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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2008–0095; FRL–8404–7]

Tristyrylphenol Ethoxylates (CAS Reg. No. 70559-25-0) and (CAS Reg. No. 99734-09-5); 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 poly(oxy-1,2-ethanediyl), α-[2,4,6-tris(1-phenylethyl)phenyl]-ω-hydroxy- (CAS Reg. No. 70559–25–0) and poly(oxy-1,2-ethanediyl), α-[tris(1-phenylethyl)phenyl]-ω-hydroxy-, (CAS Reg. No. 99734–09–5), herein referred to in this document as tristyrylphenol ethoxylates when used as inert ingredients in post-harvest applications to citrus crops, group 10, under 40 CFR 180.1288 at a maximum of 10.0% in pesticide formulations with azoxystrobin and fludioxonil. Syngenta Crop Protection, Inc. 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 the tristyrylphenol ethoxylates.

DATES: This regulation is effective March 25, 2009. Objections and requests for hearings must be received on or before May 26, 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–2008–0095. 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**.

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 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. 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–2008–0095 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 May 26, 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–2008–0095, 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 March 12, 2008 (73 FR 13225) (FRL–8354–6), 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 7E7305) by Syngenta Crop Protection, Inc., P.O. Box 18300, Greensboro, NC 27409. The petition requested that 40 CFR 180.910 be amended by establishing an exemption

from the requirement of a tolerance for residues of the tristyrylphenol ethoxylates when used as inert ingredients in post-harvest applications at a maximum of 10.0% in pesticide formulations. That notice included a summary of the petition prepared by the petitioner. This request is specific for the post-harvest uses of these tristyrylphenol ethoxylates and does not impact the existing pre-harvest tolerance exemptions under 40 CFR 180.920 granted by the Agency for these tristyrylphenol ethoxylates with a limit of not more than 15% in pesticide formulations. There were no comments received in response to the notice of filing.

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 the tristyrylphenol ethoxylates are discussed in this unit.

In 2006, EPA reassessed the inert ingredient tolerance exemptions under 40 CFR 180.920 for the tristyrylphenol ethoxylates when used as inert ingredients at not more than 15% in pesticide formulations applied to growing crops. This tolerance reassessment document can be found at *http://www.epa.gov/opprd001/inerts/decisiondoc_a2k.html*. As stated in that document, the tristyrylphenol ethoxylates have similar use patterns, restrictions/limitations, and potential exposures. A Structure Activity Relationship (SAR) assessment for the tristyrylphenol ethoxylates was performed by the Agency's Office of Pollution Prevention and Toxics (OPPT) Structure Activity Team (SAT). In the 2006 document, the SAT determined that the data presented on the analog compounds within the tristyrylphenol ethoxalates are adequate to characterize the expected toxicity of subject chemicals (CAS Reg. Nos. 70559–25–0 and 99734–09–5) for the reasons set forth in Unit VII below. The available toxicity database for the tristyrylphenol ethoxylates consists of studies on some of the tristyrylphenol ethoxylate chemicals, such as CAS Reg. No. 90093–37–1 and 119432–41–6, and guideline studies on an analog chemical, CAS Reg. No. 105362–40–1. The studies on the tristyrylphenol ethoxylate chemicals and analog chemicals were considered appropriate to evaluate the toxicity of the tristyrylphenol ethoxylates because these chemicals share a common chemical structure and are members of the same chemical class. The tristyrylphenol ethoxylates and analog chemicals share a close structural similarity and same functional groups with the only difference being in the associated counterions. Therefore, the toxicity of these chemicals are expected to be similar.

An acute toxicity battery conducted on the tristyrylphenol ethoxylates resulted in low acute oral toxicity, slight skin irritation, and slight eye irritation. In subchronic toxicity studies, the primary toxicity appears to be to the kidney and thyroid in rats and the liver in dogs. The kidney effects in rats appear to be the most sensitive endpoint. In this study, there were minimal effects observed at 100 milligrams/kilogram/day (mg/kg/day) but these effects were not considered adverse effects. Therefore, the no observed effect level (NOEL) for the study was 30 mg/kg/day and the no observed adverse effect level (NOAEL) was 100 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 submitted mutagenicity studies, the tristyrylphenol ethoxylates are not likely to be mutagenic. There are no carcinogenicity studies available on the tristyrylphenol ethoxylates; however, the primary toxicity appears to be to the kidney and thyroid in rats and liver in dogs. The kidney effects in rats appear to be the most sensitive endpoint. The Agency has considerable knowledge of the intratubular mineralization toxic effect to the kidneys and has determined that by preventing the intratubular mineralization in the kidney, tumor formation is unlikely to occur. Since these kidney effects are the most sensitive endpoint, protective measures for kidney toxicity will be protective of any other long term effects. The thyroid toxicity in rats was observed at 1,500 mg/kg/day and the NOAEL was 500 mg/kg/day. The Agency has determined the mode of action of the compound causing thyroid toxicity and concluded that a dose preventing thyroid toxicity would be protective of both cancer and non cancer effects on the thyroid. In addition, the Agency also recognizes that the rats are more sensitive to thyroid effects than humans. The NOAEL used as the point of departure in calculating the chronic reference dose (cRfD) selected for this risk assessment is protective of any thyroid effects and is approximately 10 fold lower than the NOAEL established for the thyroid effects. There is not a concern for the liver toxicity seen in the dog study because the liver effects at dosages of 500 mg/kg/day were marginal and seen in only one dog out of six. The SAR models predicted low concern for the

