

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.

**VIII. 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: September 21, 2004.

**Lois Rossi,**

*Director, Registration 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 180.579 is amended by designating the text of paragraph (a) as paragraph (a)(1) and alphabetically adding new commodities to the table in paragraph (a)(1) and by adding new paragraph (a)(2) and text to paragraph (d) to read as follows:

**§ 180.579 Fenamidone; tolerances for residues.**

(a) \* \* \*

(1) Tolerances are established for residues of fenamidone (4H-imidazol-4-one, 3,5-dihydro-5-methyl-2-(methylthio)-5-phenyl-3-(phenylamino), (S)-) from the application of the fungicide fenamidone in or on the following raw agricultural commodities:

Commodity	Parts per million
garlic, bulb .....	0.20
garlic, great headed .....	0.20
Grape (imported) .....	1.0
Leek .....	1.5
* * *	*
Onion, dry bulb .....	0.20
Onion, green .....	1.5
Onion, welsch .....	1.5
Shallot, bulb .....	0.20
Shallot, fresh leaves .....	1.5
Tomato .....	1.0
Tomato, paste .....	2.2
Tomato, puree .....	2.0
Vegetable, cucurbit, group 09 ..	0.15
Vegetable, tuberous and corm, subgroup 01C .....	0.02

(2) Tolerances are established for the combined residues of fenamidone (4H-imidazol-4-one, 3,5-dihydro-5-methyl-2-(methylthio)-5-phenyl-3-(phenylamino), (S)-) and its metabolite RPA 717879 (2,4-imidazolidinedione, 5-methyl-5-phenyl), expressed as parent compound, in or on the following commodities:

Commodity	Parts per million
beef, fat .....	0.10
beef, meat .....	0.10
beef, meat byproducts .....	0.10
goat, fat .....	0.10
goat, meat .....	0.10
goat, meat byproducts .....	0.10
milk .....	0.02
sheep, fat .....	0.10
sheep, meat .....	0.10
sheep, meat byproduct .....	0.10

\* \* \* \* \*

(d) *Indirect or inadvertent residues.* Tolerances are established for residues of the fungicide fenamidone (4H-imidazol-4-one, 3,5-dihydro-5-methyl-2-(methylthio)-5-phenyl-3-(phenylamino), (S)-) and its metabolite RPA 717879 (2,4-imidazolidinedione, 5-methyl-5-phenyl) in or on the following agricultural commodities when present therein as a result of application of fenamidone to the crops in paragraph (a)(1).

Commodity	Parts per million
Wheat, grain .....	0.10
Wheat, hay .....	0.50

Commodity	Parts per million
Wheat, forage .....	0.15
Wheat, straw .....	0.35

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**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 180**

[OPP-2004-0300; FRL-7677-6]

**Citrate Esters; Exemption from the Requirement of a Tolerance**

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

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes exemptions from the requirement of a tolerance for residues of acetyl tributyl citrate (ATBC) also known as citric acid, 2-(acetyloxy)-, tributyl ester (CAS Reg. No. 77-90-7) and triethyl citrate (TEC) also known as citric acid, triethyl ester (CAS Reg. No. 77-93-0) when used as inert ingredients in pesticide products. Morflex 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 exemptions from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of ATBC or TEC.

**DATES:** This regulation is effective September 29, 2004. Objections and requests for hearings must be received on or before November 29, 2004.

**ADDRESSES:** To submit a written objection or hearing request follow the detailed instructions as provided in Unit XI. of the **SUPPLEMENTARY INFORMATION.** EPA has established a docket for this action under Docket identification (ID) number OPP-2004-0300. 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:** Kathryn Boyle, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-6304; e-mail address: [boyle.kathryn@epa.gov](mailto:boyle.kathryn@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 code 111)
- Animal Production (NAICS code 112)
- Food manufacturing (NAICS code 311)
- Pesticide manufacturing (NAICS code 32532)

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 Get Electronic Documents and Other Related Information?*

In addition to using EDOCKET at (<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 January 5, 2001 (66 FR 1129) (FRL-6761-4), EPA issued a notice pursuant to section 408 of the FFDCFA, 21 U.S.C. 346a, as amended by the FQPA (Public Law 104-170), announcing the filing of pesticide petitions (PP (8E4966 and 8E4967) by Morflex Inc., 2110 High Point Road, Greensboro, NC 27403. That notice

included a summary of the petition prepared by the petitioner.

