Overview of the
Phenol/Sodium Phenate Preliminary Risk Assessment,
September 13, 2004

Introduction

This document summarizes EPA's preliminary human health and ecological risk findings and conclusions for the antimicrobial pesticide **phenol/sodium phenate**, as presented fully in the following nine documents:

1. Incidents reported with Phenol: Human Health Effect Report, PC Code 64001 and 64002, Case 4074, Antimicrobials Division, 7/24/04., Jonathan Chen, Ph.D.

2. Product Chemistry Science Chapter on Phenol. PC Code 64001 and 64002, Case 4074, Antimicrobials Division, 8/4/04, A. Najm Shamim, Ph.D.

3. Phenol/Sodium Phenate: Toxicology Disciplinary Chapter for the Reregistration Eligibility Decision Document, PC Code 64001 and 64002, Case 4074, Antimicrobials Division, 7/6/04, Michelle M. Centra, Pharmacologist and Timothy F. McMahon, Ph.D.

4. Phenol/Sodium Phenate: Dietary Exposure Assessments for the Reregistration Eligibility Decision. PC Code 64001 and 64002, Case 4074, Antimicrobials Division, 5/18/04, A. Najm Shamim, Ph.D.

5. Phenols Occupational/Residential Exposure Assessment. PC Code 64001 and 64002, Case 4074 Antimicrobials Division, 6/11/04, Timothy Leighton.

6. Report of the Antimicrobials Division Toxicology Endpoint Selection Committee. PC Code 64001 and 64002, Case 4074 Antimicrobials Division, 3/9/04, Timothy F. McMahon, Ph.D.

7. Science Chapter on: Environmental Fate Studies and Environmental Fate Assessment of Phenol. PC Code 64001 and 64002, Case 4074, Antimicrobials Division, 1/29/04, A. Najm Shamim, Ph.D.

8. Ecological Hazard and Environmental Risk Assessment: Phenol. PC Code 64001 and 64002, Case 4074, Antimicrobials Division, **7/28/04,** Kathryn Montague, M.S.

9. Phenols Preliminary Risk Assessment. PC Code 64001 and 64002, Case 4074, 7/7/04, Tim McMahon, Ph.D.

The purpose of this overview summary is to assist the reader by identifying the key features, findings, and conclusions of these risk assessments. This standard overview format was developed in response to comments and requests from the public which indicated that prior risk assessments for other chemicals were difficult to understand and too lengthy, as well as that it was not easy to compare the assessments for different chemicals due to the use of different formats.

Risks summarized in this document are those that result only from the use of Phenol/Sodium Phenate. The Food Quality Protection Act requires that the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity". The reason for consideration of other substances is due to the possibility that low level exposures to multiple chemical substances that cause a common toxic effect by a common mechanism could lead to the same adverse health effect as would a higher level of exposure to any of the other substances individually. Although it is possible that Phenol/Sodium Phenate may express toxicity through a common mechanism with other compounds, at this time, the Agency does not have sufficient reliable information to make this determination. Consequently, the risks summarized herein are only for Phenol/Sodium Phenate. If EPA identifies other substances that share a common mechanism of toxicity with Phenol/Sodium Phenate, aggregate exposure assessments will be performed on each chemical, followed by a cumulative risk assessment.

Once the risk assessments are available to the public, there will be an opportunity for the public to view them and to comment on them. Public comments may be submitted to the OPP electronic docket at: www.epa.gov/edocket under the docket number OPP-2004-0305. Meetings with stakeholders (e.g., registrants, distributors, etc.) are planned to discuss the identified risks and to solicit input on risk mitigation strategies. This feedback will be used to complete the Reregistration Eligibility Decision (RED) document, which will include the resultant risk management decisions. The Agency plans to conduct a closure conference call with interested stakeholders to discuss the final regulatory decisions presented in the RED.

PROFILE

ANTIMICROBIAL

Phenol is used as a surface cleaner in commercial-transportation facilities, institutions, industrial premises, eating establishments, indoor residential areas and medical premises.

The following information is based on the currently registered uses of Phenol/Sodium Phenate.

