that Executive Order 13132, entitled ''Federalism'' (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled ''Consultation and Coordination with Indian Tribal Governments'' (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

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

VII. Congressional Review Act

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

List of Subjects in 40 CFR Part 180

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

Dated: April 26, 2016.

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 § 180.666, amend the table in paragraph (a) as follows:
■ i. Add alphabetically the entries ''Citrus, dried pulp'', ''Citrus, oil'', ''Fruit, citrus, group 10–10'', ''Grass forage, fodder and hay, group 17'', ''Milk, fat'', ''Non-grass animal feed, group 18'', ''Poultry, fat'', ''Poultry, meat'' and ''Poultry, meat byproduct''.
■ ii. Revise the following entries ''Cattle, fat'', ''Cattle, meat byproduct'', ''Egg'', ''Goat, fat'', ''Goat, meat byproduct'', ''Horse, fat'', ''Horse, meat byproduct'', ''Milk'', ''Sheep, fat,'' and ''Sheep, meat byproduct''.
■ iii. Remove from the table in paragraph (d) the entry ''non-grass animal feeds, group 18''.

The amendments read as follows:

§ 180.666 Fluxapyroxad; tolerances for residues.

(a) * * *

Commodity	Parts per million
* * * * *	
Cattle, fat	0.06
* * * * *	
Cattle, meat byproduct	0.04
Citrus, dried pulp	3.0
Citrus, oil	40
* * * * *	
Egg	0.01
Fruit, citrus, group 10–10	1.0
* * * * *	
Grass, forage, fodder and hay, group 17	40
Goat, fat	0.06
* * * * *	
Goat, meat byproduct	0.04
* * * * *	
Horse, fat	0.06
* * * * *	
Horse, meat byproduct	0.04
Milk	0.01
Milk, fat	0.15
Non-grass animal feed, group 18	30
* * * * *	
Poultry, fat	0.01
Poultry, meat	0.01
Poultry, meat byproduct	0.01
* * * * *	
Sheep, fat	0.06
* * * * *	
Sheep, meat byproduct	0.04
* * * * *	

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[FR Doc. 2016–10581 Filed 5–4–16; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2015–0213; FRL–9945–58]

Butanedioic Acid, 2-sulfo-, C-C9-11-isoalkyl esters, C10-rich, Disodium 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 butanedioic acid, 2-sulfo-, C-C9-11-isoalkyl esters, C10-rich, disodium salts (CAS Reg. No. 815583–91–6) when used as an inert ingredient (surfactant) in pesticides applied to growing crops and raw agricultural commodities after harvest under 40 CFR 180.910 limited to maximum concentration of 10% by weight in pesticide formulations. Keller and Heckman LLP on behalf of Cytec Industries, Inc. submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting establishment of an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of butanedioic acid, 2-sulfo-, C-C9-11-isoalkyl esters, C10-rich, disodium salts.

DATES: This regulation is effective May 5, 2016. Objections and requests for hearings must be received on or before July 5, 2016, 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–2015–0213, 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–2015–0213 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 July 5, 2016. 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–2015–0213, 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 May 20, 2015 (80 FR 28925) (FRL–9927–39), EPA issued a document pursuant to FFDCA section 408, 21 U.S.C. 346a, announcing the filing of a pesticide petition (PP IN–10760) by Keller and Heckman LLP, (1001 G Street NW., Suite 500, Washington, DC 20001) on behalf of Cytec Industries, Inc. (5 Garret Mountain Plaza, Woodland Park, NJ 07424). The petition requested that 40 CFR 180.910 be amended by establishing an exemption from the requirement of a tolerance for residues of butanedioic acid, 2-sulfo-, C-C9-11-isoalkyl esters, C10-rich, disodium salts (CAS Reg. No. 815583–91–6) when used as an inert ingredient (surfactant) in pesticide formulations applied to growing crops and raw agricultural commodities after harvest. That document referenced a summary of the petition prepared by Keller and Heckman LLP, on behalf of Cytec Industries, 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.

