

effects under conditions of the study and that 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 under "Group E" (no evidence of carcinogenicity) by EPA's OPP/HED's 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 published uses is 0.000985 mg/kg/bwt/day. This represents 2% of the RfD. The proposed tolerance contributes 0.000001 mg/kg/bwt/day. This represents no significant increase in the RfD. Dietary exposure from the existing uses and proposed use will not exceed the reference dose for any subpopulation (including infants and children) based on the information available from EPA's Dietary Risk Evaluation System.

The nature of the imidacloprid residue in plants and livestock is adequately understood. The residues of concern are combined residues of imidacloprid and its metabolites containing the 6-chloropyridinyl moiety, all calculated as imidacloprid. The analytical method is a common moiety method for imidacloprid and its metabolites containing the 6-chloropyridinyl moiety using a permanganate oxidation, silyl derivatization, and capillary GC-MS selective ion monitoring. Imidacloprid and its metabolites are stable in the commodities when frozen for at least 24 months. There are adequate amounts of geographically representative crop field trial data to show that combined residues of imidacloprid and its metabolites, all calculated as imidacloprid, will not exceed the proposed tolerance on mangoes at 0.2 ppm when use as directed.

There are currently no actions pending against the continued registration of this chemical.

This pesticide is considered useful for the purposes for which the tolerance is sought and capable of achieving the intended physical or technical effect. Based on the information and data considered, the Agency has determined that the tolerances established by amending 40 CFR part 180 will protect the public health. Therefore, the tolerance is established as set forth below.

Any person adversely affected by this regulation may, within 30 days after publication of this document in the **Federal Register**, file written objections

to the regulation and may also request a hearing on those objections. Objections and hearing requests must be filed with the Hearing Clerk, at the address given above (40 CFR 178.20). A copy of the objections and/or hearing requests filed with the Hearing Clerk should be submitted to the OPP docket for this rulemaking. The objections submitted must specify the provisions of the regulation deemed objectionable and the grounds for the objections (40 CFR 178.25). Each objection must be accompanied by the fee prescribed by 40 CFR 180.33(i). If a hearing is requested, the objections must include a statement of the factual issue(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). 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 issue(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

Under Executive Order 12866 (58 FR 51735, October 4, 1993), the Agency must determine whether the regulatory action is "significant" and therefore subject to all the requirements of the Executive Order, i.e., Regulatory Impact Analysis, review by the Office of Management and Budget (OMB). Under section 3(f), the order defines "significant" as those actions likely to lead to a rule (1) having an annual effect on the economy of \$100 million or more, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or tribal governments or communities (also known as "economically significant"); (2) creating serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement, grants, user fees, or loan programs; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this Executive Order.

Pursuant to the terms of this Executive Order, EPA has determined that this rule is not "significant" and is therefore not subject to OMB review.

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 new tolerances or raising tolerance levels or establishing exemptions 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

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

Dated: February 21, 1995.

Stephen L. Johnson,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR part 180 is amended as follows:

PART 180—[AMENDED]

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

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

2. In § 180.472, by amending paragraph (a) in the table therein by adding and alphabetically inserting the entry for mango, to read as follows:

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

(a) * * *

| | Commodity | Part per million |
|-------------|-----------|------------------|
| * | * | * |
| Mango | | 0.2 |
| * | * | * |

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40 CFR Part 180

[OPP-300374A; FRL-4933-7]

RIN 2070-AB78

3,5-Bis(6-Isocyanatohexyl)-2H-1,3,5-Oxadiazine-2,4,6-(3H,5H)-Trione, Polymer With Diethylenetriamine; Tolerance Exemption

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This document establishes an exemption from the requirement of a tolerance for residues of 3,5-*bis*(6-isocyanatohexyl)-2*H*-1,3,5-oxadiazine-2,4,6-(3*H*,5*H*)-trione, polymer with diethylenetriamine (CAS Reg. No. 87823-33-4), when used as an inert ingredient (encapsulating agent) in pesticide formulations applied to growing crops. Miles, Inc., requested this regulation.

EFFECTIVE DATE: This regulation becomes effective March 8, 1995.

ADDRESSES: Written objections, identified by the document control number, [OPP-300374A], may be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. A copy of any objections and hearing requests filed with the Hearing Clerk should be identified by the document control number and submitted 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 copy of objections and hearing request to: Rm. 1132, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202. Fees accompanying objections shall be labeled "Tolerance Petition Fees" and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251.

