

MRA member at the time of the test. For firewalled conformity assessment bodies, the firewalled conformity assessment body must be one that the Commission accredited by order at or before the time the product was tested, even though the order will not have included the test methods in the regulations specified in this notice. If the third party conformity assessment body has not been accredited by a Commission order as a firewalled conformity assessment body, the Commission will not accept a certificate of compliance based on testing performed by the third party conformity assessment body before it is accredited, by Commission order, as a firewalled conformity assessment body;

- The third party conformity assessment body's application for testing using the test methods in the regulations identified in this notice is accepted by the CPSC on or before September 20, 2010;
- The product was tested on or after July 21, 2010 with respect to the regulations identified in this notice;
- The accreditation scope in effect for the third party conformity assessment body at the time of testing expressly included testing to the regulations identified earlier in part I of this document;
- The test results show compliance with the applicable current standards and/or regulations; and
- The third party conformity assessment body's accreditation, including inclusion in its scope the standards described in part I of this notice, remains in effect through the effective date for mandatory third party testing and manufacturer/private labeler certification for conformity with 16 CFR parts 1630 and/or 1631.

Dated: July 15, 2010.

**Todd A. Stevenson,**

*Secretary, Consumer Product Safety Commission.*

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## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 180

[EPA-HQ-OPP-2009-0692; FRL-8830-6]

#### Poly(oxy-1,2-ethanediyl), $\alpha$ -isotridecyl- $\omega$ -methoxy; 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 poly(oxy-1,2-ethanediyl),  $\alpha$ -isotridecyl- $\omega$ -methoxy (CAS Reg. No. 345642-79-7) when used as an inert ingredient (surfactant) at a maximum concentration of 10% in pesticide formulations under 40 CFR 180.920 on growing crops only. Bayer CropScience 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 poly(oxy-1,2-ethanediyl),  $\alpha$ -isotridecyl- $\omega$ -methoxy.

**DATES:** This regulation is effective July 21, 2010. Objections and requests for hearings must be received on or before September 20, 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-2009-0692. 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:** Deirdre Sunderland, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 603-0851; e-mail address: [sunderland.deirdre@epa.gov](mailto:sunderland.deirdre@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-2009-0692 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 September 20, 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-2009-0692, 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 January 6, 2010 (75 FR 864) (FRL-8801-5), EPA issued a notice pursuant to section 408 of FFDCA, 21 U.S.C. 346a, announcing the filing of a pesticide petition (PP 9E7580) by Bayer CropScience, 2 T.X. Alexander Dr., P.O. Box 12014, Research Triangle Park, NC 27709. The petition requested that 40 CFR 180.920 be amended by establishing an exemption from the requirement of a tolerance for residues of poly(oxy-1,2-ethanediyl),  $\alpha$ -isotridecyl- $\omega$ -methoxy (CAS No. 345642-79-7) when used as an inert ingredient (surfactant) in pesticide formulations applied pre-harvest to all crops without limitation. That notice referenced a summary of the petition prepared by Bayer CropScience, the petitioner, which is available in the docket, <http://www.regulations.gov>. There were no comments received in response to the notice of filing. Based upon review of the data supporting the petition, EPA has limited the amount in formulation to 10%. This limitation is based on the Agency's risk assessment which can be found at <http://www.regulations.gov> in document "Decision Document for Petition Number 9E7580; Poly(oxy-1,2-ethanediyl),  $\alpha$ -isotridecyl- $\omega$ -methoxy (CAS Reg. No. 345642-79-7)" in docket ID number EPA-HQ-OPP-2009-0692.

## 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 poly(oxy-1,2-ethanediyl),  $\alpha$ -isotridecyl- $\omega$ -methoxy including exposure resulting from the exemption established by this action. EPA's assessment of exposures and risks associated with poly(oxy-1,2-ethanediyl),  $\alpha$ -isotridecyl- $\omega$ -methoxy 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 poly(oxy-1,2-ethanediyl),  $\alpha$ -isotridecyl- $\omega$ -methoxy 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 available toxicity data include an acute toxicity battery, a combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (OPPTS Harmonized Test Guideline 870.3650), and two mutagenicity studies (OPPTS Harmonized Test Guideline 870.5100). In addition, sufficient toxicity data are available on the metabolite. Acute studies (OPPTS Harmonized Test Guidelines 870.1100 and 870.1200 (acute inhalation study not provided)) showed low acute toxicity (Toxicity Category III) with an oral LD<sub>50</sub> >2000 milligrams/kilogram (mg/kg) and acute dermal LD<sub>50</sub> >2000 mg/kg. Irritation studies (OPPTS Harmonized Test Guidelines 870.2400 and 870.2500) on rabbits revealed slight skin irritation (Toxicity Category IV) and severe eye irritation (Toxicity Category II). In addition, a skin sensitization study (OPPTS Harmonized Test Guidelines

870.2600) in guinea pigs showed skin sensitization when exposed to poly(oxy-1,2-ethanediyl),  $\alpha$ -isotridecyl- $\omega$ -methoxy.

In an OPPTS Harmonized Test Guideline 870.3650 poly(oxy-1,2-ethanediyl),  $\alpha$ -isotridecyl- $\omega$ -methoxy was administered by gavage prior to mating through postnatal day 4 (~6–7 weeks). Clinical signs of toxicity included increased incidences of oral and urine staining ( $\geq 150$  milligrams/kilogram/day (mg/kg/day)) and a slight decrease in body weight and body weight gain (300 mg/kg/day male rats, pre-mating period); however, no treatment-related effects were observed during the remainder of the study. Additionally female rats ( $\geq 150$  mg/kg/day) exhibited a decrease in hind-limb strength and rearing in open-field.

At necropsy females in the high dose (300 mg/kg/day) group showed a statistically significant increase in absolute and relative adrenal weight, relative kidney weight, and absolute liver weight. Females in the mid and high dose group ( $\geq 150$  mg/kg/day) showed a statistically significant increase in relative liver weight. In the absence of any collaborative blood or histopathologic findings the effect seen in the liver is considered as an adaptive response. An increased incidence of minimal to moderate epithelial cell hyperplasia was noted in the non-glandular epithelium of the stomach of high-dose male and female rats indicating local irritation which is likely due to the irritation induced by gavage treatment of chemicals with irritative properties.

A LOEL was not established for poly(oxy-1,2-ethanediyl),  $\alpha$ -isotridecyl- $\omega$ -methoxy in male Wistar rats. The NOAEL for male rats is the highest dose tested, 300 mg/kg/day. The NOAEL for female rats is 45 mg/kg/day based on the functional observational battery observations (i.e. decrease in rearing in open field and hind limb grip strength) seen at the LOEL of 150 mg/kg/day.

The OPPTS 870.3650 study on poly(oxy-1,2-ethanediyl),  $\alpha$ -isotridecyl- $\omega$ -methoxy was also used to evaluate reproductive and developmental toxicity. No test material-related effects were observed on reproductive (e.g., mating, fertility, or gestation indices, days to insemination, gestation length, or number of implants) or developmental (e.g., mean litter size, viability, clinical signs of toxicity, or body weight of the pups) parameters at any dose tested; therefore, the NOAEL for poly(oxy-1,2-ethanediyl),  $\alpha$ -isotridecyl- $\omega$ -methoxy for reproductive and developmental parameters is 300 mg/kg/day (highest dose tested).

Evidence of neurotoxicity was observed in the OPPTS 870.3650 study which showed a decrease in rearing in open field and hind limb grip strength for mid- and high-dose female rats ( $\geq 150$  mg/kg/day). No evidence of immunotoxicity was observed in the database.

There are no carcinogenicity studies available in the database; however, poly(oxy-1,2-ethanediyl),  $\alpha$ -isotridecyl- $\omega$ -methoxy tested negative in two mutagenicity assays (OPPTS Harmonized Test Guideline 870.5100) and no evidence of specific target organ toxicity was observed in the OPPTS 870.3650 study. In addition, no evidence of carcinogenicity was observed in studies on the metabolite  $\alpha$ -isotridecyl- $\omega$ -hydroxy-poly(oxy-1,2-ethanediyl) (CAS Reg. No. 9043-30-5) (**Federal Register**, August 5, 2009 (74 FR 38935, FRL-8430-1)). The Agency does not anticipate poly(oxy-1,2-ethanediyl),  $\alpha$ -isotridecyl- $\omega$ -methoxy to be carcinogenic.

Based on available information the Agency has concluded that poly(oxy-1,2-ethanediyl),  $\alpha$ -isotridecyl- $\omega$ -methoxy has a higher toxicity than its metabolite; therefore, conducting the risk assessment on the parent would be protective of the metabolite.

#### 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://](http://www.epa.gov/pesticides/factsheets/riskassess.htm)

[www.epa.gov/pesticides/factsheets/riskassess.htm](http://www.epa.gov/pesticides/factsheets/riskassess.htm).

The POD for the risk assessment for all durations and routes of exposure was from the OPPTS Harmonized Test Guideline 870.3650 toxicity study in rats. The NOAEL was 45 mg/kg/day and the LOAEL was 150 mg/kg/day based on rearing in the open field and hind limb grip strength. A 300 fold uncertainty factor was used for the chronic exposure (10X interspecies extrapolation, 10X for intraspecies variability and 3X FQPA factor).

The residential, occupational, and aggregate level of concern (LOC) is for MOEs that are less than 300 and is based on 10X interspecies extrapolation, 10X for intraspecies variability and 3X FQPA factor. Dermal absorption was estimated to be 10% based on the large molecular weight of the chemical and the lack of water solubility. A 100% inhalation was assumed.

#### C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to poly(oxy-1,2-ethanediyl),  $\alpha$ -isotridecyl- $\omega$ -methoxy, EPA considered exposure under the proposed exemption from the requirement of a tolerance. EPA assessed dietary exposures from poly(oxy-1,2-ethanediyl),  $\alpha$ -isotridecyl- $\omega$ -methoxy in food as follows:

i. *Acute exposure.* No adverse effects attributable to a single exposure of poly(oxy-1,2-ethanediyl),  $\alpha$ -isotridecyl- $\omega$ -methoxy was seen in the toxicity databases. Therefore, acute dietary risk assessments for poly(oxy-1,2-ethanediyl),  $\alpha$ -isotridecyl- $\omega$ -methoxy is not required.

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 poly(oxy-1,2-ethanediyl),  $\alpha$ -isotridecyl- $\omega$ -methoxy. In the absence of specific residue data, EPA has developed an approach which uses surrogate information to derive upper bound exposure estimates for the subject inert ingredient. Upper bound exposure estimates are based on the highest tolerance for a given commodity from a list of high-use insecticides, herbicides, and fungicides. A complete description of the general approach taken to assess inert ingredient risks in the absence of residue data is contained in the memorandum entitled “Alkyl

Amines Polyalkoxylates (Cluster 4): Acute and Chronic Aggregate (Food and Drinking Water) Dietary Exposure and Risk Assessments for the Inerts.” (D361707, S. Piper, 2/25/09) and can be found at <http://www.regulations.gov> in docket ID number EPA-HQ-OPP-2008-0738.

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

The Agency believes the assumptions used to estimate dietary exposures lead to an extremely conservative assessment of dietary risk due to a series of compounded conservatisms. First, assuming that the level of residue for an inert ingredient is equal to the level of residue for the active ingredient will overstate exposure. The concentrations of active ingredient in agricultural products is generally at least 50% of the product and often can be much higher. Further, pesticide products rarely have a single inert ingredient; rather there is generally a combination of different inert ingredients used which additionally reduces the concentration of any single inert ingredient in the pesticide product in relation to that of the active ingredient. In the case of poly(oxy-1,2-ethanediyl),  $\alpha$ -isotridecyl- $\omega$ -methoxy, EPA made a specific adjustment to the dietary exposure assessment to account for the use limitations of the amount of poly(oxy-1,2-ethanediyl),  $\alpha$ -isotridecyl- $\omega$ -methoxy that may be in formulations (no more than 10% by weight in pesticide formulations) and assumed that the poly(oxy-1,2-ethanediyl),  $\alpha$ -isotridecyl- $\omega$ -methoxy are present at the maximum limitations 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, 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.* Based on the lack of evidence of carcinogenicity and specific organ toxicity in available studies, along with the lack of carcinogenicity in metabolite studies, poly(oxy-1,2-ethanediyl),  $\alpha$ -isotridecyl- $\omega$ -methoxy is not expected to pose a cancer risk to humans. 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 poly(oxy-1,2-ethanediyl),  $\alpha$ -isotridecyl- $\omega$ -methoxy. Tolerance level residues and/or 100% were assumed for all food commodities.

2. *Dietary exposure from drinking water.* For the purpose of the screening level dietary risk assessment to support this request for an exemption from the requirement of a tolerance for poly(oxy-1,2-ethanediyl),  $\alpha$ -isotridecyl- $\omega$ -methoxy, a conservative drinking water concentration value of 100 parts per billion (ppb) based on screening level modeling was used to assess the contribution to drinking water for the chronic dietary risk assessments for parent compound. These values were directly entered into the dietary exposure model.

3. *From non-dietary exposure.* The term “residential exposure” is used in this document to refer to non-occupational, non-dietary exposure (e.g., textiles (clothing and diapers), carpets, swimming pools, and hard surface disinfection on walls, floors, and tables).

There are no known or anticipated residential uses and therefore, a residential risk assessment was not conducted.

