

register the pesticide product Bedoukian Z-11-Hexadecenyl Acetate Technical Pheromone containing an active ingredient not included in any previously registered product pursuant to the provisions of section 3(c)(5) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended.

**FOR FURTHER INFORMATION CONTACT:**

Andrew Bryceland, Biopesticides and Pollution Prevention Division (7511C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: 703-305-6928; and e-mail address bryceland.andrew@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/>.

To access a fact sheet which provides more detail on this registration, go to the Home Page for the Office of Pesticide Programs at <http://www.epa.gov/pesticides/>, and select “fact sheet.”

2. *In person.* The Agency has established an official record for this action under docket control number OPP-30503A. 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 Hwy., 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.

In accordance with section 3(c)(2) of FIFRA, a copy of the approved label, the list of data references, the data and other scientific information used to support registration, except for material specifically protected by section 10 of FIFRA, are also available for public inspection. Requests for data must be made in accordance with the provisions of the Freedom of Information Act and must be addressed to the Freedom of Information Office A-101, 1200 Pennsylvania Ave., NW., Washington, DC 20460. The request should identify the product name and registration number and specify the data or information desired.

A paper copy of the fact sheet, which provides more detail on this registration, may be obtained from the National Technical Information Service NTIS, 5285 Port Royal Road, Springfield, VA 22161.

**II. Did EPA Approve the Application?**

The Agency approved the application after considering all required data on risks associated with the proposed use

of Z-11-hexadecenyl acetate, and information on social, economic, and environmental benefits to be derived from use. Specifically, the Agency has considered the nature of the chemical and its pattern of use, application methods and rates, and level and extent of potential exposure. Based on these reviews, the Agency was able to make basic health and safety determinations which show that use of Z-11-hexadecenyl acetate when used in accordance with widespread and commonly recognized practice, will not generally cause unreasonable adverse effects to the environment.

**III. Approved Application**

EPA issued a notice, published in the **Federal Register** of December 13, 2000 (65 FR 77874) (FRL-6749-2), which announced that Bedoukian Research, Inc., 21 Finance Drive, Danbury, CT 06810-4192, had submitted an application to register the pesticide product, Bedoukian Z-11-Hexadecenyl Acetate Technical Pheromone, a lepidopteran pheromone fungicide, containing the active ingredient Z-11-hexadecenyl acetate. This product was not previously registered.

The application (EPA Registration Number 52991-15) was approved on August 31, 2001, for use in the incorporation into end-use products intended for agricultural application. This product is not for direct treatment of pests.

**List of Subjects**

Environmental protection, Pesticides and pests.

Dated: October 24, 2001.

**Janet L. Andersen,**

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

[FR Doc. 01-27596 Filed 11-6-01; 8:45 am]

**BILLING CODE 6560-50-S**

**ENVIRONMENTAL PROTECTION AGENCY**

[PF-917A; FRL-6808-5]

**Notice of Filing 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-917A, must be received on or before December 7, 2001.

**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-917A in the subject line on the first page of your response.

**FOR FURTHER INFORMATION CONTACT:** By mail: George LaRocca, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 305-6100; e-mail address: miller.joanne@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	Crop production
	112	Animal production
	311	Food manufacturing
	32532	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-917A. 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-917A 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-917A. 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: October 27, 2001.

### Peter Caulkins,

Acting Director, Registration 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 petitioner. 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.

### Aventis CropScience

#### PP OF 6080

EPA published an initial filing of the pesticide petition (PP OF 6080) in the **Federal Register** of February 17, 2000 (65 FR 8143) (FRL-6490-2). This notice announces the filing of the revised pesticide petition proposing the establishment of regulations for residues of deltamethrin, a pesticide chemical, in or on various food commodities. The revised petition is for changes made for the proposed tolerances for deltamethrin in/on almond hull, three crop subgroups and rapeseed and to include the proposed import tolerances for two tropical fruits as petitioned through the Minor Crop Pest Management program (IR-4).

