

#### 4. Collection of Information

This rule calls for no new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

#### 5. Federalism

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on State or local governments and would either preempt State law or impose a substantial direct cost of compliance on them. We have analyzed this rule under that Order and have determined that it does not have implications for federalism.

#### 6. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places or vessels.

#### 7. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of \$100,000,000 or more in any one year. Though this rule will not result in such expenditure, we do discuss the effects of this rule elsewhere in this preamble.

#### 8. Taking of Private Property

This rule will not affect a taking of private property or otherwise have taking implications under Executive Order 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights.

#### 9. Civil Justice Reform

This rule meets applicable standards in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

#### 10. Protection of Children

We have analyzed this rule under Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks. This rule is not an economically significant rule and does not create an environmental risk to health or risk to safety that may disproportionately affect children.

#### 11. Indian Tribal Governments

This rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

#### 12. Energy Effects

This action is not a “significant energy action” under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use.

#### 13. Technical Standards

This rule does not use technical standards. Therefore, we did not consider the use of voluntary consensus standards.

#### 14. Environment

We have analyzed this rule under Department of Homeland Security Management Directive 023–01 and Commandant Instruction M16475.ID, which guides the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves establishing a safety zone, requiring a permit wherein an analysis of the environmental impact of the regulations was performed. This rule is categorically excluded, under paragraph 34(h) of Figure 2–1 of the Commandant Instruction. An environmental analysis checklist supporting this determination and a Categorical Exclusion Determination are available in the docket where indicated under **ADDRESSES**.

#### List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR Part 165 as follows:

#### PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

■ 1. The authority citation for part 165 continues to read as follows:

**Authority:** 33 U.S.C., 1231; 46 U.S.C. Chapter 701, 3306, 3703; 50 U.S.C. 191, 195;

33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Pub. L. 107–295, 116 Stat. 2064; Department of Homeland Security Delegation No. 0170.1.

■ 2. Add § 165.T08–0410 to read as follows:

#### § 165.T08–0410 Safety Zone; Upper Mississippi River, Mile 662.8 to 663.9.

(a) *Location.* The following area is a safety zone: All waters of the Upper Mississippi River, mile 662.8 to 663.9, extending the entire width of the waterway.

(b) *Effective Date.* This rule is effective and enforceable on August 10, 2013.

(c) *Periods of Enforcement.* This rule will be enforced during the following time period: From 8:30 p.m. until 10 p.m. for all waters from mile 662.8 to 663.9. The Captain of the Port Upper Mississippi River will inform the public of the enforcement periods via local notice to mariners and subsequent changes by broadcast notice to mariners.

(d) *Regulations.* (1) In accordance with the general regulations in § 165.23 of this part, entry into this zone is prohibited unless authorized by the Captain of the Port Upper Mississippi River or a designated representative.

(2) Persons or vessels requiring entry into or passage through the zone must request permission from the Captain of the Port Upper Mississippi River or a designated representative. The Captain of the Port Upper Mississippi River representative may be contacted at 314–269–2332.

(3) All persons and vessels shall comply with the instructions of the Captain of the Port Upper Mississippi River or their designated representative. Designated Captain of the Port representatives include United States Coast Guard commissioned, warrant, and petty officers.

Dated: July 10, 2013.

**B.L. Black,**

*Captain, U.S. Coast Guard, Captain of the Port Upper Mississippi River.*

[FR Doc. 2013–18342 Filed 7–30–13; 8:45 am]

**BILLING CODE 9110–04–P**

#### ENVIRONMENTAL PROTECTION AGENCY

#### 40 CFR Part 180

[EPA–HQ–OPP–2012–0908; FRL–9389–8]

#### Sorbitan Monooleate Ethylene Oxide Adduct; 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 sorbitan, mono-9-octadecenoate, poly(oxy-1,2-ethanediyl) derivs., (Z)- (CAS Reg. No 9005-65-6) (also known as “sorbitan monooleate ethylene oxide adduct” and as “polysorbate 80”) when used as an inert ingredient in antimicrobial formulations for use on food-contact surfaces in public eating places, dairy-processing equipment, and food-processing equipment and utensils. Exponent, on behalf of Ecolab, Inc. submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting the establishment of an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of sorbitan monooleate ethylene oxide adduct.

