



Fatty Acid Monoesters with Glycerol or Propanediol

PC Codes:

011292 - Glycerol Monocaprylate (octanoic acid monoester with 1,2,3-propanetriol)

011291 - Glycerol monocaprate (decanoic acid monoester with glycerol)

011290 - Glycerol monolaurate (dodecanoic acid monoester with glycerol)

082074 - Propylene glycol monocaprylate (octanoic acid monoester with 1,2-propanediol)

011289 - Propylene glycol monocaprate (decanoic acid monoester with 1,2-propanediol)

011288 - Propylene glycol monolaurate (dodecanoic acid monoester with 1,2-propanediol)

Preliminary Work Plan and Summary Document Registration Review: Initial Docket

Case 6016

September 2017

Approved by:

A handwritten signature in black ink, appearing to read "Robert McNally", is written over a horizontal line.

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9/28/17

Date

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ACRONYMS AND ABBREVIATIONS

AI or a.i.	Active Ingredient
AD	The EPA's Antimicrobial Division
BPPD	The EPA's Biopesticides and Pollution Prevention Division
C.F.R.	Code of Federal Regulations
DCI	Data Call-In
EDSP	Endocrine Disruptor Screening Program
EPA	U.S. Environmental Protection Agency
FFDCA	Federal Food, Drug, and Cosmetic Act
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FQPA	Food Quality Protection Act
FR	Federal Register
FWP	Final Work Plan
IDS	Incident Data System
MRID No.	Master Record Identification Number: The EPA's system of recording and tracking studies submitted to the Office of Pesticide Programs.
MRL	Maximum Residue Limit
OPP	The EPA's Office of Pesticide Programs
PC Code	Pesticide chemical code: a six-digit number assigned by OPP to identify pesticide chemicals.
PWP	Preliminary Work Plan
TGAI	Technical grade of the active ingredient
TMDL	Total Maximum Daily Load
US	United States

I. PRELIMINARY WORK PLAN

A. Overview

The docket (EPA-HQ-OPP-2017-0353) for fatty acid monoesters is now open, initiating the first public comment period for this registration review case (case number 6016). This registration review case includes the following pesticide active ingredients: Glycerol monocaprylate (octanoic acid monoester with 1,2,3-propanetriol), Glycerol monocaprinate (decanoic acid monoester with glycerol), Glycerol monolaurate (dodecanoic acid monoester with glycerol), Propylene glycol monocaprylate (octanoic acid monoester with 1,2-propanediol), Propylene glycol monocaprinate (decanoic acid monoester with 1,2-propanediol), and Propylene glycol monolaurate (dodecanoic acid monoester with 1,2-propanediol). These active ingredients were grouped into one registration review case pursuant 40 CFR Part 155.42(a). These substances consist of three glycerol and three propylene glycol monoesters, which all contain the same fatty acids (C8, C10, and C12 straight chain saturated fatty acids). The fatty acid monoesters work by disrupting microbial and mite membranes and likely strips the cuticles of the insect/microbe.

Products containing the fatty acid monoesters are registered for both antimicrobial and biopesticide use. The registered antimicrobial use is as a preservative in industrial and institutional products including: oils, lubricants, solvents, non-potable/nonfood water systems, detergents, cleaners, and surfactants. The registered biochemical use is for use on food and feed crops before harvest to protect against mites, and after harvest to prevent microbial damage during storage. There are eleven currently registered fatty acid monoester products, of which, nine are classified as biopesticides and two are classified as antimicrobial pesticides.

This preliminary work plan (PWP) explains what the U.S. Environmental Protection Agency's (EPA) Office of Pesticide Programs (OPP) knows about the fatty acid monoesters, highlights its anticipated data and assessment needs, identifies the types of information that would be especially useful in conducting the review, and provides an anticipated timeline for completing the registration review process for the fatty acid monoesters.

The registration review process was designed to include a public participation component and, by sharing this information in the docket, EPA intends to inform the public of what it knows about the fatty acid monoesters and what types of new data or other information would be helpful to receive as it moves toward a decision on this compound. The EPA encourages all interested stakeholders to review the PWP and to provide comments and additional information that will help the EPA's decision-making process for this biochemical pesticide. Interested stakeholders could include the following: environmental nonprofit or interest groups; pesticide manufacturers; agricultural labor or commodity groups; commercial, institutional, residential, and other users of pesticides; or the public at large. In addition to general areas on which persons may wish to comment, there are some areas identified in the PWP about which the EPA specifically seeks comments and information.

The PWP begins by describing the statutory and regulatory authorities for registration review. Next, it provides background on the fatty acid monoesters, which includes a description of its mode of action, the currently registered pesticide products, application rates and methods, use sites, and tolerance exemption information. Then, it lists the anticipated data needs, risk assessments, and a projected registration review timeline for this case. Finally, the PWP provides guidance for commenters, explains the next steps EPA will be taking, summarizes background information, and lists supporting studies, risk assessments, and other documents available for the registration review of the fatty acid monoesters.

Further information about this case, including background and supporting documents, is available at <http://www.regulations.gov> (under “SEARCH for: Rules, Comments, Adjudications or Supporting Documents,” enter the docket identification number, which is indicated above).

B. Statutory and Regulatory Authority

The Food Quality Protection Act (FQPA) of 1996 mandated a registration review program. All pesticides distributed or sold in the United States (US) must generally be registered by the EPA, based on scientific data showing that they will not cause unreasonable risks to human health or the environment when used as directed on the product labeling. The registration review program is intended to make sure that, as the ability to assess risk evolves and as policies and practices change, all registered pesticides continue to meet the statutory standard of no unreasonable adverse effects to human health or the environment. Changes in science, public policy, and pesticide use practices will occur over time. Through the Registration Review program, the EPA periodically reevaluates pesticides to make sure that, as change occurs, products in the marketplace can continue to be used safely. Information on this program is provided on the EPA’s website. (See <http://www2.epa.gov/pesticide-reevaluation> .)

The EPA is implementing the registration review program pursuant to Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) section 3(g), and will review each registered pesticide every 15 years to determine whether it continues to meet the FIFRA standard for registration. The regulations governing registration review begin at 40 C.F.R. § 155.40. The EPA will consider benefits information and data as required by FIFRA. The public phase of registration review begins when the initial docket is opened for each case. The docket is the EPA’s opportunity to state what it knows about the pesticide and what additional risk analyses and data or information it believes are needed to make a registration review decision. After reviewing and responding to comments and data received in the docket during this initial comment period, the EPA will develop a Final Work Plan (FWP) and the anticipated schedule for the registration review of fatty acid monoesters.

C. Background and Regulatory Information

i. Summary of the Active Ingredient, Usage and Associated Pesticide Products

The substances discussed in this PWP belong to the family of chemicals commonly referred to as the fatty acid monoesters. This registration review case only covers the glycerol and propylene glycol fatty acid monoesters. The glycerol fatty acid monoesters (glycerol monocaprylate, glycerol monocaprate, and glycerol monolaurate) occur naturally in all living organisms, while propylene glycol fatty monoesters (propylene glycol monocaprylate, propylene glycol monocaprate, and propylene glycol monolaurate) are synthetically manufactured. All fatty acid monoesters discussed in this document have been found to display similar toxicity and are metabolized by the same metabolic pathways. Products containing fatty acid monoesters as pesticide active ingredients are registered for use as preservatives, surface cleaners and on food crops (pre-harvest to protect against mites and post-harvest to prevent microbial damage during storage). Furthermore, the polyglycerol esters are approved by the Food and Drug Administration (FDA) for use in/on food and feed (21 C.F.R. 172.854).