EPA has received a pesticide petition (PP OF 6080) from Aventis CropScience, P.O. Box 12014, 2 T.W. Alexander

Drive, Research Triangle Park, N.C. 27709 proposing, pursuant to section 408(d) of the FFDCA, 21 U.S.C. 346a(d), to amend 40 CFR part 180 by establishing a tolerance for residues of deltamethrin in or on the raw agricultural commodities bulb vegetables, cucurbit vegetables, fruiting vegetables, head and brassica vegetables and mustard greens, leafy vegetables, root vegetables (except sugarbeet), tuberous and corm vegetables, carambola and litchi fruits (import only), pome fruits, stone fruits, tree nuts, ruminant and poultry commodities, milk, milkfat, eggs, canola and rapeseed, field corn, sorghum, soybeans, sunflowers and wheat grain and grain dust (post harvest). Based on the fact that tralomethrin, another synthetic pyrethroid insecticide, is rapidly metabolized in plants and animals to deltamethrin, and the toxicological profile of the two compounds is similar, it is appropriate to consider a combined exposure assessment for tralomethrin and deltamethrin. The proposed tolerances range from 0.02 to 7.0 parts per million (ppm). EPA has determined that the petition contains 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 petition. Additional data may be needed before EPA rules on the petition.

### A. Residue Chemistry

1. *Plant metabolism.* Deltamethrin metabolism studies in tomatoes, corn, apples, and cotton demonstrate the same metabolic pathway. Furthermore, plant metabolism studies have been conducted following application of tralomethrin in cotton, corn, cabbage, and tomatoes. These studies have demonstrated that the metabolism of tralomethrin involves debromination to deltamethrin and its isomers. Thus, a similar metabolic pathway has been shown to occur in a variety of crops following either direct application of deltamethrin (cotton, corn, apples, and tomatoes) or in-plant formation of deltamethrin via debromination of applied tralomethrin (tomatoes, cotton, corn, and cabbage). As a result of this substantial information base, it is concluded that the residues of toxicological concern in/on growing crops following application of tralomethrin or deltamethrin are tralomethrin, *cis*-deltamethrin, and its isomers, *trans*-deltamethrin and *alpha-R*-deltamethrin.

2. *Analytical method.* Analytical methods for determining residues of tralomethrin and deltamethrin in various commodities for which registrations have been approved, or are being sought, have been submitted to the Agency. These methods, are based on gas chromatography (GLC) equipped with an electron capture detector (ECD) and a DB-1 (or equivalent) capillary column, and are used for the determination of tralomethrin, *cis*-deltamethrin, *trans*-deltamethrin, and *alpha-R*-deltamethrin in various raw agricultural, animal-derived, and processed commodities. These methods were independently validated and are appropriate for the determination of residues of tralomethrin and deltamethrin in various food and feed commodities after application of these ingredients to target growing crops, and after use in food/feed handling establishments.

3. *Magnitude of residues.* Residues of tralomethrin, deltamethrin, and its metabolites are not expected to exceed the established and/or proposed tolerance levels as a result of the use of these active ingredients on target crops, or at target sites.

### B. Toxicological Profile

1. *Acute toxicity.* The acute oral LD<sub>50</sub> values of deltamethrin in the rat were 66.7 milligrams/kilogram (mg/kg) for males and 86 mg/kg for females, and for tralomethrin 99 mg/kg for males and 157 mg/kg for females when administered in sesame oil. The oral LD<sub>50</sub> for deltamethrin when administered in aqueous methyl cellulose was greater than 5,000 mg/kg for both sexes. The dermal LD<sub>50</sub> in rabbits was greater than 2,000 mg/kg for both materials. Inhalation 4-hour LC<sub>50</sub> values in the rat were 2.2 mg/L for deltamethrin and greater than 0.286 mg/L for tralomethrin.

2. *Genotoxicity.* No indication of genotoxicity was noted in a battery of *in vivo* and *in vitro* studies conducted with either deltamethrin or tralomethrin.

3. *Reproductive and developmental toxicity—i. Deltamethrin.* A rat development toxicity study conducted with deltamethrin indicated a maternal no observed adverse effect level (NOAEL) of 3.3 mg/kg/day based on clinical observations, decreased weight gain and mortality. The developmental NOAEL was 11 mg/kg/day highest dose tested (HDT). In a rabbit development toxicity study with deltamethrin, the maternal NOAEL was considered to be 10 mg/kg/day based on decreased defecation at 25 and 100 mg/kg/day, and mortality at 100 mg/kg/day. The developmental NOAEL was considered

to be 25 mg/kg/day based on retarded ossification of the public and tail bones at 100 mg/kg (HDT).

