

**Authority:** 49 U.S.C. 106(g), 40103, 40106, 40113, 40114, 40120, 44502, 44514, 44701, 44719, 44721–44722.

■ 2. Part 97 is amended to read as follows:

By amending: § 97.23 VOR, VOR/DME, VOR or TACAN, and VOR/DME or TACAN; § 97.25 LOC, LOC/DME, LDA, LDA/DME, SDF, SDF/DME; § 97.27 NDB, NDB/DME; § 97.29 ILS,

ILS/DME, MLS, MLS/DME, MLS/RNAV; § 97.31 RADAR SIAPs; § 97.33 RNAV SIAPs; and § 97.35 COPTER SIAPs, Identified as follows:

*Effective Upon Publication*

AIRAC date	State	City	Airport	FDC No.	FDC date	Subject
19–Nov–09	SD	HURON .....	HURON REGIONAL .....	9/2314	9/22/09	RNAV (GPS) RWY 30, AMDT 1.
19–Nov–09	AL	HAMILTON .....	MARION COUNTY–RANKIN FITE.	9/2958	10/3/09	RNAV (GPS) RWY 18, ORIG–A.
17–Dec–09	WA	EVERETT .....	SNOHOMISH COUNTY (PAINE FLD).	9/3976	10/7/09	VOR/DME RWY 16R, ORIG.
17–Dec–09	WA	EVERETT .....	SNOHOMISH COUNTY (PAINE FLD).	9/3977	10/7/09	VOR RWY 16R, ORIG.

[FR Doc. E9–25489 Filed 10–27–09; 8:45 am] BILLING CODE 4910–13–P

**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 180**

[EPA–HQ–OPP–2008–0760; FRL–8436–6]

**Ulocladium oudemansii (U3 Strain); 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 fungicide, *Ulocladium oudemansii* (U3 Strain), in or on all food commodities when applied or used pre-harvest only, and excluding applications made post-harvest or to processed commodities. Botry-Zen, Ltd. 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 *Ulocladium oudemansii* (U3 Strain).

**DATES:** This regulation is effective October 28, 2009. Objections and requests for hearings must be received on or before December 28, 2009, 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–2008–0760. 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:** Denise Greenway, Biopesticides and Pollution Prevention Division (7511P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–8263; e-mail address: [greenway.denise@epa.gov](mailto:greenway.denise@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 Access Electronic Copies of this Document?*

In addition to accessing electronically available documents 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 e-CFR site at <http://www.gpoaccess.gov/ecfr>.

*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–2008–0760 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 December 28, 2009.

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-2008-0760, 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 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 November 14, 2008 (73 FR 67512) (FRL-8388-3), EPA issued a notice pursuant to section 408(d)(3) of FFDCFA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide tolerance petition (PP 7F7269) by Botry-Zen, Ltd., 21 Willis St., P.O. Box 5664, Dunedin, New Zealand. The petition requested that 40 CFR part 180 be amended by establishing an exemption from the requirement of a tolerance for residues of *Ulocladium oudemansii* (U3 Strain). This notice stated that a summary of the petition prepared by the petitioner, Botry-Zen, Ltd., was included in the docket. In response to EPA's notice announcing the filing of this petition, one comment was received from an anonymous person. The commenter complained of perceived inadequacy regarding the Agency's assessment of the subject petition, expressed dissatisfaction with the Agency's overall history concerning pesticide petition approvals, EPA's ability to protect the health of the American public, and opined that human testing should be conducted on the subject active ingredient. The commenter did not provide, however, any information in support of his/her position or specify the desired human studies assessment parameter(s). Before issuing any tolerance exemption, the Agency examines the potential effects of the pesticide on humans and the environment. For this particular microbial pesticide, EPA conducted a comprehensive assessment of

*Ulocladium oudemansii* (U3 Strain), including a review of the acceptable studies and other supporting information addressing the potential effects of this pesticide. EPA's review of these data and information indicated that the active ingredient is not toxic to test animals when administered via the oral, dermal, or intraperitoneal routes of exposure and is unlikely under the conditions of use to be a human health hazard by the pulmonary route because the large aggregated fungal spore material is not respirable. Also, there was no evidence that the active ingredient is a mutagen. In addition, the active ingredient was not infective or pathogenic to test animals when administered via the oral, dermal or intravenous routes. Moreover, growth temperature analysis has shown that *Ulocladium oudemansii* (U3 strain) does not grow above 30 °C, making infection of humans and other mammals having normal body temperatures above 37 °C unlikely. No reports of hypersensitivity have been recorded in personnel working with this organism. Based on these data, the Agency has concluded that there is a reasonable certainty that no harm will result from dietary exposure to residues of *Ulocladium oudemansii* (U3 Strain), when applied or used pre-harvest only in or on all food commodities (excluding applications made post-harvest or to processed commodities). Thus, under the standard in FFDCFA section 408(c)(2), an exemption from the requirement of a tolerance is appropriate.

Section 408(c)(2)(A)(i) of 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 exemption is "safe." Section 408(c)(2)(A)(ii) of 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. Pursuant to section 408(c)(2)(B) of FFDCFA, 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 FFDCFA, 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 FFDCFA 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 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.

*Ulocladium oudemansii* is a naturally occurring soil saprophyte found worldwide. The subject of this tolerance exemption, *Ulocladium oudemansii* (U3 strain), was originally isolated from kiwifruit leaf litter debris in 1995 from a Massey University kiwifruit research plot in New Zealand. The active ingredient is the asexual spore of the soil saprophytic fungus *Ulocladium oudemansii*. *Ulocladium oudemansii* (U3 Strain) is a fungicide intended for the control of the plant pathogens, *Botrytis cinerea* and *Sclerotinia sclerotiorum*, when applied pre-harvest to growing fruit and vegetable crops or ornamental plants. The organism controls the pathogens by occupying their ecological niche, in dead and senescent plant material, and out-competing them for space and nutrients. *Ulocladium oudemansii* (U3 strain) is non-invasive and does not damage living plant tissue.

An acceptable acute oral toxicity/pathogenicity study performed in rats (MRID 472465-03) demonstrated the lack of mammalian toxicity at tested levels of exposure to *Ulocladium oudemansii* (U3 Strain). In this study, *Ulocladium oudemansii* (U3 Strain) was not toxic, infective nor pathogenic to rats given an oral dose of  $1 \times 10^8$  colony forming units (CFU) per animal. The study resulted in a classification of

Toxicity Category IV for this strain of *Ulocladium oudemansii*.

An acceptable acute intraperitoneal injection toxicity/pathogenicity study in rats (MRID 472465-02) demonstrated that *Ulocladium oudemansii* (U3 Strain) was neither toxic, pathogenic nor infective to rats dosed intraperitoneally with greater than  $10^7$  CFU of the test material.

An acceptable acute dermal toxicity/pathogenicity study in rats (MRID 472465-04) demonstrated that *Ulocladium oudemansii* (U3 Strain) was not toxic, infective nor pathogenic to rats when treated dermally at  $1 \times 10^8$  CFU/animal. There were no treatment-related clinical signs, dermal irritation, necropsy findings or changes in body weight. No test organism was recovered from blood, brain, kidney, liver, cervical lymph nodes or spleen of any animal. The study resulted in a classification of Toxicity Category III for this strain of *Ulocladium oudemansii*.

An acceptable acute eye irritation study in rabbits (MRID 472465-06) demonstrated that *Ulocladium oudemansii* (U3 Strain) administered at a purity of not less than  $2 \times 10^8$  CFU/gram (g) and a minimum spore viability of 90% at 0.1 milliliter (ml)/animal is non-irritating. The study resulted in a classification of Toxicity Category IV for this strain of *Ulocladium oudemansii*.

An acceptable primary dermal irritation study in rabbits (MRID 472465-07) demonstrated that *Ulocladium oudemansii* (U3 Strain) administered at a purity of not less than  $2 \times 10^8$  CFU/g and a minimum spore viability of 90% at 0.5 ml/animal is non-irritating. The study resulted in a classification of Toxicity Category IV for this strain of *Ulocladium oudemansii*.

An acceptable skin sensitization test in guinea pigs (MRID 472465-08) demonstrated that *Ulocladium oudemansii* (U3 Strain) administered at a purity of not less than  $2 \times 10^8$  CFU/g and a minimum spore viability of 90% is not a dermal sensitizer. Furthermore, there have been no reports of hypersensitivity associated with *Ulocladium oudemansii* (U3 Strain).

Although not triggered by results of the Tier I toxicology studies, nor otherwise required, an acceptable bacterial reverse mutation study was submitted which showed the active ingredient to be non-mutagenic under test conditions in the tested species.

In addition to the acceptable toxicology studies summarized above, the Agency considered this other toxicology data and information in assessing the petitioner's tolerance exemption request.

*Pulmonary Toxicity/Pathogenicity.* A submitted acute pulmonary toxicity/pathogenicity study in rats (MRID 472465-05) did not satisfy the guideline requirement because the large aggregated fungal spore test material could not be manipulated into a particle size suitable for respiration in an inhalation study. The Agency notes that large particles such as these are unlikely to be inhaled and deposited in the pulmonary region, while any deposited in the naso-pharyngeal region are removed by coughing, sneezing or physical wiping from the nasal area. Particles deposited in the tracheobronchial region are removed by the mucociliary escalator system. Particles could be swallowed, but would represent no human health concern based on the lack of mammalian toxicity observed in the acceptable *Ulocladium oudemansii* (U3 Strain) acute oral toxicity/pathogenicity study cited above. The Agency concludes that, under conditions of use, *Ulocladium oudemansii* (U3 Strain) is unlikely to present a significant inhalation hazard to humans because the large aggregated fungal spore material is not respirable. In justifying its waiver request for this guideline study, Botry-Zen, Ltd. included in its rationale a discussion of the inability to dose test animals due both to the large size of the test particles and their rapid sedimentation in solution, and argued that any respirable dust or fines would not be expected to be toxic or irritating, based upon results from the acute oral and other submitted toxicology/pathogenicity studies summarized in this Unit. The presented rationale supports the Agency's decision to waive this data requirement.

#### IV. Aggregate Exposures

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

##### A. Dietary Exposure

*Ulocladium oudemansii*, a common soil fungus, is ubiquitous in the environment and exists worldwide as a naturally-occurring saprophyte, i.e., an organism that lives and feeds on dead and decaying plant matter. The subject of this tolerance exemption, *Ulocladium oudemansii* (U3 strain), was originally isolated from kiwifruit leaf litter. Spores of *Ulocladium oudemansii* (U3 strain),

when deposited under the suitable environmental conditions on dead or decaying plant debris, will germinate and colonize the necrotic plant tissue. But if such decayed vegetative matter is not available, or becomes exhausted, the fungus cannot survive. Therefore, despite its presence in soils, dietary exposure from the proposed use of *Ulocladium oudemansii* (U3 strain) will be minimal on food due to its limited viability in the absence of a decayed plant material nutrient source. Also, there are no known mycotoxins associated with *Ulocladium* species, and the submitted toxicological studies indicate no risk to human health from dietary exposure to *Ulocladium oudemansii* (U3 strain). Furthermore, the fungus produces no recognized toxins, enzymes or virulence factors normally associated with mammalian invasiveness or toxicity. Additionally, growth temperature analysis has shown that *Ulocladium oudemansii* (U3 strain) does not grow above 30 °C, making infection of humans and other mammals having normal body temperatures at or above 37 °C unlikely.

1. *Food.* As discussed above, *Ulocladium oudemansii* (U3 Strain) applied to food crops to control plant pathogens will not survive except on dead or decaying plant tissues. Food crops exhibiting such tissues are of poor quality, are not commonly consumed, and are not commercially marketed. Good quality food free of such decayed material will not support the fungus and so *Ulocladium oudemansii* (U3 Strain) residues would not be expected. Due to the limited survivability of *Ulocladium oudemansii* (U3 Strain) once its decayed plant material nutrient source is exhausted, dietary exposure to the naturally-occurring microbe from the proposed pre-harvest applications to food crops is unlikely. Even if oral exposure from ingestion of poor-quality treated crops should occur, the hazard posed to adults, infants and children from food-related exposures to *Ulocladium oudemansii* (U3 Strain) will be minimal due to the demonstrated lack of acute oral toxicity/pathogenicity associated with the microbial pesticide. Based on the evaluation of the submitted data, there are no dietary risks that exceed the Agency's level of concern.

2. *Drinking water exposure.* Exposure of humans to residues of *Ulocladium oudemansii* (U3 Strain) in consumed drinking water would be unlikely. *Ulocladium oudemansii* (U3 Strain) is not known to grow or thrive in aquatic environments. Potential exposure via surface water would be negligible and exposure via drinking water would be

impossible to measure. *Ulocladium oudemansii* (U3 Strain) is intended for use on agricultural and horticultural plants, and has limited survival potential once its carrier nutrient source is depleted. The risk of the microorganism passing through soil to groundwater is minimal to unlikely. Additionally, the fungus would not tolerate municipal drinking water treatment processes, such as chlorination, pH adjustment, high temperature and/or anaerobic conditions. More importantly, even if oral exposure to this ubiquitous microbe should occur through drinking water, due to its demonstrated lack of acute oral toxicity/pathogenicity, the Agency concludes that there is a reasonable certainty that no harm will result from such exposure.

#### B. Other Non-Occupational Exposure

The proposed pesticide uses of *Ulocladium oudemansii* (U3 Strain) being established by this rule are limited to commercial agricultural and horticultural settings. There are no residential uses.

The only other exposure is what people would normally encounter as part of the natural environment, not as a result of pesticide use. There have not been reports of disease or other effects from human exposure to *Ulocladium oudemansii* (U3 Strain) naturally present in soils.

#### V. Cumulative Effects

Section 408(b)(2)(D)(v) of FFDCA requires the Agency, when considering whether to establish, modify, or revoke a tolerance, to consider "available information" concerning the cumulative effects of pesticide residues and "other substances that have a common mechanism of toxicity." These considerations include the cumulative effects of such residues on infants and children. Because, there is no indication of mammalian toxicity from *Ulocladium oudemansii* (U3 Strain), the Agency concludes that *Ulocladium oudemansii* (U3 Strain) does not share a common mechanism of toxicity with other substances. Therefore, section 408(b)(2)(D)(v) does not apply.

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

FFDCA section 408(b)(2)(C), as amended by the Food Quality Protection Act (FQPA) of 1996, 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) also 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.

Based on the toxicity information discussed in Unit III., EPA concludes that there is a reasonable certainty that no harm will result to the U.S. population, including infants and children, from aggregate exposure to residues of *Ulocladium oudemansii* (U3 Strain). 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 available on *Ulocladium oudemansii* (U3 Strain) demonstrate a lack of toxicity/pathogenicity potential. *Ulocladium oudemansii* (U3 Strain) is not known to produce any recognized toxins, virulence factors or enzymes normally associated with mammalian invasiveness or toxicity. Thus, there are no threshold effects of concern and, as a result, the Agency has concluded that the additional tenfold margin of safety for infants and children is unnecessary in this instance.

#### VII. Other Considerations

##### A. Endocrine Disruptors

*Ulocladium oudemansii* is a ubiquitous organism in the environment. The subject of this tolerance exemption, *Ulocladium oudemansii* (U3 Strain), is non-toxic to mammals. To date, there is no evidence to suggest that *Ulocladium oudemansii* (U3 Strain) affects the immune system, functions in a manner similar to any known hormone, or that it acts as an endocrine disruptor. Indeed, the submitted toxicity/pathogenicity studies in rodents indicate that, following several routes of exposure, the immune system is intact and able to process and clear the active ingredient. Therefore, it is unlikely that this organism will have estrogenic or endocrine effects.

##### B. Analytical Method(s)

The Agency is establishing an exemption from the requirement of a tolerance for residues of *Ulocladium oudemansii* (U3 Strain), applied pre-harvest only, in or on all food commodities (excluding applications made post-harvest or to processed commodities), for the reasons stated

above. Because the organism thrives on dead/decaying plant matter and does not damage living plant tissues, residues of *Ulocladium oudemansii* (U3 Strain) are not expected on food crops. Even if food crops carried such residues, the hazard posed from food-related exposures to *Ulocladium oudemansii* (U3 Strain) will be minimal due to the demonstrated lack of acute oral toxicity/pathogenicity associated with the microbial pesticide. Therefore, the Agency has concluded that an analytical method is not required for enforcement purposes for detecting *Ulocladium oudemansii* (U3 Strain) residues resulting from its pre-harvest use as a pesticide.

##### C. Codex Maximum Residue Level

No Codex maximum residue level exists for the microbial fungicide, *Ulocladium oudemansii* (U3 Strain).

#### VIII. Conclusions

There is a reasonable certainty that no harm will result from aggregate exposure to the U.S. population, including infants and children, to residues of the *Ulocladium oudemansii* (U3 Strain) in or on all food and feed commodities when *Ulocladium oudemansii* (U3 Strain) is used as a pre-harvest-only microbial fungicide (thereby excluding applications made post-harvest or to processed commodities), in accordance with good agricultural practices. This includes all anticipated dietary exposures and all other exposures for which there is reliable information. The Agency has arrived at this conclusion because, as discussed above, no toxic effects to mammals have been observed.

#### IX. Statutory and Executive Order Reviews

This final rule establishes an exemption from 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, 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 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, 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 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: October 18, 2009.

**Debra Edwards,**

*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 180.1292 is added to subpart D to read as follows:

#### § 180.1292 *Ulocladium oudemansii* (U3 Strain); exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established in/on all food commodities for residues of *Ulocladium oudemansii* (U3 Strain), when applied or used pre-harvest-only, excluding applications made post-harvest or to processed commodities, as a microbial fungicide in accordance with good agricultural practices.

[FR Doc. E9-25969 Filed 10-27-09; 8:45 am]

**BILLING CODE 6560-50-S**

#### ENVIRONMENTAL PROTECTION AGENCY

#### 40 CFR Part 180

[EPA-HQ-OPP-2007-1025; FRL-8434-5]

#### Cold Pressed Neem Oil; 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 biochemical pesticide, cold pressed neem oil on all food commodities when applied/used on/in food commodities. Plasma Power Limited of India 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 cold pressed neem oil.

**DATES:** This regulation is effective October 28, 2009. Objections and requests for hearings must be received on or before December 28, 2009, 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-2007-1025. 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:** Driss Benmhend, Biopesticides and Pollution Prevention Division (7511P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 308-9525; e-mail address: [benmhend.driss@epa.gov](mailto:benmhend.driss@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