E 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2023-0407; FRL-12919-01-OCSPP]

Mandipropamid; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance action for residues of mandipropamid in or on papaya. Under the Federal Food, Drug, and Cosmetic Act (FFDCA), Syngenta Crop Protection, LLC submitted a petition to EPA requesting that EPA establish a maximum permissible level for residues of this pesticide in or on the identified commodities.

DATES: This regulation 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-2023-0407, is available online at https://www.regulations.gov or in-person at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor instructions and additional information about the docket available at *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. 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).

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. *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 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-2023-0407 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-2023-0407, 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/where-send-comments-epa-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 September 19, 2023 (88 FR 64398 (FRL-10579-08-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 3E9047) by Syngenta Crop Protection, LLC (P.O. Box 18300, Greensboro, NC 27419). The petition requested that 40 CFR part 180 be amended by establishing tolerances for residues of the fungicide mandipropamid in or on; papaya, whole fruit at 0.8 part per million (ppm); papaya, peel at 3 ppm; and papaya, pulp at 0.015 ppm. That document referenced a summary of the petition that was prepared by Syngenta, the registrant, which is available in the docket, *https://www.regulations.gov*. There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petition, EPA is establishing the tolerance on Papaya at 0.9 ppm. The reason for this change is explained in Unit IV.C.

III. Final Tolerance Action

A. *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 mandipropamid including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with mandipropamid 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 of the same pesticide chemical. Where scientific information concerning a particular chemical remains unchanged, the content of those sections would not vary between tolerance rulemaking, 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 several tolerance rulemakings for mandipropamid in which EPA concluded, based on the available information, that there is a reasonable certainty that no harm would result from aggregate exposure to mandipropamid 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. "*Mandipropamid. Human Health Risk Assessment for Proposed Label Amendments for the Tuberous and Corm Vegetable Crop Subgroup (1C) and Tobacco, a Tolerance Without U.S. Registration for Papaya, and Non-Food Status for Non-Bearing Strawberries and Non-Bearing Members of the Tree Nut Crop Group 14-12*," which is available in the docket for this action at *https:// www.regulations.gov.*

B. *Toxicological Profile*

For a discussion of the Toxicological Profile of mandipropamid, see Unit III.A. of the rulemaking published in the Federal Register of March 22, 2019 (84 FR 10695) (FRL-9987-25). In 2020 the Agency published a draft risk assessment for the registration review of mandipropamid, but this assessment did not result in any changes to the conclusions from the 2019 rulemaking.

C. *Toxicological Points of Departure/Levels of Concern*

A summary of the toxicological endpoints for mandipropamid used for human health risk assessment is discussed in Unit III.B of the March 22, 2019 final rule.

D. *Exposure Assessment*

In evaluating dietary exposure to mandipropamid, EPA considered exposure under the petitioned-for tolerances as well as all existing tolerances in 40 CFR 180.637. An acute dietary risk assessment was not performed since no endpoint attributable to a single exposure (dose) was identified from the available oral toxicity database. In conducting the chronic dietary exposure assessment, EPA used the Dietary Exposure Evaluation Model software using the Food Commodity Intake Database (DEEM–FCID), Version 4.02, which uses the 2005–2010 food consumption data from the United States Department of Agriculture (USDA) National Health and Nutrition Examination Survey, What We Eat in America (NHANES/WWEIA). The chronic dietary exposure assessment is unrefined, assuming tolerance level residues and 100 percent crop treated (PCT). Based on the lack of evidence of carcinogenicity or genotoxicity, the Agency has classified mandipropamid as "Not Likely to be Carcinogenic to Humans" and therefore, there is no concern for cancer risk.

I. Dietary exposure from drinking water.

Since this request is for a tolerance without U.S. registration the action will not impact drinking water exposure estimates. The estimated drinking water concentrations (EDWCs) included all residues of concern in drinking water: mandipropamid, SYN504851, and

SYN500003. EPA used the Pesticide in Water Calculator (PWC) to determine both the groundwater and surface water EDWCs. For the chronic dietary risk assessment, the mandipropamid EDWCs are 21.9 ppb in surface water and 62.8 ppb in groundwater. The groundwater value was based on the Wisconsin corn scenario. Because the groundwater value is higher than the surface water value, it was used in the chronic dietary exposure assessment. It was incorporated into the DEEM-FCID model in the food categories "water, direct, all sources" and "water, indirect, all sources."

II. From non-dietary exposure.

There are no residential (non-occupational) uses proposed or currently registered for mandipropamid. Therefore, residential exposures were not assessed.

III. Cumulative effects from substances with a common mechanism of toxicity.

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 mandipropamid and any other substances and mandipropamid does not appear to produce a toxic metabolite produced by other substances. Therefore, for the purposes of this action, EPA has not assumed that mandipropamid has a common mechanism of toxicity with other substances.

E. *Safety Factor for Infants and Children*

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.

EPA continues to conclude that there are reliable data to support the reduction of the Food Quality Protection Act (FQPA) safety factor from 10X to 1X. See Unit III.D. of the March 22, 2019, rulemaking for a discussion of the Agency's rationale for that determination.

F. *Aggregate Risk and Determination of Safety*

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing dietary exposure estimates to the acute population adjusted dose (aPAD) and the 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 to ensure that an adequate margin of exposure (MOE) exists.

An acute dietary exposure assessment was not performed as there were no indications of an adverse effect attributable to a single dose. Chronic dietary risks (food and water) are below the Agency's level of concern of 100% of the cPAD; they are 44% of the cPAD for children 1 to less than 2 years old, the population subgroup receiving the highest exposure. As there are no residential uses for mandipropamid, the short-term and chronic aggregate risk estimates are equivalent to the chronic dietary risk estimates, which are not of concern.

Cancer risk was not assessed for mandipropamid because it is classified as "Not Likely to be Carcinogenic to Humans."

Therefore, based on the risk assessments and information described above, 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 mandipropamid residues, including its metabolites and degradates. More detailed information about the Agency's analysis can be found at *https://www.regulations.gov* in the document titled "Mandipropamid. Human Health Risk Assessment for Proposed Label Amendments for the Tuberous and Corm Vegetable Crop

Subgroup (1C) and Tobacco, a Tolerance Without U.S. Registration for Papaya, and Non-Food Status for Non-Bearing Strawberries and Non-Bearing Members of the Tree Nut Crop Group 14-12" in docket ID number EPA-HQ-OPP-2023-0407.

IV. Other Considerations

A. *Analytical Enforcement Methodology*

Under a previous action, Syngenta submitted an updated version of Method 415/01. HED reviewed the updated method, Method 415/02 (W. Drew, D428278, 2/23/2016). This method is essentially the same as Method RAM 415/01, with the exception that it was modified by the addition of a second ion transition for determination of mandipropamid, inclusion of specific LC/MS/MS conditions, and modification to include analysis of hops. Method 415/02 underwent a successful independent laboratory validation, has a validated LOQ of 0.010 ppm, and is adequate for enforcement of mandipropamid tolerances.

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 does not have established MRLs for mandipropamid on papaya.

C. *Revisions to Petitioned-For Tolerances*

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 establishing a tolerance that varies from what was

requested. The petitioner proposed a tolerance of 0.8 ppm for Papaya, Whole Fruit; 3 ppm for Papaya, Peel; and 0.015 ppm for Papaya, Pulp. Although the proposed tolerances are for Papaya, Whole Fruit; Papaya, Peel; and Papaya, Pulp, EPA has determined that a tolerance for Papaya only is appropriate because papaya is the only commodity of the three petitioned-for commodities for which the U.S. establishes tolerances, based on the OCSPP residue chemistry guideline 860.1000. Using papaya only, the OECD MRL calculation procedures generated a value of 0.9 ppm as the appropriate tolerance**.** As a result, the EPA-recommended tolerance for papaya is higher than the tolerance proposed by the petitioner.

V. Conclusion

Therefore, a tolerance is established for residues of mandipropamid (4-chloro-N-[2-[3-methoxy-4-(2-propyn-1-yloxy)phenyl]ethyl]-α-(2-propyn-1-yloxy)benzeneacetamide) in or on Papaya at 0.9 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.

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: August 6, 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. Amend § 180.637 by:

a. In the table in paragraph (a):

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

ii. Adding in alphabetical order an entry for "Papaya".

The additions read as follows:

§ 180.637 Mandipropamid; tolerances for residues.

(a) * * *

Table 1 to Paragraph (a)

Commodity	Parts per million
* * *	* * * *
Papaya[2]	0.9
* * *	* * * *

[1] There are no U.S. registrations allowing use of mandipropamid on cacao as of October 28, 2019.

[2] There is no U.S. registration for use of this pesticide on papaya as of **[INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**

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[FR Doc. 2025-15555 Filed: 8/14/2025 8:45 am; Publication Date: 8/15/2025]