process, please contact the person listed under **FOR FURTHER INFORMATION CONTACT**.

List of Subjects

Environmental protection, Reporting and recordkeeping requirements.

Dated: December 3, 2001.

Stephen L. Johnson,

Assistant Administrator for Prevention, Pesticides and Toxic Substances.

[FR Doc. 01–30597 Filed 12–11–01; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[PF–1053; FRL–6809–8]

Notice of Filing of a Pesticide Petition to Establish a Tolerance for a Certain Pesticide Chemical in or on Food

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the initial filing of a pesticide petition proposing the establishment of regulations for residues of a certain pesticide chemical in or on various food commodities.

DATES: Comments, identified by docket control number PF–1053, must be received on or before January 11, 2002.

ADDRESSES: Comments may be submitted by mail, electronically, or in person. Please follow the detailed instructions for each method as provided in Unit I.C. of the **SUPPLEMENTARY INFORMATION**. To ensure proper receipt by EPA, it is imperative that you identify docket control number PF–1053 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Carol E. Frazer PhD., Biopesticides and Pollution Prevention Division, (7511), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; 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 affected by this action if you are an agricultural producer, food manufacturer or pesticide manufacturer. Potentially affected categories and entities may include, but are not limited to:

Categories	NAICS Codes	Examples of potentially affected entities
Industry	111 112 311 32532	Crop production Animal production Food manufacturing Pesticide manufacturing

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 the table could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. If you have questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Get Additional Information, Including Copies of this Document and Other Related Documents?

1. *Electronically*. You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at http://www.epa.gov/. To access this document, on the Home Page select ''Laws and Regulations,'' ''Regulations and Proposed Rules,'' and then look up the entry for this document under the ''**Federal Register**—Environmental Documents.'' You can also go directly to the **Federal Register** listings at http://www.epa.gov/fedrgstr/.

2. *In person*. The Agency has established an official record for this action under docket control number PF–1053. The official record consists of the documents specifically referenced in this action, any public comments received during an applicable comment period, and other information related to this action, including any information claimed as confidential business information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period, is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

C. How and to Whom Do I Submit Comments?

You may submit comments through the mail, in person, or electronically. To ensure proper receipt by EPA, it is imperative that you identify docket control number PF–1053 in the subject line on the first page of your response.

1. *By mail*. Submit your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

2. *In person or by courier*. Deliver your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA. The PIRIB is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

3. *Electronically*. You may submit your comments electronically by e-mail to: opp-docket@epa.gov, or you can submit a computer disk as described above. Do not submit any information electronically that you consider to be CBI. Avoid the use of special characters and any form of encryption. Electronic submissions will be accepted in Wordperfect 6.1/8.0 or ASCII file format. All comments in electronic form must be identified by docket control number PF–1053. Electronic comments may also be filed online at many Federal Depository Libraries.

D. How Should I Handle CBI That I Want to Submit to the Agency?

Do not submit any information electronically that you consider to be CBI. You may claim information that you submit to EPA in response to this document as CBI 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. In addition to one complete version of the comment that includes any information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public version of the official record. Information not marked confidential

will be included in the public version of the official record without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the person identified under **FOR FURTHER INFORMATION CONTACT**.

E. What Should I Consider as I Prepare My Comments for EPA?

You may find the following suggestions helpful for preparing your comments:

1. Explain your views as clearly as possible.
2. Describe any assumptions that you used.
3. Provide copies of any technical information and/or data you used that support your views.
4. If you estimate potential burden or costs, explain how you arrived at the estimate that you provide.
5. Provide specific examples to illustrate your concerns.
6. Make sure to submit your comments by the deadline in this notice.
7. To ensure proper receipt by EPA, be sure to identify the docket control number assigned to this action in the subject line on the first page of your response. You may also provide the name, date, and **Federal Register** citation.

II. What Action is the Agency Taking?

EPA has received a pesticide petition as follows proposing the establishment and/or amendment of regulations for residues of a certain pesticide chemical in or on various food commodities under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a. EPA has determined that this petition contains data or information regarding the elements set forth in section 408(d)(2); however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data support granting of the petition. Additional data may be needed before EPA rules on the petition.

List of Subjects

Environmental protection, Agricultural commodities, Feed additives, Food additives, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: November 27, 2001.

