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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2015-0232; FRL-9941-15]

Poly(oxy-1,2-ethanediyl), α-(3-carboxy-1-oxosulfopropyl)-ω-hydroxy-, alkyl (C_{10}-C_{16}) ethers, disodium salts; 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-(3-carboxy-1-oxosulfopropyl)-ω-hydroxy-, alkyl (C_{10}-C_{16}) ethers, disodium salts with a polyoxyethylene (POE) content averaging 5-15 moles, specifically CAS Reg. Nos. 68815-56-5, 68954-91-6, 1013906-64-3, and 1024612-24-5, when used as inert ingredients (surfactants) in pesticide formulations applied to crops at a concentration not to exceed 10% by weight under 40 CFR 180.910. Keller and Heckman LLP on behalf of Cytec Industries, Inc., submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting the establishment of exemptions from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of these poly(oxy-1,2-ethanediyl), α-(3-carboxy-1-oxosulfopropyl)-ω-hydroxy-, alkyl (C_{10}-C_{16}) ethers, disodium salts.

DATES: This regulation is effective [*insert date of publication in the* **Federal Register**]. Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the* **Federal Register**], 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: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2015-0232, is available at *http://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets*.

FOR FURTHER INFORMATION CONTACT: Susan Lewis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; main telephone number: (703) 305-7090; email address: *RDFRNotices@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. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but

rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

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.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl*.

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-2015-0232 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 [*insert date 60 days after date of publication in the* **Federal Register**]. 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 (excluding any Confidential Business Information (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 the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2015-0232, by one of the following methods:

• *Federal eRulemaking Portal*: *http://www.regulations.gov*. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

• *Mail*: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

• *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.html*.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets*.

II. Petition for Exemption

In the **Federal Register** of May 20, 2015 (80 FR 28925) (FRL-9927-39), EPA issued a document pursuant to FFDCA section 408, 21 U.S.C. 346a, announcing the filing of a pesticide petition (PP IN-10759) by Keller and Heckman LLP, 1001 G Street, NW, Suite 500 West, Washington, DC 20001 on behalf of Cytec Industries, Inc., 5 Garret Mountain Plaza Woodland Park, NJ 07424. The petition requested that 40 CFR 180.910 be amended by establishing an exemption from the requirement of a tolerance for residues of poly(oxy-1,2-ethanediyl), α-(3-carboxy-1-oxosulfopropyl)-ω-hydroxy-, (C_{10}-C_{16}) alkylethers, disodium salts with a polyoxyethylene (POE) content averaging 5-15 specifically poly(oxy-1,2-ethanediyl), α-(3-carboxy-1-oxosulfopropyl)-ω- hydroxy-, C_{10-12}-alkyl ethers, disodium salts, the poly(oxyethylene) content averages 5-15 moles (CAS Reg. No.

68954-91-6); poly(oxy-1,2-ethanediyl), α-(3-carboxy-1-oxosulfopropyl)-ω-hydroxy-, C_{10-16}-alkyl ethers, disodium salts, the poly(oxyethylene) content averages 5-15 moles (CAS Reg, No. 68815-56-5); poly(oxy-1,2-ethanediyl), α-(3-carboxy-1-oxosulfopropyl)-ω-hydroxy-, C_{12-14}-alkyl ethers, disodium salts, the poly(oxyethylene) content averages 5-15 moles (CAS Reg. No. 1024612-24-5); and poly(oxy-1,2-ethanediyl), α-(3-carboxy-1-oxosulfopropyl)-ω-(isotridecyloxy)-, sodium salt (1:2), the poly(oxyethylene) content averages 5-15 moles (CAS Reg. No. 1013906-64-3) when used as an inert ingredient (surfactant) in pesticide formulations applied to growing crops and raw agricultural commodities at a concentration not to exceed 10% by weight. That document referenced a summary of the petition prepared by Keller and Heckman LLP, on behalf of Cytec Industries, Inc., the petitioner, which is available in the docket, *http://www.regulations.gov*. Comments were not received on the notice of filing.

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 FFDCA section 408(c)(2)(A), 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 poly(oxy-1,2-ethanediyl), α-(3-carboxy-1-oxosulfopropyl)-ω-hydroxy-, alkyl ethers, disodium salts including exposure resulting from the exemption established by this action. EPA's assessment of exposures and risks associated with poly(oxy-1,2-ethanediyl), α-(3-carboxy-1-oxosulfopropyl)-ω-hydroxy-, alkyl ethers, disodium salts 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 poly(oxy-1,2-ethanediyl), α-(3-carboxy-1-oxosulfopropyl)-ω-hydroxy-, alkyl (C_{10}-C_{16}) ethers, disodium salts 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 this unit.

