List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: July 30, 2009.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

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

PART 180—[AMENDED]

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

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

■ 2. In § 180.920, the table is amended by adding alphabetically the following inert ingredients:

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

* * * * *

Inert Ingredients	Limits	Uses
* * * * * *	*	
Diethanolamine salts of alkyl (C_8-C_{24}) benzenesulfonic acid (CAS Reg. Nos. 26545–53–9 and 68953–97–9).	Not to exceed 7% of pesticide formulation.	Surfactants, related adjuvants of surfactants
* * * * * *	*	
Dimethylaminopropylamine, isopropylamine, ethanolamine, and triethanolamine salts of alkyl (C_8-C_{24}) benzenesulfonic acid (CAS Reg. Nos. 26264–05–1, 27323–41–7, 55470–69–4, 68411–31–4, 68584–24–7, 68584–25–8, 68648–81–7, 68648–96–4, 68649–00–3, 68910–32–7, 68953–93–5, 90194–42–6, 90194–53–9, 90218–35–2, 157966–96–6, 319926–68–6, 877677–48–0, 1093628–27–3).		Surfactants, related adjuvants of surfactants
* * * * * *	*	

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

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

* * * * *

Inert Ingredients	Limits	Uses
* * * * * *	*	
Diethanolamine salts of alkyl (C_8-C_{24}) benzenesulfonic acid (CAS Reg. Nos. 26545–53–9 and 68953–97–9).	Not to exceed 7% of pesticide formulation.	Surfactants, related adjuvants of surfactants
* * * * * *	*	
Dimethylaminopropylamine, isopropylamine, ethanolamine, and triethanolamine salts of alkyl (C_8-C_{24}) benzenesulfonic acid (CAS Reg. Nos. 26264–05–1, 27323–41–7, 55470–69–4, 68411–31–4, 68584–24–7, 68584–25–8, 68648–81–7, 68648–96–4, 68649–00–3, 68910–32–7, 68953–93–5, 90194–42–6, 90194–53–9, 90218–35–2, 157966–96–6, 319926–68–6, 877677–48–0, 1093628–27–3).		Surfactants, related adjuvants of surfactants
* * * * * *	*	

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2009–0145; FRL–8430–1]

Alkyl Alcohol Alkoxylates; 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 α-alkyl-ω-hydroxypoly (oxypropylene) and/or poly (oxyethylene) polymers where the alkyl chain contains a minimum of six carbons when used as an inert ingredient in pesticide formulations. The Joint Inerts Task Force (JITF), Cluster Support Team Number 1, submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of α-alkyl-ω-hydroxypoly (oxypropylene) and/or poly (oxyethylene) polymers where the alkyl chain contains a minimum of six carbons.

DATES: This regulation is effective August 5, 2009. Objections and requests for hearings must be received on or before October 5, 2009, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2009–0145. 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: Kerry Leifer, Registration Division (7505P), Office of Pesticide Programs,

Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–8811; e-mail address: leifer.kerry@*epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to those engaged in the following activities:

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

This listing is not intended to be exhaustive, but rather to provide a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Access Electronic Copies of this Document?

In addition to accessing electronically available documents at *http://www.regulations.gov*, you may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr*. You may also access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR cite at *http://www.gpoaccess.gov/ecfr*. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at *http://www.epa.gpo/opptsfrs/home/guidelin.htm*.

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. 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–2009–0145 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk as required by 40 CFR part 178 on or before October 5, 2009.

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket that is described in **ADDRESSES**. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit this copy, identified by docket ID number EPA–HQ–OPP–2009–0145, by one of the following methods:

- *Federal eRulemaking Portal*: *http://www.regulations.gov*. Follow the on-line instructions for submitting comments.
- *Mail*: Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.
- *Delivery*: OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket Facility's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305–5805.

II. Background

In the **Federal Register** of April 15, 2009 (74 FR 17487) (FRL–8409–7), EPA issued a notice pursuant to section 408 of FFDCA, 21 U.S.C. 346a, announcing the receipt of a pesticide petition (PP [9E7534]) filed by The Joint Inerts Task Force, Cluster Support Team 1 (CST 1), c/o CropLife America, 1156 15th Street, NW., Suite 400, Washington, DC 20005. The petition requested that 40 CFR 180.910, 40 CFR 180.930, 40 CFR 180.940a, and 40 CFR 180.960 be amended by establishing an exemption from the requirement of a tolerance for residues of a group of substances known as α-alkyl-ω-hydroxypoly (oxypropylene) and/or poly (oxyethylene) polymers where the alkyl chain contains a minimum of 6 carbons, herein referred to in this document as AAA. AAAs are used as inert ingredients in pesticide products. That notice referenced a summary of the petition prepared by The Joint Inerts Task Force (JITF), Cluster Support Team Number 1 (CST 1)], the petitioner, which is available to the public in the docket, http://www.regulations.gov. There were no comments received in response to the notice of filing.

This petition was submitted in response to a final rule of August 9, 2006, (71 FR 45415) in which the Agency revoked, under section 408(e)(1) of the Federal Food, Drug, and Cosmetic Act (FFDCA), the existing exemptions from the requirement of a tolerance for residues of certain inert ingredients because of insufficient data to make the determination of safety required by FFDCA section 408(b)(2). The expiration date for the tolerance exemptions subject to revocation was August 9, 2008, which was later extended to August 9, 2009 by a final rule published in the **Federal Register** of August 4, 2008 (73 FR 45312) to allow for data to be submitted to support the establishment of tolerance exemptions for these inert ingredients prior to the effective date of the tolerance exemption revocation.

