B. Toxicological Profile

Since dimethylether (DME) exists as a gas at room temperature and any exposure to humans would occur via inhalation, all toxicity testing conducted with DME was done via inhalation or in the vapor phase.

1. *Acute toxicity*. An acute inhalation toxicity study was conducted in rats. The 4–hr LC_{50} was determined to be 164,000 parts per million (ppm), EPA category IV.

2. *Genotoxicty*—i. An *in vitro* Ames/*Salmonella* mutagenicity assay in five commonly used strains was negative for mutagenic potential.

ii. An *in vitro* chromosomal aberration test in cultured human lymphocytes was negative for chromosomal aberrations.

3. *Reproductive and developmental toxicity*—i. Reproductive organs in male and female rats were examined histopathologically following inhalation of 0, 2,000, 10,000, or 25,000 ppm DME for 6, 12, 16, and 24 months. The no observed adverse effect level (NOAEL) in this study was 25,000 ppm as no compound-related effects on the reproductive organs of either male or female rats were observed.

ii. Developmental toxicity testing was conducted in rats exposed via inhalation to DME during days 6–15 of gestation. Fetal body weight (bwt) was decreased at the 20,000 and 40,000 ppm levels (of borderline statistical significance in the 20,000 ppm group) and there was an increased incidence of several skeletal variations (partial rib development in the lumbar region and partial or complete doubling of one or more vertebral centra). The NOAEL for the conceptus was 1,250 ppm. In comparison to maternal effect levels, DME was not demonstrated to represent a unique hazard to the rat conceptus.

4. *Subchronic toxicity*. Male and female Wistar rats were exposed to 0, 200, 2,000, or 20,000 ppm DME via inhalation for 30 weeks. At the 20,000 ppm level, male rats showed a significant reduction in liver weight accompanied by raised serum glutamic pyruvic transaminase (SGPT) levels. In the 20,000 ppm females, there was no significant effect on liver weight but SGPT levels were raised. The NOAEL in this study was 2,000 ppm.

5. *Chronic toxicity*. A 2–year DME inhalation study was conducted in rats for 6 hours/day, 5 days/week at concentrations of 0, 2,000, 10,000, or 25,000 ppm. The NOAEL was 2,000 ppm based on an increase in bwt and a decrease in survival in male rats exposed to 10,000 or 25,000 ppm DME vapors and on hemolytic effects noted in male rats exposed to 25,000 ppm DME vapors for 6 months. No neoplastic lesions were observed that could be attributable to DME exposure. DME was not carcinogenic.

6. *Animal metabolism*. Dimethylether is a volatile, stable compound. While no metabolism studies were identified, the primary route of DME elimination from the body is likely to be exhalation of parent compound.

7. *Endocrine disruption*. No adverse endocrine effects have been suggested or reported in any toxicity tests conducted with DME.

C. Aggregate Exposure

1. *Dietary exposure*. Dimethylether exists as a vapor at atmospheric pressure and ambient temperatures. It is handled and contained in aerosol products as a liquefied gas under its own vapor pressure which is 63 psig at 70°F. Upon release from container pressure, as when product is dispensed, dimethylether vaporizes completely with essentially no residue. Dimethylether is intended as an inert ingredient and propellant for pesticide formulations applied in food handling areas and establishments; these products are not intended for direct application to foods. Dietary exposure from use of dimethylether in these types of products is believed to be minimal, as discussed in food and drinking water below.

i. *Food*. Based on its physical properties, when dimethylether is used as a propellant in pesticide formulations applied in food handling areas and establishments, no residue is expected on or in food. Upon dispensing the insect control product, the dimethylether will vaporize and dissipate quickly, affording no residue or accumulation.

ii. *Drinking water*. Similarly, since dimethylether will vaporize completely at ambient conditions, no accumulation is expected in drinking water. There would be no liquid dimethylether to migrate to groundwater aquifers or surface water bodies that may serve as suitable drinking water sources.

