PART 174—[AMENDED]

1. The authority citation for part 174 continues to read as follows:


2. Add § 174.532 to subpart W to read as follows:

§ 174.532 Bacillus thuringiensis eCry3.1Ab protein in corn; temporary exemption from the requirement of a tolerance.

Residues of Bacillus thuringiensis eCry3.1Ab protein in corn, in or on the food and feed commodities of corn; corn field; corn, sweet; and corn, pop are exempt temporarily from the requirement of a tolerance when Bacillus thuringiensis eCry3.1Ab protein in corn is used as a plant-incorporated protectant in accordance with the terms of Experimental Use Permit 67979-EUP-8. This temporary exemption from the requirement of a tolerance expires and is revoked on June 16, 2012.

[FR Doc. 2010–14330 Filed 6–15–10; 8:45 am]
BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180


Sodium 1,4-Dialkyl Sulfosuccinates; 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 sodium 1,4-dialkyl sulfosuccinates including sodium 1,4-dihexyl sulfosuccinate (CAS Reg. No. 3006–15–3); sodium 1,4-diisobutyl sulfosuccinate (CAS Reg. No. 127–39–9); and sodium 1,4-dipentyl sulfosuccinate (CAS Reg. No. 922–80–5) when used as an inert ingredient in pesticide formulations for pre-harvest and post-harvest uses, as well as, for application to animals under 40 CFR 180.910 and 40 CFR 180.930, respectively. The Joint Inerts Task Force (JITF), Cluster Support Team 13 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 the sodium 1,4-dialkyl sulfosuccinates.

DATES: This regulation is effective June 16, 2010. Objections and requests for hearings must be received on or before August 16, 2010, 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: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2008–0739. All documents in the docket are listed in the docket index available at http://www.regulations.gov. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at http://www.regulations.gov, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5005.

FOR FURTHER INFORMATION CONTACT: Karen Samek, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 347–8825; e-mail address: samek.karen@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. Potentially affected entities may include, but are not limited to:

• Crop production (NAICS code 111).
• Animal production (NAICS code 112).

• Food manufacturing (NAICS code 311).
• Pesticide manufacturing (NAICS code 32532).

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under FOR FURTHER INFORMATION CONTACT.

B. How Can I Get Electronic Access to Other Related Information?


C. Can I File an Objection or Hearing Request?

Under section 408(g) of FFDCA, 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. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. 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–2008–0739 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 August 16, 2010. 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 that does not contain any CBI for inclusion in the public docket that is described in ADDRESSES. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit your copies, identified by docket ID number
II. Petition for Exemption

In the Federal Register of March 19, 2010 (75 FR 13277) (FRL–8813–2), EPA issued a notice pursuant to section 408 of FFDCA, 21 U.S.C. 346a, announcing the filing of a pesticide petition (PP 9E7647) by the Joint Inerts Task Force, Cluster Support Team 13, EPA Company Number 84949, c/o CropLife America, 1156 15th St., NW., Suite 400, Washington, DC 20005. The petition requested that 40 CFR 180.910 and 40 CFR 180.930 be amended by establishing exemptions from the requirement of a tolerances for residues of sodium 1,4-diaryl sulfosuccinates including sodium 1,4-dihexyl sulfosuccinate (CAS Reg. No. 3006–15–3); sodium 1,4-dioctyl sulfosuccinate (CAS Reg. No. 127–39–9); and sodium 1,4-dipentyl sulfosuccinate (CAS Reg. No. 922–80–5) when used as inert ingredients in pesticide formulations for pre-harvest and post-harvest uses, as well as, for application to animals. For ease of reading this document the sodium 1,4-diaryl sulfosuccinates will be referred to as SDSS. That notice referenced a summary of the petition prepared by the Joint Inerts Task Force (JITF), Cluster Support Team Number 13 (CST 13), the petitioner, which is available in the docket, http://www.regulations.gov. No comments were received in the docket. However, the Agency received one comment by e-mail. The comment was received from a private citizen who opposed the authorization to sell any pesticide that leaves a residue on food. The Agency understands the commenter’s concerns and recognizes that some individuals believe that no residue of pesticides should be allowed. However, under the existing legal framework provided by section 408 of the FFDCA EPA is authorized to establish pesticide tolerances or exemptions where persons seeking such tolerances or exemptions have demonstrated that the pesticide meets the safety standard imposed by that statute.

EPA previously published a final rule to establish a tolerance for SDSS under 40 CFR 180.920 in the Federal Register of July 8, 2009 (74 FR 32433) (FRL–8423–3). That final rule established a tolerance exemption for SDSS when used as an inert ingredient in pesticide formulations applied to growing crops only.

