

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

2. Section 180.361 is amended as follows:

- i. In paragraph (a) by adding a paragraph heading.
- ii. In paragraph (b) by transferring the entry in the table for "Peanuts, hulls" to the table in paragraph (a), and by revising the remainder of paragraph (b).
- iii. In paragraph (c) by adding a paragraph heading.
- iv. By adding and reserving paragraph (d).

§ 180.361 Pendimethalin, tolerances for residues.

(a) *General.* * * *

(b) *Section 18 emergency exemptions.* Time-limited tolerances are established for residues of the herbicide pendimethalin in connection with use of the pesticide under section 18 emergency exemptions granted by EPA. The tolerances will expire and are revoked on the dates specified in the following table:

Commodity	Parts per million	Expiration/ Revocation Date
Mint hay, fresh	0.1 ppm	5/31/98
Mint oil	5.0 ppm	5/31/98

(c) *Tolerances with regional registrations.* * * *

(d) *Indirect or inadvertent residues.*

[Reserved]

[FR Doc. 97-13643 Filed 5-22-97; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP-300488/PP-6F04625; FRL-5716-9]

RIN 2070-AB78

Pelargonic Acid; Exemption from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This document establishes an exemption from the requirement of a tolerance for residues of pelargonic acid when used as an herbicide in or on all food commodities. Mycogen Corporation submitted a petition to EPA under the Federal Food, Drug and Cosmetic Act (FFDCA) as amended by the Food Quality Protection Act of 1996 (FQPA) requesting the exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level

for residues of this herbicide in or on all food commodities.

EFFECTIVE DATE: May 23, 1997.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP-300488/PP 6F04625], may be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections and hearing requests shall be labeled "Tolerance Petition Fees" and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251. 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.

A copy of objections and hearing requests filed with the Hearing Clerk may also be submitted electronically to the OPP by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov. Copies of objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of objections and hearing requests will also be accepted on disks in WordPerfect in 5.1 file format or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the docket control number [OPP-300488/PP 6F04625]. No Confidential Business Information (CBI) should be submitted through e-mail. Electronic copies of objections and hearing requests on this rule may be filed online at many Federal Depository Libraries. Additional information on electronic submissions can be found in Unit VIII. of this preamble.

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, telephone number, and e-mail address: 5th Floor CS, 2800 Crystal Drive, Arlington, VA 22202, (703)-308-8715; email: mendelsohn.mike@epamail.epa.gov. **SUPPLEMENTARY INFORMATION:** In the **Federal Register** of January 24, 1997 (62 FR 3688)(FRL-5579-3), EPA issued a notice pursuant to section 408(d) of

FFDCA, 21 U.S.C. 346a(d) announcing the filing of a pesticide petition for an exemption from the requirement of a tolerance by Mycogen Corporation, 4980 Carroll Canyon Rd., San Diego, CA 92121. The notice contained a summary of the petition prepared by the petitioner and this summary contained conclusions and arguments to support its conclusion that the petition complied with the FQPA (Pub. L. 104-170). The petition requested that 40 CFR 180.1159 be amended to exempt pelargonic acid from the requirement for a tolerance for all food commodities (formerly raw agricultural commodities).

There were no comments received in response to the notice of filing. The data submitted in the petition and other relevant material have been evaluated. The toxicology data listed below were considered in support of this exemption from the requirement of a tolerance.

I. Toxicological Profile

Pelargonic acid, at high dose levels, showed no significant effects in a 14 day feeding study, a chronic dermal study, and a developmental toxicity study. In addition, there was no mutagenicity in an *in vivo* mouse micronucleus assay nor in a *Salmonella* reverse gene mutation assay. Further, the purported mutation observed at cytotoxic levels with S9 activation in the mouse lymphoma assay was determined not relevant to dietary risk. The results of these studies were determined applicable to evaluate human risk and the validity, completeness, and reliability of the available data from the studies were considered.

A. Acute Toxicity

A battery of acute toxicity studies place technical pelargonic acid in the following Toxicity Categories: primary eye irritation (Toxicity Category II), primary dermal irritation (Toxicity Category II), oral toxicity (Toxicity Category IV), dermal and inhalation toxicity (Toxicity Category III). Based on the results from the sensitization test, pelargonic acid was not considered a dermal sensitizer. (MRID Nos. 438435-01, -02, -03, -04, -05, and -06)

B. Mutagenicity

Pelargonic acid was shown not to be mutagenic via the Ames test (*Salmonella*/reverse mutation assay) or the *in vivo* cytogenetics study using the micronucleus assay (MRID Nos. 436037-02, and -03). In a mouse lymphoma forward mutation assay, pelargonic acid induced a purported weak mutagenic response at levels greater than or equal to 50 g/ml in

mouse TK +/- lymphoma cells in the presence of S9 metabolic activation (MRID No. 436037-01). However, this event occurred in the presence of increasing toxicity and may indicate gross chromosomal changes or damage rather than actual mutational changes within the TK gene locus.

In the review of the blossom thinning tolerance exemption for pelargonic acid (40 CFR 180.1159), the Agency used the mouse lymphoma forward mutation assay mentioned above in the determination of acceptable exposure limits for the active ingredient. The Agency has reexamined that study along with related testing as part of the review for the present proposed tolerance. As a result of the second review, the Agency has determined that the sum of the toxicological information submitted in support of the pelargonic acid tolerance exemption shows that it is unnecessary to set dietary limits for the active ingredient based upon a mutagenicity endpoint.

C. Oral Toxicity

A 14-day range-finding oral toxicity study in rats (MRID No. 438435-07) showed no systemic toxicity with either sex at the highest dose tested, 20,000 ppm (1,834 mg/kg/day). Further, no adverse effects on survival, clinical signs, body weight gain, food consumption, hematology, clinical chemistry or gross pathology were observed. Three animals per sex per dose were tested and organ weights and histopathology data were not available. The Agency determined that a 90-day oral study was not necessary for dietary risk assessment due to the following factors:

1. The lack of effects at extremely high doses in the range finding study mentioned above. Further, it is doubtful that increasing the number of animals from 3 to 10 per sex per dose and adding histopathology data would alter the toxicology profile.

2. The nature of the pelargonic acid (i.e., fatty acid) and its ubiquity in nature.

3. The use of pelargonic acid as a food additive (21 CFR 172.515 and 21 CFR 173.315).

4. The results from the acute mammalian toxicology studies.

5. The unlikelihood of prolonged human exposure via the oral route due to the proposed use patterns (i.e., control weeds before planting and prior to harvesting, burndown weeds to facilitate harvest, harvest aid or desiccant to root and tuber vegetables, bulb vegetables or cotton, and blossom thinning in tree fruits) and that dietary exposure would be minimized via plant

metabolism of pelargonic acid through oxidative degradation pathways common for fatty acids.

D. Chronic Dermal Toxicity

In a chronic toxicity/carcinogenicity study in mice (MRID No. 439618-01), which evaluated the effects of pelargonic acid following repeated dermal applications of 50 mg per mouse twice a week for 80 weeks, no treatment-related clinical signs of toxicity were observed at any dose level. For example, mean body weights were similar between treated and untreated control animals. Histopathology revealed no treatment-related non-neoplastic or neoplastic lesions either of the skin or the internal organs. Although classified as supplementary, the study does provide scientifically valid information and adequately assesses the chronic toxicity and the carcinogenic potential of pelargonic acid by the dermal route.

A 90-day dermal study was not deemed necessary for dietary risk assessment because no evidence of systemic toxicity or carcinogenicity were observed in mice following repeated dermal applications as well as limited exposure via the dermal route.

E. Developmental Toxicity

In a developmental toxicity study in rats (MRID No. 438435-08), treatment had no adverse effects on clinical signs, body weights, body weight gain, or food/water consumption. No fetal toxicity was observed between the treated or the untreated controls. Moreover, the mean number of viable fetuses, early or late resorptions, implantation sites, corpora lutea, pre- and post-implantation losses, sex ratios and fetal body weights were comparable to those of the control group. The no observed effect level (NOEL) for maternal and developmental toxicity was 1,500 mg/kg/day with the lowest observed effect level (LOEL) greater than 1,500 mg/kg/day.

F. Metabolism in Plants and Animals

Pelargonic acid, commonly referred to as nonanoic acid, is a nine (9)-carbon straight-chain fatty acid found naturally in apples (224 ppb), in the skin of grapes (385 ppm), in grape pulp (143 ppm), and in other foods such as cheese and milk, rice, beans, oranges, and potatoes at levels of 10 to 100 ppm (MRID Nos. 429005-01, -02). The oxidative degradation of fatty acids, such as pelargonic acid, into two (2)-carbon fragments through enzymatically-catalyzed reactions is a well-documented central metabolic pathway in animals and plants.

Residue chemistry data were not required for a human health effects assessment of the subject active ingredient because of the lack of mammalian toxicity. Both available information concerning the dietary consumption patterns of consumers, and major identifiable subgroups of consumers including infants and children, and safety factors which, in the opinion of experts qualified by scientific training and experience to evaluate the safety of food additives, are generally recognized as appropriate for the use of animal experimentation data were not evaluated because the lack of mammalian toxicity at high levels of exposure demonstrate the safety of the product at levels above possible maximum exposure levels.

II. Cumulative Effects

The Agency has considered available information on the cumulative effects of such residues and other substances that have a common mode of toxicity. These considerations included the cumulative effects on infants and children of such residues and other substances with a common mechanism of toxicity. Because there is no indication of mammalian toxicity to pelargonic acid, there are no cumulative effects.

III. Aggregate Exposures

The Agency has considered available information on the aggregate exposure levels of consumers (and major identifiable subgroups of consumers) to the pesticide chemical residue and to other related substances. These considerations include dietary exposure under the tolerance exemption and all other tolerances or exemptions in effect for the pesticide's chemical residue, and exposure from non-occupational sources.

Pelargonic acid is cleared by the Food and Drug Administration as a synthetic food flavoring agent (21 CFR 172.515), as an adjuvant, production aid and sanitizer to be used in contact with food (21 CFR 178.1010(b)), and in washing or to assist in lye peeling of fruits and vegetables (up to 1%) (21 CFR 173.315). Application of the end-use products will not directly contact edible portions of desirable food commodities. For pelargonic acid's use to control weeds before planting and as a blossom thinner in tree fruits, dietary exposure would be minimized via plant metabolism of pelargonic acid through oxidative degradation pathways common for fatty acids. For pelargonic acid's use as a harvest aid or desiccant to root and tuber vegetables, bulb vegetables, or cotton, dietary exposure is minimized by the 24-hour pre-harvest interval, via

plant metabolism of pelargonic acid through oxidative degradation pathways common for fatty acids, and the fact that pelargonic acid is not systemic. For pelargonic acid's use in controlling weeds prior to harvesting and burndown of weeds to facilitate harvest, any residues on food commodities will occur primarily as a result of spray drift. In an effort to estimate the worst case dietary exposure due to spray drift, Mycogen used the application of pelargonic acid between grape vine rows as a model (MRID No. 438435-09). They estimated a worst case deposition of 10% of the pelargonic acid (not the diluted end-product) applied per acre with 2 applications at a maximum application rate of 42 lbs pelargonic acid per acre. Thus, they estimated a maximum application rate to grapes via spray drift of 8.4 lbs pelargonic acid/acre. Mycogen then went on to estimate the daily consumption level of pelargonic acid from treated grapes using the worst case scenario to be 0.397 mg/kg/day. The Agency agrees that this is a representative worst case and notes that this exposure dose is well below the highest daily feeding dose of 1,834 mg/kg/day (20,000 ppm) used in the 14-day oral range-finding study which showed no signs of toxicity or abnormalities. Exposure via the skin or inhalation route is possible through residential use of the herbicide product. Oral exposure may occur from ingestion of produce and drinking water.

IV. Safety Determination for U.S. Population, Infants and Children

A. Population in General

A determination of safety for the population in general has been made by the Agency due to the insignificant exposure expected beyond the naturally occurring background levels, the metabolism of fatty acids in mammalian systems, and the toxicology profile.

B. Infants and Children

A determination of safety for infants and children has been made by the Agency due to the insignificant exposure expected beyond the naturally occurring background levels, the metabolism of fatty acids in mammalian systems, and the toxicology profile. FFDCA section 408 provides that EPA shall apply an additional tenfold margin of exposure (safety) for infants and children in the case of threshold effects to account for pre- and post-natal toxicity and the completeness of the database unless EPA determines that a different margin of exposure (safety) will be safe for infants and children. In this instance, EPA believes there is

reliable data to support the conclusion that pelargonic acid is not toxic to mammals, including infants and children, and thus there are no threshold effects of concern. As a result, the provision requiring an additional margin of exposure does not apply.

V. Endocrine Effects

EPA does not have any information on pelargonic acid regarding endocrine effects. The Agency is not requiring information on the endocrine effects of pelargonic acid or any other fatty acids at this time; Congress allowed 3 years after August 3, 1996, for the Agency to implement a screening and testing program with respect to endocrine effects.

VI. Conclusion

There is a reasonable certainty that no harm will result from aggregate exposure to the United States population, including infants and children, to pelargonic acid. As a result, EPA modifies the exemption from tolerance requirements for pelargonic acid as provided herein.

VII. Objections and Hearing Requests

The new FFDCA section 408(g) provides essentially the same process for persons to "object" to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d) as was provided in the old section 408 and in section 409. However, the period for filing objections is 60 days, rather than 30 days. EPA currently has procedural regulations which governs the submission of objections and hearing requests. These regulations will require some modification to reflect the new law. However, until those modifications can be made, EPA will continue to use those procedural regulations with appropriate adjustments to reflect the new law.

Any person may, by July 22, 1997, file written objections to any aspect of this regulation (including the automatic revocation provision) and may also request a hearing on those objections. Objections and hearing requests must be filed with the Hearing Clerk, at the address given under the ADDRESSES section (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). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information 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.

VIII. Public Docket

EPA has established a record for this rulemaking under docket control number [OPP-300488] (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 8:30 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.

Electronic comments may be sent directly to EPA at:
opp-docket@epamail.epa.gov.

Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption.

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 Virginia address in "ADDRESSES" at the beginning of this document.

IX. Regulatory Assessment Requirements

This document finalizes an exemption from the tolerance requirement under section 408 of the FFDCA and therefore does not impose any other regulatory requirements. As such, the Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled Regulatory Planning and Review (58 FR 51735, October 4, 1993). Since this final rule does not impose any requirements, it does not contain any information collections subject to approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 et seq., or require any other action under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104-4). Nor does it require any prior consultation as specified by Executive Order 12875, entitled Enhancing the Intergovernmental Partnership (58 FR 58093, October 28, 1993), or special considerations as required by Executive Order 12898, entitled Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations (59 FR 7629, February 16, 1994), or require OMB review in accordance with Executive Order 13045, entitled Protection of Children from Environmental Health Risks and Safety Risks (62 FR 19885, April 23, 1997).

In addition, pursuant to section 605(b) of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 et seq.), the Agency hereby certifies that this rule will not have a significant adverse economic impact on a substantial number of small entities. This determination is based on the fact that this action does not impose any requirements and therefore does not have any adverse economic impacts. In accordance with Small Business Administration (SBA) policy, this determination will be provided to the Chief Counsel for Advocacy of the SBA upon request.

X. Submission to Congress and the General Accounting Office

Under 5 U.S.C. 801(a)(1)(A), as added by the Small Business Regulatory Enforcement Fairness Act of 1996, the Agency has submitted a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the General Accounting Office prior to publication

of this rule in today's **Federal Register**. This is not a major rule as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

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

Dated: May 6, 1997.

Daniel M. Barolo,

Director, Office of Pesticide Programs.

Therefore, 40 CFR Chapter I 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 180.1159 is revised to read as follows:

§ 180.1159 Pelargonic acid; exemption from the requirement of tolerances.

(a) Pelargonic acid is exempt from the requirement of a tolerance on tree fruits 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.

(b) Pelargonic acid when used as an herbicide is exempt from the requirement of a tolerance on all plant food commodities provided that:

(1) Applications are not made directly to the food commodity except when used as a harvest aid or desiccant to: any root and tuber vegetable, bulb vegetable or cotton.

(2) When pelargonic acid is used as a harvest aid or desiccant, applications must be made no later than 24 hours prior to harvest.

[FR Doc. 97-13644 Filed 5-22-97; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 282

[FRL-5827-1]

Underground Storage Tank Program: Approved State Program for Mississippi

AGENCY: Environmental Protection Agency (EPA).

ACTION: Immediate final rule.

SUMMARY: The Resource Conservation and Recovery Act of 1976, as amended (RCRA), authorizes the Environmental

Protection Agency (EPA) to grant approval to states to operate their underground storage tank programs in lieu of the federal program. 40 CFR part 282 codifies EPA's decision to approve state programs and incorporates by reference those provisions of the state statutes and regulations that will be subject to EPA's inspection and enforcement authorities under sections 9005 and 9006 of RCRA subtitle I and other applicable statutory and regulatory provisions. This rule codifies in part 282 the prior approval of Mississippi's underground storage tank program and incorporates by reference appropriate provisions of state statutes and regulations.

DATES: This regulation is effective July 22, 1997, unless EPA publishes a prior Federal Register document withdrawing this immediate final rule. All comments on the codification of Mississippi's underground storage tank program must be received by the close of business June 23, 1997. The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register, as of July 22, 1997, in accordance with 5 U.S.C. 552(a).

ADDRESSES: Comments may be mailed to the Docket Clerk, U.S. EPA Region 4, Atlanta Federal Center, UST Section, 61 Forsyth Street, SW., Atlanta, GA 30303-3104. Comments received by EPA may be inspected in the public docket, located in the EPA Region 4 Library from 8 a.m. to 4:30 p.m., Monday through Friday, excluding federal holidays.

FOR FURTHER INFORMATION CONTACT: John Mason, U.S. EPA Region 4, Atlanta Federal Center, UST Section, 61 Forsyth Street, SW., Atlanta, GA 30303-3104. Phone: John Mason (404) 562-9441.

SUPPLEMENTARY INFORMATION:

Background

Section 9004 of the Resource Conservation and Recovery Act of 1976, as amended, (RCRA), 42 U.S.C. 6991c, allows the U.S. Environmental Protection Agency to approve state underground storage tank programs to operate in the state in lieu of the federal underground storage tank program. EPA published a **Federal Register** document announcing its decision to grant approval to Mississippi on June 11, 1990 (55 FR 23549). Approval was effective on July 11, 1990.

EPA codifies its approval of State programs in 40 CFR part 282 and incorporates by reference therein the state statutes and regulations that will be subject to EPA's inspection and enforcement authorities under sections