

Pesticide Chemical	CAS Reg. No.	Limits
Sulfuric acid monododecyl ester, sodium salt (sodium lauryl sulfate)	151-21-3	None
1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3-dichloro-	2782-57-2	When ready for use, the end-use concentration of all di- or trichloroisocyanuric acid chemicals in the solution is not to exceed 100 ppm determined as total available chlorine
1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3-dichloro-, potassium salt	2244-21-5	When ready for use, the end-use concentration of all di- or trichloroisocyanuric acid chemicals in the solution is not to exceed 100 ppm determined as total available chlorine
1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3-dichloro-, sodium salt	2893-78-9	When ready for use, the end-use concentration of all di- or trichloroisocyanuric acid chemicals in the solution is not to exceed 100 ppm determined as total available chlorine
1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-trichloro-	87-90-1	When ready for use, the end-use concentration of all di- or trichloroisocyanuric acid chemicals in the solution is not to exceed 100 ppm determined as total available chlorine
1,3,5-Triazine, N,N',N''-trichloro-2,4,6-triamino-	7673-09-8	When ready for use, the end-use concentration of all di- or trichloroisocyanuric acid chemicals in the solution is not to exceed 200 ppm determined as total available chlorine
Xylenesulfonic acid, sodium salt	1300-72-7	When ready for use, the end-use concentration is not to exceed 62 ppm

§ 180.1001 [Removed]

- 13. Section 180.1001 is removed.
- 14. In § 180.1067, paragraph (b) is revised to read as follows:

§ 180.1067 Methyl eugenol and malathion combination; exemption from the requirement of a tolerance.

* * * * *

(b) This combination is to be impregnated on a carrier (cigarette filter tips (cellulose acetate); cotton strings; fiberboard squares) or mixed with a gel cleared under 40 CFR 180.920 or 180.950.

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[FR Doc. 04-9578 Filed 4-27-04; 8:45 am]
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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP-2004-0067; FRL-7351-6]

Citronellol; Exemption from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of the citronellol on all food commodity when applied/ used to control Tetranychid mites. Natural Plant Protection S.A. 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 an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of citronellol.

DATES: This regulation is effective April 28, 2004. Objections and requests for hearings, identified by docket ID number OPP-2004-0067, must be received on or before June 28, 2004.

ADDRESSES: To submit a written objection or hearing request follow the detailed instructions as provided in Unit VIII. of the **SUPPLEMENTARY INFORMATION**. EPA has established a docket for this action under docket ID number OPP-2004-0067. All documents in the docket are listed in the EDOCKET index at <http://www.epa.gov/edocket/>. Although listed in the index, some information is not publicly available, i.e., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in EDOCKET or in hard copy at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal

holidays. The docket telephone number is (703) 305-5805.

FOR FURTHER INFORMATION CONTACT: Raderrio Wilkins, Biopesticides and Pollution Prevention Division (7511C), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 308-1259; e-mail address: Wilkins.Raderrio@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to:

- Crop production (NAICS 111)
- Animal production (NAICS 112)
- Pesticide manufacturing (NAICS 32532)

• Food manufacturing (NAICS 311)
This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Access Electronic Copies of this Document and Other Related Information?

In addition to using EDOCKET (<http://www.epa.gov/edocket/>), you may access this **Federal Register** document electronically through the EPA Internet under the "**Federal Register**" listings at <http://www.epa.gov/fedrgstr/>. A frequently updated electronic version of 40 CFR part 180 is available at E-CFR Beta Site Two at <http://www.gpoaccess.gov/ecfr/>.

II. Background and Statutory Findings

In the **Federal Register** of May 23, 2000 (65 FR 33318) (FRL-6557-1), EPA issued a notice pursuant to section 408(d)(3) of the FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide tolerance petition (OF6145) by Natural Plant Protection S.A., 4061 North 156th Drive, Goodyear, AZ 85338. This notice included a summary of the petition prepared by the petitioner Natural Plant Protection S.A. There were no comments received in response to the notice of filing.

The petition requested that 40 CFR part 180 be amended by establishing a temporary exemption from the requirement of a tolerance for residues of citronellol.

Section 408(c)(2)(A)(i) of the FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the exemption is "safe." Section 408(c)(2)(A)(ii) of the FFDCA defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Pursuant to section 408(c)(2)(B), in establishing or maintaining in effect an exemption from the requirement of a tolerance, EPA must take into account the factors set forth in section 408(b)(2)(C), which require EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . ." Additionally, section 408(b)(2)(D) of the FFDCA requires that the Agency consider "available information concerning the cumulative effects of a particular pesticide's

residues" and "other substances that have a common mechanism of toxicity."

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of pesticides. Second, EPA examines exposure to the pesticide through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings.

III. Toxicological Profile

Consistent with section 408(b)(2)(D) of the FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action and considered its validity, completeness, and reliability and the relationship of this information to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

Citronellol is a monoterpene alcohol found in over 30 essential oils, and is widely used as a fragrance component in the manufacture of perfumes, cosmetics, detergents and household cleaners. It is a naturally occurring substance in black currants, certain other fruits, wines, beer, and black tea. This chemical is also used as a synthetic flavoring agent in alcoholic and non-alcoholic beverages, and as a spice. Citronellol is generally regarded as safe (GRAS) under section 409 of FFDCA (21 CFR 172.515) as a synthetic flavoring agent and adjuvant which is permitted to be added directly to food for human consumption. It is also contained in approximately 25 essential oils, oleoresins and plant extracts that are GRAS under section 409 of FFDCA (21 CFR 182.20). The toxicity studies submitted in support of this tolerance exemption are referenced below.

1. *Acute oral toxicity (OPPTS Harmonized Guideline 870.1100; 152-10; MRID 45262003)*. Male and female Sprague-Dawley rats were tested with a single exposure to a pesticide product containing an active ingredient, citronellol, at 0.42% of the product. The pesticide was tested at doses ranging from 2,500 to 5,500 milligrams/kilogram/body weight (mg/kg/bwt) and observed for 14 days. The oral lethal dose (LD)₅₀ for males and females were 5,242 mg/kg and 3,573 mg/kg, respectively. Classification: Acceptable. Toxicity Category III, based on the LD₅₀ of female Sprague-Dawley rats.

2. *Acute dermal toxicity (OPPTS Harmonized Guideline 870.1200; 152-11; MRID 45262004)*. Male and female New Zealand white rabbits were given 5,050 mg/kg of a pesticide product

containing an active ingredient, citronellol, at 0.42% of the product, and observed for 14 days. Classification: Acceptable. Toxicity Category: IV.

3. *Acute inhalation toxicity (OPPTS Harmonized Guideline 870.1300; 152-12; MRID 45262005)*. Male and female Sprague-Dawley rats were exposed for 4 hours to an atmospheric concentration of 2.64 mg/L of a pesticide product containing citronellol as an active ingredient and observed for 14 days. The acute inhalation LC₅₀ was > 2.64 mg/L. Classification: Acceptable. Toxicity Category: IV.

4. *Primary eye irritation (OPPTS Harmonized Guideline 870.2400; 152-13; MRID 45262006)*. An acute eye irritation study was conducted in male and female albino New Zealand white rabbits using a pesticide product containing an active ingredient, citronellol, at 0.42% of the product. The test substance was moderately irritating to the eyes of the test animals, causing corneal opacity (cloudiness) and conjunctivitis (redness) that cleared within 10 days following this exposure. Classification: Acceptable. Toxicity: Category II.

5. *Primary dermal irritation (OPPTS Harmonized Guideline 870.2500; 152-14; MRID 45262007)*. The shaved skin of male and female New Zealand White rabbits was exposed to a single 0.5 mL dose of a pesticide product containing the active ingredient, citronellol, at 0.42% of the product, for 4 hours and observed for 14 days for signs of skin irritation. The test substance was moderately irritating to the skin of the test animals, causing very slight to well-defined erythema (skin redness) that cleared within 14 days following exposure. Classification: Acceptable. Toxicity Category: III.

6. *Hypersensitivity (OPPTS Harmonized Guideline 870.2500; 152-15; MRID 45262008)*. The shaved skin of male and female Hartley guinea pigs was treated once weekly for 3 weeks with a pesticide product containing the active ingredient, citronellol, at 0.42% of the product. Skin redness (irritation) followed each treatment cleared within 48 hours. A challenge dose was given to an untreated site, and the animals observed for signs of allergic reaction (hypersensitivity) to the test material. The treated test and naive control animals showed no allergenicity (swelling, redness) at 24 and 48 hours after this challenge dose. The pesticide product was not a dermal sensitizer in Hartley guinea pigs. Classification: Acceptable.

The pesticide registrant requested waivers of required studies on the technical grade of the active ingredient

