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

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TABLE 1 TO § 180.960

Polymer	CAS No.
* * * * * * *	
Oxirane, 2-(phenoxymethyl)-, polymer with oxirane, monobutyl ether, block, minimum number average molecular weight (in amu), 2300 Daltons	CAS Reg. No. 1010819–15–4.
* * * * * * *	

[FR Doc. 2022–19295 Filed 9–6–22; 8:45 am]
BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2018–0520; FRL–10188–01–OCSPP]

Thymol; 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 thymol (5-methyl-2-isopropyl-1-phenol) in or on all food commodities when used in accordance with good agricultural practices. Sci Reg, Inc., on behalf of Eden Research PLC, 6 Priory Ct., Priory Court Business Park, Poulton, Cirencester, GL7 5JB, United Kingdom, 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 thymol when used in accordance with this exemption.

DATES: This regulation is effective September 7, 2022. Objections and requests for hearings must be received on or before November 7, 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–2018–0520, 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 and the OPP Docket is (202) 566–1744. For the latest status information on EPA/DC services, docket access, visit *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Charles Smith, Biopesticides and Pollution Prevention Division (7511P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; main telephone number: (703) 305–7090; email address: *BPPDFRNotices@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 Office of the Federal Register's e-CFR site at *https://www.ecfr.gov/current/title-40.*

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. 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–2018–0520 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 November 7, 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–2018–0520 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.*

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *https://www.epa.gov/dockets.*

II. Background and Statutory Findings

In the **Federal Register** of August 24, 2018 (83 FR 42818) (FRL–9982–37), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide tolerance petition (PP 8F8680) by Eden Research PLC, 6 Priory Ct., Priory Court Business Park, Poulton, Cirencester, GL7 5JB, United Kingdom (c/o SciReg, Inc., 12733 Director's Loop, Woodbridge, VA 22192). The petition requested that 40 CFR part 180 be amended by establishing an exemption from the requirement of a tolerance for residues of thymol (5-methyl-2-isopropyl-1-phenol) in or on raw agricultural commodities and processed foods when used in accordance with good agricultural practices. That document referenced a summary of the petition prepared by the petitioner Eden Research plc, c/o SciReg, Inc., which is available in the docket, *https://www.regulations.gov.* There were no substantive comments received in response to the notice of filing.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(c)(2)(A)(i) of FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the exemption is ''safe.'' Section 408(c)(2)(A)(ii) of FFDCA defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings but does not include occupational exposure. 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 ''available information concerning the cumulative effects of a particular pesticide's residues'' and ''other substances that have a common mechanism of toxicity.''

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 harm to human health. If EPA is able to determine that a tolerance is not necessary to ensure that there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, 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 thymol including exposure resulting from the exemption established by this action. EPA's assessment of exposures and risks associated with thymol follows.

IV. Toxicological Profile

Thymol is a constituent of oil of thyme, a naturally occurring mixture of compounds in the plant, *Thymus vulgaris.* Thymol has long been a regular part of the human diet and is listed as an approved food additive by FDA (21 CFR 172.515). Thymol has a long history of safe use as a direct food additive. Additionally, the source plant (thyme), from which thymol is extracted, is acknowledged by FDA as generally recognized as safe (GRAS) (21 CFR 182.10 and 182.20).

In conducting its hazard assessment for thymol, EPA relied on data from the open scientific literature which includes a combined repeated dose oral toxicity study with the reproduction/developmental toxicity screening test, genotoxicity studies, and a 6-month inhalation study. In these data, no adverse effects were seen at the highest dose tested of 200 mg/kg/day. For guideline studies, EPA generally recommends testing at a limit dose of 1000 mg/kg/day. However, based on the data reviewed from the open literature along with a body of knowledge regarding thymol such as its low toxicity; rapid degradation into the environment; and natural occurrence and widespread use in foods that are commonly consumed and a part of the human diet, EPA would not expect to see adverse effects at higher doses.

Regarding the overall acute toxicological profile of thymol, the active ingredient is of minimal toxicity. Thymol is of low acute oral toxicity (Toxicity Category III), inhalation toxicity (Toxicity Category IV) and dermal toxicity (Toxicity Category III). It is corrosive to the skin and eye (Toxicity Category I) and may or may not be a dermal sensitizer (inconclusive).

With regard to subchronic oral, dermal and inhalation toxicity, EPA granted waivers for these data requirements based on a weight of the evidence approach (WOE). Specific to the 90-day oral toxicity, as stated in section IV. of this document, thymol has a documented and long history of use as a direct food additive as a flavoring agent and preservative. Moreover, thymol is commonly consumed as it is used in ice cream, non-alcoholic beverages, candy, baked goods, chewing gum, lime blossom honey and pesto sauce. In a thymol report from the European Medicines Evaluation Agency, the Committee of Experts on Flavoring Substances of the Council of Europe established an upper limit of 50 mg/kg in food and 10 mg/kg in beverages.

Regarding the 90-day dermal toxicity, thymol is a constituent of oil of thyme, a naturally occurring mixture in the plant *Thymus vulgaris* (thyme). It is currently used in cosmetics and human medicine. For example, oil of thyme and thymol have been proposed for use as a skin penetration enhancer for transdermal drug delivery. In addition, all dermal margins of exposure (MOEs) were well above the Agency's Level of Concern (LOC) of 100. MOE's for occupational handler exposure range from 980 to 22,000.

In terms of the 90 day-inhalation toxicity, thymol has low inhalation toxicity. In human medicine, it is administered via inhalation to treat a range of infections in the upper respiratory tract and is added to the anesthetic halothane as a preservative and is inhaled by patients undergoing surgery. Furthermore, the MOEs calculated using a POD of 200 mg/kg/day were significantly above 10X the LOC of 100 for inhalation exposure scenarios, ranging from 370,000 to 8,000,000.

EPA granted a waiver for the developmental data requirement due to thymol's long history of exposure to the human population without apparent toxic effects. It has long been a part of the human diet and is recognized as a GRAS essential oil by FDA (21 CFR 182.20). Furthermore, in a reproductive safety assessment, no adverse effects were seen up to a dose of 1,875 mg/kg, the highest dose tested.

In terms of mutagenicity, the active ingredient was determined to be non-mutagenic, and no adverse effects were identified relative to either

developmental toxicity or reproductive toxicity.

In conclusion, there were no adverse subchronic effects for any oral, dermal, inhalation, or developmental routes of exposure and as stated previously, EPA has granted a waiver of these data requirements based on a WOE approach for the subchronic toxicity testing considering all the available thymol hazard and exposure data. This WOE approach includes the following rationale:

1. Exposure from all routes and in all scenarios of thymol is considered to be negligible due to the following reasons: (a) Thymol is moderately volatile with a vapor pressure of 3.4 Pa @25oC; volatilization from both moist and dry soil surfaces is expected due to thymol's Henry's Law Constant of 4.44 × 10-3 atm/m3/mol and vapor pressure; thymol is expected to exist solely as a vapor in the ambient atmosphere, which would be readily degraded in the atmosphere by reaction with photochemically-produced hydroxyl radicals; the half-life for this reaction in the air is estimated to be 3.6 hours; (b) In a batch system using an activated sludge inoculum, thymol was found to be 94.8% readily biodegradable with a degradation rate of 15.6 mg COD/g-hr.

2. Thymol is naturally occurring and has long been part of the normal human diet. It is currently FDA-approved for use as a synthetic flavoring (21 CFR 172.515), a preservative, a direct food additive, and an indirect food additive in adhesives (21 CFR 175.105).

3. Thymol demonstrates low toxicity throughout its toxicity database. No adverse effects were observed to highest dose tested (200 mg/kg/day) in thymol's toxicity database. The database includes a combined repeated dose oral toxicity study with the reproduction/developmental toxicity screening test, several genotoxicity studies, and a 6-month inhalation study. Data from the open literature indicates that thymol is rapidly metabolized as well as rapidly excreted. Thus, high levels of thymol would likely not be found present in the body after 24 hours, with the majority of thymol and related metabolites being eliminated through the urine after 6 hours.

4. Pesticidal use of thymol is unlikely to contribute significantly to overall human exposure for the following reasons: (a) Thymol is naturally-occuring, and thus humans have had a long history of exposure to it. (b) It is FDA-approved for use as direct food additive. (c) Thymol is currently used in foods, cosmetics, and human medicine. (d) Dietary exposure is expected to be low based on thymol's physical/chemical properties (readily biodegradable, non-persistent). (e) Limited thymol residue data is available on honey, however extrapolating from this information, thymol residues on grapevine and other food crops would not be significantly greater and therefore not contribute significantly to the overall dietary exposure of thymol.

A. Toxicological Points of Departure/Levels of Concern

Based on the toxicological profile, EPA did not identify any toxicological endpoints of concern for assessing risk for this chemical.

B. Exposure Assessment

1. *Dietary exposure from food, feed uses, and drinking water.* Thymol naturally occurs in foods, is widely used as a food additive, and is consumed by humans through the diet. As part of its qualitative risk assessment for thymol, the Agency considered the potential for any additional dietary exposure to residues of thymol from its proposed use as a fungicide and nematicide on agricultural use sites. EPA concludes that such dietary (food and drinking water) exposures are likely to be negligible, due to the short half-life and biodegradable nature of thymol. A quantitative dietary exposure assessment was not conducted since a toxicological endpoint for risk assessment was not identified.

2. *Residential exposure.* The term ''residential exposure'' is used in this document to refer to non-occupational, non-dietary exposure. Currently, thymol is not registered for any pesticidal uses that would result in residential exposure. Residential exposure may occur from non-pesticidal uses such as essential oils, household cleaning products, and mouthwash. However, a quantitative residential exposure assessment was not conducted since a toxicological endpoint for risk assessment was not identified.

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 a tolerance 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 that thymol shares a common mechanism of toxicity with any other substances, and thymol does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed thymol 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.*

C. Safety Factor for Infants and Children

FFDCA Section 408(b)(2)(C) provides that EPA shall retain 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 (FQPA) safety factor. 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. EPA has determined that a qualitative risk assessment rather than a quantitative risk assessment would be most appropriate for the proposed use based on the toxicity profile of this active ingredient along with a long history of human exposure of thymol. For this reason, a FQPA safety factor is not required at this time.

D. Aggregate Risks

Based on the available data and information, EPA has concluded that a qualitative aggregate risk assessment is appropriate to support this action, and that risks of concern are not anticipated from aggregate exposure to thymol. This conclusion is based on the minimal toxicity of thymol, long history of human exposure to thymol, and expected rapid degradation of thymol in the environment. A full explanation of the data upon which EPA relied and its risk assessment based on those data can be found in the December 15, 2021, document entitled ''Risk Assessment for FIFRA Section 3 Registrations of Thymol Technical, containing 99.34%% Thymol as its Active Ingredient, Mevalone, containing 6.42% Thymol, as an Active Ingredient, and Cedroz, Containing 11.9% Thymol as its Active Ingredient. Tolerance Exemption Petition for Thymol''. This document, as well as other relevant information, is available in the docket for this action as described under **ADDRESSES**.

V. Determination of Safety for U.S. Population, Infants and Children

Based on the Agency's assessment, EPA concludes that there is reasonable certainty that no harm will result to the U.S. population, including infants and children, from aggregate exposure to residues of thymol. Therefore, the establishment of an exemption from the requirement of a tolerance for residues of thymol (5-methyl-2-isopropyl-1-phenol) in or on all food commodities when used in accordance with good agricultural practices is safe under FFDCA section 408.

VI. Other Considerations

Analytical Enforcement Methodology

An analytical method is not required for enforcement purposes since the Agency is establishing an exemption from the requirement of a tolerance without any numerical limitation.

VII. Conclusion

Therefore, an exemption from the requirement of a tolerance is established for residues of thymol (5-methyl-2-isopropyl-1-phenol) in or on all food commodities when used in accordance with good agricultural practices.

In addition, as a housekeeping measure, EPA is removing time-limited exemptions from the requirement of a tolerance for residues of thymol on honey and honeycomb in connection with use of the pesticide under section 18 emergency exemptions granted by the EPA. These exemptions expired on June 30, 2007.

VIII. Statutory and Executive Order Reviews

This action establishes an exemption from the requirement of 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 12898, entitled ''Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations'' (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance exemption in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply. This action directly regulates growers, food processors, food handlers, and food retailers, not States or Tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or Tribal Governments, on the relationship between the National Government and the States or Tribal Governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian Tribes. Thus, the Agency has determined that Executive Order 13132, entitled ''Federalism'' (64 FR 43255, August 10, 1999), and Executive Order 13175, entitled ''Consultation and Coordination with Indian Tribal Governments'' (65 FR 67249, November 9, 2000), do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

IX. 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: September 1, 2022.

Charles Smith,

Director, Biopesticides and Pollution Prevention 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. Amend § 180.1240 by revising paragraph (a) to read as follows:

§ 180.1240 Thymol; exemption from the requirement of a tolerance.

(a) An exemption from the requirement of a tolerance is established for thymol (5-methyl-2-isopropyl-1-phenol) in or on all food commodities when used in accordance with good agricultural practices.

* * * * *

[FR Doc. 2022–19294 Filed 9–6–22; 8:45 am]

BILLING CODE 6560–50–P

CORPORATION FOR NATIONAL AND COMMUNITY SERVICE

45 CFR Part 2502

RIN 3045–AA77

Employee Indemnification Regulations

AGENCY: Corporation for National and Community Service.

ACTION: Final rule.

SUMMARY: The Corporation for National and Community Service (operating as AmeriCorps), is finalizing regulations to indemnify AmeriCorps employees who, because of conduct taken within the scope of employment with AmeriCorps, have a verdict, judgment, monetary award, or personal damages claim issued against them that is not otherwise covered by the Federal Tort Claims Act. These regulations set out how AmeriCorps employees may request indemnification or settlement of a claim and the circumstances in which AmeriCorps may approve indemnification or settlement of a claim.

DATES: Effective November 7, 2022.

FOR FURTHER INFORMATION CONTACT: Kiara Rhodes, Associate General