



BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2017-0666; FRL-9976-39]

Ethoxylated Fatty Acid Methyl Esters; 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 -(1-oxoalkyl)- ω -methoxy-, where the alkyl chain contains a minimum of 6 and a maximum of 18 carbons and the oxyethylene content is 3-13 moles, when used as an inert ingredient (stabilizer and solubilizing agent) in pesticide formulations applied to growing crops or raw agricultural commodities after harvest at a concentration not to exceed 25% by weight in the formulation. This related group of compounds are collectively known as the ethoxylated fatty acid methyl esters (EFAMEs). BASF Corporation submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting establishment of an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of ethoxylated fatty acid methyl esters when used in accordance with the terms of the exemption.

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-2017-0666, 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: Michael Goodis, 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-2017-0666 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-2017-0666, 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 February 27, 2018 (83 FR 8408) (FRL-9972-17), EPA issued a document pursuant to FFDCA section 408, 21 U.S.C. 346a, announcing the filing of a pesticide petition (PP IN-11023) by BASF Corporation, 100 Park Avenue, Florham Park, NJ 07932. 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 -(1-oxoalkyl)- ω -methoxy-, where the alkyl chain contains a minimum of 6 and a maximum of 18 carbons and the oxyethylene content is 3-13 moles (CAS Reg. Nos. 53100-65-5, 194289-64-0, 34398-00-0, 9006-27-3, 32761-35-6, 53467-81-5, 518299-31-5, 34397-99-4) when used as an inert ingredient (stabilizer and solubilizing agent) in pesticide formulations applied to growing crops or raw agricultural commodities after harvest at a concentration not to exceed 25% by weight in the formulation. That document referenced a summary of the petition prepared by BASF Corporation, the petitioner, which is available in the docket, <http://www.regulations.gov>. No comments were received in response to the notice of filing that are relevant to establishment of this exemption.

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 ethoxylated fatty acid methyl esters including exposure resulting from the exemption established by this action. EPA's assessment of exposures and risks associated with ethoxylated fatty acid methyl esters 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. A series of acute toxicology studies have been conducted with representative EFAMEs. The acute toxicity study test substance was C6-10 ethoxylated fatty acid methyl ester (degree of ethoxylation is 10.6 EO). The studies show that the EFAMEs are practically non-toxic when ingested or inhaled via acute exposure. Skin and eye irritation studies indicate that the EFAMEs are slight skin and eye irritants. The skin sensitization potential of the EFAMEs could not be determined based on the ambiguous result in the Buehler assay.

The genotoxicity studies conducted with representative EFAMEs including bacterial reverse mutation (Ames) test, mouse micronucleus assay and an *in vitro* mouse lymphoma assay were negative.

Repeat dose data are not available for the EFAMEs; however, several repeat dose studies have been conducted with fatty acid methyl/alkyl esters and alcohol ethoxylates and these studies can be bridged to the EFAMEs based upon the structural similarities between EFAMEs and alcohol ethoxylates which are both nonionic surfactants in which the surfactant properties of each generally result in similar toxicological effects, at comparable dose levels) and the structural similarities of EFAMEs with fatty acid methyl/alkyl esters (both having terminal methoxy or alkoxy groups bound to a fatty acid or fatty acid derivative). The NOAEL of 50 mg/kg/day from a chronic rat oral feeding study is the lowest NOAEL observed and is equal to the lowest NOAEL seen in the subchronic feeding studies. The lowest LOAEL in the subchronic studies, as well as the LOAEL in the chronic rat oral feeding study was established at 250 mg/kg/day based on reduced food consumption and body weight gain. In a dermal toxicity study no signs of tumors were observed and the dermal NOAEL was reported to be 300 mg/kg/day. Most of the 90-day studies reported NOAELs ranging from 50-200 mg/kg/day.

The NOAELs for reproductive performance of males and females, as well as off- spring toxicity are considered to range from > 250 mg/kg/day to 1,000 mg/kg/day. None of the studies reported adverse reproductive, developmental, neurotoxic, or immunotoxic effects at dose levels below the range of > 250 mg/kg/day to 1,000 mg/kg/day.

