

through 10:45 p.m. on May 29, 2010. The Captain of the Port, Sector Lake Michigan, or his or her on-scene representative may terminate this operation at any time.

(c) *Regulations.* (1) In accordance with the general regulations in § 165.23 of this part, entry into, transiting, or anchoring within this safety zone is prohibited unless authorized by the Captain of the Port, Sector Lake Michigan, or his or her on-scene representative.

(2) This safety zone is closed to all vessel traffic, except as may be permitted by the Captain of the Port, Sector Lake Michigan, or his or her on-scene representative.

(3) The "on-scene representative" of the Captain of the Port, Sector Lake Michigan, is any Coast Guard commissioned, warrant or petty officer who has been designated by the Captain of the Port, Sector Lake Michigan, to act on his or her behalf. The on-scene representative of the Captain of the Port, Sector Lake Michigan, will be aboard either a Coast Guard or Coast Guard Auxiliary vessel.

(4) Vessel operators desiring to enter or operate within the safety zone shall contact the Captain of the Port, Sector Lake Michigan, or his or her on-scene representative to obtain permission to do so. The Captain of the Port, Sector Lake Michigan, or his or her on-scene representative may be contacted via VHF Channel 16. Vessel operators given permission to enter or operate in the safety zone must comply with all directions given to them by the Captain of the Port, Sector Lake Michigan, or his or her on-scene representative.

Dated: April 8, 2010.

L. Barndt,

Captain, U.S. Coast Guard, Captain of the Port, Sector Lake Michigan.

[FR Doc. 2010-9797 Filed 4-27-10; 8:45 am]

BILLING CODE 9110-04-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[USCG-2010-0251]

RIN 1625-AA00

Safety Zone; Milwaukee Harbor, Milwaukee, WI

AGENCY: Coast Guard, DHS.

ACTION: Notice of enforcement of regulation.

SUMMARY: The Coast Guard will enforce the safety zone for annual fireworks events in the Captain of the Port, Sector Lake Michigan, during four separate periods between 9:15 p.m. on June 12, 2010 and 10:30 p.m. on June 24, 2010. This action is necessary and intended to ensure safety of life on the navigable waters of the United States immediately prior to, during, and immediately after fireworks events. This action will establish restrictions upon, and control movement of, vessels in a specified area immediately prior to, during, and immediately after fireworks events. During the enforcement period, no person or vessel may enter the safety zones without permission of the Captain of the Port, Sector Lake Michigan.

DATES: The regulations in 33 CFR 165.935 will be enforced during four separate periods between 9:15 p.m. on June 12, 2010 and 10:30 p.m. on June 24, 2010.

FOR FURTHER INFORMATION CONTACT: If you have questions on this notice, call or e-mail BM1 Adam Kraft, Prevention Department, Coast Guard Sector Lake Michigan, Milwaukee, WI at 414-747-7154, e-mail Adam.D.Kraft@uscg.mil.

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce the safety zone listed in 33 CFR 165.935, Safety Zones, Milwaukee Harbor, Milwaukee, WI, for the following events:

(1) *Pridefest fireworks display* on June 12, 2010 from 9:15 p.m. through 10 p.m.

(2) *Polish Festival fireworks display* on June 18, 2010 from 9:15 p.m. through 10 p.m.; on June 19, 2010 from 9:15 p.m. through 10 p.m.

(3) *Summerfest fireworks display* on June 24, 2010 from 9:15 p.m. through 10:30 p.m.

All vessels must obtain permission from the Captain of the Port, Sector Lake Michigan, or his or her on-scene representative to enter, move within, or exit the safety zone. Vessels and persons granted permission to enter the safety zone shall obey all lawful orders or directions of the Captain of the Port, Sector Lake Michigan, or his or her on-scene representative. While within a safety zone, all vessels shall operate at the minimum speed necessary to maintain a safe course.

This notice is issued under authority of 33 CFR 165.935 Safety Zone, Milwaukee Harbor, Milwaukee, WI and 5 U.S.C. 552(a). In addition to this notice in the **Federal Register**, the Coast Guard will provide the maritime community with advance notification of these enforcement periods via broadcast Notice to Mariners or Local Notice to Mariners. The Captain of the Port, Sector Lake Michigan, will issue a

Broadcast Notice to Mariners notifying the public when enforcement of the safety zone established by this section is suspended. If the Captain of the Port, Sector Lake Michigan, determines that the safety zone need not be enforced for the full duration stated in this notice, he or she may use a Broadcast Notice to Mariners to grant general permission to enter the safety zone. The Captain of the Port, Sector Lake Michigan, or his or her on-scene representative may be contacted via VHF Channel 16.

Dated: April 8, 2010.

L. Barndt,

Captain, U.S. Coast Guard, Captain of the Port, Sector Lake Michigan.

[FR Doc. 2010-9799 Filed 4-27-10; 8:45 am]

BILLING CODE 9110-04-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2009-0165; FRL-8816-4]

Phosphate Ester, Tallowamine, Ethoxylated; 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 phosphate ester, tallowamine, ethoxylated (CAS Reg. No. 68308-48-5), herein referred to in this document as PETAE when used as an inert ingredient at a maximum of 20% by weight in pesticide formulations applied in or on growing crops. Huntsman Corporation submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting establishment of an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of PETAE.

DATES: This regulation is effective April 28, 2010. Objections and requests for hearings must be received on or before June 28, 2010, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA-HQ-OPP-2009-0165. 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: Alganesh Debesai, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 308-8353; e-mail address: debesai.alganesh@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

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

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

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

You may access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's e-CFR cite at <http://www.gpoaccess.gov/ecfr>. To access the OPPTS harmonized test guidelines

referenced in this document electronically, please go to <http://www.epa.gov/oppts> and select "Test Methods and Guidelines."

C. Can I File an Objection or Hearing Request?

Under section 408(g) of FFDCA, 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2009-0165 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 June 28, 2010. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket that is described in **ADDRESSES**. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit your copies, identified by docket ID number EPA-HQ-OPP-2009-0165, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the on-line instructions for submitting comments.

- *Mail:* Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Delivery:* OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket Facility's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305-5805.

II. Petition for Exemption

In the **Federal Register** of April 8, 2009 (74 FR 15975) (FRL-8407-4), EPA issued a notice pursuant to section 408

of FFDCA, 21 U.S.C. 346a, announcing the filing of a pesticide petition (PP 8E7477) by Huntsman Corporation, 8600 Gosling Road, Woodlands, TX 77381. The petition requested that 40 CFR 180.920 be amended by establishing an exemption from the requirement of a tolerance for residues of tallowamine, ethoxylated, mixture of dihydrogen phosphate and monohydrogen phosphate esters and the corresponding ammonium, calcium, potassium, and sodium salts of the phosphate esters, where the poly(oxyethylene) content averages 2-20 moles, (CAS Reg. No. 68308-48-5) when used as an inert ingredient as surfactants, related adjuvants of surfactants in pesticide formulations applied to growing crops at a maximum of 20% by weight in pesticide formulations. That notice referenced a summary of the petition prepared by Huntsman Corporation, the petitioner, which is available in the docket, <http://www.regulations.gov>. There were no comments received in response to the notice of filing.

III. Inert Ingredient Definition

Inert ingredients are all ingredients that are not active ingredients as defined in 40 CFR 153.125 and include, but are not limited to, the following types of ingredients (except when they have a pesticidal efficacy of their own): Solvents such as alcohols and hydrocarbons; surfactants such as polyoxyethylene polymers and fatty acids; carriers such as clay and diatomaceous earth; thickeners such as carrageenan and modified cellulose; wetting, spreading, and dispersing agents; propellants in aerosol dispensers; microencapsulating agents; and emulsifiers. The term "inert" is not intended to imply nontoxicity; the ingredient may or may not be chemically active. Generally, EPA has exempted inert ingredients from the requirement of a tolerance based on the low toxicity of the individual inert ingredients.

IV. Aggregate Risk Assessment and Determination of Safety

Section 408(c)(2)(A)(i) of FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is "safe." Section 408(b)(2)(A)(ii) of FFDCA defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is

reliable information.” This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . .”

EPA establishes exemptions from the requirement of a tolerance only in those cases where it can be clearly demonstrated that the risks from aggregate exposure to pesticide chemical residues under reasonably foreseeable circumstances will pose no appreciable risks to human health. In order to determine the risks from aggregate exposure to pesticide inert ingredients, the Agency considers the toxicity of the inert in conjunction with possible exposure to residues of the inert ingredient through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings. If EPA is able to determine that a finite tolerance is not necessary to ensure that there is a reasonable certainty that no harm will result from aggregate exposure to the inert ingredient, an exemption from the requirement of a tolerance may be established.

Consistent with section 408(c)(2)(A) of FFDCA, and the factors specified in FFDCA section 408(c)(2)(B), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for PETAE including exposure resulting from the exemption established by this action. EPA’s assessment of exposures and risks associated with PETAE follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered their validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also

considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. Specific information on the studies received and the nature of the adverse effects caused by PETAE as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies are discussed in this unit.

The following provides a brief summary of the risk assessment and conclusions for the Agency’s review of PETAE. The Agency’s full decision document for this action is available in the Agency’s electronic docket (*regulations.gov*) under the docket number EPA-HQ-OPP-2009-0165. The database on PETAE is limited, however, the Agency has determined that studies on alkyl amine polyalkoxylates (AAPs) can be used to assess the toxicity of the PETAE because PETAE is a phosphate ester form of AAPs. The Agency has recently evaluated AAPs in docket ID number EPA-HQ-OPP-2008-0738.

PETAE is not acutely toxic via oral, dermal, and inhalation routes of exposure. It is extremely irritating to the eyes and slightly irritating to the skin. It is not a dermal sensitizer. In a Combined Repeated Dose Toxicity Study with the Reproduction/ Developmental Toxicity Screening Test, clinical signs of toxicity (abnormal respiratory sounds, dyspnea, piloerection, and emaciation), mortality and decreased food consumptions and decreased in body weights were observed in parental animals at 200 milligrams/kilogram/day (mg/kg/day). The clinical signs observed in this study are indicative of local irritation. No effects on functional observation battery (FOB) parameters were observed. The gestation index was decreased primarily due to mortality of females. Decreased in corpora lutea and implantation sites were observed at the highest dose tested (200 mg/kg/day). Decrease in pups’ body weight gain was observed on day 4 at the high dose only. No mutagenicity studies are available in the database; however, there was no evidence that AAPs are mutagenic or clastogenic.

There are no chronic toxicity or carcinogenicity studies available in the database. There is no evidence that the AAPs are carcinogenic. The Agency used a qualitative structure activity relationship (QSAR) database, DEREK11, to determine if there were structural alerts for a representative large molecule, as well as a smaller molecule that had been extensively dealkylated, with the amine group intact. No structural alerts were identified. Therefore, there are no triggers for carcinogenicity of PETAE in the database.

B. Toxicological Points of Departure/ Levels of Concern

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

A summary of the toxicological endpoints for PETAE used for human risk assessment is shown in the following table:

SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR PETAE 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 (General population including infants and children) | No appropriate endpoints were identified for acute dietary risk assessment. | | |

SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR PETAE FOR USE IN HUMAN 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 = 100 mg/kg/day UF _A = 10x UF _H = 10x FQPA SF = 3x | Chronic RfD = 1 mg/kg/day cPAD = 0.33 mg/kg/day | OECD 422 Reproduction/Developmental Screen in rats (MRID 47600707) LOAEL = 200 mg/kg/day based on mortalities, clinical signs, decreased body weight and/or body weight gain and decreased food consumption in both sexes CAS 7664–38–2 |
| Incidental Oral Short-Term and Intermediate-Term Dermal and Inhalation | NOAEL = 100 mg/kg/day UF _A = 10x UF _H = 10x FQPA SF = 3x (10% Dermal absorption; 100% inhalation and oral toxicity assumed equivalent) | Residential/Occupational LOC for MOE = 300 | OECD 422 Reproduction/Developmental Screen in rats (MRID 47600707) LOAEL = 200 mg/kg/day based on mortalities, clinical signs, decreased body weight and/or body weight gain and decreased food consumption in both sexes CAS 7664–38–2 |
| Cancer (Oral, dermal, inhalation) | Classification: No animal toxicity data available for an assessment. Based on SAR analysis, PETAE is not expected to be carcinogenic. | | |

UF_A = extrapolation from animal to human (interspecies).

UF_H = potential variation in sensitivity among members of the human population (intraspecies).

FQPA SF = Food Quality Protection Act Safety Factor.

PAD = population adjusted dose (a = acute, c = chronic).

RfD = reference dose.

MOE = margin of exposure.

LOC = level of concern.

C. Exposure Assessment

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

i. *Acute exposure.* No adverse effect attributable to a single exposure of the PETAE was seen in the toxicity databases; therefore, an acute dietary exposure assessment for the PETAE was not conducted.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment, EPA used food consumption information from the United States Department of Agriculture (USDA) 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII). As to residue levels in food, no residue data were submitted for PETAE. 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 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 in relation to that of the active ingredient. In the case of the PETAE, EPA made a specific adjustment to the dietary exposure assessment to account for the use limitations of the amount of PETAE that may be in formulations (no more than 20% by weight in pesticide formulations) and assumed that the PETAE are present at the maximum limitation rather than at equal quantities with the active ingredient. This remains a very conservative assumption because surfactants are generally used at levels far below this percentage.

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, 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 QSAR database, DEREK11, to determine if there were structural alerts suggestive of carcinogenicity. No structural alerts for carcinogenicity were identified. Therefore, a quantitative dietary exposure assessment was not conducted for the purpose of evaluating cancer risk.

2. *Dietary exposure from drinking water.* For the purpose of the screening level dietary risk assessment to support this request for an exemption from the requirement of a tolerance for PETAE, a conservative drinking water concentration value of 100 parts per billion (ppb) based on screening level modeling was used to assess the contribution to drinking water for the chronic dietary risk assessments for parent compound. These values were directly entered into the dietary exposure model.

3. *From non-dietary exposure.* The term "residential exposure" is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets). PETAE may be used in inert ingredients in pesticide products that are registered for specific uses that may result in both

indoor and outdoor residential exposures.

A screening level residential exposure and risk assessment was conducted for products containing the PETAE as inert ingredients. In this assessment, the Agency selected representative scenarios, based on end-use product application methods and labeled application rates. The residential products are typically formulated as liquids in concentrates or as wettable powders. PETAE has no pesticidal properties, and is added to pesticide formulations for its adjuvant property. PETAE is not generally added to any pesticides intended for indoor use (i.e., where the Agency would typically assess crack and crevice/pet uses). Therefore, EPA assumed no indoor uses exist. Similarly, residential post application dermal and oral exposure assessments were also performed utilizing high end indoor and outdoor exposure 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 PETAE to share a common mechanism of toxicity with any other substances, and PETAE does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that PETAE 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 prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* In the case of PETAE, there was no increased susceptibility to the offspring of rats following prenatal and postnatal exposure in the OPPTS Harmonized Test Guideline 870.3650 reproductive/developmental screening study. Decreased litter size and body weight gain in pups was observed at 200 mg/kg/day where maternal/paternal toxicity was manifested based on mortalities, clinical signs, decreased body weight and/or body weight gain and decreased food consumption in male and female rats at 200 mg/kg/day. There is no concern for residual uncertainties because clear NOAELs were established for parental and offspring toxicities.

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

i. The toxicity data available on the PETAE consists of one OPPTS Harmonized Test Guideline 870.3650 combined repeated dose toxicity study with the reproduction/development toxicity screening test (rat); acute oral, dermal, inhalation skin irritation and sensitization, and eye toxicity data. The other studies were bridged from AAPs since PETAE is a phosphate ester form of AAPs which have been recently assessed by the Agency in docket ID number EPA-HQ-OPP-2008-0738. There was no evidence of immunotoxicity in the database. Furthermore, these compounds do not belong to a class of chemicals that would be expected to be immunotoxic and, there was no evidence that the AAPs are mutagenic or clastogenic.

ii. No quantitative or qualitative increased susceptibility was demonstrated in the offspring in the OPPTS Harmonized Test Guideline

870.3650 combined repeated dose toxicity study with the reproduction/developmental toxicity screening test in rats following prenatal and postnatal exposure.

iii. There are no chronic studies or carcinogenicity studies available in the database. EPA has considerable information on the general toxicity of surfactants. These compounds are shown to cause local irritation and corrosive effects on membrane. EPA recently assessed the toxicity of AAPs. PETAE is a phosphate ester form of AAPs. The database on AAPs indicates that the effects do not increase in severity over time (4 weeks to 13 weeks). Based on the lack of progression of severity of effects with time along with the considerable similarities of effects across the species tested and the observation that the vast majority of the effects observed were related to local irritation and corrosive effects, EPA concludes that chronic data are unlikely to show significant differences from existing studies. In addition, the concern for chronic effects for PETAE is low based on SAR, DEREK11 analysis and available data on AAPs. Based on the above evidence, EPA concluded that the FQPA factor of 3X for the lack of chronic studies would be adequate and protective.

iv. No treatment-related effects on FOB parameters were observed in the OPPTS Harmonized Test Guideline 870.3650. In addition, no evidence of treatment-related clinical signs of neurotoxicity were observed in the available toxicological studies. EPA concluded that there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

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 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 PETAE in drinking water. These assessments will not underestimate the exposure and risks posed by PETAE. Based on the above considerations, EPA has reduced the FQPA factor to 3X.

E. Aggregate Risks and Determination of Safety

Determination of safety section. EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-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.* An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. No adverse effect resulting from a single oral exposure was identified, and no acute dietary endpoint was selected. Therefore, PETAE is 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 and the use limitations of not more than 20% by weight in pesticide formulations, the chronic dietary exposure from food and water to PETAE is 23.2% of the cPAD for the U.S. population and 75.6% of the cPAD for children 1 to 2 years 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).

PETAE is currently used as an inert ingredient in pesticide products that are registered for uses that could result in short-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short-term residential exposures to PETAE.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the combined short-term food, water, and residential exposures result in aggregate MOEs of 1,040 and 1,147 for adult males and females, respectively. Adult residential exposure combines high end dermal and inhalation handler exposure from indoor hand wiping 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 600 for children. Children's residential exposure includes total exposures associated with contact with treated lawns (dermal and hand-to-mouth exposures). Because EPA's level of concern for PETAE is a MOE of 300 or below, these MOEs are not of concern.

4. *Intermediate-term risk.*

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

PETAE is currently used as an inert ingredient in pesticide products that are registered for uses that could result in intermediate-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with intermediate-term residential exposures to PETAE.

Using the exposure assumptions described in this unit for intermediate-term exposures, EPA has concluded that the combined intermediate-term food, water, and residential exposures result in aggregate MOEs of 1,040 and 1,147 for adult males and females, respectively. Adult residential exposure includes high end post application dermal exposure from contact with treated lawns. EPA has concluded the combined intermediate-term aggregated food, water, and residential exposures result in an aggregate MOE of 680 for children. Children's residential exposure includes total exposures associated with contact with treated lawns (dermal and hand-to-mouth exposures). Because EPA's LOC for PETAE is a MOE of 300 or below, 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 PETAE.

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 PETAE residues.

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 PETAE

nor have any CODEX Maximum Residue Levels (MRLs) been established for any food crops at this time.

VI. Conclusions

Therefore, an exemption from the requirement of a tolerance is established under 40 CFR 180.920 for PETAE (CAS Reg. No. 68308-48-5) when used as an inert ingredient (as surfactants, related adjuvants of surfactants) in pesticide formulations applied to growing crops at a maximum of 20% by weight in pesticide formulations.

VII. Statutory and Executive Order Reviews

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

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

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

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

VIII. Congressional Review Act

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

List of Subjects in 40 CFR Part 180

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

Dated: April 15, 2010.

G. Jeffrey Herndon,
Acting 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 ingredient to read as follows:

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

* * * * *

| Inert ingredients | Limits | Uses |
|---|--|---|
| Tallowamine, ethoxylated, mixture of dihydrogen phosphate and monohydrogen phosphate esters and the corresponding ammonium, calcium, potassium, and sodium salts of the phosphate esters, where the poly(oxyethylene) content averages 2–20 moles (CAS Reg. No. 68308-48-5) | Not to exceed 20% of pesticide formulation | Surfactants, related adjuvants of surfactants |

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2009-0551; FRL-8818-8]

Cyprodinil; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of cyprodinil in or on canola, seed. Syngenta Crop Protection, Inc. requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective April 28, 2010. Objections and requests for hearings must be received on or before June 28, 2010, and must be filed in accordance with the instructions