

Commodity	Parts per million
Sheep, meat byproducts .....	0.05

(b) *Section 18 emergency exemptions.*  
[Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.*  
[Reserved]

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## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 180

[OPP-2004-0142; FRL-7710-9]

#### Trifluralin; Pesticide Tolerance

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes a tolerance for residues of trifluralin in spearmint and peppermint oil under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA). The FQPA substantially rewrote section 408 of FFDCA. As a result, the revisions made it necessary, once again, to establish tolerances for mint oils that had previously been deemed unnecessary.

**DATES:** This regulation is effective April 27, 2005. Objections and requests for hearings must be received on or before June 27, 2005.

**ADDRESSES:** To submit a written objection or hearing request follow the detailed instructions as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION.** EPA has established a docket for this action under Docket identification (ID) number OPP-2004-0142. 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., 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, 1801 S. Bell St., 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:** John W. Pates, Jr., Special Review and Reregistration Division (7508C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: 703-308-8195; e-mail address: [pates.john@epa.gov](mailto:pates.john@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), e.g., agricultural workers; greenhouse, nursery, and floriculture workers; farmers.
- Animal production (NAICS 112), e.g., cattle ranchers and farmers, dairy cattle farmers, livestock farmers.
- Food manufacturing (NAICS 311), e.g., agricultural workers; farmers; greenhouse, nursery, and floriculture workers; ranchers; pesticide applicators.
- Pesticide manufacturing (NAICS 32532), e.g., agricultural workers; commercial applicators; farmers; greenhouse, nursery, and floriculture workers; residential users.

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

In the **Federal Register** of November 24, 2004 (69 FR 68287) (FRL-7686-4), EPA on its own initiative, under section 408(e) of FFDCA, 21 U.S.C. 346a(e), announced a proposal to establish a permanent tolerance for residues of the herbicide trifluralin in spearmint and peppermint oil at 2.0 parts per million (ppm). The proposal included a summary of the exposure assessment prepared by the Agency. The Agency received three submissions for comment; two from private citizens and one from Dow AgroSciences, the registrant.

## III. Response to Comments

Comments received from the registrant address the following areas: evidence of errors and inconsistencies/miscalculations, belief that potential risks are significantly overstated, belief that unrealistic assumptions have been made, and the position that relevant information has been omitted and not incorporated into the Agency's decision(s). Additionally, the registrant has asked for clarification on labeling requirements. However, in general, the registrant does agree with the assessments that have been conducted for the human health and residue chemistry risk studies available for trifluralin. Furthermore, the registrant does not state any objections to the establishment of a permanent tolerance for residues of the herbicide trifluralin in peppermint and spearmint oil at 2.0 ppm.

One of the private citizen's comments raised objections to any establishment of a tolerance for trifluralin. The citizen's comments and EPA's response to those comments follow:

1. *Comment.* Both 28-day dermal and developmental toxicity tests on rabbits as well as a 1-year oral capsule study on dogs have no validity and are abusive to the test animals.

*EPA response.* This commenter's objections to animal testing have been addressed in prior rulemaking documents. See 69 FR 63083, 63096 (October 29, 2004).

2. *Comment.* 1994 surveys of food intake are out of date.

*EPA response.* Consumption survey data is used in part to determine acute and chronic exposure. In assessing exposure to trifluralin, EPA relied on food consumption data as reported by respondents in the United States Department of Agriculture (USDA) 1994-1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII). These surveys are generally updated every 10 years or so.

The commenter claims the USDA surveys are out of date. The basis for this assertion is the commenter's observation that Americans are obese. This type of unsupported allegation is insufficient to call into question EPA's reliance on scientifically-designed studies. In any event, EPA's experience has been that while eating patterns change over time, these changes are generally marginal between surveys.

3. *Comment.* The DEEM software is not suitable for evaluating exposure/risk *EPA response.* The commenter provides no basis for claiming that the DEEM is unsuitable for risk assessment. For this reason alone, the comment is insignificant. EPA would note, however, that the DEEM software has been thoroughly tested by the Agency and has been reviewed by an independent body of technical experts, the FIFRA Scientific Advisory Panel, and found to be suitable for evaluating risks of pesticide residues on food. The results of that review may be found at <http://www.epa.gov/scipoly/sap/2000/february/partialfinalreport06292000.pdf>.

4. *Comment.* Exposure to residential handlers makes the product too dangerous to be sold.

*EPA response.* The commenter states that if there are any exposures to residential handlers, then the product is far too dangerous to use or be sold. In response, EPA would first note that this tolerance rulemaking is being conducted under the FFDCA, and EPA does not regulate the sale or use of pesticides in residential settings under the FFDCA, although EPA does consider exposure from residential uses of pesticides in determining whether pesticide tolerances are safe. Decisions on whether a pesticide may be sold and distributed for residential uses is made pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136 et seq. Based on its uses, trifluralin has been assessed under the FFDCA for the residential applicator as well as other potential contact sources. Residential exposure scenarios were developed based on the use sites, formulations, application rates, and the various other equipment that could be used during applications. Residential risk estimates are also based on estimates (and assumptions) regarding the body weight of a typical homeowner/applicator, the area treated per application, and the seasonal duration (in days) of exposure. It is also assumed that residential applicators complete all elements of an application (mix/load/apply) without use of protective equipment (assessments are based on an assumption that individuals

will be wearing short-sleeved shirts and short pants). For short-term non-cancer risks to residential handlers, a margin of exposure (MOE) of less than 100 exceeds the Agency's level of concern. For residential handlers, calculations of short-term inhalation non-cancer risk indicate that the MOEs are greater than 100 for all residential handler scenarios. Likewise, residential handler cancer risk indicates that all scenarios are below the Agency's level of concern. Therefore, the Agency is confident that no unreasonable risk exists (excluding any misuse) based on the assumptions made, likely scenarios, and the conservative approach used in determining any potential risk problem for residential handlers.

Another private citizen objected to allowing this genetically-modified crop to become a legal use in the United States or anywhere else. The commenter argued that genetic modification of plants is an unknown danger to humans as well as a wide variety of other species. In response, EPA would note that the commenter is mistaken in concluding that the production of trifluralin involves genetic modification of plants.

#### IV. Conclusion

Based on the information, analysis, and conclusions in the November 24, 2004 (69 FR 68287) proposal, a tolerance is established for residues of trifluralin, alpha, alpha, alpha-trifluoro-2,6-dinitro-*N,N*-dipropyl-*p*-toluidine, in or on spearmint and peppermint oil at 2.0 ppm.

#### V. Objections and Hearing Requests

Under section 408(g) of FFDCA, as amended by FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The 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 FFDCA by FQPA, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) of FFDCA 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 FFDCA, as was provided in the old sections 408 and 409 of FFDCA. 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-2004-0142 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 27, 2005.

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 (1900L), 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 Suite 350, 1099 14<sup>th</sup> St., NW., Washington, DC 20005. 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 (202) 564-6255.

2. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit V.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-2004-0142, 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).

**VI. Statutory and Executive Order Reviews**

This final rule establishes a tolerance under section 408(d) of FFDCA on EPA's own initiative. 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). Pursuant to the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 et seq.), the Agency hereby certifies that this rule will not have significant negative economic impact on a substantial number of small entities. 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 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.

**VII. 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 20, 2005.

**Debra Edwards,**  
*Director, Special Review and Reregistration Division, 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 180.207 is amended by adding alphabetically entries for "peppermint oil," and "spearmint oil" to the table in paragraph (a). For the convenience of the reader the entire table to paragraph (a) is shown below.