for acute toxicity, genotoxicity, reproductive toxicity, developmental toxicity, subchronic toxicity in mammalian species, and acute toxicity to non-target species. The waivers were based on the ubiquity of citronellol in nature; the long history of its use in cosmetics, fragrances, detergents, and household cleaners; the natural occurrence in fruits and beverages; the widespread use as a synthetic flavoring agent and adjuvant; and the low anticipated exposure to humans and the environment due to the very low concentration of citronellol in the pesticide product. In addition, data on the toxicity of citronellol from publicly available technical literature was presented to the Agency (MRID 452620-10) for acute oral toxicity in the rat (Toxicity Category III), acute dermal toxicity (Toxicity Category IV, no species indicated), dermal irritation (moderate in humans), and mutagenicity/genotoxicity (negative in Ames assay in three *Salmonella typhimurium* strains tested at 100 g). Toxicity data were also submitted for citronellyl acetate (and other esters of citronellol), which is widely used as a flavoring agent. According to the World Health Organization (WHO), dietary intake of citronellol is estimated, based on the quantity of citronellyl acetate consumed in the diet (Food Additives Series 40; 49th meeting of the Joint FAO/WHO Expert Committee on Food Additives (JEFCA), 1998). The rationale for the use of citronellyl acetate toxicity data to estimate the dietary toxicity of citronellol is based on data demonstrating that citronellyl acetate is readily hydrolyzed to citronellol in the intestines of mammals, and that citronellol is further metabolized to non-toxic, polar compounds that are excreted in the urine (JEFCA 1998). Data obtained from toxicity studies using citronellyl acetate as the test substance demonstrated an acute oral Toxicity Category IV in rat; no adverse effects with an oral dose of 290 mg/kg/day for 14 days and 13 weeks in mice, and no adverse effects in a chronic dietary/carcinogenicity study in rats fed 290 mg/kg/day for 103 weeks. Further, based on the data submitted by the registrant for the pesticide product, data on citronellol from the public literature, and the data on citronellyl acetate form the public literature, the no adverse effects to humans would be anticipated via acute, subchronic, or chronic dietary exposures to citronellol, particularly at the low levels of citronellol in the pesticide product under consideration for registration by the Agency.

IV. Aggregate Exposures

In examining aggregate exposure, section 408 of the FFDCFA directs EPA to consider available information concerning exposures from the pesticide residue in food and all other non-occupational exposures, including drinking water from ground water or surface water and exposure through pesticide use in gardens, lawns, or buildings (residential and other indoor uses).

A. Dietary Exposure

1. *Food.* Dietary exposure is expected to occur for most, if not all individuals to citronellol primarily from the consumption of fruits, beverages, food seasonings and use as a flavoring agent/adjuvant in a wide variety of foods. The end-use product contains a low concentration of citronellol (0.42%) which is further reduced by dilution with water (no less than approximately 1:156 v/v) prior to application. Based on the extremely low application rate required to achieve the desired pesticidal effects, the Agency concluded that dietary exposure resulting from the proposed use on agricultural and green house crops will be minimal and lower than levels of citronellol currently consumed in foods where it is naturally occurring and/or present as a food additive.

2. *Drinking water exposure.* Citronellol residues in drinking water are expected to be minimal from its use as a pesticide. The pesticide product has a low use rate and the concentration of citronellol in the pesticide product is 0.42%. The product is not intended for aquatic use. Citronellol is insoluble in water and biodegrades rapidly in the soil, precluding its entry into the ground water and/or surface water. Therefore, the Agency has concluded that it is highly unlikely that any residues resulting from the pesticidal use of citronellol would migrate into drinking water from natural sources.

B. Other Non-Occupational Exposure

1. *Dermal exposure.* Non-occupational dermal exposures to citronellol from its pesticidal use are expected to be minimal to non-existent. Human dermal exposures to citronellol occur primarily from its use as a fragrance in cosmetics, soaps, detergents, creams, lotions, and dermally applied insect repellents, not from an agricultural use as a pesticide.

2. *Inhalation exposure.* Non-occupational inhalation exposures to citronellol from its pesticidal use are expected to be minimal to non-existent. The main sources of human exposure to

citronellol by this route are from its use as a fragrance in cosmetics, soaps, detergents, creams, lotions, and dermally applied insect repellents.

V. Cumulative Effects

Section 408(b)(2)(D)(v) of the FFDCFA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider the "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity."

EPA does not have, at this time, available data to determine whether citronellol has a common mechanism of toxicity with any other substances. Its mode of action is as a repellent, which is considered by the Agency as a non-toxic mode of action on target pest species. Further, citronellol does not appear to produce a toxic metabolite produced by other substances. Therefore, for the purpose of this tolerance exemption action, EPA has not assumed that citronellol has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's website at <http://www.epa.gov/pesticides/cumulative/>.

VI. Determination of Safety for U.S. Population, Infants and Children

1. *U.S. population.* The Agency has determined that there is reasonable certainty that no harm will result from aggregate exposure to residues of citronellol to the U.S. population. This includes all anticipated dietary exposures and other exposures for which there is reliable information. The Agency arrived at this conclusion based on the anticipated low acute exposure estimates from its pesticidal use, the low mammalian toxicity of citronellol, the widespread use of citronellol in the human diet, cosmetics, and fragrances found in a variety of food products and beverages, and in insect repellents, and that citronellol is considered GRAS under 21 CFR 172.515 as a synthetic flavoring and adjuvant permitted to be added directly to food for human consumption.

2. *Infants and children.* FFDCFA section 408 provides that EPA shall apply an additional tenfold margin of

exposure for infants and children in the case of threshold effects. In this instance, based on all the available information, including a lack of threshold effects, the Agency concluded that citronellol is practically non-toxic to mammals, including infants and children. Since there are no effects of concern, the application of an additional margin of safety does not apply.

VII. Other Considerations

A. Endocrine Disruptors

Based on available data, no endocrine system-related effects have been identified with consumption of citronellol. It is a naturally occurring substance and a food additive in a variety of food products, is widely used as a fragrance in the cosmetic industry, and is a component of several dermally applied insect repellents. In addition, there is no evidence to suggest that citronellol affects the immune system's function in any manner.

B. Analytical Method(s)

The Agency proposed to establish an exemption from the requirement of a tolerance without any numerical limitation for the reasons stated above, including citronellol's low toxicity. For the same reasons, the Agency concludes that an analytical method is not required for enforcement purposes for citronellol.

C. Codex Maximum Residue Level

There are no codex maximum residue levels established for residues of citronellol.

VIII. Objections and Hearing Requests

Under section 408(g) of the FFDCFA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to reflect the amendments made to the FFDCFA by the FQPA, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) of the FFDCFA 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) of the FFDCFA, as was provided in the old sections 408 and 409 of the FFDCFA. However, the period for filing objections is now 60 days, rather than 30 days.

A. What Do I Need to Do to File an Objection or Request a Hearing?

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number OPP-2004-0067 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before June 28, 2004.

1. *Filing the request.* Your objection must specify the specific provisions in the regulation that you object to, and the grounds for the objections (40 CFR 178.25). If a hearing is requested, the objections must include a statement of the factual issues(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). 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.

Mail your written request to: Office of the Hearing Clerk (1900C), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001. You may also deliver your request to the Office of the Hearing Clerk in Rm. 104, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (703) 603-0061.

2. *Tolerance fee payment.* If you file an objection or request a hearing, you must also pay the fee prescribed by 40 CFR 180.33(i) or request a waiver of that fee pursuant to 40 CFR 180.33(m). You must mail the fee to: EPA Headquarters Accounting Operations Branch, Office of Pesticide Programs, P.O. Box 360277M, Pittsburgh, PA 15251. Please identify the fee submission by labeling it "Tolerance Petition Fees."

EPA is authorized to waive any fee requirement "when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection." For additional information regarding the waiver of these fees, you may contact James Tompkins by phone at (703) 305-

5697, by e-mail at tompkins.jim@epa.gov, or by mailing a request for information to Mr. Tompkins at Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

If you would like to request a waiver of the tolerance objection fees, you must mail your request for such a waiver to: James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

3. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VIII.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in ADDRESSES. Mail your copies, identified by docket ID number OPP-2004-0067, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001. In person or by courier, bring a copy to the location of the PIRIB described in ADDRESSES. You may also send an electronic copy of your request via e-mail to: opp-docket@epa.gov. Please use an ASCII file format and avoid 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 6.1/8.0 or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

B. When Will the Agency Grant a Request for a Hearing?

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

IX. Statutory and Executive Order Reviews

This final rule establishes an exemption from the tolerance

requirement on all food commodities under section 408(d) of the FFDCa in response to a petition submitted to the Agency. 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). Because this rule has been exempted from review under Executive Order 12866 due to its lack of significance, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104-4). Nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104-113, section 12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of the FFDCa, such as the exemption in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure "meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications." "Policies

that have federalism implications" is defined in the Executive Order to include regulations that have "substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government." This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of the FFDCa. For these same reasons, the Agency has determined that this rule does not have any "tribal implications" as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure "meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications." "Policies that have tribal implications" is defined in the Executive Order to include regulations that have "substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes." This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

X. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit 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 United States prior to publication of this final rule in the **Federal Register**. This final rule 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: April 19, 2004.

James Jones,

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. 321(q), 346a and 371.

■ 2. Section 180.1248 is added to subpart D to read as follows:

§ 180.1248 Exemption of citronellol from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of the biochemical pesticide citronellol in or on all food commodities.

[FR Doc. 04-9618 Filed 4-27-04; 8:45 am]

BILLING CODE 6560-50-S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP-2004-0068; FRL-7351-1]

Geraniol; Exemption from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of the geraniol on all food commodity when applied/used to control Tetranychid mites. Natural Plant Protection S.A. 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 an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of geraniol.

DATES: This regulation is effective April 28, 2004. Objections and requests for hearings, identified by docket ID number OPP-2004-0068, must be received on or before June 28, 2004.

ADDRESSES: To submit a written objection or hearing request follow the detailed instructions as provided in Unit VIII. of the **SUPPLEMENTARY INFORMATION**. EPA has established a