Depending on the degree of alkoxylation, each of the AAA substances included in the petition can vary in number average molecular weight from a range of approximately 260 to 4,000. In the case where the minimum number average molecular weight of an AAA is 1,100 or more, the petition's basis of support for the establishment of an exemption from the requirement of a tolerance under 40 CFR 180.960 is the fact that such high molecular weight AAAs would meet the criteria for a low-risk polymer as defined in 40 CFR 723.250. For the remaining AAAs (i.e., the ones with molecular weights between 260 and 1,100), the petition seeks to establish tolerance exemptions for all AAAs under 40 CFR 180.910, 40 CFR 180.930, and 40 CFR 180.940(a). Therefore, in its consideration of the petition the Agency has conducted an assessment specific to the establishment of an exemption from the requirement of a tolerance for the lower weight AAAs under 40 CFR 180.910, 40 CFR 180.930, and 40 CFR 180.940(a) as well as an assessment specific to the establishment of an exemption from the requirement of a tolerance under 40 CFR 180.960 for the ''high molecular weight'' AAAs.

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(b)(2)(A)(i) of FFDCA allows EPA to establish an exemption from the requirement of a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) of FFDCA defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....''

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of pesticides. Second, EPA examines exposure to the pesticide through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings.

Consistent with section 408(b)(2)(D) of FFDCA, and the factors specified in section 408(b)(2)(D) of FFDCA, 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 the petitioned-for exemption from the requirement of a tolerance for residue of AAAs when used as an inert ingredient in pesticide formulations applied pre- and post-harvest, applied to livestock, and used in antimicrobial formulations, and as a low risk polymer as defined in 40 CFR 723.250. EPA's assessment of exposures and risks associated with establishing tolerances follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its 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.

1. *For lower weight AAAs under 40 CFR 180.910, 40 CFR 180.930, and 40 CFR 180.940a.* The available toxicology database includes acute studies, subchronic (rat and dog) studies, a mutagenicity study, three OPPTS Harmonized Guideline 870.3650 combined repeated dose toxicity studies with the reproduction/developmental toxicity screening tests, an OPPTS Harmonized Guideline 870.3550 reproduction/developmental toxicity screening test, an OPPTS harmonized Test Guideline 870.3800 reproduction and fertility effects study, and reproduction and developmental effects studies.

The AAAs are not acutely toxic by the oral and dermal routes of exposure under normal use conditions. Concentrated materials are generally moderate to severe eye and skin irritants and may be skin sensitizers. There is no evidence of mutagenicity in the Ames assay (bacterial strains).

Following subchronic exposure to rats and dogs, decreases in body weight and food consumption were observed, but no specific target organ toxicity or neurotoxicity was seen. No effects were detected in a functional observational battery (FOB) or motor activity assessment. In a 90–day dermal toxicity study with AAA surfactant, no systemic toxicity was observed at doses up to 125 mg/kg/day (the highest dose tested). In an OPPTS Harmonized Guideline 870.3650 study with the AAA surfactant CAS No. 9004–98–2, parental toxicity observed at 110 mg/kg/day included decreased absolute and relative thymus weight, decreased body weight gain and decreased food consumption in females, and clinical signs in both sexes. These clinical signs are indicative of local irritation effects rather than systemic effects and thus were not used as a basis for evaluating the safety of the AAA surfactants. No reproductive or developmental/offspring toxicity was observed. In the second OPPTS Harmonized Guideline 870.3650 study with the AAA surfactant CAS 103818–93–5, parental systemic toxicity was observed at 300 mg/kg/day (HDT), based on decreased body weight gain (in males) and clinical signs (orange/red perioral staining and moderate salivation) in both sexes. No reproductive or developmental/offspring toxicity was observed. In the third OPPTS Harmonized Guideline 870.3650 study with the AAA surfactant CAS RN 64366–70–7, parental systemic toxicity was observed at 500 mg/kg/day (HDT), based on decreased body weight in males. No reproductive or developmental/offspring toxicity was observed.

In an OPPTS Harmonized Test Guideline 870.3550 reproduction/developmental toxicity screening test with the AAA surfactant CAS No. 84133–50–6, parental toxicity was observed at 470 mg/kg/day based on clinical signs (ptosis and hypoactivity), decreased absolute body weight, body weight gain, and food consumption. Reproductive toxicity was observed, as evidenced by the microscopic changes in the testes and epididymides (testicular atrophy, increased intraluminal exfoliated spermatogenic cells in epididymides, and dilated seminiferous tubules). Developmental/offspring toxicity was observed at 470 mg/kg/day (the highest dose tested), based on decreased litter size and increased postimplantation loss.

In a reproduction and developmental effects study with the AAA surfactant CAS 68951–67–7, the only significant effects observed in female rats were decreased body weight and body weight gain during premating at 400.8 mg/kg/day. At this maternally toxic dose, offspring toxicity observed was decreased body weight on lactation day (LD) 21 (both sexes in F_{1A}, F_{1B}, F_{2A}, and F_{2B}). No treatment-related effects were observed on reproductive parameters.

