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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2018-0070; FRL-9998-57]

C_{10}-C_{16} Alkylbenzene 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 C_{10}-C_{16} branched and linear alkylbenzene sulfonates, including benzenesulfonic acid, dodecyl (CAS Reg, No. 27176-87-0) and benzenesulfonic acid, dodecyl-, sodium salt (CAS Reg. No. 25155-30-0), when used as an active or inert ingredient in antimicrobial pesticide formulations applied to food-contact surfaces in public eating places, dairy-processing equipment, and food-processing equipment and utensils at a maximum concentration not to exceed 700 parts per million (ppm). Exponent, Inc., on behalf of Ecolab, Inc., 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.

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 S**UPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2018-0070, 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: Anita Pease, Antimicrobials Division (7510P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; main telephone number: (703) 308-6411; email address: *ADFRNotices@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), e.g., agricultural workers; greenhouse, nursery, and floriculture workers; farmers.

• Animal production (NAICS code 112), e.g., cattle ranchers and farmers, dairy cattle farmers, livestock farmers.

• Food manufacturing (NAICS code 311), e.g., agricultural workers; farmers; greenhouse, nursery, and floriculture workers; ranchers; pesticide applicators.

• Pesticide manufacturing (NAICS code 32532), e.g., agricultural workers; commercial applicators; farmers; greenhouse, nursery, and floriculture workers; residential users.

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*.

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-2018-0070 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 August 4, 2019. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2018-0070, 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. Summary of Petitioned-For Exemption

In the **Federal Register** of April 11, 2018 (83 FR 15528) (FRL-9975-57), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide tolerance petition (PP 7F8626) by Exponent, Inc., 1150 Connecticut Avenue NW, Suite 1100, Washington, DC 20036 on behalf of Ecolab, Inc., 1 Ecolab Place, 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 C_{10}-C_{16} branched and linear alkylbenzene sulfonates when used as an active ingredient in antimicrobial pesticide formulations applied to 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 700 ppm. That document referenced a summary of the petition prepared by Exponent, Inc., on behalf of Ecolab, Inc., the registrant/petitioner, which is available in the docket, *http://www.regulations.gov*. Comments were submitted to the docket in response to the notice of filing, one of which was relevant to this rulemaking. The Agency's response is located in Unit IV.B. below.

III. 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 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 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 ...."

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 C_{10}-C_{16} alkylbenzene sulfonates including exposure resulting from the exemption established by this action. EPA's assessment of exposures and risks associated with C_{10}-C_{16} alkylbenzene sulfonates follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its 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.

Alkylbenzene sulfonates (ABS) are compounds that consist of a sulfonated aromatic ring with an alkyl chain of varying lengths; C_{10}–C_{16} refers to the number of carbons in the alkyl chain. These compounds may exist in either branched or linear form, depending upon where the aromatic ring is attached to the chain of carbons; the linear form is more common. The most common linear alkylbenzene sulfonate compounds used in pesticide formulations are (1) benzenesulfonic acid, dodecyl (CAS Reg. No. 27176-87-0) and (2) benzenesulfonic acid, dodecyl-, sodium salt (CAS Reg. No. 25155-30-0), both of which are currently approved for use as active and inert ingredients in registered pesticide products. Due to the similarity of production methods, product mixtures, and commercial use sites, as well as the similar or identical physical, chemical, and toxicological properties of ABS compounds, EPA's dietary risk assessment covers all registered ABS compounds, including both branched and linear forms and those compounds of chain lengths C_{10}-C_{16}; the toxicity data indicate that the toxicological profile is the same for the branched and linear form and that the length of the carbon alkyl chain does not change the toxicity of the ABS compound.

