operating-day average, unless otherwise indicated in specific paragraphs.

Group of coal-fired units	Federal emission limitation
Cholla Power Plant Units 2, 3, and 4	0.055
Coronado Generating Station Units 1 and 2	0.065

* * * * *

(4) * * *

(ii) The owners/operators of each unit subject to this paragraph (f) shall comply with the applicable PM_{10} and SO_2 emissions limits submitted to EPA as part of the Arizona Regional Haze SIP in a letter dated February 28, 2011, and approved into the Arizona State Implementation Plan on December 5, 2012, as well as the related compliance, recordkeeping and reporting of this paragraph (f) no later than the following dates:

Unit	Compliance date	
	PM_{10}	SO_2
Cholla Power Plant, Unit 2	April 1, 2016	April 1, 2016.
Cholla Power Plant, Unit 3	June 3, 2013	June 3, 2013.
Cholla Power Plant, Unit 4	June 3, 2013	June 3, 2013.
Coronado Generating Station, Unit 1	June 3, 2013	June 3, 2013.
Coronado Generating Station, Unit 2	June 3, 2013	June 3, 2013.

* * * * *

(5) * * *

(i) * * *

(A) At all times after the compliance date specified in paragraph (f)(4) of this section, the owner/operator of each coal-fired unit shall maintain, calibrate, and operate a CEMS, in full compliance with the requirements found at 40 CFR part 75, to accurately measure SO_2, NO_X, diluent, and stack gas volumetric flow rate from each unit. In addition, the owner/operator of Cholla Units 2, 3, and 4 shall calibrate, maintain, and operate a CEMS, in full compliance with the requirements found at 40 CFR part 75, to accurately measure SO_2 emissions and diluent at the inlet of the sulfur dioxide control device. All valid CEMS hourly data shall be used to determine compliance with the emission limitations for NO_X and SO_2 in paragraph (f)(3) of this section for each unit. When the CEMS is out-of-control as defined by 40 CFR part 75, that CEMs data shall be treated as missing data, and not used to calculate the emission average. Each required CEMS must obtain valid data for at least 90 percent of the unit operating hours, on an annual basis.

(B) The owner/operator of each unit shall comply with the quality assurance procedures for CEMS found in 40 CFR part 75. In addition to these 40 CFR part 75 requirements, relative accuracy test audits shall be calculated for both the NO_X and SO_2 pounds per hour measurement and the heat input measurement. The CEMs monitoring data shall not be bias adjusted. The inlet SO_2 and diluent monitors required by this rule shall also meet the Quality Assurance/Quality Control (QA/QC) requirements of 40 CFR part 75. The testing and evaluation of the inlet monitors and the calculations of relative accuracy for lb/hr of NO_X, SO_2 and heat input shall be performed each time the 40 CFR part 75 CEMS undergo relative accuracy testing. In addition, relative accuracy test audits shall be performed in the units of lb/MMBtu for the inlet and outlet SO_2 monitors at Cholla Units 2, 3, and 4.

(ii) * * *

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(B) [Reserved]

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[FR Doc. 2015–07987 Filed 4–9–15; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2013–0756; FRL–9923–64]

Secondary (C_{13}-C_{17}) Alkane Sulfonates; 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 two secondary alkane (C_{13}-C_{17}) sulfonates (CAS Reg. Nos. 85711–69–9 and 97489–15–1) when used as inert ingredients (surfactant) in pesticide formulations applied to growing crops at a maximum concentration not to exceed 40% by weight. Exponent, on behalf of Clariant Corporation, submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting establishment of an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of secondary alkane (C_{13}-C_{17}) sulfonates.

DATES: This regulation is effective April 10, 2015. Objections and requests for hearings must be received on or before June 9, 2015, 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–2013–0756, 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, 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 Publishing 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–2013–0756 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before June 9, 2015. 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–2013–0756, 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 February 21, 2014 (79 FR 9870) (FRL–9904–98), EPA issued a document pursuant to FFDCA section 408, 21 U.S.C. 346a, announcing the filing of a pesticide petition (PP IN–10630) by Exponent, 1150 Connecticut Ave. NW., Washington, DC 20036 on behalf of Clariant Corporation, 4000 Monroe Rd., Charlotte, NC 28205. The petition requested that 40 CFR 180.920 be amended by establishing an exemption from the requirement of a tolerance for residues of two inert ingredients, collectively referred to as secondary alkane (C_{13}-C_{17}) sulfonates (SAS): Sulfonic acids, C_{13}-$_{17}$-sec-alkane, sodium salts (CAS Reg. No. 85711–69–9) and sulfonic acids, C_{14}-$_{17}$-sec-alkane, sodium salts (CAS Reg. No. 97489–15–1) when used as surfactants in pesticide formulations applied to growing crops. 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 is limiting the tolerance exemption to pesticide formulations in which the maximum concentration of the secondary alkane sulfonates is 40% by weight. This limitation is based on the Agency's risk assessment which can be found at *http://www.regulations.gov* in document ''Secondary Alkane (C_{13}-C_{17}) Sulfonates (SAS); Human Health Risk Assessment and Ecological Effects Assessment to Support Proposed Exemption from the Requirement of a Tolerance When Used as an Inert Ingredient in Pre-harvest Pesticide Products Under 40 CFR 180.920'' in docket ID number EPA–HQ–OPP–2013–0756.

