

responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). 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 action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

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 (NTTAA) (15 U.S.C. 272 note).

## VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), 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 the rule in the **Federal Register**. This action 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: August 8, 2019.

Michael Goodis,

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 § 180.350, paragraph (a):

■ a. Revise the introductory text.

■ b. Add alphabetically the entries for "Fruit, citrus, group 10–10"; "Fruit, citrus, group 10–10, dried pulp"; "Fruit,

citrus, group 10–10, oil"; "Leaf petiole vegetable subgroup 22B"; "Vegetable, *Brassica*, head and stem, group 5–16"; "Vegetable, bulb, group 3–07"; and "Vegetable, leafy, group 4–16" to the table.

The revision and additions read as follows:

#### § 180.350 Nitrapyrin; tolerances for residues.

(a) *General.* Tolerances are established for residues of the nitrification inhibitor nitrapyrin, including its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels specified below is to be determined by measuring only the sum of nitrapyrin (2-chloro-6-(trichloromethyl) pyridine) and its 6-CPA metabolite (6-chloro-picolinic acid), calculated as the stoichiometric equivalent of nitrapyrin, in or on the commodity:

Commodity	Parts per million
* * * *	*
Fruit, citrus, group 10–10 .....	0.06
Fruit, citrus, group 10–10, dried pulp .....	0.5
Fruit, citrus, group 10–10, oil .....	2
Leaf petiole vegetable subgroup 22B .....	0.5
* * * *	*
Vegetable, <i>Brassica</i> , head and stem, group 5–16 .....	0.1
Vegetable, bulb, group 3–07 .....	0.3
Vegetable, leafy, group 4–16 .....	0.4
* * * *	*

\* \* \* \*

[FR Doc. 2019–18382 Filed 8–26–19; 8:45 am]

BILLING CODE 6560–50–P

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 180

[EPA–HQ–OPP–2019–0093; FRL–9996–95]

#### Oxirane, 2-methyl-, Polymer With Oxirane, Monoundecyl Ether, Branched and Linear; 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 oxirane, 2-methyl-, polymer with oxirane, monoundecyl ether, branched and linear (CAS Reg. No. 2222805–23–2)

when used as an inert ingredient in a pesticide chemical formulation. Exponent, Inc. on behalf of Clariant Corporation submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting an amendment to an existing requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of oxirane, 2-methyl-, polymer with oxirane, monoundecyl ether, branched and linear.

**DATES:** This regulation is effective August 27, 2019. Objections and requests for hearings must be received on or before October 28, 2019, 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:** The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2019–0093, is available at <http://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW, Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPP Docket is (703) 305–5805. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

#### FOR FURTHER INFORMATION CONTACT:

Michael Goodis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; main telephone number: (703) 305–7090; email address: [RDPRNotices@epa.gov](mailto:RDPRNotices@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. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).

- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

*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 Publishing Office's e-CFR site at [http://www.ecfr.gov/cgi-bin/text-id?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab\\_02.tpl](http://www.ecfr.gov/cgi-bin/text-id?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl).

*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-2019-0093 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 October 28, 2019. 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 (excluding any Confidential Business Information (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 the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2019-0093, by one of the following methods:

- **Federal eRulemaking Portal:** <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

- **Mail:** OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW, Washington, DC 20460-0001.

- **Hand Delivery:** To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.html>. Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is

available at <http://www.epa.gov/dockets>.

## II. Petition for Exemption

In the **Federal Register** of August 5, 2009 (74 FR 38935) (FRL-8430-1), EPA issued a final rule, announcing the establishment of a tolerance exemption pursuant to a pesticide petition (PP 9E7534) by The Joint Inerts Task Force, Cluster Support Team 1 (CST 1), c/o CropLife America, 1156 15th Street NW, Suite 400, Washington, DC 20005. The petition requested that 40 CFR 180.910, 180.930, 180.940(a) and 180.960 be amended by establishing an exemption from the requirement of a tolerance for residues of a group of substances known as  $\alpha$ -alkyl- $\omega$ -hydroxypoly(oxypropylene) and/or poly(oxyethylene) polymers where the alkyl chain contains a minimum of 6 carbons, herein referred to in this document as AAA.

