ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2009–0131; FRL–8836–5]

Alkyl Alcohol Alkoxylate Phosphate Derivatives; 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 alkyl alcohol alkoxylate phosphate derivatives (AAAPD) when used under 40 CFR part 910 as an inert ingredient—surfactant and related adjuvants of surfactants for pre- and post-harvest uses and application to animals in pesticide formulations under 40 CFR part 930, limited to a maximum of 30% by weight in end-use products. The Joint Inerts Task Force (JITF), Cluster Support Team Number 2 (CST 2) 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 AAAPDs.

DATES: This regulation is effective August 20, 2010. Objections and requests for hearings must be received on or before October 19, 2010, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2009–0131. 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: Lisa Austin, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–7894; e-mail address: *austin.lisa@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 cite at *http://www.gpoaccess.gov/ecfr*. To access the OPPTS harmonized test guidelines referenced in this document electronically, please go to *http://www.epa.gov/oppts* and select "Test Methods and Guidelines."

C. Can I File an Objection or Hearing Request?

Under section 408(g) of FFDCA, 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2009–0131 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 October 19, 2010. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket that is described in **ADDRESSES**. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit your copies, identified by docket ID number EPA–HQ–OPP–2009–0131, 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 February 4, 2010 (75 FR 5793) (FRL–8807–5), EPA issued a notice pursuant to section 408 of FFDCA, 21 U.S.C. 346a, announcing the filing of a pesticide petition (PP 9E7628) by the Joint Inerts Task Force, Cluster Support Team 2 (CST 2), c/o CropLife America, 1156 15th Street, NW., Suite 400, Washington, DC 20005. The petition requested that 40 CFR 180.910 and 40 CFR 180.930 be amended by establishing an exemption from the requirement of a tolerance for residues of AAAPDs when used as an inert ingredient surfactant and related adjuvants of surfactants in pesticide formulations applied to growing crops, raw agricultural commodities and food-producing animals limited to a maximum of 30% by weight in end-use