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 secondary alkane (C_{13}-C_{17}) sulfonates including exposure resulting from the exemption established by this action. EPA's assessment of exposures and risks associated with secondary alkane (C_{13}-C_{17}) sulfonates 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 secondary alkane (C_{13}-C_{17}) sulfonates (also referred to as SAS) 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 Agency relied on data on CAS Reg. No. 85711–69–9 (sulfonic acids (C_{13}-C_{17} secondary alkane) to assess both inert ingredients. Bridging data in this manner is appropriate because CAS Reg. No. 97489–15–1 (sulfonic acids, C_{14}-C_{17} secondary alkane) has an alkyl carbon chain length that falls within the carbon chain length range of CAS Reg. No. 85711–69–9 (sulfonic acids, C_{13}-C_{17} secondary alkane) and toxic effects attributable to the C_{14}-C_{17} secondary alkane sulfonate would be observed in toxicity testing of the C_{13}-C_{17} secondary alkane sulfonate.

The acute oral lethal dose (LD_{50}) for SAS in rats is >500 milligram/kilogram (mg/kg). The acute dermal LD_{50} in mice is >200 mg/kg. Secondary alkane (C_{13}-C_{17}) sulfonate is not a dermal irritant based on primary skin irritation study in rabbits and it is not a dermal sensitizer in guinea pigs.

A chronic toxicity study was conducted on SAS in rats and demonstrated a NOAEL of 4,000 parts per million (ppm) (equivalent to 168 milligram/kilogram body weight/day (mg/kg bw/day) in males and 227 mg/kg bw/day in females), and a LOAEL of 20,000 ppm (equivalent to 920 mg/kg bw/day in males and 1,281 mg/kg bw/day in females) based on reduced body weight, body weight gain, and the clinical signs of reduced grooming in males and females.

In a 2-generation reproduction study in rats dosed with SAS, there was no indication that offspring were more susceptible than the parental adults. The parental systemic LOAEL was 3,000 ppm (equivalent to 177 mg/kg bw/day in males and 181 mg/kg bw/day in females), based on decreased body weight gain during premating and on reduced organ weight. The parental NOAEL was 1,000 ppm (equivalent to 58.2 mg/kg bw/day for males and 66 mg/kg bw/day for females). The offspring LOAEL was 3,000 ppm (equivalent to 177 mg/kg bw/day) based on decreased pre- and post-implantation loss and decreased weight gain in offspring. The offspring NOAEL was 1,000 ppm (equivalent to 58.2 mg/kg bw/day).

Secondary alkane (C_{13}-C_{17}) sulfonates were not mutagenic when tested in the *in vitro* mammalian cell gene mutation assay and in the *Salmonella typhimurium* reverse mutation assay.

In a combined oral (dietary) chronic toxicity/carcinogenicity study of SAS in rats, there were no treatment-related neoplastic or non-neoplastic microscopic findings observed up to 2.0% (equivalent to 805 mg/kg bw/day in males and 1,032 mg/kg bw/day in females), the highest dose tested. A LOAEL was not identified. Although body weight of high-dose males and females were lower by about 20% relative to controls throughout most of the study, decreased body weight was not viewed as an adverse effect since higher survival rates were observed in this group compared to controls.

In a dermal carcinogenicity study of SAS in mice, no indication of increased incidence relative to controls of malignant neoplasms was observed. No LOAEL was demonstrated. The NOAEL was 1.0% (equivalent to 0.6 mg/treatment), the highest concentration applied to the skin.

Secondary alkane (C_{13}-C_{17}) sulfonates are rapidly absorbed and excreted in the urine and feces. Secondary alkane (C_{13}-C_{17}) sulfonates have a low potential for dermal absorption based on a dermal penetration study in rats.

