

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2013-0601; FRL-9922-29]

9-Octadecenoic Acid (9Z)-, Sulfonated, Oxidized and its Potassium and Sodium Salts; 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 9-octadecenoic acid (9Z)-, sulfonated, oxidized; 9-octadecenoic acid (9Z)-, sulfonated, oxidized, potassium salts; and 9-octadecenoic acid (9Z)-, sulfonated, oxidized, sodium salts, when used as an inert ingredient in antimicrobial pesticide formulations used on food contact surfaces in public eating places, dairy processing equipment and food processing equipment and utensils at a maximum end-use concentration not to exceed 250 parts per million (ppm). Ecolab 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 9-octadecenoic acid (9Z)-, sulfonated, oxidized and its potassium and sodium salts.

DATES: This regulation is effective [*insert date of publication in the Federal Register*].

Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the Federal Register*], 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-2013-0601, 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: Susan Lewis, Director, 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*.

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. 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-2013-0601 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 *[insert date 60 days after date of publication in the **Federal Register**]*. 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-2013-0601, 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 September 12, 2013 (78 FR 56185) (FRL-9399-7), EPA issued a document pursuant to FFDCA section 408, 21 U.S.C. 346a, announcing the filing of a pesticide petition (PP IN-10549) by Ecolab, Inc. 370 N. Wabasha Street, 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 9-octadecenoic acid (9Z)-, sulfonated, oxidized (CAS Reg. No. 1315321-93-7); 9-octadecenoic acid (9Z)-, sulfonated, oxidized, potassium salts (CAS Reg. No. 1315321-94-8); and 9-octadecenoic acid (9Z)-, sulfonated, oxidized, sodium salts, (CAS No. 1315321-95-9) when used as an inert ingredient in antimicrobial pesticide formulations used on food contact surfaces in public eating places, dairy processing equipment, and

food processing equipment and utensils at a maximum end-use concentration not to exceed 250 ppm. That document referenced a summary of the petition prepared by Ecolab Inc, 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 FFDCFA 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 FFDCFA 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 9-octadecenoic acid (9Z)-, sulfonated, oxidized and its potassium and sodium salts including exposure resulting from the exemption established by this action. EPA's assessment of exposures

and risks associated with 9-octadecenoic acid (9Z)-, sulfonated, oxidized and its potassium and sodium salts 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 9-octadecenoic acid (9Z)-, sulfonated, oxidized and its potassium and sodium salt (also referred to as peroxy sulfonated oleic acid (PSOA)) as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies discussed in this unit.

Peroxy sulfonated oleic acid is acutely toxic via the oral route and is highly corrosive via the dermal and inhalation routes of exposure. In a 28-day oral toxicity study (OECD Guideline 407), rats were administered PSOA via gavage at dose levels of 15 milligrams/kilogram/day (mg/kg/day) and 50 mg/kg/day. No observable adverse effects were seen at either dose level but since no systemic effects were observed, the dosing was considered by the Agency to not be adequate.

In a developmental toxicity (OECD Guideline 414) study with PSOA, the parental NOAEL for systemic effects was 50 mg/kg bw/day, the highest dose tested. The NOAEL for embryotoxic, fetotoxic and developmental effects was also 50 mg/kg bw/day, the highest dose tested.

The dosing in the 28-day gavage study and the developmental toxicity studies was considered inadequate because animals were not challenged at higher doses. The applicant suggested that the higher doses were not utilized because of the corrosive nature of the chemical. Since there was no evidence of corrosivity in the study, a 14-day oral toxicity study was conducted at dose levels of 100 mg/kg/day, 300 mg/kg/day and 1,000 mg/kg/day. The study results confirmed that higher doses would have been corrosive.

In a series of genotoxicity studies PSOA is negative for inducing mutations in bacterial and mammalian cells, with and without metabolic activation. In the *in vitro* chromosome aberration study using human lymphocytes, PSOA was positive with and without metabolic activation. However, the *in vivo* micronucleus assay in rats was negative.

A neurotoxicity study was not conducted with PSOA. However, detailed functional observations were made among the parameters measured in the 28-day subchronic oral feeding study. There were no PSOA related changes in any of the parameters measured, including functional observations battery (FOB). No evidence of neurotoxicity was observed. An immunotoxicity study was not conducted with PSOA. However, minimal hemorrhage in the thymus was observed after the recovery period in the 14-day oral toxicity study with rats. Since, this effect is a common background lesion it is not considered indicative of potential immunotoxicity. There are no known chronic toxicity studies with PSOA and no available PSOA mammalian metabolism studies.

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>.

Table 1.--Summary of Toxicological Dose and Endpoints for 9-octadecenoic acid (9Z)-, sulfonated, oxidized and its potassium and sodium salt for use in Human Risk Assessment

Exposure/Scenario	Dose Used in Risk Assessment, Interspecies and Intraspecies and Any Traditional UF	Special FQPA SF and LOC for Risk Assessment	Study and Toxicological Effects
Acute dietary (all populations)	An endpoint attributable to a single dose exposure has not been identified		

Chronic dietary (all populations)	NOAEL= 50 mg/kg/day UF _A = 10X UF _H = 10X Chronic RfD = 0.5 mg/kg/day	FQPA SF = 1X cPAD = chronic RfD/Special	14-day and 28-day rat oral toxicity study in rats LOAEL = 300 mg/kg/day based on gastrointestinal irritation
Cancer (Oral, dermal, inhalation)	NA	NA	NA

FQPA SF = Food Quality Protection Act Safety Factor. LOAEL = lowest-observed-adverse-effect-level. LOC = level of concern. mg/kg/day = milligram/kilogram/day. MOE = margin of exposure. NOAEL = no-observed-adverse-effect-level. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. UF = uncertainty factor. UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies)

C. Exposure Assessment

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

In the absence of actual dietary exposure data resulting from this use, EPA has utilized a conservative, health-protective method of estimating dietary intake that is based upon conservative assumptions related to the amount of residues that can be transferred to foods as a result of the proposed use of 9-octadecenoic acid (9Z)-, sulfonated, oxidized and its potassium and sodium salts in food contact sanitizing pesticide products. This same methodology has been utilized by EPA in estimating dietary exposures to antimicrobial pesticides used in food-handling settings. A complete description of the approach used to assess dietary exposures resulting from food contact sanitizing solution uses of nitric acid can be found at <http://www.regulations.gov> in document “Peroxy Sulfonated Oleic Acids; Human Health Risk Assessment and Ecological Effects

Assessment to Support Proposed Exemption from the Requirement of a Tolerance When Used as Inert Ingredients in Pesticide Formulations,’’ pp. 14-15 in docket ID number EPA–HQ–OPP–2013-0601. EPA assessed dietary exposures from 9-octadecenoic acid (9Z)-, sulfonated, oxidized and its potassium and sodium salts in food as follows:

i. *Acute exposure.* No adverse effects attributable to a single exposure of PSOA were seen in the toxicity databases. Therefore, an acute dietary exposure assessment for 9-octadecenoic acid (9Z)-, sulfonated, oxidized and its potassium and sodium salts is not necessary.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment, the Agency believes the assumptions used to estimate chronic dietary exposures lead to an extremely conservative assessment of chronic dietary risk due to a series of compounded conservative assumptions. First, when a surface is treated with a disinfectant, a quantity of the disinfectant remains on the surface (residual solution). In the absence of any other data, EPA has used an estimated worst-case concentration of 1 mg of residual solution per square centimeter (cm) of treated surface area for this quantity. Second, the conservatism of this methodology is compounded by EPA’s decision to assume a worst case scenario that all food that an individual consumers will come into contact with 4,000 cm² of sanitized non-porous food contact surfaces. This contact area represents all the surface area from silverware, china, and glass used by a person who regularly eats three meals per day at an institutional or public facility. Third, EPA assumes that 100% of the material present on food contact surfaces will migrate to food.

2. *Dietary exposure from drinking water.* Due to the proposed use pattern, the Agency believes PSOA will not enter surface water or ground water as a result of the proposed use. Therefore a dietary exposure assessment for drinking water is not necessary.

3. *From non-dietary exposure.* The term “residential exposure” is used in this document to refer to non-occupational, non-dietary exposure. Peroxy sulfonated oleic acids are not used as an inert ingredient in pesticide products that are registered for specific uses that may result in both indoor and outdoor residential exposures. Therefore, a residential exposure and risk assessment was not conducted for PSOA.

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 peroxy sulfonated oleic acids to share a common mechanism of toxicity with any other substances, and peroxy sulfonated oleic acids do not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that peroxy sulfonated oleic acids do 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.* There is no concern for fetal susceptibility. There were no treatment related effects observed in a developmental toxicity study in rats up to the maximum dose tested (50 mg/kg/day). Based on the corrosive nature of PSOA toxicity testing at doses greater than 100 mg/kg/day results in local effects (i.e., severe gastrointestinal irritation) with other observed systemic effects being secondary to the irritation effects. Therefore, based on the available data, there are no concerns for residual uncertainties concerning prenatal and postnatal toxicity.

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. That decision is based on the following findings:

i. The NOAEL used for risk assessment is based on the corrosive effects of PSOA which occur at dose levels below which any systemic toxicity is observed and is therefore protective of potential developmental and reproductive effects.

ii. There is no indication that PSOA is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

iii. There is no indication that PSOA is an immunotoxic chemical and there is no need for additional UFs to account for immunotoxicity.

iv. There is no evidence that PSOA results in increased susceptibility in *in utero* rodents.

v. There are no residual uncertainties identified in the exposure databases. EPA made conservative (health-protective) assumptions regarding dietary exposure to PSOA. This assessment will not underestimate the exposure and risks posed by PSOA.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). The aPAD and cPAD represent the highest safe exposures, taking into account all appropriate SFs. EPA calculates the aPAD and cPAD by dividing the POD by all applicable UFs. For linear cancer risks, EPA calculates the probability of additional cancer cases 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 POD to ensure that the MOE called for by the product of all applicable UFs is not exceeded.

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, peroxy sulfonated oleic acids are 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 peroxy sulfonated oleic acids from food and water will utilize 18% of the cPAD for children 1-2 years old, the population group receiving the highest exposure. There are no residential uses for peroxy sulfonated oleic acids. Based on the explanation in Unit IIIC.3 residential use patterns, chronic residential exposure to residues of peroxy sulfonated oleic acids 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 there are no residential uses, short-term residential exposures are not likely to occur, and no short-term adverse effect was identified therefore peroxy sulfonated oleic acids are not expected to pose a short--term aggregate 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 there are no residential uses, intermediate-term residential exposures are not likely to occur, and peroxy sulfonated oleic acids are not expected to pose an intermediate-term aggregate risk.

5. *Aggregate cancer risk for U.S. population.* Based upon negative response for mutagenicity in a battery of genotoxicity tests, and lack of any structural alerts for carcinogenicity, peroxy sulfonated oleic acids are not expected to pose a cancer risk to humans.

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 peroxy sulfonated oleic acids 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 peroxy sulfonated oleic acids of in or on any food commodities. EPA is establishing a limitation on the amount of peroxy sulfonated oleic acids 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 for which the final end use concentration of peroxy sulfonated oleic acids in antimicrobial food contact surface sanitizing solutions would exceed 250 ppm.

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 peroxy sulfonated oleic acids.

VI. Conclusions

Therefore, an exemption from the requirement of a tolerance is established under 40 CFR 180.940(a) for residues of 9-octadecenoic acid (9Z)-, sulfonated, oxidized (CAS Reg. No. 1315321-93-7); 9-octadecenoic acid (9Z)-, sulfonated, oxidized, potassium salts (CAS Reg. No. 1315321-94-8); and 9-octadecenoic acid (9Z)-, sulfonated, oxidized, sodium salts, (CAS No. 1315321-95-9) when used as an inert ingredient in antimicrobial pesticide formulations used on food contact surfaces in public eating places, dairy processing equipment and food processing equipment and utensils at a maximum end-use concentration not to exceed 250 ppm.

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: February 25, 2015.

Susan Lewis,
 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(a), alphabetically add the following inert ingredients to 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).

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(a) * * *

Pesticide Chemical	CAS Reg. No.	Limits
* * * * *	* * * * *	* * * * *
9-Octadecenoic acid (9Z)-, sulfonated, oxidized	1315321-93-7	When ready for use, the end-use concentration is not to exceed 250 ppm
9-Octadecenoic acid (9Z)-, sulfonated, oxidized, potassium salts	1315321-94-8	When ready for use, the end-use concentration is not to exceed 250 ppm
9-Octadecenoic acid (9Z)-, sulfonated, oxidized, sodium salts	1315321-95-9	When ready for use, the end-use concentration is not to exceed 250 ppm
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