The petition requested that 40 CFR 180.1001 (c), and (e) be amended by establishing an exemption from the requirement of a tolerance for residues of acetyl tributyl citrate (ATBC) also known as citric acid, 2-(acetyloxy)-, tributyl ester (CAS Reg. No. 77-90-7) and triethyl citrate (TEC) also known as citric acid, triethyl ester (CAS Reg. No. 77-93-0). There were no comments received in response to the notice of filing.

Section 408(b)(2)(A)(i) of the FFDCFA 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 tolerance is "safe." Section 408(b)(2)(A)(ii) of the FFDCFA 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. Section 408(b)(2)(C) of the FFDCFA requires 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. . . ."

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. Inert Ingredient Definition**

Inert ingredients are all ingredients that are not active ingredients as defined in 40 CFR 153.125 and include, but are not limited to, the following types of ingredients (except when they have a pesticidal efficacy of their own): Solvents such as alcohols and hydrocarbons; surfactants such as polyoxyethylene polymers and fatty acids; carriers such as clay and diatomaceous earth; thickeners such as carrageenan and modified cellulose; wetting, spreading, and dispersing agents; propellants in aerosol dispensers; microencapsulating agents; and emulsifiers. The term "inert" is not intended to imply nontoxicity; the ingredient may or may not be

chemically active. Generally, EPA has exempted inert ingredients from the requirement of a tolerance based on the low toxicity of the individual inert ingredients.

**IV. Toxicological Profile**

Consistent with section 408(b)(2)(D) of the FFDCFA, 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. The nature of the toxic effects caused by ATBC also known as citric acid, 2-(acetyloxy)-, tributyl ester (CAS Reg. No. 77-90-7) and TEC also known as citric acid, triethyl ester (CAS Reg. No. 77-93-0) are discussed in this unit. Both chemicals are derivatives of citric acid. ATBC is prepared by esterification of butyl alcohol with citric acid, followed by acetylation. TEC is prepared by esterification of ethyl alcohol with citric acid.

The Agency evaluated the toxicity data base submitted by the petitioner, Morflex which included a 2-generation reproductive study, and several articles from open literature. Other reliable sources of information used by the Agency in performing this assessment are information from the internet on (1) World Health Organization (WHO) evaluations, (2) British Industrial Biological Research Association (BIBRA) abstracts, and (3) the Opinion of the European Commission, Health and Consumer Protection Directorate-General (CSTEE), and (4) structure-activity-relationship (SAR) assessments performed on surrogate chemicals as prepared by the Agency's Office of Pollution Prevention and Toxics. The toxicological databases for these chemicals are a mixture of guideline studies performed in the last 15 years and older studies from the 1970s and 1950s. These older studies are more difficult to evaluate given the different standards of reporting that existed some years ago.

Both ATBC and TEC have low acute oral toxicity (Toxicity Category IV). Ocular irritation is moderate. Both are Toxicity Category IV for dermal irritation. Neither are human sensitizers. Both chemicals have been reviewed by other entities. None of these organizations indicated any specific concerns for ATBC or TEC. Based on the submitted studies, neither ATBC or TEC is mutagenic.

In a rat metabolism study, ATBC was readily absorbed and rapidly excreted in urine and feces within 48 hours. The following metabolites were detected in the urine: Acetyl citrate, monobutyl citrate, acetyl monobutyl citrate, dibutyl citrate, and acetyl dibutyl citrate. ATBC was hydrolyzed in both human and rat liver homogenates resulting in n-butanol and tributyl citrate (TBC). However, in human serum the half-life was 7 hours versus 30 minutes in the rat. These *in vivo* and *in vitro* studies indicate that ATBC is hydrolysed.

No metabolism studies were reviewed for TEC. However, it is expected that all citrate esters would undergo hydrolysis to citric acid and the corresponding alcohol. For TEC, this would be ethanol. The human body is able to effectively metabolize both ethanol and citric acid. Thus, the human body has known pathways to metabolize TEC hydrolysis metabolites.