The current petition seeks to expand the exemptions for AAA by adding additional CAS Reg. Nos. In the **Federal Register** of May 13, 2019 (84 FR 20843) (FRL-9991-91), EPA issued a document pursuant to FFDCA section 408, 21 U.S.C. 346a, announcing the filing of a pesticide petition (PP IN-11254) by Exponent Inc. on behalf of Clariant Corporation, Suite 1100, 1150 Connecticut Avenue NW, Washington DC 20036. The petition requested that 40 CFR 180.910, 180.930, 180.940(a) and 180.960 be amended by establishing an exemption from the requirement of a tolerance for residues of oxirane, 2-methyl-, polymer with oxirane, monoundecyl ether, branched and linear (CAS Reg. No. 2222805-23-2). That document referenced a summary of the petition prepared by Exponent, 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 confirmed that the requested CAS Reg. No. is acceptable for consideration under the currently approved descriptor. This determination is based on the Agency's risk assessment which can be found at <http://www.regulations.gov> in document "Alkyl Alcohol Alkoxyates (AAA-JITF CST 1 Inert Ingredient), Human Health Risk Assessment to Support Proposed Exemption from the Requirement of a Tolerance under 40 CFR 180.960 when used as an Inert Ingredient in Pesticide Formulations" in docket ID number EPA-HQ-OPP-2009-0145.

## 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 FFDCA section 408(c)(2)(A), 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 oxirane, 2-methyl-, polymer with oxirane, monoundecyl ether, branched and linear including exposure resulting from the exemption established by this action. EPA's assessment of exposures and risks associated with oxirane, 2-methyl-, polymer with oxirane, monoundecyl ether, branched and linear 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 AAA 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 the final rule published in the **Federal Register** of August 5, 2009 (74 FR 38935) (FRL-8430-1).

#### 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 AAA used for human risk assessment is discussed in Unit IV of the final rule published in the **Federal Register** of August 5, 2009 (74 FR 38938) (FRL-8430-1).

#### C. Exposure Assessment

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

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

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment, EPA used food consumption information from the U.S. Department of Agriculture (USDA) 1994-1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII).

iii. *Cancer.* The Agency used a qualitative structure activity relationship (SAR) database, DEREK11, to determine if there were structural alerts suggestive of carcinogenicity. No structural alerts for carcinogenicity were identified. The AAAs are not expected to be carcinogenic. Therefore, a cancer dietary exposure assessment is not necessary to assess cancer risk.

2. *Dietary exposure from drinking water.* The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for the AAAs in drinking water.

3. *From non-dietary exposure.* The term "residential exposure" is used in this document to refer to nonoccupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets). The AAAs may be used in inert ingredients in

pesticide products that are registered for specific uses that may result in both indoor and outdoor residential exposures. A screening level residential exposure and risk assessment was completed for products containing the AAAs as inert ingredients.

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 AAA to share a common mechanism of toxicity with any other substances, and AAA does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that AAA 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 the lower weight AAA surfactants, there was no evidence of increased susceptibility to the offspring of rats following prenatal and postnatal exposure in the reproductive/developmental screening studies on several representative AAA surfactants. Decreased litter size and increased post-implantation loss were observed in one OPPTS Harmonized Guideline 870.3550 reproduction/developmental toxicity screening study at 470 mg/kg/day where maternal/paternal toxicity was manifested as one maternal death (GD

22), decreased body weight, bodyweight gain and food consumption and clinical signs (ptosis and hypoactivity) and microscopic changes in the testes (atrophy) and epididymides (increased intraluminal exfoliated spermatogenic cells) and dilated seminiferous tubules at the same dose (470 mg/kg/day). The maternal and offspring toxicity NOAEL was 168 mg/kg/day. The offspring toxicity in the OPPTS Harmonized Test Guideline 870.3650 study was manifested in the presence of more severe maternal toxicity (deaths), therefore, EPA concluded that there is no evidence of increased susceptibility in this study. In addition, there was no evidence of increased susceptibility in other submitted studies.