Although no immunotoxicity or neurotoxicity studies on SAS were available in the database, no evidence of immunotoxicity or neurotoxicity was observed in the submitted 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 the NOAEL and the LOAEL are identified. Uncertainty/safety factors (UF) 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 secondary alkane (C_{13}-C_{17}) sulfonates used for human risk assessment is shown in Table 1 of this unit.

The 2-generation reproductive toxicity study in rats was selected for oral, dietary, dermal, and inhalation exposure scenarios (all durations) for this risk assessment. The parental systemic NOAEL in this study was 1,000 ppm (equivalent to 58.2 mg/kg bw/day for males) based on reduced body weight gain during premating and on reduced organ weight seen at the LOAEL of 3,000 ppm (equivalent to 177 mg/kg bw/day). The rationale for selecting this study for the dietary, dermal, and inhalation exposure scenario is based on the fact that this study provided the lowest and most conservative toxicity endpoint and route-specific studies are available.

A default 100% inhalation absorption will be used for inhalation exposure scenarios. A 50% dermal absorption rate will be used for dermal exposure scenarios based on the toxicokinetic dermal absorption study.

TABLE 1—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR SECONDARY ALKANE (C_{13}-C_{17}) SULFONATES FOR USE IN HUMAN RISK ASSESSMENT

Exposure/scenario	Point of departure and uncertainty/ safety factors	RfD, PAD, LOC for risk assessment	Study and toxicological effects
Chronic dietary (All populations)	NOAEL = 58.2 mg/ kg bw/day. UF_A = 10x UF_H = 10x FQPA SF = 1x	Chronic RfD = 0.582 mg/kg bw/day. cPAD = 0.58 mg/kg bw/day.	Rat reproductive toxicity study. LOAEL = 177 mg/kg bw/day based on decreased weight gain during premating and reduced organ weight.
Cancer (Oral, dermal, inhalation).	Based on the lack of increased incidence of tumor formation compared to controls in multiple carcinogenicity studies and the lack of mutagenicity, SAS is considered not likely to be carcinogenic.		

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_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 secondary alkane (C_{13}-C_{17}) sulfonates, EPA considered exposure under the proposed exemption from the requirement of a tolerance. EPA assessed dietary exposures from secondary alkane (C_{13}-C_{17}) sulfonates in food as follows:

i. *Acute Exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide chemical, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure. No such effects were identified in the toxicological studies for SAS; therefore, a quantitative acute dietary exposure assessment is unnecessary.

ii. *Chronic exposure.* The chronic dietary exposure assessment for this inert ingredient utilizes the Dietary Exposure Evaluation Model Food Commodity Intake Database (DEEM–FCID), Version 3.16, EPA, which includes food consumption information from the U.S. Department of Agriculture's National Health and Nutrition Examination Survey, ''What We Eat In America'', (NHANES/ WWEIA). This dietary survey was conducted from 2003 to 2008. In the absence of actual residue data, the inert ingredient evaluation is based on a highly conservative model which assumes that the residue level of the inert ingredient would be no higher than the highest established tolerance for an active ingredient on a given commodity. Implicit in this assumption is that there would be similar rates of degradation between the active and inert ingredient (if any) and that the concentration of inert ingredient in the scenarios leading to these highest of tolerances would be no higher than the concentration of the active ingredient. The model assumes 100 percent crop treated (PCT) for all crops and that every food eaten by a person each day has tolerance-level residues. A complete description of the general approach taken to assess inert ingredient risks in the absence of residue data is contained in the memorandum entitled ''Alkyl Amines Polyalkoxylates (Cluster 4): Acute and Chronic Aggregate (Food and Drinking Water) Dietary Exposure and Risk Assessments for the Inerts'' (D361707, S. Piper, 2/25/09) and can be found at *http://www.regulations.gov* in docket ID number EPA–HQ–OPP–2008–0738.

iii *Cancer.* Based on the data summarized in Unit III.A., EPA has concluded that SAS does not pose a cancer risk to humans. Therefore, a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

2. *Dietary exposure from drinking water.* For the purpose of the screening level dietary risk assessment to support this request for an exemption from the requirement of a tolerance for secondary alkane (C_{13}-C_{17}) sulfonates, a conservative drinking water concentration value of 100 parts per billion (ppb) based on screening level modeling was used to assess the contribution to drinking water for the chronic dietary risk assessments for parent compound. These values were directly entered into the dietary exposure model.

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

Based on the use pattern for pesticide products containing SAS as an inert ingredient, there are no residential uses and thus no residential exposures are expected.

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 secondary alkane (C_{13}-C_{17}) sulfonates to share a common mechanism of toxicity with any other substances, and secondary alkane (C_{13}-C_{17}) sulfonates do not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that secondary alkane (C_{13}-C_{17}) sulfonates 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 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 Food Quality Protection Act Safety Factor (FQPA 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 a 2-generation reproduction toxicity study, there was no evidence of susceptibility of infants and children to SAS. In this study, the offspring and parental toxicity NOAEL was 1,000 ppm (equivalent to 58.2 mg/kg bw/day) based decreased pre- and post-implantation loss and decreased weight gain in offspring and decreased body weight gain during premating and on reduced organ weight in parental animals seen at the LOAEL was 3,000 ppm (equivalent to 177 mg/kg bw/day).

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 toxicity database for secondary alkane (C_{13}-C_{17}) sulfonates includes a subchronic toxicity study, a 2-generation reproduction study, chronic/carcinogenicity studies, several mutagenicity studies, and two toxicokinetic studies. The Agency concludes that for this ingredient, the results of these studies provide a reliable basis for assessing the range of potential effects to infants and children, such that the Agency has determined that no additional data are necessary at this time to evaluate effects to infants and children.

ii. There is no indication that SAS 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 evidence of increased susceptibility due to pre-or post-natal exposure to SAS in infants and children.

iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100 percent crop treated (PCT) and tolerance-level residues. EPA made conservative (protective) assumptions utilizing a 100 ppb default value in the ground and surface water modeling used to assess exposure to secondary alkane (C_{13}-C_{17}) sulfonates in drinking water. These assessments will not underestimate the exposure and risks posed by secondary alkane (C_{13}-C_{17}) sulfonates.

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, therefore, an acute dietary exposure assessment was not conducted.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to SAS from food and water will utilize 97.1% of the cPAD for children 1–2 years old, the population group receiving the greatest exposure.

3. *Short-term and intermediate-term risk.* Short-term and intermediate-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). A short-term/intermediate-term adverse effect was identified; however, SAS is not used as inert ingredient in any pesticide product registered for any use patterns that would result in short-term or intermediate-term residential exposure. Because there is no short-term or intermediate-term residential exposure and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess short-term risk), no further assessment of short-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating short-term risk for SAS.

4. *Aggregate cancer risk for U.S. population.* Based on the lack of evidence of carcinogenicity in two rodent carcinogenicity studies, secondary alkane (C_{13}-C_{17}) sulfonates are not expected to pose a cancer risk to humans.

5. *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 secondary alkane (C_{13}-C_{17}) sulfonates residues.

V. Other Considerations

A. Analytical Enforcement Methodology

Although EPA is establishing a limitation on the amount of SAS that may be used in pesticide formulations, an analytical enforcement methodology is not necessary for this exemption. The 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 use on growing crops with concentrations of SAS exceeding 40% by weight of the formulation.

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 secondary alkane (C_{13}-C_{17}) sulfonates.

VI. Conclusions

Therefore, an exemption from the requirement of a tolerance is established

under 40 CFR 180.920 for sulfonic acids, C_{13-17}-sec-alkane, sodium salts (CAS Reg. No. 85711–69–9) and sulfonic acids, C_{14-17}-sec-alkane, sodium salts (CAS Reg. No. 97489–15–1) when used as inert ingredients (surfactant) in pesticide formulations applied to growing crops at not more than 40% by weight of the pesticide formulation.

VII. Statutory and Executive Order Reviews

This action 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 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 exemption 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: March 10, 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 § 180.920, add alphabetically the following inert ingredients to the table to read as follows:

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

* * * * *

Inert ingredients	Limits	Uses
* * *	* * *	*
Sulfonic acids, C_{13-17}-sec-alkane, sodium salts (CAS Reg. No. 85711–69–9).	Not to exceed 40% by weight in non-residential use pesticide formulation only.	Surfactant.
Sulfonic acids, C_{14-17}-sec-alkane, sodium salts (CAS Reg. No. 97489–15–1).	Not to exceed 40% by weight in non-residential pesticide formulation only.	Surfactant.
* * *	* * *	*

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2013–0798; FRL–9925–02]

Pyraclostrobin; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of pyraclostrobin in or on the herb subgroup 19A, dill seed, the stone fruit group 12–12, and the tree nut group 14–12, except pistachio. Interregional Research Project Number 4 (IR–4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective April 10, 2015. Objections and requests for hearings must be received on or before