ALASKA—CARBON MONOXIDE

Designated area	Designation		Classification	
	Date [1]	Type	Date [1]	Type
Anchorage Area:				
Anchorage Election District (part) Anchorage nonattainment area boundary.	July 23, 2004	Attainment.		
The Anchorage Nonattainment Area is contained within the boundary described as follows: Beginning at a point on the centerline of the New Seward Highway five hundred (500) feet of the centerline of O'Malley Road; thence, Westerly along a line five hundred (500) south of and parallel to the centerline of O'Malley Road and its westerly extension thereof to a point on the mean high tide line of the Turnagain Arm; thence, Northeasterly along the mean high tide line to a point five hundred (500) feet west of the southerly extension of the centerline of Sand Lake Road; thence, Northerly along a line five hundred (500) feet west of and parallel to the southerly extension of the centerline of Sand Lake Road to a point on the southerly boundary of the International Airport property; thence, Westerly along said property line of the International Airport to an angle point in said property line; thence, Easterly, along said property line and its easterly extension thereof to a point five hundred (500) feet west of the southerly extension of the centerline of Wisconsin Street; thence, Northerly along said line to a point on the mean high tide line of the Knik Arm; thence, Northeasterly along the mean high tide line to a point on a line parallel and five hundred (500) feet north of the centerline of Thompson Street and the westerly extension thereof; thence, Easterly along said line to a point five hundred (55) feet east of Boniface Parkway; thence, Southerly along a line five hundred (500) feet east of and parallel to the centerline of Boniface Parkway to a point five hundred (500) feet north of the Glenn Highway; thence, Easterly and northeasterly along a line five hundred (500) feet north of and parallel to the centerline of the Glenn Highway to a point five hundred (500) feet east of the northerly extension of the centerline of Muldoon Road; thence, Southerly along a line five hundred (500) feet east of and parallel to the centerline of Muldoon Road and continuing southwesterly on a line of curvature five hundred (500) feet southeasterly of the centerline of curvature where Muldoon Road becomes Tudor Road to a point five hundred (500) south of the centerline of Tudor Road; thence, Westerly along a line five hundred (500) feet south of the centerline of Tudor Road to a point five hundred (500) feet east of the centerline to Lake Otis Parkway; thence, Westerly along a line five hundred (500) feet south of the centerline of O'Malley Road, ending at the centerline of the New Seward Highway, which is the point of the beginning.				
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[1] This date is November 15, 1990 unless otherwise noted.

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[FR Doc. 04–14216 Filed 6–22–04; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2003–0379; FRL–7352–6]

C8, C10, and C12 Straight-Chain Fatty Acid Monoesters of Glycerol and Propylene Glycol; Exemption from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of the C8, C10, and C12 straight-chain fatty acid monoesters of glycerol and propylene glycol on all raw agricultural commodities and food when applied/used in accordance with good agricultural practices. 3M Corporation submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA), requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of C8, C10, and C12 straight-chain fatty acid monoesters of glycerol and propylene glycol.

DATES: This regulation is effective June 23, 2004. Objections and requests for hearings, must be received on or before August 23, 2004.

ADDRESSES: To submit a written objection or hearing request follow the detailed instructions provided in Unit VIII. of the **SUPPLEMENTARY INFORMATION**. EPA has established a docket for this action under Docket ID number OPP–2003–0379. All documents in the docket are listed in the EDOCKET index at *http://www.epa.gov/edocket*. Although listed in the index, some information is not publicly available, i.e., confidential

business information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in EDOCKET or in hard copy at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1801 S. Bell St., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Carol E. Frazer, Biopesticides and Pollution Prevention Division (7511C), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–8810; e-mail address: *frazer.carol@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to:

- Crop production (NAICS 111), e.g., farmer.
- Animal production (NAICS 112), e.g., rancher.
- Food manufacturing (NAICS 311), e.g., restaurant.
- Pesticide manufacturing (NAICS 32532).

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Access Electronic Copies of this Document and Other Related Information?

In addition to using EDOCKET (*http://www.epa.gov/edocket/*), you may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr/*. A frequently updated electronic version of 40 CFR part 180 is available at E-CFR Beta Site Two at *http://www.gpoaccess.gov/ecfr/*.

II. Background and Statutory Findings

In the **Federal Register** of December 12, 2001 (66 FR 64251) (FRL–6809–8), EPA issued a notice pursuant to section 408(d)(3) of the FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide tolerance petition (PP 1F6314) by 3M Corporation, 3M Center, St. Paul, MN 55144–1000. This notice included a summary of the petition prepared by the petitioner 3M Corporation. There were no comments received in response to the notice of filing.