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(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 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 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 section 408(c)(2)(A) of FFDCA, 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 SDSS including exposure resulting from the exemption established by this action. EPA’s assessment of exposures and risks associated with SDSS 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.

SDSS have moderate to low acute oral toxicity and low dermal acute toxicity. There was no hazard identified in a combined repeat dose rat reproductive/developmental screening study at the limit dose of 1,000 milligrams/kilogram/day (mg/kg/day) to either parental animals or their offspring. There is no concern for neurotoxicity, immunotoxicity or carcinogenicity for SDSS.

Specific information on the studies received and the nature of any observed effects caused by SDSS 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://

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 no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). 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 (RID) – 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.

There was no hazard identified in a combined repeated dose toxicity study with the reproduction/developmental toxicity screening test in rats with SDSS at the limit dose of 1,000 mg/kg/day to either parental animals or their offspring. Thus, due to their low potential hazard and lack of a hazard endpoint, the Agency has determined that a quantitative risk assessment using safety factors applied to a POD protective of an identified hazard endpoint is not appropriate.

No mutagenicity, genotoxicity, or chronic toxicity data have been located for any of the SDSS. However, no structural alerts for genotoxicity or carcinogenicity were identified in a qualitative structure activity relationship (QSAR) database, DEREK Version 11. In addition, data for similar compounds showed they are not mutagenic or carcinogenic. The primary alcohol mammalian metabolites of SDSS have been shown to be negative in the in vitro Ames test. Furthermore, a structurally similar compound that is also used as an inert ingredient, sodium diocyl sulfosuccinate (CAS Reg. No. 577–11–7) was not mutagenic, or carcinogenic in a chronic rat study or a tumor promotion study. Based on the above, SDSS are not expected to be carcinogenic.

C. Exposure Assessment

1. Dietary exposure from food and feed uses and drinking water. Since an endpoint for risk assessment was not identified, an exposure assessment for SDSS was not conducted. Any possible dietary exposure of SDSS from their use as inert ingredients in pesticide products would be through consumption of food to which pesticide products containing SDSS have been applied and through drinking water (from runoff). There is no non-dietary exposure.

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). Since an endpoint for risk assessment was not identified, a quantitative residential exposure assessment for SDSS was not conducted. Residential exposures to SDSS may occur as a result of the use of pesticide products containing SDSS as inert ingredients (such as antimicrobial hard surface cleaners) as well as from other, non pesticidal, residential use products containing SDSS.

3. 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 SDSS to share a common mechanism of toxicity with any other substances, and SDSS does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that SDSS 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 http://www.epa.gov/pesticides/cumulative.

D. Safety Factor for Infants and Children

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.

The toxicity database for SDSS is adequate for FQPA assessment and the potential exposure is adequately characterized given the low toxicity of the chemical. There was no hazard identified in a combined repeat dose rat reproductive/developmental screening study at the limit dose of 1,000 mg/kg/ day to either parental animals or their offspring. There is no concern for neurotoxicity, immunotoxicity or carcinogenicity for SDSS.

Based on this information, there is no concern, at this time, for increased sensitivity to infants and children to SDSS when used as inert ingredients in pesticide formulations for pre-harvest and post-harvest uses, as well as for application to animals, therefore a safety factor analysis has not been used to assess risk. For the same reason, EPA has determined that an additional safety factor is not needed to protect the safety of infants and children.

E. Aggregate Risks and Determination of Safety

Given the lack of concern for hazard posed by SDSS, EPA concludes that there are no dietary or aggregate dietary/ non-dietary risks of concern as a result of exposure to SDSS in food and water or from residential exposure.

Taking into consideration all available information on SDSS, EPA has determined that there is a reasonable certainty that no harm to any population subgroup will result from aggregate exposure to SDSS under reasonable foreseeable circumstances. Therefore, the establishment of an exemption from tolerance under section 40 CFR 180.910 and 40 CFR 180.930 for sodium 1,4-dialkyl sulfosuccinates including sodium 1,4-dihexyl sulfosuccinate (CAS
Reg. No. 3006–15–3); sodium 1,4-diisobutyl sulfosuccinate (CAS Reg. No. 127–39–9); and sodium 1,4-dipentyl sulfosuccinate (CAS Reg. No. 922–80–5) when used as an inert ingredient in pesticide formulations for pre-harvest and post-harvest uses, as well as, for application to animals, is safe under FFDCA section 408.

V. Other Considerations

A. 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.

B. International Residue Limits

The Agency is not aware of any country requiring a tolerance for SDSS nor have any CODEX Maximum Residue Levels been established for any food crops at this time.

