

<sup>4</sup> Attainment date extended to June 15, 2011.

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[FR Doc. 2010-17969 Filed 7-22-10; 8:45 am]

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## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 180

EPA-HQ-OPP-2009-0407; FRL-8835-6

### Trichoderma Hamatum Isolate 382; Exemption from the Requirement of a Tolerance

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

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes an exemption from the requirement of a tolerance for residues of the microbial pesticide, *Trichoderma hamatum* isolate 382, in or on all food commodities when applied as a fungicide and used in accordance with good agricultural practices. Interregional Research Project Number 4 (IR-4) of Rutgers University (on behalf of Sellew and Associates, LLC) submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of *Trichoderma hamatum* isolate 382 under the FFDCA.

**DATES:** This regulation is effective July 23, 2010. Objections and requests for hearings must be received on or before September 21, 2010, 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-2009-0407. All documents in the docket are listed in the docket index available at <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 Office of Pesticide Programs (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:** Ann Sibold, Biopesticides and Pollution Prevention Division (7511P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-6502; e-mail address: [sibold.ann@epa.gov](mailto:sibold.ann@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 Access to Other Related Information?

You may access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's e-CFR site at <http://www.gpoaccess.gov/ecfr>. To access the Harmonized Test Guidelines referenced in this document electronically, please go to <http://www.epa.gov/ocsp> and select "Test Methods and Guidelines."

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

Under FFDCA section 408(g), 21 U.S.C. 346a(g), any person may file an objection to any aspect of this regulation

and may also request a hearing on those objections. 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-2009-0407 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before September 21, 2010. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

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. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit a copy of your non-CBI objection or hearing request, identified by docket ID number EPA-HQ-OPP-2009-0407 by one of the following methods:

- **Federal eRulemaking Portal:** <http://www.regulations.gov>. Follow the on-line instructions for submitting comments.
- **Mail:** 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 Facility'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 July 22, 2009 (74 FR 36200) (FRL-8425-8), 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 7E7188) by IR-4, Rutgers University, 500 College Road, East, Suite 201W, Princeton, NJ 08540 (on behalf of Sellew and Associates, LLC, 84 Shadybrook Lane, Carlisle, MA 01741). The petition requested that 40 CFR part 180 be amended by establishing an exemption from the requirement of a tolerance for residues of *Trichoderma hamatum*

isolate 382. This notice referenced a summary of the petition prepared by the petitioner, IR-4 (on behalf of Sellew and Associates, LLC), which is available in the docket, <http://www.regulations.gov>. A comment was received on the notice of filing. EPA's response to this comment is discussed in Unit VII.C.

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 exemption 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 require EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue...." Additionally, section 408(b)(2)(D) of FFDCA requires that the Agency consider "available information concerning the cumulative effects of a particular pesticide's residues and other substances that have a common mechanism of toxicity."

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

### III. Toxicological Profile

Consistent with section 408(b)(2)(D) of 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.

#### A. Overview of *Trichoderma Hamatum* Isolate 382.

*Trichoderma hamatum* isolate 382 is a naturally occurring fungus that is found widely in soils, potting media, corn grits, and flour, as well as on root surfaces of various plants, decaying bark, fruits, and vegetables. Indeed, *Trichoderma hamatum* populations have been measured at levels between  $1 \times 10^4$  and  $1 \times 10^8$  colony-forming units (cfu) per gram dry weight of container media alone. As a pesticidal active ingredient, *Trichoderma hamatum* isolate 382 will be mixed with or applied to soilless potting media or compost mainly to induce systemic resistance to diseases of roots and aboveground plant parts. It may also suppress the activity of certain soilborne plant pathogens (including *Pythium* species, *Phytophthora* species, *Fusarium* species, *Rhizoctonia solani*, *Sclerotium rolfsii*, and *Thielaviopsis basicola*) and protect the foliage of some plant species from powdery mildew, *Botrytis* blight, *Phytophthora* blights, and dieback diseases (e.g., *Botryosphaeria* dieback) through competition for nutrients and space. No relationships are known between the *Trichoderma* genus and any pathogen of humans, animals, or plants. Most notably, *Trichoderma hamatum* isolate 382 is not considered a dermatophyte fungus in that it is not classified into any of the three genera (*Microsporum*, *Epidermophyton*, and *Trichophyton*) known to cause skin disease in animals and humans.

