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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2019-0591; FRL-10011-33]

Long Chain Alcohols; 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 long chain alcohols when used as inert ingredients (carrier/adjuvant and coating agent/binder) in pesticide products applied to/on all growing crops and raw agricultural commodities after harvest, and to/on animals, and in certain antimicrobial formulations. Spring Trading Company on behalf of Sasol Chemicals (USA) LLC., submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting an establishment of an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of certain long chain alcohols when used in accordance with these exemptions.

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-2019-0591, 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>.

Please note that due to the public health emergency the EPA Docket Center (EPA/DC) and Reading Room was closed to public visitors on March 31, 2020. Our EPA/DC staff will continue to provide customer service via email, phone, and webform. For further information on EPA/DC services, docket contact information and the current status of the EPA/DC and Reading Room, please visit <https://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Michael L. Goodis, 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 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 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-2019-0591 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-2019-0591, 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 February 11, 2020 (85 FR 7708) (FRL-10005-02), EPA issued a document pursuant to FFDCA section 408, 21 U.S.C. 346a, announcing the filing of a pesticide petition (IN-11284) by Spring Trading Company (203 Dogwood Trail, Magnolia, TX 77354) on behalf of Sasol Chemicals (USA) LLC (12120 Wickchester Lane, Houston, TX 77224). The petition requested that 40 CFR be amended by establishing an exemption from the requirement of a tolerance for residues of certain long chain alcohols (CAS Reg. Nos.: 112-42-5, 112-72-1, 112-92-5, 629-96-9, 661-19-8, 68603-17-8, 1190630-03-5, 1430895-61-6, and 1430895-62-7) when used as inert ingredients (carrier/adjuvant and coating agent/binder) in pesticide formulations applied to/on all growing crops and raw agricultural commodities after harvest under 40 CFR 180.910, to/on animals under 180.930, and in certain antimicrobial formulations under 180.940(a). That document referenced a summary of the petition prepared by Spring

Trading Company on behalf of Sasol Chemicals (USA) LLC, 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 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. Under FFDCA section 408(c)(2)(B), EPA must take into account, among other considerations, the factors in subparagraphs (C) and (D) of subsection (b)(2). 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 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 certain long chain alcohols including exposure resulting from the exemption established by this action. EPA's assessment of exposures and risks associated with certain long chain alcohols 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 the relevant long chain alcohols as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at <http://www.regulations.gov> in the document Long Chain Alcohols; 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-2019-0591.

Toxicological data for several long chain alcohols (C₁₂-C₃₄) are used as surrogate data for the proposed long chain alcohols since long chain alcohols are structurally similar, differing only in carbon chain length so toxicity is expected to be similar.

The acute oral, dermal, and inhalation toxicities are low in rats treated with long chain alcohols. They are mildly to non-irritating to the rabbit eye and moderately to non-irritating to rabbit skin. Long chain alcohols are not skin sensitizers.

No toxicity is observed in repeated dose studies conducted with long chain alcohols administered via diet and gavage to rats, mice, dogs and rabbits.

Mutagenicity is not expected with long chain alcohols since negative results are observed in mutagenicity studies.

Neurotoxicity and immunotoxicity studies are not available for review. However, no evidence of neurotoxicity or immunotoxicity is observed in any of the available studies on long chain alcohols.

B. Toxicological Points of Departure/Levels of Concern

The available toxicity studies indicate that long chain alcohols have very low overall toxicity. Acute oral toxicity studies show LD₅₀s above 2,000 mg/kg in rats. Repeated dose

studies show no toxicity at doses as high as 2,000 mg/kg/day, twice the limit dose of 1,000 mg/kg/day. Since no toxicity is observed, an endpoint of concern for risk assessment purposes was not identified. EPA assessed dietary and other non-occupational exposures qualitatively.

C. Exposure Assessment

1. *Dietary exposure from drinking water, food and feed uses.* In evaluating dietary exposure to long chain alcohols, EPA considered exposure under the proposed exemption from the requirement of a tolerance. EPA assessed dietary exposures from long chain alcohols in food as follows:

Dietary exposure (food and drinking water) to long chain alcohols may occur following ingestion of foods with residues from their use in accordance with this exemption. Dietary exposure may also occur from direct and indirect food contact uses under the Food and Drug Administration Code of Federal Regulations Title 21. However, a quantitative dietary exposure assessment was not conducted since a toxicological endpoint for risk assessment was not identified.

2. *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).

Long chain alcohols may be used in pesticide products and non-pesticide products that may be used in and around the home. Based on the discussion above regarding the toxicity of the long chain alcohols, a quantitative residential exposure assessment for long chain alcohols was not conducted.

3. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCFA 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.”

Based on the available data, long chain alcohols do not have a toxic mechanism; therefore, section 408(b)(2)(D)(v) does not apply.

D. Safety Factor for Infants and Children

Based on the lack of threshold effects, EPA has not identified any toxicological endpoints of concern and is conducting a qualitative assessment of long chain alcohols. 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. Based on an assessment of long chain alcohols, EPA has concluded that there are no toxicological endpoints of concern for the U.S. population, including infants and children.

E. Aggregate Risks and Determination of Safety

Because no toxicological endpoints of concern were identified, 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 long chain alcohols residues.

V. Other Considerations

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, an exemption from the requirement of a tolerance is established for residues of long chain alcohols: 1-undecanol (CAS Reg. No. 112-42-5), 1-tetradecanol (CAS Reg. No. 112-

72-1), 1-octadecanol (CAS Reg. No. 112-92-5), 1-eicosanol (CAS Reg. No. 629-96-9), 1-docosanol (CAS Reg. No. 661-19-8), alcohols, C₁₆₋₁₈, distn. residues (CAS Reg. No. 68603-17-8 & CAS Reg. No. 1190630-03-5), alkenes, C₁₈₋₂₂, mixed with polyethylene, oxidized, hydrolyzed, distn. residues from C₁₆₋₁₈ alcs. manuf. (CAS Reg. No. 1430895-61-6), alkenes, C₁₈₋₂₂, mixed with polyethylene, oxidized, hydrolyzed, distn. residues from C₂₀₋₂₂ alcs. manuf. (CAS Reg. No. 1430895-62-7) when used as inert ingredients (carrier/adjuvant and coating agent/binder) in pesticide formulations applied to/on all growing crops and raw agricultural commodities after harvest under 40 CFR 180.910, to/on animals under 180.930, and in certain antimicrobial formulations under 180.940(a).

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), nor is it considered 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 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 26, 2020.

Michael Goodis,

Director, Registration Division, Office of Pesticide Programs.

Therefore, for the reasons stated in the preamble, the EPA amends 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 §180.910, amend Table 1 by adding “1-undecanol (CAS Reg. No. 112-42-5), 1-tetradecanol (CAS Reg. No. 112-72-1), 1-octadecanol (CAS Reg. No. 112-92-5), 1-eicosanol (CAS Reg. No. 629-96-9), 1-docosanol (CAS Reg. No. 661-19-8), alcohols, C16-18, distn. residues (CAS Reg. No. 68603-17-8 & CAS Reg. No. 1190630-03-5), alkenes, C18-22, mixed with polyethylene, oxidized, hydrolyzed, distn. residues from C16-18 alcs. manuf. (CAS Reg. No. 1430895-61-6), alkenes, C18-22, mixed with polyethylene, oxidized, hydrolyzed, distn. residues from C20-22 alcs. manuf. (CAS Reg. No. 1430895-62-7)” in alphabetical order to read as follows:

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

* * * * *

Table 1 to 180.910

Inert ingredients	Limits	Uses
* * * * *	* * *	
1-undecanol (CAS Reg. No. 112-42-5), 1-tetradecanol (CAS Reg. No. 112-72-1), 1-octadecanol (CAS Reg. No. 112-92-5), 1-eicosanol (CAS Reg. No. 629-96-9), 1-docosanol (CAS Reg. No. 661-19-8), alcohols, C ₁₆₋₁₈ , distn. residues (CAS Reg. No. 68603-17-8 & CAS Reg. No. 1190630-03-5), alkenes, C ₁₈₋₂₂ , mixed with polyethylene, oxidized, hydrolyzed, distn. residues from C ₁₆₋₁₈ alcs. manuf. (CAS Reg. No. 1430895-61-6), alkenes, C ₁₈₋₂₂ , mixed with polyethylene,		Carrier/Adjuvant and Coating Agent/Binder

oxidized, hydrolyzed, distn. residues from C ₂₀₋₂₂ alcs. manuf. (CAS Reg. No. 1430895-62-7)		
* * * *	* *	*

