

**ENVIRONMENTAL PROTECTION AGENCY**
**40 CFR Part 180**

[EPA-HQ-OPP-2009-0325; FRL-8813-7]

**Hexythiazox; Pesticide Tolerances**

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

**ACTION:** Final rule.

**SUMMARY:** This regulation revises the tolerance for combined residues of hexythiazox in or on grape. Gowan Company requested the tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA).

**DATES:** This regulation is effective March 17, 2010. Objections and requests for hearings must be received on or before May 17, 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-2009-0325. 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:** Olga Odiott, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 308-9369 e-mail address: [odiott.olga@epa.gov](mailto:odiott.olga@epa.gov).

**SUPPLEMENTARY INFORMATION:**
**I. General Information**
**A. Does this Action Apply to Me?**

You may be potentially affected by this action if you are an agricultural

producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to those engaged in the following activities:

- Crop production (NAICS code 111).
- 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 to provide 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 EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR cite 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. 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-2009-0325 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 May 17, 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 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 this copy, identified by docket ID number EPA-

HQ-OPP-2009-0325, 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. Petition for Tolerance**

In the **Federal Register** of August 19, 2009 (FR 41898) (FRL-8426-7), 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 petition (PP 9F7556) by Gowan Company, 370 South Main Street; Yuma, AZ 85364. The petition requested that 40 CFR 180.448 be amended by revising the established tolerance for combined residues of the insecticide hexythiazox, (trans-5-(4-chlorophenyl)-N-cyclohexyl-4-methyl-2-oxothiazolidine-3-carboxamide) and its metabolites containing the (4-chlorophenyl)-4-methyl-2-oxo-3-thiazolidine moiety, in or on grape from 0.75 to 1.0 part per million (ppm); plum from 0.10 to 1.0 ppm; and plum, prune, dried from 0.40 to 1.0 ppm. That notice referenced a summary of the petition prepared by Gowan Company, the registrant, which is available to the public in the docket, <http://www.regulations.gov>. There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petition, EPA has determined that there is insufficient residue chemistry data to support the proposed tolerances for the stone fruit use, therefore, this action only addresses the tolerance for grape. The Agency is also revising the tolerance expression for hexythiazox. The reason for these changes are explained in Unit IV.D.

**III. Aggregate Risk Assessment and Determination of Safety**

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish 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. . . .”

Consistent with section 408(b)(2)(D) of FFDCA, and the factors specified in section 408(b)(2)(D) of FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for hexythiazox including exposure resulting from the tolerances established by this action. EPA’s assessment of exposures and risks associated with hexythiazox follows.

#### A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies 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. Hexythiazox has a low order of acute toxicity by the oral, dermal and inhalation routes of exposure. It produces mild eye irritation, is not a dermal irritant, and is negative for dermal sensitization.

The target organs of hexythiazox are the liver and adrenal glands in dogs, rats and mice, with the dog being the most sensitive species. The chronic dog study showed increased liver and adrenal weights, along with associated hypertrophy of the liver and adrenal glands. The subchronic toxicity study in rats showed increased liver and adrenal weights, as well as fatty degeneration of the adrenal zona fasciculate. Effects observed in the chronic feeding/carcinogenicity studies in rats and mice included decreased body weight gain and increased liver weights.

Hexythiazox is not a developmental or reproductive toxicant. The toxicology database for hexythiazox provides no

indication of increased susceptibility in rats or rabbits from *in utero* and postnatal exposure to hexythiazox. The database does not show any evidence of treatment-related effects on the nervous system or the immune system.

Hexythiazox is classified as “Likely to be Carcinogenic to Humans” based upon increased incidences of benign and malignant liver tumors in high-dose female mice, and benign mammary gland tumors, observed in high-dose male rats. There was no evidence of carcinogenicity in male mice and female rats. However, EPA determined that a non-quantitative risk assessment approach (i.e., nonlinear, reference dose (RfD) approach) was appropriate for hexythiazox based on the following considerations:

1. The liver tumors in mice are a very common tumor in that species were only observed in high-dose females.

2. The mammary tumors in rats were benign and were only observed in high-dose male rats.

3. Hexythiazox was shown to be non-mutagenic in mammalian somatic cells and germ cells.

Additionally, the chronic no-observed-adverse-effect-level (NOAEL) used for establishing the chronic RfD (2.5 mg/kg/day, from the 1-year toxicity feeding study in the dog), is approximately 65-fold lower than the lowest dose that induced tumors (in female mice at 163 milligrams/kilogram/day (mg/kg/day). Therefore, the chronic RfD of 0.025 mg/kg/day is judged to be protective of all chronic effects including potential carcinogenicity of hexythiazox.

Specific information on the studies received and the nature of the adverse effects caused by hexythiazox as well as the NOAEL and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at <http://www.regulations.gov> in document “Hexythiazox. Human Health Risk Assessment to Support Amended Use on Grapes Reducing the Preharvest Interval from 28-Days to 7-Days and to Add Uses on Turf, Gardens and Ornamentals,” page 27 in docket ID number EPA-HQ-OPP-2009-0325.

#### B. Toxicological Points of Departure/Levels of Concern

Once a pesticide’s toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment.

PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which NOAEL and the LOAEL of concern are identified. Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level generally referred to as a PAD or a RfD and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see <http://www.epa.gov/pesticides/factsheets/riskassess.htm>.

A summary of the toxicological endpoints for hexythiazox used for human risk assessment can be found at <http://www.regulations.gov> in document “Hexythiazox.” “Human Health Risk Assessment to Support Amended Use on Grapes Reducing the Preharvest Interval from 28-Days to 7-Days and to Add Uses on Turf, Gardens and Ornamentals,” page 12 in docket ID number EPA-HQ-OPP-2009-0325

#### C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to hexythiazox, EPA considered exposure under the petitioned-for tolerances as well as all existing hexythiazox tolerances in 40 CFR 180.448. EPA assessed dietary exposures from hexythiazox in food as follows:

- i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure.

No such effects were identified in the toxicological studies for hexythiazox; therefore, a quantitative acute dietary exposure assessment is unnecessary.

- ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the U.S. Department of Agriculture (USDA) 1994–1996 and 1998 Continuing Surveys of Food Intakes by Individuals (CSFII). As to residue levels in food, EPA used tolerance level residues, assumed 100 percent crop treated (PCT), and incorporated default processing factors.

- iii. *Cancer.* As discussed in this unit, EPA has determined that the chronic RfD is sufficient to evaluate all chronic

risks for this chemical, including carcinogenic potential. Cancer risk was quantified using the same estimates as discussed in Unit III.C.1.ii., chronic exposure.

*iv. Anticipated residue and PCT information.* EPA did not use anticipated residue and/or PCT information in the dietary assessment for hexythiazox. Tolerance level residues and/or 100 PCT were assumed for all food commodities.

*2. Dietary exposure from drinking water.* The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for hexythiazox in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of hexythiazox. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at <http://www.epa.gov/oppefed1/models/water/index.htm>.

Based on the Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS) the estimated drinking water concentration (EDWC) of hexythiazox for chronic exposures for non-cancer and cancer assessments is estimated to be 4.1 parts per billion (ppb) for surface water. Since surface water residue values greatly exceed groundwater EDWCs, surface water residues were used in the dietary risk assessment.

The modeled EDWC was directly entered into the dietary exposure model.

*3. From non-dietary exposure.* The term “residential exposure” is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets).

Hexythiazox is not currently registered for any specific use patterns that would result in residential exposure. However, the following uses that could result in residential exposures are pending registration in the near future and are included in this risk assessment: Turf, gardens, ornamental landscape plantings, ornamental plants, trees and vines in nurseries, residential fruit trees, nut trees and caneberries, and orchids. Residential handler exposures are expected to be short-term (1 to 30 days) via either the dermal or inhalation routes of exposures. Since a quantitative dermal risk assessment is not required for hexythiazox; MOEs were calculated for the inhalation route of exposure only. Both adults and children may be exposed to hexythiazox residues from contact with treated lawns or treated

residential plants. Adult postapplication exposures were not assessed since no quantitative dermal risk assessment is required for hexythiazox and inhalation exposures are typically negligible in outdoor settings. The exposure assessment for children included incidental oral exposure resulting from transfer of residues from the hands or objects to the mouth, and from incidental ingestion of soil. No quantitative dermal risk assessment is required.

Residential handler risks are not of concern as short-term inhalation MOEs range from 40,000,000 to 820,000,000. Postapplication risks for children are not of concern as incidental oral short-term MOEs range from 2,600 to 3,200,000 and intermediate-term MOEs range from 5,600 to 3,200,000 (MOEs which exceed 100 are not of concern). None of the subject uses are expected to result in long-term residential exposures.

Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at <http://www.epa.gov/pesticides/trac/science/trac6a05.pdf>.

*4. 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 hexythiazox to share a common mechanism of toxicity with any other substances, and hexythiazox does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that hexythiazox 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>.

#### *D. Safety Factor for Infants and Children*

*1. In general.* 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.

*2. Prenatal and postnatal sensitivity.* The prenatal and postnatal toxicology data base indicates no increased susceptibility of rats or rabbits to *in utero* and/or postnatal exposure to hexythiazox.

*3. Conclusion.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X. That decision is based on the following findings:

i. The toxicity database for hexythiazox is incomplete under the new 40 CFR part 158 data requirements for conventional pesticides, which requires certain generic testing, including acute and subchronic neurotoxicity studies and an immunotoxicity study. However, the toxicology database does not show any evidence of treatment-related effects on the nervous system or the immune system. The overall weight of evidence suggests that this chemical does not directly target either system. Although acute and subchronic neurotoxicity studies and an immunotoxicity study are required as a part of new data requirements in the 40 CFR part 158 for conventional pesticide registrations, the Agency does not believe that conducting these studies will result in a lower POD than any currently used for risk assessment, and therefore, a database uncertainty factor (UF<sub>DB</sub>) is not needed to account for the lack of these studies.

ii. There is no indication that hexythiazox is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

iii. There is no evidence that hexythiazox results in increased susceptibility in *in utero* rats or rabbits in the prenatal developmental studies or in young rats in the two-generation reproduction study.

iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100 PCT and tolerance-level residues. The dietary risk assessment is highly conservative and not expected to underestimate risk. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to hexythiazox in drinking water. EPA

used similarly conservative assumptions to assess postapplication exposure of children as well as incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by hexythiazox.

#### *E. Aggregate Risks and Determination of Safety*

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute population adjusted-dose (aPAD) and chronic population adjusted-dose (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-term, intermediate-term, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

**1. Acute risk.** An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. No adverse effect resulting from a single oral exposure was identified and no acute dietary endpoint was selected. Therefore, hexythiazox is not expected to pose an acute risk.

**2. Chronic risk.** Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to hexythiazox from food and water will utilize 49% of the cPAD for (children 1 to 2 years old) the population group receiving the greatest exposure. Based on the explanation in Unit III.C.3., regarding residential use patterns, chronic residential exposure to residues of hexythiazox is not expected.

**3. Short-term risk.** Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

There are potential short-term exposures from the pending residential uses for hexythiazox. The Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short-term residential exposures to hexythiazox.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the combined short-term food, water, and residential exposures result in aggregate MOEs of 16,000 for adults and 1,300 for children. Because EPA's level of concern for hexythiazox is a MOE of 100 or below, these MOEs are not of concern.

#### *4. Intermediate-term risk.*

Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

There are potential intermediate-term exposures from the pending residential uses for hexythiazox. The Agency has determined that it is appropriate to aggregate chronic exposure through food and water with intermediate-term residential exposure to hexythiazox.

Using the exposure assumptions described in this unit for intermediate-term exposures, EPA has concluded that the combined intermediate-term food, water, and residential exposures result in aggregate MOEs of 16,000 for adults and 1,700 for children. Because EPA's level of concern for hexythiazox is a MOE of 100 or below, these MOEs are not of concern.

**5. Aggregate cancer risk for U.S. population.** EPA has classified hexythiazox as "Likely to be Carcinogenic to Humans," but has determined that there is insufficient evidence to quantify risk using a cancer slope factor. As discussed in Unit III.A EPA concluded that regulation based on the chronic RfD will be protective for both chronic and carcinogenic risks. As noted in this unit there are no chronic risks of concern.

**6. Determination of safety.** Based on these risk assessments, 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 hexythiazox residues.

### **IV. Other Considerations**

#### *A. Analytical Enforcement Methodology*

Adequate enforcement methodology (high performance liquid chromatography with UV detection (HPLC/UV)) is available to enforce the tolerance expression. The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; e-mail address: [residuemethods@epa.gov](mailto:residuemethods@epa.gov).

#### *B. International Residue Limits*

A Codex MRL is established at 1.0 ppm for grape. The Agency has harmonized the residue level, but notes that it is not possible to harmonize the tolerance expression at this time as the Codex maximum residue limit (MRL) includes parent only. There are no currently established Canadian or Mexican MRLs for residues of hexythiazox in/on grape.

#### *C. Revisions to Petitioned-For Tolerances*

The Agency has revised the tolerance expression to clarify 1. that, as provided in FFDCA section 408(a)(3), the tolerance covers metabolites and degradates of hexythiazox not specifically mentioned; and 2. that compliance with the specified tolerance levels is to be determined by measuring only the specific compounds mentioned in the tolerance expression. The Agency determined that there is insufficient residue chemistry data to support the proposed tolerances for the stone fruit use; therefore, this action only addresses the tolerance for grape.

### **V. Conclusion**

Therefore, the tolerance for residues of hexythiazox, in or on grape is revised from 0.75 ppm to 1.0 ppm.

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

This final rule establishes tolerances 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).

## VII. 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: March 8, 2010.

**Lois Rossi,**

*Director, Registration Division, Office of Pesticide Programs.*

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

Commodity	Parts per million
Grape .....	1.0

(b) *Section 18 emergency exemptions.* Time-limited tolerances are established for residues of hexythiazox, including its metabolites and degradates, in connection with use of the pesticide under section 18 emergency exemptions granted by EPA. Compliance with the tolerance levels specified below is to be determined by measuring only hexythiazox and its metabolites containing the (4-chlorophenyl)-4-methyl-2-oxo-3-thiazolidine moiety, calculated as the stoichiometric equivalent of hexythiazox.

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[FR Doc. 2010–5692 Filed 3–16–10; 8:45 am]

BILLING CODE 6560–50–S

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 180

[EPA–HQ–OPP–2009–0845; FRL–8814–3]

### Tetraethoxysilane, Polymer with Hexamethyldisiloxane; Tolerance Exemption

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

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes an exemption from the requirement of a tolerance for residues of

## 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. § 180.448 revise the introductory text in paragraph (a), and revise the entry “Grape” in the table in paragraph (a), and revise introductory text in paragraphs (b), and (c) to read as follows:

### §180.448 Hexythiazox; tolerance for residues.

(a) *General.* Tolerances are established for residues of hexythiazox, including its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels specified below is to be determined by measuring only hexythiazox and its metabolites containing the (4-chlorophenyl)-4-methyl-2-oxo-3-thiazolidine moiety, calculated as the stoichiometric equivalent of hexythiazox.

tetraethoxysilane, polymer with hexamethyldisiloxane, minimum number average molecular weight (in AMU) 2,500 (CAS Reg. No. 104133–09–7) when used as an inert ingredient in a pesticide chemical formulation under 40 CFR 180.960. Wacker Chemical Corporation 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 tetraethoxysilane, polymer with hexamethyldisiloxane, on food or feed commodities.

**DATES:** This regulation is effective March 17, 2010. Objections and requests for hearings must be received on or before May 17, 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

\* \* \* \* \*

(c) *Tolerances with regional registrations.* Tolerances with regional registrations as defined by 40 CFR 180.1(n), are established for residues of hexythiazox, including its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels specified below is to be determined by