



ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2020-0244; FRL-10167-01-OCSP]

Hypochlorous Acid; Exemption from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is exempting residues of the antimicrobial pesticide ingredient hypochlorous acid from the requirement of a tolerance when used on or applied to food-contact surfaces in public eating places. The EPA is finalizing this rule on its own initiative under the Federal Food, Drug, and Cosmetic Act (FFDCA) to address residues identified as part of the EPA's registration review program under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).

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-2020-0244, is available at <https://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 and the OPP Docket is (202) 566-1744. For the latest status information on EPA/DC services, docket access, visit <https://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Anita Pease, Antimicrobials Division
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SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are a 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 office of the Federal Register's e-CFR site at <https://www.ecfr.gov/current/title-40>.

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 numbers EPA-HQ-OPP-2020-0244 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-2020-0244, by one of the following methods:

- *Federal eRulemaking Portal*: <https://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

- *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 <https://www.epa.gov/dockets/where-send-comments-epa-dockets>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <https://www.epa.gov/dockets>.

II. Summary of Rule-For Exemption

What action is the agency taking?

In the *Federal Register* of May 17, 2022 (87 FR 29843) (FRL-9460-01), EPA proposed to exempt residues of the antimicrobial pesticide ingredient hypochlorous acid from the requirement of a tolerance when used on or applied to food-contact surfaces in public eating places. This exemption covers residues of hypochlorous acid that may be found in food as a result of the use of these antimicrobials on food-contact surfaces in public eating places. These exemptions were proposed on EPA's own initiative under section 408(e) of the FFDCA, 21

U.S.C. 346a(e). No comments were received on EPA's proposal. Therefore, EPA is finalizing the exemption from the requirement of a tolerance for residues of the antimicrobial pesticide ingredient hypochlorous acid when used on or applied to food-contact surfaces in public eating places.

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 hypochlorous acid.

As noted in the "Hypochlorous Acid Interim Decision", there are tolerance exemptions under 40 CFR § 180.940(b) and (c), which state that solutions containing hypochlorous acid may be applied to dairy-processing equipment, and food-processing equipment and utensils, with the limitation that the end-use concentration of hypochlorous acid does not exceed 200 parts per million (ppm) determined as total available chlorine. Because the current tolerance exemptions

do not cover the antimicrobial products registered for use in public eating areas, the EPA is now establishing a tolerance exemption under section 40 CFR § 180.940(a), which would cover all food-contact uses of hypochlorous acid pesticide products in public eating areas not to exceed 200 ppm determined as total available chlorine.

EPA's safety determination for establishing a hypochlorous acid tolerance exemption under section 40 CFR § 180.940(a) is based on chemical similarity to sodium, calcium, and potassium hypochlorites. Hypochlorous acid risk conclusions, including those related to dietary and aggregate exposure, can be bridged to the risk conclusions from the reevaluation of the sodium, calcium, and potassium hypochlorites (see docket EPA-HQ-OPP-2012-0004 at <https://www.regulations.gov>). Because EPA did not identify any dietary or aggregate risks of concern for the sodium, calcium, and potassium hypochlorites, due to the lack of toxicity of these substances, there are no dietary or aggregate risks of concern for hypochlorous acid due to a lack of toxicity for hypochlorous acid. For further information, the "Hypochlorous Acid Interim Decision" can be found at <https://www.regulations.gov> in docket identification number EPA-HQ-OPP-2020-0244.

Based on the lack of any aggregate risks of concern, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or specifically to infants and children, from aggregate exposure to hypochlorous acid residues. Thus, EPA has determined that the exemption from the requirement of a tolerance for residues of hypochlorous acid is safe.

IV. Analytical Enforcement Methodology

An analytical method for residue is not required for enforcement purposes since the EPA is not establishing a numerical tolerance for residues of hypochlorous acid in or on any food commodities. EPA is establishing limitations on the amount of hypochlorous acid that may be used in antimicrobial pesticide formulations applied to food-contact surfaces in public eating places, dairy-processing equipment, and 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 antimicrobial pesticide formulation applied to food-contact surfaces in public eating places, dairy-processing equipment, and food-processing equipment and utensils that allows for the end-use concentration of hypochlorous acid in the ready to use product to exceed the 200 ppm limit determined as total available chlorine.

V. Conclusion

Therefore, EPA is establishing an exemption under 40 CFR § 180.940(a) from the requirement of a tolerance for residues of hypochlorous acid when used in antimicrobial formulations applied to food-contact surfaces in public eating places, dairy-processing equipment, and food-processing equipment and utensils not to exceed 200 ppm determined as total available chlorine. Because the existing entries for hypochlorous acid in paragraphs (b) and (c) are duplicative of the new exemption in paragraph (a) of section 40 CFR § 180.940, EPA is removing the tolerance exemptions for hypochlorous acid in paragraphs (b) and (c), as unnecessary.

VI. Statutory and Executive Order Reviews

This action establishes an exemption from the requirement of a tolerance under FFDCA 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 action has been exempted from review under Executive Order 12866 due to its lack of significance, 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). This action does not contain any information collection 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 action does not involve any technical standards that would require EPA 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).

VII. Congressional Review Act

Pursuant to the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), the EPA 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), 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 pesticide listed in this rule, the EPA hereby certifies that this action will not have a significant negative economic impact on a substantial number of small entities. Furthermore, for the pesticide named in this rule, the EPA knows of no extraordinary circumstances that exist as to the present rule that would change EPA's previous analysis. No comments were submitted concerning EPA's similar determination in the rule.

In addition, the EPA has determined that this action 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 action directly regulates growers, food processors, food handlers, and food retailers, not States or Tribes. This action 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 EPA has determined that this action 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 action 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 action.

List of Subjects in 40 CFR Part 180

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

Dated: September 7, 2022.

Anita Pease,

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. Amend § 180.940, by:

a. Adding in alphabetical order the pesticide chemical “Hypochlorous Acid” in table 1 to paragraph (a).

b. Removing the entry “Hypochlorous Acid” from the table in paragraph (b).

c. Removing the entry “Hypochlorous Acid” from the table in paragraph (c).

The addition reads as follows:

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

* * * * *

(a) * * *

Table 1 to Paragraph (a)

Pesticide Chemical	CAS Reg. No.	Limits
* * * * *	* * * * *	* *
Hypochlorous Acid	7790-92-3	When ready for use, the end-use concentration of all hypochlorous acid chemicals in the solution is not to exceed 200 ppm determined as total available chlorine.
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