Based upon review of the data supporting the petition, EPA has limited the maximum concentration of butanedioic acid, 2-sulfo-, C-C9-11-isoalkyl esters, C10-rich, disodium salts to 10% by weight in pesticide formulations. This limitation is based on the Agency's risk assessment which can be found at *http://www.regulations.gov* in document ''Butanedioic acid, 2-sulfo-, C-C9-11-isoalkyl esters, C10-rich, disodium salts (CAS Reg No. 815583–91–6); Human Health Risk Assessment and Ecological Effects Assessment to Support Proposed Exemption from the Requirement of a Tolerance When Used as an Inert Ingredient in Pesticide Formulations'' in docket ID number EPA–HQ–OPP–2015–0213.

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 exemption is ''safe.'' Section 408(c)(2)(A)(ii) of FFDCA defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. 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 or exemption 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 ingredient 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 butanedioic acid, 2-sulfo-, C-C9-11-isoalkyl esters, C10-rich, disodium salts including exposure resulting from the exemption established by this action. EPA's assessment of exposures and risks associated with butanedioic acid, 2-sulfo-, C-C9-11-isoalkyl esters, C10-rich, disodium 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 butanedioic acid, 2-sulfo-, C-C9-11-isoalkyl esters, C10-rich, disodium 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.

Butanedioic acid, 2-sulfo-, C-C9-11-isoalkyl esters, C10-rich, disodium salts is of low acute oral and dermal toxicity in rats. The acute oral and dermal LD_{50}s are >1,600 milligram/kilogram (mg/kg). It is irritating to the eyes but not the skin of rabbits. Neither inhalation nor sensitization studies are available.

90-day oral toxicity studies are available in rats and dogs. In the rat, toxicity is manifested as decreased body weight and food efficiency at 4% (equivalent to 3,080 milligram/kilogram/day (mg/kg/day)) of butanedioic acid, 2-sulfo-, C-C9-11-isoalkyl esters, C10-rich, disodium salts. In dogs, toxicity is manifested as testicular atrophy at 0.5% (equivalent to 125 mg/kg/day). The NOAEL in this study is 0.12% (equivalent to 30 mg/kg/day). The chronic reference dose (cRfD) is based on this study.

A combined reproductive and developmental study on rats is available with butanedioic acid, 2-sulfo-, C-C9-11-isoalkyl esters, C10-rich, disodium salts. Quantitative fetal susceptibility is observed as reduced pup weight at 1% (equivalent to 750 mg/kg/day). Maternal toxicity is reported only with regard to reproduction toxicity and included a reduced number of viable embryos and live-born per litter, and reduced fertility, viability and lactation indices at 4% (equivalent to 3,000 mg/kg/day).

Butanedioic acid, 2-sulfo-, C-C9-11-isoalkyl esters, C10-rich, disodium salts is not expected to be carcinogenic based on the absence of structural alerts using the Derek Nexus program and the lack of mutagenicity in two Ames tests.

Neurotoxicity and immunotoxicity studies with butanedioic acid, 2-sulfo-, C-C9-11-isoalkyl esters, C10-rich, disodium salts are not available for review. However, no evidence of potential neurotoxicity or immunotoxicity is observed in the submitted studies.

Metabolism studies with butanedioic acid, 2-sulfo-, C-C9-11-isoalkyl esters, C10-rich, disodium salts are not available for review. However, it is expected that these salts will readily hydrolyze (primarily in the intestine, blood and liver) by carboxylesterases resulting in the corresponding alcohol (C9-C l1 isoalkyl, Cl0 rich). The fatty alcohol is expected to be metabolized via normal metabolic pathways (oxidation, followed by normal fatty acid metabolism).

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.*

An acute effect was not found in the database therefore an acute dietary assessment was not conducted. The cRfD as well as all exposure scenarios was based on the 90-day oral toxicity study in the dog. In this study, the LOAEL was 0.5% (equivalent to 125 mg/kg/day) based on testicular atrophy in males. The NOAEL was 0.12% (equivalent to 30 mg/kg/day). This represents the lowest NOAEL in the most sensitive species in the toxicity database. The standard uncertainty factors were applied to account for interspecies (10x) and intraspecies (10x) variations. Default values of 100% absorption were used for the dermal and inhalation factors.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to butanedioic acid, 2-sulfo-, C-C9-11-isoalkyl esters, C10-rich, disodium salts, EPA considered exposure under the proposed exemption from the requirement of a tolerance. EPA assessed dietary exposures from butanedioic acid, 2-sulfo-, C-C9-11-isoalkyl esters, C10-rich, disodium salts in food as follows:

Dietary exposure (food and drinking water) to butanedioic acid, 2-sulfo-, C-C9-11-isoalkyl esters, C10-rich, disodium salts can occur following ingestion of foods with residues from treated crops. Because no adverse effects attributable to a single exposure of butanedioic acid, 2-sulfo-, C-C9-11-isoalkyl esters, C10-rich, disodium salts are seen in the toxicity databases, an acute dietary risk assessment was not conducted. For the chronic dietary risk assessment, EPA used the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM–FCID™, Version 3.16, and food consumption information from the U.S. Department of Agriculture's (USDA's) 2003–2008 National Health and Nutrition Examination Survey, What We Eat in America (NHANES/WWEIA). As to residue levels in food, no residue data were submitted for butanedioic acid, 2-sulfo-, C-C9-11-isoalkyl esters, C10-rich, disodium salts. 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. 100 percent crop treated (PCT), default processing

factors, and tolerance-level residues were assumed for all foods, and the assessment incorporated the use limitation that the ingredient will be present in pesticide formulations at a concentration of not more than 10% by weight. 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 butanedioic acid, 2-sulfo-, C-C9-11-isoalkyl esters, C10-rich, disodium 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).

Butanedioic acid, 2-sulfo-, C-C9-11-isoalkyl esters, C10-rich, disodium salts may be used in inert ingredients in products that are registered for specific uses that may result in residential exposure, such as pesticides used in and around the home. Based on the available data for products registered for residential use, the Agency concluded that products containing inert chemicals similar to butanedioic acid, 2-sulfo-, C-C9-11-isoalkyl esters, C10-rich, disodium salts (ie surfactant) usually comprise no more than 2–5% of the inert ingredient in the final product. Therefore, the Agency conducted an assessment to represent conservative residential exposure by assessing butanedioic acid, 2-sulfo-, C-C9-11-isoalkyl esters, C10-rich, disodium salts in pesticide formulations (outdoor scenarios) and in disinfectant-type uses (indoor scenarios) at no more than 5% in the final formulation.

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 butanedioic acid, 2-sulfo-, C-C9-11-isoalkyl esters, C10-rich, disodium salts to share a common mechanism of toxicity with any other substances, and butanedioic acid, 2-sulfo-, C-C9-11-isoalkyl esters, C10-rich, disodium 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 butanedioic acid, 2-sulfo-, C-C9-11-isoalkyl esters, C10-rich, disodium 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 Web site at *http://www.epa.gov/pesticides/cumulative.*

D. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the Food Quality Protection Act Safety Factor (FQPA SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* The toxicity database for butanedioic acid, 2-sulfo-, C-C9-11-isoalkyl esters, C10-rich, disodium salts contains subchronic, combined reproduction/teratology and mutagenicity studies. There is no indication of potential neurotoxicity or immunotoxicity in the available studies. Quantitative increased fetal susceptibility was observed in the combined reproduction/teratology study in rats. Fetal toxicity (reduced pup weight) was observed at the lowest dose tested, 750 mg/kg/day. Maternal/reproduction toxicity was observed at 3,000 mg/kg/day and manifested as a reduction in the number of viable embryos, live-born per litter, fertility, viability, and lactation indices. The addition of a 10x FQPA safety factor to account for quantitative susceptibility and LOAEL to NOAEL extrapolation is not necessary because it would result in a cRfD of 0.75 mg/kg/day and the established cRfD is 0.30 mg/kg/day. The cRfD is considerably lower and will be protective of fetal susceptibility and effects observed at 750 mg/kg/day. Therefore, retention of the FQPA safety factor is unnecessary. There is low concern for reproduction toxicity since the aforementioned effects occurred above the limit dose of 1,000 mg/kg/day and a clear NOAEL of 750 mg/kg/day was established. Therefore, the established cRfD will be protective of these effects. In addition, the Agency used the most conservative (highest) exposure estimates and assumptions, including 100 PCT and tolerance-level residues for all foods, conservative estimates of drinking water exposure, and a conservative assessment of potential residential exposure for infants and children. Therefore, the FQPA SF of 10x is reduced to 1x.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. No adverse effect resulting from a single oral exposure was identified and no acute dietary endpoint was selected. Therefore, butanedioic acid, 2-sulfo-, C-C9-11-isoalkyl esters, C10-rich, disodium 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 butanedioic acid, 2-sulfo-, C-C9-11-isoalkyl esters, C10-rich, disodium salts from food and water will utilize 47.9% of the cPAD for children 1–2 years old, the population group 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).

Butanedioic acid, 2-sulfo-, C-C9-11-isoalkyl esters, C10-rich, disodium salts may be used as inert ingredients in pesticide products 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 butanedioic acid, 2-sulfo-, C-C9-11-isoalkyl esters, C10-rich, disodium salts. Using the exposure assumptions described above, EPA has concluded that the combined short-term aggregated food, water, and residential exposures result in MOEs of 126 for both adult males and females. Adult residential exposure combines high end dermal and inhalation handler exposure from liquids/trigger sprayer/home garden use with a high end post application dermal exposure from contact with treated lawns. Also, EPA has concluded the combined short-term aggregated food, water, and residential exposures result in an aggregate MOE of 135 for children. Children's residential exposure includes total exposures associated with contact with treated lawns (dermal and hand-to-mouth exposures). As the level of concern is for MOEs that are lower than 100, 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).

Butanedioic acid, 2-sulfo-, C-C9-11-isoalkyl esters, C10-rich, disodium salts may be used as inert ingredients in pesticide products that could result in intermediate-term residential exposure and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with intermediate-term residential exposures to butanedioic acid, 2-sulfo-, C-C9-11-isoalkyl esters, C10-rich, disodium salts. Using the exposure assumptions described above, EPA has concluded that the combined intermediate-term food, water, and residential exposures result in aggregate MOEs of 480 for adult males and females. Adult residential exposure combines liquids/trigger sprayer/home garden use with a high end post application dermal exposure from contact with treated lawns. As the level of concern is for MOEs that are lower than 100, this MOE is not of concern. EPA has concluded the combined intermediate-term aggregated food, water, and residential exposures result in an aggregate MOE of 158 for children. Children's residential exposure includes total exposures associated with contact with treated surfaces (dermal and hand-to-mouth exposures). As the level of concern is for MOEs that are lower than 100, this MOE is not of concern.

5. *Aggregate cancer risk for U.S. population.* Based on a DEREK structural alert analysis and the lack of mutagenicity, butanedioic acid, 2-sulfo-, C-C9-11-isoalkyl esters, C10-rich, disodium salts is 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 butanedioic acid, 2-sulfo-, C-C9-11-isoalkyl esters, C10-rich, disodium salts residues.

V. Other Considerations

An analytical method is not required for enforcement purposes since the Agency is not establishing a numerical tolerance for residues of butanedioic acid, 2-sulfo-, C-C9-11-isoalkyl esters, C10-rich, disodium salts in or on any food commodities. EPA is establishing limitations on the amount of butanedioic acid, 2-sulfo-, C-C9-11-isoalkyl esters, C10-rich, disodium salts that may be used in pesticide formulations applied to growing crops. These 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 growing crops or raw agricultural commodities after harvest for sale or distribution that exceeds 10% by weight of butanedioic acid, 2-sulfo-, C-C9-11-isoalkyl esters, C10-rich, disodium salts unless additional data are submitted.

VI. Conclusions

Therefore, an exemption from the requirement of a tolerance is established under 40 CFR 180. 910 for of butanedioic acid, 2-sulfo-, C-C9-11-isoalkyl esters, C10-rich, disodium salts (CAS Reg. No. 815583–91–6) when used as inert ingredients (surfactant) at a maximum concentration of 10% by weight in pesticide formulations applied to growing crops or to raw agricultural commodities after harvest.

