PART 63 MAJOR & AREA SOURCE RULE DELEGATIONS—SOUTH CAROLINA [1]—Continued

	Source category	Subpart	SCDHEC
	Primary Metals Prod. Mfg Valves and Pipe Fittings Mfg Ferroalloys Production		

[1] State program approved on June 26, 1995. Delegation table last updated on February 23, 2009.

* * * * *

[FR Doc. E9–10154 Filed 5–12–09; 8:45 am]
BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2008–0093; FRL–8412–5]

Calcium Lactate Pentahydrate; 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 calcium lactate pentahydrate (CAS Reg. No. 5743–47–5) when used as an inert ingredient in pesticide formulations applied to growing crops or to raw agricultural commodities after harvest. SynTech Global LLC, on behalf of BioNext sprl submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Federal Quality Protection Act of 1996 (FQPA), requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of calcium lactate pentahydrate.

DATES: This regulation is effective May 13, 2009. Objections and requests for hearings must be received on or before July 13, 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–2008–0093. 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: Karen Samek, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 347–8825; e-mail address: *samek.karen@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**.

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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–2008–0093 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 July 13, 2009.

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- *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 June 4, 2008 (73 FR 31862) (FRL–8365–3), EPA issued a notice pursuant to section 408 of FFDCA, 21 U.S.C. 346a, as amended by FQPA (Public Law 104–170), announcing the filing of a pesticide petition (PP 7F7311) by SynTech Global LLC on behalf of BioNext sprl, Passage des deportes, 2, B-5030 Gembloux, Belgium. The petition requested that 40 CFR 180.910 be amended by establishing an exemption from the requirement of a tolerance for residues of calcium lactate pentahydrate when used as an inert ingredient in pesticide formulations with the active ingredient *Candida oleophila strain O* as a post-harvest treatment on stored apples and pears to control *Botrytis cinerea* (grey mold) and *Penicillium expansum* (blue mold). That notice included a summary of the petition prepared by the petitioner. There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petition, EPA has modified the exemption requested to include an exemption from the requirement of a tolerance for residues of calcium lactate pentahydrate (CAS Reg. No. 5743–47–5) under 40 CFR 180.910 when used as an inert ingredient in pesticide formulations applied to growing crops or to raw agricultural commodities after harvest. The reason for these changes are explained in Unit IV.

Section 408(b)(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(b)(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. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . .''

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

III. Inert Ingredient Definition

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

IV. Toxicological Profile

Consistent with section 408(b)(2)(D) of 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 calcium lactate pentahydrate are discussed in this unit.

The Agency has reviewed the data submitted by the petitioner. The data submitted includes data on lactic acid, as well as data on calcium lactate. Because it is likely that calcium lactate readily disassociates to lactic acid and calcium in the body, the Agency has concluded that the data on lactic acid can be used in conjunction with the data on calcium lactate and that these data are adequate to characterize the toxicity of calcium lactate pentahydrate.

Acute oral and inhalation toxicity of lactic acid to rats and acute dermal toxicity of lactic acid to rabbits are low. L(+)-Lactic acid is severely irritating and corrosive to rabbit skin. It is expected to be severely irritating to the eyes. Dilute solutions are irritating to the eyes of rabbits. L(+)-Lactic acid is not a dermal sensitizer in guinea pigs. Repeat oral exposure of rats to calcium lactate for 90 days produced no toxicity at doses up to 5,000 milligrams/kilograms/day (mg/kg/day). No neurotoxicity studies are available; however, no signs of neurotoxicity were observed in any of the available studies. Based on the results of the mutagenicity studies, calcium lactate pentahydrate is not likely to be mutagenic. A 2–year bioassay of calcium lactate in rats showed no evidence of carcinogenicity or any systemic toxicity at doses up to 5,000 mg/kg/day.

No developmental or reproductive toxicity studies are available for calcium lactate pentahydrate, however, the Agency concluded that no developmental or reproductive studies are needed because there is no systemic toxicity identified at doses up to 5,000 mg/kg/day in a 2–year chronic toxicity study. In addition, a developmental toxicity study for lactic acid resulted in no maternal or developmental effects and none of the reproductive parameters were affected in mice at 570 mg/kg/day (only dose tested).

V. 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).

Calcium lactate is used as a food additive and is a normal constituent of the human diet. It is used as a firming agent in canned fruits and can be found in jellies and preserves. It can be found naturally in aged cheese and is used medically to treat calcium deficiencies. Food and Drug Administration allows the use of calcium lactate as a direct human food ingredient and has granted calcium lactate generally recognized as safe (GRAS) status for use as a firming agent, flavor enhancer, leavening agent, nutrient supplement, stabilizer, and thickener.

The primary route of exposure to calcium lactate pentahydrate from its

use as an inert ingredient in pesticide products would most likely be through consumption of food to which pesticide products containing it have been applied, and possibly through drinking water (from runoff). Residential (dermal and inhalation) exposures from home garden uses are possible.

No hazard was identified for the acute and chronic dietary assessment (food and drinking water), or for the short-, intermediate-, and long-term residential assessments, and therefore no aggregate risk assessments were performed.

VI. 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 pesticide ingredients 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 calcium lactate pentahydrate and any other substances and calcium lactate pentahydrate 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 calcium lactate pentahydrate have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's website at *http://www.epa.gov/pesticides/cumulative*.

VII. Determination of Safety for Infants and Children

Section 408(b)(2)(c) of FFDCA provides that EPA shall apply an additional tenfold (10X) 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 on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA safety factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

The toxicity database for calcium lactate is adequate for FQPA assessement and the potential exposure is adequately characterized given the low toxicity of the chemical. No acute or subchronic neurotoxicity studies are available, but there were no clinical signs of neurotoxicity observed in the available database at doses up to 5,000 mg/kg/day. Therefore, the Agency concluded that these studies are not required. No developmental or reproductive toxicity studies are available for calcium lactate pentahydrate, however, the Agency concluded that no developmental or reproductive studies are needed because there is no systemic toxicity identified at doses up to 5,000 mg/kg/day in a two–year chronic toxicity study. In addition, a developmental toxicity study for lactic acid resulted in no maternal or developmental effects and none of the reproductive parameters were affected in mice at 570 mg/kg/day (only dose tested).

In 1973, World Health Organization (WHO) evaluated lactic acid as well as its ammonium, calcium, potassium, and sodium slats and stated that ''There is some evidence that babies in their first three months of life have difficulties in utilizing small amounts of DL and D(-) lactic acids.'' (INCHEM. (1974). Seventeenth Report of the Joint FAO/WHO Expert Committee on Food Additives, Lactic acid and its ammonium, calcium, potassium and sodium salts. WHO Technical Report Series, No. 539; FAO Nutrition Meetings Report Series, 1974, No. 53. *http://www.inchem.org/documents/jecfa/jecmono/v05je86.htm*). EPA believes that exposure of premature or very young infants to lactic acid is unlikely. As stated in the Agency's reassessment document for lactic acid, ''First, premature or very young infants ingest only formula or breast milk. (It is generally recommended that infants not consume solid food until 4 to 6 months of age). Regulation of infant formulas is under the purview of FDA. (*www.fda.gov/fdac/features/596_baby.html*).'' (Stehlin, I; (1996). Infant Formula: Second Best but Good Enough. *FDA Consumer Magazine.* 30 (5)). To carry out their regulation of infant foods and infant formulas, FDA published in 21 CFR 184.1207(c)(2) a very specific limitation that calcium lactate cannot be used in infant foods and infant formulas. Therefore, infants consuming only infant formula or breast milk are not exposed to calcium lactate. Once past this initial time-period, there is no longer a concern for potential sensitivity to infants and children. Older infants, like adults, process calcium lactate through well understood metabolic pathways.

Based on this information, there is no concern, at this time, for increased sensitivity to infants and children to calcium lactate pentahydrate when used as an inert ingredient in pesticide formulations applied to growing crops or to raw agricultural commodities after harvest and a safety factor analysis has not been used to assess risk. For the same reason, EPA has determined that an additional safety factor is not needed to protect the safety of infants and children.

VIII. Determination of Safety for U.S. Population

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

Residues of concern are not anticipated for dietary exposure (food and drinking water) or for residential exposure from the use of calcium lactate pentahydrate for the proposed use pattern as an inert ingredient in pesticide products. As discussed in Unit VIII., EPA expects aggregate exposure to calcium lactate to pose no appreciable dietary risk given that the data on calcium lactate show a lack of any systemic toxicity at doses of up 5,000 mg/kg/day and a lack of any apparent developmental effects and that lactic acid is a normal component of human intermediary metabolism Furthermore, according to the FDA website *http://www.cfsan.fda.gov/~dms/opascogd.html* ''the Select committee concluded that: There is no evidence in the available information on L(+) calcium lactate that demonstrates or suggests reasonable grounds to suspect a hazard to the public when they are

used at levels that are now current or that might reasonably be expected in the future. There is no evidence in the available information on either of the isomers of lactic acid, their calcium slats, and their racemates that demonstrates or suggests reasonable grounds to suspect a hazard to individuals beyond infancy when they are used at levels that are now current or that might reasonable be expected in the future.''

Taking into consideration all available information on calcium lactate pentahydrate, EPA concludes that there is a reasonable certainty that no harm will result to the general population or to infants and children from aggregate exposure to calcium lactate pentahydrate. Therefore, the establishment of an exemption from tolerance under 40 CFR 180.910 for residues of calcium lactate pentahydrate when used as an inert ingredient in pesticide formulations applied to growing crops or to raw agricultural commodities after harvest can be considered safe under section 408 of FFDCA.

IX. Other Considerations

A. Endocrine Disruptors

EPA is required under FFDCA, as amended by FQPA, to develop a screening program to determine whether certain substances (including all pesticide active and other ingredients) ''may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or other such endocrine effects as the Administrator may designate.'' Following recommendations of its Endocrine Disruptor and Testing Advisory Committee (EDSTAC), EPA determined that there was a scientific basis for including, as part of the program, the androgen and thyroid hormone systems, in addition to the estrogen hormone system. EPA also adopted EDSTAC's recommendation that the program include evaluations of potential effects in wildlife. For pesticide chemicals, EPA will use the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, and to the extent that effects in wildlife may help determine whether a substance may have an effect in humans, FFDCA authority to require the wildlife evaluations. As the science develops and resources allow, screening of additional hormone systems may be added to the Endocrine Disruptor Screening Program (EDSP).

When additional appropriate screening and/or testing protocols being considered under the Agency's EDSP have been developed, calcium lactate pentahydrate may be subjected to further screening and/or testing to better characterize effects related to endocrine disruption.

B. Analytical Method

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

C. International Tolerances

The Agency is not aware of any country requiring a tolerance for calcium lactate pentahydrate nor have any CODEX Maximum Residue Levels been established for any food crops at this time.

D. Revisions to Petitioned-For Exemption

Based upon review of the data supporting the petition, EPA has modified the exemption requested to include an exemption from the requirement of a tolerance for residues of calcium lactate pentahydrate (CAS Reg. No. 5743–47–5) under 40 CFR 180.910 when used as an inert ingredient in pesticide formulations applied to growing crops or to raw agricultural commodities after harvest because no hazard was identified and therefore, no limitations are necessary.

X. Conclusions

Based on the information in this preamble, EPA concludes that there is a reasonable certainty of no harm from aggregate exposure to residues of calcium lactate pentahydrate. Accordingly, EPA finds that exempting calcium lactate pentahydrate from the requirement of a tolerance when used as an inert ingredient in pesticide formulations applied to growing crops or to raw agricultural commodities after harvest will be safe.

XI. 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, 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 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).

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 final rule in the **Federal Register**. This final rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: April 29, 2009.

Meredith F. Laws,

Acting Director, Registration Division, Office of Pesticide Programs.

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

PART 180—[AMENDED]

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

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

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

■ 2. In §180.910, the table is amended by adding alphabetically the following inert ingredient to read as follows:

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

* * * * *

Inert ingredients	Limits	Uses
* * *	*	*
Calcium lactate pentahydrate (CAS Reg. No. 5743–47–5).	.....	Nutrient, stabilizer
* * *	*	*

[FR Doc. E9–10769 Filed 5–12–09; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2008–0164; FRL–8412–9]

Candida oleophila Strain O; 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, *Candida oleophila* Strain O, on apples and pears when applied/used as a post-harvest biofungicide. BioNext sprl (in care of SynTech Global, 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 *Candida oleophila* Strain O.

DATES: This regulation is effective May 13, 2009. Objections and requests for hearings must be received on or before July 13, 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–2008–0164. 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: Jeannine Kausch, Biopesticides and Pollution Prevention Division (7511P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 347-8920; e-mail address: kausch.jeannine@*epa.gov*.

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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–2008–0164, by one of the following methods.