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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2013-0467; FRL-9961-68]

Cumene Sulfonic Acid and its Ammonium, Calcium, Magnesium, Potassium, Sodium and Zinc 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 cumene sulfonic acid and its ammonium, calcium, magnesium, potassium, sodium and zinc salts when used as an inert ingredient (surfactants, related adjuvants of surfactants) in pesticide formulations applied to growing crops and to animals. Huntsman Petrochemical LLC 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 cumene sulfonic acid and its ammonium, calcium, magnesium, potassium, sodium and zinc salts when applied or used under these conditions.

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-2013-0467, is available at <http://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Michael Goodis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; main telephone number: (703) 305-7090; email address: RDFRNotices@epa.gov.

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

C. How Can I File an Objection or Hearing Request?

Under FFDCFA 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-2013-0467 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-2013-0467, 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 July 19, 2013 (78 FR 43115) (FRL-9392-9), EPA issued a document pursuant to FFDCIA section 408, 21 U.S.C. 346a, announcing the filing of a pesticide petition (PP IN-10565) by Huntsman Corp., 8600 Gosling Rd., The Woodlands, TX 77381. The petition requested that 40 CFR 180.920 and 180.930 be amended by establishing an exemption from the requirement of a tolerance for residues of cumene sulfonic acid and its ammonium, calcium, magnesium, potassium, sodium and zinc salts (CAS Reg. Nos. 15763-76-5, 16066-35-6, 164524-02-1, 28085-69-0, 28348-53-0, 28631-63-2, 32073-22-6, 37475-88-0, 37953-05-2, and 90959-88-9) when used as an inert ingredient (surfactant, related adjuvants of surfactants) in pesticide formulations applied to growing crops and to animals. That document referenced a summary of the petition prepared by Huntsman Corp., the petitioner, which is available in the docket, <http://www.regulations.gov>. There were no comments received in response to the notice of filing.

III. Inert Ingredient Definition

Inert ingredients are all ingredients that are not active ingredients as defined in 40 CFR 153.125 and include, but are not limited to, the following types of ingredients (except when they have a pesticidal efficacy of their own): solvents such as alcohols and hydrocarbons; surfactants such as polyoxyethylene polymers and fatty acids; carriers such as clay and

diatomaceous earth; thickeners such as carrageenan and modified cellulose; wetting, spreading, and dispersing agents; propellants in aerosol dispensers; microencapsulating agents; and emulsifiers. The term “inert” is not intended to imply nontoxicity; the ingredient may or may not be chemically active. Generally, EPA has exempted inert ingredients from the requirement of a tolerance based on the low toxicity of the individual inert ingredients.

IV. Aggregate Risk Assessment and Determination of Safety

Section 408(c)(2)(A)(i) of FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is “safe.” Section 408(b)(2)(A)(ii) of FFDCA defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . .”

EPA establishes exemptions from the requirement of a tolerance only in those cases where it can be clearly demonstrated that the risks from aggregate exposure to pesticide chemical residues under reasonably foreseeable circumstances will pose no appreciable risks to human health. In order to determine the risks from aggregate exposure to pesticide inert ingredients, the Agency considers the toxicity of the inert in conjunction with possible exposure to residues of the inert ingredient through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings. If EPA is able to determine that a finite tolerance

is not necessary to ensure that there is a reasonable certainty that no harm will result from aggregate exposure to the inert ingredient, an exemption from the requirement of a tolerance may be established.

Consistent with FFDCA section 408(c)(2)(A), and the factors specified in FFDCA section 408(c)(2)(B), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for cumene sulfonic acid and its ammonium, calcium, magnesium, potassium, sodium and zinc salts including exposure resulting from the exemption established by this action. EPA's assessment of exposures and risks associated with cumene sulfonic acid and its ammonium, calcium, magnesium, potassium, sodium and zinc 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.

The toxicity of cumene sulfonic acid and its ammonium, calcium, magnesium, potassium, sodium and zinc salts was considered in an October 2005 health assessment performed by the Organization for Economic Cooperation and Development (OECD) in the Screening Information Data Set (SIDS) Initial Assessment Profile (SIAP) for the Hydrotropes Category.

