



BILLING CODE 6560-50-P

## **ENVIRONMENTAL PROTECTION AGENCY**

### **40 CFR Part 180**

**[EPA-HQ-OPP-2017-0155 and EPA-HQ-OPP-2019-0383; FRL-10008-84]**

### **Hexythiazox; Pesticide Tolerances**

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

**ACTION:** Final rule.

**SUMMARY:** This regulation amends the existing tolerances for residues of the ovicide/miticide hexythiazox in or on Caneberry, Subgroup 13-07A, by increasing the current tolerance from 1 part per million (ppm) to 3 ppm; and on Date, dried, by increasing the current tolerance from 1.0 ppm to 3 ppm. This regulation also establishes a tolerance for residues of the ovicide/miticide hexythiazox in or on Tea, dried at 15 ppm. Gowan Company and the Tea Association of the USA, Inc. requested these tolerances and tolerance revisions under the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. section 346a.

**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 dockets for this action, identified by docket identification (ID) numbers EPA-HQ-OPP-2017-0155 and EPA-HQ-OPP-2019-0383, are 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 note that due to the public health emergency, the EPA Docket Center (EPA/DC) and Reading Room was closed to public visitors on March 31, 2020. Our EPA/DC staff will continue to provide customer service via email, phone, and webform. For further information on EPA/DC services, docket contact information and the current status of the EPA/DC and Reading Room, please visit *HYPERLINK "https://www.epa.gov/dockets" https://www.epa.gov/dockets*.

**FOR FURTHER INFORMATION CONTACT:** Michael L. Goodis, Director, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Avenue, 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 Publishing Office's e-CFR site at

*[http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab\\_02.tpl](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 numbers EPA-HQ-OPP-2017-0155 and EPA-HQ-OPP-2019-0383 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 numbers EPA-HQ-OPP-2017-0155 and EPA-HQ-OPP-2019-0383, 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. Summary of Petitioned-For Tolerance**

In the **Federal Register** of February 11, 2020 (85 FR 7708) (FRL-10005-02), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 9F8737) by Gowan Company, P.O. Box 5569, Yuma, AZ 85366-5569. The petition requested that 40 CFR 180.448 be amended by increasing the existing tolerances for residues of the ovicide/miticide hexythiazox, (4*R*,5*R*)-*rel*-5-(4-chlorophenyl)-*N*-cyclohexyl-4-methyl-2-oxo-3-thiazolidinecarboxamide, in or on caneberry, subgroup 13-07A to 3.0 parts per million (ppm) and date, dried to 3.0 ppm.

In addition, in the **Federal Register** of August 30, 2019 (84 FR 45702) (FRL-9998-15), EPA issued another document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 9E8756) by the Tea Association of the USA, Inc., 362 5<sup>th</sup> Avenue, Suite 1002, New York, NY 10001-2251. This petition requested that 40 CFR part 180.448 be amended by establishing tolerances for residues of the ovicide/miticide hexythiazox, (4*R*,5*R*)-*rel*-5-(4-chlorophenyl)-*N*-cyclohexyl-4-methyl-2-oxo-3-thiazolidinecarboxamide, in or on tea, dried at 15.0 ppm.

These documents referenced summaries of the petitions prepared by the Gowan Company and the Tea Association of the USA, Inc., which are available in the referenced dockets, *HYPERLINK "http://www.regulations.gov" http://www.regulations.gov*. There were no substantive comments received in response to either notice of filing.

### **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 hexythiazox including exposure resulting from the tolerances established by this action. A summary of EPA's assessment of exposures and risks associated with hexythiazox follows.

In the **Federal Register** on October 30, 2017 (82 FR 50084) (FRL-9968-12), EPA published a final rule amending an existing tolerance for residues of the ovicide/miticide

hexythiazox in or on Hop, dried cone based on the Agency's determination that aggregate exposure to hexythiazox is safe for the U.S. general population and all population subgroups, including infants and children. That document contains a summary of the toxicological profile and points of departure (PODs), assumptions for exposure assessment, and the EPA's determination regarding the children's safety factor which have not changed.

The toxicological endpoints table included in the last rule included inhalation exposure scenarios because EPA had concluded that there was a potential for residential handler inhalation exposure from uses on the label. EPA now assumes that products requiring personal protective equipment (PPE) on the label are not intended for homeowner use and there is no residential exposure associated with hexythiazox. Therefore, the aggregate exposure assessment no longer includes residential handler exposures, and the inhalation point of departure is no longer relevant for the FFDCA safety determination of hexythiazox. More detailed information on the risk assessment supporting the October 30, 2017 **Federal Register** can be found in the document entitled, "Hexythiazox: Human Health Risk Assessment for Amended Use on Hops" by going to <http://www.regulations.gov>. The referenced document is available in docket ID number EPA-HQ-OPP-2017-0155.

