



BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2018-0763; FRL-9999-81]

Sodium Lauryl Sulfate; 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 the fungicide and miticide sodium lauryl sulfate in or on all food commodities when used in accordance with label directions and good agricultural practices. Central Coast Garden Products 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 lauryl sulfate under FFDCA.

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-2018-0763, 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: Robert McNally, Biopesticides and Pollution Prevention Division (7511P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; main telephone number: (703) 305-7090; email address: BPPDFRNotices@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 Publishing 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 FFDCCA 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-2017-0763 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-2018-0763, 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. Background

In the *Federal Register* of March 18, 2019 (84 FR 9737) (FRL-9989-71), EPA issued a document pursuant to FFDCFA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide tolerance petition (PP 8F8688) by Central Coast Garden Products, 1354 Dayton St., Unit N, Salinas, CA 93901. The petition requested that 40 CFR part 180 be amended by establishing an exemption from the requirement of a tolerance for residues of Sodium Lauryl Sulfate (SLS) (CAS No. 151-21-3) in or on all raw agricultural commodities. That document referenced a summary of the petition prepared by the petitioner, Central Coast Garden Products, which is available in the docket via <http://www.regulations.gov>. There were no comments received in response to the notice of filing.

III. Final Rule

A. EPA's Safety Determination

Section 408(c)(2)(A)(i) of FFDCFA 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 FFDCFA 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. Pursuant to FFDCFA

section 408(c)(2)(B), in establishing or maintaining in effect an exemption from the requirement of a tolerance, EPA must take into account the factors set forth in FFDCA section 408(b)(2)(C) and (D), which require EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance or tolerance 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” Additionally, FFDCA section 408(b)(2)(D) requires that EPA consider “available information concerning the cumulative effects of [a particular pesticide’s] . . . residues and other substances that have a common mechanism of toxicity.”

EPA evaluated the available toxicity and exposure data on sodium lauryl sulfate and considered its validity, completeness, and reliability, as well as the relationship of this information to human risk. EPA also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

Sodium lauryl sulfate (also called sodium dodecyl sulfate) is an amphiphilic anionic surfactant that is widely used in cleaning products, cosmetics, personal care products, foods, pesticide products, lubricants and paints.

As a pesticide, the chemical is exempt from the requirements of Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) as a minimum risk active ingredient under the specifications in 40 CFR 152.25(f). As an inert ingredient in pesticide products, SLS is approved for nonfood and food uses without limitation as a surfactant for pre- and post-harvest uses (40 CFR 180.910) and as a surfactant applied to animals (40 CFR 180.930). For antimicrobial pesticide products, SLS is approved for use in food-contact sanitizing solutions with an end-use concentration limit of 350 ppm (40 CFR 180.940(a), (b), and (c)). Currently, there is one

federally-registered product where SLS is an active ingredient, an antiviral tissue, which was registered in 2009.

The Food and Drug Administration (FDA) has approved its use as a direct and indirect food additive (with limitations) under 21 CFR 172.210, 172.822, 175.105, 175.300, 175.320, 176.170, 176.180, 176.210, 177.1200, 177.1210, 177.1630, 177.2600, 177.2800, 178.1010 and 179.45. These uses include emulsifier, whipping aid, coating and wetting agent. The chemical is also considered to be a Generally Recognized as Safe (GRAS) substance (21 CFR 172.822 (with limitations); Flavor and Extract Manufacturers Association (FEMA) # 4437).

Overall, SLS is considered to be of low toxicity. Based on the available information and the fact that humans have been exposed to SLS for decades in food and nonfood products, the chemical is considered to have a history of safe use. The target organ is the liver, but no adverse effects were seen at or below 430 milligram/kilogram/day (mg/kg/day). There is no evidence of increased susceptibility in the developmental and reproductive toxicity studies. Moreover, no neurotoxicity, genotoxicity, or carcinogenicity have been observed in the available database, which includes the following studies: Acute toxicity, repeat dose (gavage and dietary) toxicity, developmental toxicity, reproductive toxicity, genotoxicity and carcinogenicity.

With regard to potential dietary exposure to SLS, the Agency expects that upon approval of this exemption, SLS may be used in any number of pesticide products, as it is listed as an active ingredient that can be used in minimum risk pesticide products without regulation under FIFRA (except as directed in 40 CFR 152.25(f)). Moreover, as noted above, SLS has been found safe for use as an inert ingredient in pesticide products and has been approved by FDA for use as a food additive. The Agency anticipates contributions to dietary exposures (food and drinking water) to be negligible due to the physical and chemical properties of SLS, which degrades

rapidly in the environment and is highly soluble in water. Furthermore, any minimal residues that might be consumed are expected to be readily metabolized.

Due to the low toxicity of SLS, long history of safe use, and expected minimal dietary exposure, the Agency did not identify any points of departure for a quantitative assessment of SLS.

As part of its risk assessment for SLS, the Agency has further considered the potential risks of residential exposures, aggregate exposures, and cumulative risk. Based on SLS's low toxicity, anticipated negligible dietary exposure and history of safe use in consumer products, no risks of concern have been identified relative to residential (non-occupational) pesticidal uses or any aggregate of exposures to products containing SLS. Similarly, no risks of concern were identified for cumulative exposures to SLS since no common mechanism of toxicity was identified for either SLS or its metabolites.

Therefore, based on the lack of toxicity and expected low exposures, EPA has determined that there is a reasonable certainty that no harm will result to the U.S. population, including infants and children, from aggregate exposure to SLS. The data upon which EPA relied to make its safety determination, as well as other relevant information, including the Agency's dietary risk assessment, is available in the docket for this action as described under **ADDRESSES**.

Based on its safety determination, EPA is establishing an exemption from the requirement of a tolerance for residues of the fungicide and miticide sodium lauryl sulfate in or on all food commodities when used on accordance with label directions and good agricultural practices.

B. Analytical Enforcement Methodology

An analytical method is not required for enforcement purposes due to lack of concern for

exposures, which supports the establishment of an exemption for residues of sodium lauryl sulfate.

IV. Statutory and Executive Order Reviews

This action establishes an exemption from the requirement of a tolerance under FFDCA section 408(d) in response to a petition submitted to EPA. 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), nor is it a regulatory action under Executive Order 13771, entitled “Reducing Regulations and Controlling Regulatory Costs” (82 FR 9339, February 3, 2017). 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 exemption in this action, 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. As a result, this action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, EPA 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, EPA 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 EPA’s 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).

V. 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: September 17, 2019.

Richard Keigwin,

Director, 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. Add § 180.1372 to subpart D to read as follows:

§180.1372 Sodium lauryl sulfate; exemption from the requirement of a tolerance.

Residues of the fungicide and miticide sodium lauryl sulfate (CAS No. 151-21-3) in or on all food commodities are exempt from the requirement of a tolerance, when used in accordance with label directions and good agricultural practices.

[FR Doc. 2019-21121 Filed: 10/1/2019 8:45 am; Publication Date: 10/2/2019]