Inert Ingredients	Limits	Uses
*	* * * *	
α-(p-nonylphenol)-ω-hydroxypoly(oxyethylene) mixture of dihydrogen phosphate and monohydrogen phosphate esters and the corresponding ammonium, calcium, magnesium, potassium, sodium, and zinc salts of the phosphate esters; the nonyl group is a propylene trimer isomer and the poly(oxyethylene) content averages 4-14 or 30 moles (CAS Reg. Nos. 51811-79-1, 59139-23-0, 67922-57-0, 68412-53-3, 68553-97-9, 68954-84-7, 99821-14-4, 152143-22-1, 51609-41-7, 37340-60-6, 106151-63-7, 68584-47-4, 52503-15-8, 68458-49-1).	Not to exceed 7% of pesticide formulation. Expires May 17, 2012.	Surfactants, related adjuvants of surfactants
*	* * * *	
α-(p-nonylphenol)-ω-hydroxypoly(oxyethylene) sulfate, ammonium, calcium, magnesium, potassium, sodium, and zinc salts the nonyl group is propylene trimer isomer and the poly(oxyethylene) content averages 4 moles (CAS Reg Nos. 9014-90-8, 9051-57-4, 9081-17-8, 68649-55-8, 68891-33-8).	Not to exceed 7% of pesticide formulation. Expires May 17, 2012.	Surfactants, related adjuvants of surfactants
*	* * * *	

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■ 3. Section 180.930 is amended by adding alphabetically the following entries in the table of inert ingredients to read as follows:

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

* * * * *

Inert Ingredients	Limits	Uses
*	* * * *	
α-(p-nonylphenol)-ω-hydroxypoly(oxyethylene) mixture of dihydrogen phosphate and monohydrogen phosphate esters and the corresponding ammonium, calcium, magnesium, potassium, sodium, and zinc salts of the phosphate esters; the nonyl group is a propylene trimer isomer and the poly(oxyethylene) content averages 4-14 or 30 moles (CAS Reg. Nos. 51811-79-1, 59139-23-0, 67922-57-0, 68412-53-3, 68553-97-9, 68954-84-7, 99821-14-4, 152143-22-1, 51609-41-7, 37340-60-6, 106151-63-7, 68584-47-4, 52503-15-8, 68458-49-1).	Not to exceed 7% of pesticide formulation. Expires May 17, 2012.	Surfactants, related adjuvants of surfactants
*	* * * *	
α-(p-nonylphenol)-ω-hydroxypoly(oxyethylene) sulfate, ammonium, calcium, magnesium, potassium, sodium, and zinc salts the nonyl group is propylene trimer isomer and the poly(oxyethylene) content averages 4 moles (CAS Reg Nos. 9014-90-8, 9051-57-4, 9081-17-8, 68649-55-8, 68891-33-8).	Not to exceed 7% of pesticide formulation. Expires May 17, 2012.	Surfactants, related adjuvants of surfactants

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[FR Doc. 2010–11687 Filed 5–14–10; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2008–0890; FRL–8824–3]

α-[p-(1,1,3,3-Tetramethylbutyl)phenyl]-ω-hydroxypoly(oxyethylene); Time-Limited Exemption from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a time-limited exemption from the requirement of a tolerance for residues of α-[*p*-(1,1,3,3-tetramethylbutyl)phenyl]-ω-hydroxypoly(oxyethylene) when used as an inert ingredient at levels not to exceed 7% in pesticide formulations applied to growing crops and raw agricultural commodities after harvest. The Joint Inerts Task Force, Cluster Support Team Number 5 requested an exemption for the requirement of a tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA). The exemption from the requirement of a tolerance expires on May 17, 2012. This regulation eliminates the need to establish a maximum permissible level for residues of α-[*p*-(1,1,3,3-tetramethylbutyl)phenyl]-ω-hydroxypoly(oxyethylene).

DATES: This regulation is effective May 17, 2010. Objections and requests for hearings must be received on or before July 16, 2010, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2008–0890. 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:

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

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

B. How Can I Get Electronic Access to Other Related Information?

You may access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's e-CFR cite at *http://www.gpoaccess.gov/ecfr*. To access the harmonized test guidelines referenced in this document electronically, please go to *http://www.epa.gov/ocspp* and select "Test Methods and Guidelines."