Janet L. Andersen,

Director, Biopesticides and Pollution Prevention Division, Office of Pesticide Programs.

Summary of Petition

The petitioner summary of the pesticide petition is printed below as required by section 408(d)(3) of the FFDCA. The summary of the petition was prepared by the petitioner and represents the view of the petitioners. EPA is publishing the petition summary verbatim without editing it in any way. The petition summary announces the availability of a description of the analytical methods available to EPA for the detection and measurement of the pesticide chemical residues or an explanation of why no such method is needed.

EPA has received a pesticide petition (PP) 1F6314 from 3M, St. Paul, Minnesota 55144–1000, proposing pursuant to section 408(d) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(d), to amend 40 CFR part 180 to establish an exemption from the requirement of a tolerance for the biochemical pesticides the C_8, C_{10} and C_{12} saturated fatty acid monoesters of glycerol and propylene glycol in or on all raw agricultural commodities and food.

Pursuant to section 408(d)(2)(A)(i) of the FFDCA, as amended, 3M has submitted the following summary of information, data, and arguments in support of their pesticide petition. This summary was prepared by 3M and EPA has not fully evaluated the merits of the pesticide petition. The summary may have been edited by EPA if the terminology used was unclear, the summary contained extraneous material, or the summary unintentionally made the reader conclude that the findings reflected EPA's position and not the position of the petitioner.

3M

PP 1F6314

A. Product Name and Proposed Use Practices

3M's VWX–42 Technology System is comprised of six very closely related active ingredients that are used singly or in combination against Gram positive and Gram negative bacteria, fungi, yeasts and lipid coated viruses to control spoilage of food and feed crops after harvest. The choice of which active ingredient or mix of ingredients to use is determined by the identity of the pest organisms to be controlled and the characteristics desired for the end-use formulation. The active ingredients are generally applied at levels between 0.1% and 1% in the diluted formulation at a rate sufficient to wet thoroughly the commodity being treated.

B. Product Identity/Chemistry

1. *Identity of the pesticide and corresponding residues*. The Chemical Abstract Services (CAS) index names for the six active ingredients are as follows:

- Octanoic acid, monoester with 1,2,3-propanetriol, CAS Registry No. 26402–26–6;
- Decanoic acid, monoester with 1,2,3-propanetriol, CAS Registry No. 26402–22–2;
- Dodecanoic acid, monoester with 1,2,3-propanetriol, CAS Registry No. 27215–38–9;
- Octanoic acid, monoester with 1,2-propanediol, CAS Registry No. 68332–79–6;
- Decanoic acid, monoester with 1,2-propanediol, CAS Registry No. 68795–69–7; and
- Dodecanoic acid, monoester with 1,2-propanediol, CAS Registry No. 27194–74–7.

The residues expected in treated raw agricultural commodities and food are the parent compounds and/or their hydrolysis products (metabolites). The hydrolysis products are a mixture of the free fatty acid and glycerol or propylene glycol. The glycerol fatty acid monoesters are natural components in dietary fats and natural breakdown products from the metabolism of fat (triacylglycerol) in all living systems. The propylene glycol monoesters are metabolized by the same pathways and with the same ease as glycerol. Both types of active ingredient are metabolized by living matter as food. The first step in their metabolism is hydrolysis to free fatty acid and glycerol or propylene glycol.

2. *Magnitude of residue at the time of harvest and method used to determine the residue*. An unreasonable worst cast physical model was constructed to generate the residue data. A typical end-use formulation was prepared containing one of the active ingredients. A typical diluted treatment solution (0.86% active ingredient by weight) was prepared by diluting the formulation with water. Eighteen different raw agricultural commodities were obtained from local supermarkets in St. Paul, Minnesota and treated with the diluted formulation by soaking at room temperature for 15 minutes. Ten samples of each commodity were weighed to the nearest milligram before treatment and allowed to drain on a wire grate for 1 minute before reweighing. The difference between pre- and post-soak weights was used as the measure of residue for each commodity sample.

