BILE DUCT, INFLAMMATION, CHRONIC,-
MINIMAL
LUNG (LU) :
-PERIBRONCHIAL/PERIVASCULAR,
INFILTRATION, LYMPHOID,-MINIMAL
MARROW, FEMUR (FM) :
-HYPERCELLULAR,-PRESENT
PARATHYROID (PT) :
-UNILATERALLY EXAMINED,-PRESENT
SPLEEN (SP) :
-EXTRAMEDULLARY HEMATOPOIESIS,
INCREASED,-MODERATE
-PIGMENT,-MINIMAL

^COLLECTED/TAKEN (XW) :
-LIVER SECTIONS, IN METHANOL

^DEATH COMMENT (DC) :
-SCHEDULED SACRIFICE,-PRESENT

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 752

STUDY NUMBER: 483287

ANIMAL NUMBER: A37584 SEX: MALE DOSE GROUP: 7 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/13/91 STUDY DAY OF DEATH: 97 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 27.2 GRAMS
DATE AND TIME OF NECROPSY: 11/13/91 13:08 PROSECTOR: ADEPOLAHAN AKINSOLA RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), EPIDIDYMIS (EP), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE),
KIDNEY (KD), LACRIMAL GL, EX (EO), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU), MAND SALIVARY GL (SG),
MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON), NERVE, SCIATIC (SN),
PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), PROSTATE (PR), RECTUM (RE), SKIN (SK), SKIN, OTHER (SS),
SPLEEN (SP), STOMACH, GL (ST), STOMACH, NONGL (SU), TESTIS (TE), THYMUS (TH), THYROID (TY), TONGUE (TO),
TRACHEA (TR), URINARY BLADDER (UB)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:

ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, STERNUM (SB), BRAIN W/STEM (BR), COLON (CO),
CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC), DUODENUM (DU), EPIDIDYMIS (EP), ESOPHAGUS (ES),
EYE (EY), GALLBLADDER (GB), HARDERIAN GLAND (HG), HEART (HT), HEMATO NEOPLASIA (HN), ILEUM (IL), JEJUNUM (JE),
LACRIMAL GL, EX (EO), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), MAND SALIVARY GL (SG), MARROW, STERNUM (SE),
MUSCLE, ABDOM (MA), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON), NERVE, SCIATIC (SN), PANCREAS (PA), PITUITARY (PI),
PROSTATE (PR), RECTUM (RE), SALIVARY, OTHER (OS), SKIN (SK), STOMACH, GL (ST), STOMACH, NONGL (SU), TESTIS (TE),
THYMUS (TH), THYROID (TY), TONGUE (TO), TRACHEA (TR), URINARY BLADDER (UB)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 753

STUDY NUMBER: 483287

ANIMAL NUMBER: A37585 SEX: MALE DOSE GROUP: 7 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/14/91 STUDY DAY OF DEATH: 98 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 29.1 GRAMS
DATE AND TIME OF NECROPSY: 11/14/91 8:15 PROSECTOR: ADEFOLAHAN AKINSOLA RECORDER: ADEFOLAHAN AKINSOLA
POST-FIX WEIGHER: DANIEL JACK PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.18	.634 %	.355	WEIGHT TAKEN
LUNG (LU)	.16	.550 %	.308	WEIGHT TAKEN
PROSTATE (PR)	.035	.1213 %	.0679	WEIGHT TAKEN
BRAIN W/STEM (BR)	.52	1.787 %	1.000	WEIGHT TAKEN
HEART (HT)	.16	.533 %	.299	WEIGHT TAKEN
SPLEEN (SP)	.06	.209 %	.117	WEIGHT TAKEN
KIDNEY (KD)	.44	1.496 %	.837	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	3.84	13.201 %	7.389	WEIGHT TAKEN
TESTIS (TE)	.19	.667 %	.373	WEIGHT TAKEN
EPIDIDYMIS (EP)	.11	.374 %	.209	WEIGHT TAKEN
ADRENAL (AD)	.015	.0505 %	.0283	WEIGHT TAKEN
THYMUS (TH)	.04	.131 %	.073	WEIGHT TAKEN

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE
OBSERVATIONS

PATHOLOGY OBSERVATIONS
NECROPSY

HISTOPATHOLOGY

ADRENAL, CORTEX (AC) :
-HYPERTROPHY, ZONA FASCICULATA, -MINIMAL
EPIDIDYMIS (EP) :
-INFLAMMATION, CHRONIC, -MINIMAL
-LUMEN, DEBRIS, CELLULAR, -PRESENT
ILEUM (IL) :
-HYPERPLASIA, LYMPHOID, -PRESENT
KIDNEY (KD) :
-HYPERPLASIA, LYMPHOID, -MINIMAL
LACRIMAL GL, EX (EO) :
-UNILATERALLY EXAMINED, -PRESENT
LI, EXTRAHEPATIC (LI1) :
-PIGMENT, PAS POSITIVE, -MODERATE
-PIGMENT, IRON POSITIVE, -SLIGHT
-PIGMENT, LIPOFUSCIN POSITIVE, -MINIMAL
LI, INTRAHEPATIC (LI0) :
-PIGMENT, PAS POSITIVE, -SEVERE
-PIGMENT, IRON POSITIVE, -MODERATE

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 754

STUDY NUMBER: 483287

ANIMAL NUMBER: A37585 SEX: MALE DOSE GROUP: 7 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/14/91 STUDY DAY OF DEATH: 98 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 29.1 GRAMS
DATE AND TIME OF NECROPSY: 11/14/91 8:15 PROSECTOR: ADEFOLAHAN AKINSOLA RECORDER: ADEFOLAHAN AKINSOLA
POST-FIX WEIGHER: DANIEL JACK PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

CLINICAL OBSERVATIONS

P A T H O L O G Y O B S E R V A T I O N S (CONTINUED)
NECROPSY

HISTOPATHOLOGY

LIVER (LI) :
-PALE AREA; MEDIAN LOBE, FEW, TAN, 5 X
5 MM
-ENLARGED, MODERATE; ALL LOBES
-DARK; ALL LOBES, DARK BROWN

LI, INTRAHEPATIC (LIO) :
-PIGMENT, BILE POSITIVE, -MINIMAL
-PIGMENT, LIPOFUSCIN POSITIVE, -MODERATE
LIVER (LI) :
-HEPATOCYTE, HYPERTROPHY,
CENTROLOBULAR, -MODERATELY SEVERE
-VACUOLIZATION, -MINIMAL
-PIGMENT, BILE, -MODERATE
-KUPFFER CELL/MACROPHAGE, PIGMENT, -
SLIGHT
-HEPATOCYTE, PIGMENT, -MINIMAL
-NECROSIS, -MODERATE, FOCAL
-NECROSIS, INDIVIDUAL CELL, -MODERATE
-BILE DUCT, INFLAMMATION, CHRONIC, -
MINIMAL
LN, OTHER (LN) :
-MACROPHAGES, PIGMENTED, -PRESENT
>NOTE: >PANCREATIC.
NERVE, OPTIC (ON) :
-UNILATERALLY EXAMINED, -PRESENT
PARATHYROID (PT) :
-UNILATERALLY EXAMINED, -PRESENT
PROSTATE (PR) :
-INFLAMMATION, CHRONIC, -MINIMAL
SPLEEN (SP) :
-EXTRAMEDULLARY HEMATOPOIESIS,
INCREASED, -SLIGHT
-PIGMENT, -MINIMAL
STOMACH, GL (ST) :
-HYPERPLASIA, -MINIMAL
URINARY BLADDER (UB) :
-INFLAMMATION, CHRONIC, -MINIMAL

^COLLECTED/TAKEN (XW) :
-LIVER SECTIONS, IN METHANOL

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 755

STUDY NUMBER: 483287

ANIMAL NUMBER: A37585 SEX: MALE DOSE GROUP: 7 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/14/91 STUDY DAY OF DEATH: 98 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 29.1 GRAMS
DATE AND TIME OF NECROPSY: 11/14/91 8:15 PROSECTOR: ADEPOLAHAN AKINSOLA RECORDER: ADEPOLAHAN AKINSOLA
POST-FIX WEIGHER: DANIEL JACK PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

CLINICAL OBSERVATIONS PATHOLOGY OBSERVATIONS (CONTINUED)
NECROPSY HISTOPATHOLOGY

^DEATH COMMENT (DC) :
-SCHEDULED SACRIFICE, -PRESENT

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), EPIDIDYMIS (EP), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE),
KIDNEY (KD), LACRIMAL GL, EX (EO), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU), MAND SALIVARY GL (SG),
MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON), NERVE, SCIATIC (SN),
PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), PROSTATE (PR), RECTUM (RE), SKIN (SK), SKIN, OTHER (SS),
SPLEEN (SP), STOMACH, GL (ST), STOMACH, NONGL (SU), TESTIS (TE), THYMUS (TH), THYROID (TY), TONGUE (TO),
TRACHEA (TR), URINARY BLADDER (UB)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:

ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, STERNUM (SB), BRAIN W/STEM (BR), CECUM (CE),
COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC), DUODENUM (DU), ESOPHAGUS (ES), EYE (EY),
GALLBLADDER (GB), HARDERIAN GLAND (HG), HEART (HT), HEMATO NEOPLASIA (HN), JEJUNUM (JE), LN, MANDIBULAR (MN),
LN, MESENTERIC (MS), LUNG (LU), MAND SALIVARY GL (SG), MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, ABDOM (MA),
MUSCLE, SKELETAL (SM), NERVE, SCIATIC (SN), PANCREAS (PA), PITUITARY (PI), RECTUM (RE), SALIVARY, OTHER (OS),
SKIN (SK), STOMACH, NONGL (SU), TESTIS (TE), THYMUS (TH), THYROID (TY), TONGUE (TO), TRACHEA (TR)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 756

STUDY NUMBER: 483287

ANIMAL NUMBER: A37406 SEX: FEMALE DOSE GROUP: 1 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/11/91 STUDY DAY OF DEATH: 95 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 23.6 GRAMS
DATE AND TIME OF NECROPSY: 11/11/91 9:13 PROSECTOR: JANE EARHARDT RECORDER: JANE EARHARDT
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.10	.444 %	.186	WEIGHT TAKEN
LUNG (LU)	.18	.762 %	.319	WEIGHT TAKEN
UTERUS (UT)	.16	.698 %	.292	WEIGHT TAKEN
BRAIN W/STEM (BR)	.56	2.391 %	1.000	WEIGHT TAKEN
HEART (HT)	.13	.563 %	.235	WEIGHT TAKEN
SPLEEN (SP)	.06	.244 %	.102	WEIGHT TAKEN
KIDNEY (KD)	.40	1.711 %	.716	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	1.04	4.411 %	1.845	WEIGHT TAKEN
ADRENAL (AD)	.012	.0521 %	.0218	WEIGHT TAKEN
OVARY (OV)	.036	.1521 %	.0636	WEIGHT TAKEN
THYMUS (TH)	.04	.149 %	.062	WEIGHT TAKEN

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO RERMARKABLE
OBSERVATIONS

PATHOLOGY OBSERVATIONS
NECROPSY

^COLLECTED/TAKEN (XW) :
-LIVER SECTIONS, IN METHANOL

HISTOPATHOLOGY

ADRENAL, CORTEX (AC) :
-PIGMENT,-MINIMAL
-VACUOLIZATION, X-ZONE,-MINIMAL
-HYPERPLASIA, SUBCAPSULAR CELL,-MINIMAL
LIVER (LI) :
-EXTRAMEDULLARY HEMATOPOIESIS,
INCREASED,-MINIMAL
LN, MANDIBULAR (MN) :
-MACROPHAGES, PIGMENTED,-MINIMAL
LN, MESENTERIC (MS) :
-MACROPHAGES, PIGMENTED,-MINIMAL
PITUITARY (PI) :
^TISSUE MISSING
SPLEEN (SP) :
-PIGMENT,-MINIMAL

^DEATH COMMENT (DC) :
-SCHEDULED SACRIFICE,-PRESENT

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 757

STUDY NUMBER: 483287

ANIMAL NUMBER: A37406 SEX: FEMALE DOSE GROUP: 1 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/11/91 STUDY DAY OF DEATH: 95 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 23.6 GRAMS
DATE AND TIME OF NECROPSY: 11/11/91 9:13 PROSECTOR: JANE EARHARDT RECORDER: JANE EARHARDT
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE), KIDNEY (KD),
LACRIMAL GL, EX (EO), LIVER (LI), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU), MAMMARY, FEMALE (MF),
MAND SALIVARY GL (SG), MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON),
NERVE, SCIATIC (SN), OVARY (OV), PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), RECTUM (RE), SKIN (SK),
SKIN, OTHER (SS), SPLEEN (SP), STOMACH, GL (ST), STOMACH, NONGL (SU), THYMUS (TH), THYROID (TY), TONGUE (TO),
TRACHEA (TR), URINARY BLADDER (UB), UTERUS (UT), UTERUS, CERVIX (CV), VAGINA (VA)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:

ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, STERNUM (SB), BRAIN W/STEM (BR), CECUM (CE),
COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC), DUODENUM (DU), ESOPHAGUS (ES), EYE (EY),
GALLBLADDER (GB), HARDERIAN GLAND (HG), HEART (HT), HEMATO NEOPLASIA (HN), ILEUM (IL), JEJUNUM (JE), KIDNEY (KD),
LACRIMAL GL, EX (EO), LUNG (LU), MAMMARY, FEMALE (MF), MAND SALIVARY GL (SG), MARROW, FEMUR (FM), MARROW, STERNUM (SE),
MUSCLE, ABDOM (MA), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON), NERVE, SCIATIC (SN), OVARY (OV), OVIDUCT (OD),
PANCREAS (PA), PARATHYROID (PT), RECTUM (RE), SALIVARY, OTHER (OS), SKIN (SK), STOMACH, GL (ST), STOMACH, NONGL (SU),
THYMUS (TH), THYROID (TY), TONGUE (TO), TRACHEA (TR), URINARY BLADDER (UB), UTERUS (UT), UTERUS, CERVIX (CV),
VAGINA (VA)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 758

STUDY NUMBER: 483287

ANIMAL NUMBER: A37407 SEX: FEMALE DOSE GROUP: 1 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/11/91 STUDY DAY OF DEATH: 95 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 24.5 GRAMS
DATE AND TIME OF NECROPSY: 11/11/91 10:24 PROSECTOR: DOUGLAS HERNDON RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.14	.569 %	.260	WEIGHT TAKEN
LUNG (LU)	.18	.718 %	.328	WEIGHT TAKEN
UTERUS (UT)	.33	1.367 %	.625	WEIGHT TAKEN
BRAIN W/STEM (BR)	.54	2.189 %	1.000	WEIGHT TAKEN
HEART (HT)	.14	.574 %	.262	WEIGHT TAKEN
SPLEEN (SP)	.08	.328 %	.150	WEIGHT TAKEN
KIDNEY (KD)	.37	1.493 %	.682	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	1.06	4.333 %	1.979	WEIGHT TAKEN
ADRENAL (AD)	.013	.0514 %	.0235	WEIGHT TAKEN
OVARY (OV)	.046	.1861 %	.0850	WEIGHT TAKEN
THYMUS (TH)	.03	.109 %	.050	WEIGHT TAKEN

CLINICAL OBSERVATIONS

PATHOLOGY OBSERVATIONS
NECROPSY

HISTOPATHOLOGY

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE
OBSERVATIONS

ADRENAL, CORTEX (AC) :
-PIGMENT,-MINIMAL
-VACUOLIZATION, X-ZONE,-MINIMAL
-HYPERPLASIA, SUBCAPSULAR CELL,-MINIMAL
LN, MANDIBULAR (MN) :
-MACROPHAGES, PIGMENTED,-MINIMAL
LN, MESENTERIC (MS) :
-MACROPHAGES, PIGMENTED,-MINIMAL
NERVE, OPTIC (ON) :
-UNILATERALLY EXAMINED,-PRESENT
PANCREAS (PA) :
-INFLAMMATION, CHRONIC,-MINIMAL
SPLEEN (SP) :
-EXTRAMEDULLARY HEMATOPOIESIS,
INCREASED,-SLIGHT
-PIGMENT,-SLIGHT
UTERUS (UT) :
-HYPERPLASIA, CYSTIC ENDOMETRIAL,-
MINIMAL

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 759

STUDY NUMBER: 483287

ANIMAL NUMBER: A37407 SEX: FEMALE DOSE GROUP: 1 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/11/91 STUDY DAY OF DEATH: 95 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 24.5 GRAMS
DATE AND TIME OF NECROPSY: 11/11/91 10:24 PROSECTOR: DOUGLAS HERNDON RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

CLINICAL OBSERVATIONS P A T H O L O G Y O B S E R V A T I O N S (CONTINUED)
NECROPSY HISTOPATHOLOGY

^COLLECTED/TAKEN (XW) :
-LIVER SECTIONS, IN METHANOL

^DEATH COMMENT (DC) :
-SCHEDULED SACRIFICE, -PRESENT

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE), KIDNEY (KD),
LACRIMAL GL, EX (EO), LIVER (LI), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU), MAMMARY, FEMALE (MF),
MAND SALIVARY GL (SG), MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON),
NERVE, SCIATIC (SN), OVARY (OV), PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), RECTUM (RE), SKIN (SK),
SKIN, OTHER (SS), SPLEEN (SP), STOMACH, GL (ST), STOMACH, NONGL (SU), THYMUS (TH), THYROID (TY), TONGUE (TO),
TRACHEA (TR), URINARY BLADDER (UB), UTERUS (UT), UTERUS, CERVIX (CV), VAGINA (VA)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:

ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, STERNUM (SB), BRAIN W/STEM (BR), CECUM (CE),
COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC), DUODENUM (DU), ESOPHAGUS (ES), EYE (EY),
GALLBLADDER (GB), HARDERIAN GLAND (HG), HEART (HT), HEMATO NEOPLASIA (HN), ILEUM (IL), JEJUNUM (JE), KIDNEY (KD),
LACRIMAL GL, EX (EO), LIVER (LI), LUNG (LU), MAMMARY, FEMALE (MF), MAND SALIVARY GL (SG), MARROW, FEMUR (FM),
MARROW, STERNUM (SE), MUSCLE, ABDOM (MA), MUSCLE, SKELETAL (SM), NERVE, SCIATIC (SN), OVARY (OV), OVIDUCT (OD),
PARATHYROID (PT), PITUITARY (PI), RECTUM (RE), SALIVARY, OTHER (OS), SKIN (SK), STOMACH, GL (ST), STOMACH, NONGL (SU),
THYMUS (TH), THYROID (TY), TONGUE (TO), TRACHEA (TR), URINARY BLADDER (UB), UTERUS, CERVIX (CV), VAGINA (VA)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 760

STUDY NUMBER: 483287

ANIMAL NUMBER: A37408 SEX: FEMALE DOSE GROUP: 1 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/11/91 STUDY DAY OF DEATH: 95 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 25.9 GRAMS
DATE AND TIME OF NECROPSY: 11/11/91 11:29 PROSECTOR: DOUGLAS HERNDON RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.15	.583 %	.275	WEIGHT TAKEN
LUNG (LU)	.19	.724 %	.342	WEIGHT TAKEN
UTERUS (UT)	.18	.691 %	.326	WEIGHT TAKEN
BRAIN W/STEM (BR)	.55	2.119 %	1.000	WEIGHT TAKEN
HEART (HT)	.14	.551 %	.260	WEIGHT TAKEN
SPLEEN (SP)	.09	.330 %	.156	WEIGHT TAKEN
KIDNEY (KD)	.40	1.558 %	.735	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	1.31	5.058 %	2.387	WEIGHT TAKEN
ADRENAL (AD)	.012	.0467 %	.0220	WEIGHT TAKEN
OVARY (OV)	.100	.3842 %	.1813	WEIGHT TAKEN
THYMUS (TH)	.02	.076 %	.036	WEIGHT TAKEN

CLINICAL OBSERVATIONS	PATHOLOGY OBSERVATIONS NECROPSY	HISTOPATHOLOGY
-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS		ADRENAL, CORTEX (AC) : -PIGMENT,-MINIMAL -VACUOLIZATION, X-ZONE,-MINIMAL -HYPERPLASIA, SUBCAPSULAR CELL,-MINIMAL CAVITY, ABDOM (PC) : -ADHESION,-PRESENT >NOTE:>PANCREAS TO SPLEEN. HARDERIAN GLAND (HG) : -INFLAMMATION, CHRONIC,-PRESENT LACRIMAL GL, EX (EO) : -UNILATERALLY EXAMINED,-PRESENT LIVER (LI) : -INFLAMMATION, CHRONIC/CHRONIC ACTIVE,- MINIMAL LN, MANDIBULAR (MN) : -MACROPHAGES, PIGMENTED,-MINIMAL LN, MESENTERIC (MS) : -MACROPHAGES, PIGMENTED,-MINIMAL

HAZLETON WASHINGTON, INC.
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APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 761

STUDY NUMBER: 483287

ANIMAL NUMBER: A37408 SEX: FEMALE DOSE GROUP: 1 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/11/91 STUDY DAY OF DEATH: 95 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 25.9 GRAMS
DATE AND TIME OF NECROPSY: 11/11/91 11:29 PROSECTOR: DOUGLAS HERNDON RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

CLINICAL OBSERVATIONS	P A T H O L O G Y O B S E R V A T I O N S (CONTINUED)	HISTOPATHOLOGY
	NECROPSY	
		LUNG (LU) : -PERIBRONCHIAL/PERIVASCULAR, INFILTRATION, LYMPHOID,-MINIMAL PARATHYROID (PT) : -UNILATERALLY EXAMINED,-PRESENT SPLEEN (SP) : -EXTRAMEDULLARY HEMATOPOIESIS, INCREASED,-MODERATE -PIGMENT,-SLIGHT STOMACH, GL (ST) : -INFLAMMATION, CHRONIC,-MINIMAL UTERUS (UT) : -HYPOPLASIA,-MINIMAL ^COLLECTED/TAKEN (XW) : -LIVER SECTIONS, IN METHANOL ^DEATH COMMENT (DC) : -SCHEDULED SACRIFICE,-PRESENT

HAZLETON WASHINGTON, INC.
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13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 762

STUDY NUMBER: 483287

ANIMAL NUMBER: A37408 SEX: FEMALE DOSE GROUP: 1 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/11/91 STUDY DAY OF DEATH: 95 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 25.9 GRAMS
DATE AND TIME OF NECROPSY: 11/11/91 11:29 PROSECTOR: DOUGLAS HERNDON RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE), KIDNEY (KD),
LACRIMAL GL, EX (EO), LIVER (LI), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU), MAMMARY, FEMALE (MF),
MAND SALIVARY GL (SG), MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON),
NERVE, SCIATIC (SN), OVARY (OV), PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), RECTUM (RE), SKIN (SK),
SKIN, OTHER (SS), SPLEEN (SP), STOMACH, GL (ST), STOMACH, NONGL (SU), THYMUS (TH), THYROID (TY), TONGUE (TO),
TRACHEA (TR), URINARY BLADDER (UB), UTERUS (UT), UTERUS, CERVIX (CV), VAGINA (VA)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:

ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, STERNUM (SB), BRAIN W/STEM (BR), CECUM (CE),
COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC), DUODENUM (DU), ESOPHAGUS (ES), EYE (EY),
GALLBLADDER (GB), HEART (HT), HEMATO NEOPLASIA (HN), ILEUM (IL), JEJUNUM (JE), KIDNEY (KD), MAMMARY, FEMALE (MF),
MAND SALIVARY GL (SG), MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, ABDOM (MA), MUSCLE, SKELETAL (SM),
NERVE, OPTIC (ON), NERVE, SCIATIC (SN), OVARY (OV), OVIDUCT (OD), PANCREAS (PA), PITUITARY (PI), RECTUM (RE),
SALIVARY, OTHER (OS), SKIN (SK), STOMACH, NONGL (SU), THYMUS (TH), THYROID (TY), TONGUE (TO), TRACHEA (TR),
URINARY BLADDER (UB), UTERUS, CERVIX (CV), VAGINA (VA)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 763

STUDY NUMBER: 483287

ANIMAL NUMBER: A37409 SEX: FEMALE DOSE GROUP: 1 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/11/91 STUDY DAY OF DEATH: 95 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 21.8 GRAMS
DATE AND TIME OF NECROPSY: 11/11/91 13:45 PROSECTOR: ADEFOLAHAN AKINSOLA RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KACYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.14	.640 %	.277	WEIGHT TAKEN
LUNG (LU)	.15	.695 %	.301	WEIGHT TAKEN
UTERUS (UT)	.26	1.204 %	.522	WEIGHT TAKEN
BRAIN W/STEM (BR)	.50	2.307 %	1.000	WEIGHT TAKEN
HEART (HT)	.12	.554 %	.240	WEIGHT TAKEN
SPLEEN (SP)	.05	.224 %	.097	WEIGHT TAKEN
KIDNEY (KD)	.35	1.622 %	.703	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	.83	3.799 %	1.647	WEIGHT TAKEN
ADRENAL (AD)	.010	.0468 %	.0203	WEIGHT TAKEN
OVARY (OV)	.033	.1514 %	.0656	WEIGHT TAKEN
THYMUS (TH)	.02	.096 %	.042	WEIGHT TAKEN

CLINICAL OBSERVATIONS	PATHOLOGY OBSERVATIONS NECROPSY	HISTOPATHOLOGY
-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS	<p>^COLLECTED/TAKEN (XW) : -LIVER SECTIONS, IN METHANOL</p>	<p>ADRENAL, CORTEX (AC) : -VACUOLIZATION, X-ZONE,-MINIMAL -HYPERPLASIA, SUBCAPSULAR CELL,-MINIMAL LACRIMAL GL, EX (EO) : -UNILATERALLY EXAMINED,-PRESENT LN, MANDIBULAR (MN) : -MACROPHAGES, PIGMENTED,-MINIMAL LN, MESENTERIC (MS) : -NECROSIS, LYMPHOID,-MINIMAL NERVE, OPTIC (ON) : >TISSUE MISSING SPLEEN (SP) : -PIGMENT,-SLIGHT THYMUS (TH) : -NECROSIS, LYMPHOID,-SLIGHT</p> <p>^DEATH COMMENT (DC) : -SCHEDULED SACRIFICE,-PRESENT</p>

APPENDIX 13B

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 764

STUDY NUMBER: 483287

ANIMAL NUMBER: A37409 SEX: FEMALE DOSE GROUP: 1 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/11/91 STUDY DAY OF DEATH: 95 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 21.8 GRAMS
DATE AND TIME OF NECROPSY: 11/11/91 13:45 PROSECTOR: ADEFOLAHAN AKINSOLA RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE), KIDNEY (KD),
LACRIMAL GL, EX (EO), LIVER (LI), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU), MAMMARY, FEMALE (MF),
MAND SALIVARY GL (SG), MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON),
NERVE, SCIATIC (SN), OVARY (OV), PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), RECTUM (RE), SKIN (SK),
SKIN, OTHER (SS), SPLEEN (SP), STOMACH, GL (ST), STOMACH, NONGL (SU), THYMUS (TH), THYROID (TY), TONGUE (TO),
TRACHEA (TR), URINARY BLADDER (UB), UTERUS (UT), UTERUS, CERVIX (CV), VAGINA (VA)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:

ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, STERNUM (SB), BRAIN W/STEM (BR), CECUM (CE),
COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC), DUODENUM (DU), ESOPHAGUS (ES), EYE (EY),
GALLBLADDER (GB), HARDERIAN GLAND (HG), HEART (HT), HEMATO NEOPLASIA (HN), ILEUM (IL), JEJUNUM (JE), KIDNEY (KD),
LIVER (LI), LUNG (LU), MAMMARY, FEMALE (MF), MAND SALIVARY GL (SG), MARROW, FEMUR (FM), MARROW, STERNUM (SE),
MUSCLE, ABDOM (MA), MUSCLE, SKELETAL (SM), NERVE, SCIATIC (SN), OVARY (OV), OVIDUCT (OD), PANCREAS (PA),
PARATHYROID (PT), PITUITARY (PI), RECTUM (RE), SALIVARY, OTHER (OS), SKIN (SK), STOMACH, GL (ST), STOMACH, NONGL (SU),
THYROID (TY), TONGUE (TO), TRACHEA (TR), URINARY BLADDER (UB), UTERUS (UT), UTERUS, CERVIX (CV), VAGINA (VA)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 765

STUDY NUMBER: 483287

ANIMAL NUMBER: A37410 SEX: FEMALE DOSE GROUP: 1 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/12/91 STUDY DAY OF DEATH: 96 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 25.4 GRAMS
DATE AND TIME OF NECROPSY: 11/12/91 9:03 PROSECTOR: JANE EARHARDT RECORDER: JANE EARHARDT
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	O R G A N S T A T U S
MAND SALIVARY GL (SG)	.17	.660 %	.283	WEIGHT TAKEN
LUNG (LU)	.21	.811 %	.348	WEIGHT TAKEN
UTERUS (UT)	.31	1.206 %	.518	WEIGHT TAKEN
BRAIN W/STEM (BR)	.59	2.330 %	1.000	WEIGHT TAKEN
HEART (HT)	.15	.609 %	.262	WEIGHT TAKEN
SPLEEN (SP)	.08	.309 %	.132	WEIGHT TAKEN
KIDNEY (KD)	.41	1.620 %	.695	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	1.19	4.692 %	2.014	WEIGHT TAKEN
ADRENAL (AD)	.014	.0539 %	.0232	WEIGHT TAKEN
OVARY (OV)	.069	.2705 %	.1161	WEIGHT TAKEN
THYMUS (TH)	.03	.115 %	.049	WEIGHT TAKEN

CLINICAL OBSERVATIONS	PATHOLOGY OBSERVATIONS NECROPSY	HISTOPATHOLOGY
-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS		ADRENAL, CORTEX (AC) : -PIGMENT,-SLIGHT -VACUOLIZATION, X-ZONE,-MINIMAL EYE (EY) : >TISSUE MISSING KIDNEY (KD) : -INFLAMMATION, CHRONIC,-MINIMAL LIVER (LI) : -NECROSIS,-MINIMAL, FOCAL -INFLAMMATION, CHRONIC/CHRONIC ACTIVE,- MINIMAL LN, MANDIBULAR (MN) : >TISSUE MISSING NERVE, OPTIC (ON) : >TISSUE MISSING PITUITARY (PI) : >TISSUE MISSING

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 766

STUDY NUMBER: 483287

ANIMAL NUMBER: A37410 SEX: FEMALE DOSE GROUP: 1 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/12/91 STUDY DAY OF DEATH: 96 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 25.4 GRAMS
DATE AND TIME OF NECROPSY: 11/12/91 9:03 PROSECTOR: JANE EARHARDT RECORDER: JANE EARHARDT
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

CLINICAL OBSERVATIONS

P A T H O L O G Y O B S E R V A T I O N S (CONTINUED)
NECROPSY

HISTOPATHOLOGY

SPLEEN (SP) :
-EXTRAMEDULLARY HEMATOPOIESIS,
INCREASED, -SLIGHT
-PIGMENT, -MINIMAL
STOMACH, GL (ST) :
-INFLAMMATION, CHRONIC, -MINIMAL
UTERUS (UT) :
-HYPERPLASIA, CYSTIC ENDOMETRIAL, -
MINIMAL

^COLLECTED/TAKEN (XW) :
-LIVER SECTIONS, IN METHANOL

^DEATH COMMENT (DC) :
-SCHEDULED SACRIFICE, -PRESENT

HAZLETON WASHINGTON, INC.
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APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 767

STUDY NUMBER: 483287

ANIMAL NUMBER: A37410 SEX: FEMALE DOSE GROUP: 1 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/12/91 STUDY DAY OF DEATH: 96 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 25.4 GRAMS
DATE AND TIME OF NECROPSY: 11/12/91 9:03 PROSECTOR: JANE EARHARDT RECORDER: JANE EARHARDT
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE), KIDNEY (KD),
LACRIMAL GL, EX (EO), LIVER (LI), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU), MAMMARY, FEMALE (MF),
MAND SALIVARY GL (SG), MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON),
NERVE, SCIATIC (SN), OVARY (OV), PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), RECTUM (RE), SKIN (SK),
SKIN, OTHER (SS), SPLEEN (SP), STOMACH, GL (ST), STOMACH, NONGL (SU), THYMUS (TH), THYROID (TY), TONGUE (TO),
TRACHEA (TR), URINARY BLADDER (UB), UTERUS (UT), UTERUS, CERVIX (CV), VAGINA (VA)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:

ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, STERNUM (SB), BRAIN W/STEM (BR), CECUM (CE),
COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC), DUODENUM (DU), ESOPHAGUS (ES),
GALLBLADDER (GB), HEART (HT), HEMATO NEOPLASIA (HN), ILEUM (IL), JEJUNUM (JE), LACRIMAL GL, EX (EO),
LN, MESENTERIC (MS), LUNG (LU), MAMMARY, FEMALE (MF), MAND SALIVARY GL (SG), MARROW, FEMUR (FM), MARROW, STERNUM (SE),
MUSCLE, ABDOM (MA), MUSCLE, SKELETAL (SM), NERVE, SCIATIC (SN), OVARY (OV), OVIDUCT (OD), PANCREAS (PA),
PARATHYROID (PT), RECTUM (RE), SALIVARY, OTHER (OS), SKIN (SK), STOMACH, NONGL (SU), THYMUS (TH), THYROID (TY),
TONGUE (TO), TRACHEA (TR), URINARY BLADDER (UB), UTERUS, CERVIX (CV), VAGINA (VA)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 768

STUDY NUMBER: 483287

ANIMAL NUMBER: A37411 SEX: FEMALE DOSE GROUP: 1 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/12/91 STUDY DAY OF DEATH: 96 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 24.1 GRAMS
DATE AND TIME OF NECROPSY: 11/12/91 9:57 PROSECTOR: JANE EARHARDT RECORDER: JANE EARHARDT
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.17	.702 %	.338	WEIGHT TAKEN
LUNG (LU)	.19	.770 %	.371	WEIGHT TAKEN
UTERUS (UT)	.29	1.184 %	.571	WEIGHT TAKEN
BRAIN W/STEM (BR)	.50	2.073 %	1.000	WEIGHT TAKEN
HEART (HT)	.14	.592 %	.285	WEIGHT TAKEN
SPLEEN (SP)	.09	.363 %	.175	WEIGHT TAKEN
KIDNEY (KD)	.35	1.457 %	.703	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	1.11	4.617 %	2.227	WEIGHT TAKEN
ADRENAL (AD)	.015	.0622 %	.0300	WEIGHT TAKEN
OVARY (OV)	.028	.1183 %	.0570	WEIGHT TAKEN
THYMUS (TH)	.04	.147 %	.071	WEIGHT TAKEN

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE
OBSERVATIONS

PATHOLOGY OBSERVATIONS
NECROPSY

HISTOPATHOLOGY

ADRENAL, CORTEX (AC) :
-PIGMENT, -MINIMAL
-VACUOLIZATION, X-ZONE, -SLIGHT
-HYPERPLASIA, SUBCAPSULAR CELL, -MINIMAL
LN, MESENTERIC (MS) :
-MACROPHAGES, PIGMENTED, -MINIMAL
LN, OTHER (LN) :
>UNREMARKABLE
>NOTE:>SUBCUTANEOUS AND PANCREATIC.
SPLEEN (SP) :
-EXTRAMEDULLARY HEMATOPOIESIS,
INCREASED, -SLIGHT
-PIGMENT, -SLIGHT
STOMACH, GL (ST) :
-HYPERPLASIA, CYSTIC, -MINIMAL

^COLLECTED/TAKEN (XW) :
-LIVER SECTIONS, IN METHANOL

^DEATH COMMENT (DC) :
-SCHEDULED SACRIFICE, -PRESENT

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 769

STUDY NUMBER: 483287

ANIMAL NUMBER: A37411 SEX: FEMALE DOSE GROUP: 1 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/12/91 STUDY DAY OF DEATH: 96 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 24.1 GRAMS
DATE AND TIME OF NECROPSY: 11/12/91 9:57 PROSECTOR: JANE EARHARDT RECORDER: JANE EARHARDT
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE), KIDNEY (KD),
LACRIMAL GL, EX (EO), LIVER (LI), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU), MAMMARY, FEMALE (MF),
MAND SALIVARY GL (SG), MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON),
NERVE, SCIATIC (SN), OVARY (OV), PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), RECTUM (RE), SKIN (SK),
SKIN, OTHER (SS), SPLEEN (SP), STOMACH, GL (ST), STOMACH, NONGL (SU), THYMUS (TH), THYROID (TY), TONGUE (TO),
TRACHEA (TR), URINARY BLADDER (UB), UTERUS (UT), UTERUS, CERVIX (CV), VAGINA (VA)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:

ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, STERNUM (SB), BRAIN W/STEM (BR), CECUM (CE),
COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC), DUODENUM (DU), ESOPHAGUS (ES), EYE (EY),
GALLBLADDER (GB), HARDERIAN GLAND (HG), HEART (HT), HEMATO NEOPLASIA (HN), ILEUM (IL), JEJUNUM (JE), KIDNEY (KD),
LACRIMAL GL, EX (EO), LIVER (LI), LN, MANDIBULAR (MN), LUNG (LU), MAMMARY, FEMALE (MF), MAND SALIVARY GL (SG),
MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, ABDOM (MA), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON),
NERVE, SCIATIC (SN), OVARY (OV), OVIDUCT (OD), PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), RECTUM (RE),
SALIVARY, OTHER (OS), SKIN (SK), STOMACH, NONGL (SU), THYMUS (TH), THYROID (TY), TONGUE (TO), TRACHEA (TR),
URINARY BLADDER (UB), UTERUS (UT), UTERUS, CERVIX (CV), VAGINA (VA)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 770

STUDY NUMBER: 483287

ANIMAL NUMBER: A37412 SEX: FEMALE DOSE GROUP: 1 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/12/91 STUDY DAY OF DEATH: 96 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 23.2 GRAMS
DATE AND TIME OF NECROPSY: 11/12/91 11:06 PROSECTOR: DOUGLAS HERNDON RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.11	.493 %	.234	WEIGHT TAKEN
LUNG (LU)	.19	.807 %	.383	WEIGHT TAKEN
UTERUS (UT)	.23	.989 %	.470	WEIGHT TAKEN
BRAIN W/STEM (BR)	.49	2.105 %	1.000	WEIGHT TAKEN
HEART (HT)	.12	.518 %	.246	WEIGHT TAKEN
SPLEEN (SP)	.06	.260 %	.123	WEIGHT TAKEN
KIDNEY (KD)	.35	1.493 %	.709	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	1.01	4.358 %	2.070	WEIGHT TAKEN
ADRENAL (AD)	.014	.0586 %	.0279	WEIGHT TAKEN
OVARY (OV)	.047	.2039 %	.0969	WEIGHT TAKEN
THYMUS (TH)	.02	.086 %	.041	WEIGHT TAKEN

CLINICAL OBSERVATIONS	PATHOLOGY OBSERVATIONS NECROPSY	HISTOPATHOLOGY
-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS		ADRENAL, CORTEX (AC) : -PIGMENT,-MINIMAL -VACUOLIZATION, X-ZONE,-SLIGHT EYE (EY) : >TISSUE MISSING LIVER (LI) : -KUPFFER CELL/MACROPHAGE, PIGMENT,- MINIMAL -INFLAMMATION, CHRONIC/CHRONIC ACTIVE,- MINIMAL LN, MANDIBULAR (MN) : -MACROPHAGES, PIGMENTED,-MINIMAL LN, MESENTERIC (MS) : >TISSUE MISSING LN, OTHER (LN) : >UNREMARKABLE >NOTE:>SUBCUTANEOUS. NERVE, OPTIC (ON) : >TISSUE MISSING

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 771

STUDY NUMBER: 483287

ANIMAL NUMBER: A37412 SEX: FEMALE DOSE GROUP: 1 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/12/91 STUDY DAY OF DEATH: 96 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 23.2 GRAMS
DATE AND TIME OF NECROPSY: 11/12/91 11:06 PROSECTOR: DOUGLAS HERNDON RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

CLINICAL OBSERVATIONS

P A T H O L O G Y O B S E R V A T I O N S (CONTINUED)
NECROPSY

HISTOPATHOLOGY

PARATHYROID (PT) :
-UNILATERALLY EXAMINED, -PRESENT
PITUITARY (PI) :
-CYST, -PRESENT
SPLEEN (SP) :
-EXTRAMEDULLARY HEMATOPOIESIS,
INCREASED, -MINIMAL
-PIGMENT, -SLIGHT
URINARY BLADDER (UB) :
-INFLAMMATION, CHRONIC, -MINIMAL

^COLLECTED/TAKEN (XW) :
-LIVER SECTIONS, IN METHANOL

^DEATH COMMENT (DC) :
-SCHEDULED SACRIFICE, -PRESENT

HAZLETON WASHINGTON, INC.
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APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 772

STUDY NUMBER: 483287

ANIMAL NUMBER: A37412 SEX: FEMALE DOSE GROUP: 1 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/12/91 STUDY DAY OF DEATH: 96 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 23.2 GRAMS
DATE AND TIME OF NECROPSY: 11/12/91 11:06 PROSECTOR: DOUGLAS HERNDON RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE), KIDNEY (KD),
LACRIMAL GL, EX (EO), LIVER (LI), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU), MAMMARY, FEMALE (MF),
MAND SALIVARY GL (SG), MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON),
NERVE, SCIATIC (SN), OVARY (OV), PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), RECTUM (RE), SKIN (SK),
SKIN, OTHER (SS), SPLEEN (SP), STOMACH, GL (ST), STOMACH, NONGL (SU), THYMUS (TH), THYROID (TY), TONGUE (TO),
TRACHEA (TR), URINARY BLADDER (UB), UTERUS (UT), UTERUS, CERVIX (CV), VAGINA (VA)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:

ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, STERNUM (SB), BRAIN W/STEM (BR), CECUM (CE),
COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC), DUODENUM (DU), ESOPHAGUS (ES),
GALLBLADDER (GB), HEART (HT), HEMATO NEOPLASIA (HN), ILEUM (IL), JEJUNUM (JE), KIDNEY (KD), LACRIMAL GL, EX (EO),
LUNG (LU), MAMMARY, FEMALE (MF), MAND SALIVARY GL (SG), MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, ABDOM (MA),
MUSCLE, SKELETAL (SM), NERVE, SCIATIC (SN), OVARY (OV), OVIDUCT (OD), PANCREAS (PA), RECTUM (RE), SALIVARY, OTHER (OS),
SKIN (SK), STOMACH, GL (ST), STOMACH, NONGL (SU), THYMUS (TH), THYROID (TY), TONGUE (TO), TRACHEA (TR),
UTERUS (UT), UTERUS, CERVIX (CV), VAGINA (VA)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 773

STUDY NUMBER: 483287

ANIMAL NUMBER: A37413 SEX: FEMALE DOSE GROUP: 1 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/12/91 STUDY DAY OF DEATH: 96 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 23.7 GRAMS
DATE AND TIME OF NECROPSY: 11/12/91 13:16 PROSECTOR: JANE EARHARDT RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.16	.674 %	.290	WEIGHT TAKEN
LUNG (LU)	.17	.700 %	.302	WEIGHT TAKEN
UTERUS (UT)	.17	.738 %	.318	WEIGHT TAKEN
BRAIN W/STEM (BR)	.55	2.322 %	1.000	WEIGHT TAKEN
HEART (HT)	.14	.600 %	.258	WEIGHT TAKEN
SPLEEN (SP)	.07	.299 %	.129	WEIGHT TAKEN
KIDNEY (KD)	.34	1.442 %	.621	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	1.01	4.254 %	1.833	WEIGHT TAKEN
ADRENAL (AD)	.013	.0549 %	.0236	WEIGHT TAKEN
OVARY (OV)	.035	.1473 %	.0634	WEIGHT TAKEN
THYMUS (TH)	.03	.148 %	.064	WEIGHT TAKEN

CLINICAL OBSERVATIONS

PATHOLOGY OBSERVATIONS
NECROPSY

HISTOPATHOLOGY

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE
OBSERVATIONS

ADRENAL, CORTEX (AC) :
-VACUOLIZATION, X-ZONE,-MINIMAL
-HYPERPLASIA, SUBCAPSULAR CELL,-MINIMAL
BONE, FEMUR (FE) :
>TISSUE MISSING
CORD, CERVICAL (CS) :
>TISSUE MISSING
CORD, LUMBAR (LC) :
>TISSUE MISSING
CORD, THORACIC (TC) :
>TISSUE MISSING
LACRIMAL GL, EX (EO) :
>TISSUE MISSING
LIVER (LI) :
-INFLAMMATION, CHRONIC/CHRONIC ACTIVE,-
MINIMAL
LN, MESENTERIC (MS) :
-MACROPHAGES, PIGMENTED,-MINIMAL

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 774

STUDY NUMBER: 483287

ANIMAL NUMBER: A37413 SEX: FEMALE DOSE GROUP: 1 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/12/91 STUDY DAY OF DEATH: 96 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 23.7 GRAMS
DATE AND TIME OF NECROPSY: 11/12/91 13:16 PROSECTOR: JANE EARHARDT RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

CLINICAL OBSERVATIONS PATHOLOGY OBSERVATIONS (CONTINUED) HISTOPATHOLOGY
NECROPSY

MARROW, FEMUR (FM) :
>TISSUE MISSING
MUSCLE, SKELETAL (SM) :
>TISSUE MISSING
NERVE, SCIATIC (SN) :
>TISSUE MISSING
PARATHYROID (PT) :
-UNILATERALLY EXAMINED, -PRESENT
PITUITARY (PI) :
>TISSUE MISSING
SPLEEN (SP) :
-EXTRAMEDULLARY HEMATOPOIESIS,
INCREASED, -SLIGHT
-PIGMENT, -SLIGHT
TONGUE (TO) :
>TISSUE MISSING
UTERUS (UT) :
-HYPERPLASIA, CYSTIC ENDOMETRIAL, -
MINIMAL

^COLLECTED/TAKEN (XW) :
-LIVER SECTIONS, IN METHANOL

^DEATH COMMENT (DC) :
-SCHEDULED SACRIFICE, -PRESENT

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 775

STUDY NUMBER: 483287

ANIMAL NUMBER: A37413 SEX: FEMALE DOSE GROUP: 1 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/12/91 STUDY DAY OF DEATH: 96 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 23.7 GRAMS
DATE AND TIME OF NECROPSY: 11/12/91 13:16 PROSECTOR: JANE EARHARDT RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE), KIDNEY (KD),
LACRIMAL GL, EX (EO), LIVER (LI), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU), MAMMARY, FEMALE (MF),
MAND SALIVARY GL (SG), MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON),
NERVE, SCIATIC (SN), OVARY (OV), PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), RECTUM (RE), SKIN (SK),
SKIN, OTHER (SS), SPLEEN (SP), STOMACH, GL (ST), STOMACH, NONGL (SU), THYMUS (TH), THYROID (TY), TONGUE (TO),
TRACHEA (TR), URINARY BLADDER (UB), UTERUS (UT), UTERUS, CERVIX (CV), VAGINA (VA)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:

ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, STERNUM (SB), BRAIN W/STEM (BR), CECUM (CE), COLON (CO),
DUODENUM (DU), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HARDERIAN GLAND (HG), HEART (HT), HEMATO NEOPLASIA (HN),
ILEUM (IL), JEJUNUM (JE), KIDNEY (KD), LN, MANDIBULAR (MN), LUNG (LU), MAMMARY, FEMALE (MF), MAND SALIVARY GL (SG),
MARROW, STERNUM (SE), MUSCLE, ABDOM (MA), NERVE, OPTIC (ON), OVARY (OV), OVIDUCT (OD), PANCREAS (PA), RECTUM (RE),
SALIVARY, OTHER (OS), SKIN (SK), STOMACH, GL (ST), STOMACH, NONGL (SU), THYMUS (TH), THYROID (TY), TRACHEA (TR),
URINARY BLADDER (UB), UTERUS, CERVIX (CV), VAGINA (VA)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 776

STUDY NUMBER: 483287

ANIMAL NUMBER: A37414 SEX: FEMALE DOSE GROUP: 1 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/13/91 STUDY DAY OF DEATH: 97 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 20.4 GRAMS
DATE AND TIME OF NECROPSY: 11/19/91 8:51 PROSECTOR: SCOTT BELL RECORDER: SCOTT BELL
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.14	.709 %	.276	WEIGHT TAKEN
LUNG (LU)	.17	.822 %	.320	WEIGHT TAKEN
UTERUS (UT)	.16	.763 %	.297	WEIGHT TAKEN
BRAIN W/STEM (BR)	.52	2.566 %	1.000	WEIGHT TAKEN
HEART (HT)	.15	.730 %	.284	WEIGHT TAKEN
SPLEEN (SP)	.04	.203 %	.079	WEIGHT TAKEN
KIDNEY (KD)	.34	1.655 %	.645	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	.95	4.632 %	1.806	WEIGHT TAKEN
ADRENAL (AD)	.014	.0706 %	.0275	WEIGHT TAKEN
OVARY (OV)	.044	.2142 %	.0835	WEIGHT TAKEN
THYMUS (TH)	.03	.153 %	.060	WEIGHT TAKEN

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE
OBSERVATIONS

PATHOLOGY OBSERVATIONS
NECROPSY

HISTOPATHOLOGY

ADRENAL, CORTEX (AC) :
-VACUOLIZATION, X-ZONE,-MODERATE
-HYPERPLASIA, SUBCAPSULAR CELL,-MINIMAL
KIDNEY (KD) :
-INFLAMMATION, CHRONIC,-MINIMAL
-HYPERPLASIA, LYMPHOID,-MINIMAL
LN, MANDIBULAR (MN) :
-MACROPHAGES, PIGMENTED,-MINIMAL
LN, OTHER (LN) :
>UNREMARKABLE
>NOTE:>SUBCUTANEOUS AND PANCREATIC.
LUNG (LU) :
-PERIBRONCHIAL/PERIVASCULAR,
INFILTRATION, LYMPHOID,-MINIMAL
SPLEEN (SP) :
-EXTRAMEDULLARY HEMATOPOIESIS,
INCREASED,-MINIMAL
-PIGMENT,-SLIGHT

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 777

STUDY NUMBER: 483287

ANIMAL NUMBER: A37414 SEX: FEMALE DOSE GROUP: 1 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/13/91 STUDY DAY OF DEATH: 97 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 20.4 GRAMS
DATE AND TIME OF NECROPSY: 11/19/91 8:51 PROSECTOR: SCOTT BELL RECORDER: SCOTT BELL
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

CLINICAL OBSERVATIONS	P A T H O L O G Y O B S E R V A T I O N S (CONTINUED)		HISTOPATHOLOGY
	NECROPSY		
			THYMUS (TH) : -CYST,-PRESENT
			UTERUS (UT) : -HYPERPLASIA, CYSTIC ENDOMETRIAL,- MINIMAL
			-HYPOPLASIA,-MINIMAL
	^COLLECTED/TAKEN (XW) : -LIVER SECTIONS, IN METHANOL		
			^DEATH COMMENT (DC) : -SCHEDULED SACRIFICE,-PRESENT

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE), KIDNEY (KD),
LACRIMAL GL, EX (EO), LIVER (LI), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU), MAMMARY, FEMALE (MF),
MAND SALIVARY GL (SG), MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON),
NERVE, SCIATIC (SN), OVARY (OV), PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), RECTUM (RE), SKIN (SK),
SKIN, OTHER (SS), SPLEEN (SP), STOMACH, GL (ST), STOMACH, NONGL (SU), THYMUS (TH), THYROID (TY), TONGUE (TO),
TRACHEA (TR), URINARY BLADDER (UB), UTERUS (UT), UTERUS, CERVIX (CV), VAGINA (VA)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:

ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, STERNUM (SB), BRAIN W/STEM (BR), CECUM (CE),
COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC), DUODENUM (DU), ESOPHAGUS (ES), EYE (EY),
GALLBLADDER (GB), HARDERIAN GLAND (HG), HEART (HT), HEMATO NEOPLASIA (HN), ILEUM (IL), JEJUNUM (JE),
LACRIMAL GL, EX (EO), LIVER (LI), LN, MESENTERIC (MS), MAMMARY, FEMALE (MF), MAND SALIVARY GL (SG),
MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, ABDOM (MA), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON),
NERVE, SCIATIC (SN), OVARY (OV), OVIDUCT (OD), PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), RECTUM (RE),
SALIVARY, OTHER (OS), SKIN (SK), STOMACH, GL (ST), STOMACH, NONGL (SU), THYROID (TY), TONGUE (TO), TRACHEA (TR),
URINARY BLADDER (UB), UTERUS, CERVIX (CV), VAGINA (VA)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 778

STUDY NUMBER: 483287

ANIMAL NUMBER: A37415 SEX: FEMALE DOSE GROUP: 1 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/13/91 STUDY DAY OF DEATH: 97 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 25.5 GRAMS
DATE AND TIME OF NECROPSY: 11/13/91 9:42 PROSECTOR: LINDA RUMBLE RECORDER: LINDA RUMBLE
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.14	.545 %	.285	WEIGHT TAKEN
LUNG (LU)	.22	.873 %	.456	WEIGHT TAKEN
UTERUS (UT)	.21	.820 %	.429	WEIGHT TAKEN
BRAIN W/STEM (BR)	.49	1.913 %	1.000	WEIGHT TAKEN
HEART (HT)	.15	.591 %	.309	WEIGHT TAKEN
SPLEEN (SP)	.10	.384 %	.201	WEIGHT TAKEN
KIDNEY (KD)	.39	1.525 %	.797	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	1.30	5.111 %	2.672	WEIGHT TAKEN
ADRENAL (AD)	.012	.0467 %	.0244	WEIGHT TAKEN
OVARY (OV)	.049	.1937 %	.1013	WEIGHT TAKEN
THYMUS (TH)	.04	.170 %	.089	WEIGHT TAKEN

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE
OBSERVATIONS

PATHOLOGY OBSERVATIONS
NECROPSY

HISTOPATHOLOGY

ADRENAL, CORTEX (AC) :
-VACUOLIZATION, X-ZONE,-SLIGHT
-HYPERPLASIA, SUBCAPSULAR CELL,-MINIMAL
LACRIMAL GL, EX (EO) :
-INFLAMMATION, CHRONIC,-MINIMAL
LIVER (LI) :
-INFLAMMATION, CHRONIC/CHRONIC ACTIVE,-
MINIMAL
-BILE DUCT, INFLAMMATION, CHRONIC,-
MINIMAL
LN, OTHER (LN) :
>UNREMARKABLE
>NOTE:>SUBCUTANEOUS.
LUNG (LU) :
-PERIBRONCHIAL/PERIVASCULAR,
INFILTRATION, LYMPHOID,-MINIMAL
NERVE, OPTIC (ON) :
-UNILATERALLY EXAMINED,-PRESENT

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 779

STUDY NUMBER: 483287

ANIMAL NUMBER: A37415 SEX: FEMALE DOSE GROUP: 1 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/13/91 STUDY DAY OF DEATH: 97 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 25.5 GRAMS
DATE AND TIME OF NECROPSY: 11/13/91 9:42 PROSECTOR: LINDA RUMBLE RECORDER: LINDA RUMBLE
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

CLINICAL OBSERVATIONS	P A T H O L O G Y O B S E R V A T I O N S (CONTINUED) NECROPSY	HISTOPATHOLOGY
		OVARY (OV) : -FOLLICLE, CYST, -PRESENT RECTUM (RE) : -HYPERPLASIA, LYMPHOID, -PRESENT SPLEEN (SP) : -EXTRAMEDULLARY HEMATOPOIESIS, INCREASED, -SLIGHT -PIGMENT, -SLIGHT STOMACH, GL (ST) : -HYPERPLASIA, CYSTIC, -MINIMAL UTERUS (UT) : -HYPERPLASIA, CYSTIC ENDOMETRIAL, - MINIMAL ^COLLECTED/TAKEN (XW) : -LIVER SECTIONS, IN METHANOL ^DEATH COMMENT (DC) : -SCHEDULED SACRIFICE, -PRESENT

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 780

STUDY NUMBER: 483287

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DATE AND TIME OF NECROPSY: 11/13/91 9:42 PROSECTOR: LINDA RUMBLE RECORDER: LINDA RUMBLE
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE), KIDNEY (KD),
LACRIMAL GL, EX (EO), LIVER (LI), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU), MAMMARY, FEMALE (MF),
MAND SALIVARY GL (SG), MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON),
NERVE, SCIATIC (SN), OVARY (OV), PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), RECTUM (RE), SKIN (SK),
SKIN, OTHER (SS), SPLEEN (SP), STOMACH, GL (ST), STOMACH, NONGL (SU), THYMUS (TH), THYROID (TY), TONGUE (TO),
TRACHEA (TR), URINARY BLADDER (UB), UTERUS (UT), UTERUS, CERVIX (CV), VAGINA (VA)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:

ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, STERNUM (SB), BRAIN W/STEM (BR), CECUM (CE),
COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC), DUODENUM (DU), ESOPHAGUS (ES), EYE (EY),
GALLBLADDER (GB), HARDERIAN GLAND (HG), HEART (HT), HEMATO NEOPLASIA (HN), ILEUM (IL), JEJUNUM (JE), KIDNEY (KD),
LN, MANDIBULAR (MN), LN, MESENTERIC (MS), MAMMARY, FEMALE (MF), MAND SALIVARY GL (SG), MARROW, FEMUR (FM),
MARROW, STERNUM (SE), MUSCLE, ABDOM (MA), MUSCLE, SKELETAL (SM), NERVE, SCIATIC (SN), OVIDUCT (OD), PANCREAS (PA),
PARATHYROID (PT), PITUITARY (PI), SALIVARY, OTHER (OS), SKIN (SK), STOMACH, NONGL (SU), THYMUS (TH), THYROID (TY),
TONGUE (TO), TRACHEA (TR), URINARY BLADDER (UB), UTERUS, CERVIX (CV), VAGINA (VA)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 781

STUDY NUMBER: 483287

ANIMAL NUMBER: A37416 SEX: FEMALE DOSE GROUP: 1 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/13/91 STUDY DAY OF DEATH: 97 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 25.5 GRAMS
DATE AND TIME OF NECROPSY: 11/13/91 10:55 PROSECTOR: SCOTT BELL RECORDER: SCOTT BELL
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.17	.673 %	.338	WEIGHT TAKEN
LUNG (LU)	.19	.755 %	.379	WEIGHT TAKEN
UTERUS (UT)	.14	.538 %	.270	WEIGHT TAKEN
BRAIN W/STEM (BR)	.51	1.989 %	1.000	WEIGHT TAKEN
HEART (HT)	.13	.521 %	.262	WEIGHT TAKEN
SPLEEN (SP)	.06	.252 %	.127	WEIGHT TAKEN
KIDNEY (KD)	.41	1.602 %	.805	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	1.19	4.654 %	2.339	WEIGHT TAKEN
ADRENAL (AD)	.016	.0624 %	.0313	WEIGHT TAKEN
OVARY (OV)	.030	.1169 %	.0587	WEIGHT TAKEN
THYMUS (TH)	.05	.204 %	.103	WEIGHT TAKEN

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE
OBSERVATIONS

PATHOLOGY OBSERVATIONS
NECROPSY

HISTOPATHOLOGY

ADRENAL, CORTEX (AC) :
-PIGMENT,-MINIMAL
-VACUOLIZATION, X-ZONE,-MINIMAL
-HYPERPLASIA, SUBCAPSULAR CELL,-MINIMAL
EYE (EV) :
-CORNEA, MINERALIZATION,-SLIGHT, FOCAL
KIDNEY (KD) :
-INFLAMMATION, CHRONIC,-MINIMAL
-TUBULE, MINERALIZATION,-MINIMAL
LIVER (LI) :
-INFLAMMATION, CHRONIC/CHRONIC ACTIVE,-
MINIMAL
LN, OTHER (LN) :
>UNREMARKABLE
>NOTE:>SUBCUTANEOUS.
LUNG (LU) :
-PERIBRONCHIAL/PERIVASCULAR,
INFILTRATION, LYMPHOID,-MINIMAL

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 782

STUDY NUMBER: 483287

ANIMAL NUMBER: A37416 SEX: FEMALE DOSE GROUP: 1 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/13/91 STUDY DAY OF DEATH: 97 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 25.5 GRAMS
DATE AND TIME OF NECROPSY: 11/13/91 10:55 PROSECTOR: SCOTT BELL RECORDER: SCOTT BELL
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

CLINICAL OBSERVATIONS P A T H O L O G Y O B S E R V A T I O N S (CONTINUED)
NECROPSY HISTOPATHOLOGY

^COLLECTED/TAKEN (XW) :
-LIVER SECTIONS, IN METHANOL

NERVE, OPTIC (ON) :
-UNILATERALLY EXAMINED, -PRESENT
SPLEEN (SP) :
-EXTRAMEDULLARY HEMATOPOIESIS,
INCREASED, -MINIMAL
-PIGMENT, -SLIGHT
URINARY BLADDER (UB) :
>TISSUE MISSING
UTERUS (UT) :
-HYPOPLASIA, -MODERATE
UTERUS, CERVIX (CV) :
-HYPOPLASIA, -MINIMAL
VAGINA (VA) :
-CYST, KERATIN, -PRESENT

^DEATH COMMENT (DC) :
-SCHEDULED SACRIFICE, -PRESENT

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 783

STUDY NUMBER: 483287

ANIMAL NUMBER: A37416 SEX: FEMALE DOSE GROUP: 1 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
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DATE AND TIME OF NECROPSY: 11/13/91 10:55 PROSECTOR: SCOTT BELL RECORDER: SCOTT BELL
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE), KIDNEY (KD),
LACRIMAL GL, EX (EO), LIVER (LI), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU), MAMMARY, FEMALE (MF),
MAND SALIVARY GL (SG), MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON),
NERVE, SCIATIC (SN), OVARY (OV), PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), RECTUM (RE), SKIN (SK),
SKIN, OTHER (SS), SPLEEN (SP), STOMACH, GL (ST), STOMACH, NONGL (SU), THYMUS (TH), THYROID (TY), TONGUE (TO),
TRACHEA (TR), URINARY BLADDER (UB), UTERUS (UT), UTERUS, CERVIX (CV), VAGINA (VA)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:

ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, STERNUM (SB), BRAIN W/STEM (BR), CECUM (CE),
COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC), DUODENUM (DU), ESOPHAGUS (ES),
GALLBLADDER (GB), HARDERIAN GLAND (HG), HEART (HT), HEMATO NEOPLASIA (HN), ILEUM (IL), JEJUNUM (JE),
LACRIMAL GL, EX (EO), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), MAMMARY, FEMALE (MF), MAND SALIVARY GL (SG),
MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, ABDOM (MA), MUSCLE, SKELETAL (SM), NERVE, SCIATIC (SN), OVARY (OV),
OVIDUCT (OD), PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), RECTUM (RE), SALIVARY, OTHER (OS), SKIN (SK),
STOMACH, GL (ST), STOMACH, NONGL (SU), THYMUS (TH), THYROID (TY), TONGUE (TO), TRACHEA (TR)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 784

STUDY NUMBER: 483287

ANIMAL NUMBER: A37417 SEX: FEMALE DOSE GROUP: 1 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/13/91 STUDY DAY OF DEATH: 97 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 22.5 GRAMS
DATE AND TIME OF NECROPSY: 11/13/91 13:21 PROSECTOR: SCOTT BELL RECORDER: SCOTT BELL
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.13	.600 %	.264	WEIGHT TAKEN
LUNG (LU)	.18	.780 %	.343	WEIGHT TAKEN
UTERUS (UT)	.29	1.280 %	.563	WEIGHT TAKEN
BRAIN W/STEM (BR)	.51	2.272 %	1.000	WEIGHT TAKEN
HEART (HT)	.13	.581 %	.256	WEIGHT TAKEN
SPLEEN (SP)	.06	.248 %	.109	WEIGHT TAKEN
KIDNEY (KD)	.40	1.769 %	.779	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	.95	4.244 %	1.868	WEIGHT TAKEN
ADRENAL (AD)	.012	.0516 %	.0227	WEIGHT TAKEN
OVARY (OV)	.046	.2058 %	.0906	WEIGHT TAKEN
THYMUS (TH)	.02	.108 %	.048	WEIGHT TAKEN

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE
OBSERVATIONS

PATHOLOGY OBSERVATIONS
NECROPSY

HISTOPATHOLOGY

ADRENAL, CORTEX (AC) :
-VACUOLIZATION, X-ZONE,-MODERATE
-HYPERPLASIA, SUBCAPSULAR CELL,-MINIMAL
HARDERIAN GLAND (HG) :
-INFLAMMATION, CHRONIC,-PRESENT
HEART (HT) :
-INFLAMMATION, CHRONIC,-MINIMAL
LIVER (LI) :
-KUPFFER CELL/MACROPHAGE, PIGMENT,-
MINIMAL
-INFLAMMATION, CHRONIC/CHRONIC ACTIVE,-
MINIMAL
LN, MANDIBULAR (MN) :
-MACROPHAGES, PIGMENTED,-MINIMAL
NERVE, OPTIC (ON) :
-UNILATERALLY EXAMINED,-PRESENT
PANCREAS (PA) :
-ISLET CELL, HYPERPLASIA,-MINIMAL

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

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PAGE: 785

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DATE AND TIME OF NECROPSY: 11/13/91 13:21 PROSECTOR: SCOTT BELL RECORDER: SCOTT BELL
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

CLINICAL OBSERVATIONS PATHOLOGY OBSERVATIONS (CONTINUED) HISTOPATHOLOGY
NECROPSY

^COLLECTED/TAKEN (XW) :
-LIVER SECTIONS, IN METHANOL

PARATHYROID (PT) :
-UNILATERALLY EXAMINED, -PRESENT
RECTUM (RE) :
-HYPERPLASIA, LYMPHOID, -PRESENT
SPLEEN (SP) :
-PIGMENT, -SLIGHT
THYMUS (TH) :
-NECROSIS, LYMPHOID, -MODERATE
UTERUS (UT) :
-HYPERPLASIA, CYSTIC ENDOMETRIAL, -
MINIMAL

^DEATH COMMENT (DC) :
-SCHEDULED SACRIFICE, -PRESENT

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
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THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE), KIDNEY (KD),
LACRIMAL GL, EX (EO), LIVER (LI), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU), MAMMARY, FEMALE (MF),
MAND SALIVARY GL (SG), MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON),
NERVE, SCIATIC (SN), OVARY (OV), PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), RECTUM (RE), SKIN (SK),
SKIN, OTHER (SS), SPLEEN (SP), STOMACH, GL (ST), STOMACH, NONGL (SU), THYMUS (TH), THYROID (TY), TONGUE (TO),
TRACHEA (TR), URINARY BLADDER (UB), UTERUS (UT), UTERUS, CERVIX (CV), VAGINA (VA)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:

ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, STERNUM (SB), BRAIN W/STEM (BR), CECUM (CE),
COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC), DUODENUM (DU), ESOPHAGUS (ES), EYE (EY),
GALLBLADDER (GB), HEMATO NEOPLASIA (HN), ILEUM (IL), JEJUNUM (JE), KIDNEY (KD), LACRIMAL GL, EX (EO),
LN, MESENTERIC (MS), LUNG (LU), MAMMARY, FEMALE (MF), MAND SALIVARY GL (SG), MARROW, FEMUR (FM), MARROW, STERNUM (SE),
MUSCLE, ABDOM (MA), MUSCLE, SKELETAL (SM), NERVE, SCIATIC (SN), OVARY (OV), OVIDUCT (OD), PITUITARY (PI), SKIN (SK),
STOMACH, GL (ST), STOMACH, NONGL (SU), THYROID (TY), TONGUE (TO), TRACHEA (TR), URINARY BLADDER (UB),
UTERUS, CERVIX (CV), VAGINA (VA)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 787

STUDY NUMBER: 483287

ANIMAL NUMBER: A37418 SEX: FEMALE DOSE GROUP: 1 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/14/91 STUDY DAY OF DEATH: 98 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 24.6 GRAMS
DATE AND TIME OF NECROPSY: 11/14/91 8:09 PROSECTOR: FRED AGEY RECORDER: FRED AGEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.19	.775 %	.391	WEIGHT TAKEN
LUNG (LU)	.16	.643 %	.325	WEIGHT TAKEN
UTERUS (UT)	.21	.848 %	.428	WEIGHT TAKEN
BRAIN W/STEM (BR)	.49	1.981 %	1.000	WEIGHT TAKEN
HEART (HT)	.13	.517 %	.261	WEIGHT TAKEN
SPLEEN (SP)	.06	.254 %	.128	WEIGHT TAKEN
KIDNEY (KD)	.36	1.466 %	.740	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	1.09	4.421 %	2.232	WEIGHT TAKEN
ADRENAL (AD)	.012	.0500 %	.0252	WEIGHT TAKEN
OVARY (OV)	.024	.0963 %	.0486	WEIGHT TAKEN
THYMUS (TH)	.04	.143 %	.072	WEIGHT TAKEN

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE
OBSERVATIONS

PATHOLOGY OBSERVATIONS
NECROPSY

HISTOPATHOLOGY

ADRENAL, CORTEX (AC) :
-PIGMENT,-MINIMAL
-HYPERPLASIA, SUBCAPSULAR CELL,-MINIMAL
KIDNEY (KD) :
-INFLAMMATION, CHRONIC,-MINIMAL
-PIGMENT,-MINIMAL
LIVER (LI) :
-BILE DUCT, INFLAMMATION, CHRONIC,-
MINIMAL
LN, MANDIBULAR (MN) :
-MACROPHAGES, PIGMENTED,-MINIMAL
LN, MESENTERIC (MS) :
-MACROPHAGES, PIGMENTED,-MINIMAL
LN, OTHER (LN) :
>UNREMARKABLE
>NOTE:>SUBCUTANEOUS.
PANCREAS (PA) :
-INFLAMMATION, CHRONIC,-MINIMAL

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 788

STUDY NUMBER: 483287

ANIMAL NUMBER: A37418 SEX: FEMALE DOSE GROUP: 1 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/14/91 STUDY DAY OF DEATH: 98 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 24.6 GRAMS
DATE AND TIME OF NECROPSY: 11/14/91 8:09 PROSECTOR: FRED AGEY RECORDER: FRED AGEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

CLINICAL OBSERVATIONS PATHOLOGY OBSERVATIONS (CONTINUED) HISTOPATHOLOGY
NECROPSY

^COLLECTED/TAKEN (XW) :
-LIVER SECTIONS, IN METHANOL

SPLEEN (SP) :
-EXTRAMEDULLARY HEMATOPOIESIS,
INCREASED, -MINIMAL
-PIGMENT, -MINIMAL
STOMACH, GL (ST) :
-INFLAMMATION, CHRONIC, -MINIMAL
UTERUS (UT) :
-HYPERPLASIA, CYSTIC ENDOMETRIAL, -
MINIMAL

^DEATH COMMENT (DC) :
-SCHEDULED SACRIFICE, -PRESENT

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 789

STUDY NUMBER: 483287

ANIMAL NUMBER: A37418 SEX: FEMALE DOSE GROUP: 1 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/14/91 STUDY DAY OF DEATH: 98 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 24.6 GRAMS
DATE AND TIME OF NECROPSY: 11/14/91 8:09 PROSECTOR: FRED AGEY RECORDER: FRED AGEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE), KIDNEY (KD),
LACRIMAL GL, EX (EO), LIVER (LI), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU), MAMMARY, FEMALE (MF),
MAND SALIVARY GL (SG), MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON),
NERVE, SCIATIC (SN), OVARY (OV), PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), RECTUM (RE), SKIN (SK),
SKIN, OTHER (SS), SPLEEN (SP), STOMACH, GL (ST), STOMACH, NONGL (SU), THYMUS (TH), THYROID (TY), TONGUE (TO),
TRACHEA (TR), URINARY BLADDER (UB), UTERUS (UT), UTERUS, CERVIX (CV), VAGINA (VA)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:

ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, STERNUM (SB), BRAIN W/STEM (BR), CECUM (CE),
COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC), DUODENUM (DU), ESOPHAGUS (ES), EYE (EY),
GALLBLADDER (GB), HARDERIAN GLAND (HG), HEART (HT), HEMATO NEOPLASIA (HN), ILEUM (IL), JEJUNUM (JE),
LACRIMAL GL, EX (EO), LUNG (LU), MAMMARY, FEMALE (MF), MAND SALIVARY GL (SG), MARROW, FEMUR (FM), MARROW, STERNUM (SE),
MUSCLE, ABDOM (MA), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON), NERVE, SCIATIC (SN), OVARY (OV), OVIDUCT (OD),
PARATHYROID (PT), PITUITARY (PI), RECTUM (RE), SALIVARY, OTHER (OS), SKIN (SK), STOMACH, NONGL (SU), THYMUS (TH),
THYROID (TY), TONGUE (TO), TRACHEA (TR), URINARY BLADDER (UB), UTERUS, CERVIX (CV), VAGINA (VA)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 790

STUDY NUMBER: 483287

ANIMAL NUMBER: A37419 SEX: FEMALE DOSE GROUP: 1 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/14/91 STUDY DAY OF DEATH: 98 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 26.5 GRAMS
DATE AND TIME OF NECROPSY: 11/14/91 9:07 PROSECTOR: JANE EARHARDT RECORDER: JANE EARHARDT
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.15	.576 %	.265	WEIGHT TAKEN
LUNG (LU)	.23	.877 %	.403	WEIGHT TAKEN
UTERUS (UT)	.15	.583 %	.268	WEIGHT TAKEN
BRAIN W/STEM (BR)	.58	2.174 %	1.000	WEIGHT TAKEN
HEART (HT)	.13	.504 %	.232	WEIGHT TAKEN
SPLEEN (SP)	.11	.412 %	.190	WEIGHT TAKEN
KIDNEY (KD)	.41	1.558 %	.717	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	1.19	4.508 %	2.074	WEIGHT TAKEN
ADRENAL (AD)	.013	.0502 %	.0231	WEIGHT TAKEN
OVARY (OV)	.040	.1521 %	.0700	WEIGHT TAKEN
THYMUS (TH)	.03	.118 %	.054	WEIGHT TAKEN

CLINICAL OBSERVATIONS	PATHOLOGY OBSERVATIONS NECROPSY	HISTOPATHOLOGY
-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS		ADRENAL, CORTEX (AC) : -PIGMENT,-MINIMAL -VACUOLIZATION, X-ZONE,-MODERATE -HYPERPLASIA, SUBCAPSULAR CELL,-MINIMAL COLON (CO) : -HYPERPLASIA, LYMPHOID,-PRESENT LN, MANDIBULAR (MN) : -MACROPHAGES, PIGMENTED,-MINIMAL LN, MESENTERIC (MS) : -MACROPHAGES, PIGMENTED,-MINIMAL LN, OTHER (LN) : >UNREMARKABLE >NOTE:>SUBCUTANEOUS. LUNG (LU) : -PERIBRONCHIAL/PERIVASCULAR, INFILTRATION, LYMPHOID,-MINIMAL -INFLAMMATION, CHRONIC,-MINIMAL NERVE, OPTIC (ON) : -UNILATERALLY EXAMINED,-PRESENT

HAZLETON WASHINGTON, INC.
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APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 791

STUDY NUMBER: 483287

ANIMAL NUMBER: A37419 SEX: FEMALE DOSE GROUP: 1 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/14/91 STUDY DAY OF DEATH: 98 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 26.5 GRAMS
DATE AND TIME OF NECROPSY: 11/14/91 9:07 PROSECTOR: JANE EARHARDT RECORDER: JANE EARHARDT
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

CLINICAL OBSERVATIONS	PATHOLOGY OBSERVATIONS (CONTINUED) NECROPSY	HISTOPATHOLOGY
		PARATHYROID (PT) : -UNILATERALLY EXAMINED, -PRESENT SPLEEN (SP) : -EXTRAMEDULLARY HEMATOPOIESIS, INCREASED, -SLIGHT -PIGMENT, -SLIGHT STOMACH, GL (ST) : -INFLAMMATION, CHRONIC, -MINIMAL URINARY BLADDER (UB) : -INFLAMMATION, CHRONIC, -MINIMAL UTERUS (UT) : -HYPERPLASIA, CYSTIC ENDOMETRIAL, - MINIMAL ^COLLECTED/TAKEN (XW) : -LIVER SECTIONS, IN METHANOL ^DEATH COMMENT (DC) : -SCHEDULED SACRIFICE, -PRESENT

HAZLETON WASHINGTON, INC.
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13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 792

STUDY NUMBER: 483287

ANIMAL NUMBER: A37419 SEX: FEMALE DOSE GROUP: 1 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/14/91 STUDY DAY OF DEATH: 98 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 26.5 GRAMS
DATE AND TIME OF NECROPSY: 11/14/91 9:07 PROSECTOR: JANE EARHARDT RECORDER: JANE EARHARDT
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE), KIDNEY (KD),
LACRIMAL GL, EX (EO), LIVER (LI), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU), MAMMARY, FEMALE (MF),
MAND SALIVARY GL (SG), MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON),
NERVE, SCIATIC (SN), OVARY (OV), PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), RECTUM (RE), SKIN (SK),
SKIN, OTHER (SS), SPLEEN (SP), STOMACH, GL (ST), STOMACH, NONGL (SU), THYMUS (TH), THYROID (TY), TONGUE (TO),
TRACHEA (TR), URINARY BLADDER (UB), UTERUS (UT), UTERUS, CERVIX (CV), VAGINA (VA)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:

ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, STERNUM (SB), BRAIN W/STEM (BR), CECUM (CE),
CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC), DUODENUM (DU), ESOPHAGUS (ES), EYE (EY),
GALLBLADDER (GB), HARDERIAN GLAND (HG), HEART (HT), HEMATO NEOPLASIA (HN), ILEUM (IL), JEJUNUM (JE), KIDNEY (KD),
LACRIMAL GL, EX (EO), LIVER (LI), MAMMARY, FEMALE (MF), MAND SALIVARY GL (SG), MARROW, FEMUR (FM),
MARROW, STERNUM (SE), MUSCLE, ABDOM (MA), MUSCLE, SKELETAL (SM), NERVE, SCIATIC (SN), OVARY (OV), OVIDUCT (OD),
PANCREAS (PA), PITUITARY (PI), RECTUM (RE), SALIVARY, OTHER (OS), SKIN (SK), STOMACH, NONGL (SU), THYMUS (TH),
THYROID (TY), TONGUE (TO), TRACHEA (TR), UTERUS, CERVIX (CV), VAGINA (VA)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 793

STUDY NUMBER: 483287

ANIMAL NUMBER: A37420 SEX: FEMALE DOSE GROUP: 1 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/14/91 STUDY DAY OF DEATH: 98 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 22.5 GRAMS
DATE AND TIME OF NECROPSY: 11/14/91 10:00 PROSECTOR: JANE EARHARDT RECORDER: JANE EARHARDT
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.16	.729 %	.308	WEIGHT TAKEN
LUNG (LU)	.20	.894 %	.378	WEIGHT TAKEN
UTERUS (UT)	.18	.778 %	.329	WEIGHT TAKEN
BRAIN W/STEM (BR)	.53	2.367 %	1.000	WEIGHT TAKEN
HEART (HT)	.12	.541 %	.229	WEIGHT TAKEN
SPLEEN (SP)	.06	.261 %	.110	WEIGHT TAKEN
KIDNEY (KD)	.39	1.728 %	.730	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	1.01	4.492 %	1.898	WEIGHT TAKEN
ADRENAL (AD)	.015	.0667 %	.0282	WEIGHT TAKEN
OVARY (OV)	.032	.1444 %	.0610	WEIGHT TAKEN
THYMUS (TH)	.03	.123 %	.052	WEIGHT TAKEN

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE
OBSERVATIONS

PATHOLOGY OBSERVATIONS
NECROPSY

HISTOPATHOLOGY

ADRENAL, CORTEX (AC) :
-VACUOLIZATION, X-ZONE,-MODERATELY
SEVERE
CAVITY, ABDOM (PC) :
-ADHESION,-PRESENT
>NOTE:>PANCREAS TO SPLEEN
KIDNEY (KD) :
-INFLAMMATION, CHRONIC,-MINIMAL
-PIGMENT,-MINIMAL
-CYST,-PRESENT
LN, MANDIBULAR (MN) :
-MACROPHAGES, PIGMENTED,-MINIMAL
LUNG (LU) :
-PERIBRONCHIAL/PERIVASCULAR,
INFILTRATION, LYMPHOID,-MINIMAL
PARATHYROID (PT) :
-UNILATERALLY EXAMINED,-PRESENT

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 794

STUDY NUMBER: 483287

ANIMAL NUMBER: A37420 SEX: FEMALE DOSE GROUP: 1 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/14/91 STUDY DAY OF DEATH: 98 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 22.5 GRAMS
DATE AND TIME OF NECROPSY: 11/14/91 10:00 PROSECTOR: JANE EARHARDT RECORDER: JANE EARHARDT
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

CLINICAL OBSERVATIONS	P A T H O L O G Y O B S E R V A T I O N S (CONTINUED) NECROPSY	HISTOPATHOLOGY
		SPLEEN (SP) : -EXTRAMEDULLARY HEMATOPOIESIS, INCREASED,-SLIGHT -PIGMENT,-SLIGHT UTERUS, CERVIX (CV) : >TISSUE MISSING
	^COLLECTED/TAKEN (XW) : -LIVER SECTIONS, IN METHANOL	^DEATH COMMENT (DC) : -SCHEDULED SACRIFICE,-PRESENT
THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY: ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB), BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC), DUODENUM (DU), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE), KIDNEY (KD), LACRIMAL GL, EX (EO), LIVER (LI), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU), MAMMARY, FEMALE (MF), MAND SALIVARY GL (SG), MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON), NERVE, SCIATIC (SN), OVARY (OV), PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), RECTUM (RE), SKIN (SK), SKIN, OTHER (SS), SPLEEN (SP), STOMACH, GL (ST), STOMACH, NONGL (SU), THYMUS (TH), THYROID (TY), TONGUE (TO), TRACHEA (TR), URINARY BLADDER (UB), UTERUS (UT), UTERUS, CERVIX (CV), VAGINA (VA)		
THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION: ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, STERNUM (SB), BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC), DUODENUM (DU), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HARDERIAN GLAND (HG), HEART (HT), HEMATO NEOPLASIA (HN), ILEUM (IL), JEJUNUM (JE), LACRIMAL GL, EX (EO), LIVER (LI), LN, MESENTERIC (MS), MAMMARY, FEMALE (MF), MAND SALIVARY GL (SG), MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, ABDOM (MA), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON), NERVE, SCIATIC (SN), OVARY (OV), OVIDUCT (OD), PANCREAS (PA), PITUITARY (PI), RECTUM (RE), SALIVARY, OTHER (OS), SKIN (SK), STOMACH, GL (ST), STOMACH, NONGL (SU), THYMUS (TH), THYROID (TY), TONGUE (TO), TRACHEA (TR), URINARY BLADDER (UB), UTERUS (UT), VAGINA (VA)		

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 795

STUDY NUMBER: 483287

ANIMAL NUMBER: A37436 SEX: FEMALE DOSE GROUP: 2 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/11/91 STUDY DAY OF DEATH: 95 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 22.2 GRAMS
DATE AND TIME OF NECROPSY: 11/11/91 9:19 PROSECTOR: DOUGLAS HERNDON RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.14	.652 %	.276	WEIGHT TAKEN
LUNG (LU)	.16	.708 %	.299	WEIGHT TAKEN
UTERUS (UT)	.24	1.073 %	.454	WEIGHT TAKEN
BRAIN W/STEM (BR)	.52	2.364 %	1.000	WEIGHT TAKEN
HEART (HT)	.14	.613 %	.259	WEIGHT TAKEN
SPLEEN (SP)	.08	.370 %	.156	WEIGHT TAKEN
KIDNEY (KD)	.35	1.583 %	.670	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	1.11	5.016 %	2.122	WEIGHT TAKEN
ADRENAL (AD)	.012	.0523 %	.0221	WEIGHT TAKEN
OVARY (OV)	.044	.2000 %	.0846	WEIGHT TAKEN
THYMUS (TH)	.03	.117 %	.050	WEIGHT TAKEN

CLINICAL OBSERVATIONS	PATHOLOGY OBSERVATIONS NECROPSY	HISTOPATHOLOGY
-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS	^COLLECTED/TAKEN (XW) : -LIVER SECTIONS, IN METHANOL	LIVER (LI) : -INFLAMMATION, CHRONIC/CHRONIC ACTIVE,- MINIMAL

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE), KIDNEY (KD),
LACRIMAL GL, EX (EO), LIVER (LI), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU), MAMMARY, FEMALE (MF),
MAND SALIVARY GL (SG), MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON),
NERVE, SCIATIC (SN), OVARY (OV), PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), RECTUM (RE), SKIN (SK),
SKIN, OTHER (SS), SPLEEN (SP), STOMACH, GL (ST), STOMACH, NONGL (SU), THYMUS (TH), THYROID (TY), TONGUE (TO),
TRACHEA (TR), URINARY BLADDER (UB), UTERUS (UT), UTERUS, CERVIX (CV), VAGINA (VA)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 796

STUDY NUMBER: 483287

ANIMAL NUMBER: A37437 SEX: FEMALE DOSE GROUP: 2 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/11/91 STUDY DAY OF DEATH: 95 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 25.4 GRAMS
DATE AND TIME OF NECROPSY: 11/11/91 10:31 PROSECTOR: FRED AGEY RECORDER: FRED AGEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.20	.788 %	.412	WEIGHT TAKEN
LUNG (LU)	.20	.772 %	.403	WEIGHT TAKEN
UTERUS (UT)	.43	1.701 %	.889	WEIGHT TAKEN
BRAIN W/STEM (BR)	.49	1.914 %	1.000	WEIGHT TAKEN
HEART (HT)	.12	.480 %	.251	WEIGHT TAKEN
SPLEEN (SP)	.10	.404 %	.211	WEIGHT TAKEN
KIDNEY (KD)	.38	1.513 %	.791	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	1.27	4.996 %	2.611	WEIGHT TAKEN
ADRENAL (AD)	.011	.0445 %	.0232	WEIGHT TAKEN
OVARY (OV)	.046	.1795 %	.0938	WEIGHT TAKEN
THYMUS (TH)	.04	.172 %	.090	WEIGHT TAKEN

CLINICAL OBSERVATIONS	PATHOLOGY OBSERVATIONS NECROPSY	HISTOPATHOLOGY
-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS	UTERUS (UT) : -LUMEN, FLUID; BOTH HORNS, MODERATE AMOUNT, CLEAR -DARK; BOTH HORNS, DARK RED -DISTENDED, MODERATE; BOTH HORNS ^COLLECTED/TAKEN (XW) : -LIVER SECTIONS, IN METHANOL	LIVER (LI) : -INFLAMMATION, CHRONIC/CHRONIC ACTIVE,- MINIMAL UTERUS (UT) : -HYPERPLASIA, CYSTIC ENDOMETRIAL,- MINIMAL

APPENDIX 13B

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 797

STUDY NUMBER: 483287

ANIMAL NUMBER: A37437 SEX: FEMALE DOSE GROUP: 2 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/11/91 STUDY DAY OF DEATH: 95 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 25.4 GRAMS
DATE AND TIME OF NECROPSY: 11/11/91 10:31 PROSECTOR: FRED AGEY RECORDER: FRED AGEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE), KIDNEY (KD),
LACRIMAL GL, EX (EO), LIVER (LI), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU), MAMMARY, FEMALE (MF),
MAND SALIVARY GL (SG), MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON),
NERVE, SCIATIC (SN), OVARY (OV), PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), RECTUM (RE), SKIN (SK),
SKIN, OTHER (SS), SPLEEN (SP), STOMACH, GL (ST), STOMACH, NONGL (SU), THYMUS (TH), THYROID (TY), TONGUE (TO),
TRACHEA (TR), URINARY BLADDER (UB), UTERUS, CERVIX (CV), VAGINA (VA)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE, (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93

PAGE: 798

STUDY NUMBER: 483287

ANIMAL NUMBER: A37438 SEX: FEMALE DOSE GROUP: 2 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/11/91 STUDY DAY OF DEATH: 95 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 21.8 GRAMS
DATE AND TIME OF NECROPSY: 11/11/91 11:23 PROSECTOR: JANE EARHARDT RECORDER: JANE EARHARDT
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.10	.478 %	.194	WEIGHT TAKEN
LUNG (LU)	.19	.883 %	.358	WEIGHT TAKEN
UTERUS (UT)	.15	.665 %	.270	WEIGHT TAKEN
BRAIN W/STEM (BR)	.54	2.465 %	1.000	WEIGHT TAKEN
HEART (HT)	.15	.705 %	.286	WEIGHT TAKEN
SPLEEN (SP)	.08	.360 %	.146	WEIGHT TAKEN
KIDNEY (KD)	.34	1.576 %	.639	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	1.06	4.882 %	1.981	WEIGHT TAKEN
ADRENAL (AD)	.013	.0587 %	.0238	WEIGHT TAKEN
OVARY (OV)	.030	.1394 %	.0566	WEIGHT TAKEN
THYMUS (TH)	.03	.138 %	.056	WEIGHT TAKEN

CLINICAL OBSERVATIONS

PATHOLOGY OBSERVATIONS
NECROPSY

HISTOPATHOLOGY

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE
OBSERVATIONS

^COLLECTED/TAKEN (XW) :
-LIVER SECTIONS, IN METHANOL

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE), KIDNEY (KD),
LACRIMAL GL, EX (EO), LIVER (LI), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU), MAMMARY, FEMALE (MF),
MAND SALIVARY GL (SG), MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON),
NERVE, SCIATIC (SN), OVARY (OV), PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), RECTUM (RE), SKIN (SK),
SKIN, OTHER (SS), SPLEEN (SP), STOMACH, GL (ST), STOMACH, NONGL (SU), THYMUS (TH), THYROID (TY), TONGUE (TO),
TRACHEA (TR), URINARY BLADDER (UB), UTERUS (UT), UTERUS, CERVIX (CV), VAGINA (VA)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:
LIVER (LI)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 799

STUDY NUMBER: 483287

ANIMAL NUMBER: A37439 SEX: FEMALE DOSE GROUP: 2 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/11/91 STUDY DAY OF DEATH: 95 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 25.9 GRAMS
DATE AND TIME OF NECROPSY: 11/11/91 13:55 PROSECTOR: SCOTT BELL RECORDER: SCOTT BELL
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.12	.445 %	.204	WEIGHT TAKEN
LUNG (LU)	.18	.676 %	.310	WEIGHT TAKEN
UTERUS (UT)	.25	.977 %	.448	WEIGHT TAKEN
BRAIN W/STEM (BR)	.57	2.183 %	1.000	WEIGHT TAKEN
HEART (HT)	.16	.603 %	.276	WEIGHT TAKEN
SPLEEN (SP)	.08	.303 %	.139	WEIGHT TAKEN
KIDNEY (KD)	.37	1.412 %	.647	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	1.31	5.070 %	2.323	WEIGHT TAKEN
ADRENAL (AD)	.013	.0506 %	.0232	WEIGHT TAKEN
OVARY (OV)	.074	.2838 %	.1300	WEIGHT TAKEN
THYMUS (TH)	.05	.205 %	.094	WEIGHT TAKEN

CLINICAL OBSERVATIONS

PATHOLOGY OBSERVATIONS
NECROPSY

HISTOPATHOLOGY

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE
OBSERVATIONS

^COLLECTED/TAKEN (XW) :
-LIVER SECTIONS, IN METHANOL

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE), KIDNEY (KD),
LACRIMAL GL, EX (EO), LIVER (LI), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU), MAMMARY, FEMALE (MF),
MAND SALIVARY GL (SG), MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON),
NERVE, SCIATIC (SN), OVARY (OV), PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), RECTUM (RE), SKIN (SK),
SKIN, OTHER (SS), SPLEEN (SP), STOMACH, GL (ST), STOMACH, NONGL (SU), THYMUS (TH), THYROID (TY), TONGUE (TO),
TRACHEA (TR), URINARY BLADDER (UB), UTERUS (UT), UTERUS, CERVIX (CV), VAGINA (VA)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:
LIVER (LI)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 800

STUDY NUMBER: 483287

ANIMAL NUMBER: A37440 SEX: FEMALE DOSE GROUP: 2 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/12/91 STUDY DAY OF DEATH: 96 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 25.1 GRAMS
DATE AND TIME OF NECROPSY: 11/12/91 9:17 PROSECTOR: SCOTT BELL RECORDER: SCOTT BELL
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.15	.608 %	.289	WEIGHT TAKEN
LUNG (LU)	.18	.736 %	.350	WEIGHT TAKEN
UTERUS (UT)	.39	1.561 %	.743	WEIGHT TAKEN
BRAIN W/STEM (BR)	.53	2.101 %	1.000	WEIGHT TAKEN
HEART (HT)	.14	.564 %	.268	WEIGHT TAKEN
SPLEEN (SP)	.07	.284 %	.135	WEIGHT TAKEN
KIDNEY (KD)	.37	1.455 %	.693	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	1.15	4.563 %	2.172	WEIGHT TAKEN
ADRENAL (AD)	.006	.0239 %	.0114	WEIGHT TAKEN
OVARY (OV)	.038	.1526 %	.0726	WEIGHT TAKEN
THYMUS (TH)	.05	.207 %	.098	WEIGHT TAKEN

CLINICAL OBSERVATIONS	PATHOLOGY OBSERVATIONS NECROPSY	HISTOPATHOLOGY
-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS	OVARY (OV) : -CYST; RIGHT, ONE, CLEAR, 3 X 3 MM ^COLLECTED/TAKEN (XW) : -LIVER SECTIONS, IN METHANOL	LIVER (LI) : -NECROSIS, INDIVIDUAL CELL,-MINIMAL OVARY (OV) : UNREMARKABLE

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE, (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 801

STUDY NUMBER: 483287

ANIMAL NUMBER: A37440 SEX: FEMALE DOSE GROUP: 2 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/12/91 STUDY DAY OF DEATH: 96 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 25.1 GRAMS
DATE AND TIME OF NECROPSY: 11/12/91 9:17 PROSECTOR: SCOTT BELL RECORDER: SCOTT BELL
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE), KIDNEY (KD),
LACRIMAL GL, EX (EO), LIVER (LI), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU), MAMMARY, FEMALE (MF),
MAND SALIVARY GL (SG), MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON),
NERVE, SCIATIC (SN), PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), RECTUM (RE), SKIN (SK), SKIN, OTHER (SS),
SPLEEN (SP), STOMACH, GL (ST), STOMACH, NONGL (SU), THYMUS (TH), THYROID (TY), TONGUE (TO), TRACHEA (TR),
URINARY BLADDER (UB), UTERUS (UT), UTERUS, CERVIX (CV), VAGINA (VA)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:
OVIDUCT (OD)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 802

STUDY NUMBER: 483287

ANIMAL NUMBER: A37441 SEX: FEMALE DOSE GROUP: 2 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/12/91 STUDY DAY OF DEATH: 96 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 25.6 GRAMS
DATE AND TIME OF NECROPSY: 11/12/91 10:04 PROSECTOR: DOUGLAS HERNDON RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.13	.523 %	.251	WEIGHT TAKEN
LUNG (LU)	.19	.723 %	.346	WEIGHT TAKEN
UTERUS (UT)	.34	1.339 %	.642	WEIGHT TAKEN
BRAIN W/STEM (BR)	.53	2.086 %	1.000	WEIGHT TAKEN
HEART (HT)	.16	.613 %	.294	WEIGHT TAKEN
SPLEEN (SP)	.08	.293 %	.140	WEIGHT TAKEN
KIDNEY (KD)	.38	1.483 %	.711	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	1.30	5.084 %	2.437	WEIGHT TAKEN
ADRENAL (AD)	.011	.0422 %	.0202	WEIGHT TAKEN
OVARY (OV)	.048	.1859 %	.0891	WEIGHT TAKEN
THYMUS (TH)	.03	.109 %	.052	WEIGHT TAKEN

CLINICAL OBSERVATIONS	PATHOLOGY OBSERVATIONS NECROPSY	HISTOPATHOLOGY
-LAST PHYSICAL EXAM: NORMAL-NO REMARKABLE OBSERVATIONS	^COLLECTED/TAKEN (XW) : -LIVER SECTIONS, IN METHANOL	

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE), KIDNEY (KD),
LACRIMAL GL, EX (EO), LIVER (LI), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU), MAMMARY, FEMALE (MF),
MAND SALIVARY GL (SG), MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON),
NERVE, SCIATIC (SN), OVARY (OV), PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), RECTUM (RE), SKIN (SK),
SKIN, OTHER (SS), SPLEEN (SP), STOMACH, GL (ST), STOMACH, NONGL (SU), THYMUS (TH), THYROID (TY), TONGUE (TO),
TRACHEA (TR), URINARY BLADDER (UB), UTERUS (UT), UTERUS, CERVIX (CV), VAGINA (VA)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:
LIVER (LI)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 803

STUDY NUMBER: 483287

ANIMAL NUMBER: A37442 SEX: FEMALE DOSE GROUP: 2 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/12/91 STUDY DAY OF DEATH: 96 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 23.7 GRAMS
DATE AND TIME OF NECROPSY: 11/12/91 11:13 PROSECTOR: SONNY DIKES RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.11	.465 %	.214	WEIGHT TAKEN
LUNG (LU)	.16	.696 %	.321	WEIGHT TAKEN
UTERUS (UT)	.15	.634 %	.292	WEIGHT TAKEN
BRAIN W/STEM (BR)	.51	2.169 %	1.000	WEIGHT TAKEN
HEART (HT)	.13	.560 %	.258	WEIGHT TAKEN
SPLEEN (SP)	.07	.296 %	.136	WEIGHT TAKEN
KIDNEY (KD)	.35	1.483 %	.684	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	1.11	4.664 %	2.150	WEIGHT TAKEN
ADRENAL (AD)	.011	.0468 %	.0216	WEIGHT TAKEN
OVARY (OV)	.068	.2869 %	.1323	WEIGHT TAKEN
THYMUS (TH)	.03	.126 %	.058	WEIGHT TAKEN

CLINICAL OBSERVATIONS	PATHOLOGY OBSERVATIONS NECROPSY	HISTOPATHOLOGY
-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS	^COLLECTED/TAKEN (XW) : -LIVER SECTIONS, IN METHANOL	

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE), KIDNEY (KD),
LACRIMAL GL, EX (EO), LIVER (LI), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU), MAMMARY, FEMALE (MF),
MAND SALIVARY GL (SG), MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON),
NERVE, SCIATIC (SN), OVARY (OV), PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), RECTUM (RE), SKIN (SK),
SKIN, OTHER (SS), SPLEEN (SP), STOMACH, GL (ST), STOMACH, NONGL (SU), THYMUS (TH), THYROID (TY), TONGUE (TO),
TRACHEA (TR), URINARY BLADDER (UB), UTERUS (UT), UTERUS, CERVIX (CV), VAGINA (VA)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:
LIVER (LI)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

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STUDY NUMBER: 483287

ANIMAL NUMBER: A37443 SEX: FEMALE DOSE GROUP: 2 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/12/91 STUDY DAY OF DEATH: 96 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 23.1 GRAMS
DATE AND TIME OF NECROPSY: 11/12/91 13:25 PROSECTOR: FRED AGEY RECORDER: FRED AGEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.14	.623 %	.273	WEIGHT TAKEN
LUNG (LU)	.18	.759 %	.332	WEIGHT TAKEN
UTERUS (UT)	.15	.664 %	.291	WEIGHT TAKEN
BRAIN W/STEM (BR)	.53	2.284 %	1.000	WEIGHT TAKEN
HEART (HT)	.13	.569 %	.249	WEIGHT TAKEN
SPLEEN (SP)	.06	.263 %	.115	WEIGHT TAKEN
KIDNEY (KD)	.39	1.695 %	.742	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	1.12	4.849 %	2.123	WEIGHT TAKEN
ADRENAL (AD)	.011	.0476 %	.0208	WEIGHT TAKEN
OVARY (OV)	.036	.1545 %	.0677	WEIGHT TAKEN
THYMUS (TH)	.02	.104 %	.046	WEIGHT TAKEN

CLINICAL OBSERVATIONS

PATHOLOGY OBSERVATIONS
NECROPSY

HISTOPATHOLOGY

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE
OBSERVATIONS

LIVER (LI) :
-HEPATOCTYE, HYPERTROPHY,
CENTROLOBULAR,-MINIMAL
-INFLAMMATION, CHRONIC/CHRONIC ACTIVE,-
MINIMAL

^COLLECTED/TAKEN (XW) :
-LIVER SECTIONS, IN METHANOL

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE), KIDNEY (KD),
LACRIMAL GL, EX (EO), LIVER (LI), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU), MAMMARY, FEMALE (MF),
MAND SALIVARY GL (SG), MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON),
NERVE, SCIATIC (SN), OVARY (OV), PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), RECTUM (RE), SKIN (SK),
SKIN, OTHER (SS), SPLEEN (SP), STOMACH, GL (ST), STOMACH, NONGL (SU), THYMUS (TH), THYROID (TY), TONGUE (TO),
TRACHEA (TR), URINARY BLADDER (UB), UTERUS (UT), UTERUS, CERVIX (CV), VAGINA (VA)

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 805

STUDY NUMBER: 483287

ANIMAL NUMBER: A37443 SEX: FEMALE DOSE GROUP: 2 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/12/91 STUDY DAY OF DEATH: 96 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 23.1 GRAMS
DATE AND TIME OF NECROPSY: 11/12/91 13:25 PROSECTOR: FRED AGEY RECORDER: FRED AGEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 806

STUDY NUMBER: 483287

ANIMAL NUMBER: A37444 SEX: FEMALE DOSE GROUP: 2 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/13/91 STUDY DAY OF DEATH: 97 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 21.8 GRAMS
DATE AND TIME OF NECROPSY: 11/12/91 8:55 PROSECTOR: FRED AGEY RECORDER: FRED AGEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	O R G A N S T A T U S
MAND SALIVARY GL (SG)	.15	.694 %	.291	WEIGHT TAKEN
LUNG (LU)	.19	.859 %	.360	WEIGHT TAKEN
UTERUS (UT)	.30	1.359 %	.570	WEIGHT TAKEN
BRAIN W/STEM (BR)	.52	2.385 %	1.000	WEIGHT TAKEN
HEART (HT)	.12	.549 %	.230	WEIGHT TAKEN
SPLEEN (SP)	.06	.272 %	.114	WEIGHT TAKEN
KIDNEY (KD)	.35	1.609 %	.675	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	1.03	4.735 %	1.986	WEIGHT TAKEN
ADRENAL (AD)	.005	.0234 %	.0098	WEIGHT TAKEN
OVARY (OV)	.046	.2115 %	.0887	WEIGHT TAKEN
THYMUS (TH)	.02	.081 %	.034	WEIGHT TAKEN

CLINICAL OBSERVATIONS	P A T H O L O G Y O B S E R V A T I O N S NECROPSY	HISTOPATHOLOGY
-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS	UTERUS (UT) : -DISTENDED, MODERATE; BOTH HORNS ^COLLECTED/TAKEN (XW) : -LIVER SECTIONS, IN METHANOL	LIVER (LI) : -INFLAMMATION, CHRONIC/CHRONIC ACTIVE,- MINIMAL UTERUS (UT) : -HYPERPLASIA, CYSTIC ENDOMETRIAL,- SLIGHT

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE), KIDNEY (KD),
LACRIMAL GL, EX (EO), LIVER (LI), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU), MAMMARY, FEMALE (MF),
MAND SALIVARY GL (SG), MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON),
NERVE, SCIATIC (SN), OVARY (OV), PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), RECTUM (RE), SKIN (SK),
SKIN, OTHER (SS), SPLEEN (SP), STOMACH, GL (ST), STOMACH, NONGL (SU), THYMUS (TH), THYROID (TY), TONGUE (TO),
TRACHEA (TR), URINARY BLADDER (UB), UTERUS, CERVIX (CV), VAGINA (VA)

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
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STUDY NUMBER: 483287

ANIMAL NUMBER: A37444 SEX: FEMALE DOSE GROUP: 2 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/13/91 STUDY DAY OF DEATH: 97 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 21.8 GRAMS
DATE AND TIME OF NECROPSY: 11/12/91 8:55 PROSECTOR: FRED AGEY RECORDER: FRED AGEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
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STUDY NUMBER: 483287

ANIMAL NUMBER: A37445 SEX: FEMALE DOSE GROUP: 2 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/13/91 STUDY DAY OF DEATH: 97 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 25.0 GRAMS
DATE AND TIME OF NECROPSY: 11/13/91 9:43 PROSECTOR: ADEFOLOHAN AKINSOLA RECORDER: JOHN CROWLEY
POST-FIX WEAHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEAHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.12	.466 %	.235	WEIGHT TAKEN
LUNG (LU)	.19	.748 %	.377	WEIGHT TAKEN
UTERUS (UT)	.19	.774 %	.391	WEIGHT TAKEN
BRAIN W/STEM (BR)	.50	1.983 %	1.000	WEIGHT TAKEN
HEART (HT)	.15	.610 %	.307	WEIGHT TAKEN
SPLEEN (SP)	.09	.372 %	.188	WEIGHT TAKEN
KIDNEY (KD)	.50	2.000 %	1.009	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	1.35	5.382 %	2.715	WEIGHT TAKEN
ADRENAL (AD)	.011	.0452 %	.0228	WEIGHT TAKEN
OVARY (OV)	.061	.2436 %	.1229	WEIGHT TAKEN
THYMUS (TH)	.04	.147 %	.074	WEIGHT TAKEN

CLINICAL OBSERVATIONS	PATHOLOGY OBSERVATIONS NECROPSY	HISTOPATHOLOGY
-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS	OVARY (OV) : -CYST: LEFT, ONE, CLEAR, 3 X 3 MM ^COLLECTED/TAKEN (XW) : -LIVER SECTIONS, IN METHANOL	LIVER (LI) : -HEPATOCYTE, HYPERTROPHY, CENTROLOBULAR,-MINIMAL OVARY (OV) : -BURSA, CYST,-PRESENT

HAZLETON WASHINGTON, INC.
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APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 809

STUDY NUMBER: 483287

ANIMAL NUMBER: A37445 SEX: FEMALE DOSE GROUP: 2 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/13/91 STUDY DAY OF DEATH: 97 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 25.0 GRAMS
DATE AND TIME OF NECROPSY: 11/13/91 9:43 PROSECTOR: ADEFOLAHAN AKINSOLA RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE), KIDNEY (KD),
LACRIMAL GL, EX (EO), LIVER (LI), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU), MAMMARY, FEMALE (MF),
MAND SALIVARY GL (SG), MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON),
NERVE, SCIATIC (SN), PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), RECTUM (RE), SKIN (SK), SKIN, OTHER (SS),
SPLEEN (SP), STOMACH, GL (ST), STOMACH, NONGL (SU), THYMUS (TH), THYROID (TY), TONGUE (TO), TRACHEA (TR),
URINARY BLADDER (UB), UTERUS (UT), UTERUS, CERVIX (CV), VAGINA (VA)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:
OVIDUCT (OD)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 810

STUDY NUMBER: 483287

ANIMAL NUMBER: A37446 SEX: FEMALE DOSE GROUP: 2 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/13/91 STUDY DAY OF DEATH: 97 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 22.0 GRAMS
DATE AND TIME OF NECROPSY: 11/13/91 11:05 PROSECTOR: LINDA RUMBLE RECORDER: LINDA RUMBLE
POST-FIX WEIGHER: JANE EARTHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.12	.547 %	.228	WEIGHT TAKEN
LUNG (LU)	.17	.786 %	.327	WEIGHT TAKEN
UTERUS (UT)	.24	1.075 %	.448	WEIGHT TAKEN
BRAIN W/STEM (BR)	.53	2.402 %	1.000	WEIGHT TAKEN
HEART (HT)	.14	.648 %	.270	WEIGHT TAKEN
SPLEEN (SP)	.08	.351 %	.146	WEIGHT TAKEN
KIDNEY (KD)	.34	1.529 %	.637	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	1.22	5.529 %	2.302	WEIGHT TAKEN
ADRENAL (AD)	.013	.0605 %	.0252	WEIGHT TAKEN
OVARY (OV)	.047	.2141 %	.0891	WEIGHT TAKEN
THYMUS (TH)	.01	.039 %	.016	WEIGHT TAKEN

CLINICAL OBSERVATIONS	PATHOLOGY OBSERVATIONS NECROPSY	HISTOPATHOLOGY
-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS	^COLLECTED/TAKEN (XW) : -LIVER SECTIONS, IN METHANOL	LIVER (LI) : -INFLAMMATION, CHRONIC/CHRONIC ACTIVE,- MINIMAL

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE), KIDNEY (KD),
LACRIMAL GL, EX (EO), LIVER (LI), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU), MAMMARY, FEMALE (MF),
MAND SALIVARY GL (SG), MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON),
NERVE, SCIATIC (SN), OVARY (OV), PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), RECTUM (RE), SKIN (SK),
SKIN, OTHER (SS), SPLEEN (SP), STOMACH, GL (ST), STOMACH, NONGL (SU), THYMUS (TH), THYROID (TY), TONGUE (TO),
TRACHEA (TR), URINARY BLADDER (UB), UTERUS (UT), UTERUS, CERVIX (CV), VAGINA (VA)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 811

STUDY NUMBER: 483287

ANIMAL NUMBER: A37447 SEX: FEMALE DOSE GROUP: 2 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/13/91 STUDY DAY OF DEATH: 97 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 24.6 GRAMS
DATE AND TIME OF NECROPSY: 11/13/91 13:30 PROSECTOR: LINDA RUMBLE RECORDER: LINDA RUMBLE
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.14	.572 %	.270	WEIGHT TAKEN
LUNG (LU)	.21	.837 %	.395	WEIGHT TAKEN
UTERUS (UT)	.16	.642 %	.303	WEIGHT TAKEN
BRAIN W/STEM (BR)	.52	2.119 %	1.000	WEIGHT TAKEN
HEART (HT)	.15	.622 %	.294	WEIGHT TAKEN
SPLEEN (SP)	.07	.282 %	.133	WEIGHT TAKEN
KIDNEY (KD)	.39	1.598 %	.754	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	1.23	4.991 %	2.356	WEIGHT TAKEN
ADRENAL (AD)	.016	.0659 %	.0311	WEIGHT TAKEN
OVARY (OV)	.043	.1748 %	.0825	WEIGHT TAKEN
THYMUS (TH)	.02	.087 %	.041	WEIGHT TAKEN

CLINICAL OBSERVATIONS	PATHOLOGY OBSERVATIONS NECROPSY	HISTOPATHOLOGY
-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS	STOMACH, GL (ST) : -DARK AREA; MUCOSA, SEVERAL, BLACK, PINPOINT TO 3 X 2 MM ^COLLECTED/TAKEN (XW) : -LIVER SECTIONS, IN METHANOL	LIVER (LI) : -VACUOLIZATION,-MINIMAL -NECROSIS, INDIVIDUAL CELL,-MINIMAL -INFLAMMATION, CHRONIC/CHRONIC ACTIVE,- MINIMAL STOMACH, GL (ST) : -MUCOSA, NECROSIS,-SLIGHT

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 812

STUDY NUMBER: 483287

ANIMAL NUMBER: A37447 SEX: FEMALE DOSE GROUP: 2 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/13/91 STUDY DAY OF DEATH: 97 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 24.6 GRAMS
DATE AND TIME OF NECROPSY: 11/13/91 13:30 PROSECTOR: LINDA RUMBLE RECORDER: LINDA RUMBLE
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE), KIDNEY (KD),
LACRIMAL GL, EX (EO), LIVER (LI), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU), MAMMARY, FEMALE (MF),
MAND SALIVARY GL (SG), MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON),
NERVE, SCIATIC (SN), OVARY (OV), PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), RECTUM (RE), SKIN (SK),
SKIN, OTHER (SS), SPLEEN (SP), STOMACH, NONGL (SU), THYMUS (TH), THYROID (TY), TONGUE (TO), TRACHEA (TR),
URINARY BLADDER (UB), UTERUS (UT), UTERUS, CERVIX (CV), VAGINA (VA)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:

STOMACH, NONGL (SU)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
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APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 813

STUDY NUMBER: 483287

ANIMAL NUMBER: A37448 SEX: FEMALE DOSE GROUP: 2 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/14/91 STUDY DAY OF DEATH: 98 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 21.6 GRAMS
DATE AND TIME OF NECROPSY: 11/14/91 8:13 PROSECTOR: JANE EARHARDT RECORDER: JANE EARHARDT
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.15	.713 %	.297	WEIGHT TAKEN
LUNG (LU)	.18	.842 %	.351	WEIGHT TAKEN
UTERUS (UT)	.23	1.082 %	.451	WEIGHT TAKEN
BRAIN W/STEM (BR)	.52	2.402 %	1.000	WEIGHT TAKEN
HEART (HT)	.14	.668 %	.278	WEIGHT TAKEN
SPLEEN (SP)	.06	.295 %	.123	WEIGHT TAKEN
KIDNEY (KD)	.38	1.744 %	.726	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	1.04	4.819 %	2.006	WEIGHT TAKEN
ADRENAL (AD)	.012	.0546 %	.0227	WEIGHT TAKEN
OVARY (OV)	.062	.2889 %	.1203	WEIGHT TAKEN
THYMUS (TH)	.03	.133 %	.056	WEIGHT TAKEN

CLINICAL OBSERVATIONS	PATHOLOGY OBSERVATIONS NECROPSY	HISTOPATHOLOGY
-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS	^COLLECTED/TAKEN (XW) : -LIVER SECTIONS, IN METHANOL	

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE), KIDNEY (KD),
LACRIMAL GL, EX (EO), LIVER (LI), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU), MAMMARY, FEMALE (MF),
MAND SALIVARY GL (SG), MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON),
NERVE, SCIATIC (SN), OVARY (OV), PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), RECTUM (RE), SKIN (SK),
SKIN, OTHER (SS), SPLEEN (SP), STOMACH, GL (ST), STOMACH, NONGL (SU), THYMUS (TH), THYROID (TY), TONGUE (TO),
TRACHEA (TR), URINARY BLADDER (UB), UTERUS (UT), UTERUS, CERVIX (CV), VAGINA (VA)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:
LIVER (LI)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 814

STUDY NUMBER: 483287

ANIMAL NUMBER: A37449 SEX: FEMALE DOSE GROUP: 2 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/14/91 STUDY DAY OF DEATH: 98 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 24.2 GRAMS
DATE AND TIME OF NECROPSY: 11/14/91 9:17 PROSECTOR: SCOTT BELL RECORDER: SCOTT BELL
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.15	.638 %	.315	WEIGHT TAKEN
LUNG (LU)	.21	.865 %	.428	WEIGHT TAKEN
UTERUS (UT)	.26	1.085 %	.536	WEIGHT TAKEN
BRAIN W/STEM (BR)	.49	2.024 %	1.000	WEIGHT TAKEN
HEART (HT)	.15	.602 %	.298	WEIGHT TAKEN
SPLEEN (SP)	.10	.401 %	.198	WEIGHT TAKEN
KIDNEY (KD)	.37	1.519 %	.751	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	1.22	5.057 %	2.499	WEIGHT TAKEN
ADRENAL (AD)	.011	.0471 %	.0233	WEIGHT TAKEN
OVARY (OV)	.036	.1500 %	.0741	WEIGHT TAKEN
THYMUS (TH)	.02	.097 %	.048	WEIGHT TAKEN

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE
OBSERVATIONS

P A T H O L O G Y O B S E R V A T I O N S
NECROPSY

OVARY (OV) :
-CYST; BOTH, ONE EACH, CLEAR TO WHITE,
2 X 2 MM
^COLLECTED/TAKEN (XW) :
-LIVER SECTIONS, IN METHANOL

HISTOPATHOLOGY

LIVER (LI) :
-NECROSIS, INDIVIDUAL CELL,-MINIMAL
-INFLAMMATION, CHRONIC/CHRONIC ACTIVE,-
MINIMAL
OVARY (OV) :
-BURSA, CYST,-PRESENT

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 815

STUDY NUMBER: 483287

ANIMAL NUMBER: A37449 SEX: FEMALE DOSE GROUP: 2 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/14/91 STUDY DAY OF DEATH: 98 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 24.2 GRAMS
DATE AND TIME OF NECROPSY: 11/14/91 9:17 PROSECTOR: SCOTT BELL RECORDER: SCOTT BELL
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE), KIDNEY (KD),
LACRIMAL GL, EX (EO), LIVER (LI), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU), MAMMARY, FEMALE (MF),
MAND SALIVARY GL (SG), MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON),
NERVE, SCIATIC (SN), PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), RECTUM (RE), SKIN (SK), SKIN, OTHER (SS),
SPLEEN (SP), STOMACH, GL (ST), STOMACH, NONGL (SU), THYMUS (TH), THYROID (TY), TONGUE (TO), TRACHEA (TR),
URINARY BLADDER (UB), UTERUS (UT), UTERUS, CERVIX (CV), VAGINA (VA)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:
OVIDUCT (OD)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 816

STUDY NUMBER: 483287

ANIMAL NUMBER: A37450 SEX: FEMALE DOSE GROUP: 2 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/14/91 STUDY DAY OF DEATH: 98 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 22.3 GRAMS
DATE AND TIME OF NECROPSY: 11/14/91 10:05 PROSECTOR: ADEPOLAHAN AKINSOLA RECORDER: ADEPOLAHAN AKINSOLA
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.17	.745 %	.322	WEIGHT TAKEN
LUNG (LU)	.17	.771 %	.333	WEIGHT TAKEN
UTERUS (UT)	.31	1.369 %	.591	WEIGHT TAKEN
BRAIN W/STEM (BR)	.52	2.314 %	1.000	WEIGHT TAKEN
HEART (HT)	.12	.544 %	.235	WEIGHT TAKEN
SPLEEN (SP)	.06	.262 %	.113	WEIGHT TAKEN
KIDNEY (KD)	.40	1.804 %	.779	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	.90	4.028 %	1.741	WEIGHT TAKEN
ADRENAL (AD)	.011	.0502 %	.0217	WEIGHT TAKEN
OVARY (OV)	.061	.2744 %	.1186	WEIGHT TAKEN
THYMUS (TH)	.03	.123 %	.053	WEIGHT TAKEN

CLINICAL OBSERVATIONS

PATHOLOGY OBSERVATIONS
NECROPSY

HISTOPATHOLOGY

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE
OBSERVATIONS

OVARY (OV) :
-CYST; LEFT, ONE, CLEAR, 3 X 3 MM
^COLLECTED/TAKEN (XW) :
-LIVER SECTIONS, IN METHANOL

OVARY (OV) :
-FOLLICLE, CYST,-PRESENT

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)

PRINTED: 21-JAN-93
PAGE: 817

INDIVIDUAL ANIMAL SUMMARY REPORT

STUDY NUMBER: 483287

ANIMAL NUMBER: A37450 SEX: FEMALE DOSE GROUP: 2 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/14/91 STUDY DAY OF DEATH: 98 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 22.3 GRAMS
DATE AND TIME OF NECROPSY: 11/14/91 10:05 PROSECTOR: ADEPOLAHAN AKINSOLA RECORDER: ADEPOLAHAN AKINSOLA
POST-FIX WEIGHER: JANE EARMHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE), KIDNEY (KD),
LACRIMAL GL, EX (EO), LIVER (LI), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU), MAMMARY, FEMALE (MF),
MAND SALIVARY GL (SG), MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON),
NERVE, SCIATIC (SN), PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), RECTUM (RE), SKIN (SK), SKIN, OTHER (SS),
SPLEEN (SP), STOMACH, GL (ST), STOMACH, NONGL (SU), THYMUS (TH), THYROID (TY), TONGUE (TO), TRACHEA (TR),
URINARY BLADDER (UB), UTERUS (UT), UTERUS, CERVIX (CV), VAGINA (VA)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:

LIVER (LI), OVIDUCT (OD)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 818

STUDY NUMBER: 483287

ANIMAL NUMBER: A37466 SEX: FEMALE DOSE GROUP: 3 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/11/91 STUDY DAY OF DEATH: 95 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 25.5 GRAMS
DATE AND TIME OF NECROPSY: 11/11/91 9:30 PROSECTOR: FRED AGEY RECORDER: FRED AGEY
POST-FIX WEIGHER: JANE EARNHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.15	.582 %	.321	WEIGHT TAKEN
LUNG (LU)	.16	.634 %	.350	WEIGHT TAKEN
UTERUS (UT)	.18	.696 %	.384	WEIGHT TAKEN
BRAIN W/STEM (BR)	.46	1.813 %	1.000	WEIGHT TAKEN
HEART (HT)	.15	.578 %	.319	WEIGHT TAKEN
SPLEEN (SP)	.07	.271 %	.149	WEIGHT TAKEN
KIDNEY (KD)	.43	1.689 %	.932	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	1.48	5.800 %	3.199	WEIGHT TAKEN
ADRENAL (AD)	.009	.0333 %	.0184	WEIGHT TAKEN
OVARY (OV)	.028	.1110 %	.0612	WEIGHT TAKEN
THYMUS (TH)	.02	.076 %	.042	WEIGHT TAKEN

CLINICAL OBSERVATIONS	PATHOLOGY OBSERVATIONS NECROPSY	HISTOPATHOLOGY
-LAST PHYSICAL EXAM: NORMAL-NO REMARKABLE OBSERVATIONS	BRAIN W/STEM (BR) : >NOTE: HISTOLOGY NOTE: DUPLICATE FOUND IN WET AT HISTOLOGY. NONE PROCESSED. HEART (HT) : >NOTE: HISTOLOGY NOTE: DUPLICATE FOUND IN WET AT HISTOLOGY. NONE PROCESSED. KIDNEY (KD) : >NOTE: HISTOLOGY NOTE: DUPLICATES FOUND IN WET AT HISTOLOGY. BOTH SETS OF KIDNEYS PROCESSED.	ADRENAL, CORTEX (AC) : -VACUOLIZATION, X-ZONE, -SLIGHT ADRENAL, MEDULLA (AM) : -UNILATERALLY EXAMINED, -PRESENT BRAIN W/STEM (BR) : >NOT REQUIRED TO BE EXAMINED FOR ANIMAL HEART (HT) : >NOT REQUIRED TO BE EXAMINED FOR ANIMAL KIDNEY (KD) : -TUBULE, REGENERATION, -MINIMAL LIVER (LI) : -KUPFFER CELL/MACROPHAGE, PIGMENT, - MINIMAL

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 819

STUDY NUMBER: 483287

ANIMAL NUMBER: A37466 SEX: FEMALE DOSE GROUP: 3 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/11/91 STUDY DAY OF DEATH: 95 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 25.5 GRAMS
DATE AND TIME OF NECROPSY: 11/11/91 9:30 PROSECTOR: FRED AGEY RECORDER: FRED AGEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

CLINICAL OBSERVATIONS

P A T H O L O G Y O B S E R V A T I O N S (CONTINUED)
NECROPSY

HISTOPATHOLOGY

SPLEEN (SP) :
>NOTE:>HISTOLOGY NOTE: DUPLICATE FOUND
IN WET AT HISTOLOGY. BOTH
SPLEENS PROCESSED.
UTERUS (UT) :
>NOTE:>HISTOLOGY NOTE: DUPLICATE FOUND
IN WET. SECTION FROM BOTH SETS
OF UTERUS PROCESSED.
^COLLECTED/TAKEN (XW) :
-LIVER SECTIONS, IN METHANOL

LIVER (LI) :
-INFLAMMATION, CHRONIC/CHRONIC ACTIVE, -
MINIMAL
SPLEEN (SP) :
>NOT REQUIRED TO BE EXAMINED FOR ANIMAL
UTERUS (UT) :
-HYPOPLASIA, -MINIMAL

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE), KIDNEY (KD),
LACRIMAL GL, EX (EO), LIVER (LI), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU), MAMMARY, FEMALE (MF),
MAND SALIVARY GL (SG), MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON),
NERVE, SCIATIC (SN), OVARY (OV), PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), RECTUM (RE), SKIN (SK),
SKIN, OTHER (SS), SPLEEN (SP), STOMACH, GL (ST), STOMACH, NONGL (SU), THYMUS (TH), THYROID (TY), TONGUE (TO),
TRACHEA (TR), URINARY BLADDER (UB), UTERUS (UT), UTERUS, CERVIX (CV), VAGINA (VA)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:
UTERUS, CERVIX (CV)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 820

STUDY NUMBER: 483287

ANIMAL NUMBER: A37467 SEX: FEMALE DOSE GROUP: 3 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/11/91 STUDY DAY OF DEATH: 95 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 21.6 GRAMS
DATE AND TIME OF NECROPSY: 11/11/91 10:36 PROSECTOR: SCOTT BELL RECORDER: SCOTT BELL
POST-FIX WEIGHER: JANE EARNHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.12	.570 %	.238	WEIGHT TAKEN
LUNG (LU)	.18	.833 %	.347	WEIGHT TAKEN
UTERUS (UT)	.20	.932 %	.389	WEIGHT TAKEN
BRAIN W/STEM (BR)	.52	2.399 %	1.000	WEIGHT TAKEN
HEART (HT)	.14	.640 %	.267	WEIGHT TAKEN
SPLEEN (SP)	.04	.169 %	.071	WEIGHT TAKEN
KIDNEY (KD)	.36	1.676 %	.699	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	1.06	4.895 %	2.041	WEIGHT TAKEN
ADRENAL (AD)	.015	.0713 %	.0297	WEIGHT TAKEN
OVARY (OV)	.049	.2269 %	.0946	WEIGHT TAKEN
THYMUS (TH)	.02	.111 %	.046	WEIGHT TAKEN

CLINICAL OBSERVATIONS	PATHOLOGY OBSERVATIONS NECROPSY	HISTOPATHOLOGY
-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS	OVARY (OV) : -CYST; LEFT, ONE, CLEAR, 2 X 2 MM ^COLLECTED/TAKEN (XW) : -LIVER SECTIONS, IN METHANOL	OVARY (OV) : >UNREMARKABLE

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 821

STUDY NUMBER: 483287

ANIMAL NUMBER: A37467 SEX: FEMALE DOSE GROUP: 3 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/11/91 STUDY DAY OF DEATH: 95 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 21.6 GRAMS
DATE AND TIME OF NECROPSY: 11/11/91 10:36 PROSECTOR: SCOTT BELL RECORDER: SCOTT BELL
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE), KIDNEY (KD),
LACRIMAL GL, EX (EO), LIVER (LI), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU), MAMMARY, FEMALE (MF),
MAND SALIVARY GL (SG), MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON),
NERVE, SCIATIC (SN), PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), RECTUM (RE), SKIN (SK), SKIN, OTHER (SS),
SPLEEN (SP), STOMACH, GL (ST), STOMACH, NONGL (SU), THYMUS (TH), THYROID (TY), TONGUE (TO), TRACHEA (TR),
URINARY BLADDER (UB), UTERUS (UT), UTERUS, CERVIX (CV), VAGINA (VA)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:

LIVER (LI), OVIDUCT (OD)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 822

STUDY NUMBER: 483287

ANIMAL NUMBER: A37468 SEX: FEMALE DOSE GROUP: 3 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/11/91 STUDY DAY OF DEATH: 95 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 22.3 GRAMS
DATE AND TIME OF NECROPSY: 11/11/91 11:40 PROSECTOR: JANE EARHARDT RECORDER: JANE EARHARDT
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.10	.458 %	.198	WEIGHT TAKEN
LUNG (LU)	.15	.694 %	.300	WEIGHT TAKEN
UTERUS (UT)	.41	1.854 %	.801	WEIGHT TAKEN
BRAIN W/STEM (BR)	.52	2.314 %	1.000	WEIGHT TAKEN
HEART (HT)	.14	.608 %	.263	WEIGHT TAKEN
SPLEEN (SP)	.08	.368 %	.159	WEIGHT TAKEN
KIDNEY (KD)	.35	1.585 %	.685	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	1.09	4.908 %	2.121	WEIGHT TAKEN
ADRENAL (AD)	.016	.0722 %	.0312	WEIGHT TAKEN
OVARY (OV)	.035	.1565 %	.0676	WEIGHT TAKEN
THYMUS (TH)	.02	.112 %	.048	WEIGHT TAKEN

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE
OBSERVATIONS

PATHOLOGY OBSERVATIONS
NECROPSY

UTERUS (UT) :
-WALL, THICKENED, MODERATE; BOTH HORNS
^COLLECTED/TAKEN (XW) :
-LIVER SECTIONS, IN METHANOL

HISTOPATHOLOGY

ADRENAL, CORTEX (AC) :
-PIGMENT,-MINIMAL
-VACUOLIZATION, X-ZONE,-SLIGHT
-HYPERPLASIA, SUBCAPSULAR CELL,-MINIMAL
LIVER (LI) :
-HEPATOCTE, HYPERTROPHY,
CENTROLOBULAR,-MINIMAL
-NECROSIS,-MINIMAL, FOCAL
-INFLAMMATION, CHRONIC/CHRONIC ACTIVE,-
MINIMAL, FOCAL
UTERUS (UT) :
-HYPERPLASIA, CYSTIC ENDOMETRIAL,-
MODERATE

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 823

STUDY NUMBER: 483287

ANIMAL NUMBER: A37468 SEX: FEMALE DOSE GROUP: 3 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/11/91 STUDY DAY OF DEATH: 95 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 22.3 GRAMS
DATE AND TIME OF NECROPSY: 11/11/91 11:40 PROSECTOR: JANE EARHARDT RECORDER: JANE EARHARDT
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE), KIDNEY (KD),
LACRIMAL GL, EX (EO), LIVER (LI), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU), MAMMARY, FEMALE (MF),
MAND SALIVARY GL (SG), MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON),
NERVE, SCIATIC (SN), OVARY (OV), PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), RECTUM (RE), SKIN (SK),
SKIN, OTHER (SS), SPLEEN (SP), STOMACH, GL (ST), STOMACH, NONGL (SU), THYMUS (TH), THYROID (TY), TONGUE (TO),
TRACHEA (TR), URINARY BLADDER (UB), UTERUS, CERVIX (CV), VAGINA (VA)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:

ADRENAL, MEDULLA (AM), KIDNEY (KD), UTERUS, CERVIX (CV)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 824

STUDY NUMBER: 483287

ANIMAL NUMBER: A37469 SEX: FEMALE DOSE GROUP: 3 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/11/91 STUDY DAY OF DEATH: 95 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 26.0 GRAMS
DATE AND TIME OF NECROPSY: 11/11/91 13:56 PROSECTOR: FRED AGEY RECORDER: FRED AGEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.20	.782 %	.415	WEIGHT TAKEN
LUNG (LU)	.19	.713 %	.378	WEIGHT TAKEN
UTERUS (UT)	.11	.406 %	.215	WEIGHT TAKEN
BRAIN W/STEM (BR)	.49	1.885 %	1.000	WEIGHT TAKEN
HEART (HT)	.13	.500 %	.265	WEIGHT TAKEN
SPLEEN (SP)	.07	.286 %	.152	WEIGHT TAKEN
KIDNEY (KD)	.34	1.307 %	.694	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	1.45	5.582 %	2.961	WEIGHT TAKEN
ADRENAL (AD)	.015	.0569 %	.0302	WEIGHT TAKEN
OVARY (OV)	.026	.1008 %	.0535	WEIGHT TAKEN
THYMUS (TH)	.04	.161 %	.085	WEIGHT TAKEN

CLINICAL OBSERVATIONS	PATHOLOGY OBSERVATIONS NECROPSY	HISTOPATHOLOGY
-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS	LIVER (LI) : -PALE AREA; MEDIAN LOBE, AT HILUS, ONE, TAN, 2 X 2 MM ^COLLECTED/TAKEN (XW) : -LIVER SECTIONS, IN METHANOL	LIVER (LI) : >UNREMARKABLE

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE), KIDNEY (KD),
LACRIMAL GL, EX (EO), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU), MAMMARY, FEMALE (MF), MAND SALIVARY GL (SG),
MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON), NERVE, SCIATIC (SN),
OVARY (OV), PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), RECTUM (RE), SKIN (SK), SKIN, OTHER (SS), SPLEEN (SP),
STOMACH, GL (ST), STOMACH, NONGL (SU), THYMUS (TH), THYROID (TY), TONGUE (TO), TRACHEA (TR), URINARY BLADDER (UB),
UTERUS (UT), UTERUS, CERVIX (CV), VAGINA (VA)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 825

STUDY NUMBER: 483287

ANIMAL NUMBER: A37470 SEX: FEMALE DOSE GROUP: 3 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/12/91 STUDY DAY OF DEATH: 96 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 23.9 GRAMS
DATE AND TIME OF NECROPSY: 11/12/91 9:13 PROSECTOR: FRED AGEY RECORDER: FRED AGEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.18	.748 %	.350	WEIGHT TAKEN
LUNG (LU)	.20	.855 %	.400	WEIGHT TAKEN
UTERUS (UT)	.11	.451 %	.211	WEIGHT TAKEN
BRAIN W/STEM (BR)	.51	2.137 %	1.000	WEIGHT TAKEN
HEART (HT)	.14	.579 %	.271	WEIGHT TAKEN
SPLEEN (SP)	.08	.325 %	.152	WEIGHT TAKEN
KIDNEY (KD)	.35	1.470 %	.688	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	1.35	5.654 %	2.646	WEIGHT TAKEN
ADRENAL (AD)	.015	.0636 %	.0298	WEIGHT TAKEN
OVARY (OV)	.050	.2092 %	.0979	WEIGHT TAKEN
THYMUS (TH)	.03	.133 %	.062	WEIGHT TAKEN

CLINICAL OBSERVATIONS	PATHOLOGY OBSERVATIONS NECROPSY	HISTOPATHOLOGY
-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS		ADRENAL, CORTEX (AC) : -VACUOLIZATION, X-ZONE, -SLIGHT ADRENAL, MEDULLA (AM) : -UNILATERALLY EXAMINED, -PRESENT KIDNEY (KD) : -INFLAMMATION, CHRONIC, -MINIMAL LIVER (LI) : -HEPATOCYTE, HYPERTROPHY, CENTROLOBULAR, -MINIMAL UTERUS (UT) : -HYPERPLASIA, CYSTIC ENDOMETRIAL, - SLIGHT
	^COLLECTED/TAKEN (XW) : -LIVER SECTIONS, IN METHANOL	

HAZLETON WASHINGTON, INC.
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APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 826

STUDY NUMBER: 483287

ANIMAL NUMBER: A37470 SEX: FEMALE DOSE GROUP: 3 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/12/91 STUDY DAY OF DEATH: 96 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 23.9 GRAMS
DATE AND TIME OF NECROPSY: 11/12/91 9:13 PROSECTOR: FRED AGEY RECORDER: FRED AGEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE), KIDNEY (KD),
LACRIMAL GL, EX (EO), LIVER (LI), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU), MAMMARY, FEMALE (MF),
MAND SALIVARY GL (SG), MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON),
NERVE, SCIATIC (SN), OVARY (OV), PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), RECTUM (RE), SKIN (SK),
SKIN, OTHER (SS), SPLEEN (SP), STOMACH, GL (ST), STOMACH, NONGL (SU), THYMUS (TH), THYROID (TY), TONGUE (TO),
TRACHEA (TR), URINARY BLADDER (UB), UTERUS (UT), UTERUS, CERVIX (CV), VAGINA (VA)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:
UTERUS, CERVIX (CV)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 827

STUDY NUMBER: 483287

ANIMAL NUMBER: A37471 SEX: FEMALE DOSE GROUP: 3 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/12/91 STUDY DAY OF DEATH: 96 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 24.8 GRAMS
DATE AND TIME OF NECROPSY: 11/12/91 10:05 PROSECTOR: SONNY DIKES RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.12	.496 %	.241	WEIGHT TAKEN
LUNG (LU)	.16	.652 %	.316	WEIGHT TAKEN
UTERUS (UT)	.29	1.159 %	.563	WEIGHT TAKEN
BRAIN W/STEM (BR)	.51	2.059 %	1.000	WEIGHT TAKEN
HEART (HT)	.14	.556 %	.270	WEIGHT TAKEN
SPLEEN (SP)	.11	.435 %	.211	WEIGHT TAKEN
KIDNEY (KD)	.33	1.345 %	.653	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	1.34	5.408 %	2.626	WEIGHT TAKEN
ADRENAL (AD)	.010	.0399 %	.0194	WEIGHT TAKEN
OVARY (OV)	.045	.1823 %	.0885	WEIGHT TAKEN
THYMUS (TH)	.04	.161 %	.078	WEIGHT TAKEN

CLINICAL OBSERVATIONS	P A T H O L O G Y O B S E R V A T I O N S NECROPSY	HISTOPATHOLOGY
-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS	^COLLECTED/TAKEN (XW) : -LIVER SECTIONS, IN METHANOL	LIVER (LI) : -NECROSIS,-MINIMAL, MULTI-FOCAL -INFLAMMATION, CHRONIC/CHRONIC ACTIVE,- MINIMAL

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE), KIDNEY (KD),
LACRIMAL GL, EX (EO), LIVER (LI), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU), MAMMARY, FEMALE (MF),
MAND SALIVARY GL (SG), MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON),
NERVE, SCIATIC (SN), OVARY (OV), PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), RECTUM (RE), SKIN (SK),
SKIN, OTHER (SS), SPLEEN (SP), STOMACH, GL (ST), STOMACH, NONGL (SU), THYMUS (TH), THYROID (TY), TONGUE (TO),
TRACHEA (TR), URINARY BLADDER (UB), UTERUS (UT), UTERUS, CERVIX (CV), VAGINA (VA)

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 828

STUDY NUMBER: 483287

ANIMAL NUMBER: A37471 SEX: FEMALE DOSE GROUP: 3 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/12/91 STUDY DAY OF DEATH: 96 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 24.8 GRAMS
DATE AND TIME OF NECROPSY: 11/12/91 10:05 PROSECTOR: SONNY DIKES RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 829

STUDY NUMBER: 483287

ANIMAL NUMBER: A37472 SEX: FEMALE DOSE GROUP: 3 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/12/91 STUDY DAY OF DEATH: 96 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 22.2 GRAMS
DATE AND TIME OF NECROPSY: 11/12/91 11:15 PROSECTOR: FRED AGEY RECORDER: FRED AGEY
POST-FIX WEAHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEAHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.13	.583 %	.279	WEIGHT TAKEN
LUNG (LU)	.20	.890 %	.426	WEIGHT TAKEN
UTERUS (UT)	.16	.740 %	.354	WEIGHT TAKEN
BRAIN W/STEM (BR)	.46	2.091 %	1.000	WEIGHT TAKEN
HEART (HT)	.16	.699 %	.334	WEIGHT TAKEN
SPLEEN (SP)	.08	.377 %	.181	WEIGHT TAKEN
KIDNEY (KD)	.32	1.463 %	.699	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	1.18	5.318 %	2.543	WEIGHT TAKEN
ADRENAL (AD)	.013	.0577 %	.0276	WEIGHT TAKEN
OVARY (OV)	.038	.1698 %	.0812	WEIGHT TAKEN
THYMUS (TH)	.03	.147 %	.070	WEIGHT TAKEN

CLINICAL OBSERVATIONS	PATHOLOGY OBSERVATIONS NECROPSY	HISTOPATHOLOGY
-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS	LIVER (LI) : -DARK; ALL LOBES, DARK BROWN ^COLLECTED/TAKEN (XW) : -LIVER SECTIONS, IN METHANOL	ADRENAL, CORTEX (AC) : -VACUOLIZATION, X-ZONE,-MODERATE -HYPERPLASIA, SUBCAPSULAR CELL,-MINIMAL LIVER (LI) : -KUPFFER CELL/MACROPHAGE, PIGMENT,- MINIMAL -NECROSIS,-MINIMAL, FOCAL -INFLAMMATION, CHRONIC/CHRONIC ACTIVE,- MINIMAL UTERUS (UT) : -HYPERPLASIA, CYSTIC ENDOMETRIAL,- MINIMAL

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 830

STUDY NUMBER: 483287

ANIMAL NUMBER: A37472 SEX: FEMALE DOSE GROUP: 3 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/12/91 STUDY DAY OF DEATH: 96 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 22.2 GRAMS
DATE AND TIME OF NECROPSY: 11/12/91 11:15 PROSECTOR: FRED AGEY RECORDER: FRED AGEY
POST-FIX WEIGHER: JANE FARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE), KIDNEY (KD),
LACRIMAL GL, EX (EO), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU), MAMMARY, FEMALE (MF), MAND SALIVARY GL (SG),
MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON), NERVE, SCIATIC (SN),
OVARY (OV), PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), RECTUM (RE), SKIN (SK), SKIN, OTHER (SS), SPLEEN (SP),
STOMACH, GL (ST), STOMACH, NONGL (SU), THYMUS (TH), THYROID (TY), TONGUE (TO), TRACHEA (TR), URINARY BLADDER (UB),
UTERUS (UT), UTERUS, CERVIX (CV), VAGINA (VA)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:

ADRENAL, MEDULLA (AM), KIDNEY (KD), UTERUS, CERVIX (CV)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 831

STUDY NUMBER: 483287

ANIMAL NUMBER: A37473 SEX: FEMALE DOSE GROUP: 3 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/12/91 STUDY DAY OF DEATH: 96 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 26.0 GRAMS
DATE AND TIME OF NECROPSY: 11/12/91 13:30 PROSECTOR: SCOTT BELL RECORDER: SCOTT BELL
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.19	.713 %	.319	WEIGHT TAKEN
LUNG (LU)	.17	.663 %	.297	WEIGHT TAKEN
UTERUS (UT)	.40	1.528 %	.684	WEIGHT TAKEN
BRAIN W/STEM (BR)	.58	2.233 %	1.000	WEIGHT TAKEN
HEART (HT)	.16	.602 %	.270	WEIGHT TAKEN
SPLEEN (SP)	.10	.380 %	.170	WEIGHT TAKEN
KIDNEY (KD)	.40	1.533 %	.687	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	1.39	5.340 %	2.391	WEIGHT TAKEN
ADRENAL (AD)	.010	.0388 %	.0174	WEIGHT TAKEN
OVARY (OV)	.059	.2281 %	.1021	WEIGHT TAKEN
THYMUS (TH)	.03	.115 %	.051	WEIGHT TAKEN

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE
OBSERVATIONS

PATHOLOGY OBSERVATIONS
NECROPSY

OVARY (OV) :
-CYST; BOTH, ONE EACH, CLEAR TO RED, 3
X 3 MM
STOMACH, GL (ST) :
-DARK AREA; MUCOSA, FEW, BLACK,
PINPOINT TO 2 X 2 MM
UTERUS (UT) :
-WALL, THICKENED, MODERATE; BOTH HORNS
^COLLECTED/TAKEN (XW) :
-LIVER SECTIONS, IN METHANOL

HISTOPATHOLOGY

LIVER (LI) :
-NECROSIS, INDIVIDUAL CELL,-MINIMAL
-INFLAMMATION, CHRONIC/CHRONIC ACTIVE,-
MINIMAL
OVARY (OV) :
-FOLLICLE, CYST,-PRESENT
STOMACH, GL (ST) :
-HYPERPLASIA, CYSTIC,-SLIGHT
-MUCOSA, NECROSIS,-MODERATE
UTERUS (UT) :
-HYPERPLASIA, CYSTIC ENDOMETRIAL,-
SLIGHT

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 832

STUDY NUMBER: 483287

ANIMAL NUMBER: A37473 SEX: FEMALE DOSE GROUP: 3 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/12/91 STUDY DAY OF DEATH: 96 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 26.0 GRAMS
DATE AND TIME OF NECROPSY: 11/12/91 13:30 PROSECTOR: SCOTT BELL RECORDER: SCOTT BELL
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE), KIDNEY (KD),
LACRIMAL GL, EX (EO), LIVER (LI), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU), MAMMARY, FEMALE (MF),
MAND SALIVARY GL (SG), MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON),
NERVE, SCIATIC (SN), PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), RECTUM (RE), SKIN (SK), SKIN, OTHER (SS),
SPLEEN (SP), STOMACH, NONGL (SU), THYMUS (TH), THYROID (TY), TONGUE (TO), TRACHEA (TR), URINARY BLADDER (UB),
UTERUS, CERVIX (CV), VAGINA (VA)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:

OVIDUCT (OD), STOMACH, NONGL (SU)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 833

STUDY NUMBER: 483287

ANIMAL NUMBER: A37474 SEX: FEMALE DOSE GROUP: 3 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/13/91 STUDY DAY OF DEATH: 97 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 24.9 GRAMS
DATE AND TIME OF NECROPSY: 11/13/91 9:00 PROSECTOR: ADEFOLAHAN AKINSOLA RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.17	.684 %	.331	WEIGHT TAKEN
LUNG (LU)	.17	.670 %	.324	WEIGHT TAKEN
UTERUS (UT)	.14	.567 %	.274	WEIGHT TAKEN
BRAIN W/STEM (BR)	.51	2.067 %	1.000	WEIGHT TAKEN
HEART (HT)	.17	.685 %	.331	WEIGHT TAKEN
SPLEEN (SP)	.07	.274 %	.133	WEIGHT TAKEN
KIDNEY (KD)	.36	1.457 %	.705	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	1.53	6.150 %	2.975	WEIGHT TAKEN
ADRENAL (AD)	.009	.0365 %	.0177	WEIGHT TAKEN
OVARY (OV)	.025	.1012 %	.0490	WEIGHT TAKEN
THYMUS (TH)	.05	.183 %	.089	WEIGHT TAKEN

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE
OBSERVATIONS

PATHOLOGY OBSERVATIONS
NECROPSY

HISTOPATHOLOGY

LIVER (LI) :
-HEPATOCYTE, HYPERTROPHY,
CENTROLOBULAR,-MINIMAL
-INFLAMMATION, CHRONIC/CHRONIC ACTIVE,-
MINIMAL

^COLLECTED/TAKEN (XW) :
-LIVER SECTIONS, IN METHANOL

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE), KIDNEY (KD),
LACRIMAL GL, EX (EO), LIVER (LI), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU), MAMMARY, FEMALE (MF),
MAND SALIVARY GL (SG), MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON),
NERVE, SCIATIC (SN), OVARY (OV), PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), RECTUM (RE), SKIN (SK),
SKIN, OTHER (SS), SPLEEN (SP), STOMACH, GL (ST), STOMACH, NONGL (SU), THYMUS (TH), THYROID (TY), TONGUE (TO),
TRACHEA (TR), URINARY BLADDER (UB), UTERUS (UT), UTERUS, CERVIX (CV), VAGINA (VA)

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 834

STUDY NUMBER: 483287

ANIMAL NUMBER: A37474 SEX: FEMALE DOSE GROUP: 3 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/13/91 STUDY DAY OF DEATH: 97 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 24.9 GRAMS
DATE AND TIME OF NECROPSY: 11/13/91 9:00 PROSECTOR: ADEPOLAHAN AKINSOLA RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
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APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 835

STUDY NUMBER: 483287

ANIMAL NUMBER: A37475 SEX: FEMALE DOSE GROUP: 3 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/13/91 STUDY DAY OF DEATH: 97 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 22.9 GRAMS
DATE AND TIME OF NECROPSY: 11/13/91 10:00 PROSECTOR: SCOTT BELL RECORDER: SCOTT BELL
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.17	.758 %	.324	WEIGHT TAKEN
LUNG (LU)	.18	.790 %	.338	WEIGHT TAKEN
UTERUS (UT)	.27	1.194 %	.511	WEIGHT TAKEN
BRAIN W/STEM (BR)	.54	2.338 %	1.000	WEIGHT TAKEN
HEART (HT)	.18	.803 %	.343	WEIGHT TAKEN
SPLEEN (SP)	.08	.368 %	.157	WEIGHT TAKEN
KIDNEY (KD)	.36	1.577 %	.674	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	1.30	5.686 %	2.432	WEIGHT TAKEN
ADRENAL (AD)	.015	.0642 %	.0275	WEIGHT TAKEN
OVARY (OV)	.064	.2812 %	.1203	WEIGHT TAKEN
THYMUS (TH)	.03	.113 %	.048	WEIGHT TAKEN

CLINICAL OBSERVATIONS	PATHOLOGY OBSERVATIONS NECROPSY	HISTOPATHOLOGY
-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS	LIVER (LI) : -ENLARGED, MODERATE; ALL LOBES -MASS; BOTH PAPILLARY PROCESS, ONE EACH, INVOLVING ENTIRE, TAN, BLACK, 7 X 5 MM, CUT SURFACE: SAME -DARK AREA; LEFT LATERAL, MEDIAN LOBES, ONE EACH, BLACK, 5 X 3 MM OVARY (OV) : -CYST; BOTH, ONE EACH, CLEAR, 3 X 3 MM ^COLLECTED/TAKEN (XW) : -LIVER SECTIONS, IN METHANOL	LIVER (LI) : -INFLAMMATION, CHRONIC/CHRONIC ACTIVE, - MINIMAL -INFARCT, -PRESENT OVARY (OV) : -BURSA, CYST, -PRESENT

HAZLETON WASHINGTON, INC.
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APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 836

STUDY NUMBER: 483287

ANIMAL NUMBER: A37475 SEX: FEMALE DOSE GROUP: 3 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/13/91 STUDY DAY OF DEATH: 97 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 22.9 GRAMS
DATE AND TIME OF NECROPSY: 11/13/91 10:00 PROSECTOR: SCOTT BELL RECORDER: SCOTT BELL
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE), KIDNEY (KD),
LACRIMAL GL, EX (EO), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU), MAMMARY, FEMALE (MF), MAND SALIVARY GL (SG),
MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON), NERVE, SCIATIC (SN),
PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), RECTUM (RE), SKIN (SK), SKIN, OTHER (SS), SPLEEN (SP),
STOMACH, GL (ST), STOMACH, NONGL (SU), THYMUS (TH), THYROID (TY), TONGUE (TO), TRACHEA (TR), URINARY BLADDER (UB),
UTERUS (UT), UTERUS, CERVIX (CV), VAGINA (VA)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:
OVIDUCT (OD)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 837

STUDY NUMBER: 483287

ANIMAL NUMBER: A37476 SEX: FEMALE DOSE GROUP: 3 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/13/91 STUDY DAY OF DEATH: 97 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 26.8 GRAMS
DATE AND TIME OF NECROPSY: 11/13/91 11:05 PROSECTOR: FRED AGEY RECORDER: FRED AGEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.19	.706 %	.418	WEIGHT TAKEN
LUNG (LU)	.20	.735 %	.435	WEIGHT TAKEN
UTERUS (UT)	.20	.754 %	.446	WEIGHT TAKEN
BRAIN W/STEM (BR)	.45	1.691 %	1.000	WEIGHT TAKEN
HEART (HT)	.15	.546 %	.323	WEIGHT TAKEN
SPLEEN (SP)	.09	.323 %	.191	WEIGHT TAKEN
KIDNEY (KD)	.42	1.572 %	.930	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	2.02	7.529 %	4.454	WEIGHT TAKEN
ADRENAL (AD)	.011	.0399 %	.0236	WEIGHT TAKEN
OVARY (OV)	.059	.2209 %	.1307	WEIGHT TAKEN
THYMUS (TH)	.05	.181 %	.107	WEIGHT TAKEN

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE
OBSERVATIONS

PATHOLOGY OBSERVATIONS
NECROPSY

OVARY (OV) :
-CYST; RIGHT, ONE, CLEAR, 2 X 2 MM
UTERUS (UT) :
-DARK; BOTH HORNS, DARK RED
-DISTENDED, MODERATE; BOTH HORNS
^COLLECTED/TAKEN (XW) :
-LIVER SECTIONS, IN METHANOL

HISTOPATHOLOGY

ADRENAL, CORTEX (AC) :
-PIGMENT,-MINIMAL
-VACUOLIZATION, X-ZONE,-SLIGHT
ADRENAL, MEDULLA (AM) :
-UNILATERALLY EXAMINED,-PRESENT
LIVER (LI) :
-VACUOLIZATION,-MINIMAL
OVARY (OV) :
-BURSA, CYST,-PRESENT
UTERUS (UT) :
-HYPERPLASIA, CYSTIC ENDOMETRIAL,-
MINIMAL

HAZLETON WASHINGTON, INC.
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APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 838

STUDY NUMBER: 483287

ANIMAL NUMBER: A37476 SEX: FEMALE DOSE GROUP: 3 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/13/91 STUDY DAY OF DEATH: 97 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 26.8 GRAMS
DATE AND TIME OF NECROPSY: 11/13/91 11:05 PROSECTOR: FRED AGEY RECORDER: FRED AGEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE), KIDNEY (KD),
LACRIMAL GL, EX (EO), LIVER (LI), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU), MAMMARY, FEMALE (MF),
MAND SALIVARY GL (SG), MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON),
NERVE, SCIATIC (SN), PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), RECTUM (RE), SKIN (SK), SKIN, OTHER (SS),
SPLEEN (SP), STOMACH, GL (ST), STOMACH, NONGL (SU), THYMUS (TH), THYROID (TY), TONGUE (TO), TRACHEA (TR),
URINARY BLADDER (UB), UTERUS, CERVIX (CV), VAGINA (VA)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:
KIDNEY (KD), OVIDUCT (OD), UTERUS, CERVIX (CV)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 839

STUDY NUMBER: 483287

ANIMAL NUMBER: A37477 SEX: FEMALE DOSE GROUP: 3 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/13/91 STUDY DAY OF DEATH: 97 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 24.7 GRAMS
DATE AND TIME OF NECROPSY: 11/13/91 13:32 PROSECTOR: ADEFOLAHAN AKINSOLA RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.19	.789 %	.397	WEIGHT TAKEN
LUNG (LU)	.19	.758 %	.382	WEIGHT TAKEN
UTERUS (UT)	.14	.563 %	.284	WEIGHT TAKEN
BRAIN W/STEM (BR)	.49	1.986 %	1.000	WEIGHT TAKEN
HEART (HT)	.13	.539 %	.271	WEIGHT TAKEN
SPLEEN (SP)	.07	.299 %	.151	WEIGHT TAKEN
KIDNEY (KD)	.38	1.519 %	.765	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	1.51	6.131 %	3.087	WEIGHT TAKEN
ADRENAL (AD)	.013	.0534 %	.0269	WEIGHT TAKEN
OVARY (OV)	.046	.1879 %	.0946	WEIGHT TAKEN
THYMUS (TH)	.02	.094 %	.047	WEIGHT TAKEN

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE
OBSERVATIONS

PATHOLOGY OBSERVATIONS
NECROPSY

HISTOPATHOLOGY

ADRENAL, CORTEX (AC) :
-PIGMENT,-MINIMAL
-HYPERPLASIA, SUBCAPSULAR CELL,-MINIMAL
ADRENAL, MEDULLA (AM) :
-UNILATERALLY EXAMINED,-PRESENT
KIDNEY (KD) :
-INFLAMMATION, CHRONIC,-MINIMAL
LIVER (LI) :
-NECROSIS, INDIVIDUAL CELL,-MINIMAL
-INFLAMMATION, CHRONIC/CHRONIC ACTIVE,-
MINIMAL
UTERUS (UT) :
>TISSUE MISSING
UTERUS, CERVIX (CV) :
>TISSUE MISSING

^COLLECTED/TAKEN (XW) :
-LIVER SECTIONS, IN METHANOL

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 840

STUDY NUMBER: 483287

ANIMAL NUMBER: A37477 SEX: FEMALE DOSE GROUP: 3 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/13/91 STUDY DAY OF DEATH: 97 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 24.7 GRAMS
DATE AND TIME OF NECROPSY: 11/13/91 13:32 PROSECTOR: ADEFOLAHAN AKINSOLA RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE), KIDNEY (KD),
LACRIMAL GL, EX (EO), LIVER (LI), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU), MAMMARY, FEMALE (MF),
MAND SALIVARY GL (SG), MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON),
NERVE, SCIATIC (SN), OVARY (OV), PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), RECTUM (RE), SKIN (SK),
SKIN, OTHER (SS), SPLEEN (SP), STOMACH, GL (ST), STOMACH, NONGL (SU), THYMUS (TH), THYROID (TY), TONGUE (TO),
TRACHEA (TR), URINARY BLADDER (UB), UTERUS (UT), UTERUS, CERVIX (CV), VAGINA (VA)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 841

STUDY NUMBER: 483287

ANIMAL NUMBER: A37478 SEX: FEMALE DOSE GROUP: 3 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/14/91 STUDY DAY OF DEATH: 98 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 24.9 GRAMS
DATE AND TIME OF NECROPSY: 11/14/91 8:25 PROSECTOR: SCOTT BELL RECORDER: SCOTT BELL
POST-FIX WEIGHER: DANIEL JACK PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	O R G A N S T A T U S
MAND SALIVARY GL (SG)	.17	.676 %	.323	WEIGHT TAKEN
LUNG (LU)	.20	.794 %	.379	WEIGHT TAKEN
UTERUS (UT)	.31	1.263 %	.603	WEIGHT TAKEN
BRAIN W/STEM (BR)	.52	2.096 %	1.000	WEIGHT TAKEN
HEART (HT)	.15	.604 %	.288	WEIGHT TAKEN
SPLEEN (SP)	.06	.261 %	.125	WEIGHT TAKEN
KIDNEY (KD)	.35	1.396 %	.666	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	1.37	5.486 %	2.617	WEIGHT TAKEN
ADRENAL (AD)	.018	.0739 %	.0353	WEIGHT TAKEN
OVARY (OV)	.041	.1647 %	.0786	WEIGHT TAKEN
THYMUS (TH)	.03	.125 %	.060	WEIGHT TAKEN

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE
OBSERVATIONS

P A T H O L O G Y O B S E R V A T I O N S
NECROPSY

OVARY (OV) :
-CYST; BOTH, ONE EACH, CLEAR TO WHITE,
2 X 2 MM

^COLLECTED/TAKEN (XW) :
-LIVER SECTIONS, IN METHANOL

HISTOPATHOLOGY

ADRENAL, CORTEX (AC) :
-VACUOLIZATION, X-ZONE,-MODERATE
LIVER (LI) :
-INFLAMMATION, CHRONIC/CHRONIC ACTIVE,-
MINIMAL
OVARY (OV) :
-FOLLICLE, CYST,-PRESENT
UTERUS (UT) :
-HYPERPLASIA, CYSTIC ENDOMETRIAL,-
SLIGHT

HAZLETON WASHINGTON, INC.
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APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 842

STUDY NUMBER: 483287

ANIMAL NUMBER: A37478 SEX: FEMALE DOSE GROUP: 3 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/14/91 STUDY DAY OF DEATH: 98 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 24.9 GRAMS
DATE AND TIME OF NECROPSY: 11/14/91 8:25 PROSECTOR: SCOTT BELL RECORDER: SCOTT BELL
POST-FIX WEIGHER: DANIEL JACK PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE), KIDNEY (KD),
LACRIMAL GL, EX (EO), LIVER (LI), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU), MAMMARY, FEMALE (MF),
MAND SALIVARY GL (SG), MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON),
NERVE, SCIATIC (SN), PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), RECTUM (RE), SKIN (SK), SKIN, OTHER (SS),
SPLEEN (SP), STOMACH, GL (ST), STOMACH, NONGL (SU), THYMUS (TH), THYROID (TY), TONGUE (TO), TRACHEA (TR),
URINARY BLADDER (UB), UTERUS (UT), UTERUS, CERVIX (CV), VAGINA (VA)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:

ADRENAL, MEDULLA (AM), KIDNEY (KD), OVIDUCT (OD), UTERUS, CERVIX (CV)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 843

STUDY NUMBER: 483287

ANIMAL NUMBER: A37479 SEX: FEMALE DOSE GROUP: 3 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/14/91 STUDY DAY OF DEATH: 98 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 23.9 GRAMS
DATE AND TIME OF NECROPSY: 01/14/91 9:20 PROSECTOR: ADEFOLAHAN AKINSOLA RECORDER: ADEFOLAHAN AKINSOLA
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.15	.608 %	.266	WEIGHT TAKEN
LUNG (LU)	.19	.804 %	.351	WEIGHT TAKEN
UTERUS (UT)	.22	.901 %	.394	WEIGHT TAKEN
BRAIN W/STEM (BR)	.55	2.288 %	1.000	WEIGHT TAKEN
HEART (HT)	.17	.728 %	.318	WEIGHT TAKEN
SPLEEN (SP)	.07	.297 %	.130	WEIGHT TAKEN
KIDNEY (KD)	.46	1.935 %	.846	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	1.34	5.607 %	2.450	WEIGHT TAKEN
ADRENAL (AD)	.016	.0653 %	.0285	WEIGHT TAKEN
OVARY (OV)	.040	.1678 %	.0733	WEIGHT TAKEN
THYMUS (TH)	.02	.078 %	.034	WEIGHT TAKEN

CLINICAL OBSERVATIONS	PATHOLOGY OBSERVATIONS NECROPSY	HISTOPATHOLOGY
-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS	^COLLECTED/TAKEN (XW) : -LIVER SECTIONS, IN METHANOL	ADRENAL, CORTEX (AC) : -PIGMENT,-MINIMAL -VACUOLIZATION, X-ZONE,-MINIMAL UTERUS (UT) : -HYPERPLASIA, CYSTIC ENDOMETRIAL,- MINIMAL

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 844

STUDY NUMBER: 483287

ANIMAL NUMBER: A37479 SEX: FEMALE DOSE GROUP: 3 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/14/91 STUDY DAY OF DEATH: 98 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 23.9 GRAMS
DATE AND TIME OF NECROPSY: 01/14/91 9:20 PROSECTOR: ADEFOLAHAN AKINSOLA RECORDER: ADEFOLAHAN AKINSOLA
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE), KIDNEY (KD),
LACRIMAL GL, EX (EO), LIVER (LI), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU), MAMMARY, FEMALE (MF),
MAND SALIVARY GL (SG), MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON),
NERVE, SCIATIC (SN), OVARY (OV), PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), RECTUM (RE), SKIN (SK),
SKIN, OTHER (SS), SPLEEN (SP), STOMACH, GL (ST), STOMACH, NONGL (SU), THYMUS (TH), THYROID (TY), TONGUE (TO),
TRACHEA (TR), URINARY BLADDER (UB), UTERUS (UT), UTERUS, CERVIX (CV), VAGINA (VA)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:

ADRENAL, MEDULLA (AM), KIDNEY (KD), LIVER (LI), UTERUS, CERVIX (CV)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 845

STUDY NUMBER: 483287

ANIMAL NUMBER: A37480 SEX: FEMALE DOSE GROUP: 3 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/14/91 STUDY DAY OF DEATH: 98 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 23.4 GRAMS
DATE AND TIME OF NECROPSY: 11/14/91 10:12 PROSECTOR: SCOTT BELL RECORDER: SCOTT BELL
POST-FIX WEIGHER: DANIEL JACK PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.18	.750 %	.344	WEIGHT TAKEN
LUNG (LU)	.19	.818 %	.375	WEIGHT TAKEN
UTERUS (UT)	.18	.770 %	.353	WEIGHT TAKEN
BRAIN W/STEM (BR)	.51	2.180 %	1.000	WEIGHT TAKEN
HEART (HT)	.13	.576 %	.264	WEIGHT TAKEN
SPLEEN (SP)	.08	.335 %	.154	WEIGHT TAKEN
KIDNEY (KD)	.36	1.546 %	.709	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	1.52	6.494 %	2.978	WEIGHT TAKEN
ADRENAL (AD)	.016	.0705 %	.0323	WEIGHT TAKEN
OVARY (OV)	.042	.1786 %	.0819	WEIGHT TAKEN
THYMUS (TH)	.03	.150 %	.069	WEIGHT TAKEN

CLINICAL OBSERVATIONS	PATHOLOGY OBSERVATIONS NECROPSY	HISTOPATHOLOGY
-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS	LIVER (LI) : -PALE AREA; ALL LOBES, FEW, TAN, PINPOINT -DARK; ALL LOBES, DARK BROWN STOMACH, GL (ST) : -DARK AREA; MUCOSA, FEW, BLACK, PINPOINT TO 2 X 2 MM ^COLLECTED/TAKEN (XW) : -LIVER SECTIONS, IN METHANOL	ADRENAL, CORTEX (AC) : -VACUOLIZATION, X-ZONE,-MINIMAL -HYPERPLASIA, SUBCAPSULAR CELL,-MINIMAL KIDNEY (KD) : -INFLAMMATION, CHRONIC,-MINIMAL LIVER (LI) : -VACUOLIZATION,-SLIGHT STOMACH, GL (ST) : -HYPERPLASIA,-MINIMAL -INFLAMMATION, CHRONIC,-MINIMAL UTERUS (UT) : -HYPOPLASIA,-MINIMAL

