



This document is scheduled to be published in the Federal Register on 10/16/2015 and available online at <http://federalregister.gov/a/2015-26297>, and on FDsys.gov

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2015-0363; FRL-9933-98]

2-propen-1-aminium, *N,N*-dimethyl-*N*-propenyl-, chloride, homopolymer; 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 2-propen-1-aminium, *N,N*-dimethyl-*N*-propenyl-, chloride, homopolymer (PolyDADMAC, CAS No. 26062-79-3) when used as an inert ingredient under 40 CFR 180.940(a) as a dispersing aid in food contact surface sanitizing solutions at less than 0.6% by weight in the final product. Scientific & Regulatory Solutions, L.L.C., on behalf of SNF, Inc. submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting establishment of an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of PolyDADMAC.

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-2015-0363, 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. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Susan Lewis, 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 Printing 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 FFDCa section 408(g), 21 U.S.C. 346a, 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-2015-0363 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-2015-0363, 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 July 17, 2015 (80 FR 42462) (FRL-9929-13), EPA issued a document pursuant to FFDCA section 408, 21 U.S.C. 346a, announcing the filing of a pesticide petition (PP IN-10750) by Scientific & Regulatory Solutions, L.L.C., 3450 Old Washington Rd # 303, Waldorf, MD 20602 on behalf of SNF, Inc., 1 Chemical Plant Road, Riceboro, GA 31321. The

petition requested that 40 CFR 180.940(a) be amended by establishing an exemption from the requirement of a tolerance for residues of PolyDADMAC, (CAS No. 26062-79-3) when used as an inert ingredient as a dispersing aid in pesticide formulations at less than 0.6% by weight. That document referenced a summary of the petition prepared by Scientific & Regulatory Solutions, L.L.C., on behalf of SNF, Inc., the petitioner, which is available in the docket, <http://www.regulations.gov>. There were no comments received in response to the notice of filing.

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 FFDCFA 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 FFDCFA 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 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 aggregate exposure to pesticide chemical residues under reasonably foreseeable circumstances will pose no appreciable risks to human health. In order to determine the risks from aggregate exposure to pesticide inert ingredients, the Agency considers the toxicity of the inert in conjunction with possible exposure to residues of the inert ingredient through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings. If EPA is able to determine that a finite tolerance is not necessary to ensure that there is a reasonable certainty that no harm will result from aggregate exposure to the inert ingredient, an exemption from the requirement of a tolerance may be established.

Consistent with FFDCA section 408(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 PolyDADMAC including exposure resulting from the exemption established by this action. EPA's assessment of exposures and risks associated with PolyDADMAC follows.

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 PolyDADMAC 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 this unit.

A single dose feeding study with rats classified PolyDADMAC as “slightly toxic” at a dose level of 5 milliliter/kilogram (mL/kg) (approx. 2,000 milligram/kilogram (mg/kg)). The results of two skin irritation studies performed with rabbits indicate that PolyDADMAC is not a skin irritant. In two eye irritation studies performed with PolyDADMAC on rabbits, the results indicate that the product was slightly irritating to the eyes and that the effects were totally reversed within 72 hours following exposure. In an eye study performed with PolyDADMAC on cultured fibroblasts, the results indicate that PolyDADMAC is slightly irritating. In a teratology study performed with Sprague-Dawley rats, the administration of 600 milligram/kilogram/day (mg/kg/day) of PolyDADMAC, and to a lesser extent, at the 450 and 150 mg/kg/day test groups, elicited a significant reduction in maternal food consumption during the first half of the dosing period. The NOAEL for PolyDADMAC on embryonic development is 600 mg/kg/day. A multi-generational study performed with PolyDADMAC using Sprague-Dawley rats dosed with 0.375, 12.5, and 125 mg/kg/day (oral gavage) showed no increase in reproductive failure, nor were there any effects upon the fertility index or any other F1 or F2 generation parameters. The inferred NOAEL from the study was 125 mg/kg/day. The two genotoxicity studies performed with PolyDADMAC were negative in both an Ames test and in a mouse micronucleus assay. There are no carcinogenicity studies available for PolyDADMAC. However, no significant systemic toxicity was observed in the

teratology, multi-generational and mutagenicity toxicity studies. In the absence of significant systemic toxicity, and lack of mutagenicity concerns, PolyDADMAC is not likely to be carcinogenic.

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 the NOAEL and the LOAEL are identified. 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>.