The six fatty acid monoesters discussed here were initially registered under FIFRA as manufacturing-use products (MPs) on September 30, 2003, by 3M Corporation (April 14, 2004; FRL-7352-4).

On June 23, 2004, EPA published a FRN to establish an exemption from the requirement of a tolerance for the fatty acid monoesters, and to eliminate the requirement of a tolerance for the fatty acid monoesters of glycol and propylene glycol (EPA-OPP-2003-0379; FRL-7352-6).

On September 21, 2005, EPA published a FRN to modify the previous tolerance exemption dated June 23, 2004, in order to amend the existing tolerance exemption to allow post-harvest uses of fatty acid monoesters of glycol and propylene glycol (EPA-OPP-2004-0344; FRL-7719-7).

The C8, C10, and C12 straight – chain fatty acid monoesters of glycerol (glycerol monocaprylate, glycerol monocaprate, and glycerol monolaurate) and propylene glycol (propylene glycol monocaprylate, propylene glycol monocaprate, and propylene glycol monolaurate) are exempt from the requirement of a tolerance in or on all food commodities when used in accordance with approved label rates and good agricultural practice. [69 FR 34944, June 23, 2004]

Table 1.0 provides a summary of the chemical facts for the fatty acid monoesters discussed in this PWP:

Table 1. Chemical Facts for Fatty Acid Monoesters with Glycerol or Propandiol						
Name	Propylene Glycol monolaurate dodecanoic acid monoester with 1,2-propanediol	Propylene glycol monocaprate	Glycerol monolaurate	Glycerol monocaprate	Octanoic acid, monoester with 1,2,3-propanetriol	Octanoic acid, ester with 1,2-propanediol
PC code	011288	011289	011290	011291	011292	082074
Case Number	6016					
CAS Number	27194-74-7	68795-69-7	27215-38-9	26402-22-2	26402-26-6	68332-79-06
Year first registered	2003					
Pesticide Type	Preservative, Disinfectant, Miticide and Antimicrobial (e.g., fungicide and bactericide)					
Chemical class	Biochemical and Antimicrobial					
Reregistration Eligibility Decision (RED)	Not applicable; the fatty acid monoesters were registered after November, 1984, and thus were not subject to reregistration.					
Tolerance Reassessment Eligibility Decision (TRED)	None					
Cumulative group	Esters					

Table 1. Chemical Facts for Fatty Acid Monoesters with Glycerol or Propandiol	
40 CFR Citation	40 C.F.R. §180.1250 C8, C10, and C12 fatty acid monoesters of glycerol and propylene glycol; exemption from the requirement of a tolerance. The C8, C10, and C12 straight – chain fatty acid monoesters of glycerol (glycerol monocaprylate, glycerol monocaprinate, and glycerol monolaurate) and propylene glycol (propylene glycol monocaprylate, propylene glycol monocaprinate, and propylene glycol monolaurate) are exempt from the requirement of a tolerance in or on all food commodities when used in accordance with approved label rates and good agricultural practice. [69 FR 34944, June 23, 2004]
Non-pesticidal uses	shampoos, conditions, lotions, facial cleansers and make-up.

Table 2. Use Information for Fatty Acid Monoesters with Glycerol or Propandiol	
Summary of Use	Broad spectrum preservative registered for use to control organisms that cause spoilage and decay.
Use Sites	Biopesticide: It is registered for use on food and feed crops before harvest to protect against mites, and after harvest to prevent microbial damage during storage.
	Antimicrobial: It is registered for use as a preservative in industrial and institutional products including; oils, lubricants, solvents, non-potable/nonfood water systems, detergents, cleaners, and surfactants.
Summary of Usage	EPA has no available usage data for fatty acid monoesters.
Formulation Types	Liquid
Application Method	Conventional spray and submerge in diluted solution.
Technical Registrant	3M Corporation
No. of Registrations	11 (7 manufacturing-use products and 4 end-use products).
Restricted Use	No

Table 3. Information About the Currently Registered Fatty Acid Monoesters with Glycerol or Propandiol					
EPA Registration Number	Product Name (% Active Ingredient; Formulation Type)	Date Registered	Application Rates	Application Methods	Use Sites
10350-68	VWX-42 Technology glycerol monocaprinate	September 30, 2003	Manufacturing technical use product.	Formulation into end use products, broad spectrum antimicrobial agent.	Post-harvest use on crops (e.g., fruits and vegetables).

Table 3. Information About the Currently Registered Fatty Acid Monoesters with Glycerol or Propandiol

EPA Registration Number	Product Name (% Active Ingredient; Formulation Type)	Date Registered	Application Rates	Application Methods	Use Sites
	(88.21% - Octanoic acid) VWX-42 Technology glycerol monocaprate (1.43% - Glycerol monocaprate)				
10350-67	VWX-42 Technology Propylene Glycol Monolaurate (75.85% - Propylene Glycol Monolaurate)	September 30, 2003	Manufacturing technical use product.	For use in end use products for post-harvest treatment of crops and foods.	Post-harvest use on crops (e.g., fruits and vegetables).
10350-66	VWX-42 Technology Propylene Glycol Monocaprate (71.37% - Propylene Glycol Monocaprate) (.59% - Propyleneglycol monolaurate) (0.77% - Octanoic acid)	September 30, 2003	Manufacturing technical use product.	Formulation into end use products, broad spectrum antimicrobial agent.	Post-harvest use on crops (e.g., fruits and vegetables).
10350-65	VWX-42 Technology glycerol monocaprate (.11% - Glycerol monocaprate) (93.5% - Glycerol monolaurate)	September 30, 2003	Manufacturing technical use product.	Formulation into end use products for postharvest treatment of crops and food.	Post-harvest use on crops (e.g., fruits and vegetables).
10350-64	VWX-42 Technology glycerol monocaprate	September 30, 2003	Manufacturing technical use product.	Formulation into end use products for postharvest treatment of crops and food.	Post-harvest use on crops (e.g., fruits and vegetables).

