

| 40 CFR citation                                                                | OMB control No. |
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| 721.7285 .....                                                                 | 2070-0012       |
| 721.7286 .....                                                                 | 2070-0038       |
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| 721.7785 .....                                                                 | 2070-0012       |
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| 721.8153 .....                                                                 | 2070-0012       |
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| 721.8660 .....                                                                 | 2070-0012       |
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| 721.9490 .....                                                                 | 2070-0012       |
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| 721.9508 .....                                                                 | 2070-0012       |
| 721.9509 .....                                                                 | 2070-0012       |
| 721.9513 .....                                                                 | 2070-0012       |
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| 721.9516 .....                                                                 | 2070-0012       |
| 721.9517 .....                                                                 | 2070-0012       |
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| 721.9573 .....                                                                 | 2070-0012       |
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| 721.9595 .....                                                                 | 2070-0012       |
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| 721.9661 .....                                                                 | 2070-0012       |
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| 721.9663 .....                                                                 | 2070-0012       |
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| 721.9672 .....                                                                 | 2070-0012       |
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| 721.9685 .....                                                                 | 2070-0012       |
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| 721.9719 .....                                                                 | 2070-0012       |
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| 721.9785 .....                                                                 | 2070-0012       |
| 721.9790 .....                                                                 | 2070-0012       |
| 721.9795 .....                                                                 | 2070-0012       |
| 721.9798 .....                                                                 | 2070-0012       |
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| 721.9810 .....                                                                 | 2070-0012       |
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| 721.9965 .....                                                                 | 2070-0012       |
| 721.9969 .....                                                                 | 2070-0012       |
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| 721.9973 .....                                                                 | 2070-0012       |
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| <b>Lead-Based Paint Poisoning Prevention in Certain Residential Structures</b> |                 |
| Part 745, subpart E .....                                                      | 2070-0158       |
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**PART 157—[AMENDED]**

1. The authority citation for part 157 continues to read as follows:

**Authority:** 7 U.S.C. 136w.

2. Remove at the end of § 157.36 the parenthetical phrase containing the OMB control number.

**PART 372—[AMENDED]**

1. The authority citation for part 372 continues to read as follows:

**Authority:** 42 U.S.C. 11023 and 11048.

2. The effective date for §§ 372.27 and 372.95 is March 17, 1995.

**PART 720—[AMENDED]**

1. The authority citation for part 720 continues to read as follows:

**Authority:** 15 U.S.C. 2604, 2607, and 2613.

2. Remove at the end of § 720.102 the parenthetical phrase containing the OMB control number.

[FR Doc. 00-16076 Filed 6-23-00; 8:45 am]

**BILLING CODE 6560-50-F**

**ENVIRONMENTAL PROTECTION AGENCY****40 CFR Part 180**

**[OPP-300987; FRL-6499-5]**

**RIN 2070-AB78**

**Prallethrin [(RS)-2-methyl-4-oxo-3-(2-propynyl) cyclopent-2-enyl (1RS)-cis, trans-chrysanthemate]; Pesticide Tolerance**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes a tolerance for residues of 1.0 ppm of prallethrin (RS)-2-methyl-4-oxo-3-(2-propynyl)cyclopent-2-enyl (1RS)-cis, trans-chrysanthemate in or on all food items in food handling establishments where food and food products are held, processed, prepared, and/or served. McLaughlin Gormley King Company requested this tolerance under the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996.

**DATES:** This regulation is effective June 26, 2000. Objections and requests for hearings, identified by docket control number OPP-300987, must be received by EPA on or before August 25, 2000.

**ADDRESSES:** Written objections and hearing requests may be submitted by mail, in person, or by courier. Please

follow the detailed instructions for each method as provided in Unit VI. of the "SUPPLEMENTARY INFORMATION." To ensure proper receipt by EPA, your objections and hearing requests must identify docket control number OPP-300987 in the subject line on the first page of your response.

**FOR FURTHER INFORMATION CONTACT:** By mail: Kevin Sweeney, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, Ariel Rios Bldg., 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 305-5063; and e-mail address: sweeney.kevin@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:

| Cat-egories | NAICS codes                | Examples of poten-tially affected entities                                             |
|-------------|----------------------------|----------------------------------------------------------------------------------------|
| Industry    | 111<br>112<br>311<br>32532 | Crop production<br>Animal production<br>Food manufacturing<br>Pesticide manufac-turing |

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 OPP-300987. The official record consists of the documents specifically referenced in this action, 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.

## II. Background and Statutory Findings

In the **Federal Register** of October 21, 1993 (58 FR 54353) (FRL-4645-7), EPA issued a notice that McLaughlin Gormley King Co. (MGK), 8810 Tenth Avenue North, Minneapolis, MN 55427, had submitted food additive petition 3H5651 to EPA proposing to amend 40 CFR part 186 by establishing a regulation, pursuant to section 409 of the Federal Food, Drug, and Cosmetic Act (FFDCA) 21 U.S.C. 348(e), for residues of prallethrin in or on food as a result of use in food handling establishments at 1.0 part per million (ppm). On September 5, 1997, MGK at the request of EPA, submitted an amendment to bring the notice into conformity with the Food Quality Protection Act of 1996 (FQPA).

In the **Federal Register** of September 25, 1997 (62 FR 50337) (FRL-5748-2), EPA issued a notice pursuant to section 408 of FFDCA 21 U.S.C. 346a as amended by FQPA (Public Law 104-170) announcing the filing of a pesticide petition (PP 7F4915) for tolerance by McLaughlin Gormley King Company, 8810 Tenth Avenue North, Minneapolis, MN 55427. This notice included a summary of the petition prepared by McLaughlin Gormley King, the registrant. There were no comments received in response to the notice of filing.

The petition requested that a new regulation be established under 40 CFR part 180 for tolerances of prallethrin

[(*RS*)-2-methyl-4-oxo-3-(2-propynyl)cyclopent-2-enyl (*1RS*)-*cis*, *trans*-chrysanthemate at 1.0 ppm, in or on all food items in food handling establishments where food and food products are held, processed, prepared, and/or served.

Section 408(b)(2)(A)(i) of the FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is “safe.” Section 408(b)(2)(A)(ii) defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....”

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. For further discussion of the regulatory requirements of section 408 and a complete description of the risk assessment process, see the final rule on Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997) (FRL-5754-7).

## III. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure, consistent with section 408(b)(2), for a tolerance for residues of prallethrin in or on all food items in food handling establishments where food and food products are held, processed, prepared, and/or served at 1.0 ppm. EPA’s assessment of the dietary exposures and risks associated with establishing the tolerance follows.

### A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the

sensitivities of major identifiable subgroups of consumers, including infants and children. The nature of the toxic effects caused by prallethrin are discussed in this unit.

1. A battery of acute toxicity studies places prallethrin in Toxicity Category II for acute oral ( $LD_{50} > 50$  milligrams/kilograms (mg/kg)) and acute inhalation ( $LD_{50} > 0.05$  mg/L); Category III for primary eye irritation, Category IV for acute dermal ( $LD_{50} > 5,000$  mg/kg) and primary dermal irritation. Prallethrin is a non-sensitizer. The NOAEL for acute delayed neurotoxicity is 100 mg/kg bodyweight.