PolyDADMAC is a large molecular weight chemical which satisfies all of the TSCA Polymer Exemption Rule except for its cationic properties. Generally, high molecular weight polymers are unlikely to be absorbed significantly through any route of exposure. In the case of PolyDADMAC, this is evidenced by: No systemic toxicity up to 600 mg/kg/day in the teratology study, no systemic toxicity in the multi-generational reproduction study up to 125 mg/kg/day, and low acute toxicity. Therefore, no adverse effect level endpoints have been selected for PolyDADMAC,

and EPA concludes that it is not necessary to assess quantitative dietary risk or risk from exposure via dermal or inhalation.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to PolyDADMAC, EPA considered exposure under the proposed exemption from the requirement of a tolerance. EPA assessed dietary exposures from PolyDADMAC in food as follows: Acute dietary assessments take into account exposure estimates from dietary consumption of food and drinking water. Chronic dietary assessments take into account dietary food and drinking water as well as food contact surface sanitation uses. In the case of PolyDADMAC, there are no current or proposed crop pesticidal uses; therefore oral exposures from that route (including exposure through drinking water) are not expected. Dietary exposure to PolyDADMAC can occur through its use in food contact sanitizing solutions. However, PolyDADMAC is a large molecular weight chemical which is unlikely to be absorbed significantly through any route of exposure and no endpoints have been selected for it. The Agency has not identified any concerns for carcinogenicity relating to PolyDADMAC; therefore, a cancer dietary exposure assessment was not performed.

2. *Dietary exposure from drinking water.* PolyDADMAC residues may be found in drinking water. However, since an endpoint of concern was not identified for the dietary assessment (food and drinking water), a quantitative dietary exposure risk assessment was not conducted.

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).

While there are no current or proposed residential uses for PolyDADMAC, it is possible that PolyDADMAC may be used as an inert ingredient in pesticide products for which residential exposures may result. However, in the case of PolyDADMAC no applicable endpoints of concern for residential exposures have been identified and a quantitative exposure assessment from residential exposures was not performed.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance or exemption from a tolerance, the Agency consider “available information” concerning the cumulative effects of a particular pesticide's residues and “other substances that have a common mechanism of toxicity.”

EPA has not found PolyDADMAC to share a common mechanism of toxicity with any other substances, and PolyDADMAC does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that PolyDADMAC 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 <http://www.epa.gov/pesticides/cumulative>.

D. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the

Food Quality Protection Act Safety Factor (FQPA 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.

2. *Prenatal and postnatal sensitivity.* Teratology and multi-generational studies in laboratory animals indicate that PolyDADMAC caused no increase in reproductive failure nor were there any PolyDADMAC related effects upon the fertility index or any other F1 or F2 generation parameters (e.g., litter size, pup weight, fertility and parturition, reproductive indices such as mating index, fecundity index, male or female fertility indices, etc.). Finally, there was no remarkable pathology noted upon necropsy of any of the test animals. Neurotoxicity was not observed in a reproduction/developmental screening study in rats where neurotoxicity parameters were evaluated.

3. *Conclusion.* Based on an assessment of PolyDADMAC, EPA has concluded that there are no toxicological endpoints of concern for the U.S. population, including infants and children, and has conducted a qualitative assessment. 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.

E. Aggregate Risks and Determination of Safety

Determination of safety section. 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.

Based on the lack of any endpoints of concern, 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 PolyDADMAC residues.

V. Other Considerations

A. 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.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDC section 408(b)(4). The Codex Alimentarius is a joint United Nation Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDC section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established a MRL for PolyDADMAC.

VI. Conclusions

Therefore, an exemption from the requirement of a tolerance is established under 40 CFR 180.940(a) for PolyDADMAC (CAS No. 26062-79-3) when used as an inert ingredient as a dispersing aid in food contact surface sanitizing solutions at less than 0.6% by weight in the final product.

VII. Statutory and Executive Order Reviews

This action establishes 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 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: October 7, 2015.

Susan Lewis,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180--[AMENDED]

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(a), add alphabetically the inert ingredient “2-propen-1-aminium, *N,N*-dimethyl-*N*-propenyl-, chloride, homopolymer (CAS No. 26062-79-3)” to the table to read as follows:

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

* * * * *

(a) * * *

Pesticide Chemical	CAS Reg. No.	Limits
* * * * *	* *	
2-propen-1-aminium, <i>N,N</i> -dimethyl- <i>N</i> -propenyl-, chloride, homopolymer	26062-79-3	When ready for use, the end-use concentration is not to exceed 0.6%.
* * * * *	* *	

* * * * *

[FR Doc. 2015-26297 Filed: 10/15/2015 08:45 am; Publication Date: 10/16/2015]