products for the α-alkyl (minimum C_6 linear or branched, saturated and or unsaturated)-ω-hydroxypolyoxyethylene polymer with or without polyoxypropylene, mixture of di- and monohydrogen phosphate esters and the corresponding ammonium, calcium, magnesium, monoethanolamine, potassium, sodium and zinc salts of the phosphate esters; minimum oxyethylene content averages 2 moles; minimum oxypropylene content is 0 moles, including: Poly(oxy-1 ,2-ethanediyl), α-tridecyl- ω -hydroxy-, phosphate (9046–01–9); Poly(oxy-1 ,2-ethanediyl), α-dodecyl-ω-hydroxy-, phosphate (39464–66–9); Poly(oxy-1 ,2-ethanediyl), α-hexadecyl-ω-hydroxy-, phosphate (50643–20–4); Poly(oxy-1 ,2-ethanediyl), α-decyl-ω-hydroxy-, phosphate (52019–36–0); Poly(oxy-1 ,2-ethanediyl), α-hydro-ω-hydroxy-, mono-$C_{12–15}$-alkyl ethers, phosphates (68071–35–2); Polyphosphoric acids, esters with polyethylene glycol decyl ether (68458–48–0); Poly(oxy-1 ,2-ethanediyl), α-hydro-ω-hydroxy-, mono-$C_{10–14}$-alkyl ethers, phosphates (68585–36–4); Poly(oxy-1,2-ethanediyl), α-hydro-ω-hydroxy-, mono-$C_{12–15}$-branched alkyl ethers, phosphates (68815–11–2); Poly(oxy-1 ,2-ethanediyl), α-hydro-ω-hydroxy-, mono-$C_{10–12}$-alkyl ethers, phosphates (68908–64–5); Poly(oxy-1 ,2-ethanediyl), α-hydro-ω-hydroxy-, mono-$C_{12–14}$-aIkyl ethers, phosphates (68511–37–5); Poly(oxy-1 ,2-ethanediyl), α-hydro-ω-hydroxy-, mono-$C_{8–10}$-alkyl ethers, phosphates (68130–47–2); Poly(oxy-1 ,2-ethanediyl), α-dodecyl-ω-hydroxy-, phosphate, sodium salt (42612–52–2); Poly(oxy-1 ,2-ethanediyl), α-dodecyl-ω-hydroxy-, phosphate, potassium salt (58318–92–6); Poly(oxy-1 ,2-ethanediyl), α-hexadecyl-ω–hydroxy-, phosphate, potassium salt (60267–55–2); Poly(oxy-1 ,2-ethanediyl), α-decyl- ω hydroxy-, phosphate, potassium salt (68070–99–5); Poly(oxy-1,2-ethanediyl), α-tridecyl-ω-hydroxy-, phosphate, potassium salt (68186–36–7); Poly(oxy1,2-ethanediyl), α-decyl-ω-hydroxy-, phosphate, sodium salt (68186–37–8); Poly(oxy-1,2-ethanediyl), α-hydro-ω-hydroxy-, mono-$C_{12–15}$-alkyl ethers, phosphates, sodium salts (68610–65–1); Poly(oxy-1 ,2-ethanediyl), α-isodecyl- ω-hydroxy-, phosphate, potassium salt (68071–17–0); (branched C_{10}) Poly(oxy-1,2-ethanediyl), α-phosphono-ω-[(2- propylheptyl)oxy]-, potassium salt (1:2) (936100–29–7); (branched C_{10}) Poly(oxy-1,2-ethanediyl), α-phosphono-ω-[(2-propylheptyl)oxy]-, sodium salt (1:2) (936100–30–0); Poly(oxy-1,2- ethanediyl), α-isotridecyl-ω-hydroxy-, phosphate (73038–25–2); Poly(oxy-1 ,2- ethanediyl), α-hydro-ω-hydroxy-, mono-$C_{11–14}$-isoalkyl ethers, C_{13}-rich, phosphates (78330–24–2); Poly(oxy-1 ,2-ethanediyl),α-hydro-ω-hydroxy-, mono(C_{10}-rich $C_{9–11}$-isoalkyl) ethers, phosphates (154518–39–5); Poly(oxy-1 ,2-ethanediyl), α-hydro-ω-hydroxy-, mono-$C_{12–14}$-sec-alkyl ethers, phosphates (317833–96–8); Poly(oxy-1 ,2-ethanediyl), α-isodecyl-ω-hydroxy-, phosphate (108818–88–8); Poly(oxy-1, 2- ethanediyl), α-phosphono-ω-[(2-propylheptyl)oxy] (873662–29–4); Poly(oxy-1, 2-ethanediyl), α-dodecyl-ω-hydroxy-, phosphate, monoethanolamine salt (61837–79–4); Poly(oxy-1 ,2-ethanediyl), α-tridecyl-ω-hydroxy-, phosphate monoethanolamine salt (68311–02–4); Poly(oxy-1,2-ethanediyl), α-decyl-ω-hydroxy-, phosphate, monoethanolamine salt (68425–73–0); Oxirane, methyl-, polymer with oxirane, phosphate (37280–82–3); Oxirane, methyl-, polymer with oxirane, mono-$C_{10–16}$-alkyl ethers, phosphates (68649–29–6); Oxirane, methyl-, polymer with oxirane, phosphate, potassium salt (67711–84–6); and Oxirane, methyl-, polymer with oxirane, mono-$C_{10–16}$-alkyl ethers, phosphates, potassium salt (68891–13–4). That notice referenced a summary of the petition prepared by The Joint Inerts Task Force (JITF), Cluster Support Team Number 2 (CST 2), the petitioner, which is available in the docket, *http://www.regulations.gov*. There were no comments received in response to 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 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 AAAPDs including exposure resulting from the exemption established by this action. EPA's assessment of exposures and risks associated with AAAPDs 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 AAAPDs 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 AAAPDs are not acutely toxic by the oral and dermal routes of exposure under normal use conditions; however, concentrated materials are generally moderate to severe eye and skin irritants and may be skin sensitizers. Following subchronic exposure to rats, gastrointestinal irritation (increased incidences of hyperplasia, submucosal edema, and ulceration) was observed, but no specific target organ toxicity or neurotoxicity was seen. No neurotoxicological effects were detected in a functional observational battery or a motor activity assessment. No reproductive effects were noted in the database. There was a qualitative increase in susceptibility to pups seen in a rat developmental/reproductive toxicity screening study; however, effects were seen only in one study and were in the presence of maternal toxicity. Further, a clear NOAEL was established for the developmental effects and this NOAEL is significantly higher than the toxicological points of departure selected for risk assessment. There are no carcinogenicity concerns based on structure activity modeling. Points of departure for chronic dietary, incidental oral, inhalation, and dermal exposure were selected from a 2–generation reproduction and fertility effects study in rats. The endpoint was decreased absolute and relative liver weights and increased incidence in the number of animals with minimal hepatocyte necrosis in males.

