



ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2019-0607; FRL-10022-79]

Poly(oxy-1,2-ethanediyl), α , α' -{[4-[(3-sulfophenyl)azo]phenyl]imino}di-2,1-ethanediyl}bis[ω -hydroxy-, monosodium salt; 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 Poly(oxy-1,2-ethanediyl), α , α' -{[4-[(3-sulfophenyl)azo]phenyl]imino}di-2,1-ethanediyl}bis[ω -hydroxy-, monosodium salt when used as an inert ingredient (colorant) in pesticide formulations applied to seed treatment slurries for raw agricultural commodities and not to exceed 20% weight/weight (wt/wt). Milliken Chemical 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 Poly(oxy-1,2-ethanediyl), α , α' -{[4-[(3-sulfophenyl)azo]phenyl]imino}di-2,1-ethanediyl}bis[ω -hydroxy-, monosodium salt.

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-2019-0607, 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.

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: 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 FFDC 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-2019-0607 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-2019-0607, 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 (PP IN-11359) by Milliken Chemical, 920 Milliken Rd. M-209 Spartanburg, SC 29303. The petition requested that 40 CFR 180.920 be amended by establishing an exemption from the requirement of a tolerance for residues of Poly(oxy-1,2-ethanediyl), α , α' -[[4-[(3-sulfophenyl)azo]phenyl]imino]di-2,1-ethanediyl]bis[ω -hydroxy-, monosodium salt (CAS Reg. No. N/A) when used as an inert ingredient (colorant) in pesticide formulations applied to seed treatment slurries for raw agricultural commodities not to exceed 20% (wt/wt). That document referenced a summary of the petition prepared by Milliken Chemical, 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 tolerance is “safe.” Section 408(c)(2)(A)(ii) of FFDCa defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other

exposures for which there is reliable information.” This includes exposure through drinking water and in residential settings but does not include occupational exposure. Section 408(b)(2)(C) and (c)(2)(B) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance or 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....”

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 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 Poly(oxy-1,2-ethanediyl), α, α' -[[4-[(3-sulfophenyl)azo]phenyl]imino]di-2,1-ethanediyl}bis[ω -hydroxy-, monosodium salt including exposure resulting from the exemption established by this action. EPA's assessment of exposures and risks associated with Poly(oxy-1,2-ethanediyl), α, α' -[[4-[(3-sulfophenyl)azo]phenyl]imino]di-2,1-ethanediyl}bis[ω -hydroxy-, monosodium salt 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 Poly(oxy-1,2-ethanediyl), α , α' -{[4-[(3-sulfophenyl)azo]phenyl]imino}di-2,1-ethanediyl}bis[ω -hydroxy-, monosodium salt as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies are discussed in this unit.

In acute studies, exposure to Poly(oxy-1,2-ethanediyl), α , α' -{[4-[(3-sulfophenyl)azo]phenyl]imino}di-2,1-ethanediyl}bis[ω -hydroxy-, monosodium salt resulted in no observable or minimal toxicity. The acute oral median lethal dose (LD₅₀) in rats is > 2,000 mg/kg. Minimal dermal irritation was observed in an acute dermal study with rabbits. No indications of sensitization have been observed in local lymph node assay.

Two reverse mutation assays (OECD 471), a mouse lymphoma assay (OECD 476) and an in vitro micronucleus test (OECD 487) found Poly(oxy-1,2-ethanediyl), α , α' -{[4-[(3-sulfophenyl)azo]phenyl]imino}di-2,1-ethanediyl}bis[ω -hydroxy-, monosodium salt to not be mutagenic.

In a combined repeat dose developmental/reproduction study (OECD 422), there were no adverse effects from oral administration of Poly(oxy-1,2-ethanediyl), α , α' -{[4-[(3-sulfophenyl)azo]phenyl]imino}di-2,1-ethanediyl}bis[ω -hydroxy-, monosodium salt up to 1000 mg/kg/day on any parameter measured, including gonadal function, mating performance, conception, development of the conceptus or parturition. The NOAEL for these parameters was 1000 mg/kg/day for males and females. The NOAEL for reproductive performance and fetal/developmental toxicity was also considered to be 1,000 mg/kg/day.

B. Toxicological Points of Departure/Levels of Concern

Based on available studies provided for Poly(oxy-1,2-ethanediyl), α , α' -{[4-[(3-sulfophenyl)azo]phenyl]imino}di-2,1-ethanediyl}bis[ω -hydroxy-, monosodium salt, no toxicological endpoint of concern was identified, and a quantitative risk assessment is not required for this compound.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to Poly(oxy-1,2-ethanediyl), α , α' -{[4-[(3-sulfophenyl)azo]phenyl]imino}di-2,1-ethanediyl}bis[ω -hydroxy-, monosodium salt, EPA considered exposure under the proposed exemption from the requirement of a tolerance. EPA assessed dietary exposures from Poly(oxy-1,2-ethanediyl), α , α' -{[4-[(3-sulfophenyl)azo]phenyl]imino}di-2,1-ethanediyl}bis[ω -hydroxy-, monosodium salt in food as follows:

Dietary exposure (food and drinking water) to Poly(oxy-1,2-ethanediyl), α , α' -{[4-[(3-sulfophenyl)azo]phenyl]imino}di-2,1-ethanediyl}bis[ω -hydroxy-, monosodium salt is not expected to occur due to its intended use as a colorant for seed treatment. Seed treatment formulas containing Poly(oxy-1,2-ethanediyl), α , α' -{[4-[(3-sulfophenyl)azo]phenyl]imino}di-2,1-ethanediyl}bis[ω -hydroxy-, monosodium salt will be applied directly to seeds and if released into the environment, the colorant would not be taken up by the germinating seedling and translocated within the plant vascular system to result in crop residues and dietary exposures.

