ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

Alcohols, C10–16, Ethoxylated, Sulfates, Mono(hydroxyethyl)ammonium Salts (CAS No. 157627–92–4); 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 alcohols, C10–16, ethoxylated, sulfates, mono(hydroxyethyl)ammonium salts (CAS No. 157627–92–4); when used as an inert ingredient in pesticide formulations used pre- and post-harvest as well as in formulations applied to livestock. Spring Regulatory Sciences, on behalf of BASF Corporation, submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting an exemption from the requirement of a tolerance for specific uses. This regulation eliminates the need to establish a maximum permissible level for residues of alcohols, C10–16, ethoxylated, sulfates, mono(hydroxyethyl)ammonium salts (CAS No. 157627–92–4) on food or feed commodities or when applied to livestock.

DATES: This regulation is effective February 2, 2022. Objections and requests for hearings must be received on or before April 4, 2022, 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–2021–0656, 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 is (202) 566–1744, and the telephone number for the OPP Docket is (703) 305–5805.

Due to the public health concerns related to COVID–19, the EPA Docket Center (EPA/DC) and Reading Room is closed to visitors with limited exceptions. The staff continues to provide remote customer service via email, phone, and webform. For the latest status information on EPA/DC services and docket access, visit https://www.epa.gov/dockets.

FOR FURTHER INFORMATION CONTACT: Marietta Echeverria, 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: RDRFNotices@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?


C. 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–2021–0656 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 April 4, 2022. 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–2021–0656, 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), EPA issued a document pursuant to FFDCA section 408, 21 U.S.C. 346a, announcing the receipt of a pesticide petition (PP IN–11530) filed by Spring Regulatory Sciences (6620 Cypresswood Dr. Suite 250, Spring, TX 77379), on behalf of BASF Corporation (100 Park Avenue, Florham Park, New Jersey 07932). The petition requested that 40 CFR 180.910 and 180.930 be amended by establishing an exemption from the requirement of a tolerance for residues of alcohols, C10–16, ethoxylated, sulfates, mono(hydroxyethyl)ammonium salts (CAS No. 157627–92–4) for use as an inert ingredient at no more than 30% by weight of the final pesticide formulation. That document included a summary of the petition prepared by the petitioner and solicited comments on the petition’s request. The Agency did not receive any public comments.

III. Inert Ingredient Definition

Inert ingredients are all ingredients that are not active ingredients as defined in 40 CFR 153.123, 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. Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is “safe.” Section 408(b)(2)(A)(ii) of FFDCA defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” This includes exposure through drinking water and in residential settings but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue.”

EPA establishes exemptions from the requirement of a tolerance only in those cases where it can be shown that the risks from aggregate exposure to pesticide chemical residues under reasonably foreseeable circumstances will pose no appreciable risks to human health. In order to determine the risks from aggregate exposure to pesticide inert ingredients, the Agency considers the toxicity of the inert in conjunction with possible exposure to residues of the inert ingredient through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings. If EPA is able to determine that a finite tolerance is not necessary to ensure that there is a reasonable certainty that no harm will result from aggregate exposure to the inert ingredient, an exemption from the requirement of a tolerance may be established.

Consistent with FFDCA section 408(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 alcohols, C10–16, ethoxylated, sulfates, mono(hydroxyethyl)ammonium salts including exposure resulting from the exemption established by this action. EPA’s assessment of exposures and risks associated with alcohols, C10–16, ethoxylated, sulfates, mono(hydroxyethyl)ammonium salts follows.

In an effort to streamline its publications in the Federal Register, EPA is not reprinting sections that repeat what has been previously published for tolerance rulemakings of the same pesticide chemical. Where scientific information concerning a particular chemical remains unchanged, the content of those sections would not vary between tolerance rulemakings, and republishing the same sections is unnecessary. EPA considers referral back to those sections as sufficient to provide an explanation of the information EPA considered in making its safety determination for the new rulemaking.

EPA has previously published tolerance rulemakings for alkyl alcohol alkoxylate phosphate derivatives (AAAPDs) and alkyl alcohol alkoxylate sulfate derivatives (AAASDs), in which EPA concluded, based on the available information, that there is a reasonable certainty that no harm would result from aggregate exposure to AAAPDs and AAASDs, and established tolerances for residues of those chemicals. EPA is incorporating previously published sections from that rulemaking as described further in this rulemaking, as they remain unchanged. The past rule EPA cites here covers AAAPDs and AAASDs, which are collectively referred to as alkyl alcohol alkoxylate phosphate and sulfate derivatives (AAAPSDs). Alcohols, C10–16, ethoxylated, sulfates, mono(hydroxyethyl)ammonium salts (CAS No. 157627–92–4) and other AAAPSDs previously assessed by EPA, the data used in the 2009 risk assessment for AAAPSDs is considered appropriate to assess alcohols, C10–16, ethoxylated, sulfates, mono(hydroxyethyl)ammonium salts.

A. Toxicological Profile

The Toxicological Profile of alcohols, C10–16, ethoxylated, sulfates, mono(hydroxyethyl)ammonium salts remain unchanged from the Toxicological Profile in Unit IV.A. of the July 29, 2009 rulemaking (74 FR 37571) (FRL–8424–6). Refer to that section for a discussion of the Toxicological Profile of AAAPSDs.

B. Toxicological Points of Departure/Levels of Concern

The Toxicological Points of Departure/Levels of Concern of alcohols, C10–16, ethoxylated, sulfates, mono(hydroxyethyl)ammonium salts remain unchanged from the Toxicological Profile in Unit IV.B of the July 29, 2009 rulemaking (74 FR 37571) (FRL–8424–6). Refer to that section for a discussion of the Toxicological Points of Departure/Levels of Concern of AAAPSDs.

C. Exposure Assessment

The exposure assessment for alcohols, C10–16, ethoxylated, sulfates, mono(hydroxyethyl)ammonium salts remain unchanged from the July 29, 2009 rulemaking and supporting human health risk assessment (D365210, June 8, 2009). Provided that the AAAPSDs are limited to no more than 30% by weight in the final formulation, there were no dietary, residential or aggregate risks of concern for the U.S. population and all subpopulations. No occupational risks of concern were identified when assuming that mixer/loader/applicators will wear chemical-resistant gloves. Based on this human health risk assessment, an exemption from the requirement of a tolerance was established under 40 CFR 180.920 for pre-harvest use of AAAPDs to no more than 30% by weight in pesticide end-use products. This risk assessment also supported the use of the AAASD inert ingredients in pesticide formulations intended for use pre- and post-harvest (40 CFR 180.910) as well as for use on livestock (40 CFR 180.930). Therefore, provided alcohols, C10–16, ethoxylated, sulfates, mono(hydroxyethyl)ammonium salts are limited to no more than 30% by weight in the final formulation, there
are no dietary, residential or aggregate risks of concern for the U.S. population and all subpopulations. As a result, the Agency has determined that a tolerance is not necessary to protect public health.

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 alcohols, C10–16, ethoxylated, sulfates, mono(hydroxyethyl)ammonium salts share a common mechanism of toxicity with any other substances, and alcohols, C10–16, ethoxylated, sulfates, mono(hydroxyethyl)ammonium salts do not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that alcohols, C10–16, ethoxylated, sulfates, mono(hydroxyethyl)ammonium salts do 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. Additional Safety Factor for the Protection of 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 data base unless EPA concludes that a different margin of safety will be safe for infants and children. EPA continues to conclude that there is reliable data showing that the safety of infants and children would be adequately protected if the Food Quality Protection Act (FQPA) safety factor were reduced from 10x to 1x. The reasons for that decision are articulated in Unit IV.D. of the July 29, 2009 rulemaking.

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 alcohols, C10–16, ethoxylated, sulfates, mono(hydroxyethyl)ammonium salts. More detailed information about the Agency’s analysis can be found at https://www.regulations.gov in the documents titled “Alkyl Alcohol Alkoxylate Phosphate and Sulfate Derivatives (AAAPDs and AAASDs—JITF CST 2 Inert Ingredients). Human Health Risk Assessment to Support Proposed Exemption from the Requirement of a Tolerance When Used as Inert Ingredients in Pesticide Formulations” and “IN–11530; Petition to Add Alcohols, C10–16, Ethoxylated, Sulfates, Mono(hydroxyethyl)ammonium Salts (CAS No. 157627–92–4) to the Current Tolerance Exemption for Alkyl Alcohol Alkoxylate Phosphate and Sulfate Derivatives (AAAPSDs)”. These documents can be found in docket ID numbers EPA–HQ–OPP–2009–0131 and EPA–HQ–OPP–2021–0656.

V. Other Considerations

A. Analytical Enforcement Methodology

An analytical method is not required for enforcement purposes since the Agency is not establishing a numerical tolerance for residues of alcohols, C10–16, ethoxylated, sulfates, mono(hydroxyethyl)ammonium salts in or on any food commodities. EPA is establishing a limitation on the amount of alcohols, C10–16, ethoxylated, sulfates, mono(hydroxyethyl)ammonium salts that may be used in pesticide formulations. This 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 food use that exceeds 30% by weight of alcohols, C10–16, ethoxylated, sulfates, mono(hydroxyethyl)ammonium salts in the final pesticide formulation.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established a MRL for alcohols, C10–16, ethoxylated, sulfates, mono(hydroxyethyl)ammonium salts.

VI. Conclusion

EPA finds that exempting residues of alcohols, C10–16, ethoxylated, sulfates, mono(hydroxyethyl)ammonium salts from the requirement of a tolerance will be safe. Therefore, an exemption from the requirement of a tolerance is established under 40 CFR 180.910 and 180.930 for alcohols, C10–16, ethoxylated, sulfates, mono(hydroxyethyl)ammonium salts when used as an inert ingredient at no more than 30% by weight in pesticide formulations.

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 12988, 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: January 20, 2022.

Marietta Echeverria,
Acting 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:


2. In § 180.910, revise the inert ingredient(s) in the table 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

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<th>Inert ingredients</th>
<th>Limits</th>
<th>Uses</th>
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\(-alkyl(C_6-C_{15})-\)

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

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<tr>
<th>Inert ingredients</th>
<th>Limits</th>
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<tr>
<td>- Not to exceed 30% of formulation.</td>
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<td>Surfactants, related adjuvants of surfactants.</td>
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