An acute dietary risk assessment is not required since no endpoint attributable to a single oral exposure was identified from the available toxicity database. Thus, there are no acute dietary risk estimates of concern for the U.S. general population or any population subgroup, including infants and children. EPA conducted an updated chronic dietary exposure assessment, taking into consideration exposures from already established tolerances as well as the new and modified tolerances in this action. Chronic risks are below the Agency's level of concern: 97% of the chronic population adjusted dose (cPAD) for children 1-2 years old, the population group with

the highest exposure. Hexythiazox is classified as “Likely to be Carcinogenic to Humans.” Based on the results of the chronic assessment, which is protective of potential carcinogenicity, EPA does not expect exposure to hexythiazox to pose a cancer risk. Using the exposure assumptions described for short-term exposures, EPA has concluded the combined short-term food, water, and residential exposures result in aggregate margins of exposures above the level of concern of 100 for all scenarios assessed and are not of concern.

Therefore, based on the risk assessments and information described above, EPA concludes there is a reasonable certainty that no harm will result to the U.S. general population, or to infants and children, from aggregate exposure to hexythiazox residues. More detailed information on the subject action to amend the existing tolerances in or on Caneberry, Subgroup 13-07A and on Date, dried, and to establish a tolerance in or on Tea, dried can be found in the document entitled, “Hexythiazox: Human Health Risk Assessment for Amended Tolerances on Caneberry Subgroup 13-07A and Dates, Dried and Establishment of a Tolerance Without U.S. Registration for Residues in Tea” by going to <http://www.regulations.gov>. The referenced document is available in the dockets established by this action, which are described under ADDRESSES. Locate and click on the hyperlinks for docket ID numbers EPA-HQ-OPP-2017-0155 and EPA-HQ-OPP-2019-0383.

#### **IV. Other Considerations**

##### *A. Analytical Enforcement Methodology*

An adequate High-Performance Liquid Chromatograph/Ultraviolet Detection (HPLC/UV) analytical method is available for the enforcement of tolerances for residues of hexythiazox and its metabolites containing the PT-1-3 moiety in crop and livestock commodities. This method is listed in the U.S. EPA Index of Residue Analytical Methods under hexythiazox

as method AMR-985-87. Hexythiazox has been tested FDA Multiresidue protocols C through E and the findings have been forwarded to the FDA. Hexythiazox metabolites were not recovered through protocols C through E.

The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Road, Ft. Meade, MD 20755-5350; telephone number: (410) 305-2905; email address: *HYPERLINK "mailto:residuemethods@epa.gov" residuemethods@epa.gov*.

#### *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 FFDCa section 408(b)(4). The Codex Alimentarius is a joint United Nations 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, FFDCa section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has established an MRL on tea at 15 ppm, which harmonizes with the U.S. tolerance on tea. Codex has also established an MRL for date at 2 ppm. The U.S. tolerance is not harmonized with this MRL because the U.S. method for measuring residues includes the metabolites, whereas the Codex MRL only includes measurement of the parent compound. The Codex has not established an MRL for residues of hexythiazox on raspberry, a representative

commodity for caneberry subgroup 13-07A.

## **V. Conclusion**

Therefore, tolerances are amended for residues of the ovicide/miticide hexythiazox, (4*R*,5*R*)-*rel*-5-(4-chlorophenyl)-*N*-cyclohexyl-4-methyl-2-oxo-3-thiazolidinecarboxamide, in or on Caneberry, subgroup 13-07A at 3 parts per million (ppm) and Date, dried at 3 ppm; and a new tolerance is being established in or on Tea, dried at 15 ppm.

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

This action establishes and modifies tolerances 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), nor is it considered a regulatory action under 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.*), 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).

## **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: June 24, 2020.

**Michael Goodis,**

*Director, Registration Division, Office of Pesticide Programs.*

Therefore, 40 CFR chapter I is amended 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. In § 180.448 amend the table in paragraph (a) by revising the entries for “Caneberry subgroup 13-07A” and “Date, dried fruit” and adding in alphabetical order an entry for “Tea, dried” to read as follows:

**§ 180.448 Hexythiazox; tolerances for residues.**

(a) \* \* \*

Commodity	Parts per million
* * *	* * *
Caneberry, Subgroup 13-07A	3
* * *	* * *
Date, dried	3
* * *	* * *
Tea, dried <sup>1</sup>	15
* * *	* * *

<sup>1</sup>There are no U.S. registrations for this commodity as of [*insert date of publication in the Federal Register*].

\* \* \* \* \*