Specific information on the studies received and the nature of the adverse effects caused by ethoxylated fatty acid methyl esters as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at <http://www.regulations.gov> in the document

Ethoxylated Fatty Acid Methyl Esters (CAS Reg. Nos. 53100-65-5, 194289-64-0, 34398-00-0, 9006-27-3, 32761-35-6, 53467-81-5, 518299-31-5, 34397-99-4); “Human Health Risk Assessment and Ecological Effects Assessment to Support Proposed Exemption from the Requirement of a Tolerance When Used as an Inert Ingredient” in docket ID number EPA-HQ-OPP-2017-0666.

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 effect attributed to a single dose was not identified in the toxicology database. The point of departure for chronic dietary exposures as well as dermal and inhalation exposures is based on a NOAEL of 50 mg/kg/day from a chronic oral feeding study in rats with the EFAMEs surrogate chemical, alcohol ethoxylate. In this study, the LOAEL was 250 mg/kg/day based upon reduced food consumption and body weight gain and elevated organ-to-body weight ratios. This

represents the lowest NOAEL in the most sensitive species in the toxicity database. The standard uncertainty factors were applied to account for interspecies (10x) and intraspecies (10x) variations. The FQPA safety factor was reduced to 1x to account for completeness of the toxicity and exposure database and lack of increased prenatal or postnatal sensitivity as well as a lack of concern for neurotoxicity. A dermal absorption factor of 100% was used and a default value of 100% absorption was used for the inhalation absorption factor. The resultant chronic population adjusted dose (cPAD) is 0.5 mg/kg/day and acceptable MOEs for residential exposures are ≥ 100 .

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to ethoxylated fatty acid methyl esters, EPA considered exposure under the proposed exemption from the requirement of a tolerance. EPA assessed dietary exposures from ethoxylated fatty acid methyl esters in food as follows.

Dietary exposure (food and drinking water) to ethoxylated fatty acid methyl esters can occur following ingestion of foods with residues from treated crops. Because no adverse effects attributable to a single exposure of ethoxylated fatty acid methyl esters 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). As to residue levels in food, no residue data were submitted for ethoxylated fatty acid methyl esters. 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. One hundred percent crop treated was assumed, default processing factors, and tolerance-level residues for all foods and use limitations of not more than 25% in pesticide formulations. 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.

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 ethoxylated fatty acid methyl esters, 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). Ethoxylated fatty acid methyl esters may be used as inert ingredients in products that are registered for specific uses that may result in residential exposure, such as pesticides used in and around the home. The Agency conducted a conservative assessment of potential residential exposure by assessing ethoxylated fatty acid methyl esters in pesticide formulations (outdoor scenarios) and in disinfectant-type uses (indoor scenarios). The Agency’s assessment of adult residential exposure combines high-end dermal and inhalation handler exposure from liquids/trigger

sprayer/home garden and indoor hard surface, wiping with a high-end post application dermal exposure from contact with treated lawns. The Agency's assessment of children's residential exposure includes total post-application exposures associated with total exposures associated with contact with treated lawns and surfaces (dermal and hand-to-mouth exposures).

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCFA 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 ethoxylated fatty acid methyl esters to share a common mechanism of toxicity with any other substances, and ethoxylated fatty acid methyl esters does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that ethoxylated fatty acid methyl esters does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at <http://www.epa.gov/pesticides/cumulative>.

D. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(C) of FFDCFA 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 ethoxylated fatty acid methyl esters contains subchronic and developmental toxicity studies conducted with surrogate chemicals. The NOAELs for reproductive performance of males and females, as well as offspring toxicity are considered to range from > 250 mg/kg/day to 1,000 mg/kg/day. None of the studies reported effects on the reproductive system or effects indicative of neurotoxicity.

