

the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000) do not apply to this rule. In addition, This rule does not 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).

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).

**XII. Congressional Review Act**

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report 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 rule in the **Federal Register**. This 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: February 6, 2008.

**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 §180.960, the table is amended by alphabetically adding the following polymer to read as follows:

**§ 180.960 Polymers; exemptions from the requirement of a tolerance.**

\* \* \*

Polymer	CAS Reg. No.
* * * 1-propanesulfonic acid, 2-methyl-2-[(1-oxo-2-propenyl)amino]-, monosodium salt, polymer with ethenol and ethenyl acetate, minimum number average molecular weight (in amu) 50,000. * * *	* * * 107568-12-7 * * *

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**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 180**

[EPA-HQ-OPP-2005-0306; FRL-8347-8]

**Vitamin E, d-alpha tocopherol, dl-alpha tocopherol, d-alpha tocopheryl acetate, and dl-alpha tocopheryl acetate; Inert Ingredients; 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 under 40 CFR 180.910 for residues of vitamin E (CAS Reg. No. 1406-18-4), d-alpha tocopherol (CAS Reg. No. 9-02-9), dl-alpha tocopherol (CAS Reg. No. 10191-41-0), d-alpha tocopheryl acetate (CAS Reg. No. 58-95-7), and dl-alpha tocopheryl acetate (CAS Reg. No. 7695-91-2) in or on raw agricultural commodities when applied or used as inert ingredients in pesticide formulations. Because these five substances are chemically-similar, for the sake of simplicity, discussion of vitamin E in this rule (unless otherwise noted) can be considered to be vitamin E *per se* and/or one of the two alcohols (d-alpha tocopherol, dl-alpha tocopherol) or two acetates (d-alpha tocopheryl acetate, dl-alpha tocopheryl acetate). BASF Corporation submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996, requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of vitamin E.

**DATES:** This regulation is effective February 20, 2008. Objections and requests for hearings must be received on or before April 21, 2008, and must

be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

**ADDRESSES:** EPA has established a docket for this action under docket identification (ID) number EPA-HQ-OPP-2005-0306. To access the electronic docket, go to <http://www.regulations.gov>, select “Advanced Search,” then “Docket Search.” Insert the docket ID number where indicated and select the “Submit” button. Follow the instructions on the regulations.gov website to view the docket index or access available documents. All documents in the docket are listed in the docket index available in regulations.gov. Although listed in the index, some information is not publicly available, e.g., 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 in the electronic docket at <http://www.regulations.gov>, or, if only available in hard copy, at the Office of Pesticide Programs (OPP) Regulatory Public Docket in Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The hours of operation of this Docket Facility are from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305-5805.

**FOR FURTHER INFORMATION CONTACT:** Kathleen Martin, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 308-2857; e-mail address: [martin.kathleen@epa.gov](mailto:martin.kathleen@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. To determine whether you or your business may be affected by this action, you should carefully examine the applicability provisions in 40 CFR 152. 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?*

In addition to accessing an electronic copy of this **Federal Register** document through the electronic docket at <http://www.regulations.gov>, you may access this **Federal Register** document electronically through the EPA Internet under the "**Federal Register**" listings at <http://www.epa.gov/fedrgstr>. You may also access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's pilot e-CFR site at <http://www.gpoaccess.gov/ecfr>.

#### *C. Can I File an Objection or Hearing Request?*

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. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2005-0306 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 April 21, 2008.

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket that is described in **ADDRESSES**. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit your copies, identified by docket ID number EPA-HQ-OPP-2005-0306, by one of the following methods:

- **Federal eRulemaking Portal:** <http://www.regulations.gov>. Follow the on-line instructions for submitting comments.

- **Mail:** Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- **Delivery:** OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305-5805.

## **II. Background and Statutory Findings**

In the **Federal Register** of April 4, 2007 (72 FR 16352) (FRL-8119-2), 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 tolerance petition (PP 5E6996) by BASF Corporation, PO Box 13528; Research Triangle Park, NC 27709. The petition requested that 40 CFR part 180 be amended by establishing an exemption from the requirement of a tolerance for residues of d-alpha tocopherol, d-alpha tocopheryl acetate, dl-alpha tocopherol acetate, dl-alpha tocopheryl, and/or vitamin E. That notice included a summary of the petition prepared by the petitioner BASF Corporation. Please note that the April 4, 2007 notice amended a previous Notice of Filing for that petition; it was published on January 18, 2006 (71 FR 2925) and was limited to a single substance, alpha-tocopherol (CAS Reg. No. 10191-41-0). BASF asked to amend the petition because it was too narrowly defined: "Alpha-tocopherol is known to be the most biologically active form of Vitamin E. However, the ester of alpha-tocopherol (alpha-tocopheryl acetate) is also a common source of Vitamin E. Alpha-tocopheryl acetate is converted to alpha-tocopherol in the body upon ingestion. For purposes of this rule, BASF requests that the acetate and alcohol forms of Vitamin E be viewed as equivalent substances and that the existing petition 5E6996 be amended to include the closely related Vitamin E substances." Between the two notices, one comment was received in response to the notices of filing; it was addressed.

Section 408(c)(2)(A)(i) of 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 tolerance is "safe." Section 408(c)(2)(A)(ii) of 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) of FFDCA, 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) of FFDCA, which 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. The following provides a brief summary of the risk assessment and conclusions for the Agency's review of vitamin E. The full decision document for this action is available on EPA's Electronic Docket at <http://www.regulations.gov/> under docket number EPA-HQ-OPP-2005-0306.

## **III. Toxicological Profile**

Consistent with section 408(b)(2)(D) of 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. The nature of the toxic effects caused by vitamin E is discussed in this unit.

In brief, the Agency reviewed the available information on vitamin E submitted by the petitioner as well as additional information available to EPA in two international, peer-reviewed evaluations of vitamin E. The toxicity database is sufficient. In summary, vitamin E has low acute oral toxicity. Alpha-tocopherol has an lethal dose

(LD)<sub>50</sub> greater than 2,000 milligrams/kilograms bodyweight (mg/kg bw) in mice, rats, and rabbits. In subchronic toxicity testing vitamin E appears to elicit systemic toxicity to rats only at high doses, with the target organs being the liver and blood. Vitamin E has not been shown to be neurotoxic, mutagenic, or carcinogenic. Finally, no developmental and reproductive effects have been shown.

#### IV. Aggregate Exposures

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

EPA does not have information available to assess the potential for exposure to vitamin E in consumer products. Nevertheless, given vitamin E's known role in human physiology and its presence in various foods such as nuts and vegetable oils, it is unlikely that residential exposures of concern would result from the use of vitamin E in nonpesticide products and as an ingredient in pesticide. Therefore, no further aggregate assessment is necessary.

#### Dietary Exposure

1. *Food.* EPA estimated dietary exposures for use of vitamin E as an inert ingredient using Dietary Exposure Evaluation Model (DEEM<sup>TM</sup>), a generic screening model that assumes that the inert ingredient is used on all commodities and that 100 percent of crops are treated with the inert ingredient. Generic chronic exposure for the overall U.S. population was estimated at 0.12 mg/kg/day.

2. *Drinking water exposure.* Surface water concentration of vitamin E was estimated at 0.065 parts per billion (ppb); EPA's Pesticide Root Zone Model - Exposure Analysis Modeling System (PRZM-EXAMS) model was used. Groundwater concentration was estimated at 0.0015 ppb using EPA's screening concentration in groundwater (SCI-GROW) model.

#### V. Cumulative Effects

Section 408(b)(2)(D)(v) of 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 vitamin E (CAS Reg. Nos. 1406-18-4; 59-02-9; 10191-41-0; 58-95-7; and 7695-91-2) and any other substances and, this material does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that vitamin E (CAS Reg. Nos. 1406-18-4; 59-02-9; 10191-41-0; 58-95-7; and 7695-91-2) 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 (OPP) 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

Based on the information in this preamble, EPA concludes that there is a reasonable certainty of no harm from aggregate exposure to residues. Accordingly, EPA finds that exempting from the requirement of a tolerance will be safe.

#### VII. Other Considerations

##### A. Analytical Method(s)

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.

##### B. International Tolerances

The Agency is not aware of any country requiring a tolerance for vitamin E (CAS Reg. No. 1406-18-4), d-alpha tocopherol (CAS Reg. No. 9-02-9), dl-alpha tocopherol (CAS Reg. No. 10191-41-0), d-alpha tocopheryl acetate (CAS Reg. No. 58-95-7), or dl-alpha tocopheryl acetate (CAS Reg. No. 7695-91-2), nor have any CODEX Maximum Residue Levels (MRLs) been established for any food crops at this time.

#### VIII. Statutory and Executive Order Reviews

This final rule establishes a tolerance under section 408(d) of 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 final rule has been exempted from review under Executive Order 12866, this final 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) or Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). 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.*, 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).

Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of FFDCA, such as the tolerance 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.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000) do not apply to this final rule. In addition, this final rule does not 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).

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).

**IX. Congressional Review Act**

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report 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: February 6, 2008.

**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 section 180.910 the table is amended by adding alphabetically the following inert ingredients to read as follows:

**§ 180.910 Inert ingredients used pre-harvest and post-harvest; exemptions from the requirement of a tolerance.**

\* \* \* \* \*

Inert ingredients	Limits	Uses
d-Alpha tocopherol (CAS Reg. No. 9-02-9)	None	Safener
d-Alpha tocopheryl acetate (CAS Reg. No. 58-95-7)	None	Safener
dl-Alpha tocopherol (CAS Reg. No. 10191-41-0)	None	Safener
dl-Alpha tocopheryl acetate (CAS Reg. No. 7695-91-2)	None	Safener
Vitamin E (CAS Reg. No. 1406-18-4)	None	Safener

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**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 180**

[EPA-HQ-OPP-2007-0193; FRL-8349-4]

**Carfentrazone-ethyl; Pesticide Tolerance**

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

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes a tolerance for residues of carfentrazone-ethyl, (ethyl-alpha-2-dichloro-5-[4-(difluoromethyl)-4,5-dihydro-3-methyl-5-oxo-1H-1,2,4-triazol-1-yl]-4-fluorobenzene propanoate) and the metabolite carfentrazone-chloropropionic acid (alpha, 2-dichloro-5-[4-(difluoromethyl)-4,5-dihydro-3-methyl-5-oxo-1H-1,2,4-triazol-1-yl]-4-fluorobenzene propanoic acid) in or on barley, bran at 0.80 ppm; barley, flour at 0.80 ppm; grain, aspirated grain fractions at 1.8 ppm; grain, cereal, group 15 (except rice grain and sorghum grain) at 0.10 ppm; grain, cereal, stover at 0.80 ppm; grain, cereal, straw at 3.0 ppm; hog, fat at 0.10 ppm; hog, meat at 0.10 ppm; hog, meat byproducts at 0.10 ppm; millet, flour at 0.80 ppm; oat, flour at 0.80 ppm; poultry, meat byproducts at 0.10 ppm; rice, grain at 1.3 ppm; rice,

hulls at 3.5 ppm; rye, bran at 0.80 ppm; rye, flour at 0.80 ppm; sorghum, grain at 0.25 ppm; soybean, seed at 0.10 ppm; sugarcane at 0.15 ppm; wheat, bran at 0.80 ppm; wheat, flour at 0.80 ppm; wheat, germ at 0.80 ppm; wheat, middlings at 0.80 ppm; and wheat, shorts at 0.80 ppm. FMC Corporation requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA).

**DATES:** This regulation is effective February 20, 2008. Objections and requests for hearings must be received on or before April 21, 2008, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

**ADDRESSES:** EPA has established a docket for this action under docket identification (ID) number EPA-HQ-OPP-2007-0193. To access the electronic docket, go to <http://www.regulations.gov>, select “Advanced Search,” then “Docket Search.” Insert the docket ID number where indicated and select the “Submit” button. Follow the instructions on the regulations.gov website to view the docket index or access available documents. All documents in the docket are listed in the docket index available in [www.regulations.gov](http://www.regulations.gov). Although listed in the index, some information is not publicly available, e.g., 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 in the electronic docket at <http://www.regulations.gov>, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305-5805.

**FOR FURTHER INFORMATION CONTACT:** Joanne I. Miller, Registration Division (7505P), 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 those engaged in the following activities:

- Crop production (NAICS code 111), e.g., agricultural workers; greenhouse,