The ATBC 2-generation reproductive toxicity study was recently re-evaluated by the Agency. No adverse reproductive performance was observed at any dose. The reproductive toxicity no observed adverse level (NOAEL) was 1,000 milligrams/kilograms/day (mg/kg/day), the highest dose tested. A lowest observed adverse level (LOAEL) was not observed. The parental no observed level (NOEL) and the offspring NOEL is 1,000 mg/kg/day. The parental lowest observed level (LOEL) and the offspring LOEL was not observed.

The available information consists of the FDA-affirmed GRAS status of TEC (21 CFR 184.1911), ATBC's approval as a synthetic flavoring substance under 21 CFR 172.515, the approval of both ATBC and TEC under 21 CFR 181.27 as prior sanctioned plasticizers, the abstracts of the BIBRA toxicity profiles, several evaluations by the World Health Organization, the SAR assessments of the structurally-related chemicals, the CSTE Opinion, and the toxicity studies submitted by the petitioner. Taken together the weight of evidence of the available information indicate chemicals of lower toxicity.

Greater detail on the Agency's review and evaluation of the submitted studies and articles from open literature are in the ATBC and TEC Science Assessment in EDOCKET at (<http://www.epa.gov/edocket/>) (See OPP-2004-0300).

#### V. Aggregate Exposures

In examining aggregate exposure, section 408 of the FFDCA 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).

EPA establishes exemptions from the requirement of a tolerance only in those cases where it can be clearly demonstrated that the risks from aggregate exposure to pesticide chemical residues under reasonably foreseeable circumstances will pose no appreciable risks to human health. In order to determine the risks from aggregate exposure to pesticide inert ingredients, the Agency considers the toxicity of the inert in conjunction with possible exposure to residues of the inert ingredient through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings. If EPA is able to determine that a finite tolerance is not necessary to ensure that there is a reasonable certainty that no harm will result from aggregate exposure to the inert ingredient, an exemption from the requirement of a tolerance may be established.

Various publicly-available screening-level models were used to estimate some of the existing levels of exposure that could occur in and around the home. To assure protectiveness, these models create estimates that are deliberately intended to over-estimate exposure. All modeling (with the exception of the CSTE plastic toy scenario) was performed by EPA. The highest potential exposure level was 0.422 mg/kg/day for children (1-2 years old) for dietary exposure through consumption of food (as a result of application of a pesticide product containing either ATBC or TEC to crops). All of the screening-level exposures are much less than any of the NOAELs/NOELs from the repeated dose oral toxicity studies. Greater detail on the Agency's exposure assessment are in the ATBC and TEC Science Assessment in EDOCKET at (<http://www.epa.gov/edocket/>) (See OPP-2004-0300).

#### VI. Cumulative Effects

Section 408(b)(2)(D)(v) of the FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, 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."

Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to acetyl tributyl citrate, triethyl citrate or

any citrate esters. These esters do not appear to produce a toxic metabolite produced by other substances. These are lower toxicity chemicals; therefore, the resultant risks separately and/or combined should also be low. For the purposes of this action, therefore, EPA has not assumed that acetyl tributyl citrate or triethyl citrate have 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/>.

#### VII. Children's Safety Factor

The toxicity database for ATBC includes a rat oral reproductive toxicity study in which NOELs of 1,000 mg/kg/day were identified. There are also the SARs on structurally-related citrate esters which did not indicate any concerns for developmental or reproductive toxicity.

ATBC, given the additional acetylation step, is the more complex, larger molecule. The acetylation step also increases the number of possible metabolites as evidenced by the results of the ATBC rat metabolism study. ATBC data can be used as surrogate data for TEC. TEC cannot be used as surrogate data for ATBC. ATBC is the more toxic of the two chemicals and has the larger available data base.

There is sufficient information for the Agency to judge the potential for developmental and reproductive effects of ATBC and TEC. No additional data are needed to assess the toxicity of ATBC and TEC. There is no reason to expect that the reasonably, foreseeable uses of ATBC and TEC will constitute any significant hazard. EPA has not used a safety factor analysis to assess the risk. For the same reasons the additional tenfold safety factor is unnecessary.

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

The Agency believes that ATBC and TEC are of low toxicity. Of highest consideration in this judgement is the body's ability to effectively metabolize both ATBC and TEC to citric acid and the corresponding alcohols. The metabolism studies provided by the petitioner were helpful in reaching this determination. Both of these chemicals

are well-studied. FDA, WHO, and CSTE have all conducted assessments on the uses of these chemicals. No toxicological concerns were specified in any of the reviews and evaluations.

The Agency has used various screening-level models to estimate some of the existing levels of exposure to ATBC and TEC. To assure protectiveness, these estimates are deliberately intended to over-estimate exposure. Given the consistent pattern of NOAELs/NOELs of 1,000 mg/kg/day, an understanding of the metabolism of ATBC and TEC, and a significant gap between very over-estimated exposure numbers and the NOAELs/NOELs, there is no need to pursue further numerical refinements to the estimated exposures.

EPA concludes that there is a reasonable certainty of no harm from aggregate exposure to residues of citric acid, 2-(acetyloxy)-, tributyl ester (CAS Reg. No. 77-90-7) and citric acid, triethyl ester (CAS Reg. No. 77-93-0). Accordingly, EPA finds that exempting citric acid, 2-(acetyloxy)-, tributyl ester (CAS Reg. No. 77-90-7) and citric acid, triethyl ester (CAS Reg. No. 77-93-0) will be safe.

## IX. Other Considerations

### A. Endocrine Disruptors

FQPA requires EPA to develop a screening program to determine whether certain substances, including all pesticide chemicals (both inert and active ingredients), "may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or such other endocrine effect." EPA has been working with interested stakeholders to develop a screening and testing program as well as a priority setting scheme. As the Agency proceeds with implementation of this program, further testing of products containing ATBC and TEC for endocrine effects may be required.

### B. Analytical Method

An analytical method is not required for enforcement purposes since the Agency is establishing an exemption from the requirement of a tolerance without any numerical limitation.

### C. Existing Exemptions

There is an existing tolerance exemption for acetyl tributyl citrate (CAS Reg. No. 77-90-7) in 40 CFR 180.930 when used as a component of plastic animal tags.

### D. International Tolerances

The Agency is not aware of any country requiring a tolerance for ATBC or TEC nor have any CODEX maximum

residue levels been established for any food crops at this time.

### E. List 4A (Minimal Risk) Classification

The Agency established 40 CFR 180.950 (see the rationale in the proposed rule published January 15, 2002 (67 FR 1925) (FRL-6807-8)) to collect the tolerance exemptions for those substances classified as List 4A, i.e., minimal risk substances. As part of evaluating an inert ingredient and establishing the tolerance exemption, the Agency determines the chemical's list classification. Given the available information which indicates the body's ability to effectively metabolize both ATBC and TEC to citric acid and the corresponding alcohols and the consistent pattern of NOAELs/NOELs of 1,000 mg/kg/day, citric acid, 2-(acetyloxy)-, tributyl ester (CAS Reg. No. 77-90-7) and citric acid, triethyl ester (CAS Reg. No. 77-93-0) are to be classified as List 4A inert ingredients.

## X. Conclusions

Based on the information in this preamble, EPA concludes that there is a reasonable certainty of no harm from aggregate exposure to residues of acetyl tributyl citrate (ATBC) also known as citric acid, 2-(acetyloxy)-, tributyl ester (CAS Reg. No. 77-90-7) and triethyl citrate (TEC) also known as citric acid, triethyl ester (CAS Reg. No. 77-93-0). Accordingly, EPA finds that exempting citric acid, 2-(acetyloxy)-, tributyl ester (CAS Reg. No. 77-90-7) and citric acid, triethyl ester (CAS Reg. No. 77-93-0) from the requirement of a tolerance will be safe.

Therefore, the exemptions from the requirement of a tolerance for citric acid, 2-(acetyloxy)-, tributyl ester (CAS Reg. No. 77-90-7) and citric acid, triethyl ester (CAS Reg. No. 77-93-0) are established in 40 CFR 180.950. Since the tolerance exemptions are established under 40 CFR 180.950, the existing tolerance exemption for acetyl tributyl citrate (CAS Reg. No. 77-90-7) in 40 CFR 180.930 is a duplication, and will be removed.

## XI. Objections and Hearing Requests

Under section 408(g) of the FFDCA, 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. 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 the FFDCA 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 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 the FFDCA, as was provided in the old FFDCA sections 408 and 409 of the 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-2004-0300 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 November 29, 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 (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 XI.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-2004-0300, 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).

#### **XII. Statutory and Executive Order Reviews**

This final rule establishes two exemptions from the tolerance requirement 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.

#### **XIII. 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: September 14, 2004.

**Lois Rossi,**

*Director, Registration 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. In § 180.930, the table is amended by removing the entry for “acetyl tributyl citrate” (CAS Reg. No. 77-90-7).

■ 3. In § 180.950, the table in paragraph (e) is amended by adding alphabetically

the following inert ingredients to read as follows

**§ 180.950 Tolerance exemptions for minimal risk active and inert ingredients.**

\* \* \* \* \*  
(e) \* \* \*

Chemical Name	CAS No.
Citric acid, 2-(acetyloxy)-, tributyl ester .....	77-90-7
Citric acid, triethyl ester ..	77-93-0

[FR Doc. 04-21587 Filed 9-28-04; 8:45 am]

BILLING CODE 6560-50-S

**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 180**

[OPP-2004-0256; FRL-7678-9]

**Carfentrazone-ethyl; Pesticide Tolerance**

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

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes a tolerance for combined residues of carfentrazone-ethyl and its metabolite in or on certain raw agricultural commodities. FMC Corporation and Interregional Research Project Number 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA).

**DATES:** This regulation is effective September 29, 2004. Objections and requests for hearings must be received on or before November 29, 2004.

**ADDRESSES:** To submit a written objection or hearing request follow the detailed instructions as provided in Unit VII. of the **SUPPLEMENTARY INFORMATION.** EPA has established a docket for this action under Docket identification (ID) number OPP-2004-0256. 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:** Joanne I. Miller, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-6224; e-mail address: [miller.joanne@epa.gov](mailto:miller.joanne@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 and Statutory Findings**

In the **Federal Register** of March 31, 2004 (69 FR 16921) (FRL-7348-4), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petitions (PP 2F6468 and 3E6746) by FMC Corporation, 1735 Market Street, Philadelphia, PA 19103 and IR-4, Technology Center, of New Jersey, 681 U.S. Highway #1 South, North Brunswick, NJ 08902-3390. That notice included a summary of the petition prepared by FMC Corporation, the registrant. Comments on the petition were filed by B. Sachau, 15 Elm St., Florham Park, NJ 07932. A response to these comments is provided in Unit V.

In the **Federal Register** of July 28, 2004 (69 FR 45042) (FRL-7365-2), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petitions (PP 2F6468, 3E6746, 4E6814, and 3F6584) by FMC Corporation, 1735 Market Street, Philadelphia, PA 19103 and IR-4, Technology Center, of New Jersey, 681 U.S. Highway #1 South, North Brunswick, NJ 08902-3390. That notice included a summary of the petition prepared by FMC Corporation, the registrant. Comments on the petition were filed by B. Sachau, 15 Elm St., Florham Park, NJ 07932, and Bonita Poulin, R. R. #3, Brockville, Ont. A response to these comments is provided in Section V.

The petitions requested that 40 CFR 180.515(a) be amended by establishing proposed tolerances for combined residues of the herbicide carfentrazone-ethyl (ethyl-alpha,2-dichloro-5-[4-(difluoromethyl)-4,5-dihydro-3-methyl-5-oxo-1H-1,2,4-triazol-1-yl]-4-fluorobenzenepropanoate and the metabolite carfentrazone-ethyl chloropropionic acid (alpha,2-dichloro-5-[4-(difluoromethyl)-4,5-dihydro-3-methyl-5-oxo-1H-1,2,4-triazol-1-yl]-4-fluorobenzenepropanoic acid), in or on: Acerola at 0.1 parts per million (ppm); almond hulls at 0.20 ppm and grass, forage, fodder and hay, group 17 at 12 ppm; hops at 0.05 ppm; avocado at 0.1 ppm; atemoya at 0.1 ppm; banana at 0.1 ppm; berry group 13 at 0.1 ppm; birida at 0.1 ppm; borage, seed at 0.1 ppm; cacao at 0.1 ppm; cactus at 0.1 ppm; canistel at 0.1 ppm; cherimoya at 0.1 ppm; citrus, crop group 10 at 0.1 ppm; citrus cultivars and/or hybrids of grapefruit and pummelo, including uniq fruit at 0.1 ppm; coconut at 0.1 ppm; coffee at 0.1 ppm; crambe, seed at 0.1 ppm; custard apple at 0.1 ppm; date at