

List of Subjects in 40 CFR Part 81

Environmental protection, Air pollution control, National parks, Wilderness areas.

Authority: 42 U.S.C. 7401-7671q.

Dated: January 25, 1995.

John P. DeVillars,

Regional Administrator, Region I.

[FR Doc. 95-4295 Filed 2-21-95; 8:45 am]

BILLING CODE 6560-50-P

40 CFR Part 180

[OPP-300379; FRL-4934-8]

RIN 2070-AC18

Extended Tolerance on Dried Hops for Imidacloprid

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA proposes to extend the tolerance for residues of the insecticide 1-[(6-chloro-3-pyridinyl) methyl]-N-nitro-2-imidazolidinimine and its metabolites (common name "imidacloprid") in or on dried hops at 3.0 parts per million (ppm). On its own initiative, EPA proposes to extend the tolerance to allow time to review a petition from the Interregional Research Project No. 4 (IR-4).

DATES: Written comments, identified by the document control number, [OPP-300379], may be submitted on or before March 24, 1995.

ADDRESSES: Comments may be submitted to: Public Docket and Freedom of Information Section, Field Operations Division (7506C), Office of Pesticide Programs, 401 M St., SW., Washington, DC 20604. In person, bring comments to: Rm. 1132, CM #2, Arlington, VA 22202.

Information submitted as a comment concerning this document may be claimed confidential by marking any part or all of that information "Confidential Business Information" (CBI). Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the comment 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. All written comments will be available for public inspection in Rm. 1132 at the address given below, from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays.

FOR FURTHER INFORMATION CONTACT: By mail: Dennis H. Edwards, Jr., Product

Manager (PM) 19, Registration Division (7505C), Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm. 207, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202, (703)-305-6386.

SUPPLEMENTARY INFORMATION: On its own initiative and pursuant to section 408(e) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(e), the Agency established in 40 CFR 180.472 a time-limited tolerance for the residues of imidacloprid on dried hops at 3.0 parts per million (ppm) (see the **Federal Register** of June 28, 1994 (59 FR 33204)). EPA established this tolerance because EPA had granted a petition for an emergency exemption under section 18 of the Federal Insecticide, Fungicide and Rodenticide Act, 7 U.S.C. 136p, for the use of imidacloprid on hops in the States of Washington, Oregon, and Idaho; imidacloprid is used in other countries which export hops to the United States; and the database for imidacloprid is relatively complete. At that time, a third field residue trial was outstanding. Since then, the Interregional Research Project No. 4 (IR-4) has submitted a pesticide petition to the Agency requesting that a tolerance be established in or on dried hops. This petition is currently in review. The Agency may not complete its review of the IR-4 petition before the time-limited tolerance would expire. EPA does not believe that its risk assessment will significantly change as a result of the IR-4 petition. Therefore, the Agency is proposing to extend this tolerance for an additional 1-year period, i.e., to June 28, 1996.

In the **Federal Register** of November 30, 1994 (59 FR 61278), EPA revised 40 CFR 180.472 and removed the time-limited designation for commodities listed in paragraph (a). The listing for "Hops, dried" at 3.0 ppm inadvertently was left in paragraph (a) in the new list of commodities without a time-limited designation. Hops should have retained the time-limited designation, June 28, 1995, and been moved to a new paragraph. This change was made by a technical amendment published in the **Federal Register** of February 22, 1995.

All relevant materials have been evaluated. The toxicology data considered in support of the tolerance include:

1. A three generation rat reproduction study that showed a NOEL of 100 ppm (8 mg/kg/bwt); rat and rabbit teratology studies were negative at doses up to 30 mg/kg/bwt and 24 mg/kg/bwt, respectively.

2. A 2-year rat feeding/carcinogenicity study that was negative for carcinogenic effects under the conditions of the study and had a NOEL of 100 ppm (5.7 mg/kg/bwt in males and 7.6 mg/kg/bwt in females) for noncarcinogenic effects, which included decreased body weight gain in females at 300 ppm and increased thyroid lesions in males at 300 ppm and females at 900 ppm.

3. A 1-year dog feeding study that showed a NOEL of 1,250 ppm (41 mg/kg/bwt).

4. A 2-year mouse carcinogenicity study that was negative for carcinogenic effects under the conditions of the study and had a NOEL of 1,000 ppm (208 mg/kg/day).

There is no cancer risk associated with exposure to this chemical. Imidacloprid has been classified as a "Group E" (no evidence of carcinogenicity for humans) carcinogen by the OPP Reference Dose (RfD) Committee.

The reference dose (RfD), based on the 2-year rat feeding/carcinogenic study with a NOEL of 5.7 mg/kg/bwt and 100-fold uncertainty factor, is calculated to be 0.057 mg/kg/bwt. The theoretical maximum residue contribution (TMRC) from the proposed tolerances is 0.000984 mg/kg/bwt/day and utilizes 2% percent of the ADI.

The nature of the residue in plants and livestock is adequately understood. Spent hops are not considered a poultry feed item; therefore, secondary imidacloprid tolerances for poultry and eggs are not required. The analytical method is a common moiety method for imidacloprid and its metabolites containing the 6-chloropyridinyl moiety in plants using a permanganate oxidation, silyl derivatization, and capillary GC-MS-selective ion monitoring. The magnitude of the residue crop field trial data for imidacloprid on hops indicates that residues of total imidacloprid will not exceed the proposed tolerance when the formulations are used as directed. The extension for this use will expire on June 28, 1996.

This pesticide is considered useful for the purposes for which the tolerances are sought. Based on the above information considered by the Agency, the tolerance established by amending 40 CFR part 180 would protect the public health. Therefore, it is proposed that the tolerance be established as set forth below. Any person who has registered or submitted an application for registration of a pesticide, under FIFRA, as amended, which contains any of the ingredients listed herein, may request within 30 days after publication of this document in the **Federal Register**

that this rulemaking proposal be referred to an Advisory Committee in accordance with FFDCA section 408(e).

Interested persons are invited to submit written comments on the proposed regulation. Comments must bear notation indicating the document control number, [OPP-300379]. All written comments filed in response to this document will be available in the Public Docket and Freedom of Information Section, at the address given above from 8 a.m. to 4 p.m., Monday through Friday, except legal holidays.

Pursuant to the requirements of the Regulatory Flexibility Act (Pub. L. 96-354, 94 Stat. 1164, 5 U.S.C. 601-612), the Administrator has determined that regulations establishing exemption from tolerance requirements do not have a significant economic impact on a substantial number of small entities. A certification statement to this effect was published in the **Federal Register** of May 4, 1981 (46 FR 24950).

List of Subjects in 40 CFR Part 180

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

Dated: February 10, 1995.

Stephen L. Johnson,

Director, Registration Division, Office of Pesticide Programs.

Therefore, it is proposed that chapter I of title 40 of the Code of Federal Regulations be amended as follows:

PART 180—[AMENDED]

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

Authority: 21 U.S.C. 346a and 371.

2. In 180.472, by revising paragraph (d), to read as follows:

§ 180.472 1-[(6-Chloro-3-pyridinyl) methyl]-N-nitro-2-imidazolidinimine; tolerances for residues.

* * * * *

(d) A time-limited tolerance, to expire June 28, 1996, is established permitting the combined residues of the insecticide 1-[(6-chloro-3-pyridinyl)methyl]-N-nitro-2-imidazolidinimine and its metabolites containing the chloropyridinyl moiety, all expressed as 1-[(6-chloro-3-pyridinyl)methyl]-N-nitro-2-imidazolidinimine, in or on the following raw agricultural commodity:

Commodity	Parts per million
Hops, dried	3.0

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40 CFR Part 180

[PP 2E4071/P603; FRL 4936-2]

RIN 2070-AC18

Methyl Anthranilate; Exemptions from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA proposes to establish exemptions from the requirement of a tolerance for residues of the biochemical methyl anthranilate in or on the raw agricultural commodities blueberry, cherry, and grape when the pesticide is used in accordance with good agricultural practices. The Interregional Research Project No. 4 (IR-4) requested these exemptions in a petition submitted to EPA.

DATES: Comments, identified by the document control number, [PP 2E4071/P603], must be received on or before March 24, 1995.

ADDRESSES: By mail, submit written comments to: Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW, Washington, DC 20460. In person, bring comments to: Rm. 1132, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202. Information submitted as a comment concerning this notice may be claimed confidential by marking any part or all of that information as "Confidential Business Information" (CBI).

Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the comment 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. All written comments will be available for public inspection in Rm. 1132 at the address given above, from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays.

FOR FURTHER INFORMATION CONTACT: By mail: Hoyt Jamerson, Registration

Division (7505W), Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Sixth Floor, Crystal Station #1, 2800 Jefferson Davis Hwy., Arlington, VA 22202, (703)-308-8783.

SUPPLEMENTARY INFORMATION: The Interregional Research Project No. 4 (IR-4), New Jersey Agricultural Experiment Station, P.O. Box 231, Rutgers University, New Brunswick, NJ 08903, has submitted pesticide petition (PP) 2E4071 to EPA on behalf of the Agricultural Experiment Station of Washington. Pesticide petition 2E4071 requests that the Administrator, pursuant to section 408(e) of the Federal Food, Drug and Cosmetic Act (FFDCA), 21 U.S.C. 346a(e), establish exemptions from the requirement of a tolerance for residues of the biochemical methyl anthranilate in or on the raw agricultural commodities blueberry, cherry, and grape. Methyl anthranilate will be applied as a dilute foliar spray to these crops to repel birds and reduce bird depredation. Methyl anthranilate is a natural constituent of food that can be found in grape and citrus. Methyl anthranilate is also synthetically produced and used in the purified form (not less than 99 percent pure) as a flavoring agent in beverages, ice cream, candy, baked goods, gelatins, puddings, and chewing gum. The synthetic product mimics the chemical structure and function of the natural plant constituent. Methyl anthranilate is listed by the Food and Drug Administration (FDA) as a flavoring compound under 21 CFR 182.60, and is classified generally recognized as safe (GRAS) by the Expert Panel of the Flavor and Extract Manufacturer's Association (FEMA). Registrants who produce end-use products for this active ingredient that are intended for use on blueberry, cherry, or grape will be required to use methyl anthranilate produced to meet or exceed U.S. Food Chemical Codex and U.S. Pharmacopoeia specifications.

Residue data submitted with the petition indicate that residues of methyl anthranilate would not exceed 35 parts per million (ppm) on blueberry, cherry, and grape from the proposed use. The incremental dietary exposure to methyl anthranilate is not significant compared to naturally occurring levels, or levels resulting from use of the chemical as a flavoring agent. For example, naturally occurring levels of methyl anthranilate are reported at 33 ppm in concord grapes, and the use of methyl anthranilate as a flavoring agent results in residues of approximately 30 ppm in