The petition requested that 40 CFR part 180 be amended by establishing an exemption from the requirement of a tolerance for residues of C8, C10, and C12 straight-chain fatty acid monoesters of glycerol and propylene glycol.

Section 408(c)(2)(A)(i) of the FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the exemption is ''safe.'' Section 408(c)(2)(A)(ii) of the FFDCA defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Pursuant to section 408(c)(2)(B), in establishing or maintaining in effect an exemption from the requirement of a tolerance, EPA must take into account the factors set forth in section 408(b)(2)(C), which require EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . . '' Additionally, section 408(b)(2)(D) of the FFDCA 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.''

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of pesticides. Second, EPA examines exposure to the pesticide through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings.

III. Toxicological Profile

Consistent with section 408(b)(2)(D) of the FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action and considered its validity, completeness, and reliability and the relationship of this information to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

The fatty acid monoesters of glycerol and propylene glycol are six closely-related monoesters of C8, C10, and C12 straight-chain fatty acids. There are three glycerol monoesters (glycerol monocaprylate, glycerol monocaprate, and glycerol monolaurate), and three propylene glycol monoesters (propylene glycol monocaprylate, propylene glycol monocaprate, and propylene glycol monolaurate).

In vertebrate organisms (including humans), glycerol fatty acid monoesters are formed naturally as part of the metabolism of triglycerides. They also occur naturally in vegetable oils (e.g., coconut and palm oils) and in saw palmetto leaves and berries. Glycerol fatty acid monoesters are, in addition, used as direct food additives. Propylene glycol fatty acid monoesters, also used as direct food additives, are naturally metabolized in vertebrate systems in an identical manner to the glycerol fatty acid monoesters.

Toxicity studies supporting this tolerance exemption are referenced below. More detailed analyses of these studies can be found in the specific Agency review of the studies (Ref. 1). Additional information relevant to toxicity also has been published and is cited in Ref. 2.

Acute toxicity studies were generated to support EPA registration of the C8, C10, and C12 straight-chain fatty acid monoesters of glycerol and propylene glycol as biochemical pesticides. In all studies, EPA limit doses were used, and the test compounds were found to be non-toxic at the limit dose, but all tests were not conducted on each of the six active ingredients. Instead, a full acute toxicity test battery (6 studies) was generated for the C8 propylene glycol monoester (propylene glycol monocaprylate) and for the C12 glycerol ester (glycerol monolaurate), thereby bounding the chemical structures of all six active ingredients. In addition, because all six active ingredients are known to be identical with respect to acute toxicity and metabolism, a 90–day

rat oral toxicity study was conducted on propylene glycol monocaprylate only. The registrant requested and was granted waivers from toxicity testing for the additional monoesters (Ref. 3), since the metabolism and toxicity of the active ingredients have been well-documented for many years in the scientific literature. This represented all six active ingredients.

1. *Acute oral toxicity for glycerol monolaurate (OPPTS Harmonized Guideline 870.1100; 152–10; MRID 45405505): Non-toxic*. Fasted rats (three male and three female) received a single oral gavage of glycerol monolaurate formulated in corn oil and administered at a dose level of 5,000 milligrams/kilogram of body weight (mg/kg bwt). All rats survived and gained weight throughout the study with the exception of one female with a slight weight loss on the final day. Piloerection and increased salivation were observed in all rats within minutes of dosing. Normal salivation resumed shortly after dosing and piloerection resolved by day 3 in males and day 4 in females. No abnormalities were revealed in any rats at the macroscopic examination at study termination on day 15. The acute oral lethal dose $(LD)_{50}$ for rats was >5,000 mg/kg. Classification: Acceptable; Toxicity Category IV (Ref. 4).

2. *Acute oral toxicity for propylene glycol monocaprylate (OPPTS Harmonized Guideline 870.1100; 152–10; MRID 45428501): Non-toxic*. Fasted rats (three males and three females) received a single oral gavage of propylene glycol monocaprylate administered at a dose of 5,000 mg/kg bwt. All rats survived and gained weight throughout the study. Piloerection (all rats) and increased salivation (one female only) were evident within a few minutes of dosing, with piloerection persisting for the remainder of day 1. Piloerection was resolved by day 2 in females and by day 4 in males. No abnormalities were revealed in any animal at the macroscopic examination at study termination on day 15. The acute oral LD_{50} for rats was >5,000 mg/kg. Classification: Acceptable; Toxicity Category IV (Ref. 5).

3. *Acute dermal toxicity for glycerol monolaurate (OPPTS Harmonized Guideline 870.1200; 152–11; MRID 45428501): Non-toxic*. Ten rats (five males and five females) received a single topical application of glycerol monolaurate formulated in corn oil and administered at a dose of 5,000 mg/kg bwt. All rats survived and had normal weight gains throughout the study, with the exception of two females with low or no weight gain during week 1. No clinical signs of reaction to treatment were observed in any animal throughout the study, and no macroscopic abnormalities were observed in any animal at study termination on day 15. The acute dermal LD_{50} for rats was >5,000 mg/kg. Classification: Acceptable; Toxicity Category IV (Ref. 6).

4. *Acute dermal toxicity for propylene glycol monocaprylate (OPPTS Harmonized Guideline 870.1200; 152–11; MRID 45428503): Non-toxic*. Ten rats (five males and five females) received a single topical application of propylene glycol monocaprylate at a dose of 5,000 mg/kg bwt. All rats survived and gained weight, with the exception of one female with a slight weight loss during week 2. No macroscopic abnormalities were observed in any animal at study termination on day 15. The acute dermal LD_{50} for rats was >5,000 mg/kg. Classification: Acceptable; Toxicity Category IV (Ref. 7).

5. *Acute inhalation for glycerol monolaurate (OPPTS Harmonized Guideline 870.1300; 152–12; MRID 45405506): Harmless by inhalation*. In all instances, the aerosol generator was blocked following the start of generation. The waxiness of glycerol monolaurate made it impossible to generate aerosols. Because respirable particles cannot be produced from such low-melting waxy materials, the test substance is considered harmless by the inhalation route of exposure under normal handling conditions. Classification: Acceptable; Toxicity Category IV (Ref. 8).

6. *Acute inhalation for propylene glycol monocaprylate (OPPTS Harmonized Guideline 870.1300; 152–12; MRID 45405507): Non-toxic*. Ten rats (five males and five females) were exposed for 4 hours to a droplet aerosol generated from propylene glycol monocaprylate at a target concentration of 5 mg/liter (L). Another group (five males and five females), exposed to clean dry air only, were controls. The mass median aerodynamic (MMAD) was 2.0 microns and was within the ideal range (1 micron to 4 microns) for an acute inhalation study. Approximately 88% of the particles were considered a respirable size (less than 7 microns in aerodynamic diameter). The lethal concentration $(LC)_{5O}$ (4–hour inhalation) for propylene glycol monocaprylate was >4.92 mg/L (4,920 ppm) in air. EPA's limit dose for this test is 2 mg/L. Classification: Acceptable; Toxicity Category IV (Ref. 9).

7. *Eye irritation for glycerol monolaurate (OPPTS Harmonized Guideline 870.2400, 152–13, MRID 45405508): Slight irritant*. Each of three rabbits was administered a single ocular dose of 0.1 milliliter (mL) (mean weight 60 mg) of glycerol monolaurate and observed for up to 7 days after instillation. The instillation in one animal elicited a corneal lesion and iritis (both Grade 1) 48 hours post-dose. All rabbits exhibited transient conjunctival inflammation (up to Grade 3). Resolution was complete in two instances within approximately 72 hours of dosing and, in one animal, 7 days after dosing. Glycerol monolaurate is considered a slight eye irritant. Classification: Acceptable; Toxicity Category III (Ref. 10).

8. *Eye irritation for propylene glycol monocaprylate (OPPTS Harmonized Guideline 870.2400, 152–13, MRID 45405509): Slight irritant*. Three rabbits were each administered a single ocular dose of 0.1 mL of propylene glycol monocaprylate and observed for up to 7 days after instillation. The test substance elicited a transient, slight to well-defined conjunctival irritation in two rabbits. Propylene glycol monocaprylate is not considered a major ocular irritant. Classification: Acceptable; Toxicity Category III (Ref. 11).

9. *Skin irritation for glycerol monolaurate (OPPTS Harmonized Guideline 870.2500, 152–14, MRID 45405510): Non-Irritant*. Each of three rabbits was administered a single dermal dose of 0.5 g of glycerol monolaurate under semi-occlusive conditions for 4 hours and observed for up to 7 days. The test material produced transient slight erythema in 2 animals that resolved by 72 hours; the third animal had well-defined erythema at 48 hours that resolved by day 7. Glycerol monolaurate is not considered a dermal irritant. Classification: Acceptable; Toxicity Category IV (Ref. 12).

10. *Skin irritation for propylene glycol monocaprylate (OPPTS Harmonized Guideline 870.2500, 152–14, MRID 45405511): Non-irritant*. Each of three rabbits was administered a single dermal dose of 0.5 mL of propylene glycol monocaprylate under semi-occlusive conditions for 4 hours and observed for up to 11 days. The test substance produced only slight erythema in all animals. Propylene glycol monocaprylate is not considered a dermal irritant. Classification: Acceptable; Toxicity Category IV (Ref. 13).

11. *Skin sensitization for glycerol monolaurate (OPPTS Harmonized Guideline 870.2600, 152–15, MRID 45428504): Non-sensitizer*. Guinea pigs (10 test and 5 control) were dosed by intradermal injection and topical

application. Based on the results of a preliminary study, and in compliance with regulatory guidelines, the following dose levels were selected:

Intradermal injection: 2.5% w/v (weight/volume) in sterile water.

Topical application: 10% w/v in sterile water.

Challenge applications: 0.5% and 1% w/v in sterile water.

Following the first challenge application, negative responses were observed in six test animals, inconclusive responses in three animals and a positive response was observed in the remaining test animal. A second challenge was conducted to clarify these reactions. Following the second challenge application, glycerol monolaurate did not produce dermal reactions in any test or control animal. Glycerol monolaurate is not thought to cause skin sensitization. The sensitivity of the guinea pig strain used by the laboratory is checked periodically with a weak/moderate sensitizer - hexyl cinnamic aldehyde (HCA). In this study, HCA produced evidence of skin sensitization (delayed contact hypersensitivity) in 9 of the 10 animals, thus confirming the sensitivity and reliability of the experimental technique. Classification: Acceptable. (Ref. 14)

12. *Skin sensitization for propylene glycol monocaprylate (OPPTS Harmonized Guideline 870.2600, 152–15, MRID 45448201): Potential sensitizer*. The guinea pigs (10 test and 5 control) were dosed by intradermal injection and topical application. Based on the results of a preliminary study and in compliance with the regulatory guidelines, the following dose levels were selected:

Intradermal injection: 0.5% v/v in sterile water.

Topical application: as supplied.

Challenge application: 25% and 50% v/v in sterile water.

In this study, propylene glycol monocaprylate produced evidence of skin sensitization (delayed contact hypersensitivity) in all of the test animals. Propylene glycol monocaprylate may cause skin sensitization in humans. Propylene glycol itself is known to cause allergic reactions in patients receiving medical treatments containing this substance. The sensitivity of the guinea pig strain used is checked periodically by the laboratory with a weak to moderate sensitizer-HCA. In this study, HCA produced evidence of skin sensitization (delayed contact hypersensitivity) in 9 of the 10 animals, thus confirming the sensitivity and reliability of the experimental technique. This risk, however, is mitigated as long as the products are used according to the precautionary statements on the label, which advise washing thoroughly with soap and water after handling and that prolonged or frequently repeated skin contact may cause allergic reactions in some individuals. Classification: Acceptable (Ref. 15).

13. *28–Day oral for propylene glycol monocaprylate (OPPTS Harmonized Guideline 870.3050, MRID 45441101): Non-toxic*. The effects of propylene glycol monocaprylate (T–7475.8) were assessed in rats (groups of five males and five females) by oral gavage administration once a day for 4 weeks, employing dose levels of 0, 500, 750, or 1,000 mg/kg/day. Doses up to 1,000 mg/kg/day were well tolerated with the only effects noted being higher protein and albumin values and a higher lung and liver weight, all in females. In the absence of histopathological examination, the toxicological importance of these findings is unclear. However, it was considered that 1,000 mg/kg/day was well tolerated and that it would be suitable for use as a high dose level in the subsequent 13–week toxicity study. Classification: Acceptable (Ref. 16).

14. *13–Week oral for propylene glycol monocaprylate (OPPTS Harmonized Guideline 870.3100 and 870.7800, MRID 45428505): Non-toxic*. The systemic toxicity of propylene glycol monocaprylate (T–7475.8) was assessed in groups of rats (20 males and 20 females per group) by oral gavage administration at 0, 100, 500, or 1,000 mg/kg/day dose levels for 13 weeks. There were no unscheduled deaths in any of the groups and clinical observation, neurotoxicity, metabolic parameters, and organ histopathology indicated no changes of toxicological significance. It was concluded that a dosage of 1,000 mg/kg/day was considered to be a no observable adverse effect level (NOAEL) for either sex. Classification: Acceptable (Ref. 17).

15. *Genotoxicity*. Fatty acid monoesters of glycerol and propylene glycol in vertebrate systems are immediately metabolized to polyols and free fatty acids. Upon ingestion these compounds become indistinguishable from those in living systems. Polyols and free fatty acids in living systems are not genotoxic. Hence, waivers were requested and granted for all genotoxicity testing requirements on the basis that conducting such tests would not be of value to EPA in its evaluation of risks. The fatty acid monoesters of glycerol and propylene glycol are already known not to be genotoxic from a metabolic standpoint.

16. *Reproductive and developmental toxicity*. On their metabolic basis, fatty acid monoesters of glycerol and propylene glycol and their natural breakdown products are known not to be reproductive or developmental toxicants. Waivers therefore were requested and granted for all such testing requirements on the basis that conducting such tests would not be of value to EPA in its evaluation of risks (for both the registration action and this tolerance exemption action).