Table 3. Information About the Currently Registered Fatty Acid Monoesters with Glycerol or Propandiol

EPA Registration Number	Product Name (% Active Ingredient; Formulation Type)	Date Registered	Application Rates	Application Methods	Use Sites
	(86.68% - Glycerol monocaprate) (0.68% - Octanoic acid)				
10350-60	VWX-42 Technology Propylene Glycol (71.37% - Octanoic acid)	September 30, 2003	Manufacturing technical use product.	Formulation into end use products, broad spectrum antimicrobial agent.	Post-harvest use on crops (e.g., fruits and vegetables).
10350-61	VWX-42 Technology PEP1 (.021% - Propylene glycol monocaprate) (9.610% - Octanoic acid, ester with 1,2 propanediol)	June 29, 2004	For 1 liter to 1 gallon of diluted solution, mix 2 to 8 oz. of product with 0.5 oz. to 2 oz. of lactic acid and 31 oz. to 118 oz. of water.	Submerge potatoes in diluted treatment solution, for 13 to 15 minutes within 24 hours of mixing.	Potatoes
11581-3	Acaritouch (70.81% - Propylene Glycol Monolaurate)	November 28, 2008	Mix 12 to 25 ounces of Acaritouch per 100 gallons of water. Apply sufficient spray to cover the crop. 50 gallons of total spray volume per acre.	Spray application, apply on plants in sufficient water to thoroughly to cover plant. Make two applications 7 days apart. Interval treatment 3 to 5 days apart if the temperatures are such that mite eggs could hatch early.	Used on crops such as; cucurbits, pome fruits, stone fruits, grapes, nut crops, hops, berries, fruiting vegetables, tuberous and corm vegetables, cereal grains, citrus, cotton, and ornamentals.
10350-527	Propylene Glycol Monocaprylate (97.18% - Octanoic acid)	November 14, 2013	Manufacturing technical use product.	Formulation into end use products.	N/A
10350-529 (AD)	HANTO Propylene glycol monocaprylate (.4% - Octanoic acid)	December 12, 2013	Scrub surface with treated wipe; use enough wipes for treated surfaces to remain visibly wet for 30 seconds.	Clean surface with wipe product.	Hard non-porous surfaces (sealed wood, sealed stone, plastic, chrome, crystal, fiberglass, metals, and glazed tile and porcelain).

Table 3. Information About the Currently Registered Fatty Acid Monoesters with Glycerol or Propandiol

EPA Registration Number	Product Name (% Active Ingredient; Formulation Type)	Date Registered	Application Rates	Application Methods	Use Sites
90344-1 (AD)	PolyLaurin 120 (11.3% - Propylene Glycol Monolaurate) (1.4% - Glycerol Laurate)	May 27, 2015	Apply between 1.5% to 25% by weight of PolyLaurin™ 120 depending on the matrix being preserved, the normal handling of the product, and product function.	PolyLaurin™ 120 is a material preservative additive for use in the preservation of products including paints, coatings, adhesives, film forming agents, cleaning, and industrial products.	Preservative in industrial and institutional products including: oils, lubricants, solvents, and non-potable/nonfood water systems. In addition to industrial solution products (e.g., detergents, cleaners, and surfactants).

ii. Tolerance Actions

§180.1250 C8, C10, and C12 fatty acid monoesters of glycerol and propylene glycol; exemption from the requirement of a tolerance.

The C8, C10, and C12 straight-chain fatty acid monoesters of glycerol (glycerol monocaprylate, glycerol monocaprinate, and glycerol monolaurate) and propylene glycol (propylene glycol monocaprylate, propylene glycol monocaprinate, and propylene glycol monolaurate) are exempt from the requirement of a tolerance in or on all food commodities when used in accordance with approved label rates and good agricultural practice. [69 FR 34944, June 23, 2004]

D. Anticipated Data Needs and Risk Assessments

The Agency does not anticipate issuing a data call-in for antimicrobial fatty acid monoester products.

For biochemical uses, shown below are tables of the current data requirements for biochemical pesticides as set forth in 40 C.F.R. § 158, subpart U. They are arrayed by scientific discipline (i.e., product chemistry, human health assessment, and non-target organisms) and descriptions are included regarding how the data requirements have been fulfilled or waived. At this time, the following data gaps (anticipated data needs) have been identified for the biochemical uses:

- Product chemistry data requirements for biochemical uses:
 - pH – data not submitted and are needed for PC Codes 011289 and 011291.
 - UV/Visible light absorption – data not submitted and are needed for PC Codes 011289 and 082074.

- Density – only a predicted value from an estimation program is available and an experimental value is required for PC Code 011289
- Boiling point – only a predicted value from an estimation program is available and an experimental value is required for PC Code 011291
- Partition coefficients – predicted values from estimation programs were submitted and experimental values are required for PC Codes 011288, 011289, 011290, 011291, and 011292. Note: these data may not be required for some of the substances if experimental solubility data indicate that the substances are partially or completely soluble in water. Only predicted values for solubility are available for PC Codes 011289, 011290 and 011291. Since PC Codes 011288 and 011292 are considered to be insoluble, partition coefficient data are required.
- Solubility in water – predicted values from estimation programs were submitted and experimental values are required for PC Codes 011289, 011290 and 011291.
- Vapor pressure - predicted values from estimation programs were submitted and experimental values are required for PC Codes 011289, 011290, 011291 and 011292.
- Nontarget organism data requirements for biochemical uses:
 - Terrestrial plant toxicity (seedling emergence) - data requirement has not been addressed for PC Code 011288.
 - Terrestrial plant toxicity (vegetative vigor) - data requirement has not been addressed for PC Code 011288.

A Data Call-In (DCI) is anticipated to be issued for these outstanding product chemistry and non-target organism data requirements for applicable biochemical uses. Human health risk assessments have been conducted by both the Biopesticides and Pollution Prevention Division (BPPD) and the Antimicrobial division (AD) in 2003, 2013 and 2015 respectively; these assessments are sufficient and the Agency does not anticipate the need to conduct a new human health risk assessment. A non-target organism risk assessment will not be conducted for antimicrobial uses during registration review, but will be conducted during registration review for biochemical uses.

i. Product Chemistry (40 C.F.R. § 158.2030)

With the exception of the data identified above, the Product Chemistry data requirements for fatty acid monoesters have all been fulfilled. Table 4 and Table 5 below capture how the data requirements were fulfilled and provide summary product chemistry information the active ingredients.

Table 4. Summary of Product Analysis Data for Fatty Acid Monoesters

Guideline Number	Data Requirement	Has Data Requirement Been Addressed? How?	MRID PC Code: 011288	MRID PC Code: 011289	MRID PC Code: 082074	MRID PC Code: 011290	MRID PC Code: 011291	MRID PC Code: 011292
880.1100	Product Identity and Composition	Yes - Study	45405401 45852401 49443901	45405401	45405401 48838301	45405401 49443901	45405401	45405401
880.1200	Description of Starting Materials, Production, and Formulation Process	Yes - Study	45405401 45852401 49443901	45405401	45405401 48838301	45405401 49443901	45405401	45405401
880.1400	Discussion of Formation of Impurities	Yes – Study	45405401 45852401 49443901	45405401	45405401 48838301	45405401 49443901	45405401	45405401
830.1700	Preliminary Analysis	Yes – Study	45405501 45852401 49443901	45405501	45405501 48838302 48838306	45405501 49443901	45405501	45405501
830.1750	Certified Limits	Yes - Study	45405501 45852401	45405501	45405501 48838301	45405501	45405501	45405501
830.1800	Enforcement Analytical Method	Yes - Study	45405504 45852401 49443903	45405504	45405504 48838307	45405504 49443901	45405504	45405504

Table 5. Summary of Physical and Chemical Characteristics for Fatty Acid Monoesters

Guideline Number	Data Requirement/ How addressed?	Result/ MRID PC Code: 011288	Result/ MRID PC Code: 011289	Result/ MRID PC Code: 082074	Result/ MRID PC Code: 011290	Result/ MRID PC Code: 011291	Result/ MRID PC Code: 011292
830.6302	Color Yes – Study	Pale yellow 45852401 49443902	Clear 45405502	Clear 45405502 48838303	White 45405502 49443902	White 45405502	White 45405502
830.6303	Physical State Yes – Study	Liquid 45852401 49443902	Oily liquid 45405502	Oily liquid 45405502 48838301	Granular, waxy solid 45405502 49443902	Granular, waxy solid 45405502	Granular, waxy solid 45405502