2. *Non-dietary exposure*. The greatest potential for residential exposure to dimethylether would be via inhalation routes. However, even when these pesticide products are used in small areas, estimated dimethylether levels will be lower and of much shorter duration than recognized and accepted levels that are considered safe for chronic lifetime exposures. Additionally, tests have shown that such aerosol propellants dissipate within minutes of use.

D. Cumulative Effects

There is no reliable information that would indicate or suggest that dimethylether has any toxic effect on mammals that would be cumulative with those of any other chemical.

E. Safety Determination

1. *U.S. population*. Since potential dietary exposures are expected to be minimal, if any, and since potential inhalation exposures are estimated much lower than recognized and accepted levels considered safe for chronic lifetime exposures, dimethylether is not likely to pose any significant risk to the general U.S. population.

2. *Infants and children*. To the best of our knowledge, there is no information that suggests infants and children are more susceptible to exposure to or effects of dimethylether. The lack of significant toxicity in reproductive/developmental studies on dimethylether suggests that growing organisms are not at increased risks. Since potential dietary exposures to infants and children are minimal, if any, based on anticipated use, it is unlikely that any significant risks exist. Direct exposures to infants and children via inhalation are not anticipated for the intended use of dimethylether.

F. International Tolerances

DuPont is not aware of any tolerances for dimethylether outside the United States.

[FR Doc. 00–24438 Filed 9–26–00; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[PF–977; FRL–6746–4]

Notice of Filing Pesticide Petitions to Establish a Tolerance for Certain Pesticide Chemicals in or on Food

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

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

DATES: Comments, identified by docket control number PF–977, must be received on or before October 27, 2000.

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–977 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: For Pesticide Petition PP (0E6118), contact Shaja R. Brothers, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 308–3194; e-mail address: brothers.shaja@epa.gov.

For Pesticide Petition PP (0F6146), contact Thomas C. Harris, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 308–9423; e-mail address: harris.thomas@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–977. 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–977 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–977. 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 pesticide petitions as follows proposing the establishment and/or amendment of regulations for residues of certain pesticide chemicals in or on various food commodities under section 408 of the Federal Food, Drug, and Comestic Act (FFDCA), 21 U.S.C. 346a. EPA has determined that these petitions contain 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 petitions. Additional data may be needed before EPA rules on the petitions.

List of Subjects

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

Dated: September 15, 2000.

James Jones,

Director, Registration Division, Office of Pesticide Programs.

Summaries of Petitions

Petitioners summaries of the pesticide petitions are printed below as required by section 408(d)(3) of the FFDCA. The summaries of the petitions were prepared by the petitioners and represent the views of the petitioners. The petitions summaries 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.

Interregional Research Project Number 4

Novartis Crop Protection Inc.

0E6118 and 0F6146

EPA has received a pesticide petition (0E6118) from Interregional Research Project Number 4, 681 U.S. Highway #1 South, North Brunswick NJ 08902–3390. EPA has also received a pesticide petition (PP 0F6146) from Novartis Crop Protection Inc., Post Office Box 18300, Greensboro NC 27419–8300. These petitions propose, pursuant to section 408(d) of the FFDCA, 21 U.S.C. 346a(d), to amend 40 CFR part 180 by establishing tolerances for residues of the insecticide, avermectin (a mixture of avermectins containing greater than or equal to 80% avermectin B_{1a} (5-O-demethyl avermectin A_1) and less than or equal to 20% avermectin B_{1b} (5-O-demethyl-25-de(1-methylethyl) avermectin A_1)) and its delta 8,9–isomer in or on the food commodities at the tolerance level as follows:

1. PP 0E6118, which was submitted by IR–4, proposes the establishment of a tolerance for celeriac (roots and tops) at 0.05 parts per million (ppm).

