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**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 180**

**[EPA-HQ-OPP-2013-0219; FRL-10008-87]**

**RIN 2070-ZA16**

**Dipropylene Glycol and Triethylene Glycol; Exemption from the Requirement of a Pesticide Tolerance**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Proposed rule.

**SUMMARY:** EPA is proposing to exempt residues of the antimicrobial pesticide ingredients dipropylene glycol and triethylene glycol from the requirement of a tolerance when used on or applied to food-contact surfaces in public eating places, dairy-processing equipment, and food-processing equipment and utensils. This rulemaking is proposed on the Agency's own initiative under the Federal Food, Drug, and Cosmetic Act (FFDCA) to address residues identified as part of the Agency's registration review program under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).

**DATES:** Comments must be received on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

**ADDRESSES:** Submit your comments, identified by docket identification (ID) numbers EPA-HQ-OPP-2013-0219 and EPA-HQ-OPP-2013-0218 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 Confidential Business Information (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>.

**FOR FURTHER INFORMATION CONTACT:** Anita Pease, Antimicrobials Division (7508P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave, NW., Washington, DC 20460-0001; telephone number: 703-305-0392; email address: [Pease.Anita@epa.gov](mailto:Pease.Anita@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 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. What Should I Consider as I Prepare My Comments for EPA?*

1. *Submitting CBI.* Do not submit this information to EPA through *regulations.gov* or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD-ROM that you mail to EPA, mark the outside of the disk or CD-ROM as CBI and then identify electronically within the disk or CD-ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When preparing and submitting your comments, see the commenting tips at <http://www.epa.gov/dockets/comments.html>.

## **II. Background**

### *A. What Action is the Agency Taking?*

EPA is proposing to establish an exemption from the requirement of a tolerance for residues of the antimicrobial pesticides dipropylene glycol and triethylene glycol on food-contact surfaces in public eating places, dairy-processing equipment, and food-processing equipment and utensils. EPA is proposing this exemption to cover residues of dipropylene glycol and triethylene glycol that may be found in food as a result of the use of these antimicrobials on food-contact surfaces.

As noted in the December 2017, *Propylene Glycol, Dipropylene Glycol and Triethylene Glycol Interim Registration Review Decision* (“*Glycol Interim Decision*”) (available at <http://www.regulations.gov> in docket ID numbers EPA-HQ-OPP-2013-0219 and EPA-HQ-OPP-2013-0218), dipropylene glycol and triethylene glycol are registered for use as disinfectants on food-contact surfaces in public eating places, dairy-processing equipment, and food-processing

equipment and utensils. As a result of that use, residues of dipropylene glycol and triethylene glycol may be found in food that comes into contact with treated surfaces.

According to the Agency's 2016 Antimicrobial Use Site Index (<https://www.epa.gov/pesticide-registration/antimicrobial-pesticide-use-site-index>), EPA categorizes that use as an "indirect food use." 40 CFR 158W requires a tolerance or exemption for direct and indirect food uses. Historically, EPA did not require a tolerance or tolerance exemption for the registered uses of dipropylene glycol and triethylene glycol because the labels required a potable water rinse after application. EPA's scientific assumption had been that if an antimicrobial pesticide use required a potable water rinse on the label, residues of the pesticide would be rinsed away. With no residues available to transfer to foods coming into contact with the treated food surface, the use was considered nonfood, and no tolerance or tolerance exemption was needed. That presumption of no available residues for transfer is no longer supportable because available data now suggests that a potable water rinse may not be 100% efficient in removing residues; therefore, the Agency no longer considers a use to be "nonfood" just because the label requires a potable water rinse. Absent information supporting a conclusion that no residues would be available for transfer to food from the use, a tolerance or tolerance exemption is required. As of this time, the Agency has not received any information supporting a conclusion that residues of dipropylene glycol and triethylene glycol would not be available for transfer to food after application to food surfaces.

*B. What is the Agency's Authority for Taking this Action?*

A "tolerance" represents the maximum level for residues of pesticide chemicals legally allowed in or on raw agricultural commodities and processed foods. Section 408 of FFDCA, 21 U.S.C. 346(a), authorizes the establishment of tolerances, exemptions from tolerance

requirements, modifications in tolerances, and revocation of tolerances for residues of pesticide chemicals in or on raw agricultural commodities and processed foods. Without a tolerance or exemption, food containing pesticide residues are considered unsafe and therefore “adulterated” under FFDCA section 402(a), 21 U.S.C. 342(a). Such food may not be distributed in interstate commerce, 21 U.S.C. 331(a).

Section 408(e)(1)(B) of the FFDCA authorizes EPA to issue an exemption from the requirement of a tolerance on its own initiative. 21 U.S.C. 346a(e)(1)(B). It is under section 408(e) of the FFDCA that EPA is proposing to establish the exemption in this rulemaking. The standard for establishing an exemption is found in section 408(c)(2)(A) of the FFDCA and is discussed below. 21 U.S.C. 346a(c)(2)(A).

### **III. Aggregate Risk Assessment and Determination of Safety**

Section 408(c)(2)(A)(i) of FFDCA allows EPA to establish an exemption from the requirement of 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(c)(2)(A)(ii) of FFDCA defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” This includes exposure through drinking water and in residential settings but does not include occupational exposure. Section 408(c)(2)(B) requires EPA to take into account, among other things, the considerations set forth in section 408(b)(2)(C) and (D). Specifically, 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....”