carcinogenicity of the compounds. Considering the lack of mutagenicity, the lack of target organ toxicity in subchronic studies and known mode of action for the target organ toxicity seen, and the SAR prediction, the Agency concluded that carcinogenicity concerns are unlikely for the tristyrylphenol ethoxylates.

The developmental toxicity study in which rats were administered CAS Reg. No. 119432–41–6, resulted in a NOAEL of 300 mg/kg/day for maternal toxicity (based on reduced body weights and increase in liver weights and loose feces seen at the lowest observed adverse effect level (LOAEL) of 1,000 mg/kg/day) and a NOAEL of 300 mg/kg/day for developmental toxicity based on increased skeletal variations (increased incidence of all unossified proximal phalanges of the hind limb seen at the LOAEL of 1,000 mg/kg/day).

The cRfD of 0.5 mg/kg/day was established based on the 90–day subchronic toxicity study in dogs, with a NOAEL of 50 mg/kg/day and a safety factor of 100 (10x for interspecies and 10x for intraspecies variations). Since the Food Quality Protection Act (FQPA) safety factor is reduced from 10x to 1x, the chronic population adjusted dose (cPAD) is equal to the cRfD. In the dog study, the NOAEL of 50 mg/kg/day was based on equivocal liver toxicity seen at the LOAEL of 500 mg/kg/day. Therefore, in this dog study, the NOAEL would be between 50–500 mg/kg/day. Since the NOAEL for the subchronic rat studies is 100 mg/kg/day based on kidney and thyroid toxicity, choosing the NOAEL of 50 mg/kg/day would be protective of both the liver effects seen in the dog and the kidney and thyroid effects seen in the rat.

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).

EPA establishes exemptions from the requirement of a tolerance only in those cases where it can be clearly 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.

The primary route of exposure to these chemicals from their use as inert ingredients in pesticide products would most likely be through consumption of food to which pesticide products containing them have been applied, and possibly through drinking water (from runoff). Dermal and inhalation exposures are also possible from residential use of pesticide products containing these inert ingredients. However, the quantitative exposure assessment via inhalation and dermal routes of exposure was not performed because negligible inhalation and dermal absorption is expected based on the physicochemical properties of the compounds.

There are no data available on tristyrylphenol ethoxylates residues in food or on non-occupational exposures to tristyrylphenol ethoxylates. In the absence of actual residue data for tristyrylphenol ethoxylates, the Agency performed a dietary (food and drinking water) exposure assessment for tristyrylphenol ethoxylates that included both the existing pre-harvest uses and the proposed post-harvest use on citrus crops in formulations of azoxystrobin and fludioxonil using worst-case assumptions as detailed below. The dietary exposure was calculated as a percentage of the cRfD. The chronic dietary estimate for the U.S. Population was 12.2% (non-nursing infants were the most highly exposed population with a chronic exposure estimate occupying 35.6% of the cPAD). In addition, this exposure assessment assumed that:

- Tristyrylphenol ethoxylates would be used as an inert ingredient in all food use pesticide formulations applied to all crops.
- One hundred percent of all food crops would be treated with pesticides containing tristyrylphenol ethoxylates.
- Tristyrylphenol ethoxylates residues would be present in all crops at levels equal to or exceeding the highest established tolerance levels for any pesticide active ingredient for both the existing preharvest uses and the proposed postharvest use, and
- A conservative default value of 1,000 parts per billion (ppb) for the concentration of an inert ingredient in all sources of drinking water was used. This approach is highly conservative as it is extremely unlikely that tristyrylphenol ethoxylates would have such use as pesticide product inert ingredients and be present in food commodities and drinking water at such high levels. In addition, this highly conservative exposure assessment is protective of any possible non-occupational exposures to tristyrylphenol ethoxylates as it results in exposure estimates orders of magnitude greater than the high-end exposure estimates for residential uses of pesticides routinely used by the Office of Pesticide Programs.

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 tristyrylphenol ethoxylates and any other substances and tristyrylphenol ethoxylates do not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that tristyrylphenol ethoxylates 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. Additional Safety Factor for the Protection of Infants and Children

Section 408 of the FFDCA 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 on toxicity and exposure unless EPA determines that a different margin of safety will be safe for infants

and children. EPA concluded that the FQPA safety factor could be removed for tristyrylphenol ethoxylates for the following reasons:

1. EPA has sufficient data to assess the toxicity of tristyrylphenol ethoxylates. The data presented in the assessment on the tristyrylphenol ethoxylates are adequate to characterize the expected behavior of the subject chemicals. There are no carcinogenicity studies available on the tristyrylphenol ethoxylates; however, the primary toxicity appears to be to the kidney and thyroid in rats and liver in dogs. The kidney effects in rats appear to be the most sensitive endpoint. The Agency has considerable knowledge of the intratubular mineralization toxic effect to the kidneys and has determined that by preventing the intratubular mineralization in the kidney, tumor formation is unlikely to occur. Since these kidney effects are the most sensitive endpoint, protective measures for kidney toxicity will be protective of any other long term effects. Further, EPA concluded that there is no need for the additional FQPA safety factor for use of subchronic toxicity for long term exposure assessment. The critical effect seen in the subchronic study (intratubular mineralization in the kidney) is believed to occur as a result of precipitation of a chemical based on its physicochemical properties. Precipitation of a chemical based on its physiochemical properties is a function primarily of dose level rather than duration of dosing. Thus, once the threshold for precipitation of the chemical is established (as it was in the subchronic dog study), this threshold level would be considered protective of any short or long term exposure. Therefore, the additional safety factor for the lack of long term studies is not warranted.

2. EPA concluded that there is no evidence of increased susceptibility to infants and children. The developmental toxicity study in which rats were administered (CAS Reg. No. 119432–41–6) resulted in a NOAEL of 300 mg/kg/day for maternal toxicity (based on reduced body weights and increase in liver weights and loose feces seen at the LOAEL of 1,000 mg/kg/day) and a NOAEL of 300 mg/kg/day for developmental toxicity based on increased skeletal variations (increased incidence of all unossified proximal phalanges of the hind limb seen at the LOAEL of 1,000 mg/kg/day). Fetal effects were seen only at the limit dose and in the presence of maternal toxicity.

3. No rabbit developmental study or reproductive toxicity studies are available for these chemicals, however, the developmental toxicity study in rats indicates no robust developmental toxicity at the limit dose and none of the reproductive parameters were affected in the rat developmental study at the limit dose of 1,000 mg/kg/day. This endpoint in the developmental study is considered conservative since the incidence of skeletal variations seen at 1,000 mg/kg/day was marginal.

4. There is no indication in the database that the tristyrylphenol ethoxylates are neurotoxic chemicals and there is no evidence of increased susceptibility. Therefore, there is no need for a developmental neurotoxicity study.

5. There are no residual uncertainties identified in the exposure databases. In the absence of actual exposure data on tristyrylphenol ethoxylates, a highly conservative dietary exposure assessment would not underestimate the risk to infants and children. Based on overall weight of evidence, the FQPA factor of 10X was reduced to 1X.

VIII. Determination of Safety for U.S. Population

Residues of concern are not anticipated for dietary exposure (food and drinking water) or for residential exposure (inhalation and dermal). EPA determines whether pesticide chemical exposures are safe by comparing aggregate exposure estimates to the dose at which no adverse effects were seen in the most sensitive animal studies. In the case of tristyrylphenol ethoxylates, the estimated exposures are compared to a dose level equal to the chronic RfD of 0.5 mg/kg/day (based on the subchronic dog study). Utilizing a highly conservative aggregate exposure assessment, the resulting chronic exposure estimates do not exceed the Agency's level of concern (non-nursing infants were the most highly exposed population with the chronic exposure estimates occupying 35.6% of the cPAD). In addition, this highly conservative exposure assessment is protective of any possible non-occupational exposures to the tristyrylphenol ethoxylates as it results in exposure estimates orders of magnitude greater than the high-end exposure estimates for residential uses of pesticides routinely used by the Office of Pesticides Programs.

Taking into consideration all available information on the tristyrylphenol ethoxylates, it has been determined that there is a reasonable certainty that no harm to any population subgroup, including infants and children, will result from aggregate exposure to these chemicals when used as inert ingredients in post-harvest applications to citrus crops, group 10, at a maximum of 10.0% in pesticide formulations with azoxystrobin and fludioxonil, when considering dietary exposure and all other non-occupational sources of pesticide exposure for which there is reliable information. Therefore, the exemption from the requirement of a tolerance for residues of poly(oxy-1,2-ethanediyl), α-[2,4,6-tris(1-phenylethyl)phenyl]-ω-hydroxy- (CAS Reg. No. 70559–25–0) and poly(oxy-1,2-ethanediyl), α-[tris(1-phenylethyl)phenyl]-ω-hydroxy-, (CAS Reg. No. 99734–09–5), when used as inert ingredients in post-harvest applications to citrus crops, group 10, under 40 CFR 180.1288 at a maximum of 10.0% in pesticide formulations with azoxystrobin and fludioxonil can be considered safe under section 408 of the FFDCA.

IX. Other Considerations

A. 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.

B. Existing Exemptions

The tristyrylphenol ethoxylates (CAS Reg. No. 70559–25–0 and CAS Reg. No. 99734–09–5) are exempted from the requirement of a tolerance under 40 CFR 180.920 when used as inert ingredients at not more than 15% in pesticide formulations applied to growing crops only.

C. International Tolerances

The Agency is not aware of any country requiring a tolerance for the tristyrylphenol ethoxylates nor have any CODEX Maximum Residue Levels (MRLs) been established for any food crops at this time.

X. Conclusions

Accordingly, an exemption from the requirement for a tolerance is established for poly(oxy-1,2-ethanediyl), α-[2,4,6-tris(1-phenylethyl)phenyl]-ω-hydroxy- (CAS Reg. No. 70559–25–0) and poly(oxy-1,2-ethanediyl), α-[tris(1-phenylethyl)phenyl]-ω-hydroxy-, (CAS Reg. No. 99734–09–5), when used as inert ingredients in post-harvest applications to citrus crops, group 10, under 40 CFR 180.1288 at a maximum of 10.0% in pesticide formulations with azoxystrobin and fludioxonil.

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: March 4, 2009.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

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

PART 180—[AMENDED]

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

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

■ 2. Section 180.1288 is added to read as follows:

§ 180.1288 Tristyrylphenol ethoxylates; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of poly(oxy-1,2-ethanediyl), α-[2,4,6-tris(1-phenylethyl)phenyl]-ω-hydroxy-, (CAS Reg. No. 70559–25–0) and poly(oxy-1,2-ethanediyl), α-[tris(1-phenylethyl)phenyl]-ω-hydroxy-, (CAS Reg. No. 99734–09–5) on citrus crops, group 10, when used as inert ingredients under the following conditions:

(a) They are applied post-harvest;

(b) They are used as inert ingredients in pesticide formulations with azoxystrobin and fludioxonil; and

(c) They constitute no more than 10.0% of the formulated pesticide product.

[FR Doc. E9–6259 Filed 3–24–09; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 271

[EPA–R06–RCRA–2008–0756–; FRL–8784–9]

New Mexico: Final Authorization of State Hazardous Waste Management Program Revision

AGENCY: Environmental Protection Agency (EPA).

ACTION: Immediate final rule.

SUMMARY: The State of New Mexico has applied to the EPA for final authorization to administer the provisions of the Used Oil program under the Resource Conservation and Recovery Act (RCRA). The EPA has determined that the statutes and regulations of the State of New Mexico Used Oil program satisfy all requirements needed to qualify for final authorization, and is authorizing the State's changes through this immediate final action. The EPA is publishing this rule to authorize the changes without a prior proposal because we believe this action is not controversial and do not expect comments that oppose it. Unless we receive written comments which oppose this authorization during the comment period, the decision to authorize New Mexico's changes to its hazardous waste program will take effect. If we receive comments that oppose this action, we will publish a document in the **Federal Register** withdrawing this rule before it takes effect, and a separate document in the proposed rules section of this **Federal Register** will serve as a proposal to authorize the changes.

DATES: This final authorization will become effective on May 26, 2009 unless the EPA receives adverse written comment by April 24, 2009. If the EPA receives such comment, it will publish a timely withdrawal of this immediate final rule in the **Federal Register** and inform the public that this authorization will not take effect.

ADDRESSES: Submit your comments by one of the following methods:

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

2. *E-mail: patterson.alima@epa.gov.*

3. *Mail:* Alima Patterson, Region 6, Regional Authorization Coordinator, State/Tribal Oversight Section (6PD–O), Multimedia Planning and Permitting Division, EPA Region 6, 1445 Ross Avenue, Dallas, Texas 75202–2733.

4. *Hand Delivery or Courier.* Deliver your comments to Alima Patterson,