In an OPPTS Harmonized Test Guideline 870.3800 reproduction and fertility effects study with AAA surfactant CAS 68951–67–7, clinical signs observed at 250 mg/kg/day were increased incidences of lachrymation, incidences of unkemptness, hunched posture, chromodacryorrhea and periocular swelling in F0 and F1 females. These effects may be attributed to local irritant effects. No treatment-related effects were observed on reproduction or the offspring at 250 mg/kg/day (HDT).

It is generally accepted that increased ethoxylation decreases lipophilicity resulting in decreased absorption and decreased toxicity. The lower molecular weight AAAs would be expected to be absorbed and distributed more readily than higher molecular weight AAAs and

therefore to potentially be more toxic. The representative ethoxylated compounds tested have the lowest weight percent ethoxylation and lowest molecular weight of the series and are potentially the most bioavailable of the series. Although metabolism data are not available, the major metabolic pathway for AAA surfactants is expected to include the hydrolysis of ether linkage to the corresponding alkyl alcohol and polyalkoxylate (POE or POE/POP) group which subsequently undergoes oxidative degradation and/or excretion.

There is no evidence that the AAA surfactants are carcinogenic. The Agency used a qualitative structure activity relationship (SAR) database, DEREK Version 11, to determine if there were structural alerts. No structural alerts were identified. In addition, there was little concern about any of the postulated metabolites having greater toxicity than the parent compounds.

Specific information on the studies received and the nature of the adverse effects caused by AAA, 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 document Alkyl Alcohol Alkoxylates (AAA - JITF CST 1 Inert Ingredient). Human Health Risk Assessment to Support Proposed Exemption from the Requirement of a Tolerance When Used as an Inert Ingredient in Pesticide Formulations at pp 13–20 and pp 61–75 in docket ID number EPA–HQ–OPP–2009–0145.

2. *For the high molecular weight AAAs under 40 CFR 180.960.* In the case of certain chemical substances that are defined as polymers, the Agency has established a set of criteria to identify categories of polymers expected to present minimal or no risk. The definition of a polymer is given in 40 CFR 723.250(b) and the exclusion criteria for identifying these low-risk polymers are described in 40 CFR 723.250(d). The high molecular weight AAAs conform to the definition of a polymer given in 40 CFR 723.250(b) and meet the following criteria that are used to identify low-risk polymers.

i. The polymer is not a cationic polymer nor is it reasonably anticipated to become a cationic polymer in a natural aquatic environment.

ii. The polymer does contain as an integral part of its composition the atomic elements carbon, hydrogen, and oxygen.

iii. The polymer does not contain as an integral part of its composition, except as impurities, any element other than those listed in 40 CFR 723.250(d)(2)(ii).

iv. The polymer is neither designed nor can it be reasonably anticipated to substantially degrade, decompose, or depolymerize.

v. The polymer is manufactured or imported from monomers and/or reactants that are already included on the TSCA Chemical Substance Inventory or manufactured under an applicable TSCA section 5 exemption.

vi. The polymer is not a water absorbing polymer with a number average molecular weight (MW) greater than or equal to 10,000 daltons.

Additionally, the polymers also meet as required the following exemption criteria specified in 40 CFR 723.250(e).

The polymer's number average MW of 1,100 daltons is greater than 1,000 and less than 10,000 daltons. The polymer contains less than 10% oligomeric material below MW 500 and less than 25% oligomeric material below MW 1,000, and the polymer does not contain any reactive functional groups.

Thus, the high molecular weight AAAs meet the criteria for a polymer to be considered low risk under 40 CFR 723.250. Generally, polymers of this size would be poorly absorbed by all routes of exposure, including through the intact gastrointestinal tract or through intact human skin, and therefore, no mammalian toxicity is anticipated from dietary, inhalation, or dermal exposure to the high molecular weight AAAs.

B. Toxicological Endpoints

For hazards that have a threshold below which there is no appreciable risk, a toxicological point of departure (POD) is identified as the basis for derivation of reference values for risk assessment. The POD may be defined as the highest dose at which no adverse effects are observed (the NOAEL) in the toxicology study identified as appropriate for use in risk assessment. However, if a NOAEL cannot be determined, the lowest dose at which adverse effects of concern are identified (the LOAEL) or a Benchmark Dose (BMD) approach is sometimes used for risk assessment. Uncertainty/safety factors (UFs) are used in conjunction with the POD to take into account uncertainties inherent in the extrapolation from laboratory animal data to humans and in the variations in sensitivity among members of the human population as well as other unknowns. Safety is assessed for acute and chronic dietary risks by comparing aggregate food and water exposure to the pesticide to the acute population adjusted dose (aPAD) and chronic population adjusted dose (cPAD). The aPAD and cPAD are calculated by dividing the POD by all applicable UFs. Aggregate short-, intermediate-, and chronic-term risks are evaluated by comparing food, water, and residential exposure to the POD to ensure that the margin of exposure (MOE) called for by the product of all applicable UFs is not exceeded. This latter value is referred to as the Level of Concern (LOC).

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 greater than that 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.*

1. *For the lower weight AAAs under 40 CFR 180.910, 40 CFR 180.930, and 40 CFR 180.940a.* A summary of the toxicological endpoints for the AAAs used for human heatlh risk assessment is shown in the following Table.