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 poly(oxy-1,2-ethanediyl),  $\alpha$ -isotridecyl- $\omega$ -methoxy to share a common mechanism of toxicity with any other substances, and poly(oxy-1,2-ethanediyl),  $\alpha$ -isotridecyl- $\omega$ -methoxy does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that poly(oxy-1,2-ethanediyl),  $\alpha$ -isotridecyl- $\omega$ -methoxy 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.* The OPPTS Harmonized Test Guideline 870.3650 study on poly(oxy-1,2-ethanediyl),  $\alpha$ -isotridecyl- $\omega$ -methoxy was also used to evaluate reproductive and developmental toxicity. There was

no evidence of increased susceptibility of infants and children in the available database. No test material-related effects were observed on reproductive or developmental parameters at any dose tested; therefore, the NOAEL for poly(oxy-1,2-ethanediyl),  $\alpha$ -isotridecyl- $\omega$ -methoxy for reproductive and developmental parameters is 300 mg/kg/day (highest dose tested). The parental systemic toxicity NOAEL is 45 mg/kg/day and the LOAEL of 150 mg/kg/day is based on clinical signs of neurotoxicity.

3. *Conclusion.* Although there is no evidence of increased susceptibility in infants and children, in order to be protective in the absence of a developmental neurotoxicity study and the extrapolation from subchronic to chronic, a 3X FQPA safety factor has been retained.

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

i. There is no evidence that poly(oxy-1,2-ethanediyl),  $\alpha$ -isotridecyl- $\omega$ -methoxy results in increased susceptibility in *in utero* rats in an OPPTS Harmonized Test Guideline 870.3650 study, a combined repeated dose toxicity study with reproduction/developmental toxicity test parameters.

ii. Evidence of neurotoxicity was observed in the OPPTS 870.3650 Harmonized Test Guideline study which showed a decrease in rearing in open field and hind limb grip strength in females in the mid- and high-dose groups ( $\geq 150$  mg/kg/day). EPA concluded that the 3X FQPA database uncertainty factor is adequate because the evidence of neurotoxicity was observed only in females while males had no effects at doses up to and including 300 mg/kg/day and a lack of a significant dose response in females. No chronic toxicity or carcinogenicity studies are available in the database; however, the Agency notes that surfactants are surface-active materials that can damage the structural integrity of cellular membranes at high dose levels. Thus, surfactants are often corrosive and irritating in concentrated solutions. The observed toxicity seen in the repeated dose studies, such as microscopic lesions or decreased body weight gain, are attributed to the corrosive and irritating nature of these surfactants. The Agency has considerable toxicity information on surfactants, which indicates that the effects do not progressively increase in severity over time. In addition, use of the full 10X interspecies factor will

actually provide an additional margin of safety because it is not expected that humans' response to local irritation/corrosiveness effects would be markedly different from animals. No evidence of immunotoxicity was observed in the database.

iii. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 10% in formulation and a default 100 ppb concentration in drinking water. The I DEEM models uses highly conservative assumption and assumes that all crop/crop groups are treated with all pesticide classifications (e.g., fungicides, insecticides, herbicides). There are no currently approved uses of poly(oxy-1,2-ethanediyl),  $\alpha$ -isotridecyl- $\omega$ -methoxy in pesticide products; therefore, this is a highly conservative estimate. In addition, it is unlikely that poly(oxy-1,2-ethanediyl),  $\alpha$ -isotridecyl- $\omega$ -methoxy will appear in drinking water. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to poly(oxy-1,2-ethanediyl),  $\alpha$ -isotridecyl- $\omega$ -methoxy in drinking water. These assessments will not underestimate the exposure and risks posed by poly(oxy-1,2-ethanediyl),  $\alpha$ -isotridecyl- $\omega$ -methoxy.

iv. Sufficient data exist on the metabolite  $\alpha$ -isotridecyl- $\omega$ -hydroxy-poly(oxy-1,2-ethanediyl) (CAS Reg. No. 9043-30-5) and it has recently been assessed by the Agency (**Federal Register**, August 5, 2009 (74 FR 38935, FRL-8430-1)). Based on available information it has been concluded that poly(oxy-1,2-ethanediyl),  $\alpha$ -isotridecyl- $\omega$ -methoxy has a higher toxicity than its metabolite and therefore, conducting the risk assessment on the parent would be protective of the metabolite.

#### *E. Aggregate Risks and Determination of Safety*

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

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, poly(oxy-1,2-ethanediyl),  $\alpha$ -isotridecyl- $\omega$ -methoxy is not expected to pose an acute risk.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to poly(oxy-1,2-ethanediyl),  $\alpha$ -isotridecyl- $\omega$ -methoxy from food and water will utilize 84.9% of the cPAD for children 1-2 years old, the population group receiving the greatest exposure. There are no residential uses for poly(oxy-1,2-ethanediyl),  $\alpha$ -isotridecyl- $\omega$ -methoxy.

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).

A short-term adverse effect was identified; however, poly(oxy-1,2-ethanediyl),  $\alpha$ -isotridecyl- $\omega$ -methoxy is not currently used as an inert ingredient in pesticide products that are registered for any use patterns that would result in short-term residential exposure. Short-term risk is assessed based on short-term residential exposure plus chronic dietary exposure. Because there is no short-term residential exposure and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess short-term risk), no further assessment of short-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating short-term risk for poly(oxy-1,2-ethanediyl),  $\alpha$ -isotridecyl- $\omega$ -methoxy.

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).

An intermediate-term adverse effect was identified; however, poly(oxy-1,2-ethanediyl),  $\alpha$ -isotridecyl- $\omega$ -methoxy is not currently used as an inert ingredient in pesticide products that are registered for any use patterns that would result in intermediate-term residential exposure. Intermediate-term risk is assessed based on intermediate-term residential exposure plus chronic dietary exposure. Because there is no intermediate-term residential exposure and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess intermediate-term risk), no further assessment of intermediate-term

risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating intermediate-term risk for poly(oxy-1,2-ethanediyl),  $\alpha$ -isotridecyl- $\omega$ -methoxy.

5. *Aggregate cancer risk for U.S. population.* The Agency has not identified any concerns for carcinogenicity relating to poly(oxy-1,2-ethanediyl),  $\alpha$ -isotridecyl- $\omega$ -methoxy. Therefore, an aggregate cancer risk was not conducted.

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 poly(oxy-1,2-ethanediyl),  $\alpha$ -isotridecyl- $\omega$ -methoxy 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 poly(oxy-1,2-ethanediyl),  $\alpha$ -isotridecyl- $\omega$ -methoxy in or on any food commodities. EPA is establishing a limitation on the amount of poly(oxy-1,2-ethanediyl),  $\alpha$ -isotridecyl- $\omega$ -methoxy that may be used in pesticide formulations. That limitation will be enforced through the pesticide registration process under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136 *et seq.* EPA will not register any pesticide for sale or distribution that contains greater than 10% of poly(oxy-1,2-ethanediyl),  $\alpha$ -isotridecyl- $\omega$ -methoxy by weight in the pesticide formulation.

### B. International Residue Limits

The Agency is not aware of any country requiring a tolerance for poly(oxy-1,2-ethanediyl),  $\alpha$ -isotridecyl- $\omega$ -methoxy 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 poly(oxy-1,2-ethanediyl),  $\alpha$ -isotridecyl- $\omega$ -methoxy (CAS Reg. No. 345642-79-7) when used as an inert ingredient (surfactant) in pesticide formulations applied to growing crops at a maximum of 10% 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: July 8, 2010.

**Lois Rossi,**

*Director, Registration Division, Office of Pesticide Programs.*

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

### PART 180—[AMENDED]

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

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

■ 2. In §180.920, 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
* Poly(oxy-1,2-ethanediyl), α-isotridecyl-ω-methoxy (CAS Reg. No. 345642-79-7)	* At a maximum of 10% in formulation	* Surfactant

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**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 180**

[EPA-HQ-OPP-2010-0528; FRL-8834-8]

**Pyraclostrobin; Pesticide Tolerances**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes tolerances for residues of pyraclostrobin in or on alfalfa and poultry, and increases tolerances for residues in or on soybean. BASF Corporation requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

**DATES:** This regulation is effective July 21, 2010. Objections and requests for hearings must be received on or before September 20, 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-2010-0528. 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:** Shaunta Hill, Registration Division (7504P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 347-8961; e-mail address: [hill.shaunta@epa.gov](mailto:hill.shaunta@epa.gov).

**SUPPLEMENTARY INFORMATION:**

**I. General Information**

*A. Does this Action Apply to Me?*

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

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

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

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

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at <http://www.gpoaccess.gov/ecfr>.

*C. How Can I File an Objection or Hearing Request?*

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation

in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2010-0528 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 September 20, 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. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit a copy of your non-CBI objection or hearing request, identified by docket ID number EPA-HQ-OPP-2010-0528, 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. Summary of Petitioned-For Tolerance**

In the **Federal Register** of February 4, 2010 (75 FR 5792) (FRL-9110-5) and June 8, 2010 (75 FR 32465) (FRL-8827-5), EPA issued notices pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of pesticide petitions PP 9F7590 and PP 9F7528, respectively, by BASF Corporation, P.O. Box 13528, Research