ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2021-0682; FRL-9932-01-OCSPP]

Sodium dioctyl sulfosuccinate (CAS Reg. No. 577-11-7); Tolerance Exemption

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of sodium dioctyl sulfosuccinate (CAS Reg. No. 577-11-7) 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 under 40 CFR 180.940(a). Spring Regulatory Sciences, on behalf of Evonik Corporation, submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of sodium dioctyl sulfosuccinate (CAS Reg. No. 577-11-7) when used in accordance with this exemption.

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-2021-0682, is available at *https://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 and the OPP Docket is (202) 566-1744. Please review the visitor instructions and additional information about the docket available at *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Marietta Echeverria, Registration Division (7505T), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; main telephone number: (202) 566-1030; 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 Office of the Federal Register's e-CFR site at *https://www.ecfr.gov/current /title40.*

C. Can I File an Objection or Hearing Request?

Under FFDCA section 408(g), 21 U.S.C. 346a(g), 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-2021-0682 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-2021-0682, by one of the following methods.

• *Federal eRulemaking Portal*: *https://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 *https://www.epa.gov/dockets/contacts.html*.

Additional instructions on commenting or visiting the docket, along with more

information about dockets generally, is available at *https://www.epa.gov/dockets*.

II. Petition for Exemption

In the *Federal Register* of October 21, 2021 (86 FR 58239) (FRL-8792–04–OCSPP), EPA issued a document pursuant to FFDCA section 408, 21 U.S.C. 346a, announcing the receipt of a pesticide petition (PP IN-11566) by Spring Regulatory Sciences (6620 Cypresswood Dr, Suite 250, Spring, TX 77379), on behalf of Evonik Corporation, (P.O. Box 34628, Richmond, VA 23234). The petition requested that 40 CFR 180.940(a) be amended by establishing an exemption from the requirement of a tolerance for residues of sodium dioctyl sulfosuccinate (CAS Reg. No. 577-11-7) for use as an inert ingredient in antimicrobial pesticide formulations. That document referenced a summary of the petition prepared by the petitioner, which is available in the docket, and solicited comments on the petitioner's request at http://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(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 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 shown that the risks from aggregate exposure to pesticide chemical residues under reasonably foreseeable circumstances will pose no harm 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 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(b)(2)(D), 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 and considered its validity, completeness and reliability and the relationship of this information 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. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure to sodium dioctyl sulfosuccinate including exposure resulting from the exemption established by this action. EPA's assessment of exposures and risks associated with sodium dioctyl sulfosuccinate 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. Sodium dioctyl sulfosuccinate is also known as dioctyl sodium sulfosuccinate or DSS. Specific information on the studies received and the nature of the adverse effects caused by sodium dioctyl sulfosuccinate, 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 the November 5, 2012 document titled "Dioctyl Sodium Sulfosuccinate: Preliminary Human Health Risk Assessment in Support of Registration Review," which is available at *https://www.regulations.gov* in docket ID number EPA-HQ-OPP-2010-1006, and in the June 10th, 2022 document titled "IN-11566; Petition to an amend Tolerance Exemption for Sodium dioctyl sulfosuccinate (CAS No. 577-11-7), adding it to the approved list of food use inert ingredients under 40 CFR 180.940(a) in Pesticide Formulations." which is available at *https://www.regulations.gov* in the docket for this action.

Sodium dioctyl sulfosuccinate has low acute oral, dermal and inhalation toxicity. It is neither a skin sensitizer nor a skin or eye irritant. Toxicity to offspring occurred in the reproduction and developmental studies only at the limit dose and in the presence of parental toxicity. The subchronic toxicity, chronic toxicity, and mutagenicity studies did

not demonstrate any significant toxicity of sodium dioctyl sulfosuccinate.

In a 90-day oral toxicity study in Sprague-Dawley rats with sodium dioctyl sulfosuccinate, no adverse effects were observed up to the highest dose tested and the NOAEL is 1000 mg/kg/day.

B. Toxicological Points of Departure/Levels of Concern

The toxicological points of departure/levels of concern of sodium dioctyl sulfosuccinate remain unchanged from the Toxicological Profile in Preliminary Human Health Risk Assessment in Support of Registration Review. D405928, November 5, 2012. No toxicological endpoints of concern were identified for sodium dioctyl sulfosuccinate because there was no offspring susceptibility and the only effects observed occurred at the limit dose.

C. Exposure Assessment

Dietary and residential (non-occupational and non-dietary) exposures are expected from the proposed and existing uses of sodium dioctyl sulfosuccinate. However, no quantitative dietary or residential exposure assessments were conducted because no toxicological endpoints of concern were identified.

D. 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 determined that sodium dioctyl sulfosuccinate share a common mechanism of toxicity with any other substances, and sodium dioctyl sulfosuccinate does not appear to produce a toxic metabolite produced by other substances. For the purposes of this action, therefore, EPA has assumed that sodium dioctyl sulfosuccinate 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 *https://www.epa.gov/pesticides/cumulative*.

E. Safety Factor for Infants and Children

Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database unless EPA concludes that a different margin of safety will be safe for infants and children. Based on an assessment of sodium dioctyl sulfosuccinate, EPA has concluded that there are no toxicological endpoints of concern for the U.S. population, including infants and children, and a qualitative assessment is being conducted for sodium dioctyl sulfosuccinate. The qualitative assessment does not use safety factors for assessing risk, and no additional safety factor is needed for assessing risk to infants and children.

F. Determination of Safety

Therefore, based on the risk assessments and information described above, EPA concludes there is a reasonable certainty that no harm will result to the general population, or to infants and children, from aggregate exposure to sodium dioctyl sulfosuccinate residues. More detailed information about the Agency's analysis can be found at *https://www.regulations.gov* in the November 5, 2012 document titled "Dioctyl Sodium Sulfosuccinate: Preliminary Human Health Risk Assessment in Support of Registration Review" in docket ID number EPA-HQ-OPP-2010-1006, and in the June 10th, 2022 document titled "IN-11566; Petition to an amend Tolerance Exemption for Sodium dioctyl sulfosuccinate (CAS No. 577-11-7), adding it to the approved list of food use inert ingredients under 40 CFR 180.940(a) in Pesticide Formulations." in the docket for this action.

V. Other Considerations

Analytical Enforcement Methodology

An analytical method is not required for enforcement purposes since the Agency is not establishing a numerical tolerance for residues of sodium dioctyl sulfosuccinate in or on any food commodities.

VI. Conclusion

Therefore, an exemption from the requirement of a tolerance is established under 40 CFR 180.940(a) for sodium dioctyl sulfosuccinate 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.

VII. Statutory and Executive Order Reviews

This action establishes a tolerance exemption 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 exemption in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5

U.S.C. 601 *et seq.*), do not apply.

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

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

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: June 22, 2022.

Marietta Echeverria,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, for the reasons stated in the preamble, EPA is amending 40 CFR chapter I as follows:

PART 180--TOLERANCES AND EXEMPTIONS FOR PESTICIDE CHEMICAL RESIDUES IN FOOD

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

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

2. In § 180.940, amend Table 1 to Paragraph (a) by adding, in alphabetical order, an entry for "Sodium dioctyl sulfosuccinate" to read as follows:

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

* * * * *

Table 1 to Paragraph (a)

Pesticide Chemical	CAS Reg. No.	Limits
* * * * * * *		
Sodium dioctyl sulfosuccinate	577-11-7	None
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[FR Doc. 2022-14067 Filed: 6/30/2022 8:45 am; Publication Date: 7/1/2022]