• Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);

• Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);

• Does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);

• Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);

• Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);

• Is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA; and

• Does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, this rule does not have Tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), because the SIP is not approved to apply in Indian country located in the State, and EPA notes that it will not impose substantial direct costs on Tribal governments or preempt Tribal law.

The Congressional Review Act, 5 U.S.C. 801 *et seq.,* as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this action 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 the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a "major rule" as defined by 5 U.S.C. 804(2).

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by January 31, 2011. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. Parties with objections to this direct final rule are encouraged to file a comment in response to the parallel notice of proposed rulemaking for this action published in the proposed rules section of today's **Federal Register**, rather than file an immediate petition for judicial review of this direct final rule, so that EPA can withdraw this direct final rule and address the comment in the proposed rulemaking. This action may not be challenged later in proceedings to enforce its requirements. (*See* section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Carbon monoxide, Incorporation by reference, Intergovernmental relations, Nitrogen dioxide, Particulate matter, Ozone, Reporting and recordkeeping requirements, Volatile organic compounds.

Dated: November 10, 2010.

A. Stanley Meiburg,

Acting Regional Administrator, Region 4.

■ 40 CFR part 52 is amended as follows:

PART 52—[AMENDED]

■ 1. The authority citation for part 52 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

Subpart L—Georgia

■ 2. Section 52.570(c) is amended by revising the entry for "391–3–1–.02(2)(zz)" to read as follows:

§ 52.570 Identification of plan.

* * * * *

(c) * * *

EPA-APPROVED GEORGIA REGULATIONS

State citation	Title/Subject	State effective date	EPA approval date	Explanation
*	*	*	*	* * *
391–3–1–.02(2)(zz)	Gasoline Dispensing Facility—Stage II.	1/9/05	12/1/10 [Insert citation of publication].	Exemption for initial fueling of vehicles equipped with ORVR from Stage II requirements; allowing mixing of Stage II components when supported by third party certification and prior written approval of GA EPD.
*	*	*	*	* * *

* * * * *

[FR Doc. 2010–30119 Filed 11–30–10; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2008–0095; FRL–8851–6]

Tristyrylphenol Ethoxylates; 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-[tris(1-phenylethyl)phenyl]-ω-hydroxy-, (CAS Reg. No. 99734–09–5), here in referred to as tristyrylphenol ethoxylate, when used as an inert ingredient post-harvest as a surfactant under 40 CFR 180.910 with a maximum of 15 percent by

weight in pesticide formulations. Ag-Chem Consulting, on behalf of LG Life Science, submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting the establishment of an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of tristyrylphenol ethoxylate.

DATES: This regulation is effective December 1, 2010. Objections and requests for hearings must be received on or before January 31, 2011, 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 get electronic access to other related information?

You may access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://www.gpoaccess.gov/ecfr.*

C. How can I file an objection or hearing request?

Under FFDCA section 408(g), 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–2008–0095 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 January 31, 2011. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit a copy of your non-CBI objection or hearing request, identified by docket ID number EPA–HQ–OPP–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. Petition for Exemption

In the **Federal Register** of June 23, 2010 (75 FR 35801) (FRL–8831–3), EPA issued a notice pursuant to section 408 of FFDCA, 21 U.S.C. 346a, announcing the filing of a pesticide petition (PP 0E7701) by Ag-Chem Consulting, 12208 Quinque Lane, Clifton, VA 21024, on behalf of LG Life Science, 910 Sylvan Ave., Englewood Cliffs, NJ 07632. The petition requested that 40 CFR 180.910 be amended by establishing an exemption from the requirement of a tolerance for residues of tristyrylphenol ethoxylate (CAS Reg. No. 99734–09–5) when used as an inert ingredient as a surfactant with a maximum of 10 percent by weight in pesticide formulations applied to food areas and food contact surfaces in food service and food handling establishments. That notice referenced a summary of the petition prepared by Ag-Chem Consulting, the petitioner, which is available 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 modified the exemption requested by limiting tristyrylphenol ethoxylate (CAS Reg. No. 99734–09–5) to a maximum of 15 percent by weight in pesticide formulations. This limitation is based on the Agency's risk assessment which can be found at *http://www.regulations.gov* in document "PC Code: 800900; Decision Document for Pesticide Petition 0E7701; poly(oxy-1,2-ethanediyl), α-[tris(1-phenylethyl)phenyl]-ω-hydroxy-, (CAS Reg. No. 99734–09–5) for use post-harvest under 40 CFR 180.910 as an inert ingredient as a surfactant with a maximum of 15 percent by weight in pesticide formulations" in docket ID number EPA–HQ–OPP–2008–0095.

It should be noted that there are other tolerance exemptions under 40 CFR 180.920 and 40 CFR 180.1288 that apply to this tristyrylphenol ethoxylate compound (CAS Reg. No. 99734–09–5),

as well as, other closely related tristyrylphenol ethoxylate chemicals. The Agency believes that these existing exemptions could be consolidated at a later date by establishing a pre- and post-harvest exemption under 40 CFR 180.910 for these tristyrylphenol ethoxylate compounds since these chemicals share a common chemical structure and are members of the same chemical class.

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 polymers 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. Aggregate Risk Assessment and Determination of Safety

Section 408(c)(2)(A)(i) of FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the 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 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.

Consistent with section 408(c)(2)(A) of FFDCA, and the factors specified in FFDCA section 408(c)(2)(B), 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 tristyrylphenol ethoxylate including exposure resulting from the exemption established by this action. EPA's assessment of exposures and risks associated with tristyrylphenol ethoxylate follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered their 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. Specific information on the studies received and the nature of the adverse effects caused by the tristyrylphenol ethoxylates as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies are discussed in the final rule published in the **Federal Register** of March 25, 2009 (74 FR 12621) (FRL–8404–7). As stated in that document, the available toxicity database for the tristyrylphenol ethoxylates consists of studies on some of the tristyrylphenol ethoxylate chemicals, such as CAS Reg. Nos. 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 is expected to be similar. The Agency has determined that these data are appropriate and adequate to characterize the toxicity of the tristyrylphenol ethoxylates.

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 no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level—generally referred to as a population-adjusted dose (PAD) or a reference dose (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 used for human risk assessment is discussed in Unit IV of the final rule published in the **Federal Register** of March 25, 2009 (74 FR 12621) (FRL–8404–7).

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to tristyrylphenol ethoxylate, EPA considered exposure under the proposed exemption from the requirement of a tolerance as well as the other existing exemptions from tolerance for other closely related tristyrylphenol ethoxylate chemicals. EPA assessed dietary exposures from

tristyrylphenol ethoxylate in food as follows:

i. *Acute exposure.* No adverse effects attributable to a single exposure of tristyrylphenol ethoxylate were seen in the toxicity databases. Therefore, an acute dietary risk assessment for tristyrylphenol ethoxylate is not necessary.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment, EPA used food consumption information from the United States Department of Agriculture (USDA) [1994–1996 and 1998] Nationwide Continuing Surveys of Food Intake by Individuals (CSFII). As to residue levels in food, no residue data were submitted for tristyrylphenol ethoxylate. In the absence of specific residue data, EPA has developed an approach which uses surrogate information to derive upper bound exposure estimates for the subject inert ingredient. Upper bound exposure estimates are based on the highest tolerance for a given commodity from a list of high-use insecticides, herbicides, and fungicides. A complete description of the general approach taken to assess inert ingredient risks in the absence of residue data is contained in the memorandum entitled "Alkyl Amines Polyalkoxylates (Cluster 4): Acute and Chronic Aggregate (Food and Drinking Water) Dietary Exposure and Risk Assessments for the Inerts." (D361707, S. Piper, 2/25/09) and can be found at *http://www.regulations.gov* in docket ID number EPA–HQ–OPP–2008–0738.

In the dietary exposure assessment, the Agency assumed that the residue level of the inert ingredient would be no higher than the highest tolerance for a given commodity. Implicit in this assumption is that there would be similar rates of degradation (if any) between the active and inert ingredient and that the concentration of inert ingredient in the scenarios leading to these highest of tolerances would be no higher than the concentration of the active ingredient.

The Agency believes the assumptions used to estimate dietary exposures lead to an extremely conservative assessment of dietary risk due to a series of compounded conservatisms. First, assuming that the level of residue for an inert ingredient is equal to the level of residue for the active ingredient will overstate exposure. The concentration of active ingredient in agricultural products is generally at least 50 percent of the product and often can be much higher. Further, pesticide products rarely have a single inert ingredient; rather there is generally a combination of different inert ingredients used which additionally reduces the concentration of any single inert ingredient in the pesticide product in relation to that of the active ingredient. In the case of tristyrylphenol ethoxylate, EPA made a specific adjustment to the dietary exposure assessment to account for the use limitations of the amount of tristyrylphenol ethoxylate that may be in formulations (no more than 15 percent by weight in pesticide) and assumed that tristyrylphenol ethoxylate is present at the maximum limitations rather than at equal quantities with the active ingredient. In addition, in a previous risk assessment (2009) which can be found at *http://www.regulations.gov* in docket ID number EPA–HQ–OPP–2009–0095, the Agency concluded that residues following post harvest application to citrus crops would not be likely to exceed three times the residue attained following pre-harvest application. Therefore, the Agency applied a correction factor of 3x to the citrus crop group to account for the potentially higher residues from post-harvest treatment of this use.

Second, the conservatism of this methodology is compounded by EPA's decision to assume that, for each commodity, the active ingredient which will serve as a guide to the potential level of inert ingredient residues is the active ingredient with the highest tolerance level. This assumption overstates residue values because it would be highly unlikely, given the high number of inert ingredients, that a single inert ingredient or class of ingredients would be present at the level of the active ingredient in the highest tolerance for every commodity. Finally, a third compounding conservatism is EPA's assumption that all foods contain the inert ingredient at the highest tolerance level. In other words, EPA assumed 100 percent of all foods are treated with the inert ingredient at the rate and manner necessary to produce the highest residue legally possible for an active ingredient. In summary, EPA chose a very conservative method for estimating what level of inert residue could be on food, then used this methodology to choose the highest possible residue that could be found on food and assumed that all food contained this residue. No consideration was given to potential degradation between harvest and consumption even though monitoring data shows that tolerance level residues are typically one to two orders of magnitude higher than actual residues in food when distributed in commerce.

Accordingly, although sufficient information to quantify actual residue levels in food is not available, the compounding of these conservative assumptions will lead to a significant exaggeration of actual exposures. EPA does not believe that this approach underestimates exposure in the absence of residue data.

iii. *Cancer.* Considering the lack of mutagenicity, the lack of target organ toxicity in subchronic studies and known mode of action for the target organ toxicity, and the SAR predictions, the Agency concluded that carcinogenicity concerns are unlikely for the tristyrylphenol ethoxylate. Therefore, a cancer dietary exposure assessment was not performed.

iv. *Anticipated residue and percent crop treated (PCT) information.* EPA did not use anticipated residue and/or PCT information in the dietary assessment for tristyrylphenol ethoxylate. Tolerance level residues and/or 100 percent CT were assumed for all food commodities.

2. *Dietary exposure from drinking water.* For the purpose of the screening level dietary risk assessment to support this request for an exemption from the requirement of a tolerance for tristyrylphenol ethoxylate, a conservative drinking water concentration value of 100 ppb based on screening level modeling was used to assess the contribution to drinking water for the chronic dietary risk assessments for parent compound. These values were 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.,* textiles (clothing and diapers), carpets, swimming pools, and hard surface disinfection on walls, floors, tables).

Tristyrylphenol ethoxylate may be used as an inert ingredient in pesticide products that are registered for specific uses that may result in both outdoor and indoor residential exposures. In addition, tristyrylphenol ethoxylate may be used as an inert ingredient in pesticide formulations that are used in and around the home. Although dermal and inhalation exposures are possible from residential use of pesticide products containing this inert ingredient, negligible inhalation and dermal absorption is expected based on the molecular weight and the physicochemical properties of the compound. A screening level residential exposure and risk assessment was completed for products containing tristyrylphenol ethoxylate as an inert ingredient. The Agency conducted an assessment to represent worst-case residential exposure by assessing post

application exposures and risks from tristyrylphenol ethoxylate in pesticide formulations (Outdoor Scenarios) and tristyrylphenol ethoxylate in disinfectant-type uses (Indoor Scenarios). Further details of this residential exposure and risk analysis can be found in the document (D364751) in docket ID number EPA–HQ–OPP–2008–0710.

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 tristyrylphenol ethoxylate to share a common mechanism of toxicity with any other substances, and tristyrylphenol ethoxylate does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that tristyrylphenol ethoxylate 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 Web site 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. 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:

2. EPA has sufficient data to assess the toxicity of the tristyrylphenol ethoxylates. The data presented in the assessment on the tristyrylphenol ethoxylates are adequate to characterize the expected behavior of the subject chemical. The primary toxicity appears to be to the kidney and thyroid in rats and liver in dogs. Because the 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.

3. 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.

4. 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.

5. 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 or the acute neurotoxicity and 90-day neurotoxicity studies.

6. No treatment related effects were observed on the thymus or spleen at very high doses, indicating a lack of immunotoxic effects. Therefore, a functional immunotoxicity test is not required at this time and no additional uncertainty factor is required because of the lack of a immunotoxicity study.

7. 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. 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 the tristyrylphenol ethoxylates. Based on overall weight of evidence, the FQPA factor of 10X was reduced to 1X.

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 PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, 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, tristyrylphenol ethoxylate is not expected to pose an acute risk.

2. *Chronic risk.* A chronic aggregate risk assessment takes into account exposure estimates from chronic dietary consumption of food and drinking water. Using the exposure assumptions discussed in this unit for chronic exposure and the use limitations of not more than 15 percent by weight in pesticide formulations, the chronic dietary exposure from food and water to tristyrylphenol ethoxylate is 13.5 percent of the cPAD for the U.S. population and 43.6 percent of the cPAD for children 1 to 2 years old, the most highly exposed population subgroup.

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). Tristyrylphenol ethoxylate is used as an inert ingredient in pesticide products that are currently registered for uses that could result in short-term residential exposure and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short-term residential exposures to tristyrylphenol ethoxylate. Using the exposure assumptions described in this document, EPA has concluded that the combined short-term aggregated food, water, and residential exposures result in aggregate MOEs of 91 for both adult males and females respectively. Adult residential exposure combines high end dermal and inhalation handler exposure from indoor hand wiping with a high end post application dermal exposure from contact with treated lawns. The models assume high end application rates, and high end exposures representing worst case scenarios, as well as, assuming that the inert ingredients are used on all commodities and that 100 percent of crops are treated and that residues will be present for every consumed commodity (including meat, milk, poultry, and eggs) that is included in the Dietary Exposure Evaluation Model (DEEM™). Considering the extremely conservative nature of this screening level model the Agency concluded that this MOE is not of a concern. EPA has concluded that the combined short-term aggregated food, water, and residential exposures result in an aggregate MOE of 207 for children. Children's residential exposure includes total exposures associated with contact with treated lawns (dermal and hand-to-mouth exposures). As the level of concern is for MOEs that are lower than 100, 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). 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). Tristyrylphenol ethoxylate is currently registered for uses that could result in intermediate-term residential exposure and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with intermediate-term residential exposures to tristyrylphenol ethoxylate. Using the exposure assumptions described in this document, EPA has concluded that the combined intermediate-term aggregated food, water, and residential exposures result in aggregate MOE of 869 for adult males and a MOE of 898 for adult females. Adult residential exposure includes high end post application dermal exposure from contact with treated lawns. EPA has concluded the combined intermediate-term aggregated food, water, and residential exposures result in an aggregate MOE of 218 for children. Children's residential exposure includes total exposures associated with contact with treated lawns (dermal and hand-to-mouth exposures). As the level of concern is for MOEs that are lower than 100, this MOE is not of concern.

5. *Aggregate cancer risk for U.S. population.* The Agency has not identified any concerns for carcinogenicity relating to the tristyrylphenol ethoxylate.

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 tristyrylphenol ethoxylate residues.

V. Other Considerations

A. Analytical Enforcement Methodology

An analytical method is not required for enforcement purposes since the Agency is not establishing a numerical tolerance for residue of tristyrylphenol ethoxylate in or on any food commodities. EPA is establishing a limitation on the amount of tristyrylphenol ethoxylate that may be used in pesticide formulations. That limitation will be enforced through the pesticide registration process under the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), 7 U.S.C. 136 *et seq.* EPA will not register any pesticide for sale or distribution that contains greater than 15 percent of tristyrylphenol ethoxylate by weight in food use pesticide formulations.

B. International Residue Limits

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

The Codex has not established a MRL for tristyrylphenol ethoxylate.

VI. Conclusions

Therefore, an exemption from the requirement of a tolerance is established under 40 CFR 180.910 for poly(oxy-1,2-ethanediyl), α-[tris(1-phenylethyl)phenyl]-ω-hydroxy-, (CAS Reg. No. 99734–09–5), when used post-harvest as an inert ingredient as a surfactant with a maximum of 15 percent by weight in pesticide formulations.

VII. Statutory and Executive Order Reviews

This final rule establishes an exemption from the requirement of 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 exemption in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes,

nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 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).

VIII. 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: November 18, 2010.

G. Jeffrey Herndon,

Acting 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. In § 180.910, add alphabetically the following inert ingredient to the table to read as follows:

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

* * * * *

Inert ingredients	Limits	Uses
* * *	* * *	*
Poly(oxy-1,2-ethanediyl), α-[tris(1-phenylethyl)phenyl]-ω-hydroxy-, (CAS Reg. No. 99734–09–5).	For use in post-harvest applications; Not to exceed 15% by weight in pesticide formulations.	Surfactants.
* * *	* * *	*

[FR Doc. 2010–29992 Filed 11–30–10; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2010–0136; FRL–8850–9]

Spiroxamine; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of spiroxamine, [(8-(1,1-dimethylethyl)-*N*-ethyl-*N*-propyl-1, 4-dioxaspiro[4,5]decane-2-methanamine)], including its metabolites and degradates in or on artichoke, globe, import at 0.7 parts per million (ppm) asparagus, import at 0.05 ppm; and vegetables, fruiting, crop group 8, import at 1.2 ppm. Bayer CropScience requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective December 1, 2010. Objections and requests for hearings must be received on or before January 31, 2011, 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–2010–0136. 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: Tamue L. Gibson, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; *telephone number:* (703) 305–9096; *e-mail address: gibson.tamue@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