**§ 180.207 Trifluralin; tolerances for residues.**

(a) \* \* \*

Commodity	Parts per million
Alfalfa, hay .....	0.2
Asparagus .....	0.05
Barley, hay .....	0.05
Barley, straw .....	0.05
Bean, mung, sprouts .....	2.0
Carrot, roots .....	1.0
Corn, field, forage .....	0.05
Corn, field, grain .....	0.05
Corn, field, stover .....	0.05

Commodity	Parts per million
Cotton, unlinted seed .....	0.05
Cress, upland .....	0.05
Flax, seed .....	0.05
Fruit, citrus, group 10 .....	0.05
Fruit, stone, group 12 .....	0.05
Grain, crop, except corn, sweet and rice grain .....	0.05
Grape .....	0.05
Hop .....	0.05
Legume, forage .....	0.05
Nut, tree, group 14 .....	0.05
Peanut .....	0.05
Peppermint oil .....	2.0
Peppermint, tops .....	0.05
Rapeseed, seed .....	0.05
Safflower, seed .....	0.05
Sorghum, forage .....	0.05
Sorghum, grain, stover .....	0.05
Spearmint oil .....	2.0
Spearmint, tops .....	0.05
Sugarcane, cane .....	0.05
Sunflower, seed .....	0.05
Vegetable, cucurbit, group 9 ....	0.05
Vegetable, fruiting, group 8 .....	0.05
Vegetables, leafy .....	0.05
Vegetables, root (exc. carrots) ..	0.05
Vegetables, seed and pod .....	0.05
Wheat, grain .....	0.05
Wheat, straw .....	0.05

\* \* \* \* \*

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**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 300**

[FRL-7903-7]

**National Priorities List for Uncontrolled Hazardous Waste Sites**

**AGENCY:** Environmental Protection Agency.

**ACTION:** Final rule.

**SUMMARY:** The Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (“CERCLA” or “the Act”), as amended, requires that the National Oil and Hazardous Substances Pollution Contingency Plan (“NCP”) include a list of national priorities among the known releases or threatened releases of hazardous substances, pollutants, or contaminants throughout the United States. The National Priorities List (“NPL”) constitutes this list. The NPL is intended primarily to guide the Environmental Protection Agency (“EPA” or “the Agency”) in determining which sites warrant further investigation. These further investigations will allow EPA to assess the nature and extent of public health and environmental risks associated with

the site and to determine what CERCLA-financed remedial action(s), if any, may be appropriate. This rule adds ten new sites to the General Superfund Section of the NPL.

**DATES:** *Effective Date:* The effective date for this amendment to the NCP shall be May 27, 2005.

**ADDRESSES:** For addresses for the Headquarters and Regional dockets, as well as further details on what these dockets contain, see section II, “Availability of Information to the Public” in the **SUPPLEMENTARY INFORMATION** portion of this preamble.

**FOR FURTHER INFORMATION CONTACT:** Terry Jeng, phone (703) 603-8852, State, Tribal and Site Identification Branch; Assessment and Remediation Division; Office of Superfund Remediation and Technology Innovation (mail code 5204G); U.S. Environmental Protection Agency; 1200 Pennsylvania Avenue, NW.; Washington, DC 20460; or the Superfund Hotline, phone (800) 424-9346 or (703) 412-9810 in the Washington, DC, metropolitan area.

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**I. Background**

*A. What Are CERCLA and SARA?*

In 1980, Congress enacted the Comprehensive Environmental Response, Compensation, and Liability Act, 42 U.S.C. 9601-9675 (“CERCLA” or “the Act”), in response to the dangers of uncontrolled releases or threatened releases of hazardous substances, and releases or substantial threats of releases into the environment of any pollutant or contaminant which may present an imminent or substantial danger to the public health or welfare. CERCLA was amended on October 17, 1986, by the Superfund Amendments and Reauthorization Act (“SARA”), Public Law 99-499, 100 Stat. 1613 *et seq.*

*B. What Is the NCP?*

To implement CERCLA, EPA promulgated the revised National Oil and Hazardous Substances Pollution Contingency Plan (“NCP”), 40 CFR part 300, on July 16, 1982 (47 FR 31180), pursuant to CERCLA section 105 and Executive Order 12316 (46 FR 42237, August 20, 1981). The NCP sets guidelines and procedures for responding to releases and threatened releases of hazardous substances, or releases or substantial threats of releases