In conjunction with Experimental Use Permit 69006-EUP-1, which was effective from January 1, 1996 until January 1, 1998, a temporary exemption from the requirement of a tolerance was established previously for *Trichoderma hamatum* isolate 382 for use on selected ornamentals and vegetable bedding plants in or on the raw agricultural commodities broccoli, cabbage, cauliflower, cucumber, eggplant, lettuce, cantaloupe, pepper, tomato, and watermelon (61 FR 28580, June 5, 1996, FRL-5371-2). This temporary exemption expired on March 1, 1998. Although there are no currently existing tolerances or tolerance exemptions for *Trichoderma hamatum* species, there are permanent tolerance exemptions established for all food commodities for two strains of a closely related *Trichoderma* species: *Trichoderma harzianum* KRL-AG2 (ATCC #20847) strain T-22 under 40 CFR 180.1102 (64 FR 16856, April 7, 1999 FRL-6070-3) and *Trichoderma harzianum* strain T-39 under 40 CFR 180.1201 (65 FR 38753, June 22, 2000, FRL-6383-7).

The petitioner submitted Tier I mammalian toxicology data for the active ingredient, *Trichoderma hamatum* isolate 382. EPA has reviewed and found these data acceptable to support the establishment of a permanent exemption from the requirement of a tolerance for residues of *Trichoderma hamatum* isolate 382. These studies indicate that the active ingredient is not toxic, infective, and/or pathogenic to rats when administered by the oral, pulmonary, or injection routes of exposure and is only slightly irritating to the skin. Furthermore, even with extensive experimental uses in the mid- to late-1990s and subsequent compilation of data to support potential pesticide products, no *Trichoderma hamatum* isolate 382-related hypersensitivity incidents have been reported to EPA. The overall conclusions from these data are described in Unit III.B., while more in-depth synopses of the study results can be found in the risk assessments and Biopesticides Registration Action Document provided as references in Unit III.C.

#### B. Microbial Pesticide Toxicology Data Requirements

1. *Acute oral toxicity and pathogenicity – rat* (Harmonized Test Guideline 885.3050; Master Record Identification Number (MRID No.) 455836-03). An acceptable acute oral and pathogenicity study demonstrated that *Trichoderma hamatum* isolate 382 was not toxic, infective, and/or pathogenic to rats when dosed at up to  $3.9 \times 10^8$  cfu/animal (U.S. EPA 2009, 2010b, 2010c).

2. *Acute pulmonary toxicity and pathogenicity – rat* (Harmonized Test Guideline 885.3150; MRID Nos. 460106-02 and 469997-01). An acceptable acute pulmonary toxicity and pathogenicity study demonstrated that *Trichoderma hamatum* isolate 382 was not toxic, infective, and/or pathogenic to rats when dosed intratracheally at  $1.3 \times 10^7$  cfu/animal (U.S. EPA 2009, 2010b, 2010c).

3. *Acute injection toxicity and pathogenicity – rat* (Harmonized Test Guideline 885.3200; MRID No. 475989-08). An acceptable acute injection toxicity and pathogenicity study demonstrated that *Trichoderma hamatum* isolate 382 was not toxic, infective, and/or pathogenic in rats when dosed intraperitoneally at  $4.0 \times 10^7$  cfu/animal (U.S. EPA 2009, 2010b, 2010c).

4. *Hypersensitivity incidents* (Harmonized Test Guideline 885.3400). No hypersensitivity incidents involving *Trichoderma hamatum* isolate 382 and

occurring during fermentation, processing, formulation, or research have been reported to the Agency. Any future hypersensitivity incidents must be reported per 40 CFR 158.2140 (U.S. EPA 2010c).

5. *Acute oral toxicity (Harmonized Test Guideline 870.1100; MRID No. 475989-04), acute dermal toxicity (Harmonized Test Guideline 870.1200; MRID No. 475989-04), and acute inhalation toxicity (Harmonized Test Guideline 870.1300; MRID No. 475989-04).* The Agency waived these acute toxicity data requirements based on *Trichoderma hamatum* isolate 382's ubiquitous presence in the environment (see Unit III.A.) and the absence of incidents of hypersensitivity, allergies, or other adverse effects, despite varying uses of *Trichoderma hamatum* isolate 382 since 1996 (e.g., research activities performed in accordance with the terms of an experimental use permit) (U.S. EPA 2009, 2010c).

6. *Primary dermal irritation – rabbit (Harmonized Test Guideline 870.2500; MRID 475989-05).* An acceptable primary dermal irritation study demonstrated that *Trichoderma hamatum* isolate 382 was slightly irritating to the skin of rabbits. The study resulted in a classification of Toxicity Category IV for this strain of *Trichoderma hamatum* (U.S. EPA 2009, 2010a, 2010c).

#### C. References

1. U.S. EPA. 2009. Review of Product Chemistry, Manufacturing Process, and Acute Toxicity Studies of the End Use Product (EP) Floraguard (EPA Reg. No. 74205-G) Containing the Active Ingredient (AI) *Trichoderma hamatum* isolate 382 (0.9%). Memorandum from I. Barsoum, Ph.D. and J. Kough, Ph.D. to A. Sibold dated December 14, 2009 (available as “Supporting & Related Materials” within Docket Number EPA-HQ-OPP-2010-0489 at <http://www.regulations.gov>).

2. U.S. EPA. 2010a. Review of the Registrant's Response to the Deficiencies Found by the Agency in Its Review of Product Chemistry, Manufacturing Process, and Acute Toxicity Studies of the Product *Trichoderma hamatum* isolate 382 (EPA Reg. No. 74205-G). Memorandum from I. Barsoum, Ph.D. and J. Kough, Ph.D. to A. Sibold dated April 27, 2010 (available as “Supporting & Related Materials” within Docket Number EPA-HQ-OPP-2010-0489 at <http://www.regulations.gov>).

3. U.S. EPA. 2010b. Review of Information to Support a Food Tolerance Determination for *Trichoderma hamatum* isolate 382

(ATCC# 20765), the Active Ingredient in Floraguard Related to Tolerance Petition (7E7188). Memorandum from J. Kough, Ph.D. to A. Sibold dated May 18, 2010 (available as “Supporting & Related Materials” within Docket Number EPA-HQ-OPP-2010-0489 at <http://www.regulations.gov>).

4. U.S. EPA. 2010c. *Trichoderma hamatum* isolate 382 Biopesticides Registration Action Document dated June 1, 2010 (available as “Supporting & Related Materials” within Docket Number EPA-HQ-OPP-2010-0489 at <http://www.regulations.gov>).

#### IV. Aggregate Exposures

In examining aggregate exposure, section 408 of 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).

##### A. Dietary Exposure

Dietary exposure to the microbial pesticide may occur (more likely through food than drinking water), but the lack of acute oral toxicity, infectivity, and/or pathogenicity, based on a toxicology test on rats presented in Unit III.B., is just one of several factors supporting the establishment of a permanent exemption from the requirement of a tolerance for residues of *Trichoderma hamatum* isolate 382.

1. *Food.* Dietary exposure to the microbial active ingredient is expected to be minimal. *Trichoderma hamatum* isolate 382 is only intended for directed application to or incorporation into soilless potting media or compost. These application methods are not conducive to residue accumulation in crops. Moreover, *Trichoderma* species live in soils and are unlikely to persist on plants. Any spores that end up on plants due to application as a pesticide would decrease over time as a result of weathering, desiccation, and ultraviolet radiation, which can kill even quiescent forms of the fungus. In the remote likelihood that the applied fungus grew on the edible portions of treated crops, the results of the toxicology testing demonstrated that no toxicity, infectivity, and/or pathogenicity in treated animals occurred, even when dosed with high levels of *Trichoderma hamatum* isolate 382 by the oral route of exposure (see additional discussion in Unit III.B.).

2. *Drinking water exposure.* Drinking water exposure is expected to be

negligible because the microbial fungicide will not be applied to water. Further, *Trichoderma hamatum* isolate 382 is a soil microorganism and would not proliferate in aquatic environments. Moreover, the Agency believes that *Trichoderma* species within the soil will not likely percolate into water due to the large size of the fungal spores and the fact that they adhere readily to soil particles. Even in the unlikely event that dietary exposure occurs through drinking water, the results of the oral toxicology testing, as described in Unit III.B., demonstrated that no toxicity, infectivity, and/or pathogenicity in treated animals occurred.

##### B. Other Non-Occupational Exposure

*Trichoderma hamatum* isolate 382 is a naturally occurring microorganism and is ubiquitous in the environment. As a pesticidal active ingredient, *Trichoderma hamatum* isolate 382 will be applied to or incorporated into soilless potting media or compost predominantly in greenhouses. Although some applications may take place in residential areas, there is no evidence of any concern for inhalation or dermal toxicity at exposure levels several orders of magnitude higher than would be expected to be encountered by a typical residential end user (see Unit III.B.). Additionally, as anticipated given that there are no recognized relationships between the *Trichoderma* genus and any pathogen of humans and animals, there have been no reports of adverse effects to humans from inhalation or dermal exposure to this widespread fungus.

#### V. Cumulative Effects from Substances with a Common Mechanism of Toxicity

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.”

EPA has not found *Trichoderma hamatum* isolate 382 to share a common mechanism of toxicity with any other substances, and *Trichoderma hamatum* isolate 382 does not appear to produce a toxic metabolite as its mode against the target pests. For the purposes of this tolerance exemption action, therefore, EPA has assumed that *Trichoderma hamatum* isolate 382 does not 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 EPA's website at <http://www.epa.gov/pesticides/cumulative>.

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

FFDCA section 408(b)(2)(C) provides that EPA shall assess the available information about consumption patterns among infants and children, special susceptibility of infants and children to pesticide chemical residues, and the cumulative effects on infants and children of the residues and other substances with a common mechanism of toxicity. In addition, FFDCA section 408(b)(2)(C) provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database unless EPA determines that a different margin of safety will be safe for infants and children. Margins of exposure (safety), which are often referred to as uncertainty factors, are incorporated into EPA risk assessments either directly or through the use of a margin of exposure analysis, or by using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk.

Based on the acute toxicity and pathogenicity data discussed in Unit III.B., as well as the ubiquity of *Trichoderma hamatum* isolate 382 in the environment without reported adverse effects to humans, EPA concludes that there is a reasonable certainty that no harm will result to the United States population, including infants and children, from aggregate exposure to the residues of *Trichoderma hamatum* isolate 382. This includes all anticipated dietary exposures and all other exposures for which there is reliable information. The Agency has arrived at this conclusion because the data and information available on *Trichoderma hamatum* isolate 382 do not demonstrate toxic, pathogenic, and/or infective potential to mammals. Thus, there are no threshold effects of concern and, as a result, an additional margin of safety is not necessary.

## VII. Other Considerations

### A. Analytical Enforcement Methodology

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 Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with

international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. In this context, EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established a MRL for *Trichoderma hamatum* isolate 382.

### C. Response to Comments

One comment, which specifically stated that the petition should be rejected without full testing for 20 years, was received in response to the notice of filing. The Agency notes that the data requirements do not require 20 years of testing, and no current information available to EPA suggests the need for 20 years worth of data to characterize the pesticide's toxicity, infectivity and/or pathogenicity. For the proposed uses of the microbial active ingredient (i.e., applications to or incorporation into soilless potting media or compost), the Agency has concluded that there is a reasonable certainty that no harm will result to the United States population, including infants and children, from aggregate exposure to the residues of *Trichoderma hamatum* isolate 382. Thus, under the standard in FFDCA section 408(c)(2), an exemption from the requirement of a tolerance for residues of *Trichoderma hamatum* isolate 382 is appropriate.

## VIII. Conclusions

The Agency concludes that there is a reasonable certainty that no harm will result to the United States population, including infants and children, from aggregate exposure to residues of *Trichoderma hamatum* isolate 382. Therefore, an exemption is established for residues of *Trichoderma hamatum* isolate 382 in or on all food commodities when applied as a fungicide and used in accordance with good agricultural practices.

## IX. Statutory and Executive Order Reviews

This final rule establishes a tolerance exemption 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, entitled *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 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.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes. As a result, 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. 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 9, 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).

#### X. 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: July 14, 2010.

**Steven Bradbury,**

*Director, Office of Pesticide Programs.*

■ Therefore, 40 CFR chapter I is amended as follows:

#### PART 180—[AMENDED]

■ 1. The authority citation for part 180 continues to read as follows:

**Authority:** 21 U.S.C. 321(q), 346a and 371.

■ 2. Section 180.1298 is added to subpart D to read as follows:

#### **§ 180.1298 *Trichoderma hamatum* isolate 382; exemption from the requirement of a tolerance.**

An exemption from the requirement of a tolerance is established for residues of *Trichoderma hamatum* isolate 382 in or on all food commodities when applied as a fungicide and used in accordance with good agricultural practices.

[FR Doc. 2010–18076 Filed 7–22–10; 8:45 am]

**BILLING CODE 6560–50–S**

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 180

[EPA–HQ–OPP–2009–0138; FRL–8825–6]

#### **2-Propanol, 1,1',1''-nitritoltris-; Exemption from the Requirement of a Tolerance**

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

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes an exemption from the requirement of a tolerance for residues of 2-Propanol, 1,1',1''-nitritoltris- (TIPA) (CAS No. 122–20–3) when used as an inert ingredient for use as a neutralizer on growing crops and raw agricultural commodities pre- and post-harvest. Dow AgroSciences, LLC submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting establishment of an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of TIPA.

**DATES:** This regulation is effective July 23, 2010. Objections and requests for hearings must be received on or before September 21, 2010, 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–2009–0138. All documents in the docket are listed in the docket index available at <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:** Lisa Austin, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200

Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–7894; e-mail address: [austin.lisa@epa.gov](mailto:austin.lisa@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 Access to Other Related Information?*

You may access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's e-CFR cite at <http://www.gpoaccess.gov/ecfr>. To access the harmonized test guidelines referenced in this document electronically, please go to <http://www.epa.gov/oppts> and select “Test Methods and Guidelines.”

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

Under section 408(g) of FFDCA, 21 U.S.C. 346a, 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–2009–0138 in the subject line on the first page of your submission. All