Consistent with FFDCA section 408(b)(2)(D), 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 to support the establishment of exemptions from the requirement of a tolerance for residues of dipropylene glycol and triethylene glycol.

As noted in the *Glycol Interim Decision*, there is no evidence of adverse effects for dipropylene and triethylene glycol in the toxicity database; therefore, EPA did not identify any toxicological endpoints of concern for assessing risk. Although the current uses have the potential to result in exposure to residues of dipropylene and triethylene glycol in or on food, including uses of these chemicals as inert ingredients, the low order of toxicity and low application rates from the current uses of these chemicals support a conclusion that exemptions from the requirement of a tolerance for these pesticide chemicals when used in antimicrobial formulations on food-contact surfaces in public eating places, on dairy-processing equipment, and on food-processing equipment and utensils would be safe. Based on the low order of toxicity and low exposure levels, EPA concludes that there is a reasonable certainty that no harm will result to the U.S. population, including all subpopulation groups, from aggregate exposure to dipropylene glycol or triethylene glycol. For further information, the *Glycol Interim Decision* can be found at <https://www.regulations.gov> in docket identification numbers EPA-HQ-OPP-2013-0218 (propylene and dipropylene glycol) and EPA-HQ-OPP-2013-0219 (triethylene glycol).

#### **IV. Analytical Enforcement Methodology**

An analytical method for residue is not needed. Due to the lack of risk, EPA is establishing exemptions without limits for dipropylene glycol and triethylene glycol; therefore, measuring residues of dipropylene glycol and triethylene glycol is not necessary.

## **V. Conclusion**

Therefore, EPA is proposing to establish an exemption from the requirement of a tolerance for residues of dipropylene glycol and triethylene glycol when used in antimicrobial formulations applied to food-contact surfaces in public eating places, dairy-processing equipment, and food-processing equipment and utensils.

## **IV. Statutory and Executive Order Reviews**

In this document, EPA is proposing to establish exemptions from the requirement of a tolerance under FFDCFA section 408(e). 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 proposed rule has been exempted from review under Executive Order 12866 due to its lack of significance, this proposed rule 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), nor is it subject to Executive Order 13771, entitled “Reducing Regulations and Controlling Regulatory Costs” (82 FR 9339, February 3, 2017). This proposed rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), or 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.*). Nor does it require any special considerations as required by Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994); or OMB review or any other Agency action under Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997). This proposed rule 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).

Pursuant to the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), the Agency previously assessed whether establishment of tolerances, exemptions from tolerances, raising of tolerance levels, expansion of exemptions, or revocations might significantly impact a substantial number of small entities and concluded that, as a general matter, these actions do not impose a significant economic impact on a substantial number of small entities. These analyses for tolerance establishments and modifications, and for tolerance revocations were published in the *Federal Register* of May 4, 1981 (46 FR 24950) and December 17, 1997 (62 FR 66020) (FRL-5753-1), respectively, and were provided to the Chief Counsel for Advocacy of the Small Business Administration. Taking into account this analysis, and available information concerning the pesticides listed in this proposed rule, the Agency hereby certifies that this proposed rule will not have a significant negative economic impact on a substantial number of small entities. Furthermore, for the pesticides named in this proposed rule, the Agency knows of no extraordinary circumstances that exist as to the present proposed rule that would change EPA's previous analysis. Any comments about the Agency's determination should be submitted to the EPA along with comments on the proposed rule and will be addressed prior to issuing a final rule.

In addition, the Agency has determined that this proposed rule will not have a substantial direct effect on 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, as specified in Executive Order 13132, entitled "Federalism" (64 FR 43255, August 10, 1999).

Executive Order 13132 requires EPA to develop an accountable process to ensure “meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.” “Policies that have federalism implications” is defined in the Executive order to include regulations that 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.” This proposed rule directly regulates growers, food processors, food handlers, and food retailers, not States. This proposed rule does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). For these same reasons, the Agency has determined that this proposed rule does not have any “tribal implications” as described in Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000). Executive Order 13175 requires EPA to develop an accountable process to ensure “meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.” “Policies that have tribal implications” is defined in the Executive order to include regulations that have “substantial direct effects on one or more Indian tribes, 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.” This proposed rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this proposed rule.

#### **List of Subjects in 40 CFR Part 180**

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: May 3, 2020.

**Richard Keigwin,**

*Director, Office of Pesticide Programs.*

Therefore, it is proposed that 40 CFR chapter I be 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. Revise § 180.940 to add alphabetically the entries of “Dipropylene glycol” and “Triethylene glycol” in the table in paragraph (a) to read as follows:

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

\*\*\*\*\*

(a) \*\*\*\*\*

<b>Pesticide Chemical</b>	<b>CAS Reg. No.</b>	<b>Limits</b>
***	**	**
Dipropylene glycol	25265-71-8	None
***	**	**
Triethylene glycol	112-27-6	None
***	**	**

[FR Doc. 2020-10805 Filed: 5/21/2020 8:45 am; Publication Date: 5/22/2020]