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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2014-0325; FRL-9930-22]

Ethanesulfonic Acid, 2-hydroxy and the Corresponding Ammonium, Sodium, Potassium, Calcium, Magnesium, 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 ethanesulfonic acid, 2-hydroxy- (CAS Reg. No. 107-36-8); ethanesulfonic acid, 2-hydroxy-, ammonium salt (CAS Reg. No. 57267-78-4); ethanesulfonic acid, 2-hydroxy-, sodium salt (CAS Reg. No. 1562-00-1); ethanesulfonic acid, 2-hydroxy-, potassium salt (CAS Reg. No. 1561-99-5); ethanesulfonic acid, 2-hydroxy-, calcium salt (CAS Reg. No. 10550-47-7); ethanesulfonic acid, 2-hydroxy-, magnesium salt (CAS Reg. No. 17345-56-1), and ethanesulfonic acid, 2-hydroxy-, zinc salt (CAS Reg. No. 129756-32-7) when used as inert ingredients (chelator, sequestrant and conditioning agent) in pesticide formulations applied to growing crops and raw agricultural commodities after harvest and applied to animals. Technology Sciences Group Inc. (1150 18th St., NW Suite 1000 Washington, D.C. 20036) on behalf of Huntsman Corporation (8600 Gosling Rd., The Woodlands, TX 77381) 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 ethanesulfonic acid, 2-hydroxy- and its corresponding ammonium, sodium, potassium, calcium, magnesium, and zinc salts**.**

DATES: This regulation is effective [*insert date of publication in the* **Federal Register**]. Objections and requests for hearings must be received on or before [*insert date 60 days after*

date of publication in the **Federal Register**], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2014-0325, 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*. To access the OCSPP test guidelines referenced in this document electronically, please go to *http://www.epa.gov/ocspp* and select "Test Methods and Guidelines."

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

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2014-0325 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-2014-0325, 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 August 1, 2014 (79 FR 44729) (FRL-9911-67), EPA issued a document pursuant to FFDCA section 408, 21 U.S.C. 346a, announcing the filing of a pesticide petition (PP IN-10684) by Technology Sciences Group Inc. (1150 18th St., NW Suite 1000 Washington, D.C. 20036) on behalf of Huntsman Corporation (8600 Gosling Rd., The Woodlands, TX 77381). The petition requested that 40 CFR 180.910 and 40 CFR 180.930 be amended by establishing an exemption from the requirement of a tolerance for residues of ethanesulfonic acid, 2-hydroxy- (CAS Reg. No. 107-36-8); ethanesulfonic acid, 2-hydroxy-, ammonium salt (CAS Reg. No. 57267-78-4); ethanesulfonic acid, 2-hydroxy-, sodium salt (CAS Reg. No. 1562-00-1); ethanesulfonic acid, 2-hydroxy-, potassium salt (CAS Reg. No. 1561-99-5); ethanesulfonic acid, 2-hydroxy-, calcium salt (CAS Reg. No. 10550-47-7); ethanesulfonic acid, 2-hydroxy-, magnesium salt (CAS Reg. No. 17345-56-1), and ethanesulfonic acid, 2-hydroxy-, zinc salt (CAS Reg. No. 129756-32-7) when used as inert ingredients (chelator, sequestrant, and conditioning agent) in pesticide formulations applied to growing crops and raw agricultural commodities after harvest and applied to animals in accordance with 40 CFR 180.910 and 180.930, respectively. That document referenced a summary of the petition prepared by Technology Sciences Group Inc., the petitioner, which is available in the docket, *http://www.regulations.gov*. There were no comments received in response to the notice of filing.

III. Inert Ingredient Definition

Inert ingredients are all ingredients that are not active ingredients as defined in 40 CFR 153.125 and include, but are not limited to, the following types of ingredients (except when they have a pesticidal efficacy of their own): Solvents such as alcohols and hydrocarbons; surfactants such as polyoxyethylene polymers and fatty acids; carriers such as clay and diatomaceous earth; thickeners such as carrageenan and modified cellulose; wetting, spreading, and dispersing agents; propellants in aerosol dispensers; microencapsulating agents; and emulsifiers. The term "inert" is not intended to imply nontoxicity; the ingredient may or may not be chemically active.