FOR FURTHER INFORMATION CONTACT: By mail: Connie Welch, Registration Support Branch, Registration Division (7508W), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Westfield Building North, 6th Fl., 2800 Crystal Drive, Arlington, VA 22202, (703)-308-8470.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of January 12, 1995 (60 FR 2921), EPA issued a proposed rule that gave notice that Miles, Inc., 8400 Hawthorn Rd., P.O. Box 4913, Kansas City, MO 64120-0013, had submitted pesticide petition (PP) 4E4416 to EPA requesting that the Administrator, pursuant to section 408(e) of the Federal Food, Drug, and Cosmetic Act (FFDCA) (21 U.S.C. 346a(e)), propose to amend 40 CFR 180.1001(d) by establishing an exemption from the requirement of a tolerance for residues of 3,5-*bis*(6-isocyanatohexyl)-2*H*-1,3,5-oxadiazine-2,4,6-(3*H*,5*H*)-trione, polymer with diethylenetriamine (CAS Reg. No. 87823-33-4), when used as an inert

ingredient (encapsulating agent) in growing crops under 40 CFR 180.1001(d).

Inert ingredients are all ingredients that are not active ingredients as defined in 40 CFR 153.125, and include, but are not limited to, the following types of ingredients (except when they have a pesticidal efficacy of their own): solvents such as alcohols and hydrocarbons; surfactants such as polyoxyethylene polymers and fatty acids; carriers such as clay and diatomaceous earth; thickeners such as carrageenan and modified cellulose; wetting, spreading, and dispersing agents; propellants in aerosol dispensers; microencapsulating agents; and emulsifiers. The term "inert" is not intended to imply nontoxicity; the ingredient may or may not be chemically active.

There were no comments or requests for referral to an advisory committee received in response to the proposed rule.

The data submitted relevant to the proposal and other relevant material have been evaluated and discussed in the proposed rule. Based on the data and information considered, the Agency concludes that the tolerance exemption will protect the public health. Therefore, the tolerance exemption is established as set forth below.

Any person adversely affected by this regulation may, within 30 days after publication of this document in the **Federal Register**, file written objections and/or request a hearing with the Hearing Clerk, at the address given above (40 CFR 178.20). A copy of the objections and/or hearing requests filed with the Hearing Clerk should be submitted to the OPP docket for this rulemaking. The objections submitted must specify the provisions of the regulation deemed objectionable and the grounds for the objections (40 CFR 178.25). Each objection must be accompanied by the fee prescribed by 40 CFR 180.33(i). If a hearing is requested, the objections must include a statement of the factual issue(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). 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

issue(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

Under Executive Order 12866 (58 FR 51735, Oct. 4, 1993), the Agency must determine whether the regulatory action is "significant" and therefore subject to review by the Office of Management and Budget (OMB) and the requirements of the Executive Order. Under section 3(f), the order defines a "significant regulatory action" as an action that is likely to result in a rule (1) having an annual effect on the economy of \$100 million or more, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities (also referred to as "economically significant"); (2) creating serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement, grants, user fees, or loan programs or the rights and obligations or recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this Executive Order.

Pursuant to the terms of the Executive Order, EPA has determined that this rule is not "significant" and is therefore not subject to OMB review.

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 new tolerances or raising tolerance levels or establishing exemptions 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

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

Dated: February 24, 1995.

Stephen L. Johnson,
Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR part 180 is amended as follows:

PART 180—[AMENDED]

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

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

alphabetically inserting the inert ingredient, to read as follows:

§ 180.1001 Exemptions from the requirement of a tolerance.

* * * *
* * * *
(d) * * *

2. Section 180.1001(d) is amended in the table therein by adding and

| Inert ingredients | Limits | Uses |
|--|--------|---------------------|
| 3,5-Bis(6-isocyanatohexyl)-2 <i>H</i> -1,3,5-oxadiazine-2,4,6-(3 <i>H</i> ,5 <i>H</i>)-trione, polymer with diethylenetriamine (CAS Reg. No. 87823-33-4); minimum number average molecular weight 1,000,000.. | | Encapsulating agent |

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[FR Doc. 95-5652 Filed 3-7-95; 8:45 am]
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40 CFR Part 180
[PP 6F3392/R2105; FRL-4933-1]
RIN 2070-AB78

Pesticide Tolerance for Clofentezine

AGENCY: Environmental Protection Agency (EPA).
ACTION: Final rule.

SUMMARY: This rule establishes a tolerance for residues of the insecticide clofentezine in or on the raw agricultural commodity apples. AgroEvo USA Corp. (formerly Nor-Am Chemical Co.) requested this regulation to establish a maximum permissible level for residues of the insecticide.

EFFECTIVE DATE: This regulation is effective February 22, 1995.

ADDRESSES: Written objections and hearing requests, identified by the document control number, [PP 6F3392/R2105], may be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. A copy of any objections and hearing requests filed with the Hearing Clerk should be identified by the document control number and submitted 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 copy of objections and hearing requests to Rm. 1132, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202. Fees accompanying objections shall be labeled "Tolerance Petition Fees" and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251.

FOR FURTHER INFORMATION CONTACT: By mail: Dennis H. Edwards, Product Manager (PM) 19, Registration Division (7505C), Office of Pesticide Programs, 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)-305-3686.

SUPPLEMENTARY INFORMATION: EPA issued a notice, published in the **Federal Register** of June 4, 1986 (51 FR 20343), which announce that Nor-Am Chemical Co. of Little Falls Centre One, 2711 Centerville Rd., Wilmington, DE 19803, had submitted a pesticide petition to EPA requesting that the Administrator, pursuant to section 408(d) of the Federal Food, Drug and Cosmetic Act (FFDCA), 21 U.S.C. 346a(d), propose to amend 40 CFR 180.446 by establishing tolerances for residues of the insecticide clofentezine 3,b-bis(2-chlorophenyl)-1,2,4,5-tetrazine in or on the commodities apples at 0.05 part per million (ppm), meat at 0.05 ppm, meat byproducts at 0.05 ppm, milk at 0.01 ppm, and poultry and poultry byproducts at 0.05. A feed additive tolerance was proposed for dry apple pomace at 1.0 ppm.

Subsequent to the original notice of filing, EPA issued a notice, published **Federal Register** of May 27, 1992 (57 FR 22232), which announced that the Nor-Am Chemical Co. was amending pesticide petition 6F3392 by increasing the proposed tolerance in/on apples to 0.01 ppm, withdrawing the proposed feed additive tolerance, and withdrawing the petition for animal tolerances since they have already been established.

There were no comments or requests for referral to an advisory committee received in response to the notice of filings.

The scientific data submitted in the petition and other relevant material have been evaluated. The toxicological

data considered in support of the tolerance include a 1-year dog feeding study with a no-observed-effect level (NOEL) of 50 ppm (1.25 mg/kg/day); a mouse carcinogenicity study which was negative at the doses tested, 50 ppm (7.5 mg/kg/day), 500 ppm (75 mg/kg/day), and 5,000 ppm (750 mg/kg/day); a multi-generation rat study with a NOEL of 400 ppm (20 mg/kg/day) (highest dose tested (HDT)); a rat teratology study which was negative at 3,200 mg/kg/day (HDT) and had a developmental NOEL of 3,200 mg/kg/day; a rabbit teratology study which was negative at 3,000 mg/kg/day (HDT) also had a NOEL of 1,000 mg/kg/day for maternal toxicity (reduced litter and fetal body weights); and a 2-year rat chronic feeding/carcinogenicity study which showed an increase in the incidence of centrilobular hepatocyte hypertrophy and showed a statistically significant increase in thyroid follicular cell tumors in male rats at 400 ppm (20 mg/kg/day (HDT). Gene mutation, chromosomal aberrations, and diet DNA damage tests were negative for genetic toxicity.

The registrant (Nor-AM) also submitted additional thyroid studies intended to show that there was an indirect mechanism for the follicular cell tumors associated with clofentezine's liver toxicity. The Agency has reviewed the data in accordance with criteria outlined in a draft document entitled, "Thyroid Follicular Cell Carcinogenesis: Mechanistic and Science Policy Considerations," (December 15, 1987). While this document is still undergoing Agency review, and the assessment procedures set forth therein have not been adopted by the Agency, the draft does provide a useful framework in which to consider the issue. Although the additional thyroid function studies suggest the possibility of an indirect mechanism for follicular cell tumor induction that may be associated with clofentezine's liver toxicity, the Agency believes that