The commodities obtained from supermarket shelves, particularly beans, had inevitably lost moisture between the time of harvest and the time when they were treated to generate residue data. The treatment solution, being

aqueous, under the test conditions replaced moisture lost since harvest. In some cases, the absorption of the diluted aqueous pesticide formulation by the commodity was substantially greater than what would be expected if it had been treated immediately after harvest and treated by wetting its surface rather than soaking. Although certain residue levels determined by our worst-case physical model were clearly excessive, all of the experimentally determined values were included in the dietary analysis in keeping with the intended worst-case nature of the assessment. The experimentally determined residue levels used in the aggregate dietary risk assessment ranged from 10 to 400 parts per million (ppm) (milligrams/kilograms (mg/kg) commodity) active ingredient residue.

3. *A statement of why an analytical method for detecting and measuring the levels of the pesticide residue are not needed.* An exemption from tolerance is sought because use of the VWX-42 Technology System active ingredients will create only minuscule exposures (< 1 mg/kg-bodyweight (bwt)/day) when compared to the natural levels of such compounds in living tissue and in foods (~50–100 grams per/day (g/day)), and compared to the levels permitted in food as direct additives (g/day). Hence, there will be no need to monitor for pesticide residues and there is no need for an analytical method for detecting and measuring such residues in the commodities treated.

C. Mammalian Toxicological Profile

A substantial body of primary toxicology data were generated to support EPA registration as biochemical pesticides. In all studies, EPA's limit doses were used and the test compounds were found to be safe, but all tests were not conducted on all 6 active ingredients. Propylene glycol monocaprylate (the C_8 ester) was selected as the test material to represent all 6 active ingredients in subchronic testing (90–day rat oral toxicity study). Because the metabolism and toxicity of the VWX-42 Technology System active ingredients have been well documented in the scientific literature and all six active ingredients are known to be identical with respect to toxicity and metabolism, a new 90–day study was conducted on only 1 of the 6 active ingredients. A full acute toxicity test battery (6 studies) was generated on the C_8 propylene glycol monoester and on the C_{12} glycerol ester, thereby bounding the chemical structures of all 6 ingredients.

The results of the individual studies are summarized below.

1. *Acute oral toxicity (rat) for glycerol monolaurate: Non-toxic.* A group of 6 fasted rats (3 male and 3 female) received a single oral gavage dose of glycerol monolaurate, formulated in corn oil and administered at a dose level of 5,000 mg/kg bwt, in a limit test. No abnormalities were revealed in any of the animals at the macroscopic examination at study termination on Day 15.

The acute lethal oral dose to rats was demonstrated to be greater than 5,000 mg/kg.

2. *Acute oral toxicity (rat) for propylene glycol monocaprylate: Non-toxic.* A group of 6 fasted rats (3 males and 3 females) received a single oral gavage dose of the test substance administered at a dosage of 5,000 mg/kg bwt. Clinical signs of reaction to treatment were confined to piloerection (all rats) and increased salivation (one female only), both evident within a few minutes of dosing with only piloerection persistent during the remainder of Day 1. There were no signs of reaction to treatment and piloerection had resolved by Day 2 in female rats and by Day 4 in male rats. No abnormalities were revealed in any of the animals at the macroscopic examination at study termination on Day 15.

The acute lethal oral dose to rats of propylene glycol monocaprylate was demonstrated in this study to be greater than 5,000 mg/kg bwt.

3. *Acute dermal toxicity (rat) for glycerol monolaurate: Non-toxic.* A group of 10 rats (5 males and 5 females) received a single topical application of glycerol monolaurate formulated in corn oil and administered at a dosage of 5,000 mg/kg bwt. There were no clinical signs of reaction to treatment observed in any animal throughout the study. All animals were killed as scheduled at study termination (Day 15) and subjected to a macroscopic examination. No macroscopic abnormalities were observed for animals killed at study termination on Day 15.

The acute lethal dermal dose to rats of glycerol monolaurate was demonstrated to be greater than 5,000 mg/kg bwt.

4. *Acute dermal toxicity (rat) for propylene glycol monocaprylate: Non-toxic.* A study was performed to assess the acute dermal toxicity of propylene glycol monocaprylate to the rat. A group of 10 rats (5 males and 5 females) received a single topical application of the test substance at a dosage of 5,000 mg/kg bwt. All animals were killed as scheduled at study termination (Day 15) and subjected to a macroscopic examination. No macroscopic abnormalities were observed for animals killed at study termination on Day 15.

The acute lethal dermal dose to rats of propylene glycol monocaprylate was demonstrated to be greater than 5,000 mg/kg bwt.