Generally, EPA has exempted inert ingredients from the requirement of a tolerance based on the low toxicity of the individual inert ingredients.

IV. Aggregate Risk Assessment and Determination of Safety

Section 408(c)(2)(A)(i) of 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 ethanesulfonic acid, 2-hydroxy and the corresponding ammonium, sodium, potassium, calcium, magnesium, and zinc salts (also referred to as isethionic acid and its salts) including exposure resulting from the exemption established

by this action. EPA's assessment of exposures and risks associated with isethionic acid and its salts follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered their validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. Specific information on the studies received and the nature of the adverse effects caused by isethionic acid and its salts as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies are discussed in this unit.

Isethionate salts are expected to metabolize and dissociate into isethionic acid in the body. Therefore, toxicity for each of the isethionate salt forms are expected to have equal toxicity and share similar physical and chemical characteristics. Studies on isethionic acid or any one of its salt can be considered relevant for the entire group.

The acute oral toxicity of isethionic acid ammonium salt is low. The acute oral lethal dose $(LD)_{50}$ in rats were > 1,000 milligram/kilogram/body weight (mg/kg-bw). The acute dermal toxicity in rats was > 1,000 mg/kg-bw. Ammonium isethionate is a minimal eye irritant based on a primary eye irritation study in rabbits. Ammonium isethionate is not dermally irritating based on a primary skin irritation study in rabbits. Ammonium isethionate has an acute inhalation lethal concentration $(LC)_{50}$ > 6.295 milligram/liter (mg/L) and is not a dermal sensitizer.

In a 90-day oral toxicity study on rats via gavage with sodium isethionate, decreased mean corpuscular hemoglobin concentration, increased mean absolute and relative reticulocyte counts, increased spleen weights and microscopic changes in the liver, bile duct, and spleen were observed at 1,000 milligram/kilogram/day (mg/kg/day) (LOAEL). Effects showed complete reversal after exposure was discontinued. The NOAEL for sodium isethionate was identified in this study as 200 mg/kg/day.

In an OSCPP Harmonized Test Guideline 870.3650 combined repeated dose toxicity study with the reproduction/developmental toxicity screening test, ammonium isethionate was administered to rats by gavage. The parental systemic LOAEL for ammonium isethionate is 500

mg/kg/day based on absolute and relative kidney weights and relative adrenal weights, and the parental systemic NOAEL is 250 mg/kg/day. The reproductive/developmental LOAEL for ammonium isethionate in rats was not identified, and the reproductive/developmental NOAEL is greater than or equal to 500 mg/kg/day.

Ammonium isethionate was negative for mutagenicity or chromosomal aberrations in a battery of tests of genotoxicity including a reverse gene mutation assay in bacteria, an *in vitro* mammalian cell gene mutation test using mouse lymphoma cells and an *in vitro* mammalian cell micronucleus test.

The OncoLogic™ structure-activity model was used to evaluate the likelihood that isethionic acid and its salts may cause cancer. Structure-activity modeling using Oncologic indicates that isethionic acid does not contain structural alerts of potential concern for carcinogenicity. Based on the negative results for genotoxicity as well as the structure-activity model for carcinogenicity there is a low concern for isethionic acid and its salts as potential carcinogens.

No neurotoxicity studies were available in the database for isethionic acid and its salts. However, a functional observational battery (FOB) and locomotor activity patterns were evaluated in the combined reproduction/developmental toxicity screening test and 90-day oral toxicity study. No alterations in the FOB or locomotor activity patterns were observed.

No Immunotoxicity studies on isethionic acid and its salts were available in the database. Increased spleen weights and microscopic changes in the spleen were observed in the 90-day toxicity study in rats; however, the chronic reference dose (cRfD) is based on this study and is protective of these effects.