TYPE OF PESTICIDE

Sanitizer, bacteriostat, fungicide/fungistat, Tuberculocide, disinfectant, and Virucide

SUMMARY OF USE SITES

Indoor Food:
For use in Eating Establishments Equipment/ Utensils (Food Contact)

Indoor Non-Food Residential:
For use on Bathroom Premises, Hard Surfaces, Diaper Pails, Dogs/Canines, Household/Domestic Dwellings, Indoor Premises, Solid Waste Containers (Garbage Cans), Rugs, Carpets, Swimming Pool Related Surfaces,

Indoor Non-Food, Commercial & Industrial:
For use in Animal Cages, Commercial- Transportation Facilities, Buses, Boats, Trains, Airplanes, Automobiles, Ambulances Institutional/Industrial Floors, Industrial Premises/Equipment, Laundry Equipment, Veterinary Hospital Premises, Athletic Facilities.

Indoor non-food materials preservative:
For use in the preservation of Paints, Latex, Specialty Industrial Products, Metal Working Cutting Fluids, Coatings, Plastics, Polymers, Polyurethane, Synthetic Yarns, Polishes, Emulsions, Wax, Air Ducts.

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Indoor Medical:
For Use in Hospital- Critical Items (Surgical Instruments/Pacemakers), Hospital-Non Critical Items (Bedpans/Furniture, Hospital-Semi Critical Items(Catheters/Inhalation Equipment),Hospital/ Medical Institutions- Non conductive Floors, Critical Premises (Burn Wards), Noncritical Premises, Patient Premises, Institutions Premises (Human/Veterinary), Hemodialysis Machines.

TARGET PESTS:
Animal Pathogenic Bacteria (G- And G+ Vegetative), Pseudomonas SPP., Mycobacterium SPP. (Tubercle Bacilli), Animal Pathogenic Fungi, Hydrophilic Viruses, Polio virus Type 1, Parvo virus, Lipophilic Viruses, Vaccinia Virus, Influenza A2 (Hong Kong, Japan, Japan 305/57 Asian Strain), HIV- I (human Immunodeficiency Virus), Mold/Mildew

FORMULATION TYPES REGISTERED
Phenol/Sodium Phenate is formulated as a pressurized liquid (aerosol spray), as a liquid concentrate, as a ready-to-use liquid, and as an impregnated towelette.

METHOD AND RATES OF APPLICATION

Concentrations of phenol/sodium phenate in products range from 1.6% to 8.2%, 1.6% (being the most common concentration)

Sanitize Non-food Contact Surfaces: Before Treatment, clean surface of loose dirt. Spray 4 to 6 inches from surface for 3-4 seconds until covered with mist. Allow to air dry and remain undisturbed for 15 minutes.

Food Handling areas: Spray for use at start of day/ End of Day anti-microbial treatment on precleaned surfaces.

Hospital Use: Spray for use to precleaned or decontaminate critical or semi critical medical devices prior to sterilization or high level disinfection.

Disinfectant towelette contact times: HIV-1 (AIDS virus) on hard nonporous surfaces: Kills in one minute Staphylococcus aureus, Salmonella colorists. Pseudomonas aerogenes, Trichophylon mentagrophytes (Athlete's Foot fungus) on hard nonporous surfaces in 3 minutes.

Vegetative organisms including Streptococcus progenies, streptococcus solitarius, Escherichia coli, "Herpes Simplexs types 1/F and 2/G (oral, ocular and genital) Influenza A, Canine pavovirus, Cylomegalovirus, Coronavirus and Polio type 1 viruses on hard inanimate surfaces and Mycobacterium tuberculosis at 20 degrees Celsius/68 Degrees Fereignhieht, or above 10 minutes.

Dialysis Machines: Single Patient Delivery Systems. Place 150cc (5.04oz) into the hemdialysate system. Multipatinet Selivery Systems Place 3.0 liters (33.87 oz) into the hemdialysate system. Maintain product in system for minimum of 10 minutes.

Industrial Additive: Add 2-5% by weight of active ingredients.