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: April 26, 2016.

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 ingredient ''Butanedioic acid, 2-sulfo-, C-C9-11-isoalkyl esters, C10-rich, disodium salts (CAS Reg. No. 815583–91–6)'' 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
* * *	* * *	*
Butanedioic acid, 2-sulfo-, C-C9-11-isoalkyl esters, C10-rich, disodium salts (CAS Reg. No. 815583–91–6).	Not to exceed 10% by weight in pesticide formulation for agricultural use.	Surfactant.
* * *	* * *	*

[FR Doc. 2016–10582 Filed 5–4–16; 8:45 am]

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DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 36

[Docket No. FWS–R7–NWRS–2014–0003; FF07RKNA00 FXRS12610700000 167]

RIN 1018–AX56

Refuge-Specific Regulations; Public Use; Kenai National Wildlife Refuge

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Final rule.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), are amending the regulations for Kenai National Wildlife Refuge (Kenai NWR or Refuge) that govern existing general public use and recreation. These changes will implement management direction and decisions from our June 2010 Kenai NWR revised comprehensive conservation plan and June 2007 Skilak Wildlife Recreation Area final revised management plan. The amendments to the regulations are designed to enhance natural resource protection, public use activities, and public safety on the Refuge; are necessary to ensure the compatibility of public use activities with the Refuge's purposes and the Refuge System's purposes; and ensure consistency with management policies and approved Refuge management plans.

DATES: This rule is effective June 6, 2016.

FOR FURTHER INFORMATION CONTACT: Andy Loranger, Refuge Manager, Kenai NWR, P.O. Box 2139, Ski Hill Rd., Soldotna, AK 99669; telephone: 907–262–7021; facsimile 907–262–3599. If you use a telecommunications device for the deaf (TDD), call the Federal Information Relay Service (FIRS) at 800–877–8339.

SUPPLEMENTARY INFORMATION:

Background

President Franklin D. Roosevelt established the Kenai National Moose Range (Moose Range) on December 16, 1941, for the purpose of ''protecting the natural breeding and feeding range of the giant Kenai moose on the Kenai Peninsula, Alaska, which in this area presents a unique wildlife feature and an unusual opportunity for the study in its natural environment of the practical management of a big game species that has considerable local economic value'' (Executive Order 8979; see 6 FR 6471, December 18, 1941).

Section 303(4) of the Alaska National Interest Lands Conservation Act of 1980 (ANILCA) (16 U.S.C. 3101 *et seq.*) substantially affected the Moose Range by modifying its boundaries and broadening its purposes from moose conservation to protection and conservation of a broad array of fish, wildlife, habitats, and other resources, and to providing educational and recreational opportunities. ANILCA also redesignated the Moose Range as the Kenai National Wildlife Refuge (NWR or Refuge) and increased the size of the Refuge to 1.92 million acres, of which approximately two-thirds were designated as Wilderness and made part of the National Wilderness Preservation System.

ANILCA sets out additional purposes for each refuge in Alaska; the purposes of Kenai NWR are set forth in section 303(4)(B) of ANILCA. The purposes identify some of the reasons why Congress established the Refuge and set the management priorities for the Refuge. The purposes are as follows:

(1) To conserve fish and wildlife populations and habitats in their natural diversity including, but not limited to, moose, bears, mountain goats, Dall sheep, wolves and other furbearers, salmonoids and other fish, waterfowl and other migratory and nonmigratory birds;

(2) To fulfill the international treaty obligations of the United States with respect to fish and wildlife and their habitats;

(3) To ensure, to the maximum extent practicable and in a manner consistent with the purposes set forth in (1), above, water quality and necessary water quantity within the Refuge;

(4) To provide, in a manner consistent with (1) and (2), above, opportunities for scientific research, interpretation, environmental education, and land management training; and

(5) To provide, in a manner compatible with these purposes, opportunities for fish and wildlife-oriented recreation.

The Wilderness Act of 1964 (16 U.S.C. 1131–1136) provides the following purposes for wilderness areas, including the Kenai wilderness area: