E 6560-50-P

**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 180**

**[EPA-HQ-OPP-2025-3360; FRL-13301-01-OCSPP]**

# Oxirane, 2-phenyl-, polymer with oxirane, mono(hydrogen 2-sulfobutanedioate), octyl ether, sodium salt (1:2) in Pesticide Formulations; Exemption from the Requirement for 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 oxirane, 2-phenyl-, polymer with oxirane, mono(hydrogen 2-sulfobutanedioate), octyl ether, sodium salt (1:2) (CAS Reg. No 2983072-24-6); (also known as oxirane, 2-phenyl-, polymer with oxirane, monooctyl ether, sulphosuccinated, disodium salt) when used as an inert ingredient in a pesticide chemical formulation under 40 CFR 180.960. Spring Regulatory Sciences on behalf of Evonik Corporation submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of oxirane, 2-phenyl-, polymer with oxirane, mono(hydrogen 2-sulfobutanedioate), octyl ether, sodium salt (1:2) on food or feed commodities 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 this document).

**ADDRESSES:** The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2025-3360, is available online at *https://www.regulations.gov*. Additional information

about dockets generally, along with instructions for visiting the docket in-person, is available at *https://www.epa.gov/dockets*.

**FOR FURTHER INFORMATION CONTACT:** Charles Smith, Registration Division (7505T), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW, Washington, DC 20460-0001; main telephone number: (202) 566-1030; 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).

If you have any questions regarding the applicability of this proposed action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. *What is EPA's authority for taking this action?*

EPA is issuing this rulemaking under section 408 of the FFDCA, 21 U.S.C. 346a. FFDCA section 408(c)(2)(A)(i) 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." FFDCA section 408(c)(2)(A)(ii) defines "safe" to mean that "there

is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings but does not include occupational exposure. Pursuant to FFDCA section 408(c)(2)(B), in establishing or maintaining in effect an exemption from the requirement of a tolerance, EPA must take into account the factors set forth in FFDCA section 408(b)(2)(C), which require 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.... " Additionally, FFDCA section 408(b)(2)(D) requires that the Agency consider, among other things, "available information concerning the cumulative effects of a particular pesticide's residues" and "other substances that have a common mechanism of toxicity."

C. *How can I file an objection or hearing request?*

Under FFDCA 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. If you fail to file an objection to the final rule within the time period specified in the final rule, you will have waived the right to raise any issues resolved in the final rule. 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 the docket ID number EPA-HQ-OPP-2025-3360 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*]**.

EPA's Office of Administrative Law Judges (OALJ), in which the Hearing Clerk is housed, urges parties to file and serve documents by electronic means only, notwithstanding any other particular requirements set forth in other procedural rules governing those proceedings. *See*

"Order Urging Electronic Filing and Service," dated December 3, 2025, which can be found at *https://www.epa.gov/system/files/documents/2025-12/2025-12-03-order-urging-electronic-filing-and-service.pdf*. Although EPA's regulations require submission via U.S. Mail or hand delivery, EPA intends to treat submissions filed via electronic means as properly filed submissions; therefore, EPA believes the preference for submission via electronic means will not be prejudicial. When submitting documents to the OALJ electronically, a person should utilize the OALJ e-filing system at *https://yosemite.epa.gov/oa/eab/eab-alj_upload.nsf*.

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 at *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. If you wish to include CBI in your request, please follow the applicable instructions at *https://www.epa.gov/dockets/commenting-epa-dockets#rules* and clearly mark the information that you claim to be CBI. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice.

**II. Petition for Exemption**

In the *Federal Register* of January 28, 2026 (91 FR 3701) (FRL-12474-11-OCSPP), EPA published a notice pursuant to FFDCA section 408, 21 U.S.C. 346a, announcing the receipt of a pesticide petition (PP IN-11999) filed by Spring Regulatory Sciences on behalf of Evonik Corporation, 7801 Whitepine Road, Richmond, VA 23237. The petition requested that 40 CFR 180.960 be amended by establishing an exemption from the requirement of a tolerance for residues of oxirane, 2-phenyl-, polymer with oxirane, mono(hydrogen 2-sulfobutanedioate), octyl ether, sodium salt (1:2) (CAS Reg. No 2983072-24-6). That document included a summary of the petition prepared by Spring Regulatory Sciences on behalf of Evonik Corporation, the petitioner, which is available in the docket.

The Agency received one comment from a private citizen expressing concerns regarding the Agency not fully evaluating submitted data, the need for aggregate and cumulative exposure considerations, and application of the Food Quality Protection Act (FQPA) safety factor as well as concerns for chemical-resistant pests. The notice EPA published on January 28, 2026, is a procedural action through which the Agency gives notice of the receipt of a petition and solicits public comment prior to completing its scientific evaluation. The statement that the Agency has not fully evaluated the submitted data reflects this statutory design and does not indicate a deficiency in the petition. As outlined in the following sections of this final rule, the Agency has made a safety determination based on the low-risk polymer criteria under 40 CFR 723.250. Additionally, aggregate exposure, cumulative effects, and the need for the FQPA safety factor for infants and children are addressed within this final rule. Since no toxicity endpoints of concern were identified, the FQPA safety factor was not used and aggregate risks were assessed qualitatively. No common mechanisms of toxicity warranting a cumulative assessment were identified. For more details, please see units IV.A. through IV.D. of this document. To the extent the comment raises issues pertaining to other regulatory actions, the Agency is responding herein only as they relate to the action at hand. The commenter is encouraged to submit comments on those separate actions through the appropriate dockets, provided the applicable comment periods remain open.

**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. Final Tolerance Actions

A. *Aggregate Risk Assessment and Determination of Safety*

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), 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 oxirane, 2-phenyl-, polymer with oxirane, mono(hydrogen 2-sulfobutanedioate), octyl ether, sodium salt (1:2) including exposure resulting from the exemption established by this action. EPA's assessment of exposures and risks associated with oxirane, 2-phenyl-, polymer with oxirane, mono(hydrogen 2-sulfobutanedioate), octyl ether, sodium salt (1:2) follows.

B. *Low Risk Polymer Criteria*

In the case of certain chemical substances that are defined as polymers, the Agency has established a set of criteria to identify categories of polymers expected to present minimal or no risk. The definition of a polymer is given in 40 CFR 723.250(b) and the exclusion criteria for identifying these low-risk polymers are described in 40 CFR 723.250(d). Oxirane, 2-phenyl-,

polymer with oxirane, mono(hydrogen 2-sulfobutanedioate), octyl ether, sodium salt (1:2) conforms to the definition of a polymer given in 40 CFR 723.250(b) and meets the following criteria that are used to identify low-risk polymers.

1. The polymer is not a cationic polymer nor is it reasonably anticipated to become a cationic polymer in a natural aquatic environment.

2. The polymer does contain as an integral part of its composition at least two of the atomic elements carbon, hydrogen, nitrogen, oxygen, silicon, and sulfur.

3. The polymer does not contain as an integral part of its composition, except as impurities, any element other than those listed in 40 CFR 723.250(d)(2)(ii).

4. The polymer is neither designed nor can it be reasonably anticipated to substantially degrade, decompose, or depolymerize. An available biodegradation study supports that oxirane, 2-phenyl-, polymer with oxirane, mono(hydrogen 2-sulfobutanedioate), octyl ether, sodium salt (1:2) is not readily biodegradable (MRID 52502501).

5. The polymer is manufactured or imported from monomers and/or reactants that are already included on the TSCA Chemical Substance Inventory or manufactured under an applicable TSCA section 5 exemption.

6. The polymer is not a water absorbing polymer with a number average molecular weight (MW) greater than or equal to 10,000 Daltons.