17. *Scientific literature on toxicity and metabolism*. Basic toxicity testing on mono- and diacylglycerols and saturated fatty acids was conducted in the 1930–1960 period and included intermediate-term and long-term studies. Less work has been published on propylene glycol saturated fatty acid esters, but the available data are adequate to demonstrate equivalence between propylene glycol esters and acylglycerols. Comprehensive reviews of these chemicals prepared by a number of sources including the Food and Drug Administration (FDA) and the Food and Agricultural Organization of the United Nations (FAO) and the World Health Organization (WHO) are available through the Joint FAO/WHO Expert Committee on Food Additives (JECFA). The no observed adverse effect levels (NOAELs) for monoacylglycerols, regardless of the saturated fatty acid, are similar. Rats can be fed from 10–15% in the diet for a lifetime without ill effects, dose levels corresponding to 5 g/kg bwt/day. Rats fed propylene glycol monosuccinate and monostearate at levels up to 10% of the diet for 6 months showed no evidence of gross or histological pathology attributable to treatment. Dogs fed at the same levels for 6 months showed no signs of toxicity.

The fatty acid moiety in monoacylglycerols is of no consequence because vertebrate systems are capable of metabolizing each of the acids in the range of C8 to C18 with equal facility. In fact, oxidation of fatty acids is a primary source of energy in vertebrate systems. Fatty acids are supplied in the diet in the form of triacylglycerols (fats) which are hydrolyzed by pancreatic lipase enzymes to form free fatty acids, glycerol and monoacylglycerols. The glycerol monoester active ingredients are indistinguishable from the natural acylglycerols and fatty acids found in the intestine following ingestion of fats. Specificity of the pancreatic lipase enzyme is independent of the nature of the fatty acid. It is also not stereospecific in its action and glycerol esters and propylene glycol esters are hydrolyzed by it with equal facility.

Studies with 14C-labeled propylene glycol show that it is readily absorbed from the gastrointestinal tract and rapidly converted in the liver to 14C-glycogen or 14CO2. Similarly, when 14C-glycerol is administered to rats, radiolabel appears in expired CO2, blood glucose, liver glycogen, liver fat and liver phosphatides within 15 minutes. Within 6 hours, 40% of the label is contained in expired CO2 and the remainder is distributed through the test animal. Very small amounts are excreted.

FDA has looked at metabolism of propylene glycol mono- and distearates as model compounds to represent propylene glycol fatty acids. In studies on radiolabeled propylene glycol distearate the rate-limiting factor in the metabolism was found to be hydrolysis of the ester, which is complete in about 3 hours. In 5 hours, 94% of the propylene glycol is absorbed and 94% of the absorbed material is found in expired CO2 in 72 hours. The fatty acid portion of the ester is absorbed and metabolized more slowly than the propylene glycol. Only 51% of the stearic acid label was expired as CO2 in the same period.

In addition, there is a long history of consumption by humans of fatty acids and their monoesters in food and the Agency knows of no instance where these have been associated with any toxic effects related to the consumption of food. Due to this knowledge of fatty acid monoesters' presence and function in the human system (Ref. 2) and the recent acute testing, EPA believes the fatty acid monoesters are unlikely to be carcinogenic or have other long-term toxic effects.

The data from the toxicity studies (Ref. 1) and the additional information from the scientific literature submitted by the registrant (Ref. 2) are sufficient to support the current waiver requests, and to demonstrate that no substantial risks to human health are expected from the use of glycerol or propylene glycol fatty acid monoesters, when used in accordance with good agricultural practices and in accordance with all relevant labeling.

IV. Aggregate Exposures

In examining aggregate exposure, section 408 of the FFDCA directs EPA to consider available information concerning exposures from the pesticide residue in food and all other non-occupational exposures, including drinking water from ground water or surface water and exposure through pesticide use in gardens, lawns, or buildings (residential and other indoor uses).

A. Dietary Exposure

Aggregate dietary exposure estimates were generated using EPA's Dietary Exposure Potential Model (DEPM) customarily used by the agency. The model is designed to generate dietary exposure estimates by combining food consumption and residue data. In this case, food consumption data came from the 10th National Food Consumption Survey conducted during the 3–year period of 1994–1996 by the Agricultural Research Service of the U.S. Department of Agriculture. These data are also known as the Continuing Survey of Food Intake by Individuals, 1994–1996 (CSFII 1994–1996).

1. *Food*. Food residue estimates were generated for use in the DEPM analysis to simulate broad use of the fatty acid monoesters of glycerol and propylene glycol. Specifically, residue estimates were constructed for all food commodities corresponding to 18 raw agricultural commodities (RACs) for which residue data were generated for the following major food groups: Fruits; vegetables; beverages; and infant food. In keeping with the worst case nature of the analysis, residue data for a tested commodity was used also for similar commodities not tested (e.g., spinach values were used for other delicate greens; kale values were used for other heavy greens such as collard; peach values were used for apricots). It was also assumed residue levels are not changed by cooking and that fruit and vegetable mixtures contain 50% of one or more RAC, unless the composition of the mixture is specified. Total dietary exposure estimates were generated using the model for the U.S. population and 20 subpopulations, including non-nursing infants and children. The subpopulation groups were defined by age, gender, geographic location, ethnicity and income level. All calculations represented residue levels assuming treatment of 100% of every commodity consumed in the U.S. for which residue estimates could be generated, another severe worst-case assumption. The model produced data tables containing the consumption of each food, its assumed residue level and the calculated exposure from that consumption in µg/kg-bwt/day for each of the subpopulations. For all subpopulation groups, the commodity that contributed in the analysis the most to exposure was cooked green beans. This result reflects the fact that green beans absorbed an unexpectedly large amount of treatment solution in the experimental procedure used to generate RAC residue estimates. Based upon the worst-case data and assumptions described above, the model calculated the highest exposure of 0.5 mg/kg bwt/day for non-nursing infants. Dietary exposure for the total U.S. population was less than 0.2 mg/kg bwt/day. These levels are below the FDA approved dosage for addition to prepared foods, and the highest dose accepted as a chronic NOAEL for either sex was 5,000 times higher (Ref. 17).

2. *Drinking water exposure*. All anticipated or proposed uses of glycerol and propylene glycol fatty acid monoesters will be indoors and the compounds are not soluble in water. Hence, drinking water is not a feasible route of exposure.

B. Other Non-Occupational Exposure

Glycerol fatty acid monoesters are natural components of dietary fats and natural breakdown products from metabolism of fat (triacylglycerol) in all living systems. Additionally, fatty acid esters of both glycerol and propylene glycol occur as direct food additives.

1. *Dermal exposure*. Results of the acute dermal toxicity studies for glycerol monolaurate and propylene glycol monocaprylate indicated no toxicity (Toxicity Category IV) at the maximum dose tested (5,000 mg/kg) with no significant dermal irritation (Toxicity Category IV). Based on these results, the anticipated risks from dermal exposure are minimal. Dermal sensitization may occur with the propylene glycol monoesters as the caprylate is a potential sensitizer. This risk, however, is mitigated as long as the products are used according to the precautionary statements on the label, which advise washing thoroughly with soap and water after handling and that prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.

2. *Inhalation exposure*. Because the inhalation toxicity study for propylene glycol monocaprylate showed no toxicity (Toxicity Category IV), and the glycerol fatty acid monoesters are waxy solids at room temperature (not present as respirable particles), the risks anticipated for this route of exposure are minimal.

V. Cumulative Effects

Section 408(b)(2)(D)(v) of FFDCA requires the Agency, when considering whether to establish, modify, or revoke a tolerance, to consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.'' These considerations include the possible cumulative effects of such residues on infants and children.

In assessing their cumulative effects, the fatty acid monoesters of glycerol and propylene glycol are members of a much larger class of compounds that are toxicologically and metabolically equivalent. All vertebrate systems deal with this class of compounds as food rather than toxicants. Glycerol fatty acid monoesters are natural components in dietary fats and natural breakdown products from metabolism of fat (triacylglycerol) in all living systems. Fatty acid esters of propylene glycol also occur as direct food additives in the human diet in substantial quantities. The use of fatty acid monoesters of glycerol and propylene glycol as pesticides will contribute a negligible amount (total U.S. population worst case estimate less than 0.2 mg/kg/day) to the existing cumulative exposure to the class of compounds when compared to natural levels of such compounds and their metabolites in tissue and foods (50–100 g/day in humans for glycerol esters), and to the levels permitted in food as direct additives (grams per day). Accordingly, exposure to these monoesters as a result of their label directed use as pesticides on raw agricultural food or feed commodities will result in a negligible increase in the cumulative exposure to this class of compounds over the present exposure, occurring as a result of daily consumption by the human population of this class of compounds from both naturally occurring sources and processed foods.

VI. Determination of Safety for U.S. Population, Infants and Children

1. *U.S. population*. It is doubtful harm will result from aggregate exposure to residues of the fatty acid monoesters of glycerol or propylene glycol in the U.S. population. This includes all anticipated dietary exposures and all other exposures for which there is reliable information. The Agency has arrived at this conclusion based on the very low levels of mammalian toxicity (no toxicity at the maximum doses tested, Toxicity Category IV) associated with the fatty acid monoesters of glycerol and propylene glycol and the long history of their consumption.

2. *Infants and children*. FFDCA section 408 provides that EPA shall apply an additional tenfold margin of exposure (safety) for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the data base unless EPA determines a different margin of exposure will be safe for infants and children. Margins of exposure (safety) are often referred to as uncertainty factors. The registrant used the NOAEL of 1,000 mg/kg bwt/day determined in the 90–day oral toxicity study in rats to calculate an estimated exposure of the active ingredients to the U.S. population of 0.13 mg/kg bwt/day and to non-nursing infants of 0.44 mg/kg bwt/day. The corresponding margins of exposure were calculated to be 7,690 for the U.S. population and 2,270 for non-nursing infants (Ref. 2).

In this instance, based on all the available information, the Agency concludes that the C8, C10, and C12 monoesters of glycerol and propylene glycol are virtually non-toxic to mammals, including infants and children. Further, the provisions of consumption patterns, special susceptibility, and cumulative effects do not apply. Since no toxic endpoints have been identified, any hazard is impossible to determine. As a result, EPA has not used a margin of exposure approach to assess the safety of the C8, C10, and C12 monoesters of glycerol and propylene glycol. Based on their abundance in nature and long history of use by humans without deleterious effects, there is reasonable certainty that no harm will result from aggregate exposure to the U.S. population, including infants and children, to residues of these glycerol and propylene glycol straight-chain fatty acid monoesters. This includes all anticipated dietary exposures and all other exposures for which there are reliable information. Thus, the Agency has determined that the additional margin of safety is not necessary to protect infants and children and that not adding any additional margin of safety will be safe for infants and children.

VII. Other Considerations

A. Endocrine Disruptors

EPA is required under the FFDCA, as amended by FQPA, to develop a screening program to determine whether certain substances (including all pesticide active and other ingredients) may have an effect in humans that is similar to an effect produced by a naturally-occurring estrogen, or other such endocrine effects as the Administrator may designate. Following the recommendations of its Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC), EPA determined that there was scientific basis for including, as part of the program, the androgen- and thyroid hormone systems, in addition to the estrogen hormone system. EPA also adopted EDSTAC's recommendation that the Program include evaluations of potential effects in wildlife. For pesticide chemicals, EPA will use FIFRA and, to the extent that effects in wildlife may help determine whether a substance may have an effect in humans, FFDCA authority to require the wildlife evaluations. As the science develops and resources allow, screening of additional hormone systems may be added to the Endocrine Disruptor Screening Program (EDSP).

Based on the weight of the evidence of available data, no endocrine system-related effects are identified for the C8, C10, or C12 fatty acid monoesters of glycerol or propylene glycol and none is expected since they are natural components of vertebrate systems. Thus, there is no impact via endocrine-related effects on the Agency's safety finding set forth in this Final Rule for C8, C10, or C12 fatty acid monoesters of glycerol or propylene glycol.

B. Analytical Method(s)

The Agency proposes to establish an exemption from the requirement of a tolerance for the C8, C10, and C12 straight-chain fatty acid monoesters of glycerol and propylene glycol without any numerical limitation, based on their lack of mammalian toxicity. Their use will create only minuscule exposures (<1 mg/kg bwt/day) when compared to the natural levels of such compounds in living tissue and in foods (50–100 grams (g)/day), and compared to the levels permitted in food as direct additives (g/day). Based on this, the Agency has concluded that an analytical method is not required for enforcement purposes for the fatty acid monoesters of glycerol or propylene glycol.

C. Codex Maximum Residue Level

There are no CODEX values for the C8, C10, and C12 straight-chain saturated fatty acid monoesters of glycerol or propylene glycol.

D. Conclusions

Based on the toxicology data submitted and other information available to the Agency, there is reasonable certainty no harm will result to the U.S. population, including infants and children, from aggregate exposure of residues of the C8, C10, and C12 straight-chain fatty acid monoesters of glycerol or propylene glycol when the product is used in accordance with good agricultural practices and in accordance with all relevant labeling. This includes all anticipated dietary exposures and all other exposures about which there is reliable information. As a result, EPA is establishing an exemption from tolerance requirements pursuant to FFDCA 408(c) and (d) for residues of the C8, C10, and C12 straight-chain fatty acid monoesters of glycerol and

propylene glycol in or on all food commodities.

VIII. Objections and Hearing Requests

Under section 408(g) of the FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to reflect the amendments made to the FFDCA by the FQPA, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) of the FFDCA provides essentially the same process for persons to ''object '' to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d) of the FFDCA, as was provided in the old sections 408 and 409 of the FFDCA. However, the period for filing objections is now 60 days, rather than 30 days.

A. What Do I Need to Do to File an Objection or Request a Hearing?

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number OPP–2003–0379 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before August 23, 2004.

1. *Filing the request.* Your objection must specify the specific provisions in the regulation that you object to, and the grounds for the objections (40 CFR 178.25). If a hearing is requested, the objections must include a statement of the factual issues(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

Mail your written request to: Office of the Hearing Clerk (1900C), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. You may also deliver your request to the Office of the Hearing Clerk in Rm. 104, Crystal Mall #2, 1801 S. Bell St., Arlington, VA. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (703) 603–0061.

2. *Tolerance fee payment.* If you file an objection or request a hearing, you must also pay the fee prescribed by 40 CFR 180.33(i) or request a waiver of that fee pursuant to 40 CFR 180.33(m). You must mail the fee to: EPA Headquarters Accounting Operations Branch, Office of Pesticide Programs, P.O. Box 360277M, Pittsburgh, PA 15251. Please identify the fee submission by labeling it ''Tolerance Petition Fees. ''

EPA is authorized to waive any fee requirement ''when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection.'' For additional information regarding the waiver of these fees, you may contact James Tompkins by phone at (703) 305–5697, by e-mail at *tompkins.jim@epa.gov*, or by mailing a request for information to Mr. Tompkins at Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.

If you would like to request a waiver of the tolerance objection fees, you must mail your request for such a waiver to: James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.

3. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VIII.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in Unit I.B.1. Mail your copies, identified by docket ID number OPP–2004–0379, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.1. You may also send an electronic copy of your request via e-mail to: *opp-docket@epa.gov.* Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

B. When Will the Agency Grant a Request for a Hearing?

A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

IX. References

1. USEPA. Science Review in Support of the Registration of the Technical Grade Active Ingredient (TGAI) Product, VMX–42 Technology Propylene Glycol Monocaprylate, memo from Jones, Russell S., Ph.D., to Carol E. Frazer, Ph.D., April 4, 2003.

2. Dubeck, J.B., S.M. Price, and A.P. Jovanovich. Petition Proposing an Exemption from Tolerance for Pesticide Residues in or on Raw Agricultural Commodities and Processed Food. 3M, St. Paul, MN. April 13, 2001.

3. Jovanovich, A.P., Ph.D., MBA. Application for Pesticide Registration VWX–42 Technology. Request for Waivers. May 2, 2001.

4. Blanchard, Emma L., B.Sc. (Hons.). Acute oral toxicity study. MRID 45405505.

5. Coleman, David G., B.Sc. (Hons.). Acute oral toxicity study. MRID 45428501.

6. Coleman, David G., B.Sc. (Hons.). Acute dermal toxicity study. MRID 45428502.

7. Coleman, David G., B.Sc. (Hons.). Acute dermal toxicity study. MRID 45428503.

8. Paul, Graham R., B.Sc. (Hons.), M.Sc. Biol., M.I. Biol. Acute inhalation toxicity study. MRID 45405506.

9. Paul, Graham R., B.Sc. (Hons.), M.Sc. Biol., M.I. Biol. Acute inhalation toxicity study. MRID 45405507.

10. Blanchard, Emma L., B.Sc. (Hons.). Primary eye irritation study. MRID 45405508.

11. Blanchard, Emma L., B.Sc. (Hons.). Primary eye irritation study. MRID 45405509.

12. Blanchard, Emma L., B.Sc. (Hons.). Primary dermal irritation study. MRID 45405510.

13. Blanchard, Emma L., B.Sc. (Hons.). Primary dermal irritation study. MRID 45405511.

14. Coleman, David G., B.Sc. (Hons.). Dermal sensitization study. MRID 45428504.

15. Coleman, David G., B.Sc. (Hons.). Dermal Sensitization study. MRID 45448201.

16. Bottomley, Sarah M., B.Sc. (Hons.), M.Sc., C.Biol., M.I.Biol. 28–Day oral toxicity study in rats. MRID 45441101.

17. Bottomley, Sarah M., B.Sc. (Hons.), M.Sc., C.Biol., M.I.Biol. 90–Day oral toxicity study in rats. MRID 45428505.

X. Statutory and Executive Order Reviews

This final rule establishes an exemption from the tolerance requirement under section 408(d) of the FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this rule has been exempted from review under Executive Order 12866 due to its lack of significance, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4). Nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of the FFDCA, such as the exemption in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications '' is defined in the Executive Order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of the FFDCA. For these same reasons, the Agency has determined that this rule does not have any ''tribal implications'' as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' ''Policies that have tribal implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.'' This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

XI. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a ''major rule '' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: June 10, 2004.

James Jones,

Director, Office of Pesticide Programs.

■ Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. Section 180.1250 is added to subpart D to read as follows:

§ 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 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.

[FR Doc. 04–14222 Filed 6–22–04; 8:45 am]

BILLING CODE 6560–50–S