2. PP 0F6146, which was submitted by Novartis Crop Protection Inc., proposes the establishment of tolerances for avocado at 0.02 ppm, grass forage at 0.001 ppm, grass hay at 0.001 ppm, stone fruit crop group at 0.015 ppm, mint tops at 0.01 ppm, tree nut crop group and pistachios at 0.005 ppm, and the tuberous and corm vegetables crop subgroup at 0.005 ppm.

A. Residue Chemistry

1. *Plant metabolism*. The metabolism of abamectin in plants is adequately understood and the residues of concern include the parent insecticide, abamectin or avermectin B1 (which is a mixture of a minimum of 80% avermectin B_{1a} and a maximum of 20% avermectin B1b) and the delta 8,9–isomer of the B_{1a} and of the B_{1b} components of the parent insecticide.

2. *Analytical method*. The analytical methods involves homogenization, filtration, partition, and cleanup with analysis by high performance liquid chromotography (HPLC)-fluorescence detection. The methods are sufficiently sensitive to detect residues at or above the tolerances proposed. All methods have undergone independent laboratory validation as required by PR Notice 88–5.

3. *Magnitude of residues*. Complete residue data for abamectin for the petitioned tolerances has been submitted. The data support the requested tolerances.

B. Toxicological Profile

1. *Acute toxicity*. The data base includes the following studies:

i. A rat acute oral study with a lethal dose $(LD)_{50}$ of 4.4 to 11.8 mg/kg (males) and 10.9 to 14.9 milligrams/kilograms (mg/kg) (females).

ii. An acute oral toxicity in the CF–1 mouse with the delta 8,9–isomer has LD_{50} greater than 80 mg/kg.

iii. A rabbit acute dermal study with a LD_{50} >2,000 mg/kg.

iv. A rat acute inhalation study with a LC_{50} >5.73 mg/L.

v. A primary eye irritation study in rabbits which showed irritation.

vi. A primary dermal irritation study in rabbits which showed no irritation.

vii. A primary dermal sensitization study in guinea pigs which showed no skin sensitization potential.

viii. An acute oral toxicity study in monkeys with a no observed adverse effect level (NOAEL) of 1.0 mg/kg based upon emesis at 2.0 mg/kg.

2. *Genotoxicity*. The Ames assays conducted with and without metabolic activation were both negative. The V–79 mammalian cell mutagenesis assays conducted with and without metabolic activation did not produce mutations. In an alkaline elution/rat hepatocyte assay, abamectin was found to induce single strand DNA breaks without significant toxicity in rat hepatocytes treated *in vitro* at doses greater than 0.2 mM. This *in vitro* dose of 0.2 mM is biologically unobtainable *in vivo*, due to the toxicity of the compound. However, at these potentially lethal doses, *in vivo* treatment did not induce DNA single strand breaks in hepatocytes. In the mouse bone marrow assay, abamectin was not found to induce chromosomal damage. There are also many studies and a great deal of clinical and follow-up experience with regard to ivermectin, a closely similar human and animal drug.

3. *Reproductive and developmental toxicity*. In a 2–generation study in rats the NOAEL was established at 0.12 mg/kg/day in pups based upon retinal folds, decreased body weight (bwt), and mortality. The NOAELs for systemic and reproductive toxicity were 0.4 mg/kg/day. In the 2–generations reproduction study in rats with the delta 8,9–isomer, the NOAEL was 0.4 mg/kg/day and the lowest observed adverse effect level (LOAEL) was greater than 0.4 mg/kg/day highest dose tested (HDT).

In an oral developmental toxicity study in the CF–1 mouse the maternal NOAEL was 0.05 mg/kg/day based upon decreased bwts and tremors. The fetal NOAEL was 0.20 mg/kg/day based upon cleft palates. In an oral developmental toxicity study with the delta 8,9–isomer in CF–1 mice the maternal NOAEL was 0.10 mg/kg/day based upon decreased bwts. The fetal NOAEL was 0.06 mg/kg/day based upon cleft palate. In an oral developmental toxicity study in rabbits the maternal NOAEL was 1.0 mg/kg/day based upon decreased bwts and tremors. The fetal NOAEL was 1.0 mg/kg/day based upon clubbed feet. In an oral developmental toxicity study in rats the maternal and fetal NOAEL was 1.6 mg/kg/day, the HDT. In an oral developmental toxicity study with the delta 8,9–isomer the maternal NOAEL in CF–1 mice that expressed P-glycoprotein was greater than 1.5 mg/kg/day, the highest and only dose tested. No cleft palates were observed in fetuses that expressed normal levels of P-glycoprotein, but fetuses with low or

no levels of P-glycoprotein had increased incidence of cleft palates.

4. *Subchronic toxicity*. Subchronic toxicity studies included the following:

i. A rat 8–week feeding study with a NOAEL of 1.4 mg/kg/day based upon tremors.

ii. A rat 14–week oral toxicity study with a NOAEL of 0.4 mg/kg/day, the HDT.

iii. A dog 12–week feeding study with a NOAEL of 0.5 mg/kg/day based upon mydriasis.

iv. A dog 18–week oral study with a NOAEL of 0.25 mg/kg/day based upon mortality.

v. A. CD–1 mouse 84–day feeding study with a NOAEL of 4 mg/kg/day based upon decreased bwts.

5. *Chronic toxicity*. A rat 53–week carcinogencity feeding study was negative for carcinogencity, with a NOAEL of 1.5 mg/kg/day based upon tremors. A CD–1 mouse 94–week carcinogencity feeding study was negative for carcinogencity, with a NOAEL of 4 mg/kg/day based upon decreased bwts. A dog 53–week chronic feeding study was negative for carcinogencity, with a NOAEL of 0.25 mg/kg/day based upon mydriasis.

6. *Animal metabolism*. Rats were given oral doses of 0.14 or 1.4 mg/kg bwt/day of abamectin or 1.4 mg/kg bwt/day of the delta–8,9 isomer. Over 7 days, the percentages excreted in urine were 0.3–1% of the administered dose of abamectin and 0.4% of the dose of the isomer. The animals eliminated 69–82% of the dose of abamectin and 94% of the dose of isomer in feces. In rats, goats, and cattle, unchanged parent compound accounted for up to 50% of the total radioactive residues in tissues. The 24–hydroxymethyl derivative of abamectin was found in rats, goats, and cattle treated with the compound and in rats treated with the delta–8,9 isomer, and the 3''-O-demethyl derivative was found in rats and cattle administered abamectin and in rats administered the isomer.

7. *Metabolite toxicology*. There are no metabolites of concern based on a differential metabolism between plants and animals. The potential hazard of the 24–hydroxymethyl or the 3''-O-demethyl animal metabolites was evaluated in through toxicology studies with abamectin photolytic break-down product, the delta 8,9–isomer.

8. *Endocrine disruption*. There is no evidence that abamectin is an endocrine disrupter. Evaluation of the rat multi-generational study demonstrated no effect on the time to mating or on the mating and fertility indices, suggesting no effects on the estrous cycle, on mating behavior, or on male or female fertility at doses up to 0.4 mg/kg/day, the HDT. Furthermore, the range finding study demonstrated no adverse effect on female fertility at doses up to 1.5 mg/kg/day, the HDT. Similarly, chronic and subchronic toxicity studies in mice, rats, and, dogs did not demonstrate any evidence of toxicity to the male or female reproductive tract, or to the thyroid or pituitary (based upon organ weights and gross and histopathologic examination). In the developmental studies, the pattern of toxicity observed does not seem suggestive of any endocrine effect. Finally, experience with ivermectin in breeding animals, including sperm evaluations in multiple species, shows no adverse effects suggestive of endocrine disruption.

C. Aggregate Exposure

1. *Dietary exposure*—i. *Food*. An acute assessment was conducted for avermectin B_{1a} and B_{1b} residues using the Dietary Exposure Evaluation Model (DEEM™) and food consumption information from United State Department of Agriculture's (USDA)'s 1994–1996 continuing survey of food intake by individuals (CSFII). Acute dietary exposure to the adult male subpopulation was compared to an acute reference dose (RfD) of 0.0025 mg/kg/day based on a NOAEL of 0.25 mg/kg/day from a 1–year dog study and a 100X uncertainty factor (UF). For all other populations (containing females, infants and children) an acute population adjusted dose (PAD) of 0.00083 mg/kg/day was used and reflects an appropriate 300X UF. This tier 3 probabilistic analysis included the entire distribution of field trial residues and percent of crop treated information was incorporated by adding zeroes into the residue distribution file (RDF) representing the percent of crop not treated. Non-detected residues of avermectin B_{1a} were entered into the software as 1/2 the limit of quantitation (1/2 (LOQ)) and non-detected residues of avermectin B_{1b} were entered in as 1/4 LOQ since the production ratio of B_{1a}:B_{1b} is 80:20. The acute dietary exposure results for the male (20 + years) population shows that 2.6% of the acute RfD was utilized at the 99.9th percentile of exposure. For the general U.S. population at the 99.9th percentile, exposure was 13.2% of the acute PAD. The most sensitive subpopulation was non-nursing infants (< 1–year old) with 39.3% of the acute PAD at the 99.9th percentile.

For the male subpopulation, chronic exposure was compared to the chronic RfD of 0.0012 mg/kg/day from a 2–generation reproduction study in rats and a 100X UF. A 300X UF was utilized for populations containing females (13 + years old) and infants and children and the exposures were compared to a PAD of 0.0004 mg/kg/day. Residue values, taken from field trials conducted at maximum application rates and minimum pre-harvest intervals (PHI), were averaged and incorporated into the assessment. Residue values were adjusted with percent of crop treated information. For the male population (both 13–19 years and 20 + years), exposure was 0.3% of the chronic RfD. The chronic exposure results indicate that the U.S. population utilizes 1.3% of the chronic PAD. The most sensitive subpopulation was non-nursing infants with 2.9% of the chronic PAD. These results are conservative in that residue values were generated from field trials with maximum application rates and minimum post PHI. In addition, a significant reduction in residues would be expected as abamectin-treated commodities travel through food commerce, food preparation and storage.

ii. *Drinking water. Acute exposure* The estimated maximum concentration of abamectin in surface water is 0.88 parts per billion (ppb) (Peak estimated environmental concentration ((EEC) value from EPA's Pesticide Root Zone Model (PRZM)/EXAMS). This is an estimated environmental concentration based on the use of abamectin on strawberries (the maximum use rate on registered and proposed uses). Use rates for crops on the current petition are all below the maximum use rate for strawberries. Novartis believes the estimates of abamectin exposure in water derived from the PRZM/EXAMS models are significantly overstated. EPA noted that the certainty of the concentrations estimated for strawberries is low, due to uncertainty on the amount of runoff from plant beds covered in plastic mulch and uncertainty on the amount of degradation of abamectin on black plastic compared to soil. Although there is a high degree of uncertainty to this analysis, this is the best available estimate of concentrations of abamectin in drinking water.

Based on the EPA's ''Interim Guidance for Conducting Drinking Water Exposure and Risk Assessments'' document (12/2/97), the acute drinking water levels of comparison ($(DWLOC_{acute})$) were calculated for abamectin. For the adult male subpopulation, the $DWLOC_{acute}$ was determined based on an acute RfD of 0.0025 mg/kg/day based on a NOAEL of 0.25 mg/kg/day from a 1–year dog study and a 100X UF. For all other populations (containing females,

infants, and children), the $DWLOC_{acute}$ was determined based on a population adjusted dose PAD of 0.00083 mg/kg/day and reflects an appropriate 300X UF. The acute dietary exposure results for the male (20 + years) population shows an exposure estimate of 0.000066 mg/kg bwt/day at the 99.9th percentile of exposure, thus a $DWLOC_{acute}$ of 85 for this subpopulation. For the general U.S. population at the 99.9th percentile, an exposure estimate of 0.000110 mg/kg bwt/day was determined, thus a DWLOC acute of 25. The most exposed subpopulation was non-nursing infants (<1 year old) with an exposure estimate of 0.000327 mg/kg bwt/day at the 99.9th percentile, thus a $DWLOC_{acute}$ of 3 for this subpopulation. Based on this analysis, abamectin EECs do not exceed the calculated acute DWLOCs. Based on a maximum EEC of 0.88 ppb, acute exposure through the consumption of drinking water is below 19% of the acute population adjusted dose for all subpopulations.

Chronic exposure. The estimated maximum concentrations of abamectin in surface and ground water are 0.37 ppb (Mean of annual values from PRZM/EXAMS) and 0.002 ppb screening concentration in ground water (SCI-GROW), respectively. These are EECs based on the use of abamectin on strawberries (the maximum use rate on registered and proposed uses). Use rates for crops on the current petition are all below the maximum use rate for strawberries. The chronic drinking water levels of comparison ($DWLOC_{chronic}$) were calculated for abamectin. For the adult male subpopulation, the $DWLOC_{chronic}$ was determined based on the chronic RfD of 0.0012 mg/kg/day from a 2–generation reproduction study in rats and a 100X uncertainty factor. A 300X UF was utilized for populations containing females (13 + years old) and infants and children and the $DWLOC_{chronic}$ was determined based on a population-adjusted dose PAD of 0.0004 mg/kg/day. The chronic dietary exposure results for the male (13–19 yrs and 20 + years) population shows an exposure estimate of 0.000004 mg/kg bwt/day, thus a $DWLOC_{chronic}$ of 42 for this subpopulation. For the general U.S. population, an exposure estimate of 0.000005 mg/kg bwt/day was determined, thus a $DWLOC_{chronic}$ of 14. The most exposed subpopulation was non-nursing infants (<**1** year old) with an exposure estimate of 0.000012 mg/kg bwt/day, thus a $DWLOC_{chronic}$ of 2.3 for this subpopulation. Based on this analysis, abamectin EECs do not exceed the calculated chronic DWLOCs. Based on a maximum EEC of 0.37 ppb, chronic exposure through the consumption of drinking water is below 16% of the chronic population adjusted dose for all subpopulations.

2. *Non-dietary exposure*. Avermectin's registered residential uses include indoor crack/crevice and outdoor application to lawns. For lawn uses, EPA conducted a risk assessment for adult applicators and post-application exposure to avermectin using the EPA's draft SOPs for residential exposure assessments. The highest predicted exposure, oral hand to mouth for children, resulted in a calculated margin of exposure (MOE) of 14,000. For children's post-application exposure to avermectin from indoor crack/crevice products, valid exposure studies demonstrate there is no exposure and therefore no risk for indoor residential scenarios. Short- and intermediate-term risk for the registered uses do not exceed EPA's level of concern.

i. *Chronic exposure and risk*. Chronic exposures for the residential uses are not expected.

ii. *Short- and intermediate-term exposure and risk*. Risk for the registered uses do not exceed EPA's level of concern.

D. Cumulative Effects

Section 408(b)(2)(D)(v) requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide residue and ''other substances that have a common mechanism of toxicity.'' The EPA stated in the **Federal Register** (FR) document published April 7, 1999, (Volume 64 Page 16843) (FRL-6070-6) that it does not have, at this time, available data to determine whether avermectin has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment.

E. Safety Determination

1. *U.S. population*. Using the exposure assumptions described above and based on the completeness and reliability of the toxicity data base, Novartis has calculated aggregate exposure levels for this chemical. The calculations show that chronic dietary exposure is below 100% of the RfD and the predicted acute exposure is below 100% of the acute RfD for all subpopulations. Chronic exposure through the consumption of drinking water has been estimated to be well below any level of concern. Acute exposure to residues of abamectin in drinking water has been estimated to be above the drinking water level of comparison DWLOC for children (1-6 years old) but the certainty of this calculation is low due to the uncertainty on the amount of runoff from strawberry plant beds covered in plastic mulch and the uncertainty on the amount of degradation of abamectin on black plastic as compared to soil. Novartis concludes that there is a reasonable certainty that no harm will result from aggregate exposure to abamectin residues.

2. *Infants and children*. The food quality protection act (Public Law 104–170) (FQPA) authorizes the employment of an additional safety factor of up to 10X to guard against the possibility of prenatal or postnatal toxicity, or to account for an incomplete data base on toxicity or exposure. EPA has chosen to retain the FQPA safety factor for abamectin based on several reasons including evidence of neurotoxicity, susceptibility of neonatal rat pups, similarity to ivermectin, lack of a developmental neurotoxicity study, and concern for exposure to infants and children. It is the opinion of Novartis that a 3X safety factor is more appropriate for abamectin at this time. EPA has evaluated abamectin repeatedly since its introduction in 1985 and has found repeatedly that the level of dietary exposure is sufficiently low to provide ample margins of safety to guard against any potential adverse effects of abamectin. In addition, valid exposure studies demonstrate there is no exposure via indoor applications of abamectin products. Novartis states that the data base for abamectin is complete and that the developmental neurotoxicity study is a new and not yet initially required study. Additionally, there is much more information regarding human risk potential than is the case with most pesticides, because of the widespread animal-drug and human-drug uses of ivermectin, the closely related analog of abamectin.

It is the opinion of Novartis that the use of a full 10X safety factor to address risks to infants and children is not necessary. The established chronic endpoint for abamectin in the neonatal rat is overly conservative. Similar endpoints for ivermectin are not used by the Food and Drug Administration (FDA) to support the allowable daily intake for ivermectin residues in food from treated animals. No evidence of toxicity was observed in neonatal rhesus monkeys after 14 days of repeated administration of 0.1 mg/kg/day HDT and in juvenile rhesus monkeys after repeated administration of 1.0 mg/kg/day HDT. The comparative data on

abamectin and ivermectin in primates also clearly demonstrate the dose response for exposure to either compound is much less steep than that seen in the neonatal rat. Single doses as high as 24 mg/kg of either abamectin or ivermectin in rhesus monkeys did not result in mortality; however, this dose was more than 2 times the LD_{50} in the adult rat and more than 20 times the LD_{50} in the neonatal rat. The absence of a steep dose-response curve in primates provides a further margin of safety regarding the probability of toxicity occurring in infants or children exposed to avermectin compounds. The significant human clinical experience and widespread animal drug uses of ivermectin without systemically toxic, developmental, or postnatal effects supports the safety of abamectin to infants and children.

F. International Tolerances

There are no abamectin Codex maximum residue levels for avocados, celeriac, grass forage, grass hay, stone fruit, mint, tree nut crop group, pistachios and tuberous and corm vegetables crop subgroup.

[FR Doc. 00–24575 Filed 9–26–00; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[OPP–50872; FRL–6739–9]

Issuance of Experimental Use Permits

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA has granted experimental use permits (EUPs) to the following pesticide applicants. An EUP permits use of a pesticide for experimental or research purposes only in accordance with the limitations in the permit.

FOR FURTHER INFORMATION CONTACT: By mail: Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

In person or by telephone: Contact the designated person at the following address at the office location, telephone number, or e-mail address cited in each experimental use permit: 1921 Jefferson Davis Hwy., Arlington, VA.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

This action is directed to the public in general. Although this action may be of particular interest to those persons who conduct or sponsor research on pesticides, the Agency has not attempted to describe all the specific entities that may be affected by this action. If you have any questions regarding the information in this action, consult the designated contact person listed for the individual EUP.

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

You may obtain electronic copies of this document from the EPA Internet Home Page at http://www.epa.gov/. 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/.

II. EUPs

EPA has issued the following EUPs:

11312–EUP–105. Issuance. Agricultural Research Service (ARS) of the U.S. Department of Agriculture (USDA), Beltsville, MD 20705. This EUP allows the use of 26 pounds of the insecticide Phloxine B on 200 acres of field corn to evaluate the control of northern, southern, western, and mexican corn rootworms. The program is authorized only in the States of Nebraska and South Dakota. The EUP is effective from August 1, 2000 to October 1, 2000. The Agency considers this EUP to be non-food/non-feed because of the low use rate (1–2 oz per acre), the site of application (outer shucks of the corn), type of harvesting (mechanical harvesting and separation of shucks from ear), and composting of the shucks in the ground following application of product. (Daniel Peacock; Rm. 223, Crystal Mall #2; telephone number: (703) 305–5407; e-mail address: peacock.dan@epa.gov).

62719–EUP–44. Amendment. Dow AgroSciences LLC, 9330 Zionsville Rd., Indianapolis, IN 46268–1054. This experimental use permit allows the use of 3,379,758 pounds of the soil fumigants 1,3-dichloropropene and chloropicrin from the product InLine on 15,000 acres of soil, treated using drip irrigations systems only, to be planted to the commodities cauliflower, cucumbers, eggplant, lettuce, melons, onions, peppers, pineapples, squash, strawberries, and tomatoes to evaluate the control of nematodes, symphylans and certain soil-borne diseases. The program is authorized only in the States of Alabama, Arizona, California, Colorado, Delaware, Florida, Georgia, Hawaii, Idaho, Michigan, New Jersey, New Mexico, North Carolina, Oregon, South Carolina, Texas, Virginia, and Washington. The experimental use permit is effective from June 25, 1999 to June 25, 2002. (Mary L. Waller, Product Manager (21); Rm. 249, Crystal Mall #2; telephone number: (703) 308–9354; e-mail address: waller.mary@epa.gov).

62719–EUP–46. Issuance. Dow AgroSciences LLC, 9330 Zionsville Rd., Indianapolis, IN 46268–1054. This experimental use permit allows the use of 237,350 pounds of the nematicide 1,3-dichloropropene on 5,000 acres of golf course turf to evaluate the control of plant parasitic nematodes. The program is authorized only in the State of Florida. The experimental use permit is effective from August 28, 2000 to August 28, 2001. (Mary L. Waller; Rm. 249, Crystal Mall #2; telephone number: (703) 308–9354; e-mail address: waller.mary@epa.gov).

Persons wishing to review these EUPs are referred to the designated contact person. Inquiries concerning these permits should be directed to the persons cited above. It is suggested that interested persons call before visiting the EPA office, so that the appropriate file may be made available for inspection purposes from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays.

Authority: 7 U.S.C. 136.

List of Subjects

Environmental protection, Experimental use permits.

Dated: September 18, 2000.

James Jones,

Director, Registration Division, Office of Pesticide Programs.

[FR Doc. 00–24679 Filed 9–26–00; 8:45 am]

BILLING CODE 6560–50–S

FEDERAL MARITIME COMMISSION

Notice of Agreement(s) Filed

The Commission hereby gives notice of the filing of the following agreement(s) under the Shipping Act of 1984. Interested parties can review or obtain copies of agreements at the Washington, DC offices of the Commission, 800 North Capitol Street, N.W., Room 962. Interested parties may submit comments on an agreement to the Secretary, Federal Maritime Commission, Washington, DC 20573, within 10 days of the date this notice appears in the **Federal Register**.

Agreement No.: 011560–002.