**DATES:** This regulation is effective July 31, 2013. Objections and requests for hearings must be received on or before September 30, 2013, 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-2012-0908, 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), EPA West 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:** Lois Rossi, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460-0001; 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 40 CFR part 180 through the Government Printing 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).

#### *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-2012-0908 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 30, 2013. 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-2012-0908, 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.htm>. 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 February 15, 2013 (78 FR 11129) (FRL-9378-4), EPA issued a document pursuant to FFDCA section 408, 21 U.S.C. 346a, announcing the filing of a pesticide petition (PP IN-10524) by Exponent, on behalf of Ecolab, Inc., 370 Wabasha St., St. Paul MN 55102. The petition requested that 40 CFR 180.940(a) be amended by establishing an exemption from the requirement of a tolerance for residues of sorbitan monooleate ethylene oxide adduct when used as an inert ingredient in antimicrobial formulations applied to food-contact surfaces in public eating places, dairy-processing equipment, and food-processing equipment and utensils. 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.

### **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 sorbitan monooleate ethylene oxide adduct including exposure resulting from the exemption established by this action. EPA's assessment of exposures and risks associated with sorbitan monooleate ethylene oxide adduct 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 sorbitan monooleate ethylene oxide adduct 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 acute oral toxicity of sorbitan monooleate ethylene oxide adduct is low; the LD<sub>50</sub> was >25,000 mg/kg in the rat and mouse. Also, no systemic or adverse effects were observed in rats following a single oral dose of 22,000 mg/kg/day. Sorbitan monooleate ethylene oxide adduct did not cause eye irritation in rabbits. It was not a dermal sensitizer in guinea pigs. Acute dermal toxicity was not observed in rabbits exposed to sorbitan sesquileate ethoxylate, a substance that is closely related to sorbitan monooleate ethylene oxide adduct.

Sorbitan monooleate ethylene oxide adduct was administered via the diet to rats in a subchronic toxicity study. Systemic toxicity was not observed in rats following exposure to 2,500 mg/kg/day of sorbitan monooleate ethylene oxide adduct in the diet for 13 weeks.

In developmental and reproduction toxicity studies, rats and mice administered sorbitan monooleate ethylene oxide adduct at doses >10,000 mg/kg/day exhibited toxicity. These doses well exceed the limit dose of 1,000 mg/kg/day.

Available mutagenicity studies included the rec-assay, reverse mutation assay, chromosome aberration test, a mouse micronucleus assay, and a dominant lethal test. Sorbitan monooleate ethylene oxide adduct was negative for inducing mutations and aberrations in all of the studies. Therefore, sorbitan monooleate ethylene oxide adduct is considered nonmutagenic.

Evidence of carcinogenicity was not observed in mice. In rats, the incidence of adrenal medulla malignant and benign pheochromocytoma is 4% and 58%, respectively, in high dose males. The historical control ranges for malignant and total benign pheochromocytoma are 0–20% and 22–48%, respectively. The incidence of total benign adrenal medulla pheochromocytoma (29/50, 58%) was marginally increased though not significantly in high dose (50,000 ppm) males only when compared to control male rats (21/50, 42%). Nevertheless, the Agency concluded that the concern for carcinogenicity is low based on the following:

1. The adrenal medulla pheochromocytomas were observed in only one sex and species at an extremely high dose, 2,500 mg/kg/day, which is in excess of 2.5 times the limit dose;

2. The increased incidence was observed in benign tumors;

3. The lack of mutagenicity of sorbitan monooleate ethylene oxide adduct; and

4. General low toxicity of the substance. Therefore, a cancer risk assessment was not conducted.

Neurotoxicity parameters were evaluated in a reproduction toxicity study in rats with sorbitan monooleate ethylene oxide adduct. Evidence of neurotoxicity was not observed.

Although no immunotoxicity studies were available for review, none of the submitted studies indicated any evidence of immunotoxicity.

A metabolism study in rats showed that sorbitan monooleate ethylene oxide adduct administered orally is hydrolyzed, poorly absorbed, and excreted mainly in the feces. Bioaccumulation was not observed.

#### B. Toxicological Points of Departure/ Levels of Concern

The available toxicity studies indicate that sorbitan monooleate ethylene oxide adduct has very low toxicity. The toxicity database consists of toxicity data on subchronic and chronic exposures; carcinogenicity, developmental, reproduction, mutagenicity and metabolism. Although a developmental study in rabbits and a dermal toxicity study are not available, there is no concern for the lack of these studies. There is no concern for the lack of a developmental study in rabbits because fetal susceptibility was not observed in the available developmental and reproduction studies in rats and mice. Also, toxicity was only observed at doses (>10,000 mg/kg/day) well above the limit dose.

In regard to the sorbitan monooleate ethylene oxide adduct toxicity database, the lowest NOAEL (100 mg/kg/day) was observed in a developmental study in rats where 100 mg/kg/day was the only tested dose. However, the results in this study were considered unreliable because the effects were not reproducible in other studies conducted with the same species, at higher doses and longer exposure. In these remaining studies, toxicity was observed only at doses >2,500 mg/kg/day, well above the limit dose of 1,000 mg/kg/day. Therefore, since no endpoint of concern was identified for the acute and chronic dietary exposure assessment and short and intermediate dermal and inhalation exposure, a quantitative risk assessment

for sorbitan monooleate ethylene oxide adduct is not necessary.

### C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to sorbitan monooleate ethylene oxide adduct, EPA considered exposure under the proposed exemption from the requirement of a tolerance (40 CFR 180.940(a)) and as an inert ingredient used in pesticide formulations applied to growing crops and animals under the existing exemptions from the requirement of a tolerance given at 40 CFR 180.910 and 180.930. EPA assessed dietary exposures from sorbitan monooleate ethylene oxide adduct in food as follows:

Sorbitan monooleate ethylene oxide adducts are used as surfactants, related adjuvants of surfactants, emulsifiers, buffering agents, and corrosion inhibitors in a variety of residential pesticide products including yard, garden, and turf products, as well as in agricultural crop products, applied to growing crops, raw agricultural commodities after harvest, and/or to animals. Additionally, they are used extensively as emulsifiers, stabilizers and thickeners in food, cosmetics, personal care and medical products, and lubricants.

For the general population, the majority of exposure to sorbitan monooleate ethylene oxide adduct occurs from the extensive use in consumer products and as FDA-approved direct and indirect food additives. Under this exemption from the requirement of a tolerance, residues of this chemical also may be found on food-contact surfaces, such as tableware and utensils, and in dairies and beverage- and food-processing plants. Because no hazard endpoint of concern was identified for the acute and chronic dietary assessment (food and drinking water), a quantitative dietary exposure risk assessment was not conducted.

2. *Dietary exposure from drinking water.* Sorbitan monooleate ethylene oxide adduct is not expected to be present in drinking water based on its physical/chemical properties. Further, a hazard endpoint of concern was not identified for the acute and chronic dietary assessment; therefore, a quantitative dietary exposure risk assessment was not conducted.

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,

tables). In the case of sorbitan monooleate ethylene oxide adduct, the request is for use as an inert ingredient in antimicrobial formulations for use on food contact surfaces. Sorbitan monooleate ethylene oxide adduct may also be used in personal care products and in products that are registered for specific uses that may result in residential exposure. However, based on the lack of toxicity, a quantitative exposure assessment from "residential exposures" was not performed.

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 sorbitan monooleate ethylene oxide adduct to share a common mechanism of toxicity with any other substances, and sorbitan monooleate ethylene oxide adduct does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that sorbitan monooleate ethylene oxide adduct 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 Web site 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.

As part of its qualitative assessment, the Agency did not use safety factors for assessing risk, and no additional safety factor is needed for assessing risk to infants and children. The toxicity

database contains several acute and subchronic, carcinogenicity, development toxicity, reproductive toxicity, and mutagenicity studies. The available toxicity studies indicate that sorbitan monooleate ethylene oxide adduct has very low toxicity. The lowest NOAEL (100 mg/kg/day) was observed in a developmental study where 100 mg/kg/day was the only tested dose. However, in the remaining studies where more than one dose was tested, toxicity was observed only at doses >2,500 mg/kg/day, well above the limit dose of 1,000 mg/kg/day. Further, fetal toxicity was only observed at doses >10,000 mg/kg/day. Although no neurotoxicity studies are available for sorbitan monooleate ethylene oxide adduct, EPA is not concerned for neurotoxic effects because neurotoxicity was not observed in a developmental study in rats where neurotoxic parameters were evaluated. Also, although no immunotoxicity studies are available for sorbitan monooleate ethylene oxide adduct, none of the submitted studies showed any indications of immunotoxicity. Thus, there is no residual uncertainty with regard to pre- and post-natal toxicity of sorbitan monooleate ethylene oxide adduct.