Table 5. Summary of Physical and Chemical Characteristics for Fatty Acid Monoesters

Guideline Number	Data Requirement/ How addressed?	Result/ MRID PC Code: 011288	Result/ MRID PC Code: 011289	Result/ MRID PC Code: 082074	Result/ MRID PC Code: 011290	Result/ MRID PC Code: 011291	Result/ MRID PC Code: 011292
830.6304	Odor Yes – Study	Cooking oil odor 45852401 49443902	Cooking oil odor 45405502	Cooking oil odor 45405502 48838301	Vegetable fat odor 45405502 49443902	Vegetable fat odor 45405502	Vegetable fat odor 45405502
830.6313	Stability to Normal and Elevated Temperatures, Metals and Metal Ions Yes – Study	Stable to metals, decomposition starts at 200°C 45852401	Stable at 54°C for up to 14 days; not anticipated to come into contact with metals or metal ions during storage. 45405503	Stable at 54°C for up to 14 days; not anticipated to come into contact with metals or metal ions during storage. 45405503 48838301	Stable at 54°C for up to 14 days; not anticipated to come into contact with metals or metal ions during storage. 45405503	Data bridged from PC Code 011290, based on chemical similarity.	Data bridged from PC Code 011290, based on chemical similarity.
830.6315	Flammability Yes – Study or not required	174°C 45852401	Not required for TGAI/EP	No flash point identified (70, 100, 140, & 200°F)	Not required for TGAI/EP	Not required for TGAI/EP	Not required for TGAI/EP
830.6317	Storage Stability Yes – Study or not required	Not required for TGAI/EP	Not required for TGAI/EP	Not required for TGAI/EP	Not required for TGAI/EP	Not required for TGAI/EP	Not required for TGAI/EP
830.6319	Miscibility Yes – Not required	Not required for TGAI/EP	Not required for TGAI/EP	Not required for TGAI/EP	Not required for TGAI/EP	Not required for TGAI/EP	Not required for TGAI/EP
830.6320	Corrosion Characteristics Yes – Study is not required	Not required for TGAI/EP	Not required for TGAI/EP	Not required for TGAI/EP	Not required for TGAI/EP	Not required for TGAI/EP	Not required for TGAI/EP

Table 5. Summary of Physical and Chemical Characteristics for Fatty Acid Monoesters

Guideline Number	Data Requirement/ How addressed?	Result/ MRID PC Code: 011288	Result/ MRID PC Code: 011289	Result/ MRID PC Code: 082074	Result/ MRID PC Code: 011290	Result/ MRID PC Code: 011291	Result/ MRID PC Code: 011292
830.7000	pH Yes - Study	5.9 (1% solution) 45852401 3.8 (1% solution) 49443902	Data gap	5.0 ± 0.3 at 23°C 48838303	8.0-8.6 (5% solution) 49443902	Data gap	Not required: substance is practically insoluble in water
830.7050	UV/Visible Light Absorption Yes - Study	A _{max} 210 nm [ε 64.78] 45852401 45852402	Data gap	Data gap	λ _{max} at 238 nm; λ _{min} at 295 nm 49443902	λ _{max} at 238 nm; λ _{min} at 287 nm and 291 nm 49443902	λ _{max} at 238 nm; λ _{min} at 295 nm 49443902
830.7100	Viscosity Yes – Study or not required	Not required for TGAI/EP	Not required for TGAI/EP	11.3 cP at 24.9° C 48838303	Not required for TGAI/EP	Not required for TGAI/EP	Not required for TGAI/EP
830.7200	Melting Point Yes -Study or not required	8.3°C 45852401 45852402	Not required: not a solid	Not required: not a solid	63°C 45405502 23-27°C 49443902	52.8°C 45405502	28-30°C 45405502
830.7220	Boiling Point Yes - Study	246.6°C 45852401 45852402 138-141°C at 0.6 torr 49443902	308°C* 45405502	280°C 45405502 267.6°C 48838303	380°C 45405502	Not required: not a liquid	340°C 45405502
830.7300	Density/ Relative Density/Bulk Density (Specific Gravity) Yes – Study or data	0.92 g/ml at 25°C 45852401 0.905-0.915 g/ml 49443902	0.9 ± 0.1 g/cm ³ *****	0.9318 g/cm ³ at 27°C 45405502 0.9374 g/ml at 23°C 48838303	1.08 g/cm ³ at 21°C 45405502 0.98 g/ml 49443902	1.090 g/cm ³ at 27°C 45405502	1.08 g/cm ³ (temp. not reported) 45405502

Table 5. Summary of Physical and Chemical Characteristics for Fatty Acid Monoesters

Guideline Number	Data Requirement/ How addressed?	Result/ MRID PC Code: 011288	Result/ MRID PC Code: 011289	Result/ MRID PC Code: 082074	Result/ MRID PC Code: 011290	Result/ MRID PC Code: 011291	Result/ MRID PC Code: 011292
830.7520	Particle Size, Fiber Length, and Diameter Distribution/ Yes-Waived	Not required: not a water insoluble and fibrous substance.	Not required: not a water insoluble and fibrous substance.	Not required: not a water insoluble and fibrous substance.	Not required: not a water insoluble and fibrous substance.	Not required: not a water insoluble and fibrous substance.	Not required: not a water insoluble and fibrous substance.
830.7550 830.7560 830.7570	Partition Coefficient (n-Octanol Water) Yes-Data	log P = 4.83**	log P = 3.95****	log P = 3.35**	log P = 4.22***	log P = 2.82**	log P = 2.06***
830.7840	Water Solubility Yes - Study or data	4 mg/l 45852401 45852402 Practically insoluble 49443902	62 mg/l* 45405502	82 mg/l at 23°C 48838303	12.6 mg/l* 45405502 Practically insoluble 49443902	125 mg/l* 45405502	Practically insoluble 49443902
830.7950	Vapor Pressure Yes - Study	0.162 Pa at 25°C 45852401 45852402	3.8 x 10 ⁻⁵ * mm Hg 45405502	4.1 x 10 ⁻³ mm Hg at 20°C; 7.0 x 10 ⁻² mm Hg at 55°C 48838303	2.87 x 10 ⁻⁸ * mm Hg 45405502	9.27 x 10 ⁻⁸ * mm Hg 45405502	2.33 x 10 ⁻⁶ * mm Hg 45405502

* Value obtained using a predictive model in MRID 45405502

**Value obtained using EPA's Chemistry Dashboard: <https://comptox.epa.gov/dashboard/>

***Value obtained using a predictive model in MRID 49443902

****Value obtained using a predictive model from <http://www.chemspider.com>**ii. Human Health Assessment (40 C.F.R. § 158.2050)*****Hazard Characterization and Risk***