The hydrotropes category covers "toluene sulfonic acid, sodium salt," "xylene sulfonic acid, sodium salt" and "cumene sulfonic acid, sodium salt." This category also includes isomeric forms (ortho, meta, and/or para) of the respective sulfonic acid salts (sodium, ammonium, calcium and potassium). OECD notes that the hydrotropes category may be initially considered

as three sub-groups: the methyl, dimethyl and methylethyl benzene sulfonates, (or the toluene, xylene and cumene sulfonates). Although the counter ion will also determine the physical and chemical behavior of the compounds, the chemical reactivity and classification for this purpose is not expected to be affected by the difference in counter ion. The structures as well as the physical/chemical and toxicological properties of these chemical entities are essentially the same. The three subgroups are expected to be generally comparable and predictable in their chemical behavior (as such or in solution) and that members from one subgroup may be useful for interpolations across to other subgroups and to the hydrotropes category in general. Therefore, on this basis, data on other members of the hydrotrope category can be used in a 'read across' fashion to determine the toxicity of cumene sulfonic acid and its ammonium, calcium, magnesium, potassium, sodium and zinc salts

Cumene sulfonic acid and its salts and the structurally related hydrotropes are categorized as having low acute toxicity via the oral, dermal, and inhalation. They are not dermal irritants or dermal sensitizers and are considered slight eye irritants.

Several subchronic studies via the oral route for hydrotropes are available in the database. In two 14-day toxicity studies in mice and rats with sodium xylene sulfonate, no significant treatment related toxicity was observed at doses up to 4% in the diet (approximately 4,000 mg/kg/day) in mice. In rats, there were some mortalities which were not observed in a dose-related manner as well as losses of body weight that were attributable to palatability of the test article. These effects were not considered as adverse findings. In a repeat study in rats, mortality was not observed at doses up to 4% in the diet. A 90-day subchronic toxicity study conducted in Wistar rats with doses of sodium xylene sulfonate up to 5% in the diet. A decrease in relative spleen weight in females, along with some clinical chemistry and hematology changes were observed at the highest dose (3,454 mg/kg/day). In a separate 90-day toxicity study in rats

and mice, no treatment related effects were observed in mice and rats given sodium xylene sulfonate in the diet at 2% (approximately 2,439 and 2,467 mg/kg/day in mice and rats, respectively). In a 90-day dietary toxicity study with sodium cumene sulfonate in Wistar rats, no evidence of systemic toxicity was observed at doses up to 0.5 % in the diet, equivalent to 114 mg/kg/day (corrected for purity of the test substance). Dermal toxicity studies for 17 days and 90 days duration were conducted in mice and rats. No systemic toxicity was observed in mice and rats exposed dermally to sodium xylene sulfonate at doses up to 1,620 and 500 mg/kg/day in mice and rats, respectively. The results of a 2-year dermal toxicity study showed no evidence of skin neoplasms or any other neoplasms at doses up to 727 and 240 mg/kg/day in mice and rats, respectively.

Hydrotropes were tested for their mutagenic potential in various *in vivo* and *in vitro* genotoxicity assays. Sodium xylene sulfonate gave a negative response in a mouse lymphoma assay, the Ames assay, Sister Chromatid Exchange assay, (positive at cytotoxic concentrations only), a Chromosome Aberration Test and three mouse micronucleus assays. Calcium xylene sulfonate and sodium cumene sulfonate were negative for mutagenicity in the Ames test. No evidence of tumors were observed in mice and rats treated dermally with sodium xylene sulfonate for two years at doses of 0, 60, 120 and 240 mg/kg/day for rats and 0, 182, 364 and 727 mg/kg/day for mice.

No reproductive toxicity studies are available for the hydrotropes, although available oral and dermal toxicity studies with various hydrotropes included examination of reproductive organs of both sexes. The OECD SIDS assessment included reviews of a 91-day oral rat feeding study with sodium cumene sulfonate, a 90-day feeding study with sodium xylene sulfonate (mice and rats) and the 2-year dermal studies with sodium xylene sulfonate (in mice and rats) which included examination of the reproductive organs of both sexes. There was no evidence

from these studies to suggest that hydrotropes would have an adverse effect on reproductive organs by either the oral or dermal route. No developmental toxicity studies in rats and rabbits are available in the cumene sulfonic acid and its salts. However, a developmental study in rats is available for a surrogate hydrotrope, calcium xylene sulfonate. In this study the NOAEL for maternal and fetal toxicity was the highest dose tested, 3,000 mg/kg/day (936 mg/kg/day, corrected for purity of test material). Based on this information, there is no evidence to consider cumene sulfonic acid and its salts as being developmental toxicants.

Specific information on the studies received and the nature of the adverse effects caused by cumene sulfonic acid and its salts and the other members of the hydrotropes category 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 document, "Decision Document for Petition Number 1E7936; sodium xylene sulfonate Human Health Risk and Ecological Effects Assessments for Proposed Exemption from the Requirement of a Tolerance When Used as Inert Ingredients in Pesticide Formulations." at pp. 8-14 in docket ID number EPA-HQ-OPP-2011-0951

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>.

No endpoint of concern following a single dose was identified in the available database. The Agency identified a NOAEL of 763 mg/kg/day for systemic toxicity, which was selected from an oral subchronic study. Effects observed in this study were a decrease in spleen weight in females along with some clinical chemistry and hematology changes at the LOAEL of 3,454 mg/kg/day. No adverse effects were reported in males. This study was used for chronic dietary exposure assessment. An uncertainty factor of 100X is applied (10X for interspecies extrapolation and 10X for intraspecies variability). For several reasons, no additional uncertainty factor is necessary for the use of subchronic study data for chronic exposure assessment. First there was a wide dose spread between the toxic effects seen at the LOAEL of 3,454 mg/kg/day and the NOAEL of 763 mg/kg/day. Second, the changes observed in clinical chemistry and hematological parameters were small in magnitude and no effects on organs were observed in the study. Therefore, the changes observed were not considered toxicologically significant. Finally, the NOAEL in a separate 90-day study in rats was 2,467 mg/kg/day indicating the lower NOAEL value in the selected study is an artifact of dose selection. Therefore, EPA concluded that there is no need to retain an additional uncertainty factor for use of a short-term study for long-term exposure assessment.

Based on the physicochemical data and lack of systemic toxicity in the available dermal toxicity studies, EPA concluded that there is no need to conduct quantitative dermal risk exposure assessment.

No data are available on the inhalation toxicity of cumene sulfonic acid and its salts, however, as a solid with an extremely low vapor pressure and a particle size that is not in the respirable range, the likelihood of significant inhalation exposure to the inert ingredient as a gas, vapor, or aerosol is negligible.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to cumene sulfonic acid and its salts, EPA considered exposure under the proposed exemption from the requirement of a tolerance for use as an inert ingredient in pesticide formulations applied to growing crops and animals under the proposed exemptions from the requirement of a tolerance given at 40 CFR 180.920 and 40 CFR 180.930. EPA assessed dietary exposures from cumene sulfonic acid and its salts 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 one-day or single exposure. No such effects were identified in the toxicological studies for cumene sulfonic acid and its salts, 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, 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.

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 cumene sulfonic acid and its salts, 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 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).

Cumene sulfonic acid and its salts may be used as inert ingredient in pesticide products that are registered for specific uses that may result in indoor or outdoor residential inhalation and dermal exposures. A screening-level residential exposure and risk assessment was completed

utilizing conservative residential exposure assumptions. The Agency assessed short- and intermediate-term exposures for residential handlers that would result from low pressure handwand, hose end sprayer and trigger sprayer for outdoor scenarios of each pesticide type, herbicide, insecticide and fungicide and mopping, wiping and aerosol sprays for indoor scenarios. The Agency assessed post-application short-term dermal exposure for children and adults as well as short-term hand-to-mouth exposure for children from contact with treated lawns.

