UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

MEMORANDUM

DATE: 09/10/2019

SUBJECT: Risk Assessment for Non-Target Organisms and Environmental Fate in Support of the Registration Review for Fatty Acid Monoesters with Glycerol or Propanediol; Case No. 6016.

Registration Review Case Number:	6016
Chemical Class:	Biochemical
PC Codes:	011288, 011289, 011290, 011291, 011292, & 082074
CAS Numbers:	27194-74-7, 68795-69-7, 27215-38-9, 26402-22-2, 26402-26-6, & 68332-79-06
Active Ingredient Tolerance/Exemption:	40 CFR §180.1250

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EXECUTIVE SUMMARY

A Preliminary Work Plan (PWP) for the Registration Review of Fatty Acid Monoesters with Glycerol or Propanediol (FAM) was completed in September 2017 which stated, "Based on the available hazard data and the potential for exposure, a risk assessment will need to be conducted for non-target organisms." This memorandum contains the non-target organism and environmental fate risk assessment to support of this Registration Review. There are two EPA-registered products in BPPD for biochemical pesticide use sites that contain FAMs as their active ingredients (Acaritouch®, EPA Reg. No. 11581-3; and VWX-42 Technology PEPl; EPA Reg. No. 10350-61). Acaritouch® (EPA Reg. No. 11581-3) is intended for use outdoors (agriculture use). The second product, VWX-42 Technology PEPl (EPA Reg. No. 10350-61) is intended for

use as a potato dip for potatoes treated and stored in enclosed facilities. According to the 2017 PWP, non-target organism data were not required for biochemical pesticide products registered for indoor use and, therefore, VWX-42 Technology PEPl is not considered in this review. Other FAM active ingredients included in this case (PC Codes 011290, 011291, 011292) currently do not have associated registered products. However, all FAMs are considered structurally-similar and functionally-identical to one another (see "Description of the Active Ingredient" below). Therefore, information submitted for one FAM is used to support all FAMs, and the conclusions herein for Acaritouch® would apply to all FAMs.

Acaritouch®, containing 70.81% Propylene Glycol Monolaurate as its active ingredient, is the only product that will result in exposure of non-target organisms. Based upon the results of toxicity tests and the low potential for exposure, the risks to nontarget bird, plant, aquatic organisms and insect species, including endangered/threatened species and their designated critical habitats from use of FAMs as an active ingredient in pesticide products, are expected to be negligible. Therefore, EPA has reached a "No Effect" determination for direct and indirect effects to endangered/threatened bird, mammal, plant, aquatic organisms and insect species and their designated critical habitats.

Propylene Glycol Monolaurate may be used as a surrogate for all registered Fatty Acid Monoesters (FAMs) with Glycerol or Propanediol (US EPA, 2017). Information supporting the use of Propylene Glycol Monolaurate as a surrogate for all FAMs is discussed below in the Description of the Active Ingredient.

Description of the Active Ingredient

Propylene Glycol Monolaurate (dodecanoic acid monoester with 1,2- propanediol) belongs to the family of chemicals commonly referred to as fatty acid monoesters (FAMs). Propylene glycol fatty acid monoesters (such as Propylene Glycol Monolaurate) are synthetically manufactured, but are structurally-similar and functionally identical to glycerol fatty acid monoesters (such as glycerol monolaurate) that occur naturally in all living organisms. All FAMs have been found to display similar toxicity and are metabolized by the same metabolic pathways (US EPA, 2017). Studies with propylene glycol show that it is readily absorbed from the gastrointestinal tract and rapidly converted in the liver to 14C-glycogen or $14CO_2$. Studies with glycerol show that it is metabolized into expired CO_2, blood glucose, liver fat, glycogen and phosphatides within 15 minutes (US EPA, 2017). 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) (US EPA, 2017). 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). Fatty Acid Monoesters

with Glycerol or Propanediol are exempt from the requirements of tolerances under 40 CFR §180.1250.

The active ingredient Propylene Glycol Monolaurate is used against Gram-positive and Gram-negative bacteria, fungi, yeasts and lipid coated viruses to suppress and control mites present on fruits, vegetables, and ornamental plants, and to inhibit the growth of spoilage organisms (such as *Erwinia carotovora* and *Fusarium solanum*) on stored potatoes. The mode of action is to act as a membrane disruptor of the target pests. In vertebrate organisms (e.g., humans), propylene glycol fatty acid monoesters are formed as part of the metabolism of triglycerides and occur naturally in vegetable oils (e.g., coconut and palm oils), and in saw palmetto leaves and berries (US EPA, 2013).

Biopesticide Use Pattern

According to the product label for the end-use product, Acaritouch®, the product is to be applied twice at up to 25 fluid ounces (fl oz) per acre per application, with 3- to 7-day intervals between applications, to suppress and control mites present on fruits, vegetables, and ornamental plants and those newly emerged. Also, when applied in rotation with other miticides, Acaritouch® may be applied up to 8 times during the season up to the day before harvest. The label does not indicate whether the eight applications may be applied consecutively, but is assumed that only two applications may be applied consecutively.

According to the product label for Acaritouch® (70.81% active ingredient), the product bulk density is 7.7 lbs product/gallon [or 7.7 lbs/128 fluid ounces (fl oz)]. Therefore, the amount of Propylene Glycol Monolaurate applied per application is:

$$\frac{\text{7.7 lbs product}}{\text{128 fl oz}} = \frac{\text{X lbs product}}{\text{25 fl oz}}$$

X = 1.51 lbs product/25 fl oz/application

1.51 lbs product/A x 0.7081 active ingredient = **1.07 lbs a.i./A/application**

Non-Target Organism Hazard Assessment

A September 2019 search of EPA's ECOTOXicology knowledgebase (ECOTOX, 2019) using all the CAS Registry numbers associated with this Registration Review case produced only two reports of toxicity to fish associated with CAS # 27215-38-9, Glycerol Monolaurate. These results are expected given the available nontarget data for FAMs, as shown in Table 1. All non-

target organism study data and data waiver information are summarized below in Table 1.

Table 1. Summary of Nontarget Organism Data for Propylene Glycol Monolaurate

Guideline Number	Data Requirement/How Addressed?	Result	MRID Number or Reference
850.1100[1]	Acute Oral Toxicity Yes - Study	LD_{50} > 40,000 mg/kg[1]	45852403
870.3100[1]	90-day Oral Toxicity Yes - Study	NOAEL ≥ 1000 mg/kg/day	45428505
850.2100[2]	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
850.2200[2]	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
850.1075[2]	Fish Acute Toxicity, Freshwater/ Yes - Study	96-hour LC_{50} = 4.8 mg/l NOEC = 3.80 mg/l Moderately toxic	45852412
850.1010[2]	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/	Waived based on lack of observed toxicity in 18 field efficacy trials at the maximum label rate and known metabolism into innocuous substances.	50555801
850.4150	Terrestrial Plant Toxicity, Vegetative Vigor/	Waived based on lack of observed toxicity in 18 field efficacy trials at the maximum label rate and known metabolism into innocuous substances.	50555801
880.4350[2]	Nontarget Insect Testing Yes - Studies	Honey bee (*Apis mellifera*): 48-hour LD_{50} > 66 to <132 µg a.i./bee Practically nontoxic Predatory mite (*Phytoseiulus persimilis*): 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%.	45852415[4] 45852416[4]

Table 1. Summary of Nontarget Organism Data for Propylene Glycol Monolaurate			
Guideline Number	**Data Requirement/How Addressed?**	**Result**	**MRID Number or Reference**
850.4500[2, 3]	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] Highest FAM dose tested; data are obtained from Table 6, p. 18 of Preliminary Work Plan for Fatty Acid Monoesters with Glycerol or Propanediol, EPA-HQ-OPP-2017-0353 (US EPA, 2017).
[2] Data are obtained from Table 7, p. 23 of Preliminary Work Plan for Fatty Acid Monoesters with Glycerol or Propanediol, EPA-HQ-OPP-2017-0353 (US EPA, 2017).
[3] The algal growth inhibition study is not a BPPD or AD data requirement.
[4] 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.

Estimated Environmental Concentrations (EECs) of Fatty Acid Monoesters

Terrestrial exposure estimates were not conducted due to the lack of any identified toxicological endpoints in mammalian toxicity testing and the ability of birds to metabolize FAMs via the same metabolic pathways that are present in mammals (US EPA, 2017).

Aquatic exposures to FAMs were estimated using the Pesticide in Water Calculator (PWC v1.52; US EPA, 2016) model. Based on available data and estimated properties informing environmental fate and ecotoxicity, a screening level aquatic risk assessment finds no risk of concern for listed aquatic animals. Based on the same conceptual model used in the PWC model, the active ingredient is applied to ten hectares draining into a farm pond (20,000,000 liters).

Physical/Chemical properties for the model were based on glycerol monocaprylate Cas. No. 26402-26-6 (PC Code 011292).
Molecular Weight: 218 g/mol
K_{oc}: 10 mL/g o.c.(EPISuite)
Solubility: 16,617 mg/L (EPISuite)
Vapor Pressure: 2.3E-6 torr (EPISuite)
Application Efficiency: 95% (aerial OPP assumption)
Spray Drift: 12.5% (aerial application drift with ASAE Fine to Medium droplet size)
Mississippi Soybean scenario with application on emergence day (vulnerable scenario and timing); stable to all biotic and abiotic degradation (conservative assumption)

The maximum application rate is 1.07 lbs a.i./acre/application (2 applications allowed), however, the analysis below assumes one application due to the expected rapid biodegradability.

10 ha = 24.7 acres
1.07 lbs (max application rate) x 24.7 acres = 26.4 lbs = 11,975,000 mg
Farm Pond conc. with all pesticide mass = 11,975,000 mg/20,000,000 L = 0.599 mg/L

Additionally, the Agency expects FAMs to be readily adsorbed to soil/sediment and readily broken down by microorganisms in soil, sewage sludge, surface waters, and other environmental matrices. Between abiotic and biotic processes, biodegradation is expected to be a rapid process, proportional to temperatures and microbial load in the environment. Movement into ground and surface waters and, therefore, exposure to aquatic organisms is expected to be minimal.

NON-TARGET ORGANISM AND ENDANGERED SPECIES RISK ASSESSMENT

Mammalian Wildlife Toxicity (Acute Oral Toxicity, OCSPP 870.1100; 90-day Oral Toxicity, OCSPP 870.3100):

The database of submitted toxicity studies and published literature is sufficient to assess the hazards and risks associated with uses of the six fatty acid monoesters. Summaries of toxicity data and waivers are provided in Table 6 of the Preliminary Work Plan for Fatty Acid Monoesters with Glycerol or Propanediol, EPA-HQ-OPP-2017-0353 (US EPA, 2017). Mammalian oral toxicity values are presented in Table 1 of this document. Toxicity studies are not available for each individual active ingredient. However, toxicology data and information have been bridged to support the data requirements for all fatty acid monoesters based on the substantial chemical, structural and functional similarity of these substances, and the similar metabolic pathways of the substances (US EPA, 2017). 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, and glycerol and propylene glycol monoesters are almost identical metabolically (US EPA, 2017).

An acute oral toxicity study in the rat conducted using propylene glycol monolaurate showed no adverse effects at up to 40000 mg/kg-bw/day (5x the limit dose). 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-bw/day. 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 exposures…” to mammals. From

a metabolic perspective, fatty acid monoesters and their natural metabolites/degradates are not known to be reproductive or developmental toxicants. (US EPA, 2017). Based on the information above, it is highly unlikely that any adverse effects will occur to mammalian wildlife via acute oral and/or dietary exposure to fatty acid monoesters or their metabolic breakdown products. There are no risk concerns for non-target mammalian wildlife, including threatened and endangered species.

Avian Acute Toxicity (OCSPP 850.2100) and Avian Dietary Toxicity (OCSPP 850.2200):

Guideline studies were not submitted for either avian acute oral toxicity testing (OCSPP 850.2100) or avian dietary toxicity testing (OCSPP 850.2200). In lieu of Guideline studies, waiver requests were submitted to support the registration of Acaritouch®, with Propylene Glycol Monolaurate as its active ingredient (reviewed in US EPA, 2003). The waiver requests are based on the ability of birds to metabolize FAMs via the same metabolic pathways that are present in mammals. In vertebrates, propylene glycol fatty acid esters are hydrolyzed in the gastrointestinal tract via pancreatic lipase to yield free fatty acids and propylene glycol (WHO, 1974). Pancreatic lipase is produced in birds (Levey et al., 1999; and Sayari et al., 2000) to digest dietary triglycerides to free fatty acids, as in mammals. The free fatty acids released via pancreatic lipase activity are indistinguishable from fatty acids released from other sources. Propylene glycol has extremely low toxicity to birds and is recommended for use as vehicle for test substance suspension in the EPA Guideline study for avian oral toxicity (OPPTS 850.2100). Propylene glycol is metabolized in the liver of birds and mammals to lactic acid and pyruvic acid (Ruddick, 1972). Based on the information above, it is highly unlikely that any adverse effects will occur to birds via acute oral and/or dietary exposure to Propylene Glycol Monolaurate or its metabolic breakdown products. There are no risk concerns for non-target birds, including threatened and endangered species.

Aquatic Organisms: Fish Acute Toxicity, Freshwater (OCSPP 850.1075), Aquatic Invertebrate Acute Toxicity, Freshwater (OCSPP 850.1010) and Algal Toxicity (OCSPP 850.4400)

Freshwater fish acute toxicity testing (OCSPP 850.1075) reported a 96-hr LC50 = 4.8 ppm (moderately toxic). Aquatic Invertebrate Acute Toxicity, Freshwater testing (OCSPP 850.1010) reported a 48-hr EC50 = 0.52 ppm (highly toxic). Algal toxicity testing (OCSPP 850.4400; Table 1) indicated that the most conservative endpoint (growth inhibition) was the 72-hour EC_{50} = 1.99 mg/l (1.99 ppm). The adverse effects information on aquatic organisms normally would trigger the need for the submission of Tier II Biochemical Pesticide Environmental Fate studies. However, aquatic environmental concentrations were estimated using the Pesticide in Water Calculator (PWC v1.52; US EPA, 2016) model [see discussion under Estimated Environmental Concentrations (EECs) of Fatty Acid Monoesters above].

FAM concentrations in water were estimated to be 0.599 mg/L following application of the end-use product. The lowest aquatic animal endpoint is 0.520 mg/L; therefore, the concentration would need to be reduced by 17x to not exceed the listed species LOC of 0.05. That is, up to 5.8% of what is applied at the maximum application rate could enter the farm pond to not exceed the listed species LOC.

Assuming properties of one the fatty acid monoesters (glycerol monocaprylate) and conservative model estimates [see discussion under Estimated Environmental Concentrations (EECs) of Fatty Acid Monoesters above], 2.4% of the chemical applied to the field would enter the farm pond. If a second application were assumed and mass were doubled to 4.8% of the mass associated with a single application, the resulting concentration in the farm pond what still be below the endangered species LOC. This assumes stability to all forms of degradation despite the chemical's expected rapid degradation.

FAMs are known to have good water-in-oil emulsion properties. They are essentially fatty acids joined to glycol moieties via ester bonds. The ester component is intended to increase the solubility in water and allow better mixing of otherwise insoluble substances (fats/oils) in end-use products. Released into the environment, fatty acid monoesters would be expected to adsorb (but not chemically bond) to other compounds such as soil or sediment. The ester bonds would then be readily cleaved with weakly acid soil moisture (which is abundant in the environment). Therefore, fatty acid monoesters would be expected to readily degrade into their components (glycerol/ propylene glycol and fatty acid) following their application in end-use products.

As previously discussed, the Agency considers the FAMs to be structurally and chemically equivalent (see "Description of the Active Ingredient" above), and would be expected to act similarly to fatty acids in the environment. Though their mode of action is still poorly understood, fatty acids work through various interactions with the cell membrane resulting in membrane disruption and loss of cell contents. Exposure to microorganisms would probably hasten the process of degradation.

Based on the information above, it is highly unlikely that any adverse effects will occur to aquatic organisms due to a lack of exposure to fatty acid monoesters and their metabolic breakdown products. There are no risk concerns for non-target aquatic organisms, including threatened and endangered species.

Terrestrial Plant Toxicity, Seedling Emergence (OCSPP 850.4100)
Terrestrial Plant Toxicity, Vegetative Vigor (OCSPP 850.4150)

Guideline studies were not submitted for either terrestrial plant toxicity, seedling emergence (OCSPP 850.4100) or terrestrial plant toxicity, vegetative vigor. In lieu of Guideline studies, the registrant submitted a compendium of 18 product performance studies conducted between the years 2000 through 2006 on the following crops: pome fruits (3); cucurbits (1); grapes (3); stone fruit (1); nut crops (3); berries (2); fruiting vegetables (1); hops (2); and cereals (1). All studies were conducted using Acaritouch® (EPA Reg. No. 11581-3) containing 70.81% Propylene Glycol Monolaurate as its active ingredient according to EPA-approved label use directions. Phytotoxicity was not observed or mentioned in any of the studies. Although none of the studies provided information to specifically address seedling emergence and seedling vigor, the weight-of-evidence from other technical sources indicate that there is little concern for adverse effects on seedlings and seedling vigor following application of Acaritouch®. First, 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 (see Preliminary Workplan and Summary Document for Fatty Acid Monoesters with Glycerol and Propanediol, dated September 2017). Second, a USDA evaluation of Propylene Glycol Monolaurate (Technical Evaluation Report, Propylene Glycol Monolaurate) did not express any concerns for phytotoxicity and cited a report by Heaton (2003) to the California Department of Pesticide Regulation that Propylene Glycol Monolaurate was "Negative" for phytotoxicity.

Nontarget Insect Testing (OCSPP 880.3350)

Nontarget Insect testing (Acute honey bee contact toxicity; OSCPP 880.3350) indicated that the honey bee acute 48-hour LD_{50} > 66 to <132 µg a.i./bee (Table 1). The Agency considers any bee $LD_{50} \geq 25$ µg/bee to be practically non-toxic. In addition, a Tier I screening model (BeeREX, v 1.0; US EPA, 2015) was used to calculate the risk quotient (RQ) for bees exposed by acute contact to foliar sprays of Propylene Glycol Monolaurate, based on an application rate of 1.07 lb a.i./A and a conservative LD_{50} of 66 µg/bee. The BeeREX calculated an RQ = 0.04, which is below the LOC of 0.05 for non-target insects. Other data reviewed by the Agency indicated that there were no apparent effects on predatory mite (*Phytoseiulus persimilis* at application rates of up to 10.5 mg a.i./6-8 mites; mite eggs exposed to the same application rate had survival rates of up to 96.4% (Table 1). There are no risk concerns for non-target insects, including threatened and endangered species.

NON-TARGET ORGANISM AND ENDANGERED SPECIES RISK ASSESSMENT SUMMARY

Based upon the results of toxicity tests, rapid degradation in the environment, and the low potential for exposure, the risks to nontarget bird, plant, aquatic organisms and insect species, including endangered/threatened species and their designated critical habitats, from fatty acid monoesters as an active ingredient in pesticide products are expected to be negligible. Therefore, EPA has reached a "No Effect" determination for direct and indirect effects to endangered/threatened bird, mammal, plant, aquatic organism and insect species and their designated critical habitats.

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