

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.

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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**