A 3-generation rat reproduction study and a more recent, 2-generation rat reproduction study with deltamethrin indicated the NOAEL for both parents and offspring was 80 ppm (4–12 mg/kg/day for adults and 18–44 mg/kg/day for offspring) based on clinical signs of toxicity, reduced weight gain and mortality at 320 ppm (HDT).

ii. *Tralomethrin*. In a rat developmental toxicity study with tralomethrin, the NOAEL for maternal and developmental toxicity was judged to be greater than or equal to 18 mg/kg/day (HDT).

No evidence of developmental toxicity was observed in either of two rabbit developmental toxicity studies conducted with tralomethrin. In one study, the maternal NOAEL was 12.5 mg/kg/day based on mortality, while the developmental NOAEL was judged to be greater than or equal to 25 mg/kg/day (HDT). In the second study, the maternal NOAEL was 8 mg/kg/day based on body weight effects while the developmental NOAEL was 32 mg/kg/day (HDT).

In a 2-generation reproduction study with tralomethrin in rats, the parental NOAEL was 0.75 mg/kg/day based on body weight deficits while the NOAEL for offspring was 3.0 mg/kg/day, also based on body weight deficits.

4. *Subchronic toxicity*—i. *Deltamethrin*. A 90-day rat oral toxicity study was conducted with deltamethrin which was administered by gavage. The NOAEL was judged to be 1.0 mg/kg/day based on reduced body weight gain and slight hypersensitivity. In more recent 90-day rat dietary study with deltamethrin, the NOAEL was judged to be 300 ppm (23.9 mg/kg/day for males, 30.5 mg/kg/day for females) based on uncoordinated movement, unsteady gait, tremors, increased sensitivity to sound, shakes and spasmodic convulsions. The difference in the NOAELs between the two studies is attributed to the different routes of exposure (gavage in oil vs. administered in diet).

A 12-week study was conducted with deltamethrin in mice. The NOAEL was 300 ppm (61.5 mg/kg/day in males and 77.0 mg/kg/day in females) based on chronic contractions, convulsions, poor condition, decreased weight gain and mortality.

Two 13-week dog studies were conducted with deltamethrin. In the first study, beagle dogs were administered deltamethrin by capsule using PEG 200 as a vehicle. The NOAEL for this study was 1 mg/kg/day based on

tremors, unsteadiness, jerking movements, salivation, vomiting, liquid feces and/or dilation of the pupils. In the second study, deltamethrin was administered by capsule without a vehicle to beagle dogs. The NOAEL for this study was 10 mg/kg/day based on unsteady gait, tremors, head shaking, vomiting and salivation. The difference in toxicity between the two studies is attributed to the enhanced absorption resulting from the use of PEG 200 as a vehicle in the first study.

A 21-day dermal toxicity study was conducted with deltamethrin in rats. The NOAEL for systemic toxicity was determined to be 1,000 mg/kg/day.

In a subchronic inhalation study, rats were exposed to aerosolized deltamethrin for 6 hours per day, 5 days per week, for a total of 14 days over 3 weeks. Based on slightly decreased body weights and neurological effects at higher dose levels, it was concluded that 3 g/L was the no observable effect concentration for systemic effects in this study.

ii. *Tralomethrin*. Tralomethrin was administered by gavage in corn oil to rats for 13 weeks. Based on mortality, decreased activity and motor control, soft stools, labored breathing and significantly lower absolute and relative mean liver weights, the NOAEL was considered to be 1 mg/kg/day.

Tralomethrin was administered by capsule to beagle dogs for 13 weeks. The NOAEL for this study was 1.0 mg/kg/day based on refusal of milk supplement, tremors, exaggerated patellar response, unsteadiness and uncoordinated movement.

A 21-day dermal toxicity study was conducted with tralomethrin on rats. No systemic effects were observed; therefore, the systemic NOAEL for this study was 1,000 mg/kg/day.

5. *Chronic toxicity*—i. *Deltamethrin*. Deltamethrin was administered in the diet to beagle dogs for 2 years. No treatment-related effects were observed and the NOAEL was judged to be 40 ppm (1.1 mg/kg/day). In a more recent study, deltamethrin was administered by capsule (without a vehicle) to beagle dogs for 1-year. The NOAEL in this study was considered to be 1 mg/kg/day based on clinical signs, decreased food consumption and changes in several hematology and blood chemistry parameters.

Two rat chronic toxicity/oncogenicity studies were conducted with deltamethrin. In the first study, the test substance was administered via the diet to rats for 2 years. The NOAEL for this study was 20 ppm (1 mg/kg/day) based on slightly decreased weight gain. In a more recent study, deltamethrin was

administered to rats in the diet for 2 years. The NOAEL for this study was considered to be 25 ppm (1.1 and 1.5 mg/kg/day for males and females, respectively) based on neurological signs, weight gain effects and increased incidence and severity of eosinophilic hepatocytes and/or balloon cells. No evidence of carcinogenicity was noted in either study.

Two mouse oncogenicity studies were conducted with deltamethrin. In the first study, deltamethrin was administered in the diet for 2 years. No adverse effects were observed and the NOAEL was judged to be 100 ppm (12 and 15 mg/kg/day, respectively, for males and females). In a more recent study, deltamethrin was administered in the diet to mice for 97 weeks. The NOAEL was considered to be 1,000 ppm (15.7 and 19.6 mg/kg/day) based on a higher incidence of poor physical condition and a slight transient weight reduction. There was no evidence of oncogenicity in either study.

ii. *Tralomethrin*. Tralomethrin was administered to beagle dogs by capsule for 1-year at initial dosages of 0, 0.75, 3.0 and 10.0 mg/kg/day. Due to trembling, ataxia, prostration and convulsions, the high dosage was lowered to 8 mg/kg/day at study week 4 and lowered again to 6 mg/kg/day on study week 14. On the fourteenth week of study, the 0.75 mg/kg/day dosage was raised to 1.0 mg/kg/day. Based on body weight changes, convulsions, tremors, ataxia and salivation, the NOAEL for this study was considered to be 1 mg/kg/day.

Tralomethrin was administered by gavage to rats for 24 months. The NOAEL for this study was 0.75 mg/kg/day based on salivation, uncoordinated movement, inability to support weight on limbs and decreased body weight parameters. No evidence of carcinogenicity was observed.

A 2-year mouse oncogenicity study was conducted with tralomethrin administered by gavage. The NOAEL was judged to be 0.75 mg/kg/day based on higher incidences of dermatitis and mortality, salivation, uncoordinated involuntary movements and aggressiveness. No evidence of oncogenicity was observed.

6. *Animal metabolism*—i. *Deltamethrin*. The absorption of deltamethrin appears to be highly dependent upon the route and vehicle of administration. Once absorbed, deltamethrin is rapidly and extensively metabolized and excreted, primarily within the first 48 hours.

ii. *Tralomethrin*. Tralomethrin is rapidly metabolized to deltamethrin after debromination. The metabolic

pattern of the *in vivo* debrominated tralomethrin is exactly the same as that of the metabolic pattern of deltamethrin.

7. *Endocrine disruption.* No special studies have been conducted to investigate the potential of deltamethrin or tralomethrin to induce estrogenic or other endocrine effects. However, the standard battery of required toxicity studies has been completed. These studies include an evaluation of the potential effects on reproduction and development, and an evaluation of the pathology of the endocrine organs following repeated or long-term exposure. These studies are generally considered to be sufficient to detect any endocrine effects, yet no such effects were detected. Thus, the potential for deltamethrin or tralomethrin to produce any significant endocrine effects is considered to be minimal.

8. *Neurotoxicity.* Acute delayed neurotoxicity studies in hens were conducted for both deltamethrin and tralomethrin. In both cases, the study results were negative indicating that neither material causes delayed neurotoxicity.

In an acute neurotoxicity study with deltamethrin in rats, mortality and numerous clinical signs of neurotoxicity (including altered gait, salivation, tremors, convulsions, writhing, and reduced grip strength) were noted after a single oral administration of a dose of 50 mg/kg. In addition, potential effects (limited to a single male and female) were observed at a dose level of 15 mg/kg. Therefore, the NOAEL for this study was 5 mg/kg.

In a subchronic neurotoxicity study with deltamethrin in rats, mortality, decreased weight gain and numerous clinical signs of neurotoxicity (including writhing, hind limb splay, convulsions, lurching, and reduced grip strength) were noted after daily dietary administration for 13 consecutive weeks at 800 ppm. The NOAEL for systemic toxicity and neurotoxicity in this study was found to be 200 ppm (14 and 16 mg/kg/day for males and females, respectively).

### C. Aggregate Exposure

Based on the fact that tralomethrin is rapidly metabolized in plants and animals to deltamethrin, and the toxicological profile of the two compounds is similar, it is appropriate to consider combined exposure assessments for tralomethrin and deltamethrin. Deltamethrin and tralomethrin are broad spectrum insecticides used to control pests of crops, ornamental plants and turf, and domestic indoor and outdoor (including dog collars and direct application to

livestock), commercial, and industrial food use areas. Thus, aggregate non-occupational exposure could include exposures resulting from non-food uses in addition to consumption of potential residues in food and water. Exposure via drinking water is expected to be negligible since deltamethrin binds tightly to soil and rapidly degrades in water.

1. *Dietary exposure—i. Food.* Food tolerances have been established for residues of tralomethrin and/or deltamethrin and its metabolites in or on a variety of raw agricultural commodities. These tolerances, in support of registrations, currently exist for residues of tralomethrin on broccoli, cottonseed, head lettuce, leaf lettuce, soybeans, sunflower seed, and cottonseed oil. Also, tolerances in support of registrations currently exist for deltamethrin on cottonseed and cottonseed oil. Additionally, tolerances have been established for tralomethrin to support its use in food/feed handling establishments, and for deltamethrin on tomatoes and concentrated tomato products to support the importation of tomato commodities treated with deltamethrin. Further, a food/feed handling establishment tolerance has recently been established for deltamethrin. Additional tolerances are being proposed for deltamethrin in the subject pesticide tolerance petition. Potential acute exposures from these relevant food commodities were estimated using a Tier 3 acute dietary risk assessment (Monte Carlo Analysis) following EPA guidance. Potential chronic exposures from food commodities under the established food and feed additive tolerances for deltamethrin and tralomethrin, plus the tolerances for deltamethrin associated with use in food/feed handling areas, and the tolerances proposed in this petition for deltamethrin, were estimated using NOVIGEN's DEEM (Dietary Exposure Evaluation Model). This chronic risk assessment was conducted using anticipated residues based on field trial or monitoring data, percent crop treated, and percent food handling establishments treated.

ii. *Drinking water.* USEPA's Standard Operating Procedure (SOP) for Drinking Water Exposure and Risk Assessments was used to perform the drinking water analysis for deltamethrin. The SOP compares a calculated drinking water level of comparison (DWLOC) value to the drinking water estimated concentration (DWECC) value. The DWECC value results from either the monitoring data residues and modeled water residues. If the DWLOC value exceeds the DWECC value then there is reasonable

certainty that no harm will result from aggregate exposure.

The calculated drinking water levels of comparison (DWLOC) for short-term exposure for all adults, children 1-6 and infants were estimated to be 1,784 parts per billion (ppb), 926 ppb and 555 ppb, respectively. All of these DWLOC values exceed the short-term modeled deltamethrin water residue of 0.063 ppb. The calculated DWLOC for chronic exposure for all adults, children 1-6 and infants were estimated to be 355 ppb, 185 ppb and 112 ppb, respectively. All of these DWLOC values exceed the chronic modeled deltamethrin water residue of 0.004 ppb. Therefore, there is reasonable certainty that no harm will result from water exposure to deltamethrin residues.

2. *Non-dietary exposure.* As noted above, deltamethrin and tralomethrin are broad spectrum insecticides registered for use on a variety of food and feed commodities. Additionally, registrations are held for non-agricultural applications including turf and lawn care treatments, broadcast carpet treatments (professional use only), indoor fogger, spot, crack and crevice treatments, dog collars, insect baits, lawn and garden sprays and indoor and outdoor residential, industrial and institutional sites including those for food/feed handling establishments.

To evaluate non-dietary exposure, the "flea infestation control" scenario was chosen to represent a plausible but worst case non-dietary (indoor and outdoor) non-occupational exposure. This scenario provides a situation where deltamethrin and/or tralomethrin are commonly used and can be used concurrently for a multitude of uses, e.g., spot and/or broadcast treatment of infested indoor surfaces such as carpets and rugs, treatment of pets and treatment of the lawn. This hypothetical situation provides a very conservative, upper bound estimate of potential non-dietary exposures. Consequently, if health risks are acceptable under these conditions, the potential risks associated with other more likely scenarios would also be acceptable.

Because tralomethrin is rapidly metabolized to deltamethrin, and the toxicology profiles of deltamethrin and tralomethrin are virtually identical, an aggregate (non-dietary + chronic dietary) exposure/risk assessment was conducted for the combination of both active ingredients. The total exposure to both materials was expressed as "deltamethrin equivalents" and this was compared to the toxicology endpoints identified for deltamethrin.

#### D. Cumulative Effects

When considering a tolerance, the Agency must consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity." Aventis CropScience believes that "available information" in this context includes not only toxicity, chemistry, and exposure data, but also scientific policies and methodologies for understanding common mechanisms of toxicity and conducting cumulative risk assessments.

Further, Aventis does not have, at this time, available data to determine whether tralomethrin and deltamethrin have a common mechanism of toxicity with other substances. For the purposes of this tolerance action, therefore, no assumption has been made that tralomethrin and deltamethrin have a common mechanism of toxicity with other substances.

#### E. Safety Determination

1. *U.S. population.* The toxicity and residue data base for deltamethrin and tralomethrin is considered to be valid, reliable and essentially complete according to existing regulatory requirements. No evidence of oncogenicity has been observed for either compound. In accordance with EPA's "Toxicology Endpoint Selection Process" Guidance Document for acute exposures, the toxicology endpoint from the deltamethrin rat acute neurotoxicity study, 5.0 mg/kg/day, was used. For chronic exposures to deltamethrin and tralomethrin, the Reference Dose (RfD) of 0.01 mg/kg body weight/day established for deltamethrin based on the NOAEL from the 2-year rat feeding study and a 100-fold safety factor to account for interspecies extrapolation and intraspecies variation was used.

For the overall U.S. population, acute dietary exposure at the 99.9th percentile results in utilization of 5.3% of the acute RfD that is equivalent to a Margin of Exposure (MOE) of 1,901. For the overall U.S. population, chronic dietary exposure results in a utilization of 1.0% of the RfD. Using an upper bound estimate of potential non-dietary exposures for a worst case scenario (flea treatment) results in a MOE of at least 59,229 for adults. Utilizing the scenario of chronic dietary exposure plus an upper bound estimate of potential non-dietary exposure from a worst case scenario (flea treatment), it is shown that for aggregate exposure to

deltamethrin and tralomethrin there is an MOE of 15,559 for adults. For acute and short-term exposures there is generally no concern for MOEs greater than 100. For chronic exposure, there is generally no concern for exposure below 100% of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health.

In conclusion, there is reasonable certainty that no harm will result to the U.S. population, in general, from dietary or aggregate exposure to deltamethrin and/or tralomethrin.

2. *Infants and children.* Data from developmental toxicity studies in rats and rabbits, and multi-generation reproduction studies in rats, are generally used to assess the potential for increased sensitivity of infants and children. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from pesticide exposure during prenatal development. Reproduction studies provide information relating to reproductive and other effects on adults and offspring from prenatal and postnatal exposure to the pesticide. None of these studies conducted with deltamethrin or tralomethrin indicated developmental or reproductive effects as a result of exposure to these materials.

FFDCA section 408 provides that EPA may apply an additional safety factor for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the data base. Based on the current toxicological data requirements, the data base relative to prenatal and postnatal effects in children is complete. Although no indication of increased susceptibility to younger animals was noted in any of the above studies, or in the majority of studies with other pyrethroids, several publications have reported that deltamethrin is more toxic to neonate and weaning animals than to adults. However, a joint industry group was unable to reproduce these findings. Furthermore, the RfD (0.01 mg/kg/day) that has been established for deltamethrin is already more than 1,000-fold lower than the lowest NOAEL from the developmental and reproduction studies. Therefore, the RfD of 0.01 mg/kg/day is appropriate for assessing chronic aggregate risk to infants and children and an additional uncertainty factor is not warranted.

Also, the NOAEL of 5.0 mg/kg/day from the rat acute neurotoxicity study is appropriate to use in acute dietary, short-term non-dietary, and aggregate exposure assessments.

For the population subgroup described as infants, less than 1 year old, the acute dietary exposure at the 99.9th percentile utilizes 7.2% of the acute RfD that is equivalent to a MOE of 1,382. For the population subgroup described as children 1-6 years old, the acute dietary exposure at the 99.9th percentile utilizes 6.7% of the acute RfD that is equivalent to a MOE of 1,504. For infants less than 1 year old, chronic dietary exposure results in a utilization of 0.9% of the RfD, and for children 1-6 years old 2.3% of the RfD is utilized. Using an upper bound estimate of potential non-dietary exposures for a worst case scenario (flea treatment) results in an MOE of at least 15,015 for infants less than 1 year old, and an MOE of at least 15,974 for children 1-6 years old. Utilizing the scenario of chronic dietary exposure plus an upper bound estimate of potential non-dietary exposure from a worst case scenario (flea treatment) it is shown that for aggregate exposure to deltamethrin and tralomethrin, there is an MOE of at least 4,900 for infants less than 1 year old, and an MOE of 4,250 for children 1-6 years old. For acute and short-term exposures there is generally no concern for MOEs greater than 100. For chronic exposure, there is generally no concern for exposure below 100% of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health.

In summary, there is reasonable certainty that no harm will result to infants and children from aggregate exposure to either deltamethrin or tralomethrin.

#### F. International Tolerances

Deltamethrin is a broad spectrum insecticide used throughout the world to control pests of livestock, crops, ornamentals plants and turf, and household, commercial, and industrial food use areas. A reevaluation of the maximum residue limits (MRLs) was conducted in 1994, in accordance with the EC Directive (91/414/EEC) Registration Requirements for Plant Protection Products. A comparison of the proposed/current CODEX MRLs and proposed/established tolerances for deltamethrin is presented below:

Commodity	Proposed Tolerance (USEPA) (PPM)	Proposed/Current MRL (CODEX) (PPM)
Almond hulls	1.2	--
Apples, wet pomace	1.2	--
Artichokes	0.5	0.05
Brassica, head and stem crop subgroup 5A, excluding cabbage	0.50	0.2 (brassica vegetables)
Bulb vegetables	1.5	0.1 (bulb vegetables, except fennel, bulb)
Cabbage (w/wrapper leaves)	1.5	--
Cabbage (w/o wrapper leaves)	0.15	0.2 (brassica vegetables)
Carambola (star fruit)	0.2	--
Corn, field grain	0.06	1.0 (cereal grains)
Corn, forage (field)	0.7	--
Corn, fodder/stover (field)	7.0	0.5 (straw and fodder, cereal grains)
Corn, refined oil	0.6	--
Corn, flour	0.18	--
Corn, meal	0.12	--
Corn, milled by products	0.18	--
Cucurbit vegetables	0.06	0.2
Eggs	0.02	--
Fruiting vegetables	0.25	0.2
Leafy vegetables	4.5	0.5
Lichi fruit	0.2	--
Milk, fat (reflecting 0.02 ppm in whole milk)	0.1	0.02 (milks); and 0.03 cattle milk
Mustard greens	4.5	0.2 (brassica vegetables)
Pome fruit	0.2	0.1
Poultry, fat	0.05	0.5 (chicken fat)
Poultry, mbyp	0.02	--
Poultry, meat	0.02	0.01 (poultry meat); and 0.03 (chicken muscle)
Prunes	2.4	--
Rapeseed (including canola and crambe)	0.12	0.1 (oilseed)
Root vegetable, except sugarbeet (subgroup 1B): roots	0.15	0.01 (root and tuber vegetables)
Ruminant fat	0.04	0.5
Ruminant mbyp	0.02	0.05 (edible offal, mammalian)
Ruminant meat	0.02	0.5
Sorghum, forage	0.5	--
Sorghum, fodder/stover	2.0	0.5 (straw and fodder, cereal grains)
Sorghum, grain	0.5	1.0 (cereal grains)

Commodity	Proposed Tolerance (USEPA) (PPM)	Proposed/Current MRL (CODEX) (PPM)
Soybeans	0.05	0.5 (legume animal feeds, dry weight)
Stone fruit	0.6	0.05
Sunflower seeds	0.05	0.1 (oilseed)
Tops	4.0	--
Tree nuts	0.1	--
Tuberous and corm vegetables subgroup 1C, excluding artichokes	0.04	0.01 (root and tuber vegetables)
Wheat gluten (post harvest)	1.4	--
Wheat, grain (post harvest)	2.0	1.0
Wheat, grain dust (post harvest)	2.7	--

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## ENVIRONMENTAL PROTECTION AGENCY

[PF-1050; FRL-6807-9]

### Notice of Filing 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-1050, must be received on or before December 7, 2001.

**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-1050 in the subject line on the first page of your response.

**FOR FURTHER INFORMATION CONTACT:** By mail: Treva C. Alston, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 308-8373; e-mail address: alston.treva@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-1050. 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-1050 in the subject line on the first page of your response.