No metabolism studies were available in the database for isethionic acid and its salts.

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*.

A summary of the toxicological endpoints for isethionic acid and its salts used for human risk assessment is shown in Table 1 of this unit.

Table 1.--Summary of Toxicological Doses and Endpoints for Isethionic Acid and its Salts for Use in Human Risk Assessment

Exposure/Scenario	Point of Departure and Uncertainty/Safety Factors	RfD, PAD, LOC for Risk Assessment	Study and Toxicological Effects
Acute dietary (Females 13-50 years of age)	An acute effect was not found in the database therefore an acute dietary assessment is not necessary		
Acute dietary (General population including infants and children)	An acute effect was not found in the database therefore an acute dietary assessment is not necessary		
Chronic dietary (All populations)	NOAEL= 200 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 1x	Chronic RfD = 200 mg/kg/day cPAD = 2.0 mg/kg/day	90-day oral toxicity-rat LOAEL = 1,000 mg/kg/day based on decreased body weight, changes in hematology parameters, increased spleen weights, macroscopic changes in the liver and microscopic changes in the liver, bile duct

			and spleen
Incidental oral short-term (1 to 30 days)	NOAEL= 200 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 1x	LOC for MOE = 100	90-day oral toxicity-rat LOAEL = 1,000 mg/kg/day based on decreased body weight, changes in hematology parameters, increased spleen weights, macroscopic changes in the liver and microscopic changes in the liver, bile duct and spleen
Incidental oral intermediate-term (1 to 6 months)	NOAEL= 200 mg/kg/day UF_A= 10x UF_H= 10x FQPA SF = 1x	LOC for MOE = 100	90-day oral toxicity-rat LOAEL = 1,000 mg/kg/day based on decreased body weight, changes in hematology parameters, increased spleen weights, macroscopic changes in the liver and microscopic changes in the liver, bile duct and spleen
Dermal short-term (1 to 30 days)	Dermal (or oral) study NOAEL = 200 mg/kg/day (dermal absorption rate = 100% UF_A = 10x UF_H = 10x FQPA SF = 1x	LOC for MOE = 100	90-day oral toxicity-rat LOAEL = 1,000 mg/kg/day based on decreased body weight, changes in hematology parameters, increased spleen weights, macroscopic changes in the liver and microscopic changes in the liver, bile duct and spleen
Dermal intermediate-term (1 to 6 months)	Dermal (or oral) study NOAEL = 200 mg/kg/day (dermal absorption rate = 100% UF_A = 10x UF_H = 10x FQPA SF = 1x	LOC for MOE = 100	90-day oral toxicity-rat LOAEL = 1,000 mg/kg/day based on decreased body weight, changes in hematology parameters, increased spleen weights, macroscopic changes in the liver and microscopic changes in the liver, bile duct and spleen

Inhalation short-term (1 to 30 days)	Inhalation (or oral) study NOAEL= 200 mg/kg/day (inhalation absorption rate = 100%) UF_A = 10x UF_H = 10x FQPA SF = 1x	LOC for MOE = 100	90-day oral toxicity-rat LOAEL = 1,000 mg/kg/day based on decreased body weight, changes in hematology parameters, increased spleen weights, macroscopic changes in the liver and microscopic changes in the liver, bile duct and spleen
Inhalation (1 to 6 months)	Inhalation (or oral) study NOAEL= 200 mg/kg/day (inhalation absorption rate = 100%) UF_A = 10x UF_H = 10x FQPA SF = 1x	LOC for MOE = 100	90-day oral toxicity-rat LOAEL = 1,000 mg/kg/day based on decreased body weight, changes in hematology parameters, increased spleen weights, macroscopic changes in the liver and microscopic changes in the liver, bile duct and spleen
Cancer (Oral, dermal, inhalation)	Based on structural activity analysis, lack of effects suggestive of potential carcinogenicity in subchronic studies and negative results for genotoxicity in bacterial and mammalian cell assays, there is a low concern for the salts of isethionate and isethionic acid as potential carcinogens		

