



ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2024-0212; FRL-12816-01-OCSP]

Pyroxasulfone; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of pyroxasulfone in or on the nut, tree, group 14-12; the fruit, small, vine climbing, except fuzzy kiwifruit, subgroup 13-07F; and almond hulls. K-I Chemical U.S.A., Inc. requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

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-2024-0212, is available 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 Ave., NW., Washington, DC 20460-0001; 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 docket ID number EPA-HQ-OPP-2024-0212 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 December 9, 2024 (89 FR 97577) (FRL-11682-10-OCSP), 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 3F9073) by K-I Chemical U.S.A., Inc., c/o Landis International, Inc., P.O. Box 5126, Valdosta, GA 31603-5126. The petition requested that 40 CFR 180.659 be amended by establishing tolerances for residues of pyrozasulfone, (3-[(5-difluoromethoxy-1-methyl-3-(trifluoromethyl)pyrazol-4-yl)methylsulfonyl]-4,5-dihydro-5,5-dimethyl-1,2-oxazole), including its metabolites M-1, M-3, M-25, and M-28, in or on nut, tree, group 14-12 at 0.07 parts per million (ppm); fruit, small, vine climbing, except fuzzy kiwifruit, subgroup 13-07F at 0.07 ppm; and almond, hulls at 0.15 ppm. That document referenced a summary of the petition prepared by the petitioner and included in the docket.

There were no comments received in response to the notice of filing.

III. Final Tolerance Action

A. EPA's safety determination.

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 pyrozasulfone including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with pyrozasulfone is summarized in this unit. In an effort to streamline its publications in the *Federal Register*, EPA is not reprinting sections that repeat what has been previously published in 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 previously published several tolerance rulemakings for pyrooxasulfone, in which EPA concluded, based on the available information, that there is a reasonable certainty that no harm would result from aggregate exposure to pyrooxasulfone and established tolerances for residues of that chemical. EPA is incorporating previously published sections of those rulemakings that remain unchanged, as described further in this rulemaking. Specific information on the risk assessment conducted in support of this action, including on the studies received and the nature of the adverse effects caused by pyrooxasulfone, can be found in the document titled “Pyrooxasulfone: Human Health Risk Assessment for the New Section 3 Uses on Fruit, Small, Vine Climbing, Except Fuzzy Kiwifruit, Subgroup 13-07F and Nut, Tree, Group 14-12” (hereinafter “Pyrooxasulfone Human Health Risk Assessment”), which is available in the docket.

B. Toxicological profile.

For a discussion of the Toxicological Profile of pyrooxasulfone, see Unit III.A. of the rulemaking published in the *Federal Register* of October 29, 2018 (83 FR 54259) (FRL-9983-29).

C. Toxicological points of departure/levels of concern.

Once a pesticide’s toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level, generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD), and a safe margin of exposure

(MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see <https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/assessing-human-health-risk-pesticides>.

More detailed information on the toxicological endpoints for pyrooxasulfone used for human health risk assessment can be found in the Pyrooxasulfone Human Health Risk Assessment that is in the docket.

D. Exposure assessment.

Much of the exposure assessment remains unchanged from the rulemaking of October 29, 2018, as described in Unit III.C. of that rulemaking, although the new exposure assessment incorporates the additional dietary exposure from the petitioned-for tolerances. Other changes are described in this unit.

Acute and chronic dietary exposure assessments were conducted using DEEM-FCID Version 4.02. This software uses 2005-2010 food consumption data from the U.S. Department of Agriculture's (USDA's) National Health and Nutrition Examination Survey, What We Eat in America, (NHANES/WWEIA).

For both the acute and chronic risk assessments EPA assumed 100 percent crop treated (PCT). Residues in or on food were based on tolerance level residues for all commodities with the following exceptions, which were based on tolerance level residues adjusted to include additional metabolites of concern for risk assessment: cereal grains (*i.e.*, corn, field, grain; corn, pop, grain; corn, sweet, kernel plus cob with husks removed (K+CWHR); and wheat, grain); cottonseed, subgroup 20C; milk; and soybean, seed. The assessments used default processing factors and the highest estimated drinking water concentrations (EDWCs) from acute and chronic ground water exposures.

For a summary of the drinking water numbers used, see Unit III.C. of the rulemaking of October 29, 2018. For the acute dietary risk assessment, a water concentration value of 210 parts per billion (ppb) was used to assess the contribution to drinking water. For the chronic dietary risk assessment, a water concentration value of 174 ppb was used to assess the contribution to drinking water.

The registered and proposed uses of pyrooxasulfone are not expected to result in residential exposure. There are no proposed residential uses at this time and existing registrations with residential use sites are not expected to result in residential handler or post-application exposure based on the label directions and directed use patterns (soil-directed application), providing no residential contribution to the aggregate. Therefore, the acute and chronic exposure estimates represent all aggregate exposure.

E. Cumulative exposure.

FFDCA section 408(b)(2)(D)(v) 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 pyrooxasulfone and any other substances, and pyrooxasulfone does not appear to produce a toxic metabolite produced by other substances. For the purposes of this action, therefore, EPA has not assumed that pyrooxasulfone has a common mechanism of toxicity with other substances.

F. Safety factor for infants and children.

1. *In general.* FFDCA section 408(b)(2)(C) provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for

infants and children. This additional margin of safety is commonly referred to as the Food Quality Protection Act (FQPA) safety factor.

2. *Prenatal and postnatal sensitivity.* Pyroxasulfone did not exhibit developmental toxicity in the rat guideline study at the limit dose of 1000 mg/kg/day although it exhibited slight developmental toxicity in rabbits (reduced fetal weight and increase fetal resorptions) at the limit dose of 1000 mg/kg/day. However, developmental effects (decreased brain weight and morphometric changes) were noted in offspring at 300 mg/kg/day in the rat developmental neurotoxicity (DNT) study compared to no maternal toxicity at ≥ 900 mg/kg/day. In a reproductive toxicity in rats, reduced pup body weight during lactation occurred at similar or higher doses causing pronounced maternal toxicity (reduced body weight and cardiac, nerve, liver, muscle and urinary system toxicity).

3. *Conclusion.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA safety factor were reduced to 1X. That decision is based on the following findings:

- The toxicity database for pyroxasulfone is complete.
- The neurotoxicity database, including acute, subchronic and chronic studies, shows adverse effects from pyroxasulfone exposure in mice, rats and dogs, with dogs showing the most sensitivity. Although the DNT study indicated offspring are more sensitive to neurotoxic effects of pyroxasulfone, the dose-response is well characterized for neurotoxicity and a NOAEL is identified; therefore, there is no residual uncertainty with regard to neurotoxic effects for which a 10X must be retained.
- The available database shows evidence of increased susceptibility of fetuses and offspring in a DNT study in rats and in a developmental study in rabbits following in *utero* or post-natal exposure to pyroxasulfone. The Agency concludes, however, that there is no residual uncertainty concerning these effects. The available studies show clear NOAELs and LOAELs for these effects, which are occurring only at doses much higher than the endpoints on which the

Agency is regulating (i.e., all PODs selected for risk assessment are protective of the offspring effects).

- There are no residual uncertainties in the exposure databases. The dietary food exposure assessments were performed based on 100 PCT and tolerance-level residues or residues based on field trials. EPA made conservative (protective) assumptions in the ground or surface water modeling used to assess exposure to pyrooxasulfone in drinking water. These assessments will not underestimate the exposure and risks posed by pyrooxasulfone.

G. Aggregate risks and determination of safety.

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute population-adjusted dose (aPAD) and chronic population-adjusted dose (cPAD). Short-, intermediate-, and chronic-term aggregate risks are evaluated by comparing the estimated total food, water, and residential exposure to the appropriate points of departure (POD) to ensure that an adequate margin of exposure (MOE) exists.

Acute dietary (food and drinking water) risks are below the Agency's level of concern of 100% of the aPAD; they are 4.0% of the aPAD for all infants less than 1 year old, which is the population subgroup with the highest exposure estimate. Chronic dietary (food and drinking water) risks are below the Agency's level of concern of 100% of the cPAD; they are 70% of the cPAD for all infants less than 1 year old, which is the population subgroup with the highest exposure estimate.

The Agency has determined that the quantification of risk using a non-linear approach (i.e., RfD) will adequately account for all chronic toxicity, including carcinogenicity, that could result from exposure to pyrooxasulfone. Therefore, a separate cancer dietary (food and drinking water) exposure and risk assessment was not conducted.

Therefore, based on the risk assessment and information described in this document, EPA concludes there is a reasonable certainty that no harm will result to the general population, or to

infants and children, from aggregate exposure to pyroxasulfone residues.

IV. Other Considerations

A. Analytical enforcement methodology.

For a discussion of the available analytical enforcement method, see Unit IV.A. in the rulemaking of October 29, 2018.

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 not established a MRL for residues of pyroxasulfone in or on any of the petitioned-for commodities associated with this regulatory action.

V. Conclusion

Therefore, tolerances are established for residues of pyroxasulfone, including its metabolites and degradates, in or on the Nut, tree, group 14-12 at 0.07 ppm; fruit, small, vine climbing, except fuzzy kiwifruit, subgroup 13-07F at 0.07 ppm; and almond, hulls at 0.15 ppm.

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 documented in the pesticide-specific registration review documents, *located* in each chemical docket at <https://www.regulations.gov>.

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: July 24, 2025.

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. In § 180.659, add alphabetically to the table in paragraph (a)(5) the commodities “Almond, hulls”; “Fruit, small, vine climbing, except fuzzy kiwifruit, subgroup 13-07F”; and “Nut, tree, group 14-12” to read as follows:

§ 180.659. Pyroxasulfone; tolerances for residues.

(a) * * *

(5) * * *

Commodity	Parts per million
Almond, hulls	0.15
* * * * *	*
Fruit, small, vine climbing, except fuzzy kiwifruit, subgroup 13-07F	0.07
* * * * *	*
Nut, tree, group 14-12	0.07
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