



ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2021-0164; FRL-8678-01-OCSP]

C10-C18-Alkyl dimethyl amine oxides (ADAOs); 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 C10-C18-Alkyl dimethyl amine oxides herein referred to as ADAOs when used as inert ingredients (surfactants/foaming agents) in antimicrobial pesticide formulations applied to food-contact surfaces in public eating places, dairy-processing equipment, food-processing equipment and utensils, limited to not more than 1,350 parts per million (ppm) at the end-use concentration in pesticide formulations. Technology Sciences Group Inc. on behalf of Mason Chemical Company submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting an amendment to an existing requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of ADAOs when used in accordance with this 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-2021-0164, 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 FFDCFA 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-2021-0164 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-2021-0164, 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 March 22, 2021 (86 FR 15162) (FRL-10021-44), EPA issued a document pursuant to FFDCFA section 408, 21 U.S.C. 346a, announcing the filing of a pesticide petition (PP IN-11435) by Technology Sciences Group Inc., 1150 18th Street NW, Suite 1000, Washington, DC 20036, on behalf of Mason Chemical Company, 9075 Centre Point Dr., Suite 400, West Chester, OH 45069. The petition requested that 40 CFR 180.940(a) be amended by establishing an exemption from the requirement of a tolerance for residues of ADAOs when used as inert ingredients used as surfactants and foaming agents in antimicrobial pesticide formulations applied to food-contact surfaces in public eating places, dairy-processing equipment, food-processing equipment and utensils. That document referenced a summary of the petition prepared by Technology Sciences Group Inc. on behalf of the Mason Chemical Company, the petitioner, which is available in the docket at <http://www.regulations.gov>. There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petition, EPA has limited the maximum concentration of ADAOs to not more than 1,350 ppm at the end-use concentration in pesticide formulations. This limitation is based on the Agency's risk assessment, which can be found at <http://www.regulations.gov> in document "C10-C18-Alkyldimethylamine oxides; Human Health Risk Assessment and Ecological Effects Assessment to Support Proposed Exemption from the Requirement of a Tolerance When Used as Inert Ingredients in Pesticide Formulations" in docket ID number EPA-HQ-OPP-2021-0164.

III. Inert Ingredient Definition

Inert ingredients are all ingredients that are not active ingredients as defined in 40 CFR 153.125 and include, but are not limited to, the following types of ingredients (except when they have a pesticidal efficacy of their own): solvents such as alcohols and hydrocarbons; surfactants

such as polyoxyethylene polymers and fatty acids; carriers such as clay and diatomaceous earth; thickeners such as carrageenan and modified cellulose; wetting, spreading, and dispersing agents; propellants in aerosol dispensers; microencapsulating agents; and emulsifiers. The term “inert” is not intended to imply nontoxicity; the ingredient may or may not be chemically active. Generally, EPA has exempted inert ingredients from the requirement of a tolerance based on the low toxicity of the individual inert ingredients.

IV. Aggregate Risk Assessment and Determination of Safety

Section 408(c)(2)(A)(i) of FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is “safe.” Section 408(b)(2)(A)(ii) of FFDCA defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” This includes exposure through drinking water and in residential settings but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue.”

EPA establishes exemptions from the requirement of a tolerance only in those cases where it can be clearly demonstrated that the risks from aggregate exposure to pesticide chemical residues under reasonably foreseeable circumstances will pose no 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 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 ADAOs, including exposure resulting from the exemption established by this action. EPA's assessment of exposures and risks associated with ADAOs follows.

On October 7, 2009, EPA published in the *Federal Register* a final rule establishing an exemption from the requirement of a tolerance for residues of ADAOs when used as an inert ingredient in pesticide formulations applied to raw agricultural commodities pre- and post-harvest. See 74 FR 51474 (FRL-8437-3). That document contains a summary of the toxicological profile, toxicological points of departure/levels of concern, certain assumptions for exposure assessment, and the Agency's determination regarding the children's safety factor, which have not changed except as described below.

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 ADAOs 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 Unit IV.A of the final rule published in the *Federal Register* of October 7, 2009 (74 FR 51474) (FRL-8437-3).

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure

to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level - generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD) - and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see <http://www.epa.gov/pesticides/factsheets/riskassess.htm>.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to ADAOs, EPA considered exposure under the proposed exemption from the requirement of a tolerance. To assess dietary exposures from ADAOs in food, the Agency calculated the Daily Dietary Dose (DDD) and the Estimated Daily Intake (EDI) using U.S. Food and Drug Administration (FDA) Food Contact Surface Sanitizing Solution Dietary Exposure Assessment Model. EPA's assessment used FDA's default assumptions for the amount of residual solution or quantity of solution remaining on the treated surface without rinsing with potable water (1 mg/cm²); surface area of the treated surface which comes into contact with food (4,000 cm²); and the pesticide migration fraction (100%). EPA used an application rate of ADAOs of 1350 ppm, which was provided by the petitioner. EPA also derived exposure amounts for population subgroups by accounting for body weights and adjusting for relative food consumption using data from the National Health and Nutrition Examination Survey (NHANES) (specifically the 2003-2008 survey data).

ADAOs are currently exempt from the requirements of a tolerance under 40 CFR 180.910 for use as inert ingredients in pesticide formulations applied to growing crops or to raw agricultural commodities after harvest limited to 15% by weight in pesticide formulations and use as a surfactant. One of the ADAO chemicals in the group, alkyl (C10-16) dimethyl amine oxide, is also approved as an antibacterial agent in dishwashing detergent for residential use. Potential dietary exposures from these uses were included in the overall dietary exposure.

2. *Dietary exposure from drinking water.* The proposed use of ADAOs will not result in measurable levels in surface water or ground water and therefore will not contribute to dietary exposure.