TABLE—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR THE AAAS FOR USE IN HUMAN HEALTH RISK ASSESSMENT

Exposure/Scenario	Point of Departure and Uncertainty/Safety Factors	RfD, PAD, LOC for Risk Assessment	Study and Toxicological Effects
Acute dietary (all populations)	No appropriate endpoint was identified for acute dietary assessment.		

TABLE—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR THE AAAS FOR USE IN HUMAN HEALTH RISK ASSESSMENT—Continued

Exposure/Scenario	Point of Departure and Uncertainty/Safety Factors	RfD, PAD, LOC for Risk Assessment	Study and Toxicological Effects
Chronic dietary (all populations)	NOAEL= 168 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 1x	Chronic RfD = 1.68 mg/kg/day cPAD = 1.68 mg/kg/day	OPPTS harmonized Test Guideline 870.3550 reproduction/developmental toxicity screening test MRID 47676801 (2009) LOAEL = 470 mg/kg/day based on one maternal death (GD 22), decreased body weight, body weight gain, and food consumption, increased clinical signs (ptosis and hypoactivity), and microscopic changes of the testes and epididymides (testicular atrophy, increased intraluminal exfoliated spermatogenic cells in epididymides, and dilated seminiferous tubules) in parental animals, decreased litter size, and increased postimplantation loss.
Incidental Oral and Inhalation (all durations)	NOAEL= 168 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 1x	Residential LOC for MOE = 100	OPPTS harmonized Test Guideline 870.3550 reproduction/developmental toxicity screening test MRID 47676801 (2009) LOAEL = 470 mg/kg/day based on one maternal death (GD 22), decreased body weight, body weight gain, and food consumption, increased clinical signs (ptosis and hypoactivity), and microscopic changes of the testes and epididymides (testicular atrophy, increased intraluminal exfoliated spermatogenic cells in epididymides, and dilated seminiferous tubules) in parental animals, decreased litter size, and increased postimplantation loss.
Dermal (all durations)	NOAEL= 168 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 1x	Residential LOC for MOE = 100	OPPTS harmonized Test Guideline 870.3550 reproduction/developmental toxicity screening test MRID 47676801 (2009) Oral LOAEL = 470 mg/kg/day based on one maternal death (GD 22), decreased body weight, body weight gain, and food consumption, increased clinical signs (ptosis and hypoactivity), and microscopic changes of the testes and epididymides (testicular atrophy, increased intraluminal exfoliated spermatogenic cells in epididymides, and dilated seminiferous tubules) in parental animals, decreased litter size, and increased postimplantation loss. The final dose used to quantify dermal risk must correct for 50% dermal absorption, and should be multiplied by 3 to take into account the differences in rat and human skin penetration. The resulting dose = 1,000 mg/kg/day
Cancer (oral, dermal, inhalation)	Classification: Based on SAR analysis, AAA surfactrants are not expected to be carcinogenic.		

Point of Departure (POD) = A data point or an estimated point that is derived from observed dose-response data and used to mark the beginning of extrapolation to determine risk associated with lower environmentally relevant human exposures. NOAEL = no observed adverse effect level. LOAEL = lowest observed adverse effect level. UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies). PAD = population adjusted dose (a=acute, c=chronic). FQPA SF = FQPA Safety Factor. RfD = reference dose. MOE = margin of exposure. LOC = level of concern. N/A = not applicable.

2. *For the high molecular weight AAAs under 40 CFR 180.960.* Since the high molecular weight AAAs conform to the criteria that identify a low risk polymer, and are not likely to be absorbed significantly by any route of exposure, there are no concerns for risks associated with any potential exposure scenarios that are reasonably foreseeable. Thus, due to their low potential hazard, it was determined that a quantitative risk assessment using safety factors applied to a point of departure protective of an identified hazard endpoint is not appropriate for the high molecular weight AAAs, and an exposure assessment is not necessary. For the same reason, an additional safety factor to protect infants and children is not needed.

C. Exposure Assessment

Sufficient data were provided on the chemical identity of the AAAs; 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 information, as well as information on other surfactants and chemicals of similar size and functionality to determine the residues of concern for these inert ingredients. The Agency has concluded that a risk assessment based on toxicity data for the parent compounds is not likely to underestimate risk.

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to the lower weight AAAs, EPA considered exposure under the petitioned-for exemptions from the requirement of a tolerance. EPA assessed dietary exposures from the lower weight AAAs in food as follows:

i. *Acute exposure.* No adverse effects attributable to a single exposure of the AAAs was seen in the toxicity databases. Therefore, acute dietary risk assessments for the AAAs are not necessary.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment, EPA used food consumption information from the U.S. 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 AAAs. In the absence of specific residue data, EPA has developed an approach which uses surrogate

information to derive upper bound exposure estimates for the subject inert ingredient. Upper bound exposure estimates are based on the highest tolerance for a given commodity from a list of high-use insecticides, herbicides, and fungicides. A complete description of the general approach taken to assess inert ingredient risks in the absence of residue data is contained in the memorandum entitled *Alkyl Amines Polyalkoxylates (Cluster 4): Acute and Chronic Aggregate (Food and Drinking Water) Dietary Exposure and Risk Assessments for the Inerts.* (D361707, S. Piper, 2/25/09) and can be found at *http://www.regulations.gov* in docket ID number EPA–HQ–OPP–2008–0738.