C. Can I File an Objection or Hearing Request?

Under section 408(g) of FFDCA, 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2008–0890 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before July 16, 2010. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket that is described in **ADDRESSES**. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit your copies, identified by docket ID number EPA–HQ–OPP–2008–0890, 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 8E7466) by the Joint Inerts Task Force, Cluster Support Team 5, c/o CropLife America, 1156 15th Street, NW., Suite 400, Washington, DC 20005. The petition requested that 40 CFR 180.910 be amended by establishing an exemption from the requirement of a tolerance for residues of α-[*p*-(1,1,3,3-tetramethylbutyl)phenyl]-ω-hydroxypoly(oxyethylene) produced by the condensation of 1 mole of *p*-(1,1,3,3-tetramethylbutyl)phenol with a range of 1–14 or 30–70 moles of ethylene oxide: if a blend of products is used, the average range number of moles of ethylene oxide reacted to produce any product that is a component of the blend shall be in the range of 1–14 or 30–70 (herein referred to in this document as octylphenol ethoxylate or OPE) when used as an inert ingredient in pesticide formulations applied to growing crops and raw agricultural commodities after harvest. That notice referenced a summary of the petition prepared by the Joint Inerts Task Force, Cluster Support Teams 5, 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. These tolerances expire on May 17, 2012.

Based upon review of the data supporting the petition, EPA has determined that the 40 CFR 180.910 exemption from the requirement of a tolerance for octylphenol ethoxylate should be time-limited for a period of two years and include a use limitation of not to exceed 7% by weight of the pesticide formulation. This limitation is discussed further in Units IV.C. and V.C. and is based on the Agency's risk assessment which can be found at *http://www.regulations.gov* in the document "Alkylphenol Ethoxylates (APEs - JITF CST 5 Inert Ingredients). Revised 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–2008–0890.

This petition was submitted in response to a final rule that was published in the **Federal Register** of August 9, 2006 (71 FR 45415) (FRL–8084–1) in which the Agency revoked, under section 408(e)(1) of 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 section 408(b)(2) of FFDCA. The expiration date for the tolerance exemptions subject to revocation was August 9, 2008, which was later extended to August 9, 2009, in the **Federal Register** of August 4, 2008 (73

FR 45317) (FRL–8373–6) to allow for data to be submitted to support the establishment of tolerance exemptions for those inert ingredients prior to the effective date of the tolerance exemption revocation. The effective date of the revocation for α-[*p*-(1,1,3,3-tetramethylbutyl)phenyl]-ω-hydroxypoly(oxyethylene) was subsequently extended on August 7, 2009 (74 FR 39543) (FRL–8431–8), October 9, 2009 (74 FR 52148) (FRL–8794–1), and February 9, 2010 (75 FR 6314) (FRL–8812–3). The current effective date of the revocation is May 9, 2010.

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...."

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 octylphenol ethoxylate including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with octkylphenol ethoxylate 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.

Octylphenol ethoxylate has low to moderate acute oral and dermal toxicity, is a mild to moderate skin irritant, and an eye irritant. Based on the analysis of the studies in the open literature, there is both positive and negative evidence that octylphenol ethoxylate is mutagenic in bacteria (*Salmonella typhimurium*) and mammalian (Chinese hamster ovary, mouse lymphoma) cells. In the Harmonized Guideline 870.3650 combined repeated dose toxicity study with the reproduction/developmental toxicity screening test in rats with octylphenol ethoxylate, there was no evidence of increased susceptibility. Additionally, there was no evidence of neurotoxicity, developmental toxicity, or reproductive toxicity in that same study. The Agency has identified octylphenol as a potential metabolite/degradate of concern. The Agency considered available toxicity data on octylphenol as well as toxicity data on the structurally related nonylphenol when assessing the hazard for this potential metabolite/degradate. The major effects seen in the octylphenol/nonylphenol databases are consistent with potential disturbances in estrogenic activity, but a complete mode of action analysis has not been conducted. These effects are the most sensitive endpoints for both substances and were considered the key findings for regulatory purposes. The Agency has used available data on the nonylphenol and octylphenol, which specifically look at these effects, to establish toxicity endpoints for both octylphenol ethoxylate and degradates of concern. The Agency considers the toxicity database to be sufficient to address potential hazards, and the Agency is regulating on the most sensitive endpoints seen in the database; effects which are well characterized with clear no-observed-adverse-effect levels (NOAEL).

Specific information on the studies received and the nature of the toxic effects caused by octylphenol ethoxylate as well as the NOAEL and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at *http://www.regulations.gov* in document "Alkylphenol Ethoxylates (APEs - JITF CST 5 Inert Ingredients). Revised Human Health Risk Assessment to Support Proposed Exemption from the Requirement of a Tolerance When Used as Inert Ingredients in Pesticide Formulations," pp. 9–20 in docket ID number EPA–HQ–OPP–2008–0890.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern (LOC) to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors (UF/SF) are used in conjunction with the POD to calculate a safe exposure level – generally referred to as a population-adjusted dose (PAD (a = acute, c = chronic)) or a reference dose (RfD), and a safe margin of exposure (MOE) or level of concern. For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see *http://www.epa.gov/pesticides/factsheets/riskassess.htm*.

A summary of the toxicological endpoints for octylphenol ethoxylate used for human risk assessment is shown in the Table of this unit.

TABLE — SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR OCTYLPHENOL ETHOXYLATES AND ITS METABOLITES (INCLUDING OCTYLPHENOL) FOR USE IN HUMAN RISK ASSESSMENT

Exposure/Scenario	Point of Departure and Uncertainty/ Safety Factors	RfD, PAD, LOC for Risk Assessment	Study and Toxicological Effects
Acute dietary (Females 13–50 years of age)	NOAEL = 15.6 milligrams/kilograms/day (mg/kg/day) UF_A = 10x UF_H = 10x Food Quality Protection Act Safety Factor (FQPA SF) = 1x	Acute RfD = 0.156 mg/kg/day aPAD = 0.156 mg/kg/day	Initiation and maintenance of pregnancy in rats (octylphenol) LOAEL = 31.3 mg/kg/day based on on increased % post-implantation loss following exposure of dams during gestation days 0–8.
Acute dietary (General population including infants and children)	An endpoint attributable to a single exposure was not seen in the database; therefore a point of departure was not selected.		
Chronic dietary (All populations)	NOAEL= 10 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 1x	Chronic RfD = 0.1 mg/kg/day cPAD = 0.1 mg/kg/day	2–Generation reproduction study in rats (octylphenol) LOAEL = 50 mg/kg/day based on significant increases in pituitary weight (↑12%, males), decreases in ovary weight (↓18%) in F_0 animals; timing of vaginal opening significantly accelerated in F_1 females; decreases in the numbers of implants and live F_2 pups born
Incidental oral and inhalation (short-term (1 to 30 days) and intermediate-term (1 to 6 months)	NOAEL= 150 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 10x	Residential LOC for MOE = 1,000. Occupational LOC for MOE = 100	Harmonized Guideline 870.3650 combined repeated dose toxicity study with the reproduction/developmental toxicity screening test in rats (octylphenol ethoxylate) LOAEL = 300 mg/kg/day based on clinical signs (pushing head through bedding after dosing), decreased body-weight gain in both sexes during the premating period, decreased thymus weight in females, increased liver weight in males, and increased incidence of centrilobular hepatocyte hypertrophy in males.
Dermal short-term (1 to 30 days) and intermediate-term (1 to 6 months)	Oral study NOAEL = 150 mg/kg/day (dermal absorption rate = 1%Dermal equivalent dose = 10,000 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 10x = UF_{DB}	Residential LOC for MOE = 1,000 Occupational LOC for MOE = 100	Harmonized Guideline 870.3650 combined repeated dose toxicity study with the reproduction/developmental toxicity screening test in rats (octylphenol ethoxylate) LOAEL = 300 mg/kg/day based on clinical signs (pushing head through bedding after dosing), decreased body-weight gain in both sexes during the premating period, decreased thymus weight in females, increased liver weight in males, and increased incidence of centrilobular hepatocyte hypertrophy in males
Cancer (Oral, dermal, inhalation)	Classification: Not classified; no alerts identified in structure-activity database (DEREK Version 11) with respect to carcinogenicity; potential mutagenicity concern identified in open literature for octylphenol ethoxylate and metabolite. Based on a weight of the evidence consideration of the available data, the Agency believes that cancer risks would be negligible.		

UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies). UF_{DB} = to account for the absence of data or other data deficiency.

C. Exposure Assessment

Very limited information is available for octylphenol ethoxylate with respect to plant and animal metabolism/degradation. There is extensive information in the literature on environmental degradation, and some information on bacterial and mammalian metabolism, all of which indicate similar degradation of the octylphenol ethoxylate compounds. The ethoxylate moiety is degraded by sequential removal of the ethoxylate groups, eventually degrading to octylphenol. There are studies in the literature that suggest that plants have the ability to take up octylphenol ethoxylate residues from treated soil.

While the Agency does not expect that the use of octylphenol ethoxylate as an inert ingredient in pesticide formulations would result solely in exposure to octylphenol, there are no available data on the exact nature of octylphenol ethoxylate residues in food and drinking water resulting from the use of octylphenol ethoxylate as an inert ingredient. Therefore, the Agency has concluded that the residues of concern in food and drinking water are the octylphenol ethoxylate compounds, their partially de-ethoxylated degradation products, as well as the degradation product octylphenol, and has conservatively assumed that in the case of food and drinking water exposures all exposure will be in the form of exposure to octylphenol, the potential metabolite/degradate of greatest toxicological concern.

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to octylphenol ethoxylate, EPA considered exposure from the petitioned-for exemption from the requirement of a tolerance. EPA assessed dietary exposures from octylphenol ethoxylate in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1–day or single exposure. Such effects were identified for octylphenol ethoxylate. A hazard endpoint for acute exposure to octylphenol ethoxylate was identified only for females ages 13–49; no hazard endpoints for acute exposure were identified for any other population group. In estimating acute dietary exposure, EPA used food consumption information from the United States Department of Agriculture (USDA) 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII).

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA 1994–1996 and 1998 CSFII.

As to residue levels in food, in the absence of specific residue data, both the acute and chronic dietary exposure assessments are conducted using 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 can be found at *http://www.regulations.gov* in the document "Alkyl Amines Polyalkoxylates (Cluster 4): Acute and Chronic Aggregate (Food and Drinking Water) Dietary Exposure and Risk Assessments for the Inerts" in docket ID number EPA–HQ–OPP–2008–0738.

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

The Agency believes the assumptions used to estimate dietary exposures lead to an extremely conservative assessment of dietary risk due to a series of compounded conservatisms. First, assuming that the level of residue for an inert ingredient is equal to the level of residue for the active ingredient will overstate exposure. The concentrations of active ingredient in agricultural products are generally at least 50% 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 relative to that of the active ingredient. EPA made a specific adjustment to the dietary exposure assessment to account for the use limitations of the amount of the surfactant octylphenol ethoxylate that may be in formulations (no more than 7%) and assumed that octylphenol ethoxylate is at the maximum limitation rather than at equal quantities with the active ingredient. This remains a very conservative assumption because surfactants are generally used at levels far below these percentages. For example, EPA examined several of the pesticide products associated with the tolerance/commodity combination which are the driver of the risk assessment and found that these products did not contain surfactants at levels greater than 2.25% and that none of the surfactants was octylphenol ethoxylate.

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 ingredient residue could be on food, and 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. Based on a weight of the evidence consideration of the available data, the Agency believes that cancer risks would be negligible. 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 octylphenol ethoxylate. Tolerance level residues and/or 100 PCT 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 octylphenol ethoxylate. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of octylphenol ethoxylate. Further information

regarding EPA drinking water models used in 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 octylphenol ethoxylate. Modeling runs on four surrogate inert ingredients using a range of physical chemical properties that would bracket those of octylphenol ethoxylate 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 "Alkylphenol Ethoxylates (APEs - JITF CST 5 Inert Ingredients). Revised Human Health Risk Assessment to Support Proposed Exemption from the Requirement of a Tolerance When Used as Inert Ingredients in Pesticide Formulations," p. 22 and Appendix C in docket ID number EPA–HQ–OPP–2008–0890.

For the purpose of the screening level dietary risk assessment to support this request for an exemption from the requirement of a tolerance for octylphenol ethoxylate, a conservative drinking water concentration value of 100 ppb based on screening level modeling was used to assess the contribution to drinking water for acute and chronic dietary risk assessments for the parent compounds and for the metabolites of concern. These values, which are 10 to 1,000 times greater than the highest levels of these substance seen in numerous surface and ground water monitoring studies, were directly entered into the acute and chronic dietary exposure models.

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). Octylphenol ethoxylate may be used as an inert ingredient in pesticide products that are registered for specific uses that may result in residential exposures. A screening level residential exposure and risk assessment was completed for pesticide products containing octylphenol ethoxylate as an inert ingredient. In this assessment, representative scenarios, based on end-use product application methods and labeled application rates, were selected. For each of the use scenarios, the Agency assessed residential handler (applicator) inhalation and dermal exposure for use scenarios with high exposure potential (i.e., exposure scenarios with high-end unit exposure values) to serve as a screening assessment for all potential residential pesticides containing octylphenol ethoxylate. Similarly, residential postapplication dermal and oral exposure assessments were also performed utilizing high-end exposure scenarios. In the case of octylphenol ethoxylate, non-dietary exposures are to octylphenol ethoxylate only as there is no appreciable metabolism or degradation of octylphenol ethoxylate in any of the representative residential use scenarios. Further details of this residential exposure and risk analysis can be found at *http://www.regulations.gov* in the document "JITF Inert Ingredients. Residential and Occupational Exposure Assessment Algorithms and Assumptions Appendix for the Human Health Risk Assessments to Support Proposed Exemption from the Requirement of a Tolerance When Used as Inert Ingredients in Pesticide Formulations" in docket ID number EPA–HQ–OPP–2008–0710.

Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at *http://www.epa.gov/pesticides/trac/science/trac6a05.pdf*.

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 octylphenol ethoxylate to share a common mechanism of toxicity with any other substances, and octylphenol ethoxylate does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that octylphenol ethoxylate does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at *http://www.epa.gov/pesticides/cumulative*.

D. Safety Factor for Infants and Children

1. *In general*. Section 408(b)(2)(C) of 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 pre-natal and post-natal 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 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. *Pre-natal and post-natal sensitivity*. In the case of octylphenol ethoxylate, there was no increased susceptibility to the offspring of rats following pre-natal and post-natal exposure in the Harmonized Guideline 870.3650 combined repeated dose toxicity study with the reproduction/developmental toxicity screening test. The offspring effects (decreased body weight in male and female offspring) occurred at 300 mg/kg/day in the presence of maternal toxicity, which was manifested as clinical signs, decreased body-weight gain, increased liver weight and liver hypertrophy in males, and decreased thymus weight in females at 300 mg/kg/day. However, a study referenced in the petition (Hazelden and Wilson, 1986) suggests more severe developmental effects (supernumerary rib) following gestational exposure via the diet during gestation days 6–17. The Harmonized Guideline 870.3650 study did not include a skeletal examination of the offspring. Since the Harmonized Guideline 870.3650 study with octylphenol ethoxylate did not assess its impact on the estrogen system, it cannot be used alone to properly assess the most sensitive endpoint. However, selecting the POD from the Harmonized Guideline 870.3650 study, which is based on a NOAEL of 150 mg/kg/day and decreased body-weight gain in both sexes during the premating period, decreased thymus weight in females, and increased liver weight and liver hypertrophy in males at the LOAEL of 300 mg/kg/day, and retaining the FQPA SF of 10X is comparable to using the POD from the reproduction studies on the most toxicologically potent compound (nonylphenol) that assessed estrogenic activity (endpoint: Accelerated vaginal opening; POD: 10 mg/kg/day). The endpoint (accelerated vaginal opening) and point of departure (10 mg/kg/day) are considered health protective of effects not assessed in the Harmonized Guideline 870.3650 studies on the octylphenol ethoxylate.

For the octylphenol metabolite, the 2–generation reproduction study in rats showed a delay in the acquisition of preputial separation in both the F_1 and F_2 pups, and the timing of vaginal opening was accelerated in a study in prepubertal female rats. For the related nonylphenol, two of the multigeneration reproduction studies in rats and two studies in prepubertal female rats showed acceleration in the acquisition of vaginal patency. A delay in preputial separation was observed in male rats in a pubertal onset assay. The combined toxicology databases currently available on octylphenol and nonylphenol identify accelerated vaginal opening as the most consistent and sensitive endpoint, and a clear NOAEL of 10 mg/kg/day has been demonstrated.

In a developmental toxicity study with octylphenol ethoxylate, developmental toxicity was demonstrated, as evidenced by the increased incidence of supernumerary ribs following exposure to the dams during gestation days 6–17. However, the low pregnancy rate among all groups (56%–70%) in this study makes interpretation of the results difficult. Additionally, the Harmonized Guideline 870.3650 study did not include a skeletal examination of the offspring. A developmental toxicity study was identified in the octylphenol database, and a clear NOAEL of 15.6 mg/kg/day (post-implantation loss) was established. The POD for octylphenol was selected from this study for the acute dietary (females 13+) exposure. This study is considered appropriate and health protective of effects observed in the developmental toxicity study with octylphenol ethoxylate.

Since the rat reproduction studies on the most toxicologically potent compound (nonylphenol) identified a clear NOAEL of 10 mg/kg/day for the most sensitive endpoint (accelerated vaginal opening), and the selected POD of 10 mg/kg/day (NOAEL for accelerated vaginal opening) for the dietary risk assessment is protective of offspring effects, there are no residual concerns.

3. *Conclusion*. EPA has determined that the FQPA SF can be reduced to 1X for the octylphenol metabolite upon which the dietary assessment is based. This decision is based on the following findings:

i. The most sensitive endpoint from the most toxicologically potent compound (nonylphenol) was selected for risk assessment and is considered health protective. The database for nonylphenol is protective of octylphenol, which has a limited database. There are several studies on nonylphenol (two multigeneration reproduction studies, pubertal onset assays, uterotrophic assays), which demonstrate acceleration of vaginal opening in the rat. Accelerated vaginal opening is the most consistent and sensitive endpoint identified. Clear NOAELs for this endpoint have been identified following exposure to nonylphenol.

ii. While endpoints were not selected from the Harmonized Guideline 870.3650 study in rats following pre-natal and post-natal exposure to octylphenol ethoxylate based on concerns that the study did not look for impacts on the estrogen system, the Agency does note that no increased susceptibility was demonstrated in the offspring in the Harmonized Guideline 870.3650 study in rats following pre-natal and post-natal exposure to octylphenol ethoxylate.

iii. Although a developmental toxicity study was identified in the open literature for octylphenol ethoxylate with a developmental NOAEL of 70/mg/kg/day, a developmental study on octylphenol demonstrated an increase in post-implantation loss following exposure to the dams from gestation day 0–8. A clear NOAEL of 15.6 mg/kg/day was established for the offspring effects. Since the POD selected from that study for acute dietary exposure to the octylphenol metabolite is 15.6 mg/kg/day, this value is considered health protective of offspring effects that might be found following octylphenol ethoxylate exposure.

iv. There is a 2–generation reproduction study in rats on octylphenol that demonstrates no adverse effects on reproductive function.

v. Although the available mammalian toxicity database does not include any chronic toxicity data, there is one 2–generation reproduction study on octylphenol and several multigeneration reproduction studies on the most toxicologically potent compound in the risk assessment, nonylphenol, in which test animals were dosed for extended periods of time and across generations.

vi. No evidence of neurotoxicity was demonstrated in the database for octylphenol ethoxylate, octylphenol, or nonylphenol and thus there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

vii. The exposure assessments used in this risk assessment are considered to be highly conservative. In the absence of substantial information on environmental degradation, the Agency has conducted an assessment which assumes that 100% of octylphenol ethoxylate is degradated to the more toxic degradate, octylphenol. Further, the assessment assumed residues of octylphenol will be present in all foods consumed at levels consistent with the highest established pesticide tolerance, and in drinking water at a high-end estimated level of 100 ppb. The Agency anticipates that this assessment will signifcantly overestimate risk.

EPA has determined that the FQPA safety factor should be retained (10X) for octylphenol ethoxylate, the compound upon which the residential assessment is based. This decision is based on the following findings:

a. Although endpoints from the Harmonized Guideline 870.3650 study in rats following pre-natal and post-natal exposure to the octylphenol ethoxylate were selected for the residential and occupational exposure risk assessments, there are concerns that the study did not look for the most sensitive endpoints for the estrogen system.

b. The Agency does note that no increased susceptibility was demonstrated in the offspring in the Harmonized Guideline 870.3650 study in rats following pre-natal and post-natal exposure to octylphenol ethoxylate.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the aPAD and cPAD. For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-term, intermediate-term, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk*. Using the exposure assumptions discussed in this unit for acute exposure, including the limitation of use of octylphenol ethoxylate to not more than 7% of the pesticide product, the acute dietary exposure from food and water to octylphenol ethoxylate willl occupy 37% of the aPAD for females 13 to 49 years old, the only population group for which an acute toxicity endpoint was established.

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, including the limitation of use of octylphenol ethoxylate to not more than 7% of the pesticide product, EPA has concluded that chronic exposure to octylphenol ethoxylate from food and water will utilize 90% of the cPAD for children 1–2 years old the population group

receiving the greatest exposure. Based on the explanation in Unit IV.C.3., regarding residential use patterns, chronic residential exposure to residues of octylphenol is not expected.

3. *Short-term and intermediate-term risk*. Short-term and intermediate-term aggregate exposure takes into account short-term and intermediate term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Short-term and intermediate-term aggregate risk assessments for octylphenol ethoxylate combine high end residential short-term or intermediate-term exposures with average food and drinking water exposures, and compare this total to a short-term or intermediate-term POD.

The POD for the dietary risk assessment is 10 mg/kg/day and the LOC when examining the MOE is 100 for octylphenol ethoxylate. The POD for the residential risk assessment is 150 mg/kg/day and the LOC is 1,000 for octylphenol ethoxylate. For the purpose of aggregating risks from dietary and residential exposure, the Agency is using the Aggregate Risk Index (ARI) approach for aggregate risk assessment. This approach allows for combining exposures which must be compared to different NOAELs and different LOCs. Potential risks of concerns are identified by an ARI of less than 1. Short-term and intermediate-term aggregate risks for octylphenol ethoxylate are not of concern (values ranging from 1.0 to 4.3 for children and adults, respectively).

4. *Aggregate cancer risk for U.S. population*. The Agency has carefully considered the weight of the evidence with respect to carcinogenicity for both the parent compounds and for the degradate. There were no structral alerts for carcinogenicity amd there were equivocal mutagenicity findings in the literature studies. Based on a weight of the evidence consideration of the available data, the Agency believes that cancer risks would be negligible. However, due to the equivocal findings in the mutagenicity data base, the Agency is asking for confirmatory data.

5. *Determination of safety*. Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to octylphenol ethoxylate residues.

V. Other Considerations

A. Analytical Enforcement Methodology

An analytical method is not required for enforcement purposes since the Agency is not establishing a numerical tolerance for residues of octylphenol ethoxylate in or on any food commodities. EPA is establishing a limitation on the amount of octylphenol ethoxylate that may be used in pesticide formulations applied to growing crops and raw agricultural commodities. That limitation will be enforced through the pesticide registration process under the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), 7 U.S.C. 136 *et seq*. EPA will not register any such pesticide for sale or distribution that contains greater than 7% of octylphenol ethoxylate by weight in the pesticide formulation.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint U.N. Food and Agriculture Organization/ World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established a MRL for octylphenol ethoxylate.

C. Revisions to Petitioned-For Exemption from the Requirement of a Tolerance

EPA is revising the petitioned-for octylphenol ethoxylate exemption from the requirement of a tolerance under 40 CFR 180.910 by including a limitation of "not to exceed 7% of the pesticide formulation." As discussed in Unit IV.C., this limitation will ensure that there are no aggregate risks of concern. Additionally, EPA is also revising the octylphenol ethoxylate exemption from the requirement of a tolerance under 40 CFR 180.910 to include a 2-year time limitation. The exemption from the requirement of a tolerance for octylphenol ethoxylate will expire on May 17, 2012. This two-year time limitation is being established for two purposes:

1. To provide time for the development and submission of confirmatory toxicity data to address the equivocal results in the available genotoxicity studies conducted on octylphenol ethoxylate; and

2. To provide additional time, should the initial testing not confirm EPA's conclusion regarding the lack of a cancer concern, for registrants to attain EPA approval of registration amendments for reformulation of their pesticide products to remove octylphenol ethoxylate and to replace existing products with reformulated products.

EPA believes that its cancer conclusion can be confirmed by negative results in either *in vitro* or *in vivo* mutagenicity studies. EPA is recommending that supporters of the octylphenol ethoxylate tolerance exemption perform the following studies for confirmatory purposes:

A new Ames assay (Harmonized Guideline 870.5100 — Bacterial reverse mutation test) and a mouse lymphoma assay (Harmonized Guideline 870.5300 — *In vitro* mammalian cell gene mutation test).

A bone marrow assay (Harmonized Guideline 870.5395 — Mammalian erythrocyte micronucleus test).

Since *in vivo* mutagenicity studies such as the bone marrow assay are generally regarded as more definitive than *in vitro* studies, and a negative result in the bone marrow test may outweigh whatever results are found in the Ames test and mouse lymphoma assay, supporters of the octylphenol ethoxylate tolerance exemption may opt to conduct the mammalian erythrocyte micronucleus test in lieu of the two *in vitro* mutagenicity studies. If these data do not confirm EPA's cancer conclusion, then EPA will need two-year cancer bioassays in the mouse and rat (Harmonized Guideline 870.4200 — Carcinogenicity (mouse) and Harmonized Guideline 870.4300 — combined Chronic Toxicity/ Carcinogenicity (rat)) to make a safety finding in support of this tolerance exemption.

In conducting confirmatory testing, supporters of the octylphenol ethoxylate tolerance exemption should keep the following information in mind. EPA believes that the minimum time period for registrants to obtain approval of reformulated products and to replace existing products is 15 months. Thus, EPA plans to alert the registrant community no later than February 17, 2011 whether confirmatory data has been received and demonstrates that EPA's cancer conclusion was correct. If submitted data do confirm EPA's conclusion, EPA will notify registrants that it intends to remove the expiration date from the tolerance exemption prior to expiration of the exemption. If the

submitted data do not confirm the conclusion, EPA will inform registrants that they should assume that the tolerance exemption will expire on May 17, 2012 and that they should take all appropriate steps to insure that they do not release for shipment product that may result in food containing residues inconsistent with the dictates of the FFDCA. EPA does not intend to extend the expiration date for the exemption if it is determined that two-year cancer bioassays are needed to evaluate potential cancer risk. Additionally, if no confirmatory data are submitted by November 17, 2010. EPA will not have time to make a decision on any confirmatory data by February 17, 2011 and thus, at that time, EPA will inform registrants that they should assume that the tolerance exemption will expire on May 17, 2012 and that they should take all appropriate steps as indicated above.

VI. Conclusion

Therefore, an exemption from the requirement of a tolerance for residues of α-[*p*-(1,1,3,3-tetramethylbutyl)phenyl]-ω-hydroxypoly(oxyethylene) when used as an inert ingredient at levels not to exceed 7% in pesticide formulations applied to growing crops and raw agricultural commodities after harvest under 40 CFR 180.910 is established with an expiration date of May 17, 2012.

VII. Statutory and Executive Order Reviews

This final rule establishes 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 tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply.

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

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

VIII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

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

Dated: May 10, 2010.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

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

PART 180—[AMENDED]

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

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

■ 2. Section 180.910 is amended by adding alphabetically the following entry in the table of inert ingredients to read as follows:

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

* * * * *

Inert Ingredients	Limits	Uses
*	* * * *	
α-[*p*-(1,1,3,3-tetramethylbutyl)phenyl]-ω-hydroxypoly(oxyethylene) produced by the condensation of 1 mole of *p*-(1,1,3,3-tetramethylbutyl)phenol with a range of 1–14 or 30–70 moles of ethylene oxide: If a blend of products is used, the average range number of moles of ethylene oxide reacted to produce any product that is a component of the blend shall be in the range of 1–14 or 30–70 (CAS Reg. Nos. 9036–19–5, 9002–93–1).	Not to exceed 7% of pesticide formulation. Expires May 17, 2012.	Surfactants, related adjuvants of surfactants
*	* * * *	

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[FR Doc. 2010–11686 Filed 5–14–10; 8:45 am]

BILLING CODE 6560–50–S

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

43 CFR Part 8360

[LLWO25000—L12200000.PM000—241A.00]

RIN 1004–AD96

Visitor Services

AGENCY: Bureau of Land Management, Interior.

ACTION: Final rule.

SUMMARY: The Bureau of Land Management (BLM) is amending its regulations to remove the Land and Water Conservation Fund Act as one of the authorities of its recreation regulations, in accordance with the Federal Lands Recreation Enhancement Act of 2004 (REA). The final rule amends and reorders the prohibitions to separate those that apply specifically to campgrounds and picnic areas from those with more general application. The reordering is necessary to broaden the scope to include all areas where standard amenity, expanded amenity, and special recreation permit fees are charged under REA. The final rule also removes regulations that have been interpreted by the BLM Field Offices to require the BLM to publish supplementary rules for each area for failure to pay recreation fees, thus relieving the BLM from publishing separate rules for each area. Finally, this rule makes technical changes to maintain consistency with other BLM regulations.

DATES: This rule is effective on June 16, 2010.

ADDRESSES: Inquiries or suggestions should be delivered to U.S. Department of the Interior, Director (630), Bureau of Land Management, Mail Stop 401 LS, 1849 C St., NW., *Attention:* RIN: 1004–AD96, Washington, DC 20240.

FOR FURTHER INFORMATION CONTACT: For information on the substance of the rule, please contact Hal Hallett at (202) 912–7252 or Anthony Bobo Jr. at (202) 912–7248. For information on procedural matters, please contact Chandra Little at (202) 912–7403. Persons who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 to contact the above individuals during normal business hours. FIRS is available twenty-four hours a day, seven days a week, to leave a message or question with these individuals. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION:

I. Background

The BLM is revising its fee management regulations, policies, and procedures in accordance with the REA, 16 U.S.C. 6801 *et seq.,* 43 CFR part 2930 currently includes all recreation fee management regulations, including the requirement that visitors pay fees before occupying a campground or picnic area. The BLM is now amending 43 CFR part 8360 to add regulatory changes made necessary by the REA, including the removal of any language pertaining to recreation fees. In addition, the section addressing the collection of fossils is modified to include common plant fossils, reflecting long established BLM policies. The Omnibus Public Land Management Act (OPLMA) became law on March 30, 2009, after the publication of the proposed rule and includes provisions on Paleontological Resources Preservation (PRP) (Title VI, Subtitle D (Pub. L. 111–11, 123 Stat. 1172, 16 U.S.C. 470aaa *et seq.*)) The law requires that the Secretary of the Interior develop regulations to implement this subtitle. The OPLMA–PRP defines "casual collecting" as "* * * the collecting of a reasonable amount of common invertebrate and plant paleontological resources for non-commercial personal use, either by surface collection or the use of non-powered hand tools resulting in only negligible disturbance to the Earth's surface and other resources." These regulations define terms as used in this definition. However, the OPLMA–PRP does not change the BLM's basic policy for allowing casual collecting of reasonable amounts of common invertebrate and common plant fossils from public lands for personal use without a permit, and therefore, the regulations at 43 CFR part 8360 do not conflict with the OPLMA–PRP.

Other changes were made that group related regulations in the same section to simplify language and clarify the intent, and to resolve inconsistencies between the existing provisions.

II. Final Rule as Adopted and Response to Comments

On October 3, 2008, the BLM published a proposed rule (73 FR 57564) to implement REA with a 60-day public comment period that ended on December 2, 2008. The BLM received four comments on the proposed rule. These comments supported the proposed rule and suggested a few minor revisions to make the regulations consistent with other BLM regulations. The comments specifically addressed activities relating to the recreational collection of rocks and paleontological resources on BLM lands.

Section 8360.0–3 Authority

The final rule removes the Land and Water Conservation Fund Act (LWCFA) (16 U.S.C. 4601–6a) as an authority for the regulations. The enactment of the REA changed the BLM's authority to collect recreation fees. Recreation fees that were previously authorized under the LWCFA are now authorized under REA. The BLM's policies and procedures have also been revised to reflect this new and revised authority. We received no comment on this section and therefore the final rule remains as proposed.

Section 8360.0–5 Definitions

In paragraph (c), the proposed rule added the word "recreation" as a modifier to the term "developed sites and areas" in order to clarify that the definition is specific to developed recreation sites and areas. The same language is inserted elsewhere in this rule to distinguish developed recreation sites and areas from other developed sites and areas used for non-recreation purposes. We received no comment on this section, thus the final rule remains as proposed.

Section 8365.1–5 Property and Resources

We received three comments on this section that stated that removing the term "rocks" from the current 43 CFR 8365.1–5(b)(2), as proposed, would lead to uncertainty about the collecting of rocks as a hobby without a permit on public lands. The commenters suggested that we retain the term "rocks" consistent with the current regulations and with the BLM's policy of allowing recreational collection of rocks and minerals on public lands. The BLM stated in the preamble to the proposed rule that the term "rocks" should be removed because it was already covered in regulations at 43 CFR 8365.1–5(b)(4) which by reference to 43 CFR subpart 3604 allows the recreational collection of "common" rocks without a permit. However, the regulations at 43 CFR part 3600 do not address the recreational collection of rocks on public lands without a permit. The Materials Act does not allow recreational collection of rocks and payment is required. Section 8365.1–5(b) makes an exception for the