3. In §180.930;

a. Designate the table as Table 1 to 180.930; and

b. Amend newly designated Table 1 by adding, in alphabetical order, an entry for “1-undecanol (CAS Reg. No. 112-42-5), 1-tetradecanol (CAS Reg. No. 112-72-1), 1-octadecanol (CAS Reg. No. 112-92-5), 1-eicosanol (CAS Reg. No. 629-96-9), 1-docosanol (CAS Reg. No. 661-19-8), alcohols, C₁₆₋₁₈, distn. residues (CAS Reg. No. 68603-17-8 & CAS Reg. No. 1190630-03-5), alkenes, C₁₈₋₂₂, mixed with polyethylene, oxidized, hydrolyzed, distn. residues from C₁₆₋₁₈ alcs. manuf. (CAS Reg. No. 1430895-61-6), alkenes, C₁₈₋₂₂, mixed with polyethylene, oxidized, hydrolyzed, distn. residues from C₂₀₋₂₂ alcs. manuf. (CAS Reg. No. 1430895-62-7)”.

The additions read as follows:

§ 180.930 Inert ingredients applied to animals; exemptions from the requirement of a tolerance.

* * * * *

Table 1 to 180.930

Inert ingredients	Limits	Uses
* * * *	* *	*
1-undecanol (CAS Reg. No. 112-42-5), 1-tetradecanol (CAS Reg. No. 112-72-1), 1-octadecanol (CAS Reg. No. 112-92-5), 1-eicosanol (CAS Reg. No. 629-96-9), 1-docosanol (CAS Reg. No. 661-19-8), alcohols, C ₁₆₋₁₈ , distn. residues (CAS Reg. No. 68603-17-8 & CAS Reg. No. 1190630-03-5), alkenes, C ₁₈₋₂₂ , mixed with polyethylene, oxidized, hydrolyzed, distn. residues from C ₁₆₋₁₈ alcs. manuf. (CAS Reg. No. 1430895-61-6), alkenes, C ₁₈₋₂₂ , mixed with polyethylene, oxidized, hydrolyzed, distn. residues from C ₂₀₋₂₂ alcs. manuf. (CAS Reg. No. 1430895-62-7)		Carrier/Adjuvant and Coating Agent/Binder

* * * * *

4. In §180.940 amend paragraph (a) by;

a. Designating the table as Table 1 to 180.940(a); and

b. Amending newly designated Table 1 by adding, in alphabetical order, entries for “1-undecanol (CAS Reg. No. 112-42-5)”, “1-tetradecanol (CAS Reg. No. 112-72-1)”, “1-octadecanol (CAS Reg. No. 112-92-5)”, “1-eicosanol (CAS Reg. No. 629-96-9)”, “1-docosanol (CAS Reg. No. 661-19-8)”, “alcohols, C₁₆₋₁₈, distn. residues (CAS Reg. No. 68603-17-8 & CAS Reg. No. 1190630-03-5)”, “alkenes, C₁₈₋₂₂, mixed with polyethylene, oxidized, hydrolyzed, distn. residues from C₁₆₋₁₈ alcs. manuf. (CAS Reg. No. 1430895-61-6)”, “alkenes, C₁₈₋₂₂, mixed with polyethylene, oxidized, hydrolyzed, distn. residues from C₂₀₋₂₂ alcs. manuf. (CAS Reg. No. 1430895-62-7)”.

The addition reads as follows:

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

(a) * * *

Table 1 to 180.940(a)

Inert ingredients	CAS Reg. No.	Limits
* * * *	* * *	
1-undecanol	112-42-5	Carrier/Adjuvant and Coating Agent/Binder
1-tetradecanol	112-72-1	
1-octadecanol	112-92-5	
1-eicosanol	629-96-9	
1-docosanol	661-19-8	
alcohols, C ₁₆₋₁₈ , distn. residues	68603-17-8 1190630-03-5	
alkenes, C ₁₈₋₂₂ , mixed with polyethylene, oxidized, hydrolyzed, distn. residues from C ₁₆₋₁₈ alcs. manuf.	1430895-61-6	
alkenes, C ₁₈₋₂₂ , mixed with polyethylene, oxidized,	1430895-62-7	

hydrolyzed, distn. residues from C ₂₀₋₂₂ alcs. manif.		
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