There are several repeat-dose oral toxicity studies performed with linear alkybenzene sulfonates, ranging from a 28-day study in monkeys to 9-month studies conducted with rats and mice. There are also repeat-dose dermal (guinea pigs, rabbits, and rats) and inhalation studies (dogs and monkeys). Collectively, these animal data suggest that the liver, kidney, and caecum (for oral studies) are the major target organs for toxicity. The liver and kidney effects were dose- and duration-related in that mild effects (organ weight changes and serum enzyme/clinical chemistry changes indicative of mild organ effects) were seen at lower doses but increased in

severity with both dose and time.

Several developmental toxicity studies via the oral and dermal routes have been performed with ABS in rats, mice and rabbits; there were also several subcutaneous injection developmental studies reported in mice. Some developmental effects (including some terata) were observed at high doses at which maternal toxicity was also observed; however, the available information does not suggest any qualitative or quantitative susceptibility differences between pups and pregnant animals. In reproduction toxicity tests, no reproductive toxicity was observed at doses up to and including 250 mg/kg/day.

Although data are limited, there is no evidence for carcinogenicity of ABS. ABS is also negative in results of mutagenicity testing.

Specific information on the studies received and the nature of the adverse effects caused by ABS as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at *http://www.regulations.gov* in the document "Draft Risk Assessment for Alkylbenzene Sulfonates (ABS) to Support Registration Review, and Petition for a Tolerance Exemption" in docket ID number EPA-HQ-OPP-2018-0070.

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 dose 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 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 ABS used for human risk assessment is shown in Table 1. The NOAEL of 50 mg/kg/day was chosen based on the result of multiple animal studies including the three co-critical studies listed in Table 1.

Table 1. -- Summary of Toxicological Doses and Endpoints and Points of Departure for ABS for Use in Human Health Risk Assessment

Exposure Scenario	**Dose Used in Risk Assessment, UF**	**Special FQPA SF, Target MOE**	**Study and Toxicological Effects**
Acute dietary (All populations)	No endpoint was selected. No effects are attributable to a single dose in animal studies.		
Chronic dietary (All populations)	Systemic/ Reproductive Oral NOAEL = 50 mg/kg/day UF = 100x **Chronic RfD** = 0.5 mg/kg/day	FQPA SF = 1x **cPAD=** cRfD/FQPA SF = 0.5 mg/kg/day	**6-month Oral Toxicity- Rat** NOAEL= 40 mg/kg/day (0.07%) and LOAEL= 114 mg/kg/day (0.2%) based on increased caecum weight and slight kidney damage in a 6-month rat dietary study (Yoneyama *et al.* 1972 Ann. Rep. Tokyo Metrop. Res. Lab. Public Health 24:409-440)
			Developmental Toxicity- Rat Systemic/Reproductive NOAEL=50 mg/kg/day and LOAEL = 250 mg/kg/day based on decreased Day 21 female pup body weight (MRID 43498416-Bueler, E. *et al.* 1971. Tox Appl. Pharmacol. 18:83-91)
			9-month Drinking Water Study

			NOAEL=85 mg/kg/day and LOAEL = 145 mg/kg/day from 9 month drinking water rat study based on decreased body weight gain, and serum/biochemical and enzymatic changes in the liver and kidney. (Yoneyama *et al.* 1976 Ann. Rep. Tokyo Metrop. Res. Lab. Public Health 27(2): 105-112)
Short-Term Incidental Oral (1-30 days) Short-, Intermediate and Long-Term Inhalation (1 to 30 days, 1-6 months, >6 months)	Oral NOAEL = 50 mg/kg/day UF = 100x	Residential LOC for MOE = 100 Residential LOC for MOE = 100 Occupational LOC for MOE = 100	**6-month Oral Toxicity- Rat** NOAEL= 40 mg/kg/day (0.07%) and LOAEL= 114 mg/kg/day (0.2%) based on increased caecum weight and slight kidney damage in a 6-month rat dietary study (Yoneyama *et al.* 1972 Ann. Rep. Tokyo Metrop. Res. Lab. Public Health 24:409-440)
			Developmental Toxicity- Rat Systemic/Reproductive NOAEL=50 mg/kg/day and LOAEL = 250 mg/kg/day based on decreased Day 21 female pup body weight (Buehler, E. *et al.* 1971. Tox Appl. Pharmacol. 18:83-91)
			9-month Drinking Water Study NOAEL=85 mg/kg/day and LOAEL = 145 mg/kg/day from 9 month drinking water rat study based on decreased body weight gain, and serum/biochemical and enzymatic changes in the liver and kidney. (Yoneyama *et al.* 1976 Ann. Rep. Tokyo Metrop. Res. Lab. Public Health 27(2): 105-112)
Dermal	No dermal endpoint identified.		
Cancer (oral, dermal, inhalation)	No evidence of carcinogenicity in reported published literature studies in rats		