2. *Subchronic oral toxicity feeding—Rat.* In a subchronic oral toxicity study, prallethrin technical (92.0% purity) was administered by dietary admix to Crj: CD (Sprague-Dawley rats (15/sex/group) at doses of 0, 100, 300, 1,000 or 3,000 ppm (0, 7.93, 24.0, 79.1 or 230 mg/kg/day for males; 0, 8.96, 26.1, 82.3 or 244 mg/kg/day for females) for 90 days. The no observable adverse effect level (NOAEL) is 79.1 mg/kg/day and the lowest observable adverse effect level (LOAEL) is 230 mg/kg/day based on transient alopecia, decreased body weights, increased neutrophil count, decreases in hemoglobin and hematocrit, changes in clinical chemistry parameters, increased kidney weights, minimal perilobular hepatocellular hypertrophy and increased number of small follicles in the thyroid.

3. *Subchronic oral toxicity feeding—Mouse.* In a subchronic oral toxicity range-finding study, prallethrin technical (93.6% purity) was administered by dietary admix to Crl: CD-1 (ICR)BR mice (10/sex/dose group) at dietary levels of 0, 300, 3,000, 6,000 or 12,000 ppm (corresponding to an average intake of 0, 39, 374, 808 or 1,839 milligrams/kilograms/day (mg/kg/day) in males and 0, 47, 444, 890 or 1,884 mg/kg/day in females, respectively) for 13 weeks. The NOAEL is 374 mg/kg/day and the LOAEL is 808 mg/kg/day based on increases in liver weights, enlargement of hepatocytes and increases in cholesterol and creatinine levels in the serum.

4. *Subchronic oral toxicity feeding—Dog.* In a subchronic oral toxicity study, prallethrin technical (94.6% purity) was administered orally by capsule to Beagle dogs (4/sex/group) at doses of 0, 3, 10 or 30 mg/kg/day for 90 days. The NOAEL is 3 mg/kg/day and the LOAEL is 10 mg/kg/day based on tremors, decreased serum A/G ratio, increased serum cholesterol and phospholipids and enlarged livers. Mortality was observed at 30 mg/kg/day with additional clinical signs of convulsions,

ataxia, salivation, tachypnea, tachycardia and increased body temperature. In the animals that died, congestion and hemorrhage were observed in multiple organs with myocardial fiber degeneration. Granulocyte juvenile cells in the bone marrow were observed in one surviving dog.

5. *Repeated dose dermal—Rat.* In a repeat dose dermal toxicity study, prallethrin technical (93.2 % purity) was administered via the dermal route to Crl:CD (SD)BR Sprague-Dawley rats (5/sex/group) at doses of 0 (corn oil), 30, 150 or 750 mg/kg/day on 10% of the body surface, 6 hours/day for 21 consecutive days. Occlusive dressings were used and Elizabethan collars were worn during the exposure periods. The NOAEL is 30 mg/kg/day and the LOAEL is 150 mg/kg/day based on clinical signs of toxicity and decreases in body weight gain.

6. *A 28-Day inhalation—Rat.* In a 28-day inhalation toxicity study, prallethrin technical (92.0% purity) was administered via inhalation to Sprague-Dawley rats (10/sex/group) at concentrations of 0, 1.01, 4.39 or 19.6 mg/m<sup>3</sup>, 4 hours/day in deodorized kerosene solvent for 28 days. Mean concentrations of the test article and distribution of the diameters of the mist particles were measured as well as clinical signs of toxicity, body weights, food consumption, ophthalmological measurements, and hematological and blood chemistry measurements. The NOAEL is 1.01 mg/m<sup>3</sup> (0.0010 mg/L/day) and the LOAEL is 4.39 mg/m<sup>3</sup> (0.0044 mg/L/day) based on increased evidence and severity of irregular respiration, decreased spontaneous activity and nasal discharge during exposure. This is a borderline LOAEL. Study deficiencies include measuring particle sizes on only 1 day (day 21) and not measuring particle sizes in the lowest concentration.

7. *Chronic toxicity—combined chronic feeding/carcinogenicity—Rat.* In a chronic feeding/carcinogenicity study, prallethrin technical (92.0% purity) was administered by dietary admix to F344/DuCrj rats (50/sex/group with satellite groups of 40/sex/group) at doses of 0, 80, 400 or 2,000 ppm (0, 3.3, 16.3 or 83.5 mg/kg/day for males; 0, 4.0, 19.1 or 103.4 mg/kg/day for females) for 2 years. The additional satellite groups (10/sex/group) were sacrificed at 26, 52 and 78 weeks. Females appear to be slightly more susceptible to toxicity in the study. The NOAEL is 19.1 mg/kg/day and the LOAEL is 104.3 mg/kg/day based on decreases in body weight gains and histocytic infiltration of the liver in females. There was no evidence of an

carcinogenic response. Based on the results of the study, higher dose levels could have been tolerated. In the 5-week range-finding study, tremors and death were observed at 10,000 ppm (1,121 mg/kg/day for males, 1,349 mg/kg/day for females). At 2,500 ppm (210 mg/kg/day for males, 253 mg/kg/day for females), there were significant decreases in body weights and hemoglobin, however these were not below 93% of the control groups. There were effects on clinical chemistry at this dose level and an increase in relative liver weights; however, these were not considered to be toxicologically significant because there was no associated histopathology and some of the effects may not be clinically meaningful and/or may be due to dehydration or fasting (decreases in GOT and ALP, increased albumin). Increased relative liver weights are not generally considered to be toxicologically significant without increases in absolute liver weights and without any liver pathology.

8. *Chronic oral toxicity (capsule)—Dog.* In a chronic oral toxicity study, prallethrin technical (93.6% purity) was administered orally by gelatin capsule to Beagle dogs (4/sex/group) at doses of 0, 2.5, 5, 10 or 20 mg/kg/day for 52 weeks. The NOAEL is 2.5 mg/kg/day and the LOAEL is 5 mg/kg/day in females based on the death of 1 female with typical clinical signs of pyrethroid toxicity and subendocardial red discoloration in the left ventricle of the heart. At 10 mg/kg/day, trembling, rapid eye blinking, hunched posture, panting, increased serum cholesterol, phospholipids and alkaline phosphatase activity were observed.

9. *Developmental toxicity prenatal developmental study—Rat.* In an oral developmental toxicity study, prallethrin technical (93.2% purity), was administered by gavage to Crl: CD BR VAF/Plus Sprague-Dawley rats (25/group) at doses of 0 (0.5% aqueous methylcellulose vehicle), 10, 30, 100 or 300 mg/kg/day on gestation days (GDs) 6–15, inclusively. The maternal NOAEL = 10 mg/kg/day; the maternal LOAEL = 30 mg/kg/day (tremors, excessive salivation and chromorrhinorrhea). The developmental NOAEL = 300 mg/kg/day (HDT).

10. *Prenatal developmental study—Rabbit.* In an oral developmental oral toxicity study, prallethrin technical (93.2% purity) was administered by gavage to New Zealand White rabbits (20/group) at doses of 0 (0.5% aqueous methylcellulose vehicle), 10, 30, 100 or 200 mg/kg/day on gestation days (GDs) 7–19, inclusively. Dose levels were selected based on a range-finding study conducted with 6 artificially

inseminated rabbits/group at dose levels of 0, 10, 30, 60, 100, 300, 600 or 800 mg/kg/day on gestation days 7–19, inclusively. No maternal effects were observed at 60 mg/kg/day in the range-finding study. Based on these effects, the choice of 200 mg/kg/day as the high dose for the main study is considered appropriate based on tremors. In the main study, no developmental toxicity was observed at any dose level. The maternal NOAEL = 30 mg/kg/day (the number of animals in the range-finding study were too few to use 60 mg/kg/day as the NOAEL). The maternal LOAEL = 100 mg/kg/day from the range-finding study (tremors). The developmental NOAEL = 200 mg/kg/day (HDT in main study).

11. In a subcutaneous developmental toxicity study, prallethrin technical (92.0% purity) was administered by subcutaneous injection to New Zealand White rabbits (18/group) at doses of 0 (corn oil vehicle), 1, 3 or 10 mg/kg/day on gestation days (GDs) 6–18, inclusively. No toxicological effects on either dams or fetuses were observed at any dose level. However, in the range-finding study with nonpregnant animals, tremors were observed at 10 mg/kg/day and mortality, clinical signs, and weight loss were observed at 30 mg/kg/day. In the subcutaneous range-finding developmental rat study, maternal toxicity with nonpregnant animals was similar to that with pregnant animals. Therefore, by analogy, the choice of 10 mg/kg/day for the main rabbit study is considered to be appropriate, even though toxicity was not observed. The maternal NOAEL = 10 mg/kg/day (HDT); the maternal LOAEL = 30 mg/kg/day from the range-finding study (mortality, clinical signs, weight loss). The developmental NOAEL = 10 mg/kg/day (HDT).

12. *Two-generation reproduction study—Rat.* In a 2-generation reproduction study, prallethrin technical (93.6 and 92.9% purity) was administered to 30 Crl:COBS CD(SD)BR rats by dietary admix at concentrations of 0, 120, 600, 3,000 or 6,000 ppm (during premating, for males approximately 0, 6, 31, 156 or 329 mg/kg/day and for females approximately 0, 7, 37, 185 or 375 mg/kg/day). Treatment was continuous throughout the study. The two parental generations, F<sub>0</sub> and F<sub>1</sub>, produced one litter of pups each (F<sub>1</sub> litters, F<sub>2</sub> litters respectively). The parental animals received the test diet for 91 days before mating and throughout mating, pregnancy, and lactation of their litters. Pups were selected from F<sub>1</sub> litters to parent the F<sub>2</sub> generation. The F<sub>0</sub> generation produced 23 to 26 litters/group consisting of

liveborn pups, the F<sub>1</sub> generation produced 18 to 25 liveborn litters/group. There was one mortality at 3,000 ppm that was preceded by clinical signs<sup>1</sup> and weight loss. At 6,000 ppm, treatment-related mortalities in the F<sub>1</sub> generation and increased basophilia in the cortical tubules (males) were observed. The parental systemic NOAEL is 31 mg/kg/day (males) and 37 mg/kg/day (females); the parental systemic LOAEL is 156 mg/kg/day (males) and 185 mg/kg/day (females) based on decreased body weights and body weight gains, increased liver weights and microscopic findings in the liver, kidney, thyroid and pituitary. No pup toxicity was observed at dose levels of 120 and 600 ppm. At 3,000 ppm and above, decreased pup body weight was observed during the lactation period in both generations. The offspring systemic NOAEL is 31 mg/kg/day (males) and 37 mg/kg/day (females); the offspring systemic LOAEL is 156 mg/kg/day (males) and 185 mg/kg/day (females) based on decreased pup body weights during the lactation period. No reproductive effects were observed at any dose level. The reproductive NOAEL is 329 mg/kg/day (males) and 375 mg/kg/day (females) (HDT).

13. *Subchronic neurotoxicity.* In a subchronic oral mammalian neurotoxicity study, groups of Crl: CD(SD)BR rats (12 rats/sex/group) were administered prallethrin technical (93% a.i.) via dietary admix at concentrations of 0, 120, 1,200 or 6,000 ppm for 13 weeks. These concentrations correspond to group mean intakes of 0, 9.3, 74 or 363 mg/kg/day (males) and 0, 11.1, 88 and 420 mg/kg/day (females). The systemic NOAEL is 1,200 ppm (74 mg/kg/day (males), 88 mg/kg/day (females)) and the systemic LOAEL is 6,000 ppm (363 mg/kg/day (males), 420 mg/kg/day (females)) based on decreases in mean body weight and food consumption when compared to the control values. There are no indications of neuropathology; however, there were indications of a higher arousal rate in females at 6,000 ppm.

14. *Developmental neurotoxicity study.* This study is not required for this chemical at this time. It may be required in the future.

15. *There is no mutagenicity concern.* In a reverse gene mutation study in *S.*

*typhimurium* (strains TA 100, 98, 1535, 1537, 1538) and *E. coli* WP2 uvrA, prallethrin technical (91.3% purity) was tested. The solvent was DMSO. Dose levels were up to 5,000 µg/plate with and without metabolic activation (S9 mix). Prallethrin did not induce any increases in reverse mutations in any of the bacterial strains tested. The positive controls (*N*-ethyl-*N'*-nitro-*N*-nitroso-guanidine, 2-nitrofluorene, methyl methanesulfonate, sodium azide, ICR-191, benzo(a)pyrene and 2-aminoanthracene) responded appropriately with highly significant increases in reverse mutations.

16. In a forward mutation study in V79 Chinese Hamster Lung Cells with DMSO as the solvent, prallethrin technical (91.2% purity) was tested. Concentrations of the test material were up to cytotoxic levels ( $5 \times 10^{-5}$  M concentration without metabolic activation (S9),  $3 \times 10^{-4}$  M concentration with metabolic activation). Prallethrin did not induce a significant increase in forward mutations at the hypoxanthine-guanine phosphoribosyl transferase (HGPRT) locus in Chinese hamster lung (V79) cells. The positive controls (*N*-ethyl-*N'*-nitro-*N*-nitroso-guanidine and 9, 10-dimethyl-1, 2-benzanthracene) responded appropriately with marked increases in mutant colonies.

17. *Cytogenetics.* In an *in vivo* micronucleus test in CD-1 mice, prallethrin technical (93.2% purity) was tested. Corn oil was used as the solvent. Five mice/sex/dose/sacrifice time were administered single doses of corn oil vehicle (10 ml/kg) or test article (48, 95, 190 mg/kg) and sacrificed 24, 48 or 72 hours later. Cyclophosphamide was used in the positive controls and they were sacrificed 24 hours later. Prallethrin had no effect on micronucleus formation in bone marrow cells up to a lethal dose. There was no bone marrow cytotoxicity.

18. In an *in vitro* chromosomal aberration study in Chinese Hamster Ovary (CHO K1) cells with DMSO as the solvent, prallethrin technical (91.2% purity) was tested. Concentrations of the test material were up to cytotoxic levels ( $8 \times 10^{-5}$  M without metabolic activation and  $3 \times 10^{-4}$  M with metabolic activation). Prallethrin tested negatively at all doses without metabolic activation and tested positively at all doses with metabolic activation. It was not clearly dose-related but clastogenicity was seen at nontoxic and slightly toxic doses. The positive controls (mitomycin C and benzo(a)pyrene) clearly tested positively in this test.

19. In an unscheduled DNA synthesis study in rat hepatocytes with corn oil as the solvent, prallethrin technical (91.2% purity) was tested. Male Sprague-Dawley SPF rats were administered a single dose of 400 mg/kg of the test material (maximum tolerated dose) by gavage. Hepatocytes were cultured from the animals 3, 12 and 24 hours later. Prallethrin tested negatively for inducing unscheduled DNA synthesis in rat hepatocytes. The positive control, 2-acetylaminofluorene induced a statistically significant increase in unscheduled DNA synthesis in rat hepatocytes.

20. *Metabolism—Rat.* The metabolism of the *cis*- and *trans*-isomers of S-4068SF was studied in male and female rats administered a single oral gavage dose of 2.0 or 100 mg/kg <sup>14</sup>C-*cis*- or <sup>14</sup>C-*trans*-isomer of S-4068SF, or a 14-day repeated oral dose of 2.0 mg/kg/day unlabeled *cis*- or *trans*-isomer of S-4068SF. The *cis*- and *trans*-isomers of <sup>14</sup>C-S-4968SF were rapidly absorbed, distributed, metabolized, and excreted in rats under all dosing regimens. Most of the radioactivity was recovered in the urine and feces within 48 hours for both males and females for both isomers. A much greater proportion of the administered dose of the *trans*-isomer was eliminated in the urine (45.2–58.1% administered dose (AD) for males, 52.1–62.1% AD for females) than was the *cis*-isomer (13.3–15.8% AD for males, 21–23.3% AD for females). This occurred as a result of easier cleavage of the ester linkage of the *trans*-isomer by esterase. For the rats administered the *cis*-isomer, urinary excretion was a minor route compared to fecal excretion. Females excreted a greater proportion of the radioactivity in the urine than did males for both isomers. Absorption and metabolism were not saturated at the high dose since equivalent amounts of the parent compound (about 10%) were found in urine. Repeated dosing appeared to induce metabolism since only about 2% of the parent compound was found in the feces. Radioactivity accounted for less than 1% of the dose in the tissues for both isomers. The low tissue levels of radioactivity demonstrate that bioaccumulation and retention of the *cis*- and *trans*-isomers is low. No sex-related differences in the tissue distribution patterns were found, but proportionately higher residues were found in all tissues of the high-dose group. For both isomers, higher residue levels compared to other tissues were found in the kidneys (0.018–1.127 µg/g) and liver (0.013–1.14 µg/g); higher residue levels were also found in blood

<sup>1</sup> Clinical signs for this female were chromorrhinorrhea, bradypnea, labored breathing, rales, pale eyes, decreased motor activity, urine-stained fur, ungroomed coat, chromodacryorrhea and/or emaciated appearance. Although some of these signs are typical of those which may be associated with exposure to this chemical, the study authors believed that this death was not treatment-related.

(0.014–1.87 µg/g) for the *trans*-isomer, only. The major metabolic pathway was ester cleavage, particularly for the *trans*-isomer, which resulted in the metabolites (S)-4-hydroxy-3-methyl-2-(2-propynyl)cyclopent-2-en-1-one and its glucuronide conjugate or oxidation of the propynyl group to (RS)-4-hydroxy-2-(1-hydroxy-2-propynyl)-3-methylcyclopent-2-en-1-one and (RS)-4-hydroxy-2-(1-hydroxy-2-oxopropyl)-3-methylcyclopent-2-en-1-one.

The metabolism of *cis*- and *trans*-S-4068 was studied in groups of male and female Sprague-Dawley rats administered a single oral dose of 2.0 mg/kg <sup>14</sup>C-*cis*- or *trans*-S-4068 or a single subcutaneous dose of 2.0 mg/kg <sup>14</sup>C-*cis*- or <sup>14</sup>C-*trans*-S-4068. Following oral and subcutaneous administration to rats of 2.0 mg/kg of the *cis*- and *trans*-isomers of S-4068 <sup>14</sup>C-labeled at the cyclopentenyl-2 position, each isomer was readily absorbed, distributed, metabolized and excreted in the urine and feces. Total recovery was complete ranging from 96.7% to 103.9% of the administered dose (AD) for both isomers and both dose groups. There were generally no differences in absorption, distribution, metabolism, or excretion in rats dosed orally or subcutaneously. Seven days after administration of the *cis*-isomer by both routes, the mean percent recovery of radioactivity showed that the feces was the major route of excretion (70.3–83.4% AD) and the urine was a relatively minor route of excretion (16.8–27.9% AD). For rats administered 2.0 mg/kg of the *trans*-isomer by both routes, the urine was the major route of excretion (60.1–78.4% AD), and the feces was a minor route (23–41.7% AD) 7 days postdosing. The difference in the excretion pattern between the *trans*- and *cis*-isomers is due to the extent of ester cleavage; the *trans*-isomer is more readily cleaved so that it is excreted in the urine to a greater extent than the *cis*-isomer. Sex-related differences were seen in urinary excretion with females excreting greater amounts of radioactivity in the urine than males for both isomers and both administration routes. Expired air was not considered an important route of excretion since less than 0.1% of the administered dose was excreted as <sup>14</sup>CO<sub>2</sub> in orally dosed males. Radioactivity levels in tissues was low indicating that the isomers do not persist in the tissue. The <sup>14</sup>C levels in the major tissues reached a maximum within 3 hours and then decreased rapidly. Based on the metabolites identified, the major biotransformation reactions of the *cis*- and *trans*-isomers as indicated by the study author include:

(1) Oxidation at the methyls of the isobutenyl group in the acid moiety and at the C–1 or C–2 positions of the propynyl group in the alcohol moiety; (2) cleavage of the ester linkage; (3) conjugation of hydroxy derivatives with glucuronic acid and sulfuric acid.

21. *Dermal absorption*—*Rat*. A dermal absorption study was not required.

#### B. Toxicological Endpoints

1. *Acute toxicity*. The acute reference dose (RfD) is established at 0.05 mg/kg/day (NOAEL = 5; Uncertainty Factor = 100) for use in assessing acute dietary risk for the general population, including infants and children. This RfD is based on trembling observed during week 1 at the dose of 10 mg/kg/day in the chronic oral study in the dog. The FQPA safety factor for the protection of infants and children was reduced to 1X. Therefore, the acute population adjusted dose (aPAD) is equal to acute RfD divided by 1 or 0.05 mg/kg/day.

2. *Short- and intermediate-term dermal toxicity*. The short- and intermediate-term dermal endpoints were selected from the 21-day dermal study in the rat (NOAEL = 30 mg/kg/day). This endpoint is based on clinical signs (trembling, fixation, abnormal gait, sensitivity to external stimuli, vocalization, twitching and writhing spasms) and decreased body weight gain observed at 150 mg/kg/day.

3. *Long-term dermal toxicity*. The long-term dermal endpoint was selected from the 1 year oral study in dogs (NOAEL 2.5 mg/kg/day, same study as for chronic dietary exposure). The dermal absorption rate of 20% and a margin of exposure (MOE) of 100 was selected.

4. *Inhalation toxicity*. The inhalation endpoints (any exposure period; in this case, short- and intermediate-term exposure) were selected from the 28-day inhalation study in the rat NOAEL = 0.0010 mg/L/day (estimated to be 0.174 mg/kg/day). This endpoint is based on clinical signs observed during exposure (increased evidence and severity of irregular respiration, decreased spontaneous activity and nasal discharge) observed at 0.0044 mg/L/day.

5. *Chronic dietary toxicity*. EPA has established the RfD for prallethrin at 0.025 mg/kg/day. This RfD is based on a NOAEL of 2.5 mg/kg/day and an uncertainty factor of 100. The NOAEL is based on microscopic lesions of the heart and clinical signs indicative of pyrethroid toxicity observed in one female dog at the LOAEL dose of 5 mg/kg/day. The FQPA safety factor for the protection of infants and children was reduced to 1X. Since the FQPA safety factor was reduced to 1X, the chronic

Population Adjusted Dose (cPAD) is equal to the chronic RfD divided by 1 or 0.025 mg/kg/day.

4. *Carcinogenicity*. There is no evidence of carcinogenicity in either rats or mice.

#### C. Exposures and Risks

1. *From food and feed uses*. Currently, there are no agricultural uses nor established tolerances for prallethrin. The requested tolerance for 1.0 ppm for the residues of prallethrin, in or on all food items in food handling establishments where food and food products are held, processed, prepared, and/or served, will be the first food tolerance. Risk assessments were conducted by EPA to assess dietary exposures from prallethrin as follows:

i. *Acute exposure and risk*. The Agency has conducted a Tier 2 (anticipated residues and 100% crop treated) acute dietary (food only) exposure assessment for prallethrin using the Dietary Exposure Evaluation Model (DEEM). This model incorporates individual food consumption as reported by respondents in the USDA 1989–91 Continuing Survey of Food Intake by Individuals (CSFII) and accumulates exposure to the chemical for each commodity. The DEEM acute exposure analysis was performed using anticipated residues levels and 100% percent crop treated (PCT) to estimate the Anticipated Residue Concentration (ARC) for the general population and subgroups of interest. The DEEM acute dietary analysis indicates that exposure to prallethrin from dietary (food only) sources will be below the Agency's level of concern for all population subgroups (100% of the acute Population Adjusted Dose (aPAD)). The estimated exposure will occupy 89% of the aPAD for children 1–6 years (the most highly exposed population subgroup). Acute dietary risk to all other population subgroups is less than that of children 1–6 years. The Agency further notes that these acute dietary risks are significant overestimates as it was assumed that all foods would be treated, while it is believed that the maximum percentage of food handling establishments which will be treated is 12%. In addition, it was assumed that all treated foods would have the maximum residue observed in the submitted residue studies, when, in reality, a distribution of residues with many values lower than that would be encountered in actual practice.

ii. *Chronic exposure and risk*. The Agency has conducted a Tier 3 (anticipated residues and PCT data) chronic dietary (food only) exposure assessment for prallethrin using the

DEEM. This model incorporates individual food consumption as reported by respondents in the USDA 1989–91 CSFII and accumulates exposure to the chemical for each commodity. The DEEM chronic exposure analysis was performed using anticipated residues levels and 12%

PCT to estimate the ARC for the general population and subgroups of interest. The DEEM chronic dietary analysis indicates that exposure to prallethrin from dietary (food only) sources will be below the Agency's level of concern for all population subgroups (100% of the cPAD). The estimated exposure will

occupy 8.6% of the cPAD for children 1–6 years (the most highly exposed population subgroup). Chronic dietary risk to all other population subgroups is less than that of children 1–6 years (Table 1).

TABLE 1.—SUMMARY OF CHRONIC DIETARY EXPOSURE (FOOD ONLY) AND RISK FOR PRALLETHRIN

| Population Subgroup <sup>1</sup> | Chronic Dietary      |                   |
|----------------------------------|----------------------|-------------------|
|                                  | Exposure (mg/kg/day) | cPAD <sup>2</sup> |
| U.S. Population .....            | 0.000879             | 3.5               |
| Non-Nursing Infants .....        | 0.002046             | 8.2               |
| Children (1–6 years old) .....   | 0.002152             | 8.6               |
| Females 13+ (nursing) .....      | 0.001009             | 4.0               |
| Males (13–19 yrs) .....          | 0.000837             | 3.3               |

<sup>1</sup> Population subgroups shown include the U.S. General Population and the maximally exposed subpopulation of adults, infants and children, and women of child-bearing age.

<sup>2</sup> cPAD is equal to  $RfD \div FQPA \text{ Safety Factor (RfD} \div 1 \text{ in this case): } \% RfD (cPAD) = \text{Exposure (mg/kg)} \div RfD (mg/kg) \times 100$ .

Section 408(b)(2)(E) authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide chemicals that have been measured in food. If EPA relies on such information, EPA must require that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. Following the initial data submission, EPA is authorized to require similar data on a time frame it deems appropriate. As required by section 408(b)(2)(E), EPA will issue a data call-in for information relating to anticipated residues to be submitted no later than 5 years from the date of issuance of this tolerance.

Section 408(b)(2)(F) states that the Agency may use data on the actual percent of food treated for assessing chronic dietary risk only if the Agency can make the following findings: Condition 1, that the data used are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain such pesticide residue; Condition 2, that the exposure estimate does not underestimate exposure for any significant subpopulation group; and Condition 3, if data are available on pesticide use and food consumption in a particular area, the exposure estimate does not understate exposure for the population in such area. In addition, the Agency must provide for periodic evaluation of any estimates used. To provide for the periodic evaluation of the estimate of PCT as required by section 408(b)(2)(F), EPA may require registrants to submit data on PCT.

The Agency used PCT information as follows. The DEEM chronic exposure analysis was performed using anticipated residues levels and 12% PCT to estimate the ARC for the general population and subgroups of interest. This PCT value used to perform this analysis was based on estimates received from the registrant, and the fact that anticipated sales and market share for a first time food use is not expected to reach its maximum until 5 to 7 years after market entry.

The Agency believes that the three conditions listed above have been met. With respect to Condition 1, PCT estimates are derived from Federal and private market survey data, which are reliable and have a valid basis. EPA used a maximum projected PCT for chronic dietary exposure estimates. The maximum projected PCT reasonably represents an overestimate of a person's dietary exposure over a lifetime, and is unlikely to underestimate exposure to an individual because of the fact that pesticide use patterns (both regionally and nationally) tend to change continuously over time, such that an individual is unlikely to be exposed to more than the maximum projected PCT over a lifetime. The Agency is reasonably certain that the percentage of the food treated is not likely to be an underestimated. As to Conditions 2 and 3, regional consumption information and consumption information for significant subpopulations is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups. Use of this consumption information in EPA's risk assessment process ensures that EPA's exposure estimate does not understate

exposure for any significant subpopulation group and allows the Agency to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency. Other than the data available through national food consumption surveys, EPA does not have available information on the regional consumption of food to which prallethrin may be applied in a particular area.

2. *From drinking water.* Based on the use patterns, negligible amounts of prallethrin are expected in the drinking water. Any that may be poured down the drain from residential uses will be removed by water treatment plants. Therefore, it is not necessary to calculate Drinking Water Levels of Comparison (DWLOCs).

i. *Acute exposure and risk.* Not applicable based on above comments.

ii. *Chronic exposure and risk.* Not applicable based on above comments.

3. *From non-dietary exposure.* Prallethrin is currently registered for use on the following residential non-food sites: inside households, outdoor yards and patios, and pets. Four different types of products are registered for residential use: (1) Crack and crevice sprays; (2) indoor and outdoor foggers; (3) broadcast carpet and surface sprays; and (4) pet dips, sprays and shampoos. There are 23 products containing the active ingredient prallethrin that are registered for residential use. The percent active ingredient in these products ranges from 0.03% to 0.25%. The frequency and rate of application varies with each product. Registered end use products with the highest percentage of active ingredient were used to estimate high-end exposure for

residential handlers and postapplication activities. These residential uses constitute short- and intermediate-term exposures including postapplication.

i. *Chronic exposure and risk.* Based on the use patterns, long-term (several months to lifetime) exposures are not expected for residential handlers.

ii. Short- and intermediate-term exposure and risk (residential). The residential exposure assessment relies on the methodology used previously by the Agency in November 1997, for the tolerance reassessment of 10 other pyrethroids. Current uses may result in short-term exposures for residential handlers. Intermediate- and long-term exposures are not expected for residential handlers. Since no handler data were submitted to support the residential handler assessment, surrogate data were used. MOE values were estimated for short-term handler dermal and inhalation exposures for indoor crack and crevice products, carpet/surface products and pet products. The dermal MOEs for these products range from 350 for the pet mousse to 5,600 for the pet dip. The inhalation MOEs range from 450 for the use of the undiluted prallethrin formulation as a carpet broadcast and space spray to 52,000 for the pet spray. The short-term MOEs for residential handlers are above the Agency's target MOE of 100.

Based on the use patterns intermediate-term (7 days to several months) exposures are not expected for residential handlers. Short- and intermediate-term durations may occur for postapplication exposures. For postapplication exposure, no actual dissipation data were available. Surrogate data were used. It is expected that residue levels after 7 days exposure will be low to nondetectable. MOE values were estimated for short- and intermediate-term postapplication dermal exposures for carpet broadcast sprays, total release foggers and pet products. MOE values were estimated for short- and intermediate-term postapplication inhalation exposures for total release fogger products and space sprays. In addition to dermal and inhalation exposures, MOEs for postapplication incidental hand-to-mouth transfer were estimated for carpet broadcast sprays, foggers, space sprays and pet products. The dermal MOEs for these products range from 460 for the use of the undiluted prallethrin formulation as a carpet spray to 6,700 for the pet dip for adults and from 250 for the same carpet spray to 3,300 for the pet dip for children. The lowest inhalation MOEs are 1,500 for adults and 650 for children for the use of the

diluted prallethrin formulation as a space spray and 100 for adults and 47 for children for the use of the undiluted prallethrin formulation. For hand-to-mouth transfer, the MOEs range from 930 to 17,000 for the foggers in children with the exception of the inhalation MOEs for use of the undiluted prallethrin formulation as a space spray. All of the short- and intermediate-term MOEs for postapplication residential exposure are above the Agency's target MOE of 100. Since these MOEs are estimated from exposure levels measured immediately after application and it is expected that the exposure will drop to very low levels after 7 days, the intermediate-term MOE values are low bounding estimates. Due to a low postapplication inhalation MOE (47), the use of the undiluted prallethrin formulation as a space spray will not be permitted in residential and institutional sites such as homes, schools, apartments, and condominiums.

4. *Cumulative exposure to substances with a common mechanism of toxicity.* 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's residues and "other substances that have a common mechanism of toxicity."

EPA does not have, at this time, available data to determine whether prallethrin has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, prallethrin does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that prallethrin has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the final rule for Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997).

#### *D. Aggregate Risks and Determination of Safety for U.S. Population*

1. *Acute risk.* Using the exposure assumptions described in this unit, EPA has concluded that acute exposure to prallethrin from food is not expected to exceed 89% of the aPAD for any of the population subgroups analyzed. Acute aggregate exposure consists of exposures

from food and drinking water.

According to the use patterns, negligible amounts of prallethrin are expected in the drinking water and no estimates for expected environmental concentrations of prallethrin in the drinking water are necessary. As a result, acute dietary estimates are based only on exposure in the food and as stated above, are not expected to exceed 89% of the aPAD for any of the population subgroups analyzed.

2. *Chronic risk.* Chronic aggregate exposure consists of exposures from food, drinking water, and residential uses which lead to chronic exposures. Using the exposure assumptions described in this unit, EPA has concluded that chronic exposure to prallethrin from food is not expected to exceed 8.6% of the cPAD for any of the population subgroups analyzed. According to the use patterns, negligible amounts of prallethrin are expected in the drinking water and no estimates for expected environmental concentrations of prallethrin in the drinking water are necessary. Chronic residential exposures are also not expected. As a result, chronic aggregate exposure estimates are based only on exposure to the food and as stated above, are not expected to exceed 8.6% of the cPAD for any of the population subgroups analyzed.

3. *Short- and intermediate-term risk.* Short- and intermediate-term aggregate exposure takes into account chronic dietary food and water (considered to be a background exposure level) plus indoor and outdoor residential exposure. For adults, the short-term aggregate risk estimate (handler and/or postapplication exposure) includes food, dermal and inhalation exposure and the intermediate-term aggregate risk estimate (postapplication exposure only) includes food and dermal exposure (no postapplication inhalation exposure is expected for the products selected for the aggregate risk estimate for adults). For children, the short- and intermediate-term aggregate risk estimates (postapplication exposure only) include food, incidental ingestion, dermal and inhalation exposure (postapplication inhalation exposure is expected for the products selected for the aggregate risk estimates for children). As stated previously, negligible amounts of prallethrin are expected in the drinking water. The estimation of aggregate risk is based on which uses may be potentially employed simultaneously and which have the highest potential exposure (adults: carpet broadcast aerosol spray used with the pet spray; children: total release fogger and the pet mousse).

Since the Agency is recommending against the use of the undiluted prallethrin formulation as a space spray in homes and schools, the short- and intermediate-term aggregate risk estimates do not include the MOE values for this product. The most conservative short-term aggregate MOE for infants and children is 260 and the most conservative short-term aggregate MOE for adults is 250. None of the aggregate short-term MOE's for either adults or children are less than the target MOE of 100. Therefore, the short-term aggregate MOEs for both adults and children are greater than the Agency's level of concern.

Since children are not expected to be residential handlers, the intermediate-term aggregate risks for children are based on postapplication exposures only. In addition, for estimation of the intermediate oral MOE, the oral NOAEL is taken from the chronic dietary endpoint. The NOAEL from the chronic dietary endpoint is one-half the NOAEL from the acute dietary endpoint from which the short-term oral MOEs were estimated. The most conservative intermediate-term aggregate MOE for infants and children is 190 and the most conservative intermediate-term aggregated MOE for adults is 670. All of the aggregate intermediate-term MOE's for both adults and/or children are greater than the target MOE of 100 and are thus, greater than the Agency's level of concern.

4. *Aggregate cancer risk for U.S. population.* Prallethrin is classified as not likely to be a human carcinogen. Therefore a risk assessment is not required since prallethrin is not expected to pose a cancer risk.

5. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result from aggregate exposure to prallethrin residues.

#### *E. Aggregate Risks and Determination of Safety for Infants and Children*

1. *Safety factor for infants and children—i. In general.* In assessing the potential for additional sensitivity of infants and children to residues of prallethrin, EPA considered data from developmental toxicity studies in the rat and rabbit and a 2-generation reproduction study in the rat. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from maternal pesticide exposure during gestation. Reproduction studies provide information relating to effects from exposure to the pesticide on the reproductive capability of mating animals and data on systemic toxicity.

FFDCA section 408 provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the data base unless EPA determines that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a MOE analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. EPA believes that reliable data support using the standard uncertainty factor (usually 100 for combined interspecies and intraspecies variability) and not the additional tenfold MOE/uncertainty factor when EPA has a complete data base under existing guidelines and when the severity of the effect in infants or children or the potency or unusual toxic properties of a compound do not raise concerns regarding the adequacy of the standard MOE/safety factor.

ii. *Developmental toxicity studies.* See the toxicological profile in Unit III.A. of this document.

iii. *Reproductive toxicity study.* See the toxicological profile in Unit III.A. of this document.

iv. *Prenatal and postnatal sensitivity.* The reproductive and developmental data provided no indication of increased susceptibility for rats and rabbits to *in utero* and/or postnatal exposure to prallethrin. In the prenatal developmental toxicity studies in rats and rabbits, no evidence of developmental toxicity was seen at any dose level. In the 2-generation reproduction study in rats, effects in the offspring were observed only at or above treatment levels which resulted in evidence of parental toxicity. These effects (decreased pup body weights during the lactation period) were not considered to be qualitatively more serious than the effects observed in the parents (decreased body weights and body weight gains, increased liver weights and microscopic findings in the liver, kidney, thyroid and pituitary).

v. *Conclusion.* There is a complete toxicity data base for prallethrin, and exposure data are complete or are estimated based on data that reasonably accounts for potential exposures. Based on the completeness of the toxicity data base and prenatal and postnatal toxicity of prallethrin, no additional safety factor is needed to protect infants and children.

2. *Acute risk.* Acute aggregate exposure consists of exposures from food and drinking water. Using the exposure assumptions described in this

unit, EPA has concluded that acute exposure to prallethrin from food will utilize 89% of the aPAD for children (1–6 years), the most highly exposed population subgroup. As stated previously, negligible amounts of prallethrin are expected in drinking water. Therefore, EPA does not expect the acute aggregate exposure to prallethrin to exceed 100% of the aPAD. EPA generally has no concern for exposures below 100% of the aPAD because the aPAD represents the level at or below which daily aggregate dietary exposure will not pose appreciable risks to human health.

3. *Chronic risk.* Chronic aggregate exposure consists of exposures from food, drinking water, and residential uses which lead to chronic exposures. Using the exposure assumptions described in this unit, EPA has concluded that chronic exposure to prallethrin from food will utilize 8.6% of the cPAD for children (1–6 years), the most highly exposed population subgroup. As stated previously, negligible amounts of prallethrin are expected in drinking water and chronic residential exposures are not expected. Therefore, EPA does not expect the chronic aggregate exposure to prallethrin to exceed 100% of the cPAD. EPA generally has no concern for exposures below 100% of the cPAD because the cPAD represents the level at or below which daily lifetime aggregate exposure will not pose appreciable risks to human health.

4. *Short- or intermediate-term risk.* For children, the short- and intermediate-term aggregate risk estimates (postapplication exposure only) include food, incidental ingestion, dermal and inhalation exposure (postapplication inhalation exposure is expected for the products selected for the aggregate risk estimates for children). As stated previously, negligible amounts of prallethrin are expected in the drinking water. The estimation of aggregate risk is based on which uses may be potentially employed simultaneously and which have the highest potential exposure (children: total release fogger and the pet mouse). The most conservative short-term aggregate MOE for infants and children is 260. None of the aggregate short-term MOE's for either adults or children are less than the target MOE of 100.

The intermediate-term aggregate risks for children are based on postapplication exposures only. In addition, for estimation of the intermediate oral MOE, the oral NOAEL is taken from the chronic dietary endpoint. The NOAEL from the chronic

dietary endpoint is one-half the NOAEL from the acute dietary endpoint from which the short-term oral MOEs were estimated. All of the aggregate intermediate-term MOE's for children are greater than the target MOE of 100 and are thus, greater than the Agency's level of concern.

5. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to prallethrin residues.

#### IV. Other Considerations

##### A. Metabolism in Plants and Animals

Currently, there are no agricultural uses for prallethrin, therefore, there are no metabolism studies in plants and animals. For food handling establishments EPA assumes that the residue of concern will be for the parent only.

##### B. Analytical Enforcement Methodology

Adequate enforcement methodology—gas chromatography with final electron capture detection, are available for analyses of prallethrin in/on food items associated with food handling establishments. The method may be requested from: Calvin Furlow, PIRIB, IRSD (7502C), Office of Pesticide Programs, Environmental Protection Agency, Ariel Rios Bldg., 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 305-5229; e-mail address: furlow.calvin@epa.gov.

##### C. Magnitude of Residues

Adequate residue data were provided to support a tolerance of 1.0 ppm. Residue levels of prallethrin in food items resulting from the application of ULV fogger spray and contact spray to food handling establishments were below the Agency's level of concern. No residues were detected following contact sprays with the exception of 0.1 ppm prallethrin in a peanut sample at the 4x normal application rate after 10 treatments. The highest residue found in covered commodities following ULV fogger application at the label rate was 0.54 ppm in a flour sample.

##### D. International Residue Limits

There are no CODEX, Canadian, or Mexican tolerances for prallethrin. Therefore, harmonization of international tolerances is not of concern at this time.

##### E. Endocrine Disruption.

FQPA requires that EPA develop a screening program to determine whether certain substances (including all

pesticides and inert ingredients) "may have an effect in humans similar to an effect produced by a naturally occurring estrogen, or such other endocrine effect..." EPA has been working with interested stakeholders, including other government agencies, interest groups, industry and research scientists to develop a screening and testing program as well as a priority setting scheme to implement this program. The Agency's proposed Endocrine Disrupter Screening Program was published in the **Federal Register** of December 28, 1998 (63 FR 71541). The Program uses a tiered approach and anticipates issuing a Priority List of chemicals and mixtures for Tier I screening in the year 2000. As the Agency proceeds with the implementation of this program, further testing of prallethrin and its end-use products for endocrine effects may be required.

#### V. Conclusion

Therefore, the tolerance is established for residues of prallethrin, in or on all food items in food handling establishments where food and food products are held, processed, prepared, and/or served at 1.0 ppm.

#### VI. Objections and Hearing Requests

Under section 408(g) of the FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to reflect the amendments made to the FFDCA by the FQPA of 1996, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) provides essentially the same process for persons to "object" to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d), as was provided in the old FFDCA sections 408 and 409. However, the period for filing objections is now 60 days, rather than 30 days.

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

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket control number OPP-300987 in the subject line on the first page of your submission. All requests must be in writing, and must be

mailed or delivered to the Hearing Clerk on or before August 25, 2000.

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

Mail your written request to: Office of the Hearing Clerk (1900), Environmental Protection Agency, Ariel Rios Bldg., 1200 Pennsylvania Ave., NW., Washington, DC 20460. You may also deliver your request to the Office of the Hearing Clerk in Rm. C400, Waterside Mall, 401 M St., SW., Washington, DC 20460. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (202) 260-4865.

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

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

If you would like to request a waiver of the tolerance objection fees, you must mail your request for such a waiver to:

James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, Ariel Rios Bldg., 1200 Pennsylvania Ave., NW., Washington, DC 20460.

3. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VI.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in Unit I.B.2. Mail your copies, identified by docket control number OPP-300987, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, Ariel Rios Bldg., 1200 Pennsylvania Ave., NW., Washington, DC 20460. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.2. You may also send an electronic copy of your request via e-mail to: opp-docket@epa.gov. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 file format or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

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

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

#### **VII. Regulatory Assessment Requirements**

This final rule establishes a tolerance under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44

U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104-4). Nor does it require any prior consultation as specified by Executive Order 13084, entitled *Consultation and Coordination with Indian Tribal Governments* (63 FR 27655, May 19, 1998); special considerations as required by Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or require OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104-113, section 12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure "meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications." "Policies that have federalism implications" is defined in the Executive Order to include regulations that have "substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government." This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4).

#### **VIII. Submission to Congress and the Comptroller General**

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

#### **List of Subjects in 40 CFR Part 180**

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

Dated: May 11, 2000.

**Susan B. Hazen,**

*Acting Director, Office of Pesticide Programs.*

Therefore, 40 CFR chapter I is amended as follows:

#### **PART 180—[AMENDED]**

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

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

2. Section 180.545 is added to read as follows:

#### **§ 180.545 Prallethrin (RS)-2-methyl-4-oxo-3-(2-propynyl)cyclopent-2-enyl (1RS)-cis, trans-chrysanthemate; tolerances for residues.**

(a) *General.* (1) A tolerance of 1.0 ppm is established for residues of the insecticide prallethrin (RS)-2-methyl-4-oxo-3-(2-propynyl)cyclopent-2-enyl (1RS)-cis, trans-chrysanthemate as follows:

(2) In or on all food items in food handling establishments where food and food products are held, processed, prepared and/or served.

(3) Application shall be limited to space, general surface, and spot and/or crack and crevice treatment in food handling establishments where food and food products are held, processed, prepared and/or served. General surface or space spray applications may be used only when the facility is not in operation provided exposed food has been covered or removed from the area being treated prior to application. Spot and/or crack and crevice application

may be used while the facility is in operation provided exposed food is covered or removed from the area being treated prior to application. Spray concentrate shall be limited to a maximum of 2.0% active ingredient. Contamination of food or food contact surfaces shall be avoided. Food contact surfaces and equipment should be thoroughly washed with an effective cleaning compound and rinsed with potable water after use of the product.

(4) To assure safe use of the additive, its label and labeling shall conform to that registered with the U.S. Environmental Protection Agency, and it shall be used in accordance with such label and labeling.

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[FR Doc. 00-16077 Filed 6-23-00; 8:45 am]

BILLING CODE 6560-50-F

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Care Financing Administration

#### 42 CFR Parts 409, 410, 411, 413, 424, and 484

[HCFA-1139-N]

#### Medicare Program; Town Hall Meeting on July 18, 2000 to Present an Overview of the Home Health Prospective Payment System Final Rule

**AGENCY:** Health Care Financing Administration (HCFA), HHS.

**ACTION:** Notice of meeting on final rule.

**SUMMARY:** This notice announces a public meeting to provide information on the home health prospective payment system (HH PPS) final rule. We intend to publish the final rule on or about June 30, 2000 in the **Federal Register**.

**DATES:** The HH PPS town hall meeting is scheduled for Tuesday, July 18, 2000, from 10:30 a.m. until 3:30 p.m., E.S.T.

**ADDRESSES:** The meeting will be held in the HCFA Central Office Main Auditorium, 7500 Security Boulevard, Baltimore, MD 21244-1850 with satellite broadcast viewing areas located in Boston, Chicago, Atlanta, and San Francisco.

**FOR FURTHER INFORMATION CONTACT:** Robin Phillips, HCFA, (410) 786-3010 (for general information). Alison Horan,

The Lewin Group, (703) 269-5606 (for registration information).

**SUPPLEMENTARY INFORMATION:** We intend to publish the home health prospective payment system (HH PPS) final rule in the **Federal Register** on or about June 30, 2000. We are planning to hold a town hall meeting on Tuesday, July 18, 2000. We anticipate interested parties to include: the home health agency (HHA) industry association representatives, HHA administrators and owners, home care professionals, university-based and private research organizations, Congressional members and staff, home care software vendors, beneficiary advocates, and other interested parties.

In this meeting, we will provide an overview of the HH PPS final rule and will focus on a number of its key components and present past and current research efforts related to the HH PPS.

This meeting will be broadcast live from the HCFA Central Office Main Auditorium and will include four satellite broadcast viewing sites in Boston, Chicago, Atlanta, and San Francisco. All five sites have a capacity of approximately 500 individuals. The audiences viewing the broadcast via satellite will have the ability to participate in the question-and-answer period at the end of this presentation. For those who cannot attend in Baltimore, the address of the downlink sites, registration information, and satellite coordinates for this presentation will be posted on the HCFA website [www.hcfa.gov](http://www.hcfa.gov) or you may contact Alison Horan of The Lewin Group at (703) 269-5606. Once individuals are on this website, they will need to highlight the red bullet, in the lower right hand corner, titled "Events, Meetings, and Workgroups."

The meeting will conclude with a question-and-answer session including the HCFA Central Office location as well as the three-satellite downlink sites. The toll-free phone number to call to participate will be broadcast during the meeting.

While the meeting is open to the public, attendance is limited to the space available. Individuals must register in advance as described below.

The Lewin Group will handle registration for all five meeting sites. Individuals may register through on the HCFA website, [www.hcfa.gov](http://www.hcfa.gov) or you may contact Alison Horan of The Lewin Group at (703) 269-5606. Once individuals are on this website, they will need to highlight the red bullet, in the lower right hand corner, titled "Events, Meetings, and Workgroups."

Each participant will receive a confirmation letter as receipt of

registration. Each participant will be provided with a meeting agenda at the time of the meeting. If individuals have any questions regarding registration, they should contact The Lewin Group, Alison Horan of The Lewin Group at (703) 269-5606.

**Authority:** Section 1895 of the Social Security Act (42 U.S.C. 1395ff).

Dated: June 21, 2000.

**Nancy-Ann Min DeParle,**

*Administrator, Health Care Financing Administration.*

[FR Doc. 00-16045 Filed 6-23-00; 8:45 am]

BILLING CODE 4120-01-P

## DEPARTMENT OF COMMERCE

### National Oceanic and Atmospheric Administration

#### 50 CFR Part 660

[Docket No. 000619185-0185-01; I.D. 042400H]

RIN 0648-A006

#### Fisheries Off West Coast States and in the Western Pacific; Western Pacific Crustacean Fisheries; Northwestern Hawaiian Islands Lobster Fishery; Closure of the Year 2000 Fishery

**AGENCY:** National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

**ACTION:** Final rule; emergency closure.

**SUMMARY:** NMFS issues a final rule to close the 2000 Northwestern Hawaiian Islands (NWHI) commercial lobster fishery, which is scheduled to open on July 1, 2000. This rule, which is authorized by the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act), amends current regulations promulgated under the Fishery Management Plan for Crustacean Fisheries of the Western Pacific Region (FMP). NMFS is closing the lobster fishery to prevent the potential for overfishing lobster resources.

**DATES:** Effective July 1, 2000, through December 31, 2000.

**ADDRESSES:** Copies of the Environmental Assessment, Regulatory Impact Review, and Final Regulatory Flexibility Analysis (FRFA) are available from Dr. Charles Karnella, Administrator, Pacific Islands Area Office, NMFS (PIAO), 1601 Kapiolani Blvd., Rm 1101, Honolulu, HI 96814.

**FOR FURTHER INFORMATION CONTACT:** Alvin Katekaru, PIAO, 808-973-2937,