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

C. Exposure Assessment

1. *Dietary exposure from food and feed uses*. In evaluating dietary exposure to isethionic acid and its salts, EPA considered exposure under the proposed exemption from the requirement of a tolerance. EPA assessed dietary exposures from isethionic acid and its salts in food as follows:

An acute dietary risk assessment was not conducted because no endpoint of concern following a single exposure was identified in the available studies. A chronic dietary exposure assessment was completed and performed using the Dietary Exposure Evaluation Model 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 that 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 isethionic acid and its salts, a conservative drinking water concentration value of 100 parts per billion (ppb) based on screening level modeling was used to assess the contribution to drinking water for the chronic dietary risk assessments for parent compound. These values were directly entered into the dietary exposure model.

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

Isethionic acid and its salts may be used as inert ingredients 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 dermal and inhalation exposures for residential handlers that would result from low pressure hand wand, hose end sprayer and trigger sprayer for each pesticide type, herbicide, insecticide, and fungicide. The Agency assessed post-application short-term dermal exposure for children short-term hand-to-mouth and dermal exposure for children and adults from contact with treated lawns.

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 isethionic acid and its salts to share a common mechanism of toxicity with any other substances, and isethionic acid and its salts does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that isethionic acid and its salts 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 (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*. Fetal susceptibility was not observed in the combined developmental/reproduction toxicity screening test in rats. Neither offspring nor reproduction toxicity was observed in this study at dose levels up to 500 mg/kg/day in rats, 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 isethionic acid and its salts contains the following acceptable studies: Subchronic, reproduction/developmental screening study, and a mutagenicity study. The database is considered to be adequate to assess prenatal and postnatal toxicity.

ii. There is no indication that isethionic acid and its salts are neurotoxic chemicals and there is no need for a developmental neurotoxicity study or additional uncertainty factors (UF) to account for neurotoxicity.

iii. There is no indication that isethionic acid and its salts are immunotoxic chemicals. Although increased spleen weights and microscopic changes in the spleen were observed in the 90-day toxicity study in rats those effects were due to red blood cell destruction and therefore not considered an immuno toxic effect. In any event, the cRfD is based on this study and is protective of these effects. Therefore, there is no need for an Immunotoxicity study or additional UFs to account for Immunotoxicity.

iv. There is no evidence that isethionic acid and its salts result in increased susceptibility for infants and children.

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

E. Aggregate Risks and Determination of Safety

1. *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.

2. *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, isethionic acid and its salts is not expected to pose an acute risk.

3. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to isethionic acid and its salts from food and water will utilize 9.5% of the cPAD for the U.S. population and 35.3% of the cPAD for children 1-2 yrs. old, the population group receiving the greatest exposure.

4. *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). Isethionic acid and its salts may be used as an inert ingredient in pesticide products that are registered for uses that could result in short-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short-term residential exposures to isethionic acid and its salts.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the combined short-term food, water, and residential exposures result in aggregate MOEs of 187 for adults and 123 for children. Because EPA's level of concern for isethionic acid and its salts are MOEs of 100 or below, these MOEs are not of concern.

5. *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). Isethionic acid and its salts are currently used as an inert ingredient in pesticide products that are registered for uses that could result in intermediate-term residential exposure. The endpoint of concern selected for short- and intermediate-term exposure assessment is the same NOAEL, therefore intermediate term exposure is not expected to exceed short term aggregate exposure and therefore there are no concerns for intermediate-term aggregate exposure.

6. *Aggregate cancer risk for U.S. population*. The Agency has not identified any concerns for carcinogenicity relating to isethionic acid and its salts; therefore, a cancer dietary exposure assessment was not performed and an aggregate risk and aggregate cancer risk assessment is not a concern.

7. *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 isethionic acid and its salt residues.