The established cRfD will be protective of the observed adverse effect, decreased body weight gain and food consumption, which was observed at dose levels much lower than potential adverse effects to infants or children. In addition, the Agency used conservative exposure estimates, with 100 percent crop treated, tolerance-level residues, conservative drinking water modeling numbers, and a conservative assessment of potential residential exposure for infants and children. Based on the adequacy of the toxicity database, the conservative nature of the exposure assessment, and the lack of concern for prenatal and postnatal sensitivity as well as neurotoxicity, the Agency has concluded that there is reliable data to determine that infants and children will be safe if the FQPA SF of 10X is reduced to 1X.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic pesticide exposures are safe by comparing aggregate exposure estimates to the acute population adjusted dose (aPAD) and chronic population adjusted dose (cPAD). The aPAD and cPAD represent the highest safe exposures, taking into account all appropriate safety factors (SFs). EPA calculates the aPAD and cPAD by dividing the POD (i.e. toxicological endpoint) by all applicable UFs. For linear cancer risks, EPA calculates the probability of additional cancer cases given the estimated aggregate exposure. Short, intermediate, and long term aggregate risks are evaluated by comparing the estimated

aggregate food, water, and residential exposure to the POD to ensure that the MOE called for by the product of all applicable UFs is not exceeded.

Although there are no known current residential uses associated with EFAMEs, a residential exposure assessment was conducted. The level of concern for residential uses (i.e. non-occupational, non-dietary exposure) associated with the EFAMEs is low. The level of MOEs for combined residential exposure is above 100.

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, the EFAMEs are 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 EFAMEs from food and water will utilize 70% of the cPAD for children 1-2 years old, the population group receiving the greatest exposure. Generally, a dietary risk estimate that is less than 100% of the cPAD does not exceed the Agency's risk concerns.

3. *Short- intermediate- and long-term risk.* Short- intermediate- and long-term aggregate exposure takes into account short-, intermediate- and long- term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). The Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short-, intermediate- and water with sort-, intermediate- and long-term residential exposures to EFAMEs. Using the exposure assumptions describe in this unit for short-term exposures, EPA has concluded the combined respective short-, intermediate- and long- term food water, and residential exposures resulted in aggregate margin of exposures (MOE) of 335

for adults and 122 for children. Because EPA's level of concern for EFAMEs is a MOE of 100 or below, these MOEs are not of concern.

4. *Aggregate cancer risk for U.S. population.* Based on the discussion in Unit IV. A., EFAMEs is not expected to pose a cancer risk.

5. *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 ethoxylated fatty acid methyl esters residues.

V. Analytical Enforcement Methodology

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. EPA is establishing limitations on the amount of EFAMEs that may be used in pesticide formulations applied to growing crops. These limitations 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 or raw agricultural commodities after harvest for sale or distribution that exceeds 25% by weight of EFAMEs.

VI. Conclusion

Therefore, an exemption from the requirement of a tolerance is established under 40 CFR 180.910 for poly(oxy-1,2-ethanediyl), α -(1-oxoalkyl)- ω -methoxy-, where the alkyl chain contains a minimum of 6 and a maximum of 18 carbons and the oxyethylene content is 3-13 moles (CAS Reg. No. 53100-65-5, 194289-64-0, 4398-00-0, 9006-27-3, 32761-35-6, 53467-81-5, 518299-31-5, and 34397-99-4) when used as an inert ingredient (stabilizer and solubilizing agent) in pesticide formulations applied to growing crops or raw agricultural commodities after harvest at a concentration not to exceed 25% by weight in the formulation.

VII. Statutory and Executive Order Reviews

This action establishes an exemption from the requirement of a tolerance under FFDC 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); Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997); or Executive Order 13771, entitled “Reducing Regulations and Controlling Regulatory Costs” (82 FR 9339, February 3, 2017). 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 FFDC section 408(d), 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 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 FFDC 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: May 11, 2018.

Donna Davis,
Acting Director, Registration Division, Office of Pesticide Program.

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 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 -(1-oxoalkyl)- ω -methoxy-, where the alkyl chain contains a minimum of 6 and a maximum of 18 carbons and the oxyethylene content is 3-13 moles (CAS Reg. No. 53100-65-5, 194289-64-0, 34398-00-0, 9006-27-3, 32761-35-6, 53467-81-5, 518299-31-5, and 34397-99-4)	Not to exceed 25% by weight in pesticide formulation	Stabilizer, solubilizing agent
* * * *	* *	*