As stated above, ADAOs are approved for pre- and post-harvest uses and for use in dishwashing detergent. Dietary exposures from drinking water due to these uses are included in the overall dietary exposure.

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).

Indoor residential exposure may occur from use of ADAOs as inert ingredients in antimicrobial pesticide products applied to food contact surfaces. Indoor and outdoor residential exposure may also occur as a result of current approved uses of ADAOs in pesticide formulations for pre- and post-harvest application and in dishwashing detergent. ADAOs are also used in soap and hair products. The Agency’s assessment of residential exposure combines exposure from all of the aforementioned uses. A summary of certain other assumptions for exposure assessment of ADAOs is discussed in Unit IV.C. of the final rule published in the *Federal Register* of October 7, 2009 (74 FR 51474) (FRL-8437-3).

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) and (c)(2)(B) of FFDCFA 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 ADAOs to share a common mechanism of toxicity with any other substances, and ADAOs do not appear to produce a toxic metabolite produced by other substances. For the purposes of this action, therefore, EPA has assumed that ADAOs do not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at <http://www.epa.gov/pesticides/cumulative>.

D. Safety Factor for Infants and Children

Section 408(b)(2)(C) and (c)(2)(B) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the 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. EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X. The rationale for the Agency's determination regarding the children's safety factor is discussed in unit IV.D of the final rule published in the *Federal Register* of October 7, 2009 (74 FR 51474) (FRL-8437-3).

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by

comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. No adverse effect resulting from a single oral exposure was identified and no acute dietary endpoint was selected. Therefore, ADAOs are not expected to pose an acute risk.

2. *Chronic risk.* Using the exposure assumptions described for chronic exposure, EPA has concluded that chronic exposure to ADAOs from food and water will utilize 91% of the cPAD for children 1 to 2 years old, the population group receiving the greatest exposure.

3. *Short-term risk.* Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

ADAOs are currently used as an inert ingredient in pesticide products that are registered for uses that could result in short-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short-term residential exposures to ADAOs.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the combined short-term food, water, and residential exposures result in aggregate MOEs of 171 and 101 for the U.S. population and children 1 to 2 years old, respectively. Because EPA's level of concern for ADAOs is MOEs of 100 or below, these MOEs are not of concern.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

ADAOs are currently used as inert ingredients in pesticide products that are registered for uses that could result in intermediate-term residential exposure, and the Agency has determined

that it is appropriate to aggregate chronic exposure through food and water with intermediate-term residential exposures to ADAOs.

Using the exposure assumptions described in this unit for intermediate-term exposures, EPA has concluded that the combined intermediate-term food, water, and residential exposures result in aggregate MOEs of 322 and 104 for the U.S. population and children 1 to 2 years old, respectively. Because EPA's level of concern for ADAOs are MOEs of 100 or below, these MOEs are not of concern.

5. Aggregate cancer risk for U.S. population. The Agency has not identified any concerns for carcinogenicity relating to ADAOs.

6. Determination of safety. Taking into consideration all available information on ADAOs, 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 residues of ADAOs. Therefore, the establishment of an exemption from the requirement of a tolerance under 40 CFR 180. 940(a) for residues of ADAOs when used as inert ingredients in antimicrobial pesticide formulations applied to food-contact surfaces in public eating places, dairy-processing equipment, food-processing equipment, and utensils limited to not more than 1,350 ppm at the end-use concentration in pesticide formulations, is safe under FFDCA section 408.

V. Other Considerations

Analytical Enforcement Methodology

An analytical method is not required for enforcement purposes since the Agency is not establishing a numerical tolerance for residues of ADAOs in or on any food commodities. EPA is establishing limitations on the amount of ADAOs that may be used in pesticide formulations applied to food-contact surfaces in public eating places, dairy-processing equipment, food-processing equipment, and utensils. These limitations will be enforced through the pesticide registration process under the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), 7

U.S.C. 136 *et seq.* EPA will not register any pesticide formulation for food use that exceeds 1350 ppm of ADAOs in the end-use concentration in pesticide formulations.

VI. Conclusions

Therefore, an exemption from the requirement of a tolerance is established under 40 CFR 180.940(a) for C10-C18-Alkyl dimethyl amine oxides (CAS Reg. Nos. 1643-20-5, 2571-88-2, 2605-79-0, 3332-27-2, 61788-90-7, 68955-55-5, 70592-80-2, 7128-91-8, 85408-48-6, and 85408-49-7) when used as inert ingredients (surfactants/foaming agents) in antimicrobial pesticide formulations applied to food-contact surfaces in public eating places, dairy-processing equipment, food-processing equipment and utensils limited to not more than 1,350 ppm at the end-use concentration in pesticide formulations.

VII. Statutory and Executive Order Reviews

This action establishes a tolerance exemption 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).

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: August 10, 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 §180.940, in paragraph (a), amend table 180.940(a) by adding in alphabetical order an entry for the inert ingredient “C10-C18-Alkyl dimethyl amine oxides” to read as follows:

§ 180.940 Tolerance exemptions for active and inert ingredients for use in antimicrobial formulations (Food-contact surface sanitizing solutions).

* * * * *

(a) * * *

Table 180.940(a)

| Inert ingredients | CAS Reg. No. | Limits |
|-------------------------------------|---|---|
| * * * * * | * * | |
| C10-C18-Alkyl dimethyl amine oxides | 1643-20-5, 2571-88-2, 2605-79-0, 3332-27-2, 61788-90-7, 68955-55-5, 70592-80-2, 7128-91-8, 85408-48-6, and 85408-49-7 | When ready for use, the end-use concentration is not to exceed 1350 ppm |
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