Cumene sulfonic acid and its salts may also be used as a component of personal care products. The OECD SIDS assessment estimated highest human exposures resulting from personal care product use. These exposure estimates ranged from 0.02-0.14 mg/kg/day for shampoos and hair conditioners to 0.11-0.17 mg/kg/day for liquid face and hand soaps. Exposure estimates for cleaning product use and residuals on clothing range from 0.01-0.08 mg/kg/day. All exposure evaluations included conservative (protective) input assumptions (e.g., all modeled human exposures are conservative due to the use of a default assumption of 100% absorption). However, the physicochemical data and available toxicological data suggest that dermal absorption is likely to be minimal. Based on the lack of concern for dermal toxicity and the low estimates of residential exposure via the oral, dermal or inhalation routes of exposure, a quantitative residential risk assessment was not performed.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider “available information” concerning the cumulative effects of a particular pesticide's residues and “other substances that have a common mechanism of toxicity.”

EPA has not found cumene sulfonic acid and its salts to share a common mechanism of toxicity with any other substances, and cumene sulfonic acid and its salts do not appear to produce a toxic metabolite produced by other substances. While there are other chemicals belonging to the cumene sulfonic acid and its salts class of chemicals (i.e., the “hydrotropes” category) that may have a similar toxicity profile, this does not necessarily mean that all such chemicals share a common mechanism of toxicity; therefore, EPA has not assumed that cumene sulfonic acid and its salts have a common mechanism of toxicity with other substances. In any event, EPA believes that these chemicals will be used as an alternative to cumene sulfonic acid and its salts rather than in conjunction with cumene sulfonic acid and its salts and would not likely co-occur. Even if they did, the cPAD for pesticidal uses occupies only 7% of the cPAD for the general population and any potential increase in exposure to this class of chemicals will still be below any levels of concern. 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 FFDCFA 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 are no reproductive toxicity studies reported for cumene sulfonic acid and its salts. However, no effects on reproductive organs were observed at very high doses in number of studies such as a 91-day oral rat feeding study with sodium cumene sulfonate, the 90-day feeding study with sodium xylene sulfonate, and the 2-year dermal studies with sodium xylene sulfonate. Based on the above evidence, EPA concluded that cumene sulfonic acid and its salts are not likely to be a reproductive toxicant. This conclusion is in agreement with the OECD conclusion that there is no evidence to suggest that cumene sulfonic acid and its salts would have an adverse effect on reproductive organs.

In a developmental toxicity study in rats with calcium xylene sulfonate, no maternal or developmental effects were observed at doses of 3,000 mg/kg/day (equal to 936 mg/kg/day corrected for purity of test material).

There is no evidence of prenatal or postnatal sensitivity as a result of exposure to sodium xylene sulfonate

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. Available studies included several 90-day toxicity studies via oral and dermal routes, chronic studies, mutagenicity battery, a developmental study in rats and metabolism studies. These studies provide an adequate characterization of cumene sulfonic acid and its salts toxicity.

ii. There is no indication that cumene sulfonic acid and its salts is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

iii. No reproductive toxicity study or developmental toxicity study are available for cumene sulfonic acid and its salts. However, the concern for increased susceptibility of infants

and children exposure to cumene sulfonic acid and its salts are low because no effects on reproductive parameters were observed in various oral toxicity studies and the developmental toxicity in rats for surrogate chemical show lack of systemic toxicity at doses up to 936 mg/kg/day (as discussed under Unit IV.D.2.).

iv. No evidence of immunotoxicity was observed in the database except slightly decreased in spleen weight was observed at the LOAEL of 3,454 mg/kg /day. There are no concerns for immunotoxicity and an immunotoxicity study is not required because the slight decreases in spleen weights were observed at high doses without any evidence of histopathological findings.

v. No additional uncertainty factor is needed for the use of subchronic study data for chronic exposure assessment. The rationale for this decision is provided in Unit IV.B.

vi. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100% CT and tolerance-level residues. EPA made conservative (protective) assumptions in the ground water and surface water modeling used to assess exposure to sodium xylene sulfonate in drinking water. EPA used similarly conservative assumptions to assess post-application exposure of children as well as incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by cumene sulfonic acid and its salts.

E. Aggregate Risks and Determination of Safety

Determination of safety section. EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-

term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. No adverse effect resulting from a single oral exposure was identified and no acute dietary endpoint was selected.

Therefore, cumene sulfonic acid and its salts is not expected to pose an acute risk.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to cumene sulfonic acid and its salts from food and water under the proposed uses will utilize 7% of the cPAD for the U.S. population and 26% of the cPAD for children 1-2 years old, the population subgroup receiving the greatest exposure.

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). A short-term adverse effect relative to residential exposure was not identified. Short-term risk is assessed based on short-term residential exposure plus chronic dietary exposure. Because there are no short-term residential dermal exposure effects of concern and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as a POD that would be 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 cumene sulfonic acid and its salts.

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). An intermediate-term adverse effect relative to residential exposure was not identified. Intermediate-term risk is assessed based on intermediate-term

residential exposure plus chronic dietary exposure. Because there are no adverse effects identified for intermediate-term residential exposure and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as a POD that would be used to assess intermediate-term risk), no further assessment of intermediate-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating intermediate-term risk for cumene sulfonic acid and its salts.

5. *Aggregate cancer risk for U.S. population.* Based upon no evidence of carcinogenicity in two adequate rodent carcinogenicity studies via the dermal route of exposure, negative response for mutagenicity in a battery of genotoxicity tests, and lack of any structural alerts for carcinogenicity, cumene sulfonic acid and its salts 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 residues of cumene sulfonic acid and its ammonium, calcium, magnesium, potassium, sodium and zinc salts.

V. Analytical Enforcement Methodology

An analytical method is not required for enforcement purposes since the Agency is not establishing a numerical tolerance for residues of cumene sulfonic acid and its ammonium, calcium, magnesium, potassium, sodium and zinc salts.

VI. Conclusions

Therefore, an exemption from the requirement of a tolerance is established under 40 CFR 180.920 and 180.930 for cumene sulfonic acid and its ammonium, calcium, magnesium, potassium, sodium and zinc salts (CAS Reg. Nos. 15763-76-5, 16066-35-6, 164524-02-1, 28085-69-0, 28348-53-0, 28631-63-2, 32073-22-6, 37475-88-0, 37953-05-2, and 90959-88-9) when

used as an inert ingredient (surfactant, related adjuvant of surfactant in pesticide formulations applied to growing crops and animals.

VII. Statutory and Executive Order Reviews

This action establishes exemptions from the requirement of a tolerance under FFDC 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 FFDC 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 FFDC 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: April 27, 2017.

Michael Goodis,
Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180--[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

2. In §180.920, add alphabetically the inert ingredient 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
* * * *	*	* *
Cumene sulfonic acid and its ammonium, calcium, magnesium, potassium, sodium and zinc salts (CAS Reg. Nos. 15763-76-5, 16066-35-6, 164524-02-1, 28085-69-0, 28348-53-0, 28631-63-2, 32073-22-6, 37475-88-0, 37953-05-2, and 90959-88-9)		Surfactant, related adjuvant of surfactant
* * * *	*	* *

3. In §180.930, add alphabetically the inert ingredient to the table to read as follows:

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

* * * * *

Inert ingredients	Limits	Uses
* * * *	*	* *
Cumene sulfonic acid and its ammonium, calcium, magnesium, potassium, sodium and zinc salts (CAS		Surfactant, related adjuvant of surfactant

Reg. Nos. 15763-76-5, 16066-35-6, 164524-02-1, 28085-69-0, 28348-53-0, 28631-63-2, 32073-22-6, 37475-88-0, 37953-05-2, and 90959-88-9)		
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[FR Doc. 2017-12238 Filed: 6/12/2017 8:45 am; Publication Date: 6/13/2017]