### 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, sorbitan monooleate ethylene oxide adduct 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 based on the lack of toxicity of sorbitan monooleate ethylene oxide adduct and since no chronic endpoint was identified, chronic risk is not expected.

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). Because no short-term adverse effect was identified, sorbitan monooleate ethylene oxide adduct is not expected to pose a short-term risk.

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). Because no intermediate-term adverse effect was identified, sorbitan monooleate ethylene oxide adduct is not expected to pose an intermediate-term risk.

5. *Aggregate cancer risk for U.S. population.* Based on the discussion of the potential carcinogenicity of sorbitan monooleate ethylene oxide adduct in Unit IV.A., sorbitan monooleate ethylene oxide adduct is not expected to pose a cancer risk.

6. *Determination of safety.* Based on the lack of concern for hazard posed by sorbitan monooleate ethylene oxide adduct, 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 sorbitan monooleate ethylene oxide adduct.

## 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 Nations 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 sorbitan monooleate ethylene oxide adduct.

## VI. Conclusions

Therefore, an exemption from the requirement of a tolerance is established under 40 CFR 180.940(a) for sorbitan, mono-9-octadecenoate, poly(oxy-1,2-ethanediyl) derivs., (Z)- (also known as sorbitan monooleate ethylene oxide adduct) (CAS Reg. No. 9005-65-6) when used as an inert ingredient (in antimicrobial formulations) applied to food-contact surfaces in public eating places, dairy-processing equipment, and food-processing equipment and utensils.

## VII. Statutory and Executive Order Reviews

This final rule establishes an exemption from the requirement of 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 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 FFDCA section 408(d), such as the exemption to the requirement of a 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 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 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) (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 of 1995 (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: July 22, 2013.

**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 § 180.940, in paragraph (a), alphabetically add the following inert ingredient to the table 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
* * *	* *	*
Sorbitan, mono-9-octadecenoate, poly(oxy-1,2-ethanediyl) derivs., (Z)-.	9005-65-6	None.
* * *	* *	*

[FR Doc. 2013-18188 Filed 7-30-13; 8:45 am]

BILLING CODE 6560-50-P

**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 180**

[EPA-HQ-OPP-2009-0917; FRL-9391-2]

**Complex Polymeric Polyhydroxy Acids; 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 Complex Polymeric Polyhydroxy Acids in or on all food commodities. This regulation eliminates the need to establish a maximum permissible level for residues of Complex Polymeric Polyhydroxy Acids (CPPA) under FFDCA.

**DATES:** This regulation is effective July 31, 2013. Objections and requests for hearings must be received on or before September 30, 2013, 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-2009-0917, 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), EPA West 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:** Menyon Adams, Biopesticides and Pollution Prevention Division (7511P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460-0001; telephone number: (703) 347-8496; email address: [adams.menyon@epa.gov](mailto:adams.menyon@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 Printing 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). To access the OCSPP test guidelines referenced in this document electronically, please go to <http://www.epa.gov/ocspp> and select "Test Methods and Guidelines."

*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-2009-0917 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 30, 2013. 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-2009-0917, by one of the methods provided in 40 CFR 150.17(b).

**II. Background and Statutory Findings**

In the **Federal Register** of January 13, 2010 (75 FR 1775) (FRL-8805-6), EPA issued a notice pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide tolerance petition (PP 9F7645) by James R. Yowell of Spring Trading Company (the Petitioner), on behalf of Floratine Biosciences Inc., 153 N. Main St., Suite 100, Collierville, TN 38017. The petition requested that 40 CFR part 180 be amended by establishing an exemption from the requirement of a tolerance for residues of Complex Polymeric Polyhydroxy Acids. That document referenced a summary of the petition prepared by the Petitioner, which is available in the docket, <http://www.regulations.gov>. No comments were received.

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 exemption is "safe." Section 408(c)(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. Pursuant to FFDCA section 408(c)(2)(B), in establishing or maintaining in effect an exemption from the requirement of a tolerance, EPA must take into account the factors set forth in FFDCA section 408(b)(2)(C), which require EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a