5. *Acute inhalation (rat) for glycerol monolaurate: 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.

6. *Acute inhalation (rat) for propylene glycol monocaprylate: Non-toxic.* The acute toxicity of propylene monocaprylate was assessed by exposing a group of rats (5 males and 5 female), for a period of 4 hours, to a droplet aerosol generated from the test substance at a target concentration of 5 mg/L. Another group (5 male and 5 female), acting as a control was exposed to clean dry air only. The nominal concentration of propylene monocaprylate was 5.6 mg/L. The mass median aerodynamic (MMAD) was 2.0 μm and was within the ideal range (1 μm to 4 μm) for an acute inhalation study. Approximately 88% of the particles were considered of a respirable size (< 7 μm in aerodynamic diameter). The LC_{5O} (4–hour inhalation) for propylene glycol monocaprylate, is in excess of 4.92 mg/L (4920 ppm) in air. EPA's limit dose for this test is 2 mg/L.

7. *Eye irritation (rabbit) for glycerol monolaurate: Slight irritant.* Three rabbits were each administered a single ocular dose of 0.1 mL of the test substance (mean weight 60 mg) and observed for up to 7 days after instillation. The instillation in one animal elicited a corneal lesion and iritis (both Graded 1) 48 hours post dose. All 3 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. The test material is considered a slight eye irritant.

8. *Eye irritation (rabbit) for propylene glycol monocaprylate: Non-irritant.* Three rabbits were each administered a single ocular dose of 0.1 mL of propylene glycol monocaprylate test substance and observed for three days after instillation. The single instillation of propylene glycol monocaprylate elicited in two of the three rabbits a transient, slight to well-defined conjunctival irritation only. The test

substance is not considered an ocular irritant.

9. *Skin irritation (rabbit) for glycerol monolaurate: Non-Irritant.* Three rabbits were each administered a single dermal dose of 0.5 gm of the test substance glycerol monolaurate, under semi-occlusive conditions for 4 hours and observed for up to 11 days. The test material produced transient slight erythema only in one animal. The test substance is not considered a dermal irritant.

10. *Skin irritation (rabbit) for propylene glycol monocaprylate: Non-irritant.* Three rabbits were each administered a single dermal dose of 0.5 mL of the test substance propylene glycol monocaprylate under semi-occlusive conditions for 4 hours and observed for up to 11 days. Propylene glycol monocaprylate produced only slight erythema in all animals. The test substance is not considered a dermal irritant.

11. *Skin sensitization (guinea-pig) for glycerol monolaurate: Non-sensitizer.* Guinea pigs 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 in sterile water
- Topical application: 10% w/v in sterile water
- Challenge applications: 0.5 and 1% w/v in sterile water

Ten test and five control guinea pigs were used in this study. Following the first challenge application, negative responses were observed in six test animals, inconclusive responses were seen 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 of the test or control animals. Glycerol monolaurate is not considered to have the potential 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 nine of the ten animals, thus confirming the sensitivity and reliability of the experimental technique.

12. *Skin sensitization (guinea-pig) for propylene glycol monocaprylate: Potential sensitizer.* The guinea pigs 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

Ten test and five control guinea pigs were used in this study. In this study propylene glycol monocaprylate produced evidence of skin sensitization (delayed contact hypersensitivity) in all of the test animals. Propylene glycol monocaprylate is considered to have the potential to cause skin sensitization. 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 was checked periodically by the laboratory with a weak to moderate sensitizer - hexyl cinnamic aldehyde (HCA). In this study HCA produced evidence of skin sensitization (delayed contact hypersensitivity) in nine of the ten animals, thus confirming the sensitivity and reliability of the experimental technique.

13. *28–Day oral (rat): for propylene glycol monocaprylate: Non-toxic.* The effects of propylene glycol monocaprylate (T–7475.8) were assessed in rats (groups of 5 males and 5 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.

14. *13–Week oral (rat) for propylene glycol monocaprylate: 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, and 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 both sexes.

Waivers of genotoxicity, reproductive and developmental toxicity studies were also requested on the bases described below.

15. *Genotoxicity.* Because the VWX–42 active ingredients themselves in vertebrate systems are immediately metabolized like any fats to polyols and free fatty acids, upon ingestion they become indistinguishable from the natural background of such compounds in living systems. Polyols and free fatty acids in living systems are not genotoxic. Hence, waivers were requested 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 VWX–42 active ingredients are already known, from a metabolic standpoint, not to be genotoxic.

16. *Reproductive and developmental toxicity.* Also on the basis of their metabolism, the VWX–42 active ingredients, and their natural breakdown products, are known not to be reproductive or developmental toxicants. Waivers were requested for all such testing requirements on the basis that conducting such tests would not be of value to EPA in its evaluation of risks.

17. *Scientific literature on toxicity and metabolism.* Basic toxicity testing on mono and diacylglycerols and saturated fatty acids was done in the 1930–1960 period. The available data include extensive testing in intermediate and long-term studies. Less work has been published on propylene glycol saturated fatty acid esters, but the available data are adequate to demonstrate an equivalence between propylene glycol esters and acylglycerols. Comprehensive reviews are available 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) through the Joint FAO/WHO Expert Committee on Food Additives (JECFA).

The NOAELs for mono acylglycerols, 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 six months showed no evidence of gross or histological pathology attributable to treatment. Dogs fed at the same levels for six months showed no signs of toxicity.

The particular fatty acid moiety in mono acylglycerols does not matter because vertebrate systems are capable

of metabolizing each of the acids in the range of C_8 to C_{18} with equal facility. 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 mono acylglycerols. The VWX–42 gylcerol 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 ^{14}C-labeled propylene glycol show that it is readily absorbed from the gastrointestinal tract and rapidly converted in the liver to ^{14}C-glycogen or $^{14}CO_2$. In a like manner, when ^{14}C-glycerol is administered to the rat, radiolabel appears in expired CO_2, blood glucose, liver glycogen, liver fat and liver phosphatides within 15 minutes. Within 6 hours, 40% of the label is contained in expired CO_2 and the remainder is distributed through the test animal. Very small amounts are excreted.

FDA has looked at metabolism of propylene glycol mono and distearate as a 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 CO_2 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 CO_2 in the same period.

D. Aggregate Exposure

1. *Dietary exposure.* Aggregate dietary exposure estimates were generated using EPA's Dietary Exposure Potential Model (DEPM) customarily used by the agency in making such estimates. The model is designed to generate dietary exposure estimates by combining data from established food consumption data bases with residue data. In this case, food consumption data came from the 10th National Food Consumption Survey conducted during the three 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).

i. *Food.* Food residue estimates were generated for use in the DEPM analysis to simulate very broad use of the VWX–42 active ingredients. Specifically, residues estimates were constructed for all food commodities corresponding to the 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). The assumption was also made that 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.

ii. *Drinking water.* All anticipated or proposed use for the VWX–42 active ingredients will be indoors and the active ingredients are not soluble in water. Hence, drinking water is not a feasible route of exposure.

2. *Non-dietary exposure.* The only non-dietary exposures from pesticidal uses of the VWX–42 active ingredients will be occupational, i.e., commercial applicator/mixer loader exposures. Occupational exposures are not included under the FFDCA in the assessment of aggregate exposures for the purpose of establishing tolerances and exemptions from tolerance.

E. Cumulative Exposure

In assessing their cumulative effects, the VWX–42 active ingredients are members of a much larger class of compounds that are toxicologically and metabolically equivalent. This class of compounds are dealt with by all vertebrate systems 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. Toxicologically and metabolically the glycerol and propylene glycol esters are equivalent.

The proposed use of VWX–42 active ingredients as pesticides will contribute a negligible amount (total U.S. population worst case estimate <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).

F. Safety Determination

1. *U.S. population.* Generating a quantitative measure of safety, such as a margin of exposure value (MOE), is difficult for the VWX–42 active ingredients because they function as foods rather than toxicants in all test animal systems, giving no clear toxicity endpoints even when tested at levels representing a substantial portion of the diet. Both acute and subchronic primary data generated to support this petition show no observed adverse effects at the limit doses established for such tests by EPA. Subchronic and chronic exposure studies reported in the literature run at much higher levels (e.g., 10% or more of the total diet) also produced no adverse effects. In its review of such compounds, the JECFA observed that ''dietary loads of a food additive in excess of 10 percent are of little value in assessment of safety-in-use...'', and the committee based its conclusion of safety upon the biochemical and metabolic evidence that the breakdown

product of such additives are ''normal dietary constituents.''

MOE levels can be calculated for the U.S. population as shown below in Table 1, using various NOAELs, including the NOAEL for the 90–day gavage study submitted in support of this petition. These values represent the highest levels tested, not the highest level tolerated without adverse effects. JECFA has also established an allowable daily intake value (ADI) for propylene glycol monostearate of 25 mg/kg-bwt/day that may be used to derive an MOE estimate. The several MOE calculations presented in Table 1 demonstrate that exposures, even when estimated using severe worst-case assumptions, are well below any level of concern.

TABLE 1. CALCULATED MARGINS OF EXPOSURE FOR VWX–42 ACTIVE INGREDIENTS

Basis for calculation	Acceptable level	Estimated exposure	Margin of exposure
NOAEL, 90–day gavage study using propylene glycol monocaprylate	NOAEL = 1,000 mg/kg-bwt/day	U.S. Population = 0.13 mg/kg-bwt/day Non-nursing infants = 0.44 mg/kg-bwt/day	U.S. population = 7,690
FDA NOAEL, 90–day dietary study with propylene glycol monostearate*	NOAEL = 7.52% of diet (= highest dose tested = 3.22 g/kg-bwt/day)	Same as above	U.S. population = 24,770
JECFA ADI for propylene glycol monostearate*	ADI = 25 mg/kg-bwt/day including safety factor of 100	Same as above	U.S. population = 19,230

*Propylene glycol monostearate is widely accepted as a surrogate for all glycerol and propylene glycol monoesters.

2. *Infants and children*. MOE levels for infants and children can be calculated as shown in Table 2 using the same toxicity endpoints as for the U.S. population.

TABLE 2. CALCULATED MARGINS OF EXPOSURE FOR VWX–42 ACTIVE INGREDIENTS

Basis for calculation	Acceptable level	Estimated exposure	Margin of exposure
NOAEL, 90–day garage study using propylene glycol monocaprylate	NOAEL = 1,000 mg/kg-bwt/day	Non-nursing infants = 0.44 mg/kg-bwt/day Children 1–6 = 0.28 mg/kg-bwt/day Children 7–12 = 0.15 mg/kg-bwt/day	Non-nursing infants = 2,270 Children 1–6 = 3,570 Children 7–12 = 6,670
FDA NOAEL, 90–day dietary study with propylene glycol monostearate*	NOAEL = 7.52% of diet (= highest dose tested = 3.22 g/kg-bwt/day)	Same as above	Non-nursing infants = 7,320 Children 1–6 = 11,500 Children 7–12 = 21,470
JECFA ADI for propylene glycol monostearate*	ADI = 25 mg/kg-bwt/day, including safety factor of 100	Same as above	Non-nursing infants = 5,680 Children 1–6 = 8,930 Children 7–12 = 16,670

*Propylene glycol monostearate is widely accepted as a surrogate for all glycerol and propylene glycol monoesters.

G. Effects on the Immune and Endocrine Systems

Because VWX–42 active ingredients in vertebrate systems are immediately metabolized, like any fat, to polyols and free fatty acids, upon ingestion they become indistinguishable from the natural background of such compounds in living systems. On the basis that they are natural components of vertebrate systems, the VWX–42 active ingredients, and their breakdown products, are not expected to have any effect on immune and endocrine systems.

H. Existing Tolerances

No tolerances exist for any of the VWX–42 Technology System compounds as pesticide active ingredients. They may be used as inert ingredients in pesticide formulations and many clearances exist under the FFDCA for their use as direct and indirect food additives.

Mono and diglycerides from fats or oils or fat-forming acids are affirmed as GRAS as direct food additives under 21 CFR 184.1505. Mono and diglycerides of C_{8}–C_{14} fatty acids are exempt from the requirement for tolerance under 40 CFR 180.1001(c) for use as surfactants and adjuvants in pesticide formulations. Numerous fatty acids, the hydrolysis products of both the glycerol and propylene glycol esters, are themselves also affirmed as GRAS (21 CFR 184.1025).

Propylene glycol mono and diesters of fatty acids are permitted under 21 CFR 172.856 for general use in food; 21 CFR 172.860 permits the corresponding fatty acid metabolites in foods; and 21 CFR 172.863 permits salts of fatty acids in food. The monoesters are also permitted under 21 CFR 175.105 as ingredients in adhesives used in food contact applications. Propylene glycol esters of fatty acids are also cleared by USDA as emulsifiers in margarine or oleomargarine at 2% (48 FR 52696, Nov. 22, 1983).

Glycerol, a hydrolysis product of mono acylglycerols, is listed by FDA as a substance generally recognized as safe (GRAS) as a multiple purpose food additive when used in accordance with good manufacturing practice (21 CFR 182.1320) and as a GRAS substance when migrating to food from paper and

paperboard products (21 CFR 182.90). An exemption from tolerance has been established by FDA under 21 CFR 182.99 and by EPA under 40 CFR 180.1001(c) and (e) for its use as a solvent and co-solvent in pesticide formulations and as an adjuvant when added to pesticide dilutions by growers or applicators prior to application. It is also deemed GRAS by the Expert Panel of the Flavor and Extract Manufacturers'Association of America.

Propylene glycol, a hydrolysis product of the propylene glycol esters, is affirmed as GRAS under 21 CFR 184.1666. It is used as an anticaking agent, antioxidant, dough strengthener, emulsifier, flavor agent, formulation aid, humectant, processing aid, solvent and vehicle, stabilizer and thickener, surface-active agent, and tenderizer in foods at levels not to exceed current good manufacturing practice. The approved uses result in maximum levels, as served of 5% in alcoholic beverages, 24% in confections and frostings, 2.55% in frozen dairy products, 97% in seasonings and flavoring, 5% in nuts and nut products, and 2% in all other food categories. Propylene glycol is also exempt from the requirement of tolerance by EPA under 40 CFR 180.1001(c) and (e), and has been deemed GRAS by the Expert Panel of the Flavor and Extract Manufacturers' Association of America.

I. International Tolerances

No international tolerances have been established for the active ingredients in the VWX–42 Technology system. The FAO and the WHO through the JECFA has reviewed mono and diacylglycerol and propylene glycol esters of fatty acids and determined that they may be used safely in foods at levels of 1–3 grams per day for an adult. It as observed that ''alterations in the fatty acid distribution or polyglycerol content of individual members of a group of diverse substances have no toxicological bearing and only affect the physical and emulsifying properties of each ester.'' The Committee concluded safety based upon the biochemical and metabolic evidence that the breakdown products of such additives are normal dietary constituents.

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ENVIRONMENTAL PROTECTION AGENCY

[PF–1058; FRL–6812–7]

Notice of Filing a Pesticide Petition to Establish a Tolerance fora Certain Pesticide Chemical in or on Food

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the initial filing of a pesticide petition proposing the establishment of regulations for residues of a certain pesticide chemical in or on various food commodities.

DATES: Comments, identified by docket control number PF–1058, must be received on or before January 11, 2002.

ADDRESSES: Comments may be submitted by mail, electronically, or in person. Please follow the detailed instructions for each method as provided in Unit I.C. of the **SUPPLEMENTARY INFORMATION**. To ensure proper receipt by EPA, it is imperative that you identify docket control number PF–1058 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Hoyt Jamerson, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 308–9368; e-mail address: jamerson.hoyt@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

Categories	NAICS codes	Examples of potentially affected entities
Industry	111 112 311 32532	Crop production Animal production Food manufacturing Pesticide manufacturing

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 the table could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. If you have questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Get Additional Information, Including Copies of this Document and Other Related Documents?

1. *Electronically*. You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at http://www.epa.gov/. To access this document, on the Home Page select ''Laws and Regulations,'' ''Regulations and Proposed Rules,'' and then look up the entry for this document under the ''**Federal Register**—Environmental Documents.'' You can also go directly to the **Federal Register** listings at http://www.epa.gov/fedrgstr/.

2. *In person*. The Agency has established an official record for this action under docket control number PF–1058. The official record consists of the documents specifically referenced in this action, any public comments received during an applicable comment period, and other information related to this action, including any information claimed as confidential business information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period, is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

C. How and to Whom Do I Submit Comments?

You may submit comments through the mail, in person, or electronically. To ensure proper receipt by EPA, it is imperative that you identify docket control number PF–1058 in the subject line on the first page of your response.

1. *By mail*. Submit your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs