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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2024-0322; FRL-13116-01-OCSPP]

Hexythiazox; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of the insecticide hexythiazox and its metabolites in or on lemon/lime, subgroup 10-10B at 0.6 parts per million (ppm). This regulation also establishes separate regional tolerances for grapefruit, subgroup 10-10C (CA, AZ, TX only) at 0.5 ppm and orange, subgroup 10-10A (CA, AZ, TX only) at 0.5 ppm. Under the Federal Food, Drug, and Cosmetic Act (FFDCA), Gowan Company submitted a petition to EPA requesting that EPA establish a maximum permissible level for residues of this pesticide.

DATES: This rule is effective on **[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 this document.)

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2024-0322, is available online at *https://www.regulations.gov*. Additional information about dockets generally, along with instructions for visiting the docket in person, is available at *https://www.epa.gov/dockets*.

FOR FURTHER INFORMATION CONTACT: Charles Smith, Director, Registration Division (7505T), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Avenue, NW., Washington, DC 20460-0001; main telephone number: (202) 566-1030; email address: *RDFRNotices@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. Executive Summary

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 might apply to them:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. *What is EPA's authority for taking this action?*

EPA is issuing this rulemaking under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a. FFDCA section 408(b)(2)(A)(i) 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." FFDCA section 408(b)(2)(A)(ii) 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. FFDCA section 408(b)(2)(C) 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. . ."

C. *How can I file an objection or hearing request?*

Under FFDCA 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. If you fail to file an objection to the final rule within the time period specified in the final rule, you will have waived the right to raise any issues resolved in the final rule. 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 the docket ID number EPA-HQ-OPP-2024-0322 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*]**.

The EPA's Office of Administrative Law Judges (OALJ), in which the Hearing Clerk is housed, urges parties to file and serve documents by electronic means only, notwithstanding any other particular requirements set forth in other procedural rules governing those proceedings. *See* "Revised Order Urging Electronic Filing and Service," dated June 22, 2023, which can be found at *https://www.epa.gov/system/files/documents/2023-06/2023-06-22%20-%20revised%20order%20urging%20electronic%20filing%20and%20service.pdf*. Although the EPA's regulations require submission via U.S. Mail or hand delivery, the EPA intends to treat submissions filed via electronic means as properly filed submissions; therefore, the EPA believes the preference for submission via electronic means will not be prejudicial. When submitting documents to the OALJ electronically, a person should utilize the OALJ e-filing system at *https://yosemite.epa.gov/oa/eab/eab-alj_upload.nsf*.

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 at *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. If you wish to include CBI in your request, please follow the applicable instructions at *https://www.epa.gov/dockets/commenting-epa-dockets#rules* and clearly mark the information that you claim to be CBI. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice.

II. Petitioned for Tolerance

In the ***Federal Register*** of September 5, 2025 (90 FR 42897) (FRL-12474-06-OCSPP), 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 4F9135) by Gowan Company, LLC, P.O. Box 5569, Yuma, AZ 85366-5569. The pesticide petition requested that 40 CFR § 180.448 be amended by converting the existing regional tolerance for residues of the insecticide hexythiazox and its metabolites in or on the raw agricultural commodities of citrus crop group 10–10 at 0.6 parts per million (ppm) to include a national tolerance for crop subgroup 10–10B lemon/lime at 0.6 ppm, while establishing separate, remaining regional tolerances for grapefruit, subgroup 10–10C (CA, AZ, TX only) at 0.5 ppm and orange, subgroup 10–10A (CA, AZ, TX only) at 0.5 ppm. That document referenced a summary of the petition that was prepared by the petitioner and has been included in the docket. There was one (1) non-substantive comment received on October 6, 2025, in response to the notice of filing.

III. Aggregate Risk Assessment and Determination of Safety

Consistent with FFDCA section 408(b)(2)(D), and the factors specified therein, 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. EPA's assessment of exposures and risks associated with hexythiazox follows.

In an effort to streamline its publications in the ***Federal Register***, EPA is not reprinting sections that repeat what has been previously published for tolerance rulemakings for the same

pesticide chemical. Where scientific information concerning a particular chemical remains unchanged, the content of those sections would not vary between tolerance rulemakings, and EPA considers referral back to those sections as sufficient to provide an explanation of the information EPA considered in making its safety determination for the new rulemaking.

EPA has previously published tolerance rulemakings for hexythiazox in which EPA concluded, based on the available information, that there is a reasonable certainty that no harm would result from aggregate exposure to hexythiazox and established tolerances for residues of the chemical. EPA is not reprinting previously published sections from these rulemakings as described further in this rulemaking, as they remain unchanged.

Toxicological profile. For a detailed discussion of the toxicological profile of hexythiazox, see Unit III**.** of the hexythiazox tolerance rulemaking published in the ***Federal Register*** of July 20, 2020 (85 FR 43697) (FRL–10008–84).

Toxicological points of departure/levels of concern. All points of departure (POD), toxicity endpoints, and levels of concern (LOC) for hexythiazox remain unchanged from the previous human health risk assessment (July 8, 2020) which can be found in docket ID EPA-HQ-OPP-20224-0200 at *https://wwwregulations.gov*. In addition, the hazard characterization also remains unchanged. For a summary of the toxicological points of departure/levels of concern for hexythiazox used for human health risk assessment, see Tables 4.1.1. and 4.1.2. of the document entitled "Hexythiazox: Human Health Risk Assessment for the Section 3 Registration of Hexythiazox on Citrus, Fruit, Subgroup 10-10B (Lemon/Lime)." (Human Health Risk Assessment), dated December 17, 2025, in docket ID EPA-HQ-OPP-2024-0322 at https://www.regulations.gov.

Exposure assessment. An aggregate dietary (food + drinking water) exposure and risk assessment was conducted using the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database Version 4.02. This software uses 2005-2010 food consumption data from the U.S. Department of Agriculture's National Health and Nutrition Examination Survey,

What We Eat in America. An acute dietary exposure assessment is not required since no endpoint attributable to a single oral exposure was identified from the available toxicity database. The chronic dietary risk assessment was conducted using tolerance level residues, modeled drinking water estimates, assumed 100% crop treated and used the EPA's default processing factors. The chronic dietary exposure estimate for the most highly exposed population subgroup, children 1-2 years old, was 86% of the chronic population adjusted dose (cPAD).

Drinking water and non-occupational exposures. The most recent estimated drinking water concentrations from the previous human health risk assessment (July 8, 2020) can be found in docket ID EPA-HQ-OPP-2024-0200 at https://wwwregulations.gov. This new action would not exceed those calculated in the last hexythiazox drinking water assessment.

There are no new residential uses of hexythiazox at this time; however, all previously registered hexythiazox product labels with residential use sites require that handlers wear specific clothing (*e.g.*, long-sleeved shirt and long pants) and/or use Personal Protective Equipment (PPE) (*e.g.*, gloves). Therefore, EPA has made the assumption that these products are not for homeowner use and has not conducted a quantitative residential handler assessment.

Cumulative exposure. Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke 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." Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to hexythiazox and any other substances, and hexythiazox does not appear to produce a toxic metabolite produced by other substances. For the purposes of this action, therefore, EPA has not assumed that hexythiazox has a common mechanism of toxicity with other substances.

Safety factor for infants and children. EPA continues to conclude that there are reliable data to support the reduction of the Food Quality Protection Act (FQPA) safety factor for

hexythiazox from 10X to 1X since there is no evidence of increased susceptibility to *in utero* and/or postnatal exposure to hexythiazox. See Unit III. of the July 20, 2020, rulemaking for a discussion of EPA's rationale for that determination.

Aggregate risks and determination of safety. EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing dietary (food + drinking water) exposure estimates to the acute population-adjusted dose (aPAD) and chronic population-adjusted dose (cPAD). Short- and intermediate-term risks are evaluated by comparing the estimated total food, water, and residential exposure to the appropriate points of departure to ensure that an adequate margin of exposure (MOE) exists. There are no new residential uses of hexythiazox proposed at this time, therefore, a residential assessment is not required. However, residential exposures are anticipated from the registered use of hexythiazox and worst-case residential exposures have been carried forward from the 2020 Hexythiazox Human Health Risk Assessment for purpose of aggregate assessment. The short-term and intermediate-term aggregate assessment resulted in no risk estimates of concern when aggregating residential post-application exposures with the updated chronic dietary exposures. MOEs were 1,200 and 1,400 for the short- and intermediate-term aggregate assessments, respectively (LOC = 100).

Hexythiazox is classified as "Likely to be Carcinogenic to Humans" based upon increased incidences of malignant and combined benign/malignant liver tumors in female mice, and benign mammary gland tumors observed in male rats. The evidence was not strong enough to warrant the use of a linear low dose extrapolation model applied to the animal data (Q1*) for a quantitative estimation of human risk. The findings demonstrate that the chronic reference dose (RfD) is protective of the tumors observed at 163 mg/kg/day. EPA concludes that quantification of risk using a non-linear approach; *i.e.,* the chronic RfD, for hexythiazox will adequately account for all chronic toxicity, including carcinogenicity from exposure to hexythiazox. Therefore, a separate cancer assessment was not conducted, and the chronic exposure assessment is considered protective of any cancer exposures.

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 this action can be found in the Human Health Risk Assessment.

IV. Other Considerations

A. *Analytical Enforcement Methodology*

Samples were analyzed for residues of hexythiazox and its metabolite PT-1-3 using a common moiety high-performance liquid chromatography method with tandem mass spectrometry detection, Morse Laboratories Method No. Meth-220. The method provides for conversion of residues determined as PT-1-3 to hexythiazox equivalents using a molecular weight conversion factor of 1.55. The limit of quantitation, determined as the lowest level of method validation, was 0.02 ppm for hexythiazox in/on lemon. Therefore, adequate enforcement methodology is available to enforce the tolerance expressions for hexythiazox in/on lemon.

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 (MRL) 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.

There are Codex MRLs established for residues of hexythiazox in or on citrus fruit (group) at 0.5 ppm. The additional field trial data on lemon, and an updated OECD tolerance

calculation supports a national tolerance for hexythiazox on lemon/lime, subgroup 10-10B at 0.6 ppm. Therefore, EPA is establishing a national tolerance for hexythiazox on lemon/lime, subgroup 10-10B at 0.6ppm and is not harmonizing with Codex.

A regional tolerance (CA, AZ, TX only) will remain for the raw agricultural commodities of orange, subgroup 10-10A and grapefruit, subgroup 10-10C to harmonize with the Codex MRL for Fruit, citrus, group 10-10. The OECD calculations for orange, subgroup 10-10A and grapefruit, subgroup 10-10C were 0.2 ppm and 0.15 ppm and are below the Codex MRL of 0.5 ppm for citrus; therefore, EPA is recommending removing the currently established fruit, citrus, group 10-10 tolerance of 0.6 ppm and establishing regional tolerances for orange, subgroup 10-10A and grapefruit, subgroup 10-10C at 0.5 ppm to harmonize with Codex.

C. *Effective and Expiration Date(s)*

In general, a tolerance action is effective on the date of publication of the final rule in the ***Federal Register***. For actions in the final rule that lower or revoke existing tolerances, EPA will set an expiration date for the existing tolerance of six months after the date of publication of the final rule in the ***Federal Register***, in order to allow a reasonable interval for producers in exporting members of the World Trade Organization's (WTO's) Sanitary and Phytosanitary (SPS) Measures Agreement to adapt to the requirements.

D. *Revisions to Petitioned-For Tolerances*

To harmonize with Codex, the Agency is establishing regional tolerances for orange, subgroup 10-10A (CA, AZ, TX only) at 0.5 ppm and grapefruit, subgroup 10-10C (CA, AZ, TX only) at 0.5 ppm. In addition, to reflect the updates to the existing regulations from this pesticide petition, the regional tolerance for fruit, citrus group 10-10 (CA, AZ, TX only) will be removed from the table in Paragraph (c) of 40 CFR § 180.448.

V. Conclusion

Therefore, a tolerance is established for residues of the ovicide/miticide hexythiazox and its metabolites in or on lemon/lime, subgroup 10-10B at 0.6 ppm. Regional tolerances are

established for orange, subgroup 10-10A (CA, AZ, TX only) at 0.5 ppm and grapefruit, subgroup 10-10C (CA, AZ, TX only) at 0.5 ppm. The existing regional tolerance for residues of hexythiazox in or on fruit, citrus group 10-10 (CA, AZ, TX only) will be removed from the table in Paragraph (c) of 40 CFR § 180.448.

VI. Statutory and Executive Order Reviews

Additional information about these statutes and Executive Orders can be found at *https://www.epa.gov/laws-regulations/laws-and-executive-orders*.

A. *Executive Order 12866: Regulatory Planning and Review*

This action is exempt from review under Executive Order 12866 (58 FR 51735, October 4, 1993), because it establishes or modifies a pesticide tolerance or a tolerance exemption under FFDCA section 408 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.

B. *Executive Order 14192: Unleashing Prosperity Through Deregulation*

Executive Order 14192 (90 FR 9065, February 6, 2025) does not apply because actions that establish a tolerance under FFDCA section 408 are exempted from review under Executive Order 12866.

C. Paperwork *Reduction Act (PRA)*

This action does not impose an information collection burden under the PRA 44 U.S.C. 3501 *et seq*., because it does not contain any information collection activities.

D. *Regulatory Flexibility Act (RFA)*

Since tolerance actions 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 RFA, 5 U.S.C. 601 *et seq*., do not apply to this action.

E. *Unfunded Mandates Reform Act (UMRA)*

This action does not contain an unfunded mandate of $100 million or more (in 1995

dollars and adjusted annually for inflation) as described in UMRA, 2 U.S.C. 1531–1538 and does not significantly or uniquely affect small governments. The action imposes no enforceable duty on any State, local, or Tribal governments or on the private sector.

F. *Executive Order 13132: Federalism*

This action does not have federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999), because it will not 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.

G. *Executive Order 13175: Consultation and Coordination with Indian Tribal Governments*

This action does not have Tribal implications as specified in Executive Order 13175 (65 FR 67249, November 9, 2000), because it will not have substantial direct effects on Tribal governments, 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.

H. *Executive Order 13045: Protection of Children from Environmental Health Risks and Safety Risks*

This action is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997) because tolerance actions like this one are exempt from review under Executive Order 12866. However, EPA's 2021 *Policy on Children's Health* applies to this action. This rule finalizes tolerance actions under the FFDCA, which 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 ..." (FFDCA 408(b)(2)(C)). The Agency's consideration is summarized in Unit III.

I. *Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution or Use*

This action is not subject to Executive Order 13211 (66 FR 28355) (May 22, 2001) because it is not a significant regulatory action under Executive Order 12866.

J. *National Technology Transfer Advancement Act (NTTAA)*

This action does not involve technical standards that would require Agency consideration under NTTAA section 12(d), 15 U.S.C. 272.

K. *Congressional Review Act (CRA)*

This action is subject to the CRA, 5 U.S.C. 801 *et seq.*, and EPA will submit a rule report to each House of the Congress and to the Comptroller General of the United States. 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: February 10, 2026.

Charles Smith,

Director, Registration Division, Office of Pesticide Programs.

For the reasons set forth 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 § 180.448 by:

a. In paragraph (a)

i. Adding to the table the table heading "Table 1 to Paragraph (a)"; and

ii. Adding in alphabetical order an entry for "Lemon/Lime, subgroup 10-10B".

b In paragraph (c):

i. Adding to the table the table heading "Table 2 to Paragraph (c)";

ii. Removing the existing entry for "Fruit, citrus group 10-10 (CA, AZ, TX only)"; and

iii. Adding in alphabetical order entries for "Grapefruit, subgroup 10-10C (CA, AZ, TX only)" and "Orange, subgroup 10-10A (CA, AZ, TX only)".

The additions and revisions read as follows:

§ 180.448 Hexythiazox; tolerances for residues.

(a) * * *

Table 1 to Paragraph (a)

Commodity	Parts per million
* * * * * * *	
Lemon/Lime, subgroup 10-10B	0.6
* * * * * * *	

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(c) * * *

Table 2 to Paragraph (c)

Commodity	Parts per million
* * * * * * *	
Grapefruit, subgroup 10-10C (CA, AZ, TX only)	0.5

* * * * * * *	
Orange, subgroup 10-10A (CA, AZ, TX only)	0.5
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