The database of submitted toxicity studies and published literature is sufficient to assess the uses of the six fatty acid monoesters included in this case. Summaries of toxicity data and waivers are provided in Table 6. The available toxicity database for these active ingredient consists of acute

oral, irritation, sensitization and subchronic oral toxicity studies. Toxicity studies are not available for each individual active ingredient. However, toxicology data and information have been bridged to support the data requirements on the basis of the substantial chemical, structural and functional similarity of these substances, and the similar metabolic pathways of the substances. Data waivers for the subchronic dermal and inhalation toxicity, developmental toxicity and genotoxicity data requirements were originally granted by the Agency in 2003.^{1,2,3} The waivers were based on the following: 1) humans have long been exposed to the fatty acid monoesters in the diet. Glycerol fatty acid monoesters occur naturally in vegetable oils and the propylene glycol fatty acid monoesters are approved for use as direct food additives by the Food and Drug Administration (FDA) under 21 CFR 172.856. Propylene glycol alone and monoglycerides (glycerol fatty acid esters) are considered by FDA to be a Generally-Recognized-As-Safe (GRAS) direct food additives under 21 CFR 184.1666 and 184.1505, respectively; 2) humans are repeatedly exposed via the dermal route to the substances as they are used in a variety of personal care products, such as make-up, shampoos and conditioners, lotions, and facial cleansers⁴; 3) no adverse effects have been reported from exposure to these substances; 4) the substances are rapidly metabolized in vertebrate systems to polyols and free fatty acids. Upon ingestion, the substances become indistinguishable from those substances already present in living systems; 5) appropriate personal protective equipment (PPE) requirements on the label will mitigate exposure to applicators/handlers; and 6) the available toxicity data indicate no adverse effects.

With regard to the available toxicity information, acute toxicity studies indicate that fatty acid monoesters are of low oral, dermal and inhalation toxicity (Toxicity Category IV). Eye irritation studies revealed slight to mild irritation in rabbits (Toxicity Category III-IV) and dermal irritation studies revealed mild irritation in rabbits (Toxicity Category IV). The available data suggest that propylene glycol monocaprylate is a potential skin sensitizer (these data have been bridged to the other propylene glycol monoesters) and that glycerol monolaurate is not a skin sensitizer (these data have been bridged to the other glycerol monoesters). A 90-day guideline oral toxicity study in the rat conducted using propylene glycol monocaprylate showed no adverse effects up to and including the limit dose of 1,000 mg/kg/day.

While no developmental and mutagenicity data have been submitted to the Agency for the active ingredients, there are assessments and information available on the constituents of the substances. The reproductive and developmental effects of propylene glycol were evaluated by the National Toxicology Program in 2004 (NTP, 2004) and it was determined that “there is negligible concern for adverse developmental or reproductive toxicity from propylene glycol

¹ U.S. EPA (2003). Jones, Russell S. to Frazer, Carol. Science Review in Support of the Registration of the Technical Grade Active Ingredient (TGAI) Product, VMX-42 Technology Propylene Glycol Monocaprylate (EPA File Symbol No. 10350-AN). April 4, 2003.

² Federal Register (2004). Environmental Protection Agency Final Rule. C8, C10, and C12 Straight-Chain Fatty Acid Monoesters of Glycerol and Propylene Glycol; Exemption from the Requirement of a Tolerance. [OPP-2003-0379; FRL-7352-6]. p. 34937-34944. June 23, 2004.

³ U.S. EPA (2003). Jones, Russell S. to Frazer, Carol. Science Review in Support of the Registration of Acaritouch (EPA File Symbol No. 70231-E). September 29, 2003.

⁴ MRIDs 49443902 and 49016301, Currently AD would not accept the rationale that humans are already exposed in topical cosmetic applications as evidence that no data are needed for these compounds; however, the other data waiver rationale points are still considered to be valid.

exposures in humans”. From a metabolic perspective, fatty acid monoesters and their natural metabolites/degradates are not known to be reproductive or developmental toxicants. There is no evidence of special sensitivity in infants or children. There are no available information indicating that these substances are of mutagenic or genotoxic concern.⁵

Glycerol fatty acid monoesters are natural components of dietary fats and natural breakdown products from the metabolism of fat (triacylglycerol) in all living systems. The propylene glycol monoesters are metabolized in such systems by the same pathways. Glycerol and propylene glycol monoesters are almost identical metabolically, as demonstrated by a substantial list of published studies. The particular fatty acid moiety is inconsequential, because vertebrate systems are capable of metabolizing each of the acids in the range of C8 to C18 (the active ingredients are the C8, C10, and C12 straight-chain fatty acid monoesters of glycerol and propylene glycol) with equal facility. The glycerol monoesters are indistinguishable from the natural acylglycerols and fatty acids found in the intestines after the ingestion of fats. Studies with propylene glycol show that it is readily absorbed from the gastrointestinal tract and rapidly converted in the liver to 14C-glycogen or 14CO₂. Studies with glycerol show that it is metabolized into expired CO₂, blood glucose, liver fat, glycogen and phosphatides within 15 minutes.^{6,7} For the reasons discussed above, the Agency has concluded that the available toxicology data can be used to represent all of the fatty acid monoesters, where applicable.

There is a long history of consumption and use in personal care products of the fatty acid monoesters and the Agency is unaware of any instances of toxic effects from exposure to these substances.

No additional useful information was found in a search of the National Library of Medicine’s Toxicology Data Network⁸ and the RapidTox⁹ database (July 2017). Comprehensive reviews from the Food and Drug Administration (FDA), the Cosmetic Ingredient Review Expert Panel (CIR) and the Joint Food and Agricultural Organization of the United Nations (FAO)/World Health Organization (WHO) Expert Committee on Food Additives (JECFA) are available and no risks have been identified.^{4,5,6}

Because no adverse effects have been observed in the available studies, a quantitative risk assessment was not conducted for the fatty acid monoesters. The Agency considers its previous assessment to be sufficient and has determined that a qualitative risk assessment is appropriate for the pesticidal uses. The dietary and occupational exposure qualitative risk assessment is discussed below.

⁵ U.S. EPA (2015). Chen, Jonathan to Pyne, Jaclyn through Leighton, Timothy. Risk Assessment for Proposed New Use of Propylene Glycol Monolaurate and Glycerol as a Materials Preservative. May 27, 2015.

⁶ Federal Register (2004). Environmental Protection Agency Final Rule. C8, C10, and C12 Straight-Chain Fatty Acid Monoesters of Glycerol and Propylene Glycol; Exemption from the Requirement of a Tolerance. [OPP-2003-0379; FRL-7352-6]. p. 34937-34944. June 23, 2004.

⁷ MRIDs 49443902 and 49016301

⁸ TOXNET. July 2017. <https://www.toxnet.nlm.nih.gov/>.

⁹ RapidTox. July 2017. <https://comptox.epa.gov/dashboard>.

Dietary, Residential and Occupational Exposure and Risk Assessment

The Agency does not anticipate any dietary (food and drinking water) risks because of the following: 1) lack of toxicity: no adverse effects have been identified in the available toxicity studies, particularly the 90-day oral toxicity study; 2) humans have long been exposed to the fatty acid monoesters in the diet. Glycerol fatty acid monoesters occur naturally in vegetable oils and both types of fatty acid monoesters (glycerol and propylene glycol) are approved for use as direct food additives by the Food and Drug Administration (FDA) under 21 CFR 172.856; 3) the substances are rapidly metabolized in vertebrate systems to polyols and free fatty acids. Upon ingestion, the substances become indistinguishable from those substances already present in living systems. Glycerol and propylene glycol monoesters are almost identical metabolically; and 4) no adverse effects have been reported from dietary exposures to these substances.