VI. Conclusions

Therefore, an exemption from the requirement of a tolerance is established under 40 CFR 180.910 and 40 CFR 180.930 for sodium 1,4-dialkyl sulfosuccinates including sodium 1,4-dihexyl sulfosuccinate (CAS Reg. No. 3006–15–3); sodium 1,4-diisobutyl sulfosuccinate (CAS Reg. No. 127–39–9); and sodium 1,4-dipentyl sulfosuccinate (CAS Reg. No. 922–80–5) when used as an inert ingredient in pesticide formulations for pre-harvest and post-harvest uses, as well as, for application to animals.

VII. Statutory and Executive Order Reviews

This final rule establishes a tolerance under section 408(d) of FFDCA 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 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 section 408(d) of FFDCA, such as the exemptions 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 final rule 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 section 408(n)(4) of FFDCA. 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 13175, entitled Consultation and Coordination with Indian Tribal Governments (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4).

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 of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note).

VIII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 et seq., generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report to each House of the Congress and to the Comptroller General of the United States. 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 this final rule in the Federal Register. This final rule is not a “major rule” as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180


Daniel J. Rosenblatt, Acting 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:


2. In §180.910, the table is amended by adding alphabetically the following inert ingredients to read as follows:

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

<table>
<thead>
<tr>
<th>Inert Ingredients</th>
<th>Limits</th>
<th>Uses</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium 1,4-dihexyl sulfosuccinate (CAS Reg. No. 3006–15–3).</td>
<td>* *</td>
<td>Surfactants, related adjuvants of surfactants</td>
</tr>
<tr>
<td>Sodium 1,4-diisobutyl sulfosuccinate (CAS Reg. No. 127–39–9).</td>
<td>* *</td>
<td>Surfactants, related adjuvants of surfactants</td>
</tr>
<tr>
<td>Sodium 1,4-dipentyl sulfosuccinate (CAS Reg. No. 922–80–5).</td>
<td>* *</td>
<td>Surfactants, related adjuvants of surfactants</td>
</tr>
</tbody>
</table>
In § 180.930, the table is amended by adding alphabetically the following inert ingredients to read as follows:

<table>
<thead>
<tr>
<th>Inert Ingredients</th>
<th>Limits</th>
<th>Uses</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium 1,4-dihexyl sulfosuccinate (CAS Reg. No. 3006–15–3).</td>
<td>* * * * *</td>
<td>Surfactants, related adjuvants of surfactants</td>
</tr>
<tr>
<td>Sodium 1,4-diisobutyl sulfosuccinate (CAS Reg. No. 127–39–9).</td>
<td>* * * * *</td>
<td>surfactants</td>
</tr>
<tr>
<td>Sodium 1,4-dipentyl sulfosuccinate (CAS Reg. No. 922–80–5).</td>
<td>* * * * *</td>
<td>surfactants</td>
</tr>
</tbody>
</table>

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

Collectively and individually receive payments that are less than their respective legitimate and prudent expenses incurred in connection with the preparation, filing and advocacy of the Counterproposal. Each party filed a declaration in accordance with Section 1.420(j), containing an itemization of its respective legitimate and prudent expenses. The Joint Parties and Cumulus each state in its respective declaration that aside from the Settlement Agreement, neither respective licensee nor any of its members, officers, or employees is a party to any agreement, written or oral, that will require the respective licensee to pay or receive any monies or provide or receive any other consideration from or to the existing and former licensee for the actions described in each respective declaration.

Address: Federal Communications Commission, 445 12th Street, SW., Washington, DC 20554.

For further information contact: Rolanda F. Smith, Media Bureau, (202) 418–2180.

Supplementary information: This is a summary of the Commission's Memorandum Opinion and Order, MB Docket No. 05–10, adopted May 21, 2010, and released May 24, 2010. The full text of this Commission document is available for inspection and copying during normal business hours in the FCC Reference Information Center (Room CY–A257), 445 12th Street, SW., Washington, DC.

The complete text of this decision may also be purchased from the Commission's copy contractor, Best Copy and Printing, Inc., 445 12th Street, SW, Room CY–B402, Washington, DC 20554, 800–378–3160 or via the company's website, <http://www.bcpiweb.com>.

The Commission will not send a copy of this Memorandum Opinion and Order pursuant to the Congressional Review Act, see 5 U.S.C. 801(a)(1)(A), because the aforementioned petition for reconsideration was dismissed.

This document does not contain proposed information collection requirements subject to the Paperwork Reduction Act of 1995, Public Law 104–13. In addition, therefore, it does not contain any proposed information collection burden “for small business concerns with fewer than 25 employees,” pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107–198, see 44 U.S.C. 3506(c)(4).

Provisions of the Regulatory Flexibility Act of 1980 do not apply to this proceeding.

List of Subjects in 47 CFR Part 73

Federal Communications Commission.

John A. Karousos,
Assistant Chief,
Audio Division,
Media Bureau.