ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

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 August 17, 2021. Objections and requests for hearings must be received on or before October 18, 2021, 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) 305–8005.

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 manufacturing (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How can I get electronic access to other related information?


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–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 October 18, 2021. 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.
- 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 FFDCA 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 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 petition was published in the Federal Register on August 17, 2021.

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–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 October 18, 2021. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

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Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at http://www.epa.gov/dockets.
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 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 the population 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 gram/cm²) or 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 1,350 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 also 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 FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance or exemption, the Agency consider “available information” concerning the cumulative effects of a particular pesticide’s residues and “other substances that have a common mechanism of toxicity.”

EPA has not found 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 POD (aPOD) and chronic POD (cPOD). 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
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 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, i.e., safe under FFDCA section 408.

VI. Conclusions

Therefore, 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.
TABLE 180.940(a)

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<thead>
<tr>
<th>Inert ingredients</th>
<th>CAS reg. No.</th>
<th>Limits</th>
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For further information contact: For additional information, contact Brenda Boykin, Attorney Advisor, Policy and Licensing Division, Public Safety and Homeland Security Bureau, (202) 418–2062 or via email at Brenda.Boykin@fcc.gov; or Jill Coogan, Attorney Advisor, Policy and Licensing Division, Public Safety and Homeland Security Bureau, (202) 418–1499 or via email at Jill.Coogan@fcc.gov.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission’s Report and Order, FCC 21–80, adopted on June 24, 2021 and released on June 25, 2021, and the Erratum released on August 12, 2021. The complete text of this document is available for download at https://docs.fcc.gov/public/attachments/FCC-21-80A1.pdf. To request this document in accessible formats for people with disabilities (e.g., Braille, large print, electronic files, audio format, etc.) or to request reasonable accommodations (e.g., accessible format documents, sign language interpreters, CART, etc.), send an email to fcc504@fcc.gov or call the FCC’s Consumer and Governmental Affairs Bureau at (202) 418–0530 (voice), (202) 418–0432 (TTY).

Paperwork Reduction Act

The requirements in 47 CFR 9.25(b) constitute a modification of the information collection with Office of Management and Budget (OMB) Control No. 3060–1122. This modified information collection is subject to the Paperwork Reduction Act of 1995 (PRA), Public Law 104–13. The modified information collection will be submitted to OMB for review under 47 U.S.C. 3507(d), and compliance with 47 CFR 9.25(b) will not be required until after approval by OMB.

Congressional Review Act

The Commission has determined, and the Administrator of the Office of Information and Regulatory Affairs, Office of Management and Budget, concurs, that this is a major rule under the Congressional Review Act, 5 U.S.C. 804(2). The Commission will send a copy of this Report and Order to Congress and the Government Accountability Office pursuant to 5 U.S.C. 801(a)(1)(A).

Synopsis

I. Background

Congress has had a longstanding concern about the practice by some states and local jurisdictions of diverting 911 fees for non-911 purposes. Congress initially enacted measures to limit 911 fee diversion, codified in 47 U.S.C. 615a–1 (section 615a–1). Specifically, section 615a–1(f)(1) provided that nothing in the New and Emerging Technologies (NET) 911 Act, the Communications Act of 1934, or any Commission regulation or order shall prevent the imposition and collection of a fee or charge applicable to commercial mobile services or IP-enabled voice services specifically designated by a State, political subdivision thereof, Indian tribe, or village or regional corporation for the support or implementation of 9–1–1 or enhanced 9–1–1 services, provided that the fee or charge is obligated or expended only in support of 9–1–1 and enhanced 9–1–1 services, or enhancements of such services, as specified in the provision of State or local law adopting the fee or charge. The NET 911 Act also required the Commission to report annually on the collection and distribution of fees in each state for the support or implementation of 911 or E911 services, including findings on the amount of revenues obligated or expended by each state “for any purpose other than the purpose for which any such fees or charges are specified.” 2 Pursuant to this provision, the Commission has reported annually to Congress on 911 fee diversion every year since 2009. In October 2020, the Commission released a Notice of Inquiry seeking comment on the effects of fee diversion and the most effective ways to dissuade states and jurisdictions from continuing or instituting the diversion of 911/E911


2 These annual reports can be viewed at viewed at https://www.fcc.gov/general/911-fee-reports.