There is potential for residential and/or occupational exposure to the fatty acid monoesters based on its antimicrobial use as a disinfectant/sanitizer. Due to the lack of toxicity, a quantitative occupational risk assessment for exposure via the oral, dermal, and inhalation routes was not conducted. Therefore, the Agency conducted a qualitative assessment. EPA has concluded that occupational and residential exposures and risks to these active ingredients are not of concern¹⁰,¹¹. In addition, the following personal protective equipment (PPE) is retained on fatty acid monoester labels registered for agricultural use: long-sleeved shirt, long pants, shoes, socks and waterproof gloves; and a 4-hour Restricted Entry Interval (REI). No occupational or residential risks are expected from exposure to this active ingredient.

Table 6. Summary of Human Health Assessment Data for Fatty Acid Monoesters

Guideline Number	Data Requirement/ How addressed?	Result/ MRID	Result/ MRID	Result/ MRID	Result/ MRID	Result/ MRID	Result/ MRID
		PC Code: 011288	PC Code: 011289	PC Code: 082074	PC Code: 011290	PC Code: 011291	PC Code: 011292
870.1100	Acute oral toxicity	LD ₅₀ > 40,000 mg/kg	Data bridged from PC Code 082074 based on chemical similarity.	LD ₅₀ > 5,000 mg/kg	LD ₅₀ > 5,000 mg/kg	Data bridged from PC Code 011290 based on chemical similarity.	Data bridged from PC Code 011290 based on chemical similarity.
	Yes – Study	45852403		45428501	45405505		

¹⁰ U.S. EPA (2003). Jones, Russell S. to Frazer, Carol. Science Review in Support of the Registration of Acaritouch (EPA File Symbol No. 70231-E). September 29, 2003

¹¹ U.S. EPA (2015). Chen, Jonathan to Pyne, Jaclyn through Leighton, Timothy. Risk Assessment for Proposed New Use of Propylene Glycol Monolaurate and Glycerol as a Materials Preservative. May 27, 2015.

Table 6. Summary of Human Health Assessment Data for Fatty Acid Monoesters

Guideline Number	Data Requirement/ How addressed?	Result/ MRID PC Code: 011288	Result/ MRID PC Code: 011289	Result/ MRID PC Code: 082074	Result/ MRID PC Code: 011290	Result/ MRID PC Code: 011291	Result/ MRID PC Code: 011292
870.1200	Acute dermal toxicity Yes – Study	Data bridged from PC Code 082074 based on chemical similarity.	Data bridged from PC Code 082074 based on chemical similarity.	LD ₅₀ > 5,000 mg/kg 45428503	LD ₅₀ > 5,000 mg/kg 45428502	Data bridged from PC Code 011290 based on chemical similarity.	Data bridged from PC Code 011290 based on chemical similarity.
870.1300	Acute inhalation toxicity Yes – Study	Data bridged from PC Code 082074 based on chemical similarity.	Data bridged from PC Code 082074 based on chemical similarity.	LC ₅₀ > 4.92 mg/L 45405506	Aerosol unable to be generated 45405507	Data bridged from PC Code 011290 based on chemical similarity.	Data bridged from PC Code 011290 based on chemical similarity.
870.2400	Primary eye irritation Yes – Study	Mildly irritating 45852404	Data bridged from PC Code 082074 based on chemical similarity.	Slightly irritating 45405509	Mildly irritating 45405508	Data bridged from PC Code 011290 based on chemical similarity.	Data bridged from PC Code 011290 based on chemical similarity.
870.2500	Primary dermal irritation Yes – Study	Mildly irritating 45852405	Data bridged from PC Code 082074 based on chemical similarity.	Mildly irritating 45405511	Mildly irritating 45405510	Data bridged from PC Code 011290 based on chemical similarity.	Data bridged from PC Code 011290 based on chemical similarity.

Table 6. Summary of Human Health Assessment Data for Fatty Acid Monoesters

Guideline Number	Data Requirement/ How addressed?	Result/ MRID PC Code: 011288	Result/ MRID PC Code: 011289	Result/ MRID PC Code: 082074	Result/ MRID PC Code: 011290	Result/ MRID PC Code: 011291	Result/ MRID PC Code: 011292
870.2600	Skin sensitization Yes – Study	Data bridged from PC Code 082074 based on chemical similarity.	Data bridged from PC Code 082074 based on chemical similarity.	Potential sensitizer 45448201	Not a sensitizer 45428504	Data bridged from PC Code 011290 based on chemical similarity.	Data bridged from PC Code 011290 based on chemical similarity.
870.3100	90-day oral toxicity Yes – Study	Data bridged from PC Code 082074 based on chemical similarity.	Data bridged from PC Code 082074 based on chemical similarity.	NOAEL \geq 1,000 mg/kg/day ¹ 45428505 Acceptable	Data bridged from PC Code 082074 based on chemical similarity.	Data bridged from PC Code 082074 based on chemical similarity.	Data bridged from PC Code 082074 based on chemical similarity.
870.3250	90-day dermal toxicity Yes – Waived	Waived 48838304 48838305 49016301 49016303 49526401	Waived 48838304 48838305 49016301 49016303 49526401	Waived 48838304 48838305 49016301 49016303 49526401	Waived 48838304 48838305 49016301 49016303 49526401	Waived 48838304 48838305 49016301 49016303 49526401	Waived 48838304 48838305 49016301 49016303 49526401
870.3465	90-day inhalation toxicity Yes – Waived	Waived 48838304 48838305 49016301 49016303 49526401	Waived 48838304 48838305 49016301 49016303 49526401	Waived 48838304 48838305 49016301 49016303 49526401	Waived 48838304 48838305 49016301 49016303 49526401	Waived 48838304 48838305 49016301 49016303 49526401	Waived 48838304 48838305 49016301 49016303 49526401
870.3700	Prenatal developmental toxicity Yes – Waived	Waived 48838304 48838305 49016301 49016303	Waived 48838304 48838305 49016301 49016303	Waived 48838304 48838305 49016301 49016303	Waived 48838304 48838305 49016301 49016303	Waived 48838304 48838305 49016301 49016303	Waived 48838304 48838305 49016301 49016303
870.5100	Bacterial reverse mutation test Yes – Waived	Waived 48838304 48838305 49016301 49016303 49526401	Waived 48838304 48838305 49016301 49016303 49526401	Waived 48838304 48838305 49016301 49016303 49526401	Waived 48838304 48838305 49016301 49016303 49526401	Waived 48838304 48838305 49016301 49016303 49526401	Waived 48838304 48838305 49016301 49016303 49526401

Table 6. Summary of Human Health Assessment Data for Fatty Acid Monoesters

Guideline Number	Data Requirement/ How addressed?	Result/ MRID	Result/ MRID	Result/ MRID	Result/ MRID	Result/ MRID	Result/ MRID
		PC Code: 011288	PC Code: 011289	PC Code: 082074	PC Code: 011290	PC Code: 011291	PC Code: 011292
870.5300 870.5375	<i>In vitro</i> mammalian cell assay Yes - Waived	Waived	Waived	Waived	Waived	Waived	Waived
		48838304	48838304	48838304	48838304	48838304	48838304
		48838305	48838305	48838305	48838305	48838305	48838305
		49016301	49016301	49016301	49016301	49016301	49016301
		49016303	49016303	49016303	49016303	49016303	49016303
		49526401	49526401	49526401	49526401	49526401	49526401

¹ In a 28-day oral toxicity study for propylene glycol monocaprylate, the NOAEL was greater than 1,000 mg/kg/day (MRID 45441101).

iii. Organisms and Environmental Fate (40 C.F.R. § 158.2060)

Nontarget Organism Effects Profile

There is only one product registered for outdoor uses (agricultural use) for which non-target organism data requirements have been required to be addressed. All registered end-use biochemical products are for indoor use; thus the non-target organism data were not required. For the antimicrobial products, two are registered for indoor uses (an indoor disinfectant/sanitizer and a materials preservative additive in industrial paints, coatings, adhesives, cleansers, etc.). Based on the use pattern, use of these products are not anticipated to result in significant exposure to non-target organisms.¹²

The product registered for agricultural outdoor use contains propylene glycol monolaurate (PC Code: 011288) as the active ingredient. Acute toxicity data for freshwater fish, aquatic invertebrates, non-target insects and algae are available and were conducted using this chemical as the test substance. In lieu of guideline studies for the avian studies, requests for data waivers were submitted to the Agency to satisfy the data requirements. These data waivers were granted by the Agency.¹³ A July, 2017 search of EPA's ECOTOXicology knowledgebase (ECOTOX)¹⁴ did not reveal any non-target organism toxicity data for propylene glycol monolaurate (PGML). The toxicity data and data waiver information are discussed below and summarized in Table 7.

¹² U.S. EPA (2015). Chen, Jonathan to Pyne, Jaclyn through Leighton, Timothy. Risk Assessment for Proposed New Use of Propylene Glycol Monolaurate and Glycerol as a Materials Preservative. May 27, 2015.

¹³ U.S. EPA (2003). Jones, Russell S. to Frazer, Carol. Science Review in Support of the Registration of Acaritouch (EPA File Symbol No. 70231-E). September 29, 2003.

¹⁴ ECOTOX. July 2017. <https://cfpub.epa.gov/ecotox/>.

The available toxicity data indicate that PGML is moderately toxic to fish and algae, highly toxic to aquatic invertebrates, and practically nontoxic to non-target insects (including bees and predatory mites).

Data waivers were requested for the avian acute oral and dietary toxicity data requirements. The data waivers were granted by the Agency². The information provided was based on the ability of birds to metabolize propylene glycol fatty acid monoesters into innocuous substances via the same metabolic pathways present in mammals, as previously discussed in this document. Additionally, propylene glycol has extremely low toxicity to birds, and is even recommended for use as a vehicle for test substance suspension in the OCSPP guideline study for avian oral toxicity (OCSPP 850.2100). Based on the information above, toxicity to avian species from exposure to PGML is not anticipated.

The non-target plant data requirements (seedling emergence and vegetative vigor) have not been addressed and are anticipated to be required by DCI. Additionally, based on the available hazard data and the potential for exposure, a risk assessment will need to be conducted for non-target organisms.

Nontarget Organism Risk Assessment

Based on the available hazard data and the potential for exposure, a risk assessment will need to be conducted for non-target organisms.

A search of OPP's Ecological Incident Information System (EIIS) version 2.1.1 conducted on July 11, 2017, revealed no ecological incidents associated with the fatty acid monoesters; this database contains information dating back to the 1970s and was most recently updated 03/01/2016.

Environmental Fate Profile

Some environmental fate information is available for PGML and was reviewed in the Antimicrobials Division.¹⁵ Propylene glycol monolaurate is not expected to hydrolyze or degrade by photolysis, but it is expected to partition to sediment. Based on results from a Level III Fugacity Model, 69.2% of PGML is expected to partition into soil. The environmental fate estimation program developed by EPA and Syracuse Research Corp. (Estimation Programs Interface Suite [EPI Suite]) predicted half-lives of PGML to be 30 days in soil/sediment and 15 days in water. These data will be used to inform the risk assessment.

¹⁵ U.S. EPA (2015). Chen, Jonathan to Pyne, Jaclyn through Leighton, Timothy. Risk Assessment for Proposed New Use of Propylene Glycol Monolaurate and Glycerol as a Materials Preservative. May 27, 2015.

E. Threatened/Endangered Species

Threatened/endangered species will be addressed in the risk assessment that will be conducted during registration review.

Table 7. Summary of Nontarget Organism Data for Propylene Glycol Monolaurate

Guideline Number	Data Requirement/How Addressed?	Result	MRID Number
850.2100	Avian Acute Oral Toxicity/ Yes - Waiver	Waived based on lack of toxicity and known metabolism into innocuous substances.	OPP-2003-0379; FRL-7352-6. p. 34937-34944. June 23, 2004 ²
850.2200	Avian Dietary Toxicity/ Yes - Waiver	Waived based on lack of toxicity and known metabolism into innocuous substances.	OPP-2003-0379; FRL-7352-6. p. 34937-34944. June 23, 2004 ²
850.1075	Fish Acute Toxicity, Freshwater/ Yes - Study	96-hour LC ₅₀ = 4.8 mg/l NOEC = 3.80 mg/l Moderately toxic	45852412
850.1010	Aquatic Invertebrate Acute Toxicity, Freshwater/ Yes - Study	48-hour EC ₅₀ = 0.52 mg/l NOEC = 0.18 mg/l Highly toxic	45852413
850.4100	Terrestrial Plant Toxicity, Seedling Emergence/ No Study - Data Gap	Data Gap.	
850.4150	Terrestrial Plant Toxicity, Vegetative Vigor/ No Study - Data Gap	Data Gap.	
880.4350	Nontarget Insect Testing Yes - Studies	Honey bee (<i>Apis mellifera</i>): 48-hour LD ₅₀ > 66 to <132 µg a.i./bee Predatory mite (<i>Phytoseiulus persimilis</i>): No apparent effects on mites at application rates of up to 10.5 mg a.i./6-8 mites. Eggs exposed to same application rate had survival rates of up to 96.4%. Practically nontoxic	45852415 ³ 45852416 ³
850.4500 ¹	Algal Toxicity Yes - Study	Growth rate inhibition: 72-hour EC ₅₀ = 1.99 mg/l 72-hour NOEC = 0.44 mg/l 24 to 48-hour EC ₅₀ = 4.72 mg/l 24 to 72-hour EC ₅₀ = 5.11 mg/l 24 to 48-hour NOEC = 2.13 mg/l 24 to 72-hour NOEC = 2.13 mg/l Moderately toxic	45852417

¹ The algal growth inhibition study is not a BPPD or AD data requirement.

² Waivers were provided in a document entitled “Volume 70231-E-17 Request for Waivers of Specific Data Requirements. The waivers were discussed in the memorandum from Jones, Russell S. to Frazer, Carol. Science Review in Support of the Registration of Acaritouch (EPA File Symbol No. 70231-E). September 29, 2003.

³ The honeybee and predatory mite acute contact toxicity studies were conducted using the EP (Acaritouch); the amount of the active ingredient in each dose was calculated and estimated by the reviewers.

F. Endocrine Effects

As required by the Administrator under the Federal Food, Drug, and Cosmetic Act (FFDCA) section 408(p), the EPA has developed the Endocrine Disruptor Screening Program (EDSP) and has begun to implement the screening program that is to be used to test all pesticides in order to determine whether certain substances (including pesticide active and other ingredients) may have an effect in humans or wildlife similar to an effect produced by a “naturally occurring estrogen, or other such endocrine effects as the Administrator may designate.”