TECHNICAL REGISTRANTS (There is no technical grade product registered with the EPA) The following companies have phenol products registered: Alphamed Pharmaceutical Corp., Pro-Clean Products, Ristex Biochemicals, Sporicidin International

CHEMICAL FORMULA AND MOLECULAR WEIGHT

C_6H_6O

MW = 94.144

HAZARD:

Phenol/Sodium Phenate has a moderate order of acute toxicity via the oral and dermal routes of exposure (Toxicity Category II or III) and produces severe and marked irritation to the eyes and skin (Toxicity Category I or II). Phenol concentrations used in acute inhalation studies failed to induce mortality in the study animals. Therefore, toxicity endpoints and a toxicity category could not be established.

Phenol/Sodium Phenate was administered in two developmental guideline studies in the rat and mouse at concentrations of 30, 60, or 120 mg/kg/day and 70, 140, or 280 mg/kg/day, respectively. There was no evidence of toxicity in these animals at concentrations below the high dose. Fetal body weight was significantly reduced at 120 and 280 mg/kg/day in both rat and mouse studies. Additionally, female mice experienced increased mortality and clinical signs of central nervous system toxicity (tremors, ataxia, lethargy) at the high-dose (280 mg/kg/day). In a non-guideline developmental study (Kavlock, 1990), there were decreases in rat maternal body weight gain in maternal and offspring.

In a 2-generational reproductive study in rats exposed to 200, 1000, or 5000 ppm phenol in drinking water for 10 weeks/generation, there were decreases in water and food consumption, body weight and body weight gain at the high-dose (potential reduced palatability). Offspring toxic effects including decreases in body weight and litter survival were observed at 5000. This occurred concurrently with maternal toxicity (decreased maternal body weight); believed to be secondary to the animals' aversion to the flavor of phenol-treated water and resulted in decreased maternal as well as offspring body weight. In a non-guideline reproductive study (Bishop, et al. 1997) phenol was administered to mice at a concentration of 350 mg/kg. There were no treatment-related clinical signs or mortality observed in maternal, reproductive, and developmental parameters sand the LOAEL was not established (highest dose tested, 350 mg/kg).

Two carcinogenicity studies performed by the National Cancer Institute did not exhibit an incidence of neoplasms in male and female mice or rats following administration of phenol, with the exception of a statistically significant increase in the occurrence of leukemia, lymphoma, or interstitial-cell tumors in low-dose male rats. Due to the lack of significant tumors in high-dose males and the absence of significant neoplasms in mice and female rats, phenol was found to be non-carcinogenic in the 2-year drinking water studies. Although phenol-treated rats and mice experienced a decrease in mean body weight and body weight gain, the reduction was not significantly different from the respective controls and chronic toxicity was not observed at phenol concentrations up to 5000 ppm. A 20-week dermal study exhibited effects of chronic irritation and hair growth inhibition with administration of 3 mg phenol (in 200 uL acetone). A single papilloma was found 7 weeks into the study, but there was no evidence that it was significantly increased or treatment-related. In a special, mechanistic study there was no evidence of tumor initiation or hepatocyte GSH depletion following administration of 100 mg/kg/day phenol.

TOXICITY ENDPOINTS

The toxicity endpoints used in this document to assess potential risks include the chronic dietary reference dose (RfD), and short-, intermediate- and/or long-term incidental oral, dermal, and inhalation doses. The endpoints selected were reviewed by the ADTC in 2004.

Dietary Endpoints: The chronic RfD value was calculated to be 0.6 mg/kg/day, based on a developmental No Observable Adverse Effects Level (NOAEL) value of 60 mg/kg/day and an uncertainty factor of 100 (10x interspecies extrapolation, 10x intraspecies variation).

Dermal Endpoints: The Developmental Toxicity NOAEL of 60 mg/kg/day was selected for short- and intermediate-term dermal risk assessments from a developmental toxicity study in rats (Jones-Price, Ledoux, Reel, et al. 1983) based on a significant reduction from the control in mean fetal body weight/litter at the LOAEL of 120 mg/kg/day. A dermal absorption factor of 50% is used since an oral endpoint was selected. A target margin of exposure (MOE) of 100 was selected for the dermal risk assessment, based on 10x for differences among humans (intra species variability) and 10x for differences between the test animals and humans (inter species extrapolation).

Inhalation Endpoints: The endpoint used for inhalation risk assessment is a LOAEL of 0.1 mg/L from a published inhalation toxicity study (Dalin and Kristoffersson (1974)) based on alterations in sliding angle from tilting plane test, and significant increases in liver enzymes. An uncertainty factor of 300 is applied to this risk assessment for short- and intermediate-term risk assessments (10x interspecies extrapolation, 10x intraspecies variation, 3x for use of a LOAEL). For long-term risk assessments, an uncertainty factor of 1,000 is applied to the risk assessment (10x interspecies extrapolation, 10x intraspecies variation, 3x for use of a LOAEL, 3x for lack of a long-term study).

FQPA SAFETY FACTOR

On March 9, 2004, the ADTC reviewed the available toxicology data for phenol and discussed endpoint selection for use as appropriate in occupational/ residential exposure risk assessments. The ATDC determined that for acute dietary risk, there was no appropriate endpoint for assessment. The conclusion was based upon examination of the hazard data which might be used in support of such an endpoint. Body weight effects observed are not believed to be the result of a single exposure, and there were no other effects from the data that were considered reflective of an adverse effect from a single exposure. An acute RfD value was not selected.

For chronic dietary risk, the ATDC cited the published chronic RfD value in EPA's Integrated Risk Information System (IRIS) database. This RFD value is based upon an unpublished developmental toxicity study conducted according to GLP guidelines (Argus Research Laboratories, 1977). The chronic RfD value was determined to be 0.6 mg/kg/day. The ATDC determined that a special hazard-based safety factor was not required for phenol and could be reduced to 1x.

Based on Agency policy, a RfD modified by a FQPA safety factor is a population adjusted dose (PAD). The Agency calculated a chronic PAD, and used this value to estimate chronic dietary risk. The chronic PAD (cPAD) is the chronic RfD divided by the FQPA safety factor.

HUMAN HEALTH RISK ASSESSMENT

DIETARY (FOOD) RISK ASSESSMENTS

Dietary Exposure: The Agency has conducted a dietary exposure and risk assessment for use of phenol in a ready-to-use solution and in a wettable disposable cloth impregnated with phenol and sodium phenate. A counter top that is treated with either of these products may come into contact with food, which in turn may be ingested. An acute RfD value was not selected, thus the acute dietary risk was not evaluated. For chronic dietary exposure, children had the highest percentage of the chronic PAD, at 363%, which exceeds the Agency's level of concern (100% cPAD). For adult males and females, the dietary exposure is 90.7% and 77.8%, respectively, which is below the Agency's level of concern (100% of aPAD or cPAD).

Water Exposure and Risk: Phenol's use in the production of resins and other manufacturing industries, pulp mills, wood treatment facilities, and as a general disinfectant allows for the possibility of ground and surface water contamination. Despite phenol's high water solubility and poor sorption to soil, biodegradation of phenol is sufficiently rapid so that the probability of groundwater contamination will be low. Because phenol absorbs light in the region of 290-330 nm, phenol might photo degrade directly in surface water. Phenol is not expected to absorb to sediment in the water column.

Cumulative Chronic Dietary Risk - Cumulative chronic dietary risk estimates from indirect food uses (i.e., exposure to disinfectant solutions and room deodorizers) were calculated to be 36% for children, 9.0% for adult females, and 7.5% for adult males, indicating **no risk of concern** from dietary exposure

RESIDENTIAL EXPOSURE

Phenols and salts are formulated as a soluble concentrate, towelette, ready-to-use solution an aerosol spray. Based on product labels, all formulations are liquid. The following scenarios were considered for residential handlers of phenol-containing products: (1) application of paint treated with a material preservative using paintbrush/roller, (2) use of disinfectant/deodorizing spray on hard non-porous surfaces, and (3) use of disinfectant towelette on hard non-porous surfaces. Inhalation and dermal exposures were addressed for residential populations using surrogate data from the Chemical Manufacturers Association (CMA, 1992), and several studies which relate to the use patterns of PHMB. Using surrogate unit exposure data, application rates from labels, and EPA estimates of daily amount handled, exposure and risks to handlers and post-application workers were assessed. At this time, EPA does not have available chemical-specific handler or post-application exposure studies that meet Agency guidelines.

The calculated inhalation MOE's for all three scenarios are above the target MOEs of 1,000.

The calculated dermal MOEs for the following scenarios were below the target MOE of 100, and are therefore of concern: painting using a paintbrush/roller (MOE = 18.3) and wiping hard surfaces using a towelette (MOE = 41.0).

Residential post-application exposures (adults and children) are expected to be minimal because the majority of exposure is expected occur through contact with dry surfaces (e.g. paints) and the end use products are expected to be diluted. The residential post-application scenario considered in this assessment is exposure to residue from carpets that have been machine-cleaned with a product containing phenol (and phenol salts). While the label also indicates that the product may be sprayed directly onto carpet, this scenario was not evaluated due to lack of data regarding application rates. In general, dermal exposure to residues in treated carpet should be limited to contact on bare feet. However, there is also potential exposure to undressed toddlers. The dermal MOEs calculated is below the target MOE of 100. However, the potential daily dose calculated is extremely conservative, due to a lack of supporting data. The dose should not be considered indicative of the true values associated with this type of exposure. .

AGGREGATE EXPOSURE AND RISK

In order for a pesticide registration to continue, it must be shown that the use does not result in "unreasonable adverse effects on the environment". Section 2 (bb) of FIFRA defines this term to include "a human dietary risk from residues that result from a use of a pesticide in or on any food inconsistent with standard under section 408..." of FFDCA. Consequently, even though no pesticide tolerances have been established for phenol, the standards of FQPA must still be met, including "that there is reasonable certainty that no harm will result from aggregate exposure to pesticide chemical residue, including all anticipated dietary exposures and other exposures for which there are reliable information." Aggregate exposure is the total exposure to a single chemical (or its residues) that may occur from dietary (i.e., food and drinking water), residential, and other non-occupational sources, and from all known or plausible exposure routes (oral, dermal, and inhalation). Aggregate risk assessments were conducted for acute (1 day), short-term (1-30 days), intermediate-term (1-6 months) and chronic (several months to lifetime) exposures.

Dermal Aggregate Exposure: Aggregate risk assessments were considered for three short-, intermediate and long-term exposure scenarios for adults exposed to phenol and phenol salts as a result of residential handling, including: (1) application of paint treated with a material preservative using paintbrush/roller, (2) use of disinfectant/deodorizing spray on hard non-porous surfaces, and (3) Use of disinfectant towelette on hard non-porous surfaces.

The dermal MOE calculated for the paintbrush/roller application is 18.3. The dermal MOE calculated for the disinfectant/deodorizing spray is 41.0. Because these dermal MOEs are below the target MOE of 100, the application of treated paints with a material preservative using a paintbrush/roller by adults and the use of disinfectant/deodorizing spray on hard non-porous surfaces by adults, are risks of concern. As a result, an aggregate risk assessment of the application of paint or the use of the disinfectant/deodorizing spray in conjunction with another activity (i.e. the use of a disinfectant towelette on hard non-porous surfaces) would not be required to show that a composite of activities is also below the target MOE of 100.

The dermal MOEs calculated for the disinfectant towelettes on hard non-porous surfaces is 871,000. Because the dermal MOE is above the target MOE of 100, the use of

disinfectant/deodorizing spray on hard non-porous surfaces by adults, in itself, is not a significant risk. However, for other possible applications of phenol and phenol salts, the dermal MOE is below the target MOE of 100. As a result, an aggregate risk assessment, including the use of disinfectant/deodorizing spray on hard non-porous surfaces in conjunction with another activity (i.e. application of paint treated with a material preservative using paintbrush/roller or the use of a disinfectant towelette on hard non-porous surfaces) is not needed to demonstrate that a combination of two activities would be below the target MOE of 100.

Inhalation Aggregate Exposure: In two of the three adult exposure scenarios considered, the dermal MOEs were below the target MOE of 100 and demonstrate a concern of risk for these scenarios. The calculated inhalation MOEs for these same scenarios exceed the target MOE of 1,000. However, because the dermal MOEs already demonstrate a concern of risk for these scenarios, an aggregate of inhalation exposure to restate a concern of risk for these scenarios is not required.

OCCUPATIONAL EXPOSURE

A detailed human exposure risk assessment for phenol and phenol salts is provided in the Appendix. The summary of the occupational exposures are presented below.

Inhalation and dermal exposures were addressed for occupational populations using surrogate dat from the chemical Manufacturers Association (CMA, 1992) and PHED. Using surrogate unit exposure data, application rates from labels, and EPA estimates of daily amount handled, exposure and risks to handlers and post-application workers were addressed. At this time, EPA has not identified post-application scenarios for commercial uses that are not addressed by the residential post-application exposure assessment (e.g., contacting treated surfaces are represented by children's incidental oral and dermal exposures while crawling on treated surfaces such as carpets).

Six commercial/institutional scenarios have been considered in this assessment:

1. Use of disinfectant solutions in hemodialysis machines,
2. Application of paint treated with a material preservative using airless sprayer,
3. Application of paint treated with a material preservative using paintbrush/roller.
4. Use of disinfectant/deodorizing spray on hard non-porous surfaces.
5. Use of disinfectant towelette on hard non-porous surfaces.
6. Use as a material preservativeas a liquid pour.

For hemodialysis machines, the label indicates that the product can be used in single-patient and multiple-patient delivery systems. The use of this product in multi-patient delivery systems was chosen for evaluation since it involves a greater volume of product (1.0 L vs. 0.150mL) than the single-patient delivery system. It was assumed that the machines are disinfected daily and on average, a worker handles 3 machines per day.

One phenol product is listed for use as an industrial additive, and lists paint as a possible use. The label recommends 2%-5% by active ingredients be added. As a conservative measure, it is assumed that the treated paint is comprised of 5% active ingredient, by weight. Assuming that paint

has a density of 10 lbs per gallon, the concentration of phenols in paint is 0.5 lbs a.i./gallon. For the material preservative use of phenol, primary handlers adding the product during the manufacturing of paint has been selected to represent the high end of exposure for the primary handlers. It is assumed that paint is produced in 1,000 gallon batches (i.e., 10,000 lbs.). In addition, paint also has been selected to represent the high end of the exposures for the secondary handlers. Two painting scenarios were considered in this assessment: use of an airless sprayer (50 gallons per day) and use of a paintbrush/roller (5 gallons per day) to paint the exterior of a house.

The sprays and the solution used to treat the towelette contain 1.62% phenol/sodium phenate. It was assumed that the density of this solution is the same as the density of water. The label for the towelette product did not describe the quantity of product to be used, rather, the directions state that towelette to be used to wipe the surface, and then the surface should be wiped dry. In the absence of more specific use information, it was assumed that 1 liter of the solution used to wet the towelette is used by the exposed individual per day. Similarly, the aerosol spray directions state that the product can be sprayed 2-4 seconds to deodorize a room, but no data were available describing the quantity that is emitted by spraying for this time. Therefore, 1 liter of solution also was assumed for use of the aerosol spray.

The estimated short- and intermediate-term dermal MOEs for the following scenarios were below the target MOE of 100, and are therefore of concern.

6. Painting using an airless sprayer, with chemical resistant gloves (MOE= 21); and
7. Wiping hard surfaces using a towelette (MOE = 70)

The estimated short- and intermediate-term inhalation MOEs for the following scenarios were below the target MOE of 300, and are therefore of concern:

8. Painting using an airless sprayer (MOE = 88).

INCIDENT REPORT ASSESSMENT

A total of 10 individual human incident cases submitted to the EPA Office of Pesticide Programs are associated with exposed to phenol and/or sodium phenate containing products. Dermal and inhalation are the two primary route of exposure.

The most common symptoms reported for cases of dermal exposure were skin irritation/burning , rash , itching , skin discoloration/redness.

The most common symptoms reported for cases of inhalation exposure were respiratory irritation/burning, asthma/difficult breathing, throat /chest congestion and sore throat. Headache, drowsiness, night sweats and heart palpitation have also been reported when expose to the chemical through both dermal and inhalation exposure routes.

ECOLOGICAL RISK ASSESSMENT

III. ENVIRONMENTAL FATE ASSESSMENT

Phenol appears to have degradation pathways in air (calculated half life less than a day) water (measured half life less than a day), aerobic and anaerobic soils (degradation half lives less than 5 days). It is not likely to bio-accumulate in aquatic organisms**.** (Measured BCF in goldfish is 0.28 and 1.3 in golden orfe). Data on plants show that due to a high respiratory decomposition of phenol into carbon dioxide (mineralization), it is also not likely to accumulate in plants. Due to multi media degradation pathways, phenol is not likely to be an environmental concern.

IV. ECOLOGICAL/ENVIRONMENTAL RISK ASSESSMENT

Phenol/Sodium Phenate is registered with EPA as an active product and is used as an intermediate in the production of epoxy resins, the production of various other products, as a general disinfectant and in medicinal preparations. For the reregistration eligibility decision (RED) process the Agency has relied on open literature and fate properties of Phenol from open literature.

Phenol and sodium phenate also are used as sanitizers, primarily for hard surfaces and as materials preservatives. Outdoor uses, such as swimming pool waters and intermittently flooded areas, were once registered uses for phenol and sodium phenate, but are no longer supported by any registrants.

Terrestrial Animals - For indoor uses, an acute oral toxicity study using the technical grade of the active ingredient (TGAI) is required to establish the toxicity of phenol to birds. The preferred test species is either mallard duck (a waterfowl) or northern bobwhite quail (an upland game bird). No avian acute toxicity studies were identified in the reviewed literature for phenol and its salts. Avian acute oral toxicity testing (850.2100/71-1) is required to support the currently registered uses of phenol/sodium phenate. Avian dietary toxicity studies using the TGAI of phenol and sodium phenate are not required for the indoor uses of phenol/sodium phenate.

Freshwater Fish - Freshwater fish toxicity studies using the TGAI to establish the toxicity of phenol to fish. Data generally are required for only one species. Testing in two fish species is required for stable chemicals with high volume effluents (e.g., including, but not limited to, egg washing, fruit and vegetable rinses, swimming pools or materials preservatives) and if the LC_{50} in the first species is greater than(> 1 ppm. The preferred test species are rainbow trout (a coldwater fish) and bluegill sunfish (a warmwater fish), although other test species identified in OPPTS Guideline (i.e., 850.1075 (e)(4)(i)(A)) also may be used. Many freshwater fish acute toxicity studies were identified from peer-reviewed literature, but no studies have been submitted to support registration of phenol/sodium phenate. **Freshwater fish acute toxicity testing (850.1075/72-1) on one species is required to support the currently registered uses of phenol/sodium phenate.**

Acute toxicity for freshwater fish ranged from 5 mg/L (rainbow trout) to 23.9 mg/L (bluegill), with average values of 9.1 mg/L for rainbow trout and 17.1 mg/L for bluegill. These data indicate the phenol is moderately toxic to coldwater species, such as the rainbow trout, and slightly toxic to warmwater species, such as the bluegill.

RISK TO ENDANGERED SPECIES

The Agency has developed the Endangered Species Protection Program to identify pesticides whose use may cause adverse impacts on endangered and threatened species, and to implement mitigation measures that address these impacts. The Endangered Species Act requires federal agencies to ensure that their actions are not likely to jeopardize listed species or adversely modify designated critical habitat. To analyze the potential of registered pesticide uses to affect any particular species, EPA puts basic toxicity and exposure data developed for risk assessments into context for individual listed species and their locations by evaluating important ecological parameters, pesticide use information, the geographic relationship between specific pesticide uses and species locations, and biological requirements and behavioral aspects of the particular species. A determination that there is a likelihood of potential impact to a listed species may result in limitations on use of the pesticide, other measures to mitigate any potential impact, or consultations with the Fish and Wildlife Service and/or the National Marine Fisheries Service as necessary.

Based on the low likelihood of environmental exposure from the registered indoor uses, coupled with phenol's rapid degradation in air, water, and soil, as well as the low toxicity of phenol to fish, aquatic invertebrates, and aquatic plants, adverse impacts to endangered species are not expected from the registered uses of phenol/sodium phenate.