V. Analytical Enforcement Methodology

An analytical method is not required for enforcement purposes since the Agency is establishing an exemption from the requirement of a tolerance without any numerical limitation.

VI. Conclusions

Therefore, exemptions from the requirement of a tolerance are established under 40 CFR 180.910 and 40 CFR 180.930 for ethanesulfonic acid, 2-hydroxy- (CAS Reg. No. 107-36-8); ethanesulfonic acid, 2-hydroxy-, ammonium salt (CAS Reg. No. 57267-78-4); ethanesulfonic acid, 2-hydroxy-, sodium salt (CAS Reg. No. 1562-00-1); ethanesulfonic acid, 2-hydroxy-, potassium salt (CAS Reg. No. 1561-99-5); ethanesulfonic acid, 2-hydroxy-, calcium salt (CAS Reg. No. 10550-47-7); ethanesulfonic acid, 2-hydroxy-, magnesium salt (CAS Reg. No. 17345-56-1), and ethanesulfonic acid, 2-hydroxy-, zinc salt (CAS Reg. No. 129756-32-7) when used as inert ingredients (chelators, sequestrants, and conditioning agents) in pesticide formulations applied to growing crops and raw agricultural commodities after harvest and applied to animals.

VII. Statutory and Executive Order Reviews

This action establishes exemptions from the requirement of a tolerance under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR

19885, April 23, 1997). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations" (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the exemptions 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: July 21, 2015.

Susan Lewis,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180--[AMENDED]

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

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

2. In §180.910, add alphabetically the inert ingredients to the table to read as follows:

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

* * * * *

Inert ingredients	Limits	Uses
* * * * * * *		
Ethanesulfonic acid, 2-hydroxy- (CAS Reg. No. 107-36-8)		Chelator, sequestrant, or conditioning agent
Ethanesulfonic acid, 2-hydroxy-, ammonium salts (CAS Reg. No. 57267-78-4)		Chelator, sequestrant, or conditioning agent
Ethanesulfonic acid, 2-hydroxy-, calcium salts (CAS Reg. No. 10550-47-7)		Chelator, sequestrant, or conditioning agent
Ethanesulfonic acid, 2-hydroxy-, magnesium salts (CAS Reg. No. 17345-56-1)		Chelator, sequestrant, or conditioning agent
Ethanesulfonic acid, 2-hydroxy-, potassium salts (CAS Reg. No. 1561-99-5)		Chelator, sequestrant, or conditioning agent
Ethanesulfonic acid, 2-hydroxy-, sodium salts (CAS Reg. No. 1562-00-1)		Chelator, sequestrant, or conditioning agent
Ethanesulfonic acid, 2-hydroxy-, zinc salts (CAS Reg. No. 129756-32-7)		Chelator, sequestrant, or conditioning agent
* * * * * * *		

3. In § 180.930, add alphabetically the inert ingredients 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
* * * * * * *		
Ethanesulfonic acid, 2-hydroxy- (CAS Reg. No. 107-36-8)		Chelator, sequestrant, or conditioning agent
Ethanesulfonic acid, 2-hydroxy-, ammonium salts (CAS Reg. No. 57267-78-4)		Chelator, sequestrant, or conditioning agent
Ethanesulfonic acid, 2-hydroxy-, calcium salts (CAS Reg. No. 10550-47-7)		Chelator, sequestrant, or conditioning agent
Ethanesulfonic acid, 2-hydroxy-, magnesium salts (CAS Reg. No. 17345-56-1)		Chelator, sequestrant, or conditioning agent
Ethanesulfonic acid, 2-hydroxy-, potassium salts (CAS Reg. No. 1561-99-5)		Chelator, sequestrant, or conditioning agent
Ethanesulfonic acid, 2-hydroxy-, sodium salts (CAS Reg. No. 1562-00-1)		Chelator, sequestrant, or conditioning agent
Ethanesulfonic acid, 2-hydroxy-, zinc salts (CAS Reg. No. 129756-32-7)		Chelator, sequestrant, or conditioning agent
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