

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.

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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

and vegetables must be rinsed with potable water to remove, to the extent possible, residues of the chemical.

Pelargonic acid is listed by the U.S. Department of Agriculture under the USDA List of Authorized Substances, 1990, section 5.14, Fruit and Vegetable Washing Compounds.

Pelargonic acid is approved as part of a sanitizing solution for use on food-processing equipment and utensils, and dairyprocessing equipment. Its use must be in combination with decanoic acid, phosphoric acid, propionic acid, and sodium 1-octanesulfonate. The pelargonic acid-containing sanitizing solution must be drained from the treated equipment and utensils before contact with food. (21 CFR 178.1010(b)(42))

Pelargonic acid also is approved as a synthetic food flavoring agent (21 CFR 172.515) provided the minimum quantity required to produce its intended effect is used in accordance with the principles of good manufacturing practice.

II. Pelargonic Acid Natural Occurrence and Treated Apple Residue Data

Pelargonic acid is naturally present at levels up to 224 parts per billion (ppb) in apples, 385 parts per million (ppm) in the skin of grapes, and 143 ppm in grape pulp. It has been determined to be present in a number of other foods as well. The highest residues of pelargonic acid reported in apples subsequent to blossom treatment were less than 360 ppb.

A. Toxicology Assessment; Supporting Data

1. Acute toxicology of a 60% pelargonic acid emulsifiable concentrate.

Acute Oral LD₅₀ > 5,000 mg/kg
Acute Dermal LD₅₀ > 2,000 mg/kg
Acute Inhalation LC₅₀ = 5.29 mg/L
Primary Dermal Irritation - Moderate Irritant
Primary Eye Irritation - Severe Irritant
Dermal Sensitization - Non-sensitizer

2. *Mammalian cells in culture gene mutation assay in mouse lymphoma cells (L5178Y TK ±)*. Pelargonic acid was considered weakly positive for inducing mutations at the TK locus of culture mouse L5178Y TK ± cells in the presence of S9-induced metabolic activation. Mutations were induced at levels greater than or equal to 50 µg/ml. However, this occurred in the presence of increasing moderate-to-severe cytotoxicity and small colony development and may reflect gross chromosomal changes or damage rather than actual mutational changes within the TK gene locus.

3. *In vivo mammalian cytogenetics - mouse micronucleus assay*. In an *in vivo* mouse micronucleus assay, groups of ICR mice (15/sex/dose) were administered single oral doses of 1,250, 2,500, and 5,000 mg/kg *n*-pelargonic acid. The bone marrow cells were harvested 24, 48, and 72 hours post-treatment. No significant increases in the frequency of micronucleated polychromatic erythrocytes (PCEs) were observed in either sex at any dose; thus, *n*-pelargonic acid was negative in the micronucleus assay.

4. *Reverse gene mutation assay (Ames Test)*. Pelargonic acid was not mutagenic under the conditions of the study.

5. *Metabolism*. Pelargonic acid is a naturally occurring, nine-carbon saturated fatty acid. The oxidative degradation of fatty acids is a central metabolic pathway in both animals and plants. Fatty acids of varying chain lengths are metabolized into two-carbon fragments through a sequence of enzyme-catalyzed reactions. The metabolic products are then incorporated into fats, carbohydrates and amino acids.

6. *Carcinogenicity*. A summary of the results of a dermal carcinogenicity study in mice with pelargonic acid was submitted. Fifty mice were treated twice-weekly with 50 mg doses of undiluted pelargonic acid for 80 weeks. No evidence of severe dermal or systemic toxicity was seen. Histopathology revealed no tumors of the skin or the internal organs.

7. *Developmental toxicity*. The results of a developmental toxicity study in rats with pelargonic acid was submitted. Groups of 22 pregnant CD rats were given oral administration of 0 mg (corn oil) or 1,500 mg/kg pelargonic acid during days 6 through 15 of gestation. No evidence of maternal toxicity was seen. Maternal body weights and weight gain were comparable to that of the controls. No treatment-related effects were seen at C-section. No developmental toxicity was seen. Based on the above information, EPA concludes that the quantity of pelargonic acid that is proposed for use will not be harmful to humans since:

(1) The lowest level shown to weakly induce mutations in an *in vitro* test system in the presence of cytotoxicity was at the 50,000 parts per million level and the highest residues seen in treated apples were less than 360 parts per billion (ppb).

(2) Other than weak mutation at high levels in an *in vitro* test system and eye irritation, the data on pelargonic acid show no other adverse effects.

(3) The maximum application rate of pelargonic acid for blossom-thinning is 4.2 pounds per acre in a spray solution containing up to 0.31% pelargonic acid.

(4) Pelargonic acid is applied before fruit set.

B. Analytical Enforcement Method

This rule establishes an exemption from the requirement of a tolerance; therefore, the Agency has concluded that an analytical method is not required for enforcement purposes for pelargonic acid.

III. Conclusion

Based on the low toxicity of pelargonic acid and the low residue levels expected in apples and pears, the Agency concludes that establishment of a tolerance is not necessary to protect the public health for blossom thinning uses. Therefore, the exemption from tolerance is established as set forth below.

IV. Filing of Objections

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).

V. Regulatory Assessment Requirements

A. Executive Order 12866

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.

B. Regulatory Flexibility Act

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 6, 1996.

Daniel M. Barolo,

Director, Office of Pesticide Programs.

PART 180—[AMENDED]

Therefore, 40 CFR Part 180 is amended as follows:

1. The authority citation for part 180 continues to read as follows:
Authority: 21 U.S.C. 346a and 371.

2. In subpart D, by adding § 180.1159, to read as follows:

§ 180.1159 Pelargonic acid.

Pelargonic acid is exempt from the requirement of a tolerance on apples and pears provided it is used as a blossom thinner only and is in a dilution of 100 gallons of water applied to blooms at a rate not to exceed 4.2 lbs/acre with the maximum number of applications not exceeding two per year.

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40 CFR Part 271

[FRL-5420-5]

Alabama; Final Authorization of a Revision to State Hazardous Waste Management Program

AGENCY: Environmental Protection Agency.

ACTION: Immediate final rule.

SUMMARY: Alabama has applied for final authorization of a revision to its hazardous waste program under the Resource Conservation and Recovery Act (RCRA). Alabama's revision consists of the Corrective Action provision contained in HSWA Cluster I. This requirement is listed in Section B of this document. The Environmental Protection Agency (EPA) has reviewed Alabama's application and has made a decision, subject to public review and comment, that Alabama's hazardous waste program revision satisfies all of the requirements necessary to qualify for final authorization. Thus, EPA intends to approve Alabama's hazardous waste program revision. Alabama's application for program revision is available for public review and comment.

DATES: Final authorization for Alabama's program revision shall be effective April 15, 1996, unless EPA publishes a prior Federal Register action withdrawing this immediate final rule. All comments on Alabama's program revision application must be received by the close of business, March 15, 1996.

ADDRESSES: Copies of Alabama's program revision application are available during 8:00 am to 4:30 pm at the following addresses for inspection and copying: Alabama Department of Environmental Management, 1751 Congressman W.L. Dickinson Drive, Montgomery, Alabama 36109-2608,

(334) 271-7700; U.S. EPA, Region 4, Library, 345 Courtland Street, NE, Atlanta, Georgia 30365; (404) 347-4216. Written comments should be sent to Al Hanke at the address listed below.

FOR FURTHER INFORMATION CONTACT: Al Hanke, Chief, State Programs Section, Waste Programs Branch, Waste Management Division, U.S. Environmental Protection Agency, 345 Courtland Street, NE, Atlanta, Georgia 30365; (404) 347-2234 vmx 2018.

SUPPLEMENTARY INFORMATION:

A. Background

States with final authorization under Section 3006(b) of the Resource Conservation and Recovery Act ("RCRA" or "the Act"), 42 U.S.C. 6926(b), have a continuing obligation to maintain a hazardous waste program that is equivalent to, consistent with, and no less stringent than the Federal hazardous waste program. In addition, as an interim measure, the Hazardous and Solid Waste Amendments of 1984 (Pub. L. 98-616, November 8, 1984, hereinafter "HSWA") allows States to revise their programs to become substantially equivalent instead of equivalent to RCRA requirements promulgated under HSWA authority.

States exercising the latter option receive "interim authorization" for the HSWA requirements under Section 3006(g) of RCRA, 42 U.S.C. 6926(g), and later apply for final authorization for the HSWA requirements. Revisions to State hazardous waste programs are necessary when Federal or State statutory or regulatory authority is modified or when certain other changes occur. Most commonly, State program revisions are necessitated by changes to EPA's regulations in 40 CFR Parts 124, 260-268 and 270.

B. Alabama

Alabama initially received final authorization for its base RCRA program effective on December 22, 1987. Alabama received authorization for revisions to its program on January 28, 1992, July 12, 1992, December 21, 1992, May 17, 1993, November 23, 1993, April 4, 1994, January 13, 1995 and October 13, 1995. On March 1, 1990, Alabama submitted a program revision application for additional program approvals. Today, Alabama is seeking approval of its program revision in accordance with 40 CFR 271.21(b)(3).

EPA has reviewed Alabama's application and has made an immediate final decision that Alabama's hazardous waste program revision satisfies all of the requirements necessary to qualify for final authorization. Consequently,