2. *Dietary exposure from drinking water.* Since a hazard endpoint of concern was not identified for the acute and chronic dietary assessment, a quantitative dietary exposure risk assessment for drinking water was not conducted.

3. *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).

Poly(oxy-1,2-ethanediyl), α , α' -{[4-[(3-sulfophenyl)azo]phenyl]imino}di-2,1-ethanediyl}bis[ω -hydroxy-, monosodium salt may be used in pesticide products and non-pesticide products used in and around the home that would have residential exposures. However, because no toxicological endpoint of concern was identified, a quantitative residential exposure assessment for Poly(oxy-1,2-ethanediyl), α , α' -{[4-[(3-sulfophenyl)azo]phenyl]imino}di-2,1-ethanediyl}bis[ω -hydroxy-, monosodium salt was not conducted.

4. *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 or exemption, 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 Poly(oxy-1,2-ethanediyl), α , α' -{[[4-[(3-sulfophenyl)azo]phenyl]imino]di-2,1-ethanediyl}bis[ω -hydroxy-, monosodium salt to share a common mechanism of toxicity with any other substances, and Poly(oxy-1,2-ethanediyl), α , α' -{[[4-[(3-sulfophenyl)azo]phenyl]imino]di-2,1-ethanediyl}bis[ω -hydroxy-, monosodium salt does not appear to produce a toxic metabolite produced by other substances. For the purposes of this action, therefore, EPA has assumed that poly(oxy-1,2-ethanediyl), α , α' -{[[4-[(3-sulfophenyl)azo]phenyl]imino]di-2,1-ethanediyl}bis[ω -hydroxy-, monosodium salt 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

Based on the lack of threshold effects, EPA has not identified any toxicological endpoints of concern and is conducting a qualitative assessment of poly(oxy-1,2-ethanediyl), α , α' -{[[4-[(3-sulfophenyl)azo]phenyl]imino]di-2,1-ethanediyl}bis[ω -hydroxy-, monosodium salt. That 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 poly(oxy-1,2-ethanediyl), α , α' -{[[4-[(3-sulfophenyl)azo]phenyl]imino]di-2,1-ethanediyl}bis[ω -hydroxy-, monosodium salt, 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

Taking into consideration all available information on poly(oxy-1,2-ethanediyl), α , α' -{[[4-[(3-sulfophenyl)azo]phenyl]imino]di-2,1-ethanediyl}bis[ω -hydroxy-, monosodium salt when

used as an inert ingredient (colorant) in pesticide formulations applied to seed treatment slurries for raw agricultural commodities and not to exceed 20% (wt/wt), EPA has determined that there is a reasonable certainty that no harm to the general population or any population subgroup, including infants and children, will result from aggregate exposure to poly(oxy-1,2-ethanediyl), α , α' -[[4-[(3-sulfophenyl)azo]phenyl]imino]di-2,1-ethanediyl}bis[ω -hydroxy-, monosodium salt. Therefore, the establishment of an exemption from tolerance under 40 CFR 180.920 for residues of poly(oxy-1,2-ethanediyl), α , α' -[[4-[(3-sulfophenyl)azo]phenyl]imino]di-2,1-ethanediyl}bis[ω -hydroxy-, monosodium salt when used as an inert ingredient (colorant) in pesticide formulations applied to seed treatment slurries for raw agricultural commodities and not to exceed 20% (wt/wt), 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

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). Codex is a joint United Nation 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 poly(oxy-1,2-ethanediyl), α , α' -[[4-[(3-sulfophenyl)azo]phenyl]imino]di-2,1-ethanediyl}bis[ω -hydroxy-, monosodium salt.

VI. Conclusions

Therefore, an exemption from the requirement of a tolerance is established under 40 CFR 180.920 for poly(oxy-1,2-ethanediyl), α , α' -[[4-[(3-sulfophenyl)azo]phenyl]imino]di-2,1-ethanediyl}bis[ω -hydroxy-, monosodium salt (CAS Reg. No. N/A) when used as an inert ingredient (colorant) in pesticide formulations applied to seed treatment slurries for raw agricultural commodities and not to exceed 20% (wt/wt).

VII. Statutory and Executive Order Reviews

This action establishes an exemption from the requirement of a tolerance under FFDC section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled "Regulatory Planning and Review" (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use" (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled "Protection of Children from Environmental Health Risks and Safety Risks" (62 FR 19885, April 23, 1997). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations" (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDC section 408(d), such as the exemption in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or Tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDC

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: May 4, 2021.

Marietta Echeverria,

Acting Director, Registration Division, Office of Pesticide Programs.

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

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

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

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

2. In §180.920, amend the table by adding in alphabetical order the inert ingredient “Poly(oxy-1,2-ethanediyl), α , α' -{[[4-[(3-sulfophenyl)azo]phenyl]imino]di-2,1-ethanediyl}bis[ω -hydroxy-, monosodium salt” to read as follows:

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

* * * * *

Inert ingredients	Limits	Uses
* * * * *	* * * * *	* * * * *
Poly(oxy-1,2-ethanediyl), α , α' -{[[4-[(3-sulfophenyl)azo]phenyl]imino]di-2,1-ethanediyl}bis[ω -hydroxy-, monosodium salt	Not to exceed 20% by weight of pesticide formulation	Colorant
* * * * *	* * * * *	* * * * *