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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

Polyoxyethylene polyoxypropylene mono(di-sec-butylphenyl) ether, herein referred to in this document as POE/POP mono(di-sec-butylphenyl) ether, when used as an inert ingredient in herbicide formulations for pre-harvest uses under 40 CFR 180.920. That notice referenced a summary of the petition prepared by The JITF, CST 20, 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.

Based upon review of the data supporting the petition, EPA has modified the exemption requested by limiting POE/POP mono(di-sec-butylphenyl) to a maximum of 30% by weight in the herbicide formulations intended for application to turf. This limitation is based on the Agency's risk assessment which can be found at *http://www.regulations.gov* in document *Polyoxyethylene Polyoxypropylene Mono(di-sec-Butylphenyl) Ether (JITF CST 20 Inert Ingredients). Human Health Risk Assessment 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–2008–0944.

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.

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 POE/POP mono(di-sec-butylphenyl) ether when used as an inert ingredient in herbicide formulations only, for pre-harvest uses, and provided that uses in herbicide formulations intended for turf application are limited to no more than 30% by weight in the final formulation. 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.

The available mammalian toxicology database consists of one combined repeated dose toxicity study with the reproduction/developmental toxicity screening test in rats for the representative POE/POP mono(di-sec-butylphenyl) ether, three subchronic oral toxicity studies (rats and dogs), and acute data on representative POE/POP mono(di-sec-butylphenyl) ether inerts.

The POE/POP mono(di-sec-butylphenyl) ether inert ingredients are not acutely toxic by the oral, dermal and inhalation routes of exposure and are slight to severe eye irritants and not a skin irritant.

The OPPTS Harmonized Guideline 870.3650 *Combined Repeated Dose Toxicity Study* with rats demonstrated that the representative POE/POP mono(di-sec-butylphenyl) ether had no effect on food consumption, body weight gain, and FOB parameters in males and females at any of the doses tested. Blood coagulation in male and female rats in the highest dose group as measured by prothrombin time, was significantly reduced. Microscopic effects observed included minimal or mild centrilobular hepatocellular hypertrophy which was seen in the liver of 4 of 5 male rats and 3 of 5 female rats in the 304 milligrams/kilogram/day (mg/kg/day) dose group. In the affected livers, centrilobular areas were more prominent due to enlarged (hypertrophied) hepatocytes with an increased amount of dense granular eosinophilic cytoplasm. As hepatocellular hypertrophy was not accompanied by inflammatory or degenerative changes, this finding was considered to be adaptive in nature, in response to metabolizing the test substance, and not adverse. An increased incidence of thyroid follicular epithelial hypertrophy and hyperplasia was observed in all male rats in the 304 mg/kg/day dose group. This follicular change was characterized by increased size of follicular epithelial cells (hypertrophy) and, in some areas, there were increased amounts of small follicles and increased cells within the follicles (hyperplasia). Thyroid

hormones were not measured in this study. It is possible that the thyroid changes were due to an indirect effect by increased metabolism of thyroid hormones by the liver. No treatment related effects were observed on litter sizes or on the early development of pups.

In a 90–day oral toxicity study performed in rats (MRID 46610818), Polyglycol 26–2 was administered to male and female rats at dose levels of 0, 5, 15, 50, 150, and 500 mg/kg/day. The no-observed-effect-level (NOAEL) was determined to be 50 mg/kg/day, and the lowest-observed-effect-level (LOAEL) was determined to be 150 mg/kg/day based up lesions in the liver and kidney of both sexes.

In a 90–day Oral Toxicity Study performed in Beagle dogs (MRID 46610819), Polyglycol 26–2 was administered orally at 0, 3, 10, 36, and 92 mg/kg/day. No evidence of adverse effects was observed at any of the doses in this study.

A similar study in Beagle dogs was carried out for Polyglycol 26–3 (MRID 46610820). No adverse effects were noted at doses up to 100 mg/kg/day (the higest dose tested). The study was classified as Acceptable/non-guideline.

There are no published metabolism studies for this series of surfactants. The mammalian metabolism pathway proposed in the petition is based on the polyalkoxylate metabolism of alkyl alchohols documented in publicly available literature. By analogy to the polyethoxylated surfactants, the significant metabolic pathway could be hydrolytic or oxidative removal of the polyalkoxylate chains to generate an isomeric mixture of di-sec butyl phenol and the polypropoxylate polyethoxylate alchohol that may be further oxidized.

The proposed polypropoxylates and polyethoxylates, alchohols and carboxylic acids, should be rapidly excreted as conjugates. The liver, lungs and gastrointestinal tract are the most important sites for phenol metabolism with excretion proceeding rapidly through conjugation to generate phenyl glucuronide and phenyl sulfate. The di-sec butyl side chains may or may not be degraded but depending on their position on the phenol, because of steric hindrance, may slow down conjugation and conjugation of the phenolic polymeric component.

There are no chronic toxicity studies available for POE/POP mono(di-sec-butylphenyl) ether. The Agency used a qualitative structure activity relationship (SAR) database, DEREK Version 11, to determine if there were structural alerts suggestive of carcinogenicity. No structural alerts were identified.

Specific information on the studies received and the nature of the adverse effects caused by POE/POP mono(di-sec-butylphenyl) ether, as well as, the NOAEL and the LOAEL from the toxicity studies can be found at *http://www.regulations.gov* in document *Polyoxyethylene Polyoxypropylene Mono(di-sec-Butylphenyl) Ether (JITF CST 20 Inert Ingredients). Human Health Risk Assessment to Support Proposed Exemption from the Requirement of a Tolerance When Used as Inert Ingredients in Pesticide Formulations* at pp 9–14 and pp 42–47 in docket ID number EPA–HQ–OPP–2008–0944.

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*.

A summary of the toxicological endpoints for POE/POP mono(di-sec-butylphenyl) ether used for human health risk assessment is shown in the following Table.

TABLE—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR POE/POP MONO(DI-SEC-BUTYLPHENYL) ETHER 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)	An effect attributable to a single exposure was not identified.		

TABLE—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR POE/POP MONO(DI-SEC-BUTYLPHENYL) ETHER 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= 82 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 1x	Chronic RfD = 0.82 mg/kg/day cPAD = 0.82 mg/kg/day	Combined Repeated Dose Toxicity Study with the Reproduction/Developmental Toxicity Screening Test-Rat OPPTS Harmonized Guideline 870.3650 Parental LOAEL = 304 mg/kg bw/day based on clinical signs in male and female rats (salivation), increased incidence of thyroid follicular epithelial hypertrophy and hyperplasia in male rats, reduction of prothrombin time in male and female rats, and reduction of activated partial thromboplastin time in female rats. Reproductive/Developmental LOAEL was not observed.
Incidental Oral, Dermal, and Inhalation (Short-, Intermediate-, and Long-Term)	NOAEL= 82 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 1x 50% dermal absorption; inhalation toxicity is assumed to be equivalent to oral toxicity.	Residential LOC for MOE = 100.	Combined Repeated Dose Toxicity Study with the Reproduction/Developmental Toxicity Screening Test-Rat OPPTS Harmonized Guideline 870.3650 Parental LOAEL = 304 mg/kg bw/day based on clinical signs in male and female rats, increased incidence of thyroid follicular epithelial hypertrophy and hyperplasia in male rats, reduction of prothrombin time in male and female rats, and reduction of activated partial thromboplastin time in female rats. Reproductive/ Developmental LOAEL was not observed.
Cancer (oral, dermal, inhalation)	Classification: No animal toxicity data available for an assessment. Based on SAR analysis, POE/POP mono(di-sec-butylphenyl) ether is 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. LOC = level of concern.

C. Exposure Assessment

Sufficient data were provided on the chemical identity of the POE/POP mono(di-sec-butylphenyl) ether inert ingredients; 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 generic cluster structures, the modeled physicochemical information, as well as the structure-activity relationship information. Additionally, information on other surfactants and chemicals of similar size and functionality was considered to determine the residues of concern for these inert ingredients.

The registrant selected Polyglycol 26–2 (CAS RN 69029–39–6), a complex mixture of polyethoxylated/polypropoxylated, POE/POP, ethers of a mixture of the three different isomeric di-sec-butyl phenols, for toxicity testing. The Agency has concluded that the cluster grouping was appropriate. Based on the chemical structure, it is likely that the parent compound will degrade in the environment to 2,4-di-sec-butyl phenol, and 2,6-di-sec-butyl phenol. The Agency considered the SAR analysis, and information in the literature, and concluded that the butylphenols are not likely to be more toxic than the parent compounds. Considering the high residue approach to the dietary risk assessment that basically assumes no degradation of the parent and 100% CT, and the fact that the two degradates are not likely to be more toxic than the parent, the parent compound risk assessment is protective of any potential toxicity effects of the butylphenols. Therefore, it is not necessary to assess the exposure to the butylphenols separately.

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to POE/POP mono(di-sec-butylphenyl) ether, EPA considered exposure under the petitioned-for exemptions from the requirement of a tolerance. EPA assessed dietary exposures from POE/POP mono(di-sec-butylphenyl) ether in food as follows:

i. *Acute exposure.* No adverse effects attributable to a single exposure of POE/POP mono(di-sec-butylphenyl) ether was seen in the toxicity databases. Therefore, acute dietary risk assessments for POE/POP mono(di-sec-butylphenyl) ether is 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 POE/POP mono(di-sec-butylphenyl) ether. 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% 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 POE/POP mono(di-sec-butylphenyl) ether, EPA made a specific adjustment to the dietary exposure assessment to account for the use of these inerts in herbicide formulations only. The Agency identified the residue drivers (crop/tolerance combinations) in this assessment that constitute the majority of the dietary risk, and has replaced the residue value with the highest herbicide tolerances for those commodities. The risk drivers for the dietary assessment for which herbicide tolerances were used were the leafy vegetable (except brassica) crop group, pome fruits, and grapes.

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% 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. POE/POP mono(di-sec-butylphenyl) ether 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 POE/POP mono(di-sec-butylphenyl) ether. 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 POE/POP mono(di-sec-butylphenyl) ether in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of POE/POP mono(di-sec-butylphenyl) ether. 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 POE/POP mono(di-sec-butylphenyl) ether. Modeling runs on four surrogate inert ingredients using a range of physical chemical properties that would bracket those of POE/POP mono(di-sec-butylphenyl) ether were conducted. Modeled acute drinking water values ranged from 0.001 parts per billion (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 *Polyoxyethylene Polyoxypropylene Mono(di-sec-Butylphenyl) Ether (JITF CST 20 Inert Ingredients). Human Health Risk Assessment to Support Proposed Exemption from the Requirement of a Tolerance When Used as Inert Ingredients in Pesticide Formulations* at pp 15–16 and 50–52 in docket ID number EPA–HQ–OPP–2008–0944.

For the purpose of the screening level dietary risk assessment to support this request for an exemption from the requirement of a tolerance for POE/POP mono(di-sec-butylphenyl) ether, 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 compounds and for the metabolites of concern. 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). POE/POP mono(di-sec-butylphenyl) ether may be used as inert ingredients in herbicide products that are registered for specific uses that may result in outdoor residential exposures. A screening level residential exposure and risk assessment was completed for herbicide products containing POE/POP mono(di-sec-butylphenyl) ether as inert ingredients. In this assessment, representative scenarios, based on end-use product application methods and labeled application rates, were selected. The POE/POP mono(di-sec-butylphenyl)

may be used as inert ingredients in pesticide formulations (herbicides) that are used around the home. The Agency did not identify any products intended for use on pets or home cleaning products that contain the POE/POP mono(di-sec-butylphenyl) ether inert ingredients. The Agency conducted an assessment to represent worst-case residential exposures to herbicides only by assessing POE/POP mono(di-sec-butylphenyl) ether in herbicide formulations (Outdoor 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 POE/POP mono(di-sec-butylphenyl) ether to share a common mechanism of toxicity with any other substances, and the POE/POP mono(di-sec-butylphenyl) ether 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 POE/POP mono(di-sec-butylphenyl) ether do not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at *http://www.epa.gov/pesticides/cumulative*.

D. Safety Factor for Infants and Children

1. *In general*. Section 408(b)(2)(c) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA safety factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity*. The available mammalian toxicology database consists of one combined repeated dose toxicity study with the reproduction/developmental toxicity screening test in rats for alkyl phenolic glycol ether, three subchronic oral toxicity studies (rats and dogs), and acute data on the representative inerts.

There was no evidence of increased susceptibility in the offspring because no developmental or reproductive toxicity was observed in the OPPTS Harmonized Guideline 870.3650 study. No treatment related effects were observed on litter sizes or on the early development of pups.

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. That decision is based on the following findings:

i. The toxicity database for POE/POP mono(di-sec-butylphenyl) ether is considered adequate for assessing the risks to infants and children (the available studies are described in Unit IV.D.2.).

ii. No developmental or reproductive toxicity was observed in the OPPTS Harmonized Guideline 870.3650 combined repeated dose toxicity study with the reproduction/developmental toxicity screening test in rats following prenatal and postnatal exposure and there are no concerns for sensitivity of the offspring.

iii. There was no evidence of neurotoxicity in the database. In addition, there is no indication that POE/POP mono(di-sec-butylphenyl) ether are neurotoxic chemicals and thus there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

iv. The primary target organ toxicity observed in the database is thyroid toxicity, prothrombin time, and body weight effects. Thyroid effects are manifested following short duration exposure and only observed at 304 mg/kg/day (the higest dose tested). The Agency has considerable knowledge and understanding of the mechanism of thyroid toxicity. The Agency concluded that any dose that prevents pertuvation of thyroid would be protective of chronic and cancer effects. Therefore, the Agency concluded that regulating at a NOAEL of 82 mg/kg/day with effects seen at 304 mg/kg/day with a hundredfold uncertainty factor (UF_A=10X; UF_h=10X) provides an adequate margin of protection and that an additional UF for extrapolation from subchronic toxicity study to a chronic exposure scenario is not needed.

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 POE/POP mono(di-sec-butylphenyl) ether 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 POE/POP mono(di-sec-butylphenyl) ether.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic pesticide exposures are safe by comparing aggregate exposure estimates to the acute populations adjusted dose (aPAD) and chronic population adjusted dose (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.

1. *Acute risk*. There was no hazard attributable to a single exposure seen in the toxicity database for POE/POP mono(di-sec-butylphenyl) ether. Therefore, the POE/POP mono(di-sec-butylphenyl) ether are not expected to pose an acute risk.

2. *Chronic risk*. A chronic aggregate risk assessment takes into account exposure estimates from chronic dietary consumption of food and drinking water. Using the exposure assumptions discussed in this unit for chronic exposure (including limiting the uses of the POE/POP mono(di-sec-butylphenyl)

ether inert ingredients in agricultural products to use in herbicide formulations and using the maximum herbicide tolerances for key commodities), the chronic dietary exposure from food and water to POE/POP mono(di-sec-butylphenyl) ether is 14% of the cPAD for the U.S. population and 36% of the cPAD for children 1 to 2 yrs old, the most highly exposed population subgroup.

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

POE/POP mono(di-sec-butylphenyl) ether 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 POE/POP mono(di-sec-butylphenyl) ether. Using the exposure assumptions described in this unit, 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, respectively. Adult residential exposure combines high end outdoor dermal and inhalation handler exposure with a high end post application dermal exposure from contact with treated lawns. EPA has concluded the combined short-term aggregated food, water, and residential exposures result in an aggregate MOE of 140 for children. Children's residential exposure includes total exposures associated with contact with treated lawns (dermal and hand-to-mouth exposures). As the level of concern is for MOEs that are lower than 100, these MOEs are not of concern.

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

POE/POP mono(di-sec-butylphenyl) ether 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 POE/POP mono(di-sec-butylphenyl) ether. Using the exposure assumptions described in this unit, EPA has concluded that the combined intermediate-term aggregated food, water, and residential exposures result in aggregate MOEs of 470 and 490 for both adult males and females, respectively. Adult residential exposure includes high end post application dermal exposure from contact with treated lawns. EPA has concluded that the combined intermediate-term aggregated food, water, and residential exposures result in an aggregate MOE of 190 for children. Children's residential exposure includes total exposures associated with contact with treated lawns (dermal and hand-to-mouth exposures). As the level of concern is for MOEs that are lower than 100, these MOEs are not of concern.

5. *Aggregate cancer risk for U.S. population*. The Agency has not identified any concerns for carcinogenicity relating to POE/POP mono(di-sec-butylphenyl) ether.

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 residues of POE/POP mono(di-sec-butylphenyl) ether.

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 POE/POP mono(di-sec-butylphenyl) ether 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 Polyoxyethylene polyoxypropylene mono(di-sec-butylphenyl) ether when used as an inert ingredient in herbicide formulations only, for pre-harvest uses under 40 CFR 180.920 and used at no more than 30% by weight in herbicide formulations intended for application to turf.

VII. Statutory and Executive Order Reviews

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

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

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (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 28, 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 § 180.920, 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
* *	* * * *	*
Polyoxyethylene polyoxypropylene mono(di-sec-butylphenyl) ether (CAS Reg. No. 69029–39–6)	Limited to herbicide formulations only, and to no more than 30% by weight in herbicide formulations intended for application to turf	Surfactants, related adjuvants of surfactants
* *	* * * *	*

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2009–0490; FRL–8428–5]

Sodium and Ammonium Naphthalenesulfonate Formaldehyde Condensates; 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 the sodium and ammonium napthalenesulfonate formaldehyde condensates, herein referred to in this document as the SANFCs, when used as inert ingredients in pesticide formulations applied to growing corps under 40 CFR 180.920. The Joint Inerts Task Force (JITF), Cluster Support Team Number 11 and Akzo Nobel Surface Chemistry, LLC, submitted petitions 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 the SANFCs.

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–2009–0490. 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