Sufficient data were provided on the chemical identity of the AAAPDs; however, limited data are available on the metabolism and environmental degradation of these compounds. The Agency relied collectively on information provided on the representative chemical structures, the submitted physicochemical data, structure activity relationship (SAR) information, as well as information on other surfactants and chemicals of similar size and functionality to determine the residues of concern for the AAAPDs. The Agency has concluded that since metabolites and environmental degradates are not likely to be more toxic than the parent compounds, a risk assessment based on the parent compounds is not likely to underestimate risk.

Specific information on the studies received and the nature of the adverse effects caused by the AAAPSDs as well as the NOAEL and the LOAEL from the toxicity studies can be found at *http://www.regulations.gov* in the document "Alkyl Alcohol Alkoxylate Phosphate and Sulfate Derivatives (AAAPDs and AAASDs-JITF CST 2 Inert Ingredients). Human Health Risk Assessment to Support Proposed Exemption from the Requirement of a Tolerance When Used as Inert Ingredients in Pesticide," pp. 11–17 in docket ID number EPA–HQ–OPP–2009–0131.

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 (U/SF) 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 for AAADPs used for human risk assessment is discussed in Unit IV. of the final rule published in the **Federal Register** of July 29, 2009 (74 FR 37571) (FRL–8424–6).

C. Exposure Assessment

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

i. *Acute and chronic exposure*. In conducting the acute and chronic dietary exposure assessments, 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 the AAAPDs. 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 ingredients. 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 dietary exposure and risk assessment can be found at *http://www.regulations.gov* in "Alkyl Amines Polyalkoxylates (Cluster 4): Acute and Chronic Aggregate (Food and Drinking Water) Dietary Exposure and Risk Assessments for the Inerts" 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 concentrations of active ingredient in agricultural products are 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 AAAPDs, EPA made a specific adjustment to the dietary exposure assessment to account for the use limitations of the amount of AAAPDs that may be in formulations (to no more than 30% and assumed that the AAAPDs are present at the maximum limitation rather than at equal quantities with the active ingredient. This remains

a very conservative assumption because surfactants are generally used at levels far below this percentage. For example, EPA examined several of the pesticide products associated with the tolerance/commodity combination which are the driver of the risk assessment and found that these products did not contain surfactants at levels greater than 2.25% and that none of the surfactants were AAAPDs.

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.

ii. *Cancer*. The Agency used a qualitative structure activity relationship (SAR) database, DEREK11, to determine if there were structural alerts suggestive of carcinogenicity. No structural alerts for carcinogenicity were identified. The Agency has not identified any concerns for carcinogenicity relating to the inerts AAAPDs. Therefore a cancer dietary exposure assessment is not necessary to assess cancer risk.

iii. *Anticipated residue and percent crop treated (PCT) information*. EPA did not use anticipated residue and/or PCT information in the dietary assessment for AAAPDs. Tolerance level residues and/or 100 PCT 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 AAAPDs, a conservative drinking water concentration value of 100 parts per billion (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).

AAAPDs are used as inert ingredients in pesticide products that are registered for specific uses that could result in indoor residential exposures and may have uses as inert ingredients in pesticide products that may result in outdoor residential exposures.

A screening level residential exposure and risk assessment was completed for products containing AAAPDs as inert ingredients. In this assessment, representative scenarios, based on end-use product application methods and labeled application rates, were selected. For each of the use scenarios, the Agency assessed residential handler (applicator) inhalation and dermal exposure for use scenarios with high exposure potential (i.e., exposure scenarios with high-end unit exposure values) to serve as a screening assessment for all potential residential pesticides containing AAAPDs. Similarly, residential postapplication dermal and oral exposure assessments were also performed utilizing high-end exposure scenarios. Further details of this residential exposure and risk analysis can be found at *http://www.regulations.gov* in document "JITF Inert Ingredients. Residential and Occupational Exposure Assessment Algorithms and Assumptions Appendix for the Human Health Risk Assessments to Support Proposed Exemption from the Requirement of a Tolerance When Used as Inert Ingredients in Pesticide Formulations" 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 AAAPDs to share a common mechanism of toxicity with any other substances, and AAAPDs do not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that AAAPDs 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 Food Quality Protection Act Safety Factor (FQPA SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional SF when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity*. The toxicity database consists of Harmonized Test Guideline OPPTS 870.3650 (combined repeated dose toxicity study with the reproduction/developmental toxicity screening test) studies in rats conducted with representative AAAPDs, as well as a 2–generation rat reproduction toxicity (Harmonized Test Guideline OPPTS 870.3800) study and a rat developmental toxicity study conducted with a representative AAASD.

In one Harmonized Test Guideline OPPTS 870.3650 study conducted with a representative AAAPD, no increased susceptibility to the offspring of rats following prenatal and postnatal

exposure was observed. In a second Harmonized Test Guideline OPPTS 870.3650 study conducted with another representative AAAPD, there was evidence of increased qualitative susceptibility as indicated by the increased number of stillborn pups and pups dying within lactation day (LD) 4/5 and clinical observations (coldness to the touch, discolored heads, and a lack of nesting behavior) at 800 milligrams/kilogram/day (mg/kg/day) where lesions in the forestomach and thymus atrophy was observed in the parental animals. However, this qualitative susceptibility seen in the Harmonized Test Guideline OPPTS 870.3650 study does not indicate a heightened risk for infants and children because a clear NOAEL (200 mg/kg/day) was established for developmental effects and an additional margin of safety is provided since the point of departure selected from the 2–generation rat reproduction study for chronic exposure is 87 mg/kg/day.

In a rat developmental study with AAASD, no maternal or developmental toxicity was observed at the limit dose. In the 2–generation reproduction study with AAASD, the only significant effects observed were liver effects characterized by dose-related decrease in absolute and relative liver weight and an increased incidence in the number of animals with 'minimal" hepatocyte necrosis in males. No treatment-related effects were observed on reproduction or in the offspring.

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

i. The toxicity database for AAAPDs is considered adequate for assessing the risks to infants and children (the available studies are described in Unit IV.D.2.).

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

iii. Although increased qualitative susceptibility was demonstrated in the offspring in a reproductive/developmental screening test portion of an Harmonized Test Guideline OPPTS 870.3650 study with another AAAPD, the Agency did not identify any residual uncertainties after establishing toxicity endpoints and traditional UFs to be used in the risk assessment of the AAAPDs.

iv. There are no residual uncertainties identified in the exposure databases. The food and drinking water assessment is not likely to underestimate exposure to any subpopulation, including those comprised of infants and children. The food exposure assessments are considered to be highly conservative as they are based on the use of the highest tolerance level from the surrogate pesticides for every food and 100 PCT is assumed for all crops. EPA also made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to AAAPDs in drinking water. EPA used similarly conservative assumptions to assess postapplication exposure of children as well as incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by AAAPDs.

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.

In conducting this aggregate risk assessment, the Agency has incorporated the petitioner's requested use limitations of AAAPDs as inert ingredients in pesticide product formulations into its exposure assessment. Specifically the petition includes a use limitation of AAAPDs at not more than 30% by weight in pesticide formulations.

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, AAAPDs 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 AAAPDs from food and water will utilize 43% of the cPAD for children 1–2 yrs 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).

AAAPDs are currently used as an inert ingredient in pesticide products that are 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 AAAPDs.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the combined short-term food, water, and residential exposures result in aggregate MOEs of 130 and 140, for adult males and females respectively, for a combined high-end dermal and inhalation handler exposure with a high-end postapplication dermal exposure and an aggregate MOE of 110 for children for a combined turf dermal exposure with hand-to-mouth exposure. Because EPA's level of concern for AAAPDs is a MOE of 100 or below, these MOEs are not of concern.

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

AAAPDs are currently used as an inert ingredient in pesticide products that are 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 AAAPDs.

Using the exposure assumptions described in this unit for intermediate-term exposures, EPA has concluded that the combined intermediate-term food, water, and residential exposures result in aggregate MOEs of 270 and 280, for adult males and females respectively, for a combined high-end dermal and inhalation handler exposure with a high-end postapplication dermal exposure and an MOE of 110 for children for a combined high-end dermal exposure with hand-to-mouth exposure. Because EPA's level of concern for AAAPDs are a MOE of 100 or below, these MOEs are not of concern.

5. *Aggregate cancer risk for U.S. population*. Based on the lack ofstructural alerts for carcinogenicity, AAAPDs are 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 AAAPDs residues.