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

The Agency believes the assumptions used to estimate dietary exposures lead to an extremely conservative assessment of dietary risk due to a series of compounded conservatisms. First, assuming that the level of residue for an inert ingredient is equal to the level of residue for the active ingredient will overstate exposure. The concentrations of active ingredient in agricultural products is generally at least 50 percent of the product and often can be much higher. Further, pesticide products rarely have a single inert ingredient; rather there is generally a combination of different inert ingredients used which additionally reduces the concentration of any single inert ingredient in the pesticide product in relation to that of the active ingredient.

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

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

iii. *Cancer*. 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 AAAs are not expected to be carcinogenic. Therefore, a cancer dietary exposure assessment is not necessary to assess cancer risk.

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

2. *Dietary exposure from drinking water*. The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for the AAAs in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of the AAAs. Further information regarding EPA drinking water models used in the pesticide exposure assessment can be found at *http://www.epa.gov/oppefed1/models/water/index.htm*.

A screening level drinking water analysis, based on the Pesticide Root Zone Model /Exposure Analysis Modeling System (PRZM/EXAMS) was performed to calculate the estimated drinking water concentrations (EDWCs) of the AAAs. Modeling runs on four surrogate inert ingredients using a range of physical chemical properties that would bracket those of the AAAs were conducted. Modeled acute drinking water values ranged from 0.001 ppb to 41 ppb. Modeled chronic drinking water values ranged from 0.0002 ppb to 19 ppb. Further details of this drinking water analysis can be found at *http://www.regulations.gov* in the document *Alkyl Alcohol Alkoxylates (AAA - JITF CST 1 Inert Ingredient). Human Health Risk Assessment to Support Proposed Exemption from the Requirement of a Tolerance When Used as an Inert Ingredient in Pesticide Formulations* at pp 20–21 and 77–79 in docket ID number EPA–HQ–OPP–2009–0145.

For the purpose of the screening level dietary risk assessment to support this request for an exemption from the requirement of a tolerance for the AAAs, a conservative drinking water concentration value of 100 ppb based on screening level modeling was used to assess the contribution to drinking water for chronic dietary risk assessments for the 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., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets). The AAAs may be used in inert ingredients in pesticide products that are registered for specific uses that may result in both indoor and outdoor residential exposures. A screening level residential exposure and risk assessment was completed for products containing the AAAs as inert ingredients. In this assessment, representative scenarios, based on end-use product application methods and labeled application rates, were selected. The AAAs may be used as inert ingredients in pesticide formulations that are used in and around the home. Additionally, these inerts may be used in pesticide products applied to pets as aerosol sprays intended for flea control on carpeted surfaces and bedding, or in shampoo products applied to pets. Lastly, these inerts may be present in home cleaning products or paint products. 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 the AAAs. Similarly, the Agency conducted an assessment to represent worst-case residential exposure by assessing post application exposures and risks from AAAs in pesticide formulations

(outdoor scenarios), AAAs in disinfectant-type uses (indoor scenarios), AAAs in shampoo pet treatments (pet product scenarios) and AAAs in paint products (paint product scenarios). Further details of this residential exposure and risk analysis can be found at *http://www.regulations.gov* in the memorandum entitled *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* (D364751, 5/7/09, Lloyd/LaMay 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 AAAs to share a common mechanism of toxicity with any other substances, and the AAAs do not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that the AAAs 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*. In the case of the lower weight AAA surfactants, there was no evidence of increased susceptibility to the offspring of rats following prenatal and postnatal exposure in the reproductive/developmental screening studies on several representative AAA surfactants. Decreased litter size and increased postimplantation loss were observed in one OPPTS Harmonized Guideline 870.3550 reproduction/developmental toxicity screening study at 470 mg/kg/day where maternal/paternal toxicity was manifested as one maternal death (GD 22), decreased body weight, body-weight gain and food consumption and clinical signs (ptosis and hypoactivity) and microscopic changes in the testes (atrophy) and epididymides (increased intraluminal exfoliated spermatogenic cells) and dilated seminiferous tubules at the same dose (470 mg/kg/day). The maternal and offspring toxicity NOAEL was 168 mg/kg/day. The offspring toxicity in the OPPTS Harmonized Test Guideline 870.3650 study was manifested in the presence of more severe maternal toxicity (deaths), therefore, EPA concluded that there is no evidence of increased susceptibility in this study. In addition, there was no evidence of increased susceptibility in other submitted studies.

3. *Conclusion*. EPA has determined that reliable data show that the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X for the lower weight AAAs. (As discussed earlier, given the low toxicological concerns with the high weight AAAs, a safety factor analysis is unnecessary). That decision as to the lower weight AAAs is based on the following findings:

i. The toxicity database for the AAAs is considered adequate for assessing the risks to infants and children. The toxicity database consists of three OPPTS Harmonized Test Guideline 870.3650 combined repeated dose toxicity studies with the reproduction/developmental toxicity screening tests, an OPPTS Harmonized Test Guidelinge 870.3550 reproduction/developmental toxicity screening test study, an OPPTS Harmonized Test Guideline 870.3800 reproduction and fertility effects study, and reproduction and developmental effects studies. The Agency noted changes in thymus weight. However, the thymus/lymph node effects are considered secondary effects caused by an overall stress response to the irritant properties of this chemical, and therefore, not an immunological response. In addition, no blood parameters were affected in the database. Furthermore, these compounds do not belong to a class of chemicals that would be expected to be immunotoxic. Also, in an OPPTS Harmonized Test Guideline 870.3550 study, testicular effects, such as, testicular atrophy, microscopic changes in the testes, epididymides and dilated seminiferous tubules were observed in male rats at the highest dose tested (470 mg/kg/day). However, none of the reproductive parameters (pregnancy rate) were affected in this study. In addition, there were no effects observed on reproductive parameters in the OPPTS Harmonized Test Guideline 870.3800 reproduction and fertility effects study. Furthermore, there was no histological findings in the testes in that study. Based on the weight of the evidence for immunotoxoicity and reproductive toxicity, there is no need to add additional uncertainty factors.

ii. EPA concluded that there is no evidence of qualitative or quantitative increased susceptivility in the available database. Therefore, there is no concern for increased susceptibility to infants and children.

iii. There is no indication that the AAAs are neurotoxic chemicals and thus there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity

iv. Although the chronic point of departure was selected from a subchronic study, longer-term studies are available that support the NOAEL selected. No additional uncertainty factor is needed for extrapolating from subchronic to chronic exposure.

v. 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% crop treated is assumed for all crops. EPA also made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to the AAAs in drinking water. EPA used similarly conservative assumptions to assess post-application exposure of children as well as incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by the AAAs.

E. Aggregate Risks and Determination of Safety

1. *For the lower weight AAAs under 40 CFR 180.910, 40 CFR 180.930, and 40 CFR 180.940a*. EPA determines whether

acute and chronic pesticide exposures are safe by comparing aggregate exposure estimates to the aPAD and cPAD. The aPAD and cPAD represent the highest safe exposures, taking into account all appropriate SFs. EPA calculates the aPAD and cPAD by dividing the POD by all applicable UFs. For linear cancer risks, EPA calculates the probability of additional cancer cases 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 POD to ensure that the MOE called for by the product of all applicable UFs is not exceeded.

i. *Acute risk.* There was no hazard attributable to a single exposure seen in the toxicity database for the AAAs. Therefore, the AAAs are not expected to pose an acute risk.

ii. *Chronic risk.* A chronic aggregate risk assessment takes into account exposure estimates from chronic dietary consumption of food and drinking water. Using the exposure assumptions discussed in this unit for chronic exposure the chronic dietary exposure from food and water to the AAAs is 11% of the cPAD for the U.S. population and 37% of the cPAD for children 1 to 2 years old, the most highly exposed population subgroup.

iii. *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).

AAAs are used as inert ingredients in pesticide products that are currently registered for uses that could result in short-term residential exposure and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short-term residential exposures to the AAAs. EPA has concluded that the combined short-term aggregated food, water, and residential exposures result in aggregate MOEs of 110 for both adult males and females. Adult residential exposure combines high end indoor inhalation handler exposure with a high-end post application to pet exposures. EPA has concluded the combined short-term aggregated food, water, and residential exposures result in an aggregate MOE of 110 for children. Children's residential exposure includes total combined pet exposures. As the level of concern is for MOEs that are lower than 100, these MOEs are not of concern.

iv. *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).

The AAAs are used as inert ingredients in pesticide products that are currently registered for uses that could result in intermediate-term residential exposure and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with intermediate-term residential exposures to the AAAs. EPA has concluded that the combined intermediate-term aggregated food, water, and residential exposures result in aggregate MOEs of 230 for both adult males and females, respectively. Adult residential exposure includes high-end post application dermal exposure from contact with treated pets. EPA has concluded that the combined intermediate-term aggregated food, water, and residential exposures result in an aggregate MOE of 110 for children. Children's residential exposure includes total combined pet exposure. As the level of concern is for MOEs that are lower than 100, these MOEs are not of concern.

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

vi. *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 residues of the lower weight AAAs.

2. *For the high molecular weight AAAs under 40 CFR 180.960.* Since AAA conforms to the criteria that identify a low-risk polymer, there are no concerns for risks associated with any potential exposure scenarios that are reasonably foreseeable. Therefore, 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 residues of the high molecular weight AAAs.

V. Other Considerations

A. 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.

B. International Residue Limits

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

VI. Conclusion

Therefore, an exemption from the requirement of a tolerance is established for residues of the lower molecular weight α-alkyl-ω-hydroxypoly (oxypropylene) and/or poly (oxyethylene) polymers where the alkyl chain contains a minimum of 6 carbons when used as an inert ingredient in pesticide formulations applied pre- and post-harvest, applied to livestock, and used in antimicrobial formulations under 40 CFR 180.910, 40 CFR 180.930, and 40 CFR 180.940(a). In addition, an exemption from the requirement of a tolerance is established for residues of the larger molecular weight compounds of α-alkyl-ω-hydroxypoly (oxypropylene) and/or poly (oxyethylene) polymers where the alkyl chain contains a minimum of 6 carbons under 40 CFR 180.960.

VII. Statutory and Executive Order Reviews

This final rule establishes an exemption from the requirement of tolerances 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 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 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: July 29, 2009.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

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

PART 180—[AMENDED]

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

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

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

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

* * * * *

Inert ingredients	Limits	Uses
* * * * *	*	*
α-alkyl-ω-hydroxypoly (oxypropylene) and/or poly (oxyethylene) polymers where the alkyl chain contains a minimum of six carbons (CAS Reg. Nos. 9002–92–0, 9004–95–9, 9005–00–9, 26183–52–8, 34398–01–1, 52292–17–8, 66455–14–9, 66455–15–0, 68002–97–1, 68131–39–5, 68131–40–8, 68154–96–1, 68213–23–0, 68439–45–2, 68439–46–3, 68526–94–3, 68439–50–9, 68439–49–6, 68551–12–2, 68951–67–7, 71243–46–4, 97043–91–9, 9043–30–5, 60828–78–6, 61827–42–7, 24938–91–8, 68439–54–3, 69011–36–5, 78330–20–8, 78330–21–9, 106232–83–1, 127036–24–2, 160875–66–1, 9004–98–2, 68920–66–1, 61804–34–0, 61791–28–4, 71060–57–6, 26468–86–0, 31726–34–8, 52609–19–5, 61791–20–6, 68155–01–1, 69013–19–0, 69364–63–2, 70879–83–3, 78330–19–5, 97953–22–5, 157627–86–6, 34398–05–5, 72905–87–4, 84133–50–6, 61702–78–1, 27306–79–2, 169107–21–5, 61791–13–7, 39587–22–9, 85422–93–1; 68154–98–3, 61725–89–1, 68002–96–0, 68154–97–2, 68439–51–0, 68551–13–3, 68603–25–8, 68937–66–6, 68987–81–5, 69227–21–0, 70750–27–5, 103818–93–5, 166736–08–9, 120313–48–6, 68213–24–1, 68458–88–8, 68551–14–4, 69013–18–9, 69227–22–1, 72854–13–8, 73049–34–0, 78330–23–1, 37311–02–7, 64366–70–7, 37251–67–5, 9087–53–0, 196823–11–7, 57679–21–7, 111905–54–5, 61827–84–7, 172588–43–1)		Surfactants, related adjuvants of surfactants
* * * * *	*	*

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

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

* * * * *

Inert Ingredients	Limits	Uses
* * * * *	*	*
α-alkyl-ω-hydroxypoly (oxypropylene) and/or poly (oxyethylene) polymers where the alkyl chain contains a minimum of six carbons (CAS Reg. Nos. 9002–92–0, 9004–95–9, 9005–00–9, 26183–52–8, 34398–01–1, 52292–17–8, 66455–14–9, 66455–15–0, 68002–97–1, 68131–39–5, 68131–40–8, 68154–96–1, 68213–23–0, 68439–45–2, 68439–46–3, 68526–94–3, 68439–50–9, 68439–49–6, 68551–12–2, 68951–67–7, 71243–46–4, 97043–91–9, 9043–30–5, 60828–78–6, 61827–42–7, 24938–91–8, 68439–54–3, 69011–36–5, 78330–20–8, 78330–21–9, 106232–83–1, 127036–24–2, 160875–66–1, 9004–98–2, 68920–66–1, 61804–34–0, 61791–28–4, 71060–57–6, 26468–86–0, 31726–34–8, 52609–19–5, 61791–20–6, 68155–01–1, 69013–19–0, 69364–63–2, 70879–83–3, 78330–19–5, 97953–22–5, 157627–86–6, 34398–05–5, 72905–87–4, 84133–50–6, 61702–78–1, 27306–79–2, 169107–21–5, 61791–13–7, 39587–22–9, 85422–93–1; 68154–98–3, 61725–89–1, 68002–96–0, 68154–97–2, 68439–51–0, 68551–13–3, 68603–25–8, 68937–66–6, 68987–81–5, 69227–21–0, 70750–27–5, 103818–93–5, 166736–08–9, 120313–48–6, 68213–24–1, 68458–88–8, 68551–14–4, 69013–18–9, 69227–22–1, 72854–13–8, 73049–34–0, 78330–23–1, 37311–02–7, 64366–70–7, 37251–67–5, 9087–53–0, 196823–11–7, 57679–21–7, 111905–54–5, 61827–84–7, 172588–43–1)	Surfactants, related adjuvants of surfactants	
* * * * *	*	*

■ 4. Section §180.940 is amended by alphabetically adding the following entry to the table in paragraph (a):

§ 180.940 Tolerance exemptions for active and inert ingredients for use in antimicrobial formulations (Food-contact surface sanitizing solutions).

(a) * * *

* * * * *

Pesticide Chemical	CAS Reg. No.	Limits
*	* * * * * *	
α-alkyl-ω-hydroxypoly (oxypropylene) and/or poly (oxyethylene) polymers where the alkyl chain contains a minimum of six carbons.	9002–92–0, 9004–95–9, 9005–00–9, 26183–52–8, 34398–01–1, 52292–17–8, 66455–14–9, 66455–15–0, 68002–97–1, 68131–39–5, 68131–40–8, 68154–96–1, 68213–23–0, 68439–45–2, 68439–46–3, 68526–94–3, 68439–50–9, 68439–49–6, 68551–12–2, 68951–67–7, 71243–46–4, 97043–91–9, 9043–30–5, 60828–78–6, 61827–42–7, 24938–91–8, 68439–54–3, 69011–36–5, 78330–20–8, 78330–21–9, 106232–83–1, 127036–24–2, 160875–66–1, 9004–98–2, 68920–66–1, 61804–34–0, 61791–28–4, 71060–57–6, 26468–86–0, 31726–34–8, 52609–19–5, 61791–20–6, 68155–01–1, 69013–19–0, 69364–63–2, 70879–83–3, 78330–19–5, 97953–22–5, 157627–86–6, 34398–05–5, 72905–87–4, 84133–50–6, 61702–78–1, 27306–79–2, 169107–21–5, 61791–13–7, 39587–22–9, 85422–93–1; 68154–98–3, 61725–89–1, 68002–96–0, 68154–97–2, 68439–51–0, 68551–13–3, 68603–25–8, 68937–66–6, 68987–81–5, 69227–21–0, 70750–27–5, 103818–93–5, 166736–08–9, 120313–48–6, 68213–24–1, 68458–88–8, 68551–14–4, 69013–18–9, 69227–22–1, 72854–13–8, 73049–34–0, 78330–23–1, 37311–02–7, 64366–70–7, 37251–67–5, 9087–53–0, 196823–11–7, 57679–21–7, 111905–54–5, 61827–84–7, 172588–43–1)	
*	* * * * * *	

■ 5. In §180.960, the table is amended by adding alphabetically the following polymers:

§ 180.960 Polymers; exemptions from the requirement of a tolerance.

* * * * *

Polymer	CAS No.
	* * * * *
α-alkyl-ω-hydroxypoly (oxypropylene) and/or poly (oxyethylene) polymers where the alkyl chain contains a minimum of six carbons, minimum number average molecular weight (in amu) 1,100.	9002–92–0, 9004–95–9, 9005–00–9, 26183–52–8, 34398–01–1, 52292–17–8, 66455–14–9, 66455–15–0, 68002–97–1, 68131–39–5, 68131–40–8, 68154–96–1, 68213–23–0, 68439–45–2, 68439–46–3, 68526–94–3, 68439–50–9, 68439–49–6, 68551–12–2, 68951–67–7, 71243–46–4, 97043–91–9, 9043–30–5, 60828–78–6, 61827–42–7, 24938–91–8, 68439–54–3, 69011–36–5, 78330–20–8, 78330–21–9, 106232–83–1, 127036–24–2, 160875–66–1, 9004–98–2, 68920–66–1, 61804–34–0, 61791–28–4, 71060–57–6, 26468–86–0, 31726–34–8, 52609–19–5, 61791–20–6, 68155–01–1, 69013–19–0, 69364–63–2, 70879–83–3, 78330–19–5, 97953–22–5, 157627–86–6, 34398–05–5, 72905–87–4, 84133–50–6, 61702–78–1, 27306–79–2, 169107–21–5, 61791–13–7, 39587–22–9, 85422–93–1; 68154–98–3, 61725–89–1, 68002–96–0, 68154–97–2, 68439–51–0, 68551–13–3, 68603–25–8, 68937–66–6, 68987–81–5, 69227–21–0, 70750–27–5, 103818–93–5, 166736–08–9, 120313–48–6, 68213–24–1, 68458–88–8, 68551–14–4, 69013–18–9, 69227–22–1, 72854–13–8, 73049–34–0, 78330–23–1, 37311–02–7, 64366–70–7, 37251–67–5, 9087–53–0, 196823–11–7, 57679–21–7, 111905–54–5, 61827–84–7, 172588–43–1
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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2008–0944; FRL–8429–4]

Polyoxyethylene polyoxypropylene mono(di-sec-butylphenyl) ether; 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 Polyoxyethylene polyoxypropylene mono(di-sec-butylphenyl) ether when used as an inert ingredient in herbicide formulations only, for pre-harvest uses and at no more than 30% by weight in herbicide formulations intended for application to turf. The Joint Inerts Task Force (JITF), Cluster Support Team Number 20, submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of Polyoxyethylene polyoxypropylene mono(di-sec-butylphenyl) ether.

DATES: This regulation is effective August 5, 2009. Objections and requests for hearings must be received on or before October 5, 2009, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2008–0944. 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: Kerry Leifer, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–8811; e-mail address: leifer.kerry@*epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to those engaged in the following activities:

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

This listing is not intended to be exhaustive, but rather to provide a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Access Electronic Copies of this Document?

In addition to accessing electronically available documents at *http://www.regulations.gov*, you may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr*. You may also access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e–CFR cite at *http://www.gpoaccess.gov/ecfr*. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at *http://www.epa.gpo/opptsfrs/home/guidelin.htm*.

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. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2008–0944 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk as required by 40 CFR part 178 on or before October 5, 2009.

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket that is described in **ADDRESSES**. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit this copy, identified by docket ID number EPA–HQ–OPP–2008–0944, by one of the following methods:

- *Federal eRulemaking Portal*: *http://www.regulations.gov*. Follow the on-line instructions for submitting comments.
- *Mail*: Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.
- *Delivery*: OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket Facility's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305–5805.

II. Background

In the **Federal Register** of March 25, 2009 (74 FR 12856) (FRL–8399–4), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 8E7494) by The Joint Inerts Task Force (JITF), Cluster Support Team 20 (CST 20), c/o CropLife America, 1156 15th Street, NW., Suite 400, Washington, DC 20005. The petition requested that 40 CFR 180.920 be amended by establishing exemptions from the requirement of a tolerance for residues of the inert ingredient