FFDCA section 408(p)(4) authorizes the Administrator, by order, to exempt from the requirements of the Estrogenic Substances Screening Program a biologic substance or other substance if a determination is made that the substance is not anticipated to produce any effect in humans similar to an effect produced by a naturally occurring estrogenic substance.

Between October 2009 and February 2010, the EPA issued test orders/data call-ins for the first group of 67 chemicals, which contains 58 pesticide active ingredients and 9 inert ingredients. A second list of chemicals identified for EDSP screening was published on June 14, 2013, and includes some pesticides scheduled for registration review and chemicals found in water. The fatty acid monoesters were not among the group of pesticide active ingredients on the lists to be screened under the EDSP.

The EPA, as part of this Preliminary Work Plan, believes that the fatty acid monoesters are substances that would not likely produce any effect in humans similar to an effect produced by a naturally occurring estrogenic substance. Pursuant to Section 408(p) (4), the EPA will determine in the future whether it can exempt this active ingredient from the requirements of the Section 408(p) EDSP. In the event the EPA does determine to exempt these substances from the EDSP, an order will be issued.

For further information on the status of the EDSP, the policies and procedures, the lists of chemicals, future lists, the test guidelines and the Tier 1 screening battery, please visit our website at <http://www.epa.gov/endo/>.

G. Incidents

A search of OPP’s Incident Data System (IDS) from 1992 through May 18, 2017, revealed no human health incidents associated with pesticide products containing the fatty acid monoesters as the active ingredient. A search of OPP’s Ecological Incident Information System (EIIIS) version 2.1.1 conducted on July 11, 2017, revealed no ecological incidents associated with the fatty acid monoesters; this database contains information dating back to the 1970s and was most recently updated March 1, 2016. EPA will consider any incident data or comments submitted in response to this Preliminary Work Plan.

H. Timeline

Below is the projected timeline for Registration Review case 6016: Fatty Acid Monoesters

Activities	Estimated Month/Year
Opening the Docket	
Open Docket and 60-Day Public Comment Period for	September 2017
Close Public Comment Period	November 2017
Case Development	
Issue Final Work Plan	March 2018
Issue Data Call-in	June 2018
Data Submission	June 2020
Open 30-Day Public Comment Period for Draft Risk Assessments	December 2021
Close Public Comment Period	January 2022
Registration Review Decision	
Open 60-Day Public Comment Period for Proposed Registration Review Decision	June 2022
Close Public Comment Period	August 2022
Final Decision	September 2022
*Estimated Total (years)	5 years

I. Guidance for Commenters

The public is invited to comment on the EPA's PWP for the fatty acid monoesters. The areas below highlight topics of special interest to the EPA where comments, information and data, or reference to sources of additional information could be of particular use. The EPA will consider all comments, as well as any additional information or data provided in a timely manner, prior to issuing a Final Work Plan for this case.

i. Environmental Justice

The EPA seeks to achieve environmental justice, the fair treatment and meaningful involvement of all people, regardless of race, color, national origin, or income, in the development, implementation, and enforcement of environmental laws, regulations, and policies. To help

address potential environmental justice issues, the EPA seeks information on any groups or segments of the population who, as a result of their location, cultural practices, or other factors, may have unusually high exposure to the pesticidal use of the fatty acid monoesters compared to the general population. **Please comment if you are aware of any subpopulations that may have atypical, unusually high exposure compared to the general population.**

ii. Water Quality

The fatty acid monoesters have not been identified as a cause of impairment for any water bodies listed as impaired under section 303(d) of the Clean Water Act.¹⁶ In addition, no Total Maximum Daily Loads (TMDLs) have been developed for these substances.¹⁷ More information on impaired water bodies and TMDLs can be found on EPA's website.¹⁸ **The EPA invites submission of water quality data for this pesticide.** To the extent possible, data should conform to the quality standards in Appendix A of the *Office of Pesticide Program's (OPP) Standard Operating Procedure: Inclusion of Impaired Water Body and Other Water Quality Data in Registration Review Risk Assessment and Management Process*¹⁹ to ensure they can be used quantitatively or qualitatively in pesticide risk assessments.

iii. Trade Irritants

Through the registration review process, the EPA intends to solicit information on trade irritants and, to the extent feasible, take steps toward facilitating irritant resolution. The EPA will work to harmonize tolerance and international Maximum Residue Limits (MRLs), and, if necessary, may modify tolerance levels to do so. **Growers and other stakeholders are asked to comment** on any trade irritant issues resulting from lack of MRLs or disparities between U.S. tolerances and MRLs in key export markets, providing as much specificity as possible regarding the nature of the concern.

There are no known MRLs for the fatty acid monoesters. Therefore, the EPA does not anticipate that current uses of the fatty acid monoesters will pose concerns as trade irritants.

iv. Additional Information

Stakeholders are also specifically asked to provide information and data that will assist the EPA in refining the risk assessments. The EPA is interested in obtaining the following information regarding the fatty acid monoesters:

- ▶ Confirmation on the following label information:
 - *Sites of application*
 - *Formulations*
 - *Application methods and equipment*
 - *Maximum application rates*
 - *Frequency of application, application intervals, and maximum number of applications*
 - *Geographic limitations on use*

¹⁶ Based on information provided at <http://water.epa.gov/lawsregs/lawsguidance/cwa/tmdl/index.cfm>.

¹⁷ Based on information provided at http://iaspub.epa.gov/apex/waters/f?p=ASKWATERS:DOC_SEARCH:0::::

¹⁸ See <http://water.epa.gov/lawsregs/lawsguidance/cwa/tmdl/index.cfm>.

¹⁹ This document can be found at http://www.epa.gov/pesticides/registration-review2/water_quality_sop.htm.

- ▶ Use or potential use distribution (*e.g.*, acreage and geographical distribution of relevant use sites)
- ▶ Median and 90th percentile reported use rates (lbs active ingredient/1,000 square feet) from usage data – national, state, and county
- ▶ Application timing (date of first application and application intervals) – national, state, and county
- ▶ Usage/use information for nonagricultural uses
- ▶ Typical application interval (days)
- ▶ State or local use restrictions
- ▶ Monitoring data

- ▶ Foreign technical registrants not listed above who supply technical fatty acid monoesters to the US market

J. Next Steps

After the 60-day comment period closes, the EPA will review and respond to any comments received in a timely manner, then issue a Final Work Plan for the fatty acid monoesters.

II. BIBLIOGRAPHY**A. Studies Supporting the Registration Review of Fatty Acid Monoesters**

MRID	CITATION
45405400	Uniquema Crop Protection Chemicals (2001) Submission of Product Chemistry Data in Support of the Application for Registration of VWX-42 Technology and the Petition for Exemption from Tolerance for Propylene Glycol Caprylate. Transmittal of 1 study.
45405401	Andrews, J.; Kabara, J.; Price, S. et al. (2001) Product Identity, Composition and Impurities: VWX-42 Technology. Unpublished study prepared by Keller and Heckman LLP. 30 p. {OPPTS 880.1100, 880.1200 and 880.1400}
45405500	3M Company (2001) Submission of Product Chemistry and Toxicity Data in Support of the Petition for Tolerance of VWX-42 Technology in/on all Crops and Food. Transmittal of 11 Studies.
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