V. Other Considerations

A. Analytical Enforcement Methodology

EPA is establishing a limitation on the amount of AAAPDs 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 30% of AAAPDs by weight in the end-use pesticide formulation.

B. International Residue Limits

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

VI. Conclusions

Therefore, an exemption from the requirement of a tolerance is established under 40 CFR 180.910 and 40 CFR 180.930 for AAAPDs when used as an inert ingredient (surfactants, related adjuvants of surfactants) in pesticide formulations applied to raw agricultural commodities, growing crops, and animals.

VII. Statutory and Executive Order Reviews

This final rule establishes a tolerance under section 408(d) of FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of FFDCA, such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq*.) do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note).

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: August 10, 2010.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

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

PART 180—[AMENDED]

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

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

■ 2. In § 180.910, the table is amended by adding alphabetically the following inert ingredients to read as follows:

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

* * * * *

Inert ingredients	Limits	Uses
* *	* * *	
α-alkyl (minimum C6 linear or branched, saturated and or unsaturated)-ω-hydroxypolyoxyethylene polymer with or without polyoxypropylene, mixture of di- and monohydrogen phosphate esters and the corresponding ammonium, calcium, magnesium, monoethanolamine, potassium, sodium and zinc salts of the phosphate esters; minimum oxyethylene content averages 2 moles; minimum oxypropylene content is 0 moles (CAS Reg. Nos. 9046–01–9, 39464–66–9, 50643–20–4, 52019–36–0, 68071–35–2, 68458–48–0, 68585–36–4, 68815–11–2, 68908–64–5, 68511–37–5, 68130–47–2, 42612–52–2, 58318–92–6, 60267–55–2, 68070–99–5, 68186–36–7, 68186–37–8, 68610–65–1, 68071–17–0, 936100–29–7, 936100–30–0, 73038–25–2, 78330–24–2, 154518–39–5, 317833–96–8, 108818–88–8, 873662–29–4, 61837–79–4, 68311–02–4, 68425–73–0, 37280–82–3, 68649–29–6, 67711–84–6, 68891–13–4.	Not to exceed 30% of pesticide formulation	Surfactants, related adjuvants of surfactants

Inert ingredients	Limits	Uses
* *	* * *	

* * * * *

■ 3. In § 180.930, the table is amended by adding alphabetically the following inert ingredients to read as follows:

§ 180.930 Inert ingredients applied to animals; exemptions from the requirement of a tolerance.

* * * * *

Inert ingredients	Limits	Uses
* *	* * *	
α-alkyl (minimum C_6 linear or branched, saturated and or unsaturated)-ω-hydroxypolyoxyethylene polymer with or without polyoxypropylene, mixture of di- and monohydrogen phosphate esters and the corresponding ammonium, calcium, magnesium, monoethanolamine, potassium, sodium and zinc salts of the phosphate esters; minimum oxyethylene content averages 2 moles; minimum oxypropylene content is 0 moles (CAS Reg. Nos. 9046–01–9, 39464–66–9, 50643–20–4, 52019–36–0, 68071–35–2, 68458–48–0, 68585–36–4, 68815–11–2, 68908–64–5, 68511–37–5, 68130–47–2, 42612–52–2, 58318–92–6, 60267–55–2, 68070–99–5, 68186–36–7, 68186–37–8, 68610–65–1, 68071–17–0, 936100–29–7, 936100–30–0, 73038–25–2, 78330–24–2, 154518–39–5, 317833–96–8, 108818–88–8, 873662–29–4, 61837–79–4, 68311–02–4, 68425–73–0, 37280–82–3, 68649–29–6, 67711–84–6, 68891–13–4.	Not to exceed 30% of pesticide formulation	Surfactants, related adjuvants of surfactants
* *	* * *	

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[FR Doc. 2010–20708 Filed 8–19–10; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2002–0185; FRL–8838–3]

2-methyl-1,3-propanediol; 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 2-methyl-1,3-propanediol (CAS Reg. No. 2163-42-0) when used as an inert ingredient in pesticide formulations applied to growing crops and raw agricultural commodities after harvest, and when used as an inert ingredient solvent and/or surfactant in pesticide formulations applied to animals (used for food). Lyondell Chemical Company 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 2-methyl-1,3-propanediol.

DATES: This regulation is effective August 20, 2010. Objections and requests for hearings must be received on or before October 19, 2010, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2002–0185. 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: Keri Grinstead, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–8373; e-mail address: *grinstead.keri@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