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 846

STUDY NUMBER: 483287

ANIMAL NUMBER: A37480 SEX: FEMALE DOSE GROUP: 3 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/14/91 STUDY DAY OF DEATH: 98 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 23.4 GRAMS
DATE AND TIME OF NECROPSY: 11/14/91 10:12 PROSECTOR: SCOTT BELL RECORDER: SCOTT BELL
POST-FIX WEIGHER: DANIEL JACK PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE), KIDNEY (KD),
LACRIMAL GL, EX (EO), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU), MAMMARY, FEMALE (MF), MAND SALIVARY GL (SG),
MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON), NERVE, SCIATIC (SN),
OVARY (OV), PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), RECTUM (RE), SKIN (SK), SKIN, OTHER (SS), SPLEEN (SP),
STOMACH, NONGL (SU), THYMUS (TH), THYROID (TY), TONGUE (TO), TRACHEA (TR), URINARY BLADDER (UB), UTERUS (UT),
UTERUS, CERVIX (CV), VAGINA (VA)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:

ADRENAL, MEDULLA (AM), STOMACH, NONGL (SU), UTERUS, CERVIX (CV)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 847

STUDY NUMBER: 483287

ANIMAL NUMBER: A37497 SEX: FEMALE DOSE GROUP: 4 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/11/91 STUDY DAY OF DEATH: 95 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 24.0 GRAMS
DATE AND TIME OF NECROPSY: 11/11/91 9:30 PROSECTOR: SCOTT BELL RECORDER: SCOTT BELL
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.16	.674 %	.325	WEIGHT TAKEN
LUNG (LU)	.16	.681 %	.328	WEIGHT TAKEN
UTERUS (UT)	.25	1.044 %	.503	WEIGHT TAKEN
BRAIN W/STEM (BR)	.50	2.076 %	1.000	WEIGHT TAKEN
HEART (HT)	.15	.613 %	.295	WEIGHT TAKEN
SPLEEN (SP)	.07	.308 %	.148	WEIGHT TAKEN
KIDNEY (KD)	.32	1.347 %	.649	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	1.57	6.547 %	3.154	WEIGHT TAKEN
ADRENAL (AD)	.016	.0654 %	.0315	WEIGHT TAKEN
OVARY (OV)	.045	.1887 %	.0909	WEIGHT TAKEN
THYMUS (TH)	.02	.104 %	.050	WEIGHT TAKEN

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE
OBSERVATIONS

PATHOLOGY OBSERVATIONS
NECROPSY

LIVER (LI) :
-DARK; ALL LOBES, DARK BROWN

^COLLECTED/TAKEN (XW) :
-LIVER SECTIONS, IN METHANOL

HISTOPATHOLOGY

ADRENAL, CORTEX (AC) :
-VACUOLIZATION, X-ZONE,-MINIMAL
-HYPERPLASIA, SUBCAPSULAR CELL,-MINIMAL
ADRENAL, MEDULLA (AM) :
-UNILATERALLY EXAMINED,-PRESENT
LIVER (LI) :
-HEPATOCYTE, HYPERTROPHY,
CENTROLOBULAR,-MINIMAL
-KUPFFER CELL/MACROPHAGE, PIGMENT,-
MINIMAL
-HEPATOCYTE, PIGMENT,-MINIMAL
-NECROSIS, INDIVIDUAL CELL,-MINIMAL
-INFLAMMATION, CHRONIC/CHRONIC ACTIVE,-
MINIMAL
UTERUS (UT) :
-HYPERPLASIA, CYSTIC ENDOMETRIAL,-
SLIGHT

APPENDIX 13B

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 848

STUDY NUMBER: 483287

ANIMAL NUMBER: A37497 SEX: FEMALE DOSE GROUP: 4 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/11/91 STUDY DAY OF DEATH: 95 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 24.0 GRAMS
DATE AND TIME OF NECROPSY: 11/11/91 9:30 PROSECTOR: SCOTT BELL RECORDER: SCOTT BELL
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE), KIDNEY (KD),
LACRIMAL GL, EX (EO), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU), MAMMARY, FEMALE (MF), MAND SALIVARY GL (SG),
MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON), NERVE, SCIATIC (SN),
OVARY (OV), PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), RECTUM (RE), SKIN (SK), SKIN, OTHER (SS), SPLEEN (SP),
STOMACH, GL (ST), STOMACH, NONGL (SU), THYMUS (TH), THYROID (TY), TONGUE (TO), TRACHEA (TR), URINARY BLADDER (UB),
UTERUS (UT), UTERUS, CERVIX (CV), VAGINA (VA)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:

KIDNEY (KD), STOMACH, GL (ST), STOMACH, NONGL (SU), UTERUS, CERVIX (CV)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 849

STUDY NUMBER: 483287

ANIMAL NUMBER: A37498 SEX: FEMALE DOSE GROUP: 4 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/11/91 STUDY DAY OF DEATH: 95 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 25.5 GRAMS
DATE AND TIME OF NECROPSY: 11/11/91 10:41 PROSECTOR: DOUGLAS HERNDON RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.15	.576 %	.297	WEIGHT TAKEN
LUNG (LU)	.19	.758 %	.390	WEIGHT TAKEN
UTERUS (UT)	.14	.556 %	.286	WEIGHT TAKEN
BRAIN W/STEM (BR)	.50	1.942 %	1.000	WEIGHT TAKEN
HEART (HT)	.12	.462 %	.238	WEIGHT TAKEN
SPLEEN (SP)	.06	.222 %	.114	WEIGHT TAKEN
KIDNEY (KD)	.42	1.649 %	.849	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	2.09	8.215 %	4.229	WEIGHT TAKEN
ADRENAL (AD)	.014	.0557 %	.0287	WEIGHT TAKEN
OVARY (OV)	.032	.1263 %	.0650	WEIGHT TAKEN
THYMUS (TH)	.04	.158 %	.081	WEIGHT TAKEN

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE
OBSERVATIONS

PATHOLOGY OBSERVATIONS
NECROPSY

LIVER (LI) :
-ENLARGED, MODERATE; ALL LOBES
-DARK; ALL LOBES, DARK BROWN

^COLLECTED/TAKEN (XW) :
-LIVER SECTIONS, IN METHANOL

HISTOPATHOLOGY

ADRENAL, CORTEX (AC) :
-VACUOLIZATION, X-ZONE,-MODERATE
ADRENAL, MEDULLA (AM) :
-UNILATERALLY EXAMINED,-PRESENT
KIDNEY (KD) :
-INFLAMMATION, SUBACUTE,-SLIGHT
LIVER (LI) :
-HEPATOCYTE, HYPERTROPHY,
CENTROLOBULAR,-MINIMAL
-VACUOLIZATION,-SLIGHT
STOMACH, GL (ST) :
-INFLAMMATION, CHRONIC,-MINIMAL
UTERUS (UT) :
-HYPOPLASIA,-MODERATE

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 850

STUDY NUMBER: 483287

ANIMAL NUMBER: A37498 SEX: FEMALE DOSE GROUP: 4 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/11/91 STUDY DAY OF DEATH: 95 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 25.5 GRAMS
DATE AND TIME OF NECROPSY: 11/11/91 10:41 PROSECTOR: DOUGLAS HERNDON RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE), KIDNEY (KD),
LACRIMAL GL, EX (EO), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU), MAMMARY, FEMALE (MP), MAND SALIVARY GL (SG),
MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON), NERVE, SCIATIC (SN),
OVARY (OV), PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), RECTUM (RE), SKIN (SK), SKIN, OTHER (SS), SPLEEN (SP),
STOMACH, GL (ST), STOMACH, NONGL (SU), THYMUS (TH), THYROID (TY), TONGUE (TO), TRACHEA (TR), URINARY BLADDER (UB),
UTERUS (UT), UTERUS, CERVIX (CV), VAGINA (VA)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:

STOMACH, NONGL (SU), UTERUS, CERVIX (CV)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 851

STUDY NUMBER: 483287

ANIMAL NUMBER: A37499 SEX: FEMALE DOSE GROUP: 4 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/11/91 STUDY DAY OF DEATH: 95 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 24.7 GRAMS
DATE AND TIME OF NECROPSY: 11/11/91 11:33 PROSECTOR: ADEPOLAHAN AKINSOLA RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.14	.558 %	.268	WEIGHT TAKEN
LUNG (LU)	.15	.609 %	.292	WEIGHT TAKEN
UTERUS (UT)	.18	.746 %	.358	WEIGHT TAKEN
BRAIN W/STEM (BR)	.51	2.084 %	1.000	WEIGHT TAKEN
HEART (HT)	.14	.557 %	.267	WEIGHT TAKEN
SPLEEN (SP)	.08	.317 %	.152	WEIGHT TAKEN
KIDNEY (KD)	.41	1.679 %	.805	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	1.98	7.998 %	3.837	WEIGHT TAKEN
ADRENAL (AD)	.010	.0417 %	.0200	WEIGHT TAKEN
OVARY (OV)	.039	.1559 %	.0748	WEIGHT TAKEN
THYMUS (TH)	.02	.086 %	.041	WEIGHT TAKEN

CLINICAL OBSERVATIONS	PATHOLOGY OBSERVATIONS NECROPSY	HISTOPATHOLOGY
-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS	LIVER (LI) : -PALE AREA; ALL LOBES, FEW, TAN, PINPOINT TO 2 X 2 MM -DARK; ALL LOBES, DARK BROWN ^COLLECTED/TAKEN (XW) : -LIVER SECTIONS, IN METHANOL	LIVER (LI) : -HEPATOCTE, HYPERTROPHY, CENTROLOBULAR,-SLIGHT -VACUOLIZATION,-MODERATE -HEPATOCTE, PIGMENT,-MINIMAL -INFLAMMATION, CHRONIC/CHRONIC ACTIVE,- MINIMAL STOMACH, GL (ST) : -HYPERPLASIA, CYSTIC,-MINIMAL

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 852

STUDY NUMBER: 483287

ANIMAL NUMBER: A37499 SEX: FEMALE DOSE GROUP: 4 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/11/91 STUDY DAY OF DEATH: 95 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 24.7 GRAMS
DATE AND TIME OF NECROPSY: 11/11/91 11:33 PROSECTOR: ADEPOLAHAN AKINSOLA RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE), KIDNEY (KD),
LACRIMAL GL, EX (EO), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU), MAMMARY, FEMALE (MF), MAND SALIVARY GL (SG),
MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON), NERVE, SCIATIC (SN),
OVARY (OV), PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), RECTUM (RE), SKIN (SK), SKIN, OTHER (SS), SPLEEN (SP),
STOMACH, GL (ST), STOMACH, NONGL (SU), THYMUS (TH), THYROID (TY), TONGUE (TO), TRACHEA (TR), URINARY BLADDER (UB),
UTERUS (UT), UTERUS, CERVIX (CV), VAGINA (VA)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), KIDNEY (KD), STOMACH, NONGL (SU), UTERUS (UT), UTERUS, CERVIX (CV)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 853

STUDY NUMBER: 483287

ANIMAL NUMBER: A37500 SEX: FEMALE DOSE GROUP: 4 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/11/91 STUDY DAY OF DEATH: 95 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 25.3 GRAMS
DATE AND TIME OF NECROPSY: 11/11/91 14:01 PROSECTOR: SONNY DIKES RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.11	.447 %	.216	WEIGHT TAKEN
LUNG (LU)	.16	.623 %	.300	WEIGHT TAKEN
UTERUS (UT)	.27	1.059 %	.511	WEIGHT TAKEN
BRAIN W/STEM (BR)	.52	2.073 %	1.000	WEIGHT TAKEN
HEART (HT)	.15	.581 %	.280	WEIGHT TAKEN
SPLEEN (SP)	.08	.312 %	.150	WEIGHT TAKEN
KIDNEY (KD)	.40	1.562 %	.753	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	2.05	8.092 %	3.904	WEIGHT TAKEN
ADRENAL (AD)	.012	.0474 %	.0229	WEIGHT TAKEN
OVARY (OV)	.031	.1217 %	.0587	WEIGHT TAKEN
THYMUS (TH)	.02	.074 %	.036	WEIGHT TAKEN

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE
OBSERVATIONS

PATHOLOGY OBSERVATIONS
NECROPSY

LIVER (LI) :
-PALE AREA; ALL LOBES, FEW, TAN,
PINPOINT TO 4 X 2 MM
-ENLARGED, SLIGHT; ALL LOBES
-DARK; ALL LOBES, DARK BROWN

^COLLECTED/TAKEN (XW) :
-LIVER SECTIONS, IN METHANOL

HISTOPATHOLOGY

ADRENAL, CORTEX (AC) :
-VACUOLIZATION, X-ZONE,-SLIGHT
-HYPERPLASIA, SUBCAPSULAR CELL,-MINIMAL
KIDNEY (KD) :
-INFLAMMATION, CHRONIC,-MINIMAL
LIVER (LI) :
-HEPATOCTE, HYPERTROPHY,
CENTROLOBULAR,-MINIMAL
-KUPFFER CELL/MACROPHAGE, PIGMENT,-
SLIGHT
-HEPATOCTE, PIGMENT,-MINIMAL
-NECROSIS, INDIVIDUAL CELL,-MINIMAL
-INFLAMMATION, CHRONIC/CHRONIC ACTIVE,-
SLIGHT

APPENDIX 13B

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 854

STUDY NUMBER: 483287

ANIMAL NUMBER: A37500 SEX: FEMALE DOSE GROUP: 4 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/11/91 STUDY DAY OF DEATH: 95 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 25.3 GRAMS
DATE AND TIME OF NECROPSY: 11/11/91 14:01 PROSECTOR: SONNY DIKES RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE), KIDNEY (KD),
LACRIMAL GL, EX (EO), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU), MAMMARY, FEMALE (MF), MAND SALIVARY GL (SG),
MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON), NERVE, SCIATIC (SN),
OVARY (OV), PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), RECTUM (RE), SKIN (SK), SKIN, OTHER (SS), SPLEEN (SP),
STOMACH, GL (ST), STOMACH, NONGL (SU), THYMUS (TH), THYROID (TY), TONGUE (TO), TRACHEA (TR), URINARY BLADDER (UB),
UTERUS (UT), UTERUS, CERVIX (CV), VAGINA (VA)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:

ADRENAL, MEDULLA (AM), STOMACH, GL (ST), STOMACH, NONGL (SU), UTERUS (UT), UTERUS, CERVIX (CV)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 855

STUDY NUMBER: 483287

ANIMAL NUMBER: A37501 SEX: FEMALE DOSE GROUP: 4 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/12/91 STUDY DAY OF DEATH: 96 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 24.7 GRAMS
DATE AND TIME OF NECROPSY: 11/12/91 9:16 PROSECTOR: SONNY DIKES RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.12	.480 %	.233	WEIGHT TAKEN
LUNG (LU)	.17	.707 %	.343	WEIGHT TAKEN
UTERUS (UT)	.13	.506 %	.246	WEIGHT TAKEN
BRAIN W/STEM (BR)	.51	2.061 %	1.000	WEIGHT TAKEN
HEART (HT)	.16	.632 %	.307	WEIGHT TAKEN
SPLEEN (SP)	.09	.345 %	.168	WEIGHT TAKEN
KIDNEY (KD)	.42	1.715 %	.832	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	1.93	7.803 %	3.786	WEIGHT TAKEN
ADRENAL (AD)	.017	.0700 %	.0340	WEIGHT TAKEN
OVARY (OV)	.031	.1255 %	.0609	WEIGHT TAKEN
THYMUS (TH)	.03	.113 %	.055	WEIGHT TAKEN

CLINICAL OBSERVATIONS	PATHOLOGY OBSERVATIONS NECROPSY	HISTOPATHOLOGY
-LAST PHYSICAL EXAM: RIGHT EAR-SORE	LIVER (LI) : -ENLARGED, SLIGHT; ALL LOBES -DARK; ALL LOBES, DARK BROWN SKIN, OTHER (SS) : -EAR, SORE; RIGHT, FEW, CRUSTY, RED, 1 X 1 MM TO 3 X 2 MM ^COLLECTED/TAKEN (XW) : -LIVER SECTIONS, IN METHANOL	LIVER (LI) : -HEPATOCYTE, HYPERTROPHY, CENTROLOBULAR, -MINIMAL -KUPFFER CELL/MACROPHAGE, PIGMENT, - MINIMAL -HEPATOCYTE, PIGMENT, -SLIGHT SKIN, OTHER (SS) : -DERMATITIS, ULCERATIVE, -PRESENT

APPENDIX 13B

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 856

STUDY NUMBER: 483287

ANIMAL NUMBER: A37501 SEX: FEMALE DOSE GROUP: 4 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/12/91 STUDY DAY OF DEATH: 96 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 24.7 GRAMS
DATE AND TIME OF NECROPSY: 11/12/91 9:16 PROSECTOR: SONNY DIKES RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE), KIDNEY (KD),
LACRIMAL GL, EX (EO), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU), MAMMARY, FEMALE (MF), MAND SALIVARY GL (SG),
MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON), NERVE, SCIATIC (SN),
OVARY (OV), PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), RECTUM (RE), SKIN (SK), SPLEEN (SP), STOMACH, GL (ST),
STOMACH, NONGL (SU), THYMUS (TH), THYROID (TY), TONGUE (TO), TRACHEA (TR), URINARY BLADDER (UB), UTERUS (UT),
UTERUS, CERVIX (CV), VAGINA (VA)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 857

STUDY NUMBER: 483287

ANIMAL NUMBER: A37502 SEX: FEMALE DOSE GROUP: 4 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/12/91 STUDY DAY OF DEATH: 96 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 23.8 GRAMS
DATE AND TIME OF NECROPSY: 11/12/91 10:10 PROSECTOR: SCOTT BELL RECORDER: SCOTT BELL
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.12	.523 %	.249	WEIGHT TAKEN
LUNG (LU)	.16	.656 %	.312	WEIGHT TAKEN
UTERUS (UT)	.16	.655 %	.312	WEIGHT TAKEN
BRAIN W/STEM (BR)	.50	2.101 %	1.000	WEIGHT TAKEN
HEART (HT)	.15	.631 %	.300	WEIGHT TAKEN
SPLEEN (SP)	.08	.345 %	.164	WEIGHT TAKEN
KIDNEY (KD)	.32	1.342 %	.639	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	1.74	7.295 %	3.472	WEIGHT TAKEN
ADRENAL (AD)	.014	.0609 %	.0290	WEIGHT TAKEN
OVARY (OV)	.031	.1319 %	.0628	WEIGHT TAKEN
THYMUS (TH)	.04	.153 %	.073	WEIGHT TAKEN

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE
OBSERVATIONS

PATHOLOGY OBSERVATIONS
NECROPSY

OVARY (OV) :
-CYST; LEFT, ONE, CLEAR, 2 X 2 MM

HISTOPATHOLOGY

ADRENAL, CORTEX (AC) :
-HYPERPLASIA, SUBCAPSULAR CELL,-MINIMAL
KIDNEY (KD) :
-INFLAMMATION, SUBACUTE,-MINIMAL
LIVER (LI) :
-HEPATOCYTE, HYPERTROPHY,
CENTROLOBULAR,-MINIMAL
-VACUOLIZATION,-SLIGHT
-HEPATOCYTE, PIGMENT,-MINIMAL
-NECROSIS,-MINIMAL, MULTI-FOCAL
-INFLAMMATION, CHRONIC/CHRONIC ACTIVE,-
MINIMAL
-BILE DUCT, INFLAMMATION, CHRONIC,-
MINIMAL
OVARY (OV) :
-BURSA, CYST,-PRESENT
-UNILATERALLY EXAMINED,-PRESENT

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 858

STUDY NUMBER: 483287

ANIMAL NUMBER: A37502 SEX: FEMALE DOSE GROUP: 4 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/12/91 STUDY DAY OF DEATH: 96 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 23.8 GRAMS
DATE AND TIME OF NECROPSY: 11/12/91 10:10 PROSECTOR: SCOTT BELL RECORDER: SCOTT BELL
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

CLINICAL OBSERVATIONS P A T H O L O G Y O B S E R V A T I O N S (CONTINUED)
NECROPSY HISTOPATHOLOGY

UTERUS (UT) :
-HYPERPLASIA, CYSTIC ENDOMETRIAL,-
MINIMAL
UTERUS, CERVIX (CV) :
»TISSUE MISSING

^COLLECTED/TAKEN (XW) :
-LIVER SECTIONS, IN METHANOL

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE), KIDNEY (KD),
LACRIMAL GL, EX (EO), LIVER (LI), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU), MAMMARY, FEMALE (MF),
MAND SALIVARY GL (SG), MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON),
NERVE, SCIATIC (SN), PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), RECTUM (RE), SKIN (SK), SKIN, OTHER (SS),
SPLEEN (SP), STOMACH, GL (ST), STOMACH, NONGL (SU), THYMUS (TH), THYROID (TY), TONGUE (TO), TRACHEA (TR),
URINARY BLADDER (UB), UTERUS (UT), UTERUS, CERVIX (CV), VAGINA (VA)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:

ADRENAL, MEDULLA (AM), OVIDUCT (OD), PANCREAS (PA), STOMACH, GL (ST), STOMACH, NONGL (SU)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 859

STUDY NUMBER: 483287

ANIMAL NUMBER: A37503 SEX: FEMALE DOSE GROUP: 4 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/12/91 STUDY DAY OF DEATH: 96 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 24.7 GRAMS
DATE AND TIME OF NECROPSY: 11/12/91 11:24 PROSECTOR: SCOTT BELL RECORDER: SCOTT BELL
POST-FIX WEAHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEAHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.14	.566 %	.258	WEIGHT TAKEN
LUNG (LU)	.19	.777 %	.355	WEIGHT TAKEN
UTERUS (UT)	.22	.887 %	.405	WEIGHT TAKEN
BRAIN W/STEM (BR)	.54	2.192 %	1.000	WEIGHT TAKEN
HEART (HT)	.13	.546 %	.249	WEIGHT TAKEN
SPLEEN (SP)	.08	.337 %	.154	WEIGHT TAKEN
KIDNEY (KD)	.33	1.355 %	.618	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	1.98	8.028 %	3.662	WEIGHT TAKEN
ADRENAL (AD)	.010	.0413 %	.0188	WEIGHT TAKEN
OVARY (OV)	.033	.1352 %	.0617	WEIGHT TAKEN
THYMUS (TH)	.04	.180 %	.082	WEIGHT TAKEN

CLINICAL OBSERVATIONS	PATHOLOGY OBSERVATIONS NECROPSY	HISTOPATHOLOGY
-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS	LIVER (LI) : -DARK; ALL LOBES, DARK BROWN OVARY (OV) : -CYST; BOTH, ONE EACH, CLEAR, 2 X 2 MM ^COLLECTED/TAKEN (XW) : -LIVER SECTIONS, IN METHANOL	LIVER (LI) : -HEPATOCYTE, HYPERTROPHY, CENTROLOBULAR,-SLIGHT -HEPATOCYTE, PIGMENT,-MINIMAL -NECROSIS,-MINIMAL, MULTI-FOCAL -NECROSIS, INDIVIDUAL CELL,-MINIMAL -INFLAMMATION, CHRONIC/CHRONIC ACTIVE,- MINIMAL OVARY (OV) : -BURSA, CYST,-PRESENT

APPENDIX 13B

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 860

STUDY NUMBER: 483287

ANIMAL NUMBER: A37503 SEX: FEMALE DOSE GROUP: 4 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/12/91 STUDY DAY OF DEATH: 96 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 24.7 GRAMS
DATE AND TIME OF NECROPSY: 11/12/91 11:24 PROSECTOR: SCOTT BELL RECORDER: SCOTT BELL
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE), KIDNEY (KD),
LACRIMAL GL, EX (EO), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU), MAMMARY, FEMALE (MF), MAND SALIVARY GL (SG),
MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON), NERVE, SCIATIC (SN),
PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), RECTUM (RE), SKIN (SK), SKIN, OTHER (SS), SPLEEN (SP),
STOMACH, GL (ST), STOMACH, NONGL (SU), THYMUS (TH), THYROID (TY), TONGUE (TO), TRACHEA (TR), URINARY BLADDER (UB),
UTERUS (UT), UTERUS, CERVIX (CV), VAGINA (VA)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:
OVIDUCT (OD)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 861

STUDY NUMBER: 483287

ANIMAL NUMBER: A37504 SEX: FEMALE DOSE GROUP: 4 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/12/91 STUDY DAY OF DEATH: 96 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 23.0 GRAMS
DATE AND TIME OF NECROPSY: 11/12/91 13:33 PROSECTOR: JANE EARHARDT RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.15	.659 %	.259	WEIGHT TAKEN
LUNG (LU)	.19	.807 %	.317	WEIGHT TAKEN
UTERUS (UT)	.15	.665 %	.262	WEIGHT TAKEN
BRAIN W/STEM (BR)	.58	2.542 %	1.000	WEIGHT TAKEN
HEART (HT)	.15	.633 %	.249	WEIGHT TAKEN
SPLEEN (SP)	.07	.310 %	.122	WEIGHT TAKEN
KIDNEY (KD)	.36	1.566 %	.616	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	1.56	6.767 %	2.662	WEIGHT TAKEN
ADRENAL (AD)	.011	.0483 %	.0190	WEIGHT TAKEN
OVARY (OV)	.028	.1239 %	.0488	WEIGHT TAKEN
THYMUS (TH)	.03	.122 %	.048	WEIGHT TAKEN

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM: NORMAL-NO REMARKABLE
OBSERVATIONS

PATHOLOGY OBSERVATIONS
NECROPSY

HISTOPATHOLOGY

LIVER (LI) :
-HEPATOCTYE, HYPERTROPHY,
CENTROLOBULAR, -MINIMAL
-VACUOLIZATION, -MINIMAL
-KUPFFER CELL/MACROPHAGE, PIGMENT, -
SLIGHT
-HEPATOCTYE, PIGMENT, -MINIMAL
-NECROSIS, -MINIMAL, MULTI-FOCAL
UTERUS (UT) :
-HYPERPLASIA, CYSTIC ENDOMETRIAL, -
SLIGHT

^COLLECTED/TAKEN (XW) :
-LIVER SECTIONS, IN METHANOL

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 862

STUDY NUMBER: 483287

ANIMAL NUMBER: A37504 SEX: FEMALE DOSE GROUP: 4 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/12/91 STUDY DAY OF DEATH: 96 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 23.0 GRAMS
DATE AND TIME OF NECROPSY: 11/12/91 13:33 PROSECTOR: JANE EARHARDT RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE), KIDNEY (KD),
LACRIMAL GL, EX (EO), LIVER (LI), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU), MAMMARY, FEMALE (MF),
MAND SALIVARY GL (SG), MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON),
NERVE, SCIATIC (SN), OVARY (OV), PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), RECTUM (RE), SKIN (SK),
SKIN, OTHER (SS), SPLEEN (SP), STOMACH, GL (ST), STOMACH, NONGL (SU), THYMUS (TH), THYROID (TY), TONGUE (TO),
TRACHEA (TR), URINARY BLADDER (UB), UTERUS (UT), UTERUS, CERVIX (CV), VAGINA (VA)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), KIDNEY (KD), STOMACH, GL (ST), STOMACH, NONGL (SU), UTERUS, CERVIX (CV)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 863

STUDY NUMBER: 483287

ANIMAL NUMBER: A37505 SEX: FEMALE DOSE GROUP: 4 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/13/91 STUDY DAY OF DEATH: 97 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 23.1 GRAMS
DATE AND TIME OF NECROPSY: 11/13/91 9:01 PROSECTOR: DOUGLAS HERNDON RECORDER: JOHN CROWLEY
POST-FIX WEAIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEAIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.12	.535 %	.259	WEIGHT TAKEN
LUNG (LU)	.17	.736 %	.355	WEIGHT TAKEN
UTERUS (UT)	.10	.450 %	.217	WEIGHT TAKEN
BRAIN W/STEM (BR)	.48	2.071 %	1.000	WEIGHT TAKEN
HEART (HT)	.13	.569 %	.275	WEIGHT TAKEN
SPLEEN (SP)	.09	.393 %	.190	WEIGHT TAKEN
KIDNEY (KD)	.35	1.521 %	.734	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	1.91	8.281 %	3.998	WEIGHT TAKEN
ADRENAL (AD)	.018	.0779 %	.0376	WEIGHT TAKEN
OVARY (OV)	.039	.1684 %	.0813	WEIGHT TAKEN
THYMUS (TH)	.03	.132 %	.064	WEIGHT TAKEN

CLINICAL OBSERVATIONS

PATHOLOGY OBSERVATIONS
NECROPSY

HISTOPATHOLOGY

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE
OBSERVATIONS

LIVER (LI) :
-HEPATOCYTE, HYPERTROPHY,
CENTROLOBULAR,-MODERATE
-HEPATOCYTE, PIGMENT,-MINIMAL
-NECROSIS, INDIVIDUAL CELL,-MINIMAL
-INFLAMMATION, CHRONIC/CHRONIC ACTIVE,-
MINIMAL

^COLLECTED/TAKEN (XW) :
-LIVER SECTIONS, IN METHANOL

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE), KIDNEY (KD),
LACRIMAL GL, EX (EO), LIVER (LI), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU), MAMMARY, FEMALE (MF),
MAND SALIVARY GL (SG), MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON),
NERVE, SCIATIC (SN), OVARY (OV), PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), RECTUM (RE), SKIN (SK),
SKIN, OTHER (SS), SPLEEN (SP), STOMACH, GL (ST), STOMACH, NONGL (SU), THYMUS (TH), THYROID (TY), TONGUE (TO),
TRACHEA (TR), URINARY BLADDER (UB), UTERUS (UT), UTERUS, CERVIX (CV), VAGINA (VA)

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 864

STUDY NUMBER: 483287

ANIMAL NUMBER: A37505	SEX: FEMALE	DOSE GROUP: 4	SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/13/91	STUDY DAY OF DEATH: 97	STUDY WEEK OF DEATH: 14	TERMINAL BODY WEIGHT: 23.1 GRAMS
DATE AND TIME OF NECROPSY: 11/13/91 9:01	PROSECTOR: DOUGLAS HERNDON	RECORDED: JOHN CROWLEY	
POST-FIX WEIGHER: JANE EARHARDT	PATHOLOGIST: NOT REQUIRED BY PROTOCOL	WEIGHER: RICHARD KAGYARE	

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 865

STUDY NUMBER: 483287

ANIMAL NUMBER: A37506 SEX: FEMALE DOSE GROUP: 4 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/13/91 STUDY DAY OF DEATH: 97 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 24.6 GRAMS
DATE AND TIME OF NECROPSY: 11/13/91 9:59 PROSECTOR: DOUGLAS HERNDON RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.12	.468 %	.207	WEIGHT TAKEN
LUNG (LU)	.24	.956 %	.422	WEIGHT TAKEN
UTERUS (UT)	.17	.687 %	.303	WEIGHT TAKEN
BRAIN W/STEM (BR)	.56	2.265 %	1.000	WEIGHT TAKEN
HEART (HT)	.15	.596 %	.263	WEIGHT TAKEN
SPLEEN (SP)	.08	.337 %	.149	WEIGHT TAKEN
KIDNEY (KD)	.37	1.507 %	.666	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	1.89	7.693 %	3.397	WEIGHT TAKEN
ADRENAL (AD)	.015	.0610 %	.0269	WEIGHT TAKEN
OVARY (OV)	.073	.2972 %	.1312	WEIGHT TAKEN
THYMUS (TH)	.03	.122 %	.054	WEIGHT TAKEN

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE
OBSERVATIONS

PATHOLOGY OBSERVATIONS
NECROPSY

LIVER (LI) :
-ENLARGED, MODERATE; ALL LOBES
-DARK; ALL LOBES, DARK BROWN

HISTOPATHOLOGY

ADRENAL, CORTEX (AC) :
-PIGMENT, -MINIMAL
-VACUOLIZATION, X-ZONE, -MINIMAL
KIDNEY (KD) :
-INFLAMMATION, SUBACUTE, -MINIMAL
LIVER (LI) :
-HEPATOCYTE, HYPERTROPHY,
CENTROLOBULAR, -MINIMAL
-VACUOLIZATION, -MINIMAL
-KUPFFER CELL/MACROPHAGE, PIGMENT, -
MINIMAL
-HEPATOCYTE, PIGMENT, -MINIMAL
-NECROSIS, INDIVIDUAL CELL, -MINIMAL
-INFLAMMATION, CHRONIC/CHRONIC ACTIVE, -
MINIMAL
-BILE DUCT, INFLAMMATION, CHRONIC, -
MINIMAL
STOMACH, GL (ST) :
-HYPERPLASIA, CYSTIC, -MINIMAL

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 866

STUDY NUMBER: 483287

ANIMAL NUMBER: A37506 SEX: FEMALE DOSE GROUP: 4 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/13/91 STUDY DAY OF DEATH: 97 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 24.6 GRAMS
DATE AND TIME OF NECROPSY: 11/13/91 9:59 PROSECTOR: DOUGLAS HERNDON RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

CLINICAL OBSERVATIONS

P A T H O L O G Y O B S E R V A T I O N S (CONTINUED)
NECROPSY

HISTOPATHOLOGY

UTERUS (UT) :
-HYPOPLASIA, -MODERATE

^COLLECTED/TAKEN (XW) :
-LIVER SECTIONS, IN METHANOL

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE), KIDNEY (KD),
LACRIMAL GL, EX (EO), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU), MAMMARY, FEMALE (MF), MAND SALIVARY GL (SG),
MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON), NERVE, SCIATIC (SN),
OVARY (OV), PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), RECTUM (RE), SKIN (SK), SKIN, OTHER (SS), SPLEEN (SP),
STOMACH, GL (ST), STOMACH, NONGL (SU), THYMUS (TH), THYROID (TY), TONGUE (TO), TRACHEA (TR), URINARY BLADDER (UB),
UTERUS (UT), UTERUS, CERVIX (CV), VAGINA (VA)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:

ADRENAL, MEDULLA (AM), STOMACH, NONGL (SU), UTERUS, CERVIX (CV)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 867

STUDY NUMBER: 483287

ANIMAL NUMBER: A37507 SEX: FEMALE DOSE GROUP: 4 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/13/91 STUDY DAY OF DEATH: 97 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 27.9 GRAMS
DATE AND TIME OF NECROPSY: 11/13/91 11:17 PROSECTOR: SCOTT BELL RECORDER: SCOTT BELL
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.15	.552 %	.283	WEIGHT TAKEN
LUNG (LU)	.23	.823 %	.422	WEIGHT TAKEN
UTERUS (UT)	.12	.440 %	.225	WEIGHT TAKEN
BRAIN W/STEM (BR)	.54	1.951 %	1.000	WEIGHT TAKEN
HEART (HT)	.19	.663 %	.340	WEIGHT TAKEN
SPLEEN (SP)	.10	.352 %	.181	WEIGHT TAKEN
KIDNEY (KD)	.38	1.351 %	.692	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	2.17	7.788 %	3.992	WEIGHT TAKEN
ADRENAL (AD)	.008	.0283 %	.0145	WEIGHT TAKEN
OVARY (OV)	.030	.1090 %	.0559	WEIGHT TAKEN
THYMUS (TH)	.03	.110 %	.056	WEIGHT TAKEN

CLINICAL OBSERVATIONS	PATHOLOGY OBSERVATIONS NECROPSY	HISTOPATHOLOGY
-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS	LIVER (LI) : -ENLARGED, SEVERE; ALL LOBES -DARK; ALL LOBES, DARK BROWN	LIVER (LI) : -HEPATOCYTE, HYPERTROPHY, CENTROLOBULAR,-MINIMAL -VACUOLIZATION,-MINIMAL -KUPFFER CELL/MACROPHAGE, PIGMENT,- MINIMAL -HEPATOCYTE, PIGMENT,-MINIMAL -NECROSIS, INDIVIDUAL CELL,-MINIMAL -INFLAMMATION, CHRONIC/CHRONIC ACTIVE,- MINIMAL
	^COLLECTED/TAKEN (XW) : -LIVER SECTIONS, IN METHANOL	

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 868

STUDY NUMBER: 483287

ANIMAL NUMBER: A37507 SEX: FEMALE DOSE GROUP: 4 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/13/91 STUDY DAY OF DEATH: 97 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 27.9 GRAMS
DATE AND TIME OF NECROPSY: 11/13/91 11:17 PROSECTOR: SCOTT BELL RECORDER: SCOTT BELL
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE), KIDNEY (KD),
LACRIMAL GL, EX (EO), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU), MAMMARY, FEMALE (MF), MAND SALIVARY GL (SG),
MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON), NERVE, SCIATIC (SN),
OVARY (OV), PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), RECTUM (RE), SKIN (SK), SKIN, OTHER (SS), SPLEEN (SP),
STOMACH, GL (ST), STOMACH, NONGL (SU), THYMUS (TH), THYROID (TY), TONGUE (TO), TRACHEA (TR), URINARY BLADDER (UB),
UTERUS (UT), UTERUS, CERVIX (CV), VAGINA (VA)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 869

STUDY NUMBER: 483287

ANIMAL NUMBER: A37508 SEX: FEMALE DOSE GROUP: 4 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/13/91 STUDY DAY OF DEATH: 97 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 25.0 GRAMS
DATE AND TIME OF NECROPSY: 11/13/91 13:32 PROSECTOR: DOUGLAS HERNDON RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.11	.439 %	.219	WEIGHT TAKEN
LUNG (LU)	.19	.756 %	.378	WEIGHT TAKEN
UTERUS (UT)	.28	1.124 %	.562	WEIGHT TAKEN
BRAIN W/STEM (BR)	.50	2.001 %	1.000	WEIGHT TAKEN
HEART (HT)	.12	.465 %	.232	WEIGHT TAKEN
SPLEEN (SP)	.08	.328 %	.164	WEIGHT TAKEN
KIDNEY (KD)	.37	1.473 %	.736	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	2.01	8.055 %	4.025	WEIGHT TAKEN
ADRENAL (AD)	.013	.0524 %	.0262	WEIGHT TAKEN
OVARY (OV)	.047	.1884 %	.0941	WEIGHT TAKEN
THYMUS (TH)	.03	.101 %	.051	WEIGHT TAKEN

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE
OBSERVATIONS

PATHOLOGY OBSERVATIONS
NECROPSY

LIVER (LI) :
-ENLARGED, MODERATE; ALL LOBES
-DARK; ALL LOBES, DARK BROWN

^COLLECTED/TAKEN (XW) :
-LIVER SECTIONS, IN METHANOL

HISTOPATHOLOGY

ADRENAL, CORTEX (AC) :
-VACUOLIZATION, X-ZONE,-MINIMAL
-HYPERPLASIA, SUBCAPSULAR CELL,-MINIMAL
KIDNEY (KD) :
-INFLAMMATION, SUBACUTE,-MINIMAL
LIVER (LI) :
-HEPATOCYTE, HYPERTROPHY,
CENTROLOBULAR,-MINIMAL
-VACUOLIZATION,-SLIGHT

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE, (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 870

STUDY NUMBER: 483287

ANIMAL NUMBER: A37508 SEX: FEMALE DOSE GROUP: 4 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/13/91 STUDY DAY OF DEATH: 97 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 25.0 GRAMS
DATE AND TIME OF NECROPSY: 11/13/91 13:32 PROSECTOR: DOUGLAS HERNDON RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE), KIDNEY (KD),
LACRIMAL GL, EX (EO), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU), MAMMARY, FEMALE (MF), MAND SALIVARY GL (SG),
MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON), NERVE, SCIATIC (SN),
OVARY (OV), PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), RECTUM (RE), SKIN (SK), SKIN, OTHER (SS), SPLEEN (SP),
STOMACH, GL (ST), STOMACH, NONGL (SU), THYMUS (TH), THYROID (TY), TONGUE (TO), TRACHEA (TR), URINARY BLADDER (UB),
UTERUS (UT), UTERUS, CERVIX (CV), VAGINA (VA)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:

ADRENAL, MEDULLA (AM), STOMACH, GL (ST), STOMACH, NONGL (SU), UTERUS (UT), UTERUS, CERVIX (CV)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 871

STUDY NUMBER: 483287

ANIMAL NUMBER: A37509 SEX: FEMALE DOSE GROUP: 4 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/14/91 STUDY DAY OF DEATH: 98 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 24.1 GRAMS
DATE AND TIME OF NECROPSY: 11/14/91 8:32 PROSECTOR: JANE EARHARDT RECORDER: JANE EARHARDT
POST-FIX WEIGHER: DANIEL JACK PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.11	.473 %	.211	WEIGHT TAKEN
LUNG (LU)	.20	.832 %	.371	WEIGHT TAKEN
UTERUS (UT)	.19	.799 %	.356	WEIGHT TAKEN
BRAIN W/STEM (BR)	.54	2.243 %	1.000	WEIGHT TAKEN
HEART (HT)	.12	.500 %	.223	WEIGHT TAKEN
SPLEEN (SP)	.09	.370 %	.165	WEIGHT TAKEN
KIDNEY (KD)	.45	1.876 %	.836	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	2.52	10.477 %	4.671	WEIGHT TAKEN
ADRENAL (AD)	.011	.0452 %	.0202	WEIGHT TAKEN
OVARY (OV)	.076	.3170 %	.1413	WEIGHT TAKEN
THYMUS (TH)	.03	.120 %	.053	WEIGHT TAKEN

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE
OBSERVATIONS

PATHOLOGY OBSERVATIONS
NECROPSY

LIVER (LI) :
-PALE AREA; ALL LOBES, FEW, TAN,
PINPOINT TO 5 X 5 MM
-DARK; ALL LOBES, DARK BROWN

OVARY (OV) :
-CYST; BOTH, ONE EACH, CLEAR, 4 X 4 MM
^COLLECTED/TAKEN (XW) :
-LIVER SECTIONS, IN METHANOL

HISTOPATHOLOGY

LIVER (LI) :
-HEPATOCYTE, HYPERTROPHY,
CENTROLOBULAR,-MINIMAL
-VACUOLIZATION,-MODERATELY SEVERE
-KUPFFER CELL/MACROPHAGE, PIGMENT,-
MINIMAL
-HEPATOCYTE, PIGMENT,-MINIMAL
-INFLAMMATION, CHRONIC/CHRONIC ACTIVE,-
MINIMAL
OVARY (OV) :
-FOLLICLE, CYST,-PRESENT

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 872

STUDY NUMBER: 483287

ANIMAL NUMBER: A37509 SEX: FEMALE DOSE GROUP: 4 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/14/91 STUDY DAY OF DEATH: 98 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 24.1 GRAMS
DATE AND TIME OF NECROPSY: 11/14/91 8:32 PROSECTOR: JANE EARHARDT RECORDER: JANE EARHARDT
POST-FIX WEIGHER: DANIEL JACK PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE), KIDNEY (KD),
LACRIMAL GL, EX (EO), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU), MAMMARY, FEMALE (MF), MAND SALIVARY GL (SG),
MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON), NERVE, SCIATIC (SN),
PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), RECTUM (RE), SKIN (SK), SKIN, OTHER (SS), SPLEEN (SP),
STOMACH, GL (ST), STOMACH, NONGL (SU), THYMUS (TH), THYROID (TY), TONGUE (TO), TRACHEA (TR), URINARY BLADDER (UB),
UTERUS (UT), UTERUS, CERVIX (CV), VAGINA (VA)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:
OVIDUCT (OD)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 873

STUDY NUMBER: 483287

ANIMAL NUMBER: A37510 SEX: FEMALE DOSE GROUP: 4 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/14/91 STUDY DAY OF DEATH: 98 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 24.8 GRAMS
DATE AND TIME OF NECROPSY: 11/14/91 9:24 PROSECTOR: JANE EARHARDT RECORDER: JANE EARHARDT
POST-FIX WEIGHER: JOHN CROWLEY PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.16	.639 %	.318	WEIGHT TAKEN
LUNG (LU)	.18	.740 %	.369	WEIGHT TAKEN
UTERUS (UT)	.24	.957 %	.477	WEIGHT TAKEN
BRAIN W/STEM (BR)	.50	2.008 %	1.000	WEIGHT TAKEN
HEART (HT)	.12	.504 %	.251	WEIGHT TAKEN
SPLEEN (SP)	.07	.298 %	.148	WEIGHT TAKEN
KIDNEY (KD)	.36	1.459 %	.727	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	1.77	7.145 %	3.558	WEIGHT TAKEN
ADRENAL (AD)	.016	.0637 %	.0317	WEIGHT TAKEN
OVARY (OV)	.051	.2052 %	.1022	WEIGHT TAKEN
THYMUS (TH)	.05	.199 %	.099	WEIGHT TAKEN

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE
OBSERVATIONS

PATHOLOGY OBSERVATIONS
NECROPSY

OVARY (OV) :
-CYST; LEFT, ONE, CLEAR, 3 X 3 MM

HISTOPATHOLOGY

KIDNEY (KD) :
-INFLAMMATION, SUBACUTE,-MINIMAL
LIVER (LI) :
-HEPATOCYTE, HYPERTROPHY,
CENTROLOBULAR,-MINIMAL
-PIGMENT, BILE,-MINIMAL
-KUPFFER CELL/MACROPHAGE, PIGMENT,-
MINIMAL
-HEPATOCYTE, PIGMENT,-MINIMAL
-NECROSIS, INDIVIDUAL CELL,-MINIMAL
-INFLAMMATION, CHRONIC/CHRONIC ACTIVE,-
MINIMAL
OVARY (OV) :
-FOLLICLE, CYST,-PRESENT
STOMACH, GL (ST) :
-HYPERPLASIA, CYSTIC,-MINIMAL
UTERUS (UT) :
-HYPERPLASIA, CYSTIC ENDOMETRIAL,-
MINIMAL

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 874

STUDY NUMBER: 483287

ANIMAL NUMBER: A37510 SEX: FEMALE DOSE GROUP: 4 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/14/91 STUDY DAY OF DEATH: 98 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 24.8 GRAMS
DATE AND TIME OF NECROPSY: 11/14/91 9:24 PROSECTOR: JANE EARHARDT RECORDER: JANE EARHARDT
POST-FIX WEIGHER: JOHN CROWLEY PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

CLINICAL OBSERVATIONS P A T H O L O G Y O B S E R V A T I O N S (CONTINUED)
NECROPSY HISTOPATHOLOGY

^COLLECTED/TAKEN (XW) :
-LIVER SECTIONS, IN METHANOL

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE), KIDNEY (KD),
LACRIMAL GL, EX (EO), LIVER (LI), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU), MAMMARY, FEMALE (MF),
MAND SALIVARY GL (SG), MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON),
NERVE, SCIATIC (SN), PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), RECTUM (RE), SKIN (SK), SKIN, OTHER (SS),
SPLEEN (SP), STOMACH, GL (ST), STOMACH, NONGL (SU), THYMUS (TH), THYROID (TY), TONGUE (TO), TRACHEA (TR),
URINARY BLADDER (UB), UTERUS (UT), UTERUS, CERVIX (CV), VAGINA (VA)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), OVIDUCT (OD), STOMACH, NONGL (SU), UTERUS, CERVIX (CV)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 875

STUDY NUMBER: 483287

ANIMAL NUMBER: A37526 SEX: FEMALE DOSE GROUP: 5 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/11/91 STUDY DAY OF DEATH: 95 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 22.0 GRAMS
DATE AND TIME OF NECROPSY: 11/11/91 9:35 PROSECTOR: JANE EARHARDT RECORDER: JANE EARHARDT
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.11	.482 %	.209	WEIGHT TAKEN
LUNG (LU)	.16	.712 %	.309	WEIGHT TAKEN
UTERUS (UT)	.11	.482 %	.209	WEIGHT TAKEN
BRAIN W/STEM (BR)	.51	2.306 %	1.000	WEIGHT TAKEN
HEART (HT)	.12	.552 %	.239	WEIGHT TAKEN
SPLEEN (SP)	.08	.374 %	.162	WEIGHT TAKEN
KIDNEY (KD)	.33	1.490 %	.646	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	2.04	9.274 %	4.021	WEIGHT TAKEN
ADRENAL (AD)	.015	.0695 %	.0302	WEIGHT TAKEN
OVARY (OV)	.040	.1805 %	.0782	WEIGHT TAKEN
THYMUS (TH)	.04	.164 %	.071	WEIGHT TAKEN

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE
OBSERVATIONS

PATHOLOGY OBSERVATIONS
NECROPSY

HISTOPATHOLOGY

ADRENAL, CORTEX (AC) :
-HYPERPLASIA, SUBCAPSULAR CELL,-MINIMAL
KIDNEY (KD) :
-INFLAMMATION, CHRONIC,-SLIGHT
-TUBULE, REGENERATION,-MINIMAL
-CYST,-PRESENT
-INFLAMMATION, SUBACUTE,-MINIMAL
-PELVIS, DILATATION,-PRESENT
LIVER (LI) :
-HEPATOCYTE, HYPERTROPHY,
CENTROLOBULAR,-SLIGHT
-KUPFFER CELL/MACROPHAGE, PIGMENT,-
MINIMAL
-HEPATOCYTE, PIGMENT,-SLIGHT
-NECROSIS, INDIVIDUAL CELL,-MINIMAL
-INFLAMMATION, CHRONIC/CHRONIC ACTIVE,-
MINIMAL

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 876

STUDY NUMBER: 483287

ANIMAL NUMBER: A37526 SEX: FEMALE DOSE GROUP: 5 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/11/91 STUDY DAY OF DEATH: 95 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 22.0 GRAMS
DATE AND TIME OF NECROPSY: 11/11/91 9:35 PROSECTOR: JANE EARHARDT RECORDER: JANE EARHARDT
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

CLINICAL OBSERVATIONS PATHOLOGY OBSERVATIONS (CONTINUED) HISTOPATHOLOGY
NECROPSY

SPLEEN (SP) :
-EXTRAMEDULLARY HEMATOPOIESIS,
INCREASED, -SLIGHT
-PIGMENT, -SLIGHT
STOMACH, GL (ST) :
-INFLAMMATION, CHRONIC, -MINIMAL
UTERUS (UT) :
-HYPOPLASIA, -MODERATELY SEVERE
UTERUS, CERVIX (CV) :
-HYPOPLASIA, -MODERATE

^COLLECTED/TAKEN (XW) :
-LIVER SECTIONS, IN METHANOL

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE), KIDNEY (KD),
LACRIMAL GL, EX (EO), LIVER (LI), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU), MAMMARY, FEMALE (MF),
MAND SALIVARY GL (SG), MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON),
NERVE, SCIATIC (SN), OVARY (OV), PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), RECTUM (RE), SKIN (SK),
SKIN, OTHER (SS), SPLEEN (SP), STOMACH, GL (ST), STOMACH, NONGL (SU), THYMUS (TH), THYROID (TY), TONGUE (TO),
TRACHEA (TR), URINARY BLADDER (UB), UTERUS (UT), UTERUS, CERVIX (CV), VAGINA (VA)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:

ADRENAL, MEDULLA (AM), MAMMARY, FEMALE (MF), SKIN (SK), STOMACH, NONGL (SU)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 877

STUDY NUMBER: 483287

ANIMAL NUMBER: A37527 SEX: FEMALE DOSE GROUP: 5 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/11/91 STUDY DAY OF DEATH: 95 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 28.2 GRAMS
DATE AND TIME OF NECROPSY: 11/11/91 10:42 PROSECTOR: ADEPOLAHAN AKINSOLA RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.20	.700 %	.414	WEIGHT TAKEN
LUNG (LU)	.17	.614 %	.363	WEIGHT TAKEN
UTERUS (UT)	.17	.617 %	.365	WEIGHT TAKEN
BRAIN W/STEM (BR)	.48	1.691 %	1.000	WEIGHT TAKEN
HEART (HT)	.17	.593 %	.351	WEIGHT TAKEN
SPLEEN (SP)	.08	.289 %	.171	WEIGHT TAKEN
KIDNEY (KD)	.41	1.453 %	.859	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	2.74	9.722 %	5.749	WEIGHT TAKEN
ADRENAL (AD)	.016	.0567 %	.0336	WEIGHT TAKEN
OVARY (OV)	.036	.1270 %	.0751	WEIGHT TAKEN
THYMUS (TH)	.03	.123 %	.073	WEIGHT TAKEN

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE
OBSERVATIONS

PATHOLOGY OBSERVATIONS
NECROPSY

LIVER (LI) :
-PALE AREA; RIGHT LATERAL LOBE, ONE,
TAN, 3 X 3 MM
-ENLARGED, MODERATE; ALL LOBES
-DARK; ALL LOBES, DARK BROWN

HISTOPATHOLOGY

ADRENAL, CORTEX (AC) :
-PIGMENT,-MINIMAL
-HYPERPLASIA, SUBCAPSULAR CELL,-MINIMAL
KIDNEY (KD) :
-INFLAMMATION, CHRONIC,-MINIMAL
-TUBULE, MINERALIZATION,-MINIMAL
LIVER (LI) :
-HEPATOCYTE, HYPERTROPHY,
CENTROLOBULAR,-MODERATE
-VACUOLIZATION,-SLIGHT
-HEPATOCYTE, PIGMENT,-MINIMAL
-NECROSIS, INDIVIDUAL CELL,-MINIMAL
-INFLAMMATION, CHRONIC/CHRONIC ACTIVE,-
MINIMAL
SPLEEN (SP) :
-EXTRAMEDULLARY HEMATOPOIESIS,
INCREASED,-SLIGHT
-PIGMENT,-SLIGHT

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 878

STUDY NUMBER: 483287

ANIMAL NUMBER: A37527 SEX: FEMALE DOSE GROUP: 5 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/11/91 STUDY DAY OF DEATH: 95 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 28.2 GRAMS
DATE AND TIME OF NECROPSY: 11/11/91 10:42 PROSECTOR: ADEFOLAHAN AKINSOLA RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

CLINICAL OBSERVATIONS PATHOLOGY OBSERVATIONS (CONTINUED) HISTOPATHOLOGY
NECROPSY

STOMACH, GL (ST) :
-HYPERPLASIA, CYSTIC, -MINIMAL
-INFLAMMATION, CHRONIC, -MINIMAL
UTERUS (UT) :
-HYPOPLASIA, -MINIMAL
UTERUS, CERVIX (CV) :
-HYPOPLASIA, -MINIMAL

^COLLECTED/TAKEN (XW) :
-LIVER SECTIONS, IN METHANOL

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE), KIDNEY (KD),
LACRIMAL GL, EX (EO), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU), MAMMARY, FEMALE (MF), MAND SALIVARY GL (SG),
MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON), NERVE, SCIATIC (SN),
OVARY (OV), PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), RECTUM (RE), SKIN (SK), SKIN, OTHER (SS), SPLEEN (SP),
STOMACH, GL (ST), STOMACH, NONGL (SU), THYMUS (TH), THYROID (TY), TONGUE (TO), TRACHEA (TR), URINARY BLADDER (UB),
UTERUS (UT), UTERUS, CERVIX (CV), VAGINA (VA)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:

ADRENAL, MEDULLA (AM), MAMMARY, FEMALE (MF), SKIN (SK), STOMACH, NONGL (SU)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 879

STUDY NUMBER: 483287

ANIMAL NUMBER: A37528 SEX: FEMALE DOSE GROUP: 5 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/11/91 STUDY DAY OF DEATH: 95 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 27.8 GRAMS
DATE AND TIME OF NECROPSY: 11/11/91 11:43 PROSECTOR: SCOTT BELL RECORDER: SCOTT BELL
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.18	.633 %	.298	WEIGHT TAKEN
LUNG (LU)	.20	.719 %	.338	WEIGHT TAKEN
UTERUS (UT)	.16	.590 %	.277	WEIGHT TAKEN
BRAIN W/STEM (BR)	.59	2.127 %	1.000	WEIGHT TAKEN
HEART (HT)	.15	.545 %	.256	WEIGHT TAKEN
SPLEEN (SP)	.08	.276 %	.130	WEIGHT TAKEN
KIDNEY (KD)	.46	1.661 %	.781	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	2.82	10.159 %	4.776	WEIGHT TAKEN
ADRENAL (AD)	.013	.0457 %	.0215	WEIGHT TAKEN
OVARY (OV)	.085	.3054 %	.1436	WEIGHT TAKEN
THYMUS (TH)	.04	.142 %	.067	WEIGHT TAKEN

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE
OBSERVATIONS

PATHOLOGY OBSERVATIONS
NECROPSY

LIVER (LI) :
-ENLARGED, SEVERE; ALL LOBES
-DARK; ALL LOBES, DARK BROWN

OVARY (OV) :
-CYST; RIGHT, ONE, CLEAR, 4 X 4 MM

HISTOPATHOLOGY

ADRENAL, CORTEX (AC) :
-VACUOLIZATION, X-ZONE,-MINIMAL
KIDNEY (KD) :
-INFLAMMATION, SUBACUTE,-MINIMAL
LIVER (LI) :
-HEPATOCYTE, HYPERTROPHY,
CENTROLOBULAR,-MODERATE
-VACUOLIZATION,-SLIGHT
-PIGMENT, BILE,-MINIMAL
-KUPFFER CELL/MACROPHAGE, PIGMENT,-
MINIMAL
-INFLAMMATION, CHRONIC/CHRONIC ACTIVE,-
MINIMAL
-BILE DUCT, INFLAMMATION, CHRONIC,-
MINIMAL
OVARY (OV) :
-FOLLICLE, CYST,-PRESENT

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 880

STUDY NUMBER: 483287

ANIMAL NUMBER: A37528 SEX: FEMALE DOSE GROUP: 5 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/11/91 STUDY DAY OF DEATH: 95 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 27.8 GRAMS
DATE AND TIME OF NECROPSY: 11/11/91 11:43 PROSECTOR: SCOTT BELL RECORDER: SCOTT BELL
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

CLINICAL OBSERVATIONS PATHOLOGY OBSERVATIONS (CONTINUED) HISTOPATHOLOGY
NECROPSY

SPLEEN (SP) :
-EXTRAMEDULLARY HEMATOPOIESIS,
INCREASED, -MINIMAL
-PIGMENT, -MINIMAL
UTERUS (UT) :
-HYPOPLASIA, -MODERATELY SEVERE

^COLLECTED/TAKEN (XW) :
-LIVER SECTIONS, IN METHANOL

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE), KIDNEY (KD),
LACRIMAL GL, EX (EO), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU), MAMMARY, FEMALE (MF), MAND SALIVARY GL (SG),
MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON), NERVE, SCIATIC (SN),
PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), RECTUM (RE), SKIN (SK), SKIN, OTHER (SS), SPLEEN (SP),
STOMACH, GL (ST), STOMACH, NONGL (SU), THYMUS (TH), THYROID (TY), TONGUE (TO), TRACHEA (TR), URINARY BLADDER (UB),
UTERUS (UT), UTERUS, CERVIX (CV), VAGINA (VA)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:

ADRENAL, MEDULLA (AM), MAMMARY, FEMALE (MF), OVIDUCT (OD), SKIN (SK), STOMACH, GL (ST), STOMACH, NONGL (SU),
UTERUS, CERVIX (CV)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 881

STUDY NUMBER: 483287

ANIMAL NUMBER: A37529 SEX: FEMALE DOSE GROUP: 5 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/11/91 STUDY DAY OF DEATH: 95 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 24.0 GRAMS
DATE AND TIME OF NECROPSY: 11/11/91 14:03 PROSECTOR: ADEFOLAHAN AKINSOLA RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.15	.635 %	.298	WEIGHT TAKEN
LUNG (LU)	.15	.621 %	.292	WEIGHT TAKEN
UTERUS (UT)	.17	.711 %	.334	WEIGHT TAKEN
BRAIN W/STEM (BR)	.51	2.129 %	1.000	WEIGHT TAKEN
HEART (HT)	.16	.646 %	.303	WEIGHT TAKEN
SPLEEN (SP)	.09	.375 %	.176	WEIGHT TAKEN
KIDNEY (KD)	.35	1.443 %	.678	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	2.39	9.961 %	4.679	WEIGHT TAKEN
ADRENAL (AD)	.012	.0508 %	.0239	WEIGHT TAKEN
OVARY (OV)	.061	.2529 %	.1188	WEIGHT TAKEN
THYMUS (TH)	.06	.243 %	.114	WEIGHT TAKEN

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE
OBSERVATIONS

PATHOLOGY OBSERVATIONS
NECROPSY

LIVER (LI) :
-PALE AREA; ALL LOBES, FEW, TAN, 2 X 2
MM
-ENLARGED, MODERATE; ALL LOBES
-DARK; ALL LOBES, DARK BROWN

HISTOPATHOLOGY

ADRENAL, CORTEX (AC) :
-PIGMENT,-MINIMAL
-VACUOLIZATION, X-ZONE,-SLIGHT
-HYPERPLASIA, SUBCAPSULAR CELL,-MINIMAL
KIDNEY (KD) :
-TUBULE, REGENERATION,-MINIMAL
LIVER (LI) :
-HEPATOCYTE, HYPERTROPHY,
CENTROLOBULAR,-SLIGHT
-VACUOLIZATION,-SLIGHT
-PIGMENT, BILE,-MINIMAL
-KUPFFER CELL/MACROPHAGE, PIGMENT,-
MINIMAL
-HEPATOCYTE, PIGMENT,-MINIMAL
-NECROSIS,-MODERATE, FOCAL
-NECROSIS, INDIVIDUAL CELL,-MINIMAL
-INFLAMMATION, CHRONIC/CHRONIC ACTIVE,-
MINIMAL

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 882

STUDY NUMBER: 483287

ANIMAL NUMBER: A37529 SEX: FEMALE DOSE GROUP: 5 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/11/91 STUDY DAY OF DEATH: 95 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 24.0 GRAMS
DATE AND TIME OF NECROPSY: 11/11/91 14:03 PROSECTOR: ADEPOLAHAN AKINSOLA RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

CLINICAL OBSERVATIONS P A T H O L O G Y O B S E R V A T I O N S (CONTINUED)
NECROPSY HISTOPATHOLOGY

STOMACH, GL (ST) :
-DARK AREA; MUCOSA, FEW, BLACK,
PINPOINT

^COLLECTED/TAKEN (XW) :
-LIVER SECTIONS, IN METHANOL

SPLEEN (SP) :
-EXTRAMEDULLARY HEMATOPOIESIS,
INCREASED, -MINIMAL
-PIGMENT, -MINIMAL
STOMACH, GL (ST) :
-HYPERPLASIA, CYSTIC, -SLIGHT
-INFLAMMATION, CHRONIC, -MINIMAL
UTERUS (UT) :
-HYPERPLASIA, CYSTIC ENDOMETRIAL, -
MINIMAL
-HYPOPLASIA, -MODERATE

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE), KIDNEY (KD),
LACRIMAL GL, EX (EO), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU), MAMMARY, FEMALE (MF), MAND SALIVARY GL (SG),
MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON), NERVE, SCIATIC (SN),
OVARY (OV), PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), RECTUM (RE), SKIN (SK), SKIN, OTHER (SS), SPLEEN (SP),
STOMACH, NONGL (SU), THYMUS (TH), THYROID (TY), TONGUE (TO), TRACHEA (TR), URINARY BLADDER (UB), UTERUS (UT),
UTERUS, CERVIX (CV), VAGINA (VA)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:

ADRENAL, MEDULLA (AM), MAMMARY, FEMALE (MF), SKIN (SK), STOMACH, NONGL (SU), UTERUS, CERVIX (CV)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 883

STUDY NUMBER: 483287

ANIMAL NUMBER: A37530 SEX: FEMALE DOSE GROUP: 5 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/12/91 STUDY DAY OF DEATH: 96 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 26.9 GRAMS
DATE AND TIME OF NECROPSY: 11/12/91 9:20 PROSECTOR: DOUGLAS HERNDON RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.13	.500 %	.286	WEIGHT TAKEN
LUNG (LU)	.19	.717 %	.410	WEIGHT TAKEN
UTERUS (UT)	.25	.942 %	.539	WEIGHT TAKEN
BRAIN W/STEM (BR)	.47	1.748 %	1.000	WEIGHT TAKEN
HEART (HT)	.13	.483 %	.276	WEIGHT TAKEN
SPLEEN (SP)	.07	.255 %	.146	WEIGHT TAKEN
KIDNEY (KD)	.41	1.527 %	.873	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	2.55	9.479 %	5.422	WEIGHT TAKEN
ADRENAL (AD)	.013	.0491 %	.0281	WEIGHT TAKEN
OVARY (OV)	.054	.2019 %	.1155	WEIGHT TAKEN
THYMUS (TH)	.04	.135 %	.077	WEIGHT TAKEN

CLINICAL OBSERVATIONS	PATHOLOGY OBSERVATIONS NECROPSY	HISTOPATHOLOGY
-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS	LIVER (LI) : -ENLARGED, MODERATE; ALL LOBES -DARK; ALL LOBES, DARK BROWN	ADRENAL, CORTEX (AC) : -VACUOLIZATION, X-ZONE,-MINIMAL LIVER (LI) : -HEPATOCTE, HYPERTROPHY, CENTROLOBULAR,-MODERATE -PIGMENT, BILE,-MINIMAL -KUPFFER CELL/MACROPHAGE, PIGMENT,- MINIMAL -HEPATOCTE, PIGMENT,-MINIMAL -NECROSIS, INDIVIDUAL CELL,-MINIMAL SPLEEN (SP) : -EXTRAMEDULLARY HEMATOPOIESIS, INCREASED,-MINIMAL -PIGMENT,-MINIMAL STOMACH, GL (ST) : -HYPERPLASIA, CYSTIC,-MINIMAL
	^COLLECTED/TAKEN (XW) : -LIVER SECTIONS, IN METHANOL	

APPENDIX 13B

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 884

STUDY NUMBER: 483287

ANIMAL NUMBER: A37530 SEX: FEMALE DOSE GROUP: 5 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/12/91 STUDY DAY OF DEATH: 96 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 26.9 GRAMS
DATE AND TIME OF NECROPSY: 11/12/91 9:20 PROSECTOR: DOUGLAS HERNDON RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE), KIDNEY (KD),
LACRIMAL GL, EX (EO), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU), MAMMARY, FEMALE (MF), MAND SALIVARY GL (SG),
MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON), NERVE, SCIATIC (SN),
OVARY (OV), PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), RECTUM (RE), SKIN (SK), SKIN, OTHER (SS), SPLEEN (SP),
STOMACH, GL (ST), STOMACH, NONGL (SU), THYMUS (TH), THYROID (TY), TONGUE (TO), TRACHEA (TR), URINARY BLADDER (UB),
UTERUS (UT), UTERUS, CERVIX (CV), VAGINA (VA)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:

ADRENAL, MEDULLA (AM), KIDNEY (KD), MAMMARY, FEMALE (MF), SKIN (SK), STOMACH, NONGL (SU), UTERUS (UT),
UTERUS, CERVIX (CV)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 885

STUDY NUMBER: 483287

ANIMAL NUMBER: A37531 SEX: FEMALE DOSE GROUP: 5 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/12/91 STUDY DAY OF DEATH: 96 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 26.5 GRAMS
DATE AND TIME OF NECROPSY: 11/12/91 10:21 PROSECTOR: SONNY DIKES RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.10	.391 %	.196	WEIGHT TAKEN
LUNG (LU)	.18	.691 %	.346	WEIGHT TAKEN
UTERUS (UT)	.12	.456 %	.228	WEIGHT TAKEN
BRAIN W/STEM (BR)	.53	1.996 %	1.000	WEIGHT TAKEN
HEART (HT)	.15	.572 %	.287	WEIGHT TAKEN
SPLEEN (SP)	.07	.278 %	.139	WEIGHT TAKEN
KIDNEY (KD)	.35	1.331 %	.667	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	2.89	10.920 %	5.470	WEIGHT TAKEN
ADRENAL (AD)	.013	.0475 %	.0238	WEIGHT TAKEN
OVARY (OV)	.033	.1245 %	.0624	WEIGHT TAKEN
THYMUS (TH)	.03	.103 %	.052	WEIGHT TAKEN

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE
OBSERVATIONS

PATHOLOGY OBSERVATIONS
NECROPSY

KIDNEY (KD) :
-MASS; RIGHT CORTEX, ONE, FIRM, TAN, 4
X 3 X 1 CM, CUT SURFACE:SAME

LIVER (LI) :
-ENLARGED, MODERATE; ALL LOBES
-DARK; ALL LOBES, DARK BROWN

HISTOPATHOLOGY

ADRENAL, CORTEX (AC) :
-PIGMENT,-MINIMAL
-VACUOLIZATION, X-ZONE,-MINIMAL
-HYPERPLASIA, SUBCAPSULAR CELL,-MINIMAL
KIDNEY (KD) :
-INFLAMMATION, CHRONIC,-SEVERE
>NOTE:>NO CHANGE CORRESPONDING TO A
CORTICAL MASS WAS OBSERVED;
HOWEVER, A SEVERE PYELITIS IN
THE RIGHT KIDNEY MAY HAVE CAUSED
SOME MACROSCOPICALLY VISIBLE
DEFORMITY.

LIVER (LI) :
-HEPATOCYTE, HYPERTROPHY,
CENTROLOBULAR,-SLIGHT
-KUPFFER CELL/MACROPHAGE, PIGMENT,-
MINIMAL
-HEPATOCYTE, PIGMENT,-MINIMAL
-NECROSIS, INDIVIDUAL CELL,-MINIMAL

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 886

STUDY NUMBER: 483287

ANIMAL NUMBER: A37531 SEX: FEMALE DOSE GROUP: 5 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/12/91 STUDY DAY OF DEATH: 96 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 26.5 GRAMS
DATE AND TIME OF NECROPSY: 11/12/91 10:21 PROSECTOR: SONNY DIKES RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

CLINICAL OBSERVATIONS PATHOLOGY OBSERVATIONS (CONTINUED) HISTOPATHOLOGY
NECROPSY

LIVER (LI) :
-INFLAMMATION, CHRONIC/CHRONIC ACTIVE, -
MINIMAL
-BILE DUCT, INFLAMMATION, CHRONIC, -
MINIMAL
SPLEEN (SP) :
-PIGMENT, -MINIMAL
STOMACH, GL (ST) :
-INFLAMMATION, CHRONIC, -MINIMAL
UTERUS (UT) :
-HYPOPLASIA, -SLIGHT

^COLLECTED/TAKEN (XW) :
-LIVER SECTIONS, IN METHANOL

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE), LACRIMAL GL, EX (EO),
LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU), MAMMARY, FEMALE (MF), MAND SALIVARY GL (SG), MARROW, FEMUR (FM),
MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON), NERVE, SCIATIC (SN), OVARY (OV), PANCREAS (PA),
PARATHYROID (PT), PITUITARY (PI), RECTUM (RE), SKIN (SK), SKIN, OTHER (SS), SPLEEN (SP), STOMACH, GL (ST),
STOMACH, NONGL (SU), THYMUS (TH), THYROID (TY), TONGUE (TO), TRACHEA (TR), URINARY BLADDER (UB), UTERUS (UT),
UTERUS, CERVIX (CV), VAGINA (VA)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:

ADRENAL, MEDULLA (AM), MAMMARY, FEMALE (MF), SKIN (SK), STOMACH, NONGL (SU), UTERUS, CERVIX (CV)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 887

STUDY NUMBER: 483287

ANIMAL NUMBER: A37532 SEX: FEMALE DOSE GROUP: 5 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/12/91 STUDY DAY OF DEATH: 96 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 23.4 GRAMS
DATE AND TIME OF NECROPSY: 11/12/91 11:20 PROSECTOR: JANE EARHARDT RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.13	.570 %	.253	WEIGHT TAKEN
LUNG (LU)	.20	.844 %	.375	WEIGHT TAKEN
UTERUS (UT)	.29	1.226 %	.544	WEIGHT TAKEN
BRAIN W/STEM (BR)	.53	2.252 %	1.000	WEIGHT TAKEN
HEART (HT)	.13	.571 %	.254	WEIGHT TAKEN
SPLEEN (SP)	.06	.268 %	.119	WEIGHT TAKEN
KIDNEY (KD)	.34	1.440 %	.639	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	1.71	7.312 %	3.247	WEIGHT TAKEN
ADRENAL (AD)	.014	.0615 %	.0273	WEIGHT TAKEN
OVARY (OV)	.038	.1641 %	.0729	WEIGHT TAKEN
THYMUS (TH)	.04	.151 %	.067	WEIGHT TAKEN

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE
OBSERVATIONS

PATHOLOGY OBSERVATIONS
NECROPSY

HISTOPATHOLOGY

ADRENAL, CORTEX (AC) :
-VACUOLIZATION, X-ZONE,-MINIMAL
KIDNEY (KD) :
-TUBULE, REGENERATION,-MINIMAL
-INFLAMMATION, SUBACUTE,-MINIMAL
LIVER (LI) :
-HEPATOCYTE, HYPERTROPHY,
CENTROLOBULAR,-SLIGHT
-PIGMENT, BILE,-MINIMAL
-KUPFFER CELL/MACROPHAGE, PIGMENT,-
SLIGHT
-HEPATOCYTE, PIGMENT,-SLIGHT
-NECROSIS,-MINIMAL, MULTI-FOCAL
-NECROSIS, INDIVIDUAL CELL,-MINIMAL
-INFLAMMATION, CHRONIC/CHRONIC ACTIVE,-
MINIMAL
-BILE DUCT, INFLAMMATION, CHRONIC,-
MINIMAL

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 888

STUDY NUMBER: 483287

ANIMAL NUMBER: A37532 SEX: FEMALE DOSE GROUP: 5 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/12/91 STUDY DAY OF DEATH: 96 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 23.4 GRAMS
DATE AND TIME OF NECROPSY: 11/12/91 11:20 PROSECTOR: JANE EARHARDT RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

CLINICAL OBSERVATIONS

P A T H O L O G Y O B S E R V A T I O N S (CONTINUED)
NECROPSY

HISTOPATHOLOGY

UTERUS (UT) :
-WALL, THICKENED, SLIGHT; BOTH HORNS

^COLLECTED/TAKEN (XW) :
-LIVER SECTIONS, IN METHANOL

SPLEEN (SP) :
-PIGMENT, -SLIGHT
UTERUS (UT) :
-HYPERPLASIA, CYSTIC ENDOMETRIAL, -
SLIGHT

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE), KIDNEY (KD),
LACRIMAL GL, EX (EO), LIVER (LI), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU), MAMMARY, FEMALE (MF),
MAND SALIVARY GL (SG), MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON),
NERVE, SCIATIC (SN), OVARY (OV), PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), RECTUM (RE), SKIN (SK),
SKIN, OTHER (SS), SPLEEN (SP), STOMACH, GL (ST), STOMACH, NONGL (SU), THYMUS (TH), THYROID (TY), TONGUE (TO),
TRACHEA (TR), URINARY BLADDER (UB), UTERUS, CERVIX (CV), VAGINA (VA)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:

ADRENAL, MEDULLA (AM), MAMMARY, FEMALE (MF), SKIN (SK), STOMACH, GL (ST), STOMACH, NONGL (SU), UTERUS, CERVIX (CV)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 889

STUDY NUMBER: 483287

ANIMAL NUMBER: A37533 SEX: FEMALE DOSE GROUP: 5 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/12/91 STUDY DAY OF DEATH: 96 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 20.3 GRAMS
DATE AND TIME OF NECROPSY: 11/12/91 12:50 PROSECTOR: SCOTT BELL RECORDER: SCOTT BELL
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.15	.729 %	.278	WEIGHT TAKEN
LUNG (LU)	.19	.949 %	.363	WEIGHT TAKEN
UTERUS (UT)	.20	.964 %	.368	WEIGHT TAKEN
BRAIN W/STEM (BR)	.53	2.617 %	1.000	WEIGHT TAKEN
HEART (HT)	.15	.746 %	.285	WEIGHT TAKEN
SPLEEN (SP)	.04	.210 %	.080	WEIGHT TAKEN
KIDNEY (KD)	.34	1.683 %	.643	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	2.00	9.858 %	3.767	WEIGHT TAKEN
ADRENAL (AD)	.007	.0355 %	.0136	WEIGHT TAKEN
OVARY (OV)	.036	.1788 %	.0683	WEIGHT TAKEN
THYMUS (TH)	.01	.046 %	.018	WEIGHT TAKEN

CLINICAL OBSERVATIONS

PATHOLOGY OBSERVATIONS
NECROPSY

HISTOPATHOLOGY

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE
OBSERVATIONS

LIVER (LI) :
-DARK; ALL LOBES, DARK BROWN

ADRENAL, CORTEX (AC) :
-VACUOLIZATION, X-ZONE,-MINIMAL
-HYPERPLASIA, SUBCAPSULAR CELL,-MINIMAL
-UNILATERALLY EXAMINED,-PRESENT
ADRENAL, MEDULLA (AM) :
-UNILATERALLY EXAMINED,-PRESENT
KIDNEY (KD) :
-TUBULE, MINERALIZATION,-MINIMAL
LIVER (LI) :
-HEPATOCYTE, HYPERTROPHY,
CENTROLOBULAR,-MINIMAL
-PIGMENT, BILE,-MINIMAL
-KUPFFER CELL/MACROPHAGE, PIGMENT,-
MINIMAL
-HEPATOCYTE, PIGMENT,-SLIGHT
-NECROSIS, INDIVIDUAL CELL,-MINIMAL
-INFLAMMATION, CHRONIC/CHRONIC ACTIVE,-
SLIGHT

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 890

STUDY NUMBER: 483287

ANIMAL NUMBER: A37533 SEX: FEMALE DOSE GROUP: 5 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/12/91 STUDY DAY OF DEATH: 96 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 20.3 GRAMS
DATE AND TIME OF NECROPSY: 11/12/91 12:50 PROSECTOR: SCOTT BELL RECORDER: SCOTT BELL
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

CLINICAL OBSERVATIONS

P A T H O L O G Y O B S E R V A T I O N S (CONTINUED)
NECROPSY

HISTOPATHOLOGY

OVARY (OV) :
-CYST; LEFT, ONE, CLEAR, 1 X 1 MM

STOMACH, GL (ST) :
-DARK AREA; MUCOSA, SEVERAL, BLACK,
PINPOINT TO 1 X 1 MM

^COLLECTED/TAKEN (XW) :
-LIVER SECTIONS, IN METHANOL
GENERAL INFORMATION (XX) :
>NOTE:>ANIMAL DIED PRIOR TO EUTHANASIA

OVARY (OV) :
-BURSA, CYST, -PRESENT
SPLEEN (SP) :
-PIGMENT, -SLIGHT
-NECROSIS, LYMPHOID, -MINIMAL
STOMACH, GL (ST) :
-HYPERPLASIA, -SLIGHT
UTERUS (UT) :
>TISSUE MISSING
UTERUS, CERVIX (CV) :
>TISSUE MISSING

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE), KIDNEY (KD),
LACRIMAL GL, EX (EO), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU), MAMMARY, FEMALE (MF), MAND SALIVARY GL (SG),
MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON), NERVE, SCIATIC (SN),
PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), RECTUM (RE), SKIN (SK), SKIN, OTHER (SS), SPLEEN (SP),
STOMACH, NONGL (SU), THYMUS (TH), THYROID (TY), TONGUE (TO), TRACHEA (TR), URINARY BLADDER (UB), UTERUS (UT),
UTERUS, CERVIX (CV), VAGINA (VA)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:

MAMMARY, FEMALE (MF), OVIDUCT (OD), SKIN (SK), STOMACH, NONGL (SU)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 891

STUDY NUMBER: 483287

ANIMAL NUMBER: A37534 SEX: FEMALE DOSE GROUP: 5 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/13/91 STUDY DAY OF DEATH: 97 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 27.7 GRAMS
DATE AND TIME OF NECROPSY: 11/13/91 9:02 PROSECTOR: LINDA RUMBLE RECORDER: LINDA RUMBLE
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.15	.533 %	.274	WEIGHT TAKEN
LUNG (LU)	.21	.744 %	.382	WEIGHT TAKEN
UTERUS (UT)	.26	.948 %	.487	WEIGHT TAKEN
BRAIN W/STEM (BR)	.54	1.945 %	1.000	WEIGHT TAKEN
HEART (HT)	.17	.631 %	.324	WEIGHT TAKEN
SPLEEN (SP)	.09	.312 %	.160	WEIGHT TAKEN
KIDNEY (KD)	.45	1.625 %	.835	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	2.54	9.172 %	4.714	WEIGHT TAKEN
ADRENAL (AD)	.008	.0292 %	.0150	WEIGHT TAKEN
OVARY (OV)	.037	.1343 %	.0690	WEIGHT TAKEN
THYMUS (TH)	.03	.099 %	.051	WEIGHT TAKEN

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE
OBSERVATIONS

PATHOLOGY OBSERVATIONS
NECROPSY

LIVER (LI) :
-ENLARGED, MODERATE; ALL LOBES
-DARK; ALL LOBES, DARK BROWN

HISTOPATHOLOGY

KIDNEY (KD) :
-TUBULE, REGENERATION,-MINIMAL
-INFLAMMATION, SUBACUTE,-MINIMAL
LIVER (LI) :
-HEPATOCYTE, HYPERTROPHY,
CENTROLOBULAR,-MINIMAL
-PIGMENT, BILE,-MINIMAL
-KUPFFER CELL/MACROPHAGE, PIGMENT,-
MINIMAL
-HEPATOCYTE, PIGMENT,-MINIMAL
-NECROSIS,-MINIMAL, FOCAL
-NECROSIS, INDIVIDUAL CELL,-MINIMAL
-INFLAMMATION, CHRONIC/CHRONIC ACTIVE,-
MINIMAL
SPLEEN (SP) :
-EXTRAMEDULLARY HEMATOPOIESIS,
INCREASED,-MINIMAL
-PIGMENT,-SLIGHT

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 892

STUDY NUMBER: 483287

ANIMAL NUMBER: A37534 SEX: FEMALE DOSE GROUP: 5 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/13/91 STUDY DAY OF DEATH: 97 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 27.7 GRAMS
DATE AND TIME OF NECROPSY: 11/13/91 9:02 PROSECTOR: LINDA RUMBLE RECORDER: LINDA RUMBLE
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

CLINICAL OBSERVATIONS

P A T H O L O G Y O B S E R V A T I O N S (CONTINUED)
NECROPSY

HISTOPATHOLOGY

UTERUS (UT) :
-HYPERPLASIA, CYSTIC ENDOMETRIAL, -
SLIGHT

^COLLECTED/TAKEN (XW) :
-LIVER SECTIONS, IN METHANOL

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE), KIDNEY (KD),
LACRIMAL GL, EX (EO), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU), MAMMARY, FEMALE (MF), MAND SALIVARY GL (SG),
MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON), NERVE, SCIATIC (SN),
OVARY (OV), PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), RECTUM (RE), SKIN (SK), SKIN, OTHER (SS), SPLEEN (SP),
STOMACH, GL (ST), STOMACH, NONGL (SU), THYMUS (TH), THYROID (TY), TONGUE (TO), TRACHEA (TR), URINARY BLADDER (UB),
UTERUS (UT), UTERUS, CERVIX (CV), VAGINA (VA)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), MAMMARY, FEMALE (MF), SKIN (SK), STOMACH, GL (ST), STOMACH, NONGL (SU),
UTERUS, CERVIX (CV)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 893

STUDY NUMBER: 483287

ANIMAL NUMBER: A37535 SEX: FEMALE DOSE GROUP: 5 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/13/91 STUDY DAY OF DEATH: 97 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 24.1 GRAMS
DATE AND TIME OF NECROPSY: 11/13/91 10:00 PROSECTOR: FRED AGEY RECORDER: FRED AGEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.12	.485 %	.228	WEIGHT TAKEN
LUNG (LU)	.18	.742 %	.349	WEIGHT TAKEN
UTERUS (UT)	.16	.671 %	.316	WEIGHT TAKEN
BRAIN W/STEM (BR)	.51	2.125 %	1.000	WEIGHT TAKEN
HEART (HT)	.15	.611 %	.288	WEIGHT TAKEN
SPLEEN (SP)	.07	.287 %	.135	WEIGHT TAKEN
KIDNEY (KD)	.42	1.729 %	.814	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	1.98	8.196 %	3.856	WEIGHT TAKEN
ADRENAL (AD)	.007	.0299 %	.0141	WEIGHT TAKEN
OVARY (OV)	.051	.2120 %	.0998	WEIGHT TAKEN
THYMUS (TH)	.04	.151 %	.071	WEIGHT TAKEN

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE
OBSERVATIONS

PATHOLOGY OBSERVATIONS
NECROPSY

LIVER (LI) :
-ENLARGED, MODERATE; ALL LOBES
-DARK; ALL LOBES, DARK BROWN

HISTOPATHOLOGY

ADRENAL, CORTEX (AC) :
-PIGMENT,-MINIMAL
-VACUOLIZATION, X-ZONE,-MINIMAL
KIDNEY (KD) :
-INFLAMMATION, SUBACUTE,-MINIMAL
LIVER (LI) :
-HEPATOCTYE, HYPERTROPHY,
CENTROLOBULAR,-MINIMAL
-VACUOLIZATION,-MINIMAL
-PIGMENT, BILE,-MINIMAL
-KUPFFER CELL/MACROPHAGE, PIGMENT,-
MINIMAL
-HEPATOCTYE, PIGMENT,-MINIMAL
-NECROSIS, INDIVIDUAL CELL,-MINIMAL
-INFLAMMATION, CHRONIC/CHRONIC ACTIVE,-
MINIMAL
SPLEEN (SP) :
-EXTRAMEDULLARY HEMATOPOIESIS,
INCREASED,-MINIMAL

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 894

STUDY NUMBER: 483287

ANIMAL NUMBER: A37535 SEX: FEMALE DOSE GROUP: 5 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/13/91 STUDY DAY OF DEATH: 97 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 24.1 GRAMS
DATE AND TIME OF NECROPSY: 11/13/91 10:00 PROSECTOR: FRED AGEY RECORDER: FRED AGEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

CLINICAL OBSERVATIONS

P A T H O L O G Y O B S E R V A T I O N S (CONTINUED)
NECROPSY

HISTOPATHOLOGY

SPLEEN (SP) :
-PIGMENT, -MINIMAL
STOMACH, GL (ST) :
-HYPERPLASIA, CYSTIC, -MINIMAL
UTERUS (UT) :
-HYPERPLASIA, CYSTIC ENDOMETRIAL, -
MINIMAL
-HYPOPLASIA, -MODERATELY SEVERE

^COLLECTED/TAKEN (XW) :
-LIVER SECTIONS, IN METHANOL

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE), KIDNEY (KD),
LACRIMAL GL, EX (EO), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU), MAMMARY, FEMALE (MF), MAND SALIVARY GL (SG),
MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON), NERVE, SCIATIC (SN),
OVARY (OV), PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), RECTUM (RE), SKIN (SK), SKIN, OTHER (SS), SPLEEN (SP),
STOMACH, GL (ST), STOMACH, NONGL (SU), THYMUS (TH), THYROID (TY), TONGUE (TO), TRACHEA (TR), URINARY BLADDER (UB),
UTERUS (UT), UTERUS, CERVIX (CV), VAGINA (VA)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:

ADRENAL, MEDULLA (AM), MAMMARY, FEMALE (MF), SKIN (SK), STOMACH, NONGL (SU), UTERUS, CERVIX (CV)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 895

STUDY NUMBER: 483287

ANIMAL NUMBER: A37536 SEX: FEMALE DOSE GROUP: 5 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/13/91 STUDY DAY OF DEATH: 97 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 25.6 GRAMS
DATE AND TIME OF NECROPSY: 11/13/91 11:17 PROSECTOR: LINDA RUMBLE RECORDER: LINDA RUMBLE
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.15	.574 %	.279	WEIGHT TAKEN
LUNG (LU)	.20	.775 %	.376	WEIGHT TAKEN
UTERUS (UT)	.14	.562 %	.273	WEIGHT TAKEN
BRAIN W/STEM (BR)	.53	2.059 %	1.000	WEIGHT TAKEN
HEART (HT)	.16	.638 %	.310	WEIGHT TAKEN
SPLEEN (SP)	.09	.353 %	.171	WEIGHT TAKEN
KIDNEY (KD)	.41	1.609 %	.781	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	2.64	10.325 %	5.014	WEIGHT TAKEN
ADRENAL (AD)	.017	.0684 %	.0332	WEIGHT TAKEN
OVARY (OV)	.039	.1508 %	.0732	WEIGHT TAKEN
THYMUS (TH)	.04	.152 %	.074	WEIGHT TAKEN

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM: NORMAL-NO REMARKABLE
OBSERVATIONS

PATHOLOGY OBSERVATIONS
NECROPSY

LIVER (LI) :
-PALE AREA; ALL LOBES, FEW, TAN,
PINPOINT TO 3 X 3 MM
-ENLARGED, MODERATE; ALL LOBES
-DARK; ALL LOBES, DARK BROWN

HISTOPATHOLOGY

ADRENAL, CORTEX (AC) :
-VACUOLIZATION, X-ZONE, -MINIMAL
-HYPERPLASIA, SUBCAPSULAR CELL, -MINIMAL
KIDNEY (KD) :
-INFLAMMATION, CHRONIC, -MINIMAL
-INFLAMMATION, SUBACUTE, -MINIMAL
LIVER (LI) :
-HEPATOCYTE, HYPERTROPHY,
CENTROLOBULAR, -SLIGHT
-VACUOLIZATION, -MINIMAL
-KUPFFER CELL/MACROPHAGE, PIGMENT, -
MINIMAL
-HEPATOCYTE, PIGMENT, -MINIMAL
-BILE DUCT, INFLAMMATION, CHRONIC, -
MINIMAL
SPLEEN (SP) :
-EXTRAMEDULLARY HEMATOPOIESIS,
INCREASED, -MINIMAL
-PIGMENT, -SLIGHT

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 896

STUDY NUMBER: 483287

ANIMAL NUMBER: A37536 SEX: FEMALE DOSE GROUP: 5 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/13/91 STUDY DAY OF DEATH: 97 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 25.6 GRAMS
DATE AND TIME OF NECROPSY: 11/13/91 11:17 PROSECTOR: LINDA RUMBLE RECORDER: LINDA RUMBLE
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

CLINICAL OBSERVATIONS

P A T H O L O G Y O B S E R V A T I O N S (CONTINUED)
NECROPSY

HISTOPATHOLOGY

STOMACH, GL (ST) :
-INFLAMMATION, CHRONIC, -MINIMAL

^COLLECTED/TAKEN (XW) :
-LIVER SECTIONS, IN METHANOL

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE), KIDNEY (KD),
LACRIMAL GL, EX (EO), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU), MAMMARY, FEMALE (MF), MAND SALIVARY GL (SG),
MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON), NERVE, SCIATIC (SN),
OVARY (OV), PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), RECTUM (RE), SKIN (SK), SKIN, OTHER (SS), SPLEEN (SP),
STOMACH, GL (ST), STOMACH, NONGL (SU), THYMUS (TH), THYROID (TY), TONGUE (TO), TRACHEA (TR), URINARY BLADDER (UB),
UTERUS (UT), UTERUS, CERVIX (CV), VAGINA (VA)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:

ADRENAL, MEDULLA (AM), MAMMARY, FEMALE (MF), SKIN (SK), STOMACH, NONGL (SU), UTERUS (UT), UTERUS, CERVIX (CV)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 897

STUDY NUMBER: 483287

ANIMAL NUMBER: A37537 SEX: FEMALE DOSE GROUP: 5 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/13/91 STUDY DAY OF DEATH: 97 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 24.7 GRAMS
DATE AND TIME OF NECROPSY: 11/13/91 13:40 PROSECTOR: SCOTT BELL RECORDER: SCOTT BELL
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.15	.610 %	.277	WEIGHT TAKEN
LUNG (LU)	.19	.768 %	.349	WEIGHT TAKEN
UTERUS (UT)	.28	1.153 %	.523	WEIGHT TAKEN
BRAIN W/STEM (BR)	.54	2.204 %	1.000	WEIGHT TAKEN
HEART (HT)	.16	.660 %	.299	WEIGHT TAKEN
SPLEEN (SP)	.06	.257 %	.117	WEIGHT TAKEN
KIDNEY (KD)	.39	1.572 %	.714	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	2.18	8.822 %	4.003	WEIGHT TAKEN
ADRENAL (AD)	.007	.0283 %	.0129	WEIGHT TAKEN
OVARY (OV)	.067	.2721 %	.1235	WEIGHT TAKEN
THYMUS (TH)	.03	.128 %	.058	WEIGHT TAKEN

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE
OBSERVATIONS

PATHOLOGY OBSERVATIONS
NECROPSY

LIVER (LI) :
-PALE AREA; ALL LOBES, FEW, WHITE,
PINPOINT TO 2 X 2 MM
-ENLARGED, MODERATE; ALL LOBES
-DARK; ALL LOBES, DARK BROWN

OVARY (OV) :
-CYST; LEFT, ONE, CLEAR, 3 X 3 MM

HISTOPATHOLOGY

ADRENAL, CORTEX (AC) :
-VACUOLIZATION, X-ZONE,-SLIGHT
-UNILATERALLY EXAMINED,-PRESENT
ADRENAL, MEDULLA (AM) :
-UNILATERALLY EXAMINED,-PRESENT
KIDNEY (KD) :
-TUBULE, REGENERATION,-MINIMAL
-INFLAMMATION, SUBACUTE,-MINIMAL
LIVER (LI) :
-HEPATOCYTE, HYPERTROPHY,
CENTROLOBULAR,-MINIMAL
-KUPFFER CELL/MACROPHAGE, PIGMENT,-
MINIMAL
-HEPATOCYTE, PIGMENT,-MINIMAL
-NECROSIS, INDIVIDUAL CELL,-MINIMAL
-INFLAMMATION, CHRONIC/CHRONIC ACTIVE,-
MINIMAL
OVARY (OV) :
-FOLLICLE, CYST,-PRESENT

APPENDIX 13B

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORTPRINTED: 21-JAN-93
PAGE: 898

STUDY NUMBER: 483287

ANIMAL NUMBER: A37537 SEX: FEMALE DOSE GROUP: 5 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
 DATE OF DEATH: 11/13/91 STUDY DAY OF DEATH: 97 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 24.7 GRAMS
 DATE AND TIME OF NECROPSY: 11/13/91 13:40 PROSECTOR: SCOTT BELL RECORDER: SCOTT BELL
 POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

CLINICAL OBSERVATIONS P A T H O L O G Y O B S E R V A T I O N S (CONTINUED)
 NECROPSY HISTOPATHOLOGY

SPLEEN (SP) :
 -PIGMENT, -MINIMAL
 UTERUS (UT) :
 -HYPERPLASIA, CYSTIC ENDOMETRIAL, -
 SLIGHT

^COLLECTED/TAKEN (XW) :
 -LIVER SECTIONS, IN METHANOL

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
 BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
 DUODENUM (DU), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE), KIDNEY (KD),
 LACRIMAL GL, EX (EO), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU), MAMMARY, FEMALE (MF), MAND SALIVARY GL (SG),
 MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON), NERVE, SCIATIC (SN),
 PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), RECTUM (RE), SKIN (SK), SKIN, OTHER (SS), SPLEEN (SP),
 STOMACH, GL (ST), STOMACH, NONGL (SU), THYMUS (TH), THYROID (TY), TONGUE (TO), TRACHEA (TR), URINARY BLADDER (UB),
 UTERUS (UT), UTERUS, CERVIX (CV), VAGINA (VA)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:

MAMMARY, FEMALE (MF), OVIDUCT (OD), SKIN (SK), STOMACH, GL (ST), STOMACH, NONGL (SU), UTERUS, CERVIX (CV)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 899

STUDY NUMBER: 483287

ANIMAL NUMBER: A37538 SEX: FEMALE DOSE GROUP: 5 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/14/91 STUDY DAY OF DEATH: 98 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 26.7 GRAMS
DATE AND TIME OF NECROPSY: 11/14/91 8:35 PROSECTOR: FRED AGEY RECORDER: FRED AGEY
POST-FIX WEIGHER: JOHN CROWLEY PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.17	.625 %	.334	WEIGHT TAKEN
LUNG (LU)	.16	.597 %	.319	WEIGHT TAKEN
UTERUS (UT)	.10	.374 %	.200	WEIGHT TAKEN
BRAIN W/STEM (BR)	.50	1.872 %	1.000	WEIGHT TAKEN
HEART (HT)	.14	.533 %	.285	WEIGHT TAKEN
SPLEEN (SP)	.10	.374 %	.200	WEIGHT TAKEN
KIDNEY (KD)	.34	1.269 %	.678	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	3.24	12.127 %	6.479	WEIGHT TAKEN
ADRENAL (AD)	.012	.0457 %	.0244	WEIGHT TAKEN
OVARY (OV)	.034	.1266 %	.0676	WEIGHT TAKEN
THYMUS (TH)	.05	.172 %	.092	WEIGHT TAKEN

CLINICAL OBSERVATIONS	PATHOLOGY OBSERVATIONS NECROPSY	HISTOPATHOLOGY
-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS	LIVER (LI) : -PALE AREA; ALL LOBES, FEW, TAN, PINPOINT -ENLARGED, MODERATE; ALL LOBES -DARK; ALL LOBES, DARK BROWN	KIDNEY (KD) : -INFLAMMATION, CHRONIC,-MINIMAL LIVER (LI) : -HEPATOCYTE, HYPERTROPHY, CENTROLOBULAR,-MODERATE -VACUOLIZATION,-MODERATELY SEVERE -KUPFFER CELL/MACROPHAGE, PIGMENT,- MINIMAL -HEPATOCYTE, PIGMENT,-MINIMAL -NECROSIS,-MINIMAL, FOCAL -INFLAMMATION, CHRONIC/CHRONIC ACTIVE,- MINIMAL MAMMARY, FEMALE (MF) : >TISSUE MISSING SPLEEN (SP) : -EXTRAMEDULLARY HEMATOPOIESIS, INCREASED,-MINIMAL -PIGMENT,-SLIGHT

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 900

STUDY NUMBER: 483287

ANIMAL NUMBER: A37538 SEX: FEMALE DOSE GROUP: 5 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/14/91 STUDY DAY OF DEATH: 98 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 26.7 GRAMS
DATE AND TIME OF NECROPSY: 11/14/91 8:35 PROSECTOR: FRED AGEY RECORDER: FRED AGEY
POST-FIX WEIGHER: JOHN CROWLEY PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

CLINICAL OBSERVATIONS P A T H O L O G Y O B S E R V A T I O N S (CONTINUED)
NECROPSY HISTOPATHOLOGY

STOMACH, GL (ST) :
-HYPERPLASIA, CYSTIC, -MINIMAL
-INFLAMMATION, CHRONIC, -MINIMAL
UTERUS (UT) :
-HYPERPLASIA, CYSTIC ENDOMETRIAL, -
MINIMAL
-HYPOPLASIA, -MINIMAL

^COLLECTED/TAKEN (XW) :
-LIVER SECTIONS, IN METHANOL

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE), KIDNEY (KD),
LACRIMAL GL, EX (EO), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU), MAMMARY, FEMALE (MF), MAND SALIVARY GL (SG),
MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON), NERVE, SCIATIC (SN),
OVARY (OV), PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), RECTUM (RE), SKIN (SK), SKIN, OTHER (SS), SPLEEN (SP),
STOMACH, GL (ST), STOMACH, NONGL (SU), THYMUS (TH), THYROID (TY), TONGUE (TO), TRACHEA (TR), URINARY BLADDER (UB),
UTERUS (UT), UTERUS, CERVIX (CV), VAGINA (VA)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), SKIN (SK), STOMACH, NONGL (SU), UTERUS, CERVIX (CV)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 901

STUDY NUMBER: 483287

ANIMAL NUMBER: A37539 SEX: FEMALE DOSE GROUP: 5 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/14/91 STUDY DAY OF DEATH: 98 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 25.5 GRAMS
DATE AND TIME OF NECROPSY: 11/14/91 9:30 PROSECTOR: FRED AGEY RECORDER: FRED AGEY
POST-FIX WEIGHER: JOHN CROWLEY PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.14	.557 %	.277	WEIGHT TAKEN
LUNG (LU)	.18	.697 %	.347	WEIGHT TAKEN
UTERUS (UT)	.14	.542 %	.270	WEIGHT TAKEN
BRAIN W/STEM (BR)	.51	2.008 %	1.000	WEIGHT TAKEN
HEART (HT)	.12	.478 %	.238	WEIGHT TAKEN
SPLEEN (SP)	.08	.301 %	.150	WEIGHT TAKEN
KIDNEY (KD)	.33	1.279 %	.637	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	1.85	7.270 %	3.620	WEIGHT TAKEN
ADRENAL (AD)	.012	.0463 %	.0230	WEIGHT TAKEN
OVARY (OV)	.034	.1341 %	.0668	WEIGHT TAKEN
THYMUS (TH)	.03	.102 %	.051	WEIGHT TAKEN

CLINICAL OBSERVATIONS	PATHOLOGY OBSERVATIONS NECROPSY	HISTOPATHOLOGY
-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS	LIVER (LI) : -ENLARGED, MODERATE; ALL LOBES -DARK; ALL LOBES, DARK BROWN	ADRENAL, CORTEX (AC) : -VACUOLIZATION, X-ZONE,-MINIMAL -HYPERPLASIA, SUBCAPSULAR CELL,-SLIGHT LIVER (LI) : -HEPATOCYTE, HYPERTROPHY, CENTROLOBULAR,-MODERATELY SEVERE -KUPFFER CELL/MACROPHAGE, PIGMENT,- MODERATELY SEVERE -HEPATOCYTE, PIGMENT,-SLIGHT -NECROSIS,-MINIMAL, MULTI-FOCAL -NECROSIS, INDIVIDUAL CELL,-MINIMAL -INFLAMMATION, CHRONIC/CHRONIC ACTIVE,- MODERATE MAMMARY, FEMALE (MF) : -TISSUE MISSING SPLEEN (SP) : -EXTRAMEDULLARY HEMATOPOIESIS, INCREASED,-MINIMAL -PIGMENT,-MINIMAL

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 902

STUDY NUMBER: 483287

ANIMAL NUMBER: A37539 SEX: FEMALE DOSE GROUP: 5 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/14/91 STUDY DAY OF DEATH: 98 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 25.5 GRAMS
DATE AND TIME OF NECROPSY: 11/14/91 9:30 PROSECTOR: FRED AGEY RECORDER: FRED AGEY
POST-FIX WEIGHER: JOHN CROWLEY PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

CLINICAL OBSERVATIONS P A T H O L O G Y O B S E R V A T I O N S (CONTINUED)
NECROPSY HISTOPATHOLOGY

UTERUS (UT) :
-HYPOPLASIA, -MINIMAL

^COLLECTED/TAKEN (XW) :
-LIVER SECTIONS, IN METHANOL

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE), KIDNEY (KD),
LACRIMAL GL, EX (EO), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU), MAMMARY, FEMALE (MF), MAND SALIVARY GL (SG),
MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON), NERVE, SCIATIC (SN),
OVARY (OV), PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), RECTUM (RE), SKIN (SK), SKIN, OTHER (SS), SPLEEN (SP),
STOMACH, GL (ST), STOMACH, NONGL (SU), THYMUS (TH), THYROID (TY), TONGUE (TO), TRACHEA (TR), URINARY BLADDER (UB),
UTERUS (UT), UTERUS, CERVIX (CV), VAGINA (VA)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:
ADRENAL, MEDULLA (AM), KIDNEY (KD), SKIN (SK), STOMACH, GL (ST), STOMACH, NONGL (SU), UTERUS, CERVIX (CV)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 903

STUDY NUMBER: 483287

ANIMAL NUMBER: A37540 SEX: FEMALE DOSE GROUP: 5 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/14/91 STUDY DAY OF DEATH: 98 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 22.0 GRAMS
DATE AND TIME OF NECROPSY: 11/14/91 10:12 PROSECTOR: FRED AGEY RECORDER: FRED AGEY
POST-FIX WEIGHER: JOHN CROWLEY PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.13	.604 %	.254	WEIGHT TAKEN
LUNG (LU)	.17	.780 %	.327	WEIGHT TAKEN
UTERUS (UT)	.09	.425 %	.179	WEIGHT TAKEN
BRAIN W/STEM (BR)	.52	2.380 %	1.000	WEIGHT TAKEN
HEART (HT)	.11	.522 %	.219	WEIGHT TAKEN
SPLEEN (SP)	.06	.284 %	.119	WEIGHT TAKEN
KIDNEY (KD)	.35	1.599 %	.672	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	2.54	11.524 %	4.841	WEIGHT TAKEN
ADRENAL (AD)	.011	.0505 %	.0212	WEIGHT TAKEN
OVARY (OV)	.030	.1377 %	.0579	WEIGHT TAKEN
THYMUS (TH)	.04	.168 %	.070	WEIGHT TAKEN

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE
OBSERVATIONS

PATHOLOGY OBSERVATIONS
NECROPSY

LIVER (LI) :
-ENLARGED, MODERATE; ALL LOBES
-DARK; ALL LOBES, DARK BROWN

HISTOPATHOLOGY

ADRENAL, CORTEX (AC) :
-VACUOLIZATION, X-ZONE, -MODERATE
KIDNEY (KD) :
-INFLAMMATION, CHRONIC, -MINIMAL
-INFLAMMATION, SUBACUTE, -MINIMAL
LIVER (LI) :
-VACUOLIZATION, -MODERATELY SEVERE
-KUPFFER CELL/MACROPHAGE, PIGMENT, -
MINIMAL
-HEPATOCYTE, PIGMENT, -MINIMAL
MAMMARY, FEMALE (MF) :
>TISSUE MISSING
SPLEEN (SP) :
-EXTRAMEDULLARY HEMATOPOIESIS,
INCREASED, -MINIMAL
-PIGMENT, -MINIMAL
UTERUS (UT) :
-HYPOPLASIA, -MODERATE

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 904

STUDY NUMBER: 483287

ANIMAL NUMBER: A37540 SEX: FEMALE DOSE GROUP: 5 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/14/91 STUDY DAY OF DEATH: 98 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 22.0 GRAMS
DATE AND TIME OF NECROPSY: 11/14/91 10:12 PROSECTOR: FRED AGEY RECORDER: FRED AGEY
POST-FIX WEIGHER: JOHN CROWLEY PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

CLINICAL OBSERVATIONS P A T H O L O G Y O B S E R V A T I O N S (CONTINUED)
NECROPSY HISTOPATHOLOGY

^COLLECTED/TAKEN (XW) :
-LIVER SECTIONS, IN METHANOL

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE), KIDNEY (KD),
LACRIMAL GL, EX (EO), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU), MAMMARY, FEMALE (MF), MAND SALIVARY GL (SG),
MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON), NERVE, SCIATIC (SN),
OVARY (OV), PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), RECTUM (RE), SKIN (SK), SKIN, OTHER (SS), SPLEEN (SP),
STOMACH, GL (ST), STOMACH, NONGL (SU), THYMUS (TH), THYROID (TY), TONGUE (TO), TRACHEA (TR), URINARY BLADDER (UB),
UTERUS (UT), UTERUS, CERVIX (CV), VAGINA (VA)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:

ADRENAL, MEDULLA (AM), SKIN (SK), STOMACH, GL (ST), STOMACH, NONGL (SU), UTERUS, CERVIX (CV)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 905

STUDY NUMBER: 483287

ANIMAL NUMBER: A37556 SEX: FEMALE DOSE GROUP: 6 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/11/91 STUDY DAY OF DEATH: 95 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 22.5 GRAMS
DATE AND TIME OF NECROPSY: 11/11/91 9:38 PROSECTOR: ADEFOLAHAN AKINSOLA RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.09	.420 %	.205	WEIGHT TAKEN
LUNG (LU)	.15	.654 %	.319	WEIGHT TAKEN
UTERUS (UT)	.16	.696 %	.340	WEIGHT TAKEN
BRAIN W/STEM (BR)	.46	2.048 %	1.000	WEIGHT TAKEN
HEART (HT)	.13	.597 %	.292	WEIGHT TAKEN
SPLEEN (SP)	.07	.311 %	.152	WEIGHT TAKEN
KIDNEY (KD)	.30	1.354 %	.661	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	2.64	11.717 %	5.720	WEIGHT TAKEN
ADRENAL (AD)	.011	.0476 %	.0232	WEIGHT TAKEN
OVARY (OV)	.040	.1769 %	.0864	WEIGHT TAKEN
THYMUS (TH)	.02	.079 %	.039	WEIGHT TAKEN

CLINICAL OBSERVATIONS	PATHOLOGY OBSERVATIONS NECROPSY	HISTOPATHOLOGY
-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS	LIVER (LI) : -PALE AREA; ALL LOBES, FEW, TAN, PINPOINT TO 2 X 2 MM -ENLARGED, MODERATE; ALL LOBES -DARK; ALL LOBES, DARK BROWN	KIDNEY (KD) : >TISSUE MISSING LIVER (LI) : -HEPATOCYTE, HYPERTROPHY, CENTROLOBULAR,-MODERATE -VACUOLIZATION,-MINIMAL -PIGMENT, BILE,-MINIMAL -KUPFFER CELL/MACROPHAGE, PIGMENT,- MINIMAL -HEPATOCYTE, PIGMENT,-SLIGHT -NECROSIS, INDIVIDUAL CELL,-MINIMAL -INFLAMMATION, CHRONIC/CHRONIC ACTIVE,- MINIMAL -EXTRAMEDULLARY HEMATOPOIESIS, INCREASED,-MINIMAL LN, OTHER (LN) : >UNREMARKABLE >NOTE:>SUBCUTANEOUS.

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 906

STUDY NUMBER: 483287

ANIMAL NUMBER: A37556 SEX: FEMALE DOSE GROUP: 6 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/11/91 STUDY DAY OF DEATH: 95 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 22.5 GRAMS
DATE AND TIME OF NECROPSY: 11/11/91 9:38 PROSECTOR: ADEFOLAHAN AKINSOLA RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

CLINICAL OBSERVATIONS P A T H O L O G Y O B S E R V A T I O N S (CONTINUED)
NECROPSY HISTOPATHOLOGY

SPLEEN (SP) :
 >TISSUE MISSING
STOMACH, GL (ST) :
 -HYPERPLASIA, CYSTIC,-MINIMAL
 -INFLAMMATION, CHRONIC,-MINIMAL
UTERUS (UT) :
 >TISSUE MISSING
UTERUS, CERVIX (CV) :
 >TISSUE MISSING

^COLLECTED/TAKEN (XW) :
 -LIVER SECTIONS, IN METHANOL

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE), KIDNEY (KD),
LACRIMAL GL, EX (EO), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU), MAMMARY, FEMALE (MF), MAND SALIVARY GL (SG),
MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON), NERVE, SCIATIC (SN),
OVARY (OV), PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), RECTUM (RE), SKIN (SK), SKIN, OTHER (SS), SPLEEN (SP),
STOMACH, GL (ST), STOMACH, NONGL (SU), THYMUS (TH), THYROID (TY), TONGUE (TO), TRACHEA (TR), URINARY BLADDER (UB),
UTERUS (UT), UTERUS, CERVIX (CV), VAGINA (VA)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:
ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), MAMMARY, FEMALE (MF), SKIN (SK), STOMACH, NONGL (SU)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 907

STUDY NUMBER: 483287

ANIMAL NUMBER: A37557 SEX: FEMALE DOSE GROUP: 6 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/11/91 STUDY DAY OF DEATH: 95 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 24.6 GRAMS
DATE AND TIME OF NECROPSY: 11/11/91 10:47 PROSECTOR: JANE EARHARDT RECORDER: JANE EARHARDT
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.13	.526 %	.238	WEIGHT TAKEN
LUNG (LU)	.18	.725 %	.327	WEIGHT TAKEN
UTERUS (UT)	.16	.639 %	.288	WEIGHT TAKEN
BRAIN W/STEM (BR)	.54	2.215 %	1.000	WEIGHT TAKEN
HEART (HT)	.12	.495 %	.223	WEIGHT TAKEN
SPLEEN (SP)	.08	.341 %	.154	WEIGHT TAKEN
KIDNEY (KD)	.38	1.546 %	.698	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	2.99	12.164 %	5.491	WEIGHT TAKEN
ADRENAL (AD)	.014	.0573 %	.0259	WEIGHT TAKEN
OVARY (OV)	.035	.1423 %	.0642	WEIGHT TAKEN
THYMUS (TH)	.04	.157 %	.071	WEIGHT TAKEN

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE
OBSERVATIONS

PATHOLOGY OBSERVATIONS
NECROPSY

HISTOPATHOLOGY

ADRENAL, CORTEX (AC) :
-PIGMENT,-MINIMAL
KIDNEY (KD) :
-INFLAMMATION, CHRONIC,-SLIGHT
-CYST,-PRESENT
LIVER (LI) :
-HEPATOCYTE, HYPERTROPHY,
CENTROLOBULAR,-MODERATE
-PIGMENT, BILE,-MINIMAL
-KUPFFER CELL/MACROPHAGE, PIGMENT,-
MINIMAL
-HEPATOCYTE, PIGMENT,-MODERATE
-NECROSIS, INDIVIDUAL CELL,-MINIMAL
-BILE DUCT, INFLAMMATION, CHRONIC,-
MINIMAL
SPLEEN (SP) :
-EXTRAMEDULLARY HEMATOPOIESIS,
INCREASED,-MODERATE
-PIGMENT,-MINIMAL

HAZLETON WASHINGTON, INC.
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APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 908

STUDY NUMBER: 483287

ANIMAL NUMBER: A37557 SEX: FEMALE DOSE GROUP: 6 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/11/91 STUDY DAY OF DEATH: 95 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 24.6 GRAMS
DATE AND TIME OF NECROPSY: 11/11/91 10:47 PROSECTOR: JANE EARHARDT RECORDER: JANE EARHARDT
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

CLINICAL OBSERVATIONS P A T H O L O G Y O B S E R V A T I O N S (CONTINUED)
NECROPSY HISTOPATHOLOGY

STOMACH, GL (ST) :
-HYPERPLASIA, CYSTIC, -MINIMAL
UTERUS (UT) :
-HYPOPLASIA, -MINIMAL

^COLLECTED/TAKEN (XW) :
-LIVER SECTIONS, IN METHANOL

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE), KIDNEY (KD),
LACRIMAL GL, EX (EO), LIVER (LI), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU), MAMMARY, FEMALE (MF),
MAND SALIVARY GL (SG), MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON),
NERVE, SCIATIC (SN), OVARY (OV), PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), RECTUM (RE), SKIN (SK),
SKIN, OTHER (SS), SPLEEN (SP), STOMACH, GL (ST), STOMACH, NONGL (SU), THYMUS (TH), THYROID (TY), TONGUE (TO),
TRACHEA (TR), URINARY BLADDER (UB), UTERUS (UT), UTERUS, CERVIX (CV), VAGINA (VA)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:

ADRENAL, MEDULLA (AM), MAMMARY, FEMALE (MF), SKIN (SK), STOMACH, NONGL (SU), UTERUS, CERVIX (CV)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 909

STUDY NUMBER: 483287

ANIMAL NUMBER: A37558 SEX: FEMALE DOSE GROUP: 6 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/11/91 STUDY DAY OF DEATH: 95 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 22.3 GRAMS
DATE AND TIME OF NECROPSY: 11/11/91 11:46 PROSECTOR: FRED AGEY RECORDER: FRED AGEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.10	.431 %	.229	WEIGHT TAKEN
LUNG (LU)	.17	.755 %	.401	WEIGHT TAKEN
UTERUS (UT)	.07	.326 %	.173	WEIGHT TAKEN
BRAIN W/STEM (BR)	.42	1.884 %	1.000	WEIGHT TAKEN
HEART (HT)	.13	.577 %	.306	WEIGHT TAKEN
SPLEEN (SP)	.05	.232 %	.123	WEIGHT TAKEN
KIDNEY (KD)	.27	1.229 %	.652	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	2.95	13.211 %	7.013	WEIGHT TAKEN
ADRENAL (AD)	.012	.0529 %	.0281	WEIGHT TAKEN
OVARY (OV)	.027	.1224 %	.0650	WEIGHT TAKEN
THYMUS (TH)	.03	.153 %	.081	WEIGHT TAKEN

CLINICAL OBSERVATIONS	PATHOLOGY OBSERVATIONS NECROPSY	HISTOPATHOLOGY
-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS	LIVER (LI) : -ENLARGED, MODERATE; ALL LOBES -DARK; ALL LOBES, DARK BROWN	ADRENAL, CORTEX (AC) : -UNILATERALLY EXAMINED,-PRESENT ADRENAL, MEDULLA (AM) : -UNILATERALLY EXAMINED,-PRESENT LIVER (LI) : -HEPATOCYTE, HYPERTROPHY, CENTROLOBULAR,-SLIGHT -VACUOLIZATION,-MINIMAL -PIGMENT, BILE,-MINIMAL -KUPFFER CELL/MACROPHAGE, PIGMENT,- SLIGHT -HEPATOCYTE, PIGMENT,-MODERATE -NECROSIS, INDIVIDUAL CELL,-MINIMAL -BILE DUCT, INFLAMMATION, CHRONIC,- MINIMAL MAMMARY, FEMALE (MF) : -DILATATION, CYSTIC,-SLIGHT -HYPOPLASIA, EPITHELIAL,-PRESENT

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 910

STUDY NUMBER: 483287

ANIMAL NUMBER: A37558 SEX: FEMALE DOSE GROUP: 6 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/11/91 STUDY DAY OF DEATH: 95 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 22.3 GRAMS
DATE AND TIME OF NECROPSY: 11/11/91 11:46 PROSECTOR: FRED AGEY RECORDER: FRED AGEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

CLINICAL OBSERVATIONS

P A T H O L O G Y O B S E R V A T I O N S (CONTINUED)
NECROPSY

HISTOPATHOLOGY

SPLEEN (SP) :
-EXTRAMEDULLARY HEMATOPOIESIS,
INCREASED, -MINIMAL
-PIGMENT, -MINIMAL
STOMACH, GL (ST) :
-HYPERPLASIA, CYSTIC, -MINIMAL
-INFLAMMATION, CHRONIC, -MINIMAL
UTERUS (UT) :
-HYPOPLASIA, -SEVERE
UTERUS, CERVIX (CV) :
>TISSUE MISSING

^COLLECTED/TAKEN (XW) :
-LIVER SECTIONS, IN METHANOL

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE), KIDNEY (KD),
LACRIMAL GL, EX (EO), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU), MAMMARY, FEMALE (MF), MAND SALIVARY GL (SG),
MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON), NERVE, SCIATIC (SN),
OVARY (OV), PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), RECTUM (RE), SKIN (SK), SKIN, OTHER (SS), SPLEEN (SP),
STOMACH, GL (ST), STOMACH, NONGL (SU), THYMUS (TH), THYROID (TY), TONGUE (TO), TRACHEA (TR), URINARY BLADDER (UB),
UTERUS (UT), UTERUS, CERVIX (CV), VAGINA (VA)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:

KIDNEY (KD), PANCREAS (PA), SKIN (SK), STOMACH, NONGL (SU)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 911

STUDY NUMBER: 483287

ANIMAL NUMBER: A37559 SEX: FEMALE DOSE GROUP: 6 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/11/91 STUDY DAY OF DEATH: 95 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 21.4 GRAMS
DATE AND TIME OF NECROPSY: 11/11/91 14:06 PROSECTOR: JANE EARHARDT RECORDER: JOHN CROWLEY
POST-FIX WEAHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEAHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.11	.527 %	.246	WEIGHT TAKEN
LUNG (LU)	.14	.660 %	.309	WEIGHT TAKEN
UTERUS (UT)	.04	.182 %	.085	WEIGHT TAKEN
BRAIN W/STEM (BR)	.46	2.138 %	1.000	WEIGHT TAKEN
HEART (HT)	.13	.597 %	.279	WEIGHT TAKEN
SPLEEN (SP)	.08	.357 %	.167	WEIGHT TAKEN
KIDNEY (KD)	.32	1.501 %	.702	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	3.40	15.875 %	7.426	WEIGHT TAKEN
ADRENAL (AD)	.016	.0729 %	.0341	WEIGHT TAKEN
OVARY (OV)	.020	.0944 %	.0442	WEIGHT TAKEN
THYMUS (TH)	.02	.076 %	.036	WEIGHT TAKEN

CLINICAL OBSERVATIONS

P A T H O L O G Y O B S E R V A T I O N S
NECROPSY

HISTOPATHOLOGY

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE
OBSERVATIONS

LIVER (LI) :
-ENLARGED, SLIGHT; ALL LOBES
-DARK; ALL LOBES, DARK BROWN

LIVER (LI) :
>TISSUE MISSING

SPLEEN (SP) :
-EXTRAMEDULLARY HEMATOPOIESIS,
INCREASED,-MODERATE
-PIGMENT,-MINIMAL
UTERUS (UT) :
-HYPOPLASIA,-SEVERE
UTERUS, CERVIX (CV) :
>TISSUE MISSING

^COLLECTED/TAKEN (XW) :
-LIVER SECTIONS, IN METHANOL

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 912

STUDY NUMBER: 483287

ANIMAL NUMBER: A37559 SEX: FEMALE DOSE GROUP: 6 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/11/91 STUDY DAY OF DEATH: 95 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 21.4 GRAMS
DATE AND TIME OF NECROPSY: 11/11/91 14:06 PROSECTOR: JANE EARHARDT RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE), KIDNEY (KD),
LACRIMAL GL, EX (EO), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU), MAMMARY, FEMALE (MF), MAND SALIVARY GL (SG),
MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON), NERVE, SCIATIC (SN),
OVARY (OV), PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), RECTUM (RE), SKIN (SK), SKIN, OTHER (SS), SPLEEN (SP),
STOMACH, GL (ST), STOMACH, NONGL (SU), THYMUS (TH), THYROID (TY), TONGUE (TO), TRACHEA (TR), URINARY BLADDER (UB),
UTERUS (UT), UTERUS, CERVIX (CV), VAGINA (VA)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), KIDNEY (KD), MAMMARY, FEMALE (MF), PANCREAS (PA), SKIN (SK),
STOMACH, GL (ST), STOMACH, NONGL (SU)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 913

STUDY NUMBER: 483287

ANIMAL NUMBER: A37560 SEX: FEMALE DOSE GROUP: 6 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/12/91 STUDY DAY OF DEATH: 96 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 22.4 GRAMS
DATE AND TIME OF NECROPSY: 11/12/91 9:20 PROSECTOR: JANE EARHARDT RECORDER: JANE EARHARDT
POST-FIX WEAHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEAHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.10	.442 %	.210	WEIGHT TAKEN
LUNG (LU)	.18	.789 %	.374	WEIGHT TAKEN
UTERUS (UT)	.04	.182 %	.086	WEIGHT TAKEN
BRAIN W/STEM (BR)	.47	2.108 %	1.000	WEIGHT TAKEN
HEART (HT)	.12	.539 %	.256	WEIGHT TAKEN
SPLEEN (SP)	.09	.391 %	.186	WEIGHT TAKEN
KIDNEY (KD)	.38	1.689 %	.801	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	3.29	14.697 %	6.972	WEIGHT TAKEN
ADRENAL (AD)	.015	.0652 %	.0309	WEIGHT TAKEN
OVARY (OV)	.039	.1746 %	.0828	WEIGHT TAKEN
THYMUS (TH)	.02	.110 %	.052	WEIGHT TAKEN

CLINICAL OBSERVATIONS	PATHOLOGY OBSERVATIONS NECROPSY	HISTOPATHOLOGY
-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS	LIVER (LI) : -ENLARGED, SLIGHT; ALL LOBES -DARK; ALL LOBES, DARK BROWN	ADRENAL, CORTEX (AC) : -PIGMENT,-MINIMAL KIDNEY (KD) : -INFLAMMATION, CHRONIC,-SLIGHT -PIGMENT,-MINIMAL -CYST,-PRESENT LIVER (LI) : -HEPATOCYTE, HYPERTROPHY, CENTROLOBULAR,-MODERATE -VACUOLIZATION,-MINIMAL -PIGMENT, BILE,-MINIMAL -KUPFFER CELL/MACROPHAGE, PIGMENT,- MINIMAL -HEPATOCYTE, PIGMENT,-SLIGHT -NECROSIS, INDIVIDUAL CELL,-MINIMAL -INFLAMMATION, CHRONIC/CHRONIC ACTIVE,- MINIMAL -BILE DUCT, INFLAMMATION, CHRONIC,- MINIMAL

HAZLETON WASHINGTON, INC.
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APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 914

STUDY NUMBER: 483287

ANIMAL NUMBER: A37560 SEX: FEMALE DOSE GROUP: 6 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/12/91 STUDY DAY OF DEATH: 96 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 22.4 GRAMS
DATE AND TIME OF NECROPSY: 11/12/91 9:20 PROSECTOR: JANE EARHARDT RECORDER: JANE EARHARDT
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

CLINICAL OBSERVATIONS P A T H O L O G Y O B S E R V A T I O N S (CONTINUED)
NECROPSY HISTOPATHOLOGY

MAMMARY, FEMALE (MF) :
-DILATATION, CYSTIC, -MINIMAL
-HYPOPLASIA, EPITHELIAL, -PRESENT
SPLEEN (SP) :
-EXTRAMEDULLARY HEMATOPOIESIS,
INCREASED, -MODERATELY SEVERE
-PIGMENT, -MINIMAL
STOMACH, GL (ST) :
-HYPERPLASIA, CYSTIC, -MINIMAL
UTERUS (UT) :
 >TISSUE MISSING
UTERUS, CERVIX (CV) :
-HYPOPLASIA, -SEVERE

^COLLECTED/TAKEN (XW) :
-LIVER SECTIONS, IN METHANOL

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE), KIDNEY (KD),
LACRIMAL GL, EX (EO), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU), MAMMARY, FEMALE (MF), MAND SALIVARY GL (SG),
MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON), NERVE, SCIATIC (SN),
OVARY (OV), PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), RECTUM (RE), SKIN (SK), SKIN, OTHER (SS), SPLEEN (SP),
STOMACH, GL (ST), STOMACH, NONGL (SU), THYMUS (TH), THYROID (TY), TONGUE (TO), TRACHEA (TR), URINARY BLADDER (UB),
UTERUS (UT), UTERUS, CERVIX (CV), VAGINA (VA)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:

ADRENAL, MEDULLA (AM), SKIN (SK), STOMACH, NONGL (SU)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 915

STUDY NUMBER: 483287

ANIMAL NUMBER: A37561 SEX: FEMALE DOSE GROUP: 6 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/12/91 STUDY DAY OF DEATH: 96 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 22.2 GRAMS
DATE AND TIME OF NECROPSY: 11/12/91 10:19 PROSECTOR: JANE EARHARDT RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.13	.572 %	.268	WEIGHT TAKEN
LUNG (LU)	.16	.728 %	.341	WEIGHT TAKEN
UTERUS (UT)	.12	.549 %	.257	WEIGHT TAKEN
BRAIN W/STEM (BR)	.47	2.135 %	1.000	WEIGHT TAKEN
HEART (HT)	.12	.536 %	.251	WEIGHT TAKEN
SPLEEN (SP)	.06	.292 %	.137	WEIGHT TAKEN
KIDNEY (KD)	.36	1.606 %	.752	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	2.98	13.405 %	6.280	WEIGHT TAKEN
ADRENAL (AD)	.016	.0707 %	.0331	WEIGHT TAKEN
OVARY (OV)	.033	.1486 %	.0696	WEIGHT TAKEN
THYMUS (TH)	.03	.130 %	.061	WEIGHT TAKEN

CLINICAL OBSERVATIONS	PATHOLOGY OBSERVATIONS NECROPSY	HISTOPATHOLOGY
-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS	LIVER (LI) : -PALE AREA; ALL LOBES, SEVERAL, TAN, 3 X 3 MM TO 5 X 3 MM -ENLARGED, MODERATE; ALL LOBES -DARK; ALL LOBES, DARK BROWN	LIVER (LI) : -HEPATOCYTE, HYPERTROPHY, CENTROLOBULAR, -SLIGHT -VACUOLIZATION, -MINIMAL -PIGMENT, BILE, -MINIMAL -KUPFFER CELL/MACROPHAGE, PIGMENT, - MODERATE -HEPATOCYTE, PIGMENT, -MINIMAL -NECROSIS, INDIVIDUAL CELL, -MINIMAL -INFLAMMATION, CHRONIC/CHRONIC ACTIVE, - MINIMAL -BILE DUCT, INFLAMMATION, CHRONIC, - SLIGHT -EXTRAMEDULLARY HEMATOPOIESIS, INCREASED, -MINIMAL SPLEEN (SP) : -EXTRAMEDULLARY HEMATOPOIESIS, INCREASED, -SLIGHT -PIGMENT, -SLIGHT

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 916

STUDY NUMBER: 483287

ANIMAL NUMBER: A37561 SEX: FEMALE DOSE GROUP: 6 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/12/91 STUDY DAY OF DEATH: 96 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 22.2 GRAMS
DATE AND TIME OF NECROPSY: 11/12/91 10:19 PROSECTOR: JANE EARHARDT RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

CLINICAL OBSERVATIONS P A T H O L O G Y O B S E R V A T I O N S (CONTINUED)
NECROPSY HISTOPATHOLOGY

UTERUS (UT) :
-HYPOPLASIA, -MODERATE
UTERUS, CERVIX (CV) :
-TISSUE MISSING

^COLLECTED/TAKEN (XW) :
-LIVER SECTIONS, IN METHANOL

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE), KIDNEY (KD),
LACRIMAL GL, EX (EO), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU), MAMMARY, FEMALE (MF), MAND SALIVARY GL (SG),
MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON), NERVE, SCIATIC (SN),
OVARY (OV), PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), RECTUM (RE), SKIN (SK), SKIN, OTHER (SS), SPLEEN (SP),
STOMACH, GL (ST), STOMACH, NONGL (SU), THYMUS (TH), THYROID (TY), TONGUE (TO), TRACHEA (TR), URINARY BLADDER (UB),
UTERUS (UT), UTERUS, CERVIX (CV), VAGINA (VA)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), KIDNEY (KD), MAMMARY, FEMALE (MF), SKIN (SK), STOMACH, GL (ST),
STOMACH, NONGL (SU)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 917

STUDY NUMBER: 483287

ANIMAL NUMBER: A37562 SEX: FEMALE DOSE GROUP: 6 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/12/91 STUDY DAY OF DEATH: 96 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 24.6 GRAMS
DATE AND TIME OF NECROPSY: 11/12/91 11:25 PROSECTOR: DOUGLAS HERNDON RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.09	.376 %	.209	WEIGHT TAKEN
LUNG (LU)	.19	.774 %	.431	WEIGHT TAKEN
UTERUS (UT)	.15	.609 %	.339	WEIGHT TAKEN
BRAIN W/STEM (BR)	.44	1.798 %	1.000	WEIGHT TAKEN
HEART (HT)	.14	.556 %	.309	WEIGHT TAKEN
SPLEEN (SP)	.07	.300 %	.167	WEIGHT TAKEN
KIDNEY (KD)	.45	1.817 %	1.011	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	3.01	12.250 %	6.813	WEIGHT TAKEN
ADRENAL (AD)	.009	.0378 %	.0210	WEIGHT TAKEN
OVARY (OV)	.029	.1187 %	.0660	WEIGHT TAKEN
THYMUS (TH)	.02	.092 %	.051	WEIGHT TAKEN

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM: NORMAL-NO REMARKABLE
OBSERVATIONS

PATHOLOGY OBSERVATIONS
NECROPSY

KIDNEY (KD) :
-H-PELVIS, DILATED; LEFT PELVIS.

LIVER (LI) :
-ENLARGED, SEVERE; ALL LOBES
-DARK; ALL LOBES, DARK BROWN

HISTOPATHOLOGY

ADRENAL, CORTEX (AC) :
-HYPERPLASIA, SUBCAPSULAR CELL, -MINIMAL
KIDNEY (KD) :
-INFLAMMATION, CHRONIC, -MINIMAL
-CYST, -PRESENT
-INFLAMMATION, SUBACUTE, -MINIMAL
-PELVIS, DILATATION, -PRESENT
LIVER (LI) :
-HEPATOCTE, HYPERTROPHY,
CENTROLOBULAR, -SLIGHT
-VACUOLIZATION, -MINIMAL
-PIGMENT, BILE, -MINIMAL
-KUPFFER CELL/MACROPHAGE, PIGMENT, -
SLIGHT
-HEPATOCTE, PIGMENT, -MODERATE
-NECROSIS, -SLIGHT, MULTI-FOCAL
-NECROSIS, INDIVIDUAL CELL, -MINIMAL
-INFLAMMATION, CHRONIC/CHRONIC ACTIVE, -
SLIGHT

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 918

STUDY NUMBER: 483287

ANIMAL NUMBER: A37562 SEX: FEMALE DOSE GROUP: 6 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/12/91 STUDY DAY OF DEATH: 96 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 24.6 GRAMS
DATE AND TIME OF NECROPSY: 11/12/91 11:25 PROSECTOR: DOUGLAS HERNDON RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

CLINICAL OBSERVATIONS	PATHOLOGY OBSERVATIONS (CONTINUED) NECROPSY	HISTOPATHOLOGY
		LIVER (LI) : -BILE DUCT, INFLAMMATION, CHRONIC,- MINIMAL MAMMARY, FEMALE (MF) : -DILATATION, CYSTIC,-MINIMAL -HYPOPLASIA, EPITHELIAL,-PRESENT SPLEEN (SP) : -EXTRAMEDULLARY HEMATOPOIESIS, INCREASED,-SLIGHT -PIGMENT,-SLIGHT STOMACH, GL (ST) : -HYPERPLASIA, CYSTIC,-MINIMAL UTERUS (UT) : -DILATATION,-PRESENT -HYPOPLASIA,-MODERATELY SEVERE
	^COLLECTED/TAKEN (XW) : -LIVER SECTIONS, IN METHANOL	

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE), LACRIMAL GL, EX (EO),
LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU), MAMMARY, FEMALE (MF), MAND SALIVARY GL (SG), MARROW, FEMUR (FM),
MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON), NERVE, SCIATIC (SN), OVARY (OV), PANCREAS (PA),
PARATHYROID (PT), PITUITARY (PI), RECTUM (RE), SKIN (SK), SKIN, OTHER (SS), SPLEEN (SP), STOMACH, GL (ST),
STOMACH, NONGL (SU), THYMUS (TH), THYROID (TY), TONGUE (TO), TRACHEA (TR), URINARY BLADDER (UB), UTERUS (UT),
UTERUS, CERVIX (CV), VAGINA (VA)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:

ADRENAL, MEDULLA (AM), SKIN (SK), STOMACH, NONGL (SU), UTERUS, CERVIX (CV)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 919

STUDY NUMBER: 483287

ANIMAL NUMBER: A37563 SEX: FEMALE DOSE GROUP: 6 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/12/91 STUDY DAY OF DEATH: 96 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 22.8 GRAMS
DATE AND TIME OF NECROPSY: 11/12/91 13:32 PROSECTOR: SONNY DIKES RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.11	.503 %	.207	WEIGHT TAKEN
LUNG (LU)	.15	.663 %	.273	WEIGHT TAKEN
UTERUS (UT)	.23	.990 %	.408	WEIGHT TAKEN
BRAIN W/STEM (BR)	.55	2.428 %	1.000	WEIGHT TAKEN
HEART (HT)	.15	.675 %	.278	WEIGHT TAKEN
SPLEEN (SP)	.06	.247 %	.102	WEIGHT TAKEN
KIDNEY (KD)	.36	1.585 %	.653	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	2.45	10.767 %	4.435	WEIGHT TAKEN
ADRENAL (AD)	.013	.0570 %	.0235	WEIGHT TAKEN
OVARY (OV)	.056	.2439 %	.1005	WEIGHT TAKEN
THYMUS (TH)	.02	.080 %	.033	WEIGHT TAKEN

CLINICAL OBSERVATIONS	PATHOLOGY OBSERVATIONS NECROPSY	HISTOPATHOLOGY
-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS	LIVER (LI) : -ENLARGED, MODERATE; ALL LOBES -DARK; ALL LOBES, DARK BROWN OVARY (OV) : -CYST; BOTH, ONE EACH, CLEAR, 3 X 3 MM	LIVER (LI) : -HEPATOCYTE, HYPERTROPHY, CENTROLOBULAR,-SLIGHT -VACUOLIZATION,-MINIMAL -PIGMENT, BILE,-MINIMAL -KUPFFER CELL/MACROPHAGE, PIGMENT,- MINIMAL -HEPATOCYTE, PIGMENT,-SLIGHT -NECROSIS, INDIVIDUAL CELL,-MINIMAL -INFLAMMATION, CHRONIC/CHRONIC ACTIVE,- MINIMAL OVARY (OV) : -FOLLICLE, CYST,-PRESENT SPLEEN (SP) : -EXTRAMEDULLARY HEMATOPOIESIS, INCREASED,-SLIGHT -PIGMENT,-SLIGHT UTERUS (UT) : -HYPOPLASIA,-MODERATE

HAZLETON WASHINGTON, INC.
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APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 920

STUDY NUMBER: 483287

ANIMAL NUMBER: A37563 SEX: FEMALE DOSE GROUP: 6 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/12/91 STUDY DAY OF DEATH: 96 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 22.8 GRAMS
DATE AND TIME OF NECROPSY: 11/12/91 13:32 PROSECTOR: SONNY DIKES RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

CLINICAL OBSERVATIONS P A T H O L O G Y O B S E R V A T I O N S (CONTINUED)
NECROPSY HISTOPATHOLOGY

^COLLECTED/TAKEN (XW) :
-LIVER SECTIONS, IN METHANOL

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE), KIDNEY (KD),
LACRIMAL GL, EX (EO), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU), MAMMARY, FEMALE (MF), MAND SALIVARY GL (SG),
MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON), NERVE, SCIATIC (SN),
PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), RECTUM (RE), SKIN (SK), SKIN, OTHER (SS), SPLEEN (SP),
STOMACH, GL (ST), STOMACH, NONGL (SU), THYMUS (TH), THYROID (TY), TONGUE (TO), TRACHEA (TR), URINARY BLADDER (UB),
UTERUS (UT), UTERUS, CERVIX (CV), VAGINA (VA)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:

ADRENAL, CORTEX (AC), KIDNEY (KD), MAMMARY, FEMALE (MF), OVIDUCT (OD), SKIN (SK), STOMACH, GL (ST),
STOMACH, NONGL (SU), UTERUS, CERVIX (CV)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 921

STUDY NUMBER: 483287

ANIMAL NUMBER: A37564 SEX: FEMALE DOSE GROUP: 6 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/13/91 STUDY DAY OF DEATH: 97 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 25.1 GRAMS
DATE AND TIME OF NECROPSY: 11/13/91 9:08 PROSECTOR: SCOTT BELL RECORDER: SCOTT BELL
POST-FIX WEAHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEAHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.16	.636 %	.315	WEIGHT TAKEN
LUNG (LU)	.17	.668 %	.331	WEIGHT TAKEN
UTERUS (UT)	.10	.379 %	.188	WEIGHT TAKEN
BRAIN W/STEM (BR)	.51	2.017 %	1.000	WEIGHT TAKEN
HEART (HT)	.14	.540 %	.268	WEIGHT TAKEN
SPLEEN (SP)	.06	.257 %	.127	WEIGHT TAKEN
KIDNEY (KD)	.36	1.425 %	.706	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	3.02	12.031 %	5.966	WEIGHT TAKEN
ADRENAL (AD)	.010	.0382 %	.0190	WEIGHT TAKEN
OVARY (OV)	.018	.0709 %	.0352	WEIGHT TAKEN
THYMUS (TH)	.03	.108 %	.054	WEIGHT TAKEN

CLINICAL OBSERVATIONS

PATHOLOGY OBSERVATIONS
NECROPSY

HISTOPATHOLOGY

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE
OBSERVATIONS

LIVER (LI) :
-ENLARGED, MODERATE; ALL LOBES
-DARK; ALL LOBES, DARK BROWN

ADRENAL, CORTEX (AC) :
-VACUOLIZATION, X-ZONE,-MINIMAL
-HYPERPLASIA, SUBCAPSULAR CELL,-MINIMAL
KIDNEY (KD) :
-INFLAMMATION, CHRONIC,-MINIMAL
LIVER (LI) :
-HEPATOCTE, HYPERTROPHY,
CENTROLOBULAR,-SLIGHT
-VACUOLIZATION,-MINIMAL
-PIGMENT, BILE,-MINIMAL
-KUPFFER CELL/MACROPHAGE, PIGMENT,-
SLIGHT
-HEPATOCTE, PIGMENT,-SLIGHT
-NECROSIS, INDIVIDUAL CELL,-MINIMAL
-INFLAMMATION, CHRONIC/CHRONIC ACTIVE,-
SLIGHT
-BILE DUCT, INFLAMMATION, CHRONIC,-
MINIMAL

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APPENDIX 13B

PRINTED: 21-JAN-93
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13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

STUDY NUMBER: 483287

ANIMAL NUMBER: A37564 SEX: FEMALE DOSE GROUP: 6 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/13/91 STUDY DAY OF DEATH: 97 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 25.1 GRAMS
DATE AND TIME OF NECROPSY: 11/13/91 9:08 PROSECTOR: SCOTT BELL RECORDER: SCOTT BELL
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

CLINICAL OBSERVATIONS PATHOLOGY OBSERVATIONS (CONTINUED) HISTOPATHOLOGY
NECROPSY

SPLEEN (SP) :
-EXTRAMEDULLARY HEMATOPOIESIS,
INCREASED, -MODERATE
-PIGMENT, -MINIMAL
-AMYLOIDOSIS, -MINIMAL
STOMACH, GL (ST) :
-HYPERPLASIA, CYSTIC, -MINIMAL
UTERUS (UT) :
-HYPOPLASIA, -MODERATE

^COLLECTED/TAKEN (XW) :
-LIVER SECTIONS, IN METHANOL

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE), KIDNEY (KD),
LACRIMAL GL, EX (EO), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU), MAMMARY, FEMALE (MF), MAND SALIVARY GL (SG),
MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON), NERVE, SCIATIC (SN),
OVARY (OV), PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), RECTUM (RE), SKIN (SK), SKIN, OTHER (SS), SPLEEN (SP),
STOMACH, GL (ST), STOMACH, NONGL (SU), THYMUS (TH), THYROID (TY), TONGUE (TO), TRACHEA (TR), URINARY BLADDER (UB),
UTERUS (UT), UTERUS, CERVIX (CV), VAGINA (VA)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:
ADRENAL, MEDULLA (AM), MAMMARY, FEMALE (MF), SKIN (SK), STOMACH, NONGL (SU), UTERUS, CERVIX (CV)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 923

STUDY NUMBER: 483287

ANIMAL NUMBER: A37565 SEX: FEMALE DOSE GROUP: 6 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/13/91 STUDY DAY OF DEATH: 97 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 23.8 GRAMS
DATE AND TIME OF NECROPSY: 11/13/91 10:00 PROSECTOR: LINDA RUMBLE RECORDER: LINDA RUMBLE
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.07	.275 %	.123	WEIGHT TAKEN
LUNG (LU)	.19	.818 %	.367	WEIGHT TAKEN
UTERUS (UT)	.13	.533 %	.240	WEIGHT TAKEN
BRAIN W/STEM (BR)	.53	2.225 %	1.000	WEIGHT TAKEN
HEART (HT)	.17	.708 %	.318	WEIGHT TAKEN
SPLEEN (SP)	.06	.272 %	.122	WEIGHT TAKEN
KIDNEY (KD)	.33	1.377 %	.619	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	3.20	13.435 %	6.038	WEIGHT TAKEN
ADRENAL (AD)	.012	.0492 %	.0221	WEIGHT TAKEN
OVARY (OV)	.034	.1441 %	.0648	WEIGHT TAKEN
THYMUS (TH)	.03	.111 %	.050	WEIGHT TAKEN

CLINICAL OBSERVATIONS	PATHOLOGY OBSERVATIONS NECROPSY	HISTOPATHOLOGY
-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS	LIVER (LI) : -ENLARGED, MODERATE; ALL LOBES -DARK; ALL LOBES, DARK BROWN	KIDNEY (KD) : -INFLAMMATION, CHRONIC,-MINIMAL LIVER (LI) : -HEPATOCYTE, HYPERTROPHY, CENTROLOBULAR,-SLIGHT -VACUOLIZATION,-MINIMAL -PIGMENT, BILE,-MINIMAL -KUPFFER CELL/MACROPHAGE, PIGMENT,- SLIGHT -HEPATOCYTE, PIGMENT,-SLIGHT -NECROSIS, INDIVIDUAL CELL,-MINIMAL -BILE DUCT, INFLAMMATION, CHRONIC,- MINIMAL SPLEEN (SP) : -EXTRAMEDULLARY HEMATOPOIESIS, INCREASED,-SLIGHT -PIGMENT,-SLIGHT STOMACH, GL (ST) : -INFLAMMATION, CHRONIC,-MINIMAL

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 924

STUDY NUMBER: 483287

ANIMAL NUMBER: A37565 SEX: FEMALE DOSE GROUP: 6 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/13/91 STUDY DAY OF DEATH: 97 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 23.8 GRAMS
DATE AND TIME OF NECROPSY: 11/13/91 10:00 PROSECTOR: LINDA RUMBLE RECORDER: LINDA RUMBLE
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

CLINICAL OBSERVATIONS

P A T H O L O G Y O B S E R V A T I O N S (CONTINUED)
NECROPSY

HISTOPATHOLOGY

UTERUS (UT) :
-HYPOPLASIA, -MODERATE

^COLLECTED/TAKEN (XW) :
-LIVER SECTIONS, IN METHANOL

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE), KIDNEY (KD),
LACRIMAL GL, EX (EO), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU), MAMMARY, FEMALE (MF), MAND SALIVARY GL (SG),
MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON), NERVE, SCIATIC (SN),
OVARY (OV), PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), RECTUM (RE), SKIN (SK), SKIN, OTHER (SS), SPLEEN (SP),
STOMACH, GL (ST), STOMACH, NONGL (SU), THYMUS (TH), THYROID (TY), TONGUE (TO), TRACHEA (TR), URINARY BLADDER (UB),
UTERUS (UT), UTERUS, CERVIX (CV), VAGINA (VA)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), MAMMARY, FEMALE (MF), SKIN (SK), STOMACH, NONGL (SU),
UTERUS, CERVIX (CV)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 925

STUDY NUMBER: 483287

ANIMAL NUMBER: A37566 SEX: FEMALE DOSE GROUP: 6 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/13/91 STUDY DAY OF DEATH: 97 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 23.5 GRAMS
DATE AND TIME OF NECROPSY: 11/13/91 11:19 PROSECTOR: ADEPOLAHAN AKINSOLA RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.12	.511 %	.258	WEIGHT TAKEN
LUNG (LU)	.17	.738 %	.373	WEIGHT TAKEN
UTERUS (UT)	.15	.642 %	.324	WEIGHT TAKEN
BRAIN W/STEM (BR)	.47	1.979 %	1.000	WEIGHT TAKEN
HEART (HT)	.13	.558 %	.282	WEIGHT TAKEN
SPLEEN (SP)	.07	.298 %	.151	WEIGHT TAKEN
KIDNEY (KD)	.35	1.490 %	.753	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	2.70	11.495 %	5.808	WEIGHT TAKEN
ADRENAL (AD)	.011	.0447 %	.0226	WEIGHT TAKEN
OVARY (OV)	.031	.1340 %	.0677	WEIGHT TAKEN
THYMUS (TH)	.03	.114 %	.058	WEIGHT TAKEN

CLINICAL OBSERVATIONS	PATHOLOGY OBSERVATIONS NECROPSY	HISTOPATHOLOGY
-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS	LIVER (LI) : -PALE AREA; ALL LOBES, SEVERAL, TAN, PINPOINT TO 1 X 1 MM -ENLARGED, MODERATE; ALL LOBES -DARK; ALL LOBES, DARK BROWN	ADRENAL, CORTEX (AC) : -PIGMENT,-MINIMAL -VACUOLIZATION, X-ZONE,-SLIGHT KIDNEY (KD) : -INFLAMMATION, CHRONIC,-MINIMAL -INFLAMMATION, SUBACUTE,-MINIMAL LIVER (LI) : -HEPATOCTYE, HYPERTROPHY, CENTROLOBULAR,-MINIMAL -VACUOLIZATION,-MINIMAL -PIGMENT, BILE,-MINIMAL -KUPFFER CELL/MACROPHAGE, PIGMENT,- SLIGHT -HEPATOCTYE, PIGMENT,-SLIGHT -NECROSIS,-MODERATE, MULTI-FOCAL -NECROSIS, INDIVIDUAL CELL,-SLIGHT -INFLAMMATION, CHRONIC/CHRONIC ACTIVE,- SLIGHT

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 926

STUDY NUMBER: 483287

ANIMAL NUMBER: A37566 SEX: FEMALE DOSE GROUP: 6 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/13/91 STUDY DAY OF DEATH: 97 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 23.5 GRAMS
DATE AND TIME OF NECROPSY: 11/13/91 11:19 PROSECTOR: ADEPOLAHAN AKINSOLA RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

CLINICAL OBSERVATIONS P A T H O L O G Y O B S E R V A T I O N S (CONTINUED)
NECROPSY HISTOPATHOLOGY

LIVER (LI) :
-BILE DUCT, INFLAMMATION, CHRONIC,-
MINIMAL
-EXTRAMEDULLARY HEMATOPOIESIS,
INCREASED,-MINIMAL
MAMMARY, FEMALE (MF) :
-TISSUE MISSING
SPLEEN (SP) :
-EXTRAMEDULLARY HEMATOPOIESIS,
INCREASED,-SLIGHT
-PIGMENT,-MINIMAL
STOMACH, GL (ST) :
-HYPERPLASIA, CYSTIC,-MINIMAL
-INFLAMMATION, ACUTE,-MINIMAL
UTERUS (UT) :
-HYPOPLASIA,-MINIMAL

^COLLECTED/TAKEN (XW) :
-LIVER SECTIONS, IN METHANOL

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 927

STUDY NUMBER: 483287

ANIMAL NUMBER: A37566 SEX: FEMALE DOSE GROUP: 6 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/13/91 STUDY DAY OF DEATH: 97 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 23.5 GRAMS
DATE AND TIME OF NECROPSY: 11/13/91 11:19 PROSECTOR: ADEPOLAHAN AKINSOLA RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE), KIDNEY (KD),
LACRIMAL GL, EX (EO), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU), MAMMARY, FEMALE (MF), MAND SALIVARY GL (SG),
MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON), NERVE, SCIATIC (SN),
OVARY (OV), PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), RECTUM (RE), SKIN (SK), SKIN, OTHER (SS), SPLEEN (SP),
STOMACH, GL (ST), STOMACH, NONGL (SU), THYMUS (TH), THYROID (TY), TONGUE (TO), TRACHEA (TR), URINARY BLADDER (UB),
UTERUS (UT), UTERUS, CERVIX (CV), VAGINA (VA)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:

ADRENAL, MEDULLA (AM), PANCREAS (PA), SKIN (SK), STOMACH, NONGL (SU), UTERUS, CERVIX (CV)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 928

STUDY NUMBER: 483287

ANIMAL NUMBER: A37567 SEX: FEMALE DOSE GROUP: 6 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/13/91 STUDY DAY OF DEATH: 97 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 27.6 GRAMS
DATE AND TIME OF NECROPSY: 11/13/91 13:45 PROSECTOR: LINDA RUMBLE RECORDER: LINDA RUMBLE
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.11	.400 %	.217	WEIGHT TAKEN
LUNG (LU)	.22	.787 %	.426	WEIGHT TAKEN
UTERUS (UT)	.11	.416 %	.225	WEIGHT TAKEN
BRAIN W/STEM (BR)	.51	1.845 %	1.000	WEIGHT TAKEN
HEART (HT)	.15	.530 %	.287	WEIGHT TAKEN
SPLEEN (SP)	.08	.282 %	.153	WEIGHT TAKEN
KIDNEY (KD)	.42	1.524 %	.826	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	3.76	13.628 %	7.388	WEIGHT TAKEN
ADRENAL (AD)	.018	.0652 %	.0354	WEIGHT TAKEN
OVARY (OV)	.046	.1656 %	.0898	WEIGHT TAKEN
THYMUS (TH)	.04	.158 %	.086	WEIGHT TAKEN

CLINICAL OBSERVATIONS	PATHOLOGY OBSERVATIONS NECROPSY	HISTOPATHOLOGY
-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS	LIVER (LI) : -PALE AREA; ALL LOBES, SEVERAL, TAN, PINPOINT TO 5 X 4 MM -ENLARGED, MODERATE; ALL LOBES -DARK; ALL LOBES, DARK BROWN	ADRENAL, CORTEX (AC) : -PIGMENT,-MINIMAL -HYPERPLASIA, SUBCAPSULAR CELL,-MINIMAL KIDNEY (KD) : -INFLAMMATION, CHRONIC,-MINIMAL LIVER (LI) : -HEPATOCYTE, HYPERTROPHY, CENTROLOBULAR,-MINIMAL -VACUOLIZATION,-SLIGHT -PIGMENT, BILE,-MINIMAL -KUPFFER CELL/MACROPHAGE, PIGMENT,- MINIMAL -HEPATOCYTE, PIGMENT,-MINIMAL -NECROSIS,-MODERATE, FOCAL -NECROSIS, INDIVIDUAL CELL,-MINIMAL -INFLAMMATION, CHRONIC/CHRONIC ACTIVE,- MINIMAL -BILE DUCT, INFLAMMATION, CHRONIC,- MINIMAL

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 929

STUDY NUMBER: 483287

ANIMAL NUMBER: A37567 SEX: FEMALE DOSE GROUP: 6 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/13/91 STUDY DAY OF DEATH: 97 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 27.6 GRAMS
DATE AND TIME OF NECROPSY: 11/13/91 13:45 PROSECTOR: LINDA RUMBLE RECORDER: LINDA RUMBLE
POST-FIX WEAHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEAHER: RICHARD KAGYARE

CLINICAL OBSERVATIONS P A T H O L O G Y O B S E R V A T I O N S (CONTINUED)
NECROPSY HISTOPATHOLOGY

SPLEEN (SP) :
-EXTRAMEDULLARY HEMATOPOIESIS,
INCREASED, -SLIGHT
-PIGMENT, -MINIMAL
STOMACH, GL (ST) :
-HYPERPLASIA, CYSTIC, -SLIGHT
-INFLAMMATION, CHRONIC, -MINIMAL
UTERUS (UT) :
-HYPOPLASIA, -SEVERE
UTERUS, CERVIX (CV) :
-HYPOPLASIA, -MODERATE

^COLLECTED/TAKEN (XW) :
-LIVER SECTIONS, IN METHANOL

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE), KIDNEY (KD),
LACRIMAL GL, EX (EO), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU), MAMMARY, FEMALE (MF), MAND SALIVARY GL (SG),
MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON), NERVE, SCIATIC (SN),
OVARY (OV), PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), RECTUM (RE), SKIN (SK), SKIN, OTHER (SS), SPLEEN (SP),
STOMACH, GL (ST), STOMACH, NONGL (SU), THYMUS (TH), THYROID (TY), TONGUE (TO), TRACHEA (TR), URINARY BLADDER (UB),
UTERUS (UT), UTERUS, CERVIX (CV), VAGINA (VA)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:
ADRENAL, MEDULLA (AM), MAMMARY, FEMALE (MF), SKIN (SK), STOMACH, NONGL (SU)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 930

STUDY NUMBER: 483287

ANIMAL NUMBER: A37568 SEX: FEMALE DOSE GROUP: 6 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/14/91 STUDY DAY OF DEATH: 98 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 23.7 GRAMS
DATE AND TIME OF NECROPSY: 11/14/91 8:42 PROSECTOR: ADEFOLAHAN AKINSOLA RECORDER: ADEFOLAHAN AKINSOLA
POST-FIX WEIGHER: DANIEL JACK PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.14	.586 %	.273	WEIGHT TAKEN
LUNG (LU)	.17	.722 %	.336	WEIGHT TAKEN
UTERUS (UT)	.11	.475 %	.221	WEIGHT TAKEN
BRAIN W/STEM (BR)	.51	2.148 %	1.000	WEIGHT TAKEN
HEART (HT)	.12	.524 %	.244	WEIGHT TAKEN
SPLEEN (SP)	.06	.274 %	.128	WEIGHT TAKEN
KIDNEY (KD)	.37	1.573 %	.732	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	3.35	14.151 %	6.589	WEIGHT TAKEN
ADRENAL (AD)	.012	.0498 %	.0232	WEIGHT TAKEN
OVARY (OV)	.047	.1992 %	.0927	WEIGHT TAKEN
THYMUS (TH)	.05	.205 %	.095	WEIGHT TAKEN

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE
OBSERVATIONS

PATHOLOGY OBSERVATIONS
NECROPSY

LIVER (LI) :
-PALE AREA; ALL LOBES, FEW, TAN,
PINPOINT TO 1 X 1 MM
-ENLARGED, MODERATE; ALL LOBES
-DARK; ALL LOBES, DARK BROWN

HISTOPATHOLOGY

ADRENAL, CORTEX (AC) :
-VACUOLIZATION, X-ZONE, -MINIMAL
KIDNEY (KD) :
-INFLAMMATION, CHRONIC, -MINIMAL
-INFLAMMATION, SUBACUTE, -MINIMAL
LIVER (LI) :
-HEPATOCYTE, HYPERTROPHY,
CENTROLOBULAR, -MINIMAL
-VACUOLIZATION, -MODERATE
-PIGMENT, BILE, -MINIMAL
-KUPFFER CELL/MACROPHAGE, PIGMENT, -
SLIGHT
-HEPATOCYTE, PIGMENT, -SLIGHT
-NECROSIS, INDIVIDUAL CELL, -MINIMAL
-INFLAMMATION, CHRONIC/CHRONIC ACTIVE, -
SLIGHT
-BILE DUCT, INFLAMMATION, CHRONIC, -
MINIMAL

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 931

STUDY NUMBER: 483287

ANIMAL NUMBER: A37568 SEX: FEMALE DOSE GROUP: 6 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/14/91 STUDY DAY OF DEATH: 98 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 23.7 GRAMS
DATE AND TIME OF NECROPSY: 11/14/91 8:42 PROSECTOR: ADEFOLAHAN AKINSOLA RECORDER: ADEFOLAHAN AKINSOLA
POST-FIX WEAHER: DANIEL JACK PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEAHER: RICHARD KAGYARE

P A T H O L O G Y O B S E R V A T I O N S (CONTINUED)
NECROPSY

CLINICAL OBSERVATIONS

HISTOPATHOLOGY

OVARY (OV) :
-CYST; LEFT, ONE, CLEAR, 2 X 2 MM

MAMMARY, FEMALE (MF) :
-DILATATION, CYSTIC, -SLIGHT
-HYPOPLASIA, EPITHELIAL, -PRESENT
OVARY (OV) :
-BURSA, CYST, -PRESENT
SPLEEN (SP) :
-EXTRAMEDULLARY HEMATOPOIESIS,
INCREASED, -SLIGHT
-PIGMENT, -MINIMAL
STOMACH, GL (ST) :
-HYPERPLASIA, CYSTIC, -MINIMAL
-INFLAMMATION, CHRONIC, -MINIMAL
-AMYLOIDOSIS, -PRESENT
UTERUS (UT) :
-HYPOPLASIA, -MODERATE

^COLLECTED/TAKEN (XW) :
-LIVER SECTIONS, IN METHANOL

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE), KIDNEY (KD),
LACRIMAL GL, EX (EO), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU), MAMMARY, FEMALE (MF), MAND SALIVARY GL (SG),
MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON), NERVE, SCIATIC (SN),
PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), RECTUM (RE), SKIN (SK), SKIN, OTHER (SS), SPLEEN (SP),
STOMACH, GL (ST), STOMACH, NONGL (SU), THYMUS (TH), THYROID (TY), TONGUE (TO), TRACHEA (TR), URINARY BLADDER (UB),
UTERUS (UT), UTERUS, CERVIX (CV), VAGINA (VA)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:

ADRENAL, MEDULLA (AM), OVIDUCT (OD), SKIN (SK), STOMACH, NONGL (SU), UTERUS, CERVIX (CV)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 932

STUDY NUMBER: 483287

ANIMAL NUMBER: A37569 SEX: FEMALE DOSE GROUP: 6 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/14/91 STUDY DAY OF DEATH: 98 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 22.7 GRAMS
DATE AND TIME OF NECROPSY: 11/14/91 9:33 PROSECTOR: SCOTT BELL RECORDER: SCOTT BELL
POST-FIX WEIGHER: DANIEL JACK PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.17	.748 %	.362	WEIGHT TAKEN
LUNG (LU)	.17	.749 %	.362	WEIGHT TAKEN
UTERUS (UT)	.11	.485 %	.235	WEIGHT TAKEN
BRAIN W/STEM (BR)	.47	2.067 %	1.000	WEIGHT TAKEN
HEART (HT)	.12	.547 %	.265	WEIGHT TAKEN
SPLEEN (SP)	.07	.287 %	.139	WEIGHT TAKEN
KIDNEY (KD)	.31	1.377 %	.666	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	3.21	14.130 %	6.835	WEIGHT TAKEN
ADRENAL (AD)	.016	.0687 %	.0332	WEIGHT TAKEN
OVARY (OV)	.042	.1850 %	.0895	WEIGHT TAKEN
THYMUS (TH)	.04	.189 %	.091	WEIGHT TAKEN

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE
OBSERVATIONS

PATHOLOGY OBSERVATIONS
NECROPSY

LIVER (LI) :
-ENLARGED, SEVERE; ALL LOBES
-DARK; ALL LOBES, DARK BROWN

HISTOPATHOLOGY

ADRENAL, CORTEX (AC) :
-VACUOLIZATION, X-ZONE,-MINIMAL
-HYPERPLASIA, SUBCAPSULAR CELL,-MINIMAL
KIDNEY (KD) :
-INFLAMMATION, CHRONIC,-SLIGHT
-CYST,-PRESENT
LIVER (LI) :
-HEPATOCYTE, HYPERTROPHY,
CENTROLOBULAR,-SLIGHT
-VACUOLIZATION,-MINIMAL
-PIGMENT, BILE,-MINIMAL
-KUPFFER CELL/MACROPHAGE, PIGMENT,-
SLIGHT
-HEPATOCYTE, PIGMENT,-SLIGHT
-NECROSIS, INDIVIDUAL CELL,-SLIGHT
-INFLAMMATION, CHRONIC/CHRONIC ACTIVE,-
MINIMAL
-BILE DUCT, INFLAMMATION, CHRONIC,-
MINIMAL

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 933

STUDY NUMBER: 483287

ANIMAL NUMBER: A37569 SEX: FEMALE DOSE GROUP: 6 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/14/91 STUDY DAY OF DEATH: 98 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 22.7 GRAMS
DATE AND TIME OF NECROPSY: 11/14/91 9:33 PROSECTOR: SCOTT BELL RECORDER: SCOTT BELL
POST-FIX WEAIGHER: DANIEL JACK PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEAIGHER: RICHARD KAGYARE

CLINICAL OBSERVATIONS

P A T H O L O G Y O B S E R V A T I O N S (CONTINUED)
NECROPSY

HISTOPATHOLOGY

OVARY (OV) :
-CYST; LEFT, ONE, CLEAR TO WHITE, 1 X
1 MM

OVARY (OV) :
-FOLLICLE, CYST, -PRESENT

SPLEEN (SP) :
-EXTRAMEDULLARY HEMATOPOIESIS,
INCREASED, -SLIGHT
-PIGMENT, -SLIGHT
STOMACH, GL (ST) :
-INFLAMMATION, CHRONIC, -MINIMAL
UTERUS (UT) :
-HYPOPLASIA, -MODERATELY SEVERE

^COLLECTED/TAKEN (XW) :
-LIVER SECTIONS, IN METHANOL

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE), KIDNEY (KD),
LACRIMAL GL, EX (EO), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU), MAMMARY, FEMALE (MF), MAND SALIVARY GL (SG),
MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON), NERVE, SCIATIC (SN),
PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), RECTUM (RE), SKIN (SK), SKIN, OTHER (SS), SPLEEN (SP),
STOMACH, GL (ST), STOMACH, NONGL (SU), THYMUS (TH), THYROID (TY), TONGUE (TO), TRACHEA (TR), URINARY BLADDER (UB),
UTERUS (UT), UTERUS, CERVIX (CV), VAGINA (VA)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:

ADRENAL, MEDULLA (AM), MAMMARY, FEMALE (MF), OVIDUCT (OD), SKIN (SK), STOMACH, NONGL (SU), UTERUS, CERVIX (CV)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 934

STUDY NUMBER: 483287

ANIMAL NUMBER: A37570 SEX: FEMALE DOSE GROUP: 6 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/14/91 STUDY DAY OF DEATH: 98 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 21.6 GRAMS
DATE AND TIME OF NECROPSY: 11/14/91 10:16 PROSECTOR: JANE EARHARDT RECORDER: JANE EARHARDT
POST-FIX WEIGHER: DANIEL JACK PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.14	.638 %	.289	WEIGHT TAKEN
LUNG (LU)	.17	.803 %	.364	WEIGHT TAKEN
UTERUS (UT)	.09	.406 %	.184	WEIGHT TAKEN
BRAIN W/STEM (BR)	.48	2.205 %	1.000	WEIGHT TAKEN
HEART (HT)	.12	.565 %	.256	WEIGHT TAKEN
SPLEEN (SP)	.06	.297 %	.135	WEIGHT TAKEN
KIDNEY (KD)	.29	1.349 %	.612	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	2.46	11.400 %	5.170	WEIGHT TAKEN
ADRENAL (AD)	.014	.0644 %	.0292	WEIGHT TAKEN
OVARY (OV)	.032	.1491 %	.0676	WEIGHT TAKEN
THYMUS (TH)	.03	.162 %	.073	WEIGHT TAKEN

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE
OBSERVATIONS

PATHOLOGY OBSERVATIONS
NECROPSY

LIVER (LI) :
-ENLARGED, MODERATE; ALL LOBES
-DARK; ALL LOBES, DARK BROWN

HISTOPATHOLOGY

KIDNEY (KD) :
-TUBULE, MINERALIZATION,-MINIMAL
-TUBULE, REGENERATION,-MINIMAL
-INFLAMMATION, SUBACUTE,-MINIMAL
LIVER (LI) :
-HEPATOCYTE, HYPERTROPHY,
CENTROLOBULAR,-SLIGHT
-VACUOLIZATION,-MINIMAL
-PIGMENT, BILE,-MINIMAL
-KUPFFER CELL/MACROPHAGE, PIGMENT,-
SLIGHT
-HEPATOCYTE, PIGMENT,-SLIGHT
-NECROSIS, INDIVIDUAL CELL,-SLIGHT
-INFLAMMATION, CHRONIC/CHRONIC ACTIVE,-
MINIMAL
-BILE DUCT, INFLAMMATION, CHRONIC,-
MINIMAL
MAMMARY, FEMALE (MF) :
-DILATATION, CYSTIC,-MINIMAL

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 935

STUDY NUMBER: 483287

ANIMAL NUMBER: A37570 SEX: FEMALE DOSE GROUP: 6 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/14/91 STUDY DAY OF DEATH: 98 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 21.6 GRAMS
DATE AND TIME OF NECROPSY: 11/14/91 10:16 PROSECTOR: JANE EARHARDT RECORDER: JANE EARHARDT
POST-FIX WEIGHER: DANIEL JACK PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

CLINICAL OBSERVATIONS P A T H O L O G Y O B S E R V A T I O N S (CONTINUED)
NECROPSY HISTOPATHOLOGY

SPLEEN (SP) :
-EXTRAMEDULLARY HEMATOPOIESIS,
INCREASED,-MINIMAL
-PIGMENT,-SLIGHT
STOMACH, GL (ST) :
-HYPERPLASIA, CYSTIC,-MINIMAL
UTERUS (UT) :
-HYPOPLASIA,-MODERATELY SEVERE

^COLLECTED/TAKEN (XW) :
-LIVER SECTIONS, IN METHANOL

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE), KIDNEY (KD),
LACRIMAL GL, EX (EO), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU), MAMMARY, FEMALE (MF), MAND SALIVARY GL (SG),
MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON), NERVE, SCIATIC (SN),
OVARY (OV), PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), RECTUM (RE), SKIN (SK), SKIN, OTHER (SS), SPLEEN (SP),
STOMACH, GL (ST), STOMACH, NONGL (SU), THYMUS (TH), THYROID (TY), TONGUE (TO), TRACHEA (TR), URINARY BLADDER (UB),
UTERUS (UT), UTERUS, CERVIX (CV), VAGINA (VA)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), PANCREAS (PA), SKIN (SK), STOMACH, NONGL (SU), UTERUS, CERVIX (CV)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 936

STUDY NUMBER: 483287

ANIMAL NUMBER: A37587 SEX: FEMALE DOSE GROUP: 7 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/11/91 STUDY DAY OF DEATH: 95 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 21.4 GRAMS
DATE AND TIME OF NECROPSY: 11/11/91 9:41 PROSECTOR: DOUGLAS HERNDON RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.09	.404 %	.181	WEIGHT TAKEN
LUNG (LU)	.15	.722 %	.324	WEIGHT TAKEN
UTERUS (UT)	.21	.995 %	.446	WEIGHT TAKEN
BRAIN W/STEM (BR)	.48	2.229 %	1.000	WEIGHT TAKEN
HEART (HT)	.13	.585 %	.262	WEIGHT TAKEN
SPLEEN (SP)	.09	.400 %	.179	WEIGHT TAKEN
KIDNEY (KD)	.37	1.730 %	.776	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	2.85	13.309 %	5.971	WEIGHT TAKEN
ADRENAL (AD)	.014	.0668 %	.0300	WEIGHT TAKEN
OVARY (OV)	.030	.1397 %	.0627	WEIGHT TAKEN
THYMUS (TH)	.03	.120 %	.054	WEIGHT TAKEN

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE
OBSERVATIONS

PATHOLOGY OBSERVATIONS
NECROPSY

LIVER (LI) :
-PALE AREA; ALL LOBES, FEW, TAN,
PINPOINT TO 3 X 3 MM
-ENLARGED, SEVERE; ALL LOBES
-DARK; ALL LOBES, DARK BROWN

HISTOPATHOLOGY

ADRENAL, CORTEX (AC) :
-PIGMENT,-MINIMAL
KIDNEY (KD) :
-INFLAMMATION, SUBACUTE,-MINIMAL
LACRIMAL GL, EX (EO) :
-UNILATERALLY EXAMINED,-PRESENT
LIVER (LI) :
-HEPATOCYTE, HYPERTROPHY,
CENTROLOBULAR,-MODERATE
-VACUOLIZATION,-MINIMAL
-PIGMENT, BILE,-MINIMAL
-KUPFFER CELL/MACROPHAGE, PIGMENT,-
MINIMAL
-HEPATOCYTE, PIGMENT,-MINIMAL
-NECROSIS,-MODERATE, MULTI-FOCAL
-NECROSIS, INDIVIDUAL CELL,-MINIMAL
-INFLAMMATION, CHRONIC/CHRONIC ACTIVE,-
SLIGHT

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 937

STUDY NUMBER: 483287

ANIMAL NUMBER: A37587 SEX: FEMALE DOSE GROUP: 7 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/11/91 STUDY DAY OF DEATH: 95 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 21.4 GRAMS
DATE AND TIME OF NECROPSY: 11/11/91 9:41 PROSECTOR: DOUGLAS HERNDON RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

CLINICAL OBSERVATIONS P A T H O L O G Y O B S E R V A T I O N S (CONTINUED)
NECROPSY HISTOPATHOLOGY

LN, MANDIBULAR (MN) :
 >TISSUE MISSING
LN, OTHER (LN) :
 -HYPERPLASIA, LYMPHOID, -PRESENT
 >NOTE: >PANCREATIC.
SPLEEN (SP) :
 -EXTRAMEDULLARY HEMATOPOIESIS,
 INCREASED, -MODERATE
 -PIGMENT, -SLIGHT
UTERUS (UT) :
 -HYPERPLASIA, CYSTIC ENDOMETRIAL, -
 MINIMAL

^COLLECTED/TAKEN (XW) :
 -LIVER SECTIONS, IN METHANOL

^DEATH COMMENT (DC) :
 -SCHEDULED SACRIFICE, -PRESENT

HAZLETON WASHINGTON, INC.
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APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 938

STUDY NUMBER: 483287

ANIMAL NUMBER: A37587 SEX: FEMALE DOSE GROUP: 7 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/11/91 STUDY DAY OF DEATH: 95 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 21.4 GRAMS
DATE AND TIME OF NECROPSY: 11/11/91 9:41 PROSECTOR: DOUGLAS HERNDON RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE), KIDNEY (KD),
LACRIMAL GL, EX (EO), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU), MAMMARY, FEMALE (MF), MAND SALIVARY GL (SG),
MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON), NERVE, SCIATIC (SN),
OVARY (OV), PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), RECTUM (RE), SKIN (SK), SKIN, OTHER (SS), SPLEEN (SP),
STOMACH, GL (ST), STOMACH, NONGL (SU), THYMUS (TH), THYROID (TY), TONGUE (TO), TRACHEA (TR), URINARY BLADDER (UB),
UTERUS (UT), UTERUS, CERVIX (CV), VAGINA (VA)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:

ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, STERNUM (SB), BRAIN W/STEM (BR), CECUM (CE),
COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC), DUODENUM (DU), ESOPHAGUS (ES), EYE (EY),
GALLBLADDER (GB), HARDERIAN GLAND (HG), HEART (HT), HEMATO NEOPLASIA (HN), ILEUM (IL), JEJUNUM (JE),
LN, MESENTERIC (MS), LUNG (LU), MAMMARY, FEMALE (MF), MAND SALIVARY GL (SG), MARROW, FEMUR (FM), MARROW, STERNUM (SE),
MUSCLE, ABDOM (MA), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON), NERVE, SCIATIC (SN), OVARY (OV), OVIDUCT (OD),
PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), RECTUM (RE), SALIVARY, OTHER (OS), SKIN (SK), STOMACH, GL (ST),
STOMACH, NONGL (SU), THYMUS (TH), THYROID (TY), TONGUE (TO), TRACHEA (TR), URINARY BLADDER (UB), UTERUS, CERVIX (CV),
VAGINA (VA)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 939

STUDY NUMBER: 483287

ANIMAL NUMBER: A37588 SEX: FEMALE DOSE GROUP: 7 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/11/91 STUDY DAY OF DEATH: 95 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 23.0 GRAMS
DATE AND TIME OF NECROPSY: 11/11/91 10:50 PROSECTOR: SCOTT BELL RECORDER: SCOTT BELL
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: NOT REQUIRED BY PROTOCOL

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.11	.472 %	.223	WEIGHT TAKEN
LUNG (LU)	.17	.727 %	.343	WEIGHT TAKEN
UTERUS (UT)	.13	.559 %	.264	WEIGHT TAKEN
BRAIN W/STEM (BR)	.49	2.117 %	1.000	WEIGHT TAKEN
HEART (HT)	.13	.580 %	.274	WEIGHT TAKEN
SPLEEN (SP)	.08	.346 %	.163	WEIGHT TAKEN
KIDNEY (KD)	.36	1.575 %	.744	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	3.80	16.520 %	7.805	WEIGHT TAKEN
ADRENAL (AD)	.015	.0635 %	.0300	WEIGHT TAKEN
OVARY (OV)	.027	.1170 %	.0553	WEIGHT TAKEN
THYMUS (TH)	.03	.132 %	.062	WEIGHT TAKEN

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE
OBSERVATIONS

PATHOLOGY OBSERVATIONS
NECROPSY

LIVER (LI) :
-PALE AREA; ALL LOBES, MULTIPLE, TAN,
WHITE, PINPOINT TO 2 X 2 MM
-ENLARGED, SEVERE; ALL LOBES
-DARK; ALL LOBES, DARK BROWN

HISTOPATHOLOGY

HARDERIAN GLAND (HG) :
-INFLAMMATION, CHRONIC, -PRESENT
HEART (HT) :
-INFLAMMATION, CHRONIC, -MINIMAL
KIDNEY (KD) :
-INFLAMMATION, CHRONIC, -MINIMAL
-TUBULE, REGENERATION, -MINIMAL
-PIGMENT, -MINIMAL
-CYST, -PRESENT
LACRIMAL GL, EX (EO) :
-UNILATERALLY EXAMINED, -PRESENT
LIVER (LI) :
-HEPATOCYTE, HYPERTROPHY,
CENTROLOBULAR, -MODERATELY SEVERE
-VACUOLIZATION, -MINIMAL
-PIGMENT, BILE, -MINIMAL
-KUPFFER CELL/MACROPHAGE, PIGMENT, -
MINIMAL
-HEPATOCYTE, PIGMENT, -MINIMAL

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 940

STUDY NUMBER: 483287

ANIMAL NUMBER: A37588 SEX: FEMALE DOSE GROUP: 7 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/11/91 STUDY DAY OF DEATH: 95 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 23.0 GRAMS
DATE AND TIME OF NECROPSY: 11/11/91 10:50 PROSECTOR: SCOTT BELL RECORDER: SCOTT BELL
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: NOT REQUIRED BY PROTOCOL

P A T H O L O G Y O B S E R V A T I O N S (CONTINUED)
NECROPSY

CLINICAL OBSERVATIONS

HISTOPATHOLOGY

STOMACH, GL (ST) :
-DARK AREA; MUCOSA, SEVERAL, BLACK,
PINPOINT

^COLLECTED/TAKEN (XW) :
-LIVER SECTIONS, IN METHANOL

LIVER (LI) :
-NECROSIS,-SLIGHT, MULTI-FOCAL
-NECROSIS, INDIVIDUAL CELL,-SLIGHT
-BILE DUCT, INFLAMMATION, CHRONIC,-
SLIGHT
LN, MANDIBULAR (MN) :
-MACROPHAGES, PIGMENTED,-MINIMAL
LN, MESENTERIC (MS) :
-MACROPHAGES, PIGMENTED,-MINIMAL
LUNG (LU) :
-PERIBRONCHIAL/PERIVASCULAR,
INFILTRATION, LYMPHOID,-MINIMAL
MARROW, FEMUR (FM) :
-HYPERCELLULAR,-PRESENT
PANCREAS (PA) :
-INFLAMMATION, CHRONIC,-MINIMAL
SPLEEN (SP) :
-EXTRAMEDULLARY HEMATOPOIESIS,
INCREASED,-MODERATE
-PIGMENT,-MINIMAL
STOMACH, GL (ST) :
-HYPERPLASIA, CYSTIC,-SLIGHT
URINARY BLADDER (UB) :
-INFLAMMATION, CHRONIC,-MINIMAL
UTERUS (UT) :
-HYPOPLASIA,-MODERATE
UTERUS, CERVIX (CV) :
-HYPOPLASIA,-MINIMAL

^DEATH COMMENT (DC) :
-SCHEDULED SACRIFICE,-PRESENT

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 941

STUDY NUMBER: 483287

ANIMAL NUMBER: A37588 SEX: FEMALE DOSE GROUP: 7 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/11/91 STUDY DAY OF DEATH: 95 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 23.0 GRAMS
DATE AND TIME OF NECROPSY: 11/11/91 10:50 PROSECTOR: SCOTT BELL RECORDER: SCOTT BELL
POST-FIX WEAHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEAHER: NOT REQUIRED BY PROTOCOL

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE), KIDNEY (KD),
LACRIMAL GL, EX (EO), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU), MAMMARY, FEMALE (MF), MAND SALIVARY GL (SG),
MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON), NERVE, SCIATIC (SN),
OVARY (OV), PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), RECTUM (RE), SKIN (SK), SKIN, OTHER (SS), SPLEEN (SP),
STOMACH, NONGL (SU), THYMUS (TH), THYROID (TY), TONGUE (TO), TRACHEA (TR), URINARY BLADDER (UB), UTERUS (UT),
UTERUS, CERVIX (CV), VAGINA (VA)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, STERNUM (SB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEMATO NEOPLASIA (HN), ILEUM (IL), JEJUNUM (JE),
MAMMARY, FEMALE (MF), MAND SALIVARY GL (SG), MARROW, STERNUM (SE), MUSCLE, ABDOM (MA), MUSCLE, SKELETAL (SM),
NERVE, OPTIC (ON), NERVE, SCIATIC (SN), OVARY (OV), OVIDUCT (OD), PARATHYROID (PT), PITUITARY (PI), RECTUM (RE),
SALIVARY, OTHER (OS), SKIN (SK), STOMACH, NONGL (SU), THYMUS (TH), THYROID (TY), TONGUE (TO), TRACHEA (TR),
VAGINA (VA)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 942

STUDY NUMBER: 483287

ANIMAL NUMBER: A37589 SEX: FEMALE DOSE GROUP: 7 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/11/91 STUDY DAY OF DEATH: 95 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 23.3 GRAMS
DATE AND TIME OF NECROPSY: 11/11/91 11:50 PROSECTOR: DOUGLAS HERNDON RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.11	.462 %	.221	WEIGHT TAKEN
LUNG (LU)	.19	.814 %	.390	WEIGHT TAKEN
UTERUS (UT)	.26	1.104 %	.529	WEIGHT TAKEN
BRAIN W/STEM (BR)	.49	2.087 %	1.000	WEIGHT TAKEN
HEART (HT)	.14	.610 %	.292	WEIGHT TAKEN
SPLEEN (SP)	.13	.550 %	.263	WEIGHT TAKEN
KIDNEY (KD)	.42	1.781 %	.853	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	2.69	11.543 %	5.531	WEIGHT TAKEN
ADRENAL (AD)	.011	.0485 %	.0232	WEIGHT TAKEN
OVARY (OV)	.051	.2180 %	.1045	WEIGHT TAKEN
THYMUS (TH)	.04	.186 %	.089	WEIGHT TAKEN

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE
OBSERVATIONS

PATHOLOGY OBSERVATIONS
NECROPSY

LIVER (LI) :
-ENLARGED, MODERATE; ALL LOBES
-DARK; ALL LOBES, DARK BROWN

HISTOPATHOLOGY

HEART (HT) :
-INFLAMMATION, CHRONIC, -MINIMAL
KIDNEY (KD) :
-INFLAMMATION, CHRONIC, -MINIMAL
LACRIMAL GL, EX (EO) :
-UNILATERALLY EXAMINED, -PRESENT
LIVER (LI) :
-HEPATOCYTE, HYPERTROPHY,
CENTROLOBULAR, -MODERATE
-PIGMENT, BILE, -MINIMAL
-KUPFFER CELL/MACROPHAGE, PIGMENT, -
MINIMAL
-NECROSIS, -SLIGHT, MULTI-FOCAL
-NECROSIS, INDIVIDUAL CELL, -MINIMAL
-BILE DUCT, INFLAMMATION, CHRONIC, -
SLIGHT
-EXTRAMEDULLARY HEMATOPOIESIS,
INCREASED, -MINIMAL

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 943

STUDY NUMBER: 483287

ANIMAL NUMBER: A37589 SEX: FEMALE DOSE GROUP: 7 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/11/91 STUDY DAY OF DEATH: 95 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 23.3 GRAMS
DATE AND TIME OF NECROPSY: 11/11/91 11:50 PROSECTOR: DOUGLAS HERNDON RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

CLINICAL OBSERVATIONS

P A T H O L O G Y O B S E R V A T I O N S (CONTINUED)
NECROPSY

HISTOPATHOLOGY

LN, MANDIBULAR (MN) :
-MACROPHAGES, PIGMENTED, -MINIMAL
MAMMARY, FEMALE (MF) :
-DILATATION, CYSTIC, -MINIMAL
-HYPOPLASIA, EPITHELIAL, -PRESENT
NERVE, OPTIC (ON) :
-UNILATERALLY EXAMINED, -PRESENT
PARATHYROID (PT) :
-UNILATERALLY EXAMINED, -PRESENT
SPLEEN (SP) :
-EXTRAMEDULLARY HEMATOPOIESIS,
INCREASED, -SLIGHT
-PIGMENT, -MINIMAL
STOMACH, GL (ST) :
-HYPERPLASIA, CYSTIC, -MINIMAL
THYROID (TY) :
-UNILATERALLY EXAMINED, -PRESENT
UTERUS (UT) :
-HYPERPLASIA, CYSTIC ENDOMETRIAL, -
MINIMAL

^COLLECTED/TAKEN (XW) :
-LIVER SECTIONS, IN METHANOL

^DEATH COMMENT (DC) :
-SCHEDULED SACRIFICE, -PRESENT

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)

PRINTED: 21-JAN-93
PAGE: 944

INDIVIDUAL ANIMAL SUMMARY REPORT

STUDY NUMBER: 483287

ANIMAL NUMBER: A37589 SEX: FEMALE DOSE GROUP: 7 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/11/91 STUDY DAY OF DEATH: 95 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 23.3 GRAMS
DATE AND TIME OF NECROPSY: 11/11/91 11:50 PROSECTOR: DOUGLAS HERNDON RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE), KIDNEY (KD),
LACRIMAL GL, EX (EO), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU), MAMMARY, FEMALE (MF), MAND SALIVARY GL (SG),
MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON), NERVE, SCIATIC (SN),
OVARY (OV), PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), RECTUM (RE), SKIN (SK), SKIN, OTHER (SS), SPLEEN (SP),
STOMACH, GL (ST), STOMACH, NONGL (SU), THYMUS (TH), THYROID (TY), TONGUE (TO), TRACHEA (TR), URINARY BLADDER (UB),
UTERUS (UT), UTERUS, CERVIX (CV), VAGINA (VA)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, STERNUM (SB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HARDERIAN GLAND (HG), HEMATO NEOPLASIA (HN), ILEUM (IL),
JEJUNUM (JE), LN, MESENTERIC (MS), LUNG (LU), MAND SALIVARY GL (SG), MARROW, FEMUR (FM), MARROW, STERNUM (SE),
MUSCLE, ABDOM (MA), MUSCLE, SKELETAL (SM), NERVE, SCIATIC (SN), OVARY (OV), OVIDUCT (OD), PANCREAS (PA),
PITUITARY (PI), RECTUM (RE), SALIVARY, OTHER (OS), SKIN (SK), STOMACH, NONGL (SU), THYMUS (TH), TONGUE (TO),
TRACHEA (TR), URINARY BLADDER (UB), UTERUS, CERVIX (CV), VAGINA (VA)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 945

STUDY NUMBER: 483287

ANIMAL NUMBER: A37590 SEX: FEMALE DOSE GROUP: 7 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/11/91 STUDY DAY OF DEATH: 95 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 18.8 GRAMS
DATE AND TIME OF NECROPSY: 11/11/91 14:15 PROSECTOR: SCOTT BELL RECORDER: SCOTT BELL
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KACYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.11	.559 %	.228	WEIGHT TAKEN
LUNG (LU)	.12	.663 %	.271	WEIGHT TAKEN
UTERUS (UT)	.06	.298 %	.122	WEIGHT TAKEN
BRAIN W/STEM (BR)	.46	2.450 %	1.000	WEIGHT TAKEN
HEART (HT)	.12	.626 %	.256	WEIGHT TAKEN
SPLEEN (SP)	.05	.249 %	.102	WEIGHT TAKEN
KIDNEY (KD)	.27	1.426 %	.582	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	2.22	11.830 %	4.828	WEIGHT TAKEN
ADRENAL (AD)	.011	.0574 %	.0234	WEIGHT TAKEN
OVARY (OV)	.030	.1606 %	.0656	WEIGHT TAKEN
THYMUS (TH)	.03	.154 %	.063	WEIGHT TAKEN

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE
OBSERVATIONS

PATHOLOGY OBSERVATIONS
NECROPSY

LIVER (LI) :
-PALE AREA; ALL LOBES, FEW, WHITE,
PINPOINT TO 1 X 1 MM
-DARK; ALL LOBES, DARK BROWN

HISTOPATHOLOGY

CECUM (CE) :
-HYPERPLASIA, LYMPHOID,-PRESENT
JEJUNUM (JE) :
-HYPERPLASIA, LYMPHOID,-PRESENT
KIDNEY (KD) :
-TUBULE, REGENERATION,-MINIMAL
-INFLAMMATION, SUBACUTE,-MINIMAL
LIVER (LI) :
-HEPATOCYTE, HYPERTROPHY,
CENTROLOBULAR,-SLIGHT
-VACUOLIZATION,-MINIMAL
-PIGMENT, BILE,-MINIMAL
-KUPFER CELL/MACROPHAGE, PIGMENT,-
MINIMAL
-HEPATOCYTE, PIGMENT,-MINIMAL
-NECROSIS,-SLIGHT, MULTI-FOCAL
-NECROSIS, INDIVIDUAL CELL,-MINIMAL
LN, MANDIBULAR (MN) :
-MACROPHAGES, PIGMENTED,-MINIMAL

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 946

STUDY NUMBER: 483287

ANIMAL NUMBER: A37590 SEX: FEMALE DOSE GROUP: 7 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/11/91 STUDY DAY OF DEATH: 95 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 18.8 GRAMS
DATE AND TIME OF NECROPSY: 11/11/91 14:15 PROSECTOR: SCOTT BELL RECORDER: SCOTT BELL
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

CLINICAL OBSERVATIONS

P A T H O L O G Y O B S E R V A T I O N S (CONTINUED)
NECROPSY

HISTOPATHOLOGY

NERVE, OPTIC (ON) :
-UNILATERALLY EXAMINED, -PRESENT
PARATHYROID (PT) :
-UNILATERALLY EXAMINED, -PRESENT
SPLEEN (SP) :
-EXTRAMEDULLARY HEMATOPOIESIS,
INCREASED, -SLIGHT
-PIGMENT, -MINIMAL
STOMACH, GL (ST) :
-HYPERPLASIA, -MINIMAL
UTERUS (UT) :
-HYPOPLASIA, -MODERATELY SEVERE
UTERUS, CERVIX (CV) :
-HYPOPLASIA, -MODERATELY SEVERE

^COLLECTED/TAKEN (XW) :
-LIVER SECTIONS, IN METHANOL

^DEATH COMMENT (DC) :
-SCHEDULED SACRIFICE, -PRESENT

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 947

STUDY NUMBER: 483287

ANIMAL NUMBER: A37590 SEX: FEMALE DOSE GROUP: 7 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/11/91 STUDY DAY OF DEATH: 95 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 18.8 GRAMS
DATE AND TIME OF NECROPSY: 11/11/91 14:15 PROSECTOR: SCOTT BELL RECORDER: SCOTT BELL
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE), KIDNEY (KD),
LACRIMAL GL, EX (EO), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU), MAMMARY, FEMALE (MF), MAND SALIVARY GL (SG),
MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON), NERVE, SCIATIC (SN),
OVARY (OV), PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), RECTUM (RE), SKIN (SK), SKIN, OTHER (SS), SPLEEN (SP),
STOMACH, GL (ST), STOMACH, NONGL (SU), THYMUS (TH), THYROID (TY), TONGUE (TO), TRACHEA (TR), URINARY BLADDER (UB),
UTERUS (UT), UTERUS, CERVIX (CV), VAGINA (VA)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, STERNUM (SB),
BRAIN W/STEM (BR), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC), DUODENUM (DU),
ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HARDERIAN GLAND (HG), HEART (HT), HEMATO NEOPLASIA (HN), ILEUM (IL),
LACRIMAL GL, EX (EO), LN, MESENTERIC (MS), LUNG (LU), MAMMARY, FEMALE (MF), MAND SALIVARY GL (SG),
MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, ABDOM (MA), MUSCLE, SKELETAL (SM), NERVE, SCIATIC (SN), OVARY (OV),
OVIDUCT (OD), PANCREAS (PA), PITUITARY (PI), RECTUM (RE), SALIVARY, OTHER (OS), SKIN (SK), STOMACH, NONGL (SU),
THYMUS (TH), THYROID (TY), TONGUE (TO), TRACHEA (TR), URINARY BLADDER (UB), VAGINA (VA)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 948

STUDY NUMBER: 483287

ANIMAL NUMBER: A37591 SEX: FEMALE DOSE GROUP: 7 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/12/91 STUDY DAY OF DEATH: 96 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 23.1 GRAMS
DATE AND TIME OF NECROPSY: 11/12/91 9:32 PROSECTOR: SCOTT BELL RECORDER: SCOTT BELL
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.10	.453 %	.216	WEIGHT TAKEN
LUNG (LU)	.16	.677 %	.323	WEIGHT TAKEN
UTERUS (UT)	.18	.786 %	.375	WEIGHT TAKEN
BRAIN W/STEM (BR)	.48	2.097 %	1.000	WEIGHT TAKEN
HEART (HT)	.15	.649 %	.310	WEIGHT TAKEN
SPLEEN (SP)	.06	.272 %	.130	WEIGHT TAKEN
KIDNEY (KD)	.30	1.317 %	.628	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	3.18	13.785 %	6.573	WEIGHT TAKEN
ADRENAL (AD)	.013	.0571 %	.0272	WEIGHT TAKEN
OVARY (OV)	.038	.1662 %	.0793	WEIGHT TAKEN
THYMUS (TH)	.04	.168 %	.080	WEIGHT TAKEN

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE
OBSERVATIONS

PATHOLOGY OBSERVATIONS
NECROPSY

LIVER (LI) :
-PALE AREA; ALL LOBES, SEVERAL, TAN,
PINPOINT TO 1 X 1 MM
-ENLARGED, SEVERE; ALL LOBES
-DARK; ALL LOBES, DARK BROWN

HISTOPATHOLOGY

CECUM (CE) :
-HYPERPLASIA, LYMPHOID, -PRESENT
LACRIMAL GL, EX (EO) :
-UNILATERALLY EXAMINED, -PRESENT
LIVER (LI) :
-HEPATOCTYE, HYPERTROPHY,
CENTROLOBULAR, -MODERATE
-VACUOLIZATION, -MINIMAL
-PIGMENT, BILE, -MINIMAL
-KUPFFER CELL/MACROPHAGE, PIGMENT, -
MINIMAL
-HEPATOCTYE, PIGMENT, -SLIGHT
-NECROSIS, -SLIGHT, MULTI-FOCAL
-NECROSIS, INDIVIDUAL CELL, -MINIMAL
-INFLAMMATION, CHRONIC/CHRONIC ACTIVE, -
SLIGHT
LN, MANDIBULAR (MN) :
-MACROPHAGES, PIGMENTED, -MINIMAL

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 949

STUDY NUMBER: 483287

ANIMAL NUMBER: A37591 SEX: FEMALE DOSE GROUP: 7 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/12/91 STUDY DAY OF DEATH: 96 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 23.1 GRAMS
DATE AND TIME OF NECROPSY: 11/12/91 9:32 PROSECTOR: SCOTT BELL RECORDER: SCOTT BELL
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

CLINICAL OBSERVATIONS

P A T H O L O G Y O B S E R V A T I O N S (CONTINUED)
NECROPSY

HISTOPATHOLOGY

LN, MESENTERIC (MS) :
-MACROPHAGES, PIGMENTED, -MINIMAL
-HYPERPLASIA, LYMPHOID, -SLIGHT
MAMMARY, FEMALE (MF) :
-DILATATION, CYSTIC, -MINIMAL
NERVE, OPTIC (ON) :
-UNILATERALLY EXAMINED, -PRESENT
PARATHYROID (PT) :
-UNILATERALLY EXAMINED, -PRESENT
SPLEEN (SP) :
-EXTRAMEDULLARY HEMATOPOIESIS,
INCREASED, -MODERATE
-PIGMENT, -MINIMAL
STOMACH, GL (ST) :
-INFLAMMATION, CHRONIC, -MINIMAL
UTERUS (UT) :
-HYPERPLASIA, CYSTIC ENDOMETRIAL, -
MINIMAL
-HYPOPLASIA, -SLIGHT

^COLLECTED/TAKEN (XW) :
-LIVER SECTIONS, IN METHANOL

^DEATH COMMENT (DC) :
-SCHEDULED SACRIFICE, -PRESENT

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 950

STUDY NUMBER: 483287

ANIMAL NUMBER: A37591 SEX: FEMALE DOSE GROUP: 7 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/12/91 STUDY DAY OF DEATH: 96 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 23.1 GRAMS
DATE AND TIME OF NECROPSY: 11/12/91 9:32 PROSECTOR: SCOTT BELL RECORDER: SCOTT BELL
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE), KIDNEY (KD),
LACRIMAL GL, EX (EO), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU), MAMMARY, FEMALE (MF), MAND SALIVARY GL (SG),
MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON), NERVE, SCIATIC (SN),
OVARY (OV), PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), RECTUM (RE), SKIN (SK), SKIN, OTHER (SS), SPLEEN (SP),
STOMACH, GL (ST), STOMACH, NONGL (SU), THYMUS (TH), THYROID (TY), TONGUE (TO), TRACHEA (TR), URINARY BLADDER (UB),
UTERUS (UT), UTERUS, CERVIX (CV), VAGINA (VA)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, STERNUM (SB),
BRAIN W/STEM (BR), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC), DUODENUM (DU),
ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HARDERIAN GLAND (HG), HEART (HT), HEMATO NEOPLASIA (HN), ILEUM (IL),
JEJUNUM (JE), KIDNEY (KD), LUNG (LU), MAND SALIVARY GL (SG), MARROW, FEMUR (FM), MARROW, STERNUM (SE),
MUSCLE, ABDOM (MA), MUSCLE, SKELETAL (SM), NERVE, SCIATIC (SN), OVARY (OV), OVIDUCT (OD), PANCREAS (PA),
PITUITARY (PI), RECTUM (RE), SALIVARY, OTHER (OS), SKIN (SK), STOMACH, NONGL (SU), THYMUS (TH), THYROID (TY),
TONGUE (TO), TRACHEA (TR), URINARY BLADDER (UB), UTERUS, CERVIX (CV), VAGINA (VA)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 951

STUDY NUMBER: 483287

ANIMAL NUMBER: A37592 SEX: FEMALE DOSE GROUP: 7 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/12/91 STUDY DAY OF DEATH: 96 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 23.2 GRAMS
DATE AND TIME OF NECROPSY: 11/12/91 10:25 PROSECTOR: SCOTT BELL RECORDER: SCOTT BELL
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.13	.573 %	.268	WEIGHT TAKEN
LUNG (LU)	.15	.650 %	.304	WEIGHT TAKEN
UTERUS (UT)	.14	.588 %	.275	WEIGHT TAKEN
BRAIN W/STEM (BR)	.50	2.140 %	1.000	WEIGHT TAKEN
HEART (HT)	.12	.534 %	.250	WEIGHT TAKEN
SPLEEN (SP)	.09	.367 %	.171	WEIGHT TAKEN
KIDNEY (KD)	.32	1.390 %	.649	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	3.47	14.969 %	6.996	WEIGHT TAKEN
ADRENAL (AD)	.012	.0517 %	.0242	WEIGHT TAKEN
OVARY (OV)	.019	.0810 %	.0379	WEIGHT TAKEN
THYMUS (TH)	.02	.089 %	.042	WEIGHT TAKEN

CLINICAL OBSERVATIONS

PATHOLOGY OBSERVATIONS
NECROPSY

HISTOPATHOLOGY

-LAST PHYSICAL EXAM:HYPOACTIVE

LIVER (LI) :
-PALE AREA; ALL LOBES, FEW, WHITE,
PINPOINT TO 3 X 2 MM
-ENLARGED, SEVERE; ALL LOBES
-DARK; ALL LOBES, DARK BROWN

CECUM (CE) :
-HYPERPLASIA, LYMPHOID, -PRESENT
EYE (EY) :
>UNREMARKABLE
>NOTE:>ONE CORNEA EXAMINED.
GALLBLADDER (GB) :
-INFLAMMATION, CHRONIC, -MINIMAL
HEART (HT) :
-INFLAMMATION, CHRONIC, -MINIMAL
KIDNEY (KD) :
-INFLAMMATION, CHRONIC, -MINIMAL
-TUBULE, REGENERATION, -MINIMAL
LIVER (LI) :
-HEPATOCYTE, HYPERTROPHY,
CENTROLOBULAR, -MODERATE
-VACUOLIZATION, -SLIGHT
-PIGMENT, BILE, -MINIMAL
-KUPFFER CELL/MACROPHAGE, PIGMENT, -
MINIMAL

HAZLETON WASHINGTON, INC.
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APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 952

STUDY NUMBER: 483287

ANIMAL NUMBER: A37592 SEX: FEMALE DOSE GROUP: 7 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/12/91 STUDY DAY OF DEATH: 96 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 23.2 GRAMS
DATE AND TIME OF NECROPSY: 11/12/91 10:25 PROSECTOR: SCOTT BELL RECORDER: SCOTT BELL
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

CLINICAL OBSERVATIONS

P A T H O L O G Y O B S E R V A T I O N S (CONTINUED)
NECROPSY

HISTOPATHOLOGY

PANCREAS (PA) :
-DARK; TAN

STOMACH, GL (ST) :
-DARK AREA; MUCOSA, FEW, BLACK,
PINPOINT

^COLLECTED/TAKEN (XW) :
-LIVER SECTIONS, IN METHANOL

LIVER (LI) :
-HEPATOCTE, PIGMENT, -MINIMAL
-NECROSIS, -MINIMAL, FOCAL
-NECROSIS, INDIVIDUAL CELL, -MINIMAL
-BILE DUCT, INFLAMMATION, CHRONIC, -
MINIMAL
LN, MANDIBULAR (MN) :
-MACROPHAGES, PIGMENTED, -MINIMAL
LN, MESENTERIC (MS) :
-MACROPHAGES, PIGMENTED, -MINIMAL
-HYPERPLASIA, LYMPHOID, -SLIGHT
PANCREAS (PA) :
 >UNREMARKABLE
PARATHYROID (PT) :
 >SECTION EXAMINED; TISSUE NOT PRESENT
SPLEEN (SP) :
 -EXTRAMEDULLARY HEMATOPOIESIS,
 INCREASED, -MODERATE
 -PIGMENT, -MINIMAL
STOMACH, GL (ST) :
 >UNREMARKABLE
UTERUS (UT) :
 -HYPOPLASIA, -MODERATELY SEVERE
UTERUS, CERVIX (CV) :
 -HYPOPLASIA, -MODERATE
^DEATH COMMENT (DC) :
 -SCHEDULED SACRIFICE, -PRESENT

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 953

STUDY NUMBER: 483287

ANIMAL NUMBER: A37592 SEX: FEMALE DOSE GROUP: 7 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/12/91 STUDY DAY OF DEATH: 96 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 23.2 GRAMS
DATE AND TIME OF NECROPSY: 11/12/91 10:25 PROSECTOR: SCOTT BELL RECORDER: SCOTT BELL
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE), KIDNEY (KD),
LACRIMAL GL, EX (EO), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU), MAMMARY, FEMALE (MF), MAND SALIVARY GL (SG),
MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON), NERVE, SCIATIC (SN),
OVARY (OV), PARATHYROID (PT), PITUITARY (PI), RECTUM (RE), SKIN (SK), SKIN, OTHER (SS), SPLEEN (SP),
STOMACH, NONGL (SU), THYMUS (TH), THYROID (TY), TONGUE (TO), TRACHEA (TR), URINARY BLADDER (UB), UTERUS (UT),
UTERUS, CERVIX (CV), VAGINA (VA)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, STERNUM (SB),
BRAIN W/STEM (BR), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC), DUODENUM (DU),
ESOPHAGUS (ES), HARDERIAN GLAND (HG), HEMATO NEOPLASIA (HN), ILEUM (IL), JEJUNUM (JE), LACRIMAL GL, EX (EO),
LUNG (LU), MAMMARY, FEMALE (MF), MAND SALIVARY GL (SG), MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, ABDOM (MA),
MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON), NERVE, SCIATIC (SN), OVARY (OV), OVIDUCT (OD), PITUITARY (PI), RECTUM (RE),
SALIVARY, OTHER (OS), SKIN (SK), STOMACH, NONGL (SU), THYMUS (TH), THYROID (TY), TONGUE (TO), TRACHEA (TR),
URINARY BLADDER (UB), VAGINA (VA)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 954

STUDY NUMBER: 483287

ANIMAL NUMBER: A37593 SEX: FEMALE DOSE GROUP: 7 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/12/91 STUDY DAY OF DEATH: 96 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 21.3 GRAMS
DATE AND TIME OF NECROPSY: 11/12/91 11:29 PROSECTOR: SONNY DIKES RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.08	.355 %	.156	WEIGHT TAKEN
LUNG (LU)	.15	.717 %	.316	WEIGHT TAKEN
UTERUS (UT)	.17	.783 %	.345	WEIGHT TAKEN
BRAIN W/STEM (BR)	.48	2.272 %	1.000	WEIGHT TAKEN
HEART (HT)	.11	.539 %	.237	WEIGHT TAKEN
SPLEEN (SP)	.06	.268 %	.118	WEIGHT TAKEN
KIDNEY (KD)	.34	1.607 %	.707	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	2.52	11.823 %	5.203	WEIGHT TAKEN
ADRENAL (AD)	.007	.0347 %	.0153	WEIGHT TAKEN
OVARY (OV)	.032	.1507 %	.0663	WEIGHT TAKEN
THYMUS (TH)	.03	.127 %	.056	WEIGHT TAKEN

CLINICAL OBSERVATIONS	PATHOLOGY OBSERVATIONS NECROPSY	HISTOPATHOLOGY
-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS	LIVER (LI) : -PALE AREA; ALL LOBES, SEVERAL, TAN, PINPOINT -ENLARGED, SEVERE; ALL LOBES -DARK; ALL LOBES, DARK BROWN	ADRENAL, CORTEX (AC) : -VACUOLIZATION, X-ZONE, -MINIMAL -HYPERPLASIA, SUBCAPSULAR CELL, -MINIMAL CECUM (CE) : -HYPERPLASIA, LYMPHOID, -PRESENT KIDNEY (KD) : -INFLAMMATION, CHRONIC, -MINIMAL LACRIMAL GL, EX (EO) : >TISSUE MISSING LIVER (LI) : -HEPATOCYTE, HYPERTROPHY, CENTROLOBULAR, -MODERATE -VACUOLIZATION, -MINIMAL -PIGMENT, BILE, -MINIMAL -KUPFFER CELL/MACROPHAGE, PIGMENT, - SLIGHT -HEPATOCYTE, PIGMENT, -MODERATE -NECROSIS, INDIVIDUAL CELL, -SLIGHT

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APPENDIX 13B

PRINTED: 21-JAN-93
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13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

STUDY NUMBER: 483287

ANIMAL NUMBER: A37593 SEX: FEMALE DOSE GROUP: 7 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/12/91 STUDY DAY OF DEATH: 96 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 21.3 GRAMS
DATE AND TIME OF NECROPSY: 11/12/91 11:29 PROSECTOR: SONNY DIKES RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

CLINICAL OBSERVATIONS	P A T H O L O G Y O B S E R V A T I O N S (CONTINUED) NECROPSY	HISTOPATHOLOGY
		LIVER (LI) : -INFLAMMATION, CHRONIC/CHRONIC ACTIVE,- SLIGHT -BILE DUCT, INFLAMMATION, CHRONIC,- MINIMAL LN, MANDIBULAR (MN) : >TISSUE MISSING LN, MESENTERIC (MS) : -MACROPHAGES, PIGMENTED,-MINIMAL MAMMARY, FEMALE (MF) : -DILATATION, CYSTIC,-MINIMAL -HYPOPLASIA, EPITHELIAL,-PRESENT RECTUM (RE) : -HYPERPLASIA, LYMPHOID,-PRESENT SPLEEN (SP) : -EXTRAMEDULLARY HEMATOPOIESIS, INCREASED,-SLIGHT -PIGMENT,-MODERATE URINARY BLADDER (UB) : -INFLAMMATION, CHRONIC,-MINIMAL UTERUS (UT) : -HYPOPLASIA,-MODERATE ^COLLECTED/TAKEN (XW) : -LIVER SECTIONS, IN METHANOL ^DEATH COMMENT (DC) : -SCHEDULED SACRIFICE,-PRESENT

HAZLETON WASHINGTON, INC.
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APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 956

STUDY NUMBER: 483287

ANIMAL NUMBER: A37593 SEX: FEMALE DOSE GROUP: 7 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/12/91 STUDY DAY OF DEATH: 96 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 21.3 GRAMS
DATE AND TIME OF NECROPSY: 11/12/91 11:29 PROSECTOR: SONNY DIKES RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE), KIDNEY (KD),
LACRIMAL GL, EX (EO), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU), MAMMARY, FEMALE (MF), MAND SALIVARY GL (SG),
MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON), NERVE, SCIATIC (SN),
OVARY (OV), PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), RECTUM (RE), SKIN (SK), SKIN, OTHER (SS), SPLEEN (SP),
STOMACH, GL (ST), STOMACH, NONGL (SU), THYMUS (TH), THYROID (TY), TONGUE (TO), TRACHEA (TR), URINARY BLADDER (UB),
UTERUS (UT), UTERUS, CERVIX (CV), VAGINA (VA)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:

ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, STERNUM (SB), BRAIN W/STEM (BR), COLON (CO),
CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC), DUODENUM (DU), ESOPHAGUS (ES), EYE (EY),
GALLBLADDER (GB), HARDERIAN GLAND (HG), HEART (HT), HEMATO NEOPLASIA (HN), ILEUM (IL), JEJUNUM (JE), LUNG (LU),
MAND SALIVARY GL (SG), MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, ABDOM (MA), MUSCLE, SKELETAL (SM),
NERVE, OPTIC (ON), NERVE, SCIATIC (SN), OVARY (OV), OVIDUCT (OD), PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI),
SALIVARY, OTHER (OS), SKIN (SK), STOMACH, GL (ST), STOMACH, NONGL (SU), THYMUS (TH), THYROID (TY), TONGUE (TO),
TRACHEA (TR), UTERUS, CERVIX (CV), VAGINA (VA)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 957

STUDY NUMBER: 483287

ANIMAL NUMBER: A37594 SEX: FEMALE DOSE GROUP: 7 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/12/91 STUDY DAY OF DEATH: 96 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 22.9 GRAMS
DATE AND TIME OF NECROPSY: 11/12/91 13:33 PROSECTOR: DOUGLAS HERNDON RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.10	.425 %	.198	WEIGHT TAKEN
LUNG (LU)	.18	.775 %	.360	WEIGHT TAKEN
UTERUS (UT)	.17	.738 %	.343	WEIGHT TAKEN
BRAIN W/STEM (BR)	.49	2.152 %	1.000	WEIGHT TAKEN
HEART (HT)	.12	.538 %	.250	WEIGHT TAKEN
SPLEEN (SP)	.05	.218 %	.101	WEIGHT TAKEN
KIDNEY (KD)	.34	1.470 %	.683	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	2.96	12.918 %	6.003	WEIGHT TAKEN
ADRENAL (AD)	.010	.0415 %	.0193	WEIGHT TAKEN
OVARY (OV)	.026	.1118 %	.0519	WEIGHT TAKEN
THYMUS (TH)	.02	.087 %	.041	WEIGHT TAKEN

CLINICAL OBSERVATIONS	PATHOLOGY OBSERVATIONS NECROPSY	HISTOPATHOLOGY
-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS	LIVER (LI) : -ENLARGED, MODERATE; ALL LOBES -DARK; ALL LOBES, DARK BROWN	ILEUM (IL) : -HYPERPLASIA, LYMPHOID,-PRESENT -AMYLOIDOSIS,-MODERATE JEJUNUM (JE) : -HYPERPLASIA, LYMPHOID,-PRESENT -AMYLOIDOSIS,-SLIGHT KIDNEY (KD) : -HYPERPLASIA, LYMPHOID,-MINIMAL -CYST,-PRESENT -INFLAMMATION, SUBACUTE,-MINIMAL LACRIMAL GL, EX (EO) : >TISSUE MISSING LIVER (LI) : -HEPATOCYTE, HYPERTROPHY, CENTROLOBULAR,-MODERATE -VACUOLIZATION,-MINIMAL -PIGMENT, BILE,-MINIMAL -KUPFFER CELL/MACROPHAGE, PIGMENT,- SLIGHT

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 958

STUDY NUMBER: 483287

ANIMAL NUMBER: A37594 SEX: FEMALE DOSE GROUP: 7 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/12/91 STUDY DAY OF DEATH: 96 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 22.9 GRAMS
DATE AND TIME OF NECROPSY: 11/12/91 13:33 PROSECTOR: DOUGLAS HERNDON RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

CLINICAL OBSERVATIONS	PATHOLOGY OBSERVATIONS (CONTINUED) NECROPSY	HISTOPATHOLOGY
		LIVER (LI) : -HEPATOCTE, PIGMENT, -MODERATE -NECROSIS, INDIVIDUAL CELL, -SLIGHT LN, MANDIBULAR (MN) : -MACROPHAGES, PIGMENTED, -MINIMAL LN, MESENTERIC (MS) : -AMYLOIDOSIS, -MINIMAL LUNG (LU) : -PERIBRONCHIAL/PERIVASCULAR, INFILTRATION, LYMPHOID, -MINIMAL MAMMARY, FEMALE (MF) : -DILATATION, CYSTIC, -SLIGHT -HYPOPLASIA, EPITHELIAL, -PRESENT NERVE, OPTIC (ON) : >TISSUE MISSING PARATHYROID (PT) : -UNILATERALLY EXAMINED, -PRESENT SPLEEN (SP) : -EXTRAMEDULLARY HEMATOPOIESIS, INCREASED, -SLIGHT -PIGMENT, -SLIGHT THYMUS (TH) : -CYST, -PRESENT UTERUS (UT) : -DILATATION, -PRESENT -HYPOPLASIA, -MODERATELY SEVERE
	^COLLECTED/TAKEN (XW) : -LIVER SECTIONS, IN METHANOL	^DEATH COMMENT (DC) : -SCHEDULED SACRIFICE, -PRESENT

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

PRINTED: 21-JAN-93
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13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

STUDY NUMBER: 483287

ANIMAL NUMBER: A37594 SEX: FEMALE DOSE GROUP: 7 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/12/91 STUDY DAY OF DEATH: 96 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 22.9 GRAMS
DATE AND TIME OF NECROPSY: 11/12/91 13:33 PROSECTOR: DOUGLAS HERNDON RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE), KIDNEY (KD),
LACRIMAL GL, EX (EO), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU), MAMMARY, FEMALE (MF), MAND SALIVARY GL (SG),
MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON), NERVE, SCIATIC (SN),
OVARY (OV), PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), RECTUM (RE), SKIN (SK), SKIN, OTHER (SS), SPLEEN (SP),
STOMACH, GL (ST), STOMACH, NONGL (SU), THYMUS (TH), THYROID (TY), TONGUE (TO), TRACHEA (TR), URINARY BLADDER (UB),
UTERUS (UT), UTERUS, CERVIX (CV), VAGINA (VA)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, STERNUM (SB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HARDERIAN GLAND (HG), HEART (HT), HEMATO NEOPLASIA (HN),
MAND SALIVARY GL (SG), MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, ABDOM (MA), MUSCLE, SKELETAL (SM),
NERVE, SCIATIC (SN), OVARY (OV), OVIDUCT (OD), PANCREAS (PA), PITUITARY (PI), RECTUM (RE), SALIVARY, OTHER (OS),
SKIN (SK), STOMACH, GL (ST), STOMACH, NONGL (SU), THYROID (TY), TONGUE (TO), TRACHEA (TR), URINARY BLADDER (UB),
UTERUS, CERVIX (CV), VAGINA (VA)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 960

STUDY NUMBER: 483287

ANIMAL NUMBER: A37595 SEX: FEMALE DOSE GROUP: 7 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/13/91 STUDY DAY OF DEATH: 97 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 22.1 GRAMS
DATE AND TIME OF NECROPSY: 11/13/91 9:13 PROSECTOR: FRED AGEY RECORDER: FRED AGEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.16	.738 %	.366	WEIGHT TAKEN
LUNG (LU)	.15	.682 %	.339	WEIGHT TAKEN
UTERUS (UT)	.09	.389 %	.193	WEIGHT TAKEN
BRAIN W/STEM (BR)	.45	2.015 %	1.000	WEIGHT TAKEN
HEART (HT)	.15	.666 %	.330	WEIGHT TAKEN
SPLEEN (SP)	.06	.261 %	.130	WEIGHT TAKEN
KIDNEY (KD)	.32	1.431 %	.710	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	3.04	13.754 %	6.826	WEIGHT TAKEN
ADRENAL (AD)	.012	.0538 %	.0267	WEIGHT TAKEN
OVARY (OV)	.032	.1457 %	.0723	WEIGHT TAKEN
THYMUS (TH)	.04	.180 %	.089	WEIGHT TAKEN

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE
OBSERVATIONS

PATHOLOGY OBSERVATIONS
NECROPSY

LIVER (LI) :
-PALE AREA; ALL LOBES, FEW, TAN,
PINPOINT TO 1 X 1 MM
-ENLARGED, MODERATE; ALL LOBES
-DARK; ALL LOBES, DARK BROWN

HISTOPATHOLOGY

CECUM (CE) :
-HYPERPLASIA, LYMPHOID,-PRESENT
HARDERIAN GLAND (HG) :
-INFLAMMATION, CHRONIC,-PRESENT
HEART (HT) :
-INFLAMMATION, CHRONIC,-MINIMAL
KIDNEY (KD) :
-INFLAMMATION, CHRONIC,-SLIGHT
-TUBULE, REGENERATION,-SLIGHT
-HYPERPLASIA, LYMPHOID,-MINIMAL
LACRIMAL GL, EX (EO) :
-UNILATERALLY EXAMINED,-PRESENT
LIVER (LI) :
-HEPATOCYTE, HYPERTROPHY,
CENTROLOBULAR,-MODERATE
-VACUOLIZATION,-MINIMAL
-PIGMENT, BILE,-MINIMAL
-KUPFER CELL/MACROPHAGE, PIGMENT,-
MINIMAL

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 961

STUDY NUMBER: 483287

ANIMAL NUMBER: A37595 SEX: FEMALE DOSE GROUP: 7 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/13/91 STUDY DAY OF DEATH: 97 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 22.1 GRAMS
DATE AND TIME OF NECROPSY: 11/13/91 9:13 PROSECTOR: FRED AGEY RECORDER: FRED AGEY
POST-FIX WEAHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEAHER: RICHARD KAGYARE

CLINICAL OBSERVATIONS P A T H O L O G Y O B S E R V A T I O N S (CONTINUED)
NECROPSY HISTOPATHOLOGY

LIVER (LI) :
-HEPATOCYTE, PIGMENT, -SLIGHT
-NECROSIS, -MINIMAL, MULTI-FOCAL
-NECROSIS, INDIVIDUAL CELL, -SLIGHT
-BILE DUCT, INFLAMMATION, CHRONIC, -
MINIMAL
LN, MANDIBULAR (MN) :
-MACROPHAGES, PIGMENTED, -MINIMAL
LN, MESENTERIC (MS) :
-MACROPHAGES, PIGMENTED, -MINIMAL
MAMMARY, FEMALE (MF) :
-DILATATION, CYSTIC, -MINIMAL
-HYPOPLASIA, EPITHELIAL, -PRESENT
MAND SALIVARY GL (SG) :
-INFLAMMATION, CHRONIC, -MINIMAL
NERVE, OPTIC (ON) :
-TISSUE MISSING
OVARY (OV) :
-FOLLICLE, CYST, -PRESENT
SPLEEN (SP) :
-EXTRAMEDULLARY HEMATOPOIESIS,
INCREASED, -SLIGHT
-PIGMENT, -SLIGHT
STOMACH, GL (ST) :
-INFLAMMATION, CHRONIC, -MINIMAL
UTERUS (UT) :
-HYPOPLASIA, -SEVERE
UTERUS, CERVIX (CV) :
-HYPOPLASIA, -MODERATE

^COLLECTED/TAKEN (XW) :
-LIVER SECTIONS, IN METHANOL

^DEATH COMMENT (DC) :
-SCHEDULED SACRIFICE, -PRESENT

APPENDIX 13B

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 962

STUDY NUMBER: 483287

ANIMAL NUMBER: A37595 SEX: FEMALE DOSE GROUP: 7 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/13/91 STUDY DAY OF DEATH: 97 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 22.1 GRAMS
DATE AND TIME OF NECROPSY: 11/13/91 9:13 PROSECTOR: FRED AGEY RECORDER: FRED AGEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE), KIDNEY (KD),
LACRIMAL GL, EX (EO), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU), MAMMARY, FEMALE (MF), MAND SALIVARY GL (SG),
MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON), NERVE, SCIATIC (SN),
OVARY (OV), PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), RECTUM (RE), SKIN (SK), SKIN, OTHER (SS), SPLEEN (SP),
STOMACH, GL (ST), STOMACH, NONGL (SU), THYMUS (TH), THYROID (TY), TONGUE (TO), TRACHEA (TR), URINARY BLADDER (UB),
UTERUS (UT), UTERUS, CERVIX (CV), VAGINA (VA)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, STERNUM (SB),
BRAIN W/STEM (BR), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC), DUODENUM (DU),
ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEMATO NEOPLASIA (HN), ILEUM (IL), JEJUNUM (JE), LUNG (LU),
MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, ABDOM (MA), MUSCLE, SKELETAL (SM), NERVE, SCIATIC (SN),
OVIDUCT (OD), PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), RECTUM (RE), SALIVARY, OTHER (OS), SKIN (SK),
STOMACH, NONGL (SU), THYMUS (TH), THYROID (TY), TONGUE (TO), TRACHEA (TR), URINARY BLADDER (UB), VAGINA (VA)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 963

STUDY NUMBER: 483287

ANIMAL NUMBER: A37596 SEX: FEMALE DOSE GROUP: 7 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/13/91 STUDY DAY OF DEATH: 97 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 18.6 GRAMS
DATE AND TIME OF NECROPSY: 11/13/91 10:02 PROSECTOR: ADEFOLAHAN AKINSOLA RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.12	.642 %	.271	WEIGHT TAKEN
LUNG (LU)	.15	.810 %	.342	WEIGHT TAKEN
UTERUS (UT)	.05	.248 %	.105	WEIGHT TAKEN
BRAIN W/STEM (BR)	.45	2.368 %	1.000	WEIGHT TAKEN
HEART (HT)	.12	.626 %	.264	WEIGHT TAKEN
SPLEEN (SP)	.12	.640 %	.270	WEIGHT TAKEN
KIDNEY (KD)	.32	1.716 %	.725	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	3.01	16.030 %	6.769	WEIGHT TAKEN
ADRENAL (AD)	.008	.0420 %	.0177	WEIGHT TAKEN
OVARY (OV)	.012	.0628 %	.0265	WEIGHT TAKEN
THYMUS (TH)	.04	.189 %	.080	WEIGHT TAKEN

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM: HYPOACTIVE; ENTIRE
BODY-PALE

PATHOLOGY OBSERVATIONS
NECROPSY

KIDNEY (KD) :
-IRREGULARLY SHAPED; BOTH

LIVER (LI) :
-PALE AREA; ALL LOBES, FEW, TAN,
PINPOINT TO 1 X 1 MM
-ENLARGED, MODERATE; ALL LOBES
-DARK; ALL LOBES, DARK BROWN

HISTOPATHOLOGY

HEART (HT) :
-INFLAMMATION, CHRONIC, -MINIMAL

ILEUM (IL) :
-AMYLOIDOSIS, -MODERATE

KIDNEY (KD) :
-INFLAMMATION, CHRONIC, -MODERATELY
SEVERE
-TUBULE, REGENERATION, -MODERATE
-CYST, -PRESENT

LIVER (LI) :
-HEPATOCYTE, HYPERTROPHY,
CENTROLOBULAR, -MODERATE
-VACUOLIZATION, -SLIGHT
-PIGMENT, BILE, -MINIMAL
-KUPFFER CELL/MACROPHAGE, PIGMENT, -
MINIMAL
-HEPATOCYTE, PIGMENT, -SLIGHT
-NECROSIS, INDIVIDUAL CELL, -MINIMAL

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 964

STUDY NUMBER: 483287

ANIMAL NUMBER: A37596 SEX: FEMALE DOSE GROUP: 7 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/13/91 STUDY DAY OF DEATH: 97 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 18.8 GRAMS
DATE AND TIME OF NECROPSY: 11/13/91 10:02 PROSECTOR: ADEFOLAHAN AKINSOLA RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

CLINICAL OBSERVATIONS PATHOLOGY OBSERVATIONS (CONTINUED) HISTOPATHOLOGY
NECROPSY

LIVER (LI) :
-INFLAMMATION, CHRONIC/CHRONIC ACTIVE, -
MINIMAL
-BILE DUCT, INFLAMMATION, CHRONIC, -
MINIMAL
LN, MANDIBULAR (MN) :
-MACROPHAGES, PIGMENTED, -MINIMAL
LN, MESENTERIC (MS) :
-AMYLOIDOSIS, -MINIMAL
MAMMARY, FEMALE (MF) :
-HYPOPLASIA, EPITHELIAL, -PRESENT
PANCREAS (PA) :
-AMYLOIDOSIS, -MINIMAL
PARATHYROID (PT) :
-UNILATERALLY EXAMINED, -PRESENT
SPLEEN (SP) :
-EXTRAMEDULLARY HEMATOPOIESIS,
INCREASED, -MODERATELY SEVERE
-PIGMENT, -MINIMAL
STOMACH, GL (ST) :
-HYPERPLASIA, -MINIMAL
-INFLAMMATION, CHRONIC, -MINIMAL
UTERUS (UT) :
-HYPOPLASIA, -SEVERE
UTERUS, CERVIX (CV) :
-HYPOPLASIA, -SEVERE
VAGINA (VA) :
-HYPOPLASIA, -PRESENT

^COLLECTED/TAKEN (XW) :
-LIVER SECTIONS, IN METHANOL

^DEATH COMMENT (DC) :
-SCHEDULED SACRIFICE, -PRESENT

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 965

STUDY NUMBER: 483287

ANIMAL NUMBER: A37596 SEX: FEMALE DOSE GROUP: 7 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/13/91 STUDY DAY OF DEATH: 97 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 18.8 GRAMS
DATE AND TIME OF NECROPSY: 11/13/91 10:02 PROSECTOR: ADEFOLAHAN AKINSOLA RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE), LACRIMAL GL, EX (EO),
LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU), MAMMARY, FEMALE (MF), MAND SALIVARY GL (SG), MARROW, FEMUR (FM),
MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON), NERVE, SCIATIC (SN), OVARY (OV), PANCREAS (PA),
PARATHYROID (PT), PITUITARY (PI), RECTUM (RE), SKIN (SK), SKIN, OTHER (SS), SPLEEN (SP), STOMACH, GL (ST),
STOMACH, NONGL (SU), THYMUS (TH), THYROID (TY), TONGUE (TO), TRACHEA (TR), URINARY BLADDER (UB), UTERUS (UT),
UTERUS, CERVIX (CV), VAGINA (VA)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, STERNUM (SB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HARDERIAN GLAND (HG), HEMATO NEOPLASIA (HN), JEJUNUM (JE),
LACRIMAL GL, EX (EO), LUNG (LU), MAND SALIVARY GL (SG), MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, ABDOM (MA),
MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON), NERVE, SCIATIC (SN), OVARY (OV), OVIDUCT (OD), PITUITARY (PI), RECTUM (RE),
SALIVARY, OTHER (OS), SKIN (SK), STOMACH, NONGL (SU), THYMUS (TH), THYROID (TY), TONGUE (TO), TRACHEA (TR),
URINARY BLADDER (UB)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 966

STUDY NUMBER: 483287

ANIMAL NUMBER: A37597 SEX: FEMALE DOSE GROUP: 7 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/13/91 STUDY DAY OF DEATH: 97 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 23.9 GRAMS
DATE AND TIME OF NECROPSY: 11/13/91 11:20 PROSECTOR: DOUGLAS HERNDON RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.15	.618 %	.312	WEIGHT TAKEN
LUNG (LU)	.20	.842 %	.425	WEIGHT TAKEN
UTERUS (UT)	.12	.508 %	.256	WEIGHT TAKEN
BRAIN W/STEM (BR)	.47	1.980 %	1.000	WEIGHT TAKEN
HEART (HT)	.11	.470 %	.237	WEIGHT TAKEN
SPLEEN (SP)	.07	.292 %	.147	WEIGHT TAKEN
KIDNEY (KD)	.36	1.513 %	.764	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	3.20	13.400 %	6.767	WEIGHT TAKEN
ADRENAL (AD)	.012	.0515 %	.0260	WEIGHT TAKEN
OVARY (OV)	.035	.1448 %	.0731	WEIGHT TAKEN
THYMUS (TH)	.04	.156 %	.079	WEIGHT TAKEN

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE
OBSERVATIONS

PATHOLOGY OBSERVATIONS
NECROPSY

LIVER (LI) :
-ENLARGED, MODERATE; ALL LOBES
-DARK; ALL LOBES, DARK BROWN

HISTOPATHOLOGY

CECUM (CE) :
-HYPERPLASIA, LYMPHOID,-PRESENT
HARDERIAN GLAND (HG) :
-INFLAMMATION, CHRONIC,-PRESENT
KIDNEY (KD) :
-INFLAMMATION, CHRONIC,-MINIMAL
-INFLAMMATION, SUBACUTE,-MINIMAL
LIVER (LI) :
-HEPATOCYTE, HYPERTROPHY,
CENTROLOBULAR,-MODERATE
-VACUOLIZATION,-SLIGHT
-PIGMENT, BILE,-MINIMAL
-KUPFFER CELL/MACROPHAGE, PIGMENT,-
MINIMAL
-HEPATOCYTE, PIGMENT,-SLIGHT
-NECROSIS, INDIVIDUAL CELL,-MINIMAL
-INFLAMMATION, CHRONIC/CHRONIC ACTIVE,-
MINIMAL

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 967

STUDY NUMBER: 483287

ANIMAL NUMBER: A37597 SEX: FEMALE DOSE GROUP: 7 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/13/91 STUDY DAY OF DEATH: 97 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 23.9 GRAMS
DATE AND TIME OF NECROPSY: 11/13/91 11:20 PROSECTOR: DOUGLAS HERNDON RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

CLINICAL OBSERVATIONS	PATHOLOGY OBSERVATIONS (CONTINUED) NECROPSY	HISTOPATHOLOGY
		LIVER (LI) : -BILE DUCT, INFLAMMATION, CHRONIC, - MINIMAL LN, MANDIBULAR (MN) : -MACROPHAGES, PIGMENTED, -MINIMAL SPLEEN (SP) : -EXTRAMEDULLARY HEMATOPOIESIS, INCREASED, -MODERATE -PIGMENT, -MINIMAL STOMACH, GL (ST) : -INFLAMMATION, CHRONIC, -MINIMAL UTERUS (UT) : -HYPOPLASIA, -MODERATELY SEVERE
	^COLLECTED/TAKEN (XW) : -LIVER SECTIONS, IN METHANOL	^DEATH COMMENT (DC) : -SCHEDULED SACRIFICE, -PRESENT

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 968

STUDY NUMBER: 483287

ANIMAL NUMBER: A37597 SEX: FEMALE DOSE GROUP: 7 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/13/91 STUDY DAY OF DEATH: 97 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 23.9 GRAMS
DATE AND TIME OF NECROPSY: 11/13/91 11:20 PROSECTOR: DOUGLAS HERNOON RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE), KIDNEY (KD),
LACRIMAL GL, EX (EO), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU), MAMMARY, FEMALE (MF), MAND SALIVARY GL (SG),
MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON), NERVE, SCIATIC (SN),
OVARY (OV), PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), RECTUM (RE), SKIN (SK), SKIN, OTHER (SS), SPLEEN (SP),
STOMACH, GL (ST), STOMACH, NONGL (SU), THYMUS (TH), THYROID (TY), TONGUE (TO), TRACHEA (TR), URINARY BLADDER (UB),
UTERUS (UT), UTERUS, CERVIX (CV), VAGINA (VA)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, STERNUM (SB),
BRAIN W/STEM (BR), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC), DUODENUM (DU),
ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), HEMATO NEOPLASIA (HN), ILEUM (IL), JEJUNUM (JE),
LACRIMAL GL, EX (EO), LN, MESENTERIC (MS), LUNG (LU), MAMMARY, FEMALE (MF), MAND SALIVARY GL (SG),
MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, ABDOM (MA), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON),
NERVE, SCIATIC (SN), OVARY (OV), OVIDUCT (OD), PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), RECTUM (RE),
SALIVARY, OTHER (OS), SKIN (SK), STOMACH, NONGL (SU), THYMUS (TH), THYROID (TY), TONGUE (TO), TRACHEA (TR),
URINARY BLADDER (UB), UTERUS, CERVIX (CV), VAGINA (VA)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 969

STUDY NUMBER: 483287

ANIMAL NUMBER: A37598 SEX: FEMALE DOSE GROUP: 7 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/13/91 STUDY DAY OF DEATH: 97 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 21.4 GRAMS
DATE AND TIME OF NECROPSY: 11/13/91 13:48 PROSECTOR: ADEFOLAHAN AKINSOLA RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.11	.534 %	.245	WEIGHT TAKEN
LUNG (LU)	.15	.686 %	.315	WEIGHT TAKEN
UTERUS (UT)	.07	.337 %	.155	WEIGHT TAKEN
BRAIN W/STEM (BR)	.47	2.179 %	1.000	WEIGHT TAKEN
HEART (HT)	.13	.606 %	.278	WEIGHT TAKEN
SPLEEN (SP)	.05	.255 %	.117	WEIGHT TAKEN
KIDNEY (KD)	.30	1.385 %	.636	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	3.10	14.500 %	6.656	WEIGHT TAKEN
ADRENAL (AD)	.010	.0458 %	.0210	WEIGHT TAKEN
OVARY (OV)	.020	.0935 %	.0429	WEIGHT TAKEN
THYMUS (TH)	.02	.084 %	.039	WEIGHT TAKEN

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE
OBSERVATIONS

PATHOLOGY OBSERVATIONS
NECROPSY

LIVER (LI) :
-PALE AREA; ALL LOBES, SEVERAL, TAN,
PINPOINT TO 1 X 1 MM
-ENLARGED, MODERATE; ALL LOBES
-DARK; ALL LOBES, DARK BROWN

HISTOPATHOLOGY

KIDNEY (KD) :
-HYPERPLASIA, LYMPHOID,-MINIMAL
LACRIMAL GL, EX (EO) :
>TISSUE MISSING
LIVER (LI) :
-HEPATOCYTE, HYPERTROPHY,
CENTROLOBULAR,-MODERATE
-VACUOLIZATION,-MODERATE
-PIGMENT, BILE,-MINIMAL
-KUPFFER CELL/MACROPHAGE, PIGMENT,-
MINIMAL
-HEPATOCYTE, PIGMENT,-SLIGHT
-INFLAMMATION, CHRONIC/CHRONIC ACTIVE,-
MINIMAL
LN, MANDIBULAR (MN) :
-MACROPHAGES, PIGMENTED,-MINIMAL
LN, MESENTERIC (MS) :
-MACROPHAGES, PIGMENTED,-MINIMAL

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 970

STUDY NUMBER: 483287

ANIMAL NUMBER: A37598 SEX: FEMALE DOSE GROUP: 7 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/13/91 STUDY DAY OF DEATH: 97 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 21.4 GRAMS
DATE AND TIME OF NECROPSY: 11/13/91 13:48 PROSECUTOR: ADEPOLAHAN AKINSOLA RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

CLINICAL OBSERVATIONS	P A T H O L O G Y O B S E R V A T I O N S (CONTINUED) NECROPSY	HISTOPATHOLOGY
		LUNG (LU) : -PERIBRONCHIAL/PERIVASCULAR, INFILTRATION, LYMPHOID,-MINIMAL MAMMARY, FEMALE (MF) : -DILATATION, CYSTIC,-MINIMAL -HYPOPLASIA, EPITHELIAL,-PRESENT NERVE, OPTIC (ON) : -UNILATERALLY EXAMINED,-PRESENT PARATHYROID (PT) : -UNILATERALLY EXAMINED,-PRESENT SPLEEN (SP) : -EXTRAMEDULLARY HEMATOPOIESIS, INCREASED,-MODERATE -PIGMENT,-MINIMAL STOMACH, GL (ST) : -HYPERPLASIA, CYSTIC,-SLIGHT -INFLAMMATION, CHRONIC,-MINIMAL THYMUS (TH) : -NECROSIS, LYMPHOID,-MINIMAL UTERUS (UT) : -HYPOPLASIA,-MODERATELY SEVERE ^COLLECTED/TAKEN (XW) : -LIVER SECTIONS, IN METHANOL ^DEATH COMMENT (DC) : -SCHEDULED SACRIFICE,-PRESENT

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APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 971

STUDY NUMBER: 483287

ANIMAL NUMBER: A37598 SEX: FEMALE DOSE GROUP: 7 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/13/91 STUDY DAY OF DEATH: 97 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 21.4 GRAMS
DATE AND TIME OF NECROPSY: 11/13/91 13:48 PROSECTOR: ADEFOLAHAN AKINSOLA RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE), KIDNEY (KD),
LACRIMAL GL, EX (EO), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU), MAMMARY, FEMALE (MF), MAND SALIVARY GL (SG),
MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON), NERVE, SCIATIC (SN),
OVARY (OV), PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), RECTUM (RE), SKIN (SK), SKIN, OTHER (SS), SPLEEN (SP),
STOMACH, GL (ST), STOMACH, NONGL (SU), THYMUS (TH), THYROID (TY), TONGUE (TO), TRACHEA (TR), URINARY BLADDER (UB),
UTERUS (UT), UTERUS, CERVIX (CV), VAGINA (VA)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, STERNUM (SB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HARDERIAN GLAND (HG), HEART (HT), HEMATO NEOPLASIA (HN),
ILEUM (IL), JEJUNUM (JE), MAND SALIVARY GL (SG), MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, ABDOM (MA),
MUSCLE, SKELETAL (SM), NERVE, SCIATIC (SN), OVARY (OV), OVIDUCT (OD), PANCREAS (PA), PITUITARY (PI), RECTUM (RE),
SALIVARY, OTHER (OS), SKIN (SK), STOMACH, NONGL (SU), THYROID (TY), TONGUE (TO), TRACHEA (TR), URINARY BLADDER (UB),
UTERUS, CERVIX (CV), VAGINA (VA)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

APPENDIX 13B

PRINTED: 21-JAN-93
PAGE: 972

STUDY NUMBER: 483287

ANIMAL NUMBER: A37599 SEX: FEMALE DOSE GROUP: 7 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/14/91 STUDY DAY OF DEATH: 98 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 23.8 GRAMS
DATE AND TIME OF NECROPSY: 11/14/91 8:43 PROSECTOR: SCOTT BELL RECORDER: SCOTT BELL
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.12	.513 %	.268	WEIGHT TAKEN
LUNG (LU)	.18	.766 %	.400	WEIGHT TAKEN
UTERUS (UT)	.07	.286 %	.149	WEIGHT TAKEN
BRAIN.W/STEM (BR)	.46	1.913 %	1.000	WEIGHT TAKEN
HEART (HT)	.13	.563 %	.294	WEIGHT TAKEN
SPLEEN (SP)	.07	.276 %	.144	WEIGHT TAKEN
KIDNEY (KD)	.28	1.190 %	.622	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	3.76	15.804 %	8.263	WEIGHT TAKEN
ADRENAL (AD)	.013	.0542 %	.0283	WEIGHT TAKEN
OVARY (OV)	.030	.1239 %	.0648	WEIGHT TAKEN
THYMUS (TH)	.03	.108 %	.056	WEIGHT TAKEN

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE
OBSERVATIONS

PATHOLOGY OBSERVATIONS
NECROPSY

HISTOPATHOLOGY

ADRENAL, CORTEX (AC) :
-PIGMENT,-MINIMAL
-VACUOLIZATION, X-ZONE,-MINIMAL
CECUM (CE) :
-HYPERPLASIA, LYMPHOID,-PRESENT
KIDNEY (KD) :
-INFLAMMATION, CHRONIC,-MINIMAL
-TUBULE, REGENERATION,-MINIMAL
-HYPERPLASIA, LYMPHOID,-MINIMAL
LI, EXTRAHEPATIC (LI1) :
-PIGMENT, PAS POSITIVE,-SEVERE
-PIGMENT, IRON POSITIVE,-SLIGHT
-PIGMENT, LIPOFUSCIN POSITIVE,-SLIGHT
LI, INTRAHEPATIC (LI0) :
-PIGMENT, PAS POSITIVE,-SEVERE
-PIGMENT, IRON POSITIVE,-MODERATELY
SEVERE
-PIGMENT, BILE POSITIVE,-MINIMAL
-PIGMENT, LIPOFUSCIN POSITIVE,-MODERATE

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 973

STUDY NUMBER: 483287

ANIMAL NUMBER: A37599 SEX: FEMALE DOSE GROUP: 7 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/14/91 STUDY DAY OF DEATH: 98 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 23.8 GRAMS
DATE AND TIME OF NECROPSY: 11/14/91 8:43 PROSECTOR: SCOTT BELL RECORDER: SCOTT BELL
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

CLINICAL OBSERVATIONS	PATHOLOGY OBSERVATIONS (CONTINUED) NECROPSY	HISTOPATHOLOGY
	LIVER (LI) : -PALE AREA; ALL LOBES, SEVERAL, TAN, PINPOINT TO 3 X 3 MM -ENLARGED, SEVERE; ALL LOBES -DARK; ALL LOBES, DARK BROWN	LIVER (LI) : -HEPATOCYTE, HYPERTROPHY, CENTROLOBULAR, -MODERATE -VACUOLIZATION, -MODERATE -PIGMENT, BILE, -SLIGHT -KUPFFER CELL/MACROPHAGE, PIGMENT, - SLIGHT -HEPATOCYTE, PIGMENT, -SLIGHT -NECROSIS, INDIVIDUAL CELL, -SLIGHT -INFLAMMATION, CHRONIC/CHRONIC ACTIVE, - SLIGHT -BILE DUCT, INFLAMMATION, CHRONIC, - MINIMAL LN, MANDIBULAR (MN) : -MACROPHAGES, PIGMENTED, -MINIMAL LUNG (LU) : -PERIBRONCHIAL/PERIVASCULAR, INFILTRATION, LYMPHOID, -MINIMAL MAMMARY, FEMALE (MF) : -DILATATION, CYSTIC, -MINIMAL -HYPOPLASIA, EPITHELIAL, -PRESENT OVARY (OV) : -FOLLICLE, CYST, -PRESENT RECTUM (RE) : -HYPERPLASIA, LYMPHOID, -PRESENT SPLEEN (SP) : -EXTRAMEDULLARY HEMATOPOIESIS, INCREASED, -SLIGHT -PIGMENT, -SLIGHT STOMACH, GL (ST) : -HYPERPLASIA, CYSTIC, -SLIGHT -INFLAMMATION, CHRONIC, -MINIMAL UTERUS (UT) : -HYPOPLASIA, -MODERATELY SEVERE

STOMACH, GL (ST) :
-MUCOSA, THICKENED, SEVERE

HAZLETON WASHINGTON, INC.
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APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 974

STUDY NUMBER: 483287

ANIMAL NUMBER: A37599 SEX: FEMALE DOSE GROUP: 7 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/14/91 STUDY DAY OF DEATH: 98 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 23.8 GRAMS
DATE AND TIME OF NECROPSY: 11/14/91 8:43 PROSECTOR: SCOTT BELL RECORDER: SCOTT BELL
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

CLINICAL OBSERVATIONS PATHOLOGY OBSERVATIONS (CONTINUED)
NECROPSY HISTOPATHOLOGY

UTERUS, CERVIX (CV) :
-HYPOPLASIA, -SLIGHT
VAGINA (VA) :
-HYPOPLASIA, -PRESENT

^COLLECTED/TAKEN (XW) :
-LIVER SECTIONS, IN METHANOL

^DEATH COMMENT (DC) :
-SCHEDULED SACRIFICE, -PRESENT

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTEX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE), KIDNEY (KD),
LACRIMAL GL, EX (EO), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU), MAMMARY, FEMALE (MF), MAND SALIVARY GL (SG),
MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON), NERVE, SCIATIC (SN),
OVARY (OV), PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), RECTUM (RE), SKIN (SK), SKIN, OTHER (SS), SPLEEN (SP),
STOMACH, NONGL (SU), THYMUS (TH), THYROID (TY), TONGUE (TO), TRACHEA (TR), URINARY BLADDER (UB), UTERUS (UT),
UTERUS, CERVIX (CV), VAGINA (VA)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:

ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, STERNUM (SB), BRAIN W/STEM (BR), COLON (CO),
CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC), DUODENUM (DU), ESOPHAGUS (ES), EYE (EY),
GALLBLADDER (GB), HARDERIAN GLAND (HG), HEART (HT), HEMATO NEOPLASIA (HN), ILEUM (IL), JEJUNUM (JE),
LACRIMAL GL, EX (EO), LN, MESENTERIC (MS), MAND SALIVARY GL (SG), MARROW, FEMUR (FM), MARROW, STERNUM (SE),
MUSCLE, ABDOM (MA), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON), NERVE, SCIATIC (SN), OVIDUCT (OD), PANCREAS (PA),
PARATHYROID (PT), PITUITARY (PI), SALIVARY, OTHER (OS), SKIN (SK), STOMACH, NONGL (SU), THYMUS (TH), THYROID (TY),
TONGUE (TO), TRACHEA (TR), URINARY BLADDER (UB)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 975

STUDY NUMBER: 483287

ANIMAL NUMBER: A37600 SEX: FEMALE DOSE GROUP: 7 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/14/91 STUDY DAY OF DEATH: 98 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 22.0 GRAMS
DATE AND TIME OF NECROPSY: 11/14/91 9:30 PROSECTOR: SONNY DIKES RECORDER: SONNY DIKES
POST-FIX WEIGHER: JANE EARNHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
MAND SALIVARY GL (SG)	.10	.462 %	.197	WEIGHT TAKEN
LUNG (LU)	.15	.701 %	.298	WEIGHT TAKEN
UTERUS (UT)	.07	.315 %	.134	WEIGHT TAKEN
BRAIN W/STEM (BR)	.52	2.352 %	1.000	WEIGHT TAKEN
HEART (HT)	.14	.619 %	.263	WEIGHT TAKEN
SPLEEN (SP)	.07	.298 %	.127	WEIGHT TAKEN
KIDNEY (KD)	.29	1.327 %	.564	WEIGHT TAKEN
LIVER/GALLBLADD (LL)	2.73	12.402 %	5.272	WEIGHT TAKEN
ADRENAL (AD)	.011	.0486 %	.0207	WEIGHT TAKEN
OVARY (OV)	.024	.1105 %	.0470	WEIGHT TAKEN
THYMUS (TH)	.04	.185 %	.078	WEIGHT TAKEN

CLINICAL OBSERVATIONS

-LAST PHYSICAL EXAM: DISTAL TAIL-SORES

PATHOLOGY OBSERVATIONS
NECROPSY

LIVER (LI) :
-PALE AREA; ALL LOBES, SEVERAL, TAN,
PINPOINT
-ENLARGED, MODERATE; ALL LOBES
-DARK; ALL LOBES, DARK BROWN

HISTOPATHOLOGY

CECUM (CE) :
-HYPERPLASIA, LYMPHOID, -PRESENT
HEART (HT) :
-INFLAMMATION, CHRONIC, -MINIMAL
ILEUM (IL) :
-AMYLOIDOSIS, -SEVERE
JEJUNUM (JE) :
-AMYLOIDOSIS, -SLIGHT
KIDNEY (KD) :
-HYPERPLASIA, LYMPHOID, -MINIMAL
LACRIMAL GL, EX (EO) :
-UNILATERALLY EXAMINED, -PRESENT
LIVER (LI) :
-HEPATOCTE, HYPERTROPHY,
CENTROLOBULAR, -MODERATE
-VACUOLIZATION, -MINIMAL
-PIGMENT, BILE, -SLIGHT
-KUPFFER CELL/MACROPHAGE, PIGMENT, -
MINIMAL

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APPENDIX 13B

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 976

STUDY NUMBER: 483287

ANIMAL NUMBER: A37600 SEX: FEMALE DOSE GROUP: 7 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/14/91 STUDY DAY OF DEATH: 98 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 22.0 GRAMS
DATE AND TIME OF NECROPSY: 11/14/91 9:30 PROSECTOR: SONNY DIKES RECORDER: SONNY DIKES
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

CLINICAL OBSERVATIONS	P A T H O L O G Y O B S E R V A T I O N S (CONTINUED) NECROPSY	HISTOPATHOLOGY
		LIVER (LI) : -HEPATOCYTE, PIGMENT, -MODERATE -NECROSIS, INDIVIDUAL CELL, -MINIMAL -BILE DUCT, INFLAMMATION, CHRONIC, -MINIMAL LN, MANDIBULAR (MN) : -MACROPHAGES, PIGMENTED, -MINIMAL LN, MESENTERIC (MS) : -MACROPHAGES, PIGMENTED, -MINIMAL -AMYLOIDOSIS, -SLIGHT LUNG (LU) : -PERIBRONCHIAL/PERIVASCULAR, INFILTRATION, LYMPHOID, -MINIMAL MAMMARY, FEMALE (MF) : -DILATATION, CYSTIC, -MINIMAL -HYPOPLASIA, EPITHELIAL, -PRESENT PARATHYROID (PT) : -UNILATERALLY EXAMINED, -PRESENT SKIN, OTHER (SS) : -DERMATITIS, ULCERATIVE, -PRESENT SPLEEN (SP) : -EXTRAMEDULLARY HEMATOPOIESIS, INCREASED, -SLIGHT -PIGMENT, -MINIMAL STOMACH, GL (ST) : -INFLAMMATION, CHRONIC, -MINIMAL UTERUS (UT) : -HYPOPLASIA, -MODERATELY SEVERE UTERUS, CERVIX (CV) : -HYPOPLASIA, -SEVERE VAGINA (VA) : -HYPOPLASIA, -PRESENT
	SKIN, OTHER (SS) : -TAIL, SORE; DISTAL PORTION, FEW, CRUSTY, RED, PINPOINT TO 3 X 3 MM	

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13B
13-WEEK SUBCHRONIC ORAL TOXICITY STUDY OF TRICLOSAN IN CD-1
MICE. (MAIN-GROUPS 1-7)
INDIVIDUAL ANIMAL SUMMARY REPORT

PRINTED: 21-JAN-93
PAGE: 977

STUDY NUMBER: 483287

ANIMAL NUMBER: A37600 SEX: FEMALE DOSE GROUP: 7 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 11/14/91 STUDY DAY OF DEATH: 98 STUDY WEEK OF DEATH: 14 TERMINAL BODY WEIGHT: 22.0 GRAMS
DATE AND TIME OF NECROPSY: 11/14/91 9:30 PROSECTOR: SONNY DIKES RECORDER: SONNY DIKES
POST-FIX WEIGHER: JANE EARHARDT PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

CLINICAL OBSERVATIONS P A T H O L O G Y O B S E R V A T I O N S (CONTINUED)
NECROPSY HISTOPATHOLOGY

^COLLECTED/TAKEN (XW) :
-LIVER SECTIONS, IN METHANOL

^DEATH COMMENT (DC) :
-SCHEDULED SACRIFICE, -PRESENT

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

ADRENAL, CORTX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, OTHER (OB),
BRAIN W/STEM (BR), CECUM (CE), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC),
DUODENUM (DU), ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HEART (HT), ILEUM (IL), JEJUNUM (JE), KIDNEY (KD),
LACRIMAL GL, EX (EO), LN, MANDIBULAR (MN), LN, MESENTERIC (MS), LUNG (LU), MAMMARY, FEMALE (MF), MAND SALIVARY GL (SG),
MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON), NERVE, SCIATIC (SN),
OVARY (OV), PANCREAS (PA), PARATHYROID (PT), PITUITARY (PI), RECTUM (RE), SKIN (SK), SPLEEN (SP), STOMACH, GL (ST),
STOMACH, NONGL (SU), THYMUS (TH), THYROID (TY), TONGUE (TO), TRACHEA (TR), URINARY BLADDER (UB), UTERUS (UT),
UTERUS, CERVIX (CV), VAGINA (VA)

THE FOLLOWING TISSUES WERE UNREMARKABLE AT MICROSCOPIC EXAMINATION:

ADRENAL, CORTX (AC), ADRENAL, MEDULLA (AM), AORTA, THORACIC (AO), BONE, FEMUR (FE), BONE, STERNUM (SB),
BRAIN W/STEM (BR), COLON (CO), CORD, CERVICAL (CS), CORD, LUMBAR (LC), CORD, THORACIC (TC), DUODENUM (DU),
ESOPHAGUS (ES), EYE (EY), GALLBLADDER (GB), HARDERIAN GLAND (HG), HEMATO NEOPLASIA (HN), MAND SALIVARY GL (SG),
MARROW, FEMUR (FM), MARROW, STERNUM (SE), MUSCLE, ABDOM (MA), MUSCLE, SKELETAL (SM), NERVE, OPTIC (ON),
NERVE, SCIATIC (SN), OVARY (OV), OVIDUCT (OD), PANCREAS (PA), PITUITARY (PI), RECTUM (RE), SALIVARY, OTHER (OS),
SKIN (SK), STOMACH, NONGL (SU), THYMUS (TH), THYROID (TY), TONGUE (TO), TRACHEA (TR), URINARY BLADDER (UB)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

Appendix 13C
Individual Animal Necropsy Data Sheet - Satellite Study
(Interim Sacrifice)
13-Week Subchronic Oral Toxicity Study of Triclosan in CD-1[®] Mice

NOTE: Animals with a sacrifice status of "P" do not have any gross observations, etc. as these animals were used for pre-study clinical pathology.

Standard Key to Individual Animal Necropsy Data Sheet

ORGAN WEIGHING STATUSES

NOT TAKEN = Organ Weight Not Taken; No Explanation Given
MISSING = Organ Missing Or Lost
UNSUITABLE = Organ Technically Unsuitable For Weighing
AUTOLYTIC = Organ Autolytic And Could Not Be Weighed
EXCLUDE = Weight Has Been Taken, But Will Be Excluded From All Calculations

OTHER SYMBOLS AND NOTATIONSLOCATIONS OF TISSUE MASSES
OBSERVED GROSSLY

DFL = Dorsal-Front-Left
DFR = Dorsal-Front-Right
DHL = Dorsal-Hind-Left
DHR = Dorsal-Hind-Right
DFM = Dorsal-Front-Mid
DHM = Dorsal-Hind-Mid
VFL = Ventral-Front-Left
VFR = Ventral-Front-Right
VHL = Ventral-Hind-Left
VHR = Ventral-Hind-Right
VFM = Ventral-Front-Mid
VHM = Ventral-Hind-Mid

SYMBOLS PREFACING NEOPLASTIC FINDINGS

B- = Primary, Benign Neoplasm
M- = Primary, Malignant Neoplasm
N- = Metastatic Neoplasm
I- = Locally Invasive Neoplasm
X- = Other Neoplasm

HAZLETON WASHINGTON, INC.
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APPENDIX 13C

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY IN TRICLOSAN IN CD-1
MICE. (SATELLITE-GROUPS 8-11)

PRINTED: 21-JAN-93
PAGE: 980

DRAFT INDIVIDUAL ANIMAL NECROPSY DATA SHEET *DRAFT*

STUDY NUMBER: 483287

ANIMAL NUMBER: A37601 SEX: MALE DOSE GROUP: 1 SACRIFICE STATUS: SCHEDULED, FIRST INTERIM SACRIFICE
DATE OF DEATH: 09/23/91 STUDY DAY OF DEATH: 46 STUDY WEEK OF DEATH: 7 TERMINAL BODY WEIGHT: 24.9 GRAMS
DATE AND TIME OF NECROPSY: 09/23/91 8:58 PROSECTOR: SCOTT BELL RECORDER: SCOTT BELL
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
LIVER/GALLBLADD (LI)	1.10	4.407 %	-----	WEIGHT TAKEN

*** GROSS PATHOLOGY OBSERVATIONS ***
ORGAN NAME SEVERITY, KEYWORD(S) OR PHRASE FREE-TEXT COMMENTS AND NOTES

^COLLECTED/TAKEN (KW)

-LIVER, IN 100% MEOH

GENERAL INFORMATION

ADDITIONAL NECROPSY COMMENT: >LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), LIVER (LI), SKIN, OTHER (SS), STOMACH, GL (ST)

*** NO ORGANS/TISSUES WERE RECORDED AS HAVING BEEN SAVED ***

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APPENDIX 13C

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY IN TRICLOSAN IN CD-1
MICE. (SATELLITE-GROUPS 8-11)

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DRAFT INDIVIDUAL ANIMAL NECROPSY DATA SHEET *DRAFT*

STUDY NUMBER: 483287

ANIMAL NUMBER: A37602 SEX: MALE DOSE GROUP: 1 SACRIFICE STATUS: SCHEDULED, FIRST INTERIM SACRIFICE
DATE OF DEATH: 09/23/91 STUDY DAY OF DEATH: 46 STUDY WEEK OF DEATH: 7 TERMINAL BODY WEIGHT: 25.3 GRAMS
DATE AND TIME OF NECROPSY: 09/23/91 9:28 PROSECTOR: FRED AGEY RECORDER: FRED AGEY
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
LIVER/GALLBLADD (LI)	1.28	5.064 %		WEIGHT TAKEN

*** GROSS PATHOLOGY OBSERVATIONS ***

ORGAN NAME	SEVERITY, KEYWORD(S) OR PHRASE	FREE-TEXT COMMENTS AND NOTES
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^COLLECTED/TAKEN (XW)

-LIVER, IN 100% MEQH

GENERAL INFORMATION

ADDITIONAL NECROPSY COMMENT: >LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), LIVER (LI), SKIN, OTHER (SS), STOMACH, GL (ST)

*** NO ORGANS/TISSUES WERE RECORDED AS HAVING BEEN SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13C

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY IN TRICLOSAN IN CD-1
MICE. (SATELLITE-GROUPS 8-11)

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DRAFT INDIVIDUAL ANIMAL NECROPSY DATA SHEET *DRAFT*

STUDY NUMBER: 483287

ANIMAL NUMBER: A37603 SEX: MALE DOSE GROUP: 1 SACRIFICE STATUS: SCHEDULED, FIRST INTERIM SACRIFICE
DATE OF DEATH: 09/23/91 STUDY DAY OF DEATH: 46 STUDY WEEK OF DEATH: 7 TERMINAL BODY WEIGHT: 25.3 GRAMS
DATE AND TIME OF NECROPSY: 09/23/91 10:05 PROSECTOR: SCOTT BELL RECORDER: SCOTT BELL
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
LIVER/GALLBLADD (LI)	1.12	4.438 %	-----	WEIGHT TAKEN

ORGAN NAME	SEVERITY, KEYWORD(S) OR PHRASE	FREE-TEXT COMMENTS AND NOTES
LIVER (LI)	-PALE AREA	-LEFT LATERAL LOBE, ONE, TAN, 4 X 3 MM
^COLLECTED/TAKEN (XW)	-LIVER, IN 100% MEOH	
GENERAL INFORMATION	ADDITIONAL NECROPSY COMMENT: >LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS	

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), SKIN, OTHER (SS), STOMACH, GL (ST)

*** NO ORGANS/TISSUES WERE RECORDED AS HAVING BEEN SAVED ***

HAZLETON WASHINGTON, INC.
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APPENDIX 13C

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY IN TRICLOSAN IN CD-1
MICE. (SATELLITE-GROUPS 8-11)

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DRAFT INDIVIDUAL ANIMAL NECROPSY DATA SHEET *DRAFT*

STUDY NUMBER: 483287

ANIMAL NUMBER: A37604 SEX: MALE DOSE GROUP: 1 SACRIFICE STATUS: SCHEDULED, FIRST INTERIM SACRIFICE
DATE OF DEATH: 09/23/91 STUDY DAY OF DEATH: 46 STUDY WEEK OF DEATH: 7 TERMINAL BODY WEIGHT: 26.4 GRAMS
DATE AND TIME OF NECROPSY: 09/23/91 10:40 PROSECTOR: SCOTT BELL RECORDER: SCOTT BELL
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
LIVER/GALLBLADD (LI)	1.24	4.714 %	-----	WEIGHT TAKEN

*** GROSS PATHOLOGY OBSERVATIONS ***
ORGAN NAME SEVERITY, KEYWORD(S) OR PHRASE FREE-TEXT COMMENTS AND NOTES

COLLECTED/TAKEN (XW)

-LIVER, IN 100% MEOH

GENERAL INFORMATION

ADDITIONAL NECROPSY COMMENT: >LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), LIVER (LI), SKIN, OTHER (SS), STOMACH, GL (ST)

*** NO ORGANS/TISSUES WERE RECORDED AS HAVING BEEN SAVED ***

APPENDIX 13C

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY IN TRICLOSAN IN CD-1
MICE. (SATELLITE-GROUPS 8-11)

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DRAFT INDIVIDUAL ANIMAL NECROPSY DATA SHEET *DRAFT*

STUDY NUMBER: 483287

ANIMAL NUMBER: A37605 SEX: MALE DOSE GROUP: 1 SACRIFICE STATUS: SCHEDULED, FIRST INTERIM SACRIFICE
DATE OF DEATH: 09/23/91 STUDY DAY OF DEATH: 46 STUDY WEEK OF DEATH: 7 TERMINAL BODY WEIGHT: 25.5 GRAMS
DATE AND TIME OF NECROPSY: 09/23/91 11:09 PROSECTOR: DOUGLAS HERNDON RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
LIVER/GALLBLADD (LI)	1.20	4.722 %	-----	WEIGHT TAKEN

*** GROSS PATHOLOGY OBSERVATIONS ***
ORGAN NAME SEVERITY, KEYWORD(S) OR PHRASE FREE-TEXT COMMENTS AND NOTES

COLLECTED/TAKEN (XW)

-LIVER, IN 100% MEOH

GENERAL INFORMATION

ADDITIONAL NECROPSY COMMENT: >LAST PHYSICAL EXAM: NORMAL-NO REMARKABLE OBSERVATIONS

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), LIVER (LI), SKIN, OTHER (SS), STOMACH, GL (ST)

*** NO ORGANS/TISSUES WERE RECORDED AS HAVING BEEN SAVED ***

APPENDIX 13C

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.13-WEEK SUBCHRONIC ORAL TOXICITY STUDY IN TRICLOSAN IN CD-1
MICE. (SATELLITE-GROUPS 8-11)PRINTED: 21-JAN-93
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DRAFT INDIVIDUAL ANIMAL NECROPSY DATA SHEET *DRAFT*

STUDY NUMBER: 483287

ANIMAL NUMBER: A37606 SEX: MALE DOSE GROUP: 1 SACRIFICE STATUS: SCHEDULED, FIRST INTERIM SACRIFICE
DATE OF DEATH: 09/24/91 STUDY DAY OF DEATH: 47 STUDY WEEK OF DEATH: 7 TERMINAL BODY WEIGHT: 26.1 GRAMS
DATE AND TIME OF NECROPSY: 09/24/91 8:27 PROSECTOR: JANE EARHARDT RECORDER: JANE EARHARDT
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
LIVER/GALLBLADD (LI)	1.35	5.178 %		WEIGHT TAKEN

*** GROSS PATHOLOGY OBSERVATIONS ***
ORGAN NAME SEVERITY, KEYWORD(S) OR PHRASE FREE-TEXT COMMENTS AND NOTES

^COLLECTED/TAKEN (XW)

-LIVER, IN 100% MEQH

GENERAL INFORMATION

ADDITIONAL NECROPSY COMMENT: >LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), LIVER (LI), SKIN, OTHER (SS), STOMACH, GL (ST)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

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13-WEEK SUBCHRONIC ORAL TOXICITY STUDY IN TRICLOSAN IN CD-1
MICE. (SATELLITE-GROUPS 8-11)

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DRAFT INDIVIDUAL ANIMAL NECROPSY DATA SHEET *DRAFT*

STUDY NUMBER: 483287

ANIMAL NUMBER: A37607 SEX: MALE DOSE GROUP: 1 SACRIFICE STATUS: SCHEDULED, FIRST INTERIM SACRIFICE
DATE OF DEATH: 09/24/91 STUDY DAY OF DEATH: 47 STUDY WEEK OF DEATH: 7 TERMINAL BODY WEIGHT: 29.8 GRAMS
DATE AND TIME OF NECROPSY: 09/24/91 9:05 PROSECTOR: SCOTT BELL RECORDER: SCOTT BELL
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
LIVER/GALLBLADD (LI)	1.35	4.524 %	-----	WEIGHT TAKEN

*** GROSS PATHOLOGY OBSERVATIONS ***

ORGAN NAME	SEVERITY, KEYWORD(S) OR PHRASE	FREE-TEXT COMMENTS AND NOTES
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^COLLECTED/TAKEN (XW)

-LIVER, IN 100% MEOH

GENERAL INFORMATION

ADDITIONAL NECROPSY COMMENT: >LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), LIVER (LI), SKIN, OTHER (SS), STOMACH, GL (ST)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

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WASHINGTON, D.C. U.S.A.

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13-WEEK SUBCHRONIC ORAL TOXICITY STUDY IN TRICLOSAN IN CD-1
MICE. (SATELLITE-GROUPS 8-11)

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DRAFT INDIVIDUAL ANIMAL NECROPSY DATA SHEET *DRAFT*

STUDY NUMBER: 483287

ANIMAL NUMBER: A37608 SEX: MALE DOSE GROUP: 1 SACRIFICE STATUS: SCHEDULED, FIRST INTERIM SACRIFICE
DATE OF DEATH: 09/24/91 STUDY DAY OF DEATH: 47 STUDY WEEK OF DEATH: 7 TERMINAL BODY WEIGHT: 25.9 GRAMS
DATE AND TIME OF NECROPSY: 09/24/91 9:50 PROSECTOR: JANE EARHARDT RECORDER: JANE EARHARDT
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
LIVER/GALLBLADD (LI)	1.26	4.880 %	-----	WEIGHT TAKEN

ORGAN NAME	SEVERITY, KEYWORD(S) OR PHRASE	FREE-TEXT COMMENTS AND NOTES
SKIN, OTHER (SS)	-EAR, SORE	-RIGHT, FEW, CRUSTY, BROWN, PINPOINT TO 3 X 2 MM
^COLLECTED/TAKEN (XW)	-LIVER, IN 100% MEOH	
GENERAL INFORMATION	ADDITIONAL NECROPSY COMMENT: >HISTOLOGY REFERENCE:EAR-SORES, IN CUP	
	ADDITIONAL NECROPSY COMMENT: >LAST PHYSICAL EXAM:RIGHT EAR-SORES	

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), LIVER (LI), STOMACH, GL (ST)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13C

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY IN TRICLOSAN IN CD-1
MICE. (SATELLITE-GROUPS 8-11)
DRAFT INDIVIDUAL ANIMAL NECROPSY DATA SHEET *DRAFT*

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STUDY NUMBER: 483287

ANIMAL NUMBER: A37609 SEX: MALE DOSE GROUP: 1 SACRIFICE STATUS: SCHEDULED, FIRST INTERIM SACRIFICE
DATE OF DEATH: 09/24/91 STUDY DAY OF DEATH: 47 STUDY WEEK OF DEATH: 7 TERMINAL BODY WEIGHT: 26.6 GRAMS
DATE AND TIME OF NECROPSY: 09/24/91 10:27 PROSECTOR: ADEFOLAHAN AKINSOLA RECORDER: ADEFOLAHAN AKINSOLA
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
LIVER/GALLBLADD (LI)	1.25	4.712 %	-----	WEIGHT TAKEN

ORGAN NAME	SEVERITY, KEYWORD(S) OR PHRASE	FREE-TEXT COMMENTS AND NOTES
^COLLECTED/TAKEN (XW)	-LIVER, IN 100% MEOH	
GENERAL INFORMATION	ADDITIONAL NECROPSY COMMENT: >LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS	

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), LIVER (LI), SKIN, OTHER (SS), STOMACH, GL (ST)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

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13-WEEK SUBCHRONIC ORAL TOXICITY STUDY IN TRICLOSAN IN CD-1
MICE. (SATELLITE-GROUPS 8-11)
DRAFT INDIVIDUAL ANIMAL NECROPSY DATA SHEET *DRAFT*

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STUDY NUMBER: 483287

ANIMAL NUMBER: A37610 SEX: MALE DOSE GROUP: 1 SACRIFICE STATUS: SCHEDULED, FIRST INTERIM SACRIFICE
DATE OF DEATH: 09/24/91 STUDY DAY OF DEATH: 47 STUDY WEEK OF DEATH: 7 TERMINAL BODY WEIGHT: 27.2 GRAMS
DATE AND TIME OF NECROPSY: 09/24/91 10:54 PROSECTOR: FRED AGEY RECORDER: FRED AGEY
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
LIVER/GALLBLADD (LI)	1.22	4.469 %	-----	WEIGHT TAKEN

*** GROSS PATHOLOGY OBSERVATIONS ***
ORGAN NAME SEVERITY, KEYWORD(S) OR PHRASE FREE-TEXT COMMENTS AND NOTES

^COLLECTED/TAKEN (XW)

-LIVER, IN 100% MEOH

GENERAL INFORMATION

ADDITIONAL NECROPSY COMMENT: >LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), LIVER (LI), SKIN, OTHER (SS), STOMACH, GL (ST)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

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13-WEEK SUBCHRONIC ORAL TOXICITY STUDY IN TRICLOSAN IN CD-1
MICE. (SATELLITE-GROUPS 8-11)

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DRAFT INDIVIDUAL ANIMAL NECROPSY DATA SHEET *DRAFT*

STUDY NUMBER: 483287

ANIMAL NUMBER: A37611 SEX: MALE DOSE GROUP: 1 SACRIFICE STATUS: UNSCHEDULED (P)
DATE OF DEATH: 08/09/91 STUDY DAY OF DEATH: 1 STUDY WEEK OF DEATH: 1 TERMINAL BODY WEIGHT: 22.0 GRAMS
DATE AND TIME OF NECROPSY: 08/13/91 10:49 PROSECTOR: NOT AVAILABLE RECORDER: NOT AVAILABLE
POST-FIX WEIGHER: NOT AVAILABLE PATHOLOGIST: NOT AVAILABLE WEIGHER: NOT AVAILABLE

*** ANIMAL HAS NO ORGAN WEIGHTS RECORDED ***

*** ANIMAL HAS NO MACROSCOPIC OBSERVATIONS RECORDED ***

*** NO ORGANS/TISSUES WERE RECORDED AS HAVING BEEN SAVED ***

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13-WEEK SUBCHRONIC ORAL TOXICITY STUDY IN TRICLOSAN IN CD-1
MICE. (SATELLITE-GROUPS 8-11)
DRAFT INDIVIDUAL ANIMAL NECROPSY DATA SHEET *DRAFT*

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STUDY NUMBER: 483287

ANIMAL NUMBER: A37612 SEX: MALE DOSE GROUP: 1 SACRIFICE STATUS: UNSCHEDULED (P)
DATE OF DEATH: 08/09/91 STUDY DAY OF DEATH: 1 STUDY WEEK OF DEATH: 1 TERMINAL BODY WEIGHT: 25.0 GRAMS
DATE AND TIME OF NECROPSY: 08/13/91 10:50 PROSECTOR: NOT AVAILABLE RECORDER: NOT AVAILABLE
POST-FIX WEIGHER: NOT AVAILABLE PATHOLOGIST: NOT AVAILABLE WEIGHER: NOT AVAILABLE

*** ANIMAL HAS NO ORGAN WEIGHTS RECORDED ***

*** ANIMAL HAS NO MACROSCOPIC OBSERVATIONS RECORDED ***

*** NO ORGANS/TISSUES WERE RECORDED AS HAVING BEEN SAVED ***

APPENDIX 13C

HAZLETON WASHINGTON, INC.
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13-WEEK SUBCHRONIC ORAL TOXICITY STUDY IN TRICLOSAN IN CD-1
MICE. (SATELLITE-GROUPS 8-11)
DRAFT INDIVIDUAL ANIMAL NECROPSY DATA SHEET *DRAFT*

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STUDY NUMBER: 483287

ANIMAL NUMBER: A37613 SEX: MALE DOSE GROUP: 1 SACRIFICE STATUS: UNSCHEDULED (P)
DATE OF DEATH: 08/09/91 STUDY DAY OF DEATH: 1 STUDY WEEK OF DEATH: 1 TERMINAL BODY WEIGHT: 25.0 GRAMS
DATE AND TIME OF NECROPSY: 08/13/91 10:50 PROSECTOR: NOT AVAILABLE RECORDER: NOT AVAILABLE
POST-FIX WEIGHER: NOT AVAILABLE PATHOLOGIST: NOT AVAILABLE WEIGHER: NOT AVAILABLE

*** ANIMAL HAS NO ORGAN WEIGHTS RECORDED ***

*** ANIMAL HAS NO MACROSCOPIC OBSERVATIONS RECORDED ***

*** NO ORGANS/TISSUES WERE RECORDED AS HAVING BEEN SAVED ***

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13-WEEK SUBCHRONIC ORAL TOXICITY STUDY IN TRICLOSAN IN CD-1
MICE. (SATELLITE-GROUPS 8-11)

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DRAFT INDIVIDUAL ANIMAL NECROPSY DATA SHEET *DRAFT*

STUDY NUMBER: 483287

ANIMAL NUMBER: A37614 SEX: MALE DOSE GROUP: 1 SACRIFICE STATUS: UNSCHEDULED (P)
DATE OF DEATH: 08/09/91 STUDY DAY OF DEATH: 1 STUDY WEEK OF DEATH: 1 TERMINAL BODY WEIGHT: 23.0 GRAMS
DATE AND TIME OF NECROPSY: 08/13/91 10:51 PROSECTOR: NOT AVAILABLE RECORDER: NOT AVAILABLE
POST-FIX WEIGHER: NOT AVAILABLE PATHOLOGIST: NOT AVAILABLE WEIGHER: NOT AVAILABLE

*** ANIMAL HAS NO ORGAN WEIGHTS RECORDED ***

*** ANIMAL HAS NO MACROSCOPIC OBSERVATIONS RECORDED ***

*** NO ORGANS/TISSUES WERE RECORDED AS HAVING BEEN SAVED ***

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13-WEEK SUBCHRONIC ORAL TOXICITY STUDY IN TRICLOSAN IN CD-1
MICE. (SATELLITE-GROUPS 8-11)

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DRAFT INDIVIDUAL ANIMAL NECROPSY DATA SHEET *DRAFT*

STUDY NUMBER: 483287

ANIMAL NUMBER: A37615 SEX: MALE DOSE GROUP: 1 SACRIFICE STATUS: UNSCHEDULED (P)
DATE OF DEATH: 08/09/91 STUDY DAY OF DEATH: 1 STUDY WEEK OF DEATH: 1 TERMINAL BODY WEIGHT: 27.0 GRAMS
DATE AND TIME OF NECROPSY: 08/13/91 10:51 PROSECTOR: NOT AVAILABLE RECORDER: NOT AVAILABLE
POST-FIX WEIGHER: NOT AVAILABLE PATHOLOGIST: NOT AVAILABLE WEIGHER: NOT AVAILABLE

*** ANIMAL HAS NO ORGAN WEIGHTS RECORDED ***

*** ANIMAL HAS NO MACROSCOPIC OBSERVATIONS RECORDED ***

*** NO ORGANS/TISSUES WERE RECORDED AS HAVING BEEN SAVED ***

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13-WEEK SUBCHRONIC ORAL TOXICITY STUDY IN TRICLOSAN IN CD-1
MICE. (SATELLITE-GROUPS 8-11)

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DRAFT INDIVIDUAL ANIMAL NECROPSY DATA SHEET *DRAFT*

STUDY NUMBER: 483287

ANIMAL NUMBER: A37616 SEX: MALE DOSE GROUP: 1 SACRIFICE STATUS: UNSCHEDULED (P)
DATE OF DEATH: 08/09/91 STUDY DAY OF DEATH: 1 STUDY WEEK OF DEATH: 1 TERMINAL BODY WEIGHT: 26.0 GRAMS
DATE AND TIME OF NECROPSY: 08/13/91 10:52 PROSECTOR: NOT AVAILABLE RECORDER: NOT AVAILABLE
POST-FIX WEIGHER: NOT AVAILABLE PATHOLOGIST: NOT AVAILABLE WEIGHER: NOT AVAILABLE

*** ANIMAL HAS NO ORGAN WEIGHTS RECORDED ***

*** ANIMAL HAS NO MACROSCOPIC OBSERVATIONS RECORDED ***

*** NO ORGANS/TISSUES WERE RECORDED AS HAVING BEEN SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13C

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY IN TRICLOSAN IN CD-1
MICE. (SATELLITE-GROUPS 8-11)

PRINTED: 21-JAN-93
PAGE: 996

DRAFT INDIVIDUAL ANIMAL NECROPSY DATA SHEET *DRAFT*

STUDY NUMBER: 483287

ANIMAL NUMBER: A37617 SEX: MALE DOSE GROUP: 1 SACRIFICE STATUS: UNSCHEDULED (P)
DATE OF DEATH: 08/09/91 STUDY DAY OF DEATH: 1 STUDY WEEK OF DEATH: 1 TERMINAL BODY WEIGHT: 27.0 GRAMS
DATE AND TIME OF NECROPSY: 08/13/91 10:52 PROSECTOR: NOT AVAILABLE RECORDER: NOT AVAILABLE
POST-FIX WEIGHER: NOT AVAILABLE PATHOLOGIST: NOT AVAILABLE WEIGHER: NOT AVAILABLE

*** ANIMAL HAS NO ORGAN WEIGHTS RECORDED ***

*** ANIMAL HAS NO MACROSCOPIC OBSERVATIONS RECORDED ***

*** NO ORGANS/TISSUES WERE RECORDED AS HAVING BEEN SAVED ***

APPENDIX 13C

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY IN TRICLOSAN IN CD-1
MICE. (SATELLITE-GROUPS 8-11)

PRINTED: 21-JAN-93
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DRAFT INDIVIDUAL ANIMAL NECROPSY DATA SHEET *DRAFT*

STUDY NUMBER: 483287

ANIMAL NUMBER: A37618 SEX: MALE DOSE GROUP: 1 SACRIFICE STATUS: UNSCHEDULED (P)
DATE OF DEATH: 08/09/91 STUDY DAY OF DEATH: 1 STUDY WEEK OF DEATH: 1 TERMINAL BODY WEIGHT: 25.0 GRAMS
DATE AND TIME OF NECROPSY: 08/13/91 10:52 PROSECTOR: NOT AVAILABLE RECORDER: NOT AVAILABLE
POST-FIX WEIGHER: NOT AVAILABLE PATHOLOGIST: NOT AVAILABLE WEIGHER: NOT AVAILABLE

*** ANIMAL HAS NO ORGAN WEIGHTS RECORDED ***

*** ANIMAL HAS NO MACROSCOPIC OBSERVATIONS RECORDED ***

*** NO ORGANS/TISSUES WERE RECORDED AS HAVING BEEN SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13C

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY IN TRICLOSAN IN CD-1
MICE. (SATELLITE-GROUPS 8-11)

PRINTED: 21-JAN-93
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DRAFT INDIVIDUAL ANIMAL NECROPSY DATA SHEET *DRAFT*

STUDY NUMBER: 483287

ANIMAL NUMBER: A37619 SEX: MALE DOSE GROUP: 1 SACRIFICE STATUS: UNSCHEDULED (P)
DATE OF DEATH: 08/09/91 STUDY DAY OF DEATH: 1 STUDY WEEK OF DEATH: 1 TERMINAL BODY WEIGHT: 27.0 GRAMS
DATE AND TIME OF NECROPSY: 08/13/91 10:53 PROSECTOR: NOT AVAILABLE RECORDER: NOT AVAILABLE
POST-FIX WEIGHER: NOT AVAILABLE PATHOLOGIST: NOT AVAILABLE WEIGHER: NOT AVAILABLE

*** ANIMAL HAS NO ORGAN WEIGHTS RECORDED ***

*** ANIMAL HAS NO MACROSCOPIC OBSERVATIONS RECORDED ***

*** NO ORGANS/TISSUES WERE RECORDED AS HAVING BEEN SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13C

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY IN TRICLOSAN IN CD-1
MICE. (SATELLITE-GROUPS 8-11)
DRAFT INDIVIDUAL ANIMAL NECROPSY DATA SHEET *DRAFT*

PRINTED: 21-JAN-93
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STUDY NUMBER: 483287

ANIMAL NUMBER: A37620 SEX: MALE DOSE GROUP: 1 SACRIFICE STATUS: UNSCHEDULED (P)
DATE OF DEATH: 08/09/91 STUDY DAY OF DEATH: 1 STUDY WEEK OF DEATH: 1 TERMINAL BODY WEIGHT: 25.0 GRAMS
DATE AND TIME OF NECROPSY: 08/13/91 10:53 PROSECTOR: NOT AVAILABLE RECORDER: NOT AVAILABLE
POST-FIX WEIGHER: NOT AVAILABLE PATHOLOGIST: NOT AVAILABLE WEIGHER: NOT AVAILABLE

*** ANIMAL HAS NO ORGAN WEIGHTS RECORDED ***

*** ANIMAL HAS NO MACROSCOPIC OBSERVATIONS RECORDED ***

*** NO ORGANS/ISSUES WERE RECORDED AS HAVING BEEN SAVED ***

APPENDIX 13C

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.13-WEEK SUBCHRONIC ORAL TOXICITY STUDY IN TRICLOSAN IN CD-1
MICE. (SATELLITE-GROUPS 8-11)PRINTED: 21-JAN-93
PAGE: 1000

DRAFT INDIVIDUAL ANIMAL NECROPSY DATA SHEET *DRAFT*

STUDY NUMBER: 483287

ANIMAL NUMBER: A37641 SEX: MALE DOSE GROUP: 2 SACRIFICE STATUS: SCHEDULED, FIRST INTERIM SACRIFICE
 DATE OF DEATH: 09/23/91 STUDY DAY OF DEATH: 46 STUDY WEEK OF DEATH: 7 TERMINAL BODY WEIGHT: 26.5 GRAMS
 DATE AND TIME OF NECROPSY: 09/23/91 8:47 PROSECTOR: DOUGLAS HERNDON RECORDER: JOHN CROWLEY
 POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
LIVER/GALLBLADD (LI)	1.39	5.236 %	-----	WEIGHT TAKEN

*** GROSS PATHOLOGY OBSERVATIONS ***

ORGAN NAME	SEVERITY, KEYWORD(S) OR PHRASE	FREE-TEXT COMMENTS AND NOTES
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^COLLECTED/TAKEN (XW)

-LIVER, IN 100% MEQH

GENERAL INFORMATION

ADDITIONAL NECROPSY COMMENT: >LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
 KIDNEY (KD), LIVER (LI), SKIN, OTHER (SS), STOMACH, GL (ST)

*** NO ORGANS/TISSUES WERE RECORDED AS HAVING BEEN SAVED ***

APPENDIX 13C

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.13-WEEK SUBCHRONIC ORAL TOXICITY STUDY IN TRICLOSAN IN CD-1
MICE. (SATELLITE-GROUPS 8-11)PRINTED: 21-JAN-93
PAGE: 1001

DRAFT INDIVIDUAL ANIMAL NECROPSY DATA SHEET *DRAFT*

STUDY NUMBER: 483287

ANIMAL NUMBER: A37642 SEX: MALE DOSE GROUP: 2 SACRIFICE STATUS: SCHEDULED, FIRST INTERIM SACRIFICE
DATE OF DEATH: 09/23/91 STUDY DAY OF DEATH: 46 STUDY WEEK OF DEATH: 7 TERMINAL BODY WEIGHT: 25.2 GRAMS
DATE AND TIME OF NECROPSY: 09/23/91 9:37 PROSECTOR: SCOTT BELL RECORDER: SCOTT BELL
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
LIVER/GALLBLADD (LI)	1.22	4.840 %	-----	WEIGHT TAKEN

*** GROSS PATHOLOGY OBSERVATIONS ***
ORGAN NAME SEVERITY, KEYWORD(S) OR PHRASE FREE-TEXT COMMENTS AND NOTES

^COLLECTED/TAKEN (XW)

-LIVER, IN 100% MEQH

GENERAL INFORMATION

ADDITIONAL NECROPSY COMMENT: >LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), LIVER (LI), SKIN, OTHER (SS), STOMACH, GL (ST)

*** NO ORGANS/TISSUES WERE RECORDED AS HAVING BEEN SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13C

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY IN TRICLOSAN IN CD-1
MICE. (SATELLITE-GROUPS 8-11)

PRINTED: 21-JAN-93
PAGE: 1002

DRAFT INDIVIDUAL ANIMAL NECROPSY DATA SHEET *DRAFT*

STUDY NUMBER: 483287

ANIMAL NUMBER: A37643 SEX: MALE DOSE GROUP: 2 SACRIFICE STATUS: SCHEDULED, FIRST INTERIM SACRIFICE
DATE OF DEATH: 09/23/91 STUDY DAY OF DEATH: 46 STUDY WEEK OF DEATH: 7 TERMINAL BODY WEIGHT: 24.1 GRAMS
DATE AND TIME OF NECROPSY: 09/23/91 10:04 PROSECTOR: DOUGLAS HERNDON RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
LIVER/GALLBLADD (LI)	1.30	5.406 %	-----	WEIGHT TAKEN

*** GROSS PATHOLOGY OBSERVATIONS ***

ORGAN NAME	SEVERITY, KEYWORD(S) OR PHRASE	FREE-TEXT COMMENTS AND NOTES
^COLLECTED/TAKEN (XW)	-LIVER, IN 100% MEOH	
GENERAL INFORMATION	ADDITIONAL NECROPSY COMMENT: >LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS	

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), LIVER (LI), SKIN, OTHER (SS), STOMACH, GL (ST)

*** NO ORGANS/TISSUES WERE RECORDED AS HAVING BEEN SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13C

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY IN TRICLOSAN IN CD-1
MICE. (SATELLITE-GROUPS 8-11)

PRINTED: 21-JAN-93
PAGE: 1003

DRAFT INDIVIDUAL ANIMAL NECROPSY DATA SHEET *DRAFT*

STUDY NUMBER: 483287

ANIMAL NUMBER: A37644 SEX: MALE DOSE GROUP: 2 SACRIFICE STATUS: SCHEDULED, FIRST INTERIM SACRIFICE
DATE OF DEATH: 09/23/91 STUDY DAY OF DEATH: 46 STUDY WEEK OF DEATH: 7 TERMINAL BODY WEIGHT: 28.8 GRAMS
DATE AND TIME OF NECROPSY: 09/23/91 10:38 PROSECTOR: FRED AGEY RECORDER: FRED AGEY
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
LIVER/GALLBLADD (LI)	1.58	5.470 %	-----	WEIGHT TAKEN

*** GROSS PATHOLOGY OBSERVATIONS ***

ORGAN NAME	SEVERITY, KEYWORD(S) OR PHRASE	FREE-TEXT COMMENTS AND NOTES
COLLECTED/TAKEN (XW)	-LIVER, IN 100% MEQH	
GENERAL INFORMATION		
	ADDITIONAL NECROPSY COMMENT:	>LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), LIVER (LI), SKIN, OTHER (SS), STOMACH, GL (ST)

*** NO ORGANS/TISSUES WERE RECORDED AS HAVING BEEN SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13C

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY IN TRICLOSAN IN CD-1
MICE. (SATELLITE-GROUPS 8-11)

PRINTED: 21-JAN-93
PAGE: 1004

DRAFT INDIVIDUAL ANIMAL NECROPSY DATA SHEET *DRAFT*

STUDY NUMBER: 483287

ANIMAL NUMBER: A37645 SEX: MALE DOSE GROUP: 2 SACRIFICE STATUS: SCHEDULED, FIRST INTERIM SACRIFICE
DATE OF DEATH: 09/23/91 STUDY DAY OF DEATH: 46 STUDY WEEK OF DEATH: 7 TERMINAL BODY WEIGHT: 22.2 GRAMS
DATE AND TIME OF NECROPSY: 09/23/91 11:18 PROSECTOR: FRED AGEY RECORDER: FRED AGEY
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
LIVER/GALLBLADD (LI)	1.59	7.166 %	-----	WEIGHT TAKEN

ORGAN NAME	SEVERITY, KEYWORD(S) OR PHRASE	FREE-TEXT COMMENTS AND NOTES
^COLLECTED/TAKEN (XW)	-LIVER, IN 100% MEQH	
GENERAL INFORMATION	ADDITIONAL NECROPSY COMMENT: >LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS	

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), LIVER (LI), SKIN, OTHER (SS), STOMACH, GL (ST)

*** NO ORGANS/TISSUES WERE RECORDED AS HAVING BEEN SAVED ***

APPENDIX 13C

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY IN TRICLOSAN IN CD-1
MICE. (SATELLITE-GROUPS 8-11)

PRINTED: 21-JAN-93
PAGE: 1005

DRAFT INDIVIDUAL ANIMAL NECROPSY DATA SHEET *DRAFT*

STUDY NUMBER: 483287

ANIMAL NUMBER: A37646 SEX: MALE DOSE GROUP: 2 SACRIFICE STATUS: SCHEDULED, FIRST INTERIM SACRIFICE
DATE OF DEATH: 09/24/91 STUDY DAY OF DEATH: 47 STUDY WEEK OF DEATH: 7 TERMINAL BODY WEIGHT: 27.1 GRAMS
DATE AND TIME OF NECROPSY: 09/24/91 8:30 PROSECTOR: SCOTT BELL RECORDER: SCOTT BELL
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
LIVER/GALLBLADD (LI)	1.26	4.661 %	-----	WEIGHT TAKEN

*** GROSS PATHOLOGY OBSERVATIONS ***

ORGAN NAME	SEVERITY, KEYWORD(S) OR PHRASE	FREE-TEXT COMMENTS AND NOTES
^COLLECTED/TAKEN (XW)	-LIVER, IN 100% MEON	
GENERAL INFORMATION	ADDITIONAL NECROPSY COMMENT: >LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS	

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), LIVER (LI), SKIN, OTHER (SS), STOMACH, GL (ST)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

APPENDIX 13C

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.13-WEEK SUBCHRONIC ORAL TOXICITY STUDY IN TRICLOSAN IN CD-1
MICE. (SATELLITE-GROUPS 8-11)PRINTED: 21-JAN-93
PAGE: 1006

DRAFT INDIVIDUAL ANIMAL NECROPSY DATA SHEET *DRAFT*

STUDY NUMBER: 483287

ANIMAL NUMBER: A37647 SEX: MALE DOSE GROUP: 2 SACRIFICE STATUS: SCHEDULED, FIRST INTERIM SACRIFICE
DATE OF DEATH: 09/24/91 STUDY DAY OF DEATH: 47 STUDY WEEK OF DEATH: 7 TERMINAL BODY WEIGHT: 25.4 GRAMS
DATE AND TIME OF NECROPSY: 09/24/91 9:04 PROSECTOR: JANE EARHARDT RECORDER: JANE EARHARDT
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
LIVER/GALLBLADD (LI)	1.12	4.428 %	-----	WEIGHT TAKEN

*** GROSS PATHOLOGY OBSERVATIONS ***
ORGAN NAME SEVERITY, KEYWORD(S) OR PHRASE FREE-TEXT COMMENTS AND NOTES

^COLLECTED/TAKEN (XW)

-LIVER, IN 100% MEQH

GENERAL INFORMATION

ADDITIONAL NECROPSY COMMENT: >LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), LIVER (LI), SKIN, OTHER (SS), STOMACH, GL (ST)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13C

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY IN TRICLOSAN IN CD-1
MICE. (SATELLITE-GROUPS 8-11)

PRINTED: 21-JAN-93
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DRAFT INDIVIDUAL ANIMAL NECROPSY DATA SHEET *DRAFT*

STUDY NUMBER: 483287

ANIMAL NUMBER: A37648 SEX: MALE DOSE GROUP: 2 SACRIFICE STATUS: SCHEDULED, FIRST INTERIM SACRIFICE
DATE OF DEATH: 09/24/91 STUDY DAY OF DEATH: 47 STUDY WEEK OF DEATH: 7 TERMINAL BODY WEIGHT: 26.6 GRAMS
DATE AND TIME OF NECROPSY: 09/24/91 9:55 PROSECTOR: ADEFOLAHAN AKINSOLA RECORDER: ADEFOLAHAN AKINSOLA
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
LIVER/GALLBLADD (LI)	1.35	5.092 %	-----	WEIGHT TAKEN

*** GROSS PATHOLOGY OBSERVATIONS ***

ORGAN NAME	SEVERITY, KEYWORD(S) OR PHRASE	FREE-TEXT COMMENTS AND NOTES
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^COLLECTED/TAKEN (XW)		
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GENERAL INFORMATION	-LIVER, IN 100% MEQH	
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ADDITIONAL NECROPSY COMMENT: >LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), LIVER (LI), SKIN, OTHER (SS), STOMACH, GL (ST)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13C

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY IN TRICLOSAN IN CD-1
MICE. (SATELLITE-GROUPS 8-11)

PRINTED: 21-JAN-93
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DRAFT INDIVIDUAL ANIMAL NECROPSY DATA SHEET *DRAFT*

STUDY NUMBER: 483287

ANIMAL NUMBER: A37649 SEX: MALE DOSE GROUP: 2 SACRIFICE STATUS: SCHEDULED, FIRST INTERIM SACRIFICE
DATE OF DEATH: 09/24/91 STUDY DAY OF DEATH: 47 STUDY WEEK OF DEATH: 7 TERMINAL BODY WEIGHT: 27.0 GRAMS
DATE AND TIME OF NECROPSY: 09/24/91 10:24 PROSECTOR: JANE EARHARDT RECORDER: JANE EARHARDT
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
LIVER/GALLBLADD (LI)	1.37	5.083 %	-----	WEIGHT TAKEN

ORGAN NAME	SEVERITY, KEYWORD(S) OR PHRASE	FREE-TEXT COMMENTS AND NOTES
^COLLECTED/TAKEN (XW)	LIVER, IN 100% MEQH	
GENERAL INFORMATION	ADDITIONAL NECROPSY COMMENT: >LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS	

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), LIVER (LI), SKIN, OTHER (SS), STOMACH, GL (ST)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13C

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY IN TRICLOSAN IN CD-1
MICE. (SATELLITE-GROUPS 8-11)

PRINTED: 21-JAN-93
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DRAFT INDIVIDUAL ANIMAL NECROPSY DATA SHEET *DRAFT*

STUDY NUMBER: 483287

ANIMAL NUMBER: A37650 SEX: MALE DOSE GROUP: 2 SACRIFICE STATUS: SCHEDULED, FIRST INTERIM SACRIFICE
DATE OF DEATH: 09/24/91 STUDY DAY OF DEATH: 47 STUDY WEEK OF DEATH: 7 TERMINAL BODY WEIGHT: 26.4 GRAMS
DATE AND TIME OF NECROPSY: 09/24/91 11:00 PROSECTOR: ADEFOLAHAN AKINSOLA RECORDER: ADEFOLAHAN AKINSOLA
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
LIVER/GALLBLADD (LI)	1.37	5.188 %		WEIGHT TAKEN

*** GROSS PATHOLOGY OBSERVATIONS ***

ORGAN NAME	SEVERITY, KEYWORD(S) OR PHRASE	FREE-TEXT COMMENTS AND NOTES
^COLLECTED/TAKEN (XW)		
GENERAL INFORMATION	-LIVER, IN 100% MEQH	
	ADDITIONAL NECROPSY COMMENT: >LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS	

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), LIVER (LI), SKIN, OTHER (SS), STOMACH, GL (ST)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

APPENDIX 13C

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.13-WEEK SUBCHRONIC ORAL TOXICITY STUDY IN TRICLOSAN IN CD-1
MICE. (SATELLITE-GROUPS 8-11)PRINTED: 21-JAN-93
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DRAFT INDIVIDUAL ANIMAL NECROPSY DATA SHEET *DRAFT*

STUDY NUMBER: 483287

ANIMAL NUMBER: A37661 SEX: MALE DOSE GROUP: 3 SACRIFICE STATUS: SCHEDULED, FIRST INTERIM SACRIFICE
 DATE OF DEATH: 09/23/91 STUDY DAY OF DEATH: 46 STUDY WEEK OF DEATH: 7 TERMINAL BODY WEIGHT: 27.0 GRAMS
 DATE AND TIME OF NECROPSY: 09/23/91 8:58 PROSECTOR: ADEFOLAHAN AKINSOLA RECORDER: JOHN CROWLEY
 POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
LIVER/GALLBLADD (LI)	2.45	9.078 %	-----	WEIGHT TAKEN

ORGAN NAME	SEVERITY, KEYWORD(S) OR PHRASE	FREE-TEXT COMMENTS AND NOTES
LIVER (LI)	-PALE AREA	-LEFT LATERAL LOBE, ONE, TAN, WHITE, 3 X 3 MM
SKIN, OTHER (SS)	-EAR, SORE	-LEFT, ONE, CRUSTY, TAN, RED, 2 X 2 MM
COLLECTED/TAKEN (XW)	-LIVER, IN 100% MEQH	
GENERAL INFORMATION	ADDITIONAL NECROPSY COMMENT: >HISTOLOGY REFERENCE: SORES, IN CUP ADDITIONAL NECROPSY COMMENT: >LAST PHYSICAL EXAM: LEFT EAR-SORES	

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
 KIDNEY (KD), STOMACH, GL (ST)

*** NO ORGANS/TISSUES WERE RECORDED AS HAVING BEEN SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13C

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY IN TRICLOSAN IN CD-1
MICE. (SATELLITE-GROUPS 8-11)

PRINTED: 21-JAN-93
PAGE: 1011

DRAFT INDIVIDUAL ANIMAL NECROPSY DATA SHEET *DRAFT*

STUDY NUMBER: 483287

ANIMAL NUMBER: A37662 SEX: MALE DOSE GROUP: 3 SACRIFICE STATUS: SCHEDULED, FIRST INTERIM SACRIFICE
DATE OF DEATH: 09/23/91 STUDY DAY OF DEATH: 46 STUDY WEEK OF DEATH: 7 TERMINAL BODY WEIGHT: 27.1 GRAMS
DATE AND TIME OF NECROPSY: 09/23/91 9:37 PROSECTOR: ADEPOLAHAN AKINSOLA RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
LIVER/GALLBLADD (LI)	2.56	9.449 %	-----	WEIGHT TAKEN

ORGAN NAME	SEVERITY, KEYWORD(S) OR PHRASE	FREE-TEXT COMMENTS AND NOTES
LIVER (LI)	-PALE AREA	-LEFT LATERAL LOBE, ONE, TAN, BROWN, PINPOINT
COLLECTED/TAKEN (XW)	-LIVER, IN 100% MEQH	
GENERAL INFORMATION	ADDITIONAL NECROPSY COMMENT: >LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS	

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), SKIN, OTHER (SS), STOMACH, GL (ST)

*** NO ORGANS/TISSUES WERE RECORDED AS HAVING BEEN SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13C

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY IN TRICLOSAN IN CD-1
MICE. (SATELLITE-GROUPS 8-11)

PRINTED: 21-JAN-93
PAGE: 1012

DRAFT INDIVIDUAL ANIMAL NECROPSY DATA SHEET *DRAFT*

STUDY NUMBER: 483287

ANIMAL NUMBER: A37663 SEX: MALE DOSE GROUP: 3 SACRIFICE STATUS: SCHEDULED, FIRST INTERIM SACRIFICE
DATE OF DEATH: 09/23/91 STUDY DAY OF DEATH: 46 STUDY WEEK OF DEATH: 7 TERMINAL BODY WEIGHT: 27.7 GRAMS
DATE AND TIME OF NECROPSY: 09/23/91 10:13 PROSECTOR: ADEFOLAHAN AKINSOLA RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
LIVER/GALLBLADD (LI)	2.55	9.213 %	-----	WEIGHT TAKEN

*** GROSS PATHOLOGY OBSERVATIONS ***

ORGAN NAME	SEVERITY, KEYWORD(S) OR PHRASE	FREE-TEXT COMMENTS AND NOTES
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COLLECTED/TAKEN (XW)

-LIVER, IN 100% MEQH

GENERAL INFORMATION

ADDITIONAL NECROPSY COMMENT: >LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), LIVER (LI), SKIN, OTHER (SS), STOMACH, GL (ST)

*** NO ORGANS/TISSUES WERE RECORDED AS HAVING BEEN SAVED ***

APPENDIX 13C

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.13-WEEK SUBCHRONIC ORAL TOXICITY STUDY IN TRICLOSAN IN CD-1
MICE. (SATELLITE-GROUPS 8-11)PRINTED: 21-JAN-93
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DRAFT INDIVIDUAL ANIMAL NECROPSY DATA SHEET *DRAFT*

STUDY NUMBER: 483287

ANIMAL NUMBER: A37664 SEX: MALE DOSE GROUP: 3 SACRIFICE STATUS: SCHEDULED, FIRST INTERIM SACRIFICE
 DATE OF DEATH: 09/23/91 STUDY DAY OF DEATH: 46 STUDY WEEK OF DEATH: 7 TERMINAL BODY WEIGHT: 25.8 GRAMS
 DATE AND TIME OF NECROPSY: 09/23/91 10:44 PROSECTOR: DOUGLAS HERNDON RECORDER: JOHN CROWLEY
 POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
LIVER/GALLSLADD (LI)	2.40	9.317 %	-----	WEIGHT TAKEN

ORGAN NAME	SEVERITY, KEYWORD(S) OR PHRASE	FREE-TEXT COMMENTS AND NOTES
LIVER (LI)	-PALE AREA -DARK	-ALL LOBES, FEW, TAN, PINPOINT TO 1 X 1 MM -ALL LOBES, DARK BROWN
^COLLECTED/TAKEN (XW)	-LIVER, IN 100% MEOH	
GENERAL INFORMATION	ADDITIONAL NECROPSY COMMENT: >LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS	

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
 KIDNEY (KD), SKIN, OTHER (SS), STOMACH, GL (ST)

*** NO ORGANS/TISSUES WERE RECORDED AS HAVING BEEN SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13C

PRINTED: 21-JAN-93
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13-WEEK SUBCHRONIC ORAL TOXICITY STUDY IN TRICLOSAN IN CD-1
MICE. (SATELLITE-GROUPS 8-11)

DRAFT INDIVIDUAL ANIMAL NECROPSY DATA SHEET *DRAFT*

STUDY NUMBER: 483287

ANIMAL NUMBER: A37665 SEX: MALE DOSE GROUP: 3 SACRIFICE STATUS: SCHEDULED, FIRST INTERIM SACRIFICE
DATE OF DEATH: 09/23/91 STUDY DAY OF DEATH: 46 STUDY WEEK OF DEATH: 7 TERMINAL BODY WEIGHT: 29.0 GRAMS
DATE AND TIME OF NECROPSY: 09/23/91 11:25 PROSECTOR: SCOTT BELL RECORDER: SCOTT BELL
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
LIVER/GALLBLADD (LI)	2.95	10.180 %	-----	WEIGHT TAKEN

ORGAN NAME	SEVERITY, KEYWORD(S) OR PHRASE	FREE-TEXT COMMENTS AND NOTES
LIVER (LI)	-PALE AREA -DARK -ENLARGED, SEVERE	-ALL LOBES, SEVERAL, TAN, PINPOINT TO 2 X 2 MM -ALL LOBES, TAN, DARK BROWN -ALL LOBES

^COLLECTED/TAKEN (XW) -LIVER, IN 100% MEOH

GENERAL INFORMATION ADDITIONAL NECROPSY COMMENT: >LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), SKIN, OTHER (SS), STOMACH, GL (ST)

*** NO ORGANS/TISSUES WERE RECORDED AS HAVING BEEN SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

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13-WEEK SUBCHRONIC ORAL TOXICITY STUDY IN TRICLOSAN IN CD-1
MICE. (SATELLITE-GROUPS 8-11)

DRAFT INDIVIDUAL ANIMAL NECROPSY DATA SHEET *DRAFT*

STUDY NUMBER: 483287

ANIMAL NUMBER: A37666 SEX: MALE DOSE GROUP: 3 SACRIFICE STATUS: SCHEDULED, FIRST INTERIM SACRIFICE
DATE OF DEATH: 09/24/91 STUDY DAY OF DEATH: 47 STUDY WEEK OF DEATH: 7 TERMINAL BODY WEIGHT: 27.1 GRAMS
DATE AND TIME OF NECROPSY: 09/24/91 8:32 PROSECTOR: FRED AGEY RECORDER: FRED AGEY
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
LIVER/GALLBLADD (LI)	2.47	9.096 %	-----	WEIGHT TAKEN

ORGAN NAME	SEVERITY, KEYWORD(S) OR PHRASE	FREE-TEXT COMMENTS AND NOTES
KIDNEY (KD)	-DARK -PALE AREA	-ALL LOBES, DARK BROWN -ALL LOBES, MULTIPLE, TAN, PINPOINT TO 3 X 3 MM
LIVER (LI)	-ENLARGED, MODERATE	-ALL LOBES
^COLLECTED/TAKEN (XW)	-LIVER, IN 100% MEQH	

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
SKIN, OTHER (SS), STOMACH, GL (ST)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13C

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY IN TRICLOSAN IN CD-1
MICE. (SATELLITE-GROUPS 8-11)

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DRAFT INDIVIDUAL ANIMAL NECROPSY DATA SHEET *DRAFT*

STUDY NUMBER: 483287

ANIMAL NUMBER: A37667 SEX: MALE DOSE GROUP: 3 SACRIFICE STATUS: SCHEDULED, FIRST INTERIM SACRIFICE
DATE OF DEATH: 09/24/91 STUDY DAY OF DEATH: 47 STUDY WEEK OF DEATH: 7 TERMINAL BODY WEIGHT: 27.6 GRAMS
DATE AND TIME OF NECROPSY: 09/24/91 9:20 PROSECTOR: ADEFOLAHAN AKINSOLA RECORDER: ADEFOLAHAN AKINSOLA
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
LIVER/GALLBLADD (LI)	2.82	10.214 %		WEIGHT TAKEN

ORGAN NAME	SEVERITY, KEYWORD(S) OR PHRASE	FREE-TEXT COMMENTS AND NOTES
LIVER (LI)	-PALE AREA	-RIGHT LATERAL LOBE, FEW, TAN, WHITE, PINPOINT
COLLECTED/TAKEN (XW)	-LIVER, IN 100% MEQH	
GENERAL INFORMATION	ADDITIONAL NECROPSY COMMENT: >LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS	

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), SKIN, OTHER (SS), STOMACH, GL (ST)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

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13-WEEK SUBCHRONIC ORAL TOXICITY STUDY IN TRICLOSAN IN CD-1
MICE. (SATELLITE-GROUPS 8-11)

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DRAFT INDIVIDUAL ANIMAL NECROPSY DATA SHEET *DRAFT*

STUDY NUMBER: 483287

ANIMAL NUMBER: A37668 SEX: MALE DOSE GROUP: 3 SACRIFICE STATUS: SCHEDULED, FIRST INTERIM SACRIFICE
DATE OF DEATH: 09/24/91 STUDY DAY OF DEATH: 47 STUDY WEEK OF DEATH: 7 TERMINAL BODY WEIGHT: 28.5 GRAMS
DATE AND TIME OF NECROPSY: 09/24/91 9:58 PROSECTOR: FRED AGEY RECORDER: FRED AGEY
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
LIVER/GALLBLADD (LI)	2.72	9.553 %	-----	WEIGHT TAKEN

ORGAN NAME	SEVERITY, KEYWORD(S) OR PHRASE	FREE-TEXT COMMENTS AND NOTES
LIVER (LI)	-PALE AREA -DARK -ENLARGED, MODERATE	-ALL LOBES, SEVERAL, TAN, WHITE, PINPOINT TO 3 X 3 MM -ALL LOBES, DARK BROWN -ALL LOBES
^COLLECTED/TAKEN (XW)	-LIVER, IN 100% MEOH	
GENERAL INFORMATION	ADDITIONAL NECROPSY COMMENT: >LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS	

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), SKIN, OTHER (SS), STOMACH, GL (ST)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

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13-WEEK SUBCHRONIC ORAL TOXICITY STUDY IN TRICLOSAN IN CD-1
MICE. (SATELLITE-GROUPS 8-11)

DRAFT INDIVIDUAL ANIMAL NECROPSY DATA SHEET *DRAFT*

STUDY NUMBER: 483287

ANIMAL NUMBER: A37669 SEX: MALE DOSE GROUP: 3 SACRIFICE STATUS: SCHEDULED, FIRST INTERIM SACRIFICE
DATE OF DEATH: 09/24/91 STUDY DAY OF DEATH: 47 STUDY WEEK OF DEATH: 7 TERMINAL BODY WEIGHT: 23.6 GRAMS
DATE AND TIME OF NECROPSY: 09/24/91 10:35 PROSECTOR: SCOTT BELL RECORDER: SCOTT BELL
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
LIVER/GALLBLADD (LI)	2.13	9.023 %	-----	WEIGHT TAKEN

ORGAN NAME	SEVERITY, KEYWORD(S) OR PHRASE	FREE-TEXT COMMENTS AND NOTES
LIVER (LI)	-DARK	-ALL LOBES, BROWN
^COLLECTED/TAKEN (XW)	-LIVER, IN 100% MEOH	
GENERAL INFORMATION	ADDITIONAL NECROPSY COMMENT: >LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS	

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), SKIN, OTHER (SS), STOMACH, GL (ST)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

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13-WEEK SUBCHRONIC ORAL TOXICITY STUDY IN TRICLOSAN IN CD-1
MICE. (SATELLITE-GROUPS 8-11)

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DRAFT INDIVIDUAL ANIMAL NECROPSY DATA SHEET *DRAFT*

STUDY NUMBER: 483287

ANIMAL NUMBER: A37670 SEX: MALE DOSE GROUP: 3 SACRIFICE STATUS: SCHEDULED, FIRST INTERIM SACRIFICE
DATE OF DEATH: 09/24/91 STUDY DAY OF DEATH: 47 STUDY WEEK OF DEATH: 7 TERMINAL BODY WEIGHT: 25.4 GRAMS
DATE AND TIME OF NECROPSY: 09/24/91 10:59 PROSECTOR: SCOTT BELL RECORDER: SCOTT BELL
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
LIVER/GALLBLADD (LI)	2.01	7.894 %	-----	WEIGHT TAKEN

ORGAN NAME	SEVERITY, KEYWORD(S) OR PHRASE	FREE-TEXT COMMENTS AND NOTES
LIVER (LI)	-PALE AREA -DARK	-ALL LOBES, SEVERAL, WHITE TO TAN, PINPOINT TO 1 X 1 MM -ALL LOBES, DARK BROWN
STOMACH, GL (ST)	-DARK AREA	-MUCOSA, FEW, BROWN, PINPOINT
^COLLECTED/TAKEN (XW)	-LIVER, IN 100% MEOH	
GENERAL INFORMATION	ADDITIONAL NECROPSY COMMENT: >HISTOLOGY REFERENCE:STOMACH, IN CUP ADDITIONAL NECROPSY COMMENT: >LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS	

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), SKIN, OTHER (SS)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

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13-WEEK SUBCHRONIC ORAL TOXICITY STUDY IN TRICLOSAN IN CD-1
MICE. (SATELLITE-GROUPS 8-11)

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DRAFT INDIVIDUAL ANIMAL NECROPSY DATA SHEET *DRAFT*

STUDY NUMBER: 483287

ANIMAL NUMBER: A37681 SEX: MALE DOSE GROUP: 4 SACRIFICE STATUS: SCHEDULED, FIRST INTERIM SACRIFICE
DATE OF DEATH: 09/23/91 STUDY DAY OF DEATH: 46 STUDY WEEK OF DEATH: 7 TERMINAL BODY WEIGHT: 22.2 GRAMS
DATE AND TIME OF NECROPSY: 09/23/91 9:02 PROSECTOR: DOUGLAS HERNDON RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
LIVER/GALLBLADD (LI)	2.88	12.955 %	-----	WEIGHT TAKEN

ORGAN NAME	SEVERITY, KEYWORD(S) OR PHRASE	FREE-TEXT COMMENTS AND NOTES
LIVER (LI)	-PALE AREA -DARK	-ALL LOBES, FEW, TAN, WHITE, PINPOINT TO 1 X 1 MM -ALL LOBES, DARK BROWN
^COLLECTED/TAKEN (XW)	-LIVER, IN 100% MEOH	
GENERAL INFORMATION	ADDITIONAL NECROPSY COMMENT: >LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS	

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), SKIN, OTHER (SS), STOMACH, GL (ST)

*** NO ORGANS/TISSUES WERE RECORDED AS HAVING BEEN SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13C

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY IN TRICLOSAN IN CD-1
MICE. (SATELLITE-GROUPS 8-11)

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DRAFT INDIVIDUAL ANIMAL NECROPSY DATA SHEET *DRAFT*

STUDY NUMBER: 483287

ANIMAL NUMBER: A37682 SEX: MALE DOSE GROUP: 4 SACRIFICE STATUS: SCHEDULED, FIRST INTERIM SACRIFICE
DATE OF DEATH: 09/23/91 STUDY DAY OF DEATH: 46 STUDY WEEK OF DEATH: 7 TERMINAL BODY WEIGHT: 21.4 GRAMS
DATE AND TIME OF NECROPSY: 09/23/91 9:40 PROSECTOR: DOUGLAS HERNDON RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
LIVER/GALLBLADD (LI)	3.26	15.220 %	-----	WEIGHT TAKEN

ORGAN NAME	SEVERITY, KEYWORD(S) OR PHRASE	FREE-TEXT COMMENTS AND NOTES
LIVER (LI)	-PALE AREA -DARK -ENLARGED, MODERATE	-ALL LOBES, SEVERAL, TAN, PINPOINT TO 5 X 3 MM -ALL LOBES, DARK BROWN -ALL LOBES
^COLLECTED/TAKEN (XW)	-LIVER, IN 100% MEQH	
GENERAL INFORMATION	ADDITIONAL NECROPSY COMMENT: >LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS	

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), SKIN, OTHER (SS), STOMACH, GL (ST)

*** NO ORGANS/TISSUES WERE RECORDED AS HAVING BEEN SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

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13-WEEK SUBCHRONIC ORAL TOXICITY STUDY IN TRICLOSAN IN CD-1
MICE, (SATELLITE-GROUPS 8-11)

DRAFT INDIVIDUAL ANIMAL NECROPSY DATA SHEET *DRAFT*

STUDY NUMBER: 483287

ANIMAL NUMBER: A37683 SEX: MALE DOSE GROUP: 4 SACRIFICE STATUS: SCHEDULED, FIRST INTERIM SACRIFICE
DATE OF DEATH: 09/23/91 STUDY DAY OF DEATH: 46 STUDY WEEK OF DEATH: 7 TERMINAL BODY WEIGHT: 24.4 GRAMS
DATE AND TIME OF NECROPSY: 09/23/91 10:11 PROSECTOR: FRED AGEY RECORDER: FRED AGEY
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
LIVER/GALLBLADD (LI)	3.51	14.396 %	-----	WEIGHT TAKEN

ORGAN NAME	SEVERITY, KEYWORD(S) OR PHRASE	FREE-TEXT COMMENTS AND NOTES
LIVER (LI)	-PALE AREA -DARK -ENLARGED, MODERATE	-ALL LOBES, MULTIPLE, TAN, WHITE, PINPOINT TO 3 X 3 MM -ALL LOBES, DARK BROWN -ALL LOBES
^COLLECTED/TAKEN (XW)	-LIVER, IN 100% MEOH	
GENERAL INFORMATION	ADDITIONAL NECROPSY COMMENT: >LAST PHYSICAL EXAM: NORMAL-NO REMARKABLE OBSERVATIONS	

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), SKIN, OTHER (SS), STOMACH, GL (ST)

*** NO ORGANS/TISSUES WERE RECORDED AS HAVING BEEN SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

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13-WEEK SUBCHRONIC ORAL TOXICITY STUDY IN TRICLOSAN IN CD-1
MICE. (SATELLITE-GROUPS 8-11)

DRAFT INDIVIDUAL ANIMAL NECROPSY DATA SHEET *DRAFT*

STUDY NUMBER: 483287

ANIMAL NUMBER: A37684 SEX: MALE DOSE GROUP: 4 SACRIFICE STATUS: SCHEDULED, FIRST INTERIM SACRIFICE
DATE OF DEATH: 09/23/91 STUDY DAY OF DEATH: 46 STUDY WEEK OF DEATH: 7 TERMINAL BODY WEIGHT: 22.5 GRAMS
DATE AND TIME OF NECROPSY: 09/23/91 10:49 PROSECTOR: ADEFOLAHAN AKINSOLA RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
LIVER/GALLBLADD (LI)	3.22	14.331 %	-----	WEIGHT TAKEN

*** GROSS PATHOLOGY OBSERVATIONS ***

ORGAN NAME	SEVERITY, KEYWORD(S) OR PHRASE	FREE-TEXT COMMENTS AND NOTES
LIVER (LI)	-PALE AREA	-ALL LOBES, TAN, WHITE, BROWN, PINPOINT TO 1.0 X 1.0 CM
^COLLECTED/TAKEN (XW)	-LIVER, IN 100% MEQH	
GENERAL INFORMATION	ADDITIONAL NECROPSY COMMENT: >LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS	

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), SKIN, OTHER (SS), STOMACH, GL (ST)

*** NO ORGANS/TISSUES WERE RECORDED AS HAVING BEEN SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

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13-WEEK SUBCHRONIC ORAL TOXICITY STUDY IN TRICLOSAN IN CD-1
MICE. (SATELLITE-GROUPS 8-11)

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DRAFT INDIVIDUAL ANIMAL NECROPSY DATA SHEET *DRAFT*

STUDY NUMBER: 483287

ANIMAL NUMBER: A37685 SEX: MALE DOSE GROUP: 4 SACRIFICE STATUS: SCHEDULED, FIRST INTERIM SACRIFICE
DATE OF DEATH: 09/23/91 STUDY DAY OF DEATH: 46 STUDY WEEK OF DEATH: 7 TERMINAL BODY WEIGHT: 22.2 GRAMS
DATE AND TIME OF NECROPSY: 09/23/91 11:25 PROSECTOR: DOUGLAS HERNDON RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
LIVER/GALLBLADD (LI)	3.20	14.426 %	-----	WEIGHT TAKEN

ORGAN NAME	SEVERITY, KEYWORD(S) OR PHRASE	FREE-TEXT COMMENTS AND NOTES
LIVER (LI)	-PALE AREA -DARK -ENLARGED, MODERATE	-ALL LOBES, FEW, TAN, PINPOINT TO 2 X 2 MM -ALL LOBES, DARK BROWN -ALL LOBES
^COLLECTED/TAKEN (XW)	-LIVER, IN 100% MEOH	
GENERAL INFORMATION	ADDITIONAL NECROPSY COMMENT: >LAST PHYSICAL EXAM: NORMAL-NO REMARKABLE OBSERVATIONS	

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), SKIN, OTHER (SS), STOMACH, GL (ST)

*** NO ORGANS/TISSUES WERE RECORDED AS HAVING BEEN SAVED ***

APPENDIX 13C

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY IN TRICLOSAN IN CD-1
MICE. (SATELLITE-GROUPS 8-11)

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DRAFT INDIVIDUAL ANIMAL NECROPSY DATA SHEET *DRAFT*

STUDY NUMBER: 483287

ANIMAL NUMBER: A37686 SEX: MALE DOSE GROUP: 4 SACRIFICE STATUS: SCHEDULED, FIRST INTERIM SACRIFICE
DATE OF DEATH: 09/24/91 STUDY DAY OF DEATH: 47 STUDY WEEK OF DEATH: 7 TERMINAL BODY WEIGHT: 27.6 GRAMS
DATE AND TIME OF NECROPSY: 09/24/91 8:40 PROSECTOR: SCOTT BELL RECORDER: SCOTT BELL
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
LIVER/GALLBLADD (LI)	3.76	13.628 %	-----	WEIGHT TAKEN

*** GROSS PATHOLOGY OBSERVATIONS ***

ORGAN NAME	SEVERITY, KEYWORD(S) OR PHRASE	FREE-TEXT COMMENTS AND NOTES
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LIVER (LI)	-PALE AREA -DARK -ENLARGED, SEVERE	-ALL LOBES, FEW, WHITE, 2 X 2 MM -ALL LOBES, DARK RED, BROWN -ALL LOBES
^COLLECTED/TAKEN (XW)	-LIVER, IN 100% MEQH	

GENERAL INFORMATION

ADDITIONAL NECROPSY COMMENT: >LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), SKIN, OTHER (SS), STOMACH, GL (ST)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13C

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY IN TRICLOSAN IN CD-1
MICE. (SATELLITE-GROUPS 8-11)

PRINTED: 21-JAN-93
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DRAFT INDIVIDUAL ANIMAL NECROPSY DATA SHEET *DRAFT*

STUDY NUMBER: 483287

ANIMAL NUMBER: A37687 SEX: MALE DOSE GROUP: 4 SACRIFICE STATUS: SCHEDULED, FIRST INTERIM SACRIFICE
DATE OF DEATH: 09/24/91 STUDY DAY OF DEATH: 47 STUDY WEEK OF DEATH: 7 TERMINAL BODY WEIGHT: 25.2 GRAMS
DATE AND TIME OF NECROPSY: 09/24/91 9:15 PROSECTOR: SCOTT BELL RECORDER: SCOTT BELL
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
LIVER/GALLBLADD (LI)	3.62	14.368 %	-----	WEIGHT TAKEN

ORGAN NAME	SEVERITY, KEYWORD(S) OR PHRASE	FREE-TEXT COMMENTS AND NOTES
LIVER (LI)	-PALE AREA -DARK -ENLARGED, SEVERE	-ALL LOBES, FEW, WHITE, PINPOINT TO 3 X 2 MM -ALL LOBES, DARK BROWN -ALL LOBES
STOMACH, GL (ST)	-DARK AREA	-MUCOSA, FEW, RED, STRIATED
^COLLECTED/TAKEN (XW)	-LIVER, IN 100% MEOH	
GENERAL INFORMATION	ADDITIONAL NECROPSY COMMENT: >HISTOLOGY REFERENCE:STOMACH, IN CUP ADDITIONAL NECROPSY COMMENT: >LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS	

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), SKIN, OTHER (SS)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13C

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY IN TRICLOSAN IN CD-1
MICE. (SATELLITE-GROUPS 8-11)

PRINTED: 21-JAN-93
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DRAFT INDIVIDUAL ANIMAL NECROPSY DATA SHEET *DRAFT*

STUDY NUMBER: 483287

ANIMAL NUMBER: A37688 SEX: MALE DOSE GROUP: 4 SACRIFICE STATUS: SCHEDULED, FIRST INTERIM SACRIFICE
DATE OF DEATH: 09/24/91 STUDY DAY OF DEATH: 47 STUDY WEEK OF DEATH: 7 TERMINAL BODY WEIGHT: 23.8 GRAMS
DATE AND TIME OF NECROPSY: 09/24/91 9:55 PROSECTOR: SCOTT BELL RECORDER: SCOTT BELL
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
LIVER/GALLBLADD (LI)	3.32	13.945 %	-----	WEIGHT TAKEN

ORGAN NAME	SEVERITY, KEYWORD(S) OR PHRASE	FREE-TEXT COMMENTS AND NOTES
LIVER (LI)	-PALE AREA -DARK -ENLARGED, MODERATE	-ALL LOBES, FEW, WHITE, PINPOINT TO 1 X 1 MM -ALL LOBES, DARK BROWN -ALL LOBES
STOMACH, GL (ST)	-DARK AREA	-MUCOSA, FEW, DARK BROWN, PINPOINT
^COLLECTED/TAKEN (XW)	-LIVER, IN 100% MEOH	
GENERAL INFORMATION	ADDITIONAL NECROPSY COMMENT: >HISTOLOGY REFERENCE:STOMACH, IN CUP ADDITIONAL NECROPSY COMMENT: >LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS	

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), SKIN, OTHER (SS)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13C

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY IN TRICLOSAN IN CD-1
MICE. (SATELLITE-GROUPS 8-11)

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DRAFT INDIVIDUAL ANIMAL NECROPSY DATA SHEET *DRAFT*

STUDY NUMBER: 483287

ANIMAL NUMBER: A37689 SEX: MALE DOSE GROUP: 4 SACRIFICE STATUS: SCHEDULED, FIRST INTERIM SACRIFICE
DATE OF DEATH: 09/24/91 STUDY DAY OF DEATH: 47 STUDY WEEK OF DEATH: 7 TERMINAL BODY WEIGHT: 23.5 GRAMS
DATE AND TIME OF NECROPSY: 09/24/91 10:31 PROSECTOR: FRED AGEY RECORDER: FRED AGEY
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
LIVER/GALLBLADD (LI)	3.33	14.166 %	-----	WEIGHT TAKEN

ORGAN NAME	SEVERITY, KEYWORD(S) OR PHRASE	FREE-TEXT COMMENTS AND NOTES
LIVER (LI)	-PALE AREA -DARK -ENLARGED, SEVERE	-ALL LOBES, MULTIPLE, TAN, WHITE, PINPOINT TO 3 X 3 MM -ALL LOBES, DARK BROWN -ALL LOBES
^COLLECTED/TAKEN (XW)	-LIVER, IN 100% MEOH	
GENERAL INFORMATION	ADDITIONAL NECROPSY COMMENT: >LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS	

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), SKIN, OTHER (SS), STOMACH, GL (ST)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13C

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY IN TRICLOSAN IN CD-1
MICE. (SATELLITE-GROUPS 8-11)

PRINTED: 21-JAN-93
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DRAFT INDIVIDUAL ANIMAL NECROPSY DATA SHEET *DRAFT*

STUDY NUMBER: 483287

ANIMAL NUMBER: A37690 SEX: MALE DOSE GROUP: 4 SACRIFICE STATUS: SCHEDULED, FIRST INTERIM SACRIFICE
DATE OF DEATH: 09/24/91 STUDY DAY OF DEATH: 47 STUDY WEEK OF DEATH: 7 TERMINAL BODY WEIGHT: 27.4 GRAMS
DATE AND TIME OF NECROPSY: 09/24/91 11:04 PROSECTOR: FRED AGEY RECORDER: FRED AGEY
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
LIVER/GALLBLADD (LI)	4.94	18.021 %	-----	WEIGHT TAKEN

ORGAN NAME	SEVERITY, KEYWORD(S) OR PHRASE	FREE-TEXT COMMENTS AND NOTES
LIVER (LI)	-PALE AREA -DARK -ENLARGED, SEVERE	-ALL LOBES, FEW, TAN, WHITE, PINPOINT TO 2 X 2 MM -ALL LOBES, DARK BROWN -ALL LOBES
^COLLECTED/TAKEN (XW)	-LIVER, IN 100% MEOH	
GENERAL INFORMATION	ADDITIONAL NECROPSY COMMENT: >LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS	

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), SKIN, OTHER (SS), STOMACH, GL (ST)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13C

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY IN TRICLOSAN IN CD-1
MICE. (SATELLITE-GROUPS 8-11)

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DRAFT INDIVIDUAL ANIMAL NECROPSY DATA SHEET *DRAFT*

STUDY NUMBER: 483287

ANIMAL NUMBER: A37621 SEX: FEMALE DOSE GROUP: 1 SACRIFICE STATUS: SCHEDULED, FIRST INTERIM SACRIFICE
DATE OF DEATH: 09/23/91 STUDY DAY OF DEATH: 46 STUDY WEEK OF DEATH: 7 TERMINAL BODY WEIGHT: 22.3 GRAMS
DATE AND TIME OF NECROPSY: 09/23/91 9:13 PROSECTOR: SCOTT BELL RECORDER: SCOTT BELL
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
LIVER/GALLBLADD (LI)	1.07	4.802 %	-----	WEIGHT TAKEN

*** GROSS PATHOLOGY OBSERVATIONS ***
ORGAN NAME SEVERITY, KEYWORD(S) OR PHRASE FREE-TEXT COMMENTS AND NOTES

^COLLECTED/TAKEN (XW)

-LIVER, IN 100% MEQH

GENERAL INFORMATION

ADDITIONAL NECROPSY COMMENT: >LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), LIVER (LI), OVARY (OV), SKIN, OTHER (SS), STOMACH, GL (ST)

*** NO ORGANS/TISSUES WERE RECORDED AS HAVING BEEN SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13C

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY IN TRICLOSAN IN CD-1
MICE. (SATELLITE-GROUPS 8-11)

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DRAFT INDIVIDUAL ANIMAL NECROPSY DATA SHEET *DRAFT*

STUDY NUMBER: 483287

ANIMAL NUMBER: A37622 SEX: FEMALE DOSE GROUP: 1 SACRIFICE STATUS: SCHEDULED, FIRST INTERIM SACRIFICE
DATE OF DEATH: 09/23/91 STUDY DAY OF DEATH: 46 STUDY WEEK OF DEATH: 7 TERMINAL BODY WEIGHT: 19.2 GRAMS
DATE AND TIME OF NECROPSY: 09/23/91 9:50 PROSECTOR: SCOTT BELL RECORDER: SCOTT BELL
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
LIVER/GALLBLADD (LI)	0.97	5.033 %	-----	WEIGHT TAKEN

*** GROSS PATHOLOGY OBSERVATIONS ***
ORGAN NAME SEVERITY, KEYWORD(S) OR PHRASE FREE-TEXT COMMENTS AND NOTES

^COLLECTED/TAKEN (XW)

-LIVER, IN 100% MEOH

GENERAL INFORMATION

ADDITIONAL NECROPSY COMMENT: >LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), LIVER (LI), OVARY (OV), SKIN, OTHER (SS), STOMACH, GL (ST)

*** NO ORGANS/TISSUES WERE RECORDED AS HAVING BEEN SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13C

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY IN TRICLOSAN IN CD-1
MICE. (SATELLITE-GROUPS 8-11)

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DRAFT INDIVIDUAL ANIMAL NECROPSY DATA SHEET *DRAFT*

STUDY NUMBER: 483287

ANIMAL NUMBER: A37623 SEX: FEMALE DOSE GROUP: 1 SACRIFICE STATUS: SCHEDULED, FIRST INTERIM SACRIFICE
DATE OF DEATH: 09/23/91 STUDY DAY OF DEATH: 46 STUDY WEEK OF DEATH: 7 TERMINAL BODY WEIGHT: 22.4 GRAMS
DATE AND TIME OF NECROPSY: 09/23/91 10:21 PROSECTOR: DOUGLAS HERNDON RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
LIVER/GALLBLADD (LI)	1.15	5.153 %	-----	WEIGHT TAKEN

*** GROSS PATHOLOGY OBSERVATIONS ***
ORGAN NAME SEVERITY, KEYWORD(S) OR PHRASE FREE-TEXT COMMENTS AND NOTES

^COLLECTED/TAKEN (XW)

GENERAL INFORMATION -LIVER, IN 100% MEQH

ADDITIONAL NECROPSY COMMENT: >LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), LIVER (LI), OVARY (OV), SKIN, OTHER (SS), STOMACH, GL (ST)

*** NO ORGANS/TISSUES WERE RECORDED AS HAVING BEEN SAVED ***

APPENDIX 13C

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.13-WEEK SUBCHRONIC ORAL TOXICITY STUDY IN TRICLOSAN IN CD-1
MICE. (SATELLITE-GROUPS 8-11)

PRINTED: 21-JAN-93

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DRAFT INDIVIDUAL ANIMAL NECROPSY DATA SHEET *DRAFT*

STUDY NUMBER: 483287

ANIMAL NUMBER: A37624 SEX: FEMALE DOSE GROUP: 1 SACRIFICE STATUS: SCHEDULED, FIRST INTERIM SACRIFICE
 DATE OF DEATH: 09/23/91 STUDY DAY OF DEATH: 46 STUDY WEEK OF DEATH: 7 TERMINAL BODY WEIGHT: 23.6 GRAMS
 DATE AND TIME OF NECROPSY: 09/23/91 10:53 PROSECTOR: DOUGLAS HERNDON RECORDER: JOHN CROWLEY
 POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
LIVER/GALLBLADD (LI)	1.16	4.911 %	-----	WEIGHT TAKEN

*** GROSS PATHOLOGY OBSERVATIONS ***

ORGAN NAME	SEVERITY, KEYWORD(S) OR PHRASE	FREE-TEXT COMMENTS AND NOTES
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COLLECTED/TAKEN (KW)

-LIVER, IN 100% MEQH

GENERAL INFORMATION

ADDITIONAL NECROPSY COMMENT: >LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
 KIDNEY (KD), LIVER (LI), OVARY (OV), SKIN, OTHER (SS), STOMACH, GL (ST)

*** NO ORGANS/TISSUES WERE RECORDED AS HAVING BEEN SAVED ***

APPENDIX 13C

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY IN TRICLOSAN IN CD-1
MICE. (SATELLITE-GROUPS 8-11)
DRAFT INDIVIDUAL ANIMAL NECROPSY DATA SHEET *DRAFT*

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STUDY NUMBER: 483287

ANIMAL NUMBER: A37625 SEX: FEMALE DOSE GROUP: 1 SACRIFICE STATUS: SCHEDULED, FIRST INTERIM SACRIFICE
DATE OF DEATH: 09/23/91 STUDY DAY OF DEATH: 46 STUDY WEEK OF DEATH: 7 TERMINAL BODY WEIGHT: 19.7 GRAMS
DATE AND TIME OF NECROPSY: 09/23/91 11:31 PROSECTOR: ADEFOLAHAN AKINSOLA RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
LIVER/GALLBLADD (LI)	0.86	4.369 %	-----	WEIGHT TAKEN

*** GROSS PATHOLOGY OBSERVATIONS ***

ORGAN NAME	SEVERITY, KEYWORD(S) OR PHRASE	FREE-TEXT COMMENTS AND NOTES
COLLECTED/TAKEN (XW)	-LIVER, IN 100% MEQH	
GENERAL INFORMATION	ADDITIONAL NECROPSY COMMENT: >LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS	

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), LIVER (LI), OVARY (OV), SKIN, OTHER (SS), STOMACH, GL (ST)

*** NO ORGANS/TISSUES WERE RECORDED AS HAVING BEEN SAVED ***

APPENDIX 13C

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.13-WEEK SUBCHRONIC ORAL TOXICITY STUDY IN TRICLOSAN IN CD-1
MICE. (SATELLITE-GROUPS 8-11)PRINTED: 21-JAN-93
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DRAFT INDIVIDUAL ANIMAL NECROPSY DATA SHEET *DRAFT*

STUDY NUMBER: 483287

ANIMAL NUMBER: A37626 SEX: FEMALE DOSE GROUP: 1 SACRIFICE STATUS: SCHEDULED, FIRST INTERIM SACRIFICE
DATE OF DEATH: 09/24/91 STUDY DAY OF DEATH: 47 STUDY WEEK OF DEATH: 7 TERMINAL BODY WEIGHT: 22.0 GRAMS
DATE AND TIME OF NECROPSY: 09/24/91 8:42 PROSECTOR: JANE EARHARDT RECORDER: JANE EARHARDT
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
LIVER/GALLBLADD (LI)	0.99	4.516 %	-----	WEIGHT TAKEN

*** GROSS PATHOLOGY OBSERVATIONS ***
ORGAN NAME SEVERITY, KEYWORD(S) OR PHRASE FREE-TEXT COMMENTS AND NOTES

^COLLECTED/TAKEN (XW)

-LIVER, IN 100% MEOH

GENERAL INFORMATION

ADDITIONAL NECROPSY COMMENT: >LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), LIVER (LI), OVARY (OV), SKIN, OTHER (SS), STOMACH, GL (ST)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13C

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY IN TRICLOSAN IN CD-1
MICE. (SATELLITE-GROUPS 8-11)

PRINTED: 21-JAN-93
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DRAFT INDIVIDUAL ANIMAL NECROPSY DATA SHEET *DRAFT*

STUDY NUMBER: 483287

ANIMAL NUMBER: A37627 SEX: FEMALE DOSE GROUP: 1 SACRIFICE STATUS: SCHEDULED, FIRST INTERIM SACRIFICE
DATE OF DEATH: 09/24/91 STUDY DAY OF DEATH: 47 STUDY WEEK OF DEATH: 7 TERMINAL BODY WEIGHT: 21.9 GRAMS
DATE AND TIME OF NECROPSY: 09/24/91 9:22 PROSECTOR: JANE EARHARDT RECORDER: JANE EARHARDT
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
LIVER/GALLBLADD (LI)	1.03	4.690 %	-----	WEIGHT TAKEN

*** GROSS PATHOLOGY OBSERVATIONS ***

ORGAN NAME	SEVERITY, KEYWORD(S) OR PHRASE	FREE-TEXT COMMENTS AND NOTES
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^COLLECTED/TAKEN (XW)

-LIVER, IN 100% MEOH

GENERAL INFORMATION

ADDITIONAL NECROPSY COMMENT: >LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), LIVER (LI), OVARY (OV), SKIN, OTHER (SS), STOMACH, GL (ST)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13C

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY IN TRICLOSAN IN CD-1
MICE. (SATELLITE-GROUPS 8-11)

DRAFT INDIVIDUAL ANIMAL NECROPSY DATA SHEET *DRAFT*

PRINTED: 21-JAN-93
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STUDY NUMBER: 483287

ANIMAL NUMBER: A37628 SEX: FEMALE DOSE GROUP: 1 SACRIFICE STATUS: SCHEDULED, FIRST INTERIM SACRIFICE
DATE OF DEATH: 09/24/91 STUDY DAY OF DEATH: 47 STUDY WEEK OF DEATH: 7 TERMINAL BODY WEIGHT: 22.2 GRAMS
DATE AND TIME OF NECROPSY: 09/24/91 10:10 PROSECTOR: ADEFOLAHAN AKINSOLA RECORDER: ADEFOLAHAN AKINSOLA
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
LIVER/GALLBLADD (LI)	1.08	4.849 %	-----	WEIGHT TAKEN

ORGAN NAME	SEVERITY, KEYWORD(S) OR PHRASE	FREE-TEXT COMMENTS AND NOTES
OVARY (OV)	-CYST	-BOTH, ONE EACH, CLEAR, 3 X 3 MM
^COLLECTED/TAKEN (XW)	-LIVER, IN 100% MEOH	
GENERAL INFORMATION	ADDITIONAL NECROPSY COMMENT: >HISTOLOGY REFERENCE: OVARY, IN CUP	
	ADDITIONAL NECROPSY COMMENT: >LAST PHYSICAL EXAM: NORMAL-NO REMARKABLE OBSERVATIONS	

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), LIVER (LI), SKIN, OTHER (SS), STOMACH, GL (ST)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13C

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY IN TRICLOSAN IN CD-1
MICE. (SATELLITE-GROUPS 8-11)
DRAFT INDIVIDUAL ANIMAL NECROPSY DATA SHEET *DRAFT*

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STUDY NUMBER: 483287

ANIMAL NUMBER: A37629 SEX: FEMALE DOSE GROUP: 1 SACRIFICE STATUS: SCHEDULED, FIRST INTERIM SACRIFICE
DATE OF DEATH: 09/24/91 STUDY DAY OF DEATH: 47 STUDY WEEK OF DEATH: 7 TERMINAL BODY WEIGHT: 22.6 GRAMS
DATE AND TIME OF NECROPSY: 09/24/91 10:43 PROSECTOR: ADEFOLAHAN AKINSOLA RECORDER: ADEFOLAHAN AKINSOLA
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
LIVER/GALLBLADD (LI)	1.02	4.518 %	-----	WEIGHT TAKEN

ORGAN NAME	SEVERITY, KEYWORD(S) OR PHRASE	FREE-TEXT COMMENTS AND NOTES
OVARY (OV)	-CYST	-BOTH, ONE EACH, CLEAR, 3 X 3 MM
COLLECTED/TAKEN (XW)	-LIVER, IN 100% MEOH	
GENERAL INFORMATION	ADDITIONAL NECROPSY COMMENT: >HISTOLOGY REFERENCE:OVARY, IN CUP	
	ADDITIONAL NECROPSY COMMENT: >LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS	

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), LIVER (LI), SKIN, OTHER (SS), STOMACH, GL (ST)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13C

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY IN TRICLOSAN IN CD-1
MICE. (SATELLITE-GROUPS 8-11)
DRAFT INDIVIDUAL ANIMAL NECROPSY DATA SHEET *DRAFT*

PRINTED: 21-JAN-93
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STUDY NUMBER: 483287

ANIMAL NUMBER: A37630 SEX: FEMALE DOSE GROUP: 1 SACRIFICE STATUS: SCHEDULED, FIRST INTERIM SACRIFICE
DATE OF DEATH: 09/24/91 STUDY DAY OF DEATH: 47 STUDY WEEK OF DEATH: 7 TERMINAL BODY WEIGHT: 23.6 GRAMS
DATE AND TIME OF NECROPSY: 09/24/91 11:12 PROSECTOR: JANE EARHARDT RECORDER: JANE EARHARDT
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
LIVER/GALLBLADD (LI)	1.16	4.921 %	-----	WEIGHT TAKEN

*** GROSS PATHOLOGY OBSERVATIONS ***
ORGAN NAME SEVERITY, KEYWORD(S) OR PHRASE FREE-TEXT COMMENTS AND NOTES

^COLLECTED/TAKEN (XW)

-LIVER, IN 100% MEOH

GENERAL INFORMATION

ADDITIONAL NECROPSY COMMENT: >LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

KIDNEY (KD), LIVER (LI), OVARY (OV), SKIN, OTHER (SS), STOMACH, GL (ST)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

APPENDIX 13C

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY IN TRICLOSAN IN CD-1
MICE. (SATELLITE-GROUPS 8-11)

PRINTED: 21-JAN-93
PAGE: 1040

DRAFT INDIVIDUAL ANIMAL NECROPSY DATA SHEET *DRAFT*

STUDY NUMBER: 483287

ANIMAL NUMBER: A37631 SEX: FEMALE DOSE GROUP: 1 SACRIFICE STATUS: UNSCHEDULED (P)
DATE OF DEATH: 08/09/91 STUDY DAY OF DEATH: 1 STUDY WEEK OF DEATH: 1 TERMINAL BODY WEIGHT: 22.0 GRAMS
DATE AND TIME OF NECROPSY: 08/13/91 11:13 PROSECTOR: NOT AVAILABLE RECORDER: NOT AVAILABLE
POST-FIX WEIGHER: NOT AVAILABLE PATHOLOGIST: NOT AVAILABLE WEIGHER: NOT AVAILABLE

*** ANIMAL HAS NO ORGAN WEIGHTS RECORDED ***

*** ANIMAL HAS NO MACROSCOPIC OBSERVATIONS RECORDED ***

*** NO ORGANS/TISSUES WERE RECORDED AS HAVING BEEN SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13C

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY IN TRICLOSAN IN CD-1
MICE. (SATELLITE-GROUPS 8-11)

PRINTED: 21-JAN-93
PAGE: 1041

DRAFT INDIVIDUAL ANIMAL NECROPSY DATA SHEET *DRAFT*

STUDY NUMBER: 483287

ANIMAL NUMBER: A37632 SEX: FEMALE DOSE GROUP: 1 SACRIFICE STATUS: UNSCHEDULED (P)
DATE OF DEATH: 08/09/91 STUDY DAY OF DEATH: 1 STUDY WEEK OF DEATH: 1 TERMINAL BODY WEIGHT: 20.0 GRAMS
DATE AND TIME OF NECROPSY: 08/13/91 11:13 PROSECTOR: NOT AVAILABLE RECORDER: NOT AVAILABLE
POST-FIX WEIGHER: NOT AVAILABLE PATHOLOGIST: NOT AVAILABLE WEIGHER: NOT AVAILABLE

*** ANIMAL HAS NO ORGAN WEIGHTS RECORDED ***

*** ANIMAL HAS NO MACROSCOPIC OBSERVATIONS RECORDED ***

*** NO ORGANS/TISSUES WERE RECORDED AS HAVING BEEN SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13C

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13-WEEK SUBCHRONIC ORAL TOXICITY STUDY IN TRICLOSAN IN CD-1
MICE. (SATELLITE-GROUPS 8-11)

DRAFT INDIVIDUAL ANIMAL NECROPSY DATA SHEET *DRAFT*

STUDY NUMBER: 483287

ANIMAL NUMBER: A37633 SEX: FEMALE DOSE GROUP: 1 SACRIFICE STATUS: UNSCHEDULED (P)
DATE OF DEATH: 08/09/91 STUDY DAY OF DEATH: 1 STUDY WEEK OF DEATH: 1 TERMINAL BODY WEIGHT: 22.0 GRAMS
DATE AND TIME OF NECROPSY: 08/13/91 11:14 PROSECTOR: NOT AVAILABLE RECORDER: NOT AVAILABLE
POST-FIX WEIGHER: NOT AVAILABLE PATHOLOGIST: NOT AVAILABLE WEIGHER: NOT AVAILABLE

*** ANIMAL HAS NO ORGAN WEIGHTS RECORDED ***

*** ANIMAL HAS NO MACROSCOPIC OBSERVATIONS RECORDED ***

*** NO ORGANS/TISSUES WERE RECORDED AS HAVING BEEN SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13C

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY IN TRICLOSAN IN CD-1
MICE. (SATELLITE-GROUPS 8-11)

PRINTED: 21-JAN-93
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DRAFT INDIVIDUAL ANIMAL NECROPSY DATA SHEET *DRAFT*

STUDY NUMBER: 483287

ANIMAL NUMBER: A37634 SEX: FEMALE DOSE GROUP: 1 SACRIFICE STATUS: UNSCHEDULED (P)
DATE OF DEATH: 08/09/91 STUDY DAY OF DEATH: 1 STUDY WEEK OF DEATH: 1 TERMINAL BODY WEIGHT: 20.0 GRAMS
DATE AND TIME OF NECROPSY: 08/13/91 11:14 PROSECTOR: NOT AVAILABLE RECORDER: NOT AVAILABLE
POST-FIX WEIGHER: NOT AVAILABLE PATHOLOGIST: NOT AVAILABLE WEIGHER: NOT AVAILABLE

*** ANIMAL HAS NO ORGAN WEIGHTS RECORDED ***

*** ANIMAL HAS NO MACROSCOPIC OBSERVATIONS RECORDED ***

*** NO ORGANS/TISSUES WERE RECORDED AS HAVING BEEN SAVED ***

APPENDIX 13C

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY IN TRICLOSAN IN CD-1
MICE. (SATELLITE-GROUPS 8-11)

PRINTED: 21-JAN-93
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DRAFT INDIVIDUAL ANIMAL NECROPSY DATA SHEET *DRAFT*

STUDY NUMBER: 483287

ANIMAL NUMBER: A37635 SEX: FEMALE DOSE GROUP: 1 SACRIFICE STATUS: UNSCHEDULED (P)
DATE OF DEATH: 08/09/91 STUDY DAY OF DEATH: 1 STUDY WEEK OF DEATH: 1 TERMINAL BODY WEIGHT: 20.0 GRAMS
DATE AND TIME OF NECROPSY: 08/13/91 11:14 PROSECTOR: NOT AVAILABLE RECORDER: NOT AVAILABLE
POST-FIX WEIGHER: NOT AVAILABLE PATHOLOGIST: NOT AVAILABLE WEIGHER: NOT AVAILABLE

*** ANIMAL HAS NO ORGAN WEIGHTS RECORDED ***

*** ANIMAL HAS NO MACROSCOPIC OBSERVATIONS RECORDED ***

*** NO ORGANS/TISSUES WERE RECORDED AS HAVING BEEN SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13C

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY IN TRICLOSAN IN CD-1
MICE. (SATELLITE-GROUPS 8-11)

PRINTED: 21-JAN-93
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DRAFT INDIVIDUAL ANIMAL NECROPSY DATA SHEET *DRAFT*

STUDY NUMBER: 483287

ANIMAL NUMBER: A37636 SEX: FEMALE DOSE GROUP: 1 SACRIFICE STATUS: UNSCHEDULED (P)
DATE OF DEATH: 08/09/91 STUDY DAY OF DEATH: 1 STUDY WEEK OF DEATH: 1 TERMINAL BODY WEIGHT: 21.0 GRAMS
DATE AND TIME OF NECROPSY: 08/13/91 11:15 PROSECTOR: NOT AVAILABLE RECORDER: NOT AVAILABLE
POST-FIX WEIGHER: NOT AVAILABLE PATHOLOGIST: NOT AVAILABLE WEIGHER: NOT AVAILABLE

*** ANIMAL HAS NO ORGAN WEIGHTS RECORDED ***

*** ANIMAL HAS NO MACROSCOPIC OBSERVATIONS RECORDED ***

*** NO ORGANS/TISSUES WERE RECORDED AS HAVING BEEN SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13C

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY IN TRICLOSAN IN CD-1
MICE. (SATELLITE-GROUPS 8-11)

PRINTED: 21-JAN-93

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DRAFT INDIVIDUAL ANIMAL NECROPSY DATA SHEET *DRAFT*

STUDY NUMBER: 483287

ANIMAL NUMBER: A37637 SEX: FEMALE DOSE GROUP: 1 SACRIFICE STATUS: UNSCHEDULED (P)
DATE OF DEATH: 08/09/91 STUDY DAY OF DEATH: 1 STUDY WEEK OF DEATH: 1 TERMINAL BODY WEIGHT: 18.0 GRAMS
DATE AND TIME OF NECROPSY: 08/13/91 11:15 PROSECTOR: NOT AVAILABLE RECORDER: NOT AVAILABLE
POST-FIX WEIGHER: NOT AVAILABLE PATHOLOGIST: NOT AVAILABLE WEIGHER: NOT AVAILABLE

*** ANIMAL HAS NO ORGAN WEIGHTS RECORDED ***

*** ANIMAL HAS NO MACROSCOPIC OBSERVATIONS RECORDED ***

*** NO ORGANS/TISSUES WERE RECORDED AS HAVING BEEN SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13C

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY IN TRICLOSAN IN CD-1
MICE. (SATELLITE-GROUPS 8-11)

PRINTED: 21-JAN-93
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DRAFT INDIVIDUAL ANIMAL NECROPSY DATA SHEET *DRAFT*

STUDY NUMBER: 483287

ANIMAL NUMBER: A37638 SEX: FEMALE DOSE GROUP: 1 SACRIFICE STATUS: UNSCHEDULED (P)
DATE OF DEATH: 08/09/91 STUDY DAY OF DEATH: 1 STUDY WEEK OF DEATH: 1 TERMINAL BODY WEIGHT: 22.0 GRAMS
DATE AND TIME OF NECROPSY: 08/13/91 11:16 PROSECTOR: NOT AVAILABLE RECORDER: NOT AVAILABLE
POST-FIX WEIGHER: NOT AVAILABLE PATHOLOGIST: NOT AVAILABLE WEIGHER: NOT AVAILABLE

*** ANIMAL HAS NO ORGAN WEIGHTS RECORDED ***

*** ANIMAL HAS NO MACROSCOPIC OBSERVATIONS RECORDED ***

*** NO ORGANS/TISSUES WERE RECORDED AS HAVING BEEN SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13C

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY IN TRICLOSAN IN CD-1
MICE. (SATELLITE-GROUPS 8-11)
DRAFT INDIVIDUAL ANIMAL NECROPSY DATA SHEET *DRAFT*

PRINTED: 21-JAN-93
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STUDY NUMBER: 483287

ANIMAL NUMBER: A37639 SEX: FEMALE DOSE GROUP: 1 SACRIFICE STATUS: UNSCHEDULED (P)
DATE OF DEATH: 08/09/91 STUDY DAY OF DEATH: 1 STUDY WEEK OF DEATH: 1 TERMINAL BODY WEIGHT: 21.0 GRAMS
DATE AND TIME OF NECROPSY: 08/13/91 11:16 PROSECTOR: NOT AVAILABLE RECORDER: NOT AVAILABLE
POST-FIX WEIGHER: NOT AVAILABLE PATHOLOGIST: NOT AVAILABLE WEIGHER: NOT AVAILABLE

*** ANIMAL HAS NO ORGAN WEIGHTS RECORDED ***

*** ANIMAL HAS NO MACROSCOPIC OBSERVATIONS RECORDED ***

*** NO ORGANS/TISSUES WERE RECORDED AS HAVING BEEN SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13C

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY IN TRICLOSAN IN CD-1
MICE. (SATELLITE-GROUPS 8-11)

PRINTED: 21-JAN-93
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DRAFT INDIVIDUAL ANIMAL NECROPSY DATA SHEET *DRAFT*

STUDY NUMBER: 483287

ANIMAL NUMBER: A37640 SEX: FEMALE DOSE GROUP: 1 SACRIFICE STATUS: UNSCHEDULED (P)
DATE OF DEATH: 08/09/91 STUDY DAY OF DEATH: 1 STUDY WEEK OF DEATH: 1 TERMINAL BODY WEIGHT: 20.0 GRAMS
DATE AND TIME OF NECROPSY: 08/13/91 11:16 PROSECTOR: NOT AVAILABLE RECORDER: NOT AVAILABLE
POST-FIX WEIGHER: NOT AVAILABLE PATHOLOGIST: NOT AVAILABLE WEIGHER: NOT AVAILABLE

*** ANIMAL HAS NO ORGAN WEIGHTS RECORDED ***

*** ANIMAL HAS NO MACROSCOPIC OBSERVATIONS RECORDED ***

*** NO ORGANS/TISSUES WERE RECORDED AS HAVING BEEN SAVED ***

APPENDIX 13C

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.13-WEEK SUBCHRONIC ORAL TOXICITY STUDY IN TRICLOSAN IN CD-1
MICE. (SATELLITE-GROUPS 8-11)PRINTED: 21-JAN-93
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DRAFT INDIVIDUAL ANIMAL NECROPSY DATA SHEET *DRAFT*

STUDY NUMBER: 483287

ANIMAL NUMBER: A37651 SEX: FEMALE DOSE GROUP: 2 SACRIFICE STATUS: SCHEDULED, FIRST INTERIM SACRIFICE
 DATE OF DEATH: 09/23/91 STUDY DAY OF DEATH: 46 STUDY WEEK OF DEATH: 7 TERMINAL BODY WEIGHT: 22.5 GRAMS
 DATE AND TIME OF NECROPSY: 09/23/91 9:09 PROSECTOR: FRED AGEY RECORDER: FRED AGEY
 POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
LIVER/GALLBLADD (LI)	1.16	5.162 %	-----	WEIGHT TAKEN

*** GROSS PATHOLOGY OBSERVATIONS ***

ORGAN NAME	SEVERITY, KEYWORD(S) OR PHRASE	FREE-TEXT COMMENTS AND NOTES
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^COLLECTED/TAKEN (KW)

-LIVER, IN 100% MEOH

GENERAL INFORMATION

ADDITIONAL NECROPSY COMMENT: >LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
 KIDNEY (KD), LIVER (LI), OVARY (OV), SKIN, OTHER (SS), STOMACH, GL (ST)

*** NO ORGANS/TISSUES WERE RECORDED AS HAVING BEEN SAVED ***

APPENDIX 13C

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY IN TRICLOSAN IN CD-1
MICE. (SATELLITE-GROUPS 8-11)

PRINTED: 21-JAN-93
PAGE: 1051

DRAFT INDIVIDUAL ANIMAL NECROPSY DATA SHEET *DRAFT*

STUDY NUMBER: 483287

ANIMAL NUMBER: A37652 SEX: FEMALE DOSE GROUP: 2 SACRIFICE STATUS: SCHEDULED, FIRST INTERIM SACRIFICE
DATE OF DEATH: 09/23/91 STUDY DAY OF DEATH: 46 STUDY WEEK OF DEATH: 7 TERMINAL BODY WEIGHT: 21.1 GRAMS
DATE AND TIME OF NECROPSY: 09/23/91 9:46 PROSECTOR: FRED AGEY RECORDER: FRED AGEY
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
LIVER/GALLBLADD (LI)	1.11	5.282 %	-----	WEIGHT TAKEN

*** GROSS PATHOLOGY OBSERVATIONS ***
ORGAN NAME SEVERITY, KEYWORD(S) OR PHRASE FREE-TEXT COMMENTS AND NOTES

^COLLECTED/TAKEN (XW)

-LIVER, IN 100% MEQH

GENERAL INFORMATION

ADDITIONAL NECROPSY COMMENT: >LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), LIVER (LI), OVARY (OV), SKIN, OTHER (SS), STOMACH, GL (ST)

*** NO ORGANS/TISSUES WERE RECORDED AS HAVING BEEN SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13C

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY IN TRICLOSAN IN CD-1
MICE. (SATELLITE-GROUPS 8-11)
DRAFT INDIVIDUAL ANIMAL NECROPSY DATA SHEET *DRAFT*

PRINTED: 21-JAN-93
PAGE: 1052

STUDY NUMBER: 483287

ANIMAL NUMBER: A37653 SEX: FEMALE DOSE GROUP: 2 SACRIFICE STATUS: SCHEDULED, FIRST INTERIM SACRIFICE
DATE OF DEATH: 09/23/91 STUDY DAY OF DEATH: 46 STUDY WEEK OF DEATH: 7 TERMINAL BODY WEIGHT: 21.8 GRAMS
DATE AND TIME OF NECROPSY: 09/23/91 10:25 PROSECTOR: SCOTT BELL RECORDER: SCOTT BELL
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
LIVER/GALLBLADD (LI)	1.30	5.972 %	-----	WEIGHT TAKEN

ORGAN NAME	SEVERITY, KEYWORD(S) OR PHRASE	FREE-TEXT COMMENTS AND NOTES
^COLLECTED/TAKEN (XW)	-LIVER, IN 100% MEQH	
GENERAL INFORMATION	ADDITIONAL NECROPSY COMMENT: >LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS	

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), LIVER (LI), OVARY (OV), SKIN, OTHER (SS), STOMACH, GL (ST)

*** NO ORGANS/TISSUES WERE RECORDED AS HAVING BEEN SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13C

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY IN TRICLOSAN IN CD-1
MICE. (SATELLITE-GROUPS 8-11)

PRINTED: 21-JAN-93
PAGE: 1053

DRAFT INDIVIDUAL ANIMAL NECROPSY DATA SHEET *DRAFT*

STUDY NUMBER: 483287

ANIMAL NUMBER: A37654 SEX: FEMALE DOSE GROUP: 2 SACRIFICE STATUS: SCHEDULED, FIRST INTERIM SACRIFICE
DATE OF DEATH: 09/23/91 STUDY DAY OF DEATH: 46 STUDY WEEK OF DEATH: 7 TERMINAL BODY WEIGHT: 21.3 GRAMS
DATE AND TIME OF NECROPSY: 09/23/91 10:57 PROSECTOR: FRED AGEY RECORDER: FRED AGEY
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
LIVER/GALLBLADD (LI)	1.18	5.521 %		WEIGHT TAKEN

ORGAN NAME	SEVERITY, KEYWORD(S) OR PHRASE	FREE-TEXT COMMENTS AND NOTES
LIVER (LI)	-PALE AREA	-LEFT LATERAL LOBE, ONE, TAN, 6 X 8 MM
^COLLECTED/TAKEN (XW)	-LIVER, IN 100% MEON	
GENERAL INFORMATION	ADDITIONAL NECROPSY COMMENT: >LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS	

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), OVARY (OV), SKIN, OTHER (SS), STOMACH, GL (ST)

*** NO ORGANS/TISSUES WERE RECORDED AS HAVING BEEN SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13C

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY IN TRICLOSAN IN CD-1
MICE. (SATELLITE-GROUPS 8-11)

PRINTED: 21-JAN-93
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DRAFT INDIVIDUAL ANIMAL NECROPSY DATA SHEET *DRAFT*

STUDY NUMBER: 483287

ANIMAL NUMBER: A37655 SEX: FEMALE DOSE GROUP: 2 SACRIFICE STATUS: SCHEDULED, FIRST INTERIM SACRIFICE
DATE OF DEATH: 09/23/91 STUDY DAY OF DEATH: 46 STUDY WEEK OF DEATH: 7 TERMINAL BODY WEIGHT: 23.3 GRAMS
DATE AND TIME OF NECROPSY: 09/23/91 11:33 PROSECTOR: FRED AGEY RECORDER: FRED AGEY
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
LIVER/GALLBLADD (LI)	1.13	4.842 %	-----	WEIGHT TAKEN

*** GROSS PATHOLOGY OBSERVATIONS ***
ORGAN NAME SEVERITY, KEYWORD(S) OR PHRASE FREE-TEXT COMMENTS AND NOTES

^COLLECTED/TAKEN (XW) -LIVER, IN 100% MEOR

GENERAL INFORMATION ADDITIONAL NECROPSY COMMENT: >LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), LIVER (LI), OVARY (OV), SKIN, OTHER (SS), STOMACH, GL (ST)

*** NO ORGANS/TISSUES WERE RECORDED AS HAVING BEEN SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13C

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY IN TRICLOSAN IN CD-1
MICE. (SATELLITE-GROUPS 8-11)

PRINTED: 21-JAN-93
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DRAFT INDIVIDUAL ANIMAL NECROPSY DATA SHEET *DRAFT*

STUDY NUMBER: 483287

ANIMAL NUMBER: A37656 SEX: FEMALE DOSE GROUP: 2 SACRIFICE STATUS: SCHEDULED, FIRST INTERIM SACRIFICE
DATE OF DEATH: 09/24/91 STUDY DAY OF DEATH: 47 STUDY WEEK OF DEATH: 7 TERMINAL BODY WEIGHT: 19.9 GRAMS
DATE AND TIME OF NECROPSY: 09/24/91 8:50 PROSECTOR: SCOTT BELL RECORDER: SCOTT BELL
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
LIVER/GALLBLADD (LI)	0.96	4.806 %	-----	WEIGHT TAKEN

*** GROSS PATHOLOGY OBSERVATIONS ***

ORGAN NAME	SEVERITY, KEYWORD(S) OR PHRASE	FREE-TEXT COMMENTS AND NOTES
COLLECTED/TAKEN (XW)	-LIVER, IN 100% MEON	
GENERAL INFORMATION	ADDITIONAL NECROPSY COMMENT: >LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS	

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), LIVER (LI), OVARY (OV), SKIN, OTHER (SS), STOMACH, GL (ST)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13C

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY IN TRICLOSAN IN CD-1
MICE. (SATELLITE-GROUPS 8-11)

PRINTED: 21-JAN-93
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DRAFT INDIVIDUAL ANIMAL NECROPSY DATA SHEET *DRAFT*

STUDY NUMBER: 483287

ANIMAL NUMBER: A37657 SEX: FEMALE DOSE GROUP: 2 SACRIFICE STATUS: SCHEDULED, FIRST INTERIM SACRIFICE
DATE OF DEATH: 09/24/91 STUDY DAY OF DEATH: 47 STUDY WEEK OF DEATH: 7 TERMINAL BODY WEIGHT: 19.9 GRAMS
DATE AND TIME OF NECROPSY: 09/24/91 9:28 PROSECTOR: ADEPOLAHAN AKINSOLA RECORDER: ADEPOLAHAN AKINSOLA
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
LIVER/GALLBLADD (LI)	0.96	4.813 %	-----	WEIGHT TAKEN

ORGAN NAME	SEVERITY, KEYWORD(S) OR PHRASE	FREE-TEXT COMMENTS AND NOTES
OVARY (OV)	-CYST	-LEFT, ONE, RED, 3 X 3 MM
^COLLECTED/TAKEN (XW)	-LIVER, IN 100% MEQH	
GENERAL INFORMATION	ADDITIONAL NECROPSY COMMENT: >HISTOLOGY REFERENCE:LEFT OVARY, IN CUP	
	ADDITIONAL NECROPSY COMMENT: >LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS	

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), LIVER (LI), SKIN, OTHER (SS), STOMACH, GL (ST)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

APPENDIX 13C

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.13-WEEK SUBCHRONIC ORAL TOXICITY STUDY IN TRICLOSAN IN CD-1
MICE. (SATELLITE-GROUPS 8-11)PRINTED: 21-JAN-93
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DRAFT INDIVIDUAL ANIMAL NECROPSY DATA SHEET *DRAFT*

STUDY NUMBER: 483287

ANIMAL NUMBER: A37658 SEX: FEMALE DOSE GROUP: 2 SACRIFICE STATUS: SCHEDULED, FIRST INTERIM SACRIFICE
DATE OF DEATH: 09/24/91 STUDY DAY OF DEATH: 47 STUDY WEEK OF DEATH: 7 TERMINAL BODY WEIGHT: 22.0 GRAMS
DATE AND TIME OF NECROPSY: 09/24/91 10:07 PROSECTOR: JANE EARHARDT RECORDER: JANE EARHARDT
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
LIVER/GALLBLADD (LI)	1.06	4.810 %	-----	WEIGHT TAKEN

*** GROSS PATHOLOGY OBSERVATIONS ***

ORGAN NAME	SEVERITY, KEYWORD(S) OR PHRASE	FREE-TEXT COMMENTS AND NOTES
------------	--------------------------------	------------------------------

^COLLECTED/TAKEN (XW)

-LIVER, IN 100% MEQH

GENERAL INFORMATION

ADDITIONAL NECROPSY COMMENT: >LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), LIVER (LI), OVARY (OV), SKIN, OTHER (SS), STOMACH, GL (ST)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13C

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY IN TRICLOSAN IN CD-1
MICE. (SATELLITE-GROUPS 8-11)

PRINTED: 21-JAN-93
PAGE: 1058

DRAFT INDIVIDUAL ANIMAL NECROPSY DATA SHEET *DRAFT*

STUDY NUMBER: 483287

ANIMAL NUMBER: A37659 SEX: FEMALE DOSE GROUP: 2 SACRIFICE STATUS: SCHEDULED, FIRST INTERIM SACRIFICE
DATE OF DEATH: 09/24/91 STUDY DAY OF DEATH: 47 STUDY WEEK OF DEATH: 7 TERMINAL BODY WEIGHT: 20.6 GRAMS
DATE AND TIME OF NECROPSY: 09/24/91 9:10 PROSECTOR: FRED AGEY RECORDER: FRED AGEY
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
LIVER/GALLBLADD (LI)	1.09	5.310 %	-----	WEIGHT TAKEN

*** GROSS PATHOLOGY OBSERVATIONS ***

ORGAN NAME	SEVERITY, KEYWORD(S) OR PHRASE	FREE-TEXT COMMENTS AND NOTES
^COLLECTED/TAKEN (XW)	-LIVER, IN 100% MEOH	
GENERAL INFORMATION (XX)	NECROPSY NOTE: >ANIMAL DIED PRIOR TO EUTHANASIA	
GENERAL INFORMATION	ADDITIONAL NECROPSY COMMENT: >LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS	

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), LIVER (LI), OVARY (OV), SKIN, OTHER (SS), STOMACH, GL (ST)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

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MICE. (SATELLITE-GROUPS 8-11)

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DRAFT INDIVIDUAL ANIMAL NECROPSY DATA SHEET *DRAFT*

STUDY NUMBER: 483287

ANIMAL NUMBER: A37660 SEX: FEMALE DOSE GROUP: 2 SACRIFICE STATUS: SCHEDULED, FIRST INTERIM SACRIFICE
DATE OF DEATH: 09/24/91 STUDY DAY OF DEATH: 47 STUDY WEEK OF DEATH: 7 TERMINAL BODY WEIGHT: 21.4 GRAMS
DATE AND TIME OF NECROPSY: 09/24/91 11:14 PROSECTOR: FRED AGEY RECORDER: FRED AGEY
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
LIVER/GALLBLADD (LI)	1.07	5.009 %	-----	WEIGHT TAKEN

*** GROSS PATHOLOGY OBSERVATIONS ***
ORGAN NAME SEVERITY, KEYWORD(S) OR PHRASE FREE-TEXT COMMENTS AND NOTES

^COLLECTED/TAKEN (XW) -LIVER, IN 100% MEOH

GENERAL INFORMATION ADDITIONAL NECROPSY COMMENT: >LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), LIVER (LI), OVARY (OV), SKIN, OTHER (SS), STOMACH, GL (ST)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

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MICE. (SATELLITE-GROUPS 8-11)

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DRAFT INDIVIDUAL ANIMAL NECROPSY DATA SHEET *DRAFT*

STUDY NUMBER: 483287

ANIMAL NUMBER: A37671 SEX: FEMALE DOSE GROUP: 3 SACRIFICE STATUS: SCHEDULED, FIRST INTERIM SACRIFICE
DATE OF DEATH: 09/23/91 STUDY DAY OF DEATH: 46 STUDY WEEK OF DEATH: 7 TERMINAL BODY WEIGHT: 21.2 GRAMS
DATE AND TIME OF NECROPSY: 09/23/91 9:20 PROSECTOR: ADEFOLAHAN AKINSOLA RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
LIVER/GALLBLADD (LI)	1.90	8.944 %	-----	WEIGHT TAKEN

*** GROSS PATHOLOGY OBSERVATIONS ***
ORGAN NAME SEVERITY, KEYWORD(S) OR PHRASE FREE-TEXT COMMENTS AND NOTES

^COLLECTED/TAKEN (XW)

-LIVER, IN 100% MEOH

GENERAL INFORMATION

ADDITIONAL NECROPSY COMMENT: >LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), LIVER (LI), OVARY (OV), SKIN, OTHER (SS), STOMACH, GL (ST)

*** NO ORGANS/TISSUES WERE RECORDED AS HAVING BEEN SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

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13-WEEK SUBCHRONIC ORAL TOXICITY STUDY IN TRICLOSAN IN CD-1
MICE. (SATELLITE-GROUPS 8-11)

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DRAFT INDIVIDUAL ANIMAL NECROPSY DATA SHEET *DRAFT*

STUDY NUMBER: 483287

ANIMAL NUMBER: A37672 SEX: FEMALE DOSE GROUP: 3 SACRIFICE STATUS: SCHEDULED, FIRST INTERIM SACRIFICE
DATE OF DEATH: 09/23/91 STUDY DAY OF DEATH: 46 STUDY WEEK OF DEATH: 7 TERMINAL BODY WEIGHT: 23.4 GRAMS
DATE AND TIME OF NECROPSY: 09/23/91 9:52 PROSECTOR: ADEFOLAHAN AKINSOLA RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
LIVER/GALLBLADD (LI)	2.07	8.844 %	-----	WEIGHT TAKEN

ORGAN NAME	SEVERITY, KEYWORD(S) OR PHRASE	FREE-TEXT COMMENTS AND NOTES
LIVER (LI)	-PALE AREA	-ALL LOBES, FEW, WHITE, TAN, PINPOINT TO 5 X 4 MM
^COLLECTED/TAKEN (XW)	-LIVER, IN 100% MEOH	
GENERAL INFORMATION	ADDITIONAL NECROPSY COMMENT: LAST PHYSICAL EXAM: NORMAL-NO REMARKABLE OBSERVATIONS	

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), OVARY (OV), SKIN, OTHER (SS), STOMACH, GL (ST)

*** NO ORGANS/TISSUES WERE RECORDED AS HAVING BEEN SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

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13-WEEK SUBCHRONIC ORAL TOXICITY STUDY IN TRICLOSAN IN CD-1
MICE. (SATELLITE-GROUPS 8-11)

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DRAFT INDIVIDUAL ANIMAL NECROPSY DATA SHEET *DRAFT*

STUDY NUMBER: 483287

ANIMAL NUMBER: A37673 SEX: FEMALE DOSE GROUP: 3 SACRIFICE STATUS: SCHEDULED, FIRST INTERIM SACRIFICE
DATE OF DEATH: 09/23/91 STUDY DAY OF DEATH: 46 STUDY WEEK OF DEATH: 7 TERMINAL BODY WEIGHT: 23.0 GRAMS
DATE AND TIME OF NECROPSY: 09/23/91 10:28 PROSECTOR: DOUGLAS HERNDON RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
LIVER/GALLBLADD (LI)	2.27	9.891 %	-----	WEIGHT TAKEN

*** GROSS PATHOLOGY OBSERVATIONS ***

ORGAN NAME	SEVERITY, KEYWORD(S) OR PHRASE	FREE-TEXT COMMENTS AND NOTES
LIVER (LI)	-PALE AREA -DARK	-ALL LOBES, SEVERAL, TAN, PINPOINT TO 2 X 2 MM -ALL LOBES, DARK BROWN
COLLECTED/TAKEN (XW)	-LIVER, IN 100% MEOH	
GENERAL INFORMATION	ADDITIONAL NECROPSY COMMENT: LAST PHYSICAL EXAM: NORMAL-NO REMARKABLE OBSERVATIONS	

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), OVARY (OV), SKIN, OTHER (SS), STOMACH, GL (ST)

*** NO ORGANS/TISSUES WERE RECORDED AS HAVING BEEN SAVED ***

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13-WEEK SUBCHRONIC ORAL TOXICITY STUDY IN TRICLOSAN IN CD-1
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DRAFT INDIVIDUAL ANIMAL NECROPSY DATA SHEET *DRAFT*

STUDY NUMBER: 483287

ANIMAL NUMBER: A37674 SEX: FEMALE DOSE GROUP: 3 SACRIFICE STATUS: SCHEDULED, FIRST INTERIM SACRIFICE
DATE OF DEATH: 09/23/91 STUDY DAY OF DEATH: 46 STUDY WEEK OF DEATH: 7 TERMINAL BODY WEIGHT: 23.7 GRAMS
DATE AND TIME OF NECROPSY: 09/23/91 11:03 PROSECTOR: SCOTT BELL RECORDER: SCOTT BELL
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
LIVER/GALLBLADD (LI)	2.01	8.474 %	-----	WEIGHT TAKEN

ORGAN NAME	SEVERITY, KEYWORD(S) OR PHRASE	FREE-TEXT COMMENTS AND NOTES
LIVER (LI)	-PALE AREA -DARK -ENLARGED, MODERATE	-LEFT LATERAL, MEDIAN LOBES, SEVERAL, TAN, PINPOINT TO 1 X 1 MM -ALL LOBES, DARK RED, BROWN -ALL LOBES
^COLLECTED/TAKEN (XW)	-LIVER, IN 100% MEOH	
GENERAL INFORMATION	ADDITIONAL NECROPSY COMMENT: >LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS	

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), OVARY (OV), SKIN, OTHER (SS), STOMACH, GL (ST)

*** NO ORGANS/TISSUES WERE RECORDED AS HAVING BEEN SAVED ***

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13-WEEK SUBCHRONIC ORAL TOXICITY STUDY IN TRICLOSAN IN CD-1
MICE. (SATELLITE-GROUPS 8-11)

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DRAFT INDIVIDUAL ANIMAL NECROPSY DATA SHEET *DRAFT*

STUDY NUMBER: 483287

ANIMAL NUMBER: A37675 SEX: FEMALE DOSE GROUP: 3 SACRIFICE STATUS: SCHEDULED, FIRST INTERIM SACRIFICE
DATE OF DEATH: 09/23/91 STUDY DAY OF DEATH: 46 STUDY WEEK OF DEATH: 7 TERMINAL BODY WEIGHT: 22.2 GRAMS
DATE AND TIME OF NECROPSY: 09/23/91 11:45 PROSECTOR: SCOTT BELL RECORDER: SCOTT BELL
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
LIVER/GALLBLADD (LI)	2.00	9.009 %	-----	WEIGHT TAKEN

ORGAN NAME	SEVERITY, KEYWORD(S) OR PHRASE	FREE-TEXT COMMENTS AND NOTES
LIVER (LI)	-PALE AREA -DARK -ENLARGED, MODERATE	-ALL LOBES, SEVERAL, TAN, PINPOINT TO 2 X 2 MM -ALL LOBES, DARK RED, BROWN -ALL LOBES
^COLLECTED/TAKEN (XW)	-LIVER, IN 100% MEQH	
GENERAL INFORMATION	ADDITIONAL NECROPSY COMMENT: >LAST PHYSICAL EXAM: NORMAL-NO REMARKABLE OBSERVATIONS	

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), OVARY (OV), SKIN, OTHER (SS), STOMACH, GL (ST)

*** NO ORGANS/TISSUES WERE RECORDED AS HAVING BEEN SAVED ***

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13-WEEK SUBCHRONIC ORAL TOXICITY STUDY IN TRICLOSAN IN CD-1
MICE. (SATELLITE-GROUPS 8-11)

DRAFT INDIVIDUAL ANIMAL NECROPSY DATA SHEET *DRAFT*

STUDY NUMBER: 483287

ANIMAL NUMBER: A37676 SEX: FEMALE DOSE GROUP: 3 SACRIFICE STATUS: SCHEDULED, FIRST INTERIM SACRIFICE
DATE OF DEATH: 09/24/91 STUDY DAY OF DEATH: 47 STUDY WEEK OF DEATH: 7 TERMINAL BODY WEIGHT: 23.5 GRAMS
DATE AND TIME OF NECROPSY: 09/24/91 8:52 PROSECTOR: JANE EARHARDT RECORDER: JANE EARHARDT
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
LIVER/GALLBLADD (LI)	2.14	9.089 %	-----	WEIGHT TAKEN

*** GROSS PATHOLOGY OBSERVATIONS ***

ORGAN NAME	SEVERITY, KEYWORD(S) OR PHRASE	FREE-TEXT COMMENTS AND NOTES
LIVER (LI)	-DARK -ENLARGED, MODERATE	-ALL LOBES, BROWN -ALL LOBES
^COLLECTED/TAKEN (XW)	-LIVER, IN 100% MEOH	
GENERAL INFORMATION	ADDITIONAL NECROPSY COMMENT: >LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS	

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), OVARY (OV), SKIN, OTHER (SS), STOMACH, GL (ST)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

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13-WEEK SUBCHRONIC ORAL TOXICITY STUDY IN TRICLOSAN IN CD-1
MICE. (SATELLITE-GROUPS 8-11)

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DRAFT INDIVIDUAL ANIMAL NECROPSY DATA SHEET *DRAFT*

STUDY NUMBER: 483287

ANIMAL NUMBER: A37677 SEX: FEMALE DOSE GROUP: 3 SACRIFICE STATUS: SCHEDULED, FIRST INTERIM SACRIFICE
DATE OF DEATH: 09/24/91 STUDY DAY OF DEATH: 47 STUDY WEEK OF DEATH: 7 TERMINAL BODY WEIGHT: 22.2 GRAMS
DATE AND TIME OF NECROPSY: 09/24/91 9:40 PROSECTOR: FRED AGEY RECORDER: FRED AGEY
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
LIVER/GALLBLADD (LI)	2.02	9.112 %		WEIGHT TAKEN

ORGAN NAME	SEVERITY, KEYWORD(S) OR PHRASE	FREE-TEXT COMMENTS AND NOTES
LIVER (LI)	-PALE AREA -DARK -ENLARGED, SEVERE	-ALL LOBES, SEVERAL, TAN, PINPOINT TO 2 X 2 MM -ALL LOBES, DARK BROWN -ALL LOBES
COLLECTED/TAKEN (XW)	-LIVER, IN 100% MEQH	
GENERAL INFORMATION	ADDITIONAL NECROPSY COMMENT: >LAST PHYSICAL EXAM: NORMAL-NO REMARKABLE OBSERVATIONS	

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), OVARY (OV), SKIN, OTHER (SS), STOMACH, GL (ST)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

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13-WEEK SUBCHRONIC ORAL TOXICITY STUDY IN TRICLOSAN IN CD-1
MICE. (SATELLITE-GROUPS 8-11)

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DRAFT INDIVIDUAL ANIMAL NECROPSY DATA SHEET *DRAFT*

STUDY NUMBER: 483287

ANIMAL NUMBER: A37678 SEX: FEMALE DOSE GROUP: 3 SACRIFICE STATUS: SCHEDULED, FIRST INTERIM SACRIFICE
DATE OF DEATH: 09/24/91 STUDY DAY OF DEATH: 47 STUDY WEEK OF DEATH: 7 TERMINAL BODY WEIGHT: 23.3 GRAMS
DATE AND TIME OF NECROPSY: 09/24/91 10:15 PROSECTOR: SCOTT BELL RECORDER: SCOTT BELL
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
LIVER/GALLBLADD (LI)	2.03	8.699 %	-----	WEIGHT TAKEN

ORGAN NAME	SEVERITY, KEYWORD(S) OR PHRASE	FREE-TEXT COMMENTS AND NOTES
LIVER (LI)	-PALE AREA -DARK	-ALL LOBES, FEW, WHITE, PINPOINT -ALL LOBES, DARK BROWN
^COLLECTED/TAKEN (XW)	-LIVER, IN 100% MEOH	
GENERAL INFORMATION	ADDITIONAL NECROPSY COMMENT: >LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS	

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), OVARY (OV), SKIN, OTHER (SS), STOMACH, GL (ST)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

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13-WEEK SUBCHRONIC ORAL TOXICITY STUDY IN TRICLOSAN IN CD-1
MICE. (SATELLITE-GROUPS 8-11)

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DRAFT INDIVIDUAL ANIMAL NECROPSY DATA SHEET *DRAFT*

STUDY NUMBER: 483287

ANIMAL NUMBER: A37679 SEX: FEMALE DOSE GROUP: 3 SACRIFICE STATUS: SCHEDULED, FIRST INTERIM SACRIFICE
DATE OF DEATH: 09/24/91 STUDY DAY OF DEATH: 47 STUDY WEEK OF DEATH: 7 TERMINAL BODY WEIGHT: 25.0 GRAMS
DATE AND TIME OF NECROPSY: 09/24/91 10:44 PROSECTOR: JANE EARHARDT RECORDER: JANE EARHARDT
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
LIVER/GALLBLADD (LI)	2.30	9.189 %	-----	WEIGHT TAKEN

ORGAN NAME	SEVERITY, KEYWORD(S) OR PHRASE	FREE-TEXT COMMENTS AND NOTES
LIVER (LI)	-PALE AREA -DARK	-LEFT LATERAL LOBE, MEDIAN LOBE, TWO, TAN, 3 X 2 MM -ALL LOBES, DARK BROWN
^COLLECTED/TAKEN (XW)	-LIVER, IN 100% MEOH	
GENERAL INFORMATION	ADDITIONAL NECROPSY COMMENT: >LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS	

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), OVARY (OV), SKIN, OTHER (SS), STOMACH, GL (ST)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

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13-WEEK SUBCHRONIC ORAL TOXICITY STUDY IN TRICLOSAN IN CD-1
MICE. (SATELLITE-GROUPS 8-11)

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DRAFT INDIVIDUAL ANIMAL NECROPSY DATA SHEET *DRAFT*

STUDY NUMBER: 483287

ANIMAL NUMBER: A37680 SEX: FEMALE DOSE GROUP: 3 SACRIFICE STATUS: SCHEDULED, FIRST INTERIM SACRIFICE
DATE OF DEATH: 09/24/91 STUDY DAY OF DEATH: 47 STUDY WEEK OF DEATH: 7 TERMINAL BODY WEIGHT: 24.0 GRAMS
DATE AND TIME OF NECROPSY: 09/24/91 11:17 PROSECTOR: SCOTT BELL RECORDER: SCOTT BELL
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
LIVER/GALLBLADD (LI)	2.11	8.809 %	-----	WEIGHT TAKEN

ORGAN NAME	SEVERITY, KEYWORD(S) OR PHRASE	FREE-TEXT COMMENTS AND NOTES
KIDNEY (KD)	-CYST	-RIGHT CORTEX, ONE, CLEAR, 1 X 1 MM
LIVER (LI)	-PALE AREA	-ALL LOBES, FEW, TAN, PINPOINT
^COLLECTED/TAKEN (XW)	-LIVER, IN 100% MEOH	
GENERAL INFORMATION	ADDITIONAL NECROPSY COMMENT: >LAST PHYSICAL EXAM: NORMAL-NO REMARKABLE OBSERVATIONS	

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
OVARY (OV), SKIN, OTHER (SS), STOMACH, GL (ST)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

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13-WEEK SUBCHRONIC ORAL TOXICITY STUDY IN TRICLOSAN IN CD-1
MICE. (SATELLITE-GROUPS 8-11)
DRAFT INDIVIDUAL ANIMAL NECROPSY DATA SHEET *DRAFT*

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STUDY NUMBER: 483287

ANIMAL NUMBER: A37691 SEX: FEMALE DOSE GROUP: 4 SACRIFICE STATUS: SCHEDULED, FIRST INTERIM SACRIFICE
DATE OF DEATH: 09/23/91 STUDY DAY OF DEATH: 46 STUDY WEEK OF DEATH: 7 TERMINAL BODY WEIGHT: 21.0 GRAMS
DATE AND TIME OF NECROPSY: 09/23/91 9:17 PROSECTOR: DOUGLAS HERNDON RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
LIVER/GALLBLADD (LI)	3.97	18.911 %		WEIGHT TAKEN

ORGAN NAME	SEVERITY, KEYWORD(S) OR PHRASE	FREE-TEXT COMMENTS AND NOTES
LIVER (LI)	-PALE AREA -DARK -ENLARGED, MODERATE	-ALL LOBES, FEW, TAN, PINPOINT TO 8 X 4 MM -ALL LOBES, DARK BROWN -ALL LOBES
^COLLECTED/TAKEN (XW)	-LIVER, IN 100% MEOH	
GENERAL INFORMATION	ADDITIONAL NECROPSY COMMENT: >LAST PHYSICAL EXAM: NORMAL-NO REMARKABLE OBSERVATIONS	

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), OVARY (OV), SKIN, OTHER (SS), STOMACH, GL (ST)

*** NO ORGANS/TISSUES WERE RECORDED AS HAVING BEEN SAVED ***

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13-WEEK SUBCHRONIC ORAL TOXICITY STUDY IN TRICLOSAN IN CD-1
MICE. (SATELLITE-GROUPS 8-11)

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DRAFT INDIVIDUAL ANIMAL NECROPSY DATA SHEET *DRAFT*

STUDY NUMBER: 483287

ANIMAL NUMBER: A37692 SEX: FEMALE DOSE GROUP: 4 SACRIFICE STATUS: SCHEDULED, FIRST INTERIM SACRIFICE
DATE OF DEATH: 09/23/91 STUDY DAY OF DEATH: 46 STUDY WEEK OF DEATH: 7 TERMINAL BODY WEIGHT: 21.2 GRAMS
DATE AND TIME OF NECROPSY: 09/23/91 9:53 PROSECTOR: DOUGLAS HERNDON RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
LIVER/GALLBLADD (LI)	2.77	13.059 %	-----	WEIGHT TAKEN

ORGAN NAME	SEVERITY, KEYWORD(S) OR PHRASE	FREE-TEXT COMMENTS AND NOTES
LIVER (LI)	-PALE AREA -DARK	-ALL LOBES, FEW, TAN, PINPOINT TO 2 X 2 MM -ALL LOBES, DARK BROWN
COLLECTED/TAKEN (XW)	-LIVER, IN 100% MECH	
GENERAL INFORMATION	ADDITIONAL NECROPSY COMMENT: LAST PHYSICAL EXAM: NORMAL-NO REMARKABLE OBSERVATIONS	

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), OVARY (OV), SKIN, OTHER (SS), STOMACH, GL (ST)

*** NO ORGANS/TISSUES WERE RECORDED AS HAVING BEEN SAVED ***

APPENDIX 13C

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY IN TRICLOSAN IN CD-1
MICE. (SATELLITE-GROUPS 8-11)

PRINTED: 21-JAN-93
PAGE: 1072

DRAFT INDIVIDUAL ANIMAL NECROPSY DATA SHEET *DRAFT*

STUDY NUMBER: 483287

ANIMAL NUMBER: A37693 SEX: FEMALE DOSE GROUP: 4 SACRIFICE STATUS: SCHEDULED, FIRST INTERIM SACRIFICE
DATE OF DEATH: 09/23/91 STUDY DAY OF DEATH: 46 STUDY WEEK OF DEATH: 7 TERMINAL BODY WEIGHT: 20.3 GRAMS
DATE AND TIME OF NECROPSY: 09/23/91 10:28 PROSECTOR: ADEFOLAHAN AKINSOLA RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
LIVER/GALLBLADD (LI)	2.46	12.108 %	-----	WEIGHT TAKEN

ORGAN NAME	SEVERITY, KEYWORD(S) OR PHRASE	FREE-TEXT COMMENTS AND NOTES
LIVER (LI)	-PALE AREA	-ALL LOBES, FEW, TAN, WHITE, PINPOINT TO 5 X 5 MM
COLLECTED/TAKEN (XW)	-LIVER, IN 100% MECH	
GENERAL INFORMATION		

ADDITIONAL NECROPSY COMMENT: >LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), OVARY (OV), SKIN, OTHER (SS), STOMACH, GL (ST)

*** NO ORGANS/TISSUES WERE RECORDED AS HAVING BEEN SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13C

PRINTED: 21-JAN-93
PAGE: 1073

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY IN TRICLOSAN IN CD-1
MICE. (SATELLITE-GROUPS 8-11)

DRAFT INDIVIDUAL ANIMAL NECROPSY DATA SHEET *DRAFT*

STUDY NUMBER: 483287

ANIMAL NUMBER: A37694 SEX: FEMALE DOSE GROUP: 4 SACRIFICE STATUS: SCHEDULED, FIRST INTERIM SACRIFICE
DATE OF DEATH: 09/23/91 STUDY DAY OF DEATH: 46 STUDY WEEK OF DEATH: 7 TERMINAL BODY WEIGHT: 21.2 GRAMS
DATE AND TIME OF NECROPSY: 09/23/91 11:13 PROSECTOR: ADEFOLAHAN AKINSOLA RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
LIVER/GALLBLADD (LI)	2.77	13.046 %	-----	WEIGHT TAKEN

ORGAN NAME	SEVERITY, KEYWORD(S) OR PHRASE	FREE-TEXT COMMENTS AND NOTES
LIVER (LI)	-PALE AREA	-RIGHT LATERAL, LEFT LATERAL LOBES, FEW, TAN, WHITE, PINPOINT
^COLLECTED/TAKEN (XW)	-LIVER, IN 100% MEOH	
GENERAL INFORMATION	ADDITIONAL NECROPSY COMMENT: >LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS	

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), OVARY (OV), SKIN, OTHER (SS), STOMACH, GL (ST)

*** NO ORGANS/TISSUES WERE RECORDED AS HAVING BEEN SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13C

PRINTED: 21-JAN-93
PAGE: 1074

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY IN TRICLOSAN IN CD-1
MICE. (SATELLITE-GROUPS 8-11)

DRAFT INDIVIDUAL ANIMAL NECROPSY DATA SHEET *DRAFT*

STUDY NUMBER: 483287

ANIMAL NUMBER: A37695 SEX: FEMALE DOSE GROUP: 4 SACRIFICE STATUS: SCHEDULED, FIRST INTERIM SACRIFICE
DATE OF DEATH: 09/23/91 STUDY DAY OF DEATH: 46 STUDY WEEK OF DEATH: 7 TERMINAL BODY WEIGHT: 22.2 GRAMS
DATE AND TIME OF NECROPSY: 09/23/91 11:36 PROSECTOR: DOUGLAS HERNDON RECORDER: JOHN CROWLEY
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
LIVER/GALLBLADD (LI)	2.58	11.609 %	-----	WEIGHT TAKEN

ORGAN NAME	SEVERITY, KEYWORD(S) OR PHRASE	FREE-TEXT COMMENTS AND NOTES
LIVER (LI)	-PALE AREA	-ALL LOBES, FEW, TAN, PINPOINT TO 2 X 2 MM
COLLECTED/TAKEN (XW)	-LIVER, IN 100% MEOH	
GENERAL INFORMATION	ADDITIONAL NECROPSY COMMENT:	LAST PHYSICAL EXAM: NORMAL-NO REMARKABLE OBSERVATIONS LAST CAGESIDE OBSERVATIONS: HUNCHED POSTURE; HYPOACTIVE

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), OVARY (OV), SKIN, OTHER (SS), STOMACH, GL (ST)

*** NO ORGANS/TISSUES WERE RECORDED AS HAVING BEEN SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13C

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY IN TRICLOSAN IN CD-1
MICE. (SATELLITE-GROUPS 8-11)

PRINTED: 21-JAN-93
PAGE: 1075

DRAFT INDIVIDUAL ANIMAL NECROPSY DATA SHEET *DRAFT*

STUDY NUMBER: 483287

ANIMAL NUMBER: A37696 SEX: FEMALE DOSE GROUP: 4 SACRIFICE STATUS: SCHEDULED, FIRST INTERIM SACRIFICE
DATE OF DEATH: 09/24/91 STUDY DAY OF DEATH: 47 STUDY WEEK OF DEATH: 7 TERMINAL BODY WEIGHT: 23.3 GRAMS
DATE AND TIME OF NECROPSY: 09/24/91 8:52 PROSECTOR: FRED AGEY RECORDER: FRED AGEY
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
LIVER/GALLBLADD (LI)	3.39	14.540 %	-----	WEIGHT TAKEN

ORGAN NAME	SEVERITY, KEYWORD(S) OR PHRASE	FREE-TEXT COMMENTS AND NOTES
LIVER (LI)	-PALE AREA -DARK -ENLARGED, SEVERE	-ALL LOBES, MULTIPLE, TAN, WHITE, PINPOINT TO 3 X 3 MM -ALL LOBES, DARK BROWN -ALL LOBES
^COLLECTED/TAKEN (XW)	-LIVER, IN 100% MEOH	
GENERAL INFORMATION	ADDITIONAL NECROPSY COMMENT: >LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS	

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), OVARY (OV), SKIN, OTHER (SS), STOMACH, GL (ST)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13C

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY IN TRICLOSAN IN CD-1
MICE. (SATELLITE-GROUPS 8-11)

PRINTED: 21-JAN-93
PAGE: 1076

DRAFT INDIVIDUAL ANIMAL NECROPSY DATA SHEET *DRAFT*

STUDY NUMBER: 483287

ANIMAL NUMBER: A37697 SEX: FEMALE DOSE GROUP: 4 SACRIFICE STATUS: SCHEDULED, FIRST INTERIM SACRIFICE
DATE OF DEATH: 09/24/91 STUDY DAY OF DEATH: 47 STUDY WEEK OF DEATH: 7 TERMINAL BODY WEIGHT: 21.6 GRAMS
DATE AND TIME OF NECROPSY: 09/24/91 9:45 PROSECTOR: SCOTT BELL RECORDER: SCOTT BELL
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
LIVER/GALLBLADD (LI)	2.93	13.572 %		WEIGHT TAKEN

*** GROSS PATHOLOGY OBSERVATIONS ***
ORGAN NAME SEVERITY, KEYWORD(S) OR PHRASE FREE-TEXT COMMENTS AND NOTES

^COLLECTED/TAKEN (XW)

-LIVER, IN 100% MEQH

GENERAL INFORMATION

ADDITIONAL NECROPSY COMMENT: >LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:

KIDNEY (KD), LIVER (LI), OVARY (OV), SKIN, OTHER (SS), STOMACH, GL (ST)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13C

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY IN TRICLOSAN IN CD-1
MICE. (SATELLITE-GROUPS 8-11)

PRINTED: 21-JAN-93
PAGE: 1077

DRAFT INDIVIDUAL ANIMAL NECROPSY DATA SHEET *DRAFT*

STUDY NUMBER: 483287

ANIMAL NUMBER: A37698 SEX: FEMALE DOSE GROUP: 4 SACRIFICE STATUS: SCHEDULED, FIRST INTERIM SACRIFICE
DATE OF DEATH: 09/24/91 STUDY DAY OF DEATH: 47 STUDY WEEK OF DEATH: 7 TERMINAL BODY WEIGHT: 24.9 GRAMS
DATE AND TIME OF NECROPSY: 09/24/91 10:18 PROSECTOR: FRED AGEY RECORDER: FRED AGEY
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
LIVER/GALLBLADD (LI)	3.21	12.886 %	-----	WEIGHT TAKEN

ORGAN NAME	SEVERITY, KEYWORD(S) OR PHRASE	FREE-TEXT COMMENTS AND NOTES
LIVER (LI)	-PALE AREA -DARK -ENLARGED, SEVERE	-ALL LOBES, MULTIPLE, TAN, WHITE, PINPOINT TO 4 X 4 MM -ALL LOBES, DARK BROWN -ALL LOBES
COLLECTED/TAKEN (XW)	-LIVER, IN 100% MEOH	

GENERAL INFORMATION

ADDITIONAL NECROPSY COMMENT: >LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), OVARY (OV), SKIN, OTHER (SS), STOMACH, GL (ST)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13C

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY IN TRICLOSAN IN CD-1
MICE. (SATELLITE-GROUPS 8-11)

PRINTED: 21-JAN-93
PAGE: 1078

DRAFT INDIVIDUAL ANIMAL NECROPSY DATA SHEET *DRAFT*

STUDY NUMBER: 483287

ANIMAL NUMBER: A37699 SEX: FEMALE DOSE GROUP: 4 SACRIFICE STATUS: SCHEDULED, FIRST INTERIM SACRIFICE
DATE OF DEATH: 09/24/91 STUDY DAY OF DEATH: 47 STUDY WEEK OF DEATH: 7 TERMINAL BODY WEIGHT: 23.4 GRAMS
DATE AND TIME OF NECROPSY: 09/24/91 10:43 PROSECTOR: SCOTT BELL RECORDER: SCOTT BELL
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
LIVER/GALLBLADD (LI)	3.06	13.071 %	-----	WEIGHT TAKEN

ORGAN NAME	SEVERITY, KEYWORD(S) OR PHRASE	FREE-TEXT COMMENTS AND NOTES
LIVER (LI)	-PALE AREA -DARK -ENLARGED, SEVERE	-ALL LOBES, FEW, WHITE, PINPOINT TO 1 X 1 MM -ALL LOBES, DARK BROWN -ALL LOBES
^COLLECTED/TAKEN (KW)	-LIVER, IN 100% MEOH	
GENERAL INFORMATION	ADDITIONAL NECROPSY COMMENT: >LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS	

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), OVARY (OV), SKIN, OTHER (SS), STOMACH, GL (ST)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

HAZLETON WASHINGTON, INC.
WASHINGTON, D.C. U.S.A.

APPENDIX 13C

13-WEEK SUBCHRONIC ORAL TOXICITY STUDY IN TRICLOSAN IN CD-1
MICE. (SATELLITE-GROUPS 8-11)

DRAFT INDIVIDUAL ANIMAL NECROPSY DATA SHEET *DRAFT*

PRINTED: 21-JAN-93
PAGE: 1079

STUDY NUMBER: 483287

ANIMAL NUMBER: A37700 SEX: FEMALE DOSE GROUP: 4 SACRIFICE STATUS: SCHEDULED, FIRST INTERIM SACRIFICE
DATE OF DEATH: 09/24/91 STUDY DAY OF DEATH: 47 STUDY WEEK OF DEATH: 7 TERMINAL BODY WEIGHT: 19.9 GRAMS
DATE AND TIME OF NECROPSY: 09/24/91 11:20 PROSECTOR: ADEFOLAHAN AKINSOLA RECORDER: ADEFOLAHAN AKINSOLA
POST-FIX WEIGHER: NOT REQUIRED BY PROTOCOL PATHOLOGIST: NOT REQUIRED BY PROTOCOL WEIGHER: RICHARD KAGYARE

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
LIVER/GALLBLADD (LI)	2.51	12.595 %	-----	WEIGHT TAKEN

ORGAN NAME	SEVERITY, KEYWORD(S) OR PHRASE	FREE-TEXT COMMENTS AND NOTES
LIVER (LI)	-PALE AREA	-ALL LOBES, SEVERAL, TAN, WHITE, PINPOINT TO 4 X 4 MM
COLLECTED/TAKEN (XW)	-LIVER, IN 100% MEOH	
GENERAL INFORMATION	ADDITIONAL NECROPSY COMMENT: >LAST PHYSICAL EXAM:NORMAL-NO REMARKABLE OBSERVATIONS	

THE FOLLOWING ORGANS WERE UNREMARKABLE AT NECROPSY:
KIDNEY (KD), OVARY (OV), SKIN, OTHER (SS), STOMACH, GL (ST)

*** ALL ORGANS/TISSUES (REQUIRED TO BE HARVESTED PER THE STUDY PROTOCOL) WERE SAVED ***

Appendix 14
Data Transformations
13-Week Subchronic Oral Toxicity Study of Triclosan in CD-1[®] Mice

NOTE: "T" indicates the final transformation used for a particular data set.

Appendix 14
Data Transformations
13-Week Subchronic Oral Toxicity Study of Triclosan in CD-1® Mice

Parameter	Interval	Sex	Transformations						
			Log10	X ²	X ^{1/2}	1/X	Arcsine X ^{1/2}	Rank X	
RBC	Week 7	M						T	
HGB	Week 7	M						T	
HCT	Week 7	M						T	
LYMPH	Week 7	M						T	
MONO	Week 7	M						T	
EOSIN	Week 7	M				T			
SEG	Week 7	F	T						
MONO	Week 7	F						T	
RBC	Week 14	M						T	
HGB	Week 14	M						T	
HCT	Week 14	M						T	
MONO	Week 14	M						T	
EOSIN	Week 14	M						T	
BASO	Week 14	M						T	
RBC	Week 14	F						T	
HGB	Week 14	F						T	
HCT	Week 14	F						T	
SEG	Week 14	F	T						
LYMPH	Week 14	F	T						
MONO	Week 14	F						T	
EOSIN	Week 14	F						T	
CREAT	Week 7	M						T	
ALT	Week 7	M	T						
ALK P	Week 7	M						T	
GGT	Week 7	M						T	
ALT	Week 7	F						T	
ALK P	Week 7	F						T	
T BILI	Week 7	F						T	
TRIGLY	Week 7	F		T					
BUN	Week 14	M	T						

Appendix 14 - Continued
Data Transformations
13-Week Subchronic Oral Toxicity Study of Triclosan in CD-1[®] Mice

Parameter	Interval	Sex	Transformations						
			Log ₁₀	X ²	X ^½	1/X	Arcsine X ^½	Rank X	
T CHOL	Week 14	M		T					
AST	Week 14	M						T	
ALT	Week 14	M	T						
ALK P	Week 14	M						T	
A/G	Week 14	M						T	
TRIGLY	Week 14	M	T						
GGT	Week 14	M						T	
GLUCOSE	Week 14	F						T	
T CHOL	Week 14	F	T						
ALT	Week 14	F	T						
LDH	Week 14	F	T						
ALK P	Week 14	F	T						
GGT	Week 14	F						T	
LIVER/GALLBLADDER ABSOLUTE WEIGHTS	Week 7	F						T	
LIVER/GALLBLADDER BODY WEIGHT RATIO	Week 7	F	T						
LIVER/GALLBLADDER ABSOLUTE WEIGHTS	Week 7	M	T						
LIVER/GALLBLADDER ABSOLUTE WEIGHTS	Week 14	F	T						
SPLEEN ABSOLUTE WEIGHTS	Week 14	F				T			
LIVER/GALLBLADDER BODY WEIGHT RATIO	Week 14	F	T						
SPLEEN BODY WEIGHT RATIO	Week 14	F						T	
LIVER/GALLBLADDER BRAIN WEIGHT RATIO	Week 14	F	T						
LIVER/GALLBLADDER ABSOLUTE WEIGHTS	Week 14	M						T	
LUNG ABSOLUTE WEIGHTS	Week 14	M						T	
SPLEEN ABSOLUTE WEIGHTS	Week 14	M				T			
KIDNEY BODY WEIGHT RATIO	Week 14	M						T	
LIVER/GALLBLADDER BODY WEIGHT RATIO	Week 14	M	T						

Appendix 14 - Continued
Data Transformations
13-Week Subchronic Oral Toxicity Study of Triclosan in CD-1[®] Mice

Parameter	Interval	Sex	Transformations					
			Log ₁₀	X ²	X ^{1/2}	1/X	Arcsine X ^{1/2}	Rank X
SPLEEN BODY WEIGHT RATIO	Week 14	M	T					
LIVER/GALLBLADDER BRAIN WEIGHT RATIO	Week 14	M	T					
BODY WEIGHT GAIN - SATELLITE STUDY	Weeks 1-6	F						T
TREND - HEMATOCRIT	Week 14	M						T
TREND - HEMATOCRIT	Week 7	F						T
TREND - LIVER/GALLBLADDER BODY WEIGHT RATIO	Week 7	M/F						T
TREND - LIVER/GALLBLADDER ABSOLUTE WEIGHTS	Week 7	M						T
TOTAL FOOD CONSUMPTION - MAIN STUDY	Weeks 1-13	M						T

Appendix 15
Protocol and Amendments
13-Week Subchronic Oral Toxicity Study of Triclosan in CD-1[®] Mice

**HAZLETON**WASHINGTON
9200 LEESBURG PIKE
VIENNA, VA. 22182-1699**PROTOCOL AMENDMENT**PROJECT NO.: 483-287 AMENDMENT NO.: 6 DATE EFFECTIVE: 11/13/92STUDY TITLE: 13-Week Subchronic Oral Toxicity Study of Triclosan in
CD-1® Mice

DISTRIBUTION: ORIGINAL SIGNED PROTOCOL TO PSO

FIXED DISTRIBUTION: (No. Copies)

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Lab Animal Medicine (1)	Sponsor (1)

PERFORMING DEPARTMENTS:

Rodent Tox	Pathology
An Chem	Histo
Tox Admin	Clinpath
PTS	Necropsy

Date and Means of Sponsor Authorization (if appropriate):

Amendment:


Change:

1. The Study Director is herewith changed to Janet A. Trutter, M.S., D.A.B.T.

Reason:

1. Resignation of Joan K. Lemen, M.S., D.A.B.T.

Management Authorization:


David J. Brusick, Ph.D. / Date
Director of ScienceSTUDY DIRECTOR: Janet A. Trutter
DATE: Nov. 12, 1992



HAZLETON
WASHINGTON
9200 LEESBURG PIKE
VIENNA, VIRGINIA 22182

PROTOCOL AMENDMENT

PROJECT NO.: <u>483-287</u> AMENDMENT NO.: <u>5</u> DATE EFFECTIVE: <u>June 10, 1992</u>	
STUDY TITLE: <u>13-Week Subchronic Oral Toxicity Study of Triclosan in CD-1® Mice</u>	
DISTRIBUTION: ORIGINAL SIGNED PROTOCOL TO PSO	
FIXED DISTRIBUTION: (No. Copies)	PERFORMING DEPARTMENTS
Health Services (1) Quality Assurance (1)	Tox Admin Necropsy
Formulations (2) Contracts (1)	Path Chron. Tox
Scientific Res. (2) Client Services (1)	Clin Path PTS
Lab Animal Medicine (1) Sponsor (1)	Histo An-Chem
Date and Means of Sponsor Authorization (if appropriate): Sponsor request at Industry Meeting on Triclosan, June 4, 1992	

Amendment:

1. The effective date for replacement of the Study Director should have been 6/5/92. In addition the study title was incorrect in Amendment #4.

Reason for change: Errors in Amendment #4

2. Target tissues identified during histopathologic examination of tissues from Group 7 will be prepared histologically from all dose groups. Tissues from Group 6 will be evaluated histopathologically. If treatment related lesions are noted, tissues from the next lower dose levels will be read. These tissues are:

- spleen, adrenal cortex, glandular stomach in males and females
- kidney, mammary gland, uterus, and cervix of females only

Reason for change: To ascertain a no-effect level for histopathologic lesions in these tissues.

3. Special staining of selected liver sections will be prepared. The stains will be recommended by Dr. John Burns, the Study Pathologist.

Reason for change: To ascertain the nature of the pigment observed during evaluation of hematoxylin and eosin sections.

STUDY DIRECTOR: Joan K. Lemen, M.S., D.A.B.T.
DATE: June 10, 1992

PROTOCOL AMENDMENT

PROJECT NO.: <u>483-287</u> AMENDMENT NO.: <u>4</u> DATE EFFECTIVE: <u>6/15/92</u>	
STUDY TITLE: <u>13-Week Subchronic Oral Toxicity Study in Triclosan</u> <u>in CD-1[®] Mice</u>	
DISTRIBUTION: ORIGINAL SIGNED PROTOCOL TO PSO	
FIXED DISTRIBUTION: (No. Copies) Health Services (1) Quality Assurance (1) Formulations (2) Contracts (1) Scientific Res. (2) Client Services (1) Lab Animal Medicine (1) Sponsor (1)	PERFORMING DEPARTMENTS: <u>Rodent Tox</u> <u>Pathology</u> <u>An.Chem</u> <u>Histo</u> <u>Tox Admin</u> <u>ClinPath</u> <u>PTS</u> <u>Necropsy</u>
Date and Means of Sponsor Authorization (if appropriate):	

Amendment:


Change:


1. The Study Director is herewith changed to Joan K. Lemen, M.S., D.A.B.T.

Reason:

1. Resignation of James L. Ivett, Ph.D.

Management Authorization:


 David J. Brusick, Ph.D. / Date
 Director, Mammalian Toxicology


 STUDY DIRECTOR: Joan K. Lemen, M.S., D.A.B.T.
 DATE: June 5, 1992



PROTOCOL AMENDMENT

PROJECT NO: 483-287 AMENDMENT NO: 3 DATE EFFECTIVE February 17, 1992
STUDY TITLE: 13-Week Subchronic Oral Toxicity Study in Triclosan
in CD-1® Mice

DISTRIBUTION: ORIGINAL SIGNED PROTOCOL TO PSO

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Toxicology (2 orange)	Sponsor ()	Formulations (2)
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Client Services (1)	Rodent Toxicology (5)	Pathology (2)
Health Services (1)	PTS Admin (1)	Histology (2)
Contracts (1)	Clinpath (1)	Necropsy (1)

Amendment:

1) Section 10.G.(4) Histopathology

Add: The liver will be examined in all terminal sacrifice animals from Groups 2-6.

Justification: The liver has been identified as a target organ for toxicity induced by the test material.

STUDY DIRECTOR: James L. Dreth

DATE: 2/17/92

PROJECT NO: 483-287 AMENDMENT NO: 2 DATE EFFECTIVE Sept. 19, 1991
STUDY TITLE: 13-Week Subchronic Oral Toxicity Study in Triclosan
in CD-1 Mice

DISTRIBUTION: ORIGINAL SIGNED PROTOCOL TO PSO

DISTRIBUTION: (No. Copies)

Toxicology (1 white)	Study Director (1)	DLAM (1)
Toxicology (2 orange)	Sponsor ()	Formulations (2)
Quality Assurance (1)	Sci. Resources (2)	Analytical Chem ()
Client Services (1)	Rodent Toxicology (5)	Pathology (2)
Health Services (1)	PTS Admin (1)	Histology (2)
Contracts (1)	Clinpath (Cazenias) (1)	Necropsy (1)

Amendment:

1) Section 10.E.(3) Sample Collection

Change: For the hematology sample the blood samples will be collected without anesthesia from the orbital sinus of the right eye, if possible. The blood sample for serum chemistry will be obtained from the abdominal vena cava under sodium pentobarbital anesthesia. The animal will be exsanguinated following blood collection. The animals sampled at the 45 day interval will be bled and subsequently subjected to gross necropsy with retention of the liver with gallbladder.

Justification: Change in blood collection procedure to attain a more consistent blood volume for serum chemistry analysis. Sponsor request to retain additional data from the study.

2) Section 10.G.(1) Gross Necropsy

Add: A complete gross examination will be conducted on the satellite animals (Groups 8 - 11) which are sacrificed at the 45 day interval.

Justification: Sponsor request to retain additional data from the study.

3) Section 10.G.(2) Organ Weights

Add: The liver with gallbladder will be weighed from those animals sacrificed at the 45 day interval.

Justification: Sponsor request to retain additional data from the study.



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Protocol Amendment No. 2
Date Effective: September 19, 1991
Page 2 of 2

4) Section 10.G.(3) Tissue Preservation

Add:

The liver with gallbladder and any gross lesions will be removed and will be preserved from the animals sacrificed at the 45 day interval. The liver will be preserved in the following manner: 1) A section of the left lateral lobe and a section of the median lobe will be taken and will be preserved in 100% methanol. 2) The remainder of the liver will be preserved in 10% neutral-buffered formalin.

Justification: Sponsor request to retain additional data from the study.

STUDY DIRECTOR: *James J. Smith*

DATE: 9/23/91



PROTOCOL AMENDMENT

PROJECT NO: 483-287 AMENDMENT NO: 1 DATE EFFECTIVE July 26, 1991
STUDY TITLE: 13-Week Subchronic Oral Toxicity Study in Triclosan
in CD-1[®] Mice

DISTRIBUTION: ORIGINAL SIGNED PROTOCOL TO PSO

DISTRIBUTION: (No. Copies)

Toxicology (1 white)	Study Director (1)	DLAM (1)
Toxicology (2 orange)	Sponsor ()	Formulations (2)
Quality Assurance (1)	Sci. Resources (2)	Analytical Chem ()
Client Services (1)	Rodent Toxicology (5)	Pathology (2)
Health Services (1)	PTS Admin (1)	Histology (2)
Contracts (1)	Clinpath (Cazenas) (1)	Necropsy (1)

Amendment:

Section 2.A.

Address:

Change: Hazleton Washington, Inc.
9200 Leesburg Turnpike
Vienna, VA 22182

Justification: Change in location of the conduct of the study.

Section 2.C.

Study Coordinator:

Add: Julie C. Delaney, B.S.

Justification: Protocol Requirement

Section 7.B.

Lot Number

Add: Batch 5.2.0211.0

Justification: Protocol Requirement

Section 7.C.

Purity

Add: Sponsor Supplied 99.7%

Justification: Protocol Requirement

Section 10.C.(3) Diet Preparation

Change: The test article concentration in the feed for each week of dosing will be based upon the previous week individual animals weight and food consumption data for each group/sex/dose.

Justification: Correction of protocol to reflect exact procedure used.

Section 10.C.(6) Absorption

Add: Though the purpose of this study is not to determine absorption of the test material, toxic or pathologic effects will serve as evidence of absorption.

Section 10.D.(6) Ophthalmology Exams

Change: Predose ophthalmology examinations will be conducted on all animals. At approximately 90 days after the initiation of dosing all surviving animals in Groups 1 - 7 will be evaluated by indirect ophthalmoscopy.

Justification: Change in sentence structure to agree with intent.

Section 10.E.(4)(a) Hematology

Add: Erythrocyte morphology

Justification: Parameter added to hematology list.

Section 10.F.(1)**Unscheduled Sacrifices and Deaths**

Change: Only animals in Groups 1-7 which are sacrificed in a moribund condition or are found dead will be subjected to a detailed gross postmortem examination. Group 8-11 animals sacrificed moribund or found dead will be discarded without necropsy.

Justification: Change of sentence to agree with protocol intent.

Section 10.G.(2)**Organ Weights**

Add: The organ weights of the Adrenal gland (paired weight), Ovaries (paired weight), and Thymus will be obtained postfixation.

Justification: Correction in protocol.

Add: Liver and gallbladder and Submaxillary salivary glands (paired weight).

Justification: Protocol clarification.



HAZLETON
WASHINGTON

HWA Project No.: 483-287
Protocol Amendment No. 1
Date Effective: July 26, 1991
Page 3 of 3

Section 10.G.(2)

Tissue Preservation

Combine: Liver and gallbladder

Add: Lacrimal glands* (extraorbital)

Change: Skin with abdominal muscle

Justification: Protocol clarification.

STUDY DIRECTOR: _____

DATE: _____

James L. Dett
8/2/91



HWA 483-287
CIBA-GEIGY Corporation

PROTOCOL

1. Study Title 13-Week Subchronic Oral Toxicity Study of Triclosan in CD-1 \circ Mice.
2. Conducting Laboratory
 - A. Address Hazleton Washington, Inc.
1330-B Piccard Drive
Rockville, Maryland 20850
 - B. Study Director James L. Ivett, Ph.D.
 - C. Study Coordinator To be assigned
3. Sponsor CIBA-GEIGY Corporation
Dyestuffs & Chemicals Division
Greensboro, NC
4. Study Monitor Keith Hostetler, Ph.D.
5. Purpose The purpose of this study is to determine the subchronic toxicity profile of triclosan when administered for at least 91 consecutive days as a feed admixture to mice. The data that are generated from this study will be utilized for the projection of daily doses for a subsequent carcinogenicity study.
6. Schedule
 - A. Anticipated Initiation Date August, 1991.
 - B. Anticipated Termination Date November, 1991.
 - C. Anticipated Submission of Audited Draft April, 1992.
7. Test Material
 - A. Identification triclosan (IRGASAN \circ DP 300)
 - B. Lot Number To be supplied by the Sponsor.



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CIBA-GEIGY Corporation

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- C. Purity To be assayed by HWA using sponsor supplied analytical procedures.
- D. Characteristics Information on the methods of synthesis and stability, as well as data on composition or other characteristics which define the test material, are on file with the originating company.
- E. Reserve Samples Reserve samples of approximately 1 gram of the test and control articles will be taken at initiation and retained. These samples as well as any remaining test material, will be forwarded to the sponsor upon issuance of the final report.
- F. Storage Room Temperature.
8. Compliance This study will be conducted in compliance with the Good Laboratory Practice Regulations of the Food and Drug Administration [21 CFR 58], the Environmental Protection Agency (TSCA [40 CFR 792] and FIFRA [40 CFR 160], the Organization for Economic Cooperation, and the OECD Development Guidelines for Testing Chemicals (ISBN 92-64-12221-4).
9. Quality Assurance Audits The protocol, in-life phases and the final report will be audited in accordance with standard operating procedures at Hazleton Washington, Inc.

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10. Experimental Design**A. Animals**

- | | |
|--------------------|---|
| (1) Species | Mouse |
| (2) Strain/Source | CD-1 [®] [Cr1:CD1 (ICR) BR] |
| (3) Age | Approximately 6 weeks of age at the time of dose initiation. |
| (4) Number/Sex | 155/sex selected for study based on body weight, physical observations, and ophthalmology. |
| (5) Identification | Pretest sequential numbers will be assigned prior to randomization. Animals will be identified with an implantable microidentification device prior to study initiation. |
| (6) Husbandry | |
| (a) Housing | Upon arrival, mice of the same sex will be housed 2 per cage. Following randomization the animals will be individually housed in suspended wire-mesh cages. |
| (b) Food | Purina [®] Certified Rodent Chow [®] 5002, <i>ad libitum</i> . Feed is analyzed by the manufacturer for levels of specified heavy metals, aflatoxin, chlorinated hydrocarbons, organophosphates and specified nutrients. Each lot number used will be recorded. |
| (c) Water | Tap water, <i>ad libitum</i> . The water is analyzed for specified pesticides and heavy metals. The results of these analyses are on file at HWA. |

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- (d) Contaminants The study director and/or the sponsor have considered possible interfering substances potentially present in animal feed and water, including the test material itself or possible structurally related materials as well as the items listed in (b) and (c) above. None of these contaminants are reasonably expected to be present in animal feed or water at levels sufficient to interfere with this study.
- (e) Environment Every attempt will be made to maintain temperatures at $72 \pm 6^{\circ}\text{F}$ with a relative humidity of $50 \pm 20\%$. A 12-hour light-dark cycle will be maintained.
- (f) Quarantine Approximately two weeks prior to release by a staff veterinarian.
- (7) Randomization No more than one week prior to compound administration using computer-generated random numbers by weight stratification with assignment to groups. At the time of randomization, the body weight variation of the animals should not exceed 2 standard deviations of the mean (by sex), and the mean body weight for each group/sex should not significantly differ.
- (8) Justification The mouse was selected for safety testing on the basis of accumulated historical data and prior experience with this species. The use of the mouse conforms with the regulatory guidelines for testing in rodents.

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B. Group Designation and Dosage Levels.

Dose levels selected for the study were selected by the sponsor based upon previous 28-day studies (sponsor information).

Group	Dose (mg/kg)	No. of Animals		Approx. Diet Conc. (ppm)
		Male	Female	
1	0	15	15	0
2	25	15	15	25 - 100
3	75	15	15	75 - 300
4	200	15	15	200 - 800
5	350	15	15	350 - 1200
6	750	15	15	750 - 2000
7	900	15	15	900 - 3000

Satellite Groups*

8	0	20	20	0
9	25	10	10	25 - 100
10	350	10	10	350 - 1200
11	900	10	10	900 - 3000

*Ten animals/sex/group will be designated for blood collection for hematology and clinical chemistry at each of the specified intervals (Predose, Group 8; Day 45, Groups 8-11).

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C. Dosing Procedures**(1) Method of Administration**

The route of administration will be oral via diet admixture for at least 91 consecutive days and will continue until the day prior to necropsy.

(2) Reason for Dosing Route

Intended human exposure is by oral route.

(3) Diet Preparation

Fresh test diets will be prepared once weekly for each group/sex/dose level (Groups 1 - 7). The dose levels used for the satellite groups will be the same as those calculated for the respective main study dose group. Dietary levels will be adjusted to 100% compound activity if required. Reserve samples from each mixed batch will be retained for concentration analysis. These samples will be discarded after the final report has been issued. The test article concentration in the feed for each week of dosing will be based upon the previous week mean body weight and food consumption data for each group/sex/dose.

*File 7/8/91
Concentration
acknowledged*

(5) Analysis of Test Formulations

The homogeneity and stability of the test material in the dietary admixture will be determined prior to or concurrently with the initiation of treatment. Samples from the control and each dose level will be analyzed weekly to verify the dose concentration using the sponsor supplied high performance liquid chromatography (HPLC) procedure (Attachment 3). The study director will be notified if the concentration of any of the dietary samples deviates from the target concentration by more than $\pm 15\%$.

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D. Observation of Animals and Records to be Maintained

- | | |
|---------------------------|--|
| (1) Clinical Observations | Twice daily - mortality and moribundity check. Once daily - cageside observation for obvious indications of a toxic effect; these effects will be recorded by exception as they are observed. Because these are cageside animal checks, the observations will not be as specific as and may not necessarily duplicate those observations recorded on body weight days when thorough physical examinations are conducted. Cageside checks for clinical signs will be recorded on the automated data collection system beginning 2 days prior to the initiation of dosing. |
| (2) Physical Examinations | Detailed clinical observations at each weighing interval except prior to necropsy. |
| (3) Body Weights | At predose on test Day -7, prior to dosing on Day 1, weekly thereafter, and prior to necropsy. |
| (4) Food Consumption | Once weekly starting one week prior to dosing (Day -7 through Day 1). |
| (5) Auditory/Physical | Auditory and physical examinations of the animals will be conducted by a staff veterinarian during the predose interval and at approximately 90 days after the initiation of dosing. |
| (6) Ophthalmology Exams | During the predose interval and at approximately 90 days after the initiation of dosing using indirect ophthalmoscopy on all animals in Groups 1 - 7. Pupils will be dilated with a mydriatic. |

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E. Clinical Laboratory Studies

- (1) Frequency During the predose interval (10 animals/sex; Group 8) and approximately 45 (Groups 8 - 11) and 91 (Groups 1 - 7) days (study termination) after the initiation of dosing.
- (2) Number of Animals 10/sex/group.
- (3) Sample Collection Collection of blood samples from orbital sinus of right eye if possible. Animals samples at the predose and 45 day interval will be sacrificed without necropsy after blood collection with sodium pentobarbital anesthesia followed by exsanguination.
- (4) Parameters Determined
- (a) Hematology
- | | |
|-------------------|------------------------|
| erythrocyte count | leukocyte count |
| hemoglobin | leukocyte differential |
| hematocrit | platelet count |
- (b) Serum Chemistry - Sampling Priority as Listed
- alkaline phosphatase
 LDH
 SGOT
 SGPT
 total bilirubin
- blood urea nitrogen
 creatinine
 G-GT
- A/G ratio
 albumin
 glucose
 total protein
 total cholesterol
 triglycerides

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F. Termination**(1) Unscheduled Sacrifices and Deaths**

Any animal showing signs of severe debility, particularly if death appears imminent will be sacrificed to prevent loss of tissues through autolysis. All animals sacrificed in a moribund condition or found dead will be subject to a detailed gross postmortem examination. Sacrifice will be performed under sodium pentobarbital anesthesia followed by exsanguination. Necropsies will be conducted by trained personnel using procedures approved by board-certified pathologists on all moribund animals and on all animals that die.

(2) Sacrifice

Animals will be necropsied on the day following the last dose (at least 91 consecutive doses). Animals will be randomly selected for necropsy to minimize bias in necropsy data collection. At sacrifice all animals will be weighed, exsanguinated under sodium pentobarbital anesthesia and necropsied. Necropsies will be performed by trained personnel using procedures approved by board-certified pathologists. A pathologist will be readily available for consultation (further participation by a pathologist is available at additional cost).

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G. Postmortem Procedures**(1) Gross Necropsy**

A complete gross examination will be conducted on all animals in Groups 1 - 7, including all (Groups 1 - 7) which died on study or were sacrificed in a moribund condition. The necropsy will include examination of the following and any findings will be recorded:

The external surface

All orifices

Cranial cavity

Carcass

External surface of the brain (at necropsy). If the tissue is processed for histopathology, the external surface of the spinal cord and cut surfaces of the brain and spinal cord will be examined at the time of tissue trimming.

The nasal cavity and nasal turbinates

The thoracic, abdominal and pelvic cavities and their viscera

The cervical tissues and organs

(2) Organ Weights

The following organs (when present) from each animal will be weighed at the scheduled necropsy following careful dissection and trimming to remove fat and other contiguous tissue in a uniform manner:

Adrenal glands (paired weight)	Prostate
Brain (including brainstem)	Spleen
Epididymides (paired weight)	Submaxillary salivary glands
Heart	Testes (paired weight)
Kidneys (paired weight)	Thymus
Liver	Uterus
Lung	
Ovaries (paired weight)	

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(3) Tissue Preservation

The following tissues (when present) from each animal will be preserved in 10% neutral buffered formalin:

Adrenal glands	Peripheral nerve (sciatic)
All gross lesions (including tissue masses)	Pituitary
Aorta	Prostate
Brain with brainstem	Skeletal Muscle (thigh)
(medulla/pons, cerebellar cortex, cerebral cortex)	Skin (abdominal muscle)
Epididymides	Small intestines (duodenum, jejunum, ileum)
Esophagus	Spinal cord (cervical, lumbar, thoracic)
Eyes with optic nerves*	Spleen
Femur with marrow and joint	Sternum with marrow
Gallbladder	Stomach (cardia, fundus, pylorus)
Heart	Submaxillary salivary glands
Kidneys	Testes
Lacrimal glands*	Thymic region
Large intestines (colon, cecum, rectum)	Thyroid with parathyroid*
Liver	Tongue
Lung	Trachea
Lymph nodes (mandibular*, mesenteric)	Urinary bladder
Mammary region**	Uterus with vagina and cervix**
Ovaries**	
Pancreas	

*At least one tissue section required.

**Tissue required for females only.

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(4) Histopathology

The above-tissues will be embedded in paraffin, sectioned, stained with hematoxylin and eosin, and examined microscopically as follows:

- (a) On all gross lesions and tissue masses.
- (b) On all tissues from animals in Groups 1 - 7 which die or are sacrificed moribund.
- (c) On all tissues from all animals in the control and high dose groups (Groups 1 and 7, respectively) necropsied at the terminal sacrifice.
- (d) On the liver and kidney from the control and all treatment groups.
- (e) On other suspected target tissues from other dose groups if specified by the Study Director after consultation with the pathologist.

Note: Items (d) and (e) will be conducted at an additional cost to the sponsor after the scope of any additional work has been defined.

11. At the termination of the study, a draft final report which includes the following information (as appropriate) will be prepared and submitted:

- Experimental Design and Methods

- Results:

Body weights and food
consumption
Clinical pathology tests
Clinical observations
Gross pathology
Growth rates and/or absolute
body weights

Histopathology
Mortality
Ophthalmoscopic findings
Organ weights
Organ/body weight ratios
Organ/brain weight ratios

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- Statistical Analyses:

Statistical methods will be those presented in Attachment #2.

- Statistical Evaluation (as deemed appropriate):

Survival rates	Clinical pathology values
Growth rates and/or absolute	Organ weights
body weights	Organ/body weight ratios
Total food consumption	Organ/brain weight ratios

All statistical analyses will be performed separately for each sex.

- Tables:

cumulative survival rates and mean body weights	summary incidence of histopathology findings
mean clinical pathology values	summary incidence of
mean compound consumption	ophthalmoscopic findings
mean food consumption	summary of clinical signs for each
mean organ weights	test group to include: a list of
mean organ/body weight ratios	each finding and number of
mean organ/brain weight ratios	animals affected
summary incidence of gross pathology findings	

- Appendices:

individual body weight	individual histopathology findings
individual clinical pathology values	individual ophthalmoscopic findings
individual clinical signs for each animal to include: the week of observation of each sign, a description of each sign, and its subsequent course	individual organ weights
individual food consumption	individual organ/body weight ratios
individual gross pathology findings	individual organ/brain weight ratios
	individual organ weights
	individual week of death
	references for clinical laboratory and statistical methods
	analytical chemistry methods and results (if performed by HWA)



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12. Record Retention

All tissue specimens, blocks and slides, all raw data and the final report (or copies thereof) will be retained according to GLP requirements.

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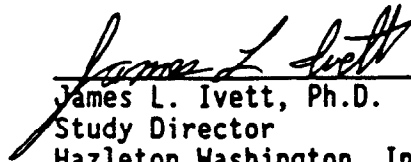


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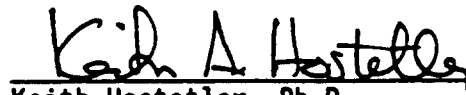
SIGNATURE PAGE

Approved by:



James L. Ivett, Ph.D.
Study Director
Hazleton Washington, Inc.

Date: July 1, 1991



Keith Hostetler, Ph.D.
Study Monitor
Ciba-Geigy Corporation

Date: July 3, 1991

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ATTACHMENT NO. 1

CONTAMINANT ANALYSIS FOR CERTIFIED FEED

This information identifies the potential contaminants monitored in laboratory feed. The Certified Feed data are provided by the manufacturer.

Feed minimum certification profile:

Heavy Metals

Maximum Concentration

Arsenic	1.0 ppm
Cadmium	0.5 ppm
Lead	1.5 ppm
Mercury	0.2 ppm

<u>Aflatoxin</u>	10 ppb
------------------	--------

Chlorinated Hydrocarbons

Aldrin	0.03 ppm
Dieldrin	0.03 ppm
Endrin	0.03 ppm
Heptachlor	0.03 ppm
Heptachlor Epoxide	0.03 ppm
Lindane	0.05 ppm
Chlordane	0.05 ppm
Mirex	0.02 ppm
Methoxychlor	0.50 ppm
Alpha BHC	0.05 ppm
Beta BHC	0.05 ppm
Delta BHC	0.05 ppm
HCB	0.05 ppm
PCB	0.15 ppm

Organophosphates

Thimet	0.5 ppm
Diazinon	0.5 ppm
Disulfaton	0.5 ppm
Methyl Parathion	0.5 ppm
Malathion	0.5 ppm
Parathion	0.5 ppm
Thiodan	0.5 ppm
Ethion	0.5 ppm
Trithion	0.5 ppm

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ATTACHMENT No. 2Analysis of Data

When deemed appropriate, statistical evaluation of the data will be performed.

Quantitative Toxicological Parameters

Body and organ weights, food consumption, and other such toxicological parameters will be analyzed by analysis of variance/covariance techniques (1-4) as appropriate. Normality/homoscedasticity of the data will be tested and transformations of distribution free methods will be used to achieve maximum power of such tests. Parametric and/or nonparametric trend tests such as regression (5) and Terpstra-Jonckheere (6) methods will be used as deemed appropriate after aforementioned preliminary statistical analyses to evaluate any possible trends in the data if they exist.

Contingency Tables

When sample sizes allow, these incidental data will be analyzed by the Cochran-Armitage test for trend and the Fisher-Irwin exact test for heterogeneity (7). Survival, if sample sizes are adequate, will be analyzed by life table techniques (8) consisting of Kaplan-Meier product limit estimates, Cox-Tarone logistic and Gehan-Breslow nonparametric tests for trend and heterogeneity of binary response data. Ninety-day studies generally do not indicate any neoplastic responses. In the case of such responses, the methods to be utilized are logistic prevalence methods (9) for trend and heterogeneity for "incidental" and aforementioned life table techniques for palpable and rapidly lethal neoplastic lesions.

Exact significance probabilities (asymptotic in some cases), instead of critical values will be used in reporting the significant findings.

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References

1. WINER, B.J. (1971). Statistical Principles in Experimental Design. McGraw-Hill, New York, 2nd Edition.
2. LEVENE, H. (1960). Robust tests for equality of variances. In Contributions to Probability and Statistics (I. Olkin, ed.). Stanford University Press, Palo Alto, pp. 278-292.
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5. DRAPER, N.R. and H. SMITH (1966). Applied Regression Analysis. Wiley, New York.
6. THAKUR, A.K. (1984). A FORTRAN program to perform the nonparametric Terpstra-Jonckheere test. Comput. Progr. Biomed. 18, 235-240.
7. THAKUR, A.K., K.J. BERRY, and P.W. MIELKE, Jr. (1985). A FORTRAN program for testing trend and heterogeneity in proportions. Comput. Progr. Biomed. 19, 229-233.
8. THOMAS, D.G., N. BRESLOW, and J.J. GART (1977). Trend and homogeneity analysis of proportions and life table data. Comput. Biomed. Res. 10, 373-381.
9. DINSE, G.E. and S.W. LAGAKOS (1983). Regression analysis of tumour prevalence data. J. Roy. Stat. Soc. Series C (Appl. Stat.) 32, 236-248.

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Appendix 16
Protocol Deviations
13-Week Subchronic Oral Toxicity Study of Triclosan in CD-1[®] Mice

Appendix 16
Protocol Deviations
13-Week Subchronic Oral Toxicity Study of Triclosan in CD-1[®] Mice

One mouse (temporary female No. 247, permanent No. 37446 Group 2) started on study that failed the pre-study auditory exam.

One female and one male mouse were housed individually on 7/23/91 (animal receipt) due to the odd number of males and females received.

Room humidity was low on the following days (1991): 10/29, 10/30, 11/3, 11/5, 11/6, and 11/12/91; humidity was high on 10/1/91.

Cageside observations for animals 37555 and 37592 were recorded as "Normal" following abnormal observations to ensure that the recovery was duly noted.

Room lights were reported by security as operating during the night on the following days: 8/27/91, 9/4/91 and 9/26/91.

Day 10 and Day 30 stabilities were performed but not required by the protocol.



SPONSOR: Ciba-Geigy

DATE: May 10, 1993

MATERIAL: Triclosan

SUBJECT: AMENDMENT #2 TO FINAL REPORT
Subchronic Oral Toxicity Study of Triclosan in CD-1 Mice
Project No. 483-287

Page No. 42 is being submitted as a correction page to correct lowest observable effect, for incorporation into the final report dated January 1993.

Study Director:

Janet A. Trutter
Janet A. Trutter, M.S., D.A.B.T.
Department of Toxicology

5/10/93
Date



SPONSOR: CIBA-GEIGY Corporation

DATE: March 29, 1993

MATERIAL: Triclosan

SUBJECT: AMENDMENT #1 TO FINAL REPORT

13-Week Subchronic Oral Toxicity Study of Triclosan in CD-1®
Mice

Project No. 483-287

Page No. 45 is being submitted as a correction page to correct the comments concerning aspartate aminotransferase, for incorporation into the final report dated January 28, 1993.

Study Director:

Janet A. Trutter
Janet A. Trutter, M.S., D.A.B.T.
Department of Toxicology

3/29/93
Date

OTC Vol. No. 116

OTC Docket Number 75N-0183 (triclosan)
September 12, 1994

Ciba-Geigy Corporation
Chemicals Division
Greensboro, N.C. 27419

Trimmer, G.W. 90-Day Subchronic Dermal Toxicity Study in the Rat with Satellite Group with Irgasan DP 300 (MRD-92-399). Exxon Biomedical Sciences, Inc. Lab. Project I.D. 139910B. July 14, 1994.

Summary

The objective of this study was to evaluate the toxicity of IRGASAN DP300 following repeated topical application when administered dermally to rats for a period of at least 90 days. In addition, a satellite recovery group was utilized to determine the reversibility, persistence, or delayed occurrence of toxic effects for at least 28 days after treatment. The test material was applied to the clipped, unabraded dorsal surface of rats 7 days per week for a minimum of 90 days. One-hundred Sprague-Dawley rats were divided into 5 groups of 10 male and 10 female rats each. Group 1 served as the carrier control group and received propylene glycol (PPG) only. Groups 2, 3, and 4, received 10, 40, and 80 mg/kg of IRGASAN DP300 in PPG, respectively. Group 5 served as a satellite recovery group. Satellite animals were treated the same as the Group 4 animals and were observed for reversibility, persistence or delayed occurrence of toxic effects for at least 28 days after treatment.

Stability of the dose solutions was demonstrated for up to 15 days at room temperature with losses of less than 3% being observed. Excellent uniformity was demonstrated with the coefficients of variation being less than 2%. Concentration verification analysis indicated all samples analyzed were within 8% of the nominal concentrations and the dose group means were within 5% of the nominals.

Dermal responses were evaluated prior to dosing on Days 0, 1, and 4, and twice weekly thereafter until study termination. Clinical observations were made daily for signs of toxicity and included nature, onset, severity, and duration of toxicological signs. Body weight and food consumption were measured weekly. Ophthalmological examinations were made prior to dose initiation and prior to main study termination. Hematology, serum chemistry, and uroanalytical studies were performed on all animals at the main study termination and again on the satellite animals at satellite group termination. All animals from

75N-183H

C1

Groups 1-4 were sacrificed on Test Days 92/93 and the satellite animals were sacrificed on Test Day 121. A full macroscopic examination was performed on all animals and selected organs and tissues were collected and weighed. A range of tissues were examined microscopically.

Five animals died prior to scheduled study termination. The two early deaths on Day 7 (one mid dose and one high dose female) and the two late deaths on Day 84 (one high dose and one satellite male) were attributed to the wrapping procedure. The death of the control animal on Day 22 was considered incidental.

Treatment-related effects were limited to dermal irritation. Erythema and/or edema was observed in all treated groups at the application site (10, 40, and 80 mg/kg; and satellite recovery), but was not observed in any control animal. The frequency and severity of dermal irritation was similar in the 40 mg/kg dose group (mid dose) and in both 80 mg/kg groups (high dose and satellite group). Erythema also was observed in the low dose group (10 mg/kg) but the onset of erythema was later and the frequency of cores was much less than observed in the higher dose groups. Edema was observed sporadically in the mid, high and satellite group animals, and even less frequently in the low dose group. Supplemental dermal observations consisting of eschar and desquamation were observed in all groups, including controls. More severe signs of dermal irritation, characterized by exfoliation and atonia, were generally limited to the mid, high and satellite recovery groups. Dermal irritation decreased dramatically in the satellite recovery group following dosing cessation. By study termination on Day 121, only one recovery animal was observed with severe erythema and eschar.

There were no statistically significant differences in mean body weight or mean food consumption of the treated and control animals of either sex during the test period.

There were no ophthalmoscopic findings which were considered to be related to treatment with Irgasan DP300.

There were no differences in hematological or quantitative uroanalytical parameters between treated and control animals of either sex which were considered to be related to treatment with Irgasan DP300. Semi-quantitative urine chemistry analysis revealed occult blood in the urine of a small number of high dose and satellite male animals, and to a lesser degree in the mid dose males, at main study termination. This was observed in the female animals, but with decreased severity and incidence. In the absence of any other significant clinical chemistry or hematological changes or correlation to microscopic findings, the significance of this finding is unknown.

There were no differences in serum chemistry parameters which were considered to be related to treatment with Irgasan DP300.

There were no differences in absolute organ weight or relative organ weight values between treated and control animals of either sex which were considered to be related to treatment with Irgasan DP300.

Dermal irritation (desquamation, exfoliation, and/or eschar) was the most significant postmortem finding and was consistent with the supplemental dermal observations noted during the inlife portion of the study. A liver mass was observed in one low dose male (10 mg/kg) and one high dose male (80 mg/kg).

Treatment-related microscopic changes were seen in the treated area of the skin of male rats of Groups, 3, 4, and 5 and female rats of Groups 2, 3, 4, and 5. In the rats of Groups 2, 3, and 4, these changes consisted of an increased incidence and/or severity of epidermal hyperplasia/hyperkeratosis, sebaceous gland hyperplasia, dermal inflammation, focal epidermal necrosis, and exudate. In the Group 5 (satellite group) rats, these changes occurred at lower frequencies and lesser intensity, but there was an increased incidence of dermal fibrosis.

In conclusion, dermal application of Irgasan DP300 did not produce conclusive evidence of systemic toxicity. Non-systemic treatment-related effects included dermal irritation which was observed in all dose groups. There appeared to be a recovery effect in the high dose animals' dermal irritation following dosing cessation for approximately four weeks. Therefore, the NOAEL (No Observable Adverse Effect Level) was established at 80 mg/kg with respect to toxicity (excluding dermal findings).

VOLUME 2 OF 2
OF
SUBMISSION

EXXON BIOMEDICAL SCIENCES, INC.

FINAL REPORT

STUDY TITLE

90-DAY SUBCHRONIC DERMAL TOXICITY STUDY IN THE RAT
WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399)

Data Requirements

Guideline: 82-3

Author

Gary W. Trimmer, B.A.

Study Completed

July 14, 1994

Sponsor

CIBA-GEIGY CORPORATION
Greensboro, North Carolina

Performing Laboratory

EXXON BIOMEDICAL SCIENCES, INC.
Toxicology Laboratory
Mettlers Road, CN 2350
East Millstone, New Jersey 08875-2350

Laboratory Project ID

139910B

STATEMENT OF NO DATA CONFIDENTIALITY CLAIMS

No claim of confidentiality is made for any information contained in this study on the basis of its falling within the scope of FIFRA Section 10(d)(1)(A), (B) or (C).

Company: Ciba-Geigy Corporation

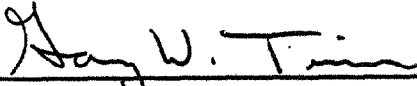
Company Agent: Keith A. Hostetler, Ph.D.

Title: Manager, Hazard Assessment

Signature: Keith A. Hostetler Date: 6/24/94


COMPLIANCE STATEMENT: GOOD LABORATORY PRACTICES

This study has been performed in accordance with EPA FIFRA Good Laboratory Practice Standards (40 CFR Part 160).



G. W. Trimmer, B.A.
Study Director

11 Aug 94
Date



K. A. Hostetler, Ph.D.
Ciba-Geigy Corporation
Sponsor Representative/Submitter

8/2/94
Date

90-DAY SUBCHRONIC DERMAL TOXICITY STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

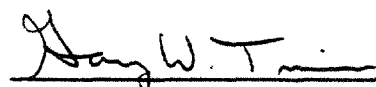
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APPROVAL SIGNATURES



G. W. Trimmer, B.A.
Study Director

14 JUL 94
Date



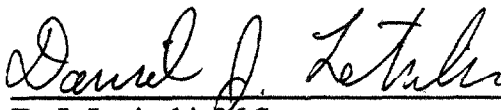
R. D. Phillips, Ph.D.
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14 JUL 94
Date



E. C. Lonardo, M.S., MT(ASCP)
Clinical Laboratory Supervisor

14 JUL 94
Date



D. J. Letinski, M.S.
Analytical Chemistry Supervisor

14 JUL 94
Date

QUALITY ASSURANCE STATEMENT

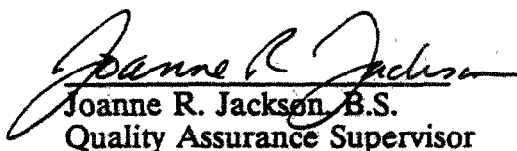
STUDY NUMBER: 139910B

TEST SUBSTANCE/ARTICLE: MRD-92-399

STUDY SPONSOR: Ciba-Geigy Corporation

Listed below are the dates that this study was inspected by the Quality Assurance Unit of Exxon Biomedical Sciences, Inc., and the dates findings were reported to the Study Director and Management.

<u>Date(s) of Inspection</u>	<u>Reported to Study Director</u>	<u>Reported to Management</u>
23,24 Nov 92	24 Nov 92	01,12 Dec 92
21,22 Dec 92	22 Dec 92	12 Jan 93
23 Feb 93	23 Feb 93	25,28 Feb 93
24-30 Jun 93 01-12 Jul 93	12 Jul 93	31 Aug 93 07 Sep 93
8-12 Jul 93	12 Jul 93	28 Jul 93 03 Aug 93
21-26 Jul 93	26 Jul 93	23,26 Aug 93
08,11 Jul 94	11 Jul 94	14 July 94


Joanne R. Jackson, B.S.
Quality Assurance Supervisor

Date  14 July 94

PERSONNEL

Study Director:	G. W. Trimmer, B.A.
Sponsor Representative:	K. A. Hostetler, Ph.D.
Mammalian Toxicology Laboratory Director:	R. D. Phillips, Ph.D.
Toxicology and Animal Care Supervisor:	R. C. Forgash, B.S.
Report Preparation Supervisor:	E. R. Frank, B.A.
Compound Preparation and Necropsy Supervisor:	M. A. Elliott, B.S.
Clinical Chemistry and Histology Supervisor:	E. E. Lonardo, M.S., MT (ASCP)
Analytical Chemistry Supervisor:	D. J. Letinski, M.S.
Quality Assurance/Archives Section Head:	J. E. Stillman, M.S.P.H., M.A., CIH
Quality Assurance Supervisor:	J. R. Jackson, B.S.
Maintenance Supervisor:	J. L. McGrath, A.S.
Veterinarian:	R. L. Harris, D.V.M.
Veterinary Pathologist:	C. F. Morris, D.V.M., D.A.C.V.P.
Veterinary Ophthalmologist:	J. M. Clinton, V.M.D.

SUMMARY

The objective of this study was to evaluate the toxicity of IRGASAN DP300 following repeated topical application when administered dermally to rats for a period of at least 90 days. In addition, a satellite recovery group was utilized to determine the reversibility, persistence, or delayed occurrence of toxic effects for at least 28 days after treatment. The test material was applied to the clipped, unabraded dorsal surface of rats 7 days per week for a minimum of 90 days. One-hundred Sprague-Dawley rats were divided into 5 groups of 10 male and 10 female rats each. Group 1 served as the carrier control group and received propylene glycol (PPG) only. Groups 2, 3, and 4, received 10, 40, and 80 mg/kg of IRGASAN DP300 in PPG, respectively. Group 5 served as a satellite recovery group. Satellite animals were treated the same as the Group 4 animals and were observed for reversibility, persistence or delayed occurrence of toxic effects for at least 28 days after treatment.

Stability of the dose solutions was demonstrated for up to 15 days at room temperature with losses of less than 3% being observed. Excellent uniformity was demonstrated with the coefficients of variation being less than 2%. Concentration verification analysis indicated all samples analyzed were within 8% of the nominal concentrations and the dose group means were within 5% of the nominals.

Dermal responses were evaluated prior to dosing on Days 0, 1, and 4, and twice weekly thereafter until study termination. Clinical observations were made daily for signs of toxicity and included nature, onset, severity, and duration of toxicological signs. Body weight and food consumption were measured weekly. Ophthalmological examinations were made prior to dose initiation and prior to main study termination. Hematology, serum chemistry, and uroanalytical studies were performed on all animals at the main study termination and again on the satellite animals at satellite group termination. All animals from Groups 1-4 were sacrificed on Test Days 92/93 and the satellite animals were sacrificed on Test Day 121. A full macroscopic examination was performed on all animals and selected organs and tissues were collected and weighed. A range of tissues were examined microscopically.

Five animals died prior to scheduled study termination. The two early deaths on Day 7 (one mid dose and one high dose female) and the two late deaths on Day 84 (one high dose and one satellite male) were attributed to the wrapping procedure. The death of the control animal on Day 22 was considered incidental.

SUMMARY (CONT'D)

Treatment-related effects were limited to dermal irritation. Erythema and/or edema was observed in all treated groups at the application site (10, 40, and 80 mg/kg; and satellite recovery), but was not observed in any control animal. The frequency and severity of dermal irritation was similar in the 40 mg/kg dose group (mid dose) and in both 80 mg/kg groups (high dose and satellite group). Erythema also was observed in the low dose group (10 mg/kg) but the onset of erythema was later and the frequency of scores was much less than observed in the higher dose groups. Edema was observed sporadically in the mid, high and satellite group animals, and even less frequently in the low dose group. Supplemental dermal observations consisting of eschar and desquamation were observed in all groups, including controls. More severe signs of dermal irritation, characterized by exfoliation and atonia, were generally limited to the mid, high and satellite recovery groups. Dermal irritation decreased dramatically in the satellite recovery group following dosing cessation. By study termination on Day 121, only one recovery animal was observed with severe erythema and eschar.

There were no statistically significant differences in mean body weight or mean food consumption of the treated and control animals of either sex during the test period.

There were no ophthalmoscopic findings which were considered to be related to treatment with Irgasan DP300.

There were no differences in hematological or quantitative uroanalytical parameters between treated and control animals of either sex which were considered to be related to treatment with Irgasan DP300. Semi-quantitative urine chemistry analysis revealed occult blood in the urine of a small number of high dose and satellite male animals, and to a lesser degree in the mid dose males, at main study termination. This was observed in the female animals, but with decreased severity and incidence. In the absence of any other significant clinical chemistry or hematological changes or correlation to microscopic findings, the significance of this finding is unknown.

There were no differences in serum chemistry parameters which were considered to be related to treatment with Irgasan DP300.

SUMMARY (CONT'D)

There were no differences in absolute organ weight or relative organ weight values between treated and control animals of either sex which were considered to be related to treatment with Irgasan DP300.

Dermal irritation (desquamation, exfoliation, and/or eschar) was the most significant postmortem finding and was consistent with the supplemental dermal observations noted during the inlife portion of the study. A liver mass was observed in one low dose male (10 mg/kg) and one high dose male (80 mg/kg).

Treatment-related microscopic changes were seen in the treated area of the skin of male rats of Groups 3, 4, and 5 and female rats of Groups 2, 3, 4, and 5. In the rats of Groups 2, 3, and 4, these changes consisted of an increased incidence and/or severity of epidermal hyperplasia/hyperkeratosis, sebaceous gland hyperplasia, dermal inflammation, focal epidermal necrosis, and exudate. In the Group 5 (satellite group) rats, these changes occurred at lower frequencies and lesser intensity, but there was an increased incidence of dermal fibrosis.

In conclusion, dermal application of Irgasan DP300 did not produce conclusive evidence of systemic toxicity. Non-systemic treatment-related effects included dermal irritation which was observed in all dose groups. There appeared to be a recovery effect in the high dose animals' dermal irritation following dosing cessation for approximately four weeks. Therefore, the NOAEL (No Observable Adverse Effect Level) was established at 80 mg/kg with respect to toxicity (excluding dermal findings).

INTRODUCTION

This study was conducted for Ciba-Geigy Corporation, Greensboro, North Carolina (subsequently referred to as the Sponsor) in order to evaluate the toxicity of IRGASAN DP300 when administered dermally to rats for a period of 90 days. In addition, a satellite recovery group was utilized to determine the reversibility, persistence, or delayed occurrence of toxic effects for at least 28 days after treatment.

The study was conducted by Exxon Biomedical Sciences, Inc. (EBSI) Toxicology Laboratory (an AAALAC accredited and JMAFF certified facility), Mettlers Road, CN 2350, East Millstone, New Jersey 08875-2350.

Justification for Selection of Test System

Rats have historically been used in toxicology evaluation and are among the species of choice for subchronic studies (Mitruka et al., 1976; Loomis, 1974, Hayes, 1982).

Justification for Selection of Dosing Route

The primary route of exposure of the test material is dermal. Therefore, topical application is an appropriate means to assay its biological effect.

Study Initiation (Protocol Signature Date)

November 25, 1992

Inlife Test Period

November 30, 1992 - March 31, 1993

MATERIALS AND METHODS

TEST MATERIAL

Material Identification

Exxon Biomedical Sciences Identification: MRD-92-399

Sponsor Identification:	IRGASAN DP300
Batch Number:	5.2.0211.0
Date Received:	September 29, 1992
Description:	Off-white powder
Storage Condition:	Room temperature

Assumed 100% pure for the purpose of dosing.

Characterization of Test Material

The methods of synthesis, fabrication, and/or derivation of the test material were the responsibility of the Sponsor and documentation is maintained at Ciba-Geigy Corporation, Greensboro, North Carolina.

Analysis of Test Material

Determination of the stability, identity, strength, purity and composition or other characteristics which appropriately identify the test material was the responsibility of the Sponsor. Documentation is maintained at Ciba-Geigy Corporation, Greensboro, North Carolina.

Analysis of the Test Material/Carrier Mixture

Analyses for stability and uniformity were performed prior to the experimental start and concentration verification was performed on Weeks 1, 5, 9, and 13. These analyses were performed at EBSI.

TEST MATERIAL (CONT'D)

Solubility

The test material was soluble in Propylene Glycol at the concentrations utilized.

Sample Retention

Two archival samples of undiluted MRD-92-399 were collected by the Compound Preparation Department and stored at room temperature.

Carrier

Propylene Glycol (PPG)

Supplier: J. T. Baker Company, Phillipsburg, N.J.

Batch Number: C40638

Date Received: October 2, 1990

Description: Colorless liquid

Analysis of the carrier documented and maintained by the supplier.

TEST SYSTEM

Test Animal

Species: Rat
Strain/stock: Crl:CDBR (VAF/Plus)
Supplier: Charles River Laboratories, Inc.
Kingston Facility; New York

Animal Receipt Information

Receipt Date: November 19, 1992
Purchase Order Number: 2GM39266

Quarantine and Acclimation Period

11 days; Examined at least once daily.

Number and Sex

50 males
50 females (nulliparous and non-pregnant)

Age at Initiation of Dosing

Males: Approximately 7-8 weeks
Females: Approximately 9-10 weeks

Weight at Initiation of Dosing

Males: 245.6 to 287.2 grams
Females: 193.5 to 242.2 grams

Animal Identification

Monel ear tags and corresponding cage identification.

TEST SYSTEM (CONT'D)

Selection

More animals than required for the conduct of the study were purchased and acclimated. Animals determined to be unsuitable for inclusion on this study because of poor health or other abnormalities were excluded from selection by the Staff Veterinarian, Study Director, and/or technical staff. Study animals were selected from the remaining animals using a computer-generated, body weight sorting program and their weight variation was within $\pm 20\%$ of the mean body weight.

Husbandry

Housing

Room Number: 520

Housing: Single housed during the study period.

Caging: Suspended stainless steel and wire mesh with absorbent paper below cages.

Feed

Purina Certified Rodent Chow (mash), ad libitum

Manufacturer: Purina Mills, Inc.
Richmond, Indiana

Analysis: Performed by Purina. Copies of the feed analyses are maintained in the EBSI Toxicology Laboratory.

Contaminants: There were no known contaminants in the feed believed to have been present at levels that may have interfered with this study.

The availability of feed was checked daily for all animals.

TEST SYSTEM (CONT'D)

Water

Automatic watering system, ad libitum

Supplier: Elizabethtown Water Company
Elizabethtown, New Jersey.

Analysis: As provided by Elizabethtown Water Company. Copies of the water analyses are maintained in the EBSI Toxicology Laboratory.

Contaminants: There were no known contaminants in the water believed to have been present at levels that may have interfered with this study.

The availability of water was checked daily for all animals.

Environmental Conditions

Temperature: 68 to 76 degrees Fahrenheit

Humidity: 40 to 70 percent relative humidity

Lighting: Approximately 12 hours light and 12 hours dark by automatic timer.

Monitored at least once daily.

EXPERIMENTAL DESIGN

Preparation of Animals

Initially, approximately 24 hours prior to the first topical administration of the test material, the fur of each rat on the dorsal surface from the shoulder region to the lumbar region was closely clipped with an electric clipper. The skin was left intact. The animals were reclipped once per week and as needed, unless contradicted by the presence of severe dermal irritation.

Preparation of Test Material Mixtures

The test material was diluted in carrier at the concentrations listed below. The mixture was prepared weekly and stored at room temperature.

Experimental Groups

DOSE GROUP	DOSE LEVEL MG/KG	CONCEN- TRATION % w/v	NUMBER OF MALES	NUMBER OF FEMALES
1 CONTROL*	0	0	10	10
2 LOW	10	0.5	10	10
3 MID	40	2.0	10	10
4 HIGH	80	4.0	10	10
5 SATELLITE**	80	4.0	10	10

* Control animals received carrier only at a dose volume of 2.0 ml/kg.

** Satellite animals were treated the same as the Group 4 animals and were then observed for reversibility, persistence or delayed occurrence of toxic effects for at least 28 days after treatment.

EXPERIMENTAL DESIGN (CONT'D)

Administration of Test Material

The test and/or control material was applied to the clipped, unabraded dorsal surface of each animal (approximately 10% of the total body surface) at the appropriate dose level at a dose volume of 2.0 ml/kg. The animal's doses were adjusted weekly based on the most recent body weight. The test/control materials were applied 7 days a week for a minimum of 13 weeks.

The appropriate dose was applied under a gauze pad placed on the dose site, covered with Blenderm tape, and wrapped with COBAN to prevent evaporation and ingestion of the test material. Daily contact exposure time was for at least 6 hours, after which time the gauze, tape, and COBAN was removed. The residual test material was removed with reverse osmosis water and a paper towel without altering the existing response or the integrity of the epidermis. The residual test material was not estimated.

Experimental Evaluation

Inlife procedures:

The animals were examined for viability twice daily Monday through Friday and once daily on Saturdays, Sundays, and holidays.

Dermal responses were evaluated prior to dosing on Days 0, 1, and 4, and twice weekly thereafter until study termination. Dermal observations were also performed on the day of terminal sacrifice. All scoring was made according to the Draize Method of Scoring (Draize, 1959) which is presented in Key A.

Detailed clinical observations were made daily and included the nature, onset, severity, and duration of toxicological signs during the test period.

Body weights were recorded pretest, and on Day 0, and weekly thereafter until study termination. Body weights were also recorded on animals dying spontaneously and on the day of sacrifice.

Food consumption was measured weekly during the test period.

EXPERIMENTAL DESIGN (CONT'D)

Ophthalmological Examination

Prior to dose initiation and the week prior to main study termination, an ophthalmological exam, using an ophthalmoscope, was performed on all animals.

Clinical Laboratory Studies: Blood and Serum

At main study termination, blood was collected from the retro-orbital sinus of all animals while under methoxyflurane anesthesia. All animals were fasted overnight prior to blood collection. Blood was collected again from the satellite animals in the same manner at satellite termination. The following parameters were measured:

Hematology^a:

hematocrit
hemoglobin
erythrocyte count
leukocyte count
(total and differential)
platelet count
mean corpuscular volume
mean corpuscular hemoglobin
mean corpuscular hemoglobin
concentration

Clotting Potential^c:

prothrombin time
activated partial
thromboplastin time

Serum Chemistry^b:

albumin
urea nitrogen
calcium
creatinine
electrolytes (Na⁺, Cl⁻, K⁺, CO₂)
glucose
phosphorus
serum alanine aminotransferase
serum aspartate aminotransferase
serum alkaline phosphatase
total protein
total bilirubin
cholesterol
triglycerides

^aHematology samples were collected in tubes containing EDTA.

^bSerum chemistry samples were collected in tubes not containing anticoagulant.

^cCoagulation samples were collected in tubes containing sodium citrate and placed on ice.

EXPERIMENTAL DESIGN (CONT'D)

Blood was also collected from all animals at their respective necropsy for possible future analysis. The samples were collected from the abdominal aorta of all animals anesthetized with methoxyflurane. The samples were collected into heparinized tubes, centrifuged, and plasma/cellular components separated and frozen.

Urine

Urine samples were collected from all animals prior to main study termination and all satellite animals prior to satellite termination. Animals were not fasted during the urine collection interval. The following parameters were measured:

Semi-Quantitative Parameters:

Color and Appearance
Microscopy of Urine Sediment
pH
Bilirubin
Ketones
Occult Blood
Urobilinogen

Quantitative Parameters:

Glucose
Protein
Specific Gravity
Volume

Termination

Main Study

The study was terminated after at least 13 weeks of dosing. All surviving animals were subjected to a gross necropsy following an overnight fast from food. Animals were sacrificed via exsanguination following methoxyflurane anesthesia.

Satellite Termination

The satellite animals were terminated after at least a 28 day recovery period. The procedure was the same as in the main study termination.

Animals Which Succumb

Necropsies were conducted on all animals that died spontaneously or were sacrificed in moribund condition.

EXPERIMENTAL DESIGN (CONT'D)

Organ Weight

The following organs from all animals which survived to study termination were weighed wet prior to placement in fixative:

liver	testes/ovaries
kidneys	brain

Postmortem Procedures

A gross necropsy was performed on all animals. The following tissues were removed from all animals and preserved in 10 percent neutral buffered formalin:

adrenal	pituitary
aorta (thoracic)	prostate
brain (cerebrum, cerebellum, brainstem)	rectum
epididymides	salivary glands
esophagus	seminal vesicles
exorbital lacrimal glands	skin (treated and untreated)
eyes	small intestine (sections from duodenum, jejunum, ileum)
femoris muscle with sciatic nerve	spinal cord (cervical, midthoracic, lumbar)
heart	spleen
kidneys	sternum with marrow
large intestine (sections from colon and cecum)	stomach
liver	testes
lungs (with mainstem bronchi)	thymus
mammary gland (inguinal, female only)	thyroid with parathyroids
mesenteric lymph nodes	trachea
ovaries and oviducts	urinary bladder
pancreas	uterus (corpus, cervix)
	all gross lesions

EXPERIMENTAL DESIGN (CONT'D)

Histopathology

Tissues from the control group, as well from all animals that succumbed during the study, were collected, processed, sectioned, stained (hematoxylin and eosin) and examined microscopically. If changes or equivocal results were seen in any of these tissues, then tissues affected were examined in the other groups. The lungs, liver, kidneys and gross lesions from the low and mid dose groups were also be processed and examined microscopically.

Records

The protocol, all raw data, sample(s) of the test material, preserved tissues, tissue blocks, tissue slides, computer programs used for data collection, the final report and supporting documentation are maintained on file in the EBSI Toxicology Laboratory Archives.

STATISTICAL ANALYSIS

Statistical treatment of the results was conducted where appropriate.

Statistical evaluation of equality of means were done by an appropriate one way analysis of variance and a test for ordered response in the dose groups. First, Bartlett's Test was performed to determine if the dose groups have equal variance (Snedecor and Cochran, 1989). If the variances were equal, the testing was done using parametric methods, otherwise nonparametric techniques were used.

For the parametric procedures, a standard one way ANOVA using the F distribution to assess significance was used (Snedecor and Cochran, 1989). If significant differences among the means were indicated, Dunnett's Test was used to determine which treatment groups differed significantly from control (Dunnett, 1964). In addition to the ANOVA, a standard regression analysis for linear response in the dose groups was performed. The regression also tested for linear lack of fit in the model.

For the nonparametric procedures the test of equality of means was performed using the Kruskal-Wallis Test (Holland and Wolf, 1973). If significant differences among the means were indicated, Dunn's Summed Rank Test was used to determine which treatment groups differed significantly from the control (Holland and Wolf, 1973). In addition to the Kruskal-Wallis Test, Jonckheere's Test for monotonic trend in the dose response was performed.

Bartlett's Test for equal variance was conducted at the 1% level of significance. All other tests were conducted at the 5% and 1% level of significance.

The statistical t-test was also used to compare the high dose and satellite animals data (where appropriate) to substantiate their equivalence in order to accurately evaluate the recovery effect (Dixon and Massey, 1969).

RESULTS

1. MORTALITY

Survival Bar Graph: Figure 1

Five animals died prior to scheduled study termination as follows:

<u>GROUP/SEX</u>	<u>ANIMAL</u>	<u>DOSE</u>	<u>TYPE OF DEATH</u>
Group 1 male	ICN297	0 MG/KG	Found Dead on Day 22
Group 4 male	ICN317	80 MG/KG	Found Dead on Day 84
Group 5 male	ICN275	Satellite	Euthanized on Day 84
Group 3 female	ICN350	40 MG/KG	Found Dead on Day 7
Group 4 female	ICN360	80 MG/KG	Found Dead on Day 7

The two early deaths on Day 7 were attributed to the wrapping procedure as indicated by the tan discoloration of the liver at postmortem examination. The cause of death of the control male (Group 1) on Day 22 was not determined, but was considered incidental.

The two animals which died on Day 84 showed a variety of changes in their organs/tissues at microscopic examination. The basis of many of these changes was potentially of an ischemic nature, and was considered the result of the wrapping procedure and not related to the test material.

2. CLINICAL INLIFE OBSERVATIONS

Incidence of Inlife Observations: Table 1

Individual Inlife Observations: Appendix A

Clinical signs observed during the test period were minimal with the majority of animals being free of abnormalities during the study. There was a low incidence of scabs, sores, alopecia, dental abnormalities, ocular discharge, and /or abnormalities of the tail observed intermittently in one or more groups. Additionally, one 10 mg/kg female was observed as emaciated, one satellite female had a swollen limb, one satellite female had a swollen ear, one control male was observed with soft stool, and one satellite male had red material penis, hypothermia, and pale extremities. All of these findings were incidental and were not considered to be treatment-related.

RESULTS (CONT'D)

3. DERMAL OBSERVATIONS

Incidence of Erythema/Edema Scores: Table 2

Incidence of Supplemental Dermal Observations: Table 3

Individual Erythema/Edema Scores: Appendix B

Individual Supplemental Dermal Observations: Appendix C

Repeated topical applications of MRD-92-399 elicited erythema and/or edema in all treated groups (10, 40, and 80 mg/kg; and satellite recovery). Erythema was not observed in any control animal.

Erythema was first observed on Day 4 in the 40 mg/kg dose group (mid dose) and in both 80 mg/kg groups (high dose and satellite group). Erythema ranged from no erythema to severe erythema. The severity of the erythema increased as the study progressed, and the majority of animals in the mid, high, and satellite dose groups were observed with severe erythema from Day 7 until dosing termination.

Erythema also was observed in the low dose group (10 mg/kg) but the onset of erythema did not occur until Day 21. Erythema ranged from well-defined to severe in several animals, but the frequency of severe erythema scores of the low dose group was much less than observed in the higher dose groups. Erythema was also observed in one control animal. However, this erythema was judged to be mechanically induced.

Edema was observed sporadically in the mid, high and satellite group animals. Edema ranged from very slight to slight and was observed primarily during the latter part of the study. Very slight edema was observed in one low dose animal. Edema was not observed in any control animal.

Supplemental dermal observations consisting of eschar and desquamation were observed in all treated groups. More severe signs of dermal irritation, characterized by exfoliation and atonia, were generally limited to the mid, high and satellite recovery groups. Desquamation was also observed in two control animals at a very low frequency. Eschar was observed in one control animal but this irritation was considered mechanically induced.

Dermal irritation decreased dramatically in the satellite recovery group following dosing cessation. By study termination on Day 121, only one recovery animal was observed with erythema (severe) and eschar.

RESULTS (CONT'D)

4. BODY WEIGHT

Mean Body Weight: Table 4

Individual Body Weight: Appendix D

Mean Body Weight Graphs: Figures 2 and 3

All animals displayed increases in body weight over their initial values. There were no statistically significant differences in mean body weight of the treated and control animals of either sex during the test period (NOTE: Satellite recovery animals not included in statistical analysis).

5. FOOD CONSUMPTION

Mean Food Consumption: Table 5

Individual Food Consumption: Appendix E

Mean Food Consumption Graphs: Figures 4 and 5

There were no statistically significant differences in mean food consumption of the treated and control animals of either sex during the test period (NOTE: Satellite recovery animals not included in statistical analysis).

6. OPHTHALMOSCOPIC EXAMINATION

Incidence of Ophthalmoscopical Observations: Table 6

Individual Ophthalmoscopical Observations: Appendix F

There were no ophthalmoscopic findings which were considered to be related to treatment with Irgasan DP300.

One control female and one 40 mg/kg dose male were observed with focal retinopathy at study termination. This lesion is not likely to be caused by exposure to an ocular toxicant. Therefore, this finding was not judged to be treatment-related.

RESULTS (CONT'D)

7. HEMATOLOGY

Mean Quantitative Hematology (Main Study Termination): Table 7

Mean Quantitative Hematology (Satellite Recovery): Table 8

Individual Quantitative Hematology: Appendix G

Individual Semi-Quantitative Hematology: Appendix H

There were no differences in hematological parameters between treated and control animals of either sex which were considered to be related to treatment with Irgasan DP300.

There was a statistically significant decrease in mean hemoglobin and hematocrit values of the 80 mg/kg dose males compared with controls. Also, though not statistically significant, the red blood cell values showed a trend in being less than the controls. Two rats in particular may have contributed to this decrease, ICN277 and ICN329. The latter rat also had occult blood in the urine. However, there were no other pathological findings in these two animals that would suggest a treatment-related effect.

There also was a statistically significant decrease in the mean corpuscular hemoglobin of the high dose females compared with controls. This isolated deviation in the female animals was not considered clinically significant since all other hematology parameters in females were within the expected range.

Mean prothrombin time of the high dose males was significantly ($p \leq 0.05$) increased compared with controls. This increase was small and within the expected range for rats of this strain and age. Therefore, this increase was not considered clinically significant.

By inspection, the differential white blood cell and red blood cell morphology counts of the treated and control animals appeared unremarkable.

Following the recovery period, there were several small, but statistically significant, differences observed in hematological parameters of the satellite group animals. In general, these differences (both increases and decreases) were minor and not considered clinically significant. The most prominent change was a significant ($p \leq 0.01$) decrease in the white blood cell counts of both the male and female animals after approximately one month of dosing cessation. This appears to indicate a recovery effect which is probably related to the skin recovery in the dose site.

RESULTS (CONT'D)

8. SERUM CHEMISTRY

Mean Serum Chemistry (Main Study Termination): Table 9

Mean Serum Chemistry (Satellite Recovery): Table 10

Individual Serum Chemistry: Appendix I

There were no differences in serum chemistry parameters which were considered to be related to treatment with Irgasan DP300.

There were several small, but statistically significant, increases and decreases in several serum chemistry parameters. These included an increase in mean alkaline phosphatase in the 80 mg/kg females, a decrease in mean triglycerides of the 80 mg/kg males, a slight decrease in mean calcium of the 40 mg/kg males, a slight decrease in the mean alanine aminotransferase of the 40 mg/kg females, and a slight increase in the urea nitrogen of the 40 and 80 mg/kg females, compared with their respective controls. In all cases, the differences (increases and decreases) were small and well within the normal range for animals of this age and strain. Therefore, these changes were not considered clinically significant.

Following the recovery period, there were several small, but statistically significant, differences observed in serum chemistry parameters of the satellite group animals. In general, these differences (both increases and decreases) were minor and not considered clinically significant.

There was a statistically significant ($p \leq 0.01$) decrease in alkaline phosphatase (ALP) of both the male and female animals after approximately one month of dosing cessation. This decrease apparently indicates a recovery effect, since there was a statistically significant increase in ALP observed in the high dose females compared with controls at the main study termination.

RESULTS (CONT'D)

9. URINE CHEMISTRY

Mean Quantitative Urine Chemistry (Main Study Termination): Table 11

Mean Quantitative Urine Chemistry (Satellite Recovery): Table 12

Individual Quantitative Urine Chemistry: Appendix J

Individual Semi-Quantitative Urine Chemistry: Appendix K

There were no differences in uroanalytical parameters between treated and control animals of either sex which were considered to be related to treatment with Irgasan DP300.

At main study termination, there were no statistically significant differences in mean urine glucose, volume, or protein between treated and control animals of either sex.

There were two small, but statistically significant, differences in uroanalytical parameters observed following the satellite recovery period. There was a statistically significant decrease in mean urine glucose and an increase in mean urine volume in the male animals after the one month recovery period (Day 120) compared with their Day 88 values. However, these differences were minor and all values were within normal range for animals of this age and strain. Additionally, there were no clinically or statistically significant changes observed following the dosing period. Therefore it is unlikely that these differences at recovery were clinically significant.

By inspection, semi-quantitative urine chemistry analysis in a small number of the animals revealed occult blood in the urine of primarily the high dose and satellite male animals, and to a lesser degree in the mid dose male animals. This also was observed in the female animals with decreased incidence and severity.

RESULTS (CONT'D)

10. ORGAN WEIGHT AND RELATIVE ORGAN WEIGHT

Mean Organ Weight (Main Study Termination): Table 13

Mean Relative Organ Weight (Main Study Termination): Table 14

Mean Relative Organ Weight (Satellite Recovery): Table 15

Individual Organ Weight: Appendix L

Individual Relative Organ Weight: Appendix M

There were no differences in absolute organ weight or relative organ weight between treated and control animals of either sex which were considered to be related to treatment with Irgasan DP300.

There was a statistically significant decrease in the mean absolute and relative ovary weight of the low dose (10 mg/kg) group compared with controls. In the absence of a clear dose response, this small difference was not considered biologically significant.

There was a statistically significant decrease in the relative brain weight of the female satellite recovery animals at recovery termination compared with control animals at main study termination. This decrease would be expected since the animals' brain size remains constant although the animal continues to increase in size. Therefore, this finding was not considered biologically or toxicologically significant.

11. GROSS POSTMORTEM EXAMINATION

Incidence of Gross Postmortem Observations: Table 16

Individual Gross Postmortem Observations: Appendix N

Dermal irritation (desquamation, exfoliation, and/or eschar) was the most significant postmortem finding and was consistent with the supplemental dermal observations noted during the inlife portion of the study. Dermal irritation was not observed in the control or satellite recovery animals.

RESULTS (CONT'D)

Other postmortem observations included a low or single incidence of ileum diverticulum; kidney abnormalities; sores palate; friable spleen; alopecia, scabs, or staining of the fur; maloccluded incisors; truncated or necrotic tail; ovarian cyst; discolored stomach or lungs; thickened or distended uterus; and/or swelling of the ear. Additionally, a liver mass was observed in one low dose (10 mg/kg) male and one high dose (80 mg/kg) male. These findings were considered incidental and unrelated to treatment.

Postmortem findings observed in the animals which died prior to scheduled sacrifice appeared unremarkable.

12. HISTOPATHOLOGY RESULTS

Histopathology Report: Appendix O

Treatment-related changes were confined to the treated areas of the skin. Microscopic examination of sections of the treated skin showed several changes, the most common of which were hyperplasia/hyperkeratosis of the epidermis, sebaceous gland hyperplasia, dermal inflammation, focal epidermal necrosis, and exudate. In the mid dose male rats (40 mg/kg dose group), there was a marginal increase in the severity of sebaceous gland hyperplasia and hyperplasia/hyperkeratosis of the epidermis, as compared with controls. The same changes were more pronounced (increased severity) in the high dose male rats (80 mg/kg), as compared with controls. Male rats from both Groups 3 and 4 also showed increased incidences of dermal inflammation, focal epidermal necrosis, and exudate formation.

Examination of treated skin areas from satellite recovery males showed a return to near control levels for the incidence and/or severity of these treatment-related changes. The satellite animals, however, did show increased dermal fibrosis, as compared with controls and other treatment animals.

RESULTS (CONT'D)

Examination of the treated areas of the skin from female rats from treatment Groups 2, 3, and 4 in general showed a spectrum of changes similar to those described for the male rats. In particular, there was a dose-related increase in the severity of sebaceous gland hyperplasia, hyperplasia/hyperkeratosis of the epidermis, dermal inflammation, and focal epidermal necrosis, as well as an increased incidence of exudate formation, as compared with controls. Microscopic examination of treated skin areas from the female satellite recovery animals showed a decrease in the incidence and/or severity of these changes, as compared with non-recovery animals. As with the male animals, however, there was an increase in the incidence of dermal fibrosis with recovery.

Although changes were found in the "treated" skin from controls (sebaceous gland hyperplasia and hyperplasia/hyperkeratosis of the epidermis), the degree of severity was less than that observed for the treated animals. The changes in the skin from the control animals were considered to have been the result of the clipping, application procedures, and the wrapping of the skin.

Sections of the untreated skin examined microscopically showed an increased incidence of epidermal hyperkeratosis in the satellite male rats. In general this change was minimal and considered to be the result of the clipping procedure and possible contamination of the untreated site and not related to test material administration. Also, in the female rats, the incidence and severity of the epidermal hyperkeratosis was similar between the control, high dose, and satellite animals.

Microscopic examination of the urinary bladder revealed significant changes in three male rats. Animal ICN291 (Group 3) had marked hyperplastic cystitis compatible with changes seen with urinary calculi. A single Group 4 male which died on Day 84 (ICN317) had widespread organ system changes including the urinary bladder which showed necrosis, hemorrhage, and peritonitis. Similar changes (hemorrhagic cystitis) were seen in a single Group 5 male rat (ICN275). This animal was sacrificed on Day 84.

Microscopic examination of the kidneys revealed a slight increase in the incidence of focal cortical tubular degeneration in male rats of Groups 3 and 5. Male rats commonly develop a progressive glomerulonephrosis which can begin at a very early age. It is felt that the focal cortical tubular degeneration occurred spontaneously and was not influenced by test material administration.

RESULTS (CONT'D)

Microscopic examination of the liver showed an increased incidence of focal necrosis in the test material-treated animals, as compared with controls. Microscopically, this was an acute change characterized by coagulative necrosis of hepatocytes and occurred in a random distribution. The distribution of this change and the lack of a dose response suggests that this is not likely due to systemic toxicity but instead was possibly a result of trauma and/or ischemia to the liver as a result of the wrapping and manipulation of the animals (Nyska, et al, 1992).

Three male rats (one from each of Groups 1, 4, and 5) and two female rats (one from each of Groups 3 and 4) died or were killed in moribund condition prior to scheduled termination. The Group 1 male showed hepatic congestion and vacuolation. The Group 4 male had widespread changes in several organ systems, especially the cardiovascular and renal systems. The Group 5 male showed a variety of changes, especially marked hepatic necrosis. The most pronounced changes in the two nonsurviving female rats was moderate hepatic necrosis. The basis for many of the changes seen in these animals is potentially of an ischemic nature and was felt to be the result of the application procedure and not direct systemic toxicity of the test material.

All other changes seen in the other tissues specified for microscopic examination were considered to have occurred spontaneously and to be unrelated to treatment. These changes generally occurred at single, similar, or low frequencies among the groups and their type or incidence was not considered to have been influenced by test material administration.

13. ANALYTICAL CHEMISTRY

Analysis of Irgasan DP300 in Propylene Glycol: Appendix P

Stability of the dose solutions was demonstrated for up to 15 days at room temperature with losses of less than 3% being observed. Excellent uniformity was demonstrated with the coefficients of variation being less than 2%. Concentration verification analysis indicated all samples analyzed were within 8% of the nominal concentrations and the dose group means were within 5% of the nominals.

DISCUSSION

The most significant effect observed during this study was dermal irritation. Dermal irritation was observed in all treated groups and was dose and time dependent. However, this irritation appeared to be readily reversible following the cessation of dosing, as indicated by the recovery of the dose site by the satellite animals during the 28-Day recovery period. Most likely, decreased white blood cell counts in male and female satellite animals following recovery also were related to the recovery of the dose site skin. Signs of systemic toxicity were not observed in any group.

There were some minor changes in the urine and/or urogenital system of several treated animals. Semi-quantitative urine chemistry analysis of the animals surviving to termination revealed occult blood and red and white blood cells in the urine of several mid dose, high dose, and satellite animals. The frequency of these effects was similar for the three groups, including the animals which died or were sacrificed on Day 84 with urogenital abnormalities. However, the effect in the mid dose group appeared to be less severe with only one animal with 3+ for occult blood, and the other three animals with trace amounts of occult blood in the urine. In comparison, the high dose and the satellite group occult blood ranged from 1+ to 3+ in two and four animals, respectively. After the recovery period, the incidence and severity of occult blood in the urine increased, and six animals were observed with occult blood ranging from 1+ to 3+.

It should be noted that urine collection via Nalgene metabolism cages is a crude method and substantial contamination from the feed and fur occurs. Additionally, the "dipstick" method for determining occult blood is crude. However, during the microscopic examination of the sediment red and/or white blood cells also were observed in several animals which had occult blood in the urine.

Treatment-related histopathologic organ changes were not observed in the majority of animals previously observed with occult blood in the urine. Therefore, based upon the weight of evidence, the significance of this finding is unknown. Therefore, these findings were not considered treatment-related.

DISCUSSION (CONT'D)

In conclusion, dermal application of Irgasan DP300 did not produce conclusive evidence of systemic toxicity. Non-systemic treatment-related effects included dermal irritation which was observed in all dose groups. There appeared to be a recovery effect in the high dose animals' dermal irritation following dosing cessation for approximately four weeks. Therefore, the NOAEL (No Observable Adverse Effect Level) was established at 80 mg/kg with respect to toxicity (excluding dermal findings).

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PROTOCOL EXCEPTIONS

ANIMAL REPLACEMENT: Group 1 male animal ICN282 was found dead on Day 0 due to improper wrapping. ICN282 was replaced with animal ICN287 on Day 1. Therefore, ICN287 had no observations or body weight measurements recorded on Day 0 (animal was weighed and observed on Day 1), was dosed for only 91 days (rather than 92 days), and had a 6-day food consumption measurement taken during Week 1 (rather than 7-day).

SLEEVE REMOVAL: The technicians discovered several animals without their sleeves intact at the time of scheduled sleeve removal. This occurrence was sporadic and observed in all groups.

TISSUE PRESERVATION: Mandibular lymph nodes were collected and preserved from all animals although not required by protocol. It is the standard procedure at EBSI to collect mandibular lymph nodes whenever the salivary glands are collected and preserved. In addition, mammary glands were collected and preserved for all animals although the protocol only required preservation of mammary glands from female animals.

It is unlikely that these protocol exceptions adversely affected the study results or integrity.

No other circumstances occurred that would have affected the quality or integrity of the data.

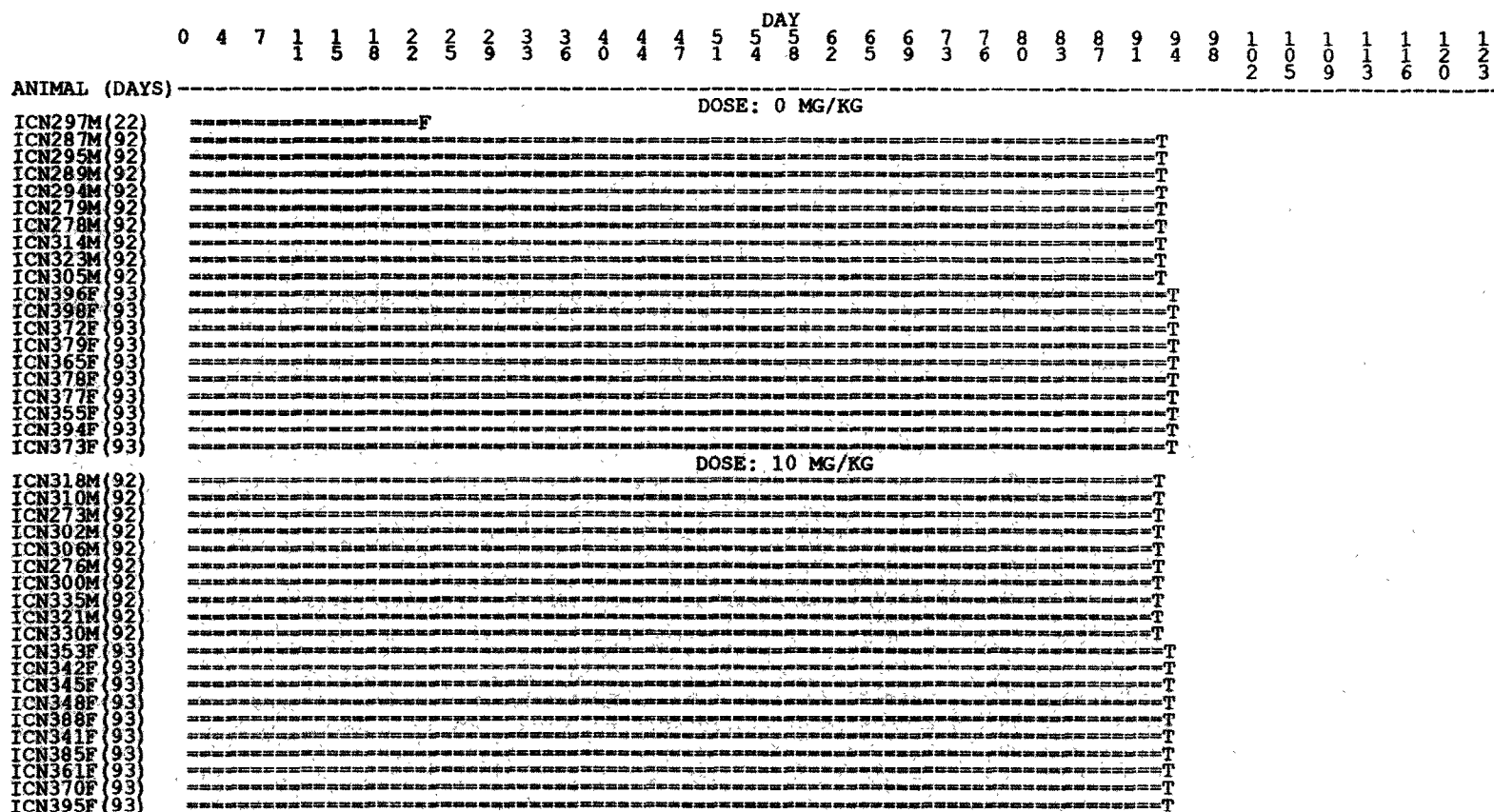
NOTES

EAR INJURY: Animal ICN386 (satellite group female) was observed with a swollen ear. On February 25, 1993, the ear was wiped with ethanol and was drained with a 25 gauge needle in order to facilitate healing. This procedure was performed under the supervision of a veterinarian pathologist. The animal's ear tag was removed on the following day and the procedure was continued until March 1, 1993, at which time no fluid could be obtained.

VETERINARY EXAMINATION: On Day 4, the veterinarian noted slight porphyrin staining around the nostrils in the Group 4 animals. The veterinarian stated that porphyrin excretion by the lacrimal glands is a sign of non-specific stress. Similar observations have been noted by Nyska et al. (1992) in occluded rat dermal studies.

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

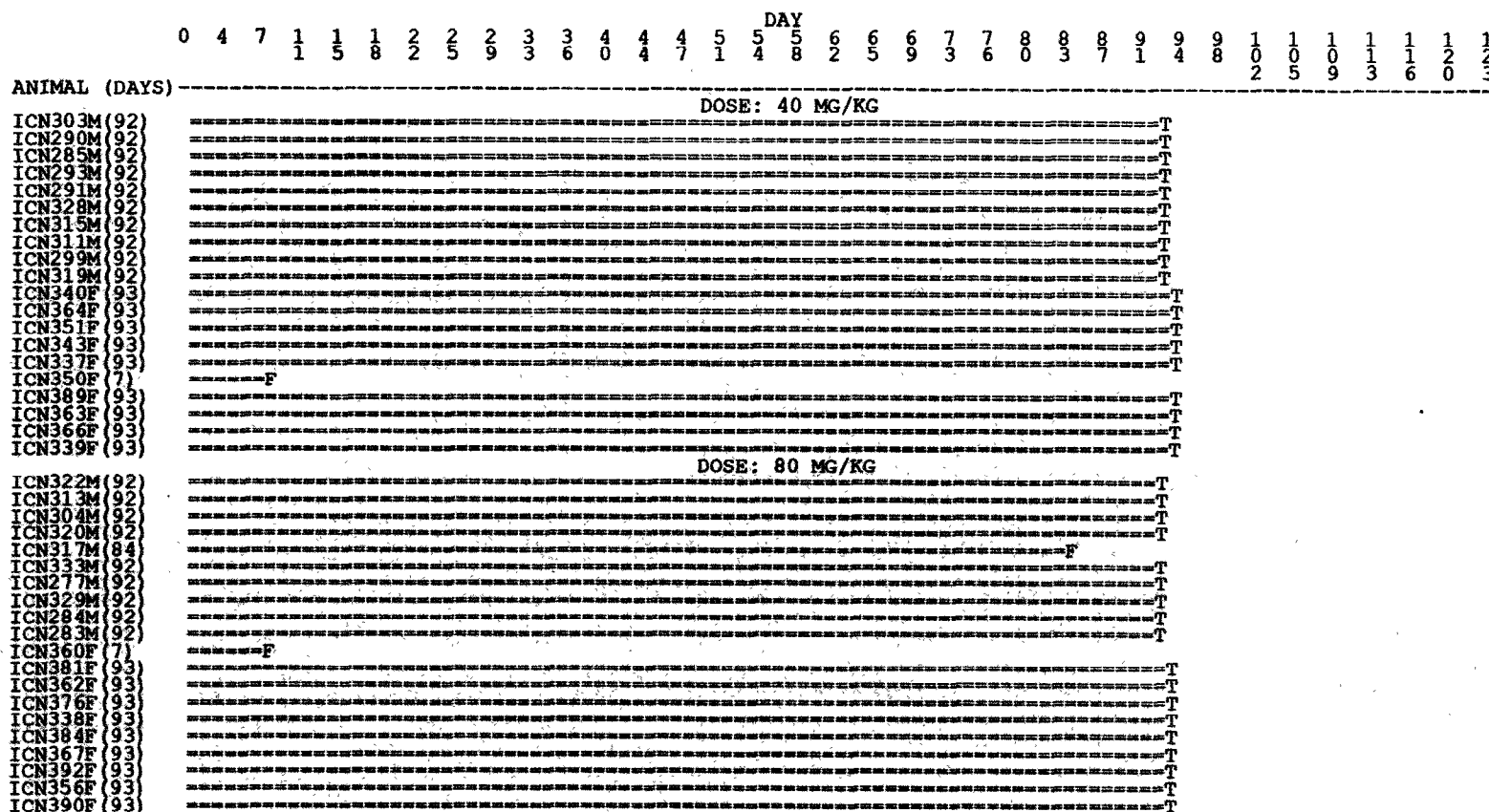
FIGURE 1 - SURVIVAL BAR GRAPH



NOTE: F - FOUND DEAD
T - TERMINAL EUTHANASIA

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

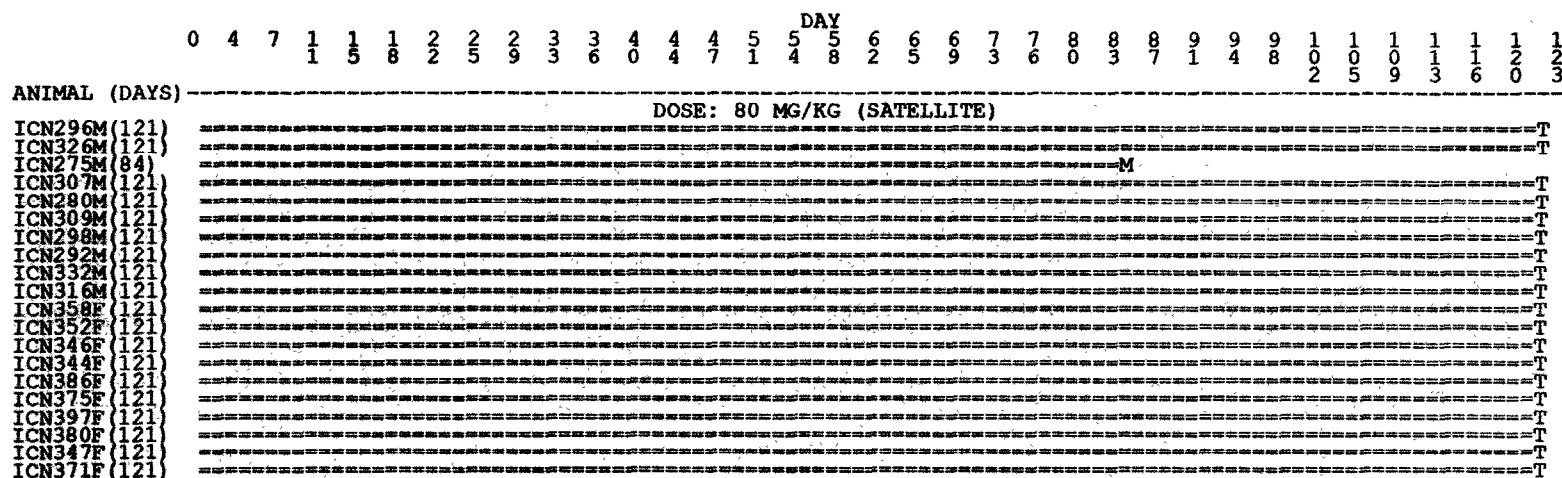
FIGURE 1 - SURVIVAL BAR GRAPH (CONT'D)



NOTE: F - FOUND DEAD
T - TERMINAL EUTHANASIA

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

FIGURE 1 - SURVIVAL BAR GRAPH (CONT'D)



NOTE: M - MORIBUND EUTHANASIA
T - TERMINAL EUTHANASIA

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

TABLE 1 - INCIDENCE OF INLIFE OBSERVATIONS

		MALES																
		D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y
		0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
SURVIVORS	0 MG/KG	9*	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10
	10 MG/KG	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10
	40 MG/KG	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10
	80 MG/KG	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10
	80 MG/KG (SATELLITE)	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10
GENERAL OBSERVATION WITHIN NORMAL LIMITS																		
	0 MG/KG	9	10	10	10	10	10	9	10	10	10	10	10	10	10	10	10	10
	10 MG/KG	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10
	40 MG/KG	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10
	80 MG/KG	10	10	9	10	10	10	10	10	10	10	10	10	10	10	10	10	10
	80 MG/KG (SATELLITE)	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10
APPEARANCE SOFT STOOL																		
	0 MG/KG	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0
	10 MG/KG	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	40 MG/KG	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	80 MG/KG	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	80 MG/KG (SATELLITE)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
SCABS																		
	0 MG/KG	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 MG/KG	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	40 MG/KG	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	80 MG/KG	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	80 MG/KG (SATELLITE)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

NOTE: * ONE ANIMAL REPLACED ON DAY 0

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

TABLE 1 - INCIDENCE OF INLIFE OBSERVATIONS (CONT'D)

		MALES																
		D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y
		1 7	1 8	1 9	2 0	2 1	2 2	2 3	2 4	2 5	2 6	2 7	2 8	2 9	3 0	3 1	3 2	3 3
SURVIVORS	0 MG/KG	10	10	10	10	10	10	9	9	9	9	9	9	9	9	9	9	9
	10 MG/KG	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10
	40 MG/KG	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10
	80 MG/KG	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10
	80 MG/KG (SATELLITE)	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10
GENERAL OBSERVATION WITHIN NORMAL LIMITS																		
	0 MG/KG	10	10	10	9	9	9	8	9	9	9	9	9	9	9	8	8	8
	10 MG/KG	10	10	10	10	9	10	9	9	10	10	10	10	10	10	10	10	10
	40 MG/KG	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10
	80 MG/KG	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10
	80 MG/KG (SATELLITE)	10	10	10	10	10	10	10	10	10	10	10	9	9	9	9	9	9
APPEARANCE BROKEN: INCISOR (S)																		
	0 MG/KG	0	0	0	1	1	1	1	0	0	0	0	0	0	0	0	0	0
	10 MG/KG	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	40 MG/KG	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	80 MG/KG	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	80 MG/KG (SATELLITE)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ALOPECIA																		
	0 MG/KG	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	1	1
	10 MG/KG	0	0	0	0	1	0	1	1	0	0	0	0	0	0	0	0	0
	40 MG/KG	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	80 MG/KG	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	80 MG/KG (SATELLITE)	0	0	0	0	0	0	0	0	0	0	0	1	1	1	1	1	1

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

TABLE 1 - INCIDENCE OF INLIFE OBSERVATIONS (CONT'D)

		MALES															
		D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y
		3 4	3 5	3 6	3 7	3 8	3 9	4 0	4 1	4 2	4 3	4 4	4 5	4 6	4 7	4 8	5 0
SURVIVORS	0 MG/KG	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9
	10 MG/KG	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10
	40 MG/KG	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10
	80 MG/KG	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10
	80 MG/KG (SATELLITE)	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10
GENERAL OBSERVATION WITHIN NORMAL LIMITS																	
	0 MG/KG	8	8	8	9	9	9	9	9	9	9	9	9	9	9	8	8
	10 MG/KG	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10
	40 MG/KG	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10
	80 MG/KG	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10
	80 MG/KG (SATELLITE)	9	9	8	8	8	8	8	8	8	8	8	8	8	8	8	8
APPEARANCE ALOPECIA																	
	0 MG/KG	1	1	1	0	0	0	0	0	0	0	0	0	0	0	1	1
	10 MG/KG	0	0	0	0	1	1	1	1	0	0	0	0	0	0	0	0
	40 MG/KG	0	0	0	0	0	0	0	0	1	1	1	1	1	1	0	0
	80 MG/KG	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	80 MG/KG (SATELLITE)	1	1	2	2	2	2	2	2	2	2	2	2	2	2	2	2

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

TABLE 1 - INCIDENCE OF INLIFE OBSERVATIONS (CONT'D)

		MALES																
		D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y
		5 1	5 2	5 3	5 4	5 5	5 6	5 7	5 8	5 9	6 0	6 1	6 2	6 3	6 4	6 5	6 6	6 7
SURVIVORS	0 MG/KG	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9
	10 MG/KG	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10
	40 MG/KG	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10
	80 MG/KG	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10
	80 MG/KG (SATELLITE)	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10
GENERAL OBSERVATION WITHIN NORMAL LIMITS																		
	0 MG/KG	8	8	8	8	8	8	8	8	8	8	8	8	8	8	8	8	8
	10 MG/KG	10	10	10	10	10	9	9	9	9	9	9	9	9	10	10	10	10
	40 MG/KG	10	10	10	10	10	10	9	9	9	9	9	9	9	9	9	9	10
	80 MG/KG	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10
	80 MG/KG (SATELLITE)	8	8	8	8	10	8	8	8	10	8	10	8	10	10	10	10	8
APPEARANCE BROKEN: INCISOR (S)																		
	0 MG/KG	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 MG/KG	0	0	0	0	0	0	0	0	0	1	1	1	1	0	0	0	0
	40 MG/KG	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	80 MG/KG	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	80 MG/KG (SATELLITE)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ALOPECIA																		
	0 MG/KG	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	10 MG/KG	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	40 MG/KG	0	0	0	0	0	0	1	1	1	1	1	1	1	1	1	1	1
	80 MG/KG	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	80 MG/KG (SATELLITE)	2	2	2	2	0	2	2	2	2	2	2	2	2	2	2	2	2
MISSING: INCISOR (S)																		
	0 MG/KG	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 MG/KG	0	0	0	0	0	1	1	1	1	0	0	0	0	0	0	0	0
	40 MG/KG	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	80 MG/KG	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	80 MG/KG (SATELLITE)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

TABLE 1 - INCIDENCE OF INLIFE OBSERVATIONS (CONT'D)

		MALES																
		D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y
		6 8	6 9	7 0	7 1	7 2	7 3	7 4	7 5	7 6	7 7	7 8	7 9	8 0	8 1	8 2	8 3	8 4
SURVIVORS	0 MG/KG	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9
	10 MG/KG	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10
	40 MG/KG	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10
	80 MG/KG	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10
	80 MG/KG (SATELLITE)	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10
GENERAL OBSERVATION WITHIN NORMAL LIMITS																		
	0 MG/KG	8	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9
	10 MG/KG	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10
	40 MG/KG	9	9	9	9	9	9	9	9	9	9	9	9	9	10	10	10	10
	80 MG/KG	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10
	80 MG/KG (SATELLITE)	8	8	8	8	8	8	8	8	8	8	8	8	8	8	7	7	7
APPEARANCE HYPOTHERMIA																		
	0 MG/KG	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 MG/KG	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	40 MG/KG	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	80 MG/KG	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	80 MG/KG (SATELLITE)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1
POOR CONDITION																		
	0 MG/KG	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 MG/KG	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	40 MG/KG	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	80 MG/KG	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	80 MG/KG (SATELLITE)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1
PALE EXTREMITIES																		
	0 MG/KG	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 MG/KG	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	40 MG/KG	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	80 MG/KG	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	80 MG/KG (SATELLITE)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1
RED MATERIAL SEEN: PENIS																		
	0 MG/KG	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 MG/KG	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	40 MG/KG	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	80 MG/KG	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	80 MG/KG (SATELLITE)	0	0	0	0	0	0	0	0	0	0	0	0	0	1	1	1	1

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

TABLE 1 - INCIDENCE OF INLIFE OBSERVATIONS (CONT'D)

		MALES																
		D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	
		6 8	6 9	7 0	7 1	7 2	7 3	7 4	7 5	7 6	7 7	7 8	7 9	8 0	8 1	8 2	8 3	8 4
ALOPECIA																		
	0 MG/KG	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 MG/KG	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	40 MG/KG	1	1	1	1	1	1	1	1	1	1	1	1	1	0	0	0	0
	80 MG/KG	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	80 MG/KG (SATELLITE)	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
OCULAR DRIED RED	OCULAR DISCHARGE																	
	0 MG/KG	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 MG/KG	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	40 MG/KG	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	80 MG/KG	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0
	80 MG/KG (SATELLITE)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

TABLE 1 - INCIDENCE OF INLIFE OBSERVATIONS (CONT'D)

		MALES															
		D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y
		8 5	8 6	8 7	8 8	8 9	9 0	9 1	9 2	9 3	9 4	9 5	9 6	9 7	9 8	9 9	1 0
																	1 1
SURVIVORS	0 MG/KG	9	9	9	9	9	9	9	9	0	0	0	0	0	0	0	0
	10 MG/KG	10	10	10	10	10	10	10	10	0	0	0	0	0	0	0	0
	40 MG/KG	10	10	10	10	10	10	10	10	0	0	0	0	0	0	0	0
	80 MG/KG	9	9	9	9	9	9	9	9	0	0	0	0	0	0	0	0
	80 MG/KG (SATELLITE)	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9
GENERAL OBSERVATION WITHIN NORMAL LIMITS																	
	0 MG/KG	9	9	9	9	9	9	9	9	0	0	0	0	0	0	0	0
	10 MG/KG	10	10	10	10	10	10	10	10	0	0	0	0	0	0	0	0
	40 MG/KG	9	9	9	9	9	8	8	8	0	0	0	0	0	0	0	0
	80 MG/KG	9	9	9	9	9	9	9	9	0	0	0	0	0	0	0	0
	80 MG/KG (SATELLITE)	7	7	7	7	7	7	7	7	8	8	9	9	9	8	8	8
APPEARANCE SORES																	
	0 MG/KG	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 MG/KG	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	40 MG/KG	0	0	0	0	1	1	1	1	0	0	0	0	0	0	0	0
	80 MG/KG	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	80 MG/KG (SATELLITE)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
BROKEN: INCISOR (S)																	
	0 MG/KG	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 MG/KG	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	40 MG/KG	0	0	0	0	0	1	1	1	0	0	0	0	0	0	0	0
	80 MG/KG	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	80 MG/KG (SATELLITE)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
MALOCCLUDED INCISORS																	
	0 MG/KG	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 MG/KG	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	40 MG/KG	0	0	0	0	1	1	1	1	0	0	0	0	0	0	0	0
	80 MG/KG	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	80 MG/KG (SATELLITE)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

TABLE 1 - INCIDENCE OF INLIFE OBSERVATIONS (CONT'D)

		MALES															
		D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y
		8 5	8 6	8 7	8 8	8 9	9 0	9 1	9 2	9 3	9 4	9 5	9 6	9 7	9 8	9 9	1 0
		1	1	1	1	1	2	2	2	1	1	0	0	0	1	1	1
ALOPECIA																	
	0 MG/KG	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 MG/KG	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	40 MG/KG	1	1	1	1	1	2	2	2	0	0	0	0	0	0	0	0
	80 MG/KG	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	80 MG/KG (SATELLITE)	2	2	2	2	2	2	2	2	1	1	0	0	0	1	1	1
MISSING: INCISOR (S)																	
	0 MG/KG	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 MG/KG	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	40 MG/KG	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	80 MG/KG	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	80 MG/KG (SATELLITE)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
OCULAR																	
DRIED RED OCULAR DISCHARGE																	
	0 MG/KG	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 MG/KG	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	40 MG/KG	0	0	0	0	1	1	1	1	0	0	0	0	0	0	0	0
	80 MG/KG	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	80 MG/KG (SATELLITE)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

TABLE 1 - INCIDENCE OF INLIFE OBSERVATIONS (CONT'D)

		MALES															
		D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y
		1 0 2	1 0 3	1 0 4	1 0 5	1 0 6	1 0 7	1 0 8	1 0 9	1 1 0	1 1 1	1 1 2	1 1 3	1 1 4	1 1 5	1 1 6	1 1 7
SURVIVORS	80 MG/KG (SATELLITE)	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9
GENERAL OBSERVATION WITHIN NORMAL LIMITS																	
APPEARANCE	80 MG/KG (SATELLITE)	8	7	7	7	7	7	7	7	6	6	6	6	6	6	6	6
SCABS	80 MG/KG (SATELLITE)	0	0	0	0	0	0	0	0	1	1	1	1	1	1	1	1
ALOPECIA	80 MG/KG (SATELLITE)	1	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
 WITH IRGASAN DP300 (MRD-92-399): 139910B

TABLE 1 - INCIDENCE OF INLIFE OBSERVATIONS (CONT'D)

		MALES		
		D A Y	D A Y	D A Y
		1 1 9	1 2 0	1 2 1
SURVIVORS	80 MG/KG (SATELLITE)	9	9	9
GENERAL OBSERVATION WITHIN NORMAL LIMITS				
APPEARANCE	80 MG/KG (SATELLITE)	6	6	6
SCABS	80 MG/KG (SATELLITE)	1	1	2
ALOPECIA	80 MG/KG (SATELLITE)	2	2	2

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

TABLE 1 - INCIDENCE OF INLIFE OBSERVATIONS (CONT'D)

		FEMALES																
		D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	
		0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
SURVIVORS	0 MG/KG	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10
	10 MG/KG	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10
	40 MG/KG	10	10	10	10	10	10	10	10	9	9	9	9	9	9	9	9	9
	80 MG/KG	10	10	10	10	10	10	10	10	9	9	9	9	9	9	9	9	9
	80 MG/KG (SATELLITE)	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10
GENERAL OBSERVATION WITHIN NORMAL LIMITS																		
	0 MG/KG	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10
	10 MG/KG	10	10	10	10	10	10	10	10	10	10	10	9	9	9	9	9	9
	40 MG/KG	10	10	10	10	10	10	10	10	9	9	9	9	9	9	9	8	8
	80 MG/KG	10	10	10	10	10	10	10	10	9	9	9	9	9	9	9	9	9
	80 MG/KG (SATELLITE)	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	9
APPEARANCE ALOPECIA																		
	0 MG/KG	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 MG/KG	0	0	0	0	0	0	0	0	0	0	0	1	1	1	1	1	1
	40 MG/KG	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	80 MG/KG	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	80 MG/KG (SATELLITE)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1
OCULAR RED OCULAR DISCHARGE																		
	0 MG/KG	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 MG/KG	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	40 MG/KG	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	1
	80 MG/KG	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	80 MG/KG (SATELLITE)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

TABLE 1 - INCIDENCE OF INLIFE OBSERVATIONS (CONT'D)

		FEMALES																
		D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y
		1 7	1 8	1 9	2 0	2 1	2 2	2 3	2 4	2 5	2 6	2 7	2 8	2 9	3 0	3 1	3 2	3 3
SURVIVORS	0 MG/KG	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10
	10 MG/KG	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10
	40 MG/KG	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9
	80 MG/KG	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9
	80 MG/KG (SATELLITE)	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10
GENERAL OBSERVATION WITHIN NORMAL LIMITS																		
	0 MG/KG	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10
	10 MG/KG	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9
	40 MG/KG	8	8	8	8	8	8	8	8	8	8	8	8	8	8	8	8	8
	80 MG/KG	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9
	80 MG/KG (SATELLITE)	9	9	9	9	9	8	8	8	8	8	8	8	8	8	8	8	8
APPEARANCE SCABS																		
	0 MG/KG	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 MG/KG	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	40 MG/KG	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	80 MG/KG	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	80 MG/KG (SATELLITE)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
BROKEN: INCISOR (S)																		
	0 MG/KG	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 MG/KG	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	40 MG/KG	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	80 MG/KG	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	80 MG/KG (SATELLITE)	0	0	0	0	0	0	0	0	0	0	0	0	0	1	1	1	1
MALOCCLUDED INCISORS																		
	0 MG/KG	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 MG/KG	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	40 MG/KG	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	80 MG/KG	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	80 MG/KG (SATELLITE)	0	0	0	0	0	0	0	0	0	0	0	0	0	1	1	1	1
ALOPECIA																		
	0 MG/KG	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 MG/KG	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	40 MG/KG	0	0	0	0	0	0	1	1	1	1	1	1	1	1	1	1	1
	80 MG/KG	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	80 MG/KG (SATELLITE)	1	1	1	1	1	2	2	2	2	2	2	2	2	2	2	2	2

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

TABLE 1 - INCIDENCE OF INLIFE OBSERVATIONS (CONT'D)

		FEMALES																
		D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y
		3 4	3 5	3 6	3 7	3 8	3 9	4 0	4 1	4 2	4 3	4 4	4 5	4 6	4 7	4 8	4 9	5 0
SURVIVORS	0 MG/KG	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10
	10 MG/KG	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10
	40 MG/KG	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9
	80 MG/KG	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9
	80 MG/KG (SATELLITE)	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10
GENERAL OBSERVATION WITHIN NORMAL LIMITS																		
	0 MG/KG	10	10	10	10	10	10	10	10	10	10	9	9	9	9	9	9	9
	10 MG/KG	9	9	9	9	9	9	9	9	9	8	8	9	9	9	9	9	9
	40 MG/KG	8	8	8	8	9	9	9	9	8	8	8	6	6	6	6	6	6
	80 MG/KG	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9
APPEARANCE SCABS	80 MG/KG (SATELLITE)	8	8	8	8	8	8	8	8	8	7	7	7	7	7	7	8	9
	0 MG/KG	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0
	10 MG/KG	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	40 MG/KG	0	0	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0
	80 MG/KG	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
SWOLLEN: LIMB (S)	80 MG/KG (SATELLITE)	0	0	0	0	0	0	0	0	0	1	1	1	1	1	1	0	0
	0 MG/KG	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 MG/KG	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	40 MG/KG	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	80 MG/KG	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
EMACIATED	80 MG/KG (SATELLITE)	0	0	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0
	0 MG/KG	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 MG/KG	0	0	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0
	40 MG/KG	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	80 MG/KG	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
BROKEN: INCISOR (S)	80 MG/KG (SATELLITE)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	0 MG/KG	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 MG/KG	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	40 MG/KG	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	80 MG/KG	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	80 MG/KG (SATELLITE)	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

TABLE 1 - INCIDENCE OF INLIFE OBSERVATIONS (CONT'D)

		FEMALES																
		D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y
		3 4	3 5	3 6	3 7	3 8	3 9	4 0	4 1	4 2	4 3	4 4	4 5	4 6	4 7	4 8	4 9	5 0
TRUNCATED: TAIL																		
	0 MG/KG	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 MG/KG	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	40 MG/KG	0	0	0	0	0	0	0	0	0	0	0	1	1	1	1	1	1
	80 MG/KG	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	80 MG/KG (SATELLITE)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
MALOCCLUDED INCISORS																		
	0 MG/KG	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 MG/KG	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	40 MG/KG	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	80 MG/KG	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	80 MG/KG (SATELLITE)	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ALOPECIA																		
	0 MG/KG	0	0	0	0	0	0	0	0	0	0	1	1	1	1	1	1	1
	10 MG/KG	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	40 MG/KG	1	1	1	0	0	0	0	1	0	0	2	2	2	2	2	2	2
	80 MG/KG	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	80 MG/KG (SATELLITE)	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	1

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

TABLE 1 - INCIDENCE OF INLIFE OBSERVATIONS (CONT'D)

		FEMALES																
		D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y
		5 1	5 2	5 3	5 4	5 5	5 6	5 7	5 8	5 9	6 0	6 1	6 2	6 3	6 4	6 5	6 6	6 7
SURVIVORS	0 MG/KG	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10
	10 MG/KG	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10
	40 MG/KG	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9
	80 MG/KG	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9
	80 MG/KG (SATELLITE)	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10
GENERAL OBSERVATION WITHIN NORMAL LIMITS																		
0 MG/KG		10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10
10 MG/KG		9	9	9	9	9	9	8	8	8	9	9	9	9	9	9	9	9
40 MG/KG		6	6	6	6	6	7	7	6	6	6	6	7	7	8	8	8	8
80 MG/KG		9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9
80 MG/KG (SATELLITE)		9	9	9	9	10	10	10	9	8	8	8	9	10	10	9	9	9
APPEARANCE SCABS																		
0 MG/KG		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
10 MG/KG		0	0	0	0	0	0	1	1	1	0	0	0	0	0	0	0	0
40 MG/KG		0	0	0	0	0	0	0	1	1	1	1	1	1	0	0	0	0
80 MG/KG		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
80 MG/KG (SATELLITE)		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
BROKEN: INCISOR (S)																		
0 MG/KG		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
10 MG/KG		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
40 MG/KG		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
80 MG/KG		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
80 MG/KG (SATELLITE)		0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	1	1
TRUNCATED: TAIL																		
0 MG/KG		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
10 MG/KG		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
40 MG/KG		1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
80 MG/KG		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
80 MG/KG (SATELLITE)		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
MALOCCLUDED INCISORS																		
0 MG/KG		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
10 MG/KG		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
40 MG/KG		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
80 MG/KG		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
80 MG/KG (SATELLITE)		0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	1	1

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

TABLE 1 - INCIDENCE OF INLIFE OBSERVATIONS (CONT'D)

		FEMALES																	
		D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	
		5 1	5 2	5 3	5 4	5 5	5 6	5 7	5 8	5 9	6 0	6 1	6 2	6 3	6 4	6 5	6 6	6 7	
ALOPECIA																			
0 MG/KG		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
10 MG/KG		1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	
40 MG/KG		2	2	2	2	2	1	1	1	1	1	1	0	0	0	0	0	0	
80 MG/KG		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
80 MG/KG (SATELLITE)		1	1	1	1	0	0	0	1	2	2	2	1	0	0	0	1	1	

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

TABLE 1 - INCIDENCE OF INLIFE OBSERVATIONS (CONT'D)

		FEMALES																
		D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y
		6 8	6 9	7 0	7 1	7 2	7 3	7 4	7 5	7 6	7 7	7 8	7 9	8 0	8 1	8 2	8 3	8 4
SURVIVORS	0 MG/KG	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10
	10 MG/KG	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10
	40 MG/KG	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9
	80 MG/KG	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9
	80 MG/KG (SATELLITE)	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10
GENERAL OBSERVATION WITHIN NORMAL LIMITS																		
	0 MG/KG	10	10	10	10	10	10	10	10	10	9	9	9	9	10	10	10	10
	10 MG/KG	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9
	40 MG/KG	8	8	8	8	7	7	7	7	7	6	6	6	6	6	6	6	6
	80 MG/KG	9	9	9	9	9	9	9	9	9	8	7	7	7	7	7	7	7
	80 MG/KG (SATELLITE)	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9
APPEARANCE SCABS																		
	0 MG/KG	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0
	10 MG/KG	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	40 MG/KG	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	80 MG/KG	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	80 MG/KG (SATELLITE)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
NECROTIC: TAIL																		
	0 MG/KG	0	0	0	0	0	0	0	0	0	1	1	1	0	0	0	0	0
	10 MG/KG	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	40 MG/KG	0	0	0	0	0	0	0	0	0	0	1	1	1	1	1	1	1
	80 MG/KG	0	0	0	0	0	0	0	0	0	0	1	1	1	1	1	1	1
	80 MG/KG (SATELLITE)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
BROKEN: INCISOR (S)																		
	0 MG/KG	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 MG/KG	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	40 MG/KG	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	80 MG/KG	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	80 MG/KG (SATELLITE)	1	1	1	1	1	1	1	1	1	1	1	0	0	0	0	0	0
TRUNCATED: TAIL																		
	0 MG/KG	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 MG/KG	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	40 MG/KG	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	80 MG/KG	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	80 MG/KG (SATELLITE)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

TABLE 1 - INCIDENCE OF INLIFE OBSERVATIONS (CONT'D)

		FEMALES																
		D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	
		6 8	6 9	7 0	7 1	7 2	7 3	7 4	7 5	7 6	7 7	7 8	7 9	8 0	8 1	8 2	8 3	8 4
MALOCCLUDED INCISORS																		
	0 MG/KG	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 MG/KG	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	40 MG/KG	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	80 MG/KG	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	80 MG/KG (SATELLITE)	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
ALOPECIA																		
	0 MG/KG	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 MG/KG	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	40 MG/KG	0	0	0	0	1	1	1	1	1	1	1	1	1	1	1	1	1
	80 MG/KG	0	0	0	0	0	0	0	0	0	1	1	1	1	1	1	1	1
	80 MG/KG (SATELLITE)	1	0	0	0	0	0	0	0	0	1	1	1	0	0	0	0	0

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

TABLE 1 - INCIDENCE OF INLIFE OBSERVATIONS (CONT'D)

		FEMALES															
		D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y
		8 5	8 6	8 7	8 8	8 9	9 0	9 1	9 2	9 3	9 4	9 5	9 6	9 7	9 8	9 9	1 0 0
SURVIVORS	0 MG/KG	10	10	10	10	10	10	10	10	10	0	0	0	0	0	0	0
	10 MG/KG	10	10	10	10	10	10	10	10	10	0	0	0	0	0	0	0
	40 MG/KG	9	9	9	9	9	9	9	9	9	0	0	0	0	0	0	0
	80 MG/KG	9	9	9	9	9	9	9	9	9	0	0	0	0	0	0	0
	80 MG/KG (SATELLITE)	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10
GENERAL OBSERVATION WITHIN NORMAL LIMITS																	
	0 MG/KG	10	10	10	10	10	10	10	10	8	0	0	0	0	0	0	0
	10 MG/KG	9	9	8	9	9	9	9	9	8	0	0	0	0	0	0	0
	40 MG/KG	7	7	7	7	7	7	7	7	7	0	0	0	0	0	0	0
	80 MG/KG	7	7	7	7	7	7	7	7	7	0	0	0	0	0	0	0
	80 MG/KG (SATELLITE)	8	8	8	8	8	8	8	8	8	8	8	8	8	8	8	8
APPEARANCE SCABS																	
	0 MG/KG	0	0	0	0	0	0	0	0	2	0	0	0	0	0	0	0
	10 MG/KG	0	0	1	0	0	0	0	0	1	0	0	0	0	0	0	0
	40 MG/KG	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	80 MG/KG	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	80 MG/KG (SATELLITE)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
SWOLLEN: EAR																	
	0 MG/KG	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 MG/KG	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	40 MG/KG	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	80 MG/KG	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	80 MG/KG (SATELLITE)	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
NECROTIC: TAIL																	
	0 MG/KG	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 MG/KG	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	40 MG/KG	1	1	1	1	1	1	1	1	1	0	0	0	0	0	0	0
	80 MG/KG	1	1	1	1	1	1	1	1	1	0	0	0	0	0	0	0
	80 MG/KG (SATELLITE)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

TABLE 1 - INCIDENCE OF INLIFE OBSERVATIONS (CONT'D)

		FEMALES																
		D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y
		8 5	8 6	8 7	8 8	8 9	9 0	9 1	9 2	9 3	9 4	9 5	9 6	9 7	9 8	9 9	1 0	1 1
BROKEN: INCISOR (S)																		
	0 MG/KG	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 MG/KG	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	40 MG/KG	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	80 MG/KG	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	80 MG/KG (SATELLITE)	1	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0
TRUNCATED: TAIL																		
	0 MG/KG	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 MG/KG	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	40 MG/KG	1	1	1	1	1	1	1	1	1	0	0	0	0	0	0	0	0
	80 MG/KG	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	80 MG/KG (SATELLITE)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
MALOCCLUDED INCISORS																		
	0 MG/KG	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 MG/KG	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	40 MG/KG	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	80 MG/KG	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	80 MG/KG (SATELLITE)	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
ALOPECIA																		
	0 MG/KG	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10 MG/KG	1	1	1	1	1	1	1	1	1	0	0	0	0	0	0	0	0
	40 MG/KG	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	80 MG/KG	1	1	1	1	1	1	1	1	1	0	0	0	0	0	0	0	0
	80 MG/KG (SATELLITE)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

TABLE 1 - INCIDENCE OF INLIFE OBSERVATIONS (CONT'D)

		FEMALES															
		D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y
		1 0 2	1 0 3	1 0 4	1 0 5	1 0 6	1 0 7	1 0 8	1 0 9	1 1 0	1 1 1	1 1 2	1 1 3	1 1 4	1 1 5	1 1 6	1 1 7
SURVIVORS	80 MG/KG (SATELLITE)	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10
GENERAL OBSERVATION WITHIN NORMAL LIMITS																	
APPEARANCE	80 MG/KG (SATELLITE)	8	8	8	8	8	8	8	8	8	8	8	8	8	8	8	8
SWOLLEN: EAR																	
MALOCCLUDED INCISORS	80 MG/KG (SATELLITE)	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
ALOPECIA	80 MG/KG (SATELLITE)	1	1	1	1	1	1	1	1	1	1	1	1	1	0	0	0
80 MG/KG (SATELLITE)		0	0	0	0	0	0	1	1	1	1	1	1	1	1	1	1

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
 WITH IRGASAN DP300 (MRD-92-399): 139910B

TABLE 1 - INCIDENCE OF INLIFE OBSERVATIONS (CONT'D)

		FEMALES		
		D A Y	D A Y	D A Y
		1 1 9	1 2 0	1 2 1
		10	10	10
SURVIVORS	80 MG/KG (SATELLITE)			
GENERAL OBSERVATION WITHIN NORMAL LIMITS				
		8	8	8
APPEARANCE	80 MG/KG (SATELLITE)			
SWOLLEN: EAR	80 MG/KG (SATELLITE)	1	1	1
ALOPECIA	80 MG/KG (SATELLITE)	1	1	1

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

KEY A - EVALUATION OF DERMAL IRRITATION

I. Dermal Observation - Draize (Draize, 1959)

Erythema and Eschar Formation (most severely affected area graded):

No erythema-	- - - - -	0
Very slight erythema (barely perceptible)-	- - - - -	1
Well-defined erythema-	- - - - -	2
Moderate to severe erythema-	- - - - -	3
Severe erythema (beet redness) to slight eschar formation (injuries in depth)-	- - - - -	4

Edema Formation (most severely affected area graded):

No edema-	- - - - -	0
Very slight edema (barely perceptible)-	- - - - -	1
Slight edema (edges of area well-defined by definite raising)-	- - - - -	2
Moderate edema (raised more than 1 mm)-	- - - - -	3
Severe edema (raised more than 1 mm and extending beyond the area of exposure)-	- - - - -	4

II. Other Dermal Observations (the following observations were noted if present):

Atonia - lack of resiliency of skin

Blanching - whitened areas

Leathery - has the texture and feel of leather

Cracking - superficial cracks in the skin

Fissuring - deep cracks in the skin (erythema score of "4" seen inside the fissure)

Desquamation - small flakes of skin coming off

Necrosis - black or brown discoloration of the skin

Exfoliation - sheets or areas larger than small flakes of skin coming off

Eschar - scab formation

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

TABLE 2 - INCIDENCE OF DERMAL ERYTHEMA/EDEMA
(SEE KEY A FOR DERMAL EVALUATIONS)

		GROUP - 0 MG/KG				
		D E R M A L S C O R E S				
		0	1	2	3	4
DAY 0	ERYTHEMA	19	0	0	0	0 N= 19*
	EDEMA	19	0	0	0	0 N= 19*
DAY 1	ERYTHEMA	20	0	0	0	0 N= 20
	EDEMA	20	0	0	0	0 N= 20
DAY 4	ERYTHEMA	20	0	0	0	0 N= 20
	EDEMA	20	0	0	0	0 N= 20
DAY 7	ERYTHEMA	20	0	0	0	0 N= 20
	EDEMA	20	0	0	0	0 N= 20
DAY 11	ERYTHEMA	20	0	0	0	0 N= 20
	EDEMA	20	0	0	0	0 N= 20
DAY 14	ERYTHEMA	20	0	0	0	0 N= 20
	EDEMA	20	0	0	0	0 N= 20
DAY 18	ERYTHEMA	20	0	0	0	0 N= 20
	EDEMA	20	0	0	0	0 N= 20
DAY 21	ERYTHEMA	20	0	0	0	0 N= 20
	EDEMA	20	0	0	0	0 N= 20
DAY 25	ERYTHEMA	19	0	0	0	0 N= 19
	EDEMA	19	0	0	0	0 N= 19
DAY 28	ERYTHEMA	19	0	0	0	0 N= 19
	EDEMA	19	0	0	0	0 N= 19
DAY 32	ERYTHEMA	19	0	0	0	0 N= 19
	EDEMA	19	0	0	0	0 N= 19
DAY 35	ERYTHEMA	19	0	0	0	0 N= 19
	EDEMA	19	0	0	0	0 N= 19
DAY 39	ERYTHEMA	19	0	0	0	0 N= 19
	EDEMA	19	0	0	0	0 N= 19
DAY 42	ERYTHEMA	19	0	0	0	0 N= 19
	EDEMA	19	0	0	0	0 N= 19
DAY 46	ERYTHEMA	19	0	0	0	0 N= 19
	EDEMA	19	0	0	0	0 N= 19
DAY 49	ERYTHEMA	18 (a)	0	0	0	0 N= 19
	EDEMA	18 (a)	0	0	0	0 N= 19

NOTE: * - ONE ANIMAL REPLACED ON DAY 0
(a) - OBSERVATION FOR ONE ANIMAL INADVERTENTLY NOT RECORDED

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

TABLE 2 - INCIDENCE OF DERMAL ERYTHEMA/EDEMA (CONT'D)
(SEE KEY A FOR DERMAL EVALUATIONS)

GROUP - 0 MG/KG

		D E R M A L S C O R E S				
		0	1	2	3	4
DAY 53	ERYTHEMA	19	0	0	0	0 N= 19
	EDEMA	19	0	0	0	0 N= 19
DAY 56	ERYTHEMA	19	0	0	0	0 N= 19
	EDEMA	19	0	0	0	0 N= 19
DAY 60	ERYTHEMA	18	0	0	0	1* N= 19
	EDEMA	19	0	0	0	0 N= 19
DAY 63	ERYTHEMA	18	0	0	0	1* N= 19
	EDEMA	19	0	0	0	0 N= 19
DAY 67	ERYTHEMA	18	0	0	0	1* N= 19
	EDEMA	19	0	0	0	0 N= 19
DAY 70	ERYTHEMA	18	0	0	0	1* N= 19
	EDEMA	19	0	0	0	0 N= 19
DAY 74	ERYTHEMA	19	0	0	0	0 N= 19
	EDEMA	19	0	0	0	0 N= 19
DAY 77	ERYTHEMA	19	0	0	0	0 N= 19
	EDEMA	19	0	0	0	0 N= 19
DAY 81	ERYTHEMA	19	0	0	0	0 N= 19
	EDEMA	19	0	0	0	0 N= 19
DAY 84	ERYTHEMA	19	0	0	0	0 N= 19
	EDEMA	19	0	0	0	0 N= 19
DAY 88	ERYTHEMA	19	0	0	0	0 N= 19
	EDEMA	19	0	0	0	0 N= 19
DAY 91	ERYTHEMA	19	0	0	0	0 N= 19
	EDEMA	19	0	0	0	0 N= 19
DAY 92	ERYTHEMA	9	0	0	0	0 N= 9
	EDEMA	9	0	0	0	0 N= 9
DAY 93	ERYTHEMA	10	0	0	0	0 N= 10
	EDEMA	10	0	0	0	0 N= 10

NOTE: * - APPEARS TO BE MECHANICALLY INDUCED

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

TABLE 2 - INCIDENCE OF DERMAL ERYTHEMA/EDEMA (CONT'D)
(SEE KEY A FOR DERMAL EVALUATIONS)

		GROUP - 10 MG/KG				
		D E R M A L S C O R E S				
		0	1	2	3	4
DAY 0	ERYTHEMA	20	0	0	0	0
	EDEMA	20	0	0	0	0
DAY 1	ERYTHEMA	20	0	0	0	0
	EDEMA	20	0	0	0	0
DAY 4	ERYTHEMA	20	0	0	0	0
	EDEMA	20	0	0	0	0
DAY 7	ERYTHEMA	20	0	0	0	0
	EDEMA	20	0	0	0	0
DAY 11	ERYTHEMA	20	0	0	0	0
	EDEMA	20	0	0	0	0
DAY 14	ERYTHEMA	20	0	0	0	0
	EDEMA	20	0	0	0	0
DAY 18	ERYTHEMA	20	0	0	0	0
	EDEMA	20	0	0	0	0
DAY 21	ERYTHEMA	19	0	1	0	0
	EDEMA	20	0	0	0	0
DAY 25	ERYTHEMA	16	0	3	1	0
	EDEMA	20	0	0	0	0
DAY 28	ERYTHEMA	16	0	1	2	1
	EDEMA	20	0	0	0	0
DAY 32	ERYTHEMA	16	0	0	0	4
	EDEMA	20	0	0	0	0
DAY 35	ERYTHEMA	16	0	0	1	3
	EDEMA	20	0	0	0	0
DAY 39	ERYTHEMA	17	0	0	1	2
	EDEMA	20	0	0	0	0
DAY 42	ERYTHEMA	17	0	0	2	1
	EDEMA	20	0	0	0	0
DAY 46	ERYTHEMA	17	0	0	0	3
	EDEMA	20	0	0	0	0
DAY 49	ERYTHEMA	16	0	1	0	3
	EDEMA	20	0	0	0	0

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

TABLE 2 - INCIDENCE OF DERMAL ERYTHEMA/EDEMA (CONT'D)
(SEE KEY A FOR DERMAL EVALUATIONS)

GROUP - 10 MG/KG

		D E R M A L S C O R E S				
		0	1	2	3	4
DAY 53	ERYTHEMA	16	0	1	0	3
	EDEMA	20	0	0	0	0
DAY 56	ERYTHEMA	17	0	0	0	3
	EDEMA	20	0	0	0	0
DAY 60	ERYTHEMA	17	0	0	0	3
	EDEMA	20	0	0	0	0
DAY 63	ERYTHEMA	16	0	0	0	4
	EDEMA	20	0	0	0	0
DAY 67	ERYTHEMA	16	0	0	0	4
	EDEMA	20	0	0	0	0
DAY 70	ERYTHEMA	16	0	0	0	4
	EDEMA	19	1	0	0	0
DAY 74	ERYTHEMA	16	0	0	0	4
	EDEMA	19	1	0	0	0
DAY 77	ERYTHEMA	16	0	0	0	4
	EDEMA	20	0	0	0	0
DAY 81	ERYTHEMA	16	0	0	0	4
	EDEMA	20	0	0	0	0
DAY 84	ERYTHEMA	17	0	0	0	3
	EDEMA	20	0	0	0	0
DAY 88	ERYTHEMA	17	0	1	0	2
	EDEMA	20	0	0	0	0
DAY 91	ERYTHEMA	16	0	2	0	2
	EDEMA	19	1	0	0	0
DAY 92	ERYTHEMA	10	0	0	0	0
	EDEMA	10	0	0	0	0
DAY 93	ERYTHEMA	6	0	2	0	2
	EDEMA	9	1	0	0	0

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

TABLE 2 - INCIDENCE OF DERMAL ERYTHEMA/EDEMA (CONT'D)
(SEE KEY A FOR DERMAL EVALUATIONS)

		GROUP - 40 MG/KG				
		D E R M A L S C O R E S				
		0	1	2	3	4
DAY 0	ERYTHEMA	20	0	0	0	0
	EDEMA	20	0	0	0	0
						N= 20
DAY 1	ERYTHEMA	20	0	0	0	0
	EDEMA	20	0	0	0	0
						N= 20
DAY 4	ERYTHEMA	10	3	3	1	3
	EDEMA	20	0	0	0	0
						N= 20
DAY 7	ERYTHEMA	3	1	2	0	14
	EDEMA	20	0	0	0	0
						N= 20
DAY 11	ERYTHEMA	4	0	0	0	15
	EDEMA	19	0	0	0	0
						N= 19
DAY 14	ERYTHEMA	7	0	0	0	12
	EDEMA	19	0	0	0	0
						N= 19
DAY 18	ERYTHEMA	8	0	0	0	11
	EDEMA	19	0	0	0	0
						N= 19
DAY 21	ERYTHEMA	7	0	1	2	9
	EDEMA	19	0	0	0	0
						N= 19
DAY 25	ERYTHEMA	5	1	1	1	11
	EDEMA	19	0	0	0	0
						N= 19
DAY 28	ERYTHEMA	4	0	3	1	11
	EDEMA	19	0	0	0	0
						N= 19
DAY 32	ERYTHEMA	2	1	0	0	16
	EDEMA	18	1	0	0	0
						N= 19
DAY 35	ERYTHEMA	2	1	0	0	16
	EDEMA	17	2	0	0	0
						N= 19
DAY 39	ERYTHEMA	2	0	0	2	15
	EDEMA	18	1	0	0	0
						N= 19
DAY 42	ERYTHEMA	2	0	0	1	16
	EDEMA	19	0	0	0	0
						N= 19
DAY 46	ERYTHEMA	1	1	0	1	16
	EDEMA	19	0	0	0	0
						N= 19
DAY 49	ERYTHEMA	2	0	1	0	16
	EDEMA	19	0	0	0	0
						N= 19

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

TABLE 2 - INCIDENCE OF DERMAL ERYTHEMA/EDEMA (CONT'D)
(SEE KEY A FOR DERMAL EVALUATIONS)

		GROUP - 40 MG/KG				
		D E R M A L S C O R E S				
		0	1	2	3	4
DAY 53	ERYTHEMA	2	0	1	0	16
	EDEMA	19	0	0	0	0
						N= 19
DAY 56	ERYTHEMA	2	0	0	0	17
	EDEMA	19	0	0	0	0
						N= 19
DAY 60	ERYTHEMA	2	0	0	0	17
	EDEMA	19	0	0	0	0
						N= 19
DAY 63	ERYTHEMA	0	0	0	0	19
	EDEMA	19	0	0	0	0
						N= 19
DAY 67	ERYTHEMA	0	0	0	0	19
	EDEMA	13	6	0	0	0
						N= 19
DAY 70	ERYTHEMA	0	0	0	0	19
	EDEMA	17	2	0	0	0
						N= 19
DAY 74	ERYTHEMA	1	0	0	0	18
	EDEMA	16	3	0	0	0
						N= 19
DAY 77	ERYTHEMA	1	0	0	0	18
	EDEMA	19	0	0	0	0
						N= 19
DAY 81	ERYTHEMA	1	0	0	1	17
	EDEMA	19	0	0	0	0
						N= 19
DAY 84	ERYTHEMA	1	0	0	0	18
	EDEMA	16	3	0	0	0
						N= 19
DAY 88	ERYTHEMA	0	0	1	0	18
	EDEMA	15	4	0	0	0
						N= 19
DAY 91	ERYTHEMA	2	0	0	0	17
	EDEMA	11	4	4	0	0
						N= 19
DAY 92	ERYTHEMA	1	0	1	0	8
	EDEMA	7	1	2	0	0
						N= 10
DAY 93	ERYTHEMA	0	0	0	0	9
	EDEMA	5	4	0	0	0
						N= 9

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

TABLE 2 - INCIDENCE OF DERMAL ERYTHEMA/EDEMA (CONT'D)
(SEE KEY A FOR DERMAL EVALUATIONS)

GROUP - 80 MG/KG

		D E R M A L S C O R E S					
		0	1	2	3	4	
DAY 0	ERYTHEMA	20	0	0	0	0	N= 20
	EDEMA	20	0	0	0	0	N= 20
DAY 1	ERYTHEMA	20	0	0	0	0	N= 20
	EDEMA	20	0	0	0	0	N= 20
DAY 4	ERYTHEMA	5	4	3	0	8	N= 20
	EDEMA	20	0	0	0	0	N= 20
DAY 7	ERYTHEMA	4	1	0	0	15	N= 20
	EDEMA	20	0	0	0	0	N= 20
DAY 11	ERYTHEMA	2	0	0	0	17	N= 19
	EDEMA	19	0	0	0	0	N= 19
DAY 14	ERYTHEMA	4	0	0	0	15	N= 19
	EDEMA	19	0	0	0	0	N= 19
DAY 18	ERYTHEMA	2	0	0	0	17	N= 19
	EDEMA	19	0	0	0	0	N= 19
DAY 21	ERYTHEMA	1	0	0	0	18	N= 19
	EDEMA	19	0	0	0	0	N= 19
DAY 25	ERYTHEMA	1	0	1	1	16	N= 19
	EDEMA	19	0	0	0	0	N= 19
DAY 28	ERYTHEMA	2	0	1	0	16	N= 19
	EDEMA	19	0	0	0	0	N= 19
DAY 32	ERYTHEMA	0	0	1	0	18	N= 19
	EDEMA	16	3	0	0	0	N= 19
DAY 35	ERYTHEMA	1	0	0	0	18	N= 19
	EDEMA	15	4	0	0	0	N= 19
DAY 39	ERYTHEMA	1	0	0	0	18	N= 19
	EDEMA	18	1	0	0	0	N= 19
DAY 42	ERYTHEMA	1	0	0	1	17	N= 19
	EDEMA	18	1	0	0	0	N= 19
DAY 46	ERYTHEMA	1	0	0	1	17	N= 19
	EDEMA	19	0	0	0	0	N= 19
DAY 49	ERYTHEMA	2	1	0	0	16	N= 19
	EDEMA	19	0	0	0	0	N= 19

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

TABLE 2 - INCIDENCE OF DERMAL ERYTHEMA/EDEMA (CONT'D)
(SEE KEY A FOR DERMAL EVALUATIONS)

GROUP - 80 MG/KG

		D E R M A L S C O R E S				
		0	1	2	3	4
DAY 53	ERYTHEMA	1	0	0	0	18
	EDEMA	19	0	0	0	0
DAY 56	ERYTHEMA	1	0	0	0	18
	EDEMA	19	0	0	0	0
DAY 60	ERYTHEMA	1	0	0	0	18
	EDEMA	17	2	0	0	0
DAY 63	ERYTHEMA	0	0	0	0	19
	EDEMA	19	0	0	0	0
DAY 67	ERYTHEMA	2	0	0	0	17
	EDEMA	14	5	0	0	0
DAY 70	ERYTHEMA	2	0	0	0	17
	EDEMA	17	2	0	0	0
DAY 74	ERYTHEMA	1	0	0	0	18
	EDEMA	13	6	0	0	0
DAY 77	ERYTHEMA	1	0	0	0	18
	EDEMA	16	3	0	0	0
DAY 81	ERYTHEMA	0	2	0	0	17
	EDEMA	19	0	0	0	0
DAY 84	ERYTHEMA	1	0	0	0	17
	EDEMA	15	3	0	0	0
DAY 88	ERYTHEMA	1	0	0	0	17
	EDEMA	16	2	0	0	0
DAY 91	ERYTHEMA	1	0	0	0	17
	EDEMA	12	3	3	0	0
DAY 92	ERYTHEMA	0	0	0	0	9
	EDEMA	7	1	1	0	0
DAY 93	ERYTHEMA	0	0	1	0	8
	EDEMA	4	4	1	0	0

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

TABLE 2 - INCIDENCE OF DERMAL ERYTHEMA/EDEMA (CONT'D)
(SEE KEY A FOR DERMAL EVALUATIONS)

GROUP - 80 MG/KG (SATELLITE)

		D E R M A L S C O R E S				
		0	1	2	3	4
DAY 0	ERYTHEMA	20	0	0	0	0
	EDEMA	20	0	0	0	0
						N= 20
DAY 1	ERYTHEMA	20	0	0	0	0
	EDEMA	20	0	0	0	0
						N= 20
DAY 4	ERYTHEMA	4	5	2	1	8
	EDEMA	20	0	0	0	0
						N= 20
DAY 7	ERYTHEMA	1	0	1	0	18
	EDEMA	20	0	0	0	0
						N= 20
DAY 11	ERYTHEMA	5	0	0	0	15
	EDEMA	20	0	0	0	0
						N= 20
DAY 14	ERYTHEMA	4	0	0	0	16
	EDEMA	20	0	0	0	0
						N= 20
DAY 18	ERYTHEMA	2	0	0	0	18
	EDEMA	20	0	0	0	0
						N= 20
DAY 21	ERYTHEMA	2	0	0	0	18
	EDEMA	20	0	0	0	0
						N= 20
DAY 25	ERYTHEMA	2	0	0	0	18
	EDEMA	20	0	0	0	0
						N= 20
DAY 28	ERYTHEMA	1	0	1	0	18
	EDEMA	20	0	0	0	0
						N= 20
DAY 32	ERYTHEMA	2	0	0	0	18
	EDEMA	18	2	0	0	0
						N= 20
DAY 35	ERYTHEMA	2	0	0	0	18
	EDEMA	20	0	0	0	0
						N= 20
DAY 39	ERYTHEMA	2	0	0	0	18
	EDEMA	20	0	0	0	0
						N= 20
DAY 42	ERYTHEMA	2	0	0	0	18
	EDEMA	20	0	0	0	0
						N= 20
DAY 46	ERYTHEMA	1	0	1	0	18
	EDEMA	19	1	0	0	0
						N= 20
DAY 49	ERYTHEMA	2	0	1	0	17
	EDEMA	20	0	0	0	0
						N= 20

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

TABLE 2 - INCIDENCE OF DERMAL ERYTHEMA/EDEMA (CONT'D)
(SEE KEY A FOR DERMAL EVALUATIONS)

		GROUP - 80 MG/KG (SATELLITE)				
		D E R M A L S C O R E S				
		0	1	2	3	4
DAY 53	ERYTHEMA	2	0	0	0	18
	EDEMA	20	0	0	0	0
DAY 56	ERYTHEMA	2	0	0	0	18
	EDEMA	19	1	0	0	0
DAY 60	ERYTHEMA	2	0	0	0	18
	EDEMA	20	0	0	0	0
DAY 63	ERYTHEMA	1	0	1	0	18
	EDEMA	20	0	0	0	0
DAY 67	ERYTHEMA	1	0	0	0	19
	EDEMA	18	2	0	0	0
DAY 70	ERYTHEMA	1	0	0	0	19
	EDEMA	15	5	0	0	0
DAY 74	ERYTHEMA	2	0	0	0	18
	EDEMA	16	4	0	0	0
DAY 77	ERYTHEMA	1	0	1	0	18
	EDEMA	16	4	0	0	0
DAY 81	ERYTHEMA	1	1	1	0	17
	EDEMA	20	0	0	0	0
DAY 84	ERYTHEMA	1	0	2	0	17
	EDEMA	14	6	0	0	0
DAY 88	ERYTHEMA	0	0	1	1	17
	EDEMA	10	9	0	0	0
DAY 91	ERYTHEMA	0	0	1	0	18
	EDEMA	11	5	3	0	0

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

TABLE 2 - INCIDENCE OF DERMAL ERYTHEMA/EDEMA (CONT'D)
(SEE KEY A FOR DERMAL EVALUATIONS)

		GROUP - 80 MG/KG (SATELLITE)				
		D E R M A L S C O R E S				
		0	1	2	3	4
DAY 95	ERYTHEMA	0	1	1	0	17
	EDEMA	12	5	2	0	0
						N= 19
DAY 98	ERYTHEMA	3	3	3	0	10
	EDEMA	19	0	0	0	0
						N= 19
DAY 102	ERYTHEMA	11	3	0	1	4
	EDEMA	19	0	0	0	0
						N= 19
DAY 105	ERYTHEMA	14	2	0	0	3
	EDEMA	19	0	0	0	0
						N= 19
DAY 109	ERYTHEMA	17	1	0	0	1
	EDEMA	19	0	0	0	0
						N= 19
DAY 112	ERYTHEMA	18	0	0	0	1
	EDEMA	19	0	0	0	0
						N= 19
DAY 116	ERYTHEMA	18	0	0	0	1
	EDEMA	19	0	0	0	0
						N= 19
DAY 119	ERYTHEMA	18	0	0	0	1
	EDEMA	19	0	0	0	0
						N= 19
DAY 121	ERYTHEMA	18	0	0	0	1
	EDEMA	19	0	0	0	0
						N= 19

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

TABLE 3 - INCIDENCE OF SUPPLEMENTAL DERMAL OBSERVATIONS
(SEE KEY A FOR DERMAL EVALUATIONS)

		DOSE: 0 MG/KG																			
TIME=		D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D
		A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A
		Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
		0	1	4	7	1	1	1	2	2	2	3	3	3	4	4	4	5	5	6	6
						1	4	8	1	5	8	2	5	9	2	6	9	3	6	0	
SEX=		M	F	M	F	M	F	M	F	M	F	M	F	M	F	M	F	M	F	M	F
DESQUAMATION		-	-	-	-	1	-	-	-	-	-	-	-	1	-	1	-	-	-	-	-
ESCHAR		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	1

TIME=		D	D	D	D	D	D	D	D	D	D
		A	A	A	A	A	A	A	A	A	A
		Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
		6	6	7	7	7	8	8	8	9	9
		3	7	0	4	7	1	4	8	1	2
											3
SEX=		M	F	M	F	M	F	M	F	M	F
DESQUAMATION		-	1	-	1	-	1	-	-	-	-
ESCHAR		-	1	-	1	-	1	-	-	-	-

NOTE: DESQUAMATION AND ESCHAR OBSERVED ON DAYS 60, 63, 67, AND 70
APPEARS TO BE MECHANICALLY INDUCED

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

TABLE 3 - INCIDENCE OF SUPPLEMENTAL DERMAL OBSERVATIONS (CONT'D)
(SEE KEY A FOR DERMAL EVALUATIONS)

		DOSE: 10 MG/KG																			
TIME=		D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D
		A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A
		Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
		0	1	4	7	1	1	1	2	2	3	3	3	4	4	4	5	5	6	6	0
		1	4	8	1	4	8	1	5	8	2	5	9	2	6	9	3	6	0		
SEX=		M	F	M	F	M	F	M	F	M	F	M	F	M	F	M	F	M	F	M	F
DESQUAMATION		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
ESCHAR		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
EXFOLIATION		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

TIME=		D	D	D	D	D	D	D	D	D	D
		A	A	A	A	A	A	A	A	A	A
		Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
		6	6	7	7	7	8	8	8	9	9
		3	7	0	4	7	1	4	8	1	2
		3	7	0	4	7	1	4	8	1	2
SEX=		M	F	M	F	M	F	M	F	M	F
DESQUAMATION		-	-	-	-	-	-	-	-	-	-
ESCHAR		-	-	-	-	-	-	-	-	-	-
EXFOLIATION		-	-	-	-	-	-	-	-	-	-

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DOSE: 40 MG/KG

TIME=	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y
	6 3	6 7	7 0	7 4	7 7	8 1	8 4	8 8	9 1	9 2	9 3									
SEX=	M	F	M	F	M	F	M	F	M	F	M	F	M	F	M	F	M	F	M	F
DESQUAMATION	9	9	10	9	9	9	9	9	6	9	3	-	7	1	10	8	8	9	9	-
ESCHAR	10	9	10	9	10	9	9	9	9	9	9	8	9	9	9	9	8	9	8	-
EXFOLIATION	1	-	-	-	-	-	-	-	3	-	3	9	1	6	-	-	-	-	-	-
ATONIA	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	1	1	-	2

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

TABLE 3 - INCIDENCE OF SUPPLEMENTAL DERMAL OBSERVATIONS (CONT'D)
(SEE KEY A FOR DERMAL EVALUATIONS)

		DOSE: 80 MG/KG																			
TIME=		D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D
		A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A
		Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
		0	1	4	7	1	1	1	2	2	2	3	3	3	4	4	4	5	5	6	0
		1	4	8	1	4	8	1	5	8	2	5	9	2	6	9	3	6	0		
SEX=		M	F	M	F	M	F	M	F	M	F	M	F	M	F	M	F	M	F	M	F
DESQUAMATION		-	-	-	-	10	6	10	7	7	2	3	6	3	5	8	3	9	9	6	9
ESCHAR		-	-	-	1	6	2	10	5	10	7	9	6	10	7	9	9	9	7	8	10
EXFOLIATION		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
ATONIA		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

TIME=		D	D	D	D	D	D	D	D	D	D
		A	A	A	A	A	A	A	A	A	A
		Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
		6	6	7	7	7	8	8	8	9	9
		3	7	0	4	7	1	4	8	1	2
SEX=		M	F	M	F	M	F	M	F	M	F
DESQUAMATION		10	9	10	9	9	9	9	6	9	1
ESCHAR		10	9	9	8	9	8	9	9	9	8
EXFOLIATION		-	-	-	-	-	-	3	-	9	8
ATONIA		-	1	-	-	-	-	-	1	-	-

NOTE: ESCHAR OBSERVED ON DAY 1 APPEARS TO BE MECHANICALLY INDUCED

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DOSE: 80 MG/KG (SATELLITE)

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90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

KEY B - STATISTICAL SYMBOLS AND ABBREVIATIONS

<u>No difference</u>	<u>p<0.05</u>	<u>p<0.01</u>	<u>Statistical Statement</u>
(PARAMETRIC)			
A-	A	A+	No statistical difference among the means Significant difference among the means
L-	L	L+	No linear response to the dose levels Response is linearly related to dose
	Q	Q+	Linear response shows lack of fit
	*	**	Mean significantly different from control mean
(NONPARAMETRIC)			
K-	K	K+	No statistical difference among the means Means differ significantly
J-	J	J+	No ordered response to the dose levels An ordered response to the dose levels
	*	**	Mean significantly different from control mean
(T-TEST)			
T-	T	T+	No statistical difference among the means Means differ significantly
NT			Data not tested

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

TABLE 4 - MEAN BODY WEIGHT (GRAMS)
(SEE KEY B FOR STATISTICAL ABBREVIATIONS)

	P R E T E S T	D A Y 0	D A Y 7	D A Y 14	D A Y 21	D A Y 28	D A Y 35	D A Y 42	D A Y 49	D A Y 56	D A Y 63
MALE	A-L-	A-L-	A-L-	A-L-	A-L-	A-L-	A-L-	A-L-	A-L-	A-L-	A-L-
0 MG/KG											
MEAN	220.8	271.8	302.9	335.1	365.7	395.8	421.7	442.7	460.8	473.1	488.5
STD.DEV.	11.3	9.9	12.0	13.8	17.5	21.3	27.2	27.2	33.0	35.6	38.5
(N)	10	9	10	10	10	9	9	9	9	9	9
10 MG/KG											
MEAN	221.5	271.9	312.3	351.3	383.2	411.4	437.0	458.8	475.5	494.2	512.4
STD.DEV.	11.2	11.3	21.1	29.2	37.6	38.8	43.0	51.1	54.8	57.0	57.7
(N)	10	10	10	10	10	10	10	10	10	10	10
40 MG/KG											
MEAN	221.2	268.7	302.8	339.4	368.8	395.7	418.2	433.9	449.0	464.7	475.3
STD.DEV.	10.6	13.3	18.9	24.3	30.1	36.6	45.4	53.7	59.4	65.1	67.3
(N)	10	10	10	10	10	10	10	10	10	10	10
80 MG/KG											
MEAN	220.7	268.1	296.0	336.2	365.6	392.7	417.8	429.8	447.5	460.9	476.5
STD.DEV.	10.6	13.6	19.7	23.6	32.1	37.1	39.9	38.6	39.2	41.7	42.9
(N)	10	10	10	10	10	10	10	10	10	10	10
FEMALE	A-L-	A-L-	A-L-	A-L-	A-L-	A-L-	A-L-	A-L-	A-L-	A-L-	A-L-
0 MG/KG											
MEAN	209.7	222.7	229.4	244.7	253.3	266.5	274.7	278.3	283.8	290.0	297.5
STD.DEV.	6.6	10.6	8.8	8.5	9.4	11.0	14.8	14.5	12.5	20.0	17.5
(N)	10	10	10	10	10	10	10	10	10	10	10
10 MG/KG											
MEAN	209.9	223.4	233.4	245.3	252.9	267.8	271.2	268.8	282.3	284.6	289.6
STD.DEV.	7.1	14.1	13.7	15.7	15.2	18.8	16.8	29.2	16.8	16.9	17.3
(N)	10	10	10	10	10	10	10	10	10	10	10
40 MG/KG											
MEAN	210.1	226.4	233.5	249.0	258.6	274.3	279.2	282.8	289.9	293.5	300.2
STD.DEV.	6.8	9.4	9.4	14.3	11.6	12.4	14.3	18.9	13.4	20.2	18.9
(N)	10	10	10	9	9	9	9	9	9	9	9
80 MG/KG											
MEAN	209.4	224.4	235.6	245.0	253.7	266.0	272.8	280.7	279.9	286.6	290.3
STD.DEV.	6.8	7.0	8.1	11.8	11.1	12.0	12.4	14.1	14.0	12.3	16.4
(N)	10	10	10	9	9	9	9	9	9	9	9

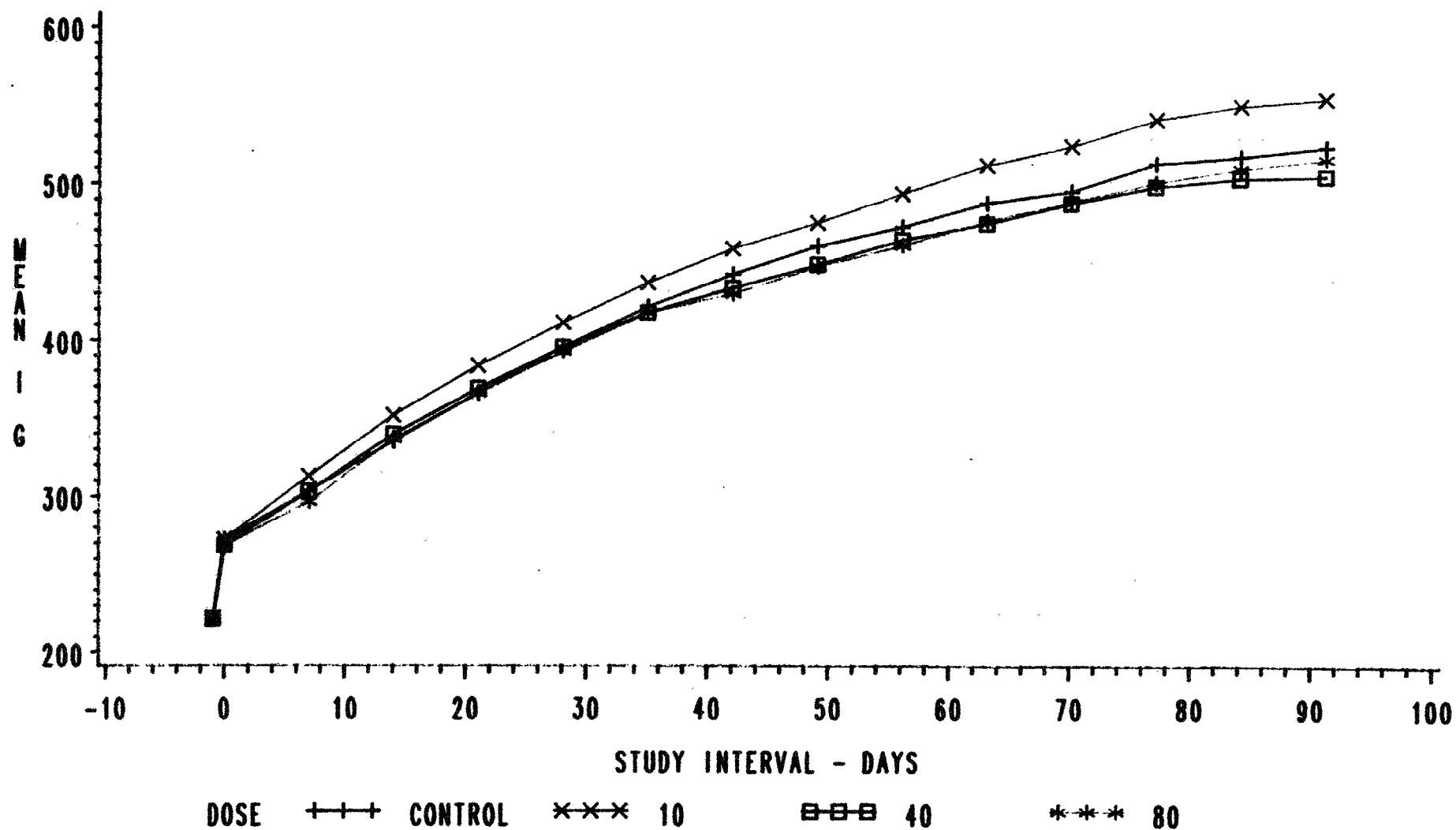
90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

TABLE 4 - MEAN BODY WEIGHT (GRAMS) (CONT'D)
(SEE KEY B FOR STATISTICAL ABBREVIATIONS)

	D A Y 7 0	D A Y 7 7	D A Y 8 4	D A Y 9 1
MALE	A-L-	A-L-	A-L-	A-L-
0 MG/KG				
MEAN	496.1	513.9	518.5	524.4
STD.DEV.	42.4	45.6	50.5	51.4
(N)	9	9	9	9
10 MG/KG				
MEAN	524.8	542.1	550.7	555.1
STD.DEV.	65.5	66.2	70.4	74.1
(N)	10	10	10	10
40 MG/KG				
MEAN	488.4	499.3	504.5	505.7
STD.DEV.	73.2	74.7	75.4	75.0
(N)	10	10	10	10
80 MG/KG				
MEAN	489.4	501.5	510.2	516.6
STD.DEV.	44.3	46.1	51.3	54.1
(N)	10	10	9	9
FEMALE	A-L-	A-L-	A-L-	A-L-
0 MG/KG				
MEAN	301.1	303.5	305.0	304.8
STD.DEV.	17.0	14.5	20.1	15.0
(N)	10	10	10	10
10 MG/KG				
MEAN	295.5	300.3	301.9	299.3
STD.DEV.	17.2	16.9	19.2	17.6
(N)	10	10	10	10
40 MG/KG				
MEAN	302.8	307.3	310.9	308.1
STD.DEV.	18.2	24.1	18.3	16.6
(N)	9	9	9	9
80 MG/KG				
MEAN	297.3	299.2	301.3	303.5
STD.DEV.	15.3	18.4	13.0	16.4
(N)	9	9	9	9

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 1399108

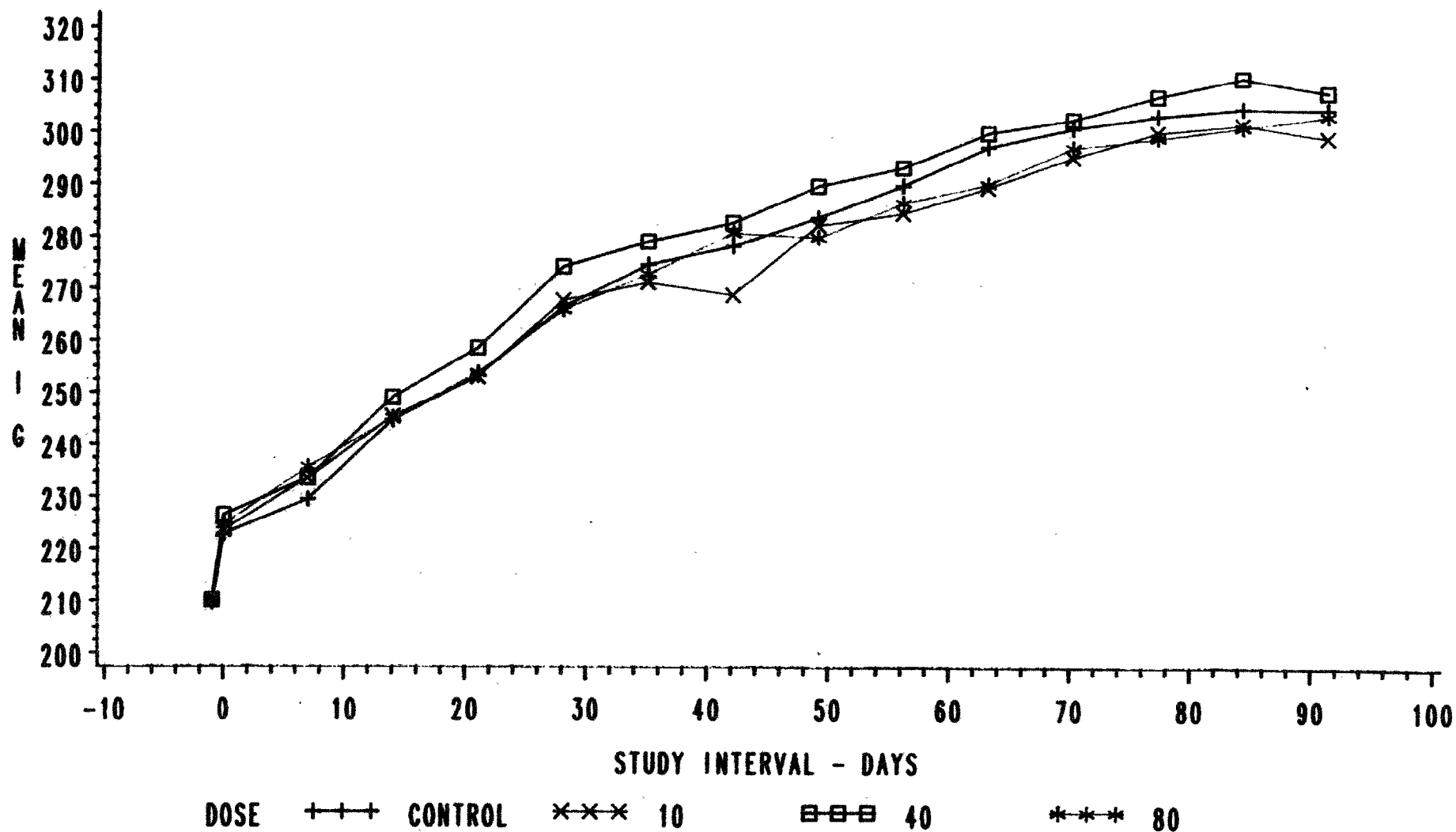
FIGURE 2 - MEAN BODY WEIGHT GRAPH - MALES



UNITS OF MEASURE FOR DOSE - MG/KG

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 1399108

FIGURE 3 - MEAN BODY WEIGHT GRAPH - FEMALES



UNITS OF MEASURE FOR DOSE - MG/KG

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

TABLE 5 - MEAN FOOD CONSUMPTION (GRAMS)
(SEE KEY B FOR STATISTICAL ABBREVIATIONS)

	WEEK 1	WEEK 2	WEEK 3	WEEK 4	WEEK 5	WEEK 6	WEEK 7	WEEK 8	WEEK 9	WEEK 10	WEEK 11
MALE	A-L-	A-L-	A-L-	A-L-	A-L-	A-L-	A-L-	A-L-	A-L-	A-L-	A-L-
0 MG/KG											
MEAN	185.9	197.2	198.4	199.7	197.1	198.8	207.9	203.9	207.1	201.1	207.6
STD.DEV.	9.8	8.2	9.7	10.6	14.0	9.6	9.3	15.4	15.8	13.5	12.8
(N)	9	10	10	9	9	9	8	9	9	8	9
10 MG/KG											
MEAN	189.8	203.7	206.8	205.8	204.8	205.5	210.4	214.1	215.5	215.0	215.8
STD.DEV.	14.6	21.2	25.5	21.4	23.4	22.4	24.2	24.1	19.4	26.4	22.8
(N)	10	10	9	10	9	10	9	9	9	10	9
40 MG/KG											
MEAN	183.3	197.3	196.9	200.4	196.0	191.7	202.7	211.2	211.8	208.0	205.0
STD.DEV.	14.0	16.1	16.8	19.6	22.2	26.8	26.2	18.8	21.5	24.4	15.2
(N)	10	10	10	10	10	10	10	9	9	10	9
80 MG/KG											
MEAN	183.2	203.8	203.1	205.5	207.1	197.9	208.4	212.3	218.6	213.4	214.2
STD.DEV.	10.6	13.2	18.2	16.6	17.5	13.2	18.4	16.6	15.2	14.9	19.7
(N)	10	10	10	10	10	10	9	10	10	10	10
FEMALE	A-L-	A-L-	A-L-	A-L-	A-L-	A-L-	A-L-	K-J	A-L-	A-L-	A-L-
0 MG/KG											
MEAN	134.0	146.7	137.7	146.8	138.0	139.1	142.8	147.6	152.2	149.5	152.2
STD.DEV.	6.3	8.3	8.7	11.3	10.0	9.3	13.7	19.8	11.6	11.1	12.9
(N)	10	10	10	9	10	10	9	10	10	10	10
10 MG/KG											
MEAN	133.1	142.7	138.6	146.1	139.3	135.6	145.6	142.5	151.3	147.1	152.4
STD.DEV.	7.9	8.6	10.3	10.9	10.5	19.5	11.5	5.9	10.8	11.0	10.8
(N)	10	10	10	10	10	10	9	9	10	9	10
40 MG/KG											
MEAN	130.6	142.6	141.7	145.5	146.4	143.4	151.4	148.2	155.0	153.0	152.9
STD.DEV.	11.5	5.0	7.4	7.0	6.2	9.7	5.9	10.2	11.0	8.2	15.4
(N)	10	9	9	9	7	9	9	9	9	9	9
80 MG/KG											
MEAN	134.1	140.6	139.5	147.2	147.0	145.5	144.7	149.1	151.4	150.9	150.3
STD.DEV.	7.3	11.3	8.7	7.3	9.1	8.4	10.8	10.1	12.6	7.4	8.6
(N)	10	9	9	9	9	9	9	9	7	9	8

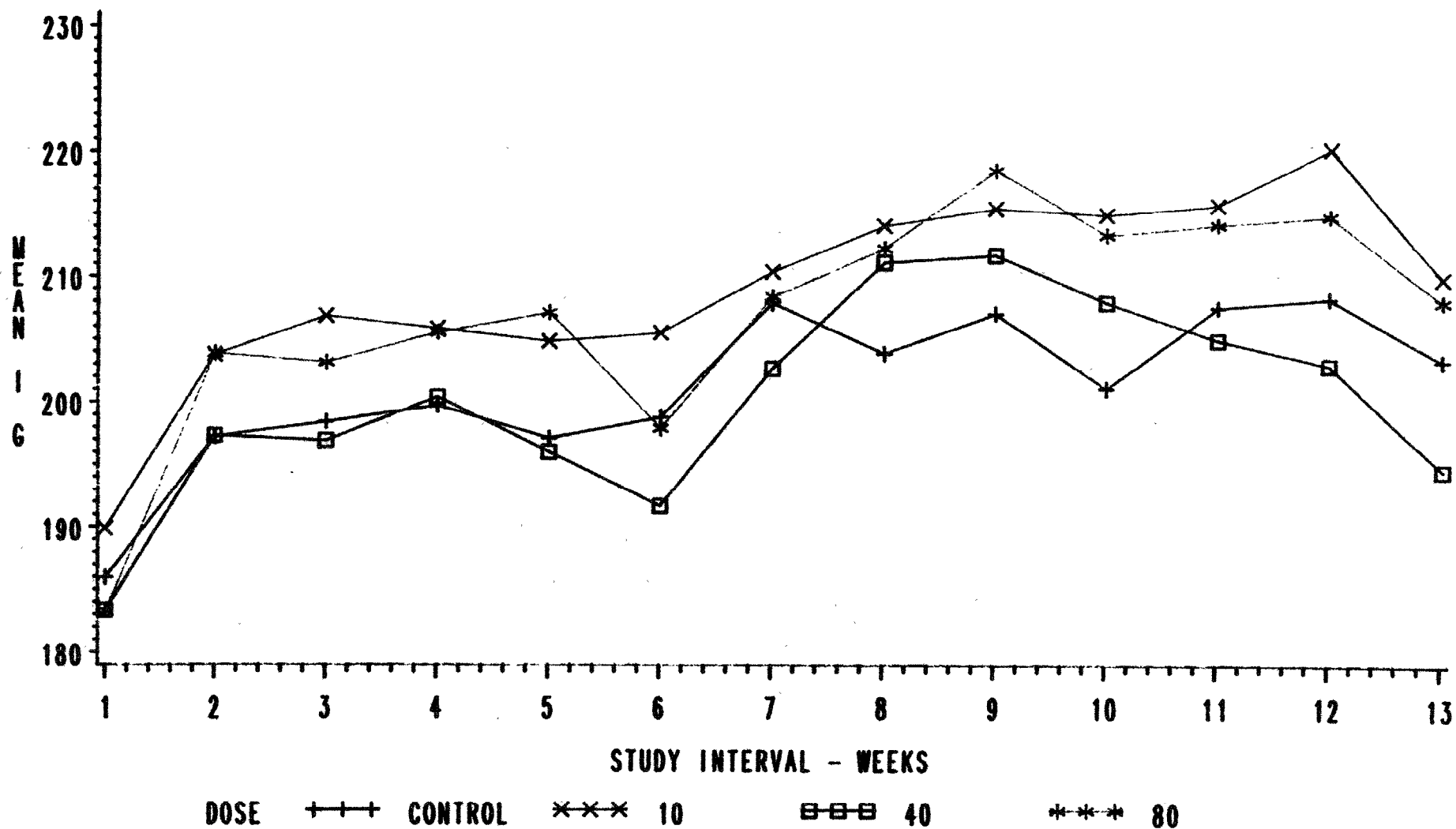
90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

TABLE 5 - MEAN FOOD CONSUMPTION (GRAMS) (CONT'D)
(SEE KEY B FOR STATISTICAL ABBREVIATIONS)

	W E E K 1 2	W E E K 1 3
MALE	A-L-	A-L-
0 MG/KG		
MEAN	208.3	203.3
STD.DEV.	14.5	11.6
(N)	9	9
10 MG/KG		
MEAN	220.3	209.9
STD.DEV.	22.7	27.8
(N)	10	10
40 MG/KG		
MEAN	203.0	194.6
STD.DEV.	18.4	14.9
(N)	9	9
80 MG/KG		
MEAN	214.9	208.0
STD.DEV.	14.4	22.0
(N)	8	8
FEMALE	K-J-	A-L-
0 MG/KG		
MEAN	156.7	151.9
STD.DEV.	14.4	13.1
(N)	10	10
10 MG/KG		
MEAN	150.7	147.0
STD.DEV.	9.8	8.7
(N)	10	10
40 MG/KG		
MEAN	157.8	150.8
STD.DEV.	12.6	8.4
(N)	9	9
80 MG/KG		
MEAN	155.3	153.9
STD.DEV.	3.1	7.5
(N)	8	7

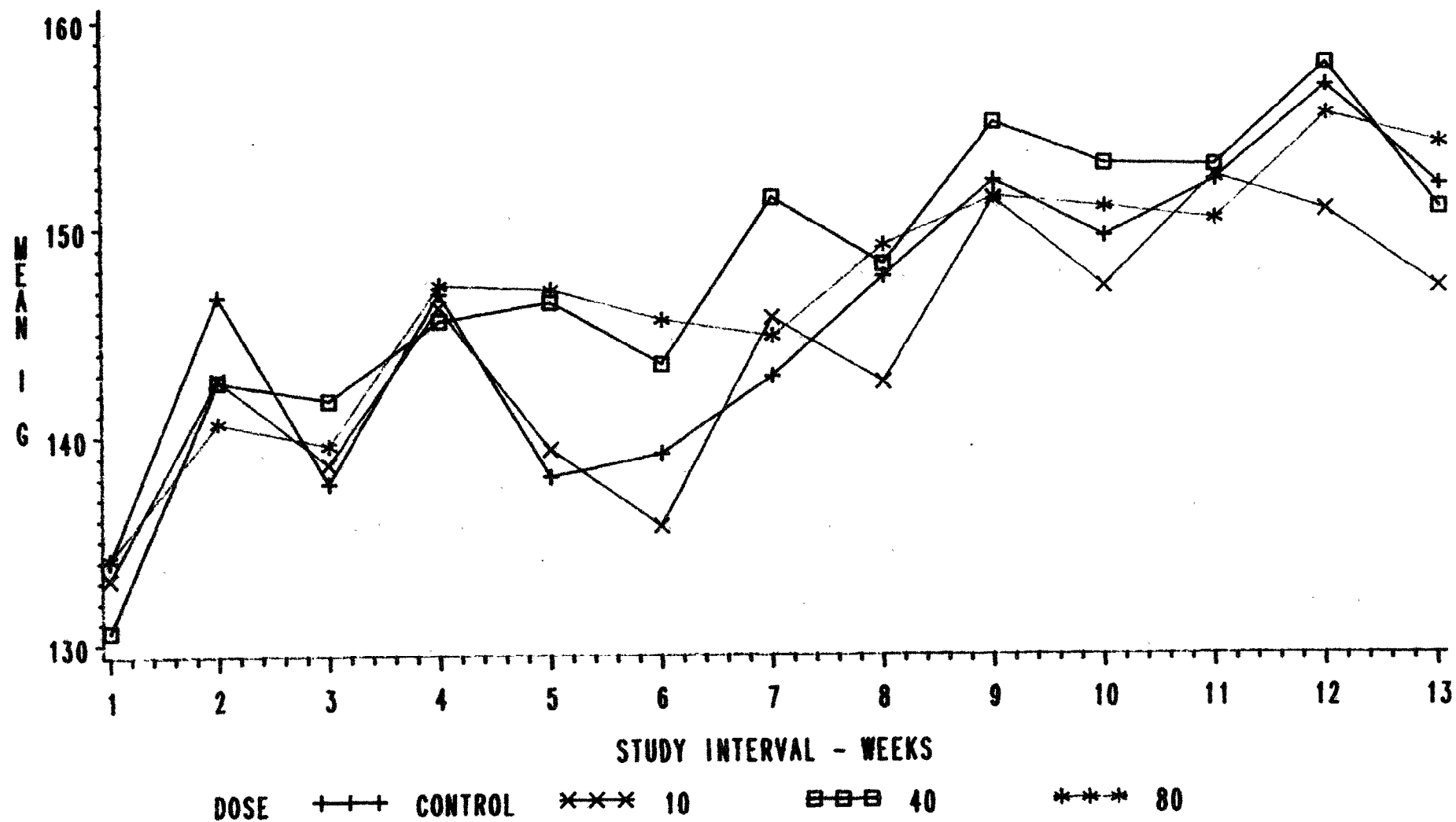
RUN 2

FIGURE 4 - MEAN FOOD CONSUMPTION GRAPH - MALES



90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-82-389): 1389108

FIGURE 5 - MEAN FOOD CONSUMPTION GRAPH - FEMALES



90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

TABLE 6 - INCIDENCE OF OPHTHALMOLOGICAL OBSERVATIONS

PRETEST										
DOSE:	0 MG/KG		10 MG/KG		40 MG/KG		80 MG/KG		80 (SATELLITE) MG/KG	
	MALE	FEMALE	MALE	FEMALE	MALE	FEMALE	MALE	FEMALE	MALE	FEMALE
NUMBER EXAMINED:	10	10	10	10	10	10	10	10	10	10
NO VISIBLE LESIONS:	10	10	10	10	10	10	10	10	10	10
TERMINAL										
DOSE:	0 MG/KG		10 MG/KG		40 MG/KG		80 MG/KG		80 (SATELLITE) MG/KG	
	MALE	FEMALE	MALE	FEMALE	MALE	FEMALE	MALE	FEMALE	MALE	FEMALE
NUMBER EXAMINED:	9	10	10	10	10	9	9	9	9	10
NO VISIBLE LESIONS:	9	9	10	10	9	9	9	9	9	10
FOCAL RETINOPATHY	0	1	0	0	1	0	0	0	0	0

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

KEY C - HEMATOLOGY ABBREVIATIONS AND METHODOLOGY

QUANTITATIVE HEMATOLOGY PARAMETERS

Abbreviation	Parameter	Specimen	Method or Reference	Units
WBC	Total Leukocytes	Whole Blood	Technicon H-1 Hematology Analyzer, Technicon Instruments, Inc.	x10E3
RBC	Erythrocytes (Red blood cells)	Whole Blood	Technicon H-1 Hematology Analyzer, Technicon Instruments, Inc.	x10E6
HGB	Hemoglobin	Whole Blood	Technicon H-1 Hematology Analyzer, Technicon Instruments, Inc.	g/dL
HCT	Hematocrit	Whole Blood	Technicon H-1 Hematology Analyzer, Technicon Instruments, Inc.	%
MCV	Mean Corpuscular Volume	Whole Blood	Technicon H-1 Hematology Analyzer, Technicon Instruments, Inc.	fl
MCH	Mean Corpuscular Hemoglobin	Calculated	Technicon H-1 Hematology Analyzer, Technicon Instruments, Inc.	pg
MCHC	Mean Corpuscular Hemoglobin Concentration (MCHC)	Calculated	Technicon H-1 Hematology Analyzer, Technicon Instruments, Inc.	g/dL
PLT	Platelets	Whole Blood	Technicon H-1 Hematology Analyzer, Technicon Instruments, Inc.	x10E3
PT	Prothrombin Time	Plasma	Coag-A-Mate, General Diagnostics	sec
APTT	Activated Partial Thromboplastin Time	Plasma	Coag-A-Mate, General Diagnostics	sec

BLOOD COLLECTION: HEMATOLOGY SAMPLES WERE COLLECTED INTO TUBES CONTAINING EDTA
PT AND APTT SAMPLES WERE COLLECTED INTO TUBES CONTAINING SODIUM CITRATE

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

KEY C - HEMATOLOGY ABBREVIATIONS AND METHODOLOGY (CONT'D)

SEMI-QUANTITATIVE HEMATOLOGY PARAMETERS

(Differential WBC and Erythrocyte Morphology)

Abbreviation	Parameter	Specimen	Method or Reference	Units
NEUT	Mature (Segmented) Neutrophils	Whole Blood	Technicon H-1 Hematology Analyzer, Technicon Instruments, Inc.	% of WBC
LYMPH	Lymphocytes	Whole Blood	H-1 Hematology Analyzer, Technicon Instruments, Inc.	% of WBC
MONO	Monocytes	Whole Blood	Technicon H-1 Hematology Analyzer, Technicon Instruments, Inc.	% of WBC
EOS	Mature (Segmented) Eosinophil	Whole Blood	Technicon H-1 Hematology Analyzer, Technicon Instruments, Inc.	% of WBC
BASO	Mature (Segmented) Basophil	Whole Blood	Technicon H-1 Hematology Analyzer, Technicon Instruments, Inc.	% of WBC
LUC	Large Unclassified Cells	Whole Blood	Technicon H-1 Hematology Analyzer, Technicon Instruments, Inc.	% of WBC
See Below (a)	Remarkable Erythrocyte or Leukocyte Morphology	Whole Blood	Technicon H-1 Hematology Analyzer, Technicon Instruments, Inc.	0 = None 1 = Slight 2 = Moderate 3 = Extreme
(a) LS Left Shift		HYPO	Hypochromia	ANISO Anisocytosis
HYPER Hyperchromia		MICRO	Microcytosis	BL Blasts
MACRO Macrocytosis		ATYP	Atypical	VAR Variation

BLOOD COLLECTION: HEMATOLOGY SAMPLES WERE COLLECTED INTO TUBES CONTAINING EDTA

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

TABLE 7 - MEAN QUANTITATIVE HEMATOLOGY: MAIN STUDY TERMINATION
(SEE KEYS B AND C FOR ABBREVIATIONS)

UNITS>>>>>	W B C	R B C	H G B	H C T	M C V	M C H	M C H C	P L T	P T	A P T T
	x10E3	x10E6	g/dL	%	fl	pg	g/dL	x10E3	sec	sec
MALE	A-L-	AL+	AL+	A+L+	A-L-	A-L-	A-L-	A+L+	A+L+	A-L-
0 MG/KG										
MEAN	12.0	9.05	16.1	47.4	53.	17.8	34.0	1041.	10.3	21.2
STD.DEV.	2.3	0.60	0.6	2.1	2.	0.6	0.6	95.	0.5	1.1
(N)	9	9	9	9	9	9	9	9	9	9
10 MG/KG										
MEAN	10.7	9.09	16.2	47.5	52.	17.8	34.1	932.	10.0	21.0
STD.DEV.	2.0	0.44	0.6	1.9	2.	0.8	0.4	129.	0.3	2.1
(N)	10	10	10	10	10	10	10	10	9	9
40 MG/KG										
MEAN	14.0	8.68	15.4	45.5	52.	17.8	33.9	1041.	10.4	22.0
STD.DEV.	3.4	0.71	1.0	2.6	2.	0.8	0.7	139.	0.4	2.6
(N)	9	9	9	9	9	9	9	9	9	9
80 MG/KG			*	*					*	
MEAN	13.2	8.32	15.0	43.9	53.	18.1	34.2	1166.	10.9	21.7
STD.DEV.	3.5	0.70	1.1	3.0	2.	0.8	0.6	157.	0.4	2.4
(N)	9	9	9	9	9	9	9	9	8	8
FEMALE	A-L-	A-L-	A-L-	A-L-	A-L-	A-L-	AL+	A-L-	A-L-	A-L-
0 MG/KG										
MEAN	7.7	7.95	15.1	43.5	55.	19.0	34.8	1048.	9.5	18.2
STD.DEV.	3.0	0.67	1.1	3.3	1.	0.5	0.5	98.	0.5	1.6
(N)	9	9	9	9	9	9	9	9	9	9
10 MG/KG										
MEAN	8.3	7.70	14.4	41.3	54.	18.7	34.8	1030.	9.6	17.8
STD.DEV.	1.4	0.77	1.4	3.8	2.	0.9	0.4	145.	0.2	1.6
(N)	8	8	8	8	8	8	8	8	7	7
40 MG/KG										
MEAN	9.7	7.86	14.7	42.7	54.	18.8	34.5	1077.	9.9	18.0
STD.DEV.	3.4	0.83	1.3	3.7	3.	0.7	0.4	254.	0.4	2.0
(N)	9	9	9	9	9	9	9	9	9	9
80 MG/KG							*			
MEAN	8.4	7.84	14.8	43.3	55.	18.9	34.2	992.	9.7	17.9
STD.DEV.	3.5	0.30	0.4	1.2	2.	0.8	0.5	155.	0.4	1.0
(N)	9	9	9	9	9	9	9	9	9	9

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

TABLE 8 - MEAN QUANTITATIVE HEMATOLOGY: SATELLITE RECOVERY
(SEE KEYS B AND C FOR ABBREVIATIONS)

	W B C	R B C	H G B	H C T	M C V	M C H	M C H C	P L T	P T	A P T T
UNITS>>>>>	x10E3	x10E6	g/dL	%	fl	pg	g/dL	x10E3	sec	sec
MALE	T+	T-	T-	T-	T-	T-	T+	T-	T-	T-
DAY 92										
MEAN	14.8	8.73	15.6	45.8	53.	17.8	34.0	1002.	10.2	20.5
STD.DEV.	4.0	0.42	0.6	1.4	2.	0.7	0.5	130.	0.6	1.6
(N)	9	9	9	9	9	9	9	9	9	9
DAY 121										
MEAN	10.3	8.74	15.4	46.6	53.	17.6	33.1	1000.	10.2	20.8
STD.DEV.	1.6	0.39	0.5	1.4	2.	0.6	0.5	103.	0.5	2.8
(N)	9	9	9	9	9	9	9	9	9	9
FEMALE	T+	T	T+	T+	T+	T-	T+	T-	T-	T-
DAY 93										
MEAN	11.6	7.31	13.8	40.2	55.	18.9	34.3	1174.	9.5	17.3
STD.DEV.	3.8	0.84	1.4	4.5	1.	0.6	0.8	169.	0.4	2.0
(N)	10	10	10	10	10	10	10	10	10	10
DAY 121										
MEAN	7.2	8.13	15.8	47.6	59.	19.5	33.3	1124.	9.3	16.9
STD.DEV.	2.7	0.26	0.4	1.1	3.	0.7	0.3	145.	0.4	1.4
(N)	10	10	10	10	10	10	10	10	10	10

RUN 2

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

KEY D - SERUM CHEMISTRY ABBREVIATIONS AND METHODOLOGY
Beckman Synchron CX5

Abbreviation	Parameter	Specimen	Method or Reference	Units
GLU	Glucose	Serum	Enzymatic Transfer with Hexokinase and concomitant reduction of NAD	mg/dL
BUN	Blood Urea Nitrogen	Serum	Enzymatic Hydrolysis with Urease	mg/dL
CREA	Creatinine	Serum	Combination with Alkaline Picrate (Jaffe)	mg/dL
Na+	Sodium	Serum	Ion-Selective Electrodes	mmol/L
K+	Potassium	Serum	Ion-Selective Electrodes	mmol/L
Cl-	Chloride	Serum	Ion-Selective Electrodes	mmol/L
CO2	Carbon Dioxide	Serum	Ion-Selective Electrodes	mmol/L
Ca	Calcium	Serum	Dye Binding with Arsenazo III	mg/dL
PHOS	Inorganic Phosphorous	Serum	Reaction with Molybdate to form Phosphomolybdate Complex	mg/dL
AST	Aspartate Aminotransferase	Serum	Enzymatic Transamination with Concurrent Oxidation of NADH	IU/L
ALT	Alanine Aminotransferase	Serum	Enzymatic Transamination with Concurrent Oxidation of NADH	IU/L
ALP	Alkaline Phosphatase	Serum	Enzymatic Hydrolysis of P-nitrophenylphosphate	IU/L
TBIL	Total Bilirubin	Serum	Diazotization with Caffeine and Sodium Benzoate (Jendrassik-Grof)	mg/dL
TP	Total Protein	Serum	Binding of Cupric Ions (Biuret)	g/dL
ALBU	Albumin	Serum	Dye Binding, Bromocresol Green (BCG)	g/dL
CHOL	Cholesterol	Serum	Enzymatic Hydrolysis and Reaction with 4-aminoantipyrine and Phenol	mg/dL
TRIG	Triglycerides	Serum	Enzymatic Hydrolysis and Reaction with (INT)	mg/dL

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

TABLE 9 - MEAN SERUM CHEMISTRY: MAIN STUDY TERMINATION
(SEE KEYS B AND D FOR ABBREVIATIONS)

	G L U	B U N	C R E A	N a +	K +	C l -	C O 2	C a	P H O S	A S T	A L T	A L P
UNITS>>>>>	mg/dL	mg/dL	mg/dL	mmol/L	mmol/L	mmol/L	mmol/L	mg/dL	mg/dL	IU/L	IU/L	IU/L
MALE	A-L-	K-J	A-L-	A-L-	A-L-	A-L-	AL	AL-	AL-Q	K-J-	K-J-	A-L-
0 MG/KG												
MEAN	111.8	14.9	0.5	144.8	4.72	106.8	27.5	10.5	6.6	124.7	52.6	115.3
STD.DEV.	14.1	3.6	0.0	1.3	0.43	1.4	1.3	0.3	0.6	17.8	11.4	28.6
(N)	9	9	9	9	9	9	9	9	9	9	9	9
10 MG/KG												
MEAN	110.5	14.9	0.5	144.2	4.87	105.9	26.8	10.3	6.2	157.5	78.9	126.3
STD.DEV.	12.7	2.0	0.1	1.5	0.34	1.7	1.0	0.3	0.3	92.8	91.1	37.2
(N)	10	10	10	10	10	10	10	10	10	10	10	10
40 MG/KG								*				
MEAN	101.0	17.3	0.5	143.5	4.57	104.8	28.3	10.2	6.2	127.6	49.3	109.8
STD.DEV.	10.2	7.4	0.1	1.6	0.41	1.6	1.4	0.3	0.5	16.0	8.3	32.6
(N)	10	10	10	10	10	10	10	10	10	10	10	10
80 MG/KG												
MEAN	106.1	15.8	0.5	143.9	4.57	105.4	28.3	10.2	6.7	148.4	61.3	130.6
STD.DEV.	16.7	1.7	0.1	1.9	0.19	1.6	1.0	0.3	0.5	48.5	23.6	51.0
(N)	9	9	9	9	9	9	9	9	9	9	9	9
FEMALE	A-L-	AL+	A-L-	A-L-	A-L-	A-L-	A-L-	A-L-	A-L-	A-L-	AL-Q	AL+
0 MG/KG												
MEAN	100.5	15.6	0.6	149.9	4.50	110.7	25.3	10.6	6.1	148.0	57.3	72.4
STD.DEV.	12.1	3.6	0.1	2.2	0.31	2.0	1.4	0.2	0.7	38.0	14.6	26.7
(N)	10	10	10	10	10	10	10	10	10	10	10	10
10 MG/KG												
MEAN	104.2	16.5	0.6	149.2	4.49	111.2	25.2	10.8	6.0	133.1	49.0	80.6
STD.DEV.	11.6	2.9	0.1	2.2	0.44	2.4	1.4	0.3	0.6	31.5	9.0	25.7
(N)	10	10	10	10	10	10	10	10	10	10	10	10
40 MG/KG		*									*	
MEAN	103.6	19.3	0.6	149.6	4.33	111.7	24.7	10.8	6.5	124.1	41.9	85.9
STD.DEV.	13.4	2.3	0.1	2.2	0.19	2.6	1.7	0.3	0.6	11.5	9.4	14.3
(N)	9	9	9	9	9	9	9	9	9	9	9	9
80 MG/KG		*									*	
MEAN	93.7	19.4	0.6	148.9	4.60	111.4	24.8	10.5	6.3	154.8	49.8	111.6
STD.DEV.	6.8	3.4	0.1	2.2	0.51	3.0	1.8	0.3	0.5	22.6	10.7	29.1
(N)	9	9	9	9	9	9	9	9	9	9	9	9

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

TABLE 9 - MEAN SERUM CHEMISTRY: MAIN STUDY TERMINATION
(SEE KEYS B AND D FOR ABBREVIATIONS)

(CONT'D)

UNITS>>>>>	T B I L mg/dL	T P g/dL	A L B U g/dL	C H O L mg/dL	T R I G mg/dL
MALE	A-L-	A-L-	AL	A-L-	AL+
0 MG/KG					
MEAN	0.58	6.9	3.8	26.3	37.
STD.DEV.	0.07	0.2	0.2	7.8	18.
(N)	9	9	9	9	9
10 MG/KG					
MEAN	0.59	6.9	3.8	33.2	39.
STD.DEV.	0.06	0.4	0.2	9.1	18.
(N)	10	10	10	10	10
40 MG/KG					
MEAN	0.54	7.0	3.6	27.3	25.
STD.DEV.	0.12	0.4	0.2	7.9	12.
(N)	10	10	10	10	10
80 MG/KG					*
MEAN	0.56	6.7	3.6	23.0	18.
STD.DEV.	0.10	0.3	0.2	7.9	6.
(N)	9	9	9	9	9
FEMALE	A-L	A-L-	A-L-	AL+	A-L-
0 MG/KG					
MEAN	0.61	7.1	4.0	30.4	23.
STD.DEV.	0.09	0.3	0.2	6.4	5.
(N)	10	10	10	10	10
10 MG/KG					
MEAN	0.59	7.3	4.1	32.1	23.
STD.DEV.	0.07	0.5	0.3	7.4	5.
(N)	10	10	10	10	10
40 MG/KG					
MEAN	0.58	7.4	4.0	27.9	21.
STD.DEV.	0.04	0.4	0.2	4.4	5.
(N)	9	9	9	9	9
80 MG/KG					
MEAN	0.54	7.1	3.9	24.1	20.
STD.DEV.	0.07	0.2	0.2	6.3	4.
(N)	9	9	9	9	9

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IIRGASAN DP300 (MRD-92-399): 139910B

TABLE 10 - MEAN SERUM CHEMISTRY: SATELLITE RECOVERY
(SEE KEYS B AND D FOR ABBREVIATIONS)

	G L U	B U N	C R E A	N a +	K +	C l -	C O 2	C a	P H O S	A S T	A L T	A L P
UNITS>>>>>	mg/dL	mg/dL	mg/dL	mmol/L	mmol/L	mmol/L	mmol/L	mg/dL	mg/dL	IU/L	IU/L	IU/L
MALE	T	T-	T-	T+	T-	T-	T-	T	T+	T-	T-	T+
DAY 92												
MEAN	103.4	16.0	0.5	145.8	4.70	106.6	27.9	10.5	7.0	143.7	55.2	140.6
STD.DEV.	6.3	2.5	0.1	0.9	0.23	1.9	1.0	0.4	0.2	32.7	11.3	34.0
(N)	9	9	9	9	9	9	9	9	9	9	9	9
DAY 121												
MEAN	115.1	14.9	0.5	143.9	4.80	105.3	27.7	10.0	6.3	149.6	50.4	95.8
STD.DEV.	11.2	2.1	0.1	0.8	0.36	1.7	1.8	0.3	0.5	42.3	26.6	20.5
(N)	9	9	9	9	9	9	9	9	9	9	9	9
FEMALE	T-	T-	T-	T	T-	T-	T-	T	T	T+	T-	T+
DAY 93												
MEAN	118.0	18.5	0.6	144.8	4.30	107.3	25.0	10.4	6.0	133.9	47.8	85.5
STD.DEV.	6.5	2.8	0.1	1.4	0.27	1.9	1.9	0.2	0.9	19.1	9.4	23.2
(N)	10	10	10	10	10	10	10	10	10	10	10	10
DAY 121												
MEAN	110.9	16.8	0.6	142.7	4.24	106.4	26.3	10.1	5.1	105.3	40.6	56.7
STD.DEV.	10.9	3.0	0.1	2.0	0.31	1.9	2.9	0.3	0.6	14.7	12.7	10.3
(N)	10	10	10	10	10	10	10	10	10	10	10	10

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

TABLE 10 - MEAN SERUM CHEMISTRY: SATELLITE RECOVERY (CONT'D)
(SEE KEYS B AND D FOR ABBREVIATIONS)

UNITS>>>>>	T B I L mg/dL	T P g/dL	A L B U g/dL	C H O L mg/dL	T R I G mg/dL
MALE	T+	T+	T-	T-	T-
DAY 92					
MEAN	0.60	6.9	3.6	30.3	34.
STD.DEV.	0.07	0.3	0.2	6.6	15.
(N)	9	9	9	9	9
DAY 121					
MEAN	0.40	6.2	3.5	35.9	31.
STD.DEV.	0.05	0.3	0.2	6.7	8.
(N)	9	9	9	9	9
FEMALE	T+	T	T-	T-	T-
DAY 93					
MEAN	0.55	6.9	3.7	25.9	23.
STD.DEV.	0.05	0.3	0.2	7.6	4.
(N)	10	10	10	10	10
DAY 121					
MEAN	0.46	6.6	3.8	34.8	23.
STD.DEV.	0.05	0.3	0.2	13.4	3.
(N)	10	10	10	10	10

RUN 2

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

KEY E - URINE CHEMISTRY ABBREVIATIONS AND METHODOLOGY

Abbreviation	Parameter	Method	Units
QUANTITATIVE URINE CHEMISTRY PARAMETERS			
UVOL	Volume	Estimation Via Graduated Collection Vial	mL
UGLU	Glucose	Enzymatic Transfer with Hexokinase and concomitant reduction of NAD (Beckman Synchron CX5)	mg/16 hr
UPROT	Protein	Pyrogallol Red (Beckman Synchron CX5)	mg/16 hr
SEMI-QUANTITATIVE URINE CHEMISTRY PARAMETERS			
SG	Specific Gravity	Refractometer Ames Division, Miles Laboratories, Inc.	
pH	Hydrogen Ion Concentration	Ames Division, Miles Laboratories, Inc. Dipstick Test	(a)
OCC BLOOD	Blood	Ames Division, Miles Laboratories, Inc. Dipstick Test	(a)
KETONES	Ketones	Ames Division, Miles Laboratories, Inc. Dipstick Test	(a)
CELLS	Cells	Counting Via Manual Microscopy WBC White blood cells EPC Epithelial cells RBC Red blood cells SP Sperm RE Renal epithelial cells TRI Trichononade	(b)
CRYSTALS	Crystals	Counting Via Manual Microscopy AM Amorphous Matter HP Hippuric Acid AU Ammonium Urate TP Triple Phosphate CC Calcium Carbonate TY Tyrosine Phosphate CP Calcium phosphate UA Uric Acid CS Calcium Sulfate	(b)
CASTS		Counting Via Manual Microscopy CGC Course Granular WCC White Blood Cell Cast FGC Fine Granular RCC Red Blood Cell Cast HYC Hyaline RTC Renal Tubular Cast	(b)
BACT	Bacteria	Counting Via Manual Microscopy	(b)
YEAST	Yeast	Counting Via Manual Microscopy	(b)
SPERM	Sperm	Counting Via Manual Microscopy	(b)
COLOR	Color	Visual Inspection	Y = Yellow
APP	Appearance	Visual Inspection	CLD = Cloudy

NOTE: (a) N = Negative; T = Trace; 1+, 2+, 3+, 4+ = Keyed to relative amount
(b) Number Per High Power Field; No entry made = None seen
TNTC = To numerous to count, more than 50 cells in the high power field
PF = Packed field, over 500 cells in the high power field

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

TABLE 11 - MEAN QUANTITATIVE URINE CHEMISTRY: MAIN STUDY TERMINATION
(SEE KEYS B AND E FOR ABBREVIATIONS)

UNITS>>>>>	U V O L	U G L U	U P R O T
	mL	mg/16hr	mg/16hr
MALE	A-L-	A-L	K-J-
0 MG/KG			
MEAN	18.	8.0	18.5
STD.DEV.	8.	1.6	8.1
(N)	9	9	9
10 MG/KG			
MEAN	15.	7.5	13.7
STD.DEV.	6.	1.7	3.6
(N)	10	10	10
40 MG/KG			
MEAN	21.	8.3	26.8
STD.DEV.	8.	2.4	41.3
(N)	10	10	10
80 MG/KG			
MEAN	16.	9.6	19.3
STD.DEV.	6.	2.5	9.8
(N)	9	9	9
FEMALE	A-L-	A-L-	A-L-Q
0 MG/KG			
MEAN	15.	8.0	2.7
STD.DEV.	5.	1.1	0.8
(N)	10	10	10
10 MG/KG			
MEAN	14.	7.0	2.7
STD.DEV.	7.	0.9	0.8
(N)	10	10	10
40 MG/KG			
MEAN	14.	7.5	3.3
STD.DEV.	7.	1.4	0.5
(N)	9	9	9
80 MG/KG			
MEAN	12.	7.3	2.4
STD.DEV.	2.	1.0	0.5
(N)	9	9	9

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

TABLE 12 - MEAN QUANTITATIVE URINE CHEMISTRY: SATELLITE RECOVERY
(SEE KEYS B AND E FOR ABBREVIATIONS)

	U V O L	U G L U	U P R O T
UNITS>>>>>	mL	mg/16hr	mg/16hr
MALE	T	T+	T-
DAY 88			
MEAN	17.	9.0	18.2
STD.DEV.	4.	0.6	6.9
(N)	9	9	9
DAY 120			
MEAN	22.	6.8	16.7
STD.DEV.	5.	1.1	8.3
(N)	9	9	9
FEMALE	T-	T-	T-
DAY 91			
MEAN	14.	7.6	3.1
STD.DEV.	6.	1.1	1.2
(N)	10	10	10
DAY 120			
MEAN	17.	7.2	2.8
STD.DEV.	7.	1.0	0.5
(N)	10	10	10

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

KEY F - ORGAN ABBREVIATIONS

<u>Abbreviation</u>	<u>Organ Name</u>
TBW or BW	Terminal Body Weight
KIDNY	Kidneys
TESTS	Testes
OVAR	Ovaries

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

TABLE 13 - MEAN ORGAN WEIGHT: MAIN STUDY TERMINATION
(SEE KEYS B AND F FOR ABBREVIATIONS)

UNITS>>>>>	T B W	L I V E R	K I D N E Y	B R A I N	T E S T E S	O V A R
	(g)	(g)	(g)	(g)	(g)	(g)
MALE	A-L-	A-L-	A-L-	A-L-	A-L-	
0 MG/KG						
MEAN	480.3	12.14	3.35	2.07	3.6145	
STD.DEV.	47.3	1.59	0.20	0.08	0.2995	
(N)	9	9	9	9	9	
10 MG/KG						
MEAN	513.3	12.99	3.57	2.09	3.7027	
STD.DEV.	69.5	1.70	0.34	0.14	0.4077	
(N)	10	9	10	10	10	
40 MG/KG						
MEAN	461.2	11.41	3.59	2.14	3.6280	
STD.DEV.	73.5	1.79	0.63	0.15	0.2755	
(N)	10	10	10	10	10	
80 MG/KG						
MEAN	469.5	11.88	3.67	2.14	3.5493	
STD.DEV.	51.1	1.00	0.41	0.12	0.3273	
(N)	9	8	9	9	9	
FEMALE	A-L-	A-L-	A-L-	A-L-		AL-Q+
0 MG/KG						
MEAN	280.2	7.57	2.11	1.99		0.107
STD.DEV.	16.1	0.75	0.16	0.11		0.017
(N)	10	10	10	10		10
10 MG/KG						*
MEAN	273.4	7.23	2.10	2.01		0.081
STD.DEV.	14.7	0.33	0.22	0.11		0.019
(N)	10	10	10	10		10
40 MG/KG						
MEAN	280.3	7.41	2.17	1.95		0.097
STD.DEV.	16.9	0.75	0.22	0.08		0.020
(N)	9	9	9	9		9
80 MG/KG						
MEAN	272.1	7.43	2.18	1.96		0.095
STD.DEV.	16.9	0.62	0.20	0.12		0.017
(N)	9	9	9	9		9

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

TABLE 14 - MEAN RELATIVE ORGAN WEIGHT: MAIN STUDY TERMINATION
(SEE KEYS B AND F FOR ABBREVIATIONS)

	L I V E R / B W	K I D N E Y / B W	B R A I N / B W	T E S T S / E W	O V A R / B W
MALE	A-L-	A-L	A-L-	A-L-	
0 MG/KG					
MEAN	0.025	0.0070	0.0044	0.0075	
STD.DEV.	0.002	0.0007	0.0005	0.0006	
(N)	9	9	9	9	
10 MG/KG					
MEAN	0.025	0.0070	0.0041	0.0073	
STD.DEV.	0.002	0.0008	0.0007	0.0008	
(N)	9	10	10	10	
40 MG/KG					
MEAN	0.025	0.0078	0.0047	0.0080	
STD.DEV.	0.001	0.0014	0.0007	0.0011	
(N)	10	10	10	10	
80 MG/KG					
MEAN	0.025	0.0078	0.0046	0.0076	
STD.DEV.	0.001	0.0007	0.0005	0.0007	
(N)	8	9	9	9	
FEMALE	A-L-	A-L-	A-L-		AL-Q
0 MG/KG					
MEAN	0.027	0.0075	0.0071		0.00038
STD.DEV.	0.001	0.0005	0.0006		0.00007
(N)	10	10	10		10
10 MG/KG					*
MEAN	0.027	0.0077	0.0074		0.00030
STD.DEV.	0.001	0.0006	0.0006		0.00007
(N)	10	10	10		10
40 MG/KG					
MEAN	0.026	0.0077	0.0070		0.00035
STD.DEV.	0.002	0.0007	0.0006		0.00006
(N)	9	9	9		9
80 MG/KG					
MEAN	0.027	0.0080	0.0072		0.00035
STD.DEV.	0.002	0.0008	0.0006		0.00005
(N)	9	9	9		9

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

TABLE 15 - MEAN RELATIVE ORGAN WEIGHT: SATELLITE RECOVERY
(SEE KEYS B AND F FOR ABBREVIATIONS)

	L I V E R / B W	K I D N Y / B W	B R A I N / B W	T E S T S / B W	O V A R / B W
MALE	T-	T-	T-	T-	
0 MG/KG					
MEAN	0.025	0.0070	0.0044	0.0075	
STD.DEV.	0.002	0.0007	0.0005	0.0006	
(N)	9	9	9	9	
80 MG/KG (SATELLITE)					
MEAN	0.024	0.0068	0.0040	0.0069	
STD.DEV.	0.001	0.0006	0.0003	0.0008	
(N)	9	9	9	9	
FEMALE	T-	T-	T		T-
0 MG/KG					
MEAN	0.027	0.0075	0.0071		0.00038
STD.DEV.	0.001	0.0005	0.0006		0.00007
(N)	10	10	10		10
80 MG/KG (SATELLITE)					
MEAN	0.026	0.0077	0.0065		0.00032
STD.DEV.	0.001	0.0006	0.0004		0.00009
(N)	10	10	10		10

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

TABLE 16 - INCIDENCE OF GROSS POSTMORTEM OBSERVATIONS
MALES

	GROUP 0 MG/KG	GROUP 10 MG/KG	GROUP 40 MG/KG	GROUP 80 MG/KG	GROUP 80 MG/KG (SATELLITE)
TOTAL AT TERMINAL SACRIFICE	9	10	10	9	9
NO OBSERVABLE ABNORMALITIES	9	8	1	0	7
DOSE SITE: desquamation	0	0	9	9	0
eschar	0	0	8	9	0
ILEUM: diverticulum	0	0	1	0	0
INCISORS: maloccluded	0	0	1	0	0
KIDNEY: dilated pelvis	0	0	1	0	1
renal calculi	0	0	1	0	0
LIVER MASS	0	1	0	1	0
PALATE: sores	0	0	1	0	0
SKIN/FUR: alopecia	0	0	1	0	1
scabs	0	0	0	0	2
staining on fur	0	0	1	0	0
SPLEEN: friable	0	1	0	0	0
TAIL: necrotic tip	0	0	0	1	0
URINARY BLADDER: distended/thickened	0	0	1	0	0
multiple cystic calculi	0	0	1	0	0

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

TABLE 16 - INCIDENCE OF GROSS POSTMORTEM OBSERVATIONS (CONT'D)
MALES (CONT'D)

	GROUP 0 MG/KG	GROUP 10 MG/KG	GROUP 40 MG/KG	GROUP 80 MG/KG	GROUP 80 MG/KG (SATELLITE)
TOTAL PRETERMINAL DEATHS	1	0	0	1	1
DOSE SITE: exfoliation	0	0	0	1	1
eschar	0	0	0	1	1
ABDOMINAL/THORACIC CAVITY: filled with red liquid:	0	0	0	1	0
CECUM: compacted ingesta	1	0	0	1	0
HEART: firm	0	0	0	1	0
KIDNEYS: larger than normal	0	0	0	0	1
discolored	0	0	0	0	1
surround by gelatinous material	0	0	0	1	0
LIVER: discolored	1	0	0	1	1
thickened/firm	0	0	0	0	1
LUNGS: discolored	0	0	0	1	0
SEMINAL VESICLES: distended	0	0	0	1	1
SKIN/FUR: anogenital staining	0	0	0	0	1
STOMACH: discolored	0	0	0	0	1
URINARY BLADDER: distended	0	0	0	1	1

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

TABLE 16 - INCIDENCE OF GROSS POSTMORTEM OBSERVATIONS (CONT'D)
FEMALES

	GROUP 0 MG/KG	GROUP 10 MG/KG	GROUP 40 MG/KG	GROUP 80 MG/KG	GROUP 80 MG/KG (SATELLITE)
TOTAL AT TERMINAL SACRIFICE	10	10	9	9	10
NO OBSERVABLE ABNORMALITIES	9	5	0	0	7
DOSE SITE: desquamation	0	4	9	9	0
eschar	0	2	9	8	0
EAR: swollen	0	0	0	0	1
LIVER: discolored	0	0	0	0	0
nodule	0	0	0	0	1
LUNGS: discolored	0	1	0	0	0
OVARY: surrounded by fluid sac	0	0	0	0	1
SKIN/FUR: alopecia	0	1	0	1	1
scabs	1	0	0	0	0
STOMACH: discolored	0	1	0	0	0
TAIL: necrotic or truncated	0	0	2	1	0
UTERUS: thickened or distended	0	0	0	2	1
TOTAL PRETERMINAL DEATHS	0	0	1	1	0
DOSE SITE: desquamation	0	0	1	0	0
eschar	0	0	1	0	0
LIVER: discolored	0	0	1	1	0

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

APPENDIX A - INDIVIDUAL INLIFE OBSERVATIONS
(+ = OBSERVATION PRESENT; - = OBSERVATION NOT PRESENT)

		DOSE GROUP - 0 MG/KG																
		D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y
		0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
ANIMAL NUMBER	OBSERVATION																	
ICN297M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN287M	WITHIN NORMAL LIMITS	R	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN295M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN289M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN294M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN279M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN278M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN314M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN323M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN305M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
	SOFT STOOL	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
ICN396F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN398F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN372F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN379F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN365F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN378F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN377F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN355F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN394F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN373F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+

NOTE: REPLACEMENT ANIMAL; NO OBSERVATION PERFORMED

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

APPENDIX A - INDIVIDUAL INLIFE OBSERVATIONS (CONT'D)
(+ = OBSERVATION PRESENT; - = OBSERVATION NOT PRESENT)

		DOSE GROUP - 0 MG/KG																
ANIMAL NUMBER	OBSERVATION	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y
		1 7	1 8	1 9	2 0	2 1	2 2	2 3	2 4	2 5	2 6	2 7	2 8	2 9	3 0	3 1	3 2	3 3
ICN297M	WITHIN NORMAL LIMITS	+	+	+	+	+												
	DEAD	-	-	-	-	-	+											
ICN287M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN295M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN289M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN294M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN279M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN278M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
	BROKEN LEFT UPPER INCISOR	-	-	-	+	+	+	+	-	-	-	-	-	-	-	-	-	-
ICN314M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	-	-	-
	ALOPECIA EXTREMITIES	-	-	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+
ICN323M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN305M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN396F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN398F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN372F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN379F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN365F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN378F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN377F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN355F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN394F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN373F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

APPENDIX A - INDIVIDUAL INLIFE OBSERVATIONS (CONT'D)
(+ = OBSERVATION PRESENT; - = OBSERVATION NOT PRESENT)

		DOSE GROUP - 0 MG/KG																
		D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y
ANIMAL NUMBER	OBSERVATION	3 4	3 5	3 6	3 7	3 8	3 9	4 0	4 1	4 2	4 3	4 4	4 5	4 6	4 7	4 8	4 9	5 0
ICN287M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN295M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN289M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN294M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN279M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN278M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN314M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
	WITHIN NORMAL LIMITS	-	-	-	+	+	+	+	+	+	+	+	+	+	+	+	-	-
	ALOPECIA EXTREMITIES	+	+	+	-	-	-	-	-	-	-	-	-	-	-	-	+	+
ICN323M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN305M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN396F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN398F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN398F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN372F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN379F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN365F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN378F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN377F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
	SCABS VENTRAL	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	ALOPECIA TRUNK	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+	+
ICN355F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN394F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN373F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

APPENDIX A - INDIVIDUAL INLIFE OBSERVATIONS (CONT'D)
(+ = OBSERVATION PRESENT; - = OBSERVATION NOT PRESENT)

		DOSE GROUP - 0 MG/KG																
		D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y
ANIMAL NUMBER	OBSERVATION	5 1	5 2	5 3	5 4	5 5	5 6	5 7	5 8	5 9	6 0	6 1	6 2	6 3	6 4	6 5	6 6	6 7
ICN287M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN295M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN289M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN294M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN279M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN278M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN314M	ALOPECIA EXTREMITIES	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN323M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN305M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN396F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN398F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN372F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN379F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN365F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN378F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN377F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN355F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN394F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN373F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

APPENDIX A - INDIVIDUAL INLIFE OBSERVATIONS (CONT'D)
(+ = OBSERVATION PRESENT; - = OBSERVATION NOT PRESENT)

		DOSE GROUP - 0 MG/KG																
ANIMAL NUMBER	OBSERVATION	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y
		6 8	6 9	7 0	7 1	7 2	7 3	7 4	7 5	7 6	7 7	7 8	7 9	8 0	8 1	8 2	8 3	8 4
ICN287M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN295M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN289M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN294M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN279M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN278M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN314M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
	WITHIN NORMAL LIMITS	-	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
	ALOPECIA EXTREMITIES	+	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
ICN323M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN305M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN396F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN398F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN398F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN372F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN379F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	-	-	-	-	+	+	+	+
	SCABS TAIL	-	-	-	-	-	-	-	-	-	-	-	-	-	+	-	-	-
	NECROTIC TAIL	-	-	-	-	-	-	-	-	-	+	+	+	-	-	-	-	-
ICN365F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN378F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN377F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN355F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN394F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN373F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

APPENDIX A - INDIVIDUAL INLIFE OBSERVATIONS (CONT'D)
(+ = OBSERVATION PRESENT; - = OBSERVATION NOT PRESENT)

		DOSE GROUP - 0 MG/KG								
		D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y
		8 5	8 6	8 7	8 8	8 9	9 0	9 1	9 2	9 3
ANIMAL NUMBER	OBSERVATION									
ICN287M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	-
ICN295M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	-
ICN289M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	-
ICN294M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	-
ICN279M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	-
ICN278M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	-
ICN314M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	-
ICN323M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	-
ICN305M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	-
ICN396F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	-
	SCABS DORSAL	+	+	+	+	+	+	+	+	-
ICN398F	WITHIN NORMAL LIMITS	-	-	-	-	-	-	-	-	+
ICN372F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+
ICN379F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+
ICN365F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+
ICN378F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+
ICN377F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+
ICN355F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+
ICN394F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+
ICN373F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+
	SCABS RIGHT LATERAL THORAX	+	+	+	+	+	+	+	+	-

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

APPENDIX A - INDIVIDUAL INLIFE OBSERVATIONS (CONT'D)
(+ = OBSERVATION PRESENT; - = OBSERVATION NOT PRESENT)

		DOSE GROUP - 10 MG/KG																
		D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y
		0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
ANIMAL NUMBER	OBSERVATION																	
ICN318M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN310M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN273M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN302M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN306M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN276M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN300M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN335M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN321M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN330M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN353F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
	ALOPECIA EXTREMITIES	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
ICN342F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN345F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN348F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN388F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN341F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN385F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN361F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN370F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN395F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

APPENDIX A - INDIVIDUAL INLIFE OBSERVATIONS (CONT'D)
(+ = OBSERVATION PRESENT; - = OBSERVATION NOT PRESENT)

		DOSE GROUP - 10 MG/KG																
		D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	
		1 7	1 8	1 9	2 0	2 1	2 2	2 3	2 4	2 5	2 6	2 7	2 8	2 9	3 0	3 1	3 2	3 3
ANIMAL NUMBER	OBSERVATION																	
ICN318M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN310M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN273M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN302M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN306M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN276M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN300M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN335M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN321M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
	ALOPECIA EXTREMITIES	-	-	-	-	+	-	-	+	-	-	-	-	-	-	-	-	-
ICN330M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN353F	ALOPECIA EXTREMITIES	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN342F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN345F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN348F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN388F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN341F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN385F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN361F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN370F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN395F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

APPENDIX A - INDIVIDUAL INLIFE OBSERVATIONS (CONT'D)
(+ = OBSERVATION PRESENT; - = OBSERVATION NOT PRESENT)

		DOSE GROUP - 10 MG/KG																
		D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y
		3 4	3 5	3 6	3 7	3 8	3 9	4 0	4 1	4 2	4 3	4 4	4 5	4 6	4 7	4 8	4 9	5 0
ANIMAL NUMBER	OBSERVATION																	
ICN318M	WITHIN NORMAL LIMITS	+	+	+	+	-	-	-	-	+	+	+	+	+	+	+	+	+
	ALOPECIA EXTREMITIES	-	-	-	-	+	+	+	+	-	-	-	-	-	-	-	-	-
ICN310M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN273M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN302M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN306M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN276M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN300M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN335M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN321M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN330M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN353F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
	ALOPECIA EXTREMITIES	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN342F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN345F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN348F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN388F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
	WITHIN NORMAL LIMITS EMACIATED SLIGHT	+	+	+	+	+	+	+	+	-	-	+	+	+	+	+	+	+
ICN341F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN385F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN361F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN370F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN395F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

APPENDIX A - INDIVIDUAL INLIFE OBSERVATIONS (CONT'D)
(+ = OBSERVATION PRESENT; - = OBSERVATION NOT PRESENT)

		DOSE GROUP - 10 MG/KG																
ANIMAL NUMBER	OBSERVATION	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y
		5 1	5 2	5 3	5 4	5 5	5 6	5 7	5 8	5 9	6 0	6 1	6 2	6 3	6 4	6 5	6 6	6 7
ICN318M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN310M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN273M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN302M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN306M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN276M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN300M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
	WITHIN NORMAL LIMITS	+	+	+	+	+	-	-	-	-	-	-	-	-	-	+	+	+
	BROKEN LEFT UPPER INCISOR	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+	+	+
	MISSING LEFT UPPER INCISOR	-	-	-	-	-	+	+	+	+	-	-	-	-	-	-	-	-
ICN335M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN321M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN330M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN353F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN342F	ALOPECIA EXTREMITIES	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN345F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN348F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN388F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
	WITHIN NORMAL LIMITS	+	+	+	+	+	+	-	-	-	+	+	+	+	+	+	+	+
	SCABS DORSAL	-	-	-	-	-	-	-	-	+	-	-	-	-	-	-	-	-
	SCABS VENTRAL	-	-	-	-	-	-	+	+	+	-	-	-	-	-	-	-	-
ICN341F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN385F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN361F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

APPENDIX A - INDIVIDUAL INLIFE OBSERVATIONS (CONT'D)
(+ = OBSERVATION PRESENT; - = OBSERVATION NOT PRESENT)

		DOSE GROUP - 10 MG/KG																
ANIMAL NUMBER	OBSERVATION	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	
		5 1	5 2	5 3	5 4	5 5	5 6	5 7	5 8	5 9	6 0	6 1	6 2	6 3	6 4	6 5	6 6	6 7
ICN370F																		
	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	
ICN395F																		
	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

APPENDIX A - INDIVIDUAL INLIFE OBSERVATIONS (CONT'D)
(+ = OBSERVATION PRESENT; - = OBSERVATION NOT PRESENT)

		DOSE GROUP - 10 MG/KG																
		D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	
ANIMAL NUMBER	OBSERVATION	6 8	6 9	7 0	7 1	7 2	7 3	7 4	7 5	7 6	7 7	7 8	7 9	8 0	8 1	8 2	8 3	8 4
ICN318M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN310M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN273M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN302M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN306M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN276M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN300M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN335M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN321M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN330M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN353F	ALOPECIA EXTREMITIES	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN342F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN345F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN348F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN388F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN341F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN385F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN361F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN370F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN395F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

APPENDIX A - INDIVIDUAL INLIFE OBSERVATIONS (CONT'D)
(+ = OBSERVATION PRESENT; - = OBSERVATION NOT PRESENT)

		DOSE GROUP - 10 MG/KG								
		D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	
		8 5	8 6	8 7	8 8	8 9	9 0	9 1	9 2	9 3
ANIMAL NUMBER	OBSERVATION									
ICN318M										
ICN310M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	-
ICN273M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	-
ICN302M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	-
ICN306M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	-
ICN276M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	-
ICN300M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	-
ICN335M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	-
ICN321M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	-
ICN330M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	-
ICN353F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	-
ICN342F	ALOPECIA EXTREMITIES	+	+	+	+	+	+	+	+	+
ICN345F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+
ICN345F	SCABS TAIL	+	+	-	+	+	+	+	+	+
ICN348F	WITHIN NORMAL LIMITS	-	-	+	-	-	-	-	-	-
ICN348F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+
ICN388F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+
ICN341F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+
ICN341F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	-
ICN341F	SCABS DORSAL	-	-	-	-	-	-	-	-	+
ICN385F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+
ICN361F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+
ICN370F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+
ICN395F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+
ICN395F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

APPENDIX A - INDIVIDUAL INLIFE OBSERVATIONS (CONT'D)
(+ = OBSERVATION PRESENT; - = OBSERVATION NOT PRESENT)

		DOSE GROUP - 40 MG/KG																
		D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y
ANIMAL NUMBER	OBSERVATION	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
ICN303M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN290M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN285M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN293M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN291M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN328M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN315M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN311M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN299M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN319M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN340F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN364F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN351F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN343F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN337F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN350F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
	DEAD	+	+	+	+	+	+	+	+									
ICN389F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN363F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
	RED OCULAR DISCHARGE RIGHT EYE	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
ICN366F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN339F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

APPENDIX A - INDIVIDUAL INLIFE OBSERVATIONS (CONT'D)
(+ - OBSERVATION PRESENT; - - OBSERVATION NOT PRESENT)

		DOSE GROUP - 40 MG/KG																
		D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	
ANIMAL NUMBER	OBSERVATION	1 7	1 8	1 9	2 0	2 1	2 2	2 3	2 4	2 5	2 6	2 7	2 8	2 9	3 0	3 1	3 2	3 3
ICN303M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN290M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN285M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN293M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN291M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN328M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN315M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN311M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN299M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN319M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN340F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN364F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN351F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN343F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
	WITHIN NORMAL LIMITS	+	+	+	+	+	+	-	-	-	-	-	-	-	-	-	-	-
	ALOPECIA EXTREMITIES	-	-	-	-	-	-	+	+	+	+	+	+	+	+	+	+	+
ICN337F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN389F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN363F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN366F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN339F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
	WITHIN NORMAL LIMITS	-	-	-	-	+	+	-	+	+	+	+	+	+	+	+	+	+
	SCABS LEFT FORE PAW	+	+	+	+	-	-	-	-	-	-	-	-	-	-	-	-	-

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

APPENDIX A - INDIVIDUAL INLIFE OBSERVATIONS (CONT'D)
(+ - OBSERVATION PRESENT; - - OBSERVATION NOT PRESENT)

ANIMAL NUMBER	OBSERVATION	DOSE GROUP - 40 MG/KG															
		D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y
		3 4	3 5	3 6	3 7	3 8	3 9	4 0	4 1	4 2	4 3	4 4	4 5	4 6	4 7	4 8	4 9 5 0
ICN303M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN290M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN285M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN293M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
	ALOPECIA EXTREMITIES	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
ICN291M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN328M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN315M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN311M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN299M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN319M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN340F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN364F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN351F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN343F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
	ALOPECIA EXTREMITIES	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
ICN337F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
	SCABS TAIL	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	TRUNCATED TAIL	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
ICN389F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN363F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN366F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
 WITH IRGASAN DP300 (MRD-92-399): 139910B

APPENDIX A - INDIVIDUAL INLIFE OBSERVATIONS (CONT'D)
 (+ = OBSERVATION PRESENT; - = OBSERVATION NOT PRESENT)

		DOSE GROUP - 40 MG/KG																	
		D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	
ANIMAL NUMBER	OBSERVATION	3 4	3 5	3 6	3 7	3 8	3 9	4 0	4 1	4 2	4 3	4 4	4 5	4 6	4 7	4 8	4 9	5 0	
ICN339F		-----																	
	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	-	-	-	-	-	-	-	
	ALOPECIA EXTREMITIES	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+	+	

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

APPENDIX A - INDIVIDUAL INLIFE OBSERVATIONS (CONT'D)
(+ = OBSERVATION PRESENT; - = OBSERVATION NOT PRESENT)

		DOSE GROUP - 40 MG/KG																
		D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y
		5 1	5 2	5 3	5 4	5 5	5 6	5 7	5 8	5 9	6 0	6 1	6 2	6 3	6 4	6 5	6 6	6 7
ANIMAL NUMBER	OBSERVATION																	
ICN303M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN290M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN285M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN293M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
	ALOPECIA EXTREMITIES	-	-	-	-	-	-	+	+	+	+	+	+	+	+	+	+	+
ICN291M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN328M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN315M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN311M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN299M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
	ALOPECIA EXTREMITIES	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN319M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN340F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN364F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN351F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN343F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
	ALOPECIA EXTREMITIES	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
ICN337F	TRUNCATED TAIL	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN389F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN363F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN366F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN339F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
	SCABS LEFT FORE PAW	-	-	-	-	-	+	+	-	-	-	-	-	-	+	+	+	+
	ALOPECIA EXTREMITIES	+	+	+	+	+	-	-	-	-	-	-	-	-	-	-	-	-

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

APPENDIX A - INDIVIDUAL INLIFE OBSERVATIONS (CONT'D)
(+ = OBSERVATION PRESENT; - = OBSERVATION NOT PRESENT)

		DOSE GROUP - 40 MG/KG																
		D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y
ANIMAL NUMBER	OBSERVATION	6 8	6 9	7 0	7 1	7 2	7 3	7 4	7 5	7 6	7 7	7 8	7 9	8 0	8 1	8 2	8 3	8 4
ICN303M																		
	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN290M																		
	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN285M																		
	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN293M																		
	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN291M																		
	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN328M																		
	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN315M																		
	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN311M																		
	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN299M																		
	WITHIN NORMAL LIMITS	-	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+
	ALOPECIA EXTREMITIES	+	+	+	+	+	+	+	+	+	+	+	+	+	-	-	-	-
ICN319M																		
	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN340F																		
	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
	NECROTIC TAIL	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+	+
ICN364F																		
	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN351F																		
	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN343F																		
	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN337F																		
	TRUNCATED TAIL	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN389F																		
	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN363F																		
	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN366F																		
	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN339F																		
	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
	ALOPECIA EXTREMITIES	-	-	-	-	+	+	+	+	+	+	+	+	+	+	+	+	-

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

APPENDIX A - INDIVIDUAL INLIFE OBSERVATIONS (CONT'D)
(+ - OBSERVATION PRESENT; - - OBSERVATION NOT PRESENT)

		DOSE GROUP - 40 MG/KG								
		D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y
		8 5	8 6	8 7	8 8	8 9	9 0	9 1	9 2	9 3
ANIMAL NUMBER	OBSERVATION									
ICN303M										
	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	-
ICN290M										
	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	-
ICN285M										
	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	-
ICN293M										
	SORES PALATE	-	-	-	-	+	+	+	+	-
	BROKEN RIGHT UPPER INCISOR	-	-	-	-	+	+	+	+	-
	MALOCCLUDED INCISORS	-	-	-	-	+	+	+	+	-
	ALOPECIA EXTREMITIES	+	+	+	+	+	+	+	+	-
	MISSING RIGHT UPPER INCISOR	-	-	-	-	+	-	-	-	-
	DRIED RED OCULAR DISCHARGE RIGHT EYE	-	-	-	-	+	+	-	+	-
	DRIED RED OCULAR DISCHARGE BOTH EYES	-	-	-	-	-	-	+	-	-
ICN291M										
	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	-
ICN328M										
	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	-
ICN315M										
	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	-
ICN311M										
	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	-
ICN299M										
	WITHIN NORMAL LIMITS	+	+	+	+	+	-	-	-	-
	ALOPECIA EXTREMITIES	-	-	-	-	-	+	+	+	-
ICN319M										
	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	-
ICN340F										
	NECROTIC TAIL	+	+	+	+	+	+	+	+	+
ICN364F										
	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+
ICN351F										
	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+
ICN343F										
	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+
ICN337F										
	TRUNCATED TAIL	+	+	+	+	+	+	+	+	+
ICN389F										
	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+
ICN363F										
	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

APPENDIX A - INDIVIDUAL INLIFE OBSERVATIONS (CONT'D)
(+ = OBSERVATION PRESENT; - = OBSERVATION NOT PRESENT)

		DOSE GROUP - 40 MG/KG								
ANIMAL NUMBER	OBSERVATION	D	D	D	D	D	D	D	D	D
		A	A	A	A	A	A	A	A	A
		Y	Y	Y	Y	Y	Y	Y	Y	Y
		8	8	8	8	8	9	9	9	9
		5	6	7	8	9	0	1	2	3

ICN366F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+
ICN339F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

APPENDIX A - INDIVIDUAL INLIFE OBSERVATIONS (CONT'D)
(+ = OBSERVATION PRESENT; - = OBSERVATION NOT PRESENT)

		DOSE GROUP - 80 MG/KG																
		D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y
		0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
ANIMAL NUMBER	OBSERVATION																	
ICN322M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN313M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN304M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN320M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN317M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
	SCABS HEAD	+	+	-	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN333M	WITHIN NORMAL LIMITS	-	-	+	-	-	-	-	-	-	-	-	-	-	-	-	-	-
ICN277M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN329M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN284M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN283M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN360F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
	DEAD	-	-	-	-	-	-	-	+									
ICN381F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN362F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN376F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN338F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN384F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN367F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN392F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN356F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN390F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

APPENDIX A - INDIVIDUAL INLIFE OBSERVATIONS (CONT'D)
(+ = OBSERVATION PRESENT; - = OBSERVATION NOT PRESENT)

		DOSE GROUP - 80 MG/KG																
ANIMAL NUMBER	OBSERVATION	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	
		1 7	1 8	1 9	2 0	2 1	2 2	2 3	2 4	2 5	2 6	2 7	2 8	2 9	3 0	3 1	3 2	3 3
ICN322M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	
ICN313M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	
ICN304M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	
ICN320M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	
ICN317M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	
ICN333M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	
ICN277M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	
ICN329M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	
ICN284M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	
ICN283M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	
ICN381F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	
ICN362F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	
ICN376F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	
ICN338F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	
ICN384F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	
ICN367F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	
ICN392F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	
ICN356F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	
ICN390F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

APPENDIX A - INDIVIDUAL INLIFE OBSERVATIONS (CONT'D)
(+ = OBSERVATION PRESENT; - = OBSERVATION NOT PRESENT)

ANIMAL NUMBER	OBSERVATION	DOSE GROUP - 80 MG/KG															
		D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y
		3 4	3 5	3 6	3 7	3 8	3 9	4 0	4 1	4 2	4 3	4 4	4 5	4 6	4 7	4 8	4 9 5 0
ICN322M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN313M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN304M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN320M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN317M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN333M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN277M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN329M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN284M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN283M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN381F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN362F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN376F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN338F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN384F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN367F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN392F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN356F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN390F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

APPENDIX A - INDIVIDUAL INLIFE OBSERVATIONS (CONT'D)
(+ = OBSERVATION PRESENT; - = OBSERVATION NOT PRESENT)

		DOSE GROUP - 80 MG/KG																
		D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y
		5 1	5 2	5 3	5 4	5 5	5 6	5 7	5 8	5 9	6 0	6 1	6 2	6 3	6 4	6 5	6 6	6 7
ANIMAL NUMBER	OBSERVATION																	
ICN322M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN313M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN304M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN320M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN317M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN333M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN277M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN329M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN284M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN283M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN381F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN362F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN376F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN338F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN384F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN367F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN392F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN356F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN390F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

APPENDIX A - INDIVIDUAL INLIFE OBSERVATIONS (CONT'D)
(+ = OBSERVATION PRESENT; - = OBSERVATION NOT PRESENT)

		DOSE GROUP - 80 MG/KG																
ANIMAL NUMBER	OBSERVATION	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y
		6 8	6 9	7 0	7 1	7 2	7 3	7 4	7 5	7 6	7 7	7 8	7 9	8 0	8 1	8 2	8 3	8 4
ICN322M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN313M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN304M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN320M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN317M	WITHIN NORMAL LIMITS DEAD	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	-
ICN333M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN277M	WITHIN NORMAL LIMITS DRIED RED OCULAR DISCHARGE RIGHT EYE	+	+	+	+	+	+	+	+	-	+	+	+	+	+	+	+	+
ICN329M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN284M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN283M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN381F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN362F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN376F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN338F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN384F	WITHIN NORMAL LIMITS NECROTIC TAIL	+	+	+	+	+	+	+	+	+	-	-	-	-	-	-	-	-
ICN367F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN392F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN356F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN390F	WITHIN NORMAL LIMITS ALOPECIA EXTREMITIES	+	+	+	+	+	+	+	+	+	-	-	-	-	-	-	-	-

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

APPENDIX A - INDIVIDUAL INLIFE OBSERVATIONS (CONT'D)
(+ = OBSERVATION PRESENT; - = OBSERVATION NOT PRESENT)

		DOSE GROUP - 80 MG/KG								
		D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	
ANIMAL NUMBER	OBSERVATION	8 5	8 6	8 7	8 8	8 9	9 0	9 1	9 2	9 3
ICN322M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	-
ICN313M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	-
ICN304M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	-
ICN320M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	-
ICN333M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	-
ICN277M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	-
ICN329M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	-
ICN284M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	-
ICN283M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	-
ICN381F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+
ICN362F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+
ICN376F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+
ICN338F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+
ICN384F	NECROTIC TAIL	+	+	+	+	+	+	+	+	+
ICN367F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+
ICN392F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+
ICN356F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+
ICN390F	ALOPECIA EXTREMITIES	+	+	+	+	+	+	+	+	+

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

APPENDIX A - INDIVIDUAL INLIFE OBSERVATIONS (CONT'D)
(+ = OBSERVATION PRESENT; - = OBSERVATION NOT PRESENT)

		DOSE GROUP - 80 MG/KG (SATELLITE)																
		D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	
		0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
ANIMAL NUMBER	OBSERVATION																	
ICN296M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN326M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN275M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN307M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN280M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN309M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN298M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN292M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN332M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN316M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN358F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
	ALOPECIA EXTREMITIES	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
ICN352F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN346F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN344F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN386F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN375F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN397F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN380F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN347F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN371F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

APPENDIX A - INDIVIDUAL INLIFE OBSERVATIONS (CONT'D)
(+ = OBSERVATION PRESENT; - = OBSERVATION NOT PRESENT)

		DOSE GROUP - 80 MG/KG (SATELLITE)																
		D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y
		1 7	1 8	1 9	2 0	2 1	2 2	2 3	2 4	2 5	2 6	2 7	2 8	2 9	3 0	3 1	3 2	3 3
ANIMAL NUMBER	OBSERVATION																	
ICN296M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN326M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN275M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN307M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN280M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
	ALOPECIA EXTREMITIES	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+
ICN309M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN298M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN292M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN332M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN316M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN358F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
	BROKEN RIGHT UPPER INCISOR	-	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+
	MALOCCLUDED INCISORS	-	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+
	ALOPECIA EXTREMITIES	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN352F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN346F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN344F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN386F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN375F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN397F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN380F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN347F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
 WITH IRGASAN DP300 (MRD-92-399): 139910B

APPENDIX A - INDIVIDUAL INLIFE OBSERVATIONS (CONT'D)
 (+ = OBSERVATION PRESENT; - = OBSERVATION NOT PRESENT)

		DOSE GROUP - 80 MG/KG (SATELLITE)																
		D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	
ANIMAL NUMBER	OBSERVATION	1 7	1 8	1 9	2 0	2 1	2 2	2 3	2 4	2 5	2 6	2 7	2 8	2 9	3 0	3 1	3 2	3 3
ICN371F	WITHIN NORMAL LIMITS	+	+	+	+	+	-	-	-	-	-	-	-	-	-	-	-	-
	ALOPECIA EXTREMITIES	-	-	-	-	-	+	+	+	+	+	+	+	+	+	+	+	+

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

APPENDIX A - INDIVIDUAL INLIFE OBSERVATIONS (CONT'D)
(+ = OBSERVATION PRESENT; - = OBSERVATION NOT PRESENT)

		DOSE GROUP - 80 MG/KG (SATELLITE)																
		D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y
ANIMAL NUMBER	OBSERVATION	3 4	3 5	3 6	3 7	3 8	3 9	4 0	4 1	4 2	4 3	4 4	4 5	4 6	4 7	4 8	4 9	5 0
ICN296M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN326M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN275M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN307M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN280M	ALOPECIA EXTREMITIES	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN309M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN298M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN292M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN332M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
	ALOPECIA EXTREMITIES	+	+	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
ICN316M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN358F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
	BROKEN RIGHT UPPER INCISOR	+	+	+	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	MALOCCLUDED INCISORS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
	ALOPECIA EXTREMITIES	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	-	-
ICN352F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN346F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN344F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN386F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN375F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN397F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
	SCABS RIGHT HINDLEG	+	+	+	+	+	+	+	+	-	-	-	-	-	-	-	-	+
	SCABS RIGHT HIND PAW	-	-	-	-	-	-	-	-	-	+	+	-	-	-	-	-	-
	SWOLLEN RIGHT HINDLEG	-	-	-	-	-	-	-	-	-	+	+	-	-	-	-	-	-
	ALOPECIA TRUNK	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	+	-

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

APPENDIX A - INDIVIDUAL INLIFE OBSERVATIONS (CONT'D)
(+ = OBSERVATION PRESENT; - = OBSERVATION NOT PRESENT)

ANIMAL NUMBER	OBSERVATION	DOSE GROUP - 80 MG/KG (SATELLITE)															
		D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y
		3 4	3 5	3 6	3 7	3 8	3 9	4 0	4 1	4 2	4 3	4 4	4 5	4 6	4 7	4 8	4 9 5 0
ICN380F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN347F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN371F	ALOPECIA EXTREMITIES	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

APPENDIX A - INDIVIDUAL INLIFE OBSERVATIONS (CONT'D)
(+ = OBSERVATION PRESENT; - = OBSERVATION NOT PRESENT)

		DOSE GROUP - 80 MG/KG (SATELLITE)																
		D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y
		5 1	5 2	5 3	5 4	5 5	5 6	5 7	5 8	5 9	6 0	6 1	6 2	6 3	6 4	6 5	6 6	6 7
ANIMAL NUMBER	OBSERVATION																	
ICN296M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN326M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN275M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN307M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN280M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
	WITHIN NORMAL LIMITS	-	-	-	-	+	-	-	-	-	-	-	-	-	-	-	-	-
	ALOPECIA EXTREMITIES	+	+	+	+	-	+	+	+	+	+	+	+	+	+	+	+	+
ICN309M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN298M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN292M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN332M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
	WITHIN NORMAL LIMITS	-	-	-	-	+	-	-	-	-	-	-	-	-	-	-	-	-
	ALOPECIA EXTREMITIES	+	+	+	+	-	+	+	+	+	+	+	+	+	+	+	+	+
ICN316M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN358F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN352F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN346F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	-	-	-	-	+	+	+	+	+	+
	ALOPECIA EXTREMITIES	-	-	-	-	-	-	-	+	+	+	+	-	-	-	-	-	-
ICN344F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN386F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN375F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN397F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN380F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ICN347F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

APPENDIX A - INDIVIDUAL INLIFE OBSERVATIONS (CONT'D)
(+ = OBSERVATION PRESENT; - = OBSERVATION NOT PRESENT)

ANIMAL NUMBER	OBSERVATION	DOSE GROUP - 80 MG/KG (SATELLITE)									
		D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y
		5 1	5 2	5 3	5 4	5 5	5 6	5 7	5 8	5 9	6 0 1
ICN371F	WITHIN NORMAL LIMITS	-	-	-	-	+	+	+	+	-	-
	TEETH CUT	-	-	-	-	-	-	-	-	-	-
	BROKEN UPPER INCISOR(S)	-	-	-	-	-	-	-	-	-	-
	BROKEN LEFT UPPER INCISOR	-	-	-	-	-	-	-	-	-	-
	MALOCCLUDED INCISORS	-	-	-	-	-	-	-	-	-	-
	ALOPECIA EXTREMITIES	+	+	+	+	-	-	-	-	+	+

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

APPENDIX A - INDIVIDUAL INLIFE OBSERVATIONS (CONT'D)
(+ = OBSERVATION PRESENT; - = OBSERVATION NOT PRESENT)

ANIMAL NUMBER	OBSERVATION	DOSE GROUP - 80 MG/KG (SATELLITE)									
		D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y
		6 8	6 9	7 0	7 1	7 2	7 3	7 4	7 5	7 6	7 7
ICN296M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+
ICN326M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+
ICN275M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+
	KILLED (UNSCHEDULED)	-	-	-	-	-	-	-	-	-	-
	HYPOTHERMIA	-	-	-	-	-	-	-	-	-	-
	POOR CONDITION EXTREME	-	-	-	-	-	-	-	-	-	-
	PALE EXTREMITIES	-	-	-	-	-	-	-	-	-	-
	RED MATERIAL SEEN PENIS	-	-	-	-	-	-	-	-	-	-
ICN307M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+
ICN280M	ALOPECIA EXTREMITIES	+	+	+	+	+	+	+	+	+	+
ICN309M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+
ICN298M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+
ICN292M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+
ICN332M	ALOPECIA EXTREMITIES	+	+	+	+	+	+	+	+	+	+
ICN316M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+
ICN358F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+
ICN352F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+
ICN346F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+
ICN344F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+
ICN386F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+
ICN375F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+
ICN397F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+
ICN380F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

APPENDIX A - INDIVIDUAL INLIFE OBSERVATIONS (CONT'D)
(+ = OBSERVATION PRESENT; - = OBSERVATION NOT PRESENT)

ANIMAL NUMBER	OBSERVATION	DOSE GROUP - 80 MG/KG (SATELLITE)										
		D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y
		6 8	6 9	7 0	7 1	7 2	7 3	7 4	7 5	7 6	7 7	7 8
ICN347F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+
ICN371F	TEETH CUT	-	-	-	-	-	+	-	-	-	-	+
	BROKEN LEFT UPPER INCISOR	+	+	+	+	+	+	+	+	+	+	+
	MALOCCLUDED INCISORS	+	+	+	+	+	+	+	+	+	+	+
	ALOPECIA EXTREMITIES	+	-	-	-	-	-	-	-	-	+	+

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

APPENDIX A - INDIVIDUAL INLIFE OBSERVATIONS (CONT'D)
(+ = OBSERVATION PRESENT; - = OBSERVATION NOT PRESENT)

		DOSE GROUP - 80 MG/KG (SATELLITE)										
		D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	
		8 5	8 6	8 7	8 8	8 9	9 0	9 1	9 2	9 3	9 4	9 5
ANIMAL NUMBER	OBSERVATION											
ICN296M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+
ICN326M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+
ICN307M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+
ICN280M	WITHIN NORMAL LIMITS	-	-	-	-	-	-	-	-	+	+	+
	ALOPECIA EXTREMITIES	+	+	+	+	+	+	+	+	-	-	-
ICN309M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+
ICN298M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+
ICN292M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+
ICN332M	WITHIN NORMAL LIMITS	-	-	-	-	-	-	-	-	-	-	+
	ALOPECIA EXTREMITIES	+	+	+	+	+	+	+	+	+	+	-
ICN316M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+
ICN358F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+
ICN352F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+
ICN346F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+
ICN344F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+
ICN386F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+
	SWOLLEN RIGHT EAR	+	+	+	+	+	+	+	+	+	+	+
ICN375F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+
ICN397F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+
ICN380F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+
ICN347F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+
ICN371F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+
	BROKEN RIGHT UPPER INCISOR	+	+	+	+	+	+	-	-	-	-	-
	MALOCCLUDED INCISORS	+	+	+	+	+	+	+	+	+	+	+

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

APPENDIX A - INDIVIDUAL INLIFE OBSERVATIONS (CONT'D)
(+ = OBSERVATION PRESENT; - = OBSERVATION NOT PRESENT)

		DOSE GROUP - 80 MG/KG (SATELLITE)											
		D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	
ANIMAL NUMBER	OBSERVATION	1 0 2	1 0 3	1 0 4	1 0 5	1 0 6	1 0 7	1 0 8	1 0 9	1 1 0	1 1 1	1 1 2	
ICN296M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	
ICN326M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	
ICN307M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	
ICN280M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	
	ALOPECIA EXTREMITIES	+	-	-	-	-	-	-	-	-	-	-	
ICN309M	WITHIN NORMAL LIMITS	-	+	+	+	+	+	+	+	+	+	+	
ICN298M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	
ICN292M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	
ICN332M	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	
ICN316M	ALOPECIA EXTREMITIES	+	+	+	+	+	+	+	+	+	+	+	
	SCABS RIGHT LATERAL CERVICAL	+	+	+	+	+	+	+	+	+	-	-	
ICN358F	WITHIN NORMAL LIMITS	-	-	-	-	-	-	-	-	-	+	+	
ICN352F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	
ICN346F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	
ICN344F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	
ICN386F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	
	SWOLLEN RIGHT EAR	+	+	+	+	+	+	+	+	+	+	+	
ICN375F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	
ICN397F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	
ICN380F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	
ICN347F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	
ICN371F	WITHIN NORMAL LIMITS	+	+	+	+	+	+	+	+	+	+	+	
	TEETH CUT	-	-	-	-	-	-	+	-	-	-	-	
	MALOCCLUDED INCISORS	+	+	+	+	+	+	+	+	+	+	+	
	ALOPECIA EXTREMITIES	-	-	-	-	-	-	+	+	+	+	+	

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

APPENDIX A - INDIVIDUAL INLIFE OBSERVATIONS (CONT'D)
(+ = OBSERVATION PRESENT; - = OBSERVATION NOT PRESENT)

ANIMAL NUMBER	OBSERVATION	DOSE GROUP - 80 MG/KG (SATELLITE)		
		D A Y	D A Y	D A Y
		1 1 9	1 2 0	1 2 1
ICN296M	WITHIN NORMAL LIMITS	+	+	+
ICN326M	WITHIN NORMAL LIMITS	+	+	+
ICN307M	WITHIN NORMAL LIMITS	+	+	+
ICN280M	SCABS DORSAL	-	-	+
ICN309M	ALOPECIA EXTREMITIES	+	+	+
ICN298M	WITHIN NORMAL LIMITS	+	+	+
ICN292M	WITHIN NORMAL LIMITS	+	+	+
ICN332M	WITHIN NORMAL LIMITS	+	+	+
ICN316M	ALOPECIA EXTREMITIES	+	+	+
ICN358F	SCABS RIGHT LATERAL CERVICAL	+	+	+
ICN352F	WITHIN NORMAL LIMITS	+	+	+
ICN346F	WITHIN NORMAL LIMITS	+	+	+
ICN344F	WITHIN NORMAL LIMITS	+	+	+
ICN386F	WITHIN NORMAL LIMITS	+	+	+
ICN375F	SWOLLEN RIGHT EAR	+	+	+
ICN397F	WITHIN NORMAL LIMITS	+	+	+
ICN380F	WITHIN NORMAL LIMITS	+	+	+
ICN347F	WITHIN NORMAL LIMITS	+	+	+
ICN371F	WITHIN NORMAL LIMITS	+	+	+
	ALOPECIA EXTREMITIES	+	+	+

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

APPENDIX B - INDIVIDUAL ERYTHEMA/EDEMA SCORES
(SEE KEY A FOR DERMAL EVALUATIONS)

DOSE: 0 MG/KG

[illegible]

NOTE: X - ANIMAL DEAD
R - REPLACEMENT ANIMAL; NO OBSERVATIONS PERFORMED
N - OBSERVATION INADVERTENTLY NO RECORDED
* - APPEARS TO BE MECHANICALLY INDUCED

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

APPENDIX B - INDIVIDUAL ERYTHEMA/EDEMA SCORES (CONT'D)
(SEE KEY A FOR DERMAL EVALUATIONS)

		DOSE: 0 MG/KG								
TIME--		D	D	D	D	D	D	D	D	
		A	A	A	A	A	A	A	A	
		Y	Y	Y	Y	Y	Y	Y	Y	
		7	7	7	8	8	8	9	9	9
		0	4	7	1	4	8	1	2	3
<hr/>										
ICN297M	ERYTHEMA	X	X	X	X	X	X	X	X	
	EDEMA	X	X	X	X	X	X	X	X	
ICN287M	ERYTHEMA	0	0	0	0	0	0	0	0	
	EDEMA	0	0	0	0	0	0	0	0	
ICN295M	ERYTHEMA	0	0	0	0	0	0	0	0	
	EDEMA	0	0	0	0	0	0	0	0	
ICN289M	ERYTHEMA	0	0	0	0	0	0	0	0	
	EDEMA	0	0	0	0	0	0	0	0	
ICN294M	ERYTHEMA	0	0	0	0	0	0	0	0	
	EDEMA	0	0	0	0	0	0	0	0	
ICN279M	ERYTHEMA	0	0	0	0	0	0	0	0	
	EDEMA	0	0	0	0	0	0	0	0	
ICN278M	ERYTHEMA	0	0	0	0	0	0	0	0	
	EDEMA	0	0	0	0	0	0	0	0	
ICN314M	ERYTHEMA	0	0	0	0	0	0	0	0	
	EDEMA	0	0	0	0	0	0	0	0	
ICN323M	ERYTHEMA	0	0	0	0	0	0	0	0	
	EDEMA	0	0	0	0	0	0	0	0	
ICN305M	ERYTHEMA	0	0	0	0	0	0	0	0	
	EDEMA	0	0	0	0	0	0	0	0	
ICN396F	ERYTHEMA	0	0	0	0	0	0	0		0
	EDEMA	0	0	0	0	0	0	0		0
ICN398F	ERYTHEMA	0	0	0	0	0	0	0		0
	EDEMA	0	0	0	0	0	0	0		0
ICN372F	ERYTHEMA	0	0	0	0	0	0	0		0
	EDEMA	0	0	0	0	0	0	0		0
ICN379F	ERYTHEMA	0	0	0	0	0	0	0		0
	EDEMA	0	0	0	0	0	0	0		0
ICN365F	ERYTHEMA	0	0	0	0	0	0	0		0
	EDEMA	0	0	0	0	0	0	0		0
ICN378F	ERYTHEMA	0	0	0	0	0	0	0		0
	EDEMA	0	0	0	0	0	0	0		0
ICN377F	ERYTHEMA	0	0	0	0	0	0	0		0
	EDEMA	0	0	0	0	0	0	0		0
ICN355F	ERYTHEMA	0	0	0	0	0	0	0		0
	EDEMA	0	0	0	0	0	0	0		0
ICN394F	ERYTHEMA	0	0	0	0	0	0	0		0
	EDEMA	0	0	0	0	0	0	0		0
ICN373F	ERYTHEMA	0	0	0	0	0	0	0		0
	EDEMA	0	0	0	0	0	0	0		0

NOTE: X - ANIMAL DEAD
* - APPEARS TO BE MECHANICALLY INDUCED

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

APPENDIX B - INDIVIDUAL ERYTHEMA/EDEMA SCORES (CONT'D)
(SEE KEY A FOR DERMAL EVALUATIONS)

		DOSE: 10 MG/KG																			
TIME=		D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D
		A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A
		Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
		0	1	4	7	1	1	1	2	2	2	3	3	3	4	4	4	5	5	6	6
						1	4	8	1	5	8	2	5	9	2	6	9	3	6	0	3
ICN318M	ERYTHEMA	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	EDEMA	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ICN310M	ERYTHEMA	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	EDEMA	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ICN273M	ERYTHEMA	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	EDEMA	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ICN302M	ERYTHEMA	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	EDEMA	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ICN306M	ERYTHEMA	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	EDEMA	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ICN276M	ERYTHEMA	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	EDEMA	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ICN300M	ERYTHEMA	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	EDEMA	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ICN335M	ERYTHEMA	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	EDEMA	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ICN321M	ERYTHEMA	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	EDEMA	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ICN330M	ERYTHEMA	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	EDEMA	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ICN353F	ERYTHEMA	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	EDEMA	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ICN342F	ERYTHEMA	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	EDEMA	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ICN345F	ERYTHEMA	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	EDEMA	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ICN348F	ERYTHEMA	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	EDEMA	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ICN388F	ERYTHEMA	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	EDEMA	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ICN341F	ERYTHEMA	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	EDEMA	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ICN385F	ERYTHEMA	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	EDEMA	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ICN361F	ERYTHEMA	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	EDEMA	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ICN370F	ERYTHEMA	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	EDEMA	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ICN395F	ERYTHEMA	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	EDEMA	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

NOTE: X = ANIMAL DEAD

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

APPENDIX B - INDIVIDUAL ERYTHEMA/EDEMA SCORES (CONT'D)
(SEE KEY A FOR DERMAL EVALUATIONS)

DOSE: 10 MG/KG

TIME=		D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y
		7 0	7 4	7 7	8 1	8 4	8 8	9 1	9 2
ICN318M	ERYTHEMA	0	0	0	0	0	0	0	0
	EDEMA	0	0	0	0	0	0	0	0
ICN310M	ERYTHEMA	0	0	0	0	0	0	0	0
	EDEMA	0	0	0	0	0	0	0	0
ICN273M	ERYTHEMA	0	0	0	0	0	0	0	0
	EDEMA	0	0	0	0	0	0	0	0
ICN302M	ERYTHEMA	0	0	0	0	0	0	0	0
	EDEMA	0	0	0	0	0	0	0	0
ICN306M	ERYTHEMA	0	0	0	0	0	0	0	0
	EDEMA	0	0	0	0	0	0	0	0
ICN276M	ERYTHEMA	0	0	0	0	0	0	0	0
	EDEMA	0	0	0	0	0	0	0	0
ICN300M	ERYTHEMA	0	0	0	0	0	0	0	0
	EDEMA	0	0	0	0	0	0	0	0
ICN335M	ERYTHEMA	0	0	0	0	0	0	0	0
	EDEMA	0	0	0	0	0	0	0	0
ICN321M	ERYTHEMA	0	0	0	0	0	0	0	0
	EDEMA	0	0	0	0	0	0	0	0
ICN330M	ERYTHEMA	0	0	0	0	0	0	0	0
	EDEMA	0	0	0	0	0	0	0	0
ICN353F	ERYTHEMA	0	0	0	0	0	0	0	0
	EDEMA	0	0	0	0	0	0	0	0
ICN342F	ERYTHEMA	4	4	4	4	4	2	0	0
	EDEMA	0	0	0	0	0	0	0	0
ICN345F	ERYTHEMA	0	0	0	0	0	0	0	0
	EDEMA	0	0	0	0	0	0	0	0
ICN348F	ERYTHEMA	4	4	4	4	0	0	2	2
	EDEMA	0	0	0	0	0	0	0	0
ICN388F	ERYTHEMA	0	0	0	0	0	0	0	0
	EDEMA	0	0	0	0	0	0	0	0
ICN341F	ERYTHEMA	0	0	0	0	0	0	2	2
	EDEMA	0	0	0	0	0	0	0	0
ICN385F	ERYTHEMA	0	0	0	0	0	0	0	0
	EDEMA	0	0	0	0	0	0	0	0
ICN361F	ERYTHEMA	0	0	0	0	0	0	0	0
	EDEMA	0	0	0	0	0	0	0	0
ICN370F	ERYTHEMA	4	4	4	4	4	4	4	4
	EDEMA	1	1	0	0	0	0	1	1
ICN395F	ERYTHEMA	4	4	4	4	4	4	4	4
	EDEMA	0	0	0	0	0	0	0	0

NOTE: X = ANIMAL DEAD

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

APPENDIX B - INDIVIDUAL ERYTHEMA/EDEMA SCORES (CONT'D)
(SEE KEY A FOR DERMAL EVALUATIONS)

		DOSE: 40 MG/KG																				
TIME=		D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	
		0	1	4	7	1 1	1 4	1 8	2 1	2 5	2 8	3 2	3 5	3 9	4 2	4 6	4 9	5 3	5 6	6 0	6 3	6 7
ICN303M	ERYTHEMA	0	0	1	2	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	
	EDEMA	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
ICN290M	ERYTHEMA	0	0	0	4	4	4	4	4	0	2	4	4	4	4	4	4	4	4	4	4	
	EDEMA	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
ICN285M	ERYTHEMA	0	0	0	1	4	4	4	0	0	0	0	1	4	4	4	4	4	4	4	4	
	EDEMA	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
ICN293M	ERYTHEMA	0	0	0	4	4	4	4	4	0	0	4	4	4	4	4	4	4	4	4	4	
	EDEMA	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
ICN291M	ERYTHEMA	0	0	2	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	
	EDEMA	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
ICN328M	ERYTHEMA	0	0	0	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	
	EDEMA	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
ICN315M	ERYTHEMA	0	0	1	4	4	4	4	4	0	0	0	0	0	0	0	0	0	0	0	0	
	EDEMA	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
ICN311M	ERYTHEMA	0	0	0	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	
	EDEMA	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
ICN299M	ERYTHEMA	0	0	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	
	EDEMA	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
ICN319M	ERYTHEMA	0	0	2	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	
	EDEMA	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
ICN340F	ERYTHEMA	0	0	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	
	EDEMA	0	0	0	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0	0	0	
ICN364F	ERYTHEMA	0	0	0	2	4	4	4	0	2	0	4	4	4	4	4	4	4	4	4	4	
	EDEMA	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
ICN351F	ERYTHEMA	0	0	0	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	
	EDEMA	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	
ICN343F	ERYTHEMA	0	0	4	4	4	4	4	2	4	3	4	4	3	4	4	4	4	4	4	4	
	EDEMA	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
ICN337F	ERYTHEMA	0	0	2	4	4	4	0	0	4	4	4	4	4	4	4	4	4	4	4	4	
	EDEMA	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
ICN350F	ERYTHEMA	0	0	1	4	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
	EDEMA	0	0	0	0	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
ICN389F	ERYTHEMA	0	0	3	4	0	0	0	0	0	2	4	4	3	4	4	4	4	4	4	4	
	EDEMA	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
ICN363F	ERYTHEMA	0	0	0	0	0	0	0	3	4	4	4	4	4	3	3	2	2	4	4	4	
	EDEMA	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
ICN366F	ERYTHEMA	0	0	0	0	0	0	0	3	3	4	4	4	4	4	4	4	4	4	4	4	
	EDEMA	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	
ICN339F	ERYTHEMA	0	0	0	0	0	0	0	0	1	2	1	0	0	0	0	0	0	0	4	4	
	EDEMA	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	

NOTE: X - ANIMAL DEAD

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

APPENDIX B - INDIVIDUAL ERYTHEMA/EDEMA SCORES (CONT'D)
(SEE KEY A FOR DERMAL EVALUATIONS)

DOSE: 40 MG/KG

TIME=	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y
	7 0	7 4	7 7	8 1	8 4	8 8	9 1	9 2	9 3
ICN303M	ERYTHEMA	4	4	4	4	4	4	4	
	EDEMA	0	1	0	0	0	0	0	
ICN290M	ERYTHEMA	4	4	4	4	4	4	4	
	EDEMA	0	0	0	0	0	0	0	
ICN285M	ERYTHEMA	4	4	4	4	4	4	4	
	EDEMA	0	0	0	0	0	0	0	
ICN293M	ERYTHEMA	4	4	4	4	4	2	0	
	EDEMA	0	0	0	0	0	0	0	
ICN291M	ERYTHEMA	4	4	4	4	4	4	4	
	EDEMA	0	0	0	0	1	1	2	
ICN328M	ERYTHEMA	4	4	4	4	4	4	4	
	EDEMA	0	1	0	0	1	1	1	
ICN315M	ERYTHEMA	4	0	0	0	0	4	0	
	EDEMA	0	0	0	0	0	0	0	
ICN311M	ERYTHEMA	4	4	4	4	4	4	4	
	EDEMA	0	0	0	0	0	0	0	
ICN299M	ERYTHEMA	4	4	4	4	4	4	4	
	EDEMA	0	1	0	0	1	0	2	
ICN319M	ERYTHEMA	4	4	4	4	4	4	4	
	EDEMA	0	0	0	0	0	0	0	
ICN340F	ERYTHEMA	4	4	4	4	4	4	4	4
	EDEMA	1	0	0	0	0	1	1	1
ICN364F	ERYTHEMA	4	4	4	4	4	4	4	4
	EDEMA	0	0	0	0	0	0	0	1
ICN351F	ERYTHEMA	4	4	4	4	4	4	4	4
	EDEMA	1	0	0	0	0	1	2	0
ICN343F	ERYTHEMA	4	4	4	4	4	4	4	4
	EDEMA	0	0	0	0	0	0	1	0
ICN337F	ERYTHEMA	4	4	4	4	4	4	4	4
	EDEMA	0	0	0	0	0	0	2	1
ICN350F	ERYTHEMA	X	X	X	X	X	X	X	X
	EDEMA	X	X	X	X	X	X	X	X
ICN389F	ERYTHEMA	4	4	4	3	4	4	4	4
	EDEMA	0	0	0	0	0	1		0
ICN363F	ERYTHEMA	4	4	4	4	4	4	4	4
	EDEMA	0	0	0	0	0	0		1
ICN366F	ERYTHEMA	4	4	4	4	4	4	4	4
	EDEMA	0	0	0	0	0	0		0
ICN339F	ERYTHEMA	4	4	4	4	4	4	4	4
	EDEMA	0	0	0	0	0	0		0

NOTE: X = ANIMAL DEAD

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

APPENDIX B - INDIVIDUAL ERYTHEMA/EDEMA SCORES (CONT'D)
(SEE KEY A FOR DERMAL EVALUATIONS)

		DOSE: 80 MG/KG																				
TIME-		D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	
		0	1	4	7	1 1	1 4	1 8	2 1	2 5	2 8	3 2	3 5	3 9	4 2	4 6	4 9	5 3	5 6	6 0	6 3	6 7
ICN322M	ERYTHEMA	0	0	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	
	EDEMA	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	
ICN313M	ERYTHEMA	0	0	2	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	
	EDEMA	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	
ICN304M	ERYTHEMA	0	0	0	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	
	EDEMA	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	1	
ICN320M	ERYTHEMA	0	0	4	4	4	4	4	4	4	4	4	4	4	4	4	1	4	4	4	4	
	EDEMA	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	4	
ICN317M	ERYTHEMA	0	0	1	4	4	4	4	4	4	4	0	0	0	0	0	4	4	4	4	0	
	EDEMA	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
ICN333M	ERYTHEMA	0	0	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	
	EDEMA	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
ICN277M	ERYTHEMA	0	0	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	
	EDEMA	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
ICN329M	ERYTHEMA	0	0	2	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	
	EDEMA	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	
ICN284M	ERYTHEMA	0	0	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	
	EDEMA	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	
ICN283M	ERYTHEMA	0	0	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	
	EDEMA	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	
ICN360F	ERYTHEMA	0	0	0	0	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
	EDEMA	0	0	0	0	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
ICN381F	ERYTHEMA	0	0	0	0	4	0	0	4	3	2	2	4	4	4	4	4	4	4	4	4	
	EDEMA	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
ICN362F	ERYTHEMA	0	0	0	0	0	0	0	4	4	4	4	4	4	3	3	0	4	4	4	4	
	EDEMA	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
ICN376F	ERYTHEMA	0	0	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	
	EDEMA	0	0	0	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0	0	0	
ICN338F	ERYTHEMA	0	0	0	0	4	0	4	4	4	4	4	4	4	4	4	4	4	4	4	4	
	EDEMA	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	
ICN384F	ERYTHEMA	0	0	2	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	
	EDEMA	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
ICN367F	ERYTHEMA	0	0	1	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	
	EDEMA	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
ICN392F	ERYTHEMA	0	0	1	1	0	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	
	EDEMA	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	
ICN356F	ERYTHEMA	0	0	1	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	
	EDEMA	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
ICN390F	ERYTHEMA	0	0	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	
	EDEMA	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	1	

NOTE: X - ANIMAL DEAD

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

APPENDIX B - INDIVIDUAL ERYTHEMA/EDEMA SCORES (CONT'D)
(SEE KEY A FOR DERMAL EVALUATIONS)

		DOSE: 80 MG/KG								
TIME=		D	D	D	D	D	D	D	D	
		A	A	A	A	A	A	A	A	
		Y	Y	Y	Y	Y	Y	Y	Y	
		7	7	7	8	8	8	9	9	9
		0	4	7	1	4	8	1	2	3
<hr/>										
ICN322M	ERYTHEMA	4	4	4	4	4	4	4	4	
	EDEMA	0	1	0	0	0	0	0	0	
ICN313M	ERYTHEMA	4	4	4	4	4	4	4	4	
	EDEMA	0	0	0	0	0	0	1	0	
ICN304M	ERYTHEMA	4	4	4	4	4	4	4	4	
	EDEMA	0	0	0	0	0	0	1	1	
ICN320M	ERYTHEMA	4	4	4	4	4	4	4	4	
	EDEMA	0	0	0	0	0	0	0	0	
ICN317M	ERYTHEMA	0	0	0	1	X	X	X	X	
	EDEMA	0	0	0	0	X	X	X	X	
ICN333M	ERYTHEMA	4	4	4	4	4	4	4	4	
	EDEMA	0	1	0	0	0	0	0	0	
ICN277M	ERYTHEMA	4	4	4	4	4	4	4	4	
	EDEMA	0	1	0	0	0	0	0	0	
ICN329M	ERYTHEMA	4	4	4	4	4	4	4	4	
	EDEMA	1	0	0	0	0	0	0	0	
ICN284M	ERYTHEMA	4	4	4	4	4	4	4	4	
	EDEMA	0	0	0	0	0	0	0	0	
ICN283M	ERYTHEMA	4	4	4	4	4	4	4	4	
	EDEMA	0	1	0	0	1	1	2	2	
ICN360F	ERYTHEMA	X	X	X	X	X	X	X		X
	EDEMA	X	X	X	X	X	X	X		X
ICN381F	ERYTHEMA	4	4	4	4	4	4	4		4
	EDEMA	0	0	0	0	0	0	0		0
ICN362F	ERYTHEMA	4	4	4	4	4	4	4		4
	EDEMA	0	0	0	0	0	0	0		0
ICN376F	ERYTHEMA	4	4	4	4	4	4	4		4
	EDEMA	1	1	1	0	0	0	0		1
ICN338F	ERYTHEMA	4	4	4	4	4	4	4		4
	EDEMA	0	0	0	0	0	0	0		1
ICN384F	ERYTHEMA	4	4	4	4	4	4	4		4
	EDEMA	0	0	0	0	0	0	1		1
ICN367F	ERYTHEMA	0	4	4	1	0	0	0		2
	EDEMA	0	0	0	0	0	0	0		0
ICN392F	ERYTHEMA	4	4	4	4	4	4	4		4
	EDEMA	0	1	1	0	1	1	2		1
ICN356F	ERYTHEMA	4	4	4	4	4	4	4		4
	EDEMA	0	0	0	0	0	0	0		0
ICN390F	ERYTHEMA	4	4	4	4	4	4	4		4
	EDEMA	0	0	1	0	1	0	2		2

NOTE: X - ANIMAL DEAD

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

APPENDIX B - INDIVIDUAL ERYTHEMA/EDEMA SCORES (CONT'D)
(SEE KEY A FOR DERMAL EVALUATIONS)

		DOSE: 80 MG/KG (SATELLITE)																				
TIME=		D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	
		0	1	4	7	1 1	1 4	1 8	2 1	2 5	2 8	3 2	3 5	3 9	4 2	4 6	4 9	5 3	5 6	6 0	6 3	6 7
ICN296M	ERYTHEMA	0	0	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	
	EDEMA	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
ICN326M	ERYTHEMA	0	0	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	
	EDEMA	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
ICN275M	ERYTHEMA	0	0	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	
	EDEMA	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
ICN307M	ERYTHEMA	0	0	0	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	
	EDEMA	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
ICN280M	ERYTHEMA	0	0	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	
	EDEMA	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
ICN309M	ERYTHEMA	0	0	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	
	EDEMA	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
ICN298M	ERYTHEMA	0	0	1	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	
	EDEMA	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
ICN292M	ERYTHEMA	0	0	2	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	
	EDEMA	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
ICN332M	ERYTHEMA	0	0	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	
	EDEMA	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
ICN316M	ERYTHEMA	0	0	1	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	
	EDEMA	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	
ICN358F	ERYTHEMA	0	0	0	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	
	EDEMA	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	
ICN352F	ERYTHEMA	0	0	3	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	
	EDEMA	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	
ICN346F	ERYTHEMA	0	0	2	4	0	0	0	4	4	2	4	4	4	4	4	4	4	4	4	4	
	EDEMA	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
ICN344F	ERYTHEMA	0	0	0	2	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	
	EDEMA	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
ICN386F	ERYTHEMA	0	0	4	4	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	EDEMA	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
ICN375F	ERYTHEMA	0	0	1	0	0	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	
	EDEMA	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
ICN397F	ERYTHEMA	0	0	4	4	0	0	4	0	0	0	0	0	0	0	0	0	0	0	0	0	
	EDEMA	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
ICN380F	ERYTHEMA	0	0	1	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	
	EDEMA	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
ICN347F	ERYTHEMA	0	0	0	4	4	4	4	4	4	4	4	4	4	4	4	2	4	4	4	4	
	EDEMA	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
ICN371F	ERYTHEMA	0	0	1	4	0	0	4	4	4	4	4	4	4	4	4	4	4	4	4	4	
	EDEMA	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	

NOTE: X - ANIMAL DEAD

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

APPENDIX B - INDIVIDUAL ERYTHEMA/EDEMA SCORES (CONT'D)
(SEE KEY A FOR DERMAL EVALUATIONS)

		DOSE: 80 MG/KG (SATELLITE)															
TIME-		D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y
		7 0	7 4	7 7	8 1	8 4	8 8	9 1	9 5	9 8	1 0 2	1 0 5	1 0 9	1 1 2	1 1 6	1 1 9	1 2 1
ICN296M	ERYTHEMA	4	4	4	1	4	4	4	4	4	0	0	0	0	0	0	0
	EDEMA	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ICN326M	ERYTHEMA	4	4	4	4	4	4	4	4	4	3	0	0	0	0	0	0
	EDEMA	0	0	0	0	1	1	1	1	0	0	0	0	0	0	0	0
ICN275M	ERYTHEMA	4	4	4	4	4	X	X	X	X	X	X	X	X	X	X	X
	EDEMA	0	1	0	0	0	X	X	X	X	X	X	X	X	X	X	X
ICN307M	ERYTHEMA	4	4	4	4	4	4	4	4	1	0	0	0	0	0	0	0
	EDEMA	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ICN280M	ERYTHEMA	4	4	4	4	4	4	4	4	4	0	0	0	0	0	0	0
	EDEMA	0	0	0	0	1	1	0	0	0	0	0	0	0	0	0	0
ICN309M	ERYTHEMA	4	4	4	4	4	4	4	4	1	0	0	0	0	0	0	0
	EDEMA	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ICN298M	ERYTHEMA	4	4	4	4	4	4	4	4	4	0	0	0	0	0	0	0
	EDEMA	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0
ICN292M	ERYTHEMA	4	4	4	4	4	4	4	4	4	1	0	0	0	0	0	0
	EDEMA	1	1	0	0	0	1	0	0	0	0	0	0	0	0	0	0
ICN332M	ERYTHEMA	4	4	4	4	4	4	4	4	4	0	0	0	0	0	0	0
	EDEMA	1	1	0	0	1	1	1	1	0	0	0	0	0	0	0	0
ICN316M	ERYTHEMA	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4
	EDEMA	1	0	0	0	0	0	1	1	0	0	0	0	0	0	0	0
ICN358F	ERYTHEMA	4	4	4	4	4	4	4	4	2	1	1	0	0	0	0	0
	EDEMA	0	1	1	0	0	0	0	1	0	0	0	0	0	0	0	0
ICN352F	ERYTHEMA	4	4	4	4	4	4	4	4	4	4	4	1	0	0	0	0
	EDEMA	0	0	1	0	1	1	2	1	0	0	0	0	0	0	0	0
ICN346F	ERYTHEMA	4	4	4	4	4	4	4	4	2	1	0	0	0	0	0	0
	EDEMA	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0
ICN344F	ERYTHEMA	4	4	4	4	4	4	4	4	2	1	1	0	0	0	0	0
	EDEMA	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ICN386F	ERYTHEMA	0	0	0	2	2	2	4	4	0	0	0	0	0	0	0	0
	EDEMA	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ICN375F	ERYTHEMA	4	4	4	4	4	4	4	4	4	0	0	0	0	0	0	0
	EDEMA	1	0	1	0	1	1	2	2	0	0	0	0	0	0	0	0
ICN397F	ERYTHEMA	4	0	0	0	0	3	2	1	0	0	0	0	0	0	0	0
	EDEMA	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ICN380F	ERYTHEMA	4	4	4	4	4	4	4	4	4	4	4	0	0	0	0	0
	EDEMA	0	0	1	0	0	1	2	2	0	0	0	0	0	0	0	0
ICN347F	ERYTHEMA	4	4	4	4	2	4	4	2	0	0	0	0	0	0	0	0
	EDEMA	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ICN371F	ERYTHEMA	4	4	4	4	4	4	4	4	4	4	0	0	0	0	0	0
	EDEMA	0	0	0	0	0	1	1	1	0	0	0	0	0	0	0	0

NOTE: X - ANIMAL DEAD

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

APPENDIX C - INDIVIDUAL SUPPLEMENTAL DERMAL OBSERVATIONS

DOSE GROUP: 0 MG/KG

TIME= D
A
Y
0 1 4 7 1 1 1 2 2 2 3 3 3 4 4 4 5 5 6 6 6 7 7 7 8 8 8 9 9 9
1 4 8 1 5 8 2 5 9 2 6 9 3 6 0 3 7 0 4 7 1 4 8 1 2 3

ANIMAL NUMBER	OBSERVATION
ICN297M	NO OBSERVATIONS ENTERED
ICN287M	NO OBSERVATIONS ENTERED
ICN295M	NO OBSERVATIONS ENTERED
ICN289M	NO OBSERVATIONS ENTERED
ICN294M	NO OBSERVATIONS ENTERED
ICN279M	NO OBSERVATIONS ENTERED
ICN278M	NO OBSERVATIONS ENTERED
ICN314M	NO OBSERVATIONS ENTERED
ICN323M	NO OBSERVATIONS ENTERED
ICN305M	NO OBSERVATIONS ENTERED
ICN396F	NO OBSERVATIONS ENTERED
ICN398F	NO OBSERVATIONS ENTERED
ICN372F	NO OBSERVATIONS ENTERED
ICN379F	NO OBSERVATIONS ENTERED
ICN365F	NO OBSERVATIONS ENTERED
ICN378F	NO OBSERVATIONS ENTERED
ICN377F	NO OBSERVATIONS ENTERED
ICN355F	NO OBSERVATIONS ENTERED
ICN394F	DESQUAMATION
	DESQUAMATION*
	ESCHAR*
ICN373F	NO OBSERVATIONS ENTERED

NOTE: + = Observation present
- = Observation not present
* = APPEARS TO BE MECHANICALLY INDUCED ON DAYS 60, 63, 67, AND 70

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		DOSE GROUP: 10 MG/KG																					
TIME=	D Y	D Y	D Y	D Y	D Y	D Y	D Y	D Y	D Y	D Y	D Y	D Y	D Y	D Y	D Y	D Y	D Y	D Y	D Y	D Y	D Y	D Y	
	0	1	4	7	1	1	2	2	2	3	3	3	4	4	4	5	5	6	6	6	7	7	7
					1	4	8	1	2	5	2	8	3	3	9	3	2	4	6	4	9	5	3
					1	4	8	1	2	5	2	8	3	3	9	3	2	4	6	4	9	5	3
					1	4	8	1	2	5	2	8	3	3	9	3	2	4	6	4	9	5	3
					1	4	8	1	2	5	2	8	3	3	9	3	2	4	6	4	9	5	3
					1	4	8	1	2	5	2	8	3	3	9	3	2	4	6	4	9	5	3
					1	4	8	1	2	5	2	8	3	3	9	3	2	4	6	4	9	5	3
					1	4	8	1	2	5	2	8	3	3	9	3	2	4	6	4	9	5	3
					1	4	8	1	2	5	2	8	3	3	9	3	2	4	6	4	9	5	3
					1	4	8	1	2	5	2	8	3	3	9	3	2	4	6	4	9	5	3
					1	4	8	1	2	5	2	8	3	3	9	3	2	4	6	4	9	5	3
					1	4	8	1	2	5	2	8	3	3	9	3	2	4	6	4	9	5	3
					1	4	8	1	2	5	2	8	3	3	9	3	2	4	6	4	9	5	3
					1	4	8	1	2	5	2	8	3	3	9	3	2	4	6	4	9	5	3
					1	4	8	1	2	5	2	8	3	3	9	3	2	4	6	4	9	5	3
					1	4	8	1	2	5	2	8	3	3	9	3	2	4	6	4	9	5	3
					1	4	8	1	2	5	2	8	3	3	9	3	2	4	6	4	9	5	3
					1	4	8	1	2	5	2	8	3	3	9	3	2	4	6	4	9	5	3
					1	4	8	1	2	5	2	8	3	3	9	3	2	4	6	4	9	5	3
					1	4	8	1	2	5	2	8	3	3	9	3	2	4	6	4	9	5	3
					1	4	8	1	2	5	2	8	3	3	9	3	2	4	6	4	9	5	3
					1	4	8	1	2	5	2	8	3	3	9	3	2	4	6	4	9	5	3
					1	4	8	1	2	5	2	8	3	3	9	3	2	4	6	4	9	5	3

NOTE: + = Observation present
- = Observation not present

[illegible]

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

APPENDIX C - INDIVIDUAL SUPPLEMENTAL DERMAL OBSERVATIONS (CONT'D)

		DOSE GROUP: 10 MG/KG																												
ANIMAL NUMBER	OBSERVATION	TIME=																												
		D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D
		A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A
		Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
		0	1	4	7	1	1	1	2	2	2	3	3	3	4	4	4	5	5	6	6	6	7	7	7	8	8	8	9	9
		1	4	8	1	5	8	2	5	9	2	6	9	3	6	0	3	7	0	4	7	1	4	8	1	2	3			
ICN370F	DESQUAMATION	-	-	-	-	-	-	-	+	+	+	+	-	+	+	+	+	+	+	+	+	+	+	+	+	-	-	+	+	-
	ESCHAR	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
	EXFOLIATION	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	+	+	-	-
ICN395F	DESQUAMATION	-	-	-	-	-	-	-	+	+	+	+	-	+	+	+	+	+	+	+	+	+	+	+	+	-	-	+	+	-
	ESCHAR	-	-	-	-	-	-	-	-	+	+	+	-	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
	EXFOLIATION	-	-	-	-	-	-	-	-	-	-	-	+	-	-	-	-	-	-	-	-	-	-	-	-	-	+	+	-	-

NOTE: + = Observation present
- = Observation not present

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

APPENDIX C - INDIVIDUAL SUPPLEMENTAL DERMAL OBSERVATIONS (CONT'D)

DOSE GROUP: 40 MG/KG

[illegible]

ANIMAL NUMBER	OBSERVATION	0	1	4	7	1	1	1	2	2	2	3	3	3	4	4	4	5	5	6	6	6	7	7	7	8	8	8	9	9	9	
		1	4	8	1	1	1	2	2	2	3	3	3	4	4	4	5	5	6	6	6	7	7	7	8	8	8	1	2	3		
ICN303M	DESQUAMATION	-	-	+	+	-	-	-	-	+	-	-	+	+	+	+	+	+	+	+	+	+	+	+	+	+	-	-	+	+	-	
	ESCHAR	-	-	-	-	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	-	
	EXFOLIATION	-	-	-	-	-	-	-	-	-	-	-	+	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
ICN290M	DESQUAMATION	-	-	+	-	-	+	+	+	+	+	-	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	-	
	ESCHAR	-	-	-	+	+	+	+	+	+	+	-	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	-	
ICN285M	DESQUAMATION	-	-	-	+	-	-	+	-	-	-	-	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	-	
	ESCHAR	-	-	-	-	+	+	+	-	-	-	-	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	-	
	ATONIA	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	+	+	-	-	-	-	-	-	-	-	-	-	-	-	-	
ICN293M	DESQUAMATION	-	-	+	+	-	-	+	+	+	-	-	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	-	
	ESCHAR	-	-	-	+	+	+	+	+	+	-	-	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	-	
ICN291M	DESQUAMATION	-	-	+	+	+	-	-	+	+	+	+	-	+	+	+	+	+	+	+	+	+	+	+	+	+	-	-	+	+	+	-
	ESCHAR	-	-	-	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	-
	EXFOLIATION	-	-	-	-	-	-	-	-	-	-	-	+	-	-	-	-	-	-	-	+	-	-	-	-	+	+	-	-	-	-	
ICN328M	DESQUAMATION	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	-	
	ESCHAR	-	-	-	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	-
	EXFOLIATION	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	-
	ATONIA	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	+	+	-	-	-	-	-	-	-	+	+	-	-	-	-	-
ICN315M	DESQUAMATION	-	-	+	-	-	-	+	+	+	-	+	-	+	+	-	-	-	-	-	+	+	+	-	-	-	-	-	-	-	-	-
	ESCHAR	-	-	-	+	+	+	+	+	+	-	-	+	+	+	-	-	-	-	+	+	+	+	-	-	-	-	-	+	-	-	-
	ATONIA	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	+	+	+	+	-	-	-	-	-	+	-	-
ICN311M	DESQUAMATION	-	-	-	-	+	-	+	+	+	-	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	-
	ESCHAR	-	-	-	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	-
	ATONIA	-	-	-	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	-
ICN299M	DESQUAMATION	-	-	+	+	-	-	+	+	+	+	-	+	+	+	+	+	+	+	+	+	+	+	+	+	+	-	+	+	+	+	-
	ESCHAR	-	-	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	-
	EXFOLIATION	-	-	-	-	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	-
ICN319M	DESQUAMATION	-	-	-	-	+	+	+	+	+	+	-	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	-
	ESCHAR	-	-	-	+	+	-	-	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	-
	EXFOLIATION	-	-	-	-	-	-	-	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	-

NOTE: + = Observation present
- = Observation not present

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

APPENDIX C - INDIVIDUAL SUPPLEMENTAL DERMAL OBSERVATIONS (CONT'D)

		DOSE GROUP: 40 MG/KG																														
TIME=		D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D
		A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A
		Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
ANIMAL NUMBER	OBSERVATION	0	1	4	7	1	1	1	2	2	2	3	3	3	4	4	4	5	5	6	6	6	7	7	7	8	8	8	9	9	9	
						1	4	8	1	5	8	2	5	9	2	6	9	3	6	0	3	7	0	4	7	1	4	8	1	2	3	
ICN340F	DESQUAMATION	-	-	+	-	-	-	-	+	+	+	+	-	+	+	+	+	+	+	+	+	+	+	+	+	-	-	+	+	-	+	
	ESCHAR	-	-	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	
	EXFOLIATION	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	+	+	-	-	-	
	ATONIA	-	-	-	-	-	-	-	-	-	-	-	+	-	-	-	+	+	-	-	-	-	-	-	-	-	-	+	-	-	+	
ICN364F	DESQUAMATION	-	-	+	+	-	-	-	+	+	+	+	-	+	+	+	+	+	+	+	+	+	+	+	+	-	-	+	+	-	+	
	ESCHAR	-	-	-	+	-	-	-	-	-	-	-	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	
	EXFOLIATION	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	+	+	-	-	-	
	ATONIA	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	+	
ICN351F	DESQUAMATION	-	-	-	+	-	+	+	+	+	+	-	+	+	+	+	+	+	+	+	+	+	+	+	+	-	+	+	-	+		
	ESCHAR	-	-	-	+	+	+	+	+	+	+	-	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	
	EXFOLIATION	-	-	-	-	-	-	-	-	-	-	-	+	+	-	-	-	-	-	-	-	-	-	-	-	-	+	+	-	-	-	
	ATONIA	-	-	-	-	-	-	-	-	-	-	-	+	-	-	+	+	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
ICN343F	DESQUAMATION	-	-	+	+	-	+	+	+	+	+	-	+	+	+	-	+	+	+	+	+	+	+	+	+	-	+	+	-	+		
	ESCHAR	-	-	+	+	+	+	+	+	+	+	-	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	
	EXFOLIATION	-	-	-	-	-	-	-	-	-	-	-	+	-	-	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	
	ATONIA	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	+	+	-	-	-	-	-	-	-	-	-	-	-	-	-	
ICN337F	DESQUAMATION	-	-	+	+	-	+	+	+	+	+	-	+	+	+	+	+	+	+	+	+	+	+	+	+	-	+	+	-	+		
	ESCHAR	-	-	-	+	+	-	-	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	
	EXFOLIATION	-	-	-	-	-	-	-	-	-	-	-	+	-	-	-	-	-	-	-	-	-	-	-	-	+	+	-	-	-	-	
	ATONIA	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	+	+	-	-	-	-	-	-	-	-	-	-	-	-	
ICN350F	DESQUAMATION	-	-	+	+	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
	ESCHAR	-	-	-	+	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
ICN389F	DESQUAMATION	-	-	+	+	-	-	-	-	+	-	-	+	+	+	-	+	-	-	+	+	+	+	+	+	-	+	+	-	+		
	ESCHAR	-	-	-	+	-	-	-	-	+	+	-	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	
	EXFOLIATION	-	-	-	-	-	-	-	-	-	-	-	+	-	-	+	+	-	-	-	-	-	-	-	-	+	-	-	-	-	-	
ICN363F	DESQUAMATION	-	-	-	-	+	-	+	+	+	-	-	+	+	-	-	+	+	+	+	+	+	+	+	-	-	+	+	-	+		
	ESCHAR	-	-	-	-	-	-	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	
	EXFOLIATION	-	-	-	-	-	-	-	-	-	-	-	+	-	-	-	-	-	-	-	-	-	-	-	-	+	-	-	-	-	-	
	ATONIA	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	+	-	-	-	-	-	-	-	-	-	-	-	-	
ICN366F	DESQUAMATION	-	-	-	-	-	-	-	+	+	+	-	+	+	+	+	+	+	+	+	+	+	+	+	-	-	+	+	-	+		
	ESCHAR	-	-	-	-	-	-	-	-	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	
	EXFOLIATION	-	-	-	-	-	-	-	-	-	-	-	+	+	-	-	-	-	+	-	-	-	-	-	-	+	+	-	-	-	-	
NOTE:		+ = Observation present - = Observation not present																														

NOTE: + = Observation present
- = Observation not present

10
 11
 12

DOSE GROUP: 40 MG/KG

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100

[illegible][illegible]

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90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

APPENDIX C - INDIVIDUAL SUPPLEMENTAL DERMAL OBSERVATIONS (CONT'D)

		DOSE GROUP: 80 MG/KG																							
TIME=		D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D
		A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A
		Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
		0	1	4	7	1	1	1	2	2	2	3	3	3	4	4	4	5	5	6	6	6	7	7	7
						1	4	8	1	5	8	2	5	9	2	6	9	3	6	0	3	7	0	4	7
ANIMAL	OBSERVATION																								
NUMBER																									
ICN360F	NO OBSERVATIONS ENTERED																								
ICN381F	DESQUAMATION	-	-	-	+	-	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
	ESCHAR	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	EXFOLIATION	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
ICN362F	DESQUAMATION	-	-	-	+	-	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
	ESCHAR	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	EXFOLIATION	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
ICN376F	DESQUAMATION	-	-	+	+	-	+	-	+	+	+	-	+	+	+	+	+	+	+	+	+	+	+	+	+
	ESCHAR*	-	+	+	+	+	+	+	+	+	+	-	+	+	+	+	+	+	+	+	+	+	+	+	+
	EXFOLIATION	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	ATONIA	-	-	-	-	-	-	-	-	-	-	+	+	-	-	-	-	-	-	-	-	-	-	-	-
ICN338F	DESQUAMATION	-	-	-	-	+	-	-	+	+	-	-	+	+	+	+	+	+	+	+	+	+	+	+	+
	ESCHAR	-	-	-	-	+	-	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
	EXFOLIATION	-	-	-	-	-	-	-	-	-	-	+	+	-	-	-	-	-	-	-	-	-	-	-	-
	ATONIA	-	-	-	-	-	-	-	-	-	-	+	-	-	-	-	-	-	-	-	-	-	-	-	-
ICN384F	DESQUAMATION	-	-	+	-	-	-	-	+	+	-	-	+	+	+	+	+	+	+	+	+	+	+	+	+
	ESCHAR	-	-	-	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
	EXFOLIATION	-	-	-	-	-	-	-	-	-	-	+	+	-	-	-	-	-	-	-	-	-	-	-	-
	ATONIA	-	-	-	-	-	-	-	-	-	-	+	-	-	-	-	-	-	-	-	-	-	-	-	-
ICN367F	DESQUAMATION	-	-	+	+	-	-	-	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
	ESCHAR	-	-	-	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
	EXFOLIATION	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
ICN392F	DESQUAMATION	-	-	+	+	+	-	+	+	+	-	-	+	+	+	+	+	+	+	+	+	+	+	+	+
	ESCHAR	-	-	-	-	-	+	+	+	+	+	-	+	+	+	+	+	+	+	+	+	+	+	+	+
	EXFOLIATION	-	-	-	-	-	-	-	-	-	-	+	+	-	-	-	-	-	-	-	-	-	-	-	-
	ATONIA	-	-	-	-	-	-	-	-	-	-	+	+	+	+	+	+	-	+	-	-	-	-	-	+
ICN356F	DESQUAMATION	-	-	+	+	-	+	+	-	+	+	-	+	+	+	+	+	+	+	+	+	+	+	+	+
	ESCHAR	-	-	-	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
	EXFOLIATION	-	-	-	-	-	-	-	-	-	-	+	+	-	-	-	-	-	-	-	-	-	-	-	-
	ATONIA	-	-	-	-	-	-	-	-	-	-	+	-	-	-	-	-	-	-	-	-	-	-	-	-

NOTE: + = Observation present
- = Observation not present
* = APPEARS TO BE MECHANICALLY INDUCED ON DAY 1

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

APPENDIX C - INDIVIDUAL SUPPLEMENTAL DERMAL OBSERVATIONS (CONT'D)

		DOSE GROUP: 80 MG/KG																																
ANIMAL NUMBER	OBSERVATION	TIME=																																
		D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	D A Y	
ICN390F		0	1	4	7	1	1	1	2	2	2	3	3	3	4	4	4	5	5	6	6	6	7	7	7	7	8	8	8	9	9	9		
						1	4	8	1	5	8	2	5	9	2	6	9	3	6	0	3	7	0	4	7	1	4	8	1	2	3			
	DESQUAMATION	-	-	+	+	+	+	+	-	+	+	-	+	+	+	+	+	+	-	+	+	+	+	+	+	+	-	-	+	+	-	+		
	ESCHAR	-	-	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	-	+	
	EXFOLIATION	-	-	-	-	-	-	-	-	-	-	-	+	+	-	-	-	+	-	-	-	-	-	-	-	-	+	+	-	-	-	-	-	
	ATONIA	-	-	-	-	-	-	-	-	-	-	-	+	-	+	+	+	+	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
NOTE:	+ = Observation present																																	
	- = Observation not present																																	

NOTE: + = Observation present
- = Observation not present

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

APPENDIX C - INDIVIDUAL SUPPLEMENTAL DERMAL OBSERVATIONS (CONT'D)

		DOSE GROUP: 80 MG/KG (SATELLITE)																																				
TIME=		D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D					
		A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A					
		Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y					
		0	1	4	7	1	1	1	2	2	2	3	3	3	4	4	4	5	5	6	6	7	7	7	8	8	8	9	9	9	1	1	1	1	1	2		
						1	4	8	1	5	8	2	5	9	2	6	9	3	6	0	3	7	0	4	7	1	4	8	1	5	8	0	0	0	1	1	1	2
ANIMAL NUMBER	OBSERVATION																																					
ICN296M	DESQUAMATION	-	-	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+		
	ESCHAR	-	-	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+		
	EXFOLIATION	-	-	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+		
	PINPOINT SCABS	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-		
ICN326M	DESQUAMATION	-	-	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+		
	ESCHAR	-	-	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+		
	EXFOLIATION	-	-	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+		
	ATONIA	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-		
ICN275M	DESQUAMATION	-	-	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+		
	ESCHAR	-	-	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+		
	EXFOLIATION	-	-	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+		
ICN307M	DESQUAMATION	-	-	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+		
	ESCHAR	-	-	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+		
	EXFOLIATION	-	-	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+		
	ATONIA	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-			
ICN280M	DESQUAMATION	-	-	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+		
	ESCHAR	-	-	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+		
	EXFOLIATION	-	-	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+		
ICN309M	DESQUAMATION	-	-	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+		
	ESCHAR	-	-	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+		
	EXFOLIATION	-	-	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+		
ICN298M	DESQUAMATION	-	-	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+		
	ESCHAR	-	-	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+		
	EXFOLIATION	-	-	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+		
ICN292M	DESQUAMATION	-	-	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+		
	ESCHAR	-	-	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+		
	EXFOLIATION	-	-	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+		
ICN332M	DESQUAMATION	-	-	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+		
	ESCHAR	-	-	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+		
	EXFOLIATION	-	-	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+		
	ATONIA	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-			
NOTE:																																						

NOTE: + = Observation present
- = Observation not present

Good
no
Good

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12

ANIMAL NUMBER	OBSERVATION
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98	98
99	99
100	100

TIME—

ICN347F

ICN371F

NOTE: + = Observation present
- = Observation not present

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90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

APPENDIX D - INDIVIDUAL BODY WEIGHT
(GRAMS)
DOSE: 0 MG/KG

TIME=	P R E	0	7	14	21	28	35	42	49	56	63	70	77
	T E S T	D A Y S	D A Y S	D A Y S	D A Y S	D A Y S	D A Y S	D A Y S	D A Y S	D A Y S	D A Y S	D A Y S	D A Y S
ICN297M	206.8	254.5	280.7	308.0	341.9	X							
ICN287M	202.2	254.5	285.6	325.0	348.8	379.8	402.9	423.7	436.4	453.7	464.7	474.9	480.2
ICN295M	212.2	265.5	302.4	340.0	378.7	415.4	454.0	469.8	489.5	493.0	495.5	496.1	515.9
ICN289M	215.6	267.9	305.6	335.0	363.1	395.0	423.5	440.9	469.9	483.4	508.0	522.7	543.7
ICN294M	219.6	262.8	310.0	345.0	377.3	399.5	422.2	448.7	476.1	496.3	517.1	516.9	549.6
ICN279M	225.0	278.8	314.6	357.0	398.3	438.4	472.3	492.8	518.2	540.0	559.9	581.5	597.0
ICN278M	228.4	277.3	303.9	327.0	353.8	379.0	400.3	424.4	435.6	450.8	464.6	476.9	498.8
ICN314M	231.5	278.0	300.1	333.0	366.4	388.0	409.9	429.5	434.0	434.7	448.3	450.4	457.3
ICN323M	232.3	275.5	319.8	349.0	378.0	399.7	425.0	452.4	473.4	480.1	500.4	504.2	522.8
ICN305M	234.4	286.3	306.4	332.0	350.5	367.3	385.1	401.9	414.4	425.8	437.6	441.5	460.1
MEAN	220.8	271.8	302.9	335.1	365.7	395.8	421.7	442.7	460.8	473.1	488.5	496.1	513.9
STD.DEV.	11.3	9.9	12.0	13.8	17.5	21.3	27.2	27.2	33.0	35.6	38.5	42.4	45.6
N	10	9	10	10	10	9	9	9	9	9	9	9	9
ICN396F	216.9	228.0	232.7	252.0	266.2	270.0	283.0	296.0	287.8	285.8	302.9	318.3	321.9
ICN398F	209.0	219.8	232.4	245.0	259.0	263.4	278.6	276.8	279.5	279.4	283.3	287.3	294.1
ICN372F	215.1	242.6	244.6	254.0	260.8	273.6	281.4	290.1	283.4	295.4	302.1	311.3	314.3
ICN379F	213.0	222.6	232.1	250.0	251.6	271.1	277.9	274.6	299.8	319.3	304.1	301.8	310.3
ICN365F	205.9	220.7	224.6	241.0	254.0	262.0	263.1	263.2	263.2	259.3	268.2	274.3	279.1
ICN378F	203.3	207.6	218.4	233.0	241.8	246.3	260.3	267.8	271.5	270.2	279.8	287.8	287.7
ICN377F	200.8	218.7	220.3	241.0	248.8	268.8	274.8	276.1	299.9	312.3	308.8	313.1	305.4
ICN355F	211.4	209.9	220.8	236.0	242.8	258.1	261.5	265.2	281.5	280.0	287.1	286.1	293.1
ICN394F	219.8	235.5	240.8	258.0	265.7	288.2	307.3	306.1	297.4	314.8	326.6	328.2	321.5
ICN373F	201.6	222.0	227.7	237.0	242.3	263.2	258.7	266.8	274.3	283.7	312.0	302.4	307.2
MEAN	209.7	222.7	229.4	244.7	253.3	266.5	274.7	278.3	283.8	290.0	297.5	301.1	303.5
STD.DEV.	6.6	10.6	8.8	8.5	9.4	11.0	14.8	14.5	12.5	20.0	17.5	17.0	14.5
N	10	10	10	10	10	10	10	10	10	10	10	10	10

NOTE: X = ANIMAL DEAD
R = REPLACEMENT ANIMAL; NO MEASUREMENT TAKEN

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

APPENDIX D - INDIVIDUAL BODY WEIGHT (CONT'D)
(GRAMS)
DOSE: 0 MG/KG

TIME=	8	9
	4	1
	D	D
	A	A
	Y	Y
	S	S
ICN297M	X	
ICN287M	492.8	496.4
ICN295M	517.4	519.9
ICN289M	546.5	553.9
ICN294M	560.2	568.2
ICN279M	610.6	620.7
ICN278M	509.8	510.0
ICN314M	444.3	458.1
ICN323M	522.5	528.4
ICN305M	462.3	464.3
MEAN	518.5	524.4
STD.DEV.	50.5	51.4
N	9	9
ICN396F	317.9	331.1
ICN398F	286.2	294.8
ICN372F	316.5	304.0
ICN379F	319.5	309.9
ICN365F	271.2	283.8
ICN378F	280.3	293.4
ICN377F	308.3	302.4
ICN355F	301.5	298.6
ICN394F	335.1	329.0
ICN373F	313.9	300.6
MEAN	305.0	304.8
STD.DEV.	20.1	15.0
N	10	10

NOTE: X = ANIMAL DEAD

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

APPENDIX D - INDIVIDUAL BODY WEIGHT (CONT'D)
(GRAMS)
DOSE: 10 MG/KG

TIME=	P	0	7	1	2	2	3	4	4	5	6	7	7
R	E			4	1	8	5	2	9	6	3	0	7
T	E												
S	T	D	D	D	D	D	D	D	D	D	D	D	D
		A	A	A	A	A	A	A	A	A	A	A	A
		Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
		S	S	S	S	S	S	S	S	S	S	S	S
ICN318M	205.2	257.8	291.0	324.0	354.0	388.1	413.7	432.1	449.8	465.0	483.0	499.9	523.4
ICN310M	207.6	258.3	295.4	331.0	359.7	389.0	420.7	441.1	458.7	475.9	491.3	505.1	512.1
ICN273M	210.0	264.0	303.6	346.0	383.1	418.4	443.2	466.2	475.0	498.6	526.5	542.0	558.2
ICN302M	217.8	263.4	298.5	326.0	343.6	358.9	374.2	374.5	382.9	411.4	438.3	441.6	467.3
ICN306M	222.1	276.5	301.1	341.0	373.3	408.3	430.8	456.8	475.5	493.7	510.7	522.3	533.6
ICN276M	222.6	268.0	306.9	344.0	375.9	407.1	427.0	451.9	470.4	490.0	514.1	519.7	535.8
ICN300M	227.7	272.8	312.4	340.0	357.7	386.1	407.9	423.7	434.5	438.3	443.3	437.5	450.3
ICN335M	230.1	286.3	362.0	421.0	472.3	503.6	535.9	570.3	592.0	621.5	642.6	669.1	689.0
ICN321M	233.6	285.9	324.8	369.0	405.1	427.0	448.3	476.6	501.6	518.3	537.2	554.8	576.1
ICN330M	238.0	285.6	327.5	371.0	406.9	427.9	468.3	495.1	514.3	529.3	537.0	556.4	575.5
MEAN	221.5	271.9	312.3	351.3	383.2	411.4	437.0	458.8	475.5	494.2	512.4	524.8	542.1
STD.DEV.	11.2	11.3	21.1	29.2	37.6	38.8	43.0	51.1	54.8	57.0	57.7	65.5	66.2
N	10	10	10	10	10	10	10	10	10	10	10	10	10
ICN353F	217.9	227.9	238.9	254.0	261.2	276.2	289.2	289.7	290.3	304.6	314.1	318.4	313.7
ICN342F	209.1	228.9	233.2	253.0	270.7	282.2	278.9	289.7	293.6	293.5	291.5	303.2	305.2
ICN345F	215.5	237.1	247.8	264.0	260.7	277.5	281.9	291.7	299.4	297.7	307.6	313.5	327.4
ICN348F	214.6	226.1	237.1	252.0	250.9	274.5	278.6	282.6	291.4	294.0	298.7	304.7	313.8
ICN388F	207.8	224.4	238.0	248.0	245.9	257.9	253.5	199.7	260.7	269.7	280.3	292.0	289.4
ICN341F	203.5	214.5	222.9	238.0	238.9	251.9	257.9	252.1	259.9	266.7	271.0	268.9	282.2
ICN385F	198.6	193.5	208.9	222.0	226.9	223.8	243.9	249.4	261.6	257.4	268.3	272.1	273.3
ICN361F	211.6	229.4	243.9	246.0	256.6	273.2	283.2	276.1	291.9	295.0	295.1	295.9	297.7
ICN370F	219.3	242.2	248.8	260.0	276.4	288.9	289.8	292.4	302.2	298.2	303.8	307.0	311.6
ICN395F	201.5	210.3	214.2	216.0	240.7	271.8	255.3	264.2	272.2	269.0	265.7	278.9	289.1
MEAN	209.9	223.4	233.4	245.3	252.9	267.8	271.2	268.8	282.3	284.6	289.6	295.5	300.3
STD.DEV.	7.1	14.1	13.7	15.7	15.2	18.8	16.8	29.2	16.8	16.9	17.3	17.2	16.9
N	10	10	10	10	10	10	10	10	10	10	10	10	10

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

APPENDIX D - INDIVIDUAL BODY WEIGHT (CONT'D)
(GRAMS)
DOSE: 10 MG/KG

	TIME- 8 4	9 1
	D A Y S	D A Y S
ICN318M	539.3	539.9
ICN310M	517.5	527.4
ICN273M	572.9	577.7
ICN302M	465.9	449.1
ICN306M	541.8	562.1
ICN276M	539.4	550.5
ICN300M	455.0	451.0
ICN335M	705.8	705.9
ICN321M	585.8	588.5
ICN330M	583.4	599.1
MEAN	550.7	555.1
STD.DEV.	70.4	74.1
N	10	10
ICN353F	323.1	325.6
ICN342F	306.0	305.8
ICN345F	332.8	328.3
ICN348F	313.0	304.3
ICN388F	291.5	295.9
ICN341F	283.8	287.7
ICN385F	272.4	273.9
ICN361F	295.6	286.4
ICN370F	314.9	301.0
ICN395F	285.6	284.2
MEAN	301.9	299.3
STD.DEV.	19.2	17.6
N	10	10

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

APPENDIX D - INDIVIDUAL BODY WEIGHT (CONT'D)
(GRAMS)
DOSE: 40 MG/KG

TIME- P R E	0	7	1 4	2 1	2 8	3 5	4 2	4 9	5 6	6 3	7 0	7 7	
T E S T	D A Y S	D A Y S	D A Y S	D A Y S	D A Y S	D A Y S	D A Y S	D A Y S	D A Y S	D A Y S	D A Y S	D A Y S	
ICN303M	205.3	249.5	286.6	315.0	334.6	356.0	374.8	382.6	400.3	410.7	427.5	441.0	459.7
ICN290M	207.0	245.6	266.6	307.0	331.7	364.3	376.0	393.1	408.1	419.4	433.7	450.4	461.4
ICN285M	212.4	263.4	305.5	347.0	376.3	408.9	438.0	464.0	480.5	499.6	514.5	532.7	546.4
ICN293M	215.8	267.9	313.8	361.0	402.2	442.2	469.1	498.1	514.6	541.0	556.9	580.9	594.2
ICN291M	222.3	270.3	307.8	342.0	367.3	386.0	414.7	433.3	447.6	461.9	445.7	455.5	458.2
ICN328M	224.9	274.6	314.4	341.0	373.7	395.2	422.8	433.0	436.8	457.4	460.0	471.2	480.3
ICN315M	228.5	287.2	335.5	387.0	423.4	464.5	495.6	519.8	549.2	573.4	594.7	611.0	628.0
ICN311M	228.7	282.9	308.0	348.0	380.7	406.5	441.2	459.3	484.4	497.8	507.5	528.3	533.1
ICN299M	232.7	267.8	286.5	312.0	333.1	350.0	346.7	343.8	348.1	355.0	370.2	370.3	381.9
ICN319M	234.8	277.4	303.3	334.0	365.1	383.5	402.9	411.6	420.0	430.9	442.1	442.3	450.1
MEAN	221.2	268.7	302.8	339.4	368.8	395.7	418.2	433.9	449.0	464.7	475.3	488.4	499.3
STD. DEV.	10.6	13.3	18.9	24.3	30.1	36.6	45.4	53.7	59.4	65.1	67.3	73.2	74.7
N	10	10	10	10	10	10	10	10	10	10	10	10	10
ICN340F	217.0	236.7	241.5	262.0	275.9	297.9	307.2	320.8	316.4	333.3	335.4	336.4	344.0
ICN364F	210.4	223.5	236.3	233.0	249.0	261.3	271.3	272.2	287.7	294.2	296.5	302.2	302.5
ICN351F	216.5	234.6	238.4	263.0	267.5	283.4	292.6	298.5	294.5	308.0	315.1	312.9	315.9
ICN343F	214.7	228.6	223.4	228.0	256.8	263.6	259.8	259.9	265.0	262.1	267.5	270.9	271.8
ICN337F	206.7	217.0	218.2	247.0	257.5	271.3	279.5	281.3	295.5	297.4	305.0	312.3	315.8
ICN350F	203.5	223.6	231.2	X									
ICN389F	200.2	214.4	230.5	254.0	256.7	270.0	278.8	270.4	288.0	289.6	292.7	301.8	291.3
ICN363F	212.3	230.0	238.1	244.0	251.7	273.7	273.9	272.7	285.5	288.5	298.5	293.4	293.7
ICN366F	218.5	241.0	250.4	270.0	272.6	285.4	284.5	296.3	291.9	295.5	305.7	307.1	340.9
ICN339F	201.6	214.7	227.4	240.0	239.9	261.7	265.5	273.2	284.6	272.8	285.7	288.2	289.9
MEAN	210.1	226.4	233.5	249.0	258.6	274.3	279.2	282.8	289.9	293.5	300.2	302.8	307.3
STD. DEV.	6.8	9.4	9.4	14.3	11.6	12.4	14.3	18.9	13.4	20.2	18.9	18.2	24.1
N	10	10	10	9	9	9	9	9	9	9	9	9	9

NOTE: X = ANIMAL DEAD

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

APPENDIX D - INDIVIDUAL BODY WEIGHT (CONT'D)
(GRAMS)
DOSE: 40 MG/KG

	TIME- 8 4	9 1
	D A Y S	D A Y S
ICN303M	470.5	467.9
ICN290M	466.2	464.2
ICN285M	547.3	558.8
ICN293M	605.9	579.3
ICN291M	465.1	464.4
ICN328M	484.9	486.5
ICN315M	630.3	642.0
ICN311M	541.2	552.4
ICN299M	386.0	389.4
ICN319M	447.4	452.4
MEAN	504.5	505.7
STD.DEV.	75.4	75.0
N	10	10
ICN340F	334.0	328.0
ICN364F	305.6	307.3
ICN351F	323.8	314.2
ICN343F	276.8	280.0
ICN337F	311.9	311.0
ICN350F	X	
ICN389F	309.5	306.0
ICN363F	300.1	300.4
ICN366F	335.0	333.9
ICN339F	301.7	292.3
MEAN	310.9	308.1
STD.DEV.	18.3	16.6
N	9	9

NOTE: X = ANIMAL DEAD

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

APPENDIX D - INDIVIDUAL BODY WEIGHT (CONT'D)
(GRAMS)
DOSE: 80 MG/KG

TIME=	P R E	0	7	1 4	2 1	2 8	3 5	4 2	4 9	5 6	6 3	7 0	7 7
T E S T	D A Y S	D A Y S	D A Y S	D A Y S	D A Y S	D A Y S	D A Y S	D A Y S	D A Y S	D A Y S	D A Y S	D A Y S	D A Y S
ICN322M	206.8	257.9	284.5	323.0	349.6	386.6	407.8	416.0	430.6	441.6	464.0	479.8	491.1
ICN313M	207.4	258.1	293.0	322.0	340.7	350.7	374.6	392.9	406.9	413.0	429.8	448.5	456.6
ICN304M	211.7	255.7	279.8	322.0	346.2	371.8	399.0	415.5	431.3	439.9	453.8	466.5	477.6
ICN320M	212.5	250.8	272.3	330.0	368.6	405.0	431.4	445.3	469.5	482.2	490.8	498.9	510.4
ICN317M	218.6	257.6	292.7	326.0	348.4	367.0	392.3	395.9	422.5	441.7	458.8	468.1	494.5
ICN333M	224.9	282.4	314.7	364.0	403.8	437.9	462.6	473.8	481.0	497.5	520.7	534.3	546.0
ICN277M	227.5	280.3	305.1	334.0	368.5	394.0	427.6	441.0	459.7	476.2	495.9	506.2	515.7
ICN329M	230.7	269.2	271.7	301.0	314.4	337.1	351.7	367.4	382.0	393.2	404.2	411.0	416.7
ICN284M	232.2	285.4	318.2	372.0	408.7	443.1	474.4	485.0	507.2	525.2	548.0	564.6	581.5
ICN283M	234.7	283.6	327.8	368.0	407.5	433.8	456.7	465.6	484.6	498.9	498.8	515.7	524.6
MEAN	220.7	268.1	296.0	336.2	365.6	392.7	417.8	429.8	447.5	460.9	476.5	489.4	501.5
STD.DEV.	10.6	13.6	19.7	23.6	32.1	37.1	39.9	38.6	39.2	41.7	42.9	44.3	46.1
N	10	10	10	10	10	10	10	10	10	10	10	10	10
ICN360F	216.8	228.9	239.3	X									
ICN381F	209.6	225.6	232.0	237.0	242.5	259.5	265.5	262.4	258.9	269.2	276.7	277.8	271.4
ICN362F	215.0	233.0	239.7	235.0	254.4	269.9	280.0	297.1	282.5	292.7	300.3	308.2	316.6
ICN376F	213.0	232.3	241.9	261.0	267.4	282.2	284.8	292.5	296.6	300.0	300.7	307.6	319.2
ICN338F	206.2	223.6	235.4	252.0	259.6	277.3	275.2	290.3	287.7	304.5	312.8	316.3	319.7
ICN384F	203.7	215.1	224.4	234.0	239.7	255.5	254.1	262.5	260.2	271.3	264.0	278.0	279.7
ICN367F	198.9	220.6	222.6	231.0	238.3	244.8	254.2	264.4	272.0	277.8	269.6	277.9	281.6
ICN392F	211.2	226.4	241.6	244.0	262.6	273.4	280.1	281.6	276.7	289.6	292.8	298.3	296.9
ICN356F	218.4	227.0	247.8	263.0	264.8	272.4	288.0	293.4	295.0	292.3	300.7	308.6	309.8
ICN390F	200.8	211.4	231.0	248.0	254.3	259.4	272.9	282.1	289.2	282.4	295.1	303.2	298.0
MEAN	209.4	224.4	235.6	245.0	253.7	266.0	272.8	280.7	279.9	286.6	290.3	297.3	299.2
STD.DEV.	6.8	7.0	8.1	11.8	11.1	12.0	12.4	14.1	14.0	12.3	16.4	15.3	18.4
N	10	10	10	9	9	9	9	9	9	9	9	9	9

NOTE: X - ANIMAL DEAD

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

APPENDIX D - INDIVIDUAL BODY WEIGHT (CONT'D)
(GRAMS)
DOSE: 80 MG/KG

TIME=	8	9
	4	1
	D	D
	A	A
	Y	Y
	S	S
ICN322M	508.4	519.6
ICN313M	456.9	455.0
ICN304M	481.3	487.2
ICN320M	519.9	532.6
ICN317M	X	
ICN333M	553.5	563.6
ICN277M	517.6	522.4
ICN329M	427.5	426.1
ICN284M	601.2	603.7
ICN283M	525.7	539.2
MEAN	510.2	516.6
STD.DEV.	51.3	54.1
N	9	9
ICN360F	X	
ICN381F	284.2	281.3
ICN362F	316.6	325.5
ICN376F	317.1	312.7
ICN338F	311.1	326.0
ICN384F	285.5	280.8
ICN367F	288.0	297.0
ICN392F	304.3	299.5
ICN356F	306.4	305.1
ICN390F	298.3	303.5
MEAN	301.3	303.5
STD.DEV.	13.0	16.4
N	9	9

NOTE: X - ANIMAL DEAD

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

APPENDIX D - INDIVIDUAL BODY WEIGHT (CONT'D)
(GRAMS)
DOSE: 80 MG/KG (SATELLITE)

TIME=	P R E	0	7	1 4	2 1	2 8	3 5	4 2	4 9	5 6	6 3	7 0	7 7
	T E S T	D A Y S	D A Y S	D A Y S	D A Y S	D A Y S	D A Y S	D A Y S	D A Y S	D A Y S	D A Y S	D A Y S	D A Y S
ICN296M	203.9	247.3	265.4	292.0	311.0	328.2	346.7	342.9	352.7	366.9	380.6	411.6	427.7
ICN326M	208.6	261.7	292.2	328.0	356.0	378.6	422.7	438.0	462.6	476.8	494.4	514.1	521.0
ICN275M	209.9	252.7	291.4	329.0	366.3	396.0	422.8	440.8	455.1	467.6	483.0	501.2	506.0
ICN307M	215.2	261.0	314.2	360.0	394.5	427.5	462.1	477.0	504.0	521.5	546.8	554.5	573.3
ICN280M	219.7	257.3	292.1	327.0	354.3	394.7	419.8	443.8	452.1	474.9	498.6	512.6	529.8
ICN309M	225.9	276.0	316.6	346.0	372.8	407.4	427.0	437.3	462.5	479.3	501.3	513.7	536.1
ICN298M	227.0	276.4	318.4	347.0	369.0	399.1	432.9	442.9	455.5	472.5	492.3	513.1	528.3
ICN292M	229.0	274.4	311.2	355.0	388.6	412.3	434.3	449.7	466.7	479.0	489.7	506.2	517.6
ICN332M	231.7	284.4	308.7	350.0	384.3	412.9	436.9	444.4	458.2	471.6	488.7	500.9	512.7
ICN316M	236.5	285.6	304.2	333.0	344.5	374.5	408.8	411.9	427.0	436.5	457.2	462.9	476.4
MEAN	220.7	267.7	301.4	336.7	364.1	393.1	421.4	432.9	449.6	464.7	483.3	499.1	512.9
STD.DEV.	11.0	13.4	16.4	19.7	24.5	27.8	29.8	35.3	38.9	40.0	42.3	37.9	38.6
N	10	10	10	10	10	10	10	10	10	10	10	10	10
ICN358F	218.0	233.5	240.0	245.0	257.6	271.5	278.7	279.8	290.6	286.5	294.5	297.0	298.3
ICN352F	208.0	212.9	224.4	233.0	234.5	260.8	260.4	271.8	280.5	274.2	295.3	290.3	292.0
ICN346F	215.3	237.6	248.7	260.0	275.1	294.0	297.8	297.4	313.3	314.5	319.1	315.1	325.8
ICN344F	212.3	224.7	231.4	240.0	269.1	282.3	281.1	296.6	302.8	318.3	309.0	324.9	328.1
ICN386F	204.3	203.1	225.6	237.0	239.5	247.8	256.6	257.2	271.8	269.7	276.9	287.4	276.7
ICN375F	202.2	219.7	232.9	250.0	263.0	274.3	280.6	285.3	288.6	295.0	298.5	307.1	308.2
ICN397F	199.7	202.1	232.3	235.0	249.2	256.5	268.5	268.0	273.7	288.4	283.9	295.9	298.7
ICN380F	212.0	234.9	244.5	247.0	262.0	279.5	287.3	290.1	300.4	305.4	310.5	310.7	316.7
ICN347F	219.9	230.9	238.9	248.0	256.7	282.3	286.3	292.6	303.5	304.7	300.6	303.6	316.2
ICN371F	201.7	217.9	230.6	251.0	264.5	274.3	279.1	291.4	284.8	290.6	296.3	282.0	316.3
MEAN	209.3	221.7	234.9	244.6	257.1	272.3	277.6	283.0	291.0	294.7	298.5	301.4	307.7
STD.DEV.	7.2	12.8	7.9	8.4	12.8	13.8	12.6	13.5	13.8	16.1	12.4	13.4	16.2
N	10	10	10	10	10	10	10	10	10	10	10	10	10

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

APPENDIX D - INDIVIDUAL BODY WEIGHT (CONT'D)
(GRAMS)
DOSE: 80 MG/KG (SATELLITE)

TIME= 8	9	1	1	1	1
4	1	0	0	1	2
		0	7	4	0
D	D	D	D	D	D
A	A	A	A	A	A
V	V	V	V	V	V
S	S	S	S	S	S
ICN296M	426.1	428.5	454.5	472.4	494.0
ICN326M	533.3	531.9	546.0	565.2	576.7
ICN275M	433.9	X			
ICN307M	586.0	597.7	606.7	624.7	640.9
ICN280M	532.1	549.0	554.9	572.9	596.7
ICN309M	541.3	556.4	566.8	586.8	601.5
ICN298M	538.3	546.5	559.8	560.9	598.3
ICN292M	526.4	535.8	543.6	569.7	587.3
ICN332M	518.7	523.7	534.2	556.1	573.0
ICN316M	482.0	490.0	516.7	550.1	574.5
MEAN	511.8	528.8	542.6	562.1	582.5
STD.DEV.	50.0	47.3	41.3	40.2	39.2
N	10	9	9	9	9
ICN358F	300.5	304.7	311.8	309.2	312.2
ICN352F	296.7	285.3	305.1	310.3	310.5
ICN346F	322.2	314.4	341.7	344.0	350.0
ICN344F	333.1	322.9	371.3	376.9	358.7
ICN386F	285.7	284.6	289.9	279.2	276.9
ICN375F	301.5	302.4	322.0	328.5	330.4
ICN397F	298.2	304.8	317.6	306.8	308.7
ICN380F	325.3	297.8	325.6	328.5	324.4
ICN347F	322.4	320.6	345.5	344.3	338.4
ICN371F	305.7	306.1	318.3	304.1	305.4
MEAN	309.1	304.4	324.9	323.2	321.6
STD.DEV.	15.5	13.0	23.0	27.4	24.0
N	10	10	10	10	10

NOTE: X = ANIMAL DEAD

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

APPENDIX E - INDIVIDUAL FOOD CONSUMPTION
(GRAMS)
DOSE: 0 MG/KG

TIME=	1	2	3	4	5	6	7	8	9	10	11	12	13
	WEEKS	WEEKS	WEEKS	WEEKS	WEEKS	WEEKS	WEEKS	WEEKS	WEEKS	WEEKS	WEEKS	WEEKS	WEEKS
ICN297M	180.8	185.7	192.2	X	204.7	201.0	208.0	206.3	206.4	213.0	206.2	212.1	203.1
ICN287M	180.8	207.5	207.6	206.0	226.8	218.5	215.5	189.8	179.2	182.3	200.6	186.2	182.9
ICN295M	195.5	206.0	209.6	216.9	193.7	198.6	207.3	211.8	223.7	221.4	214.9	213.1	213.4
ICN289M	187.5	190.9	187.3	199.1	192.9	197.9	213.8	216.9	222.9	203.2	229.3	229.6	212.6
ICN294M	187.8	197.0	200.4	194.1	192.9	197.9	213.8	216.9	222.9	203.2	229.3	229.6	212.6
ICN279M	179.8	202.2	212.5	214.0	207.6	203.5	220.6	230.1	225.0	S	215.4	224.7	219.1
ICN278M	184.8	189.4	188.9	188.6	181.3	186.7	193.4	195.1	204.2	199.1	206.9	208.8	192.4
ICN314M	166.3	190.6	197.9	193.2	190.1	192.9	S	177.4	191.5	183.0	183.1	189.4	196.3
ICN323M	200.3	207.6	202.3	198.6	192.2	202.7	208.6	204.6	212.5	207.3	212.2	210.5	210.3
ICN305M	189.9	194.6	185.4	186.9	184.6	187.4	195.8	203.3	198.2	199.7	200.1	200.0	200.0
MEAN	185.9	197.2	198.4	199.7	197.1	198.8	207.9	203.9	207.1	201.1	207.6	208.3	203.3
STD.DEV.	9.8	8.2	9.7	10.6	14.0	9.6	9.3	15.4	15.8	13.5	12.8	14.5	11.6
N	9	10	10	9	9	9	8	9	9	8	9	9	9
ICN396F	140.7	147.8	146.3	158.4	155.6	150.9	146.1	148.2	168.6	164.7	159.1	163.6	171.2
ICN398F	139.2	150.7	139.2	135.4	128.0	122.6	123.6	130.8	140.7	143.2	141.8	142.2	144.7
ICN372F	138.0	146.6	129.4	145.0	134.9	149.8	138.0	138.8	154.1	150.1	155.7	158.6	143.3
ICN379F	129.9	163.4	147.9	149.2	143.6	140.0	169.7	177.9	137.8	152.1	171.6	172.0	164.5
ICN365F	142.2	148.1	140.0	143.5	137.9	131.5	138.5	139.5	150.6	143.8	142.5	141.1	153.2
ICN378F	122.5	130.4	123.2	126.0	127.5	127.1	128.0	128.8	137.1	131.7	134.7	132.4	134.9
ICN377F	130.1	150.3	133.2	159.8	139.7	143.5	S	181.4	150.8	158.7	166.3	163.7	155.0
ICN355F	128.8	143.8	141.1	145.6	127.3	142.4	150.2	134.9	150.9	134.5	138.6	150.9	133.2
ICN394F	136.6	143.5	148.0	158.7	152.2	143.3	151.5	163.9	164.7	162.2	164.2	174.9	151.7
ICN373F	132.4	142.0	129.0	158.7	133.0	139.7	139.7	131.4	166.5	153.7	147.9	167.4	167.1
MEAN	134.0	146.7	137.7	146.8	138.0	139.1	142.8	147.6	152.2	149.5	152.2	156.7	151.9
STD.DEV.	6.3	8.3	8.7	11.3	10.0	9.3	13.7	19.8	11.6	11.1	12.9	14.4	13.1
N	10	10	10	9	10	10	9	10	10	10	10	10	10

NOTE: X = ANIMAL DEAD
S = EXCESSIVE SPILLAGE
R = REPLACEMENT ANIMAL; 6-DAY MEASUREMENT TAKEN = EXCESSIVE SPILLAGE

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

APPENDIX E - INDIVIDUAL FOOD CONSUMPTION (CONT'D)

	(GRAMS)												
	DOSE: 10 MG/KG												
TIME-	1	2	3	4	5	6	7	8	9	10	11	12	13
	WEEKS	WEEKS	WEEKS	WEEKS	WEEKS	WEEKS	WEEKS	WEEKS	WEEKS	WEEKS	WEEKS	WEEKS	WEEKS
ICN318M	176.0	184.4	186.3	195.6	205.7	194.7	195.8	206.1	213.3	212.4	213.2	223.1	206.7
ICN310M	175.7	193.2	191.9	190.8	197.1	193.7	205.7	210.8	212.1	201.4	206.6	204.8	209.7
ICN273M	186.5	198.1	208.6	214.2	199.2	198.9	197.7	203.3	225.0	215.9	207.0	221.9	200.0
ICN302M	185.8	191.4	183.0	177.0	170.0	169.0	179.3	200.0	209.2	206.6	202.9	200.0	161.1
ICN306M	193.1	216.7	219.3	219.1	219.3	217.6	235.9	236.7	238.6	238.4	S	241.9	255.0
ICN276M	184.7	191.0	S	218.7	S	217.0	S	S	227.8	201.7	207.1	204.8	205.9
ICN300M	185.4	183.2	181.3	179.0	177.8	182.6	180.8	170.8	170.7	163.3	181.9	183.2	175.7
ICN335M	227.8	253.2	262.0	248.6	246.4	244.5	244.8	254.3	S	264.9	262.3	260.6	239.7
ICN321M	190.6	213.6	213.8	205.2	203.0	207.5	220.5	215.5	228.7	219.7	230.2	229.3	217.3
ICN330M	192.3	212.4	215.3	209.8	224.9	229.2	233.0	229.4	213.7	225.9	231.1	233.5	227.5
MEAN	189.8	203.7	206.8	205.8	204.8	205.5	210.4	214.1	215.5	215.0	215.8	220.3	209.9
STD.DEV.	14.6	21.2	25.5	21.4	23.4	22.4	24.2	24.1	19.4	26.4	22.8	22.7	27.8
N	10	10	9	10	9	10	9	9	9	10	9	10	10
ICN353F	134.6	137.8	131.6	149.3	142.0	138.1	143.2	146.9	149.2	152.3	147.9	147.2	146.7
ICN342F	134.1	145.2	149.2	154.0	143.5	145.9	140.7	138.7	142.3	137.3	139.9	142.5	140.5
ICN345F	133.7	139.7	134.5	135.6	130.2	145.3	141.0	143.0	162.4	152.9	169.9	168.5	162.9
ICN348F	134.7	142.6	137.0	151.1	142.3	138.6	146.1	139.2	149.8	145.4	154.5	143.0	143.6
ICN388F	141.5	156.3	142.9	142.5	126.3	84.1	S	S	157.7	162.8	149.9	163.0	148.7
ICN341F	122.6	130.1	132.2	135.0	129.7	131.7	126.0	135.5	131.5	137.1	142.6	137.9	136.1
ICN385F	126.2	135.6	124.2	128.1	130.9	131.5	139.8	136.1	149.3	129.8	138.8	146.5	142.1
ICN361F	139.7	150.2	141.6	145.9	154.6	156.2	152.3	147.5	144.0	146.4	155.1	147.4	138.4
ICN370F	143.6	153.8	160.2	162.1	156.8	156.7	167.1	153.3	168.7	S	168.1	159.0	158.6
ICN395F	120.2	135.5	133.2	157.8	136.3	145.7	154.5	142.5	158.2	159.5	157.4	152.1	152.3
MEAN	133.1	142.7	138.6	146.1	139.3	135.6	145.6	142.5	151.3	147.1	152.4	150.7	147.0
STD.DEV.	7.9	8.6	10.3	10.9	10.5	19.5	11.5	5.9	10.8	11.0	10.8	9.8	8.7
N	10	10	10	10	10	10	9	9	10	9	10	10	10

NOTE: S = EXCESSIVE SPILLAGE

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

APPENDIX E - INDIVIDUAL FOOD CONSUMPTION (CONT'D)
(GRAMS)

DOSE: 40 MG/KG

TIME=	1	2	3	4	5	6	7	8	9	10	11	12	13
	WEEKS	WEEKS	WEEKS	WEEKS	WEEKS	WEEKS	WEEKS	WEEKS	WEEKS	WEEKS	WEEKS	WEEKS	WEEKS
ICN303M	173.2	173.9	171.8	175.8	176.0	167.0	189.9	183.5	194.7	190.7	191.2	199.0	188.5
ICN290M	157.4	181.5	186.1	197.1	185.3	184.1	197.7	190.9	195.0	194.5	191.9	186.9	190.6
ICN285M	182.4	200.6	198.1	199.3	201.3	206.9	213.3	218.6	225.3	216.5	206.1	213.8	208.1
ICN293M	194.6	219.6	223.9	228.7	224.2	218.1	226.5	230.4	238.7	243.3	226.6	229.9	191.5
ICN291M	192.2	193.2	198.1	199.4	206.5	208.9	212.3	218.4	185.7	208.7	193.4	207.1	200.9
ICN328M	191.6	192.7	185.6	189.0	187.9	183.6	187.5	198.8	191.2	196.5	193.1	196.5	193.4
ICN315M	204.0	225.1	221.9	233.1	220.8	226.1	234.9	238.7	242.0	237.4	221.1	226.6	215.1
ICN311M	181.6	195.9	205.6	213.2	215.1	206.8	225.9	221.9	225.7	232.4	225.1	226.6	215.1
ICN299M	167.5	185.2	181.2	175.8	152.2	138.0	144.9	199.2	207.6	165.8	196.3	173.1	162.6
ICN319M	188.8	205.0	196.6	192.9	190.8	177.3	193.9	199.2	207.6	194.6	196.3	194.1	200.5
MEAN	183.3	197.3	196.9	200.4	196.0	191.7	202.7	211.2	211.8	208.0	205.0	203.0	194.6
STD.DEV.	14.0	16.1	16.8	19.6	22.2	26.8	26.2	18.8	21.5	24.4	15.2	18.4	14.9
N	10	10	10	10	10	10	10	9	9	10	9	9	9
ICN340F	129.1	144.8	144.2	159.5	157.1	161.4	164.0	167.6	175.8	168.6	172.2	162.3	164.9
ICN364F	138.0	140.8	135.0	139.6	S	139.9	156.2	148.9	159.9	156.1	150.7	156.2	154.9
ICN351F	132.4	143.0	143.4	150.4	146.9	151.6	149.7	155.1	160.2	155.9	158.3	159.9	152.2
ICN343F	112.9	140.2	149.2	142.6	S	138.2	146.4	140.5	143.0	151.3	139.0	150.9	145.2
ICN337F	113.3	135.6	139.0	139.1	147.3	137.8	151.5	148.3	153.3	154.7	147.8	147.2	151.3
ICN350F	137.6	X											
ICN389F	137.8	149.4	143.0	136.8	143.6	139.6	151.4	150.6	146.6	150.6	141.8	157.5	156.2
ICN363F	127.4	137.7	135.5	148.3	138.7	131.3	143.1	140.0	146.6	142.0	141.6	146.8	141.3
ICN366F	150.4	150.6	154.6	148.0	150.4	153.6	150.5	151.2	164.8	156.6	182.8	188.2	153.9
ICN339F	127.2	141.6	131.2	145.1	140.7	137.6	149.8	131.7	145.1	141.4	141.8	151.5	137.2
MEAN	130.6	142.6	141.7	145.5	146.4	143.4	151.4	148.2	155.0	153.0	152.9	157.8	150.8
STD.DEV.	11.5	5.0	7.4	7.0	6.2	9.7	5.9	10.2	11.0	8.2	15.4	12.6	8.4
N	10	9	9	9	7	9	9	9	9	9	9	9	9

NOTE: X = ANIMAL DEAD
S = EXCESSIVE SPILLAGE

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

APPENDIX E - INDIVIDUAL FOOD CONSUMPTION (CONT'D)

(GRAMS)
DOSE: 80 MG/KG

TIME=	1	2	3	4	5	6	7	8	9	10	11	12	13
	WEEKS	WEEKS	WEEKS	WEEKS	WEEKS	WEEKS	WEEKS	WEEKS	WEEKS	WEEKS	WEEKS	WEEKS	WEEKS
ICN322M	181.4	197.9	187.0	192.9	192.6	177.1	179.9	193.5	206.1	196.1	193.6	215.1	214.6
ICN313M	197.8	202.0	193.1	178.1	184.8	189.8	203.2	195.4	204.4	210.6	212.9	209.3	
ICN304M	176.1	198.8	202.5	210.2	212.4	208.8	221.9	220.3	224.4	222.2	218.7	219.9	216.9
ICN320M	169.2	204.9	212.2	216.0	214.6	208.0	220.3	220.7	223.3	214.6	214.3	211.1	214.3
ICN317M	187.0	221.2	200.0	204.3	223.2	212.3	186.0	233.2	230.9	219.8	240.0	X	
ICN333M	191.2	208.0	212.2	219.3	217.8	195.3	220.5	196.1	205.8	207.3	198.2	S	188.2
ICN277M	179.8	187.2	186.4	197.3	199.6	198.1	220.5	218.9	224.4	207.2	204.1	204.6	195.2
ICN329M	168.2	181.8	176.7	185.6	177.6	178.2	192.6	191.2	199.3	191.3	189.3	192.9	169.9
ICN284M	183.2	217.5	229.2	224.6	230.3	213.3	230.4	233.0	249.2	244.3	251.1	241.4	235.9
ICN283M	198.3	219.0	231.4	226.3	218.0	198.3	220.6	221.1	217.8	220.2	220.2	224.6	228.7
MEAN	183.2	203.8	203.1	205.5	207.1	197.9	208.4	212.3	218.6	213.4	214.2	214.9	208.0
STD.DEV.	10.6	13.2	18.2	16.6	17.5	13.2	18.4	16.6	15.2	14.9	19.7	14.4	22.0
N	10	10	10	10	10	10	9	10	10	10	10	8	8
ICN360F	131.1	X	132.0	147.6	137.8	133.1	127.8	132.8	141.3	139.9	131.7	149.8	140.5
ICN381F	129.3	132.2	133.7	141.1	147.6	149.2	139.3	142.4	138.5	147.6	147.3	153.0	152.5
ICN362F	128.6	123.9	133.7	141.1	147.6	149.2	139.3	142.4	138.5	147.6	147.3	153.0	152.5
ICN376F	135.0	148.1	140.8	152.1	154.1	150.3	145.0	144.4	145.4	155.6	156.9	154.4	152.6
ICN388F	136.2	142.4	142.4	146.6	145.6	150.8	147.8	154.1	169.4	154.7	160.9	156.8	163.2
ICN384F	121.9	134.8	134.0	138.2	132.6	132.7	140.1	148.4	S	146.4	152.0	156.3	151.7
ICN367F	130.1	131.5	126.0	137.3	138.5	138.2	136.9	141.7	141.8	141.0	150.8	158.5	S
ICN392F	143.3	141.1	150.8	158.9	152.2	152.4	148.9	162.4	164.4	158.9	150.8	159.3	161.8
ICN356F	145.2	152.6	151.7	150.0	159.3	148.4	150.0	151.9	159.3	154.8	151.9	154.1	155.3
ICN390F	139.9	159.2	143.9	153.3	155.1	154.0	166.6	163.8	S	159.1	S	S	S
MEAN	134.1	140.6	139.5	147.2	147.0	145.5	144.7	149.1	151.4	150.9	150.3	155.3	153.9
STD.DEV.	7.3	11.3	8.7	7.3	9.1	8.4	10.8	10.1	12.6	7.4	8.6	3.1	7.5
N	10	9	9	9	9	9	9	9	7	9	8	8	7

NOTE: X = ANIMAL DEAD
S = EXCESSIVE SPILLAGE

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

APPENDIX E - INDIVIDUAL FOOD CONSUMPTION (CONT'D)

(GRAMS)
DOSE: 80 (SATELLITE) MG/KG

TIME=	1	2	3	4	5	6	7	8	9	10	11	12	13
	WEEKS	WEEKS	WEEKS	WEEKS	WEEKS	WEEKS	WEEKS	WEEKS	WEEKS	WEEKS	WEEKS	WEEKS	WEEKS
ICN296M	167.1	178.7	164.1	160.3	160.5	156.8	157.8	173.7	173.6	190.9	184.5	174.0	169.7
ICN326M	169.9	191.5	193.0	183.3	199.6	201.8	227.9	S	S	S	215.0	214.7	207.4
ICN275M	184.9	199.2	204.9	215.2	205.4	207.9	231.7	218.7	S	230.8	226.7	142.7	X
ICN307M	201.2	220.8	220.2	222.9	224.5	219.2	237.5	237.5	241.2	233.5	221.6	235.6	231.8
ICN280M	181.1	197.9	187.6	206.9	209.7	212.5	215.5	215.8	230.0	229.6	227.7	214.3	226.7
ICN309M	186.8	190.2	188.0	194.9	191.3	181.6	206.2	210.0	210.6	214.1	214.6	214.6	206.1
ICN298M	10.5\$0	199.3	190.5	193.4	200.2	187.9	202.2	201.2	208.3	210.0	219.5	209.8	195.9
ICN292M	190.0	184.6	208.3	201.2	193.1	192.6	209.5	208.0	200.9	203.2	210.0	213.7	210.0
ICN332M	190.3	203.2	207.7	208.3	213.9	201.2	210.0	218.5	226.1	219.6	215.7	220.7	207.2
ICN316M	176.8	190.0	179.3	194.3	203.1	187.0	200.6	199.6	212.6	205.9	216.4	215.2	216.3
MEAN	183.1	195.5	194.4	198.1	200.1	194.9	209.9	209.2	212.9	215.3	215.2	205.5	207.9
STD.DEV.	10.7	11.6	16.3	17.6	17.0	18.0	22.3	17.5	20.6	14.4	12.1	26.9	18.1
N	9	10	10	10	10	10	10	9	8	9	10	10	9
ICN358F	134.9	145.3	144.7	157.7	156.0	159.1	159.4	157.8	165.3	159.7	166.4	161.8	155.7
ICN352F	128.1	139.2	138.2	157.7	144.3	155.4	157.6	155.7	166.3	153.4	160.8	161.6	151.9
ICN346F	131.7	139.6	143.4	154.7	150.1	142.7	152.6	144.5	146.7	141.7	154.8	145.1	146.3
ICN344F	131.1	146.1	155.0	163.8	163.9	159.5	154.8	166.2	166.8	166.0	178.7	164.4	162.2
ICN386F	131.8	139.5	118.0	137.9	131.3	154.1	137.3	142.0	140.3	145.2	137.3	147.2	147.6
ICN375F	139.2	143.9	148.8	153.9	157.9	154.4	153.1	156.2	159.7	159.1	158.1	152.6	155.8
ICN397F	135.5	141.3	137.0	142.1	140.5	142.0	155.1	150.3	S	154.8	152.6	155.8	156.5
ICN380F	137.5	148.7	153.5	163.7	155.8	165.8	155.8	170.4	170.7	157.8	156.2	159.5	146.5
ICN347F	130.0	129.3	S	164.3	150.6	147.9	148.5	144.7	141.1	138.8	162.2	S	155.6
ICN371F	136.1	150.0	148.4	150.6	153.1	S	148.9	155.9	164.3	114.2	181.3	145.5	166.5
MEAN	133.6	142.3	143.0	154.6	150.4	153.4	151.9	154.4	157.9	149.1	160.8	154.8	154.9
STD.DEV.	3.6	6.0	11.2	9.0	9.5	7.9	6.5	9.3	11.9	15.0	12.7	7.5	6.6
N	10	10	9	10	10	9	9	10	9	10	10	9	10

NOTE: S = EXCESSIVE SPILLAGE
O = OUTLIER
\$ = VALUE EXCLUDED FROM CALCULATIONS

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

APPENDIX E - INDIVIDUAL FOOD CONSUMPTION (CONT'D)
(GRAMS)
DOSE: 80 (SATELLITE) MG/KG (CONT'D)

TIME=	1 4	1 5	1 6	1 7
WEEKS	WEEKS	WEEKS	WEEKS	WEEKS
ICN296M	234.2	209.2	201.2	159.9
ICN326M	233.6	228.7	213.1	173.0
ICN275M	X			
ICN307M	246.4	237.7	235.4	177.6
ICN280M	247.1	236.7	233.1	162.5
ICN309M	236.3	232.0	225.5	173.4
ICN298M	245.6	226.0	229.1	174.7
ICN292M	215.4	218.5	208.8	166.2
ICN332M	234.7	245.0	226.5	176.0
ICN316M	251.4	251.0	238.1	185.9
MEAN	238.3	231.6	223.4	172.1
STD.DEV.	10.9	12.9	12.8	8.1
N	9	9	9	9
ICN358F	192.7	160.0	152.8	128.4
ICN352F	199.6	168.8	150.8	130.8
ICN346F	192.3	172.2	165.5	131.3
ICN344F	243.1	233.3	152.6	130.8
ICN386F	178.2	138.6	132.2	109.7
ICN375F	194.2	172.8	160.1	137.9
ICN397F	174.7	152.7	152.1	128.1
ICN380F	188.5	157.2	142.4	117.6
ICN347F	196.4	172.5	165.4	139.0
ICN371F	182.4	153.4	142.7	119.8
MEAN	194.2	168.2	151.7	127.3
STD.DEV.	19.0	25.4	10.5	9.1
N	10	10	10	10

NOTE: X - ANIMAL DEAD

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

APPENDIX F - OPHTHALMOLOGICAL FINDINGS

DIPLOMATE, AMERICAN COLLEGE
OF VETERINARY OPHTHALMOLOGISTS

JAMES M. CLINTON, V. M. D.
ANIMAL EYE CLINIC AT SOUTH JERSEY ANIMAL HOSPITAL
ROUTE 541 ABOVE CHURCH ROAD -- P. O. BOX 118
MEDFORD, NEW JERSEY 08055
TELEPHONE (609) 654-0304

EXXON
Study: 139910B
Gary Trimmer, Study Director

Examination Date:
24 November 1992

Pre-dosing Ophthalmoscopic Examination Summary

Both eyes of all of the Crl:CD BR rats selected for eye examinations were examined by focal illumination and indirect ophthalmoscopy. Mydriasis was produced prior to examining the rats eyes and the eyes were examined in subdued light.

Lesions were identified in the following rats:

<u>Rat No.</u>	<u>Sex</u>	<u>Observations</u>
ICN301	Male	Right Eye: Mid-vitreous hemorrhage.
ICN336	Male	Right Eye: Mid-vitreous hemorrhage.

Comments

Ideally, the two rats listed above should not be included in the forthcoming study. The remaining rats are ophthalmoscopically normal and are suitable for inclusion in the forthcoming study.

Certified Original Copy:
James M. Clinton

James M. Clinton, V.M.D.

26 August 1993

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

APPENDIX F - OPHTHALMOLOGICAL FINDINGS (CONT'D)

DIPLOMATE, AMERICAN COLLEGE
OF VETERINARY OPHTHALMOLOGISTS

JAMES M. CLINTON, V. M. D.
ANIMAL EYE CLINIC AT SOUTH JERSEY ANIMAL HOSPITAL
ROUTE 541 ABOVE CHURCH ROAD -- P. O. BOX 118
MEDFORD, NEW JERSEY 08055
TELEPHONE (609) 654-0304

EXXON
Study: 139910B
G. Trimmer, Study Director

Examination Date:
23 February 1993

Final Ophthalmoscopic Examination Summary

Both eyes of all of the male and female Crl:CD BR rats remaining in the study were examined by focal illumination and indirect ophthalmoscopy. Mydriasis was produced with 1% atropine and the eyes examined in subdued light. The dose levels and group identifications were not disclosed to me until after my examinations. Subdued light was maintained until the following morning.

Lesions were identified in the following rats:

<u>Rat No.</u>	<u>Sex</u>	<u>Observations</u>
ICN372	Female	Left Eye: Focal retinopathy.
ICN319	Male	Left Eye: Focal retinopathy (massive).

Comments

The lesions noted in the two rats described above are not likely to be caused by exposure to an ocular toxicant. At this juncture, there is no evidence to suggest that the test article, as evaluated here, produces ocular changes in Rattus norvegicus.

James M. Clinton
James M. Clinton, V.M.D.
23 February 93

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

APPENDIX G - INDIVIDUAL QUANTITATIVE HEMATOLOGY
(SEE KEY C FOR ABBREVIATIONS)
DOSE: 0 MG/KG

PARAMETERS=	W B C	R B C	H G B	H C T	M C V	M C H	M C H C	P L T	P T	A P T T
UNITS=	x10E3	x10E6	g/dL	%	fl	pg	g/dL	x10E3	sec	sec
ICN297M	X	X	X	X	X	X	X	X	X	X
ICN287M	9.9	9.65	16.7	49.2	51	17.3	34.0	1099	11.5	21.5
ICN295M	12.8	9.38	16.6	48.8	52	17.7	34.0	1197	10.2	20.7
ICN289M	14.2	8.59	15.4	44.8	52	17.9	34.4	1107	10.5	20.3
ICN294M	16.7	8.73	16.1	46.3	53	18.5	34.8	935	10.4	21.3
ICN279M	9.5	8.99	16.2	47.3	53	18.0	34.2	998	10.2	20.5
ICN278M	11.5	9.29	16.4	47.6	51	17.6	34.5	978	9.6	22.8
ICN314M	9.8	7.93	14.9	44.1	56	18.8	33.8	1071	9.9	22.7
ICN323M	11.5	8.91	15.9	47.8	54	17.8	33.3	1084	10.1	19.5
ICN305M	12.5	9.94	16.7	50.7	51	16.8	33.0	898	10.0	21.7
MEAN	12.0	9.05	16.1	47.4	53	17.8	34.0	1041	10.3	21.2
STD.DEV.	2.3	0.60	0.6	2.1	2	0.6	0.6	95	0.5	1.1
N	9	9	9	9	9	9	9	9	9	9
ICN396F	8.5	8.39	15.4	44.3	53	18.3	34.7	1086	9.7	16.6
ICN398F	8.2	6.42	12.4	35.6	56	19.3	34.9	994	9.7	17.2
ICN372F	7.9	7.96	15.3	44.3	56	19.2	34.4	922	9.7	16.2
ICN379F	C	C	C	C	C	C	C	C	9.7	21.0
ICN365F	6.4	7.85	15.4	43.8	56	19.6	35.2	1016	8.2	18.9
ICN378F	14.9	8.20	15.4	44.1	54	18.7	34.8	1279	9.5	17.2
ICN377F	5.8	7.87	15.4	44.7	57	19.6	34.6	1060	9.7	18.8
ICN355F	4.1	7.80	15.1	42.3	54	19.3	35.6	1008	9.2	18.0
ICN394F	7.5	8.89	16.1	48.0	54	18.2	33.7	1030	10.0	20.0
ICN373F	6.1	8.20	15.5	44.3	54	18.9	35.0	1040	C	C
MEAN	7.7	7.95	15.1	43.5	55	19.0	34.8	1048	9.5	18.2
STD.DEV.	3.0	0.67	1.1	3.3	1	0.5	0.5	98	0.5	1.6
N	9	9	9	9	9	9	9	9	9	9

NOTE: X = ANIMAL DEAD
C = CLOTTED SAMPLE

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

APPENDIX G - INDIVIDUAL QUANTITATIVE HEMATOLOGY (CONT'D)
(SEE KEY C FOR ABBREVIATIONS)
DOSE: 10 MG/KG

PARAMETERS-	W B C	R B C	H G B	H C T	M C V	M C H	M C H C	P L T	P T	A P T T
UNITS=	x10E3	x10E6	g/dL	%	fl	pg	g/dL	x10E3	sec	sec
ICN318M	12.8	9.87	17.0	50.7	51	17.2	33.4	1074	10.2	23.6
ICN310M	12.0	9.10	15.1	44.6	49	16.6	33.8	874	9.7	16.6
ICN273M	12.7	8.82	15.5	45.1	51	17.6	34.5	924	10.2	22.2
ICN302M	12.7	8.90	15.9	47.3	53	17.9	33.7	627	9.9	20.7
ICN306M	8.0	9.37	16.7	49.3	53	17.9	33.9	999	10.0	21.8
ICN276M	11.8	9.45	16.5	48.5	51	17.5	34.1	878	10.7	19.3
ICN300M	8.0	9.01	15.7	45.7	51	17.5	34.5	1009	9.9	20.7
ICN335M	9.4	8.36	16.3	47.8	57	19.5	34.1	1069	9.9	20.7
ICN321M	10.4	8.68	16.5	47.8	55	19.0	34.5	943	10.1	21.6
ICN330M	8.8	9.36	16.4	48.2	52	17.5	34.1	919	9.7	22.8
MEAN	10.7	9.09	16.2	47.5	52	17.8	34.1	932	10.0	21.0
STD.DEV.	2.0	0.44	0.6	1.9	2	0.8	0.4	129	0.3	2.1
N	10	10	10	10	10	10	10	10	9	9
ICN353F	7.1	7.83	14.9	42.8	55	19.1	34.9	1187	9.7	18.6
ICN342F	9.2	6.99	12.3	36.0	52	17.6	34.2	876	9.0	16.0
ICN345F	C	C	C	C	C	C	C	C	9.4	20.8
ICN348F	10.6	8.25	15.0	42.9	52	18.1	34.8	870	9.7	16.8
ICN388F	C	C	C	C	C	C	C	C	9.7	17.7
ICN341F	8.1	8.09	15.7	44.7	55	19.4	35.0	971	9.7	16.4
ICN385F	6.5	6.08	12.2	34.7	57	20.1	35.2	898	9.5	18.3
ICN361F	7.9	8.01	15.6	44.2	55	19.5	35.3	1188	C	C
ICN370F	9.4	8.07	14.3	41.3	51	17.7	34.6	1055	9.0	16.0
ICN395F	7.2	8.27	15.0	43.9	53	18.2	34.2	1196	9.3	16.1
MEAN	8.3	7.70	14.4	41.3	54	18.7	34.8	1030	9.6	17.8
STD.DEV.	1.4	0.77	1.4	3.8	2	0.9	0.4	145	0.2	1.6
N	8	8	8	8	8	8	8	8	7	7

NOTE: C = CLOTTED SAMPLE
Q = QUANTITY NOT SUFFICIENT

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

APPENDIX G - INDIVIDUAL QUANTITATIVE HEMATOLOGY (CONT'D)
(SEE KEY C FOR ABBREVIATIONS)
DOSE: 40 MG/KG

PARAMETERS-	W B C	R B C	H G B	H C T	M C V	M C H	M C H C	P L T	P T	A P T T
UNITS-	x10E3	x10E6	g/dL	%	fl	pg	g/dL	x10E3	sec	sec
ICN303M	14.9	7.62	13.7	41.9	55	18.0	32.8	1223	10.0	23.6
ICN290M	13.0	9.90	16.9	50.7	51	17.1	33.4	987	10.3	20.7
ICN285M	C	C	C	C	C	C	C	C	C	C
ICN293M	13.1	8.09	15.4	44.7	55	19.1	34.5	935	10.3	26.3
ICN291M	19.1	8.48	14.7	43.6	51	17.3	33.7	1195	9.6	18.1
ICN328M	15.2	8.87	15.4	46.0	52	17.4	33.5	847	11.0	21.6
ICN315M	10.3	8.45	16.1	46.5	55	19.0	34.6	874	10.6	24.4
ICN311M	15.5	9.03	15.8	46.5	52	17.5	34.1	1153	10.5	23.0
ICN299M	16.8	8.23	14.5	43.0	52	17.6	33.7	1119	10.8	19.3
ICN319M	7.8	9.46	16.1	46.2	49	17.1	34.9	1035	10.6	20.8
MEAN	14.0	8.68	15.4	45.5	52	17.8	33.9	1041	10.4	22.0
STD.DEV.	3.4	0.71	1.0	2.6	2	0.8	0.7	139	0.4	2.6
N	9	9	9	9	9	9	9	9	9	9
ICN340F	14.4	8.35	15.1	43.9	53	18.1	34.3	1378	10.0	18.0
ICN364F	8.8	8.05	14.6	42.7	53	18.1	34.2	929	10.3	18.1
ICN351F	8.7	8.02	15.3	44.4	55	19.0	34.4	1195	9.8	21.3
ICN343F	9.8	7.80	14.8	42.4	54	19.0	34.8	1107	10.0	18.0
ICN337F	15.0	8.17	15.0	42.7	52	18.3	35.1	1305	9.4	18.9
ICN350F	X	X	X	X	X	X	X	X	X	X
ICN389F	9.9	8.69	15.9	46.4	53	18.4	34.4	1131	10.2	17.6
ICN363F	5.4	7.68	15.3	45.0	59	19.9	34.0	965	9.4	15.7
ICN366F	10.1	5.79	11.5	33.4	58	19.9	34.5	517	10.4	14.6
ICN339F	4.9	8.21	15.0	43.0	52	18.3	34.9	1162	9.6	20.2
MEAN	9.7	7.86	14.7	42.7	54	18.8	34.5	1077	9.9	18.0
STD.DEV.	3.4	0.83	1.3	3.7	3	0.7	0.4	254	0.4	2.0
N	9	9	9	9	9	9	9	9	9	9

NOTE: X = ANIMAL DEAD
C = CLOTTED SAMPLE

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

APPENDIX G - INDIVIDUAL QUANTITATIVE HEMATOLOGY (CONT'D)
(SEE KEY C FOR ABBREVIATIONS)
DOSE: 80 MG/KG

PARAMETERS=	W B C	R B C	H G B	H C T	M C V	M C H	M C H C	P L T	P T	A P T T
UNITS=	x10E3	x10E6	g/dL	%	f1	pg	g/dL	x10E3	sec	sec
ICN322M	10.7	9.34	15.5	45.8	49	16.6	33.9	1182	11.2	22.9
ICN313M	10.7	9.12	16.4	47.8	52	18.0	34.4	1064	10.9	21.0
ICN304M	15.2	8.34	15.4	45.5	55	18.4	33.8	1162	11.0	25.9
ICN320M	10.4	8.90	15.7	46.6	52	17.7	33.7	1174	11.2	21.5
ICN317M	X	X	X	X	X	X	X	X	X	X
ICN333M	13.1	7.99	15.3	43.9	55	19.2	34.9	1060	10.8	21.1
ICN277M	9.1	7.27	13.5	39.5	54	18.6	34.3	998	9.9	17.2
ICN329M	16.2	7.48	13.1	39.3	53	17.5	33.3	1534	9.9	22.7
ICN284M	13.4	8.20	14.6	42.5	52	17.8	34.3	1233	11.1	22.7
ICN283M	20.3	8.23	15.4	44.0	53	18.7	35.0	1088	10.8	21.0
MEAN	13.2	8.32	15.0	43.9	53	18.1	34.2	1166	10.9	21.7
STD.DEV.	3.5	0.70	1.1	3.0	2	0.8	0.6	157	0.4	2.4
N	9	9	9	9	9	9	9	9	8	8
ICN360F	X	X	X	X	X	X	X	X	X	X
ICN381F	7.8	7.81	15.2	43.9	56	19.4	34.6	1077	9.2	19.4
ICN362F	6.8	7.51	14.3	42.9	57	19.0	33.3	807	9.8	16.4
ICN376F	7.9	7.85	14.9	43.3	55	19.0	34.5	1230	9.7	19.1
ICN338F	7.0	7.81	14.7	42.3	54	18.8	34.8	992	9.8	17.7
ICN384F	8.2	7.81	14.2	41.5	53	18.1	34.1	1172	10.0	18.6
ICN367F	4.5	7.66	15.4	44.7	58	20.1	34.4	986	9.0	16.9
ICN392F	17.0	7.56	14.5	42.5	56	19.2	34.2	812	9.9	18.5
ICN356F	7.7	8.02	15.1	45.3	56	18.8	33.4	826	10.2	17.2
ICN390F	9.1	8.53	14.9	43.2	51	17.4	34.4	1025	9.8	17.6
MEAN	8.4	7.84	14.8	43.3	55	18.9	34.2	992	9.7	17.9
STD.DEV.	3.5	0.30	0.4	1.2	2	0.8	0.5	155	0.4	1.0
N	9	9	9	9	9	9	9	9	9	9

NOTE: X = ANIMAL DEAD
Q = QUANTITY NOT SUFFICIENT

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

APPENDIX G - INDIVIDUAL QUANTITATIVE HEMATOLOGY (CONT'D)
(SEE KEY C FOR ABBREVIATIONS)
DOSE: 80 MG/KG (SATELLITE) DAY 92/93

PARAMETERS=	W B C	R B C	H G B	H C T	M C V	M C H	M C H C	P L T	P T	A P T T
UNITS=	x10E3	x10E6	g/dL	%	fl	pg	g/dL	x10E3	sec	sec
ICN296M	12.4	8.97	16.2	47.3	53	18.1	34.3	1035	10.4	21.4
ICN326M	22.4	8.61	15.5	45.7	53	18.0	33.9	961	10.8	20.4
ICN275M	X	X	X	X	X	X	X	X	X	X
ICN307M	14.1	8.49	16.0	46.7	55	18.9	34.3	870	9.9	17.6
ICN280M	18.5	9.26	15.5	46.4	50	16.7	33.4	1120	9.9	21.2
ICN309M	13.6	9.32	16.1	47.7	51	17.2	33.7	1200	10.1	21.7
ICN298M	11.1	8.89	16.2	46.3	52	18.2	34.9	809	9.8	18.1
ICN292M	15.8	8.50	15.3	44.6	53	18.0	34.2	1093	10.8	20.7
ICN332M	8.9	8.57	14.8	44.0	51	17.3	33.8	1044	10.9	21.9
ICN316M	16.2	8.00	14.5	43.7	55	18.1	33.1	885	9.0	21.8
MEAN	14.8	8.73	15.6	45.8	53	17.8	34.0	1002	10.2	20.5
STD.DEV.	4.0	0.42	0.6	1.4	2	0.7	0.5	130	0.6	1.6
N	9	9	9	9	9	9	9	9	9	9
ICN358F	11.6	7.87	14.5	42.9	55	18.4	33.8	1103	9.8	15.1
ICN352F	13.5	7.69	14.6	42.1	55	19.0	34.7	1082	9.3	15.4
ICN346F	20.3	7.72	13.9	42.2	55	18.0	32.9	1344	9.0	16.9
ICN344F	6.3	7.77	15.1	43.4	56	19.4	34.7	1073	10.0	17.9
ICN386F	11.6	7.32	13.8	40.3	55	18.9	34.3	1475	9.2	14.8
ICN375F	11.6	6.67	13.3	38.7	58	19.9	34.4	1069	10.0	17.2
ICN397F	7.4	6.11	11.6	33.5	55	19.0	34.7	1022	9.3	18.0
ICN380F	11.3	8.39	15.4	44.9	53	18.4	34.3	1383	9.3	18.8
ICN347F	12.4	7.78	14.3	43.0	55	18.4	33.3	1201	9.7	21.5
ICN371F	9.5	5.80	11.2	31.3	54	19.3	35.7	988	9.1	17.7
MEAN	11.6	7.31	13.8	40.2	55	18.9	34.3	1174	9.5	17.3
STD.DEV.	3.8	0.84	1.4	4.5	1	0.6	0.8	169	0.4	2.0
N	10	10	10	10	10	10	10	10	10	10

NOTE: X = ANIMAL DEAD

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

APPENDIX G - INDIVIDUAL QUANTITATIVE HEMATOLOGY (CONT'D)
(SEE KEY C FOR ABBREVIATIONS)

DOSE: 80 MG/KG (SATELLITE) RECOVERY DAY 121

PARAMETERS=	W B C	R B C	H G B	H C T	M C V	M C H	M C H C	P L T	P T	A P T T
UNITS=	x10E3	x10E6	g/dL	%	fl	pg	g/dL	x10E3	sec	sec
ICN296M	8.6	8.52	15.5	46.6	55	18.2	33.3	1022	10.1	24.1
ICN326M	10.8	8.59	15.3	46.8	55	17.8	32.7	1043	11.0	19.8
ICN275M	X	X	X	X	X	X	X	X	X	X
ICN307M	10.4	8.65	16.0	48.5	56	18.5	33.0	916	9.7	18.5
ICN280M	12.9	9.49	15.5	48.1	51	16.3	32.2	1142	10.6	21.9
ICN309M	9.7	9.16	15.8	46.9	51	17.2	33.6	1106	11.0	25.9
ICN298M	9.0	8.71	15.7	46.2	53	18.0	33.9	811	9.8	17.1
ICN292M	10.8	8.64	15.2	46.6	54	17.6	32.7	1052	9.9	19.1
ICN332M	8.4	8.81	15.4	46.1	52	17.5	33.4	967	10.2	21.9
ICN316M	12.2	8.12	14.4	43.5	54	17.7	33.0	938	9.9	19.2
MEAN	10.3	8.74	15.4	46.6	53	17.6	33.1	1000	10.2	20.8
STD.DEV.	1.6	0.39	0.5	1.4	2	0.6	0.5	103	0.5	2.8
N	9	9	9	9	9	9	9	9	9	9
ICN358F	6.4	8.35	16.2	48.3	58	19.4	33.5	1004	9.8	15.1
ICN352F	4.1	8.11	15.8	46.9	58	19.5	33.7	881	9.1	14.9
ICN346F	8.1	8.40	15.7	48.0	57	18.7	32.7	1276	9.4	15.9
ICN344F	5.6	7.87	15.4	46.9	60	19.6	32.9	1078	9.3	18.0
ICN386F	4.8	8.00	15.7	47.5	59	19.7	33.1	1221	9.2	16.8
ICN375F	12.7	7.94	16.4	49.6	63	20.7	33.1	1069	8.9	19.6
ICN397F	7.9	7.93	15.7	47.4	60	19.8	33.1	1042	8.9	16.9
ICN380F	7.1	8.65	15.8	46.8	54	18.3	33.8	1361	8.8	17.0
ICN347F	10.2	8.12	15.2	45.7	56	18.8	33.4	1239	9.0	16.7
ICN371F	4.6	7.91	16.2	48.4	61	20.4	33.4	1067	9.7	17.7
MEAN	7.2	8.13	15.8	47.6	59	19.5	33.3	1124	9.3	16.9
STD.DEV.	2.7	0.26	0.4	1.1	3	0.7	0.3	145	0.4	1.4
N	10	10	10	10	10	10	10	10	10	10

NOTE: X - ANIMAL DEAD

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

APPENDIX H - INDIVIDUAL SEMI-QUANTITATIVE HEMATOLOGY
(SEE KEY C FOR ABBREVIATIONS)
DOSE: 0 MG/KG

PARAMETERS=	N E U T	L Y M P H	M O N O	E O S	B A S O	L U C	A N I S O	M I C R O	M A C R O	V A R	H Y P O	H Y P E R	L S
UNITS=	%	%	%	%	%	%							
ICN297M	X												1
ICN287M	23.4	70.8	1.9	1.3	0.3	2.3							1
ICN295M	34.8	60.0	1.6	1.3	0.3	2.0							0
ICN289M	17.0	77.6	1.4	1.8	0.3	2.0							1
ICN294M	33.9	61.3	0.7	1.5	0.3	2.2							0
ICN279M	15.1	78.8	1.7	1.3	0.3	2.9							0
ICN278M	12.6	81.3	1.8	1.3	0.3	2.8							0
ICN314M	14.5	81.1	1.1	1.6	0.2	1.6							1
ICN323M	36.2	57.8	1.0	3.6	0.2	1.2							0
ICN305M	15.9	79.9	1.0	1.3	0.3	1.7							0
MEAN	22.6	72.1	1.4	1.7	0.3	2.1							0
STD.DEV.	9.7	9.8	0.4	0.7	0.0	0.5	N/A	N/A	N/A	N/A	N/A	N/A	9
N	9	9	9	9	9	9							
ICN396F	20.7	73.7	0.8	3.3	0.2	1.3							1
ICN398F	19.2	75.0	1.1	3.4	0.1	1.2							0
ICN372F	18.8	75.5	1.0	3.1	0.2	1.5							0
ICN379F	C												0
ICN365F	10.8	84.3	0.7	2.9	0.1	1.1							0
ICN378F	9.9	85.8	0.6	2.7	0.4	0.7							0
ICN377F	10.3	84.6	1.4	2.7	0.1	0.9							0
ICN355F	13.5	79.3	0.9	4.2	0.3	1.7							0
ICN394F	14.5	82.1	0.7	1.8	0.2	1.0							0
ICN373F	20.5	75.5	0.7	1.6	0.2	1.5							0
MEAN	15.3	79.5	0.9	2.9	0.2	1.2							0
STD.DEV.	4.5	4.8	0.3	0.8	0.1	0.3	N/A	N/A	N/A	N/A	N/A	N/A	9
N	9	9	9	9	9	9							

NOTE: X - ANIMAL DEAD
C - CLOTTED SAMPLE

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

APPENDIX H - INDIVIDUAL SEMI-QUANTITATIVE HEMATOLOGY (CONT'D)
(SEE KEY C FOR ABBREVIATIONS)
DOSE: 0 MG/KG

PARAMETERS- A
T
Y
P

B
L

UNITS-

ICN297M	X	0
ICN287M	0	0
ICN295M	0	0
ICN289M	0	0
ICN294M	0	0
ICN279M	0	0
ICN278M	0	0
ICN314M	0	0
ICN323M	0	0
ICN305M	0	0
MEAN	0	0
STD. DEV.	0	0
N	9	9
ICN396F	0	0
ICN398F	0	0
ICN372F	0	0
ICN379F	C	0
ICN365F	0	0
ICN378F	0	0
ICN377F	0	0
ICN355F	0	0
ICN394F	0	0
ICN373F	0	0
MEAN	0	0
STD. DEV.	0	0
N	9	9

NOTE: X - ANIMAL DEAD
C - CLOTTED SAMPLE

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

APPENDIX H - INDIVIDUAL SEMI-QUANTITATIVE HEMATOLOGY (CONT'D)
(SEE KEY C FOR ABBREVIATIONS)
DOSE: 10 MG/KG

PARAMETERS=	N E U T	L Y M P H	M O N O	E O S	B A S O	L U C	A N I S O	M I C R O	M A C R O	V A R	H Y P O	H Y P E R	L S
UNITS=	%	%	%	%	%	%							
ICN318M	31.4	64.0	1.3	1.4	0.3	1.5							1
ICN310M	13.8	81.3	0.5	1.3	0.2	2.9							0
ICN273M	11.9	82.8	1.2	1.8	0.2	2.1							0
ICN302M	28.2	67.1	1.1	1.2	0.3	2.0							1
ICN306M	22.4	71.0	1.3	2.7	0.3	2.3							0
ICN276M	14.6	80.0	0.7	2.3	0.4	2.0							0
ICN300M	24.1	71.8	1.1	1.1	0.2	1.5							0
ICN335M	25.4	67.5	1.6	3.0	0.2	2.4							1
ICN321M	18.8	75.6	0.9	2.5	0.2	2.0							0
ICN330M	14.1	82.3	0.6	1.3	0.2	1.5							0
MEAN	20.5	74.3	1.0	1.9	0.3	2.0							0
STD. DEV.	6.8	7.0	0.3	0.7	0.1	0.4	N/A	N/A	N/A	N/A	N/A	N/A	10
N	10	10	10	10	10	10							0
ICN353F	15.1	81.8	0.7	1.1	0.2	1.1							0
ICN342F	17.4	75.3	2.1	1.6	0.1	3.5							0
ICN345F	C												0
ICN348F	13.9	81.2	1.2	2.2	0.3	1.2							0
ICN388F	C												0
ICN341F	28.7	68.2	0.5	1.9	0.1	0.6							0
ICN385F	31.9	61.3	1.3	2.8	0.2	2.4							1
ICN361F	12.9	83.6	0.6	1.2	0.3	1.3							0
ICN370F	32.6	61.9	1.0	2.7	0.2	1.6							1
ICN395F	26.9	65.6	1.4	5.1	0.3	0.7							1
MEAN	22.4	72.4	1.1	2.3	0.2	1.6							1
STD. DEV.	8.4	9.2	0.5	1.3	0.1	1.0	N/A	N/A	N/A	N/A	N/A	N/A	8
N	8	8	8	8	8	8							8

NOTE: C - CLOTTED SAMPLE

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

APPENDIX H - INDIVIDUAL SEMI-QUANTITATIVE HEMATOLOGY (CONT'D)
(SEE KEY C FOR ABBREVIATIONS)
DOSE: 10 MG/KG

PARAMETERS=	A T Y P	B L
UNITS=		
ICN318M	0	0
ICN310M	0	0
ICN273M	0	0
ICN302M	0	0
ICN306M	0	0
ICN276M	0	0
ICN300M	0	0
ICN335M	0	0
ICN321M	0	0
ICN330M	0	0
MEAN	0	0
STD.DEV.	0	0
N	10	10
ICN353F	0	0
ICN342F	0	0
ICN345F	C	0
ICN348F	0	0
ICN388F	C	0
ICN341F	0	0
ICN385F	0	0
ICN361F	0	0
ICN370F	0	0
ICN395F	0	0
MEAN	0	0
STD.DEV.	0	0
N	8	8

NOTE: C - CLOTTED SAMPLE

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

APPENDIX H - INDIVIDUAL SEMI-QUANTITATIVE HEMATOLOGY (CONT'D)
(SEE KEY C FOR ABBREVIATIONS)
DOSE: 40 MG/KG

PARAMETERS-	N E U T	L Y M P H	M O N O	E O S	B A S O	L U C	A N I S O	M I C R O	M A C R O	V A R	H Y P O	H Y P E R	L S
UNITS-	%	%	%	%	%	%							
ICN303M	30.6	61.1	0.8	3.4	0.2	3.8							1
ICN290M	32.9	63.2	0.9	1.6	0.2	1.2							1
ICN285M													
ICN293M	17.4	75.0	2.5	3.0	0.3	1.9							0
ICN291M	47.7	45.8	0.8	3.1	0.2	2.3							1
ICN328M	46.3	45.9	0.8	3.8	0.3	2.9							1
ICN315M	13.7	79.6	1.0	2.2	0.3	3.2							0
ICN311M	28.4	67.3	0.5	1.5	0.3	2.0							0
ICN299M	46.4	48.9	0.8	1.7	0.1	2.0							1
ICN319M	18.3	78.2	0.8	1.6	0.1	1.0							0
MEAN	31.3	62.8	1.0	2.4	0.2	2.3							1
STD. DEV.	13.3	13.5	0.6	0.9	0.1	0.9	N/A	N/A	N/A	N/A	N/A	N/A	1
N	9	9	9	9	9	9							9
ICN340F	28.9	64.8	1.3	2.6	0.4	2.2							1
ICN364F	31.4	63.4	0.8	2.8	0.3	1.4							1
ICN351F	27.1	67.1	0.8	3.7	0.2	1.1							1
ICN343F	31.6	64.2	0.3	2.8	0.2	0.9							1
ICN337F	36.6	56.0	1.0	4.3	0.2	1.9							1
ICN350F													
ICN389F	30.0	65.2	1.1	2.3	0.2	1.2							1
ICN363F	33.1	63.6	0.5	1.6	0.2	1.0							2
ICN366F	41.5	49.4	1.1	5.2	0.3	2.5							1
ICN339F	18.3	77.6	0.8	2.2	0.3	0.8							0
MEAN	30.9	63.5	0.9	3.1	0.3	1.4							1
STD. DEV.	6.4	7.7	0.3	1.1	0.1	0.6	N/A	N/A	N/A	N/A	N/A	N/A	1
N	9	9	9	9	9	9							9

NOTE: X - ANIMAL DEAD
C - CLOTTED SAMPLE

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

APPENDIX H - INDIVIDUAL SEMI-QUANTITATIVE HEMATOLOGY (CONT'D)
(SEE KEY C FOR ABBREVIATIONS)
DOSE: 80 MG/KG

PARAMETERS=	N E U T	L Y M P H	M O N O	E O S	B A S O	L U C	A N I S O	M I C R O	M A C R O	V A R	H Y P O	H Y P E R	L S
UNITS=	%	%	%	%	%	%							
ICN322M	27.9	67.6	0.6	2.2	0.2	1.4							1
ICN313M	45.9	45.9	0.8	1.5	0.2	1.6							1
ICN304M	30.2	65.7	0.5	2.5	0.2	0.9							1
ICN320M	20.7	75.4	1.0	1.3	0.3	1.3				1			0
ICN317M	X												
ICN333M	20.1	74.9	1.1	1.1	0.3	2.4							0
ICN277M	28.8	63.8	1.8	3.6	0.2	1.8				1			1
ICN329M	33.5	60.7	1.0	2.0	0.3	2.5							1
ICN284M	32.7	63.7	0.6	1.8	0.3	0.9							1
ICN283M	39.8	55.0	0.9	2.3	0.4	1.5							1
MEAN	31.5	63.6	0.9	2.0	0.3	1.6				1			1
STD.DEV.	9.2	9.2	0.4	0.8	0.1	0.6	N/A	N/A	N/A	0	N/A	N/A	0
N	9	9	9	9	9	9				2			9
ICN360F	X												
ICN381F	16.5	79.8	0.5	1.7	0.3	1.2							0
ICN362F	18.2	76.5	0.7	2.9	0.3	1.4							1
ICN376F	27.3	67.3	1.0	2.8	0.2	1.3							0
ICN338F	25.4	69.9	1.3	2.5	0.2	0.8							1
ICN384F	21.1	73.6	1.0	1.7	0.2	2.3							0
ICN367F	19.0	76.5	0.7	1.7	0.2	1.9							0
ICN392F	26.3	68.7	0.9	2.7	0.3	1.1							0
ICN356F	21.1	72.9	1.5	2.3	0.2	1.9							0
ICN390F	26.0	69.0	0.8	3.2	0.1	0.8							0
MEAN	22.3	72.7	0.9	2.4	0.2	1.4							0
STD.DEV.	4.0	4.3	0.3	0.6	0.1	0.5	N/A	N/A	N/A	N/A	N/A	N/A	0
N	9	9	9	9	9	9							9

NOTE: X - ANIMAL DEAD

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

APPENDIX H - INDIVIDUAL SEMI-QUANTITATIVE HEMATOLOGY (CONT'D)
(SEE KEY C FOR ABBREVIATIONS)
DOSE: 80 MG/KG

PARAMETERS= A
T
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UNITS=

ICN322M	0	0
ICN313M	0	0
ICN304M	0	0
ICN320M	0	0
ICN317M	X	
ICN333M	0	0
ICN277M	0	0
ICN329M	0	0
ICN284M	0	0
ICN283M	0	0
MEAN	0	0
STD. DEV.	0	0
N	9	9

ICN360F	X	
ICN381F	0	0
ICN362F	0	0
ICN376F	0	0
ICN338F	0	0
ICN384F	0	0
ICN367F	0	0
ICN392F	0	0
ICN356F	0	0
ICN390F	0	0
MEAN	0	0
STD. DEV.	0	0
N	9	9

NOTE: X - ANIMAL DEAD

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

APPENDIX H - INDIVIDUAL SEMI-QUANTITATIVE HEMATOLOGY (CONT'D)

(SEE KEY C FOR ABBREVIATIONS)
DOSE: 80 MG/KG (SATELLITE) DAY 92/93

PARAMETERS=	N E U T	L Y M P H	M O N O	E O S	B A S O	L U C	A N I S O	M I C R O	M A C R O	V A R	H Y P O	H Y P E R	L S
UNITS=	%	%	%	%	%	%							
ICN296M	18.9	77.4	0.9	1.1	0.2	1.6							0
ICN326M	35.3	58.9	0.9	1.5	0.4	2.9							1
ICN275M	X												
ICN307M	26.3	68.6	1.3	1.0	0.4	2.4							0
ICN280M	25.0	69.0	1.4	2.1	0.3	2.1							1
ICN309M	32.8	61.4	1.2	1.1	0.3	3.2							1
ICN298M	24.4	66.9	1.2	2.5	0.3	4.7							1
ICN292M	26.7	67.4	0.9	2.6	0.2	2.2							1
ICN332M	31.2	62.1	1.1	2.6	0.2	2.9							1
ICN316M	30.8	62.3	0.8	3.6	0.2	2.4							1
MEAN	27.9	66.0	1.1	2.0	0.3	2.7							1
STD. DEV.	5.0	5.6	0.2	0.9	0.1	0.9	N/A	N/A	N/A	N/A	N/A	N/A	0
N	9	9	9	9	9	9							9
ICN358F	33.4	62.7	0.6	2.2	0.2	0.9							1
ICN352F	25.3	67.4	1.2	3.7	0.2	2.1							1
ICN346F	24.1	71.7	0.7	1.7	0.4	1.5							0
ICN344F	19.4	75.3	0.7	2.9	0.2	1.6							0
ICN386F	24.4	71.6	1.0	1.4	0.2	1.4							1
ICN375F	29.3	64.4	1.0	3.3	0.2	1.7							1
ICN397F	22.5	72.6	1.6	2.1	0.1	1.2							1
ICN380F	54.9	41.0	0.5	2.4	0.2	1.1							1
ICN347F	13.2	81.7	1.0	1.5	0.3	2.4							0
ICN371F	44.1	50.1	0.9	3.6	0.1	1.1							1
MEAN	29.1	65.9	0.9	2.5	0.2	1.5							1
STD. DEV.	12.3	12.2	0.3	0.9	0.1	0.5	N/A	N/A	N/A	N/A	N/A	N/A	0
N	10	10	10	10	10	10							10

NOTE: X - ANIMAL DEAD

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

APPENDIX H - INDIVIDUAL SEMI-QUANTITATIVE HEMATOLOGY (CONT'D)
(SEE KEY C FOR ABBREVIATIONS)
DOSE: 80 MG/KG (SATELLITE) DAY 92/93

PARAMETERS- A
T
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P

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UNITS=

ICN296M	0	0
ICN326M	0	0
ICN275M	X	
ICN307M	0	0
ICN280M	0	0
ICN309M	0	0
ICN298M	1	0
ICN292M	0	0
ICN332M	0	0
ICN316M	0	0
MEAN	0	0
STD.DEV.	0	0
N	9	9
ICN358F	0	0
ICN352F	0	0
ICN346F	0	0
ICN344F	0	0
ICN386F	0	0
ICN375F	0	0
ICN397F	0	0
ICN380F	0	0
ICN347F	0	0
ICN371F	0	0
MEAN	0	0
STD.DEV.	0	0
N	10	10

NOTE: X - ANIMAL DEAD

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

APPENDIX H - INDIVIDUAL SEMI-QUANTITATIVE HEMATOLOGY (CONT'D)
(SEE KEY C FOR ABBREVIATIONS)
DOSE: 80 MG/KG (SATELLITE) RECOVERY DAY 121

PARAMETERS=	N E U T	L Y M P H	M O N O	E O S	B A S O	L U C	A N I S O	M I C R O	M A C R O	V A R	H Y P O	H Y P E R	L S
UNITS=	%	%	%	%	%	%							
ICN296M	17.8	78.2	1.4	0.6	0.4	1.6							0
ICN326M	33.5	60.9	2.0	1.2	0.3	2.0							1
ICN275M	X												
ICN307M	20.4	74.9	1.9	0.9	0.3	1.6							0
ICN280M	17.8	78.0	0.8	1.3	0.3	1.8					1		0
ICN309M	18.1	75.8	1.5	1.7	0.2	2.8							0
ICN298M	23.9	67.9	2.4	2.4	0.3	3.1							1
ICN292M	10.4	83.1	1.2	2.5	0.3	2.5							0
ICN332M	8.7	85.5	2.1	1.3	0.3	2.2							0
ICN316M	23.5	72.2	1.9	0.6	0.3	1.6							0
MEAN	19.3	75.2	1.7	1.4	0.3	2.1					1		0
STD.DEV.	7.4	7.5	0.5	0.7	0.1	0.6	N/A	N/A	N/A	N/A	N/A	N/A	0
N	9	9	9	9	9	9					1		9
ICN358F	7.0	87.9	1.5	2.2	0.1	1.2							0
ICN352F	18.5	77.3	1.2	1.7	0.1	1.3							0
ICN346F	7.1	88.3	1.7	1.0	0.2	1.8							0
ICN344F	13.5	82.3	0.8	2.0	0.2	1.3							0
ICN386F	11.4	84.0	0.9	2.5	0.2	1.0							0
ICN375F	18.1	76.7	2.0	1.0	0.3	1.9							0
ICN397F	17.7	78.1	1.8	1.3	0.2	0.9							0
ICN380F	8.0	88.8	0.7	1.1	0.3	1.1							0
ICN347F	25.6	69.7	1.7	1.3	0.3	1.4							0
ICN371F	11.9	83.6	2.0	1.4	0.2	0.9							0
MEAN	13.9	81.7	1.4	1.6	0.2	1.3							0
STD.DEV.	6.0	6.2	0.5	0.5	0.1	0.3	N/A	N/A	N/A	N/A	N/A	N/A	0
N	10	10	10	10	10	10							10

NOTE: X - ANIMAL DEAD

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

APPENDIX H - INDIVIDUAL SEMI-QUANTITATIVE HEMATOLOGY (CONT'D)
(SEE KEY C FOR ABBREVIATIONS)
DOSE: 80 MG/KG (SATELLITE) RECOVERY DAY 121

PARAMETERS= A
T
Y
P

B
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UNITS=

ICN296M	0	0
ICN326M	0	0
ICN275M	X	
ICN307M	0	0
ICN280M	0	0
ICN309M	0	0
ICN298M	0	0
ICN292M	0	0
ICN332M	0	0
ICN316M	0	0
MEAN	0	0
STD.DEV.	0	0
N	9	9
ICN358F	0	0
ICN352F	0	0
ICN346F	0	0
ICN344F	0	0
ICN386F	0	0
ICN375F	0	0
ICN397F	0	0
ICN380F	0	0
ICN347F	0	0
ICN371F	0	0
MEAN	0	0
STD.DEV.	0	0
N	10	10

NOTE: X - ANIMAL DEAD

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

APPENDIX I - INDIVIDUAL SERUM CHEMISTRY
(SEE KEY D FOR ABBREVIATIONS)
DOSE: 0 MG/KG

PARAMETERS=	G L U	B U N	C R E A	N a +	K +	C l -	C O 2	C a	P H O S	A S T	A L T	A L P
UNITS=	mg/dL	mg/dL	mg/dL	mmol/L	mmol/L	mmol/L	mmol/L	mg/dL	mg/dL	IU/L	IU/L	IU/L
ICN297M	X											
ICN287M	116.0	13.0	0.5	144.8	4.55	107.3	26.9	10.7	6.0	150.0	79.0	93.0
ICN295M	118.0	12.0	0.4	144.0	4.53	106.0	28.9	11.1	6.7	109.0	43.0	155.0
ICN289M	110.0	12.0	0.5	145.0	4.54	106.9	28.3	10.5	6.4	104.0	42.0	105.0
ICN294M	98.0	14.0	0.5	146.7	4.69	107.7	25.9	10.6	7.3	130.0	45.0	93.0
ICN279M	109.0	15.0	0.4	142.3	4.73	103.6	28.0	10.3	6.1	118.0	52.0	91.0
ICN278M	125.0	14.0	0.5	144.2	4.04	107.5	27.5	10.6	6.6	109.0	47.0	145.0
ICN314M	89.0	24.0	0.5	145.4	4.83	108.4	25.5	10.3	6.8	151.0	58.0	158.0
ICN323M	105.0	15.0	0.5	145.0	4.87	106.7	29.2	10.3	5.7	115.0	56.0	94.0
ICN305M	136.0	15.0	0.5	146.2	5.66	106.7	27.2	10.5	7.5	136.0	51.0	104.0
MEAN	111.8	14.9	0.5	144.8	4.72	106.8	27.5	10.5	6.6	124.7	52.6	115.3
STD. DEV.	14.1	3.6	0.0	1.3	0.43	1.4	1.3	0.3	0.6	17.8	11.4	28.6
N	9	9	9	9	9	9	9	9	9	9	9	9
ICN396F	100.0	14.0	0.6	146.7	4.50	108.6	25.6	10.7	5.4	119.0	47.0	44.0
ICN398F	104.0	20.0	0.6	151.5	4.52	110.7	25.7	10.7	5.4	171.0	53.0	75.0
ICN372F	105.0	12.0	0.5	150.9	4.21	109.2	27.7	10.4	6.4	114.0	71.0	47.0
ICN379F	95.0	14.0	0.6	149.7	3.98	111.6	23.8	10.8	6.5	146.0	57.0	90.0
ICN365F	94.0	17.0	0.6	148.0	4.72	111.6	24.6	10.5	5.6	125.0	60.0	63.0
ICN378F	93.0	14.0	0.5	148.9	4.91	110.3	25.3	10.7	5.3	158.0	87.0	78.0
ICN377F	90.0	15.0	0.5	153.0	4.48	114.7	24.3	10.3	7.2	125.0	41.0	105.0
ICN355F	93.0	16.0	0.5	148.8	4.63	108.6	27.0	10.8	7.2	120.0	38.0	34.0
ICN394F	132.0	11.0	0.7	153.5	4.13	112.9	22.9	10.9	6.5	163.0	65.0	117.0
ICN373F	99.0	23.0	0.5	148.3	4.89	109.2	25.8	10.4	5.9	239.0	54.0	71.0
MEAN	100.5	15.6	0.6	149.9	4.50	110.7	25.3	10.6	6.1	148.0	57.3	72.4
STD. DEV.	12.1	3.6	0.1	2.2	0.31	2.0	1.4	0.2	0.7	38.0	14.6	26.7
N	10	10	10	10	10	10	10	10	10	10	10	10

NOTE: X - ANIMAL DEAD

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

APPENDIX I - INDIVIDUAL SERUM CHEMISTRY (CONT'D)
(SEE KEY D FOR ABBREVIATIONS)
DOSE: 0 MG/KG (CONT'D)

PARAMETERS=	T B I L	T P	A L B U	C H O L	T R I G
UNITS=	mg/dL	g/dL	g/dL	mg/dL	mg/dL
ICN297M	X				
ICN287M	0.60	7.2	3.9	21.0	25
ICN295M	0.60	7.3	4.1	21.0	51
ICN289M	0.60	6.8	3.6	20.0	38
ICN294M	0.60	6.8	3.7	34.0	39
ICN279M	0.50	6.8	3.8	41.0	76
ICN278M	0.50	6.7	3.9	28.0	36
ICN314M	0.70	6.8	3.5	19.0	14
ICN323M	0.50	6.9	3.7	32.0	19
ICN305M	0.60	6.7	3.6	21.0	37
MEAN	0.58	6.9	3.8	26.3	37
STD.DEV.	0.07	0.2	0.2	7.8	18
N	9	9	9	9	9
ICN396F	0.60	7.2	4.2	37.0	23
ICN398F	0.70	7.1	4.1	28.0	19
ICN372F	0.60	6.9	3.9	30.0	21
ICN379F	0.40	7.5	4.3	40.0	30
ICN365F	0.70	6.9	3.9	33.0	23
ICN378F	0.70	7.0	4.0	28.0	24
ICN377F	0.60	6.7	3.9	19.0	17
ICN355F	0.60	7.1	4.0	37.0	30
ICN394F	0.60	7.6	4.2	26.0	17
ICN373F	0.60	7.0	3.9	26.0	22
MEAN	0.61	7.1	4.0	30.4	23
STD.DEV.	0.09	0.3	0.2	6.4	5
N	10	10	10	10	10

NOTE: X - ANIMAL DEAD

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

APPENDIX I - INDIVIDUAL SERUM CHEMISTRY (CONT'D)
(SEE KEY D FOR ABBREVIATIONS)
DOSE: 10 MG/KG

PARAMETERS=	G L U	B U N	C R E A	N a +	K +	C l -	C O 2	C a	P H O S	A S T	A L T	A L P
UNITS=	mg/dL	mg/dL	mg/dL	mmol/L	mmol/L	mmol/L	mmol/L	mg/dL	mg/dL	IU/L	IU/L	IU/L
ICN318M	113.0	18.0	0.5	144.8	4.75	106.9	27.3	10.3	6.2	115.0	47.0	105.0
ICN310M	105.0	13.0	0.5	145.0	4.92	108.1	26.6	9.8	6.2	117.0	54.0	160.0
ICN273M	126.0	14.0	0.5	143.1	5.16	107.5	25.0	10.4	6.4	110.0	36.0	141.0
ICN302M	95.0	18.0	0.4	143.2	4.56	104.8	27.3	10.2	6.4	411.0	337.0	122.0
ICN306M	112.0	17.0	0.5	143.3	5.39	104.0	26.4	10.7	6.0	113.0	55.0	74.0
ICN276M	107.0	13.0	0.5	146.9	5.22	107.1	26.7	10.7	6.4	146.0	47.0	122.0
ICN300M	99.0	14.0	0.5	144.5	4.98	105.6	28.1	10.3	6.3	193.0	58.0	201.0
ICN335M	136.0	13.0	0.4	145.3	4.74	106.9	27.3	10.3	5.5	106.0	41.0	79.0
ICN321M	99.0	15.0	0.7	141.4	4.21	102.9	25.2	9.8	6.2	144.0	65.0	124.0
ICN330M	113.0	14.0	0.5	144.7	4.79	104.8	27.8	10.5	5.9	120.0	49.0	135.0
MEAN	110.5	14.9	0.5	144.2	4.87	105.9	26.8	10.3	6.2	157.5	78.9	126.3
STD.DEV.	12.7	2.0	0.1	1.5	0.34	1.7	1.0	0.3	0.3	92.8	91.1	37.2
N	10	10	10	10	10	10	10	10	10	10	10	10
ICN353F	120.0	13.0	0.5	150.5	4.20	111.6	25.1	10.9	5.7	104.0	36.0	85.0
ICN342F	124.0	16.0	0.6	147.9	4.44	109.9	27.2	10.6	5.4	122.0	63.0	49.0
ICN345F	95.0	18.0	0.6	151.1	5.55	112.0	24.6	10.6	6.9	208.0	54.0	97.0
ICN348F	96.0	11.0	0.5	147.0	4.21	110.1	26.5	10.8	5.0	124.0	57.0	42.0
ICN388F	101.0	17.0	0.5	150.3	4.24	113.8	25.0	11.0	6.6	150.0	41.0	122.0
ICN341F	89.0	19.0	0.6	152.4	4.45	115.8	23.0	10.3	5.6	139.0	50.0	93.0
ICN385F	106.0	15.0	0.5	146.7	4.10	110.7	24.6	10.8	6.3	147.0	58.0	109.0
ICN361F	114.0	21.0	0.7	151.4	4.77	107.5	25.2	11.4	5.8	105.0	49.0	77.0
ICN370F	101.0	17.0	0.6	147.4	4.18	111.2	23.6	10.7	6.3	130.0	43.0	62.0
ICN395F	96.0	18.0	0.5	147.1	4.71	109.0	27.4	10.8	6.1	102.0	39.0	70.0
MEAN	104.2	16.5	0.6	149.2	4.49	111.2	25.2	10.8	6.0	133.1	49.0	80.6
STD.DEV.	11.6	2.9	0.1	2.2	0.44	2.4	1.4	0.3	0.6	31.5	9.0	25.7
N	10	10	10	10	10	10	10	10	10	10	10	10

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

APPENDIX I - INDIVIDUAL SERUM CHEMISTRY (CONT'D)
(SEE KEY D FOR ABBREVIATIONS)
DOSE: 10 MG/KG (CONT'D)

PARAMETERS=	T B I L	T P	A L B U	C H O L	T R I G
UNITS=	mg/dL	g/dL	g/dL	mg/dL	mg/dL
ICN318M	0.50	7.0	3.9	30.0	46
ICN310M	0.60	6.0	3.6	13.0	17
ICN273M	0.60	6.6	3.7	31.0	64
ICN302M	0.50	6.4	3.5	43.0	21
ICN306M	0.70	7.3	4.0	39.0	57
ICN276M	0.60	7.1	3.9	35.0	26
ICN300M	0.60	6.9	3.8	25.0	15
ICN335M	0.60	7.1	3.9	41.0	54
ICN321M	0.60	6.8	3.7	41.0	41
ICN330M	0.60	7.3	4.0	34.0	48
MEAN	0.59	6.9	3.8	33.2	39
STD. DEV.	0.06	0.4	0.2	18	
N	10	10	10	10	10
ICN353F	0.50	7.5	4.3	34.0	21
ICN342F	0.50	6.6	3.6	40.0	33
ICN345F	0.70	7.8	4.1	32.0	26
ICN348F	0.60	7.3	4.3	33.0	26
ICN388F	0.70	7.4	4.2	21.0	21
ICN341F	0.60	6.9	3.8	31.0	19
ICN385F	0.50	7.3	4.1	34.0	17
ICN361F	0.60	8.3	4.6	46.0	23
ICN370F	0.60	7.1	3.8	23.0	19
ICN395F	0.60	7.2	4.0	27.0	20
MEAN	0.59	7.3	4.1	32.1	23
STD. DEV.	0.07	0.5	0.3	7.4	5
N	10	10	10	10	10

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

APPENDIX I - INDIVIDUAL SERUM CHEMISTRY (CONT'D)
(SEE KEY D FOR ABBREVIATIONS)
DOSE: 40 MG/KG

PARAMETERS=	G L U	B U N	C R E A	N a +	K +	C l -	C O 2	C a	P H O S	A S T	A L T	A L P
UNITS=	mg/dL	mg/dL	mg/dL	mmol/L	mmol/L	mmol/L	mmol/L	mg/dL	mg/dL	IU/L	IU/L	IU/L
ICN303M	108.0	17.0	0.4	143.3	4.49	107.1	28.3	9.9	6.6	139.0	49.0	149.0
ICN290M	110.0	16.0	0.5	142.8	4.82	107.3	25.7	10.4	6.1	108.0	40.0	86.0
ICN285M	113.0	14.0	0.5	140.3	4.09	103.8	28.1	9.8	5.4	131.0	44.0	120.0
ICN293M	109.0	14.0	0.4	146.0	5.12	104.4	27.5	10.5	6.9	100.0	36.0	57.0
ICN291M	94.0	38.0	0.6	142.8	5.34	104.2	27.2	10.3	6.7	147.0	51.0	138.0
ICN328M	93.0	15.0	0.5	143.7	4.14	105.2	29.3	9.8	6.0	125.0	52.0	96.0
ICN315M	102.0	13.0	0.5	142.9	4.36	104.4	28.4	10.0	5.6	115.0	54.0	89.0
ICN311M	100.0	14.0	0.5	145.9	4.65	106.0	29.3	10.5	6.3	127.0	46.0	127.0
ICN299M	79.0	17.0	0.4	143.9	4.34	102.1	31.0	10.1	6.4	148.0	56.0	155.0
ICN319M	102.0	15.0	0.5	143.3	4.35	103.4	28.5	10.3	6.0	136.0	65.0	81.0
MEAN	101.0	17.3	0.5	143.5	4.57	104.8	28.3	10.2	6.2	127.6	49.3	109.8
STD.DEV.	10.2	7.4	0.1	1.6	0.41	1.6	1.4	0.3	0.5	16.0	8.3	32.6
N	10	10	10	10	10	10	10	10	10	10	10	10
ICN340F	103.0	20.0	0.6	150.9	4.63	111.6	24.4	10.9	6.9	131.0	42.0	101.0
ICN364F	128.0	18.0	0.6	153.5	4.45	115.6	25.1	11.0	6.0	109.0	39.0	74.0
ICN351F	106.0	19.0	0.5	148.9	4.21	109.9	26.4	10.1	6.9	119.0	32.0	101.0
ICN343F	88.0	22.0	0.6	146.7	4.08	109.9	24.9	10.5	5.8	122.0	39.0	84.0
ICN337F	122.0	15.0	0.5	148.3	4.38	108.8	26.6	11.1	6.3	107.0	35.0	55.0
ICN350F	X											
ICN389F	101.0	23.0	0.7	150.5	4.16	111.6	21.3	10.9	7.5	137.0	64.0	86.0
ICN363F	97.0	19.0	0.6	149.4	4.39	111.2	26.0	10.7	6.5	130.0	45.0	90.0
ICN366F	92.0	19.0	0.7	146.9	4.51	110.7	24.0	11.0	5.9	140.0	36.0	92.0
ICN339F	95.0	19.0	0.6	151.6	4.13	116.3	23.5	10.6	6.8	122.0	45.0	90.0
MEAN	103.6	19.3	0.6	149.6	4.33	111.7	24.7	10.8	6.5	124.1	41.9	85.9
STD.DEV.	13.4	2.3	0.1	2.2	0.19	2.6	1.7	0.3	0.6	11.5	9.4	14.3
N	9	9	9	9	9	9	9	9	9	9	9	9

NOTE: X - ANIMAL DEAD

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

APPENDIX I - INDIVIDUAL SERUM CHEMISTRY (CONT'D)
(SEE KEY D FOR ABBREVIATIONS)
DOSE: 40 MG/KG (CONT'D)

PARAMETERS=	T B I L	T P	A L B U	C H O L	T R I G
UNITS=	mg/dL	g/dL	g/dL	mg/dL	mg/dL
ICN303M	0.40	6.0	3.4	37.0	51
ICN290M	0.50	7.2	3.9	26.0	20
ICN285M	0.50	7.3	3.5	29.0	29
ICN293M	0.60	7.2	3.5	26.0	24
ICN291M	0.50	7.1	3.4	27.0	18
ICN328M	0.40	7.0	3.4	29.0	15
ICN315M	0.60	6.9	3.8	42.0	42
ICN311M	0.60	6.8	3.7	14.0	24
ICN299M	0.50	6.8	3.2	20.0	17
ICN319M	0.80	7.3	3.9	23.0	13
MEAN	0.54	7.0	3.6	27.3	25
STD.DEV.	0.12	0.4	0.2	7.9	12
N	10	10	10	10	10
ICN340F	0.60	7.9	3.9	29.0	30
ICN364F	0.60	7.6	4.1	30.0	15
ICN351F	0.50	7.3	3.8	25.0	22
ICN343F	0.60	7.0	3.8	28.0	25
ICN350F	X				
ICN337F	0.50	7.6	4.1	32.0	22
ICN389F	0.60	7.7	4.1	22.0	16
ICN363F	0.60	6.9	3.8	25.0	21
ICN366F	0.60	7.7	4.2	36.0	20
ICN339F	0.60	7.0	3.6	24.0	16
MEAN	0.58	7.4	4.0	27.9	21
STD.DEV.	0.04	0.4	0.2	4.4	5
N	9	9	9	9	9

NOTE: X - ANIMAL DEAD

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

APPENDIX I - INDIVIDUAL SERUM CHEMISTRY (CONT'D)
(SEE KEY D FOR ABBREVIATIONS)
DOSE: 80 MG/KG

PARAMETERS=	G L U	B U N	C R E A	N a +	K +	C l -	C O 2	C a	P H O S	A S T	A L T	A L P
UNITS=	mg/dL	mg/dL	mg/dL	mmol/L	mmol/L	mmol/L	mmol/L	mg/dL	mg/dL	IU/L	IU/L	IU/L
ICN322M	84.0	16.0	0.5	146.0	4.84	105.0	29.1	10.2	6.4	148.0	54.0	94.0
ICN313M	99.0	18.0	0.7	145.3	4.54	105.6	28.3	10.4	6.4	126.0	51.0	260.0
ICN304M	101.0	15.0	0.5	145.5	4.49	105.8	28.8	10.7	6.3	128.0	53.0	114.0
ICN320M	122.0	14.0	0.5	142.8	4.56	104.8	27.3	10.4	6.5	124.0	47.0	106.0
ICN317M	X											
ICN333M	111.0	18.0	0.6	144.5	4.49	106.0	28.8	10.5	6.7	125.0	44.0	125.0
ICN277M	141.0	17.0	0.6	145.4	4.87	107.1	27.8	10.0	7.8	274.0	117.0	116.0
ICN329M	99.0	13.0	0.5	143.7	4.59	107.7	26.5	9.9	7.0	155.0	81.0	104.0
ICN284M	101.0	15.0	0.4	140.9	4.56	102.3	29.8	10.1	6.9	121.0	47.0	149.0
ICN283M	97.0	16.0	0.5	141.4	4.22	104.0	28.4	10.0	6.7	135.0	58.0	107.0
MEAN	106.1	15.8	0.5	143.9	4.57	105.4	28.3	10.2	6.7	148.4	61.3	130.6
STD. DEV.	16.7	1.7	0.1	1.9	0.19	1.6	1.0	0.3	0.5	48.5	23.6	51.0
N	9	9	9	9	9	9	9	9	9	9	9	9
ICN360F	X											
ICN381F	98.0	14.0	0.5	148.6	4.87	109.9	26.1	10.9	5.4	153.0	47.0	116.0
ICN362F	90.0	19.0	0.7	147.4	4.41	111.6	22.9	10.7	5.6	136.0	37.0	86.0
ICN376F	96.0	16.0	0.6	148.6	5.13	111.8	24.7	10.7	6.6	146.0	42.0	76.0
ICN338F	102.0	22.0	0.6	149.4	5.14	115.4	21.1	10.5	6.7	141.0	46.0	98.0
ICN384F	98.0	25.0	0.5	146.0	4.98	106.5	27.1	10.2	6.9	162.0	72.0	140.0
ICN367F	84.0	20.0	0.5	153.4	4.76	115.1	24.9	10.7	6.5	209.0	59.0	131.0
ICN392F	96.0	17.0	0.5	149.0	3.74	110.1	25.2	10.6	6.2	162.0	54.0	166.0
ICN356F	97.0	20.0	0.5	150.6	4.51	113.8	25.9	10.1	6.4	135.0	41.0	97.0
ICN390F	82.0	22.0	0.6	147.1	3.90	108.8	25.0	10.1	6.4	149.0	50.0	94.0
MEAN	93.7	19.4	0.6	148.9	4.60	111.4	24.8	10.5	6.3	154.8	49.8	111.6
STD. DEV.	6.8	3.4	0.1	2.2	0.51	3.0	1.8	0.3	0.5	22.6	10.7	29.1
N	9	9	9	9	9	9	9	9	9	9	9	9

NOTE: X - ANIMAL DEAD

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

APPENDIX I - INDIVIDUAL SERUM CHEMISTRY (CONT'D)
(SEE KEY D FOR ABBREVIATIONS)
DOSE: 80 MG/KG (CONT'D)

PARAMETERS=	T B I L	T P	A L B U	C H O L	T R I G
UNITS=	mg/dL	g/dL	g/dL	mg/dL	mg/dL
ICN322M	0.50	7.2	3.7	33.0	22
ICN313M	0.60	7.1	3.8	18.0	13
ICN304M	0.50	6.5	3.5	15.0	12
ICN320M	0.60	7.0	3.8	25.0	17
ICN317M	X				
ICN333M	0.50	7.0	3.8	18.0	16
ICN277M	0.50	6.3	3.6	30.0	16
ICN329M	0.40	6.5	3.5	17.0	17
ICN284M	0.70	6.4	3.6	16.0	32
ICN283M	0.70	6.5	3.3	35.0	20
MEAN	0.56	6.7	3.6	23.0	18
STD. DEV.	0.10	0.3	0.2	7.9	6
N	9	9	9	9	9
ICN360F	X				
ICN381F	0.60	7.1	4.2	26.0	21
ICN362F	0.60	7.2	4.0	31.0	29
ICN376F	0.60	7.0	3.8	24.0	20
ICN388F	0.50	7.0	4.2	16.0	14
ICN384F	0.60	7.3	3.5	19.0	22
ICN367F	0.60	7.2	4.0	35.0	19
ICN392F	0.50	7.3	3.9	26.0	20
ICN356F	0.50	6.8	3.7	23.0	17
ICN390F	0.40	6.9	3.8	17.0	19
MEAN	0.54	7.1	3.9	24.1	20
STD. DEV.	0.07	0.2	0.2	6.3	4
N	9	9	9	9	9

NOTE: X - ANIMAL DEAD

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

APPENDIX I - INDIVIDUAL SERUM CHEMISTRY (CONT'D)
(SEE KEY D FOR ABBREVIATIONS)
DOSE: 80 MG/KG (SATELLITE) - DAY 92/93

PARAMETERS=	G L U	B U N	C R E A	N a +	K +	C l -	C O 2	C a	P H O S	A S T	A L T	A L P
UNITS=	mg/dL	mg/dL	mg/dL	mmol/L	mmol/L	mmol/L	mmol/L	mg/dL	mg/dL	IU/L	IU/L	IU/L
ICN296M	110.0	16.0	0.6	146.1	4.79	108.1	27.0	10.6	7.2	203.0	74.0	128.0
ICN326M	105.0	19.0	0.5	147.2	4.88	107.3	28.1	10.5	6.9	130.0	44.0	164.0
ICN275M	X											
ICN307M	112.0	16.0	0.6	145.1	4.21	107.7	27.7	10.5	6.8	131.0	41.0	114.0
ICN280M	95.0	15.0	0.5	145.0	4.77	105.4	28.6	10.6	7.1	134.0	57.0	133.0
ICN309M	108.0	13.0	0.4	145.7	4.58	102.9	29.0	11.3	7.0	99.0	42.0	202.0
ICN298M	99.0	14.0	0.5	146.5	5.01	106.0	29.7	10.6	6.7	157.0	52.0	84.0
ICN292M	97.0	14.0	0.4	147.0	4.76	109.0	26.9	10.3	7.2	144.0	63.0	131.0
ICN332M	107.0	16.0	0.4	144.8	4.68	105.4	27.2	10.3	6.9	113.0	60.0	142.0
ICN316M	98.0	21.0	0.5	145.0	4.62	107.9	27.2	9.6	6.8	182.0	64.0	167.0
MEAN	103.4	16.0	0.5	145.8	4.70	106.6	27.9	10.5	7.0	143.7	55.2	140.6
STD. DEV.	6.3	2.5	0.1	0.9	0.23	1.9	1.0	0.4	0.2	32.7	11.3	34.0
N	9	9	9	9	9	9	9	9	9	9	9	9
ICN358F	123.0	22.0	0.5	143.6	4.36	107.3	26.1	10.0	5.4	159.0	62.0	81.0
ICN352F	132.0	21.0	0.6	143.7	4.46	105.4	24.8	10.2	7.1	149.0	43.0	82.0
ICN346F	118.0	14.0	0.6	147.6	4.16	108.8	22.8	10.6	7.7	126.0	37.0	77.0
ICN344F	112.0	23.0	0.6	144.1	4.48	106.2	26.1	10.7	5.1	106.0	42.0	57.0
ICN386F	117.0	17.0	0.4	145.0	4.48	104.6	29.6	10.3	6.4	134.0	41.0	83.0
ICN375F	110.0	19.0	0.5	146.4	4.33	108.6	24.5	10.4	5.5	135.0	59.0	74.0
ICN397F	119.0	16.0	0.6	143.5	4.68	108.6	23.6	10.7	5.7	115.0	37.0	67.0
ICN380F	118.0	18.0	0.5	144.3	3.92	107.1	24.9	10.4	5.0	141.0	59.0	87.0
ICN347F	120.0	18.0	0.7	145.9	4.33	110.9	23.3	10.3	6.4	161.0	48.0	140.0
ICN371F	111.0	17.0	0.6	144.2	3.82	105.8	24.6	10.1	6.0	113.0	50.0	107.0
MEAN	118.0	18.5	0.6	144.8	4.30	107.3	25.0	10.4	6.0	133.9	47.8	85.5
STD. DEV.	6.5	2.8	0.1	1.4	0.27	1.9	1.9	0.2	0.9	19.1	9.4	23.2
N	10	10	10	10	10	10	10	10	10	10	10	10

NOTE: X - ANIMAL DEAD

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

APPENDIX I - INDIVIDUAL SERUM CHEMISTRY (CONT'D)
(SEE KEY D FOR ABBREVIATIONS)
DOSE: 80 MG/KG (SATELLITE) - DAY 92/93 (CONT'D)

PARAMETERS=	T B I L	T P	A L B U	C H O L	T R I G
UNITS=	mg/dL	g/dL	g/dL	mg/dL	mg/dL
ICN296M	0.60	7.0	3.7	24.0	35
ICN326M	0.60	7.3	3.6	24.0	23
ICN275M	X				
ICN307M	0.60	7.2	3.6	29.0	32
ICN280M	0.70	7.1	3.7	44.0	35
ICN309M	0.50	7.2	4.0	34.0	69
ICN298M	0.70	6.8	3.7	31.0	41
ICN292M	0.50	6.6	3.5	30.0	22
ICN332M	0.60	6.8	3.5	34.0	25
ICN316M	0.60	6.4	3.2	23.0	24
MEAN	0.60	6.9	3.6	30.3	34
STD. DEV.	0.07	0.3	0.2	6.6	15
N	9	9	9	9	9
ICN358F	0.60	6.6	3.3	32.0	18
ICN352F	0.50	6.6	3.5	22.0	25
ICN346F	0.50	6.9	3.8	30.0	21
ICN344F	0.60	7.4	4.0	26.0	22
ICN386F	0.50	6.3	3.8	40.0	23
ICN375F	0.50	7.1	3.7	17.0	22
ICN397F	0.50	7.1	4.1	25.0	32
ICN380F	0.60	7.0	3.8	21.0	26
ICN347F	0.60	7.2	3.7	31.0	23
ICN371F	0.60	7.2	3.7	15.0	19
MEAN	0.55	6.9	3.7	25.9	23
STD. DEV.	0.05	0.3	0.2	7.6	4
N	10	10	10	10	10

NOTE: X - ANIMAL DEAD

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

APPENDIX I - INDIVIDUAL SERUM CHEMISTRY (CONT'D)
(SEE KEY D FOR ABBREVIATIONS)
DOSE: 80 MG/KG (SATELLITE) RECOVERY DAY 121

PARAMETERS=	G L U	B U N	C R E A	N a +	K +	C l -	C O 2	C a	P H O S	A S T	A L T	A L P
UNITS=	mg/dL	mg/dL	mg/dL	mmol/L	mmol/L	mmol/L	mmol/L	mg/dL	mg/dL	IU/L	IU/L	IU/L
ICN296M	123.0	15.0	0.5	144.5	5.17	106.5	25.4	10.2	6.7	161.0	45.0	96.0
ICN326M	108.0	18.0	0.6	144.2	4.72	106.9	27.9	9.8	5.7	163.0	62.0	108.0
ICN275M	X											
ICN307M	125.0	18.0	0.6	144.0	4.29	106.0	26.2	10.0	5.8	126.0	30.0	72.0
ICN280M	107.0	12.0	0.4	143.7	5.06	102.3	31.5	9.9	6.3	237.0	115.0	83.0
ICN309M	105.0	13.0	0.5	145.5	4.77	102.9	27.7	10.6	6.9	101.0	32.0	125.0
ICN298M	109.0	15.0	0.5	143.1	5.00	106.5	27.6	10.0	6.6	182.0	58.0	61.0
ICN292M	108.0	13.0	0.4	142.6	4.99	105.6	27.1	9.8	6.2	143.0	37.0	99.0
ICN332M	138.0	16.0	0.5	143.6	5.06	104.0	28.9	9.8	5.9	107.0	37.0	104.0
ICN316M	113.0	14.0	0.6	144.1	4.17	106.7	26.7	10.0	7.0	126.0	38.0	114.0
MEAN	115.1	14.9	0.5	143.9	4.80	105.3	27.7	10.0	6.3	149.6	50.4	95.8
STD. DEV.	11.2	2.1	0.1	0.8	0.36	1.7	1.8	0.3	0.5	42.3	26.6	20.5
N	9	9	9	9	9	9	9	9	9	9	9	9
ICN358F	114.0	15.0	0.6	143.6	3.75	108.5	25.6	10.1	4.0	95.0	36.0	49.0
ICN352F	122.0	17.0	0.6	142.1	4.01	106.7	22.3	9.4	4.9	104.0	36.0	68.0
ICN346F	122.0	13.0	0.4	144.9	4.43	106.7	29.5	10.5	4.9	93.0	33.0	48.0
ICN344F	125.0	21.0	0.7	143.5	4.37	106.5	28.6	10.1	4.5	90.0	35.0	52.0
ICN386F	103.0	15.0	0.6	141.6	3.83	103.4	28.0	10.2	5.3	118.0	64.0	50.0
ICN375F	94.0	12.0	0.5	145.7	4.62	108.3	28.8	10.2	5.8	97.0	35.0	55.0
ICN397F	114.0	19.0	0.5	138.8	4.52	106.5	22.4	10.4	5.5	125.0	33.0	44.0
ICN380F	100.0	20.0	0.5	142.4	4.20	108.8	25.5	9.9	5.1	92.0	25.0	62.0
ICN347F	100.0	19.0	0.5	143.1	4.57	105.1	29.3	10.2	6.0	131.0	49.0	77.0
ICN371F	115.0	17.0	0.6	140.9	4.05	103.4	23.4	9.7	4.9	108.0	60.0	62.0
MEAN	110.9	16.8	0.6	142.7	4.24	106.4	26.3	10.1	5.1	105.3	40.6	56.7
STD. DEV.	10.9	3.0	0.1	2.0	0.31	1.9	2.9	0.3	0.6	14.7	12.7	10.3
N	10	10	10	10	10	10	10	10	10	10	10	10

NOTE: X - ANIMAL DEAD

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

APPENDIX I - INDIVIDUAL SERUM CHEMISTRY (CONT'D)
(SEE KEY D FOR ABBREVIATIONS)
DOSE: 80 MG/KG (SATELLITE) RECOVERY DAY 121 (CONT'D)

PARAMETERS=	T B I L	T P	A L B U	C H O L	T R I G
UNITS=	mg/dL	g/dL	g/dL	mg/dL	mg/dL
ICN296M	0.40	6.7	3.7	29.0	28
ICN326M	0.50	6.2	3.4	28.0	17
ICN275M	X				
ICN307M	0.40	6.4	3.6	34.0	27
ICN280M	0.40	6.1	3.4	48.0	29
ICN309M	0.40	6.6	3.9	35.0	43
ICN298M	0.30	6.1	3.5	39.0	36
ICN292M	0.40	5.9	3.4	40.0	32
ICN332M	0.40	6.1	3.5	41.0	41
ICN316M	0.40	6.1	3.3	29.0	25
MEAN	0.40	6.2	3.5	35.9	31
STD.DEV.	0.05	0.3	0.2	6.7	8
N	9	9	9	9	9
ICN358F	0.40	7.0	4.0	52.0	21
ICN352F	0.40	6.2	3.5	25.0	27
ICN346F	0.40	6.9	4.0	41.0	24
ICN344F	0.50	6.6	3.7	25.0	23
ICN386F	0.50	6.5	4.1	58.0	23
ICN375F	0.50	6.5	3.7	19.0	26
ICN397F	0.50	6.5	3.8	18.0	25
ICN380F	0.50	6.3	3.5	37.0	21
ICN347F	0.40	6.4	3.5	38.0	22
ICN371F	0.50	6.9	4.0	35.0	16
MEAN	0.46	6.6	3.8	34.8	23
STD.DEV.	0.05	0.3	0.2	13.4	3
N	10	10	10	10	10

NOTE: X - ANIMAL DEAD

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

APPENDIX J - INDIVIDUAL QUANTITATIVE URINE CHEMISTRY
(SEE KEY E FOR ABBREVIATIONS)
DOSE: 0 MG/KG

PARAMETERS=	U V O L	U G L U	U P R O T
UNITS=	mL	mg/16hr	mg/16hr
ICN297M	X		
ICN287M	12	7.4	27.7
ICN295M	12	9.6	19.6
ICN289M	17	9.9	13.9
ICN294M	32	5.4	22.1
ICN279M	22	7.0	11.9
ICN278M	12	8.6	13.6
ICN314M	10	6.8	8.8
ICN323M	15	7.4	15.0
ICN305M	26	10.1	33.5
MEAN	18	8.0	18.5
STD.DEV.	8	1.6	8.1
N	9	9	9
ICN396F	16	9.6	2.1
ICN398F	10	6.9	1.7
ICN372F	12	7.1	2.5
ICN379F	13	7.7	2.7
ICN365F	20	8.0	3.0
ICN378F	15	8.4	2.0
ICN377F	12	6.4	2.2
ICN355F	14	9.1	3.9
ICN394F	26	9.4	4.2
ICN373F	15	7.1	2.9
MEAN	15	8.0	2.7
STD.DEV.	5	1.1	0.8
N	10	10	10

NOTE: X = ANIMAL DEAD

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

APPENDIX J - INDIVIDUAL QUANTITATIVE URINE CHEMISTRY (CONT'D)
(SEE KEY E FOR ABBREVIATIONS)
DOSE: 10 MG/KG

PARAMETERS=	U V O L	U G L U	U P R O T
UNITS=	mL	mg/16hr	mg/16hr
ICN318M	28	9.2	21.3
ICN310M	16	8.6	13.8
ICN273M	12	6.0	9.1
ICN302M	7	5.0	13.2
ICN306M	15	8.8	13.1
ICN276M	13	4.7	8.1
ICN300M	10	8.1	15.6
ICN335M	14	9.0	14.0
ICN321M	20	7.0	14.0
ICN330M	14	8.3	15.1
MEAN	15	7.5	13.7
STD.DEV.	6	1.7	3.6
N	10	10	10
ICN353F	11	7.2	2.2
ICN342F	16	8.0	3.0
ICN345F	12	7.7	3.0
ICN348F	12	6.6	2.4
ICN388F	12	7.1	2.3
ICN341F	14	6.7	2.4
ICN385F	7	5.4	1.8
ICN361F	32	7.4	3.8
ICN370F	14	8.0	4.1
ICN395F	7	5.7	1.6
MEAN	14	7.0	2.7
STD.DEV.	7	0.9	0.8
N	10	10	10

NOTE: X = ANIMAL DEAD

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

APPENDIX J - INDIVIDUAL QUANTITATIVE URINE CHEMISTRY (CONT'D)
(SEE KEY E FOR ABBREVIATIONS)
DOSE: 40 MG/KG

PARAMETERS=	U V O L	U G L U	U P R O T
UNITS=	mL	mg/16hr	mg/16hr
ICN303M	15	6.9	11.6
ICN290M	20	11.4	14.8
ICN285M	22	9.2	15.4
ICN293M	24	5.3	19.7
ICN291M	40	6.4	144.0
ICN328M	16	8.0	9.3
ICN315M	19	8.0	11.0
ICN311M	14	7.6	14.4
ICN299M	11	6.6	9.1
ICN319M	29	13.1	18.3
MEAN	21	8.3	26.8
STD. DEV.	8	2.4	41.3
N	10	10	10
ICN340F	12	6.8	3.5
ICN364F	9	6.4	3.9
ICN351F	30	6.6	3.3
ICN343F	8	5.2	3.2
ICN337F	16	9.4	3.2
ICN350F	X		
ICN389F	15	7.4	2.7
ICN363F	12	8.8	2.4
ICN366F	18	8.8	3.2
ICN339F	10	7.7	4.0
MEAN	14	7.5	3.3
STD. DEV.	7	1.4	0.5
N	9	9	9

NOTE: X = ANIMAL DEAD

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

APPENDIX J - INDIVIDUAL QUANTITATIVE URINE CHEMISTRY (CONT'D)
(SEE KEY E FOR ABBREVIATIONS)
DOSE: 80 MG/KG

PARAMETERS=	U V O L	U G L U	U P R O T
UNITS=	mL	mg/16hr	mg/16hr
ICN322M	16	13.8	13.1
ICN313M	20	11.0	19.0
ICN304M	20	11.0	17.2
ICN320M	9	9.6	25.1
ICN317M	X		
ICN333M	18	9.5	12.1
ICN277M	8	4.8	5.8
ICN329M	8	7.6	28.1
ICN284M	24	9.1	38.4
ICN283M	18	10.3	14.8
MEAN	16	9.6	19.3
STD.DEV.	6	2.5	9.8
N	9	9	9
ICN360F	X		
ICN381F	16	5.8	1.9
ICN362F	15	8.4	2.3
ICN376F	10	6.5	3.1
ICN338F	12	8.2	2.6
ICN384F	12	8.4	2.5
ICN367F	11	7.8	2.1
ICN392F	12	7.4	2.0
ICN356F	13	7.7	3.0
ICN390F	9	5.8	1.8
MEAN	12	7.3	2.4
STD.DEV.	2	1.0	0.5
N	9	9	9

NOTE: X = ANIMAL DEAD

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

APPENDIX J - INDIVIDUAL QUANTITATIVE URINE CHEMISTRY (CONT'D)
(SEE KEY E FOR ABBREVIATIONS)
DOSE: 80 MG/KG (SATELLITE) DAY 88/91

PARAMETERS= U U U
V G P
O L R
L U O
T

UNITS=	mL	mg/16hr	mg/16hr
ICN296M	16	8.5	26.9
ICN326M	11	8.1	9.0
ICN275M	X		
ICN307M	23	9.0	12.4
ICN280M	18	9.4	27.9
ICN309M	14	9.1	16.1
ICN298M	16	8.6	12.6
ICN292M	20	10.0	14.6
ICN332M	20	9.4	19.2
ICN316M	16	8.8	25.1
MEAN	17	9.0	18.2
STD.DEV.	4	0.6	6.9
N	9	9	9
ICN358F	12	8.6	4.0
ICN352F	16	9.1	3.2
ICN346F	16	8.2	2.6
ICN344F	12	6.7	2.3
ICN386F	6	5.4	2.2
ICN375F	14	7.3	2.2
ICN397F	14	8.1	2.1
ICN380F	28	8.4	5.6
ICN347F	8	6.4	2.0
ICN371F	14	7.4	4.5
MEAN	14	7.6	3.1
STD.DEV.	6	1.1	1.2
N	10	10	10

NOTE: X = ANIMAL DEAD

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

APPENDIX J - INDIVIDUAL QUANTITATIVE URINE CHEMISTRY (CONT'D)
(SEE KEY E FOR ABBREVIATIONS)
DOSE: 80 MG/KG (SATELLITE) RECOVERY DAY 120

PARAMETERS=	U V O L	U G L U	U P R O T
UNITS=	mL	mg/16hr	mg/16hr
ICN296M	16	8.8	34.6
ICN326M	20	6.8	9.0
ICN275M	X		
ICN307M	22	6.8	10.1
ICN280M	26	6.0	22.6
ICN309M	18	7.9	16.4
ICN298M	18	5.8	11.9
ICN292M	32	5.4	9.9
ICN332M	22	7.0	20.9
ICN316M	22	7.0	15.2
MEAN	22	6.8	16.7
STD.DEV.	5	1.1	8.3
N	9	9	9
ICN358F	10	7.4	3.3
ICN352F	22	8.4	2.6
ICN346F	14	7.7	3.1
ICN344F	12	7.6	2.2
ICN386F	18	6.8	3.6
ICN375F	14	6.4	2.2
ICN397F	16	8.3	2.9
ICN380F	34	5.1	3.1
ICN347F	14	7.7	2.5
ICN371F	13	7.0	2.9
MEAN	17	7.2	2.8
STD.DEV.	7	1.0	0.5
N	10	10	10

NOTE: X = ANIMAL DEAD

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

APPENDIX K - INDIVIDUAL SEMI-QUANTITATIVE URINE CHEMISTRY
(SEE KEY E FOR ABBREVIATIONS)
Biochemical (Dipstick) Urinalysis
Dose: 0 MG/KG

Animal Number	pH	OCC BLOOD	KETONES	BILIRUBIN	UROBILINOGEN	SG
ICN297M	X					
ICN287M	7.0	N	N	N	0.2	1.042
ICN295M	7.5	N	T	1+	0.2	1.056
ICN289M	8.0	N	1+	N	0.2	1.036
ICN294M	8.0	N	T	N	0.2	1.016
ICN279M	8.0	N	T	N	0.2	1.024
ICN278M	7.5	N	T	N	0.2	1.050
ICN314M	7.0	N	T	1+	0.2	1.052
ICN323M	7.5	N	T	N	0.2	1.038
ICN305M	8.0	N	T	N	0.2	1.025
ICN396F	7.5	N	N	1+	0.2	1.052
ICN398F	7.0	N	N	N	0.2	1.060
ICN372F	7.0	N	N	N	0.2	1.046
ICN379F	7.0	N	N	N	0.2	1.050
ICN365F	8.0	N	N	N	0.2	1.034
ICN378F	8.0	N	N	N	0.2	1.046
ICN377F	7.0	N	N	N	0.2	1.050
ICN355F	8.0	N	N	N	0.2	1.050
ICN394F	7.5	N	N	N	0.2	1.028
ICN373F	7.5	N	N	N	0.2	1.042

Microscopic										Macroscopic				
Animal Number	CELLS				CRYSTALS			CASTS	OTHER					
	WBC	RBC	RE	EPC	TP	AM	CP		BACT	YEAST	SPERM	COLOR	APP	
ICN297M	X													
ICN287M	0	0	0	0	3+	0	0	0	1+	1+	2+	Y	CLD	
ICN295M	0-2	0	0	0	3+	0	0	0	1+	0	2+	Y	CLD	
ICN289M	0	0	0	0	2+	0	0	0	1+	1+	2+	Y	CLD	
ICN294M	0	0	0	0	2+	0	0	0	2+	1+	0	Y	CLD	
ICN279M	0	0	0	0	2+	0	0	0	1+	1+	1+	Y	CLD	
ICN278M	0-1	0	0	0	2+	0	0	0	2+	0	2+	Y	CLD	
ICN314M	0	0	0	0	3+	0	0	0	1+	0	1+	Y	CLD	
ICN323M	0	0	0	0	4+	0	0	0	1+	1+	2+	Y	CLD	
ICN305M	0	0	0	0	2+	0	0	0	1+	1+	2+	Y	CLD	
ICN396F	0	0	0	0	2+	3+	0	0	1+	1+	0	Y	CLD	
ICN398F	0	0	0	0	1+	0	0	0	1+	1+	0	Y	CLD	
ICN372F	0	0	0	0-1	1+	1+	0	0	1+	1+	0	Y	CLD	
ICN379F	0	0	0	0	2+	2+	0	0	1+	1+	0	Y	CLD	
ICN365F	0	0	0	0-3	2+	2+	0	0	1+	1+	0	Y	CLD	
ICN378F	0	0	0	0	3+	0	0	0	1+	1+	0	Y	CLD	
ICN377F	0	0	0	0	2+	0	0	0	1+	1+	0	Y	CLD	
ICN355F	0	0	0	0	4+	2+	0	0	1+	1+	0	Y	CLD	
ICN394F	0	0	0	0	2+	2+	0	0	1+	1+	0	Y	CLD	
ICN373F	0	0	0	0	1+	1+	0	0	1+	1+	0	Y	CLD	

NOTE: X - ANIMAL DEAD

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

APPENDIX K - INDIVIDUAL SEMI-QUANTITATIVE URINE CHEMISTRY (CONT'D)
(SEE KEY E FOR ABBREVIATIONS)
Biochemical (Dipstick) Urinalysis
Dose: 10 MG/KG

	Animal Number	pH	OCC BLOOD	KETONES	BILIRUBIN	UROBILINOGEN	SG
	ICN318M	8.0	N	N	N	0.2	1.027
	ICN310M	8.0	N	1+	N	0.2	1.035
	ICN273M	7.0	N	1+	N	0.2	1.033
	ICN302M	6.5	N	N	N	0.2	1.062
	ICN306M	7.5	N	1+	N	0.2	1.034
	ICN276M	6.5	N	T	N	0.2	1.032
	ICN300M	8.0	N	2+	1+	0.2	1.058
	ICN335M	7.0	N	1+	1+	0.2	1.044
	ICN321M	7.5	N	T	N	0.2	1.029
	ICN330M	8.0	N	1+	1+	0.2	1.046
	ICN353F	7.5	N	N	N	0.2	1.052
	ICN342F	8.0	N	N	N	0.2	1.044
	ICN345F	6.5	N	N	1+	0.2	1.058
	ICN348F	7.5	N	N	N	0.2	1.050
	ICN388F	7.0	N	N	1+	0.2	1.054
	ICN341F	7.5	N	N	N	0.2	1.046
	ICN385F	7.5	N	N	N	0.2	1.062
	ICN361F	7.5	N	N	N	0.2	1.019
	ICN370F	7.5	N	N	N	0.2	1.048
	ICN395F	8.0	N	N	1+	0.2	1.068

	Microscopic							Macroscopic					
Animal Number	CELLS				CRYSTALS			CASTS	OTHER				
	WBC	RBC	RE	EPC	TP	AM	CP		BACT	YEAST	SPERM	COLOR	APP
ICN318M	0	0	0	0	2+	0	0	0	1+	0	1+	Y	CLD
ICN310M	0	0	0	0	3+	0	0	0	1+	0	1+	Y	CLD
ICN273M	0	0	0	0	3+	0	0	0	1+	1+	1+	Y	CLD
ICN302M	0	0	0	0	2+	0	0	0	1+	1+	1+	Y	CLD
ICN306M	0	0	0	0	2+	0	0	0	1+	1+	1+	Y	CLD
ICN276M	0	0	0	0	1+	0	0	0	2+	0	1+	Y	CLD
ICN300M	0	0	0	0	2+	0	0	0	1+	1+	0	Y	CLD
ICN335M	0	0	0	0	3+	0	0	0	1+	1+	1+	Y	CLD
ICN321M	0	0	0	0	2+	0	0	0	1+	0	1+	Y	CLD
ICN330M	0	0	0	0	2+	0	0	0	1+	1+	1+	Y	CLD
ICN353F	0	0	0	0	1+	0	0	0	1+	1+	0	Y	CLD
ICN342F	0	0	0	0	4+	2+	0	0	1+	1+	0	Y	CLD
ICN345F	0	0	0	0-2	1+	0	0	0	1+	1+	0	Y	CLD
ICN348F	0	0	0	0	2+	1+	0	0	1+	1+	0	Y	CLD
ICN388F	0	0	0	0	2+	0	0	0	1+	1+	0	Y	CLD
ICN341F	0	0	0	0	2+	0	0	0	1+	1+	0	Y	CLD
ICN385F	0	0	0	0	1+	0	0	0	1+	2+	0	Y	CLD
ICN361F	0	0	0	0	1+	1+	0	0	1+	1+	0	Y	CLD
ICN370F	0-1	0	0	0-1	3+	0	0	0	1+	1+	0	Y	CLD
ICN395F	0	0	0	0	2+	0	0	0	1+	1+	0	Y	CLD

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

APPENDIX K - INDIVIDUAL SEMI-QUANTITATIVE URINE CHEMISTRY (CONT'D)
(SEE KEY E FOR ABBREVIATIONS)
Biochemical (Dipstick) Urinalysis
Dose: 40 MG/KG

Animal Number	pH	OCC BLOOD	KETONES	BILIRUBIN	UROBILINOGEN	SG
ICN303M	7.5	N	1+	N	0.2	1.035
ICN290M	8.0	NN	T	N	0.2	1.044
ICN285M	8.0	NN	T	N	0.2	1.031
ICN293M	7.5	N	T	N	0.2	1.021
ICN291M	8.5+	3+	NN	NN	0.2	1.017
ICN328M	8.0	NN	T	NN	0.2	1.038
ICN315M	7.5	NN	T	NN	0.2	1.033
ICN311M	7.5	T	1+	NN	0.2	1.042
ICN299M	8.0	N	1+	NN	0.2	1.048
ICN319M	8.0	N	T	N	0.2	1.027
ICN340F	8.0	T	N	N	0.2	1.048
ICN364F	7.5	NN	NN	1+	0.2	1.060
ICN351F	8.5	NN	NN	N	0.2	1.020
ICN343F	8.5	NN	NN	1+	0.2	1.058
ICN337F	7.0	N	N	N	0.2	1.056
ICN350F	X					
ICN389F	7.5	N	N	N	0.2	1.042
ICN363F	7.0	NN	NN	1+	0.2	1.060
ICN366F	7.5	N	NN	N	0.2	1.044
ICN339F	7.5	T	N	1+	0.2	1.062

Animal Number	Microscopic										Macroscopic		
	CELLS				CRYSTALS			CASTS	OTHER				
	WBC	RBC	RE	EPC	TP	AM	CP		BACT	YEAST	SPERM	COLOR	APP
ICN303M	0	0	0	0	2+	0	0	0	1+	1+	1+	Y	CLD
ICN290M	0	0	0	0	3+	0	0	0	1+	1+	1+	Y	CLD
ICN285M	0	0	0	0	3+	0	0	0	1+	1+	1+	Y	CLD
ICN293M	0	0	0	0	1+	0	0	0	4+	0	2+	Y	CLD
ICN291M	PF	PF	0	0-1	1+	0	0	0	2+	0	0	RED	CLD
ICN328M	0	0	0	0	3+	0	0	0	1+	1+	1+	Y	CLD
ICN315M	0	0	0	0	2+	0	0	0	2+	0	1+	Y	CLD
ICN311M	0	0	0	0	3+	0	0	0	1+	1+	1+	Y	CLD
ICN299M	0	0	0	0	3+	0	0	0	1+	0	1+	Y	CLD
ICN319M	0	0	0	0	3+	0	0	0	1+	2+	1+	Y	CLD
ICN340F	0	0	0	0	4+	0	0	0	1+	1+	0	Y	CLD
ICN364F	0	0	0	0	2+	0	0	0	1+	3+	0	Y	CLD
ICN351F	0	0	0	0	2+	0	0	0	1+	1+	0	Y	CLD
ICN343F	0	0	0	0	3+	1+	0	0	1+	1+	0	Y	CLD
ICN337F	0	0	0	0	1+	2+	0	0	1+	1+	0	Y	CLD
ICN350F	X												
ICN389F	0	0	0	0	2+	0	0	0	1+	1+	0	Y	CLD
ICN363F	0	0	0	0	1+	3+	0	0	1+	1+	0	Y	CLD
ICN366F	0	0	0	0	2+	2+	0	0	1+	1+	0	Y	CLD
ICN339F	0	0	0	0	2+	0	0	0	1+	2+	0	Y	CLD

NOTE: X - ANIMAL DEAD

PF - PACKED FIELD

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

APPENDIX K - INDIVIDUAL SEMI-QUANTITATIVE URINE CHEMISTRY (CONT'D)
(SEE KEY E FOR ABBREVIATIONS)
Biochemical (Dipstick) Urinalysis
Dose: 80 MG/KG

	Animal Number	pH	OCC BLOOD	KETONES	BILIRUBIN	UROBILINOGEN	SG
	ICN322M	7.5	N	T	1+	0.2	1.042
	ICN313M	7.5	1+	T	N	0.2	1.036
	ICN304M	8.0	N	1+	N	0.2	1.031
	ICN320M	8.0	N	1+	1+	0.2	1.054
	ICN317M	X					
	ICN333M	8.0	N	T	N	0.2	1.040
	ICN277M	7.5	N	1+	1+	0.2	1.052
	ICN329M	7.0	3+	1+	1+	1.0	1.064
	ICN284M	7.5	N	1+	N	0.2	1.029
	ICN283M	8.0	N	1+	N	0.2	1.050
	ICN360F	X					
	ICN381F	7.5	N	N	N	0.2	1.031
	ICN362F	7.5	N	N	N	0.2	1.048
	ICN376F	6.5	N	N	1+	0.2	1.056
	ICN338F	7.0	N	N	1+	0.2	1.058
	ICN384F	7.5	N	N	N	0.2	1.060
	ICN367F	8.0	N	N	N	0.2	1.062
	ICN392F	7.0	N	N	N	0.2	1.052
	ICN356F	8.0	N	N	N	0.2	1.052
	ICN390F	7.0	N	N	1+	0.2	1.062

	Microscopic							Macroscopic					
	CELLS				CRYSTALS			CASTS	OTHER				
Animal Number	WBC	RBC	RE	EPC	TP	AM	CP		BACT	YEAST	SPERM	COLOR	APP
ICN322M	0	0	0	0	2+	0	0	0	1+	2+	0	Y	CLD
ICN313M	0	0-1	0	0	2+	0	0	0	1+	1+	2+	Y	CLD
ICN304M	0	0	0	0	2+	0	0	0	1+	2+	1+	Y	CLD
ICN320M	0	0	0	0	3+	0	0	0	1+	1+	3+	Y	CLD
ICN317M	X												
ICN333M	0	0	0	0	2+	0	0	0	1+	1+	1+	Y	CLD
ICN277M	0-1	0	0	0	2+	0	0	0	1+	0	2+	Y	CLD
ICN329M	0	0	0	0	2+	0	0	0	1+	1+	0	RED	CLD
ICN284M	0	0	0	0	2+	0	0	0	1+	1+	2+	Y	CLD
ICN283M	0	0	0	0	4+	0	0	0	1+	0	2+	Y	CLD
ICN360F	X												
ICN381F	0	0	0	0	1+	2+	0	0	1+	1+	0	Y	CLD
ICN362F	0	0	0	0	1+	2+	0	0	1+	1+	0	Y	CLD
ICN376F	0	0	0	0	2+	1+	0	0	1+	1+	0	Y	CLD
ICN338F	0	0	0	0	4+	1+	0	0	1+	1+	0	Y	CLD
ICN384F	0	0	0	0	2+	2+	0	0	1+	1+	0	Y	CLD
ICN367F	0	0	0	0	1+	0	0	0	1+	1+	0	Y	CLD
ICN392F	0	0	0	0	2+	3+	0	0	1+	1+	0	Y	CLD
ICN356F	0	0	0	0	3+	2+	0	0	1+	1+	0	Y	CLD
ICN390F	0	0	0	0	2+	0	0	0	1+	1+	0	Y	CLD

NOTE: X - ANIMAL DEAD

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

APPENDIX K - INDIVIDUAL SEMI-QUANTITATIVE URINE CHEMISTRY (CONT'D)
(SEE KEY E FOR ABBREVIATIONS)
Biochemical (Dipstick) Urinalysis
DOSE: 80 MG/KG (SATELLITE) DAY 88/91

Animal Number	pH	OCC BLOOD	KETONES	BILIRUBIN	UROBILINOGEN	SG
ICN296M	8.0	N	N	N	0.2	1.040
ICN326M	8.0	N	1+	1+	0.2	1.054
ICN275M	X					
ICN307M	8.0	1+	T	N	0.2	1.030
ICN280M	7.0	N	N	N	0.2	1.040
ICN309M	8.5	N	1+	N	0.2	1.042
ICN298M	8.5	N	1+	N	0.2	1.040
ICN292M	8.0	N	1+	N	0.2	1.034
ICN332M	7.5	1+	T	N	0.2	1.034
ICN316M	8.0	3+	T	1+	0.2	1.042
ICN358F	7.0	N	N	1+	0.2	1.058
ICN352F	7.0	N	N	N	0.2	1.050
ICN346F	8.0	N	N	N	0.2	1.042
ICN344F	7.0	N	N	N	0.2	1.048
ICN386F	7.0	N	N	1+	0.2	1.078
ICN375F	7.0	N	N	N	0.2	1.048
ICN397F	7.0	N	N	N	0.2	1.048
ICN380F	8.0	1+	N	N	0.2	1.023
ICN347F	7.0	N	N	1+	0.2	1.066
ICN371F	8.0	N	N	N	0.2	1.050

Animal Number	Microscopic							Macroscopic				
	CELLS				CRYSTALS			CASTS		OTHER		
	WBC	RBC	RE	EPC	TP	AM	CP		BACT	YEAST	SPERM	COLOR
ICN296M	0	0	0	0	2+	0	0	0	1+	2+	0	Y
ICN326M	0	0	0	0	3+	0	0	0	1+	1+	0	Y
ICN275M	X											
ICN307M	4-8	4-6	0	0	4+	0	0	0	1+	0	1+	Y
ICN280M	0	0	0	0	2+	0	0	0	1+	2+	2+	Y
ICN309M	0	0	0	0	3+	0	0	0	1+	1+	2+	Y
ICN298M	0	0	0	0	3+	0	0	0	1+	1+	1+	Y
ICN292M	0	0	0	0	3+	0	0	0	1+	1+	2+	Y
ICN332M	0	0	0	0	2+	0	0	0	1+	0	2+	Y
ICN316M	0-2	PF	0	0	2+	0	0	0	1+	0	0	RED
ICN358F	0	0	0	0	2+	0	0	0	1+	1+	0	Y
ICN352F	0	0	0	0	1+	0	0	0	1+	1+	0	Y
ICN346F	0	0	0	0-3	2+	2+	0	0	1+	1+	0	Y
ICN344F	0	0	0	0	2+	2+	0	0	1+	1+	0	Y
ICN386F	0-2	0	0	0	1+	2+	0	0	1+	1+	0	Y
ICN375F	0	0	0	0	2+	0	0	0	1+	1+	0	Y
ICN397F	0	0	0	0	1+	1+	0	0	1+	1+	0	Y
ICN380F	0	0	0	0	2+	2+	0	0	1+	1+	0	Y
ICN347F	0	0	0	0	2+	0	0	0	1+	2+	0	Y
ICN371F	0	0	0	0	1+	0	0	0	1+	1+	0	Y

NOTE: X - ANIMAL DEAD

PF - PACKED FIELD

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

APPENDIX K - INDIVIDUAL SEMI-QUANTITATIVE URINE CHEMISTRY (CONT'D)

(SEE KEY E FOR ABBREVIATIONS)

Biochemical (Dipstick) Urinalysis

DOSE: 80 MG/KG (SATELLITE) - RECOVERY DAY 120

Animal Number	pH	OCC BLOOD	KETONES	BILIRUBIN	UROBILINOGEN	SG
ICN296M	8.0	N	1+	N	0.2	1.032
ICN326M	7.5	N	T	N	0.2	1.026
ICN275M	X					
ICN307M	7.0	N	T	N	0.2	1.024
ICN280M	7.0	3+	N	N	0.2	1.020
ICN309M	8.0	N	1+	N	0.2	1.029
ICN298M	8.0	2+	1+	N	0.2	1.027
ICN292M	8.0	N	1+	N	0.2	1.015
ICN332M	7.0	2+	1+	N	0.2	1.027
ICN316M	7.5	3+	T	N	0.2	1.026
ICN358F	7.5	N	N	1+	0.2	1.056
ICN352F	7.5	N	N	N	0.2	1.032
ICN346F	7.5	N	N	N	0.2	1.040
ICN344F	7.5	N	N	N	0.2	1.052
ICN386F	7.5	N	N	N	0.2	1.029
ICN375F	8.0	N	N	N	0.2	1.040
ICN397F	7.0	N	N	N	0.2	1.044
ICN380F	7.5	1+	N	N	0.2	1.015
ICN347F	7.5	1+	N	N	0.2	1.044
ICN371F	8.0	N	N	N	0.2	1.040

Microscopic										Macroscopic				
Animal Number	CELLS				CRYSTALS			CASTS		OTHER				
	WBC	RBC	RE	EPC	TP	AM	CP			BACT	YEAST	SPERM	COLOR	APP
ICN296M	0	0	0	0	1+	0	0	0		1+	0	1+	Y	CLD
ICN326M	0	0	0	0	2+	0	0	0		1+	0	1+	Y	CLD
ICN275M	X													
ICN307M	0	0-2	0	0	1+	0	0	0		1+	0	2+	Y	CLD
ICN280M	0	0-2	0	0-1	1+	0	0	0		2+	0	2+	Y	CLD
ICN309M	0	0	0	0	3+	0	0	0		1+	0	1+	Y	CLD
ICN298M	0	4-6	0	0	3+	0	0	0		1+	0	1+	Y	CLD
ICN292M	0	0	0	0	2+	0	0	0		1+	0	2+	Y	CLD
ICN332M	0	0-1	0	0	1+	0	0	0		3+	1+	1+	Y	CLD
ICN316M	0	TNTC	0	0	2+	0	0	0		1+	0	1+	Y	CLD
ICN358F	0	0	0	0	1+	0	0	0		1+	1+	0	Y	CLD
ICN352F	0	0	0	0	1+	0	0	0		1+	0	0	Y	CLD
ICN346F	0	0	0	0	1+	0	0	0		1+	0	0	Y	CLD
ICN344F	0	0	0	0	1+	0	0	0		1+	2+	0	Y	CLD
ICN386F	0	0	0	0	1+	0	0	0		2+	0	0	Y	CLD
ICN375F	0	0	0	0-1	2+	0	0	0		1+	1+	0	Y	CLD
ICN397F	0	0	0	0	1+	2+	0	0		1+	0	0	Y	CLD
ICN380F	0	0-1	0	0	1+	0	0	0		3+	0	0	Y	CLD
ICN347F	0	0-3	0	0	1+	0	0	0		1+	0	0	Y	CLD
ICN371F	0	0	0	0-1	0	0	0	0		1+	2+	0	Y	CLD

NOTE: X - ANIMAL DEAD

TNTC - TOO NUMEROUS TO COUNT

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

APPENDIX L - INDIVIDUAL ORGAN WEIGHTS
(SEE KEY F FOR ABBREVIATIONS)
DOSE: 0 MG/KG

PARAMETERS=	T B W	L I V E R	K I D N E Y	B R A I N	T E S T E S	O V A R
UNITS=	(g)	(g)	(g)	(g)	(g)	(g)
ICN297M	X					
ICN287M	450.8	11.11	3.38	1.98	3.5381	
ICN295M	470.2	12.84	3.53	2.05	3.6432	
ICN289M	519.4	12.89	3.29	2.02	3.5559	
ICN294M	516.8	13.00	3.52	2.16	4.0542	
ICN279M	562.7	14.60	3.45	2.00	4.0135	
ICN278M	468.2	12.07	3.21	2.06	3.5728	
ICN314M	414.9	8.85	2.93	2.25	3.6365	
ICN323M	491.7	12.44	3.27	2.04	3.4802	
ICN305M	428.0	11.48	3.34	2.09	3.0359	
MEAN	480.3	12.14	3.35	2.07	3.6145	
STD.DEV.	47.3	1.59	0.20	0.08	0.2995	N/A
N	9	9	9	9	9	
ICN396F	306.1	8.08	2.14	1.85		0.084
ICN398F	266.7	6.94	1.87	1.84		0.097
ICN372F	287.3	8.06	2.14	2.00		0.094
ICN379F	281.2	7.49	1.97	1.93		0.099
ICN365F	254.6	6.63	1.93	2.00		0.113
ICN378F	270.9	6.98	2.22	1.89		0.114
ICN377F	282.4	6.99	2.19	2.10		0.143
ICN355F	270.6	7.67	2.21	2.14		0.105
ICN394F	304.3	9.17	2.39	2.07		0.101
ICN373F	278.2	7.72	2.03	2.09		0.123
MEAN	280.2	7.57	2.11	1.99		0.107
STD.DEV.	16.1	0.75	0.16	0.11	N/A	0.017
N	10	10	10	10		10

NOTE: X - ANIMAL DEAD

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

APPENDIX L - INDIVIDUAL ORGAN WEIGHTS (CONT'D)
(SEE KEY F FOR ABBREVIATIONS)
DOSE: 10 MG/KG

PARAMETERS=	T B W	L I V E R	K I D N E Y	B R A I N	T E S T E S	O V A R
UNITS=	(g)	(g)	(g)	(g)	(g)	(g)
ICN318M	489.2	12.17	3.34	1.93	3.7132	
ICN310M	488.8	12.75	3.94	2.23	3.7483	
ICN273M	540.0	12.67	3.35	2.06	4.0180	
ICN302M	421.0	12.41\$M	3.13	2.03	3.2733	
ICN306M	504.4	14.01	3.69	1.88	3.8101	
ICN276M	511.9	12.56	4.13	2.35	4.1022	
ICN300M	422.5	9.69	3.05	2.20	3.2381	
ICN335M	663.8	15.98	3.64	2.02	4.1068	
ICN321M	542.4	12.94	3.69	2.02	2.9677	
ICN330M	548.7	14.15	3.70	2.14	4.0488	
MEAN	513.3	12.99	3.57	2.09	3.7027	
STD.DEV.	69.5	1.70	0.34	0.14	0.4077	N/A
N	10	9	10	10	10	
ICN353F	290.7	7.83	2.58	2.15		0.107
ICN342F	287.4	7.05	2.18	1.89		0.068
ICN345F	290.2	7.48	2.14	1.85		0.074
ICN348F	284.9	7.22	1.94	1.96		0.078
ICN388F	264.0	7.27	1.99	2.19		0.072
ICN341F	261.3	6.94	2.06	1.99		0.100
ICN385F	248.5	6.83	1.92	1.94		0.080
ICN361F	263.9	7.66	1.86	2.10		0.044
ICN370F	277.8	7.02	2.31	2.05		0.102
ICN395F	265.5	7.04	1.99	1.93		0.081
MEAN	273.4	7.23	2.10	2.01		0.081
STD.DEV.	14.7	0.33	0.22	0.11	N/A	0.019
N	10	10	10	10		10

NOTE: \$ - VALUE EXCLUDED FROM CALCULATIONS
M - MASS ON ORGAN

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

APPENDIX L - INDIVIDUAL ORGAN WEIGHTS (CONT'D)
(SEE KEY F FOR ABBREVIATIONS)
DOSE: 40 MG/KG

PARAMETERS=	T B W	L I V E R	K I D N E Y	B R A I N	T E S T E S	O V A R
UNITS=	(g)	(g)	(g)	(g)	(g)	(g)
ICN303M	426.8	10.93	2.74	2.19	3.7759	
ICN290M	422.0	11.09	3.30	1.96	3.7493	
ICN285M	508.5	12.22	3.61	2.18	3.8874	
ICN293M	537.8	13.29	4.16	2.33	3.4110	
ICN291M	406.5	10.75	4.66	2.31	3.5674	
ICN328M	444.6	9.97	3.49	2.14	3.6588	
ICN315M	594.8	14.26	3.95	2.20	3.9224	
ICN311M	507.9	12.96	4.06	2.24	3.8443	
ICN299M	351.4	8.18	2.78	2.04	3.4316	
ICN319M	411.8	10.41	3.11	1.85	3.0317	
MEAN	461.2	11.41	3.59	2.14	3.6280	
STD.DEV.	73.5	1.79	0.63	0.15	0.2755	N/A
N	10	10	10	10	10	
ICN340F	305.9	8.30	2.28	1.81		0.101
ICN364F	281.5	6.44	2.04	1.94		0.075
ICN351F	287.8	8.46	2.37	1.95		0.092
ICN343F	256.1	6.88	1.97	1.91		0.068
ICN337F	282.5	7.60	2.58	2.01		0.107
ICN350F	X					
ICN389F	270.1	7.08	1.87	2.00		0.089
ICN363F	271.4	6.94	2.17	1.88		0.094
ICN366F	303.3	8.20	2.14	1.96		0.132
ICN339F	264.0	6.80	2.09	2.10		0.117
MEAN	280.3	7.41	2.17	1.95		0.097
STD.DEV.	16.9	0.75	0.22	0.08	N/A	0.020
N	9	9	9	9		9

NOTE: X - ANIMAL DEAD

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

APPENDIX L - INDIVIDUAL ORGAN WEIGHTS (CONT'D)
(SEE KEY F FOR ABBREVIATIONS)
DOSE: 80 MG/KG

PARAMETERS=	T B W	L I V E R	K I D N E Y	B R A I N	T E S T E S	O V A R
UNITS=	(g)	(g)	(g)	(g)	(g)	(g)
ICN322M	474.4	11.60	3.35	2.31	3.6202	
ICN313M	414.7	10.73	3.36	2.18	3.6541	
ICN304M	439.4	11.25	3.93	2.11	3.6005	
ICN320M	484.0	12.51	4.12	2.31	3.3079	
ICN317M	X					
ICN333M	519.2	11.31	3.47	2.09	3.6630	
ICN277M	476.5	11.31	3.44	2.05	3.4649	
ICN329M	382.2	12.55\$M	3.15	1.91	2.8567	
ICN284M	549.2	13.78	4.36	2.13	3.7294	
ICN283M	486.3	12.57	3.87	2.13	4.0470	
MEAN	469.5	11.88	3.67	2.14	3.5493	
STD.DEV.	51.1	1.00	0.41	0.12	0.3273	N/A
N	9	8	9	9	9	
ICN360F	X					
ICN381F	252.8	6.66	2.02	1.83		0.077
ICN362F	292.6	7.65	2.14	1.77		0.108
ICN376F	284.8	7.38	1.91	1.93		0.088
ICN338F	292.9	7.75	2.40	2.04		0.105
ICN384F	255.7	6.63	1.90	1.88		0.073
ICN367F	248.8	7.70	2.27	1.95		0.086
ICN392F	268.8	8.64	2.42	2.13		0.083
ICN356F	280.9	7.10	2.27	2.00		0.109
ICN390F	272.0	7.33	2.31	2.09		0.123
MEAN	272.1	7.43	2.18	1.96		0.095
STD.DEV.	16.9	0.62	0.20	0.12	N/A	0.017
N	9	9	9	9		9

NOTE: X - ANIMAL DEAD
\$ - VALUE EXCLUDED FROM CALCULATIONS
M - MASS ON ORGAN

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

APPENDIX L - INDIVIDUAL ORGAN WEIGHTS (CONT'D)
(SEE KEY F FOR ABBREVIATIONS)
DOSE: 80 MG/KG (SATELLITE)

PARAMETERS=	T B W	L I V E R	K I D N E Y	B R A I N	T E S T E S	O V A R
UNITS=	(g)	(g)	(g)	(g)	(g)	(g)
ICN296M	460.2	11.66	3.46	2.17	3.7536	
ICN326M	545.6	12.67	3.59	2.14	3.4942	
ICN275M	X					
ICN307M	594.3	13.47	3.67	2.27	3.6985	
ICN280M	548.8	13.62	4.17	2.27	3.5687	
ICN309M	550.7	15.12	3.85	2.16	3.7126	
ICN298M	558.4	12.88	3.30	2.08	3.6388	
ICN292M	553.7	12.75	3.63	2.15	4.3299	
ICN332M	538.5	13.71	3.69	2.19	4.0157	
ICN316M	533.7	13.35	3.54	2.09	3.2665	
MEAN	542.7	13.25	3.66	2.17	3.7198	
STD.DEV.	35.4	0.95	0.25	0.07	0.3056	N/A
N	9	9	9	9	9	
ICN358F	290.6	7.66	2.27	1.95		0.068
ICN352F	291.0	8.03	2.04	1.90		0.094
ICN346F	321.9	7.91	2.29	1.97		0.135
ICN344F	333.8	8.61	2.25	2.02		0.123
ICN386F	258.7	6.91	2.08	1.91		0.060
ICN375F	303.0	7.86	2.62	1.95		0.139
ICN397F	292.9	7.59	2.29	1.88		0.108
ICN380F	304.7	7.87	2.33	1.96		0.069
ICN347F	316.8	7.96	2.39	2.00		0.092
ICN371F	284.5	7.74	2.39	1.96		0.066
MEAN	299.8	7.81	2.30	1.95		0.095
STD.DEV.	21.3	0.42	0.16	0.04	N/A	0.030
N	10	10	10	10		10

NOTE: X - ANIMAL DEAD

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

APPENDIX M - INDIVIDUAL RELATIVE ORGAN WEIGHTS
(SEE KEY F FOR ABBREVIATIONS)
DOSE: 0 MG/KG

PARAMETERS=	L I V E R / B W	K I D N Y / B W	B R A I N / B W	T E S T S / B W	O V A R / B W
ICN297M	X				
ICN287M	0.025	0.0075	0.0044	0.0078	
ICN295M	0.027	0.0075	0.0044	0.0077	
ICN289M	0.025	0.0063	0.0039	0.0068	
ICN294M	0.025	0.0068	0.0042	0.0078	
ICN279M	0.026	0.0061	0.0036	0.0071	
ICN278M	0.026	0.0069	0.0044	0.0076	
ICN314M	0.021	0.0071	0.0054	0.0088	
ICN323M	0.025	0.0067	0.0041	0.0071	
ICN305M	0.027	0.0083	0.0049	0.0071	
MEAN	0.025	0.0070	0.0044	0.0075	
STD.DEV.	0.002	0.0007	0.0005	0.0006	N/A
N	9	9	9	9	
ICN396F	0.026	0.0070	0.0060		.00027
ICN398F	0.026	0.0070	0.0069		.00036
ICN372F	0.028	0.0074	0.0070		.00033
ICN379F	0.027	0.0070	0.0069		.00035
ICN365F	0.026	0.0076	0.0079		.00044
ICN378F	0.026	0.0082	0.0070		.00042
ICN377F	0.025	0.0078	0.0074		.00051
ICN355F	0.028	0.0082	0.0079		.00039
ICN394F	0.030	0.0079	0.0068		.00033
ICN373F	0.028	0.0073	0.0075		.00044
MEAN	0.027	0.0075	0.0071		.00038
STD.DEV.	0.001	0.0005	0.0006	N/A	.00007
N	10	10	10	10	

NOTE: X - ANIMAL DEAD

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

APPENDIX M - INDIVIDUAL RELATIVE ORGAN WEIGHTS (CONT'D)
(SEE KEY F FOR ABBREVIATIONS)
DOSE: 10 MG/KG

PARAMETERS=	L I V E R / B W	K I D N Y / B W	B R A I N / B W	T E S T S / B W	O V A R / B W
ICN318M	0.025	0.0068	0.0039	0.0076	
ICN310M	0.026	0.0081	0.0046	0.0077	
ICN273M	0.023	0.0062	0.0038	0.0074	
ICN302M	0.029SM	0.0074	0.0048	0.0078	
ICN306M	0.028	0.0073	0.0037	0.0076	
ICN276M	0.025	0.0081	0.0046	0.0080	
ICN300M	0.023	0.0072	0.0052	0.0077	
ICN335M	0.024	0.0055	0.0030	0.0062	
ICN321M	0.024	0.0068	0.0037	0.0055	
ICN330M	0.026	0.0067	0.0039	0.0074	
MEAN	0.025	0.0070	0.0041	0.0073	
STD.DEV.	0.002	0.0008	0.0007	0.0008	N/A
N	9	10	10	10	
ICN353F	0.027	0.0089	0.0074		.00037
ICN342F	0.025	0.0076	0.0066		.00024
ICN345F	0.026	0.0074	0.0064		.00026
ICN348F	0.025	0.0068	0.0069		.00027
ICN388F	0.028	0.0075	0.0083		.00027
ICN341F	0.027	0.0079	0.0076		.00038
ICN385F	0.027	0.0077	0.0078		.00032
ICN361F	0.029	0.0070	0.0080		.00017
ICN370F	0.025	0.0083	0.0074		.00037
ICN395F	0.027	0.0075	0.0073		.00031
MEAN	0.027	0.0077	0.0074		.00030
STD.DEV.	0.001	0.0006	0.0006	N/A	.00007
N	10	10	10	10	

NOTE: \$ - VALUE EXCLUDED FROM CALCULATIONS
M - MASS ON ORGAN

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

APPENDIX M - INDIVIDUAL RELATIVE ORGAN WEIGHTS (CONT'D)
(SEE KEY F FOR ABBREVIATIONS)
DOSE: 40 MG/KG

PARAMETERS=	L I V E R / B W	K I D N Y / B W	B R A I N / B W	T E S T S / B W	O V A R / B W
ICN303M	0.026	0.0064	0.0051	0.0088	
ICN290M	0.026	0.0078	0.0046	0.0089	
ICN285M	0.024	0.0071	0.0043	0.0076	
ICN293M	0.025	0.0077	0.0043	0.0063	
ICN291M	0.026	0.0115	0.0057	0.0088	
ICN328M	0.022	0.0078	0.0048	0.0082	
ICN315M	0.024	0.0066	0.0037	0.0066	
ICN311M	0.026	0.0080	0.0044	0.0076	
ICN299M	0.023	0.0079	0.0058	0.0098	
ICN319M	0.025	0.0076	0.0045	0.0074	
MEAN	0.025	0.0078	0.0047	0.0080	
STD.DEV.	0.001	0.0014	0.0007	0.0011	N/A
N	10	10	10	10	
ICN340F	0.027	0.0075	0.0059		.00033
ICN364F	0.023	0.0072	0.0069		.00027
ICN351F	0.029	0.0082	0.0068		.00032
ICN343F	0.027	0.0077	0.0075		.00027
ICN337F	0.027	0.0091	0.0071		.00038
ICN350F	X				
ICN389F	0.026	0.0069	0.0074		.00033
ICN363F	0.026	0.0080	0.0069		.00035
ICN366F	0.027	0.0071	0.0065		.00044
ICN339F	0.026	0.0079	0.0080		.00044
MEAN	0.026	0.0077	0.0070		.00035
STD.DEV.	0.002	0.0007	0.0006	N/A	.00006
N	9	9	9		9

NOTE: X - ANIMAL DEAD

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

APPENDIX M - INDIVIDUAL RELATIVE ORGAN WEIGHTS (CONT'D)
(SEE KEY F FOR ABBREVIATIONS)
DOSE: 80 MG/KG

PARAMETERS-	L I V E R / B W	K I D N Y / B W	B R A I N / B W	T E S T S / B W	O V A R / B W
ICN322M	0.024	0.0071	0.0049	0.0076	
ICN313M	0.026	0.0081	0.0053	0.0088	
ICN304M	0.026	0.0089	0.0048	0.0082	
ICN320M	0.026	0.0085	0.0048	0.0068	
ICN317M	X				
ICN333M	0.022	0.0067	0.0040	0.0071	
ICN277M	0.024	0.0072	0.0043	0.0073	
ICN329M	0.033\$M	0.0082	0.0050	0.0075	
ICN284M	0.025	0.0079	0.0039	0.0068	
ICN283M	0.026	0.0080	0.0044	0.0083	
MEAN	0.025	0.0078	0.0046	0.0076	
STD.DEV.	0.001	0.0007	0.0005	0.0007	N/A
N	8	9	9	9	
ICN360F	X				
ICN381F	0.026	0.0080	0.0072		.00030
ICN362F	0.026	0.0073	0.0060		.00037
ICN376F	0.026	0.0067	0.0068		.00031
ICN338F	0.026	0.0082	0.0070		.00036
ICN384F	0.026	0.0074	0.0074		.00029
ICN367F	0.031	0.0091	0.0078		.00035
ICN392F	0.032	0.0090	0.0079		.00031
ICN356F	0.025	0.0081	0.0071		.00039
ICN390F	0.027	0.0085	0.0077		.00045
MEAN	0.027	0.0080	0.0072		.00035
STD.DEV.	0.002	0.0008	0.0006	N/A	.00005
N	9	9	9		9

NOTE: X - ANIMAL DEAD
\$ - VALUE EXCLUDED FROM CALCULATIONS
M - MASS ON ORGAN

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

APPENDIX M - INDIVIDUAL RELATIVE ORGAN WEIGHTS (CONT'D)
(SEE KEY F FOR ABBREVIATIONS)
DOSE: 80 MG/KG (SATELLITE)

PARAMETERS=	L I V E R / B W	K I D N E Y / B W	B R A I N / B W	T E S T S / B W	O V A R / B W
ICN296M	0.025	0.0075	0.0047	0.0082	
ICN326M	0.023	0.0066	0.0039	0.0064	
ICN275M	X				
ICN307M	0.023	0.0062	0.0038	0.0062	
ICN280M	0.025	0.0076	0.0041	0.0065	
ICN309M	0.027	0.0070	0.0039	0.0067	
ICN298M	0.023	0.0059	0.0037	0.0065	
ICN292M	0.023	0.0066	0.0039	0.0078	
ICN332M	0.025	0.0069	0.0041	0.0075	
ICN316M	0.025	0.0066	0.0039	0.0061	
MEAN	0.024	0.0068	0.0040	0.0069	
STD.DEV.	0.001	0.0006	0.0003	0.0008	N/A
N	9	9	9	9	
ICN358F	0.026	0.0078	0.0067		.00023
ICN352F	0.028	0.0070	0.0065		.00032
ICN346F	0.025	0.0071	0.0061		.00042
ICN344F	0.026	0.0067	0.0061		.00037
ICN386F	0.027	0.0080	0.0074		.00023
ICN375F	0.026	0.0086	0.0064		.00046
ICN397F	0.026	0.0078	0.0064		.00037
ICN380F	0.026	0.0076	0.0064		.00023
ICN347F	0.025	0.0075	0.0063		.00029
ICN371F	0.027	0.0084	0.0069		.00023
MEAN	0.026	0.0077	0.0065		.00032
STD.DEV.	0.001	0.0006	0.0004	N/A	.00009
N	10	10	10		10

NOTE: X - ANIMAL DEAD

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APPENDIX N - INDIVIDUAL GROSS POSTMORTEM OBSERVATIONS

GROUP 1: 0 MG/KG

ICN297M - FOUND DEAD ON TEST DAY 22
CECUM: Extremely compacted ingesta.
LIVER (All lobes and surfaces): Mottled Red/dark red/tan.
TERMINAL BODY WEIGHT: 343.3g

ICN287M - ALL TISSUES AND ORGANS: No observable abnormalities.

ICN295M - ALL TISSUES AND ORGANS: No observable abnormalities.

ICN289M - ALL TISSUES AND ORGANS: No observable abnormalities.

ICN294M - ALL TISSUES AND ORGANS: No observable abnormalities.

ICN279M - ALL TISSUES AND ORGANS: No observable abnormalities.

ICN278M - ALL TISSUES AND ORGANS: No observable abnormalities.

ICN314M - ALL TISSUES AND ORGANS: No observable abnormalities.

ICN323M - ALL TISSUES AND ORGANS: No observable abnormalities.

ICN305M - ALL TISSUES AND ORGANS: No observable abnormalities.

ICN396F - SKIN/FUR (Left dorsal): Scabs.

ICN398F - ALL TISSUES AND ORGANS: No observable abnormalities.

ICN372F - ALL TISSUES AND ORGANS: No observable abnormalities.

ICN379F - ALL TISSUES AND ORGANS: No observable abnormalities.

ICN365F - ALL TISSUES AND ORGANS: No observable abnormalities.

ICN378F - ALL TISSUES AND ORGANS: No observable abnormalities.

ICN377F - ALL TISSUES AND ORGANS: No observable abnormalities.

ICN355F - ALL TISSUES AND ORGANS: No observable abnormalities.

ICN394F - ALL TISSUES AND ORGANS: No observable abnormalities.

ICN373F - ALL TISSUES AND ORGANS: No observable abnormalities.

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APPENDIX N - INDIVIDUAL GROSS POSTMORTEM OBSERVATIONS (CONT'D)

GROUP 2: 10 MG/KG

ICN318M - ALL TISSUES AND ORGANS: No observable abnormalities.
ICN310M - ALL TISSUES AND ORGANS: No observable abnormalities.
ICN273M - ALL TISSUES AND ORGANS: No observable abnormalities.
ICN302M - LIVER/MASS A (Accessory lobe): 2.2 x 1.3 x 1.0 cm, red/dark red, firm; cut surface
tan/red/dark red, firm.
ICN306M - ALL TISSUES AND ORGANS: No observable abnormalities.
ICN276M - ALL TISSUES AND ORGANS: No observable abnormalities.
ICN300M - ALL TISSUES AND ORGANS: No observable abnormalities.
ICN335M - ALL TISSUES AND ORGANS: No observable abnormalities.
ICN321M - SPLEEN: Friable.
ICN330M - ALL TISSUES AND ORGANS: No observable abnormalities.
ICN353F - SKIN/FUR (Extremities): Alopecia.
ICN342F - ALL TISSUES AND ORGANS: No observable abnormalities.
ICN345F - ALL TISSUES AND ORGANS: No observable abnormalities.
ICN348F - SKIN/FUR (Dose site): Desquamation.
ICN388F - ALL TISSUES AND ORGANS: No observable abnormalities.
ICN341F - SKIN/FUR (Dose site): Desquamation.
STOMACH (Glandular mucosa): Dark red areas.
ICN385F - ALL TISSUES AND ORGANS: No observable abnormalities.
ICN361F - ALL TISSUES AND ORGANS: No observable abnormalities.
ICN370F - SKIN/FUR (Dose site): Eschar, desquamation.
ICN395F - LUNGS (All lobes and surfaces): Several dark red foci.
SKIN/FUR (Dose site): Eschar, desquamation.

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APPENDIX N - INDIVIDUAL GROSS POSTMORTEM OBSERVATIONS (CONT'D)

GROUP 3: 40 MG/KG

ICN303M - ILEUM: Diverticulum.
SKIN/FUR (Dose site): Eschar, desquamation.

ICN290M - SKIN/FUR (Dose site): Eschar, desquamation.

ICN285M - SKIN/FUR (Dose site): Eschar, desquamation.

ICN293M - INCISORS (Both uppers): Maloccluded.
PALATE: Sores.
SKIN/FUR (Dose site): Desquamation; (Around right eye): Dried red material;
(Extremities): Alopecia.

ICN291M - KIDNEY (Right): Dilated pelvis; renal calculus.
SKIN/FUR (Dose site): Eschar, desquamation.
URINARY BLADDER: Extremely distended, thickened, multiple cystic calculi.

ICN328M - SKIN/FUR (Dose site): Eschar, desquamation.

ICN315M - ALL TISSUES AND ORGANS: No observable abnormalities.

ICN311M - SKIN/FUR (Dose site): Eschar, desquamation.

ICN299M - SKIN/FUR (Dose site): Eschar, desquamation.

ICN319M - SKIN/FUR (Dose site): Eschar, desquamation.

ICN340F - SKIN/FUR (Dose site): Eschar, desquamation.
TAIL: Necrotic.

ICN364F - SKIN/FUR (Dose site): Eschar, desquamation.

ICN351F - SKIN/FUR (Dose site): Eschar, desquamation.

ICN343F - SKIN/FUR (Dose site): Eschar, desquamation.

ICN337F - SKIN/FUR (Dose site): Eschar, desquamation.
TAIL: Truncated.

ICN350F - FOUND DEAD ON DAY 7
LIVER (All lobes and surfaces): Large patches of tan areas.
SKIN/FUR (Dose site): Eschar, desquamation.
TERMINAL BODY WEIGHT: 226.3g

ICN389F - SKIN/FUR (Dose site): Eschar, desquamation.

ICN363F - SKIN/FUR (Dose site): Eschar, desquamation.

ICN366F - SKIN/FUR (Dose site): Eschar, desquamation.

ICN339F - SKIN/FUR (Dose site): Eschar, desquamation.

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APPENDIX N - INDIVIDUAL GROSS POSTMORTEM OBSERVATIONS (CONT'D)

GROUP 4: 80 MG/KG

- ICN322M - SKIN/FUR (Dose site): Eschar, desquamation.
- ICN313M - SKIN/FUR (Dose site): Eschar, desquamation.
- ICN304M - SKIN/FUR (Dose site): Eschar, desquamation.
- ICN320M - SKIN/FUR (Dose site): Eschar, desquamation.
- ICN317M - FOUND DEAD ON DAY 84
ABDOMINAL AND THORACIC CAVITIES: Filled with thin red liquid.
CECUM: Ingesta extremely compacted.
HEART: Firm.
KIDNEYS (Both): Surrounded by clear gelatinous material.
LIVER (Left lobe, diaphragmatic surface): Moderate amount of tan foci.
LUNGS (All lobes and surfaces): Dark red.
SEMINAL VESICLES: Extremely distended with creamy white material.
SKIN/FUR (Dose site): Eschar, exfoliation.
URINARY BLADDER: Extremely distended with thin red liquid.
NOTE: All tissues and organs slight postmortem changes.
TERMINAL BODY WEIGHT: 472.9g
- ICN333M - SKIN/FUR (Dose site): Eschar, desquamation.
- ICN277M - SKIN/FUR (Dose site): Eschar, desquamation.
- ICN329M - LIVER/MASS A (left lobe, visceral surface): Adhered to pancreas/stomach, 1.9 x 1.6 x 0.9 cm,
firm, red, tan, cut surface red and firm.
SKIN/FUR (Dose site): Eschar, desquamation.
- ICN284M - SKIN/FUR (Dose site): Eschar, desquamation.
TAIL: Necrotic tip.
- ICN283M - SKIN/FUR (Dose site): Eschar, desquamation.

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APPENDIX N - INDIVIDUAL GROSS POSTMORTEM OBSERVATIONS (CONT'D)

GROUP 4: 80 MG/KG

ICN360F - FOUND DEAD ON DAY 7
LIVER (All lobes and surfaces): Tan areas.
TERMINAL BODY WEIGHT: 238.7g

ICN381F - SKIN/FUR (Dose site): Eschar, desquamation.

ICN362F - SKIN/FUR (Dose site): Eschar, desquamation.

ICN376F - SKIN/FUR (Dose site): Eschar, desquamation.

ICN338F - SKIN/FUR (Dose site): Eschar, desquamation.

ICN384F - SKIN/FUR (Dose site): Eschar, desquamation;
TAIL: Tip necrotic.

ICN367F - SKIN/FUR (Dose site): Desquamation.
UTERUS: Thickened.

ICN392F - SKIN/FUR (Dose site): Eschar, desquamation.
UTERUS: Thickened.

ICN356F - SKIN/FUR (Dose site): Eschar, desquamation.

ICN390F - SKIN/FUR (Dose site): Eschar, desquamation; (Extremities): Alopecia.

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APPENDIX N - INDIVIDUAL GROSS POSTMORTEM OBSERVATIONS (CONT'D)

GROUP 5: 80 MG/KG (SATELLITE)

- ICN296M - ALL TISSUES AND ORGANS: No observable abnormalities.
- ICN326M - ALL TISSUES AND ORGANS: No observable abnormalities.
- ICN275M - MORIBUND EUTHANASIA ON DAY 84
KIDNEYS (Both): Slightly larger than normal, pale throughout, slight amount of red foci, subcapsular.
LIVER (Caudate, accessory lobes): Slight amount of tan striations; (Left lobe): Thickened, firm, reddened.
SEMINAL VESICLES: Moderately distended with thickened dark red/white creamy material.
SKIN/FUR (Dose site): Eschar, exfoliation; (Anogenital area): Moderate amount of red staining.
STOMACH (Glandular mucosa): Reddened.
URINARY BLADDER: Extremely distended with thickened dark red material.
- ICN307M - ALL TISSUES AND ORGANS: No observable abnormalities.
- ICN280M - SKIN/FUR (Dorsal thoracic): Scabs; (Extremities): Alopecia.
- ICN309M - ALL TISSUES AND ORGANS: No observable abnormalities.
- ICN298M - ALL TISSUES AND ORGANS: No observable abnormalities.
- ICN292M - ALL TISSUES AND ORGANS: No observable abnormalities.
- ICN332M - ALL TISSUES AND ORGANS: No observable abnormalities.
- ICN316M - KIDNEY (Right): Moderately dilated renal pelvis.
SKIN/FUR (Right lateral cervical): Scabs.
- ICN358F - ALL TISSUES AND ORGANS: No observable abnormalities.
- ICN352F - ALL TISSUES AND ORGANS: No observable abnormalities.
- ICN346F - ALL TISSUES AND ORGANS: No observable abnormalities.
- ICN344F - ALL TISSUES AND ORGANS: No observable abnormalities.
- ICN386F - EAR (Right): Swollen.
OVARY (Left): Surrounded by clear fluid filled sac.
- ICN375F - ALL TISSUES AND ORGANS: No observable abnormalities.
- ICN397F - ALL TISSUES AND ORGANS: No observable abnormalities.
- ICN380F - LIVER (Median lobe at cleft): One tan embedded nodule.
UTERUS: Slightly distended.
- ICN347F - ALL TISSUES AND ORGANS: No observable abnormalities.
- ICN371F - SKIN/FUR (Extremities): Alopecia.

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STUDY NUMBER 139910B - TEST MATERIAL MRD-92-399
HISTOPATHOLOGY

APPENDIX O - HISTOPATHOLOGY REPORT

SUBMITTED TO:

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Charles F. Morris August 11, 1993
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August 11, 1993

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METHOD

Microscopic examination was made of the specified tissues from five groups of male and female Cr1:CDBR rats in a 90-day repeated dose dermal toxicity study on MRD-92-399. A brief outline of the study design is shown below.

Dose Group	Dose Level (mg/kg)	Number of Rats per Group
1 (Control)*	0	10M,10F
2 (Low)	10	10M,10F
3 (Mid)	40	10M,10F
4 (High)	80	10M,10F
5 (Satellite)**	80	10M,10F

*Control animals received carrier only at 2.0 ml/kg.

**These animals were treated the same as Group 4 and then observed for reversibility, persistence or delayed occurrence of toxic effects for at least 28 additional days.

Prior to the topical administration of the test/control materials and at least once per week during the study, the hair of each animal on the dorsal surface from the shoulder region to the lumbar region was closely clipped; the skin of all animals was left intact. The test/control substances were applied to each animal (approximately 10% of the total body surface). The test/control material was applied to the clipped, unabraded dorsal surface of the skin of each rat, seven days per week, for a minimum of 13 weeks. The test/control articles were applied on a gauze pad placed on the dose site and covered with tape. The rats

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were wrapped with COBAN to prevent evaporation and ingestion of the test/control substances.

The tissues specified for microscopic examination for the Group 1 (Control), Group 4 (High) and Group 5 (Satellite) rats included: skin (treated and untreated sites), adrenal glands, aorta, brain, epididymides, esophagus, eyes, femoris muscle with sciatic nerve, heart kidneys, exorbital lacrimal glands, large intestine (colon and cecum), liver, lung, mammary gland, mesenteric lymph node, ovaries, oviducts, pancreas, pituitary, prostate, rectum, salivary glands, seminal vesicles, small intestine (duodenum, jejunum, ileum), spinal cord (cervical, midthoracic and lumbar), spleen, sternum with marrow, stomach, testes, thymus, thyroid with parathyroids, trachea, urinary bladder, uterus (corpus and cervix) and other tissues with gross lesions. In addition, the lung, liver, kidneys and other tissues with gross changes were examined from male and female rats of the intermediate dose groups. The treated skin was not routinely examined from the intermediate dose groups; sections only were examined if gross changes were described at necropsy.

The in-life portion of the study, necropsy examinations and microscopic slide preparation were performed at Exxon Biomedical Sciences, Inc. (EBSI). At necropsy, the tissues were collected and placed in 10% neutral buffered formalin. The histopathologic evaluation was performed by Research Pathology Services, Inc.

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RESULTS

The type, incidence and degree of severity of microscopic changes in the rats of the various groups are presented in Table 1. Appendix I (Tables I-1 to I-10) presents the microscopic observations for each rat of the various dosage groups. A key to the histomorphologic observations precedes Table I-1. Appendix II contains a detailed description of the microscopic observations and a correlation with the gross changes in rats of all groups, when applicable.

Treatment-related changes were confined to the treated areas of the skin. Microscopic examination of sections of the treated skin showed several changes, the most common of which were hyperplasia/hyperkeratosis of the epidermis, sebaceous gland hyperplasia, dermal inflammation, focal epidermal necrosis, and exudate (Table 1). In the mid-dose male rats (Group 3, 40 mg/kg), there was a marginal increase in the severity of sebaceous gland hyperplasia and hyperplasia/hyperkeratosis of the epidermis, as compared to the controls. The same changes were more pronounced (increased severity) in the high dose male rats (Group 4, 80 mg/kg), as compared to the controls. Male rats from both Groups 3 and 4 also showed increased incidences of dermal inflammation, focal epidermal necrosis and exudate formation.

Examination of treated skin areas from male rats of Group 5 (80 mg/kg, satellite group) showed a return in the incidence and/or severity of

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these treatment-related changes to near control levels. The Group 5 (satellite) animals, however, did show increased dermal fibrosis, as compared to controls and other treated animals (Table 1).

Examination of the treated areas of the skin from female rats from treatment Groups 2 (10 mg/kg), 3 (40 mg/kg), and 4 (80 mg/kg) in general showed a spectrum of changes similar to those described for the male rats. In particular, there was a dose-related increase in the severity of sebaceous gland hyperplasia, hyperplasia/hyperkeratosis of the epidermis, dermal inflammation, and focal epidermal necrosis, as well as an increased incidence of exudate formation, as compared to the controls. Microscopic examination of treated skin areas from the female recovery animals (Group 5, 80 mg/kg) showed a decrease in the incidence and/or severity of these changes, as compared to non-recovery animals. As with the male animals, however, there was an increase in the incidence of dermal fibrosis with recovery.

Although changes were found in the "treated" skin from control animals (sebaceous gland hyperplasia and hyperplasia/hyperkeratosis of the epidermis), the degree of severity was less than that observed for the treated animals. The changes in the skin from the control animals were considered to have been the result of the clipping, application procedures and the wrapping of the skin.

Sections of untreated skin examined microscopically showed an in-

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creased incidence of epidermal hyperkeratosis in Group 5 male rats. In general this change was minimal and considered to be the result of the clipping procedure and possible contamination of the untreated site and not related to compound administration. Also, in the female rats, the incidence and severity of epidermal hyperkeratosis was similar between the control, high dose and satellite animals.

Microscopic examination of the liver showed an increased incidence of focal necrosis in test substance-treated animals, as compared to the controls. Microscopically, this was an acute change characterized by coagulative necrosis of hepatocytes and occurred in a random distribution. The distribution of this change and the lack of a dose response indicate that this is not likely due to systemic toxicity but instead is possibly a result of trauma and/or ischemia to the liver as a result of the wrapping and manipulation of the animals.¹

Microscopic examination of the kidneys revealed a slight increase in the incidence of focal cortical tubular degeneration in male rats of Groups 3 and 5. Male rats commonly develop a progressive glomerulonephrosis which can begin at a very early age. It is felt that the focal cortical tubular degeneration occurred spontaneously and was not influenced by compound administration.

¹Nyska, A., et al., Possible pitfalls in rat extended dermal toxicity testing: an hepatic ocular syndrome, Arch. Toxicol. 66:339-346 (1992).

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Microscopic examination of the urinary bladder revealed significant changes in three male rats. Animal ICN291 (Group 3 male) had marked hyperplastic cystitis compatible with changes seen with urinary calculi. A single Group 4 male rat (ICN317) had widespread organ system changes including the urinary bladder which showed necrosis, hemorrhage and peritonitis. Similar changes (hemorrhagic cystitis) were seen in a single Group 5 male rat (ICN275). Although several other animals of both sexes showed an increase in RBCs in the urine sediment and exhibited hematuria clinically, except in a few instances, the source of the hemorrhage was not evident upon microscopic examination.

Three male rats (one from each of Groups 1, 4, and 5) and two female rats (one from each of Groups 3 and 4) died or were killed in moribund condition prior to termination of the study. The Group 1 male (ICN297) showed hepatic congestion and vacuolation. The Group 4 male (ICN317) had widespread changes in several organ systems, especially the cardiovascular and renal systems. The Group 5 male (ICN275) showed a variety of changes, especially marked hepatic necrosis. The most pronounced change in the two nonsurviving female rats was moderate hepatic necrosis. The basis for many of the changes seen in these animals is potentially of an ischemic nature and was felt to be the result of the application procedure and not direct systemic toxicity of the test material.

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All other changes seen in the other tissues specified for microscopic examination were considered to have occurred spontaneously and to be unrelated to treatment. These changes generally occurred at single, similar or low frequencies among the groups and their type or incidence was not considered to have been influenced by compound administration. These changes also are listed and summarized in the attached histomorphology tables.

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SUMMARY

Microscopic examination was made of the specified tissues from four groups of 10 male and 10 female rats in each group used in a 90-day sub-chronic dermal toxicity study on MRD-92-399. The dosages used in the study were 0 (Carrier only - propylene glycol at 2.0 ml/kg), 10, 40 or 80 mg/kg. An additional satellite group of 10 male and 10 female rats received the same treatment as the high dose group rats, but were then maintained without treatment for an additional four-week period for reversibility studies.

Treatment-related microscopic changes were seen in the treated area of the skin of male rats of Groups 3, 4, and 5 and female rats of Groups 2, 3, 4, and 5. In the rats of Groups 2, 3, and 4, these changes consisted of an increased incidence and/or severity of epidermal hyperplasia/-hyperkeratosis, sebaceous gland hyperplasia, dermal inflammation, focal epidermal necrosis, and exudate. In the Group 5 (satellite - recovery) rats, these changes occurred at lower frequencies and lesser intensity and there was an increased incidence of dermal fibrosis.

All other microscopic changes observed were considered to have occurred spontaneously and/or were related to manipulation (wrapping) of the animals and to be unrelated to treatment.

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QUALITY ASSURANCE UNIT STATEMENT

All aspects of the histopathologic evaluation and report preparation for the histopathology segment of the study listed above have been performed according to the Standard Operating Procedures of Research Pathology Services, Inc. in compliance with the "Good Laboratory Practice Standards" regulations (40 CFR 160).

Quality assurance inspections were performed on 04/19/93, 04/27/93, 04/30/93, 07/06/93, 07/09/93, 07/12/93, 07/15/93, 07/16/93 and 08/10/93, and findings were reported to management.

Karen W. Harkins
Karen W. Harkins, B.S.
Quality Assurance Unit

08-10-93
Date

**90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B**

**90-DAY SUBCHRONIC DERMAL TOXICITY STUDY IN RATS WITH SATELLITE GROUP
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TABLE 1

Incidence and Degree of Severity of Histomorphologic Observations

Dose Group:	1	2	3	4	5	1	2	3	4	5
Sex:	M	M	M	M	M	F	F	F	F	F
Number of Animals/Group:	10	10	10	10	10	10	10	10	10	10
SKIN (TREATED):										
NO. EXAMINED	10	0	9	10	10	10	4	9	10	10
NO. NORMAL	0	0	0	0	0	0	0	0	0	0
-adenitis	[0]	[0]	[1]	[0]	[0]	[0]	[0]	[0]	[0]	[0]
slight	0	0	1	0	0	0	0	0	0	0
-dermatitis, chronic	[0]	[0]	[1]	[0]	[0]	[0]	[0]	[0]	[0]	[0]
slight	0	0	1	0	0	0	0	0	0	0
-exudate	0	0	8	9	1	1	3	8	7	0
-fibrosis, dermal	[0]	[0]	[0]	[0]	[5]	[0]	[0]	[0]	[0]	[9]
minimal	0	0	0	0	2	0	0	0	0	4
slight	0	0	0	0	1	0	0	0	0	5
moderate	0	0	0	0	2	0	0	0	0	0
-hyperkeratosis, epidermis	[0]	[0]	[0]	[0]	[0]	[1]	[0]	[0]	[0]	[0]
minimal	0	0	0	0	0	1	0	0	0	0
-hyperplasia, sebaceous glands	[10]	[0]	[9]	[10]	[10]	[5]	[4]	[9]	[8]	[9]
minimal	5	0	2	0	1	3	0	0	0	2
slight	5	0	6	6	8	2	2	4	1	7
moderate	0	0	1	4	1	0	2	5	7	0
-hyperplasia/hyperkeratosis, epidermis	[10]	[0]	[9]	[10]	[10]	[9]	[4]	[9]	[10]	[10]
minimal	6	0	2	0	5	8	0	0	1	9
slight	4	0	6	5	4	0	2	3	1	1
moderate	0	0	1	5	1	1	2	5	7	0
marked	0	0	0	0	0	0	0	1	1	0
-inflammation, dermal	[0]	[0]	[7]	[8]	[1]	[0]	[4]	[8]	[7]	[0]
minimal	0	0	2	2	0	0	2	3	1	0
slight	0	0	5	6	1	0	2	3	6	0
moderate	0	0	0	0	0	0	0	2	0	0
-necrosis, epidermal, focal	[0]	[0]	[7]	[6]	[0]	[1]	[0]	[7]	[5]	[0]
slight	0	0	5	3	0	0	0	3	0	0
moderate	0	0	2	3	0	1	0	4	5	0
-vesicles, epidermis/dermis	0	0	0	1	0	0	0	0	0	0
SKIN (UNTREATED):										
NO. EXAMINED	10	0	0	10	10	10	0	1	10	10
NO. NORMAL	9	0	0	9	2	2	0	0	0	0
-exudate	0	0	0	0	1	0	0	0	0	0
-hyperkeratosis, epidermis	[0]	[0]	[0]	[1]	[8]	[8]	[0]	[1]	[10]	[10]
minimal	0	0	0	0	7	8	0	1	9	10
slight	0	0	0	1	0	0	0	0	1	0
marked	0	0	0	0	1	0	0	0	0	0
-hyperplasia, epidermis	[1]	[0]	[0]	[0]	[1]	[0]	[0]	[0]	[1]	[0]
minimal	1	0	0	0	0	0	0	0	0	0
slight	0	0	0	0	0	0	0	0	1	0
marked	0	0	0	0	1	0	0	0	0	0

[] = Total incidence of specified lesion, all grades.

**90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B**

**90-DAY SUBCHRONIC DERMAL TOXICITY STUDY IN RATS WITH SATELLITE GROUP
STUDY NUMBER 139910B - TEST MATERIAL MRD-92-399**

TABLE 1 (Continued)

Incidence and Degree of Severity of Histomorphologic Observations

Dose Group:	1	2	3	4	5	1	2	3	4	5
Sex:	M	M	M	M	M	F	F	F	F	F
Number of Animals/Group:	10	10	10	10	10	10	10	10	10	10
<u>SKIN (UNTREATED) (Continued):</u>										
-hyperplasia, sebaceous glands moderate	[0] 0	[0] 0	[0] 0	[0] 0	[1] 1	[0] 0	[0] 0	[0] 0	[0] 0	[0] 0
<u>ADRENAL GLANDS:</u>										
NO. EXAMINED	10	0	0	10	10	10	0	1	10	9
NO. NORMAL	9	0	0	10	10	10	0	1	9	8
-vacuolation, cortical, diffuse minimal	[1] 1	[0] 0	[0] 0	[0] 0	[0] 0	[0] 0	[0] 0	[0] 0	[0] 0	[0] 0
-vacuolation, cortical, focal minimal	[0] 0	[0] 0	[0] 0	[0] 0	[0] 0	[0] 0	[0] 0	[0] 0	[1] 1	[1] 1
<u>AORTA:</u>										
NO. EXAMINED	10	0	0	10	10	10	0	1	10	10
NO. NORMAL	10	0	0	9	10	10	0	1	10	10
-mineralization slight	[0] 0	[0] 0	[0] 0	[1] 1	[0] 0	[0] 0	[0] 0	[0] 0	[0] 0	[0] 0
<u>BONE (STERNUM):</u>										
NO. EXAMINED	10	0	0	10	10	10	0	1	10	10
NO. NORMAL	4	0	0	7	5	6	0	1	7	5
-necrosis, intersternal cartilage, focal minimal	[6] 6	[0] 0	[0] 0	[3] 2	[5] 2	[4] 4	[0] 0	[0] 0	[3] 3	[5] 3
slight	0	0	0	1	3	0	0	0	0	2
<u>BONE MARROW (STERNUM):</u>										
NO. EXAMINED	10	0	0	10	10	10	0	1	10	10
NO. NORMAL	10	0	0	10	8	10	0	1	10	10
-hyperplasia slight	[0] 0	[0] 0	[0] 0	[0] 0	[2] 2	[0] 0	[0] 0	[0] 0	[0] 0	[0] 0
<u>BRAIN:</u>										
NO. EXAMINED	10	0	0	10	10	10	0	1	10	10
NO. NORMAL	10	0	0	9	10	10	0	1	10	10
-mineralization, choroid plexus minimal	[0] 0	[0] 0	[0] 0	[1] 1	[0] 0	[0] 0	[0] 0	[0] 0	[0] 0	[0] 0
<u>CECUM:</u>										
NO. EXAMINED	10	0	0	10	10	10	0	1	10	10
NO. NORMAL	10	0	0	10	10	10	0	1	10	10
<u>CERVIX:</u>										
NO. EXAMINED						10	0	1	10	10
NO. NORMAL						10	0	1	10	10
<u>COLON:</u>										
NO. EXAMINED	10	0	0	10	10	10	0	1	10	10
NO. NORMAL	10	0	0	10	10	10	0	1	10	10
<u>DUODENUM:</u>										
NO. EXAMINED	10	0	0	10	10	10	0	1	10	10
NO. NORMAL	8	0	0	9	10	10	0	1	10	10
-Advanced autolysis precludes evaluation	0	0	0	1	0	0	0	0	0	0

[] = Total incidence of specified lesion, all grades.

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

90-DAY SUBCHRONIC DERMAL TOXICITY STUDY IN RATS WITH SATELLITE GROUP
STUDY NUMBER 139910B - TEST MATERIAL MRD-92-399

TABLE 1 (Continued)

Incidence and Degree of Severity of Histomorphologic Observations

Dose Group:	1	2	3	4	5	1	2	3	4	5
Sex:	M	M	M	M	M	F	F	F	F	F
Number of Animals/Group:	10	10	10	10	10	10	10	10	10	10
<u>DUODENUM (Continued):</u>										
-infiltration, mononuclear-cell minimal	[2] 2	[0] 0	[0] 0	[0] 0	[0] 0	[0] 0	[0] 0	[0] 0	[0] 0	[0] 0
<u>EPIDIDYMIDES:</u>										
NO. EXAMINED	10	0	0	10	10					
NO. NORMAL	9	0	0	9	10					
-granuloma(s), sperm	1	0	0	1	0					
<u>ESOPHAGUS:</u>										
NO. EXAMINED	10	0	0	10	10	10	0	1	10	10
NO. NORMAL	10	0	0	10	10	10	0	1	10	10
<u>EYES:</u>										
NO. EXAMINED	10	0	0	10	10	10	0	1	10	10
NO. NORMAL	10	0	0	10	10	10	0	1	10	10
<u>HEART:</u>										
NO. EXAMINED	10	0	0	10	10	10	0	1	10	10
NO. NORMAL	3	0	0	4	5	9	0	1	8	8
-fibrosis/myocarditis, chronic minimal	[0] 0	[0] 0	[0] 0	[0] 0	[0] 0	[0] 0	[0] 0	[0] 0	[0] 0	[1] 1
-hematocyst	0	0	0	0	0	0	0	0	1	0
-infiltration, mononuclear-cell, focal minimal	[7] 7	[0] 0	[0] 0	[6] 4	[5] 5	[1] 1	[0] 0	[0] 0	[0] 0	[1] 1
slight	0	0	0	2	0	0	0	0	0	0
-mineralization, focal moderate	[0] 0	[0] 0	[0] 0	[1] 1	[0] 0	[0] 0	[0] 0	[0] 0	[0] 0	[0] 0
-mineralization, vascular moderate	[0] 0	[0] 0	[0] 0	[1] 1	[0] 0	[0] 0	[0] 0	[0] 0	[0] 0	[0] 0
-necrosis, focal minimal	[0] 0	[0] 0	[0] 0	[2] 0	[1] 1	[0] 0	[0] 0	[0] 0	[0] 0	[0] 0
slight	0	0	0	2	0	0	0	0	0	0
-proliferation, myointimal, focal slight	[0] 0	[0] 0	[0] 0	[0] 0	[0] 0	[0] 0	[0] 0	[0] 0	[1] 1	[0] 0
<u>ILEUM:</u>										
NO. EXAMINED	10	0	1	10	10	10	0	1	10	10
NO. NORMAL	10	0	0	10	10	10	0	1	10	10
-inflammation, chronic marked	[0] 0	[0] 0	[1] 1	[0] 0	[0] 0	[0] 0	[0] 0	[0] 0	[0] 0	[0] 0
-necrosis marked	[0] 0	[0] 0	[1] 1	[0] 0	[0] 0	[0] 0	[0] 0	[0] 0	[0] 0	[0] 0
-peritonitis marked	[0] 0	[0] 0	[1] 1	[0] 0	[0] 0	[0] 0	[0] 0	[0] 0	[0] 0	[0] 0

[] = Total incidence of specified lesion, all grades.

**90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B**

**90-DAY SUBCHRONIC DERMAL TOXICITY STUDY IN RATS WITH SATELLITE GROUP
STUDY NUMBER 139910B - TEST MATERIAL MRD-92-399**

TABLE 1 (Continued)

Incidence and Degree of Severity of Histomorphologic Observations

Dose Group:	1	2	3	4	5	1	2	3	4	5
Sex:	M	M	M	M	M	F	F	F	F	F
Number of Animals/Group:	10	10	10	10	10	10	10	10	10	10
JEJUNUM:										
NO. EXAMINED	10	0	0	10	10	10	0	1	9	10
NO. NORMAL	10	0	0	10	10	10	0	1	9	10
KIDNEYS:										
NO. EXAMINED	10	10	10	10	10	10	10	10	10	10
NO. NORMAL	2	4	2	3	4	7	7	8	6	5
-basophilia, cortical tubules, focal	[5]	[6]	[5]	[6]	[2]	[0]	[1]	[0]	[0]	[0]
minimal	4	5	3	4	0	0	1	0	0	0
slight	1	1	2	1	1	0	0	0	0	0
moderate	0	0	0	1	1	0	0	0	0	0
-calculus	0	0	1	0	0	0	0	0	0	0
-casts	0	0	0	0	1	0	0	0	0	0
-corpora amylacea, cortex	[0]	[0]	[1]	[0]	[0]	[0]	[0]	[0]	[1]	[0]
minimal	0	0	1	0	0	0	0	0	1	0
-cyst(s), cortex	0	0	0	1	0	0	0	0	0	0
-cyst(s), medulla	1	0	0	0	0	0	0	0	0	0
-cyst(s), papilla	0	1	0	0	0	0	0	0	0	0
-degeneration, cortical tubules, focal	[1]	[0]	[3]	[1]	[4]	[0]	[0]	[1]	[0]	[0]
minimal	0	0	2	1	1	0	0	0	0	0
slight	1	0	1	0	3	0	0	1	0	0
-dilatation, cortical tubules, focal	[0]	[0]	[1]	[1]	[1]	[0]	[0]	[0]	[0]	[0]
slight	0	0	1	1	0	0	0	0	0	0
moderate	0	0	0	0	1	0	0	0	0	0
-dilatation, medullary tubules, focal	[0]	[0]	[2]	[0]	[0]	[2]	[2]	[0]	[0]	[0]
minimal	0	0	2	0	0	1	2	0	0	0
slight	0	0	0	0	0	1	0	0	0	0
-dilatation, pelvis	[0]	[0]	[1]	[1]	[1]	[0]	[0]	[0]	[0]	[0]
moderate	0	0	0	1	1	0	0	0	0	0
marked	0	0	1	0	0	0	0	0	0	0
-dilatation, tubules, papilla	[0]	[0]	[0]	[0]	[0]	[0]	[0]	[0]	[0]	[1]
slight	0	0	0	0	0	0	0	0	0	1
-fibrosis, focal	[1]	[0]	[0]	[0]	[0]	[0]	[1]	[0]	[0]	[1]
minimal	1	0	0	0	0	0	1	0	0	1
-hemorrhage, focal	[1]	[0]	[0]	[0]	[0]	[0]	[0]	[0]	[0]	[0]
minimal	1	0	0	0	0	0	0	0	0	0
-hemorrhage, perirenal fat, focal	[0]	[0]	[0]	[1]	[0]	[0]	[0]	[0]	[0]	[0]
moderate	0	0	0	1	0	0	0	0	0	0

[] = Total incidence of specified lesion, all grades.

**90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B**

**90-DAY SUBCHRONIC DERMAL TOXICITY STUDY IN RATS WITH SATELLITE GROUP
STUDY NUMBER 139910B - TEST MATERIAL MRD-92-399**

TABLE 1 (Continued)

Incidence and Degree of Severity of Histomorphologic Observations

Dose Group:	1	2	3	4	5	1	2	3	4	5
Sex:	M	M	M	M	M	F	F	F	F	F
Number of Animals/Group:	10	10	10	10	10	10	10	10	10	10
KIDNEYS (Continued):										
-hyperplasia, pelvic/papillary urothelium	[0]	[0]	[1]	[0]	[1]	[0]	[0]	[0]	[0]	[0]
slight	0	0	0	0	1	0	0	0	0	0
moderate	0	0	1	0	0	0	0	0	0	0
-infiltration, mononuclear-cell, focal	[2]	[0]	[1]	[3]	[1]	[1]	[2]	[1]	[2]	[3]
minimal	2	0	1	3	1	1	2	1	2	3
-infiltration, neutrophilic	[0]	[0]	[0]	[1]	[0]	[0]	[0]	[0]	[0]	[0]
minimal	0	0	0	1	0	0	0	0	0	0
-inflammation, chronic, focal	[1]	[0]	[0]	[0]	[0]	[0]	[0]	[0]	[1]	[0]
minimal	1	0	0	0	0	0	0	0	0	0
slight	0	0	0	0	0	0	0	0	1	0
-mineralization, cortical tubules, focal	[0]	[0]	[0]	[1]	[1]	[0]	[0]	[0]	[0]	[0]
slight	0	0	0	1	1	0	0	0	0	0
-mineralization, papilla, focal	[0]	[0]	[0]	[1]	[0]	[0]	[0]	[0]	[0]	[0]
minimal	0	0	0	1	0	0	0	0	0	0
-mineralization, pelvic	[0]	[0]	[0]	[0]	[0]	[0]	[1]	[0]	[0]	[1]
minimal	0	0	0	0	0	0	1	0	0	1
-mineralization, vascular	[0]	[0]	[0]	[1]	[0]	[0]	[0]	[0]	[0]	[0]
moderate	0	0	0	1	0	0	0	0	0	0
-necrosis, cortical tubules, focal	[0]	[0]	[0]	[1]	[1]	[0]	[0]	[0]	[0]	[0]
slight	0	0	0	1	1	0	0	0	0	0
-necrosis, papillary	[0]	[0]	[0]	[1]	[0]	[0]	[0]	[0]	[0]	[0]
moderate	0	0	0	1	0	0	0	0	0	0
-pyelonephritis	[0]	[0]	[1]	[0]	[0]	[0]	[0]	[0]	[0]	[0]
marked	0	0	1	0	0	0	0	0	0	0
LACRIMAL GLANDS:										
NO. EXAMINED	10	0	0	10	10	10	0	1	10	10
NO. NORMAL	10	0	0	10	9	10	0	1	10	10
-infiltration, mononuclear-cell, focal	[0]	[0]	[0]	[0]	[1]	[0]	[0]	[0]	[0]	[0]
minimal	0	0	0	0	1	0	0	0	0	0
LIVER:										
NO. EXAMINED	10	10	10	10	10	10	10	10	10	10
NO. NORMAL	0	1	3	0	3	3	0	0	0	5
-abscess	0	0	0	1	0	0	0	0	0	0
-adhesion(s)	0	0	0	1	0	0	0	0	0	0
-congestion	[1]	[0]	[0]	[1]	[0]	[0]	[0]	[1]	[0]	[0]
moderate	1	0	0	1	0	0	0	1	0	0

[] = Total incidence of specified lesion, all grades.

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

90-DAY SUBCHRONIC DERMAL TOXICITY STUDY IN RATS WITH SATELLITE GROUP
STUDY NUMBER 139910B - TEST MATERIAL MRD-92-399

TABLE 1 (Continued)

Incidence and Degree of Severity of Histomorphologic Observations

Dose Group:	1	2	3	4	5	1	2	3	4	5
Sex:	M	M	M	M	M	F	F	F	F	F
Number of Animals/Group:	10	10	10	10	10	10	10	10	10	10
<u>LIVER (Continued):</u>										
-dilatation, sinusoidal, focal moderate	[0] 0	[0] 0	[0] 0	[0] 0	[0] 0	[0] 0	[0] 0	[1] 1	[1] 1	[0] 0
-infarct, liver lobe	0	1	0	0	0	0	0	0	0	0
-infiltration, mixed inflammatory cell marked	[0] 0	[0] 0	[0] 0	[0] 0	[1] 1	[0] 0	[0] 0	[0] 0	[0] 0	[0] 0
-infiltration, mononuclear-cell, multifocal	[9] 9	[8] 6	[5] 3	[8] 6	[5] 5	[7] 5	[9] 6	[10] 5	[10] 7	[5] 5
minimal	9	6	3	6	5	5	6	5	7	5
slight	0	2	2	2	0	2	3	4	2	0
moderate	0	0	0	0	0	0	0	1	1	0
-infiltration, neutrophilic, focal minimal	[0] 0	[0] 0	[0] 0	[0] 0	[0] 0	[1] 1	[0] 0	[0] 0	[0] 0	[0] 0
-inflammation, granulomatous moderate	[0] 0	[0] 0	[0] 0	[1] 1	[0] 0	[0] 0	[0] 0	[0] 0	[0] 0	[0] 0
-lipidosis, tension, focal	[1] 0	[0] 0	[0] 0	[0] 0	[2] 1	[0] 0	[2] 1	[1] 1	[1] 0	[1] 0
minimal	0	0	0	0	1	0	1	1	0	0
slight	1	0	0	0	1	0	1	0	1	0
moderate	0	0	0	0	0	0	0	0	0	1
-necrosis, focal	[0] 0	[3] 0	[2] 0	[1] 0	[1] 0	[0] 0	[4] 0	[2] 0	[4] 1	[0] 0
minimal	0	0	0	0	0	0	0	0	1	0
slight	0	3	2	0	0	0	4	1	2	0
moderate	0	0	0	1	0	0	0	1	1	0
marked	0	0	0	0	1	0	0	0	0	0
-peritonitis	[0] 0	[2] 2	[1] 1	[1] 0	[0] 0	[0] 0	[0] 0	[0] 0	[0] 0	[0] 0
slight	0	2	1	0	0	0	0	0	0	0
marked	0	0	0	1	0	0	0	0	0	0
-pigment	[0] 0	[0] 0	[0] 0	[0] 0	[0] 0	[1] 1	[1] 1	[1] 1	[0] 0	[0] 0
-vacuolation, hepatocellular, centrilobular	[1] 1	[0] 0	[0] 0	[0] 0	[0] 0	[0] 0	[0] 0	[0] 0	[0] 0	[0] 0
moderate	1	0	0	0	0	0	0	0	0	0
-vacuolation, hepatocellular, focal minimal	[0] 0	[1] 1	[1] 1	[0] 0	[0] 0	[0] 0	[0] 0	[0] 0	[0] 0	[0] 0
minimal	0	1	1	0	0	0	0	0	0	0
<u>LUNG:</u>										
NO. EXAMINED	10	10	10	10	10	10	10	10	10	10
NO. NORMAL	7	7	5	7	6	9	10	8	9	8
-congestion	[0] 0	[0] 0	[0] 0	[1] 1	[0] 0	[0] 0	[0] 0	[0] 0	[0] 0	[0] 0
moderate	0	0	0	1	0	0	0	0	0	0
-hemorrhage	[0] 0	[0] 0	[0] 0	[1] 1	[0] 0	[0] 0	[0] 0	[0] 0	[0] 0	[0] 0
slight	0	0	0	1	0	0	0	0	0	0

[] = Total incidence of specified lesion, all grades.

**90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B**

**90-DAY SUBCHRONIC DERMAL TOXICITY STUDY IN RATS WITH SATELLITE GROUP
STUDY NUMBER 139910B - TEST MATERIAL MRD-92-399**

TABLE 1 (Continued)

Incidence and Degree of Severity of Histomorphologic Observations

Dose Group:	1	2	3	4	5	1	2	3	4	5
Sex:	M	M	M	M	M	F	F	F	F	F
Number of Animals/Group:	10	10	10	10	10	10	10	10	10	10
<u>LUNG (Continued):</u>										
-inflammation, interstitial, focal minimal	[0] 0	[0] 0	[3] 3	[0] 0	[0] 0	[0] 0	[0] 0	[0] 0	[0] 0	[0] 0
-macrophages, alveoli, focal minimal slight	[1] 1 0	[0] 0 0	[0] 0 0	[2] 2 0	[0] 0 0	[0] 0 0	[0] 0 0	[0] 0 0	[0] 0 0	[2] 0 2
-metaplasia, osseous, focal minimal	[0] 0	[1] 1	[1] 1	[0] 0	[1] 1	[0] 0	[0] 0	[0] 0	[0] 0	[0] 0
-mineralization slight	[0] 0	[0] 0	[0] 0	[1] 1	[0] 0	[0] 0	[0] 0	[0] 0	[0] 0	[0] 0
-mineralization, vascular minimal slight	[1] 1 0	[1] 1 0	[1] 1 0	[0] 0 0	[2] 2 0	[1] 0 1	[0] 0 0	[0] 0 0	[1] 1 0	[0] 0 0
-pleuritis, chronic minimal	[1] 1	[0] 0	[1] 1	[0] 0	[0] 0	[0] 0	[0] 0	[0] 0	[0] 0	[0] 0
-pneumonitis minimal	[0] 0	[0] 0	[0] 0	[0] 0	[0] 0	[0] 0	[0] 0	[1] 1	[0] 0	[0] 0
-proliferation, lymphoid, peribronchial/perivascular slight	[0] 0	[1] 1	[0] 0	[0] 0	[1] 1	[0] 0	[0] 0	[1] 1	[0] 0	[0] 0
<u>LYMPH NODE, MESENTERIC:</u>										
NO. EXAMINED	10	0	0	10	10	10	0	1	10	10
NO. NORMAL	8	0	0	9	10	10	0	1	10	10
-hyperplasia, lymphoid slight	[1] 1	[0] 0	[0] 0	[1] 1	[0] 0	[0] 0	[0] 0	[0] 0	[0] 0	[0] 0
-lymphadenopathy, cystic slight	[1] 1	[0] 0	[0] 0	[0] 0	[0] 0	[0] 0	[0] 0	[0] 0	[0] 0	[0] 0
<u>MAMMARY GLAND:</u>										
NO. EXAMINED						10	0	0	10	9
NO. NORMAL						10	0	0	10	9
<u>MUSCLE, FEMORIS:</u>										
NO. EXAMINED	10	0	0	10	10	10	0	1	10	10
NO. NORMAL	10	0	0	10	10	10	0	1	10	10
<u>NERVE, SCIATIC:</u>										
NO. EXAMINED	10	0	0	10	10	10	0	1	10	10
NO. NORMAL	10	0	0	10	10	10	0	1	10	10
<u>OVARIES:</u>										
NO. EXAMINED						10	0	1	10	10
NO. NORMAL						10	0	1	10	9
-cyst(s), intraovarian						0	0	0	0	1

[] = Total incidence of specified lesion, all grades.

**90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B**

**90-DAY SUBCHRONIC DERMAL TOXICITY STUDY IN RATS WITH SATELLITE GROUP
STUDY NUMBER 139910B - TEST MATERIAL MRD-92-399**

TABLE 1 (Continued)

Incidence and Degree of Severity of Histomorphologic Observations

Dose Group:	1	2	3	4	5	1	2	3	4	5
Sex:	M	M	M	M	M	F	F	F	F	F
Number of Animals/Group:	10	10	10	10	10	10	10	10	10	10
OVIDUCTS:										
NO. EXAMINED						10	0	1	10	10
NO. NORMAL						10	0	1	10	10
PALATE:										
NO. EXAMINED	0	0	1	0	0	0	0	0	0	0
NO. NORMAL	0	0	0	0	0	0	0	0	0	0
-fracture	0	0	1	0	0	0	0	0	0	0
-inflammation, chronic marked	[0] 0	[0] 0	[1] 1	[0] 0	[0] 0	[0] 0	[0] 0	[0] 0	[0] 0	[0] 0
-metaplasia, squamous slight	[0] 0	[0] 0	[1] 1	[0] 0	[0] 0	[0] 0	[0] 0	[0] 0	[0] 0	[0] 0
-ulcer	0	0	1	0	0	0	0	0	0	0
PANCREAS:										
NO. EXAMINED	10	0	0	10	10	10	0	1	10	10
NO. NORMAL	10	0	0	10	10	10	0	1	10	10
PARATHYROID:										
NO. EXAMINED	10	0	0	10	10	9	0	1	10	10
NO. NORMAL	10	0	0	10	10	9	0	1	10	10
PITUITARY:										
NO. EXAMINED	9	0	0	10	10	10	0	1	10	10
NO. NORMAL	7	0	0	10	9	9	0	1	9	8
-cyst(s)	2	0	0	0	1	1	0	0	1	2
PROSTATE:										
NO. EXAMINED	10	0	0	10	10					
NO. NORMAL	8	0	0	9	9					
-hemorrhage marked	[0] 0	[0] 0	[0] 0	[0] 0	[1] 1					
-prostatitis, interstitial slight moderate	[2] 0 2	[0] 0 0	[0] 0 0	[1] 1 0	[1] 1 0					
RECTUM:										
NO. EXAMINED	10	0	0	10	10	10	0	1	9	10
NO. NORMAL	10	0	0	10	10	10	0	1	9	10
SALIVARY GLANDS:										
NO. EXAMINED	10	0	0	10	10	10	0	1	10	10
NO. NORMAL	10	0	0	10	10	10	0	1	9	10
-infiltration, mononuclear-cell, focal minimal	[0] 0	[0] 0	[0] 0	[0] 0	[0] 0	[0] 0	[0] 0	[0] 0	[1] 1	[0] 0
SEMINAL VESICLES:										
NO. EXAMINED	10	0	0	10	10					
NO. NORMAL	10	0	0	9	10					

[] = Total incidence of specified lesion, all grades.

**90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B**

**90-DAY SUBCHRONIC DERMAL TOXICITY STUDY IN RATS WITH SATELLITE GROUP
STUDY NUMBER 139910B - TEST MATERIAL MRD-92-399**

TABLE 1 (Continued)

Incidence and Degree of Severity of Histomorphologic Observations

Dose Group:	1	2	3	4	5	1	2	3	4	5
Sex:	M	M	M	M	M	F	F	F	F	F
Number of Animals/Group:	10	10	10	10	10	10	10	10	10	10
<u>SEMINAL VESICLES (Continued):</u>										
-distention	[0]	[0]	[0]	[1]	[0]					
moderate	0	0	0	1	0					
-hemorrhage	[0]	[0]	[0]	[1]	[0]					
slight	0	0	0	1	0					
<u>SKIN (GROSS LESION):</u>										
NO. EXAMINED	0	0	0	0	2	1	0	0	0	0
NO. NORMAL	0	0	0	0	0	0	0	0	0	0
-exudate	0	0	0	0	2	1	0	0	0	0
-hyperplasia, sebaceous glands	[0]	[0]	[0]	[0]	[2]	[0]	[0]	[0]	[0]	[0]
slight	0	0	0	0	1	0	0	0	0	0
moderate	0	0	0	0	1	0	0	0	0	0
-hyperplasia/hyperkeratosis, epidermis	[0]	[0]	[0]	[0]	[2]	[1]	[0]	[0]	[0]	[0]
moderate	0	0	0	0	1	1	0	0	0	0
marked	0	0	0	0	1	0	0	0	0	0
-infiltration, neutrophilic	[0]	[0]	[0]	[0]	[1]	[0]	[0]	[0]	[0]	[0]
moderate	0	0	0	0	1	0	0	0	0	0
-inflammation, dermal	[0]	[0]	[0]	[0]	[1]	[0]	[0]	[0]	[0]	[0]
slight	0	0	0	0	1	0	0	0	0	0
-necrosis, epidermal, focal	[0]	[0]	[0]	[0]	[2]	[1]	[0]	[0]	[0]	[0]
moderate	0	0	0	0	1	1	0	0	0	0
marked	0	0	0	0	1	0	0	0	0	0
<u>SPINAL CORD, CERVICAL:</u>										
NO. EXAMINED	10	0	0	10	10	10	0	1	10	10
NO. NORMAL	10	0	0	10	10	10	0	1	10	10
<u>SPINAL CORD, LUMBAR:</u>										
NO. EXAMINED	10	0	0	10	10	10	0	1	10	10
NO. NORMAL	10	0	0	10	10	10	0	1	10	10
<u>SPINAL CORD, MIDTHORACIC:</u>										
NO. EXAMINED	10	0	0	10	10	10	0	1	10	10
NO. NORMAL	10	0	0	10	10	10	0	1	10	10
<u>SPLEEN:</u>										
NO. EXAMINED	10	1	0	10	10	10	0	1	10	10
NO. NORMAL	10	1	0	9	9	10	0	0	10	10
-atrophy	[0]	[0]	[0]	[1]	[1]	[0]	[0]	[0]	[0]	[0]
slight	0	0	0	0	1	0	0	0	0	0
moderate	0	0	0	1	0	0	0	0	0	0
-hyperplasia, lymphoid	[0]	[0]	[0]	[0]	[0]	[0]	[0]	[1]	[0]	[0]
slight	0	0	0	0	0	0	0	1	0	0
<u>STOMACH:</u>										
NO. EXAMINED	10	0	0	10	10	10	1	1	10	10
NO. NORMAL	4	0	0	5	6	8	0	0	5	8

[] = Total incidence of specified lesion, all grades.

**90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B**

**90-DAY SUBCHRONIC DERMAL TOXICITY STUDY IN RATS WITH SATELLITE GROUP
STUDY NUMBER 139910B - TEST MATERIAL MRD-92-399**

TABLE 1 (Continued)

Incidence and Degree of Severity of Histomorphologic Observations

Dose Group:	1	2	3	4	5	1	2	3	4	5
Sex:	M	M	M	M	M	F	F	F	F	F
Number of Animals/Group:	10	10	10	10	10	10	10	10	10	10
<u>STOMACH (Continued):</u>										
-adhesion(s)	0	0	0	1	0	0	0	0	0	0
-cyst(s)	1	0	0	0	0	0	0	0	0	0
-dilatation, mucosal glands	[6]	[0]	[0]	[4]	[4]	[2]	[0]	[1]	[4]	[2]
minimal	5	0	0	2	2	2	0	1	4	1
slight	1	0	0	1	2	0	0	0	0	1
moderate	0	0	0	1	0	0	0	0	0	0
-hyperplasia/hyperkeratosis, limiting										
ridge	[0]	[0]	[0]	[1]	[1]	[0]	[0]	[0]	[1]	[0]
slight	0	0	0	1	1	0	0	0	1	0
-infiltration, neutrophilic										
slight	[0]	[0]	[0]	[0]	[1]	[0]	[0]	[0]	[0]	[0]
	0	0	0	0	1	0	0	0	0	0
-necrosis, glandular mucosa, focal										
moderate	[0]	[0]	[0]	[0]	[0]	[0]	[1]	[0]	[0]	[0]
	0	0	0	0	0	0	1	0	0	0
-necrosis, nonglandular mucosa, focal										
slight	[0]	[0]	[0]	[0]	[1]	[0]	[0]	[0]	[0]	[0]
	0	0	0	0	1	0	0	0	0	0
-peritonitis										
marked	[0]	[0]	[0]	[1]	[0]	[0]	[0]	[0]	[0]	[0]
	0	0	0	1	0	0	0	0	0	0
<u>TESTES:</u>										
NO. EXAMINED	10	0	0	10	10					
NO. NORMAL	10	0	0	10	10					
<u>THYMUS:</u>										
NO. EXAMINED	10	0	0	10	10	10	0	1	10	10
NO. NORMAL	10	0	0	9	10	10	0	1	10	10
-atrophy										
moderate	[0]	[0]	[0]	[1]	[0]	[0]	[0]	[0]	[0]	[0]
	0	0	0	1	0	0	0	0	0	0
<u>THYROID:</u>										
NO. EXAMINED	10	0	0	10	10	10	0	1	10	10
NO. NORMAL	9	0	0	9	9	8	0	1	8	7
-follicle(s), cystic	0	0	0	0	0	0	0	0	0	2
-ultimobranchial body/cyst	1	0	0	1	1	2	0	0	2	1
<u>TRACHEA:</u>										
NO. EXAMINED	10	0	0	10	10	10	0	1	10	10
NO. NORMAL	10	0	0	9	10	10	0	1	10	10
-mineralization										
slight	[0]	[0]	[0]	[1]	[0]	[0]	[0]	[0]	[0]	[0]
	0	0	0	1	0	0	0	0	0	0
<u>URINARY BLADDER:</u>										
NO. EXAMINED	10	0	1	10	10	10	0	1	10	10
NO. NORMAL	10	0	0	6	7	10	0	1	10	10
-concretion, eosinophilic	0	0	0	1	2	0	0	0	0	0

[] = Total incidence of specified lesion, all grades.

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

90-DAY SUBCHRONIC DERMAL TOXICITY STUDY IN RATS WITH SATELLITE GROUP
STUDY NUMBER 139910B - TEST MATERIAL MRD-92-399

TABLE 1 (Continued)

Incidence and Degree of Severity of Histomorphologic Observations

Dose Group:	1	2	3	4	5	1	2	3	4	5
Sex:	M	M	M	M	M	F	F	F	F	F
Number of Animals/Group:	10	10	10	10	10	10	10	10	10	10
<u>URINARY BLADDER (Continued):</u>										
-cystitis, hemorrhagic marked	[0] 0	[0] 0	[0] 0	[0] 0	[1] 1	[0] 0	[0] 0	[0] 0	[0] 0	[0] 0
-cystitis, hyperplastic marked	[0] 0	[0] 0	[1] 1	[0] 0	[0] 0	[0] 0	[0] 0	[0] 0	[0] 0	[0] 0
-distention moderate marked	[0] 0 0	[0] 0 0	[0] 0 0	[2] 1 1	[0] 0 0	[0] 0 0	[0] 0 0	[0] 0 0	[0] 0 0	[0] 0 0
-hemorrhage moderate	[0] 0	[0] 0	[0] 0	[1] 1	[0] 0	[0] 0	[0] 0	[0] 0	[0] 0	[0] 0
-necrosis, focal moderate	[0] 0	[0] 0	[0] 0	[1] 1	[0] 0	[0] 0	[0] 0	[0] 0	[0] 0	[0] 0
-peritonitis moderate	[0] 0	[0] 0	[0] 0	[1] 1	[0] 0	[0] 0	[0] 0	[0] 0	[0] 0	[0] 0
<u>UTERUS:</u>										
NO. EXAMINED						10	0	1	10	10
NO. NORMAL						8	0	1	9	8
-distention, lumen slight moderate						[2] 1 1	[0] 0 0	[0] 0 0	[1] 1 0	[2] 0 2

[] = Total incidence of specified lesion, all grades.

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

90-DAY SUBCHRONIC DERMAL TOXICITY STUDY IN RATS WITH SATELLITE GROUP
STUDY NUMBER 139910B - TEST MATERIAL MRD-92-399
HISTOPATHOLOGY

APPENDIX I
INDIVIDUAL ANIMAL HISTOMORPHOLOGY TABLES

90-DAY SUBCHRONIC DERMAL TOXICITY STUDY IN RATS WITH SATELLITE GROUP
STUDY NUMBER 139910B - TEST MATERIAL MRD-92-399
HISTOPATHOLOGY

KEY TO HISTOMORPHOLOGIC OBSERVATIONS

- = No change (not remarkable, within normal histologic limits or indicated change not present).
- * = Tissue not available (specified tissue missing, insufficient tissue in plane of section, artifact precludes evaluation, or specified tissue not present in section).
- < > = Microscopic finding(s) in tissue(s) with gross observation(s).
- <-> = Within normal limits [no microscopic change(s) to correlate with the gross observation(s)].
- () = Only one of a pair of organs available for evaluation.
- A = Advanced autolysis precludes evaluation.
- P = Indicated change or lesion present.
- 1 = Minimal degree or amount of indicated change or lesion.
- 2 = Slight degree or amount of indicated change or lesion.
- 3 = Moderate degree or amount of indicated change or lesion.
- 4 = Marked degree or amount of indicated change or lesion.
- SS = Scheduled Sacrifice
- SD = Spontaneous Death
- SM = Sacrifice-Moribund

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

90-DAY SUBCHRONIC DERMAL TOXICITY STUDY IN RATS WITH SATELLITE GROUP
STUDY NUMBER 139910B - TEST MATERIAL MRD-92-399

TABLE I-1

Histomorphologic Observations

Dose Group:	1	1	1	1	1	1	1	1	1	1
Animal Number (ICN):	278	279	287	289	294	295	297	305	314	323
Sex:	M	M	M	M	M	M	M	M	M	M
Death Type:	SS	SS	SS	SS	SS	SS	SD	SS	SS	SS
<u>SKIN (TREATED):</u>										
-hyperplasia, sebaceous glands	1	1	2	2	2	2	1	2	1	1
-hyperplasia/hyperkeratosis, epidermis	1	1	2	2	2	2	1	1	1	1
<u>SKIN (UNTREATED):</u>										
-hyperplasia, epidermis	-	-	-	-	1	-	-	-	-	-
<u>ADRENAL GLANDS:</u>										
-vacuolation, cortical, diffuse	-	-	-	-	-	-	-	-	-	1
<u>AORTA:</u>										
-	-	-	-	-	-	-	-	-	-	-
<u>BONE (STERNUM):</u>										
-necrosis, intersternal cartilage, focal	1	1	1	-	-	1	-	1	1	-
<u>BONE MARROW (STERNUM):</u>										
-	-	-	-	-	-	-	-	-	-	-
<u>BRAIN:</u>										
-	-	-	-	-	-	-	-	-	-	-
<u>CECUM:</u>										
-	-	-	-	-	-	-	<->	-	-	-
<u>COLON:</u>										
-	-	-	-	-	-	-	-	-	-	-
<u>DUODENUM:</u>										
-infiltration, mononuclear-cell	-	-	-	-	-	1	-	-	1	-
<u>EPIDIDYMIDES:</u>										
-granuloma(s), sperm	-	-	p	-	-	-	-	-	-	-
<u>ESOPHAGUS:</u>										
-	-	-	-	-	-	-	-	-	-	-
<u>EYES:</u>										
-	-	-	-	-	-	-	-	-	-	-
<u>HEART:</u>										
-infiltration, mononuclear-cell, focal	1	-	1	1	1	-	-	1	1	1
<u>ILEUM:</u>										
-	-	-	-	-	-	-	-	-	-	-
<u>JEJUNUM:</u>										
-	-	-	-	-	-	-	-	-	-	-
<u>KIDNEYS:</u>										
-basophilia, cortical tubules, focal	-	-	-	-	1	1	1	2	-	1
-cyst(s), medulla	p	-	-	-	-	-	-	-	-	-
-degeneration, cortical tubules, focal	-	-	-	-	-	-	-	2	-	-
-fibrosis, focal	-	-	1	-	-	-	-	-	-	-
-hemorrhage, focal	-	-	-	-	-	1	-	-	-	-
-infiltration, mononuclear-cell, focal	-	-	-	-	-	-	-	1	1	-
-inflammation, chronic, focal	-	-	1	-	-	-	-	-	-	-
<u>LACRIMAL GLANDS:</u>										
-	-	-	-	-	-	-	-	-	-	-
<u>LIVER:</u>										
-congestion	-	-	-	-	-	-	<3>	-	-	-
-infiltration, mononuclear-cell, multifocal	1	1	1	1	1	1	-	1	1	1

**90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B**

**90-DAY SUBCHRONIC DERMAL TOXICITY STUDY IN RATS WITH SATELLITE GROUP
STUDY NUMBER 139910B - TEST MATERIAL MRD-92-399**

TABLE I-1 (Continued)

Histomorphologic Observations

Dose Group:	1	1	1	1	1	1	1	1	1
Animal Number (ICN):	278	279	287	289	294	295	297	305	314
Sex:	M	M	M	M	M	M	M	M	M
Death Type:	SS	SS	SS	SS	SS	SS	SD	SS	SS
<u>LIVER (Continued):</u>									
-lipidosis, tension, focal	-	-	-	-	-	2	-	-	-
-vacuolation, hepatocellular, centrilobular	-	-	-	-	-	-	<3>	-	-
<u>LUNG:</u>									
-macrophages, alveoli, focal	-	-	1	-	-	-	-	-	-
-mineralization, vascular	-	-	-	-	-	-	1	-	-
-pleuritis, chronic	1	-	-	-	-	-	-	-	-
<u>LYMPH NODE, MESENTERIC:</u>									
-hyperplasia, lymphoid	-	-	-	2	-	-	-	-	-
-lymphadenopathy, cystic	-	-	-	-	-	-	2	-	-
<u>MUSCLE, FEMORIS:</u>									
-	-	-	-	-	-	-	-	-	-
<u>NERVE, SCIATIC:</u>									
-	-	-	-	-	-	-	-	-	-
<u>PANCREAS:</u>									
-	-	-	-	-	-	-	-	-	-
<u>PARATHYROID:</u>									
-	-	-	-	-	-	-	-	-	-
<u>PITUITARY:</u>									
-cyst(s)	-	P	P	-	-	-	-	*	-
<u>PROSTATE:</u>									
-prostatitis, interstitial	-	-	-	-	-	3	-	-	3
<u>RECTUM:</u>									
-	-	-	-	-	-	-	-	-	-
<u>SALIVARY GLANDS:</u>									
-	-	-	-	-	-	-	-	-	-
<u>SEMINAL VESICLES:</u>									
-	-	-	-	-	-	-	-	-	-
<u>SPINAL CORD, CERVICAL:</u>									
-	-	-	-	-	-	-	-	-	-
<u>SPINAL CORD, LUMBAR:</u>									
-	-	-	-	-	-	-	-	-	-
<u>SPINAL CORD, MIDTHORACIC:</u>									
-	-	-	-	-	-	-	-	-	-
<u>SPLEEN:</u>									
-	-	-	-	-	-	-	-	-	-
<u>STOMACH:</u>									
-cyst(s)	-	-	P	-	-	-	-	-	-
-dilatation, mucosal glands	1	-	1	1	-	-	-	1	2
<u>TESTES:</u>									
-	-	-	-	-	-	-	-	-	-
<u>THYMUS:</u>									
-	-	-	-	-	-	-	-	-	-
<u>THYROID:</u>									
-ultimobranchial body/cyst	-	-	-	-	P	-	-	-	-
<u>TRACHEA:</u>									
-	-	-	-	-	-	-	-	-	-
<u>URINARY BLADDER:</u>									
-	-	-	-	-	-	-	-	-	-

**90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B**

**90-DAY SUBCHRONIC DERMAL TOXICITY STUDY IN RATS WITH SATELLITE GROUP
STUDY NUMBER 139910B - TEST MATERIAL MRD-92-399**

TABLE I-2

Histomorphologic Observations

Dose Group:	2	2	2	2	2	2	2	2	2
Animal Number (ICN):	273	276	300	302	306	310	318	321	330
Sex:	M	M	M	M	M	M	M	M	M
Death Type:	SS	SS	SS	SS	SS	SS	SS	SS	SS
KIDNEYS:									
-basophilia, cortical tubules, focal	-	1	1	1	-	1	2	1	-
-cyst(s), papilla	-	-	-	-	-	-	P	-	-
LIVER:									
-infarct, liver lobe	-	-	-	<P>	-	-	-	-	-
-infiltration, mononuclear-cell, multifocal	1	2	2	-	-	1	1	1	1
-necrosis, focal	-	-	2	<2>	-	-	-	2	-
-peritonitis	-	-	-	<2>	-	-	-	2	-
-vacuolation, hepatocellular, focal	-	1	-	-	-	-	-	-	-
LUNG:									
-metaplasia, osseous, focal	1	-	-	-	-	-	-	-	-
-mineralization, vascular	-	-	-	-	-	-	-	1	-
-proliferation, lymphoid, peribronchial/perivascular	-	-	-	-	-	-	-	-	2
SPLEEN:									
								<->	

**90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B**

**90-DAY SUBCHRONIC DERMAL TOXICITY STUDY IN RATS WITH SATELLITE GROUP
STUDY NUMBER 139910B - TEST MATERIAL MRD-92-399**

TABLE I-3

Histomorphologic Observations

Dose Group:	3	3	3	3	3	3	3	3	3	3
Animal Number (ICN):	285	290	291	293	299	303	311	315	319	328
Sex:	M	M	M	M	M	M	M	M	M	M
Death Type:	SS	SS	SS	SS	SS	SS	SS	SS	SS	SS
SKIN (TREATED):										
-adenitis	<2>	-	-	-	-	-	-	-	-	-
-dermatitis, chronic	<2>	-	-	-	-	-	-	-	-	-
-exudate	<P>	<P>	<P>	-	<P>	<P>	<P>	-	<P>	<P>
-hyperplasia, sebaceous glands	<2>	<1>	<2>	<1>	<3>	<2>	<2>	-	<2>	<2>
-hyperplasia/hyperkeratosis, epidermis	<2>	<1>	<2>	<1>	<3>	<2>	<2>	-	<2>	<2>
-inflammation, dermal	-	<1>	<2>	-	<2>	<2>	<1>	-	<2>	<2>
-necrosis, epidermal, focal	<2>	<2>	<2>	-	<3>	<2>	-	-	<2>	<3>
ILEUM:										
-inflammation, chronic	-	-	-	-	-	-	<4>	-	-	-
-necrosis	-	-	-	-	-	-	<4>	-	-	-
-peritonitis	-	-	-	-	-	-	<4>	-	-	-
KIDNEYS:										
-basophilia, cortical tubules, focal	-	2	-	1	-	-	-	2	1	1
-calculus	-	-	<P>	-	-	-	-	-	-	-
-corpora amylacea, cortex	-	-	-	-	1	-	-	-	-	-
-degeneration, cortical tubules, focal	-	1	<2>	-	-	1	-	-	-	-
-dilatation, cortical tubules, focal	-	-	-	-	-	2	-	-	-	-
-dilatation, medullary tubules, focal	-	-	-	-	1	-	-	-	1	-
-dilatation, pelvis	-	-	<4>	-	-	-	-	-	-	-
-hyperplasia, pelvic/papillary urothelium	-	-	<3>	-	-	-	-	-	-	-
-infiltration, mononuclear-cell, focal	-	-	-	-	-	-	-	-	1	-
-pyelonephritis	-	-	<4>	-	-	-	-	-	-	-
LIVER:										
-infiltration, mononuclear-cell, multifocal	1	-	-	-	1	2	-	-	1	2
-necrosis, focal	-	-	-	-	-	2	-	-	-	2
-peritonitis	-	-	-	-	-	-	2	-	-	-
-vacuolation, hepatocellular, focal	-	1	-	-	-	-	-	-	-	-
LUNG:										
-inflammation, interstitial, focal	-	-	-	-	-	1	1	-	-	1
-metaplasia, osseous, focal	-	1	-	-	-	-	-	-	-	-
-mineralization, vascular	-	-	-	-	-	1	-	-	-	-
-pleuritis, chronic	-	-	-	-	-	-	-	1	-	-
PALATE:										
-fracture	-	-	-	-	-	-	-	-	-	-
-inflammation, chronic	-	-	-	-	-	-	-	-	-	-
-metaplasia, squamous	-	-	-	-	-	-	-	-	-	-
-ulcer	-	-	-	-	-	-	-	-	-	-
URINARY BLADDER:										
-cystitis, hyperplastic	-	-	-	-	-	-	-	-	-	-

**90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B**

**90-DAY SUBCHRONIC DERMAL TOXICITY STUDY IN RATS WITH SATELLITE GROUP
STUDY NUMBER 139910B - TEST MATERIAL MRD-92-399**

TABLE I-4

Histomorphologic Observations

Dose Group:	4	4	4	4	4	4	4	4	4	4
Animal Number (ICN):	277	283	284	304	313	317	320	322	329	333
Sex:	M	M	M	M	M	M	M	M	M	M
Death Type:	SS	SS	SS	SS	SS	SD	SS	SS	SS	SS
SKIN (TREATED):										
-exudate	<P>	<P>	<P>	<P>	<P>	<P>	-	<P>	<P>	<P>
-hyperplasia, sebaceous glands	<3>	<3>	<3>	<2>	<2>	<2>	<2>	<3>	<2>	<2>
-hyperplasia/hyperkeratosis, epidermis	<2>	<3>	<2>	<2>	<3>	<3>	<2>	<3>	<2>	<3>
-inflammation, dermal	<2>	<2>	<2>	<2>	<2>	<1>	<1>	-	-	<2>
-necrosis, epidermal, focal	<3>	<2>	<3>	-	<2>	<3>	-	-	-	<2>
-vesicles, epidermis/dermis	-	-	-	-	-	-	-	<P>	-	-
SKIN (UNTREATED):										
-hyperkeratosis, epidermis	-	-	2	-	-	-	-	-	-	-
ADRENAL GLANDS:										
-	-	-	-	-	-	-	-	-	-	-
AORTA:										
-mineralization	-	-	-	-	-	2	-	-	-	-
BONE (STERNUM):										
-necrosis, intersternal cartilage, focal	-	2	1	-	-	-	1	-	-	-
BONE MARROW (STERNUM):										
-	-	-	-	-	-	-	-	-	-	-
BRAIN:										
-mineralization, choroid plexus	-	-	1	-	-	-	-	-	-	-
CECUM:										
-	-	-	-	-	-	<->	-	-	-	-
COLON:										
-	-	-	-	-	-	-	-	-	-	-
DUODENUM:										
-	-	-	-	-	-	A	-	-	-	-
EPIDIDYMIDES:										
-granuloma(s), sperm	-	-	-	P	-	-	-	-	-	-
ESOPHAGUS:										
-	-	-	-	-	-	-	-	-	-	-
EYES:										
-	-	-	-	-	-	-	-	-	-	-
HEART:										
-infiltration, mononuclear-cell, focal	-	1	2	1	1	<2>	-	1	-	-
-mineralization, focal	-	-	-	-	-	<3>	-	-	-	-
-mineralization, vascular	-	-	-	-	-	<3>	-	-	-	-
-necrosis, focal	-	-	2	-	-	<2>	-	-	-	-
ILEUM:										
-	-	-	-	-	-	-	-	-	-	-
JEJUNUM:										
-	-	-	-	-	-	-	-	-	-	-
KIDNEYS:										
-basophilia, cortical tubules, focal	-	1	1	1	-	<3>	2	-	1	-
-cyst(s), cortex	-	P	-	-	-	-	-	-	-	-
-degeneration, cortical tubules, focal	-	-	1	-	-	-	-	-	-	-
-dilatation, cortical tubules, focal	-	-	-	-	-	<2>	-	-	-	-
-dilatation, pelvis	-	-	-	-	-	<3>	-	-	-	-
-hemorrhage, perirenal fat, focal	-	-	-	-	-	<3>	-	-	-	-

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

90-DAY SUBCHRONIC DERMAL TOXICITY STUDY IN RATS WITH SATELLITE GROUP
STUDY NUMBER 139910B - TEST MATERIAL MRD-92-399

TABLE I-4 (Continued)

Histomorphologic Observations

Dose Group:	4	4	4	4	4	4	4	4	4	4
Animal Number (ICN):	277	283	284	304	313	317	320	322	329	333
Sex:	M	M	M	M	M	M	M	M	M	M
Death Type:	SS	SS	SS	SS	SS	SD	SS	SS	SS	SS
<u>KIDNEYS (Continued):</u>										
-infiltration, mononuclear-cell, focal	-	-	1	1	-	-	1	-	-	-
-infiltration, neutrophilic	-	-	-	-	-	-	1	-	-	-
-mineralization, cortical tubules, focal	-	-	-	-	-	<2>	-	-	-	-
-mineralization, papilla, focal	-	-	-	-	1	-	-	-	-	-
-mineralization, vascular	-	-	-	-	-	<3>	-	-	-	-
-necrosis, cortical tubules, focal	-	-	-	-	-	<2>	-	-	-	-
-necrosis, papillary	-	-	-	-	-	<3>	-	-	-	-
<u>LACRIMAL GLANDS:</u>										
-	-	-	-	-	-	-	-	-	-	-
<u>LIVER:</u>										
-abscess	-	-	-	-	-	-	-	-	<P>	-
-adhesion(s)	-	-	-	-	-	-	-	-	<P>	-
-congestion	-	-	-	-	-	<3>	-	-	-	-
-infiltration, mononuclear-cell, multifocal	2	1	1	2	-	-	1	1	<1>	1
-inflammation, granulomatous	-	-	-	-	3	-	-	-	-	-
-necrosis, focal	-	-	-	-	3	-	-	-	-	-
-peritonitis	-	-	-	-	-	-	-	-	<4>	-
<u>LUNG:</u>										
-congestion	-	-	-	-	-	<3>	-	-	-	-
-hemorrhage	-	-	-	-	-	<2>	-	-	-	-
-macrophages, alveoli, focal	-	-	-	-	1	-	1	-	-	-
-mineralization	-	-	-	-	-	<2>	-	-	-	-
<u>LYMPH NODE, MESENTERIC:</u>										
-hyperplasia, lymphoid	-	-	-	-	2	-	-	-	-	-
<u>MUSCLE, FEMORIS:</u>										
-	-	-	-	-	-	-	-	-	-	-
<u>NERVE, SCIATIC:</u>										
-	-	-	-	-	-	-	-	-	-	-
<u>PANCREAS:</u>										
-	-	-	-	-	-	-	-	-	-	-
<u>PARATHYROID:</u>										
-	-	-	-	-	-	-	-	-	-	-
<u>PITUITARY:</u>										
-	-	-	-	-	-	-	-	-	-	-
<u>PROSTATE:</u>										
-prostatitis, interstitial	-	-	-	-	-	2	-	-	-	-
<u>RECTUM:</u>										
-	-	-	-	-	-	-	-	-	-	-
<u>SALIVARY GLANDS:</u>										
-	-	-	-	-	-	-	-	-	-	-
<u>SEMINAL VESICLES:</u>										
-distention	-	-	-	-	-	<3>	-	-	-	-
-hemorrhage	-	-	-	-	-	<2>	-	-	-	-
<u>SPINAL CORD, CERVICAL:</u>										
-	-	-	-	-	-	-	-	-	-	-
<u>SPINAL CORD, LUMBAR:</u>										
-	-	-	-	-	-	-	-	-	-	-
<u>SPINAL CORD, MIDTHORACIC:</u>										
-	-	-	-	-	-	-	-	-	-	-

**90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B**

**90-DAY SUBCHRONIC DERMAL TOXICITY STUDY IN RATS WITH SATELLITE GROUP
STUDY NUMBER 139910B - TEST MATERIAL MRD-92-399**

TABLE I-4 (Continued)

Histomorphologic Observations

Dose Group:	4	4	4	4	4	4	4	4	4	4
Animal Number (ICN):	277	283	284	304	313	317	320	322	329	333
Sex:	M	M	M	M	M	M	M	M	M	M
Death Type:	SS	SS	SS	SS	SS	SD	SS	SS	SS	SS
<u>SPLEEN:</u>										
-atrophy	-	-	-	-	-	3	-	-	-	-
<u>STOMACH:</u>										
-adhesion(s)	-	-	-	-	-	-	-	-	P	-
-dilatation, mucosal glands	-	-	-	1	-	3	1	-	-	2
-hyperplasia/hyperkeratosis, limiting ridge	-	-	-	-	-	-	2	-	-	-
-peritonitis	-	-	-	-	-	-	-	-	4	-
<u>TESTES:</u>										
-atrophy	-	-	-	-	-	3	-	-	-	-
<u>THYMUS:</u>										
-atrophy	-	-	-	-	-	3	-	-	-	-
<u>THYROID:</u>										
-ultimobranchial body/cyst	-	-	P	-	-	-	-	-	-	-
<u>TRACHEA:</u>										
-mineralization	-	-	-	-	-	2	-	-	-	-
<u>URINARY BLADDER:</u>										
-concretion, eosinophilic	-	-	-	-	-	-	-	-	-	P
-distention	-	4	3	-	-	-	-	-	-	-
-hemorrhage	-	-	-	-	-	<3>	-	-	-	-
-necrosis, focal	-	-	-	-	-	<3>	-	-	-	-
-peritonitis	-	-	-	-	-	<3>	-	-	-	-

**90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B**

**90-DAY SUBCHRONIC DERMAL TOXICITY STUDY IN RATS WITH SATELLITE GROUP
STUDY NUMBER 139910B - TEST MATERIAL MRD-92-399**

TABLE I-5

Histomorphologic Observations

Dose Group:	5	5	5	5	5	5	5	5	5	5
Animal Number (ICN):	275	280	292	296	298	307	309	316	326	332
Sex:	M	M	M	M	M	M	M	M	M	M
Death Type:	SM	SS	SS	SS	SS	SS	SS	SS	SS	SS
<u>SKIN (TREATED):</u>										
-exudate	<P>	-	-	-	-	-	-	-	-	-
-fibrosis, dermal	-	-	-	-	-	3	3	1	2	1
-hyperplasia, sebaceous glands	<3>	2	2	2	2	2	2	2	1	2
-hyperplasia/hyperkeratosis, epidermis	<3>	2	1	1	1	2	2	2	1	1
-inflammation, dermal	<2>	-	-	-	-	-	-	-	-	-
<u>SKIN (UNTREATED):</u>										
-exudate	P	-	-	-	-	-	-	-	-	-
-hyperkeratosis, epidermis	4	1	1	-	1	1	-	1	1	1
-hyperplasia, epidermis	4	-	-	-	-	-	-	-	-	-
-hyperplasia, sebaceous glands	3	-	-	-	-	-	-	-	-	-
<u>ADRENAL GLANDS:</u>										
-	-	-	-	-	-	-	-	-	-	-
<u>AORTA:</u>										
-	-	-	-	-	-	-	-	-	-	-
<u>BONE (STERNUM):</u>										
-necrosis, intersternal cartilage, focal	-	2	-	-	-	2	-	1	2	1
<u>BONE MARROW (STERNUM):</u>										
-hyperplasia	2	-	-	-	-	-	-	-	2	-
<u>BRAIN:</u>										
-	-	-	-	-	-	-	-	-	-	-
<u>CECUM:</u>										
-	-	-	-	-	-	-	-	-	-	-
<u>COLON:</u>										
-	-	-	-	-	-	-	-	-	-	-
<u>DUODENUM:</u>										
-	-	-	-	-	-	-	-	-	-	-
<u>EPIDIDYMIDES:</u>										
-	-	-	-	-	-	-	-	-	-	-
<u>ESOPHAGUS:</u>										
-	-	-	-	-	-	-	-	-	-	-
<u>EYES:</u>										
-	-	-	-	-	-	-	-	-	-	-
<u>HEART:</u>										
-infiltration, mononuclear-cell, focal	1	-	-	-	1	1	1	-	-	1
-necrosis, focal	-	-	-	-	1	-	-	-	-	-
<u>ILEUM:</u>										
-	-	-	-	-	-	-	-	-	-	-
<u>JEJUNUM:</u>										
-	-	-	-	-	-	-	-	-	-	-
<u>KIDNEYS:</u>										
-basophilia, cortical tubules, focal	<3>	2	-	-	-	-	-	-	-	-
-casts	<P>	-	-	-	-	-	-	-	-	-
-degeneration, cortical tubules, focal	<2>	-	-	-	-	-	2	<1>	-	2
-dilatation, cortical tubules, focal	<3>	-	-	-	-	-	-	-	-	-
-dilatation, pelvis	-	-	-	-	-	-	-	<3>	-	-
-hyperplasia, pelvic/papillary urothelium	-	-	-	-	-	-	-	<2>	-	-
-infiltration, mononuclear-cell, focal	-	-	1	-	-	-	-	-	-	-
-mineralization, cortical tubules, focal	<2>	-	-	-	-	-	-	-	-	-

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 1399108

90-DAY SUBCHRONIC DERMAL TOXICITY STUDY IN RATS WITH SATELLITE GROUP
STUDY NUMBER 1399108 - TEST MATERIAL MRD-92-399

TABLE I-5 (Continued)

Histomorphologic Observations

Dose Group:	5	5	5	5	5	5	5	5	5	5
Animal Number (ICN):	275	280	292	296	298	307	309	316	326	332
Sex:	M	M	M	M	M	M	M	M	M	M
Death Type:	SM	SS	SS	SS	SS	SS	SS	SS	SS	SS
<u>KIDNEYS (Continued):</u>										
-necrosis, cortical tubules, focal	<2>	-	-	-	-	-	-	-	-	-
<u>LACRIMAL GLANDS:</u>										
-infiltration, mononuclear-cell, focal	-	-	-	-	-	1	-	-	-	-
<u>LIVER:</u>										
-infiltration, mixed inflammatory cell	<4>	-	-	-	-	-	-	-	-	-
-infiltration, mononuclear-cell, multifocal	-	1	1	-	-	1	1	-	1	-
-lipidosis, tension, focal	-	-	-	2	-	-	1	-	-	-
-necrosis, focal	<4>	-	-	-	-	-	-	-	-	-
<u>LUNG:</u>										
-metaplasia, osseous, focal	-	-	-	1	-	-	-	-	-	-
-mineralization, vascular	1	-	-	-	-	-	1	-	-	-
-proliferation, lymphoid, peribronchial/perivascular	-	-	-	-	-	-	-	-	-	2
<u>LYMPH NODE, MESENTERIC:</u>										
-	-	-	-	-	-	-	-	-	-	-
<u>MUSCLE, FEMORIS:</u>										
-	-	-	-	-	-	-	-	-	-	-
<u>NERVE, SCIATIC:</u>										
-	-	-	-	-	-	-	-	-	-	-
<u>PANCREAS:</u>										
-	-	-	-	-	-	-	-	-	-	-
<u>PARATHYROID:</u>										
-	-	-	-	-	-	-	-	-	-	-
<u>PITUITARY:</u>										
-cyst(s)	-	-	-	-	P	-	-	-	-	-
<u>PROSTATE:</u>										
-hemorrhage	4	-	-	-	-	-	-	-	-	-
-prostatitis, interstitial	2	-	-	-	-	-	-	-	-	-
<u>RECTUM:</u>										
-	-	-	-	-	-	-	-	-	-	-
<u>SALIVARY GLANDS:</u>										
-	-	-	-	-	-	-	-	-	-	-
<u>SEMINAL VESICLES:</u>										
<->	-	-	-	-	-	-	-	-	-	-
<u>SKIN (GROSS LESION):</u>										
-exudate										<P>
-hyperplasia, sebaceous glands										<3>
-hyperplasia/hyperkeratosis, epidermis										<4>
-infiltration, neutrophilic										-
-inflammation, dermal										-
-necrosis, epidermal, focal										<4>
<u>SPINAL CORD, CERVICAL:</u>										
-	-	-	-	-	-	-	-	-	-	-
<u>SPINAL CORD, LUMBAR:</u>										
-	-	-	-	-	-	-	-	-	-	-
<u>SPINAL CORD, MIDTHORACIC:</u>										
-	-	-	-	-	-	-	-	-	-	-

**90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B**

**90-DAY SUBCHRONIC DERMAL TOXICITY STUDY IN RATS WITH SATELLITE GROUP
STUDY NUMBER 139910B - TEST MATERIAL MRD-92-399**

TABLE I-5 (Continued)

Histomorphologic Observations

Dose Group:	5	5	5	5	5	5	5	5	5	5
Animal Number (ICN):	275	280	292	296	298	307	309	316	326	332
Sex:	M	M	M	M	M	M	M	M	M	M
Death Type:	SM	SS	SS	SS	SS	SS	SS	SS	SS	SS
<u>SPLEEN:</u>										
-atrophy	2	-	-	-	-	-	-	-	-	-
<u>STOMACH:</u>										
-dilatation, mucosal glands	<2>	-	-	-	-	-	-	2	1	1
-hyperplasia/hyperkeratosis, limiting ridge	-	-	-	-	-	-	-	-	2	-
-infiltration, neutrophilic	<2>	-	-	-	-	-	-	-	-	-
-necrosis, nonglandular mucosa, focal	<2>	-	-	-	-	-	-	-	-	-
<u>TESTES:</u>										
-	-	-	-	-	-	-	-	-	-	-
<u>THYMUS:</u>										
-	-	-	-	-	-	-	-	-	-	-
<u>THYROID:</u>										
-ultimobranchial body/cyst	-	P	-	-	-	-	-	-	-	-
<u>TRACHEA:</u>										
-	-	-	-	-	-	-	-	-	-	-
<u>URINARY BLADDER:</u>										
-concretion, eosinophilic	-	-	-	P	-	-	P	-	-	-
-cystitis, hemorrhagic	<4>	-	-	-	-	-	-	-	-	-

**90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B**

**90-DAY SUBCHRONIC DERMAL TOXICITY STUDY IN RATS WITH SATELLITE GROUP
STUDY NUMBER 139910B - TEST MATERIAL MRD-92-399**

TABLE I-6

Histomorphologic Observations

Dose Group:	1	1	1	1	1	1	1	1	1	1
Animal Number (ICN):	355	365	372	373	377	378	379	394	396	398
Sex:	F	F	F	F	F	F	F	F	F	F
Death Type:	SS	SS	SS	SS	SS	SS	SS	SS	SS	SS
<u>SKIN (TREATED):</u>										
-exudate	-	-	-	-	-	-	-	-	P	-
-hyperkeratosis, epidermis	-	-	1	-	-	-	-	-	-	-
-hyperplasia, sebaceous glands	-	-	-	-	1	2	1	2	-	1
-hyperplasia/hyperkeratosis, epidermis	1	1	-	1	1	1	1	1	3	1
-necrosis, epidermal, focal	-	-	-	-	-	-	-	-	3	-
<u>SKIN (UNTREATED):</u>										
-hyperkeratosis, epidermis	-	-	1	1	1	1	1	1	1	1
<u>ADRENAL GLANDS:</u>										
	-	-	-	(-)	-	-	-	-	-	-
<u>AORTA:</u>										
	-	-	-	-	-	-	-	-	-	-
<u>BONE (STERNUM):</u>										
-necrosis, intersternal cartilage, focal	-	-	-	1	1	-	1	-	-	1
<u>BONE MARROW (STERNUM):</u>										
	-	-	-	-	-	-	-	-	-	-
<u>BRAIN:</u>										
	-	-	-	-	-	-	-	-	-	-
<u>CECUM:</u>										
	-	-	-	-	-	-	-	-	-	-
<u>CERVIX:</u>										
	-	-	-	-	-	-	-	-	-	-
<u>COLON:</u>										
	-	-	-	-	-	-	-	-	-	-
<u>DUODENUM:</u>										
	-	-	-	-	-	-	-	-	-	-
<u>ESOPHAGUS:</u>										
	-	-	-	-	-	-	-	-	-	-
<u>EYES:</u>										
	-	-	-	-	-	-	-	-	-	-
<u>HEART:</u>										
-infiltration, mononuclear-cell, focal	-	-	-	1	-	-	-	-	-	-
<u>ILEUM:</u>										
	-	-	-	-	-	-	-	-	-	-
<u>JEJUNUM:</u>										
	-	-	-	-	-	-	-	-	-	-
<u>KIDNEYS:</u>										
-dilatation, medullary tubules, focal	-	-	2	-	-	1	-	-	-	-
-infiltration, mononuclear-cell, focal	-	-	-	-	-	-	1	-	-	-
<u>LACRIMAL GLANDS:</u>										
	-	-	-	(-)	-	-	-	-	-	-
<u>LIVER:</u>										
-infiltration, mononuclear-cell, multifocal	-	1	-	1	1	2	2	1	-	1
-infiltration, neutrophilic, focal	-	-	-	-	-	1	-	-	-	P
-pigment	-	-	-	-	-	-	-	-	-	P
<u>LUNG:</u>										
-mineralization, vascular	-	-	2	-	-	-	-	-	-	-
<u>LYMPH NODE, MESENTERIC:</u>										
	-	-	-	-	-	-	-	-	-	-

**90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B**

**90-DAY SUBCHRONIC DERMAL TOXICITY STUDY IN RATS WITH SATELLITE GROUP
STUDY NUMBER 139910B - TEST MATERIAL MRD-92-399**

TABLE I-6 (Continued)

Histomorphologic Observations

Dose Group:	1	1	1	1	1	1	1	1	1	1
Animal Number (ICN):	355	365	372	373	377	378	379	394	396	398
Sex:	F	F	F	F	F	F	F	F	F	F
Death Type:	SS	SS	SS	SS	SS	SS	SS	SS	SS	SS
<u>MAMMARY GLAND:</u>	-	-	-	-	-	-	-	-	-	-
<u>MUSCLE, FEMORIS:</u>	-	-	-	-	-	-	-	-	-	-
<u>NERVE, SCIATIC:</u>	-	-	-	-	-	-	-	-	-	-
<u>OVARIES:</u>	-	-	-	-	-	-	-	-	-	-
<u>OVIDUCTS:</u>	-	-	-	-	-	-	-	-	-	-
<u>PANCREAS:</u>	-	-	-	-	-	-	-	-	-	-
<u>PARATHYROID:</u>	-	-	-	-	-	-	*	-	-	-
<u>PITUITARY:</u>	-	-	-	-	-	-	-	-	-	-
-cyst(s)	-	-	-	-	-	-	-	-	P	-
<u>RECTUM:</u>	-	-	-	-	-	-	-	-	-	-
<u>SALIVARY GLANDS:</u>	-	-	-	-	-	-	-	-	-	-
<u>SKIN (GROSS LESION):</u>	-	-	-	-	-	-	-	-	-	-
-exudate	-	-	-	-	-	-	-	-	<P>	-
-hyperplasia/hyperkeratosis, epidermis	-	-	-	-	-	-	-	-	<3>	-
-necrosis, epidermal, focal	-	-	-	-	-	-	-	-	<3>	-
<u>SPINAL CORD, CERVICAL:</u>	-	-	-	-	-	-	-	-	-	-
<u>SPINAL CORD, LUMBAR:</u>	-	-	-	-	-	-	-	-	-	-
<u>SPINAL CORD, MIDTHORACIC:</u>	-	-	-	-	-	-	-	-	-	-
<u>SPLEEN:</u>	-	-	-	-	-	-	-	-	-	-
<u>STOMACH:</u>	-	-	-	-	-	-	-	-	-	-
-dilatation, mucosal glands	-	-	-	-	-	1	-	-	-	1
<u>THYMUS:</u>	-	-	-	-	-	-	-	-	-	-
<u>THYROID:</u>	-	-	-	-	-	-	-	-	-	-
-ultimobranchial body/cyst	-	-	P	-	-	-	-	-	-	P
<u>TRACHEA:</u>	-	-	-	-	-	-	-	-	-	-
<u>URINARY BLADDER:</u>	-	-	-	-	-	-	-	-	-	-
<u>UTERUS:</u>	-	-	-	-	-	-	-	-	-	-
-distention, lumen	2	-	-	-	-	-	-	-	-	3

**90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B**

**90-DAY SUBCHRONIC DERMAL TOXICITY STUDY IN RATS WITH SATELLITE GROUP
STUDY NUMBER 139910B - TEST MATERIAL MRD-92-399**

TABLE I-7

Histomorphologic Observations

Dose Group:	2	2	2	2	2	2	2	2	2	2
Animal Number (ICN):	341	342	345	348	353	361	370	385	388	395
Sex:	F	F	F	F	F	F	F	F	F	F
Death Type:	SS	SS	SS	SS	SS	SS	SS	SS	SS	SS
<u>SKIN (TREATED):</u>										
-exudate	-			<P>			<P>			<P>
-hyperplasia, sebaceous glands	<2>			<2>			<3>			<3>
-hyperplasia/hyperkeratosis, epidermis	<2>			<2>			<3>			<3>
-inflammation, dermal	<1>			<1>			<2>			<2>
<u>KIDNEYS:</u>										
-basophilia, cortical tubules, focal	-	-	-	-	-	-	-	1	-	-
-dilatation, medullary tubules, focal	-	-	-	-	1	-	-	1	-	-
-fibrosis, focal	-	-	-	-	-	-	-	1	-	-
-infiltration, mononuclear-cell, focal	1	-	-	-	1	-	-	-	-	-
-mineralization, pelvic	-	-	-	-	-	-	-	1	-	-
<u>LIVER:</u>										
-infiltration, mononuclear-cell, multifocal	2	1	1	2	1	1	1	1	-	2
-lipidosis, tension, focal	-	-	-	-	1	-	-	-	-	2
-necrosis, focal	2	-	-	2	-	-	-	-	2	2
-pigment	-	-	-	-	-	-	-	-	-	P
<u>LUNG:</u>										
-	-	-	-	-	-	-	-	-	-	<->
<u>STOMACH:</u>										
-necrosis, glandular mucosa, focal	<3>									

**90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B**

**90-DAY SUBCHRONIC DERMAL TOXICITY STUDY IN RATS WITH SATELLITE GROUP
STUDY NUMBER 139910B - TEST MATERIAL MRD-92-399**

TABLE I-8

Histomorphologic Observations

Dose Group:	3	3	3	3	3	3	3	3	3
Animal Number (ICN):	337	339	340	343	350	351	363	364	366
Sex:	F	F	F	F	F	F	F	F	F
Death Type:	SS	SS	SS	SS	SD	SS	SS	SS	SS
<u>SKIN (TREATED):</u>									
-exudate	<P>	<P>	<P>	-	<P>	<P>	<P>	<P>	<P>
-hyperplasia, sebaceous glands	<3>	<2>	<3>	<3>	<2>	<3>	<2>	<P>	<3>
-hyperplasia/hyperkeratosis, epidermis	<4>	<2>	<3>	<3>	<2>	<3>	<2>	<P>	<3>
-inflammation, dermal	<2>	-	<2>	<3>	<1>	<2>	<1>	<P>	<3>
-necrosis, epidermal, focal	<3>	-	<3>	<3>	-	<3>	<2>	<P>	<2>
<u>SKIN (UNTREATED):</u>									
-hyperkeratosis, epidermis					1				
<u>ADRENAL GLANDS:</u>									
					-				
<u>AORTA:</u>									
					-				
<u>BONE (STERNUM):</u>									
					-				
<u>BONE MARROW (STERNUM):</u>									
					-				
<u>BRAIN:</u>									
					-				
<u>CECUM:</u>									
					-				
<u>CERVIX:</u>									
					-				
<u>COLON:</u>									
					-				
<u>DUODENUM:</u>									
					-				
<u>ESOPHAGUS:</u>									
					-				
<u>EYES:</u>									
					-				
<u>HEART:</u>									
					-				
<u>ILEUM:</u>									
					-				
<u>JEJUNUM:</u>									
					-				
<u>KIDNEYS:</u>									
-degeneration, cortical tubules, focal	-	-	-	-	-	-	-	2	-
-infiltration, mononuclear-cell, focal	-	-	-	-	1	-	-	-	-
<u>LACRIMAL GLANDS:</u>									
					-				
<u>LIVER:</u>									
-congestion	-	-	-	-	<3>	-	-	-	-
-dilatation, sinusoidal, focal	-	-	-	-	<3>	-	-	-	-
-infiltration, mononuclear-cell, multifocal	1	2	2	1	<3>	2	2	1	1
-lipidosis, tension, focal	-	-	1	-	-	-	-	-	-
-necrosis, focal	-	-	2	-	<3>	-	-	-	-
-pigment	-	-	-	-	-	-	P	-	-
<u>LUNG:</u>									
-pneumonitis	-	-	-	1	-	-	-	-	-

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

90-DAY SUBCHRONIC DERMAL TOXICITY STUDY IN RATS WITH SATELLITE GROUP
STUDY NUMBER 139910B - TEST MATERIAL MRD-92-399

TABLE 1-8 (Continued)

Histomorphologic Observations

Dose Group:	3	3	3	3	3	3	3	3	3	3
Animal Number (ICN):	337	339	340	343	350	351	363	364	366	389
Sex:	F	F	F	F	F	F	F	F	F	F
Death Type:	SS	SS	SS	SS	SD	SS	SS	SS	SS	SS
<u>LUNG (Continued):</u>										
-proliferation, lymphoid, peribronchial/perivascular	2	-	-	-	-	-	-	-	-	-
<u>LYMPH NODE, MESENTERIC:</u>										
<u>MAMMARY GLAND:</u>					*					
<u>MUSCLE, FEMORIS:</u>					-					
<u>NERVE, SCIATIC:</u>					-					
<u>OVARIES:</u>					-					
<u>OVIDUCTS:</u>					-					
<u>PANCREAS:</u>					-					
<u>PARATHYROID:</u>					-					
<u>PITUITARY:</u>					-					
<u>RECTUM:</u>					-					
<u>SALIVARY GLANDS:</u>					-					
<u>SPINAL CORD, CERVICAL:</u>					-					
<u>SPINAL CORD, LUMBAR:</u>					-					
<u>SPINAL CORD, MIDTHORACIC:</u>					-					
<u>SPLEEN:</u>										
-hyperplasia, lymphoid					2					
<u>STOMACH:</u>										
-dilatation, mucosal glands					1					
<u>THYMUS:</u>					-					
<u>THYROID:</u>					-					
<u>TRACHEA:</u>					-					
<u>URINARY BLADDER:</u>					-					
<u>UTERUS:</u>					-					

**90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B**

**90-DAY SUBCHRONIC DERMAL TOXICITY STUDY IN RATS WITH SATELLITE GROUP
STUDY NUMBER 139910B - TEST MATERIAL MRD-92-399**

TABLE 1-9

Histomorphologic Observations

Dose Group:	4	4	4	4	4	4	4	4	4
Animal Number (ICN):	338	356	360	362	367	376	381	384	390
Sex:	F	F	F	F	F	F	F	F	F
Death Type:	SS	SS	SD	SS	SS	SS	SS	SS	SS
SKIN (TREATED):									
-exudate	<P>	<P>	-	<P>	-	<P>	-	<P>	<P>
-hyperplasia, sebaceous glands	<3>	-	-	<3>	<3>	<3>	<2>	<3>	<3>
-hyperplasia/hyperkeratosis, epidermis	<3>	<3>	1	<3>	<3>	<3>	<2>	<3>	<4>
-inflammation, dermal	<2>	<2>	-	<1>	-	<2>	-	<2>	<2>
-necrosis, epidermal, focal	-	<3>	-	-	-	<3>	-	<3>	<3>
SKIN (UNTREATED):									
-hyperkeratosis, epidermis	1	1	1	1	2	1	1	1	1
-hyperplasia, epidermis	-	-	-	-	2	-	-	-	-
ADRENAL GLANDS:									
-vacuolation, cortical, focal	(-)	-	1	-	-	-	-	-	-
AORTA:									
-	-	-	-	-	-	-	-	-	-
BONE (STERNUM):									
-necrosis, intersternal cartilage, focal	1	-	-	-	1	-	-	1	-
BONE MARROW (STERNUM):									
-	-	-	-	-	-	-	-	-	-
BRAIN:									
-	-	-	-	-	-	-	-	-	-
CECUM:									
-	-	-	-	-	-	-	-	-	-
CERVIX:									
-	-	-	-	-	-	-	-	-	-
COLON:									
-	-	-	-	-	-	-	-	-	-
DUODENUM:									
-	-	-	-	-	-	-	-	-	-
ESOPHAGUS:									
-	-	-	-	-	-	-	-	-	-
EYES:									
-	-	-	-	-	-	-	-	(-)	-
HEART:									
-hematocyst	-	-	-	-	-	-	-	-	P
-proliferation, myointimal, focal	-	-	-	-	2	-	-	-	-
ILEUM:									
-	-	-	-	-	-	-	-	-	-
JEJUNUM:									
-	-	-	*	-	-	-	-	-	-
KIDNEYS:									
-corpora amylacea, cortex	-	-	-	-	-	-	-	-	1
-infiltration, mononuclear-cell, focal	-	-	-	-	-	1	1	-	-
-inflammation, chronic, focal	-	-	-	-	-	-	-	2	-
LACRIMAL GLANDS:									
-	-	-	-	-	-	-	-	-	-
LIVER:									
-dilatation, sinusoidal, focal	-	-	<3>	-	-	-	-	-	-
-infiltration, mononuclear-cell, multifocal	2	1	<3>	1	1	1	1	2	1
-lipidosis, tension, focal	-	-	-	-	-	-	-	-	2

**90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B**

**90-DAY SUBCHRONIC DERMAL TOXICITY STUDY IN RATS WITH SATELLITE GROUP
STUDY NUMBER 139910B - TEST MATERIAL MRD-92-399**

TABLE I-9 (Continued)

Histomorphologic Observations

Dose Group:	4	4	4	4	4	4	4	4	4	4
Animal Number (ICN):	338	356	360	362	367	376	381	384	390	392
Sex:	F	F	F	F	F	F	F	F	F	F
Death Type:	SS	SS	SD	SS	SS	SS	SS	SS	SS	SS
<u>LIVER (Continued):</u>										
-necrosis, focal	1	-	<3>	-	-	-	-	2	-	2
<u>LUNG:</u>										
-mineralization, vascular	-	-	-	-	-	-	-	-	-	1
<u>LYMPH NODE, MESENTERIC:</u>	-	-	-	-	-	-	-	-	-	-
<u>MAMMARY GLAND:</u>	-	-	-	-	-	-	-	-	-	-
<u>MUSCLE, FEMORIS:</u>	-	-	-	-	-	-	-	-	-	-
<u>NERVE, SCIATIC:</u>	-	-	-	-	-	-	-	-	-	-
<u>OVARIES:</u>	-	-	-	-	-	-	-	-	-	-
<u>OVIDUCTS:</u>	-	-	-	-	-	-	-	-	-	-
<u>PANCREAS:</u>	-	-	-	-	-	-	-	-	-	-
<u>PARATHYROID:</u>	-	-	-	-	-	-	-	-	-	-
<u>PITUITARY:</u>										
-cyst(s)	-	-	-	-	-	-	P	-	-	-
<u>RECTUM:</u>	-	-	-	-	*	-	-	-	-	-
<u>SALIVARY GLANDS:</u>										
-infiltration, mononuclear-cell, focal	-	-	-	-	-	1	-	-	-	-
<u>SPINAL CORD, CERVICAL:</u>	-	-	-	-	-	-	-	-	-	-
<u>SPINAL CORD, LUMBAR:</u>	-	-	-	-	-	-	-	-	-	-
<u>SPINAL CORD, MIDTHORACIC:</u>	-	-	-	-	-	-	-	-	-	-
<u>SPLEEN:</u>	-	-	-	-	-	-	-	-	-	-
<u>STOMACH:</u>										
-dilatation, mucosal glands	-	-	1	1	1	-	-	-	-	1
-hyperplasia/hyperkeratosis, limiting ridge	2	-	-	-	-	-	-	-	-	-
<u>THYMUS:</u>	-	-	-	-	-	-	-	-	-	-
<u>THYROID:</u>										
-ultimobranchial body/cyst	-	-	-	-	-	-	-	-	P	P
<u>TRACHEA:</u>	-	-	-	-	-	-	-	-	-	-
<u>URINARY BLADDER:</u>	-	-	-	-	-	-	-	-	-	-
<u>UTERUS:</u>										
-distention, lumen	-	-	-	-	<2>	-	-	-	-	<->

**90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B**

**90-DAY SUBCHRONIC DERMAL TOXICITY STUDY IN RATS WITH SATELLITE GROUP
STUDY NUMBER 139910B - TEST MATERIAL MRD-92-399**

TABLE I-10

Histomorphologic Observations

Dose Group:	5	5	5	5	5	5	5	5	5	
Animal Number (ICN):	344	346	347	352	358	371	375	380	386	397
Sex:	F	F	F	F	F	F	F	F	F	F
Death Type:	SS	SS	SS	SS	SS	SS	SS	SS	SS	SS
<u>SKIN (TREATED):</u>										
-fibrosis, dermal	2	1	1	2	2	1	2	2	1	-
-hyperplasia, sebaceous glands	2	-	2	2	2	2	2	2	1	1
-hyperplasia/hyperkeratosis, epidermis	1	1	1	1	1	1	1	2	1	1
<u>SKIN (UNTREATED):</u>										
-hyperkeratosis, epidermis	1	1	1	1	1	1	1	1	1	1
<u>ADRENAL GLANDS:</u>										
-vacuolation, cortical, focal	-	-	-	-	-	1	*	-	-	-
<u>AORTA:</u>										
-	-	-	-	-	-	-	-	-	-	-
<u>BONE (STERNUM):</u>										
-necrosis, intersternal cartilage, focal	1	-	2	1	-	-	2	-	-	1
<u>BONE MARROW (STERNUM):</u>										
-	-	-	-	-	-	-	-	-	-	-
<u>BRAIN:</u>										
-	-	-	-	-	-	-	-	-	-	-
<u>CECUM:</u>										
-	-	-	-	-	-	-	-	-	-	-
<u>CERVIX:</u>										
-	-	-	-	-	-	-	-	-	-	-
<u>COLON:</u>										
-	-	-	-	-	-	-	-	-	-	-
<u>DUODENUM:</u>										
-	-	-	-	-	-	-	-	-	-	-
<u>ESOPHAGUS:</u>										
-	-	-	-	-	-	-	-	-	-	-
<u>EYES:</u>										
-	-	-	-	-	-	-	-	-	(-)	-
<u>HEART:</u>										
-fibrosis/myocarditis, chronic	-	-	-	-	1	-	-	-	-	-
-infiltration, mononuclear-cell, focal	-	-	1	-	-	-	-	-	-	-
<u>ILEUM:</u>										
-	-	-	-	-	-	-	-	-	-	-
<u>JEJUNUM:</u>										
-	-	-	-	-	-	-	-	-	-	-
<u>KIDNEYS:</u>										
-dilatation, tubules, papilla	-	2	-	-	-	-	-	-	-	-
-fibrosis, focal	-	-	-	-	-	-	-	1	-	-
-infiltration, mononuclear-cell, focal	-	-	-	-	-	-	1	1	-	1
-mineralization, pelvic	1	-	-	-	-	-	-	-	-	-
<u>LACRIMAL GLANDS:</u>										
-	-	-	-	-	-	-	-	-	-	-
<u>LIVER:</u>										
-infiltration, mononuclear-cell, multifocal	-	-	1	-	1	1	1	<1>	-	-
-lipidosis, tension, focal	-	-	-	-	-	-	-	<3>	-	-
<u>LUNG:</u>										
-macrophages, alveoli, focal	-	2	-	-	-	-	-	-	-	2

**90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B**

**90-DAY SUBCHRONIC DERMAL TOXICITY STUDY IN RATS WITH SATELLITE GROUP
STUDY NUMBER 139910B - TEST MATERIAL MRD-92-399**

TABLE I-10 (Continued)
Histomorphologic Observations

Dose Group:	5	5	5	5	5	5	5	5	5	5
Animal Number (ICN):	344	346	347	352	358	371	375	380	386	397
Sex:	F	F	F	F	F	F	F	F	F	F
Death Type:	SS	SS	SS	SS	SS	SS	SS	SS	SS	SS
<u>LYMPH NODE, MESENTERIC:</u>	-	-	-	-	-	-	-	-	-	-
<u>MAMMARY GLAND:</u>	-	*	-	-	-	-	-	-	-	-
<u>MUSCLE, FEMORIS:</u>	-	-	-	-	-	-	-	-	-	-
<u>NERVE, SCIATIC:</u>	-	-	-	-	-	-	-	-	-	-
<u>OVARIES:</u>										
-cyst(s), intraovarian	-	-	-	-	-	-	-	-	<P>	-
<u>OVIDUCTS:</u>	-	-	-	-	-	-	-	-	-	-
<u>PANCREAS:</u>	-	-	-	-	-	-	-	-	-	-
<u>PARATHYROID:</u>	-	-	-	-	-	-	-	-	-	-
<u>PITUITARY:</u>										
-cyst(s)	P	-	P	-	-	-	-	-	-	-
<u>RECTUM:</u>	-	-	-	-	-	-	-	-	-	-
<u>SALIVARY GLANDS:</u>	-	-	-	-	-	-	-	-	-	-
<u>SPINAL CORD, CERVICAL:</u>	-	-	-	-	-	-	-	-	-	-
<u>SPINAL CORD, LUMBAR:</u>	-	-	-	-	-	-	-	-	-	-
<u>SPINAL CORD, MIDTHORACIC:</u>	-	-	-	-	-	-	-	-	-	-
<u>SPLEEN:</u>	-	-	-	-	-	-	-	-	-	-
<u>STOMACH:</u>										
-dilatation, mucosal glands	-	1	-	-	-	-	2	-	-	-
<u>THYMUS:</u>	-	-	-	-	-	-	-	-	-	-
<u>THYROID:</u>										
-follicle(s), cystic	P	-	-	-	-	-	P	-	-	-
-ultimobranchial body/cyst	-	P	-	-	-	-	-	-	-	-
<u>TRACHEA:</u>	-	-	-	-	-	-	-	-	-	-
<u>URINARY BLADDER:</u>	-	-	-	-	-	-	-	-	-	-
<u>UTERUS:</u>										
-distention, lumen	3	-	3	-	-	-	-	<->	-	-

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

90-DAY SUBCHRONIC DERMAL TOXICITY STUDY IN RATS WITH SATELLITE GROUP
STUDY NUMBER 139910B - TEST MATERIAL MRD-92-399
HISTOPATHOLOGY

APPENDIX II

INDIVIDUAL ANIMAL GROSS AND HISTOMORPHOLOGY DATA

KEY TO CORRELATION OF HISTOMORPHOLOGIC OBSERVATIONS

Not applicable = Microscopic evaluation/correlation not appropriate
or not required by protocol.

**90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B**

**90-DAY SUBCHRONIC DERMAL TOXICITY STUDY IN RATS WITH SATELLITE GROUP
STUDY NUMBER 139910B - TEST MATERIAL MRD-92-399**

**Appendix II
Individual Animal Gross and Histomorphology Data**

ANIMAL NUMBER: ICN278
SEX: M

DOSE GROUP: 1
DEATH TYPE: Scheduled Sacrifice

GROSS OBSERVATION(S):

GENERAL: No gross changes.

HISTOMORPHOLOGIC OBSERVATION(S):

Not applicable

HISTOMORPHOLOGIC OBSERVATIONS:

BONE (STERNUM):	necrosis, intersternal cartilage, focal (minimal)
HEART:	infiltration, mononuclear-cell, focal (minimal)
KIDNEYS:	cyst(s), medulla
LIVER:	infiltration, mononuclear-cell, multifocal (minimal)
LUNG:	pleuritis, chronic (minimal)
SKIN (TREATED):	hyperplasia/hyperkeratosis, epidermis (minimal)
	hyperplasia, sebaceous glands (minimal)
STOMACH:	dilatation, mucosal glands (minimal)

THE FOLLOWING TISSUE(S) WERE WITHIN NORMAL LIMITS:

ADRENAL GLANDS	AORTA	BONE MARROW (STERNUM)	BRAIN
CECUM	COLON	DUODENUM	EPIDIDYIMIDES
ESOPHAGUS	EYES	ILEUM	JEJUNUM
LACRIMAL GLANDS	LYMPH NODE, MESENTERIC	MUSCLE, FEMORIS	NERVE, SCIATIC
PANCREAS	PARATHYROID	PITUITARY	PROSTATE
RECTUM	SALIVARY GLANDS	SEMINAL VESICLES	SKIN (UNTREATED)
SPINAL CORD, CERVICAL	SPINAL CORD, LUMBAR	SPINAL CORD, MIDTHORACIC	SPLEEN
TESTES	THYMUS	THYROID	TRACHEA
URINARY BLADDER			

End of Record- ICN278

**90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B**

**90-DAY SUBCHRONIC DERMAL TOXICITY STUDY IN RATS WITH SATELLITE GROUP
STUDY NUMBER 139910B - TEST MATERIAL MRD-92-399**

**Appendix II
Individual Animal Gross and Histomorphology Data**

ANIMAL NUMBER: ICN279
SEX: M

DOSE GROUP: 1
DEATH TYPE: Scheduled Sacrifice

GROSS OBSERVATION(S):

GENERAL: No gross changes.

HISTOMORPHOLOGIC OBSERVATION(S):

Not applicable

HISTOMORPHOLOGIC OBSERVATIONS:

BONE (STERNUM):	necrosis, intersternal cartilage, focal (minimal)
LIVER:	infiltration, mononuclear-cell, multifocal (minimal)
PITUITARY:	cyst(s)
SKIN (TREATED):	hyperplasia/hyperkeratosis, epidermis (minimal)
	hyperplasia, sebaceous glands (minimal)

THE FOLLOWING TISSUE(S) WERE WITHIN NORMAL LIMITS:

ADRENAL GLANDS	AORTA	BONE MARROW (STERNUM)	BRAIN
CECUM	COLON	DUODENUM	EPIDIDYMIDES
ESOPHAGUS	EYES	HEART	ILEUM
JEJUNUM	KIDNEYS	LACRIMAL GLANDS	LUNG
LYMPH NODE, MESENTERIC	MUSCLE, FEMORIS	NERVE, SCIATIC	PANCREAS
PARATHYROID	PROSTATE	RECTUM	SALIVARY GLANDS
SEMINAL VESICLES	SKIN (UNTREATED)	SPINAL CORD, CERVICAL	SPINAL CORD, LUMBAR
SPINAL CORD, MIDTHORACIC	SPLEEN	STOMACH	TESTES
THYMUS	THYROID	TRACHEA	URINARY BLADDER

End of Record- ICN279

**90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B**

**90-DAY SUBCHRONIC DERMAL TOXICITY STUDY IN RATS WITH SATELLITE GROUP
STUDY NUMBER 139910B - TEST MATERIAL MRD-92-399**

**Appendix II
Individual Animal Gross and Histomorphology Data**

ANIMAL NUMBER: ICN287
SEX: M

DOSE GROUP: 1
DEATH TYPE: Scheduled Sacrifice

GROSS OBSERVATION(S):

GENERAL: No gross changes.

HISTOMORPHOLOGIC OBSERVATION(S):

Not applicable

HISTOMORPHOLOGIC OBSERVATIONS:

BONE (STERNUM):	necrosis, intersternal cartilage, focal (minimal)
EPIDIDYMIDES:	granuloma(s), sperm
HEART:	infiltration, mononuclear-cell, focal (minimal)
KIDNEYS:	inflammation, chronic, focal (minimal)
	fibrosis, focal (minimal)
LIVER:	infiltration, mononuclear-cell, multifocal (minimal)
LUNG:	macrophages, alveoli, focal (minimal)
PITUITARY:	cyst(s)
SKIN (TREATED):	hyperplasia/hyperkeratosis, epidermis (slight)
	hyperplasia, sebaceous glands (slight)
STOMACH:	cyst(s)
	dilatation, mucosal glands (minimal)

THE FOLLOWING TISSUE(S) WERE WITHIN NORMAL LIMITS:

ADRENAL GLANDS	AORTA	BONE MARROW (STERNUM)	BRAIN
CECUM	COLON	DUODENUM	ESOPHAGUS
EYES	ILEUM	JEJUNUM	LACRIMAL GLANDS
LYMPH NODE, MESENTERIC	MUSCLE, FEMORIS	NERVE, SCIATIC	PANCREAS
PARATHYROID	PROSTATE	RECTUM	SALIVARY GLANDS
SEMINAL VESICLES	SKIN (UNTREATED)	SPINAL CORD, CERVICAL	SPINAL CORD, LUMBAR
SPINAL CORD, MIDTHORACIC	SPLEEN	TESTES	THYMUS
THYROID	TRACHEA	URINARY BLADDER	

End of Record- ICN287

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

90-DAY SUBCHRONIC DERMAL TOXICITY STUDY IN RATS WITH SATELLITE GROUP
STUDY NUMBER 139910B - TEST MATERIAL MRD-92-399

Appendix II
Individual Animal Gross and Histomorphology Data

ANIMAL NUMBER: ICN289
SEX: M

DOSE GROUP: 1
DEATH TYPE: Scheduled Sacrifice

GROSS OBSERVATION(S):

GENERAL: No gross changes.

HISTOMORPHOLOGIC OBSERVATION(S):

Not applicable

HISTOMORPHOLOGIC OBSERVATIONS:

HEART:	infiltration, mononuclear-cell, focal (minimal)
LIVER:	infiltration, mononuclear-cell, multifocal (minimal)
LYMPH NODE, MESENTERIC:	hyperplasia, lymphoid (slight)
SKIN (TREATED):	hyperplasia/hyperkeratosis, epidermis (slight)
	hyperplasia, sebaceous glands (slight)
STOMACH:	dilatation, mucosal glands (minimal)

THE FOLLOWING TISSUE(S) WERE WITHIN NORMAL LIMITS:

ADRENAL GLANDS	AORTA	BONE (STERNUM)	BONE MARROW (STERNUM)
BRAIN	CECUM	COLON	DUODENUM
EPIDIDYIMIDES	ESOPHAGUS	EYES	ILEUM
JEJUNUM	KIDNEYS	LACRIMAL GLANDS	LUNG
MUSCLE, FEMORIS	NERVE, SCIATIC	PANCREAS	PARATHYROID
PITUITARY	PROSTATE	RECTUM	SALIVARY GLANDS
SEMINAL VESICLES	SKIN (UNTREATED)	SPINAL CORD, CERVICAL	SPINAL CORD, LUMBAR
SPINAL CORD, MIDTHORACIC	SPLEEN	TESTES	THYMUS
THYROID	TRACHEA	URINARY BLADDER	

End of Record- ICN289

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

90-DAY SUBCHRONIC DERMAL TOXICITY STUDY IN RATS WITH SATELLITE GROUP
STUDY NUMBER 139910B - TEST MATERIAL MRD-92-399

Appendix II
Individual Animal Gross and Histomorphology Data

ANIMAL NUMBER: ICN295
SEX: M

DOSE GROUP: 1
DEATH TYPE: Scheduled Sacrifice

GROSS OBSERVATION(S):

GENERAL: No gross changes.

HISTOMORPHOLOGIC OBSERVATION(S):

Not applicable

HISTOMORPHOLOGIC OBSERVATIONS:

BONE (STERNUM):	necrosis, intersternal cartilage, focal (minimal)
DUODENUM:	infiltration, mononuclear-cell (minimal)
KIDNEYS:	hemorrhage, focal (minimal)
	basophilia, cortical tubules, focal (minimal)
LIVER:	lipidosis, tension, focal (slight)
	infiltration, mononuclear-cell, multifocal (minimal)
PROSTATE:	prostatitis, interstitial (moderate)
SKIN (TREATED):	hyperplasia/hyperkeratosis, epidermis (slight)
	hyperplasia, sebaceous glands (slight)

THE FOLLOWING TISSUE(S) WERE WITHIN NORMAL LIMITS:

ADRENAL GLANDS	AORTA	BONE MARROW (STERNUM)	BRAIN
CECUM	COLON	EPIDIDYMIDES	ESOPHAGUS
EYES	HEART	ILEUM	JEJUNUM
LACRIMAL GLANDS	LUNG	LYMPH NODE, MESENTERIC	MUSCLE, FEMORIS
NERVE, SCIATIC	PANCREAS	PARATHYROID	PITUITARY
RECTUM	SALIVARY GLANDS	SEMINAL VESICLES	SKIN (UNTREATED)
SPINAL CORD, CERVICAL	SPINAL CORD, LUMBAR	SPINAL CORD, MIDTHORACIC	SPLEEN
STOMACH	TESTES	THYMUS	THYROID
TRACHEA	URINARY BLADDER		

End of Record- ICN295

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

90-DAY SUBCHRONIC DERMAL TOXICITY STUDY IN RATS WITH SATELLITE GROUP
STUDY NUMBER 139910B - TEST MATERIAL MRD-92-399

Appendix II
Individual Animal Gross and Histomorphology Data

ANIMAL NUMBER: ICN297
SEX: M

DOSE GROUP: 1
DEATH TYPE: Spontaneous Death

GROSS OBSERVATION(S):

GASTROINTESTINAL TRACT: Cecum- ingesta extremely compact.
LIVER: All lobes and surfaces- mottled red/dark red/tan.

HISTOMORPHOLOGIC OBSERVATION(S):

No microscopic change to correlate, CECUM
vacuolation, hepatocellular, centrilobular congestion

HISTOMORPHOLOGIC OBSERVATIONS:

CECUM: No microscopic change to correlate
KIDNEYS: basophilia, cortical tubules, focal (minimal)
LIVER: vacuolation, hepatocellular, centrilobular (moderate) congestion (moderate)
LUNG: mineralization, vascular (minimal)
LYMPH NODE, MESENTERIC: lymphadenopathy, cystic (slight)
SKIN (TREATED): hyperplasia/hyperkeratosis, epidermis (minimal) hyperplasia, sebaceous glands (minimal)

THE FOLLOWING TISSUE(S) WERE WITHIN NORMAL LIMITS:

ADRENAL GLANDS
BRAIN
EPIDIDYMIDES
ILEUM
NERVE, SCIATIC
PROSTATE
SKIN (UNTREATED)
SPLEEN
THYROID

AORTA
CECUM
ESOPHAGUS
JEJUNUM
PANCREAS
RECTUM
SPINAL CORD, CERVICAL
STOMACH
TRACHEA

BONE (STERNUM)
COLON
EYES
LACRIMAL GLANDS
PARATHYROID
SALIVARY GLANDS
SPINAL CORD, LUMBAR
TESTES
URINARY BLADDER

BONE MARROW (STERNUM)
DUODENUM
HEART
MUSCLE, FEMORIS
PITUITARY
SEMINAL VESICLES
SPINAL CORD, MIDTHORACIC
THYMUS

End of Record- ICN297

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

90-DAY SUBCHRONIC DERMAL TOXICITY STUDY IN RATS WITH SATELLITE GROUP
STUDY NUMBER 139910B - TEST MATERIAL MRD-92-399

Appendix II
Individual Animal Gross and Histomorphology Data

ANIMAL NUMBER: ICN305
SEX: M

DOSE GROUP: 1
DEATH TYPE: Scheduled Sacrifice

GROSS OBSERVATION(S):

GENERAL: No gross changes.

HISTOMORPHOLOGIC OBSERVATION(S):

Not applicable

HISTOMORPHOLOGIC OBSERVATIONS:

BONE (STERNUM):	necrosis, intersternal cartilage, focal (minimal)
HEART:	infiltration, mononuclear-cell, focal (minimal)
KIDNEYS:	infiltration, mononuclear-cell, focal (minimal)
	degeneration, cortical tubules, focal (slight)
	basophilia, cortical tubules, focal (slight)
LIVER:	infiltration, mononuclear-cell, multifocal (minimal)
SKIN (TREATED):	hyperplasia/hyperkeratosis, epidermis (minimal)
	hyperplasia, sebaceous glands (slight)
STOMACH:	dilatation, mucosal glands (minimal)

THE FOLLOWING TISSUE(S) WERE WITHIN NORMAL LIMITS:

ADRENAL GLANDS	AORTA	BONE MARROW (STERNUM)	BRAIN
CECUM	COLON	DUODENUM	EPIDIDYMIDES
ESOPHAGUS	EYES	ILEUM	JEJUNUM
LACRIMAL GLANDS	LUNG	LYMPH NODE, MESENTERIC	MUSCLE, FEMORIS
NERVE, SCIATIC	PANCREAS	PARATHYROID	PROSTATE
RECTUM	SALIVARY GLANDS	SEMINAL VESICLES	SKIN (UNTREATED)
SPINAL CORD, CERVICAL	SPINAL CORD, LUMBAR	SPINAL CORD, MIDTHORACIC	SPLEEN
TESTES	THYMUS	THYROID	TRACHEA
URINARY BLADDER			

TISSUE(S) NOT AVAILABLE FOR EVALUATION:

PITUITARY

End of Record- ICN305

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

90-DAY SUBCHRONIC DERMAL TOXICITY STUDY IN RATS WITH SATELLITE GROUP
STUDY NUMBER 139910B - TEST MATERIAL MRD-92-399

Appendix II
Individual Animal Gross and Histomorphology Data

ANIMAL NUMBER: ICN314
SEX: M

DOSE GROUP: 1
DEATH TYPE: Scheduled Sacrifice

GROSS OBSERVATION(S):

GENERAL: No gross changes.

HISTOMORPHOLOGIC OBSERVATION(S):

Not applicable

HISTOMORPHOLOGIC OBSERVATIONS:

BONE (STERNUM):	necrosis, intersternal cartilage, focal (minimal)
DUODENUM:	infiltration, mononuclear-cell (minimal)
HEART:	infiltration, mononuclear-cell, focal (minimal)
KIDNEYS:	infiltration, mononuclear-cell, focal (minimal)
LIVER:	infiltration, mononuclear-cell, multifocal (minimal)
PROSTATE:	prostatitis, interstitial (moderate)
SKIN (TREATED):	hyperplasia/hyperkeratosis, epidermis (minimal)
	hyperplasia, sebaceous glands (minimal)
STOMACH:	dilatation, mucosal glands (slight)

THE FOLLOWING TISSUE(S) WERE WITHIN NORMAL LIMITS:

ADRENAL GLANDS	AORTA	BONE MARROW (STERNUM)	BRAIN
CECUM	COLON	EPIDIDYMIDES	ESOPHAGUS
EYES	ILEUM	JEJUNUM	LACRIMAL GLANDS
LUNG	LYMPH NODE, MESENTERIC	MUSCLE, FEMORIS	NERVE, SCIATIC
PANCREAS	PARATHYROID	PITUITARY	RECTUM
SALIVARY GLANDS	SEMINAL VESICLES	SKIN (UNTREATED)	SPINAL CORD, CERVICAL
SPINAL CORD, LUMBAR	SPINAL CORD, MIDTHORACIC	SPLEEN	TESTES
THYMUS	THYROID	TRACHEA	URINARY BLADDER

End of Record- ICN314

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

90-DAY SUBCHRONIC DERMAL TOXICITY STUDY IN RATS WITH SATELLITE GROUP
STUDY NUMBER 139910B - TEST MATERIAL MRD-92-399

Appendix II
Individual Animal Gross and Histomorphology Data

ANIMAL NUMBER: ICN323
SEX: M

DOSE GROUP: 1
DEATH TYPE: Scheduled Sacrifice

GROSS OBSERVATION(S):

GENERAL: No gross changes.

HISTOMORPHOLOGIC OBSERVATION(S):

Not applicable

HISTOMORPHOLOGIC OBSERVATIONS:

ADRENAL GLANDS:	vacuolation, cortical, diffuse (minimal)
HEART:	infiltration, mononuclear-cell, focal (minimal)
KIDNEYS:	basophilia, cortical tubules, focal (minimal)
LIVER:	infiltration, mononuclear-cell, multifocal (minimal)
SKIN (TREATED):	hyperplasia/hyperkeratosis, epidermis (minimal)
	hyperplasia, sebaceous glands (minimal)
STOMACH:	dilatation, mucosal glands (minimal)

THE FOLLOWING TISSUE(S) WERE WITHIN NORMAL LIMITS:

AORTA	BONE (STERNUM)	BONE MARROW (STERNUM)	BRAIN
CECUM	COLON	DUODENUM	EPIDIDYIMIDES
ESOPHAGUS	EYES	ILEUM	JEJUNUM
LACRIMAL GLANDS	LUNG	LYMPH NODE, MESENTERIC	MUSCLE, FEMORIS
NERVE, SCIATIC	PANCREAS	PARATHYROID	PITUITARY
PROSTATE	RECTUM	SALIVARY GLANDS	SEMINAL VESICLES
SKIN (UNTREATED)	SPINAL CORD, CERVICAL	SPINAL CORD, LUMBAR	SPINAL CORD, MIDTHORACIC
SPLEEN	TESTES	THYMUS	THYROID
TRACHEA	URINARY BLADDER		

End of Record- ICN323

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

90-DAY SUBCHRONIC DERMAL TOXICITY STUDY IN RATS WITH SATELLITE GROUP
STUDY NUMBER 139910B - TEST MATERIAL MRD-92-399

Appendix II
Individual Animal Gross and Histomorphology Data

ANIMAL NUMBER: ICN273
SEX: M

DOSE GROUP: 2
DEATH TYPE: Scheduled Sacrifice

GROSS OBSERVATION(S):

GENERAL: No gross changes.

HISTOMORPHOLOGIC OBSERVATION(S):

Not applicable

HISTOMORPHOLOGIC OBSERVATIONS:

LIVER: infiltration, mononuclear-cell, multifocal (minimal)
LUNG: metaplasia, osseous, focal (minimal)

THE FOLLOWING TISSUE(S) WERE WITHIN NORMAL LIMITS:

KIDNEYS

End of Record- ICN273

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

90-DAY SUBCHRONIC DERMAL TOXICITY STUDY IN RATS WITH SATELLITE GROUP
STUDY NUMBER 139910B - TEST MATERIAL MRD-92-399

Appendix II
Individual Animal Gross and Histomorphology Data

ANIMAL NUMBER: ICN276
SEX: M

DOSE GROUP: 2
DEATH TYPE: Scheduled Sacrifice

GROSS OBSERVATION(S):

GENERAL: No gross changes.

HISTOMORPHOLOGIC OBSERVATION(S):

Not applicable

HISTOMORPHOLOGIC OBSERVATIONS:

KIDNEYS:

basophilia, cortical tubules, focal (minimal)

LIVER:

infiltration, mononuclear-cell, multifocal (slight)

vacuolation, hepatocellular, focal (minimal)

THE FOLLOWING TISSUE(S) WERE WITHIN NORMAL LIMITS:

LUNG

End of Record- ICN276

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

90-DAY SUBCHRONIC DERMAL TOXICITY STUDY IN RATS WITH SATELLITE GROUP
STUDY NUMBER 139910B - TEST MATERIAL MRD-92-399

Appendix II
Individual Animal Gross and Histomorphology Data

ANIMAL NUMBER: ICN300
SEX: M

DOSE GROUP: 2
DEATH TYPE: Scheduled Sacrifice

GROSS OBSERVATION(S):

GENERAL: No gross changes.

HISTOMORPHOLOGIC OBSERVATION(S):

Not applicable

HISTOMORPHOLOGIC OBSERVATIONS:

KIDNEYS:

basophilia, cortical tubules, focal (minimal)

LIVER:

infiltration, mononuclear-cell, multifocal (slight)
necrosis, focal (slight)

THE FOLLOWING TISSUE(S) WERE WITHIN NORMAL LIMITS:

LUNG

End of Record- ICN300

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

90-DAY SUBCHRONIC DERMAL TOXICITY STUDY IN RATS WITH SATELLITE GROUP
STUDY NUMBER 139910B - TEST MATERIAL MRD-92-399

Appendix II
Individual Animal Gross and Histomorphology Data

ANIMAL NUMBER: ICN302
SEX: M

DOSE GROUP: 2
DEATH TYPE: Scheduled Sacrifice

GROSS OBSERVATION(S):

LIVER: Mass A- accessory lobe, 2.2 x 1.3 x 1.0cm,
red/dark red, firm, cut surface- tan/red/dark
red, firm.

HISTOMORPHOLOGIC OBSERVATION(S):

necrosis, focal
peritonitis
infarct, liver lobe

HISTOMORPHOLOGIC OBSERVATIONS:

KIDNEYS:
LIVER:

basophilia, cortical tubules, focal (minimal)
peritonitis (slight)
infarct, liver lobe
necrosis, focal (slight)

THE FOLLOWING TISSUE(S) WERE WITHIN NORMAL LIMITS:

LUNG

End of Record- ICN302

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

90-DAY SUBCHRONIC DERMAL TOXICITY STUDY IN RATS WITH SATELLITE GROUP
STUDY NUMBER 139910B - TEST MATERIAL MRD-92-399

Appendix II
Individual Animal Gross and Histomorphology Data

ANIMAL NUMBER: ICN306
SEX: M

DOSE GROUP: 2
DEATH TYPE: Scheduled Sacrifice

GROSS OBSERVATION(S):

HISTOMORPHOLOGIC OBSERVATION(S):

GENERAL: No gross changes.

Not applicable

THE FOLLOWING TISSUE(S) WERE WITHIN NORMAL LIMITS:

KIDNEYS

LIVER

LUNG

End of Record- ICN306

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

90-DAY SUBCHRONIC DERMAL TOXICITY STUDY IN RATS WITH SATELLITE GROUP
STUDY NUMBER 139910B - TEST MATERIAL MRD-92-399

Appendix II
Individual Animal Gross and Histomorphology Data

ANIMAL NUMBER: ICN310
SEX: M

DOSE GROUP: 2
DEATH TYPE: Scheduled Sacrifice

GROSS OBSERVATION(S):

GENERAL: No gross changes.

HISTOMORPHOLOGIC OBSERVATION(S):

Not applicable

HISTOMORPHOLOGIC OBSERVATIONS:

KIDNEYS:

basophilia, cortical tubules, focal (minimal)

LIVER:

infiltration, mononuclear-cell, multifocal (minimal)

THE FOLLOWING TISSUE(S) WERE WITHIN NORMAL LIMITS:

LUNG

End of Record- ICN310

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

90-DAY SUBCHRONIC DERMAL TOXICITY STUDY IN RATS WITH SATELLITE GROUP
STUDY NUMBER 139910B - TEST MATERIAL MRD-92-399

Appendix II
Individual Animal Gross and Histomorphology Data

ANIMAL NUMBER: ICN318
SEX: M

DOSE GROUP: 2
DEATH TYPE: Scheduled Sacrifice

GROSS OBSERVATION(S):

HISTOMORPHOLOGIC OBSERVATION(S):

GENERAL: No gross changes.

Not applicable

HISTOMORPHOLOGIC OBSERVATIONS:

KIDNEYS:

cyst(s), papilla

LIVER:

basophilia, cortical tubules, focal (slight)
infiltration, mononuclear-cell, multifocal (minimal)

THE FOLLOWING TISSUE(S) WERE WITHIN NORMAL LIMITS:

LUNG

End of Record- ICN318

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399); 139910B

90-DAY SUBCHRONIC DERMAL TOXICITY STUDY IN RATS WITH SATELLITE GROUP
STUDY NUMBER 139910B - TEST MATERIAL MRD-92-399

Appendix II
Individual Animal Gross and Histomorphology Data

ANIMAL NUMBER: ICN321
SEX: M

DOSE GROUP: 2
DEATH TYPE: Scheduled Sacrifice

=====

GROSS OBSERVATION(S):

SPLEEN: Friable.

HISTOMORPHOLOGIC OBSERVATION(S):

No microscopic change to correlate

HISTOMORPHOLOGIC OBSERVATIONS:

KIDNEYS:

basophilia, cortical tubules, focal (minimal)

LIVER:

peritonitis (slight)

infiltration, mononuclear-cell, multifocal (minimal)

necrosis, focal (slight)

LUNG:

mineralization, vascular (minimal)

SPLEEN:

No microscopic change to correlate

THE FOLLOWING TISSUE(S) WERE WITHIN NORMAL LIMITS:

SPLEEN

End of Record- ICN321

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

90-DAY SUBCHRONIC DERMAL TOXICITY STUDY IN RATS WITH SATELLITE GROUP
STUDY NUMBER 139910B - TEST MATERIAL MRD-92-399

Appendix II
Individual Animal Gross and Histomorphology Data

ANIMAL NUMBER: ICN330
SEX: M

DOSE GROUP: 2
DEATH TYPE: Scheduled Sacrifice

GROSS OBSERVATION(S):

HISTOMORPHOLOGIC OBSERVATION(S):

GENERAL: No gross changes.

Not applicable

HISTOMORPHOLOGIC OBSERVATIONS:

LIVER: infiltration, mononuclear-cell, multifocal (minimal)

THE FOLLOWING TISSUE(S) WERE WITHIN NORMAL LIMITS:

KIDNEYS LUNG

End of Record- ICN330

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

90-DAY SUBCHRONIC DERMAL TOXICITY STUDY IN RATS WITH SATELLITE GROUP
STUDY NUMBER 139910B - TEST MATERIAL MRD-92-399

Appendix II
Individual Animal Gross and Histomorphology Data

ANIMAL NUMBER: ICN335
SEX: M

DOSE GROUP: 2
DEATH TYPE: Scheduled Sacrifice

GROSS OBSERVATION(S):

GENERAL: No gross changes.

HISTOMORPHOLOGIC OBSERVATION(S):

Not applicable

HISTOMORPHOLOGIC OBSERVATIONS:

LIVER:

infiltration, mononuclear-cell, multifocal (minimal)

LUNG:

proliferation, lymphoid, peribronchial/perivascular (slight)

THE FOLLOWING TISSUE(S) WERE WITHIN NORMAL LIMITS:

KIDNEYS

End of Record- ICN335

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

90-DAY SUBCHRONIC DERMAL TOXICITY STUDY IN RATS WITH SATELLITE GROUP
STUDY NUMBER 139910B - TEST MATERIAL MRD-92-399

Appendix II
Individual Animal Gross and Histomorphology Data

ANIMAL NUMBER: ICN285
SEX: M

DOSE GROUP: 3
DEATH TYPE: Scheduled Sacrifice

GROSS OBSERVATION(S):

SKIN: Dose site- eschar, desquamation.

HISTOMORPHOLOGIC OBSERVATION(S):

hyperplasia/hyperkeratosis, epidermis, SKIN (TREATED)
hyperplasia, sebaceous glands, SKIN (TREATED)
exudate, SKIN (TREATED)
necrosis, epidermal, focal, SKIN (TREATED)
adenitis, SKIN (TREATED)
dermatitis, chronic, SKIN (TREATED)

HISTOMORPHOLOGIC OBSERVATIONS:

LIVER:
SKIN (TREATED):

infiltration, mononuclear-cell, multifocal (minimal)
hyperplasia/hyperkeratosis, epidermis (slight)
hyperplasia, sebaceous glands (slight)
exudate
necrosis, epidermal, focal (slight)
adenitis (slight)
dermatitis, chronic (slight)

THE FOLLOWING TISSUE(S) WERE WITHIN NORMAL LIMITS:

KIDNEYS

LUNG

End of Record- ICN285

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 1399108

90-DAY SUBCHRONIC DERMAL TOXICITY STUDY IN RATS WITH SATELLITE GROUP
STUDY NUMBER 1399108 - TEST MATERIAL MRD-92-399

Appendix II
Individual Animal Gross and Histomorphology Data

ANIMAL NUMBER: ICN290
SEX: M

DOSE GROUP: 3
DEATH TYPE: Scheduled Sacrifice

GROSS OBSERVATION(S):

SKIN: Dose site- eschar, desquamation.

HISTOMORPHOLOGIC OBSERVATION(S):

hyperplasia/hyperkeratosis, epidermis, SKIN
(TREATED)
hyperplasia, sebaceous glands, SKIN (TREATED)
exudate, SKIN (TREATED)
necrosis, epidermal, focal, SKIN (TREATED)
inflammation, dermal, SKIN (TREATED)

HISTOMORPHOLOGIC OBSERVATIONS:

KIDNEYS:

degeneration, cortical tubules, focal (minimal)
basophilia, cortical tubules, focal (slight)
vacuolation, hepatocellular, focal (minimal)
metaplasia, osseous, focal (minimal)
hyperplasia/hyperkeratosis, epidermis (minimal)
hyperplasia, sebaceous glands (minimal)
exudate
necrosis, epidermal, focal (slight)
inflammation, dermal (minimal)

LIVER:

LUNG:

SKIN (TREATED):

End of Record- ICN290

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

90-DAY SUBCHRONIC DERMAL TOXICITY STUDY IN RATS WITH SATELLITE GROUP
STUDY NUMBER 139910B - TEST MATERIAL MRD-92-399

Appendix II
Individual Animal Gross and Histomorphology Data

ANIMAL NUMBER: ICN291
SEX: M

DOSE GROUP: 3
DEATH TYPE: Scheduled Sacrifice

GROSS OBSERVATION(S):

KIDNEYS: Right- dilated pelvis, renal calculus.

SKIN: Dose site- eschar, desquamation.

URINARY BLADDER: Extremely distended, thickened,
multiple cystic calculi.

HISTOMORPHOLOGIC OBSERVATION(S):

dilatation, pelvis
hyperplasia, pelvic/papillary urothelium
degeneration, cortical tubules, focal
pyelonephritis
calculus
hyperplasia/hyperkeratosis, epidermis, SKIN
(TREATED)
hyperplasia, sebaceous glands, SKIN (TREATED)
exudate, SKIN (TREATED)
necrosis, epidermal, focal, SKIN (TREATED)
inflammation, dermal, SKIN (TREATED)
cystitis, hyperplastic

HISTOMORPHOLOGIC OBSERVATIONS:

KIDNEYS:

calculus
degeneration, cortical tubules, focal (slight)
hyperplasia, pelvic/papillary urothelium (moderate)
dilatation, pelvis (marked)
pyelonephritis (marked)

SKIN (TREATED):

hyperplasia/hyperkeratosis, epidermis (slight)
hyperplasia, sebaceous glands (slight)
exudate

URINARY BLADDER:

necrosis, epidermal, focal (slight)
inflammation, dermal (slight)
cystitis, hyperplastic (marked)

THE FOLLOWING TISSUE(S) WERE WITHIN NORMAL LIMITS:

LIVER

LUNG

End of Record- ICN291

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

90-DAY SUBCHRONIC DERMAL TOXICITY STUDY IN RATS WITH SATELLITE GROUP
STUDY NUMBER 139910B - TEST MATERIAL MRD-92-399

Appendix II
Individual Animal Gross and Histomorphology Data

ANIMAL NUMBER: ICN293
SEX: M

DOSE GROUP: 3
DEATH TYPE: Scheduled Sacrifice

GROSS OBSERVATION(S):

PALATE: Sores.

SKIN: Dose site- desquamation.

HISTOMORPHOLOGIC OBSERVATION(S):

fracture
ulcer
inflammation, chronic
metaplasia, squamous
hyperplasia/hyperkeratosis, epidermis, SKIN
(TREATED)
hyperplasia, sebaceous glands, SKIN (TREATED)

HISTOMORPHOLOGIC OBSERVATIONS:

KIDNEYS:
PALATE:

basophilia, cortical tubules, focal (minimal)
fracture
ulcer

SKIN (TREATED):

inflammation, chronic (marked)
metaplasia, squamous (slight)
hyperplasia/hyperkeratosis, epidermis (minimal)
hyperplasia, sebaceous glands (minimal)

THE FOLLOWING TISSUE(S) WERE WITHIN NORMAL LIMITS:

LIVER

LUNG

End of Record- ICN293

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

90-DAY SUBCHRONIC DERMAL TOXICITY STUDY IN RATS WITH SATELLITE GROUP
STUDY NUMBER 139910B - TEST MATERIAL MRD-92-399

Appendix II
Individual Animal Gross and Histomorphology Data

ANIMAL NUMBER: ICN299
SEX: M

DOSE GROUP: 3
DEATH TYPE: Scheduled Sacrifice

GROSS OBSERVATION(S):

SKIN: Dose site- eschar, desquamation.

HISTOMORPHOLOGIC OBSERVATION(S):

hyperplasia/hyperkeratosis, epidermis, SKIN (TREATED)
hyperplasia, sebaceous glands, SKIN (TREATED)
inflammation, dermal, SKIN (TREATED)
exudate, SKIN (TREATED)
necrosis, epidermal, focal, SKIN (TREATED)

HISTOMORPHOLOGIC OBSERVATIONS:

KIDNEYS:

corpora amylacea, cortex (minimal)

LIVER:

dilatation, medullary tubules, focal (minimal)
infiltration, mononuclear-cell, multifocal (minimal)

SKIN (TREATED):

hyperplasia/hyperkeratosis, epidermis (moderate)
hyperplasia, sebaceous glands (moderate)
inflammation, dermal (slight)
exudate
necrosis, epidermal, focal (moderate)

THE FOLLOWING TISSUE(S) WERE WITHIN NORMAL LIMITS:

LUNG

End of Record- ICN299

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

90-DAY SUBCHRONIC DERMAL TOXICITY STUDY IN RATS WITH SATELLITE GROUP
STUDY NUMBER 139910B - TEST MATERIAL MRD-92-399

Appendix II
Individual Animal Gross and Histomorphology Data

ANIMAL NUMBER: ICN303
SEX: M

DOSE GROUP: 3
DEATH TYPE: Scheduled Sacrifice

GROSS OBSERVATION(S):

GASTROINTESTINAL TRACT: Ileum- diverticulum.

SKIN: Dose site- desquamation, eschar.

HISTOMORPHOLOGIC OBSERVATION(S):

necrosis, ILEUM
inflammation, chronic, ILEUM
peritonitis, ILEUM
hyperplasia/hyperkeratosis, epidermis, SKIN
(TREATED)
exudate, SKIN (TREATED)
hyperplasia, sebaceous glands, SKIN (TREATED)
necrosis, epidermal, focal, SKIN (TREATED)
inflammation, dermal, SKIN (TREATED)

HISTOMORPHOLOGIC OBSERVATIONS:

ILEUM: necrosis (marked)
inflammation, chronic (marked)
peritonitis (marked)
KIDNEYS: degeneration, cortical tubules, focal (minimal)
dilatation, cortical tubules, focal (slight)
LIVER: infiltration, mononuclear-cell, multifocal (slight)
necrosis, focal (slight)
LUNG: inflammation, interstitial, focal (minimal)
mineralization, vascular (minimal)
SKIN (TREATED): hyperplasia/hyperkeratosis, epidermis (slight)
exudate
hyperplasia, sebaceous glands (slight)
necrosis, epidermal, focal (slight)
inflammation, dermal (slight)

End of Record- ICN303

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

90-DAY SUBCHRONIC DERMAL TOXICITY STUDY IN RATS WITH SATELLITE GROUP
STUDY NUMBER 139910B - TEST MATERIAL MRD-92-399

Appendix II
Individual Animal Gross and Histomorphology Data

ANIMAL NUMBER: ICN311
SEX: M

DOSE GROUP: 3
DEATH TYPE: Scheduled Sacrifice

=====

GROSS OBSERVATION(S):

SKIN: Dose site- eschar, desquamation.

HISTOMORPHOLOGIC OBSERVATION(S):

exudate, SKIN (TREATED)
hyperplasia/hyperkeratosis, epidermis, SKIN
(TREATED)
hyperplasia, sebaceous glands, SKIN (TREATED)
inflammation, dermal, SKIN (TREATED)

HISTOMORPHOLOGIC OBSERVATIONS:

LIVER: peritonitis (slight)
LUNG: inflammation, interstitial, focal (minimal)
SKIN (TREATED): exudate
hyperplasia/hyperkeratosis, epidermis (slight)
hyperplasia, sebaceous glands (slight)
inflammation, dermal (minimal)

THE FOLLOWING TISSUE(S) WERE WITHIN NORMAL LIMITS:

KIDNEYS

End of Record- ICN311

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 1399108

90-DAY SUBCHRONIC DERMAL TOXICITY STUDY IN RATS WITH SATELLITE GROUP
STUDY NUMBER 1399108 - TEST MATERIAL MRD-92-399

Appendix II
Individual Animal Gross and Histomorphology Data

ANIMAL NUMBER: ICN315
SEX: M

DOSE GROUP: 3
DEATH TYPE: Scheduled Sacrifice

GROSS OBSERVATION(S):

GENERAL: No gross changes.

HISTOMORPHOLOGIC OBSERVATION(S):

Not applicable

HISTOMORPHOLOGIC OBSERVATIONS:

KIDNEYS:

basophilia, cortical tubules, focal (slight)

LUNG:

pleuritis, chronic (minimal)

THE FOLLOWING TISSUE(S) WERE WITHIN NORMAL LIMITS:

LIVER

End of Record- ICN315

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

90-DAY SUBCHRONIC DERMAL TOXICITY STUDY IN RATS WITH SATELLITE GROUP
STUDY NUMBER 139910B - TEST MATERIAL MRD-92-399

Appendix II
Individual Animal Gross and Histomorphology Data

ANIMAL NUMBER: ICN319
SEX: M

DOSE GROUP: 3
DEATH TYPE: Scheduled Sacrifice

GROSS OBSERVATION(S):

SKIN: Dose site- desquamation, eschar.

HISTOMORPHOLOGIC OBSERVATION(S):

exudate, SKIN (TREATED)
hyperplasia/hyperkeratosis, epidermis, SKIN
(TREATED)
necrosis, epidermal, focal, SKIN (TREATED)
hyperplasia, sebaceous glands, SKIN (TREATED)
inflammation, dermal, SKIN (TREATED)

HISTOMORPHOLOGIC OBSERVATIONS:

KIDNEYS:

infiltration, mononuclear-cell, focal (minimal)
dilatation, medullary tubules, focal (minimal)

LIVER:

basophilia, cortical tubules, focal (minimal)
infiltration, mononuclear-cell, multifocal (minimal)

SKIN (TREATED):

exudate
hyperplasia/hyperkeratosis, epidermis (slight)
necrosis, epidermal, focal (slight)
hyperplasia, sebaceous glands (slight)
inflammation, dermal (slight)

THE FOLLOWING TISSUE(S) WERE WITHIN NORMAL LIMITS:

LUNG

End of Record- ICN319

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

90-DAY SUBCHRONIC DERMAL TOXICITY STUDY IN RATS WITH SATELLITE GROUP
STUDY NUMBER 139910B - TEST MATERIAL MRD-92-399

Appendix II
Individual Animal Gross and Histomorphology Data

ANIMAL NUMBER: ICN328
SEX: M

DOSE GROUP: 3
DEATH TYPE: Scheduled Sacrifice

GROSS OBSERVATION(S):

SKIN: Dose site- desquamation, eschar.

HISTOMORPHOLOGIC OBSERVATION(S):

necrosis, epidermal, focal, SKIN (TREATED)
hyperplasia/hyperkeratosis, epidermis, SKIN
(TREATED)
exudate, SKIN (TREATED)
hyperplasia, sebaceous glands, SKIN (TREATED)
inflammation, dermal, SKIN (TREATED)

HISTOMORPHOLOGIC OBSERVATIONS:

KIDNEYS:

LIVER:

LUNG:

SKIN (TREATED):

basophilia, cortical tubules, focal (minimal)
infiltration, mononuclear-cell, multifocal (slight)
necrosis, focal (slight)
inflammation, interstitial, focal (minimal)
necrosis, epidermal, focal (moderate)
hyperplasia/hyperkeratosis, epidermis (slight)
exudate
hyperplasia, sebaceous glands (slight)
inflammation, dermal (slight)

End of Record- ICN328

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

90-DAY SUBCHRONIC DERMAL TOXICITY STUDY IN RATS WITH SATELLITE GROUP
STUDY NUMBER 139910B - TEST MATERIAL MRD-92-399

Appendix II
Individual Animal Gross and Histomorphology Data

ANIMAL NUMBER: ICN277
SEX: M

DOSE GROUP: 4
DEATH TYPE: Scheduled Sacrifice

GROSS OBSERVATION(S):

SKIN: Dose site- desquamation, eschar.

HISTOMORPHOLOGIC OBSERVATION(S):

hyperplasia/hyperkeratosis, epidermis, SKIN (TREATED)
hyperplasia, sebaceous glands, SKIN (TREATED)
necrosis, epidermal, focal, SKIN (TREATED)
inflammation, dermal, SKIN (TREATED)
exudate, SKIN (TREATED)

HISTOMORPHOLOGIC OBSERVATIONS:

LIVER:
SKIN (TREATED):

infiltration, mononuclear-cell, multifocal (slight)
hyperplasia/hyperkeratosis, epidermis (slight)
hyperplasia, sebaceous glands (moderate)
necrosis, epidermal, focal (moderate)
inflammation, dermal (slight)
exudate

THE FOLLOWING TISSUE(S) WERE WITHIN NORMAL LIMITS:

ADRENAL GLANDS	AORTA	BONE (STERNUM)	BONE MARROW (STERNUM)
BRAIN	CECUM	COLON	DUODENUM
EPIDIDYMIDES	ESOPHAGUS	EYES	HEART
ILEUM	JEJUNUM	KIDNEYS	LACRIMAL GLANDS
LUNG	LYMPH NODE, MESENTERIC	MUSCLE, FEMORIS	NERVE, SCIATIC
PANCREAS	PARATHYROID	PITUITARY	PROSTATE
RECTUM	SALIVARY GLANDS	SEMINAL VESICLES	SKIN (UNTREATED)
SPINAL CORD, CERVICAL	SPINAL CORD, LUMBAR	SPINAL CORD, MIDTHORACIC	SPLEEN
STOMACH	TESTES	THYMUS	THYROID
TRACHEA	URINARY BLADDER		

End of Record- ICN277

**90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B**

**90-DAY SUBCHRONIC DERMAL TOXICITY STUDY IN RATS WITH SATELLITE GROUP
STUDY NUMBER 139910B - TEST MATERIAL MRD-92-399**

**Appendix II
Individual Animal Gross and Histomorphology Data**

ANIMAL NUMBER: ICN283
SEX: M

DOSE GROUP: 4
DEATH TYPE: Scheduled Sacrifice

GROSS OBSERVATION(S):

SKIN: Dose site- desquamation, eschar.

HISTOMORPHOLOGIC OBSERVATION(S):

hyperplasia/hyperkeratosis, epidermis, SKIN (TREATED)
hyperplasia, sebaceous glands, SKIN (TREATED)
exudate, SKIN (TREATED)
necrosis, epidermal, focal, SKIN (TREATED)
inflammation, dermal, SKIN (TREATED)

HISTOMORPHOLOGIC OBSERVATIONS:

BONE (STERNUM): necrosis, intersternal cartilage, focal (slight)
HEART: infiltration, mononuclear-cell, focal (minimal)
KIDNEYS: cyst(s), cortex
basophilia, cortical tubules, focal (minimal)
LIVER: infiltration, mononuclear-cell, multifocal (minimal)
SKIN (TREATED): hyperplasia/hyperkeratosis, epidermis (moderate)
hyperplasia, sebaceous glands (moderate)
exudate
necrosis, epidermal, focal (slight)
inflammation, dermal (slight)
URINARY BLADDER: distention (marked)

THE FOLLOWING TISSUE(S) WERE WITHIN NORMAL LIMITS:

ADRENAL GLANDS	AORTA	BONE MARROW (STERNUM)	BRAIN
CECUM	COLON	DUODENUM	EPIIDIDYMIDES
ESOPHAGUS	EYES	ILEUM	JEJUNUM
LACRIMAL GLANDS	LUNG	LYMPH NODE, MESENTERIC	MUSCLE, FEMORIS
NERVE, SCIATIC	PANCREAS	PARATHYROID	PITUITARY
PROSTATE	RECTUM	SALIVARY GLANDS	SEMINAL VESICLES
SKIN (UNTREATED)	SPINAL CORD, CERVICAL	SPINAL CORD, LUMBAR	SPINAL CORD, MIDTHORACIC
SPLEEN	STOMACH	TESTES	THYMUS
THYROID	TRACHEA		

End of Record- ICN283

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

90-DAY SUBCHRONIC DERMAL TOXICITY STUDY IN RATS WITH SATELLITE GROUP
STUDY NUMBER 139910B - TEST MATERIAL MRD-92-399

Appendix II
Individual Animal Gross and Histomorphology Data

ANIMAL NUMBER: ICN284
SEX: M

DOSE GROUP: 4
DEATH TYPE: Scheduled Sacrifice

GROSS OBSERVATION(S):

SKIN: Dose site- desquamation, eschar.

HISTOMORPHOLOGIC OBSERVATION(S):

hyperplasia/hyperkeratosis, epidermis, SKIN (TREATED)
hyperplasia, sebaceous glands, SKIN (TREATED)
exudate, SKIN (TREATED)
necrosis, epidermal, focal, SKIN (TREATED)
inflammation, dermal, SKIN (TREATED)

HISTOMORPHOLOGIC OBSERVATIONS:

BONE (STERNUM): necrosis, intersternal cartilage, focal (minimal)
BRAIN: mineralization, choroid plexus (minimal)
HEART: infiltration, mononuclear-cell, focal (slight)
KIDNEYS: necrosis, focal (slight)
infiltration, mononuclear-cell, focal (minimal)
degeneration, cortical tubules, focal (minimal)
basophilia, cortical tubules, focal (minimal)
LIVER: infiltration, mononuclear-cell, multifocal (minimal)
SKIN (TREATED): hyperplasia/hyperkeratosis, epidermis (slight)
hyperplasia, sebaceous glands (moderate)
exudate
necrosis, epidermal, focal (moderate)
inflammation, dermal (slight)
SKIN (UNTREATED): hyperkeratosis, epidermis (slight)
THYROID: ultimobranchial body/cyst
URINARY BLADDER: distention (moderate)

THE FOLLOWING TISSUE(S) WERE WITHIN NORMAL LIMITS:

ADRENAL GLANDS	AORTA	BONE MARROW (STERNUM)	CECUM
COLON	DUODENUM	EPIDIDYMIDES	ESOPHAGUS
EYES	ILEUM	JEJUNUM	LACRIMAL GLANDS
LUNG	LYMPH NODE, MESENTERIC	MUSCLE, FEMORIS	NERVE, SCIATIC
PANCREAS	PARATHYROID	PITUITARY	PROSTATE
RECTUM	SALIVARY GLANDS	SEMINAL VESICLES	SPINAL CORD, CERVICAL
SPINAL CORD, LUMBAR	SPINAL CORD, MIDTHORACIC	SPLEEN	STOMACH
TESTES	THYMUS	TRACHEA	

COMMENTS:

URINARY BLADDER

There is a moderate degree of flattening of the urothelium, indicating distention of the bladder.

End of Record- ICN284

**90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B**

**90-DAY SUBCHRONIC DERMAL TOXICITY STUDY IN RATS WITH SATELLITE GROUP
STUDY NUMBER 139910B - TEST MATERIAL MRD-92-399**

**Appendix II
Individual Animal Gross and Histomorphology Data**

ANIMAL NUMBER: ICN304
SEX: M

DOSE GROUP: 4
DEATH TYPE: Scheduled Sacrifice

GROSS OBSERVATION(S):

SKIN: Dose site- eschar, desquamation.

HISTOMORPHOLOGIC OBSERVATION(S):

exudate, SKIN (TREATED)
hyperplasia/hyperkeratosis, epidermis, SKIN (TREATED)
inflammation, dermal, SKIN (TREATED)
hyperplasia, sebaceous glands, SKIN (TREATED)

HISTOMORPHOLOGIC OBSERVATIONS:

EPIDIDYMIDES: granuloma(s), sperm
HEART: infiltration, mononuclear-cell, focal (minimal)
KIDNEYS: infiltration, mononuclear-cell, focal (minimal)
basophilia, cortical tubules, focal (minimal)
LIVER: infiltration, mononuclear-cell, multifocal (slight)
SKIN (TREATED): exudate
hyperplasia/hyperkeratosis, epidermis (slight)
inflammation, dermal (slight)
hyperplasia, sebaceous glands (slight)
STOMACH: dilatation, mucosal glands (minimal)

THE FOLLOWING TISSUE(S) WERE WITHIN NORMAL LIMITS:

ADRENAL GLANDS	AORTA	BONE (STERNUM)	BONE MARROW (STERNUM)
BRAIN	CECUM	COLON	DUODENUM
ESOPHAGUS	EYES	ILEUM	JEJUNUM
LACRIMAL GLANDS	LUNG	LYMPH NODE, MESENTERIC	MUSCLE, FEMORIS
NERVE, SCIATIC	PANCREAS	PARATHYROID	PITUITARY
PROSTATE	RECTUM	SALIVARY GLANDS	SEMINAL VESICLES
SKIN (UNTREATED)	SPINAL CORD, CERVICAL	SPINAL CORD, LUMBAR	SPINAL CORD, MIDTHORACIC
SPLEEN	TESTES	THYMUS	THYROID
TRACHEA	URINARY BLADDER		

End of Record- ICN304

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

90-DAY SUBCHRONIC DERMAL TOXICITY STUDY IN RATS WITH SATELLITE GROUP
STUDY NUMBER 139910B - TEST MATERIAL MRD-92-399

Appendix II
Individual Animal Gross and Histomorphology Data

ANIMAL NUMBER: ICN313
SEX: M

DOSE GROUP: 4
DEATH TYPE: Scheduled Sacrifice

GROSS OBSERVATION(S):

SKIN: Dose site- eschar, desquamation.

HISTOMORPHOLOGIC OBSERVATION(S):

hyperplasia, sebaceous glands, SKIN (TREATED)
hyperplasia/hyperkeratosis, epidermis, SKIN (TREATED)
necrosis, epidermal, focal, SKIN (TREATED)
exudate, SKIN (TREATED)
inflammation, dermal, SKIN (TREATED)

HISTOMORPHOLOGIC OBSERVATIONS:

HEART: infiltration, mononuclear-cell, focal (minimal)
KIDNEYS: mineralization, papilla, focal (minimal)
LIVER: inflammation, granulomatous (moderate)
necrosis, focal (moderate)
LUNG: macrophages, alveoli, focal (minimal)
LYMPH NODE, MESENTERIC: hyperplasia, lymphoid (slight)
SKIN (TREATED): hyperplasia, sebaceous glands (slight)
hyperplasia/hyperkeratosis, epidermis (moderate)
necrosis, epidermal, focal (slight)
exudate
inflammation, dermal (slight)

THE FOLLOWING TISSUE(S) WERE WITHIN NORMAL LIMITS:

ADRENAL GLANDS	AORTA	BONE (STERNUM)	BONE MARROW (STERNUM)
BRAIN	CECUM	COLON	DUODENUM
EPIDIDYMIDES	ESOPHAGUS	EYES	ILEUM
JEJUNUM	LACRIMAL GLANDS	MUSCLE, FEMORIS	NERVE, SCIATIC
PANCREAS	PARATHYROID	PITUITARY	PROSTATE
RECTUM	SALIVARY GLANDS	SEMINAL VESICLES	SKIN (UNTREATED)
SPINAL CORD, CERVICAL	SPINAL CORD, LUMBAR	SPINAL CORD, MIDTHORACIC	SPLEEN
STOMACH	TESTES	THYMUS	THYROID
TRACHEA	URINARY BLADDER		

End of Record- ICN313

**90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B**

**90-DAY SUBCHRONIC DERMAL TOXICITY STUDY IN RATS WITH SATELLITE GROUP
STUDY NUMBER 139910B - TEST MATERIAL MRD-92-399**

**Appendix II
Individual Animal Gross and Histomorphology Data**

ANIMAL NUMBER: ICN317
SEX: M

DOSE GROUP: 4
DEATH TYPE: Spontaneous Death

GROSS OBSERVATION(S):

GASTROINTESTINAL TRACT: Cecum- ingesta extremely compact.
GENERAL: Abdominal and thoracic cavities- filled with thin red liquid.
HEART: Firm.

KIDNEYS: Both- surrounded by clear gelatinous material.

LIVER: Left lobe, diaphragmatic surface- moderate amount of tan foci.
LUNG: All lobes and surfaces- dark red.

SEMINAL VESICLES: Extremely distended with creamy white material.

SKIN: Dose site- exfoliation, eschar.

URINARY BLADDER: Extremely distended with thin red liquid.

HISTOMORPHOLOGIC OBSERVATION(S):

No microscopic change to correlate, CECUM
Not applicable

mineralization, vascular
mineralization, focal
infiltration, mononuclear-cell, focal
necrosis, focal
dilatation, pelvis
necrosis, papillary
basophilia, cortical tubules, focal
mineralization, vascular
hemorrhage, perirenal fat, focal
dilatation, cortical tubules, focal
mineralization, cortical tubules, focal
necrosis, cortical tubules, focal
congestion

hemorrhage
congestion
mineralization
distention
hemorrhage
hyperplasia/hyperkeratosis, epidermis, SKIN (TREATED)
necrosis, epidermal, focal, SKIN (TREATED)
exudate, SKIN (TREATED)
inflammation, dermal, SKIN (TREATED)
hyperplasia, sebaceous glands, SKIN (TREATED)
hemorrhage
necrosis, focal
peritonitis

HISTOMORPHOLOGIC OBSERVATIONS:

AORTA:
CECUM:
HEART:

mineralization (slight)
No microscopic change to correlate
mineralization, vascular (moderate)
infiltration, mononuclear-cell, focal (slight)
necrosis, focal (slight)
mineralization, focal (moderate)
necrosis, papillary (moderate)
mineralization, vascular (moderate)
hemorrhage, perirenal fat, focal (moderate)
mineralization, cortical tubules, focal (slight)
necrosis, cortical tubules, focal (slight)
dilatation, cortical tubules, focal (slight)
dilatation, pelvis (moderate)

CONTINUED- ICN317

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

90-DAY SUBCHRONIC DERMAL TOXICITY STUDY IN RATS WITH SATELLITE GROUP
STUDY NUMBER 139910B - TEST MATERIAL MRD-92-399

Appendix II
Individual Animal Gross and Histomorphology Data

ANIMAL NUMBER: ICN317
SEX: M

DOSE GROUP: 4
DEATH TYPE: Spontaneous Death

HISTOMORPHOLOGIC OBSERVATIONS:

KIDNEYS:	basophilia, cortical tubules, focal (moderate)
LIVER:	congestion (moderate)
LUNG:	mineralization (slight)
	congestion (moderate)
	hemorrhage (slight)
PROSTATE:	prostatitis, interstitial (slight)
SEMINAL VESICLES:	distention (moderate)
	hemorrhage (slight)
SKIN (TREATED):	hyperplasia/hyperkeratosis, epidermis (moderate)
	necrosis, epidermal, focal (moderate)
	exudate
	inflammation, dermal (minimal)
	hyperplasia, sebaceous glands (slight)
SPLEEN:	atrophy (moderate)
STOMACH:	dilatation, mucosal glands (moderate)
THYMUS:	atrophy (moderate)
TRACHEA:	mineralization (slight)
URINARY BLADDER:	hemorrhage (moderate)
	necrosis, focal (moderate)
	peritonitis (moderate)

THE FOLLOWING TISSUE(S) WERE WITHIN NORMAL LIMITS:

ADRENAL GLANDS	BONE (STERNUM)	BONE MARROW (STERNUM)	BRAIN
CECUM	COLON	EPIDIDYIMIDES	ESOPHAGUS
EYES	ILEUM	JEJUNUM	LACRIMAL GLANDS
LYMPH NODE, MESENTERIC	MUSCLE, FEMORIS	NERVE, SCIATIC	PANCREAS
PARATHYROID	PITUITARY	RECTUM	SALIVARY GLANDS
SKIN (UNTREATED)	SPINAL CORD, CERVICAL	SPINAL CORD, LUMBAR	SPINAL CORD, MIDTHORACIC
TESTES	THYROID		

COMMENTS:

STOMACH	There is some degree of postmortem decomposition evident in the sections.
URINARY BLADDER	Some autolysis is evident in the section.

AUTOLYSIS PRECLUDES EVALUATION:

DUODENUM

End of Record- ICN317

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

90-DAY SUBCHRONIC DERMAL TOXICITY STUDY IN RATS WITH SATELLITE GROUP
STUDY NUMBER 139910B - TEST MATERIAL MRD-92-399

Appendix II
Individual Animal Gross and Histomorphology Data

ANIMAL NUMBER: ICN320
SEX: M

DOSE GROUP: 4
DEATH TYPE: Scheduled Sacrifice

GROSS OBSERVATION(S):

SKIN: Dose site- eschar, desquamation.

HISTOMORPHOLOGIC OBSERVATION(S):

hyperplasia, sebaceous glands, SKIN (TREATED)
hyperplasia/hyperkeratosis, epidermis, SKIN
(TREATED)
inflammation, dermal, SKIN (TREATED)

HISTOMORPHOLOGIC OBSERVATIONS:

BONE (STERNUM): necrosis, intersternal cartilage, focal (minimal)
KIDNEYS: infiltration, mononuclear-cell, focal (minimal)
infiltration, neutrophilic (minimal)
basophilia, cortical tubules, focal (slight)
LIVER: infiltration, mononuclear-cell, multifocal (minimal)
LUNG: macrophages, alveoli, focal (minimal)
SKIN (TREATED): hyperplasia, sebaceous glands (slight)
hyperplasia/hyperkeratosis, epidermis (slight)
inflammation, dermal (minimal)
STOMACH: hyperplasia/hyperkeratosis, limiting ridge (slight)
dilatation, mucosal glands (minimal)

THE FOLLOWING TISSUE(S) WERE WITHIN NORMAL LIMITS:

ADRENAL GLANDS	AORTA	BONE MARROW (STERNUM)	BRAIN
CECUM	COLON	DUODENUM	EPIDIDYMIDES
ESOPHAGUS	EYES	HEART	ILEUM
JEJUNUM	LACRIMAL GLANDS	LYMPH NODE, MESENTERIC	MUSCLE, FEMORIS
NERVE, SCIATIC	PANCREAS	PARATHYROID	PITUITARY
PROSTATE	RECTUM	SALIVARY GLANDS	SEMINAL VESICLES
SKIN (UNTREATED)	SPINAL CORD, CERVICAL	SPINAL CORD, LUMBAR	SPINAL CORD, MIDTHORACIC
SPLEEN	TESTES	THYMUS	THYROID
TRACHEA	URINARY BLADDER		

End of Record- ICN320

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

90-DAY SUBCHRONIC DERMAL TOXICITY STUDY IN RATS WITH SATELLITE GROUP
STUDY NUMBER 139910B - TEST MATERIAL MRD-92-399

Appendix II
Individual Animal Gross and Histomorphology Data

ANIMAL NUMBER: ICN322
SEX: M

DOSE GROUP: 4
DEATH TYPE: Scheduled Sacrifice

GROSS OBSERVATION(S):

SKIN: Dose site- eschar, desquamation.

HISTOMORPHOLOGIC OBSERVATION(S):

hyperplasia/hyperkeratosis, epidermis, SKIN (TREATED)
hyperplasia, sebaceous glands, SKIN (TREATED)
exudate, SKIN (TREATED)
vesicles, epidermis/dermis, SKIN (TREATED)

HISTOMORPHOLOGIC OBSERVATIONS:

HEART: infiltration, mononuclear-cell, focal (minimal)
LIVER: infiltration, mononuclear-cell, multifocal (minimal)
SKIN (TREATED): hyperplasia/hyperkeratosis, epidermis (moderate)
hyperplasia, sebaceous glands (moderate)
exudate
vesicles, epidermis/dermis

THE FOLLOWING TISSUE(S) WERE WITHIN NORMAL LIMITS:

ADRENAL GLANDS	AORTA	BONE (STERNUM)	BONE MARROW (STERNUM)
BRAIN	CECUM	COLON	DUODENUM
EPIDIDYIMIDES	ESOPHAGUS	EYES	ILEUM
JEJUNUM	KIDNEYS	LACRIMAL GLANDS	LUNG
LYMPH NODE, MESENTERIC	MUSCLE, FEMORIS	NERVE, SCIATIC	PANCREAS
PARATHYROID	PITUITARY	PROSTATE	RECTUM
SALIVARY GLANDS	SEMINAL VESICLES	SKIN (UNTREATED)	SPINAL CORD, CERVICAL
SPINAL CORD, LUMBAR	SPINAL CORD, MIDTHORACIC	SPLEEN	STOMACH
TESTES	THYMUS	THYROID	TRACHEA
URINARY BLADDER			

End of Record- ICN322

**90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
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**90-DAY SUBCHRONIC DERMAL TOXICITY STUDY IN RATS WITH SATELLITE GROUP
STUDY NUMBER 139910B - TEST MATERIAL MRD-92-399**

**Appendix II
Individual Animal Gross and Histomorphology Data**

ANIMAL NUMBER: ICN329
SEX: M

DOSE GROUP: 4
DEATH TYPE: Scheduled Sacrifice

GROSS OBSERVATION(S):

LIVER: Mass A- visceral surface of left lobe,
adhered to pancreas/stomach, 1.9 x 1.6 x 0.9cm,
firm, red, tan, cut surface- red, firm.

SKIN: Dose site- eschar, desquamation.

HISTOMORPHOLOGIC OBSERVATION(S):

adhesion(s)
peritonitis
infiltration, mononuclear-cell, multifocal
abscess
hyperplasia/hyperkeratosis, epidermis, SKIN
(TREATED)
hyperplasia, sebaceous glands, SKIN (TREATED)
exudate, SKIN (TREATED)

HISTOMORPHOLOGIC OBSERVATIONS:

KIDNEYS:
LIVER:

basophilia, cortical tubules; focal (minimal)
adhesion(s)
peritonitis (marked)
abscess
infiltration, mononuclear-cell, multifocal (minimal)
hyperplasia/hyperkeratosis, epidermis (slight)
hyperplasia, sebaceous glands (slight)

SKIN (TREATED):

exudate
adhesion(s)
peritonitis (marked)

STOMACH:

THE FOLLOWING TISSUE(S) WERE WITHIN NORMAL LIMITS:

ADRENAL GLANDS	AORTA	BONE (STERNUM)	BONE MARROW (STERNUM)
BRAIN	CECUM	COLON	DUODENUM
EPIDIDYMIDES	ESOPHAGUS	EYES	HEART
ILEUM	JEJUNUM	LACRIMAL GLANDS	LUNG
LYMPH NODE, MESENTERIC	MUSCLE, FEMORIS	NERVE, SCIATIC	PANCREAS
PARATHYROID	PITUITARY	PROSTATE	RECTUM
SALIVARY GLANDS	SEMINAL VESICLES	SKIN (UNTREATED)	SPINAL CORD, CERVICAL
SPINAL CORD, LUMBAR	SPINAL CORD, MIDTHORACIC	SPLEEN	TESTES
THYMUS	THYROID	TRACHEA	URINARY BLADDER

End of Record- ICN329

**90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
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**90-DAY SUBCHRONIC DERMAL TOXICITY STUDY IN RATS WITH SATELLITE GROUP
STUDY NUMBER 139910B - TEST MATERIAL MRD-92-399**

**Appendix II
Individual Animal Gross and Histomorphology Data**

ANIMAL NUMBER: ICN333
SEX: M

DOSE GROUP: 4
DEATH TYPE: Scheduled Sacrifice

GROSS OBSERVATION(S):

SKIN: Dose site- desquamation, eschar.

HISTOMORPHOLOGIC OBSERVATION(S):

hyperplasia/hyperkeratosis, epidermis, SKIN (TREATED)
necrosis, epidermal, focal, SKIN (TREATED)
exudate, SKIN (TREATED)
hyperplasia, sebaceous glands, SKIN (TREATED)
inflammation, dermal, SKIN (TREATED)

HISTOMORPHOLOGIC OBSERVATIONS:

LIVER:
SKIN (TREATED):

infiltration, mononuclear-cell, multifocal (minimal)
hyperplasia/hyperkeratosis, epidermis (moderate)
necrosis, epidermal, focal (slight)
exudate
hyperplasia, sebaceous glands (slight)
inflammation, dermal (slight)
STOMACH: dilatation, mucosal glands (slight)
URINARY BLADDER: concretion, eosinophilic

THE FOLLOWING TISSUE(S) WERE WITHIN NORMAL LIMITS:

ADRENAL GLANDS	AORTA	BONE (STERNUM)	BONE MARROW (STERNUM)
BRAIN	CECUM	COLON	DUODENUM
EPIDIDYMIDES	ESOPHAGUS	EYES	HEART
ILEUM	JEJUNUM	KIDNEYS	LACRIMAL GLANDS
LUNG	LYMPH NODE, MESENTERIC	MUSCLE, FEMORIS	NERVE, SCIATIC
PANCREAS	PARATHYROID	PITUITARY	PROSTATE
RECTUM	SALIVARY GLANDS	SEMINAL VESICLES	SKIN (UNTREATED)
SPINAL CORD, CERVICAL	SPINAL CORD, LUMBAR	SPINAL CORD, MIDTHORACIC	SPLEEN
TESTES	THYMUS	THYROID	TRACHEA

End of Record- ICN333

**90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B**

**90-DAY SUBCHRONIC DERMAL TOXICITY STUDY IN RATS WITH SATELLITE GROUP
STUDY NUMBER 139910B - TEST MATERIAL MRD-92-399**

**Appendix II
Individual Animal Gross and Histomorphology Data**

ANIMAL NUMBER: ICN275
SEX: M

DOSE GROUP: 5
DEATH TYPE: Sacrifice-Moribund

GROSS OBSERVATION(S):

GASTROINTESTINAL TRACT: Stomach- glandular mucosa reddened.

KIDNEYS: Both- slightly larger than normal, pale throughout, slight amount of red foci subcapsular.

LIVER: Caudate, accessory lobes- slight amount of tan striations; left lobe- thickened, firm, reddened.

SEMINAL VESICLES: Moderately distended with thickened dark red/white creamy material.

SKIN: Dose site- eschar, exfoliation.

URINARY BLADDER: Extremely distended with thickened dark red material.

HISTOMORPHOLOGIC OBSERVATION(S):

dilatation, mucosal glands, STOMACH
necrosis, nonglandular mucosa, focal, STOMACH
infiltration, neutrophilic, STOMACH
casts
basophilia, cortical tubules, focal
degeneration, cortical tubules, focal
dilatation, cortical tubules, focal
mineralization, cortical tubules, focal
necrosis, cortical tubules, focal
necrosis, focal
infiltration, mixed inflammatory cell

No microscopic change to correlate

hyperplasia/hyperkeratosis, epidermis, SKIN
(TREATED)
exudate, SKIN (TREATED)
hyperplasia, sebaceous glands, SKIN (TREATED)
inflammation, dermal, SKIN (TREATED)
cystitis, hemorrhagic

HISTOMORPHOLOGIC OBSERVATIONS:

BONE MARROW (STERNUM):

HEART:

KIDNEYS:

LIVER:

LUNG:

PROSTATE:

SEMINAL VESICLES:

SKIN (TREATED):

SKIN (UNTREATED):

SPLEEN:

STOMACH:

hyperplasia (slight)
infiltration, mononuclear-cell, focal (minimal)
casts
degeneration, cortical tubules, focal (slight)
mineralization, cortical tubules, focal (slight)
necrosis, cortical tubules, focal (slight)
dilatation, cortical tubules, focal (moderate)
basophilia, cortical tubules, focal (moderate)
necrosis, focal (marked)
infiltration, mixed inflammatory cell (marked)
mineralization, vascular (minimal)
hemorrhage (marked)
prostatitis, interstitial (slight)
No microscopic change to correlate
hyperplasia/hyperkeratosis, epidermis (moderate)
exudate
hyperplasia, sebaceous glands (moderate)
inflammation, dermal (slight)
exudate
hyperplasia, sebaceous glands (moderate)
hyperplasia, epidermis (marked)
hyperkeratosis, epidermis (marked)
atrophy (slight)
dilatation, mucosal glands (slight)

CONTINUED- ICN275

**90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B**

**90-DAY SUBCHRONIC DERMAL TOXICITY STUDY IN RATS WITH SATELLITE GROUP
STUDY NUMBER 139910B - TEST MATERIAL MRD-92-399**

**Appendix II
Individual Animal Gross and Histomorphology Data**

ANIMAL NUMBER: ICN275
SEX: M

DOSE GROUP: 5
DEATH TYPE: Sacrifice-Moribund

HISTOMORPHOLOGIC OBSERVATIONS:

STOMACH: necrosis, nonglandular mucosa, focal (slight)
infiltration, neutrophilic (slight)
URINARY BLADDER: cystitis, hemorrhagic (marked)

THE FOLLOWING TISSUE(S) WERE WITHIN NORMAL LIMITS:

ADRENAL GLANDS	AORTA	BONE (STERNUM)	BRAIN
CECUM	COLON	DUODENUM	EPIDIDYMIDES
ESOPHAGUS	EYES	ILEUM	JEJUNUM
LACRIMAL GLANDS	LYMPH NODE, MESENTERIC	MUSCLE, FEMORIS	NERVE, SCIATIC
PANCREAS	PARATHYROID	PITUITARY	RECTUM
SALIVARY GLANDS	SEMINAL VESICLES	SPINAL CORD, CERVICAL	SPINAL CORD, LUMBAR
SPINAL CORD, MIDTHORACIC	TESTES	THYMUS	THYROID
TRACHEA			

COMMENTS:

LIVER There is extensive necrosis of hepatocytes in the median lobe of the liver. The pattern of involvement appears to be from centrilobular hepatocytes out to midzonal hepatocytes. In this particular instance, the periportal hepatocytes have been spared. Accompanying the necrosis, there is an intense mixed inflammatory cell response comprised of neutrophils, lymphocytes and plasma cells. The pathogenesis of this change would appear to be that of anoxia and not necessarily hepatotoxicity.

End of Record- ICN275

**90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B**

**90-DAY SUBCHRONIC DERMAL TOXICITY STUDY IN RATS WITH SATELLITE GROUP
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**Appendix II
Individual Animal Gross and Histomorphology Data**

ANIMAL NUMBER: ICN280
SEX: M

DOSE GROUP: 5
DEATH TYPE: Scheduled Sacrifice

GROSS OBSERVATION(S):

SKIN: Scabs, dorsal thoracic.

HISTOMORPHOLOGIC OBSERVATION(S):

hyperplasia/hyperkeratosis, epidermis, SKIN (GROSS LESION)
necrosis, epidermal, focal, SKIN (GROSS LESION)
exudate, SKIN (GROSS LESION)
infiltration, neutrophilic, SKIN (GROSS LESION)
inflammation, dermal, SKIN (GROSS LESION)
hyperplasia, sebaceous glands, SKIN (GROSS LESION)

HISTOMORPHOLOGIC OBSERVATIONS:

BONE (STERNUM): necrosis, intersternal cartilage, focal (slight)
KIDNEYS: basophilia, cortical tubules, focal (slight)
LIVER: infiltration, mononuclear-cell, multifocal (minimal)
SKIN (GROSS LESION): hyperplasia/hyperkeratosis, epidermis (moderate)
necrosis, epidermal, focal (moderate)
exudate
infiltration, neutrophilic (moderate)
inflammation, dermal (slight)
hyperplasia, sebaceous glands (slight)
SKIN (TREATED): hyperplasia/hyperkeratosis, epidermis (slight)
hyperplasia, sebaceous glands (slight)
SKIN (UNTREATED): hyperkeratosis, epidermis (minimal)
THYROID: ultimobranchial body/cyst

THE FOLLOWING TISSUE(S) WERE WITHIN NORMAL LIMITS:

ADRENAL GLANDS	AORTA	BONE MARROW (STERNUM)	BRAIN
CECUM	COLON	DUODENUM	EPIDIDYMIDES
ESOPHAGUS	EYES	HEART	ILEUM
JEJUNUM	LACRIMAL GLANDS	LUNG	LYMPH NODE, MESENTERIC
MUSCLE, FEMORIS	NERVE, SCIATIC	PANCREAS	PARATHYROID
PITUITARY	PROSTATE	RECTUM	SALIVARY GLANDS
SEMINAL VESICLES	SPINAL CORD, CERVICAL	SPINAL CORD, LUMBAR	SPINAL CORD, MIDTHORACIC
SPLEEN	STOMACH	TESTES	THYMUS
TRACHEA	URINARY BLADDER		

End of Record- ICN280

**90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B**

**90-DAY SUBCHRONIC DERMAL TOXICITY STUDY IN RATS WITH SATELLITE GROUP
STUDY NUMBER 139910B - TEST MATERIAL MRD-92-399**

**Appendix II
Individual Animal Gross and Histomorphology Data**

ANIMAL NUMBER: ICN292
SEX: M

DOSE GROUP: 5
DEATH TYPE: Scheduled Sacrifice

GROSS OBSERVATION(S):

GENERAL: No gross changes.

HISTOMORPHOLOGIC OBSERVATION(S):

Not applicable

HISTOMORPHOLOGIC OBSERVATIONS:

KIDNEYS:	infiltration, mononuclear-cell, focal (minimal)
LIVER:	infiltration, mononuclear-cell, multifocal (minimal)
SKIN (TREATED):	hyperplasia/hyperkeratosis, epidermis (minimal)
	hyperplasia, sebaceous glands (slight)
SKIN (UNTREATED):	hyperkeratosis, epidermis (minimal)

THE FOLLOWING TISSUE(S) WERE WITHIN NORMAL LIMITS:

ADRENAL GLANDS	AORTA	BONE (STERNUM)	BONE MARROW (STERNUM)
BRAIN	CECUM	COLON	DUODENUM
EPIDIDYMIDES	ESOPHAGUS	EYES	HEART
ILEUM	JEJUNUM	LACRIMAL GLANDS	LUNG
LYMPH NODE, MESENTERIC	MUSCLE, FEMORIS	NERVE, SCIATIC	PANCREAS
PARATHYROID	PITUITARY	PROSTATE	RECTUM
SALIVARY GLANDS	SEMINAL VESICLES	SPINAL CORD, CERVICAL	SPINAL CORD, LUMBAR
SPINAL CORD, MIDTHORACIC	SPLEEN	STOMACH	TESTES
THYMUS	THYROID	TRACHEA	URINARY BLADDER

End of Record- ICN292

**90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B**

**90-DAY SUBCHRONIC DERMAL TOXICITY STUDY IN RATS WITH SATELLITE GROUP
STUDY NUMBER 139910B - TEST MATERIAL MRD-92-399**

**Appendix II
Individual Animal Gross and Histomorphology Data**

ANIMAL NUMBER: ICN296
SEX: M

DOSE GROUP: 5
DEATH TYPE: Scheduled Sacrifice

GROSS OBSERVATION(S):

GENERAL: No gross changes.

HISTOMORPHOLOGIC OBSERVATION(S):

Not applicable

HISTOMORPHOLOGIC OBSERVATIONS:

LIVER: lipidosis, tension, focal (slight)
LUNG: metaplasia, osseous, focal (minimal)
SKIN (TREATED): hyperplasia/hyperkeratosis, epidermis (minimal)
hyperplasia, sebaceous glands (slight)
URINARY BLADDER: concretion, eosinophilic

THE FOLLOWING TISSUE(S) WERE WITHIN NORMAL LIMITS:

ADRENAL GLANDS	AORTA	BONE (STERNUM)	BONE MARROW (STERNUM)
BRAIN	CECUM	COLON	DUODENUM
EPIDIDYMIDES	ESOPHAGUS	EYES	HEART
ILEUM	JEJUNUM	KIDNEYS	LACRIMAL GLANDS
LYMPH NODE, MESENTERIC	MUSCLE, FEMORIS	NERVE, SCIATIC	PANCREAS
PARATHYROID	PITUITARY	PROSTATE	RECTUM
SALIVARY GLANDS	SEMINAL VESICLES	SKIN (UNTREATED)	SPINAL CORD, CERVICAL
SPINAL CORD, LUMBAR	SPINAL CORD, MIDTHORACIC	SPLEEN	STOMACH
TESTES	THYMUS	THYROID	TRACHEA

End of Record- ICN296

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

90-DAY SUBCHRONIC DERMAL TOXICITY STUDY IN RATS WITH SATELLITE GROUP
STUDY NUMBER 139910B - TEST MATERIAL MRD-92-399

Appendix II
Individual Animal Gross and Histomorphology Data

ANIMAL NUMBER: ICN298
SEX: M

DOSE GROUP: 5
DEATH TYPE: Scheduled Sacrifice

GROSS OBSERVATION(S):

GENERAL: No gross changes.

HISTOMORPHOLOGIC OBSERVATION(S):

Not applicable

HISTOMORPHOLOGIC OBSERVATIONS:

HEART: necrosis, focal (minimal)
infiltration, mononuclear-cell, focal (minimal)
PITUITARY: cyst(s)
SKIN (TREATED): hyperplasia/hyperkeratosis, epidermis (minimal)
hyperplasia, sebaceous glands (slight)
SKIN (UNTREATED): hyperkeratosis, epidermis (minimal)

THE FOLLOWING TISSUE(S) WERE WITHIN NORMAL LIMITS:

ADRENAL GLANDS	AORTA	BONE (STERNUM)	BONE MARROW (STERNUM)
BRAIN	CECUM	COLON	DUODENUM
EPIDIDYMIDES	ESOPHAGUS	EYES	ILEUM
JEJUNUM	KIDNEYS	LACRIMAL GLANDS	LIVER
LUNG	LYMPH NODE, MESENTERIC	MUSCLE, FEMORIS	NERVE, SCIATIC
PANCREAS	PARATHYROID	PROSTATE	RECTUM
SALIVARY GLANDS	SEMINAL VESICLES	SPINAL CORD, CERVICAL	SPINAL CORD, LUMBAR
SPINAL CORD, MIDTHORACIC	SPLEEN	STOMACH	TESTES
THYMUS	THYROID	TRACHEA	URINARY BLADDER

End of Record- ICN298

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 1399108

90-DAY SUBCHRONIC DERMAL TOXICITY STUDY IN RATS WITH SATELLITE GROUP
STUDY NUMBER 1399108 - TEST MATERIAL MRD-92-399

Appendix II
Individual Animal Gross and Histomorphology Data

ANIMAL NUMBER: ICN307
SEX: M

DOSE GROUP: 5
DEATH TYPE: Scheduled Sacrifice

GROSS OBSERVATION(S):

GENERAL: No gross changes.

HISTOMORPHOLOGIC OBSERVATION(S):

Not applicable

HISTOMORPHOLOGIC OBSERVATIONS:

BONE (STERNUM):	necrosis, intersternal cartilage, focal (slight)
HEART:	infiltration, mononuclear-cell, focal (minimal)
LACRIMAL GLANDS:	infiltration, mononuclear-cell, focal (minimal)
LIVER:	infiltration, mononuclear-cell, multifocal (minimal)
SKIN (TREATED):	hyperplasia/hyperkeratosis, epidermis (slight)
	hyperplasia, sebaceous glands (slight)
	fibrosis, dermal (moderate)
SKIN (UNTREATED):	hyperkeratosis, epidermis (minimal)

THE FOLLOWING TISSUE(S) WERE WITHIN NORMAL LIMITS:

ADRENAL GLANDS	AORTA	BONE MARROW (STERNUM)	BRAIN
CECUM	COLON	DUODENUM	EPIDIDYMIDES
ESOPHAGUS	EYES	ILEUM	JEJUNUM
KIDNEYS	LUNG	LYMPH NODE, MESENTERIC	MUSCLE, FEMORIS
NERVE, SCIATIC	PANCREAS	PARATHYROID	PITUITARY
PROSTATE	RECTUM	SALIVARY GLANDS	SEMINAL VESICLES
SPINAL CORD, CERVICAL	SPINAL CORD, LUMBAR	SPINAL CORD, MIDTHORACIC	SPLEEN
STOMACH	TESTES	THYMUS	THYROID
TRACHEA	URINARY BLADDER		

End of Record- ICN307

**90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B**

**90-DAY SUBCHRONIC DERMAL TOXICITY STUDY IN RATS WITH SATELLITE GROUP
STUDY NUMBER 139910B - TEST MATERIAL MRD-92-399**

**Appendix II
Individual Animal Gross and Histomorphology Data**

ANIMAL NUMBER: ICN309
SEX: M

DOSE GROUP: 5
DEATH TYPE: Scheduled Sacrifice

GROSS OBSERVATION(S):

GENERAL: No gross changes.

HISTOMORPHOLOGIC OBSERVATION(S):

Not applicable

HISTOMORPHOLOGIC OBSERVATIONS:

HEART:	infiltration, mononuclear-cell, focal (minimal)
KIDNEYS:	degeneration, cortical tubules, focal (slight)
LIVER:	infiltration, mononuclear-cell, multifocal (minimal)
	lipidosis, tension, focal (minimal)
LUNG:	mineralization, vascular (minimal)
SKIN (TREATED):	hyperplasia/hyperkeratosis, epidermis (slight)
	hyperplasia, sebaceous glands (slight)
	fibrosis, dermal (moderate)
URINARY BLADDER:	concretion, eosinophilic

THE FOLLOWING TISSUE(S) WERE WITHIN NORMAL LIMITS:

ADRENAL GLANDS	AORTA	BONE (STERNUM)	BONE MARROW (STERNUM)
BRAIN	CECUM	COLON	DUODENUM
EPIDIDYMIDES	ESOPHAGUS	EYES	ILEUM
JEJUNUM	LACRIMAL GLANDS	LYMPH NODE, MESENTERIC	MUSCLE, FEMORIS
NERVE, SCIATIC	PANCREAS	PARATHYROID	PITUITARY
PROSTATE	RECTUM	SALIVARY GLANDS	SEMINAL VESICLES
SKIN (UNTREATED)	SPINAL CORD, CERVICAL	SPINAL CORD, LUMBAR	SPINAL CORD, MIDTHORACIC
SPLEEN	STOMACH	TESTES	THYMUS
THYROID	TRACHEA		

End of Record- ICN309

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

90-DAY SUBCHRONIC DERMAL TOXICITY STUDY IN RATS WITH SATELLITE GROUP
STUDY NUMBER 139910B - TEST MATERIAL MRD-92-399

Appendix II
Individual Animal Gross and Histomorphology Data

ANIMAL NUMBER: ICN316
SEX: M

DOSE GROUP: 5
DEATH TYPE: Scheduled Sacrifice

GROSS OBSERVATION(S):

KIDNEYS: Right- moderately dilated renal pelvis.

SKIN: Right lateral cervical, scabs.

HISTOMORPHOLOGIC OBSERVATION(S):

dilatation, pelvis
hyperplasia, pelvic/papillary urothelium
degeneration, cortical tubules, focal
hyperplasia/hyperkeratosis, epidermis, SKIN
(GROSS LESION)
necrosis, epidermal, focal, SKIN (GROSS LESION)
exudate, SKIN (GROSS LESION)
hyperplasia, sebaceous glands, SKIN (GROSS
LESION)

HISTOMORPHOLOGIC OBSERVATIONS:

BONE (STERNUM): necrosis, intersternal cartilage, focal (minimal)
KIDNEYS: degeneration, cortical tubules, focal (minimal)
hyperplasia, pelvic/papillary urothelium (slight)
dilatation, pelvis (moderate)
SKIN (GROSS LESION): hyperplasia/hyperkeratosis, epidermis (marked)
necrosis, epidermal, focal (marked)
exudate
hyperplasia, sebaceous glands (moderate)
SKIN (TREATED): hyperplasia/hyperkeratosis, epidermis (slight)
hyperplasia, sebaceous glands (slight)
fibrosis, dermal (minimal)
SKIN (UNTREATED): hyperkeratosis, epidermis (minimal)
STOMACH: dilatation, mucosal glands (slight)

THE FOLLOWING TISSUE(S) WERE WITHIN NORMAL LIMITS:

ADRENAL GLANDS	AORTA	BONE MARROW (STERNUM)	BRAIN
CECUM	COLON	DUODENUM	EPIDIDYIMIDES
ESOPHAGUS	EYES	HEART	ILEUM
JEJUNUM	LACRIMAL GLANDS	LIVER	LUNG
LYMPH NODE, MESENTERIC	MUSCLE, FEMORIS	NERVE, SCIATIC	PANCREAS
PARATHYROID	PITUITARY	PROSTATE	RECTUM
SALIVARY GLANDS	SEMINAL VESICLES	SPINAL CORD, CERVICAL	SPINAL CORD, LUMBAR
SPINAL CORD, MIDTHORACIC	SPLEEN	TESTES	THYMUS
THYROID	TRACHEA	URINARY BLADDER	

End of Record- ICN316

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

90-DAY SUBCHRONIC DERMAL TOXICITY STUDY IN RATS WITH SATELLITE GROUP
STUDY NUMBER 139910B - TEST MATERIAL MRD-92-399

Appendix II
Individual Animal Gross and Histomorphology Data

ANIMAL NUMBER: ICN326
SEX: M

DOSE GROUP: 5
DEATH TYPE: Scheduled Sacrifice

GROSS OBSERVATION(S):

GENERAL: No gross changes.

HISTOMORPHOLOGIC OBSERVATION(S):

Not applicable

HISTOMORPHOLOGIC OBSERVATIONS:

BONE (STERNUM):	necrosis, intersternal cartilage, focal (slight)
BONE MARROW (STERNUM):	hyperplasia (slight)
LIVER:	infiltration, mononuclear-cell, multifocal (minimal)
SKIN (TREATED):	hyperplasia/hyperkeratosis, epidermis (minimal)
	hyperplasia, sebaceous glands (minimal)
	fibrosis, dermal (slight)
SKIN (UNTREATED):	hyperkeratosis, epidermis (minimal)
STOMACH:	dilatation, mucosal glands (minimal)
	hyperplasia/hyperkeratosis, limiting ridge (slight)

THE FOLLOWING TISSUE(S) WERE WITHIN NORMAL LIMITS:

ADRENAL GLANDS	AORTA	BRAIN	CECUM
COLON	DUODENUM	EPIDIDYIMIDES	ESOPHAGUS
EYES	HEART	ILEUM	JEJUNUM
KIDNEYS	LACRIMAL GLANDS	LUNG	LYMPH NODE, MESENTERIC
MUSCLE, FEMORIS	NERVE, SCIATIC	PANCREAS	PARATHYROID
PITUITARY	PROSTATE	RECTUM	SALIVARY GLANDS
SEMINAL VESICLES	SPINAL CORD, CERVICAL	SPINAL CORD, LUMBAR	SPINAL CORD, MIDTHORACIC
SPLEEN	TESTES	THYMUS	THYROID
TRACHEA	URINARY BLADDER		

End of Record- ICN326

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

90-DAY SUBCHRONIC DERMAL TOXICITY STUDY IN RATS WITH SATELLITE GROUP
STUDY NUMBER 139910B - TEST MATERIAL MRD-92-399

Appendix II
Individual Animal Gross and Histomorphology Data

ANIMAL NUMBER: ICN332
SEX: M

DOSE GROUP: 5
DEATH TYPE: Scheduled Sacrifice

GROSS OBSERVATION(S):

GENERAL: No gross changes.

HISTOMORPHOLOGIC OBSERVATION(S):

Not applicable

HISTOMORPHOLOGIC OBSERVATIONS:

BONE (STERNUM):	necrosis, intersternal cartilage, focal (minimal)
HEART:	infiltration, mononuclear-cell, focal (minimal)
KIDNEYS:	degeneration, cortical tubules, focal (slight)
LUNG:	proliferation, lymphoid, peribronchial/perivascular (slight)
SKIN (TREATED):	hyperplasia/hyperkeratosis, epidermis (minimal)
	hyperplasia, sebaceous glands (slight)
	fibrosis, dermal (minimal)
SKIN (UNTREATED):	hyperkeratosis, epidermis (minimal)
STOMACH:	dilatation, mucosal glands (minimal)

THE FOLLOWING TISSUE(S) WERE WITHIN NORMAL LIMITS:

ADRENAL GLANDS	AORTA	BONE MARROW (STERNUM)	BRAIN
CECUM	COLON	DUODENUM	EPIDIDYMIDES
ESOPHAGUS	EYES	ILEUM	JEJUNUM
LACRIMAL GLANDS	LIVER	LYMPH NODE, MESENTERIC	MUSCLE, FEMORIS
NERVE, SCIATIC	PANCREAS	PARATHYROID	PITUITARY
PROSTATE	RECTUM	SALIVARY GLANDS	SEMINAL VESICLES
SPINAL CORD, CERVICAL	SPINAL CORD, LUMBAR	SPINAL CORD, MIDTHORACIC	SPLEEN
TESTES	THYMUS	THYROID	TRACHEA
URINARY BLADDER			

End of Record- ICN332

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

90-DAY SUBCHRONIC DERMAL TOXICITY STUDY IN RATS WITH SATELLITE GROUP
STUDY NUMBER 139910B - TEST MATERIAL MRD-92-399

Appendix II
Individual Animal Gross and Histomorphology Data

ANIMAL NUMBER: ICN355
SEX: F

DOSE GROUP: 1
DEATH TYPE: Scheduled Sacrifice

GROSS OBSERVATION(S):

GENERAL: No gross changes.

HISTOMORPHOLOGIC OBSERVATION(S):

Not applicable

HISTOMORPHOLOGIC OBSERVATIONS:

SKIN (TREATED):
UTERUS:

hyperplasia/hyperkeratosis, epidermis (minimal)
distention, lumen (slight)

THE FOLLOWING TISSUE(S) WERE WITHIN NORMAL LIMITS:

ADRENAL GLANDS	AORTA	BONE (STERNUM)	BONE MARROW (STERNUM)
BRAIN	CECUM	CERVIX	COLON
DUODENUM	ESOPHAGUS	EYES	HEART
ILEUM	JEJUNUM	KIDNEYS	LACRIMAL GLANDS
LIVER	LUNG	LYMPH NODE, MESENTERIC	MAMMARY GLAND
MUSCLE, FEMORIS	NERVE, SCIATIC	OVARIES	OVIDUCTS
PANCREAS	PARATHYROID	PITUITARY	RECTUM
SALIVARY GLANDS	SKIN (UNTREATED)	SPINAL CORD, CERVICAL	SPINAL CORD, LUMBAR
SPINAL CORD, MIDTHORACIC	SPLEEN	STOMACH	THYMUS
THYROID	TRACHEA	URINARY BLADDER	

End of Record- ICN355

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

90-DAY SUBCHRONIC DERMAL TOXICITY STUDY IN RATS WITH SATELLITE GROUP
STUDY NUMBER 139910B - TEST MATERIAL MRD-92-399

Appendix II
Individual Animal Gross and Histomorphology Data

ANIMAL NUMBER: ICN365
SEX: F

DOSE GROUP: 1
DEATH TYPE: Scheduled Sacrifice

GROSS OBSERVATION(S):

GENERAL: No gross changes.

HISTOMORPHOLOGIC OBSERVATION(S):

Not applicable

HISTOMORPHOLOGIC OBSERVATIONS:

LIVER: infiltration, mononuclear-cell, multifocal (minimal)
SKIN (TREATED): hyperplasia/hyperkeratosis, epidermis (minimal)

THE FOLLOWING TISSUE(S) WERE WITHIN NORMAL LIMITS:

ADRENAL GLANDS	AORTA	BONE (STERNUM)	BONE MARROW (STERNUM)
BRAIN	CECUM	CERVIX	COLON
DUODENUM	ESOPHAGUS	EYES	HEART
ILEUM	JEJUNUM	KIDNEYS	LACRIMAL GLANDS
LUNG	LYMPH NODE, MESENTERIC	MAMMARY GLAND	MUSCLE, FEMORIS
NERVE, SCIATIC	OVARIES	OVIDUCTS	PANCREAS
PARATHYROID	PITUITARY	RECTUM	SALIVARY GLANDS
SKIN (UNTREATED)	SPINAL CORD, CERVICAL	SPINAL CORD, LUMBAR	SPINAL CORD, MIDTHORACIC
SPLEEN	STOMACH	THYMUS	THYROID
TRACHEA	URINARY BLADDER	UTERUS	

End of Record- ICN365

**90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 1399108**

**90-DAY SUBCHRONIC DERMAL TOXICITY STUDY IN RATS WITH SATELLITE GROUP
STUDY NUMBER 1399108 - TEST MATERIAL MRD-92-399**

**Appendix II
Individual Animal Gross and Histomorphology Data**

ANIMAL NUMBER: ICN372
SEX: F

DOSE GROUP: 1
DEATH TYPE: Scheduled Sacrifice

GROSS OBSERVATION(S):

GENERAL: No gross changes.

HISTOMORPHOLOGIC OBSERVATION(S):

Not applicable

HISTOMORPHOLOGIC OBSERVATIONS:

KIDNEYS:	dilatation, medullary tubules, focal (slight)
LUNG:	mineralization, vascular (slight)
SKIN (TREATED):	hyperkeratosis, epidermis (minimal)
SKIN (UNTREATED):	hyperkeratosis, epidermis (minimal)
THYROID:	ultimobranchial body/cyst

THE FOLLOWING TISSUE(S) WERE WITHIN NORMAL LIMITS:

ADRENAL GLANDS	AORTA	BONE (STERNUM)	BONE MARROW (STERNUM)
BRAIN	CECUM	CERVIX	COLON
DUODENUM	ESOPHAGUS	EYES	HEART
ILEUM	JEJUNUM	LACRIMAL GLANDS	LIVER
LYMPH NODE, MESENTERIC	MAMMARY GLAND	MUSCLE, FEMORIS	NERVE, SCIATIC
OVARIES	OVIDUCTS	PANCREAS	PARATHYROID
PITUITARY	RECTUM	SALIVARY GLANDS	SPINAL CORD, CERVICAL
SPINAL CORD, LUMBAR	SPINAL CORD, MIDTHORACIC	SPLEEN	STOMACH
THYMUS	TRACHEA	URINARY BLADDER	UTERUS

End of Record- ICN372

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

90-DAY SUBCHRONIC DERMAL TOXICITY STUDY IN RATS WITH SATELLITE GROUP
STUDY NUMBER 139910B - TEST MATERIAL MRD-92-399

Appendix II
Individual Animal Gross and Histomorphology Data

ANIMAL NUMBER: ICN373
SEX: F

DOSE GROUP: 1
DEATH TYPE: Scheduled Sacrifice

GROSS OBSERVATION(S):

GENERAL: No gross changes.

HISTOMORPHOLOGIC OBSERVATION(S):

Not applicable

HISTOMORPHOLOGIC OBSERVATIONS:

BONE (STERNUM):	necrosis, intersternal cartilage, focal (minimal)
HEART:	infiltration, mononuclear-cell, focal (minimal)
LIVER:	infiltration, mononuclear-cell, multifocal (minimal)
SKIN (TREATED):	hyperplasia/hyperkeratosis, epidermis (minimal)
SKIN (UNTREATED):	hyperkeratosis, epidermis (minimal)

THE FOLLOWING TISSUE(S) WERE WITHIN NORMAL LIMITS:

ADRENAL GLANDS (1)	AORTA	BONE MARROW (STERNUM)	BRAIN
CECUM	CERVIX	COLON	DUODENUM
ESOPHAGUS	EYES	ILEUM	JEJUNUM
KIDNEYS	LACRIMAL GLANDS (1)	LUNG	LYMPH NODE, MESENTERIC
MAMMARY GLAND	MUSCLE, FEMORIS	NERVE, SCIATIC	OVARIES
OVIDUCTS	PANCREAS	PARATHYROID	PITUITARY
RECTUM	SALIVARY GLANDS	SPINAL CORD, CERVICAL	SPINAL CORD, LUMBAR
SPINAL CORD, MIDTHORACIC	SPLEEN	STOMACH	THYMUS
THYROID	TRACHEA	URINARY BLADDER	UTERUS

COMMENTS:

ADRENAL GLANDS One section is inadequate for evaluation; the other adrenal gland is within normal limits.

TISSUE(S) NOT AVAILABLE FOR EVALUATION:

ADRENAL GLANDS (1)
LACRIMAL GLANDS (1)

End of Record- ICN373

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

90-DAY SUBCHRONIC DERMAL TOXICITY STUDY IN RATS WITH SATELLITE GROUP
STUDY NUMBER 139910B - TEST MATERIAL MRD-92-399

Appendix II
Individual Animal Gross and Histomorphology Data

ANIMAL NUMBER: ICN377
SEX: F

DOSE GROUP: 1
DEATH TYPE: Scheduled Sacrifice

GROSS OBSERVATION(S):

GENERAL: No gross changes.

HISTOMORPHOLOGIC OBSERVATION(S):

Not applicable

HISTOMORPHOLOGIC OBSERVATIONS:

BONE (STERNUM):	necrosis, intersternal cartilage, focal (minimal)
LIVER:	infiltration, mononuclear-cell, multifocal (minimal)
SKIN (TREATED):	hyperplasia, sebaceous glands (minimal)
	hyperplasia/hyperkeratosis, epidermis (minimal)
SKIN (UNTREATED):	hyperkeratosis, epidermis (minimal)

THE FOLLOWING TISSUE(S) WERE WITHIN NORMAL LIMITS:

ADRENAL GLANDS	AORTA	BONE MARROW (STERNUM)	BRAIN
CECUM	CERVIX	COLON	DUODENUM
ESOPHAGUS	EYES	HEART	ILEUM
JEJUNUM	KIDNEYS	LACRIMAL GLANDS	LUNG
LYMPH NODE, MESENTERIC	MAMMARY GLAND	MUSCLE, FEMORIS	NERVE, SCIATIC
OVARIES	OVIDUCTS	PANCREAS	PARATHYROID
PITUITARY	RECTUM	SALIVARY GLANDS	SPINAL CORD, CERVICAL
SPINAL CORD, LUMBAR	SPINAL CORD, MIDTHORACIC	SPLEEN	STOMACH
THYMUS	THYROID	TRACHEA	URINARY BLADDER
UTERUS			

End of Record- ICN377

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

90-DAY SUBCHRONIC DERMAL TOXICITY STUDY IN RATS WITH SATELLITE GROUP
STUDY NUMBER 139910B - TEST MATERIAL MRD-92-399

Appendix II
Individual Animal Gross and Histomorphology Data

ANIMAL NUMBER: ICN378
SEX: F

DOSE GROUP: 1
DEATH TYPE: Scheduled Sacrifice

GROSS OBSERVATION(S):

GENERAL: No gross changes.

HISTOMORPHOLOGIC OBSERVATION(S):

Not applicable

HISTOMORPHOLOGIC OBSERVATIONS:

KIDNEYS: dilatation, medullary tubules, focal (minimal)
LIVER: infiltration, mononuclear-cell, multifocal (slight)
infiltration, neutrophilic, focal (minimal)
SKIN (TREATED): hyperplasia, sebaceous glands (slight)
hyperplasia/hyperkeratosis, epidermis (minimal)
SKIN (UNTREATED): hyperkeratosis, epidermis (minimal)
STOMACH: dilatation, mucosal glands (minimal)

THE FOLLOWING TISSUE(S) WERE WITHIN NORMAL LIMITS:

ADRENAL GLANDS	AORTA	BONE (STERNUM)	BONE MARROW (STERNUM)
BRAIN	CECUM	CERVIX	COLON
DUODENUM	ESOPHAGUS	EYES	HEART
ILEUM	JEJUNUM	LACRIMAL GLANDS	LUNG
LYMPH NODE, MESENTERIC	MAMMARY GLAND	MUSCLE, FEMORIS	NERVE, SCIATIC
OVARIES	OVIDUCTS	PANCREAS	PARATHYROID
PITUITARY	RECTUM	SALIVARY GLANDS	SPINAL CORD, CERVICAL
SPINAL CORD, LUMBAR	SPINAL CORD, MIDTHORACIC	SPLEEN	THYMUS
THYROID	TRACHEA	URINARY BLADDER	UTERUS

End of Record- ICN378

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

90-DAY SUBCHRONIC DERMAL TOXICITY STUDY IN RATS WITH SATELLITE GROUP
STUDY NUMBER 139910B - TEST MATERIAL MRD-92-399

Appendix II
Individual Animal Gross and Histomorphology Data

ANIMAL NUMBER: ICN379
SEX: F

DOSE GROUP: 1
DEATH TYPE: Scheduled Sacrifice

GROSS OBSERVATION(S):

GENERAL: No gross changes.

HISTOMORPHOLOGIC OBSERVATION(S):

Not applicable

HISTOMORPHOLOGIC OBSERVATIONS:

BONE (STERNUM):	necrosis, intersternal cartilage, focal (minimal)
KIDNEYS:	infiltration, mononuclear-cell, focal (minimal)
LIVER:	infiltration, mononuclear-cell, multifocal (slight)
SKIN (TREATED):	hyperplasia, sebaceous glands (minimal)
	hyperplasia/hyperkeratosis, epidermis (minimal)
SKIN (UNTREATED):	hyperkeratosis, epidermis (minimal)

THE FOLLOWING TISSUE(S) WERE WITHIN NORMAL LIMITS:

ADRENAL GLANDS	AORTA	BONE MARROW (STERNUM)	BRAIN
CECUM	CERVIX	COLON	DUODENUM
ESOPHAGUS	EYES	HEART	ILEUM
JEJUNUM	LACRIMAL GLANDS	LUNG	LYMPH NODE, MESENTERIC
MAMMARY GLAND	MUSCLE, FEMORIS	NERVE, SCIATIC	OVARIES
OVIDUCTS	PANCREAS	PITUITARY	RECTUM
SALIVARY GLANDS	SPINAL CORD, CERVICAL	SPINAL CORD, LUMBAR	SPINAL CORD, MIDTHORACIC
SPLEEN	STOMACH	THYMUS	THYROID
TRACHEA	URINARY BLADDER	UTERUS	

TISSUE(S) NOT AVAILABLE FOR EVALUATION:

PARATHYROID

End of Record- ICN379

**90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B**

**90-DAY SUBCHRONIC DERMAL TOXICITY STUDY IN RATS WITH SATELLITE GROUP
STUDY NUMBER 139910B - TEST MATERIAL MRD-92-399**

Appendix II
Individual Animal Gross and Histomorphology Data

ANIMAL NUMBER: ICN394
SEX: F

DOSE GROUP: 1
DEATH TYPE: Scheduled Sacrifice

GROSS OBSERVATION(S):

GENERAL: No gross changes.

HISTOMORPHOLOGIC OBSERVATION(S):

Not applicable

HISTOMORPHOLOGIC OBSERVATIONS:

LIVER: infiltration, mononuclear-cell, multifocal (minimal)
SKIN (TREATED): hyperplasia, sebaceous glands (slight)
SKIN (UNTREATED): hyperplasia/hyperkeratosis, epidermis (minimal)
hyperkeratosis, epidermis (minimal)

THE FOLLOWING TISSUE(S) WERE WITHIN NORMAL LIMITS:

ADRENAL GLANDS	AORTA	BONE (STERNUM)	BONE MARROW (STERNUM)
BRAIN	CECUM	CERVIX	COLON
DUODENUM	ESOPHAGUS	EYES	HEART
ILEUM	JEJUNUM	KIDNEYS	LACRIMAL GLANDS
LUNG	LYMPH NODE, MESENTERIC	MAMMARY GLAND	MUSCLE, FEMORIS
NERVE, SCIATIC	OVARIES	OVIDUCTS	PANCREAS
PARATHYROID	PITUITARY	RECTUM	SALIVARY GLANDS
SPINAL CORD, CERVICAL	SPINAL CORD, LUMBAR	SPINAL CORD, MIDTHORACIC	SPLEEN
STOMACH	THYMUS	THYROID	TRACHEA
URINARY BLADDER	UTERUS		

End of Record- ICN394

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

90-DAY SUBCHRONIC DERMAL TOXICITY STUDY IN RATS WITH SATELLITE GROUP
STUDY NUMBER 139910B - TEST MATERIAL MRD-92-399

Appendix II
Individual Animal Gross and Histomorphology Data

ANIMAL NUMBER: ICN396
SEX: F

DOSE GROUP: 1
DEATH TYPE: Scheduled Sacrifice

GROSS OBSERVATION(S):

SKIN: Scabs, left dorsal.

HISTOMORPHOLOGIC OBSERVATION(S):

hyperplasia/hyperkeratosis, epidermis, SKIN
(GROSS LESION)
necrosis, epidermal, focal, SKIN (GROSS LESION)
exudate, SKIN (GROSS LESION)

HISTOMORPHOLOGIC OBSERVATIONS:

PITUITARY: cyst(s)
SKIN (GROSS LESION): hyperplasia/hyperkeratosis, epidermis (moderate)
necrosis, epidermal, focal (moderate)
exudate
SKIN (TREATED): exudate
hyperplasia/hyperkeratosis, epidermis (moderate)
necrosis, epidermal, focal (moderate)
SKIN (UNTREATED): hyperkeratosis, epidermis (minimal)

THE FOLLOWING TISSUE(S) WERE WITHIN NORMAL LIMITS:

ADRENAL GLANDS	AORTA	BONE (STERNUM)	BONE MARROW (STERNUM)
BRAIN	CECUM	CERVIX	COLON
DUODENUM	ESOPHAGUS	EYES	HEART
ILEUM	JEJUNUM	KIDNEYS	LACRIMAL GLANDS
LIVER	LUNG	LYMPH NODE, MESENTERIC	MAMMARY GLAND
MUSCLE, FEMORIS	NERVE, SCIATIC	OVARIES	OVIDUCTS
PANCREAS	PARATHYROID	RECTUM	SALIVARY GLANDS
SPINAL CORD, CERVICAL	SPINAL CORD, LUMBAR	SPINAL CORD, MIDTHORACIC	SPLEEN
STOMACH	THYMUS	THYROID	TRACHEA
URINARY BLADDER	UTERUS		

End of Record- ICN396

**90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B**

**90-DAY SUBCHRONIC DERMAL TOXICITY STUDY IN RATS WITH SATELLITE GROUP
STUDY NUMBER 139910B - TEST MATERIAL MRD-92-399**

**Appendix II
Individual Animal Gross and Histomorphology Data**

ANIMAL NUMBER: ICN398
SEX: F

DOSE GROUP: 1
DEATH TYPE: Scheduled Sacrifice

GROSS OBSERVATION(S):

GENERAL: No gross changes.

HISTOMORPHOLOGIC OBSERVATION(S):

Not applicable

HISTOMORPHOLOGIC OBSERVATIONS:

BONE (STERNUM):	necrosis, intersternal cartilage, focal (minimal)
LIVER:	infiltration, mononuclear-cell, multifocal (minimal) pigment
SKIN (TREATED):	hyperplasia, sebaceous glands (minimal) hyperplasia/hyperkeratosis, epidermis (minimal)
SKIN (UNTREATED):	hyperkeratosis, epidermis (minimal)
STOMACH:	dilatation, mucosal glands (minimal)
THYROID:	ultimobranchial body/cyst
UTERUS:	distention, lumen (moderate)

THE FOLLOWING TISSUE(S) WERE WITHIN NORMAL LIMITS:

ADRENAL GLANDS	AORTA	BONE MARROW (STERNUM)	BRAIN
CECUM	CERVIX	COLON	DUODENUM
ESOPHAGUS	EYES	HEART	ILEUM
JEJUNUM	KIDNEYS	LACRIMAL GLANDS	LUNG
LYMPH NODE, MESENTERIC	MAMMARY GLAND	MUSCLE, FEMORIS	NERVE, SCIATIC
OVARIES	OVIDUCTS	PANCREAS	PARATHYROID
PITUITARY	RECTUM	SALIVARY GLANDS	SPINAL CORD, CERVICAL
SPINAL CORD, LUMBAR	SPINAL CORD, MIDTHORACIC	SPLEEN	THYMUS
TRACHEA	URINARY BLADDER		

End of Record- ICN398

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

90-DAY SUBCHRONIC DERMAL TOXICITY STUDY IN RATS WITH SATELLITE GROUP
STUDY NUMBER 139910B - TEST MATERIAL MRD-92-399

Appendix II
Individual Animal Gross and Histomorphology Data

ANIMAL NUMBER: ICN341
SEX: F

DOSE GROUP: 2
DEATH TYPE: Scheduled Sacrifice

GROSS OBSERVATION(S):

GASTROINTESTINAL TRACT: Stomach- glandular
mucosa, dark red areas.

SKIN: Dose site- desquamation.

HISTOMORPHOLOGIC OBSERVATION(S):

necrosis, glandular mucosa, focal, STOMACH

hyperplasia/hyperkeratosis, epidermis, SKIN
(TREATED)

hyperplasia, sebaceous glands, SKIN (TREATED)
inflammation, dermal, SKIN (TREATED)

HISTOMORPHOLOGIC OBSERVATIONS:

KIDNEYS:

infiltration, mononuclear-cell, focal (minimal)

LIVER:

infiltration, mononuclear-cell, multifocal (slight)

necrosis, focal (slight)

SKIN (TREATED):

hyperplasia/hyperkeratosis, epidermis (slight)

hyperplasia, sebaceous glands (slight)

inflammation, dermal (minimal)

STOMACH:

necrosis, glandular mucosa, focal (moderate)

THE FOLLOWING TISSUE(S) WERE WITHIN NORMAL LIMITS:

LUNG

End of Record- ICN341

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

90-DAY SUBCHRONIC DERMAL TOXICITY STUDY IN RATS WITH SATELLITE GROUP
STUDY NUMBER 139910B - TEST MATERIAL MRD-92-399

Appendix II
Individual Animal Gross and Histomorphology Data

ANIMAL NUMBER: ICN342
SEX: F

DOSE GROUP: 2
DEATH TYPE: Scheduled Sacrifice

GROSS OBSERVATION(S):

HISTOMORPHOLOGIC OBSERVATION(S):

GENERAL: No gross changes.

Not applicable

HISTOMORPHOLOGIC OBSERVATIONS:

LIVER: infiltration, mononuclear-cell, multifocal (minimal)

THE FOLLOWING TISSUE(S) WERE WITHIN NORMAL LIMITS:

KIDNEYS LUNG

End of Record- ICN342

**90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B**

**90-DAY SUBCHRONIC DERMAL TOXICITY STUDY IN RATS WITH SATELLITE GROUP
STUDY NUMBER 139910B - TEST MATERIAL MRD-92-399**

**Appendix II
Individual Animal Gross and Histomorphology Data**

ANIMAL NUMBER: ICN345
SEX: F

DOSE GROUP: 2
DEATH TYPE: Scheduled Sacrifice

GROSS OBSERVATION(S):

GENERAL: No gross changes.

HISTOMORPHOLOGIC OBSERVATION(S):

Not applicable

HISTOMORPHOLOGIC OBSERVATIONS:

LIVER: infiltration, mononuclear-cell, multifocal (minimal)

THE FOLLOWING TISSUE(S) WERE WITHIN NORMAL LIMITS:

KIDNEYS LUNG

End of Record- ICN345

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

90-DAY SUBCHRONIC DERMAL TOXICITY STUDY IN RATS WITH SATELLITE GROUP
STUDY NUMBER 139910B - TEST MATERIAL MRD-92-399

Appendix II
Individual Animal Gross and Histomorphology Data

ANIMAL NUMBER: ICN348
SEX: F

DOSE GROUP: 2
DEATH TYPE: Scheduled Sacrifice

GROSS OBSERVATION(S):

SKIN: Dose site- desquamation.

HISTOMORPHOLOGIC OBSERVATION(S):

hyperplasia/hyperkeratosis, epidermis, SKIN (TREATED)
hyperplasia, sebaceous glands, SKIN (TREATED)
exudate, SKIN (TREATED)
inflammation, dermal, SKIN (TREATED)

HISTOMORPHOLOGIC OBSERVATIONS:

LIVER: infiltration, mononuclear-cell, multifocal (slight)
necrosis, focal (slight)
SKIN (TREATED): exudate
inflammation, dermal (minimal)
hyperplasia/hyperkeratosis, epidermis (slight)
hyperplasia, sebaceous glands (slight)

THE FOLLOWING TISSUE(S) WERE WITHIN NORMAL LIMITS:

KIDNEYS LUNG

End of Record- ICN348

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

90-DAY SUBCHRONIC DERMAL TOXICITY STUDY IN RATS WITH SATELLITE GROUP
STUDY NUMBER 139910B - TEST MATERIAL MRD-92-399

Appendix II
Individual Animal Gross and Histomorphology Data

ANIMAL NUMBER: ICN353
SEX: F

DOSE GROUP: 2
DEATH TYPE: Scheduled Sacrifice

GROSS OBSERVATION(S):

GENERAL: No gross changes.

HISTOMORPHOLOGIC OBSERVATION(S):

Not applicable

HISTOMORPHOLOGIC OBSERVATIONS:

KIDNEYS: infiltration, mononuclear-cell, focal (minimal)
dilatation, medullary tubules, focal (minimal)
LIVER: infiltration, mononuclear-cell, multifocal (minimal)
lipidosis, tension, focal (minimal)

THE FOLLOWING TISSUE(S) WERE WITHIN NORMAL LIMITS:

LUNG

End of Record- ICN353

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 1399108

90-DAY SUBCHRONIC DERMAL TOXICITY STUDY IN RATS WITH SATELLITE GROUP
STUDY NUMBER 1399108 - TEST MATERIAL MRD-92-399

Appendix II
Individual Animal Gross and Histomorphology Data

ANIMAL NUMBER: ICN361
SEX: F

DOSE GROUP: 2
DEATH TYPE: Scheduled Sacrifice

GROSS OBSERVATION(S):

GENERAL: No gross changes.

HISTOMORPHOLOGIC OBSERVATION(S):

Not applicable

HISTOMORPHOLOGIC OBSERVATIONS:

LIVER: infiltration, mononuclear-cell, multifocal (minimal)

THE FOLLOWING TISSUE(S) WERE WITHIN NORMAL LIMITS:

KIDNEYS LUNG

End of Record- ICN361

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

90-DAY SUBCHRONIC DERMAL TOXICITY STUDY IN RATS WITH SATELLITE GROUP
STUDY NUMBER 139910B - TEST MATERIAL MRD-92-399

Appendix II
Individual Animal Gross and Histomorphology Data

ANIMAL NUMBER: ICN370
SEX: F

DOSE GROUP: 2
DEATH TYPE: Scheduled Sacrifice

GROSS OBSERVATION(S):

SKIN: Dose site- eschar and desquamation.

HISTOMORPHOLOGIC OBSERVATION(S):

hyperplasia/hyperkeratosis, epidermis, SKIN (TREATED)
hyperplasia, sebaceous glands, SKIN (TREATED)
inflammation, dermal, SKIN (TREATED)
exudate, SKIN (TREATED)

HISTOMORPHOLOGIC OBSERVATIONS:

LIVER: infiltration, mononuclear-cell, multifocal (minimal)
SKIN (TREATED): hyperplasia/hyperkeratosis, epidermis (moderate)
hyperplasia, sebaceous glands (moderate)
inflammation, dermal (slight)
exudate

THE FOLLOWING TISSUE(S) WERE WITHIN NORMAL LIMITS:

KIDNEYS LUNG

End of Record- ICN370

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

90-DAY SUBCHRONIC DERMAL TOXICITY STUDY IN RATS WITH SATELLITE GROUP
STUDY NUMBER 139910B - TEST MATERIAL MRD-92-399

Appendix II
Individual Animal Gross and Histomorphology Data

ANIMAL NUMBER: ICN385
SEX: F

DOSE GROUP: 2
DEATH TYPE: Scheduled Sacrifice

GROSS OBSERVATION(S):

HISTOMORPHOLOGIC OBSERVATION(S):

GENERAL: No gross changes.

Not applicable

HISTOMORPHOLOGIC OBSERVATIONS:

KIDNEYS:

fibrosis, focal (minimal)
dilatation, medullary tubules, focal (minimal)
mineralization, pelvic (minimal)
basophilia, cortical tubules, focal (minimal)
infiltration, mononuclear-cell, multifocal (minimal)

LIVER:

THE FOLLOWING TISSUE(S) WERE WITHIN NORMAL LIMITS:

LUNG

End of Record- ICN385

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

90-DAY SUBCHRONIC DERMAL TOXICITY STUDY IN RATS WITH SATELLITE GROUP
STUDY NUMBER 139910B - TEST MATERIAL MRD-92-399

Appendix II
Individual Animal Gross and Histomorphology Data

ANIMAL NUMBER: ICN388
SEX: F

DOSE GROUP: 2
DEATH TYPE: Scheduled Sacrifice

GROSS OBSERVATION(S):

HISTOMORPHOLOGIC OBSERVATION(S):

GENERAL: No gross changes.

Not applicable

HISTOMORPHOLOGIC OBSERVATIONS:

LIVER: necrosis, focal (slight)

THE FOLLOWING TISSUE(S) WERE WITHIN NORMAL LIMITS:

KIDNEYS LUNG

End of Record- ICN388

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

90-DAY SUBCHRONIC DERMAL TOXICITY STUDY IN RATS WITH SATELLITE GROUP
STUDY NUMBER 139910B - TEST MATERIAL MRD-92-399

Appendix II
Individual Animal Gross and Histomorphology Data

ANIMAL NUMBER: ICN395
SEX: F

DOSE GROUP: 2
DEATH TYPE: Scheduled Sacrifice

GROSS OBSERVATION(S):

LUNG: Several dark red foci, all lobes and surfaces.

SKIN: Dose site- eschar, desquamation.

HISTOMORPHOLOGIC OBSERVATION(S):

No microscopic change to correlate

hyperplasia/hyperkeratosis, epidermis, SKIN (TREATED)

hyperplasia, sebaceous glands, SKIN (TREATED)

exudate, SKIN (TREATED)

inflammation, dermal, SKIN (TREATED)

HISTOMORPHOLOGIC OBSERVATIONS:

LIVER:

lipidosis, tension, focal (slight)

infiltration, mononuclear-cell, multifocal (slight)

pigment

necrosis, focal (slight)

LUNG:

No microscopic change to correlate

SKIN (TREATED):

hyperplasia/hyperkeratosis, epidermis (moderate)

hyperplasia, sebaceous glands (moderate)

exudate

inflammation, dermal (slight)

THE FOLLOWING TISSUE(S) WERE WITHIN NORMAL LIMITS:

KIDNEYS

LUNG

End of Record- ICN395

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

90-DAY SUBCHRONIC DERMAL TOXICITY STUDY IN RATS WITH SATELLITE GROUP
STUDY NUMBER 139910B - TEST MATERIAL MRD-92-399

Appendix II
Individual Animal Gross and Histomorphology Data

ANIMAL NUMBER: ICN337
SEX: F

DOSE GROUP: 3
DEATH TYPE: Scheduled Sacrifice

GROSS OBSERVATION(S):

SKIN: Dose site- eschar, desquamation.

HISTOMORPHOLOGIC OBSERVATION(S):

hyperplasia/hyperkeratosis, epidermis, SKIN (TREATED)
hyperplasia, sebaceous glands, SKIN (TREATED)
necrosis, epidermal, focal, SKIN (TREATED)
exudate, SKIN (TREATED)
inflammation, dermal, SKIN (TREATED)

HISTOMORPHOLOGIC OBSERVATIONS:

LIVER: infiltration, mononuclear-cell; multifocal (minimal)
LUNG: proliferation, lymphoid, peribronchial/perivascular (slight)
SKIN (TREATED): hyperplasia/hyperkeratosis, epidermis (marked)
hyperplasia, sebaceous glands (moderate)
necrosis, epidermal, focal (moderate)
exudate
inflammation, dermal (slight)

THE FOLLOWING TISSUE(S) WERE WITHIN NORMAL LIMITS:

KIDNEYS

End of Record- ICN337

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

90-DAY SUBCHRONIC DERMAL TOXICITY STUDY IN RATS WITH SATELLITE GROUP
STUDY NUMBER 139910B - TEST MATERIAL MRD-92-399

Appendix II
Individual Animal Gross and Histomorphology Data

ANIMAL NUMBER: ICN339
SEX: F

DOSE GROUP: 3
DEATH TYPE: Scheduled Sacrifice

GROSS OBSERVATION(S):

SKIN: Dose site- desquamation, eschar.

HISTOMORPHOLOGIC OBSERVATION(S):

hyperplasia/hyperkeratosis, epidermis, SKIN
(TREATED)
hyperplasia, sebaceous glands, SKIN (TREATED)
exudate, SKIN (TREATED)

HISTOMORPHOLOGIC OBSERVATIONS:

LIVER:

SKIN (TREATED):

infiltration, mononuclear-cell, multifocal (slight)
hyperplasia/hyperkeratosis, epidermis (slight)
hyperplasia, sebaceous glands (slight)
exudate

THE FOLLOWING TISSUE(S) WERE WITHIN NORMAL LIMITS:

KIDNEYS

LUNG

End of Record- ICN339

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRCASAN DP300 (MRD-92-399): 139910B

90-DAY SUBCHRONIC DERMAL TOXICITY STUDY IN RATS WITH SATELLITE GROUP
STUDY NUMBER 139910B - TEST MATERIAL MRD-92-399

Appendix II
Individual Animal Gross and Histomorphology Data

ANIMAL NUMBER: ICN340
SEX: F

DOSE GROUP: 3
DEATH TYPE: Scheduled Sacrifice

GROSS OBSERVATION(S):

SKIN: Dose site- eschar, desquamation.

HISTOMORPHOLOGIC OBSERVATION(S):

hyperplasia/hyperkeratosis, epidermis, SKIN (TREATED)
hyperplasia, sebaceous glands, SKIN (TREATED)
necrosis, epidermal, focal, SKIN (TREATED)
exudate, SKIN (TREATED)
inflammation, dermal, SKIN (TREATED)

HISTOMORPHOLOGIC OBSERVATIONS:

LIVER: infiltration, mononuclear-cell, multifocal (slight)
lipidosis, tension, focal (minimal)
necrosis, focal (slight)
SKIN (TREATED): hyperplasia/hyperkeratosis, epidermis (moderate)
hyperplasia, sebaceous glands (moderate)
necrosis, epidermal, focal (moderate)
exudate
inflammation, dermal (slight)

THE FOLLOWING TISSUE(S) WERE WITHIN NORMAL LIMITS:

KIDNEYS LUNG

End of Record- ICN340

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

90-DAY SUBCHRONIC DERMAL TOXICITY STUDY IN RATS WITH SATELLITE GROUP
STUDY NUMBER 139910B - TEST MATERIAL MRD-92-399

Appendix II
Individual Animal Gross and Histomorphology Data

ANIMAL NUMBER: ICN343
SEX: F

DOSE GROUP: 3
DEATH TYPE: Scheduled Sacrifice

GROSS OBSERVATION(S):

SKIN: Dose site- eschar, desquamation.

HISTOMORPHOLOGIC OBSERVATION(S):

hyperplasia/hyperkeratosis, epidermis, SKIN (TREATED)
hyperplasia, sebaceous glands, SKIN (TREATED)
necrosis, epidermal, focal, SKIN (TREATED)
inflammation, dermal, SKIN (TREATED)

HISTOMORPHOLOGIC OBSERVATIONS:

LIVER: infiltration, mononuclear-cell, multifocal (minimal)
LUNG: pneumonitis (minimal)
SKIN (TREATED): hyperplasia/hyperkeratosis, epidermis (moderate)
hyperplasia, sebaceous glands (moderate)
necrosis, epidermal, focal (moderate)
inflammation, dermal (moderate)

THE FOLLOWING TISSUE(S) WERE WITHIN NORMAL LIMITS:

KIDNEYS

End of Record- ICN343

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

90-DAY SUBCHRONIC DERMAL TOXICITY STUDY IN RATS WITH SATELLITE GROUP
STUDY NUMBER 139910B - TEST MATERIAL MRD-92-399

Appendix II
Individual Animal Gross and Histomorphology Data

ANIMAL NUMBER: ICN350
SEX: F

DOSE GROUP: 3
DEATH TYPE: Spontaneous Death

GROSS OBSERVATION(S):

LIVER: All lobes and surfaces- large patches of tan areas.

SKIN: Dose site- desquamation, eschar.

HISTOMORPHOLOGIC OBSERVATION(S):

infiltration, mononuclear-cell, multifocal
dilatation, sinusoidal, focal
necrosis, focal
congestion
hyperplasia/hyperkeratosis, epidermis, SKIN (TREATED)
hyperplasia, sebaceous glands, SKIN (TREATED)
exudate, SKIN (TREATED)
inflammation, dermal, SKIN (TREATED)

HISTOMORPHOLOGIC OBSERVATIONS:

KIDNEYS:

LIVER:

infiltration, mononuclear-cell, focal (minimal)
infiltration, mononuclear-cell, multifocal (moderate)
dilatation, sinusoidal, focal (moderate)
necrosis, focal (moderate)
congestion (moderate)

SKIN (TREATED):

hyperplasia/hyperkeratosis, epidermis (slight)
hyperplasia, sebaceous glands (slight)
exudate

SKIN (UNTREATED):

inflammation, dermal (minimal)
hyperkeratosis, epidermis (minimal)
hyperplasia, lymphoid (slight)
dilatation, mucosal glands (minimal)

SPLEEN:

STOMACH:

THE FOLLOWING TISSUE(S) WERE WITHIN NORMAL LIMITS:

ADRENAL GLANDS

BRAIN

DUODENUM

ILEUM

LYMPH NODE, MESENTERIC

OVIDUCTS

RECTUM

SPINAL CORD, MIDTHORACIC

URINARY BLADDER

AORTA

CECUM

ESOPHAGUS

JEJUNUM

MUSCLE, FEMORIS

PANCREAS

SALIVARY GLANDS

THYMUS

UTERUS

BONE (STERNUM)

CERVIX

EYES

LACRIMAL GLANDS

NERVE, SCIATIC

PARATHYROID

SPINAL CORD, CERVICAL

THYROID

BONE MARROW (STERNUM)

COLON

HEART

LUNG

OVARIES

PITUITARY

SPINAL CORD, LUMBAR

TRACHEA

TISSUE(S) NOT AVAILABLE FOR EVALUATION:

MAMMARY GLAND

End of Record- ICN350

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

90-DAY SUBCHRONIC DERMAL TOXICITY STUDY IN RATS WITH SATELLITE GROUP
STUDY NUMBER 139910B - TEST MATERIAL MRD-92-399

Appendix II
Individual Animal Gross and Histomorphology Data

ANIMAL NUMBER: ICN351
SEX: F

DOSE GROUP: 3
DEATH TYPE: Scheduled Sacrifice

GROSS OBSERVATION(S):

SKIN: Dose site- eschar, desquamation.

HISTOMORPHOLOGIC OBSERVATION(S):

hyperplasia/hyperkeratosis, epidermis, SKIN (TREATED)
hyperplasia, sebaceous glands, SKIN (TREATED)
necrosis, epidermal, focal, SKIN (TREATED)
exudate, SKIN (TREATED)
inflammation, dermal, SKIN (TREATED)

HISTOMORPHOLOGIC OBSERVATIONS:

LIVER:
SKIN (TREATED):

infiltration, mononuclear-cell, multifocal (slight)
hyperplasia/hyperkeratosis, epidermis (moderate)
hyperplasia, sebaceous glands (moderate)
necrosis, epidermal, focal (moderate)
exudate
inflammation, dermal (slight)

THE FOLLOWING TISSUE(S) WERE WITHIN NORMAL LIMITS:

KIDNEYS LUNG

End of Record- ICN351

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 1399108

90-DAY SUBCHRONIC DERMAL TOXICITY STUDY IN RATS WITH SATELLITE GROUP
STUDY NUMBER 1399108 - TEST MATERIAL MRD-92-399

Appendix II
Individual Animal Gross and Histomorphology Data

ANIMAL NUMBER: ICN363
SEX: F

DOSE GROUP: 3
DEATH TYPE: Scheduled Sacrifice

GROSS OBSERVATION(S):

SKIN: Dose site- eschar, desquamation.

HISTOMORPHOLOGIC OBSERVATION(S):

hyperplasia/hyperkeratosis, epidermis, SKIN (TREATED)
hyperplasia, sebaceous glands, SKIN (TREATED)
necrosis, epidermal, focal, SKIN (TREATED)
exudate, SKIN (TREATED)
inflammation, dermal, SKIN (TREATED)

HISTOMORPHOLOGIC OBSERVATIONS:

LIVER: infiltration, mononuclear-cell, multifocal (slight)
pigment
SKIN (TREATED): hyperplasia/hyperkeratosis, epidermis (slight)
hyperplasia, sebaceous glands (slight)
necrosis, epidermal, focal (slight)
exudate
inflammation, dermal (minimal)

THE FOLLOWING TISSUE(S) WERE WITHIN NORMAL LIMITS:

KIDNEYS LUNG

End of Record- ICN363

**90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B**

**90-DAY SUBCHRONIC DERMAL TOXICITY STUDY IN RATS WITH SATELLITE GROUP
STUDY NUMBER 139910B - TEST MATERIAL MRD-92-399**

**Appendix II
Individual Animal Gross and Histomorphology Data**

ANIMAL NUMBER: ICN364
SEX: F

DOSE GROUP: 3
DEATH TYPE: Scheduled Sacrifice

GROSS OBSERVATION(S):

HISTOMORPHOLOGIC OBSERVATION(S):

SKIN: Dose site- desquamation, eschar.

Tissue not available, SKIN (TREATED)

HISTOMORPHOLOGIC OBSERVATIONS:

KIDNEYS:

degeneration, cortical tubules, focal (slight)

LIVER:

infiltration, mononuclear-cell, multifocal (minimal)

THE FOLLOWING TISSUE(S) WERE WITHIN NORMAL LIMITS:

LUNG

TISSUE(S) NOT AVAILABLE FOR EVALUATION:

SKIN (TREATED)

End of Record- ICN364

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399); 139910B

90-DAY SUBCHRONIC DERMAL TOXICITY STUDY IN RATS WITH SATELLITE GROUP
STUDY NUMBER 139910B - TEST MATERIAL MRD-92-399

Appendix II
Individual Animal Gross and Histomorphology Data

ANIMAL NUMBER: ICN366
SEX: F

DOSE GROUP: 3
DEATH TYPE: Scheduled Sacrifice

GROSS OBSERVATION(S):

SKIN: Dose site- eschar, desquamation.

HISTOMORPHOLOGIC OBSERVATION(S):

hyperplasia/hyperkeratosis, epidermis, SKIN (TREATED)
hyperplasia, sebaceous glands, SKIN (TREATED)
necrosis, epidermal, focal, SKIN (TREATED)
exudate, SKIN (TREATED)
inflammation, dermal, SKIN (TREATED)

HISTOMORPHOLOGIC OBSERVATIONS:

LIVER:
SKIN (TREATED):

infiltration, mononuclear-cell, multifocal (minimal)
hyperplasia/hyperkeratosis, epidermis (moderate)
hyperplasia, sebaceous glands (moderate)
necrosis, epidermal, focal (slight)
exudate
inflammation, dermal (moderate)

THE FOLLOWING TISSUE(S) WERE WITHIN NORMAL LIMITS:

KIDNEYS

LUNG

End of Record- ICN366

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

90-DAY SUBCHRONIC DERMAL TOXICITY STUDY IN RATS WITH SATELLITE GROUP
STUDY NUMBER 139910B - TEST MATERIAL MRD-92-399

Appendix II
Individual Animal Gross and Histomorphology Data

ANIMAL NUMBER: ICN389
SEX: F

DOSE GROUP: 3
DEATH TYPE: Scheduled Sacrifice

GROSS OBSERVATION(S):

SKIN: Dose site- eschar, desquamation.

HISTOMORPHOLOGIC OBSERVATION(S):

hyperplasia/hyperkeratosis, epidermis, SKIN (TREATED)
hyperplasia, sebaceous glands, SKIN (TREATED)
necrosis, epidermal, focal, SKIN (TREATED)
exudate, SKIN (TREATED)
inflammation, dermal, SKIN (TREATED)

HISTOMORPHOLOGIC OBSERVATIONS:

LIVER:
SKIN (TREATED):

infiltration, mononuclear-cell, multifocal (minimal)
hyperplasia/hyperkeratosis, epidermis (moderate)
hyperplasia, sebaceous glands (slight)
necrosis, epidermal, focal (slight)
exudate
inflammation, dermal (minimal)

THE FOLLOWING TISSUE(S) WERE WITHIN NORMAL LIMITS:

KIDNEYS LUNG

End of Record- ICN389

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

90-DAY SUBCHRONIC DERMAL TOXICITY STUDY IN RATS WITH SATELLITE GROUP
STUDY NUMBER 139910B - TEST MATERIAL MRD-92-399

Appendix II
Individual Animal Gross and Histomorphology Data

ANIMAL NUMBER: ICN338
SEX: F

DOSE GROUP: 4
DEATH TYPE: Scheduled Sacrifice

GROSS OBSERVATION(S):

SKIN: Dose site- eschar, desquamation.

HISTOMORPHOLOGIC OBSERVATION(S):

hyperplasia/hyperkeratosis, epidermis, SKIN (TREATED)
hyperplasia, sebaceous glands, SKIN (TREATED)
exudate, SKIN (TREATED)
inflammation, dermal, SKIN (TREATED)

HISTOMORPHOLOGIC OBSERVATIONS:

BONE (STERNUM):

necrosis, intersternal cartilage, focal (minimal)
infiltration, mononuclear-cell, multifocal (slight)

LIVER:

necrosis, focal (minimal)
hyperplasia/hyperkeratosis, epidermis (moderate)
hyperplasia, sebaceous glands (moderate)
exudate

SKIN (TREATED):

inflammation, dermal (slight)
hyperkeratosis, epidermis (minimal)
hyperplasia/hyperkeratosis, limiting ridge (slight)

SKIN (UNTREATED):

STOMACH:

THE FOLLOWING TISSUE(S) WERE WITHIN NORMAL LIMITS:

ADRENAL GLANDS (1)

AORTA

BONE MARROW (STERNUM)

BRAIN

CECUM

CERVIX

COLON

DUODENUM

ESOPHAGUS

EYES

HEART

ILEUM

JEJUNUM

KIDNEYS

LACRIMAL GLANDS

LUNG

LYMPH NODE, MESENTERIC

MAMMARY GLAND

MUSCLE, FEMORIS

NERVE, SCIATIC

OVARIES

OVIDUCTS

PANCREAS

PARATHYROID

PITUITARY

RECTUM

SALIVARY GLANDS

SPINAL CORD, CERVICAL

SPINAL CORD, LUMBAR

SPINAL CORD, MIDTHORACIC

SPLEEN

THYMUS

THYROID

TRACHEA

URINARY BLADDER

UTERUS

TISSUE(S) NOT AVAILABLE FOR EVALUATION:

ADRENAL GLANDS (1)

End of Record- ICN338

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

90-DAY SUBCHRONIC DERMAL TOXICITY STUDY IN RATS WITH SATELLITE GROUP
STUDY NUMBER 139910B - TEST MATERIAL MRD-92-399

Appendix II
Individual Animal Gross and Histomorphology Data

ANIMAL NUMBER: ICN356
SEX: F

DOSE GROUP: 4
DEATH TYPE: Scheduled Sacrifice

GROSS OBSERVATION(S):

SKIN: Dose site- eschar, desquamation.

HISTOMORPHOLOGIC OBSERVATION(S):

hyperplasia/hyperkeratosis, epidermis, SKIN (TREATED)
necrosis, epidermal, focal, SKIN (TREATED)
exudate, SKIN (TREATED)
inflammation, dermal, SKIN (TREATED)

HISTOMORPHOLOGIC OBSERVATIONS:

LIVER:

SKIN (TREATED):

infiltration, mononuclear-cell, multifocal (minimal)
hyperplasia/hyperkeratosis, epidermis (moderate)
necrosis, epidermal, focal (moderate)
exudate

SKIN (UNTREATED):

inflammation, dermal (slight)
hyperkeratosis, epidermis (minimal)

THE FOLLOWING TISSUE(S) WERE WITHIN NORMAL LIMITS:

ADRENAL GLANDS
BRAIN
DUODENUM
ILEUM
LUNG
NERVE, SCIATIC
PARATHYROID
SPINAL CORD, CERVICAL
STOMACH
URINARY BLADDER

AORTA
CECUM
ESOPHAGUS
JEJUNUM
LYMPH NODE, MESENTERIC
OVARIES
PITUITARY
SPINAL CORD, LUMBAR
THYMUS
UTERUS

BONE (STERNUM)
CERVIX
EYES
KIDNEYS
MAMMARY GLAND
OVIDUCTS
RECTUM
SPINAL CORD, MIDTHORACIC
THYROID

BONE MARROW (STERNUM)
COLON
HEART
LACRIMAL GLANDS
MUSCLE, FEMORIS
PANCREAS
SALIVARY GLANDS
SPLEEN
TRACHEA

End of Record- ICN356

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

90-DAY SUBCHRONIC DERMAL TOXICITY STUDY IN RATS WITH SATELLITE GROUP
STUDY NUMBER 139910B - TEST MATERIAL MRD-92-399

Appendix II
Individual Animal Gross and Histomorphology Data

ANIMAL NUMBER: ICN360
SEX: F

DOSE GROUP: 4
DEATH TYPE: Spontaneous Death

GROSS OBSERVATION(S):

LIVER: All lobes and surfaces- tan areas.

HISTOMORPHOLOGIC OBSERVATION(S):

infiltration, mononuclear-cell, multifocal
dilatation, sinusoidal, focal
necrosis, focal

HISTOMORPHOLOGIC OBSERVATIONS:

ADRENAL GLANDS:
LIVER:

vacuolation, cortical, focal (minimal)
infiltration, mononuclear-cell, multifocal (moderate)
dilatation, sinusoidal, focal (moderate)
necrosis, focal (moderate)

SKIN (TREATED):
SKIN (UNTREATED):
STOMACH:

hyperplasia/hyperkeratosis, epidermis (minimal)
hyperkeratosis, epidermis (minimal)
dilatation, mucosal glands (minimal)

THE FOLLOWING TISSUE(S) WERE WITHIN NORMAL LIMITS:

AORTA
CECUM
ESOPHAGUS
JEJUNUM
LYMPH NODE, MESENTERIC
OVARIES
PITUITARY
SPINAL CORD, LUMBAR
THYROID

BONE (STERNUM)
CERVIX
EYES
KIDNEYS
MAMMARY GLAND
OVIDUCTS
RECTUM
SPINAL CORD, MIDTHORACIC
TRACHEA

BONE MARROW (STERNUM)
COLON
HEART
LACRIMAL GLANDS
MUSCLE, FEMORIS
PANCREAS
SALIVARY GLANDS
SPLEEN
URINARY BLADDER

BRAIN
DUODENUM
ILEUM
LUNG
NERVE, SCIATIC
PARATHYROID
SPINAL CORD, CERVICAL
THYMUS
UTERUS

End of Record- ICN360

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

90-DAY SUBCHRONIC DERMAL TOXICITY STUDY IN RATS WITH SATELLITE GROUP
STUDY NUMBER 139910B - TEST MATERIAL MRD-92-399

Appendix II
Individual Animal Gross and Histomorphology Data

ANIMAL NUMBER: ICN362
SEX: F

DOSE GROUP: 4
DEATH TYPE: Scheduled Sacrifice

GROSS OBSERVATION(S):

SKIN: Dose site- eschar, desquamation.

HISTOMORPHOLOGIC OBSERVATION(S):

hyperplasia/hyperkeratosis, epidermis, SKIN
(TREATED)
exudate, SKIN (TREATED)
hyperplasia, sebaceous glands, SKIN (TREATED)
inflammation, dermal, SKIN (TREATED)

HISTOMORPHOLOGIC OBSERVATIONS:

LIVER: infiltration, mononuclear-cell, multifocal (minimal)
SKIN (TREATED): hyperplasia/hyperkeratosis, epidermis (moderate)
exudate
hyperplasia, sebaceous glands (moderate)
inflammation, dermal (minimal)
SKIN (UNTREATED): hyperkeratosis, epidermis (minimal)
STOMACH: dilatation, mucosal glands (minimal)

THE FOLLOWING TISSUE(S) WERE WITHIN NORMAL LIMITS:

ADRENAL GLANDS	AORTA	BONE (STERNUM)	BONE MARROW (STERNUM)
BRAIN	CECUM	CERVIX	COLON
DUODENUM	ESOPHAGUS	EYES	HEART
ILEUM	KIDNEYS	LACRIMAL GLANDS	LUNG
LYMPH NODE, MESENTERIC	MAMMARY GLAND	MUSCLE, FEMORIS	NERVE, SCIATIC
OVARIES	OVIDUCTS	PANCREAS	PARATHYROID
PITUITARY	RECTUM	SALIVARY GLANDS	SPINAL CORD, CERVICAL
SPINAL CORD, LUMBAR	SPINAL CORD, MIDTHORACIC	SPLEEN	THYMUS
THYROID	TRACHEA	URINARY BLADDER	UTERUS

TISSUE(S) NOT AVAILABLE FOR EVALUATION:

JEJUNUM

End of Record- ICN362

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

90-DAY SUBCHRONIC DERMAL TOXICITY STUDY IN RATS WITH SATELLITE GROUP
STUDY NUMBER 139910B - TEST MATERIAL MRD-92-399

Appendix II
Individual Animal Gross and Histomorphology Data

ANIMAL NUMBER: ICN367
SEX: F

DOSE GROUP: 4
DEATH TYPE: Scheduled Sacrifice

GROSS OBSERVATION(S):

SKIN: Dose site- desquamation.

UTERUS: Thickened.

HISTOMORPHOLOGIC OBSERVATION(S):

hyperplasia/hyperkeratosis, epidermis, SKIN
(TREATED)
hyperplasia, sebaceous glands, SKIN (TREATED)
distention, lumen

HISTOMORPHOLOGIC OBSERVATIONS:

BONE (STERNUM): necrosis, intersternal cartilage, focal (minimal)
LIVER: infiltration, mononuclear-cell, multifocal (minimal)
SKIN (TREATED): hyperplasia/hyperkeratosis, epidermis (moderate)
hyperplasia, sebaceous glands (moderate)
SKIN (UNTREATED): hyperplasia, epidermis (slight)
hyperkeratosis, epidermis (slight)
STOMACH: dilatation, mucosal glands (minimal)
UTERUS: distention, lumen (slight)

THE FOLLOWING TISSUE(S) WERE WITHIN NORMAL LIMITS:

ADRENAL GLANDS	AORTA	BONE MARROW (STERNUM)	BRAIN
CECUM	CERVIX	COLON	DUODENUM
ESOPHAGUS	EYES	HEART	ILEUM
JEJUNUM	KIDNEYS	LACRIMAL GLANDS	LUNG
LYMPH NODE, MESENTERIC	MAMMARY GLAND	MUSCLE, FEMORIS	NERVE, SCIATIC
OVARIES	OVIDUCTS	PANCREAS	PARATHYROID
PITUITARY	SALIVARY GLANDS	SPINAL CORD, CERVICAL	SPINAL CORD, LUMBAR
SPINAL CORD, MIDTHORACIC	SPLEEN	THYMUS	THYROID
TRACHEA	URINARY BLADDER		

TISSUE(S) NOT AVAILABLE FOR EVALUATION:

RECTUM

End of Record- ICN367

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

90-DAY SUBCHRONIC DERMAL TOXICITY STUDY IN RATS WITH SATELLITE GROUP
STUDY NUMBER 139910B - TEST MATERIAL MRD-92-399

Appendix II
Individual Animal Gross and Histomorphology Data

ANIMAL NUMBER: ICN376
SEX: F

DOSE GROUP: 4
DEATH TYPE: Scheduled Sacrifice

GROSS OBSERVATION(S):

SKIN: Dose site- eschar, desquamation.

HISTOMORPHOLOGIC OBSERVATION(S):

hyperplasia/hyperkeratosis, epidermis, SKIN (TREATED)
necrosis, epidermal, focal, SKIN (TREATED)
exudate, SKIN (TREATED)
hyperplasia, sebaceous glands, SKIN (TREATED)
inflammation, dermal, SKIN (TREATED)

HISTOMORPHOLOGIC OBSERVATIONS:

HEART: proliferation, myocardial, focal (slight)
LIVER: infiltration, mononuclear-cell, multifocal (minimal)
SALIVARY GLANDS: infiltration, mononuclear-cell, focal (minimal)
SKIN (TREATED): hyperplasia/hyperkeratosis, epidermis (moderate)
necrosis, epidermal, focal (moderate)
exudate
hyperplasia, sebaceous glands (moderate)
inflammation, dermal (slight)
SKIN (UNTREATED): hyperkeratosis, epidermis (minimal)

THE FOLLOWING TISSUE(S) WERE WITHIN NORMAL LIMITS:

ADRENAL GLANDS	AORTA	BONE (STERNUM)	BONE MARROW (STERNUM)
BRAIN	CECUM	CERVIX	COLON
DUODENUM	ESOPHAGUS	EYES	ILEUM
JEJUNUM	KIDNEYS	LACRIMAL GLANDS	LUNG
LYMPH NODE, MESENTERIC	MAMMARY GLAND	MUSCLE, FEMORIS	NERVE, SCIATIC
OVARIES	OVIDUCTS	PANCREAS	PARATHYROID
PITUITARY	RECTUM	SPINAL CORD, CERVICAL	SPINAL CORD, LUMBAR
SPINAL CORD, MIDTHORACIC	SPLEEN	STOMACH	THYMUS
THYROID	TRACHEA	URINARY BLADDER	UTERUS

End of Record- ICN376

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

90-DAY SUBCHRONIC DERMAL TOXICITY STUDY IN RATS WITH SATELLITE GROUP
STUDY NUMBER 139910B - TEST MATERIAL MRD-92-399

Appendix II
Individual Animal Gross and Histomorphology Data

ANIMAL NUMBER: ICN381
SEX: F

DOSE GROUP: 4
DEATH TYPE: Scheduled Sacrifice

GROSS OBSERVATION(S):

SKIN: Dose site- eschar, desquamation.

HISTOMORPHOLOGIC OBSERVATION(S):

hyperplasia/hyperkeratosis, epidermis, SKIN
(TREATED)
hyperplasia, sebaceous glands, SKIN (TREATED)

HISTOMORPHOLOGIC OBSERVATIONS:

KIDNEYS: infiltration, mononuclear-cell, focal (minimal)
LIVER: infiltration, mononuclear-cell, multifocal (minimal)
PITUITARY: cyst(s)
SKIN (TREATED): hyperplasia/hyperkeratosis, epidermis (slight)
hyperplasia, sebaceous glands (slight)
SKIN (UNTREATED): hyperkeratosis, epidermis (minimal)

THE FOLLOWING TISSUE(S) WERE WITHIN NORMAL LIMITS:

ADRENAL GLANDS	AORTA	BONE (STERNUM)	BONE MARROW (STERNUM)
BRAIN	CECUM	CERVIX	COLON
DUODENUM	ESOPHAGUS	EYES	HEART
ILEUM	JEJUNUM	LACRIMAL GLANDS	LUNG
LYMPH NODE, MESENTERIC	MAMMARY GLAND	MUSCLE, FEMORIS	NERVE, SCIATIC
OVARIES	OVIDUCTS	PANCREAS	PARATHYROID
RECTUM	SALIVARY GLANDS	SPINAL CORD, CERVICAL	SPINAL CORD, LUMBAR
SPINAL CORD, MIDTHORACIC	SPLEEN	STOMACH	THYMUS
THYROID	TRACHEA	URINARY BLADDER	UTERUS

End of Record- ICN381

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 1399108

90-DAY SUBCHRONIC DERMAL TOXICITY STUDY IN RATS WITH SATELLITE GROUP
STUDY NUMBER 1399108 - TEST MATERIAL MRD-92-399

Appendix II
Individual Animal Gross and Histomorphology Data

ANIMAL NUMBER: ICN384
SEX: F

DOSE GROUP: 4
DEATH TYPE: Scheduled Sacrifice

GROSS OBSERVATION(S):

SKIN: Dose site- desquamation, eschar.

HISTOMORPHOLOGIC OBSERVATION(S):

hyperplasia/hyperkeratosis, epidermis, SKIN (TREATED)
necrosis, epidermal, focal, SKIN (TREATED)
exudate, SKIN (TREATED)
hyperplasia, sebaceous glands, SKIN (TREATED)
inflammation, dermal, SKIN (TREATED)

HISTOMORPHOLOGIC OBSERVATIONS:

BONE (STERNUM): necrosis, intersternal cartilage, focal (minimal)
KIDNEYS: infiltration, mononuclear-cell, focal (minimal)
LIVER: infiltration, mononuclear-cell, multifocal (slight)
necrosis, focal (slight)
SKIN (TREATED): hyperplasia/hyperkeratosis, epidermis (moderate)
necrosis, epidermal, focal (moderate)
exudate
hyperplasia, sebaceous glands (moderate)
inflammation, dermal (slight)
SKIN (UNTREATED): hyperkeratosis, epidermis (minimal)

THE FOLLOWING TISSUE(S) WERE WITHIN NORMAL LIMITS:

ADRENAL GLANDS	AORTA	BONE MARROW (STERNUM)	BRAIN
CECUM	CERVIX	COLON	DUODENUM
ESOPHAGUS	EYES	HEART	ILEUM
JEJUNUM	LACRIMAL GLANDS	LUNG	LYMPH NODE, MESENTERIC
MAMMARY GLAND	MUSCLE, FEMORIS	NERVE, SCIATIC	OVARIES
OVIDUCTS	PANCREAS	PARATHYROID	PITUITARY
RECTUM	SALIVARY GLANDS	SPINAL CORD, CERVICAL	SPINAL CORD, LUMBAR
SPINAL CORD, MIDTHORACIC	SPLEEN	STOMACH	THYMUS
THYROID	TRACHEA	URINARY BLADDER	UTERUS

COMMENTS:

ADRENAL GLANDS Medulla is present in only one adrenal gland.

End of Record- ICN384

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

90-DAY SUBCHRONIC DERMAL TOXICITY STUDY IN RATS WITH SATELLITE GROUP
STUDY NUMBER 139910B - TEST MATERIAL MRD-92-399

Appendix II
Individual Animal Gross and Histomorphology Data

ANIMAL NUMBER: ICN390
SEX: F

DOSE GROUP: 4
DEATH TYPE: Scheduled Sacrifice

GROSS OBSERVATION(S):

SKIN: Dose site- eschar and desquamation.

HISTOMORPHOLOGIC OBSERVATION(S):

hyperplasia/hyperkeratosis, epidermis, SKIN (TREATED)
necrosis, epidermal, focal, SKIN (TREATED)
exudate, SKIN (TREATED)
hyperplasia, sebaceous glands, SKIN (TREATED)
inflammation, dermal, SKIN (TREATED)

HISTOMORPHOLOGIC OBSERVATIONS:

KIDNEYS:

inflammation, chronic, focal (slight)

LIVER:

infiltration, mononuclear-cell, multifocal (minimal)

SKIN (TREATED):

hyperplasia/hyperkeratosis, epidermis (marked)

necrosis, epidermal, focal (moderate)

exudate

hyperplasia, sebaceous glands (moderate)

inflammation, dermal (slight)

SKIN (UNTREATED):

hyperkeratosis, epidermis (minimal)

THYROID:

ultimobranchial body/cyst

THE FOLLOWING TISSUE(S) WERE WITHIN NORMAL LIMITS:

ADRENAL GLANDS
BRAIN
DUODENUM
ILEUM
LYMPH NODE, MESENTERIC
OVARIES
PITUITARY
SPINAL CORD, LUMBAR
THYMUS

AORTA
CECUM
ESOPHAGUS
JEJUNUM
MAMMARY GLAND
OVIDUCTS
RECTUM
SPINAL CORD, MIDTHORACIC
TRACHEA

BONE (STERNUM)
CERVIX
EYES (1)
LACRIMAL GLANDS
MUSCLE, FEMORIS
PANCREAS
SALIVARY GLANDS
SPLEEN
URINARY BLADDER

BONE MARROW (STERNUM)
COLON
HEART
LUNG
NERVE, SCIATIC
PARATHYROID
SPINAL CORD, CERVICAL
STOMACH
UTERUS

TISSUE(S) NOT AVAILABLE FOR EVALUATION:

EYES (1)

End of Record- ICN390

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

90-DAY SUBCHRONIC DERMAL TOXICITY STUDY IN RATS WITH SATELLITE GROUP
STUDY NUMBER 139910B - TEST MATERIAL MRD-92-399

Appendix II
Individual Animal Gross and Histomorphology Data

ANIMAL NUMBER: ICN392
SEX: F

DOSE GROUP: 4
DEATH TYPE: Scheduled Sacrifice

GROSS OBSERVATION(S):

SKIN: Dose site- eschar, desquamation.

UTERUS: Thickened.

HISTOMORPHOLOGIC OBSERVATION(S):

hyperplasia/hyperkeratosis, epidermis, SKIN (TREATED)
hyperplasia, sebaceous glands, SKIN (TREATED)
necrosis, epidermal, focal, SKIN (TREATED)
inflammation, dermal, SKIN (TREATED)
exudate, SKIN (TREATED)
No microscopic change to correlate

HISTOMORPHOLOGIC OBSERVATIONS:

HEART: hematocyst
KIDNEYS: corpora amylacea, cortex (minimal)
LIVER: infiltration, mononuclear-cell, multifocal (minimal)
lipidosis, tension, focal (slight)
necrosis, focal (slight)
LUNG: mineralization, vascular (minimal)
SKIN (TREATED): hyperplasia/hyperkeratosis, epidermis (moderate)
hyperplasia, sebaceous glands (moderate)
necrosis, epidermal, focal (moderate)
inflammation, dermal (slight)
exudate
SKIN (UNTREATED): hyperkeratosis, epidermis (minimal)
STOMACH: dilatation, mucosal glands (minimal)
THYROID: ultimobranchial body/cyst
UTERUS: No microscopic change to correlate

THE FOLLOWING TISSUE(S) WERE WITHIN NORMAL LIMITS:

ADRENAL GLANDS	AORTA	BONE (STERNUM)	BONE MARROW (STERNUM)
BRAIN	CECUM	CERVIX	COLON
DUODENUM	ESOPHAGUS	EYES	ILEUM
JEJUNUM	LACRIMAL GLANDS	LYMPH NODE, MESENTERIC	MAMMARY GLAND
MUSCLE, FEMORIS	NERVE, SCIATIC	OVARIES	OVIDUCTS
PANCREAS	PARATHYROID	PITUITARY	RECTUM
SALIVARY GLANDS	SPINAL CORD, CERVICAL	SPINAL CORD, LUMBAR	SPINAL CORD, MIDTHORACIC
SPLEEN	THYMUS	TRACHEA	URINARY BLADDER
UTERUS			

COMMENTS:

UTERUS There is a normal physiologic appearance to the uterus (not remarkable).

End of Record- ICN392

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

90-DAY SUBCHRONIC DERMAL TOXICITY STUDY IN RATS WITH SATELLITE GROUP
STUDY NUMBER 139910B - TEST MATERIAL MRD-92-399

Appendix II
Individual Animal Gross and Histomorphology Data

ANIMAL NUMBER: ICN344
SEX: F

DOSE GROUP: 5
DEATH TYPE: Scheduled Sacrifice

GROSS OBSERVATION(S):

GENERAL: No gross changes.

HISTOMORPHOLOGIC OBSERVATION(S):

Not applicable

HISTOMORPHOLOGIC OBSERVATIONS:

BONE (STERNUM):	necrosis, intersternal cartilage, focal (minimal)
KIDNEYS:	mineralization, pelvic (minimal)
PITUITARY:	cyst(s)
SKIN (TREATED):	hyperplasia/hyperkeratosis, epidermis (minimal)
	hyperplasia, sebaceous glands (slight)
	fibrosis, dermal (slight)
SKIN (UNTREATED):	hyperkeratosis, epidermis (minimal)
THYROID:	follicle(s), cystic
UTERUS:	distention, lumen (moderate)

THE FOLLOWING TISSUE(S) WERE WITHIN NORMAL LIMITS:

ADRENAL GLANDS	AORTA	BONE MARROW (STERNUM)	BRAIN
CECUM	CERVIX	COLON	DUODENUM
ESOPHAGUS	EYES	HEART	ILEUM
JEJUNUM	LACRIMAL GLANDS	LIVER	LUNG
LYMPH NODE, MESENTERIC	MAMMARY GLAND	MUSCLE, FEMORIS	NERVE, SCIATIC
OVARIES	OVIDUCTS	PANCREAS	PARATHYROID
RECTUM	SALIVARY GLANDS	SPINAL CORD, CERVICAL	SPINAL CORD, LUMBAR
SPINAL CORD, MIDTHORACIC	SPLEEN	STOMACH	THYMUS
TRACHEA	URINARY BLADDER		

End of Record- ICN344

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

90-DAY SUBCHRONIC DERMAL TOXICITY STUDY IN RATS WITH SATELLITE GROUP
STUDY NUMBER 139910B - TEST MATERIAL MRD-92-399

Appendix II
Individual Animal Gross and Histomorphology Data

ANIMAL NUMBER: ICN346
SEX: F

DOSE GROUP: 5
DEATH TYPE: Scheduled Sacrifice

GROSS OBSERVATION(S):

GENERAL: No gross changes.

HISTOMORPHOLOGIC OBSERVATION(S):

Not applicable

HISTOMORPHOLOGIC OBSERVATIONS:

KIDNEYS:	dilatation, tubules, papilla (slight)
LUNG:	macrophages, alveoli, focal (slight)
SKIN (TREATED):	hyperplasia/hyperkeratosis, epidermis (minimal)
	fibrosis, dermal (minimal)
SKIN (UNTREATED):	hyperkeratosis, epidermis (minimal)
STOMACH:	dilatation, mucosal glands (minimal)
THYROID:	ultimobranchial body/cyst

THE FOLLOWING TISSUE(S) WERE WITHIN NORMAL LIMITS:

ADRENAL GLANDS	AORTA	BONE (STERNUM)	BONE MARROW (STERNUM)
BRAIN	CECUM	CERVIX	COLON
DUODENUM	ESOPHAGUS	EYES	HEART
ILEUM	JEJUNUM	LACRIMAL GLANDS	LIVER
LYMPH NODE, MESENTERIC	MUSCLE, FEMORIS	NERVE, SCIATIC	OVARIES
OVIDUCTS	PANCREAS	PARATHYROID	PITUITARY
RECTUM	SALIVARY GLANDS	SPINAL CORD, CERVICAL	SPINAL CORD, LUMBAR
SPINAL CORD, MIDTHORACIC	SPLEEN	THYMUS	TRACHEA
URINARY BLADDER	UTERUS		

TISSUE(S) NOT AVAILABLE FOR EVALUATION:

MAMMARY GLAND

End of Record- ICN346

**90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B**

**90-DAY SUBCHRONIC DERMAL TOXICITY STUDY IN RATS WITH SATELLITE GROUP
STUDY NUMBER 139910B - TEST MATERIAL MRD-92-399**

**Appendix II
Individual Animal Gross and Histomorphology Data**

ANIMAL NUMBER: ICN347 DOSE GROUP: 5
SEX: F DEATH TYPE: Scheduled Sacrifice

GROSS OBSERVATION(S):

GENERAL: No gross changes.

HISTOMORPHOLOGIC OBSERVATION(S):

Not applicable

HISTOMORPHOLOGIC OBSERVATIONS:

BONE (STERNUM):	necrosis, intersternal cartilage, focal (slight)
HEART:	infiltration, mononuclear-cell, focal (minimal)
LIVER:	infiltration, mononuclear-cell, multifocal (minimal)
PITUITARY:	cyst(s)
SKIN (TREATED):	hyperplasia/hyperkeratosis, epidermis (minimal)
	hyperplasia, sebaceous glands (slight)
	fibrosis, dermal (minimal)
SKIN (UNTREATED):	hyperkeratosis, epidermis (minimal)
UTERUS:	distention, lumen (moderate)

THE FOLLOWING TISSUE(S) WERE WITHIN NORMAL LIMITS:

ADRENAL GLANDS	AORTA	BONE MARROW (STERNUM)	BRAIN
CECUM	CERVIX	COLON	DUODENUM
ESOPHAGUS	EYES	ILEUM	JEJUNUM
KIDNEYS	LACRIMAL GLANDS	LUNG	LYMPH NODE, MESENTERIC
MAMMARY GLAND	MUSCLE, FEMORIS	NERVE, SCIATIC	OVARIES
OVIDUCTS	PANCREAS	PARATHYROID	RECTUM
SALIVARY GLANDS	SPINAL CORD, CERVICAL	SPINAL CORD, LUMBAR	SPINAL CORD, MIDTHORACIC
SPLEEN	STOMACH	THYMUS	THYROID
TRACHEA	URINARY BLADDER		

End of Record- ICN347

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

90-DAY SUBCHRONIC DERMAL TOXICITY STUDY IN RATS WITH SATELLITE GROUP
STUDY NUMBER 139910B - TEST MATERIAL MRD-92-399

Appendix II
Individual Animal Gross and Histomorphology Data

ANIMAL NUMBER: ICN352
SEX: F

DOSE GROUP: 5
DEATH TYPE: Scheduled Sacrifice

GROSS OBSERVATION(S):

GENERAL: No gross changes.

HISTOMORPHOLOGIC OBSERVATION(S):

Not applicable

HISTOMORPHOLOGIC OBSERVATIONS:

BONE (STERNUM):	necrosis, intersternal cartilage, focal (minimal)
SKIN (TREATED):	hyperplasia/hyperkeratosis, epidermis (minimal)
	hyperplasia, sebaceous glands (slight)
	fibrosis, dermal (slight)
SKIN (UNTREATED):	hyperkeratosis, epidermis (minimal)

THE FOLLOWING TISSUE(S) WERE WITHIN NORMAL LIMITS:

ADRENAL GLANDS	AORTA	BONE MARROW (STERNUM)	BRAIN
CECUM	CERVIX	COLON	DUODENUM
ESOPHAGUS	EYES	HEART	ILEUM
JEJUNUM	KIDNEYS	LACRIMAL GLANDS	LIVER
LUNG	LYMPH NODE, MESENTERIC	MAMMARY GLAND	MUSCLE, FEMORIS
NERVE, SCIATIC	OVARIES	OVIDUCTS	PANCREAS
PARATHYROID	PITUITARY	RECTUM	SALIVARY GLANDS
SPINAL CORD, CERVICAL	SPINAL CORD, LUMBAR	SPINAL CORD, MIDTHORACIC	SPLEEN
STOMACH	THYMUS	THYROID	TRACHEA
URINARY BLADDER	UTERUS		

End of Record- ICN352

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

90-DAY SUBCHRONIC DERMAL TOXICITY STUDY IN RATS WITH SATELLITE GROUP
STUDY NUMBER 139910B - TEST MATERIAL MRD-92-399

Appendix II
Individual Animal Gross and Histomorphology Data

ANIMAL NUMBER: ICN358
SEX: F

DOSE GROUP: 5
DEATH TYPE: Scheduled Sacrifice

GROSS OBSERVATION(S):

GENERAL: No gross changes.

HISTOMORPHOLOGIC OBSERVATION(S):

Not applicable

HISTOMORPHOLOGIC OBSERVATIONS:

HEART: fibrosis/myocarditis, chronic (minimal)
LIVER: infiltration, mononuclear-cell, multifocal (minimal)
SKIN (TREATED): hyperplasia/hyperkeratosis, epidermis (minimal)
hyperplasia, sebaceous glands (slight)
fibrosis, dermal (slight)
SKIN (UNTREATED): hyperkeratosis, epidermis (minimal)

THE FOLLOWING TISSUE(S) WERE WITHIN NORMAL LIMITS:

ADRENAL GLANDS	AORTA	BONE (STERNUM)	BONE MARROW (STERNUM)
BRAIN	CECUM	CERVIX	COLON
DUODENUM	ESOPHAGUS	EYES	ILEUM
JEJUNUM	KIDNEYS	LACRIMAL GLANDS	LUNG
LYMPH NODE, MESENTERIC	MAMMARY GLAND	MUSCLE, FEMORIS	NERVE, SCIATIC
OVARIES	OVIDUCTS	PANCREAS	PARATHYROID
PITUITARY	RECTUM	SALIVARY GLANDS	SPINAL CORD, CERVICAL
SPINAL CORD, LUMBAR	SPINAL CORD, MIDTHORACIC	SPLEEN	STOMACH
THYMUS	THYROID	TRACHEA	URINARY BLADDER
UTERUS			

End of Record- ICN358

**90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B**

**90-DAY SUBCHRONIC DERMAL TOXICITY STUDY IN RATS WITH SATELLITE GROUP
STUDY NUMBER 139910B - TEST MATERIAL MRD-92-399**

**Appendix II
Individual Animal Gross and Histomorphology Data**

ANIMAL NUMBER: ICN371
SEX: F

DOSE GROUP: 5
DEATH TYPE: Scheduled Sacrifice

GROSS OBSERVATION(S):

GENERAL: No gross changes.

HISTOMORPHOLOGIC OBSERVATION(S):

Not applicable

HISTOMORPHOLOGIC OBSERVATIONS:

ADRENAL GLANDS:

vacuolation, cortical, focal (minimal)

LIVER:

infiltration, mononuclear-cell, multifocal (minimal)

SKIN (TREATED):

hyperplasia/hyperkeratosis, epidermis (minimal)

hyperplasia, sebaceous glands (slight)

fibrosis, dermal (minimal)

SKIN (UNTREATED):

hyperkeratosis, epidermis (minimal)

THE FOLLOWING TISSUE(S) WERE WITHIN NORMAL LIMITS:

AORTA

BONE (STERNUM)

BONE MARROW (STERNUM)

BRAIN

CECUM

CERVIX

COLON

DUODENUM

ESOPHAGUS

EYES

HEART

ILEUM

JEJUNUM

KIDNEYS

LACRIMAL GLANDS

LUNG

LYMPH NODE, MESENTERIC

MAMMARY GLAND

MUSCLE, FEMORIS

NERVE, SCIATIC

OVARIES

OVIDUCTS

PANCREAS

PARATHYROID

PITUITARY

RECTUM

SALIVARY GLANDS

SPINAL CORD, CERVICAL

SPINAL CORD, LUMBAR

SPINAL CORD, MIDTHORACIC

SPLEEN

STOMACH

THYMUS

THYROID

TRACHEA

URINARY BLADDER

UTERUS

End of Record- ICN371

**90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B**

**90-DAY SUBCHRONIC DERMAL TOXICITY STUDY IN RATS WITH SATELLITE GROUP
STUDY NUMBER 139910B - TEST MATERIAL MRD-92-399**

**Appendix II
Individual Animal Gross and Histomorphology Data**

ANIMAL NUMBER: ICN375 DOSE GROUP: 5
SEX: F DEATH TYPE: Scheduled Sacrifice

GROSS OBSERVATION(S):

GENERAL: No gross changes.

HISTOMORPHOLOGIC OBSERVATION(S):

Not applicable

HISTOMORPHOLOGIC OBSERVATIONS:

BONE (STERNUM):	necrosis, intersternal cartilage, focal (slight)
KIDNEYS:	infiltration, mononuclear-cell, focal (minimal)
LIVER:	infiltration, mononuclear-cell, multifocal (minimal)
SKIN (TREATED):	hyperplasia/hyperkeratosis, epidermis (minimal)
	hyperplasia, sebaceous glands (slight)
	fibrosis, dermal (slight)
SKIN (UNTREATED):	hyperkeratosis, epidermis (minimal)
STOMACH:	dilatation, mucosal glands (slight)
THYROID:	follicle(s), cystic

THE FOLLOWING TISSUE(S) WERE WITHIN NORMAL LIMITS:

AORTA	BONE MARROW (STERNUM)	BRAIN	CECUM
CERVIX	COLON	DUODENUM	ESOPHAGUS
EYES	HEART	ILEUM	JEJUNUM
LACRIMAL GLANDS	LUNG	LYMPH NODE, MESENTERIC	MAMMARY GLAND
MUSCLE, FEMORIS	NERVE, SCIATIC	OVARIES	OVIDUCTS
PANCREAS	PARATHYROID	PITUITARY	RECTUM
SALIVARY GLANDS	SPINAL CORD, CERVICAL	SPINAL CORD, LUMBAR	SPINAL CORD, MIDTHORACIC
SPLEEN	THYMUS	TRACHEA	URINARY BLADDER
UTERUS			

TISSUE(S) NOT AVAILABLE FOR EVALUATION:

ADRENAL GLANDS

End of Record- ICN375

**90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B**

**90-DAY SUBCHRONIC DERMAL TOXICITY STUDY IN RATS WITH SATELLITE GROUP
STUDY NUMBER 139910B - TEST MATERIAL MRD-92-399**

**Appendix II
Individual Animal Gross and Histomorphology Data**

ANIMAL NUMBER: ICN380
SEX: F

DOSE GROUP: 5
DEATH TYPE: Scheduled Sacrifice

GROSS OBSERVATION(S):

LIVER: Median lobe at cleft- one tan embedded nodule.

UTERUS: Slight distention.

HISTOMORPHOLOGIC OBSERVATION(S):

lipidosis, tension, focal
infiltration, mononuclear-cell, multifocal
No microscopic change to correlate

HISTOMORPHOLOGIC OBSERVATIONS:

KIDNEYS:

infiltration, mononuclear-cell, focal (minimal)
fibrosis, focal (minimal)

LIVER:

lipidosis, tension, focal (moderate)
infiltration, mononuclear-cell, multifocal (minimal)

SKIN (TREATED):

hyperplasia/hyperkeratosis, epidermis (slight)
fibrosis, dermal (slight)

SKIN (UNTREATED):

hyperplasia, sebaceous glands (slight)

UTERUS:

hyperkeratosis, epidermis (minimal)
No microscopic change to correlate

THE FOLLOWING TISSUE(S) WERE WITHIN NORMAL LIMITS:

ADRENAL GLANDS

AORTA

BONE (STERNUM)

BONE MARROW (STERNUM)

BRAIN

CECUM

CERVIX

COLON

DUODENUM

ESOPHAGUS

EYES

HEART

ILEUM

JEJUNUM

LACRIMAL GLANDS

LUNG

LYMPH NODE, MESENTERIC

MAMMARY GLAND

MUSCLE, FEMORIS

NERVE, SCIATIC

OVARIES

OVIDUCTS

PANCREAS

PARATHYROID

PITUITARY

RECTUM

SALIVARY GLANDS

SPINAL CORD, CERVICAL

SPINAL CORD, LUMBAR

SPINAL CORD, MIDTHORACIC

SPLEEN

STOMACH

THYMUS

THYROID

TRACHEA

URINARY BLADDER

End of Record- ICN380

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

90-DAY SUBCHRONIC DERMAL TOXICITY STUDY IN RATS WITH SATELLITE GROUP
STUDY NUMBER 139910B - TEST MATERIAL MRD-92-399

Appendix II
Individual Animal Gross and Histomorphology Data

ANIMAL NUMBER: ICN386
SEX: F

DOSE GROUP: 5
DEATH TYPE: Scheduled Sacrifice

GROSS OBSERVATION(S):

HISTOMORPHOLOGIC OBSERVATION(S):

OVARIES: Left- surrounded by clear fluid-filled
sac.

cyst(s), intraovarian

HISTOMORPHOLOGIC OBSERVATIONS:

OVARIES:

cyst(s), intraovarian

SKIN (TREATED):

hyperplasia/hyperkeratosis, epidermis (minimal)

hyperplasia, sebaceous glands (minimal)

fibrosis, dermal (minimal)

SKIN (UNTREATED):

hyperkeratosis, epidermis (minimal)

THE FOLLOWING TISSUE(S) WERE WITHIN NORMAL LIMITS:

ADRENAL GLANDS
BRAIN
DUODENUM
ILEUM
LIVER
MUSCLE, FEMORIS
PARATHYROID
SPINAL CORD, CERVICAL
STOMACH
URINARY BLADDER

AORTA
CECUM
ESOPHAGUS
JEJUNUM
LUNG
NERVE, SCIATIC
PITUITARY
SPINAL CORD, LUMBAR
THYMUS
UTERUS

BONE (STERNUM)
CERVIX
EYES (1)
KIDNEYS
LYMPH NODE, MESENTERIC
OVIDUCTS
RECTUM
SPINAL CORD, MIDTHORACIC
THYROID

BONE MARROW (STERNUM)
COLON
HEART
LACRIMAL GLANDS
MAMMARY GLAND
PANCREAS
SALIVARY GLANDS
SPLEEN
TRACHEA

TISSUE(S) NOT AVAILABLE FOR EVALUATION:

EYES (1)

End of Record- ICN386

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP300 (MRD-92-399): 139910B

90-DAY SUBCHRONIC DERMAL TOXICITY STUDY IN RATS WITH SATELLITE GROUP
STUDY NUMBER 139910B - TEST MATERIAL MRD-92-399

Appendix II
Individual Animal Gross and Histomorphology Data

ANIMAL NUMBER: ICN397
SEX: F

DOSE GROUP: 5
DEATH TYPE: Scheduled Sacrifice

GROSS OBSERVATION(S):

GENERAL: No gross changes.

HISTOMORPHOLOGIC OBSERVATION(S):

Not applicable

HISTOMORPHOLOGIC OBSERVATIONS:

BONE (STERNUM):	necrosis, intersternal cartilage, focal (minimal)
KIDNEYS:	infiltration, mononuclear-cell, focal (minimal)
LUNG:	macrophages, alveoli, focal (slight)
SKIN (TREATED):	hyperplasia/hyperkeratosis, epidermis (minimal)
SKIN (UNTREATED):	hyperplasia, sebaceous glands (minimal)
	hyperkeratosis, epidermis (minimal)

THE FOLLOWING TISSUE(S) WERE WITHIN NORMAL LIMITS:

ADRENAL GLANDS	AORTA	BONE MARROW (STERNUM)	BRAIN
CECUM	CERVIX	COLON	DUODENUM
ESOPHAGUS	EYES	HEART	ILEUM
JEJUNUM	LACRIMAL GLANDS	LIVER	LYMPH NODE, MESENTERIC
MAMMARY GLAND	MUSCLE, FEMORIS	NERVE, SCIATIC	OVARIES
OVIDUCTS	PANCREAS	PARATHYROID	PITUITARY
RECTUM	SALIVARY GLANDS	SPINAL CORD, CERVICAL	SPINAL CORD, LUMBAR
SPINAL CORD, MIDTHORACIC	SPLEEN	STOMACH	THYMUS
THYROID	TRACHEA	URINARY BLADDER	UTERUS

End of Record- ICN397

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP 300 (MRD-92-399): 139910B

APPENDIX P - ANALYTICAL CHEMISTRY REPORT
STUDY 139910B
ANALYSIS OF MRD-92-399 IN PROPYLENE GLYCOL

SUMMARY

Samples of MRD-92-399 in propylene glycol were received by the Analytical and Fate Chemistry Department from the Compound Preparation Department at EBSI for concentration verification at four week intervals over the course of the study. Additionally, uniformity and stability of the test material in propylene glycol solutions were assessed as part of EBSI study 139910A. Analysis was performed using High Pressure Liquid Chromatography (HPLC) with UV detection.

SAMPLE PREPARATION

All samples were volumetrically diluted to a nominal concentration of 100 $\mu\text{g/mL}$ with methanol prior to analysis.

STANDARD PREPARATION

A single analytical standard of the test material was prepared in methanol at a concentration of approximately 100 $\mu\text{g/mL}$.

INSTRUMENT CONDITIONS

Sample and standards were analyzed by reverse phase HPLC using a Waters C18, $\mu\text{Bondapak}$ column (300 mm x 3.9 mm, 10 μ particles) with a mobile phase of 85:15 methanol:water at a flow rate of 1 mL/min. Peak detection was accomplished using a LDC/Milton Roy SM 4000 variable wavelength UV detector at a wavelength of 279 nm. Sample injection volume was 50 μL and was performed using a Waters WISP 712 or a Waters U6K manual injector. Data was acquired using Waters 820 Maxima Chromatography software.

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP 300 (MRD-92-399): 139910B

APPENDIX P - ANALYTICAL CHEMISTRY REPORT (Cont'd)

UNIFORMITY AND STABILITY

Uniformity and stability testing was performed prior to study initiation as part of study 139910A. Stability was determined after 1, 4, 8 and 15 days of room temperature storage at concentrations of 0.5% and 10%. Uniformity of these solution was determined by diluting and analyzing triplicate aliquots taken from the stability solutions on day 1 of the stability evaluation. The stability and uniformity results are presented in Table P-1.

CONCENTRATION VERIFICATION

Concentration verification was performed at weeks 1, 5, 9 and 13 and the results are shown in Table P-2.

RESULTS

Stability of the dose solutions was demonstrated for up to 15 days at room temperature with losses of less than 3% being observed. Excellent uniformity was demonstrated with the coefficients of variations being less than 2%. Concentration verification analysis indicated all samples analyzed were within 8% of the nominal concentrations and the dose group means were within 5% of the nominals.

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP 300 (MRD-92-399): 139910B

APPENDIX P - ANALYTICAL CHEMISTRY REPORT (Cont'd)
TABLE P-1
Stability and Uniformity of MRD-92-399 in Propylene Glycol
(Results in % w/v)

Study 139910B

<u>Sample</u>	<u>Day 0</u>	<u>Day 1(*)</u>	<u>Day 4</u>	<u>Day 8</u>	<u>Day 15</u>	<u>Difference</u> <u>Day 0-15</u>
0.5%	0.510	0.547	0.505	0.505	0.526	+3.1%
		0.549				
		<u>0.538</u>				
		$\bar{X} = 0.545$				
		SD = 0.006				
		%CV = 1.10				
10%	10.6	10.7	10.0	10.1	10.3	-2.8%
		10.7				
		<u>10.4</u>				
		$\bar{X} = 10.6$				
		SD = 0.2				
		%CV = 1.89				

* Triplicate sample aliquots analyzed for uniformity.

90-DAY SUBCHRONIC DERMAL STUDY IN THE RAT WITH SATELLITE GROUP
WITH IRGASAN DP 300 (MRD-92-399): 139910B

APPENDIX P - ANALYTICAL CHEMISTRY REPORT (Cont'd)

TABLE P-2

Concentration Verification Results
MRD-92-399 In Propylene Glycol
(Results in % w/v)

Study 139910B

	<u>WEEK</u>				
<u>Sample</u>	<u>1</u>	<u>5</u>	<u>9</u>	<u>13</u>	<u>Mean</u>
Control (Group 1)	-----Not Detected-----				
0.5% (Group 2)	0.535	0.518	0.521	0.499	0.518
2% (Group 3)	2.15	2.11	2.12	2.02	2.10
4% -1 (Group 4)	4.15	4.20	4.12	3.95	4.11
4% -2 (Group 4)	No Sample	4.29	4.32	3.77	4.13