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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2014-0633; FRL-9931-07]

Methane Sulfonic Acid; 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 methane sulfonic acid (CAS Reg. No.75-75-2) when used as an inert ingredient (acidifying agent) in pesticide formulations applied to animals at a maximum concentration not to exceed 3% by weight and when used as an 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 concentration not to exceed 5,000 parts per million (ppm). Lewis & Harrison, on behalf of BASF 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 methane sulfonic acid**.**

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-2014-0633, 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 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 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-2014-0633 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-2014-0633, 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 March 4, 2015 (80 FR 11613) (FRL-9922-68), EPA issued a document pursuant to FFDCA section 408, 21 U.S.C. 346a, announcing the filing of a pesticide petition inert ingredient (PP IN-10720) by Lewis & Harrison, 122 C Street, N.W., Suite 505,

Washington, DC 20001 on behalf of BASF Corporation, 100 Park Avenue, Florham Park, NJ 07932. The petition requested that 40 CFR 180.930 and 40 CFR 180.940(a) be amended by establishing an exemption from the requirement of a tolerance for residues of methane sulfonic acid (CAS Reg. No.75-75-2) when used as an inert ingredient (acidifying agent) in pesticide formulations applied to animals at a maximum concentration not to exceed 3% by weight and when used as an 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 concentration not to exceed 5,000 ppm. That document referenced a summary of the petition prepared by Lewis & Harrison on behalf of BASF Corporation, 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 methane sulfonic acid including exposure resulting from the exemption established by this action. EPA's assessment of exposures and risks associated with methane sulfonic acid 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 methane sulfonic acid 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* on pp. 7-11 of the document titled, "Methane sulfonic acid: Decision Document for Requested Exemption from the Requirements of a Tolerance for a Food Use Inert Ingredient" in docket ID number EPA-HQ-OPP-2014-0633.

Methane sulfonic acid has moderate acute oral toxicity to rats and moderate acute dermal toxicity to rabbits. Methane sulfonic acid is corrosive to mouse skin, extremely corrosive to the eye, but showed no evidence of dermal sensitization. Following repeated nose-only inhalation exposures in rats to low concentrations, clear evidence of portal-of-entry effects, such as histopathological lesions in the nasal turbinates were observed however there was no evidence of systemic toxicity at dose levels up to 0.74 milligram/Liter (mg/L) in a 7-day study and 0.24 mg/L in a 28-day study, the highest doses tested in both studies. In a 7-day repeat dose oral feeding study in rats, no systemic toxicity was observed at doses up to 1,805

milligrams/kilograms/day (mg/kg/day). No effects were seen for parental toxicity, offspring/developmental toxicity or reproductive performance in a combined reproductive/developmental toxicity screening test at doses up to 1,000 mg/kg/day. In one developmental toxicity study in rats, no parental systemic or developmental toxicity was observed at doses up to 400 mg/kg/day. Available prenatal developmental toxicity data showed some evidence of slight maternal toxicity but no developmental effects. Methane sulfonic acid was not mutagenic and did not induce chromosomal aberrations. There are no metabolism, chronic toxicity or carcinogenicity studies available on methane sulfonic acid. However, based on the lack of systemic toxicity at 1,000 mg/kg/day and above in a combined reproductive/developmental screening study and 7-day dietary study, and the lack of mutagenicity concern, there are low concerns for cancer.

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 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*.

The oral toxicity NOAEL is taken from the developmental toxicity study with female Sprague-Dawley rats where the NOAEL was identified as 400 mg/kg/day. This dose is used for the dietary exposure assessment.

The inhalation toxicity NOAEL was taken from the repeat-dose inhalation study discussed earlier. There were no treatment related macroscopic findings in the treated animals. Microscopic findings believed attributable to the test material included mucosal necrosis, suppurative inflammation and/or nasal exudate in males and females in the 0.23 and 0.74 mg/L groups. Since this is a localized effect, it was not considered as systemic toxicity, and the NOAEL was determined to be 0.74 mg/L (~191 mg/kg/day).

The dermal toxicity NOAEL is selected from an oral developmental toxicity study with the assumption of 100% dermal absorption. Based on the results of this study, the dermal toxicity NOAEL was 400 mg/kg/day.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses*. In evaluating dietary exposure to methane sulfonic acid, EPA considered exposure under the proposed exemption from the requirement of a tolerance. EPA assessed dietary exposures from methane sulfonic acid in food as follows: Based upon the requested use patterns, humans may be exposed to methane sulfonic acid. Dietary exposure may occur as a result of residues transferred from treated food contact areas, including food/dairy processing equipment or systems.

Additional dietary exposure may occur from consuming meat and dairy products from treated dairy cattle, sheep or goats. The Agency used the dietary exposure model to assess possible residues from treated animals.

Food. To assess oral exposure from food handling surfaces, the Agency utilized the Food and Drug Administration (FDA) Food Contact Surface Sanitizing Solution Dietary Exposure Assessment Model (FDA/CFSAN OPA: Chemistry Guidance – Sanitizing Solution version 1.1; January 1993; Office of Premarket Approval now Office of Food Additive Safety). To assess dietary exposures from "clean in place" of food processing equipment the Agency utilized assessment techniques described in EPA, 2006 (Reregistration Eligibility Decision Document for Alkyl Dimethyl Benzyl Ammonium Chloride (ADBAC) U.S. EPA Document EPA 739-R-06-009 August 2006). The Agency used the dietary exposure model to assess possible residues from treated animals.

In conducting the chronic dietary exposure assessment using the Dietary Exposure Evaluation Model/Food Commodity Intake Database (DEEM-FCID)^{TM}, Version 3.16, EPA used 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. As to residue levels in food, no residue data were submitted for methane sulfonic acid. In the absence of specific residue data, EPA has developed an approach which uses surrogate information to derive upper bound exposure estimates for the subject inert ingredient. Upper bound exposure estimates are based on the highest tolerance for a given commodity from a list of high-use insecticides, herbicides, and fungicides. 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. In the case of methane sulfonic acid, EPA made specific adjustments to the dietary exposure assessment to account for the use limitations of methane sulfonic acid as an inert ingredient in pesticide formulations applied to animals (i.e., livestock used for food) only and at a maximum concentration of 3.0% by weight.

2. *Dietary exposure from drinking water*. Based upon the requested use patterns and the restrictions on maximum end-use concentrations, the Agency believes methane sulfonic acid is not likely to be present in drinking water. A quantitative assessment is not necessary.

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

Dermal and inhalation exposures may occur as a result of the use of sanitizing solutions which contain methane sulfonic acid. Such uses include mopping floors or wiping/sponging food contact surfaces i.e., counter tops. According to Antimicrobials Division, Office of Pesticide Programs Standard Operating Procedures, the Agency conducted conservative assessments of dermal and inhalation exposures for typical residential use patterns.

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 methane sulfonic acid to share a common mechanism of toxicity with any other substances, and methane sulfonic acid does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that methane sulfonic acid does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at *http://www.epa.gov/pesticides/cumulative*.

D. Safety Factor for Infants and Children

1. *In general*. Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the 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*. There was no evidence of increased sensitivity to infants and children due to pre- and post-natal exposure to methane sulfonic acid. No treatment-related effects were observed on maternal toxicity and offspring/developmental toxicity at doses up to the limit dose of 1,000 mg/kg/day in a combined reproductive/developmental toxicity study with rats.

In one developmental toxicity study in rats, there were no treatment related effects observed in the maternal animals or in the fetuses at doses up to 400 mg/kg/day (the highest dose tested). In another developmental toxicity study in rats no maternal or developmental toxicity was observed at dose levels up to 300 mg/kg/day; the highest dose tested.

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 methane sulfonic acid is complete for FQPA assessment. The available studies include two developmental toxicity studies in rats, a combined rat reproductive/developmental toxicity, two repeated dose inhalation toxicity studies in rats, and several mutagenicity studies.

ii. No treatment related effects were observed in the Functional Observation Battery and motor activity in a combined reproductive/developmental toxicity with rats at doses up to 1,000 mg/kg/day. Based on the results of this study it is concluded that methane sulfonic acid is not a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional uncertainty factors (UFs) to account for neurotoxicity.

iii. There is no evidence that methane sulfonic acid results in increased susceptibility in *in utero* rats (as discussed above).

iv. There is no immunotoxicity study available in the database, however, there was no systemic toxicity observed at the limit dose in a combined reproductive/developmental toxicity study. Therefore, there is no need for an immunotoxicity study or additional UFs to account for the lack of an immunotoxicity study.

v. There are no residual uncertainties identified in the exposure databases.

These assessments will not underestimate the exposure and risks posed by methane sulfonic acid.

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, methane sulfonic acid is not expected to pose an acute risk.

2. *Chronic risk*. Using the exposure assumptions described in this unit (and at *http://www.regulations.gov* on pp. 7-11 of the document titled, "Methane sulfonic acid: Decision Document for Requested Exemption from the Requirements of a Tolerance for a Food Use Inert Ingredient" in docket ID number EPA-HQ-OPP-2014-0633.) For chronic exposure, EPA has concluded that chronic exposure to methane sulfonic acid from food and water will utilize 0.2% of the chronic population adjusted reference dose (cPAD) for the U.S. population and 0.7% of the cPAD for children 1-2 years of age, the most highly exposed population group.

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).

Methane sulfonic acid maybe used as an inert ingredient in pesticide products that are registered for any use that could result in short-term residential exposure. It is possible that methane sulfonic acid could be used in such products and the Agency has determined that it is

appropriate to aggregate chronic exposure through food and water with potential short-term exposures to methane sulfonic acid.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded that the combined food, water and residential exposures result in aggregate short term MOEs of 1680 for adults and 300 for children (1-2 years old). EPA's level of concern for methane sulfonic acid is a MOE of 100 or below; therefore these MOEs are not of concern.

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). No intermediate-term exposure are expected from the use of methane sulfonic acid as an inert ingredient, therefore, there are no intermediate-term risk concerns.

5. *Aggregate cancer risk for U.S. population*. Aggregate cancer risk was not estimated because the Agency has not identified any concerns for cancer risk due to exposure to methane sulfonic acid.

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 methane sulfonic acid residues.

V. Other Considerations

A. Analytical Enforcement Methodology

An analytical method is not required for enforcement purposes since the Agency is not establishing a numerical tolerance for residues of methane sulfonic acid in or on any food commodities. EPA is establishing a limitation on the amount of methane sulfonic acid that may be used in pesticide formulations applied to animals and in food-contact surface antimicrobial applications. Those limitations 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 formulation for use on animals for sale or distribution that contains greater than 3% by weight of methane sulfonic acid or any food-contact surface antimicrobial formulations for sale or distribution that contains greater than 5,000 ppm of methane sulfonic acid.

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 methane sulfonic acid.

VI. Conclusions

Therefore, an exemption from the requirement of a tolerance is established under 40 CFR 180.930 and 40 CFR 180.940(a) for methane sulfonic acid (CAS Reg. No.75-75-2) when used as an inert ingredient (acidifying agent) in pesticide formulations applied to animals at a maximum concentration not to exceed 3% by weight and when used as an 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 concentration not to exceed 5,000 ppm.

VII. Statutory and Executive Order Reviews

This action establishes a tolerance under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled "Regulatory Planning and Review" (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use" (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled "Protection of Children from Environmental Health Risks and Safety Risks" (62 FR 19885, April 23, 1997). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations" (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a

proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled "Federalism" (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled "Consultation and Coordination with Indian Tribal Governments" (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq*.).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

VIII. Congressional Review Act

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

List of Subjects in 40 CFR Part 180

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

Dated: August 6, 2015.

Susan Lewis,

Director, Registration Division, Office 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 §180.930 add alphabetically the inert ingredient "Methane sulfonic acid" 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
* * *	*	* * *
Methane sulfonic acid (CAS Reg. No. 75-75-2)	Not to exceed 3.0 % by weight in pesticide formulation	Acidifying agent
* * *	*	* * *

3. In §180.940 add alphabetically the inert ingredient "Methane sulfonic acid" to the table in paragraph (a) to read as follows:

§ 180.940 Tolerance exemptions for active and inert ingredients for use in antimicrobial formulations (Food-contact surface sanitizing solutions).

* * * * *

(a) * * *

Pesticide Chemical	CAS Reg. No.	Limits
* * *	*	* * *
Methane sulfonic acid	75-75-2	When ready for use, the end use concentration is not to exceed 5,000 ppm

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[FR Doc. 2015-20252 Filed: 8/18/2015 08:45 am; Publication Date: 8/19/2015]