

Inert ingredients	Limits	Uses
*	*	*
Poly(oxy-1,2-ethanediyl), α -(1-oxoalkyl)- ω -methoxy-, where the alkyl chain contains a minimum of 6 and a maximum of 18 carbons and the oxyethylene content is 3–13 moles (CAS Reg. No. 53100–65–5, 194289–64–0, 34398–00–0, 9006–27–3, 32761–35–6, 53467–81–5, 518299–31–5, and 34397–99–4).	Not to exceed 25% by weight in pesticide formulation.	Stabilizer, solubilizing agent.
*	*	*

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2010–0234; FRL–9976–73]

Alpha-cypermethrin; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation amends existing tolerances for residues of alpha-cypermethrin in or on fruit, citrus group 10–10 and hog fat. EPA is modifying these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA) to correct an error in a previous rulemaking that established these tolerances at an unintended level.

DATES: This regulation is effective June 5, 2018. Objections and requests for hearings must be received on or before August 6, 2018, 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–2010–0234, 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:

Michael L. Goodis, Director, 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 EPA's tolerance regulations at 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–2010–0234 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 August 6, 2018. 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–2010–0234, 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. Proposed Rule

In the **Federal Register** of December 26, 2017 (82 FR 60940) (FRL–9969–97), EPA, pursuant to FFDCA section 408(e), 21 U.S.C. 346a(e), proposed revisions to existing tolerances for the insecticide alpha-cypermethrin to reduce the allowable levels of the pesticide in or on fruit, citrus, group 10–10 from 10 parts per million (ppm) to 0.35 ppm and in

or on hog, fat from 1.0 ppm to 0.10 ppm. EPA proposed this action in order to correct a typographical error that occurred in the final rule establishing these tolerances on February 1, 2013 (78 FR 7266) (FRL-9376-1). In support of the 2013 final rule, EPA reviewed residue field trial data and determined that the appropriate tolerance levels for fruit, citrus, group 10-10 and hog, fat were 0.35 ppm and 0.10 ppm, respectively. Unfortunately, the instruction to the **Federal Register** contained incorrect tolerance values for these commodities, resulting in incorrect tolerance levels being finalized in that rule. The proposal would correct that error.

In the proposal, EPA discussed the Agency's assessment of risk and proposed determination of safety for aggregate exposures to alpha-cypermethrin. In summary, the Agency concluded that the proposed tolerances for fruit, citrus, group 10-10 and hog, fat would be safe.

Two comments were received on the proposal. One simply read "Good" and the other was related to the impact of wind-power facilities on bat populations and is therefore not relevant to this action.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish 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. . . ."

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in 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 for alpha-

cypermethrin including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with alpha-cypermethrin can be found in the proposed rule published December 26, 2017, and EPA is incorporating its findings in that preamble into this final rule. For the reasons stated in the proposal, EPA concludes that there is a reasonable certainty that no harm will result to the general population, including infants and children, from aggregate exposure to alpha-cypermethrin.

IV. International Trade Considerations

A. International Residue Limits

As noted in the proposal, 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 FFDCA section 408(b)(4).

There is a Codex MRL established for citrus fruits at 0.3 ppm but not one for hog fat. Because the U.S. use patterns differ from those upon which the Codex MRLs are based, EPA is not harmonizing the U.S. tolerance for citrus fruit.

B. World Trade Organization Sanitary and Phytosanitary Measures Agreement

In this Final Rule, EPA is reducing the existing tolerances for commodities in crop group 10-10 from 10 ppm to 0.35 ppm and on hog, fat from 1.0 ppm to 0.1 ppm. The Agency is reducing these tolerances to correct the tolerance levels that EPA intended to establish in a previous rulemaking based on available residue data.

In accordance with the World Trade Organization's (WTO) Sanitary and Phytosanitary Measures (SPS) Agreement, EPA notified the WTO of its proposed tolerance revision on January 10, 2018. See <http://spsims.wto.org/en/Notifications/Search>, U.S. Notification (G/SPS/N/USA/2976). EPA also intends to submit another notification to the WTO in order to satisfy its obligation to promptly publish this rule in such a manner as to enable interested WTO members to become acquainted with this rule. In addition, the SPS Agreement requires that Members provide a "reasonable interval" between the publication of a regulation subject to the Agreement and its entry into force to allow time for producers in exporting Member countries to adapt to the new requirement. At this time, EPA is

establishing an expiration date for the existing tolerances to allow those tolerances to remain in effect for a period of six months after the effective date of this final rule, in order to address this requirement.

This reduction in tolerance levels is not discriminatory; the same food safety standard contained in the FFDCA applies equally to domestically produced and imported foods. The new tolerance levels are supported by available residue data.

V. Conclusion

Therefore, tolerances are established for residues of alpha-cypermethrin, alpha-cypermethrin, in or on fruit, citrus group 10-10 and hog fat at 0.35 and 0.10 ppm.

VI. Statutory and Executive Order Reviews

This action amends existing tolerances under FFDCA section 408(e) in an action taken on the Agency's own initiative. 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), nor is it subject to Executive Order 13771, entitled "Reducing Regulations and Controlling Regulatory Costs" (82 FR 9339, February 3, 2017). 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.*), 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 under 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 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 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. In a memorandum dated May 25, 2001, EPA determined that eight conditions must all be satisfied in order for an import tolerance or tolerance exemption revocation to adversely affect a significant number of small entity importers, and that there is a negligible joint probability of all eight conditions holding simultaneously with respect to any particular revocation. Furthermore, for alpha-cypermethrin, the Agency knows of no extraordinary circumstances that exist as to the present rule that would change EPA's previous analysis. Taking into account this analysis, and available information concerning the pesticides listed in this rule, EPA hereby certifies that this rule will not have a significant negative economic impact on a substantial number of small entities. In addition, the Agency 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. 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 Agency 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.

VII. 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: April 30, 2018.

Richard P. Keigwin, Jr.,
Director, 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 § 180.418, in the table in paragraph (a)(3):

■ i. Amend the existing entries for "Fruit, citrus, group 10-10"; and "Hog, fat" by adding footnote references and add footnote 1 to the end of the table; and

■ ii. Add alphabetically new entries for "Fruit, citrus, group 10-10"; and "Hog, fat".

The additions to the table in paragraph (a)(3) read as follows:

§ 180.418 Cypermethrin and isomers alpha-cypermethrin and zeta-cypermethrin; tolerances for residues.

(a)(3) * * *

Commodity	Parts per million
* * *	*
Fruit, citrus, group 10-10 ¹	10
Fruit, citrus, group 10-10	0.35
* * *	*
Hog, fat ¹	1.0
Hog, fat	0.10
* * *	*

¹ This tolerance expires on December 5, 2018.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 10

RIN 0906-AB18

340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Final rule; further delay of effective date.

SUMMARY: The Health Resources and Services Administration (HRSA) administers section 340B of the Public Health Service Act (PHSA), known as the "340B Drug Pricing Program" or the "340B Program." HRSA published a final rule on January 5, 2017, that set forth the calculation of the ceiling price and application of civil monetary penalties. The final rule applied to all drug manufacturers that are required to make their drugs available to covered entities under the 340B Program. On