



ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2024-0190; FRL-12647-01-OCSP]

Choline Chloride in Pesticide Formulations; 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 choline chloride (CASRN 67-48-1) when used as an inert ingredient (adjuvant) applied to or on animals. Stratacor, Inc. on behalf of Emery Olochemicals LLC, 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 choline chloride, when used in accordance with the terms of the exemption.

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-2024-0190, is available 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. Executive Summary

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 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 Federal Food, Drug, and Cosmetic Act (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.”

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. 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.

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 docket ID number EPA-HQ-OPP-2024-0190 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 "Revised Order Urging Electronic Service and Filing", dated June 22, 2023, which can be found at <https://www.epa.gov/system/files/documents/2023-06/2023-06-22%20-%20revised%20order%20urging%20electronic%20filing%20and%20service.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/HomePage?ReadForm.

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 July 1, 2024 (89 FR 54398, FRL-11682-05- OCSPP), EPA issued a document pursuant to FFDCFA section 408, 21 U.S.C. 346a, announcing the filing of a

pesticide petition (PP IN-11865) by Stratacor, Inc. (6 Christopher Court Novato, CA 94947) on behalf of Emery Olochemicals LLC (4900 Este Ave., Cincinnati, OH 45232). The petition requested that 40 CFR 180.930 be amended by establishing an exemption from the requirement of a tolerance for residues of choline chloride (CASRN 67-48-1) when used as an inert ingredient (adjuvant) in pesticide formulations applied to/on animals. That document referenced a summary of the petition prepared by Stratacor, Inc. on behalf of Emery Olochemicals LLC, the petitioner, which is available in the docket. There were no comments received in response to the notice of filing.

III. Inert Ingredient Definition

Inert ingredients are all ingredients in the pesticide 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

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 choline chloride including exposure resulting from the exemption established by this action. EPA's assessment of exposures and risks associated with choline chloride follows.

A. Toxicological Profile

The Toxicological Profile of choline chloride remains unchanged from the Toxicological Profile in Unit IV. of the 2010 rulemaking (75 FR 760, January 6, 2010) (FRL-8802-4). Choline chloride has low acute toxicity via the oral ($LD_{50} > 3,150$ mg/kg) route in rats and mice. No acute dermal toxicity study is available. However, an *in vitro* percutaneous absorption study using human skin showed a low potential for percutaneous absorption. No acute inhalation study is available; however, inhalation exposure is of low concern based on the low vapor pressure. It is slightly irritating to the skin and eye in rabbits. Choline chloride is not a sensitizer in guinea pigs.

Systemic toxicity is low following exposure to choline chloride. No toxicity is seen up to 200 and 500 mg/kg/day in subchronic and chronic studies in mice and rats, respectively. No maternal or developmental toxicity is seen up to 1,250 mg/kg/day in a developmental toxicity study in mice. No reproduction toxicity study is available, but spermatogenesis was not affected up to 83 mg/kg/day (highest dose tested) in a study evaluating the effect of choline chloride on spermatogenesis in rats. It is not genotoxic, neurotoxic, immunotoxic nor carcinogenic.

B. Toxicological Points of Departure/Levels of Concern

The Toxicological Points of Departure/Levels of Concern for choline chloride remain unchanged from the Toxicological Points of Departure/Levels of Concern discussion in Unit IV. of the 2010 rulemaking. The toxicological database for choline chloride is adequate. No new toxicological data have been received by the Agency which might alter the conclusions presented in the 2009 risk assessment. Based on the low toxicity of choline chloride in the available studies, EPA has concluded that there are no toxicological endpoints of concern for the U.S. population, including infants and children. As part of its qualitative assessment, the Agency did not use safety factors for assessing risk, and no additional safety factor is needed for assessing risk to infants and children.

C. Exposure Assessment

1. *Dietary exposure.* Dietary exposure to choline chloride may occur from eating foods

treated with pesticide formulations containing this inert ingredient and drinking water containing runoff from soils containing the treated crops. However, no toxicological endpoints of concern were selected, and therefore, a quantitative dietary exposure assessment for choline chloride was not conducted.

2. *Residential exposure.* The term “residential exposure” is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets). Although current uses of choline chloride can result in residential exposures, no toxicological endpoints were selected, and therefore, it is not necessary to conduct a quantitative assessment of residential exposures and risks.

3. *Cumulative effects from substances with a common mechanism of toxicity.* FFDC section 408(b)(2)(D)(v) 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.”

Based on the lack of toxicity in the available database, EPA has not found choline chloride to share a common mechanism of toxicity with any other substances, and choline chloride does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance exemption, therefore, EPA has assumed that choline chloride 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>.

D. Additional Safety Factor for the Protection of Infants and Children

FFDC section 408(b)(2)(C) 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 FQPA Safety Factor (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.

Based on an assessment of choline chloride EPA has concluded that there are no toxicological endpoints of concern for the U.S. population, including infants and children. Because there are no threshold effects associated with choline chloride, EPA conducted a qualitative assessment. As part of that assessment, the Agency did not use safety factors for assessing risk, and no additional safety factor is needed for assessing risk to infants and children.

E. Aggregate Risks and Determination of Safety

Because no toxicological endpoints of concern were identified, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to choline chloride residues.

F. 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.

V. Conclusions

Therefore, an exemption from the requirement of a tolerance is established for residues of choline chloride (CASRN 67-48-1) when used as an inert ingredient (adjuvant) in pesticide formulations applied to animals under 40 CFR 180.930.

VI. 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. 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.

C. 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.

D. 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.

E. 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.

F. 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.

G. 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 2021 *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 each chemical docket at <https://www.regulations.gov>.

H. 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.

I. 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.

H. 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.

I. 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.

J. 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 does not meet the criteria set forth in 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: March 17, 2025.

Charles Smith,

Director, Registration Division, Office of Pesticide Programs.

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 § 180.930, amend table 1 by adding, in alphabetical order, an entry for “Choline Chloride (CASRN 67-48-1)” to read as follows:

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

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Table 1 to 180.930

Inert Ingredients	Limits	Uses
* * * *	* * *	
Choline Chloride (CASRN 67-48-1)		Adjuvant
* * * *	* * *	