The acute oral and dermal toxicity in rats are low for poly(oxy-1,2-ethanediyl), α-(3-carboxy-1-oxosulfopropyl)-ω-hydroxy-, -alkyl (C_{10}-C_{16}) ethers, disodium salts. They are not irritating to the eyes and moderately irritating to the skin in rabbits. They are weak dermal sensitizers. Acute inhalation toxicity studies were not available.

In subchronic toxicity studies, are available in rats and dogs. (CAS Reg No. 68815-56-5) was administered via the diet in both studies and similar effects are seen in both. Bodyweight decreases are seen in dogs at 565 milligrams/kilogram/day (mg/kg/day) and in rats at 4% (equivalent to 3,519 mg/kg/day, lowest observed adverse

effect level (LOAEL)). Decreased feed efficiency is also observed at this dose in rats. The NOAELs are 140 mg/kg/day and 1% (equivalent to 770 mg/kg/day) in dogs and rats, respectively. The chronic reference dose (cRfD) is based on the 90-day oral toxicity study in dogs.

The Organization for Economic Cooperation and Development (OECD) 421 Reproduction/Developmental Toxicity Screening Test, "secondary alcohol ethoxylate", shows that parental, offspring and reproduction toxicity occur at 470 mg/kg/day. Maternal toxicity is manifested as decreased body weight and body weight gain, decreased food consumption, and clinical signs (ptosis and hypoactivity); offspring toxicity is manifested as decreased litter size, increased post-implantation loss, and microscopic changes of the testes and epididymides; and reproduction toxicity is manifested as a slightly increased incidence of microscopic changes of the testes and epididymides (testicular atrophy, increased intraluminal exfoliated spermatogenic cells in epididymides, and dilated seminiferous tubules). The parental, offspring and reproduction NOAELs are 168 mg/kg/day. Although fetal qualitative susceptibility is observed in this study, concern is low because it occurs only in the presence of maternal toxicity. Also, the cRfD is protective of these effects.

Poly(oxy-1,2-ethanediyl), α-(3-carboxy-1-oxosulfopropyl)-ω-hydroxy-, alkyl (C_{10}-C_{16}) ethers, disodium salts are not expected to be carcinogenic based on the lack of structural alerts for carcinogenicity in the Derek Nexus analysis. Also, they are not mutagenic based on the Ames and chromosomal aberration tests.

Neurotoxicity and immunotoxicity studies are not available for review. However, evidence of neurotoxicity and immunotoxicity is not observed in the submitted studies.

Poly(oxy-1,2-ethanediyl), α-(3-carboxy-1-oxosulfopropyl)-ω-hydroxy-, alkyl (C_{10}-C_{16}) ethers, disodium salts are expected to be metabolized similar to alkyl alcohol alkoxylates. These metabolites are expected to be further metabolized through degradation of the ether linkage resulting in the corresponding alkyl alcohol and polyalkoxylate group which would undergo further oxidative degradation and/or excretion. Excreted materials are mainly lower molecular weight POE-like compounds, carbon dioxide and water. Longer alkyl chain lengths are excreted at a higher proportion into expired air and less in urine and longer POE chain lengths lead to more being excreted via the feces and expired air.

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*.

An acute effect was not found in the database therefore an acute dietary assessment is not necessary. The 90-day oral toxicity study in dogs was selected for the chronic exposure for this risk assessment. The NOAEL in this study was 140 mg/kg/day. The LOAEL was 565 mg/kg/day based on decreased bodyweight. This study represents the lowest NOAEL in the database in the most sensitive species. The dermal and inhalation absorption rates were assumed to be 100%. The standard inter- and intra-species uncertainty factors were applied. The FQPA safety factor of 10X was reduced to 1X.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses*. In evaluating dietary exposure to poly(oxy-1,2-ethanediyl), α-(3-carboxy-1-oxosulfopropyl)-ω-hydroxy-, alkyl (C_{10}-C_{16}) ethers, disodium salts, EPA considered exposure under the proposed exemption from the requirement of a tolerance. EPA assessed dietary exposures from poly(oxy-1,2-ethanediyl), α-(3-carboxy-1-oxosulfopropyl)-ω-hydroxy-, alkyl (C_{10}-C_{16}) ethers, disodium salts in food as follows:

Dietary exposure (food and drinking water) to poly(oxy-1,2-ethanediyl), α-(3-carboxy-1-oxosulfopropyl)-ω-hydroxy-, alkyl (C_{10}-C_{16}) ethers, disodium salts can occur following ingestion of foods with residues from treated crops. Because no adverse effects attributable to a single exposure of poly(oxy-1,2-ethanediyl), α-(3-carboxy-1-oxosulfopropyl)-ω-hydroxy-, alkyl (C_{10}-C_{16}) ethers, disodium salts are seen in the toxicity databases, an acute dietary risk assessment is not necessary. For the chronic dietary risk assessment, EPA used the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID™, Version 3.16, and food

consumption information from the U.S. Department of Agriculture's (USDA's) 2003-2008 National Health and Nutrition Examination Survey, What We Eat in America (NHANES/WWEIA). One hundred percent crop treated was assumed, default processing factors, and tolerance-level residues for all foods and use limitations of not more than 10% by weight in pesticide formulations.

