

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 1, 1996.

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. Section 180.1001(c) is amended in the table therein by adding and alphabetically inserting the inert ingredient, to read as follows:

§ 180.1001 Exemptions from the requirement of a tolerance.

* * * * *

(c) * * *

Inert ingredient	Limits	Uses
Octadecanoic acid, 12-hydroxy-, homopolymer, octadecanoate (CAS Reg. No. 58128-22-6), minimum number-average molecular weight 1,370..	dispersing agent, related adjuvant of surfactants, surfactant, suspending agent.

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[FR Doc. 96-3021 Filed 2-13-96; 8:45 am]

BILLING CODE 6560-50-F

40 CFR Part 180

[PP PP 5F4534/R2199; FRL-4995-2]

RIN 2070-AC18

Imidacloprid; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This rule establishes a tolerance for residues of the insecticide 1-[(6-chloro-3-pyridinyl)methyl]-N-nitro-2-imidazolidinimine (proposed common name "imidacloprid") and its metabolites in or on canola seed. Gustafson, Inc. requested this regulation to establish maximum permissible levels for residues of the insecticide.

EFFECTIVE DATE: This regulation became effective February 7, 1996.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [PP 5F4534/R2199], may be submitted to: Hearing Clerk (A-110), 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 docket 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. 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.

An electronic copy of objections and hearing requests filed with the Hearing Clerk may be submitted to OPP by sending electronic mail (e-mail) to:

opp-docket@epamail.epa.gov

Copies of electronic objections and hearing requests must be submitted as an ASCII file avoiding 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 5.1 file format or ASCII file format. All copies of electronic objections and hearing requests must be identified by the docket number [PP 5F4534/R2199]. No Confidential Business Information (CBI)

should be submitted through e-mail. Copies of electronic objections and hearing requests on this rule may be filed online at many Federal Depository Libraries. Additional information on electronic submissions can be found below in this document.

FOR FURTHER INFORMATION CONTACT: By mail: Dennis H. Edwards, Jr., Product Manager (PM 19), Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Rm. 207, CM #2 1921 Jefferson Davis Highway, Arlington, VA, (703) 305-6386; e-mail: edwards.dennis@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA issued a notice published in the Federal Register of August 17, 1995 (60 FR 42884), which announced that Gustafson, Inc., P.O. Box 660065, Dallas, TX 75266-0065, had submitted to amend 40 CFR part 180 by establishing a regulation to permit residues of the insecticide (1-[(6-chloro-3-pyridinyl)methyl]-N-nitro-2-imidazolidinimine, in or on the raw agricultural commodity canola seed at 0.05 parts per million (ppm).

The Agency is currently issuing a 2-year conditional registration for use of "imidacloprid" on canola seed. Additional residue trials are needed. On June 2, 1994, the Agency issued a guidance document on crop residue trials. Among other things, this document provided guidance on the number and location of domestic crop field trials for establishment of pesticide residue trials. Based on this guidance document, the Agency determined that additional field trials are needed for canola. However, the Agency does not believe that this data will significantly change its risk assessment.

The scientific data submitted in the petition and other relevant material have been evaluated. The toxicological data considered in support of the tolerance include:

1. A three-generation rat reproduction study with no-observed-effect level (NOEL) of 100 ppm (8 mg/kg/bwt); rat and rabbit developmental toxicity studies were negative at doses up to 30 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 male and 7.6 mg/kg/bwt female) for noncarcinogenic effects that included decrease 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 with a NOEL of 1,250 ppm (41 mg/kg/bwt).

4. A 2-year mouse carcinogenicity study that was negative for carcinogenic 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) for published uses is 0.008189 mg/kg/bwt/day utilizing 14.4% of the RFD. The proposed tolerance will increase the TMRC by .000077 mg/kg/day representing an increase in the ADI of 1.5%. The TMRC will be .008266 mg/kg/day utilizing 15.9% of the RFD. For exposure of subgroups in the population, children (1-6), the TMRC for the published and proposed tolerances is 0.016934 mg/kg/day. This is equal to 29.7% of 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 when used as directed. Canola meal is a livestock feedstuff ruminant, and poultry feeding studies show transfer of imidacloprid from feedstuff to meat, milk, poultry, and eggs. The secondary tolerances in meat, milk, poultry, eggs are adequate to cover the additional use on canola.

There are presently 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 tolerance 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 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).

A record has been established for this rulemaking under docket number [PP 5F4535/R2199] (including any comments and data submitted electronically). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The public record is located in Room 1132 of the Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA.

The official record for this rulemaking, as well as the public version, as described above will be kept in paper form. Accordingly, EPA will transfer any copies of objections and hearing requests received electronically into printed, paper form as they are received and will place the paper copies in the official rulemaking record which will also include all comments submitted directly in writing. The official rulemaking record is the paper record maintained at the address in "ADDRESSES" at the beginning of this document.

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. 9-354, 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 7, 1996.

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 following commodity to read as follows:

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

(a) * * *

	Commodities					Parts per million
	*	*	*	*	*	
Canola						0.05
	*	*	*	*	*	

Residues in these commodities not in excess of the established tolerances resulting from the use described in this paragraph remaining after expiration of the conditional registration will not be considered to be actionable if the insecticide is applied during the term of and in accordance with the provisions of the above regulation.

* * * * *

[FR Doc. 96-3280 Filed 2-13-96; 8:45 am]

BILLING CODE 6560-50-F

40 CFR Part 180

[PP 4F4396/R2202; FRL-5348-9]

RIN 2070-AC78

Pelargonic Acid; Exemption From the Requirement of a Tolerance on Apples and Pears

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This rule establishes an exemption from the requirement of a tolerance for residues of pelargonic acid when used as a blossom thinning agent on apples and pears. A request for an exemption from the requirement of a tolerance was submitted by Mycogen Corporation. This regulation eliminates the need to establish a maximum

permissible level for residues of this plant regulator on apples and pears.

EFFECTIVE DATE: Effective on February 14, 1996.

ADDRESSES: Written objections and hearing requests, identified by the docket number [PP 4F4396/R2202] 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 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 Highway, 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: Mike Mendelsohn, Biopesticides and Pollution Prevention Division, Office of Pesticide Programs, U. S. Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number:

5th Floor CS, 2800 Crystal Drive, Arlington, VA 22202, (Telephone No. (703)-308-8715), e-mail:

mendelsohn.mike@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA issued a notice, published in the Federal Register of February 8, 1995 (60 FR 7539), which announced that Mycogen Corporation, 4980 Carroll Canyon Rd., San Diego, CA 92121 had submitted a pesticide petition (PP) 4F4396 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), establish an exemption from the requirement of a tolerance for the plant growth regulator pelargonic acid on apples and pears.

There were no adverse comments, or requests for referral to an advisory committee received in response to the notice of filing of the PP 4F4396.

I. Existing Food Clearances

Pelargonic acid is an approved secondary direct food additive under 21 CFR 173.315 for use in the lye peeling of fruits and vegetables. An aliphatic acid mixture of valeric, caproic, enanthoic, caprylic and pelargonic acids may be used at a level not to exceed 1 percent in a lye peeling solution. The conditions for use include a stipulation that following the use of chemicals cleared under 21 CFR 173.315 the fruit