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E 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2024-0363; FRL-13147-01-OCSPP]

Sodium Salt of Acifluorfen; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of sodium salt of acifluorfen in or on sugar beet. UPL NA, Inc. requested this tolerance 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-2024-0363, 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, Registration Division (7505T), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW, Washington, DC 20460-0001; main telephone number: (202) 566-1030; 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 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 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. 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-2024-0363 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).

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/HomePage?ReadForm.

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-2024-0363, 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*.

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 Petitioned-For Tolerance

In the Federal Register of August 27, 2024 (89 FR 68571) (FRL-11682-07-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 4F9117) by UPL NA, Inc., P.O. Box 12219, Research Triangle Park, NC 27709–2219). The petition requested that 40 CFR 180.383 be amended by establishing tolerances for residues of the herbicide acifluorfen in or on sugar beet roots and sugar beet tops at 0.06 parts per million (ppm). That document referenced a summary of the petition prepared by the petitioner, which is available in the docket. There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petition and in accordance with its authority under FFDCA section 408(d)(4)(A)(i), EPA is modifying the tolerance expression and is not establishing proposed-for tolerance in/on sugar beet tops. EPA is also removing the established Section 18 emergency exemption tolerances under 40 CFR 180.383(b) in or on sugar beet, root and sugar beet, leaf at 0.1 ppm. The reasons for these changes are explained in Unit IV.C.

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 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 sodium salt of acifluorfen including exposure resulting from the tolerances

established by this action. EPA's assessment of exposures and risks associated with sodium salt of acifluorfen 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 sodium salt of acifluorfen in which EPA concluded, based on the available information, that there is a reasonable certainty that no harm would result from aggregate exposure to sodium salt of acifluorfen and established tolerances for residues of that chemical. EPA is incorporating previously published sections from these rulemakings as described further in this rulemaking, as they remain unchanged.

A. Toxicological Profile

For a discussion of the toxicological profile of sodium salt of acifluorfen, see Unit III.A. of the final rule published in the Federal Register of July 27, 2023 (88 FR 48383) (FRL-11130-01-OCSPP).

B. 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 (LOCs) 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 http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/assessing-human-health-risk-pesticides.

A summary of the toxicological endpoints and points of departure for sodium salt of acifluorfen used for human health risk assessment can be found in the document, "Sodium Acifluorfen: Human Health Risk Assessment for Proposed Uses and Tolerances on Sugar Beets" in docket ID number EPA-HQ-OPP-2024-0363.

C. Exposure Assessment

For a summary of the assumptions used in assessing exposure of sodium salt of acifluorfen, see Unit III.C. of the July 27, 2023 final rule.

1. Dietary exposure. In the July 27, 2023 final rule, EPA assessed acute and chronic dietary (food and drinking water) exposures to sodium salt of acifluorfen from all existing tolerances in 40 CFR 180.383, including for sugar beet commodities which had higher time-limited tolerance levels (0.1 ppm) than the petitioned-for tolerances (0.06 ppm) in this action. Therefore, no new dietary analyses including drinking water were needed.

2. From non-dietary exposure. Sodium salt of acifluorfen is not registered or proposed for any uses that would result in residential exposure; therefore, direct exposure in residential settings are not expected for adults and children.

3. Cumulative effects from substances with a common mechanism of toxicity. EPA has not found sodium salt of acifluorfen to share a common mechanism of toxicity with any other substances, and it does not appear to produce a toxic metabolite produced by other substances.

For the purposes of this tolerance action, EPA has assumed that sodium salt of acifluorfen does not have a common mechanism of toxicity with other substances.

D. 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 (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity*. There is evidence of increased susceptibility following *in utero* exposure to sodium salt of acifluorfen in the Sprague Dawley rat developmental toxicity study. However, there is low concern for developmental toxicity because the effects are well characterized with clear no-observed-adverse-effect level (NOAEL) and lowest-observed-adverse-effect level (LOAEL) values and the chosen POD for risk assessment for each scenario are protective of these effects.

3. Conclusion.

EPA has determined that reliable data show that the safety of infants and children would be adequately protected if the FQPA SF were reduced from 10X to 1X. That decision is based on the following findings:

i. The toxicity database for sodium salt of acifluorfen is complete.

ii. The weight of evidence (WOE) suggests that sodium salt of acifluorfen is not neurotoxic. This conclusion is based on the following: (1) indications of treatment-related toxicity in the acute neurotoxicity study (ACN) are well-characterized, and the decreased motor activity observed could be an indication of systemic toxicity from the bolus dose; (2) the slight

effect observed in fetuses in a developmental toxicity study with Sprague-Dawley rats (dilated brain ventricles) were not reproduced in another developmental toxicity study with Wistar rats nor in developmental toxicity studies with rabbits; and (3) there was no indication of treatment-related neurotoxicity observed in any studies for structurally-related chemicals (fomesafen, lactofen, and oxyfluorfen), except for decreased motor activity in an acute neurotoxicity study with fomesafen at the same dose where general systemic toxicity (body weight loss) was observed.

iii. There is evidence that sodium salt of acifluorfen results in increased susceptibility following exposure *in utero* rats in the Sprague Dawley rat prenatal developmental study. However, there is low concern for developmental toxicity because effects are well characterized with clear NOAEL/LOAEL values and the chosen PODs for risk assessment for each scenario are protective of these effects.

iv. There are no residual uncertainties identified in the exposure database. The dietary food exposure assessments were performed based on 100% crop treated assumptions and tolerance-level residues. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to sodium salt of acifluorfen in drinking water. These assessments will not underestimate the exposure and risks posed by sodium salt of acifluorfen.

E. Aggregate Risk 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 the chronic population adjusted dose (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. Acute risk. Using the exposure assumptions discussed in this unit for acute exposure, EPA has concluded that the acute dietary exposure to sodium salt of acifluorfen from food and drinking water will occupy less than 1% of the aPAD for the general U.S. population and all population subgroups. A separate point of departure was selected for females 13-49 years old and the risk estimate was 3.9% of the aPAD for females 13-49 years old, the population subgroups receiving the greatest exposures. There are no residential uses of sodium salt of acifluorfen; therefore, the acute aggregate risk is equivalent to acute dietary risk estimates, which are below EPA's LOC (<100% of aPAD) and not of concern.

2. Chronic risk. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic dietary exposure to sodium salt of acifluorfen from food and drinking water will occupy 87% of the cPAD for all infants less than 1 year old, the population subgroup receiving the greatest exposure. There are no residential uses of sodium salt of acifluorfen; therefore, the chronic aggregate risk is equivalent to the chronic dietary risk estimate, which is below EPA's LOC (<100% cPAD) and not of concern.

3. Short- and intermediate-term risks. Short- and intermediate-term aggregate exposures take into account short- (1 to 30 days) and intermediate-term (30 days to 6 months) residential exposures plus chronic exposure to food and water (considered to be a background exposure level). Short- and intermediate-term adverse effects were identified; however, sodium salt of acifluorfen is not registered for any use patterns that would result in short- or intermediate-term residential exposures. Because there is no short- or intermediate-term residential exposure and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess short- or intermediate-term risk), no further assessment of short- or intermediate-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating short- and intermediate-term risks for sodium salt of acifluorfen.

4. Aggregate cancer risk for U.S. population. Sodium salt of acifluorfen is classified as, "likely to be carcinogenic to humans at high enough doses to cause the biochemical and histopathological changes in livers of rodents, but unlikely to be carcinogenic at doses below those causing these changes." EPA determined that the non-linear reference dose (RfD) approach will be protective for chronic effects, including carcinogenicity. Because the chronic risk is below EPA's level of concern, sodium salt of acifluorfen is not expected to pose a cancer risk to humans.

5. Determination of safety. Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children, from aggregate exposure to sodium salt of acifluorfen residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methods are available to enforce the tolerances of sodium salt of acifluorfen. The Pesticide Analytical Manual (PAM) Volume II lists Method I, a gas chromatography-electron capture detector (GC-ECD) method for the determination of sodium salt of acifluorfen in plant commodities. Identifications are confirmed by Method A, a gas chromatography-mass spectrometry (GC-MS) method.

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). Codex has not established any MRLs for sodium salt of acifluorfen.

C. Revisions to Petitioned-for Tolerances

The proposed tolerance for the commodity "sugar beet, tops" is not needed since it is not considered a significant feed item. This is based on the "revisions of Feedstuffs in Table 1

OPPTS 860.1000 (June 2008)". EPA is also revising the tolerance expression in 40 CFR 180.383(a) to General. Tolerances are established for residues of the herbicide sodium acifluorfen (sodium 5-[2-chloro-4-(trifluoromethyl)phenoxy]-2-nitrobenzoate), including its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels specified below is to be determined by measuring only the sum of acifluorfen acid (5-[2-chloro-4-(trifluoromethyl)phenoxy]-2-nitrobenzoic acid), acifluorfen methyl ester (methyl 5-[2-chloro-4-(trifluoromethyl)phenoxy]-2-nitrobenzoate), acifluorfen amine, (5-[2-chloro-4-(trifluoromethyl)phenoxy]-2-aminobenzoic acid), and acifluorfen amine methyl ester(methyl 5-[2-chloro-4-(trifluoromethyl)phenoxy]-2-aminobenzoate), calculated as the stoichiometric equivalent of acifluorfen acid, in or on the commodities based on current guidance on tolerance expressions.

Additionally, in the Federal Register of March 31, 2022 (87 FR 18717) (FRL-9657-01-OCSPP), EPA established time-limited tolerances for residues of sodium salt of acifluorfen in or on beet, sugar, leaves and beet, sugar, roots at 0.1 ppm, which expired on December 31, 2024. In the Federal Register of October 25, 2024 (89 FR 85067) (FRL-12300-01-OCSPP), EPA extended the time-limited tolerances for the above commodities until December 31, 2027. EPA is therefore removing the established tolerances for Section 18 emergency exemption tolerances under 40 CFR 180.383(b) in or on sugar beet, root and sugar beet, leaf at 0.1 ppm..

V. Conclusion

Therefore, a tolerance is established for residues of sodium salt of acifluorfen in or on "beet, sugar, roots" at 0.06 ppm. In addition, EPA is removing the established Section 18 emergency exemption tolerances under 40 CFR 180.383(b) in or on sugar beet, root and sugar beet, leaf at 0.1 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. *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.

C. *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.

D. *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.

E. *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.

F. *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.

G. *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.

H. *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.

I. *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.

J. *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.

Authority: 21 U.S.C. 321(q), 346a and 371.

Dated: September 24, 2026.

Charles Smith,

Director, Registration Division, Office of Pesticide Programs.

For the reasons set forth in the preamble, EPA amends 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 § 180.383 by:

a. In paragraph (a):

i. Revising the introductory text; and

ii. In table 1 to paragraph (a), adding in alphabetical order the entry "Beet, sugar, roots"; and

b. Removing and reserving paragraph (b).

The revision and addition read as follows:

§ 180.383 Sodium salt of acifluorfen; tolerances for residues.

(a) *General*. Tolerances are established for residues of the herbicide sodium acifluorfen (sodium 5-[2-chloro-4-(trifluoromethyl)phenoxy]-2-nitrobenzoate), including its metabolites and degradates, in or on the commodities in the following table. Compliance with the tolerance levels specified in the following table is to be determined by measuring only the sum of acifluorfen acid (5-[2-chloro-4-(trifluoromethyl)phenoxy]-2-nitrobenzoic acid), acifluorfen methyl ester(methyl 5-[2-chloro-4-(trifluoromethyl)phenoxy]-2-nitrobenzoate), acifluorfen amine, (5-[2-chloro-4-(trifluoromethyl)phenoxy]-2-aminobenzoic acid), and acifluorfen amine methyl ester(methyl 5-[2-chloro-4-(trifluoromethyl)phenoxy]-2-aminobenzoate), calculated as the stoichiometric equivalent of acifluorfen acid, in or on the commodities.

Table 1 to Paragraph (a)	
Commodity	**Parts per million**
Beet, sugar, roots	0.06
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[FR Doc. 2026-19884 Filed: 9/28/2026 8:45 am; Publication Date: 9/29/2026]