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 poly(oxy-1,2-ethanediyl), α-(3-carboxy-1-oxosulfopropyl)-ω-hydroxy-, alkyl (C_{10}-C_{16}) ethers, disodium salts, 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).

Poly(oxy-1,2-ethanediyl), α-(3-carboxy-1-oxosulfopropyl)-ω-hydroxy-, alkyl (C_{10}-C_{16}) ethers, disodium salts may be used in inert ingredients in products that are registered for specific uses that may result in residential exposure, such as pesticides used in and round the home, personal (care) products, and cosmetics. The Agency conducted an assessment to represent worst-case residential exposure by assessing poly(oxy-1,2-ethanediyl), α-(3-carboxy-1-oxosulfopropyl)-ω-hydroxy-, alkyl (C_{10}-C_{16}) ethers, disodium salts in pesticideformulations (outdoor scenarios) and in disinfectant-type uses (indoor scenarios).

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 poly(oxy-1,2-ethanediyl), α-(3-carboxy-1-oxosulfopropyl)-ω-hydroxy-, alkyl (C_{10}-C_{16}) ethers, disodium salts to share a common mechanism of toxicity with any other substances, and poly(oxy-1,2-ethanediyl), α-(3-carboxy-1-oxosulfopropyl)-ω-hydroxy-, alkyl (C_{10}-C_{16}) ethers, disodium salts do not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that poly(oxy-1,2-ethanediyl), α-(3-carboxy-1-oxosulfopropyl)-ω-hydroxy-, alkyl (C_{10}-C_{16}) ethers, disodium salts do 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 toxicity database for poly(oxy-1,2-ethanediyl), α-(3-carboxy-1-oxosulfopropyl)-ω-hydroxy-, alkyl (C_{10}-C_{16}) ethers, disodium salts contains two subchronic studies, a reproduction/developmental toxicity screening study, and mutagenicity studies. There is no indication of neurotoxicity or immunotoxicity in the available studies; therefore, there is no need to require neurotoxicity or immunotoxicity studies. Qualitative fetal susceptibility was observed in the 2-generation toxicity study in rats. However, concern for fetal effects are low since they only occurred in the presence of maternal toxicity and protecting against maternal toxicity will subsequently prevent fetal toxicity. In addition, the cRfD, 1.40 mg/kg/day, will be protective of fetal effects. In addition, the Agency used conservative exposure estimates, with 100 percent crop treated, tolerance-level residues, conservative drinking water modeling numbers, and a worst-case assessment of potential residential exposure for infants and children. Therefore, the FQPA SF of 10X is 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, poly(oxy-1,2-ethanediyl), α-(3-carboxy-1-oxosulfopropyl)-ω-hydroxy-, alkyl (C_{10}-C_{16}) ethers, disodium salts 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 , poly(oxy-1,2-ethanediyl), α-(3-carboxy-1-oxosulfopropyl)-ω-hydroxy-, alkyl (C_{10}-C_{16}) ethers, disodium salts from food and water will utilize 10.3 % of the cPAD for children 1 to 2 years old, the population group receiving the greatest exposure.

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).

Poly(oxy-1,2-ethanediyl), α-(3-carboxy-1-oxosulfopropyl)-ω-hydroxy-, alkyl(C_{10}-C_{16}) ethers, disodium salts may be used as inert ingredients in pesticide products 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 poly(oxy-1,2-ethanediyl), α-(3-carboxy-1-oxosulfopropyl)-ω-hydroxy-, alkyl (C_{10}-C_{16}) ethers, disodium salts. Using the exposure assumptions described above, EPA has concluded that the combined short-term aggregated food, water, and residential exposures result in MOEs of 151 for both adult males and females respectively. Adult residential exposure combines high-end dermal and inhalation handler exposure from indoor hard surface, wiping with a high-end post application dermal exposure from contact with treated lawns. As the level of concern is for MOEs that are lower than 100, this MOE is not of concern. EPA has concluded the combined

short-term aggregated food, water, and residential exposures result in an aggregate MOE of 430 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 MOEs is 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).

Poly(oxy-1,2-ethanediyl), α-(3-carboxy-1-oxosulfopropyl)-ω-hydroxy-, alkyl (C_{10}-C_{16}) ethers, disodium salts may be used as inert ingredients in pesticide products 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 poly(oxy-1,2-ethanediyl), α-(3-carboxy-1-oxosulfopropyl)-ω-hydroxy-, alkyl (C_{10}-C_{16}) ethers, disodium salts. Using the exposure assumptions described above, EPA has concluded that the combined intermediate-term aggregated food, water, and residential exposures result in aggregate MOEs of 1637 for adult males and females. Adult residential exposure combines Indoor hard surface, wiping with a high end post application dermal exposure from contact with treated lawns. As the level of concern is for MOEs that are lower than 100, this MOE is not of concern. EPA has concluded the combined intermediate-term aggregated food, water, and residential exposures result in an aggregate MOE of 597 for children. Children's residential exposure includes total exposures associated with contact with treated surfaces (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*. Based on a DEREK structural alert analysis and the lack of mutagenicity, poly(oxy-1,2-ethanediyl), α-(3-carboxy-1-oxosulfopropyl)-ω-hydroxy-, alkyl (C_{10}-C_{16}) ethers, disodium salts are considered not

expected to pose a cancer risk to humans.

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 poly(oxy-1,2-ethanediyl), α-(3-carboxy-1-oxosulfopropyl)-ω-hydroxy-, alkyl (C_{10}-C_{16}) ethers, disodium salts residues.

V. Other Considerations

Analytical Enforcement Methodology

An analytical method is not required for enforcement purposes since the Agency is not establishing a numerical tolerance for residues of poly(oxy-1,2-ethanediyl), α-(3-carboxy-1-oxosulfopropyl)-ω-hydroxy-, alkyl (C_{10}-C_{16}) ethers, disodium salts in or on any food commodities. EPA is establishing a limitation on the amount of poly(oxy-1,2-ethanediyl), α-(3-carboxy-1-oxosulfopropyl)-ω-hydroxy-, alkyl (C_{10}-C_{16}) ethers, disodium salts that may be used in pesticide formulations applied to growing crops. 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 formulation for use on growing crops for sale or distribution that exceed 10% of poly(oxy-1,2-ethanediyl), α-(3-carboxy-1-oxosulfopropyl)-ω-hydroxy-, alkyl (C_{10}-C_{16}) ethers, disodium salts.

VI. Conclusions

Therefore, an exemption from the requirement of a tolerance is established under 40 CFR 180.910 for the following when used as inert ingredients (surfactants) in pesticide products at a concentration not to exceed 10% in the end-use formulation.

VII. Statutory and Executive Order Reviews

This action establishes exemptions to the requirement for a tolerance under FFDCA section 408(d) 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 action has been exempted from review under Executive Order 12866, this action 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 action 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 FFDCA section 408(d), such as the exemptions 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 action 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 FFDCA section 408(n)(4). 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 action. In addition,

this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq*.).

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 (NTTAA) (15 U.S.C. 272 note).

VIII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), 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 the rule in the **Federal Register**. This action 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: January 19, 2016.

Susan Lewis,
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(s) 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-(3-carboxy-1-oxosulfopropyl)-ω-hydroxy-, C_{10-12}-alkyl ethers, disodium salts, the poly(oxyethylene) content averages 5-15 moles (CAS Reg. No. 68954-91-6)	Not to exceed 10% by weight of pesticide formulation.	Surfactant
* * * * * * *		
Poly(oxy-1,2-ethanediyl), α-(3-carboxy-1-oxosulfopropyl)-ω-hydroxy-, C_{10-16}-alkyl ethers, disodium salts, the poly(oxyethylene) content averages 5-15 moles (CAS Reg, No. 68815-56-5)	Not to exceed 10% by weight of pesticide formulation.	Surfactant
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Poly(oxy-1,2-ethanediyl), α-(3-carboxy-1-oxosulfopropyl)-ω-hydroxy-, C_{12-14}-alkyl ethers, disodium salts, the poly(oxyethylene) content averages 5-15 moles (CAS Reg. No. 1024612-24-5)	Not to exceed 10% by weight of pesticide formulation.	Surfactant
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Poly(oxy-1,2-ethanediyl), α-(3-carboxy-1-oxosulfopropyl)-ω-(isotridecyloxy)-, sodium salt (1:2), the poly(oxyethylene) content	Not to exceed 10% by weight of pesticide formulation.	Surfactant

averages 5-15 moles (CAS Reg. No. 1013906-64-3)		
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