7. The polymer does not contain certain perfluoroalkyl moieties consisting of a CF3- or longer chain length as listed in 40 CFR 723.250(d)(6).

Additionally, the polymer also meets as required the following exemption criteria: specified in 40 CFR 723.250(e):

• The polymer's number average MW of 1,900 Daltons is greater than 1,000 and less than 10,000 Daltons.

• The polymer contains less than 10% oligomeric material below MW 500 and less than 25% oligomeric material below MW 1,000.

• The polymer contains only reactive functional groups listed in 40 CFR 723.250(e)(1)(ii)(A).

Thus, oxirane, 2-phenyl-, polymer with oxirane, mono(hydrogen 2-sulfobutanedioate), octyl ether, sodium salt (1:2) meets the criteria for a polymer to be considered low risk under 40 CFR 723.250. Based on its conformance to the criteria in this unit, no mammalian toxicity is anticipated from dietary, inhalation, or dermal exposure to oxirane, 2-phenyl-, polymer with oxirane, mono(hydrogen 2-sulfobutanedioate), octyl ether, sodium salt (1:2).

C. *Exposure Assessment*

For the purposes of assessing potential exposure under this exemption, EPA considered that oxirane, 2-phenyl-, polymer with oxirane, mono(hydrogen 2-sulfobutanedioate), octyl ether, sodium salt (1:2) could be present in all raw and processed agricultural commodities and drinking water, and that non-occupational non-dietary exposure was possible. The number average MW of oxirane, 2-phenyl-, polymer with oxirane, mono(hydrogen 2-sulfobutanedioate), octyl ether, sodium salt (1:2) is 1,900 Daltons. Generally, a polymer of this size would be poorly absorbed through the intact gastrointestinal tract or through intact human skin. Since oxirane, 2-phenyl-, polymer with oxirane, mono(hydrogen 2-sulfobutanedioate), octyl ether, sodium salt (1:2) conforms to the criteria that identify a low-risk polymer, there are no concerns for risks associated with any potential exposure scenarios that are reasonably foreseeable. The Agency has determined that a tolerance is not necessary to protect the 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 found oxirane, 2-phenyl-, polymer with oxirane, mono(hydrogen 2-sulfobutanedioate), octyl ether, sodium salt (1:2) to share a common mechanism of toxicity with

any other substances, and oxirane, 2-phenyl-, polymer with oxirane, mono(hydrogen 2-sulfobutanedioate), octyl ether, sodium salt (1:2) does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance exemption, therefore, EPA has assumed that oxirane, 2-phenyl-, polymer with oxirane, mono(hydrogen 2-sulfobutanedioate), octyl ether, sodium salt (1:2) 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 *https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/cumulative-assessment-risk-pesticides*.

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 (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. Due to the expected low toxicity of oxirane, 2-phenyl-, polymer with oxirane, mono(hydrogen 2-sulfobutanedioate), octyl ether, sodium salt (1:2), EPA has not used a safety factor analysis to assess the risk. For the same reasons no additional safety factor is needed for assessing risk to infants and children.

F. *Determination of Safety*

Based on the conformance to the criteria used to identify a low-risk polymer, EPA concludes that there is a reasonable certainty of no harm to the U.S. population, including infants and children, from aggregate exposure to residues of oxirane, 2-phenyl-, polymer with oxirane, mono(hydrogen 2-sulfobutanedioate), octyl ether, sodium salt (1:2).

G. *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.

H. *Conclusion*

Accordingly, EPA finds that exempting residues of oxirane, 2-phenyl-, polymer with oxirane, mono(hydrogen 2-sulfobutanedioate), octyl ether, sodium salt (1:2) from the requirement of a tolerance will be safe.

**V. Statutory and Executive Order Reviews**

Additional information about these statutes and Executive Orders can be found at *https://www.epa.gov/laws-regulations/laws-and-executive-orders*.

A. *Executive Order 12866: Regulatory Planning and Review*

This action is exempt from review under Executive Order 12866 (58 FR 51735, October 4, 1993), because it establishes or modifies a pesticide tolerance or a tolerance exemption under FFDCA section 408 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.

B. *Executive Order 14192: Unleashing Prosperity Through Deregulation*

Executive Order 14192 (90 FR 9065, February 6, 2025) does not apply because actions that establish a tolerance under FFDCA section 408 are exempted from review under Executive Order 12866.

C. *Paperwork Reduction Act (PRA)*

This action does not impose an information collection burden under the PRA 44 U.S.C. 3501 *et seq*., because it does not contain any information collection activities.

D. *Regulatory Flexibility Act (RFA)*

This action is not subject to the RFA, 5 U.S.C. 601 *et seq*. The RFA applies only to rules subject to notice and comment rulemaking requirements under the Administrative Procedure Act (APA), 5 U.S.C. 553, or any other statute. This rule is not subject to the APA but is subject to FFDCA section 408(d), which does not require notice and comment rulemaking to take this action in response to a petition.

E. *Unfunded Mandates Reform Act (UMRA)*

This action does not contain an unfunded mandate of $100 million or more (in 1995 dollars and adjusted annually for inflation) as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. The action imposes no enforceable duty on any state, local or tribal governments or the private sector.

F. *Executive Order 13132: Federalism*

This action does not have federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999), because it will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

G. *Executive Order 13175: Consultation and Coordination with Indian Tribal Governments*

This action does not have Tribal implications as specified in Executive Order 13175 (65 FR 67249, November 9, 2000), because it will not have substantial direct effects on Tribal governments, on the relationship between the Federal government and the Indian Tribes, or on the distribution of power and responsibilities between the Federal government and Indian Tribes.

H. *Executive Order 13045: Protection of Children from Environmental Health Risks and Safety Risks*

This action is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997) because it is not a significant regulatory action under section 3(f)(1) of Executive Order 12866 (See Unit VI.A.), and because EPA does not believe the environmental health or safety risks addressed by this action present a disproportionate risk to children.

However, EPA's 2026 *Policy on Children's Health* applies to this action. This rule finalizes tolerance actions under the FFDCA, which 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 ..." (FFDCA 408(b)(2)(C)). The

Agency's consideration is documented in the pesticide-specific registration review documents, located in the applicable docket at https://www.regulations.gov.

I. *Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution or Use*

This action is not subject to Executive Order 13211 (66 FR 28355) (May 22, 2001) because it is not a significant regulatory action under Executive Order 12866.

J. *National Technology Transfer Advancement Act (NTTAA)*

This action does not involve technical standards that would require Agency consideration under NTTAA section 12(d), 15 U.S.C. 272.

K. *Congressional Review Act (CRA)*

This action is subject to the CRA, 5 U.S.C. 801 *et seq.*, and EPA will submit a rule report to each House of the Congress and to the Comptroller General of the United States. 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 7, 2026.

**Charles Smith,**

*Director, Registration Division, Office of Pesticide Programs.*

For the reasons stated in the preamble, 40 CFR chapter I is amended 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. Amend § 180.960 by adding the polymer, "oxirane, 2-phenyl-, polymer with oxirane, mono(hydrogen 2-sulfobutanedioate), octyl ether, sodium salt (1:2). Minimum number average molecular weight (in amu), 1,900 Daltons", in alphabetical order to table 1 to read as follows:

**§ 180.960 Polymers; exemptions from the requirement of a tolerance.**

* * * * *

**Table 1 to § 180.960**

| Polymer | CAS No. |
|---|---|
| * * * * | * * * |
| oxirane, 2-phenyl-, polymer with oxirane, mono(hydrogen 2-sulfobutanedioate), octyl ether, sodium salt (1:2). Minimum number average molecular weight (in amu), 1,900 Daltons | 2983072-24-6 |
| * * * * | * * * |

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