

that sulfuryl fluoride or fluoride are endocrine disrupters.

C. Aggregate Exposure

1. *Dietary exposure.* The Dietary Exposure Evaluation Model (DEEM), version 7.73, of Novigen Sciences, Inc. was used to estimate the dietary exposure to the U.S. population and critical sub-populations resulting from the use of sulfuryl fluoride under the conditions proposed. The highest potential chronic exposures to sulfuryl fluoride was to children ages 1 to 6 years resulting from the consumption of treated commodities totaling 0.000106 mg/kg/bwt/day. Likewise, the highest potential chronic exposure to fluoride was to children ages 1 to 6 years with a highest estimated exposure of 0.002419 mg/kg/bwt/day.

i. *Food.* Food tolerances as inorganic fluorine compounds exist to support the uses of cryolite (insecticide) on various food and feed commodities in the U.S. EPA, in the 1996 cryolite RED document, conservatively estimates that the "high-end" dietary exposures to fluoride due to all sources and routes (including the fluorination of water and the potential for fluoride residues resulting from the uses of cryolite) are approximately 0.085 mg/kg/bwt/day. No toxicological endpoint attributable to a single exposure was identified in the available toxicology studies on sulfuryl fluoride or inorganic fluoride that would be applicable for an acute dietary exposure.

ii. *Drinking water.* There is no anticipated exposure of sulfuryl fluoride to drinking water. As a public health tool to aid in the prevention of dental caries, fluoride is added to some domestic water supplies at generally 0.8 ppm to 1.0 ppm.

2. *Non-dietary exposure.* Sulfuryl fluoride (as Vikane specialty gas fumigant) is presently used to fumigate homes and other structures to control wood infesting insects. The existing Vikane use patterns and exposed populations are not expected to overlap with the intended post-harvest uses of ProFume.

D. Cumulative Effects

The primary degradation product of sulfuryl fluoride is fluoride. The toxicity of fluoride in various forms has been extensively reviewed and is used as an additive in treated water supplies, toothpastes, mouth rinses, and other treatments for the prevention of dental caries. It is also prescribed in therapeutic amounts for the treatment of osteoporosis. Fluoride is naturally present in both food and water in varying amounts, and has been added to

public water supplies to fight dental caries. The recommended concentration of fluoride (usually as fluorosilicic acid) in treated water supplies is 0.8 ppm to 1.0 ppm. The third report on nutrition monitoring in the United States says that food contributes only small amounts of fluoride and monitoring the diet for fluoride intake is not very useful for current public health concerns. The sub-population most susceptible to fluoride is children. For this reason a number of studies have attempted to quantify the fluoride intake from a variety of sources. The total daily intake of fluoride from water (used to prepare formula, juices, and other foods) for infants ages birth to 9 months ranged to 1.73 mg with means from 0.29 to 0.38 mg. Assuming a body weight of 10 kg, these amounts are equivalent to 0.03 to 0.04 mg/kg/day. These levels of dietary exposure in combination with the potential dietary exposures that the proposed uses of ProFume would represent (chronic dietary exposures of 0.002419 mg/kg/bwt/day) are considerably lower than EPA's MCLG for fluoride of 0.114 mg/kg/bwt/day.

E. Safety Determination

1. *U.S. population.* Aggregate risk from exposure to sulfuryl fluoride would be minimal because of its rapid dissipation from any fumigated commodity and because it is not expected to be present at the time of food consumption. The sulfuryl fluoride residues in fumigated foods are expected to be non-detectable at the point of food consumption. Furthermore, if residues were considered as high as what is found immediately following the 24-hour aeration period, the margin of exposure to the most sensitive population (children) is estimated to be greater than 80,000 for chronic exposures. Exposure to fluoride, the residue of interest for sulfuryl fluoride, can occur from foods, water, and dental treatments. The additional fluoride residues in some commodities fumigated with sulfuryl fluoride are indistinguishable from the natural levels of fluoride already present and would therefore also fall within EPA's threshold of regulation policy. Alternatively, fluoride in other commodities are expected to contribute to the fluoride that is ingested, but at levels far below other sources, especially treated water and dentrifices. Chronic exposure to fluoride resulting from the proposed uses of ProFume (0.002419 mg/kg/day) is much lower than EPA's MCLG of 0.114 mg/kg/bwt/day calculated for exposure to fluorinated water. In addition, there is no directly applicable scientific

documentation of adverse medical effects at levels of fluorine below 0.23 mg/kg/day.

2. *Infants and children.* Chronic exposure to fluoride from the consumption of ProFume treated commodities would be approximately 0.002419 mg/kg/day for a child age 1 to 6 years. This value is much lower than EPA's MCLG of 0.114 mg/kg/bwt/day calculated for exposure to fluorinated water.

F. International Tolerances

There is no Codex maximum residue level established for residues of fluoride on any food or feed crop.

[FR Doc. 02-3661 Filed 2-14-02; 8:45 am]

BILLING CODE 6560-50-S

ENVIRONMENTAL PROTECTION AGENCY

[PF-1069; FRL-6823-3]

Notice of Filing Pesticide Petitions to Establish Tolerances 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-1069, must be received on or before March 18, 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-1069, in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Susan Stanton, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 305-5218; e-mail address: stanton.susan@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" 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-1069. 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-1069 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-1069. 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 Cosmetic 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 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: February 5, 2002.

Richard P. Keigwin, Jr.

Acting Director, Registration Division, Office of Pesticide Programs.

Summaries of Petitions

Petitioner 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. EPA is publishing the petition summaries verbatim without editing them in any way. The petition summaries announce 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.

FMC Corporation, Interregional Research Project Number 4 Taipei Economic and Cultural Representative Office

PP 0E6157; 1E6234; 1E6330, 2E6402, 2F6390, 6E4630, and 6F3454

EPA has received a pesticide petition (PP 2F6390) and an amended pesticide petition (6F3454) from FMC Corporation, 1735 Market Street, Philadelphia, PA 19103 proposing, pursuant to section 408(d) of the FFDCA, 21 U.S.C. 346a(d), to amend 40 CFR part 180.442, by establishing a tolerance for residues of bifenthrin, (2-methyl 1,1'-biphenyl-3-yl) methyl-3-(2-chloro-3,3,3-trifluoro-1-propenyl)-2,2-dimethylcyclopropanecarboxylate, in or on agricultural commodities as follows:

1. PP 2F6390 proposes a tolerance in or on food products in food handling establishments at 0.01 parts per million (ppm).

2. PP 6F3454 proposes a tolerance in or on the raw agricultural commodity pears at 1.0 ppm, in or on almond hulls at 2 ppm and in or on the tree nuts crop group at 0.05 ppm.

EPA also received pesticide petitions (6E4630, 0E6157, 2E6402, and 1E6330) from the Interregional Research Project Number 4 (IR-4), 681 U.S. Highway #1 South, North Brunswick, New Jersey 08902 proposing, pursuant to section 408(d) of the FFDCA, 21 U.S.C. 346a(d), to amend 40 CFR part 180.442, by establishing a tolerance for residues of bifenthrin, in or on raw agricultural commodities as follows:

1. PP 6E4630 proposes a tolerance for the leaf petioles subgroup (4B) (includes cardoon, celery, Chinese celery, celtuce, Florence fennel, rhubarb, Swiss chard) at 2.0 ppm.

2. PP 0E6157 proposes a tolerance for the herb subgroup (19A) at 0.05 ppm.

3. PP 1E6330 proposes a tolerance for tomato at 0.15 ppm.

4. PP 2E6402 proposes a tolerance for spinach at 0.2 ppm.

In addition, EPA received a pesticide petition (1E6234) from the Taipei Economic and Cultural Representative Office in the United States, 4301 Connecticut Ave., NW., Suite 420, Washington, DC 20008-2387 proposing, pursuant to section 408(d) of the FFDCA, 21 U.S.C. 346a(d), to amend 40 CFR part 180.442, by establishing an import tolerance for residues of bifenthrin in or on carambola (starfruit) at 1.0 ppm.

EPA has determined that the petitions contain data or information regarding the elements set forth in section 408(d)(2) of the FFDCA; 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.

A. Residue Chemistry

1. *Plant metabolism.* The metabolism of bifenthrin in plants is adequately understood. Studies have been conducted to delineate the metabolism of radiolabelled bifenthrin in various crops all showing similar results. The residue of concern is the parent compound only.

2. *Analytical method.* There is a practical analytical method for detecting and measuring levels of bifenthrin in or on food with a limit of detection that allows monitoring of food with residues at or above the levels set in these tolerances Gas Chromatography with Electron Capture Detection (GC/ECD) analytical method P-2132, PP 0E3921, MRID 41658601.

3. *Magnitude of residues.* Field residue trials meeting EPA study requirements have been conducted at the maximum label rate for pears, tree nuts, the herbs subgroup, the leaf petiole subgroup, spinach and tomato. Additionally, a food handling establishment residue study was conducted. Results from the studies demonstrate that the highest bifenthrin residues found will not exceed the proposed tolerances when bifenthrin is applied following the proposed use directions. In addition, field residue trials from Taiwan were submitted in support of the import tolerance for carambola.

B. Toxicological Profile

1. *Acute toxicity.* For the purposes of assessing acute dietary risk, FMC has used the results of a recently completed oral developmental toxicity study in

rats. The maternal no observed adverse effect level (NOAEL) is 7.4 mg/kg/day (90 ppm), and is based on treatment-related clinical signs and reductions in body weights, adjusted maternal body weights, and corresponding reductions in food consumption noted among dams receiving 16.3 mg/kg/day (200 ppm). The embryo/fetal NOAEL is in excess of 16.3 mg/kg/day (200 ppm) based on the lack of any adverse fetal effects at levels up to and including 16.3 mg/kg/day (200 ppm). This acute dietary endpoint is used to determine acute dietary risks to all population subgroups.

2. *Genotoxicity.* The mouse lymphoma mutagenesis assay gave a weak positive result; however, the weight of the evidence from short-term mutagenicity tests indicate that bifenthrin is not mutagenic.

3. *Reproductive and developmental toxicity*—i. Rat reproduction study. Parental toxicity occurred as decreased body weight at 5.0 mg/kg/day with a NOAEL of 3.0 mg/kg/day. There were no developmental (pup) or reproductive effects up to 5.0 mg/kg/day (highest dose tested).

ii. Postnatal sensitivity. Based on the absence of pup toxicity up to dose levels, which produced toxicity in the parental animals, there was no evidence of special postnatal sensitivity to infants and children in the rat reproduction study.

4. *Subchronic toxicity.* The results of the 21-day dermal toxicity study in rats are used for short- and intermediate-term dermal risk calculations. The 21-day dermal toxicity study NOAEL for systemic toxicity is 50 mg/kg/day based on significant reductions in tail flick latency and on clinical signs considered indicative of systemic toxicity (i.e., exaggerated hindlimb flexion, exophthalmos and staggered gait, and vocalization).

5. *Chronic toxicity*—i. The reference dose (RfD) has been established at 0.015 mg/kg/day. This RfD is based on a 1-year oral feeding study in dogs with a NOAEL of 1.5 mg/kg/day, based on intermittent tremors observed at the lowest observed adverse effect level (LOAEL) of 3.0 mg/kg/day; an uncertainty factor of 100 is used.

ii. Bifenthrin is classified as a Group C chemical (possible human carcinogen) based upon urinary bladder tumors in mice; assignment of a Q* has not been recommended.

6. *Animal metabolism.* The metabolism of bifenthrin in animals is adequately understood. Metabolism studies in rats with single doses demonstrated that about 90% of the parent compound and its hydroxylated metabolites are excreted.

7. *Metabolite toxicology.* The Agency has previously determined that the metabolites of bifenthrin are not of toxicological concern, and need not be included in the tolerance expression.

8. *Endocrine disruption.* No special studies investigating potential estrogenic or other endocrine effects of bifenthrin have been conducted. However, no evidence of such effects was reported in the standard battery of required toxicology studies, which have been completed and found acceptable. Based on these studies, there is no evidence to suggest that bifenthrin has an adverse effect on the endocrine system.

C. Aggregate Exposure

1. *Dietary exposure.* Tolerances have been established for the residues of bifenthrin, in or on a variety of raw agricultural commodities. Tolerances, in support of registrations, currently exist for residues of bifenthrin on the following crops: Hops, strawberries, corn (grain, forage and fodder), sweet corn, eggplant, cottonseed, artichokes, peppers (bell and non-bell), lettuce (head), and grapes. Also for the crop group cucurbit vegetables and the subgroup edible-podded legume, succulent shelled peas, canberries, cabbage, rapeseed and brassica (head and stem). Also, for the livestock commodities of cattle, goats, hogs, horses, sheep, poultry, eggs, and milk. Pending tolerances for leafy petioles, leafy brassica, tree nuts crop group, tomatoes, food handling establishments, citrus, bananas, peanuts, pears, potatoes, dried shelled peas/beans, spinach, and the subgroup herbs also exist. For the purposes of assessing the potential dietary exposure for these existing and pending tolerances, FMC conducted an exposure estimate using Novigen's Dietary Exposure Evaluation Model (DEEM) software, results from field trials and processing studies, monitoring data, consumption data from the 1994–1996, 1998 USDA Continuing Surveys of Food Intakes by Individuals (CSFII), and information on the percentages of the crops treated (where available) with bifenthrin were utilized.

i. *Food—*a. *Acute dietary exposure.* Risk assessments are performed for a food-use pesticide if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure. For the purposes of assessing acute dietary risk for bifenthrin, the maternal NOAEL of 7.4 mg/kg/day from the recent oral developmental toxicity study in rats was used. The maternal LOAEL of this study of 16.3 mg/kg/day was based on treatment-related clinical signs and

reductions in body weights, adjusted maternal body weights, and corresponding reductions in food consumption. This acute dietary endpoint was used to determine acute dietary risks to all population subgroups. Available information on anticipated residues, monitoring data and percent crop treated (if no estimate was available the conservative estimate of 100% crop treatment was used) were incorporated into a Tier 3 analysis; using Monte Carlo modeling for commodities that may be consumed in a single serving. These assessments demonstrate that the MOEs at the 99.9th percentile are greater than the EPA standard of 100 for all subpopulations. The 99.9th percentile of exposure for the overall U.S. population is estimated to be 0.004623 mg/kg/day (MOE of 1600). The 99.9th percentile of exposure for children 1 to 6 years old (most highly exposed population subgroup) is estimated to be 0.009573 mg/kg/day (MOE of 773). The 99.9th percentile of exposure to all infants less than 1 year old is estimated to be 0.004535 mg/kg/day (MOE of 1631). The 99.9th percentile of exposure for nursing infants less than one 1 year old is estimated to be 0.002561 mg/kg/day (MOE of 2889). The 99.9th percentile of exposure to non-nursing infants less than 1 year old is estimated to be 0.004801 mg/kg/day (MOE of 1541). Based on the conservatism used in the analyses, actual dietary exposure will be less than that presented here. FMC concludes that based on adequate MOEs for all population subgroups, there is reasonable certainty that no harm will result from the proposed additional uses of bifenthrin.

b. *Chronic exposure.* The acceptable RfD for bifenthrin, based on a NOAEL of 1.5 mg/kg/day from the chronic dog study and an uncertainty factor of 100 (to account for interspecies and intraspecies variations), is 0.015 mg/kg/day. The endpoint effect of concern was tremors in both sexes of dogs at the LOAEL of 3.0 mg/kg/day. A chronic dietary exposure/risk assessment has been performed for bifenthrin using the RfD of 0.015 mg/kg/day. The chronic exposures for the U.S. population are estimated to be 0.000530 mg/kg/day and utilize 3.5% of the RfD. The chronic exposures for children 1 to 6 years old (most highly exposed population subgroup) is estimated to be 0.001415 mg/kg/day and utilizes 9.4% of the RfD. Chronic dietary exposure estimates for the overall U.S. population and 25 population subgroups (including infants and children) are all less than 10% of the chronic RfD of 0.015 mg/kg/day,

therefore, FMC concludes with reasonable certainty that no harm will result from the proposed additional uses of bifenthrin.

ii. *Drinking water.* EPA's draft standard operating procedures (SOP) for incorporating estimates of drinking water exposure into aggregate risk assessments was used to perform a drinking water analysis. This SOP utilizes a variety of tools to conduct drinking water assessment. These tools include water models such as FQPA Index Reservoir Screening Tool (FIRST), PRZM/EXAMS, SCIGROW and monitoring data. If monitoring data are not available, then the models are used to predict potential residues in surface water. A comparison of the calculated Drinking Water Level of Concern (DWLOC) value to the Drinking Water Estimated Concentration (DWECE) is made. If the DWLOC exceeds the DWECE value, then there is reasonable certainty that no harm will result from the short- or intermediate-term aggregate exposure. In the case of bifenthrin, monitoring data do not exist, so the FIRST model was used to estimate a surface water residue. Based on the analyses, the short-term DWLOCs were greater than 530 ppb while the modeled DWECE was 14 parts per trillion (ppt). The intermediate-term DWLOCs were greater than 1,000 ppb while the modeled DWECE was 14 ppb. Since, the calculated DWLOC values for short- and intermediate-term exposures for all adults, adult females, and toddlers exceed the modeled DWECE surface water residues, there is reasonable certainty that no harm will result from aggregate (food, water, and residential) exposure to bifenthrin residues.

2. *Non-dietary exposure.* A variety of techniques are used to assess exposure to pesticidal residues. These techniques range from utilizing straightforward algorithms to complex exposure models. The residential exposure algorithms and default factors in the EPA's Standard Operating Procedures for Residential Exposure Assessments were used in this analysis. The values used include the modifications to the default factors presented by the EPA to the Science Advisory Panel during 2001. The EPA also has created models and data bases to use in the absence of adequate data such as: Pesticide Handlers Exposure Data Base (PHED). The aggregate residential exposure analyses were based on conservative screening-level assumptions. The residential risk assessments resulted in acceptable MOEs and a clear indication of reasonable certainty of no harm. The short-term analyses, all of the route- and product-specific MOEs were greater

than 1,000, and the aggregate MOEs were greater than 100. The short-term aggregate MOEs for all adults is estimated to be 153, adult females 131, and toddlers 235. The intermediate-term analyses, all of the route- and product-specific MOEs were greater than 6,000, and the aggregate MOEs were greater than 2,000. The intermediate-term aggregate MOEs for all adults is estimated to be 4,430, adult females 4,348, and toddlers 2,394. Based on the above information, FMC concludes that bifenthrin does not pose a risk due to short- and intermediate-term aggregate exposure.

E. Cumulative Effects

To our knowledge there are currently no available data, or other reliable information indicating that any toxic effects produced by bifenthrin would be cumulative with those of other chemical compounds; thus, only the potential risks of bifenthrin have been considered in this assessment of its aggregate exposure.

E. Safety Determination

1. *U.S. population.* Using the conservative exposure assessment analyses the estimated chronic exposure to the U.S. population is 0.000530 mg/kg/day and utilizes 3.5% of the RfD. In addition, the chronic exposure estimates for all 25 population subgroups (including infants and children) are well below the chronic RfD of 0.015 mg/kg/day. The acute dietary exposure analyses at the 99.9th percentile for the U.S. population is 0.004623 with a MOE of 1600. In addition, the acute exposure estimates for population subgroups of concern (women of childbearing age, infants, and children) indicate there are adequate MOEs (greater than 100). Based on this information, FMC concludes that there is reasonable certainty that no harm will result from acute and chronic exposure to bifenthrin.

2. *Infants and children*—i. *General.* In assessing the potential for additional sensitivity of infants and children to residues of bifenthrin, FMC considered data from developmental toxicity studies in the rat and rabbit and a two-generation reproduction study in the rat. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from pesticide exposure during prenatal development to one or both parents. Reproduction studies provide information relating to effects from exposure to the systemic toxicity. FFDCA section 408, provides that the EPA may apply an additional margin of safety for infants and children in the

case of threshold effects to account for prenatal, and postnatal toxicity and completeness of the data base.

ii. *Developmental toxicity studies.* In the rabbit developmental study, there were no developmental effects observed in the fetuses exposed to bifenthrin. The maternal NOAEL was 2.67 mg/kg/day based on head and forelimb twitching at the LOAEL of 4 mg/kg/day. In the rat developmental study, the maternal NOAEL was 7.4 mg/kg/day, based on treatment-related clinical signs and reductions in body weights, adjusted maternal body weights, and corresponding reductions in food consumption noted among dams receiving the LOAEL of 16.3 mg/kg/day. The developmental NOAEL was greater than 16.3 mg/kg/day based on lack of any adverse fetal effects at levels up to and including 16.3 mg/kg/day.

iii. *Reproductive toxicity study.* In the rat reproduction study, parental toxicity occurred as decreased body weight at 5.0 mg/kg/day with a NOAEL of 3.0 mg/kg/day. There were no developmental (pup) or reproductive effects up to 5.0 mg/kg/day (highest dose tested).

iv. *Conclusion.* Based on the absence of fetal effects and pup toxicity in any of the referenced studies, FMC concludes that reliable data support use of the standard 100-fold uncertainty factor, and that an additional uncertainty factor is not needed to protect the safety of infants and children. As previously stated, aggregate exposure assessments utilized less than 10% of the RfD for either the entire U.S. population or any of the population subgroups including infants and children. Therefore, it may be concluded that there is reasonable certainty that no harm will result to infants and children from aggregate exposure to bifenthrin residues.

F. International Tolerances

There are no Codex, Canadian, or Mexican residue limits for the residue of bifenthrin in or on pears, the tree nut crop group, foods in food handling establishments, the herb subgroup, the leaf petiole subgroup, spinach, carambola or tomato.

[FR Doc. 02-3663 Filed 2-14-02; 8:45 am]

BILLING CODE 6560-50-5

ENVIRONMENTAL PROTECTION AGENCY

[OPP-50893; FRL-6823-5]

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 EUP: 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:
100-EUP-RNO. Issuance. Syngenta Crop Protection, Inc., P.O. Box 18300, Greensboro, NC 27419. This EUP allows the use of 120.8 pounds of the insecticide thiamethoxam on 1,230 sq. ft. of 615 structures over a period of 3 years to evaluate the control of termites and other nuisance pests around homes. The program is authorized only in the States of Alabama, Arizona, California, Florida, Georgia, Hawaii, Kentucky, Louisiana, Mississippi, Nebraska, North Carolina, Oklahoma, South Carolina, Tennessee, Texas, and Virginia. The