FQPA SF = Food Quality Protection Act Safety Factor. UF = Uncertainty Factor (comprised of 10x for extrapolation from animal to human (interspecies) and 10x for potential variation in sensitivity among members of the human population (intraspecies). cRfD = Chronic Reference Dose.

cPAD = Chronic Population Adjusted Dose. NOAEL= No Observable Adverse Effect Level. LOAEL= Lowest Observable Adverse Effect Level. MOE = Margin of Exposure. LOC = Level of Concern.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses*. In evaluating dietary exposure to ABS, EPA considered all dietary exposure from registered pesticide uses as well as the petitioned-for exemption. Exposure of food to products containing ABS compounds may occur from various registered product use sites including: (1) indirect food contact from residential food preparation areas, (2) indirect food contact from commercial food preparation areas such as public eating places, dairy-processing equipment, and food-processing equipment and utensils (residues in or on food permitted by 40 CFR 180.940(a)), (3) direct food uses as fruit and vegetable washes (residues in or on food permitted by 21 CFR 173.315 and 173.405), and (4) inert ingredients used in pesticide formulations as a surfactant, emulsifier, or related adjuvants of surfactants in products applied to growing agricultural crops and raw agricultural commodities after harvest (residues in or on food permitted by 40 CFR 180.910) and to animals (residues in or on food permitted by 40 CFR 180.930). EPA assessed dietary exposures from ABS in food as follows:

i. *Acute exposure.* An acute dietary risk assessment for ABS has not been conducted because no adverse effects could be attributed to a single administered oral dose.

ii. *Chronic exposure*. In developing the chronic dietary risk assessment, EPA considered estimates from four models used to evaluate risk from the various pathways of exposure to residues of ABS: the Commercial Tier 1A model for dietary exposure from use of ABS in commercial settings, including the proposed use of ABS at a limit of 700 ppm; the Indirect Dietary Residential Exposure Assessment Model (IDREAM) for dietary exposures from residential uses; Dietary Exposure Evaluation Model (DEEM) for direct applications to food via fruit and vegetables washes; and the inert Dietary Exposure Evaluation Model (iDEEM) to account for the inert uses of branched and linear alkylbenzene sulfonates in agricultural formulations. Each model run of these exposure scenarios resulted in risk levels below the

Agency's levels of concern. For purposes of the chronic dietary assessment, the Agency considered the likelihood of co-occurrence of exposures from these various use patterns. EPA determined that it was appropriate to aggregate exposure from use of ABS in commercial food preparation areas and as an inert in pesticide formulations applied to raw agricultural commodities or animals due to potential co-occurrence. The Agency concluded that it was unlikely that an individual food commodity would come into contact with and retain residues from both residential and commercial areas and thus, utilized the exposures from use in commercial settings, which were higher than residues from residential settings. In addition, EPA concluded that residues from fruit and vegetable washes were likely to be washed away and should not be included in the co-occurrence dietary assessment. Finally, the Agency included exposures from inert uses of ABS in the dietary assessment based on the likelihood that crops treated with pesticide formulations containing ABS as an inert may not be washed prior to picking up residues from use of ABS in commercial food preparation places.

For more specific information on the dietary exposure assessment for ABS can be found in the document "Draft Risk Assessment for Alkylbenzene Sulfonates (ABS) to Support Registration Review and Petition for a Tolerance Exemption," available in docket ID number EPA-HQ-2018-0070 at *http://www.regulations.gov*.

iii. *Cancer*. No evidence of carcinogenicity is reported published literature studies in rats. Therefore, a cancer dietary exposure assessment was not performed.

2. Dietary exposure from drinking water. Exposure to ABS compounds in drinking water may occur from use in registered pesticide formulations containing ABS as inert ingredient. A conservative drinking water concentration value of 100 ppb based on screening-level modeling was used to assess the contribution to drinking water for the chronic dietary risk assessments for

ABS compounds. This was 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). Residential (non-dietary) exposure may occur as follows:

• *Residential handlers*: There is a potential for short-term and intermediate-term residential handler inhalation exposure from use of products containing ABS compounds as sanitizers in or on food-contact surfaces and as turf and garden products.

• *Post-application exposures*: There is a potential for post-application exposures from products containing ABS compounds used on indoor surfaces, carpets, food-contact surfaces, lawns and turf, and materials preservatives. The durations and routes of exposure that were evaluated include short-term inhalation exposure and short-term incidental oral exposure to children.

• *Co-occurring exposures*: For purposes of the aggregate risk assessment, EPA aggregated residential handler inhalation exposure from mopping and trigger-pump spray applications and used hand-to-mouth exposure from the turf use for post-application exposures to children, as it was the highest exposure use pattern.

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 ABS to share a common mechanism of toxicity with any other

substances, and ABS does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that ABS 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 chemical, see EPA's website at *http://www.epa.gov/pesticides/cumulative*.

D. Safety Factor for Infants and Children.

1. *In general*. Section 408 of FFDCA provides that EPA shall apply an additional (10X) tenfold 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 when reliable data do not support the choice of a different factor, or, if reliable data are available, EPA uses a different additional FQPA SF value based on the use of traditional uncertainty factors (UFs) and/or FQPA SFs, as appropriate.

2. *Prenatal and postnatal sensitivity.* There was no evidence of increased sensitivity to infants and children due to pre- and post-natal exposure to ABS. The data submitted to the Agency, as well as those from published literature, demonstrate no increased susceptibility in rats, rabbits, or mice to in utero and/or early postnatal exposure to ABS. In the prenatal developmental toxicity studies in rats, rabbits, and mice and in the 2-generations reproduction study in rats, developmental effects in the fetuses or neonates occurred at or above doses that caused maternal or parental toxicity.

3. *Conclusion*. EPA has determined that reliable data show that it would be safe for infants and children to reduce the FQPA SF to 1x. That decision is based on the following findings:

i. The toxicity database for ABS is complete.

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

iii. Although there is evidence of developmental toxicity in some studies, there is no evidence of increased susceptibility. Moreover, the NOAELs and LOAELs are well-defined, and the endpoints selected for regulatory purposes are protective of those effects.

iv. There are no residual uncertainties identified in the exposure databases. The screening-level dietary assessment and the residential exposure assessment are conservative and not likely to underestimate exposures.

E. Aggregate Risks and Determination of Safety

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, ABS is not expected to pose an acute risk.

2. *Chronic risk*. Using the exposure assumptions described in this unit for co-occurring dietary chronic exposure, EPA has concluded that chronic exposure to ABS from food and water will be 23% of the cPAD for the highest exposed subpopulation (children 1 to 2) and 8.8% of the cPAD for adults. Based on the explanation in Unit III.C.3., regarding residential use patterns, chronic residential exposure to residues of ABS is not expected.

3. *Short-term risk*. Short-term aggregate risks were assessed for children and adults that

could be exposed to ABS and concluded that the combined food, water and residential non-dietary exposures result in aggregate short term MOEs of 670 at 5% inert and 250 at 25% inert for adults, and 310 for children (1 to 2 years old). EPA's level of concern for ABS is an MOE of 100 or below; therefore, ABS is not expected to pose a short-term risk.

4. *Intermediate-term risk*. An intermediate-term (1 to 6 months) aggregate assessment was performed for adults that could be exposed to ABS. Since possible intermediate term inhalation exposures are similar to the short-term and the PODs are the same, the aggregate intermediate term MOEs are 670 at 5% inert and 250 at 25% inert which exceed the target MOE of 100.

5. *Aggregate cancer risk for U.S. population*. Based on a lack of evidence of carcinogenicity for ABS in the database, ABS is not expected to pose a cancer risk to humans.

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

IV. Other Considerations

A. Analytical Enforcement Methodology.

An analytical method for food is not needed. Food contact sanitizers are typically regulated by the State health departments to ensure that the food industry is using products in compliance with the regulations in 40 CFR 180.940. The end-use solution that is applied to the food contact surface is analyzed; the food items that may come into contact with treated surface are not analyzed. An analytical method is available to analyze the use dilution that is applied to food contact surfaces. Alkylbenzene sulfonates are a class of *anionic surfactants*. An "Anionic Content by Surfactant Electrode Method" is used to determine the concentration or percent of

anionic surfactant in the use solution. The method may be requested from Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Road, Ft. Meade, MD 20755-5350; telephone no: (410) 305-2905; email address: *residuemethods@epa.gov*.

B. Response to Comments

EPA received a comment expressing concern for the use of pesticides on food that will end up in water. No supporting information was provided; therefore, it is unclear whether the issue raised is related to the safety of consumers of food containing residues of ABS or to the environmental effects of pesticides in water. Nonetheless, EPA notes that section 408 of the Federal Food, Drug and Cosmetic Act (FFDCA) authorizes EPA to set tolerances for residues of pesticide chemicals when it determines that the tolerance meets the safety standard imposed by that statute. After considering the available data, including the potential for ABS residues to end up in drinking water, EPA has made that determination for the ABS tolerances established by this final rule.

V. Conclusion

Therefore, an exemption from the requirement of a tolerance is established under 40 CFR 180.940(a) for residues of alkylbenzene sulfonates in branched and linear form of chain lengths C_{10}-C_{16}, when used as an inert or an active ingredient in antimicrobial pesticide formulations applied to 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 700 ppm. As written, this exemption covers all ABS compounds of branched or linear form with the appropriate chain length; however, the Agency is expressly clarifying that this exemption also includes the two substances that are already registered and for which tolerance exemptions have already been established—benzenesulfonic acid, dodecyl and benzenesulfonic acid, dodecyl-,

sodium salt. As this new exemption supersedes the more limited exemptions already established for those two substances, EPA is removing those exemptions from §180.940(b) and (c) as no longer necessary.

VI. 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), nor is it considered a regulatory action under Executive Order 13771, entitled "Reducing Regulations and Controlling Regulatory Costs" (82 FR 9339, February 3, 2017). 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).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq*.), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: August 29, 2019.

Anita Pease,

Director, Antimicrobials 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. Add alphabetically to the table in paragraph (a) the entry "Alkylbenzene sulfonates (branched and linear) of chain lengths C_{10}-C_{16}, including benzenesulfonic acid, dodecyl and benzenesulfonic acid, dodecyl-, sodium salt".

b. Remove from the table in paragraph (b) the entry for "Benzenesulfonic acid, dodecyl-".

c. Remove from the table in paragraph (c) the entries for "Benzenesulfonic acid, dodecyl-" and "Benzenesulfonic acid, dodecyl-, sodium salt".

The addition reads 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
* * * * *	* *	
Alkylbenzene sulfonates (branched and linear) of chain lengths C_{10}-C_{16}, including benzenesulfonic acid, dodecyl and benzenesulfonic acid, dodecyl-, sodium salt	27176-87-0 25155-30-0	When ready for use, the end-use concentration is not to exceed 700 ppm.
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