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

#### *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-, 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, AAA 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 the chronic dietary exposure from food and water to the AAAs is 11% of the cPAD for the U.S. population and 37% of the cPAD for children 1 to 2 years old, the most highly exposed population subgroup.

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).

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

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).

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

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

6. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children

from aggregate exposure to residues of the lower weight AAAs. For the high molecular weight AAAs under 40 CFR 180.960. Since AAA conforms to the criteria that identify a low-risk polymer, there are no concerns for risks associated with any potential exposure scenarios that are reasonably foreseeable. Therefore, EPA concludes that there is a reasonable certainty that no harm will result to the general population or to infants and children from aggregate exposure to residues of the high molecular weight AAAs.

## **V. Other Considerations**

### *A. Analytical Enforcement Methodology*

An analytical method is not required for enforcement purposes since the Agency is establishing an exemption from the requirement of a tolerance without any numerical limitation.

### *B. International Residue Limits*

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

The Codex has not established a MRL for AAAs.

## **VI. Conclusions**

Therefore, an exemption from the requirement of a tolerance is established for residues of the lower molecular weight  $\alpha$ -alkyl- $\omega$ -hydroxypoly(oxypropylene) and/or poly(oxyethylene) polymers where the alkyl chain contains a minimum of 6 carbons, including oxirane, 2-methyl-, polymer with oxirane, monoundecyl ether, branched and linear (CAS Reg. No. 2222805-23-2) when used as an inert ingredient in pesticide formulations applied to pre- and post-harvest, applied to livestock, and used in antimicrobial formulations under 40 CFR 180.910, 40 CFR 180.930, and 40 CFR 180.940(a). In addition, an

exemption from the requirement of a tolerance is established for residues of the larger molecular weight compounds of  $\alpha$ -alkyl- $\omega$ -hydroxypoly (oxypropylene) and/or poly (oxyethylene) polymers where the alkyl chain contains a minimum of 6 carbons, including oxirane, 2-methyl-, polymer with oxirane, monoundecyl ether, branched and linear [CAS Reg. No. 2222805-23-2] under 40 CFR 180.960.

## VII. Statutory and Executive Order Reviews

This action establishes a tolerance under FFDCA section 408(d) 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 action has been exempted from review under Executive Order 12866, this action 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 action 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 FFDCA section 408(d), 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 action 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 FFDCA section 408(n)(4). 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 action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

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 (NTTAA) (15 U.S.C. 272 note).

## VIII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), 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 the rule in the **Federal Register**. This action 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: August 16, 2019.

**Daniel Rosenblatt,**

*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 § 180.910, revise the inert ingredients " $\alpha$ -Alkyl- $\omega$ -hydroxypoly (oxypropylene) and/or poly (oxyethylene) polymers where the alkyl chain contains a minimum of six carbons" in the table to read as follows:

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

\* \* \* \* \*

Inert ingredients	Limits	Uses
<p><math>\alpha</math>-Alkyl-<math>\omega</math>-hydroxypoly (oxypropylene) and/or poly (oxyethylene) polymers where the alkyl chain contains a minimum of six carbons (CAS Reg. Nos.: 9002-92-0; 9004-95-9; 9004-98-2; 9005-00-9; 9035-85-2; 9038-29-3; 9038-43-1; 9040-05-5; 9043-30-5; 9087-53-0; 25190-05-0; 24938-91-8; 25231-21-4; 251553-55-6; 26183-52-8; 26468-86-0; 26636-39-5; 27252-75-1; 27306-79-2; 31726-34-8; 34398-01-1; 34398-05-5; 37251-67-5; 37311-00-5; 37311-01-6; 37311-02-7; 37311-04-9; 39587-22-9; 50861-66-0; 52232-09-4; 52292-17-8; 52609-19-5; 57679-21-7; 59112-62-8; 60828-78-6; 61702-78-1; 61723-78-2; 61725-89-1; 61791-13-7; 61791-20-6; 61791-28-4; 61804-34-0; 61827-42-7; 61827-84-7; 62648-50-4; 63303-01-5; 63658-45-7; 63793-60-2; 64366-70-7; 64415-24-3; 64415-25-4; 64425-86-1; 65104-72-5; 65150-81-4; 66455-14-9; 66455-15-0; 67254-71-1; 67763-08-0; 68002-96-0; 68002-97-1; 68131-39-5; 68131-40-8; 68154-96-1; 68154-97-2; 68154-98-3; 68155-01-1; 68213-23-0; 68213-24-1; 68238-81-3; 68238-82-4; 68409-58-5; 68409-59-6; 68439-30-5; 68439-45-2; 68439-46-3; 68439-48-5; 68439-49-6; 68439-50-9; 68439-51-0; 68439-53-2; 68439-54-3; 68458-88-8; 68526-94-3; 68526-95-4; 68551-12-2; 68551-13-3; 68551-14-4; 68603-20-3; 68603-25-8; 68920-66-1; 68920-69-4; 68937-66-6; 68951-67-7; 68954-94-9; 68987-81-5; 68991-48-0; 69011-36-5; 69013-18-9; 69013-19-0; 69227-20-9; 69227-21-0; 69227-22-1; 69364-63-2; 70750-27-5; 70879-83-3; 70955-07-6; 71011-10-4; 71060-57-6; 71243-46-4; 72066-65-0; 72108-90-8; 72484-69-6; 72854-13-8; 72905-87-4; 73018-31-2; 73049-34-0; 74432-13-6; 74499-34-6; 78330-19-5; 78330-20-8; 78330-21-9; 78330-23-1; 79771-03-2; 84133-50-6; 85422-93-1; 97043-91-9; 97953-22-5; 102782-43-4; 10331-86-8; 103657-84-7; 103657-85-8; 103818-93-5; 103819-03-0; 106232-83-1; 111905-54-5; 116810-31-2; 116810-32-3; 116810-33-4; 120313-48-6; 120944-68-5; 121617-09-2; 126646-02-4; 126950-62-7; 127036-24-2; 139626-71-4; 152231-44-2; 154518-36-2; 157627-86-6; 157627-88-8; 157707-41-0; 157707-43-2; 159653-49-3; 160875-66-1; 160901-20-2; 160901-09-7; 160901-19-9; 161025-21-4; 161025-22-5; 166736-08-9; 169107-21-5; 172588-43-1; 176022-76-7; 196823-11-7; 287935-46-0; 288260-45-7; 303176-75-2; 954108-36-2; 2222805-23-2).</p>		Surfactants, related adjuvants of surfactants

■ 3. In § 180.930, revise the inert ingredients “ $\alpha$ -Alkyl- $\omega$ -hydroxypoly (oxypropylene) and/or poly (oxyethylene) polymers where the alkyl

chain contains a minimum of six carbons” in the table to read as follows:

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

\* \* \* \*

Inert ingredients	Limits	Uses
<p><math>\alpha</math>-Alkyl-<math>\omega</math>-hydroxypoly (oxypropylene) and/or poly (oxyethylene) polymers where the alkyl chain contains a minimum of six carbons (CAS Reg. Nos.: 9002-92-0; 9004-95-9; 9004-98-2; 9005-00-9; 9035-85-2; 9038-29-3; 9038-43-1; 9040-05-5; 9043-30-5; 9087-53-0; 25190-05-0; 24938-91-8; 25231-21-4; 251553-55-6; 26183-52-8; 26468-86-0; 26636-39-5; 27252-75-1; 27306-79-2; 31726-34-8; 34398-01-1; 34398-05-5; 37251-67-5; 37311-00-5; 37311-01-6; 37311-02-7; 37311-04-9; 39587-22-9; 50861-66-0; 52232-09-4; 52292-17-8; 52609-19-5; 57679-21-7; 59112-62-8; 60828-78-6; 61702-78-1; 61723-78-2; 61725-89-1; 61791-13-7; 61791-20-6; 61791-28-4; 61804-34-0; 61827-42-7; 61827-84-7; 62648-50-4; 63303-01-5; 63658-45-7; 63793-60-2; 64366-70-7; 64415-24-3; 64415-25-4; 64425-86-1; 65104-72-5; 65150-81-4; 66455-14-9; 66455-15-0; 67254-71-1; 67763-08-0; 68002-96-0; 68002-97-1; 68131-39-5; 68131-40-8; 68154-96-1; 68154-97-2; 68154-98-3; 68155-01-1; 68213-23-0; 68213-24-1; 68238-81-3; 68238-82-4; 68409-58-5; 68409-59-6; 68439-30-5; 68439-45-2; 68439-46-3; 68439-48-5; 68439-49-6; 68439-50-9; 68439-51-0; 68439-53-2; 68439-54-3; 68458-88-8; 68526-94-3; 68526-95-4; 68551-12-2; 68551-13-3; 68551-14-4; 68603-20-3; 68603-25-8; 68920-66-1; 68920-69-4; 68937-66-6; 68951-67-7; 68954-94-9; 68987-81-5; 68991-48-0; 69011-36-5; 69013-18-9; 69013-19-0; 69227-20-9; 69227-21-0; 69227-22-1; 69364-63-2; 70750-27-5; 70879-83-3; 70955-07-6; 71011-10-4; 71060-57-6; 71243-46-4; 72066-65-0; 72108-90-8; 72484-69-6; 72854-13-8; 72905-87-4; 73018-31-2; 73049-34-0; 74432-13-6; 74499-34-6; 78330-19-5; 78330-20-8; 78330-21-9; 78330-23-1; 79771-03-2; 84133-50-6; 85422-93-1; 97043-91-9; 97953-22-5; 102782-43-4; 103331-86-8; 103657-84-7; 103657-85-8; 103818-93-5; 103819-03-0; 106232-83-1; 111905-54-5; 116810-31-2; 116810-32-3; 116810-33-4; 120313-48-6; 120944-68-5; 121617-09-2; 126646-02-4; 126950-62-7; 127036-24-2; 139626-71-4; 152231-44-2; 154518-36-2; 157627-86-6; 157627-88-8; 157707-41-0; 157707-43-2; 159653-49-3; 160875-66-1; 160901-20-2; 160901-09-7; 160901-19-9; 161025-21-4; 161025-22-5; 166736-08-9; 169107-21-5; 172588-43-1; 176022-76-7; 196823-11-7; 287935-46-0; 288260-45-7; 303176-75-2; 954108-36-2; 2222805-23-2).</p>	.....	Surfactants, related adjuvants of surfactants

■ 4. In § 180.940, revise the inert ingredients “ $\alpha$ -Alkyl- $\omega$ -hydroxypoly (oxypropylene) and/or poly (oxyethylene) polymers where the alkyl chain contains a minimum of six

carbons” in the table in paragraph (a) to read as follows:

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

\* \* \* \*

(a) \* \* \*

Pesticide chemical	CAS Reg. No.	Limits
<p><math>\alpha</math>-Alkyl-<math>\omega</math>-hydroxypoly (oxypropylene) and/or poly (oxyethylene) polymers where the alkyl chain contains a minimum of six carbons.</p>	<p>9002-92-0; 9004-95-9; 9004-98-2; 9005-00-9; 9035-85-2; 9038-29-3; 9038-43-1; 9040-05-5; 9043-30-5; 9087-53-0; 25190-05-0; 24938-91-8; 25231-21-4; 251553-55-6; 26183-52-8; 26468-86-0; 26636-39-5; 27252-75-1; 27306-79-2; 31726-34-8; 34398-01-1; 34398-05-5; 37251-67-5; 37311-00-5; 37311-01-6; 37311-02-7; 37311-04-9; 39587-22-9; 50861-66-0; 52232-09-4; 52292-17-8; 52609-19-5; 57679-21-7; 59112-62-8; 60828-78-6; 61702-78-1; 61723-78-2; 61725-89-1; 61791-13-7; 61791-20-6; 61791-28-4; 61804-34-0; 61827-42-7; 61827-84-7; 62648-50-4; 63303-01-5; 63658-45-7; 63793-60-2; 64366-70-7; 64415-24-3; 64415-25-4; 64425-86-1; 65104-72-5; 65150-81-4; 66455-14-9; 66455-15-0; 67254-71-1; 67763-08-0; 68002-96-0; 68002-97-1; 68131-39-5; 68131-40-8; 68154-96-1; 68154-97-2; 68154-98-3; 68155-01-1; 68213-23-0; 68213-24-1; 68238-81-3; 68238-82-4; 68409-58-5; 68409-59-6; 68439-30-5; 68439-45-2; 68439-46-3; 68439-48-5; 68439-49-6; 68439-50-9; 68439-51-0; 68439-53-2; 68439-54-3; 68458-88-8; 68526-94-3; 68526-95-4; 68551-12-2; 68551-13-3; 68551-14-4; 68603-20-3; 68603-25-8; 68920-66-1; 68920-69-4; 68937-66-6; 68951-67-7; 68954-94-9; 68987-81-5; 68991-48-0; 69011-36-5; 69013-18-9; 69013-19-0; 69227-20-9; 69227-21-0; 69227-22-1; 69364-63-2; 70750-27-5; 70879-83-3; 70955-07-6; 71011-10-4; 71060-57-6; 71243-46-4; 72066-65-0; 72108-90-8; 72484-69-6; 72854-13-8; 72905-87-4; 73018-31-2; 73049-34-0; 74432-13-6; 74499-34-6; 78330-19-5; 78330-20-8; 78330-21-9; 78330-23-1; 79771-03-2; 84133-50-6; 85422-93-1; 97043-91-9; 97953-22-5; 102782-43-4; 103331-86-8; 103657-84-7; 103657-85-8; 103818-93-5; 103819-03-0; 106232-83-1; 111905-54-5; 116810-31-2; 116810-32-3; 116810-33-4; 120313-48-6; 120944-68-5; 121617-09-2; 126646-02-4; 126950-62-7; 127036-24-2; 139626-71-4; 152231-44-2; 154518-36-2; 157627-86-6; 157627-88-8; 157707-41-0; 157707-43-2; 159653-49-3; 160875-66-1; 160901-20-2; 160901-09-7; 160901-19-9; 161025-21-4; 161025-22-5; 166736-08-9; 169107-21-5; 172588-43-1; 176022-76-7; 196823-11-7; 287935-46-0; 288260-45-7; 303176-75-2; 954108-36-2; 2222805-23-2.</p>	None

\* \* \* \* \*

■ 5. In § 180.960, revise the inert ingredients “ $\alpha$ -Alkyl- $\omega$ -hydroxypoly (oxypropylene) and/or poly

(oxyethylene) polymers where the alkyl chain contains a minimum of six carbons and a minimum number average molecular weight (in amu) 1,100” in the table to read as follows:

**\$ 180.960 Polymers; exemptions from the requirement of a tolerance.**

\* \* \* \* \*

Polymer	CAS No.
$\alpha$ -Alkyl- $\omega$ -hydroxypoly (oxypropylene) and/or poly (oxyethylene) polymers where the alkyl chain contains a minimum of six carbons and a minimum number average molecular weight (in amu) 1,100.	9002-92-0; 9004-95-9; 9004-98-2; 9005-00-9; 9035-85-2; 9038-29-3; 9038-43-1; 9040-05-5; 9043-30-5; 9087-53-0; 25190-05-0; 24938-91-8; 25231-21-4; 251553-55-6; 26183-52-8; 26468-86-0; 26636-39-5; 27252-75-1; 27306-79-2; 31726-34-8; 34398-01-1; 34398-05-5; 37251-67-5; 37311-00-5; 37311-01-6; 37311-02-7; 37311-04-9; 39587-22-9; 50861-66-0; 52232-09-4; 52292-17-8; 52609-19-5; 57679-21-7; 59112-62-8; 60828-78-6; 61702-78-1; 61723-78-2; 61725-89-1; 61791-13-7; 61791-20-6; 61791-28-4; 61804-34-0; 61827-42-7; 61827-84-7; 62648-50-4; 63303-01-5; 63658-45-7; 63793-60-2; 64366-70-7; 64415-24-3; 64415-25-4; 64425-86-1; 65104-72-5; 65150-81-4; 66455-14-9; 66455-15-0; 67254-71-1; 67763-08-0; 68002-96-0; 68002-97-1; 68131-39-5; 68131-40-8; 68154-96-1; 68154-97-2; 68154-98-3; 68155-01-1; 68213-23-0; 68213-24-1; 68238-81-3; 68238-82-4; 68409-58-5; 68409-59-6; 68439-30-5; 68439-45-2; 68439-46-3; 68439-48-5; 68439-49-6; 68439-50-9; 68439-51-0; 68439-53-2; 68439-54-3; 68458-88-8; 68526-94-3; 68526-95-4; 68551-12-2; 68551-13-3; 68551-14-4; 68603-20-3; 68603-25-8; 68920-66-1; 68920-69-4; 68937-66-6; 68951-67-7; 68954-94-9; 68987-81-5; 68991-48-0; 69011-36-5; 69013-18-9; 69013-19-0; 69227-20-9; 69227-21-0; 69227-22-1; 69364-63-2; 70750-27-5; 70879-83-3; 70955-07-6; 71011-10-4; 71060-57-6; 71243-46-4; 72066-65-0; 72108-90-8; 72484-69-6; 72854-13-8; 72905-87-4; 73018-31-2; 73049-34-0; 74432-13-6; 74499-34-6; 78330-19-5; 78330-20-8; 78330-21-9; 78330-23-1; 79771-03-2; 84133-50-6; 85422-93-1; 97043-91-9; 97953-22-5; 102782-43-4; 103331-86-8; 103657-84-7; 103657-85-8; 103818-93-5; 103819-03-0; 106232-83-1; 111905-54-5; 116810-31-2; 116810-32-3; 116810-33-4; 120313-48-6; 120944-68-5; 121617-09-2; 126646-02-4; 126950-62-7; 127036-24-2; 139626-71-4; 152231-44-2; 154518-36-2; 157627-86-6; 157627-88-8; 157707-41-0; 157707-43-2; 159653-49-3; 160875-66-1; 160901-20-2; 160901-09-7; 160901-19-9; 161025-21-4; 161025-22-5; 166736-08-9; 169107-21-5; 172588-43-1; 176022-76-7; 196823-11-7; 287935-46-0; 288260-45-7; 303176-75-2; 954108-36-2; 2222805-23-2

[FR Doc. 2019-18362 Filed 8-26-19; 8:45 am]

BILLING CODE 6560-50-P

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 180

[EPA-HQ-OPP-2018-0088; FRL-9997-10]

### Emamectin Benzoate; Pesticide Tolerances

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

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes tolerances for residues of emamectin benzoate (referred to as emamectin in this document) in or on multiple commodities which are identified and discussed later in this document. Interregional Research Project No. 4 (IR-4) and Syngenta Crop Protection, LLC requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

**DATES:** This regulation is effective August 27, 2019. Objections and requests for hearings must be received on or before October 28, 2019, 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:** The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2018-0088, is available at <http://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW, Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

**FOR FURTHER INFORMATION CONTACT:** Michael Goodis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460-0001; main telephone number: (703) 305-7090; email address: [RDfRNotices@epa.gov](mailto:RDfRNotices@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. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

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

### 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 Publishing Office's e-CFR site at [http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab\\_02.tpl](http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl).