■ 3. In § 180.920, amend table 1 to 180.920 by adding, in alphabetical order, an entry for ''1-Propanaminium, 3-amino-N-(carboxymethyl)-*N,N*-dimethyl-, N-coco acyl derivatives, hydroxides, inner salts (CAS Reg. No. 61789–40–0)'' to read as follows:

**§ 180.920 Inert ingredients used pre-harvest; exemptions from the requirement of a tolerance.**

* * * * *

TABLE 1 TO 180.920

| Inert ingredients | Limits | Uses |
|---|---|---|
| * * * | * * | * * |
| 1-Propanaminium, 3-amino-N-(carboxymethyl)-*N,N*-dimethyl-, N-coco acyl derivatives, hydroxides, inner salts (CAS Reg. No. 61789–40–0). | 10% w/w in pesticide formulation .. | Surfactant. |
| * * * | * * | * * |

[FR Doc. 2024–10182 Filed 5–9–24; 8:45 am]

**BILLING CODE 6560–50–P**

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 180

**[EPA–HQ–OPP–2022–0887; FRL–11734–01–OCSPP]**

### Cyflumetofen; Pesticide Tolerances

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

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes tolerances for residues of cyflumetofen in or on the following raw agricultural commodities: berry, low growing, subgroup 13–07G; fruit, small, vine climbing, except fuzzy kiwifruit, subgroup 13–07F; and vegetable, cucurbit, group 9. The Interregional Research Project Number 4 (IR–4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

**DATES:** This regulation is effective May 10, 2024. Objections and requests for hearings must be received on or before July 9, 2024, 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–2022–0887, is available at *https://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW, Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room and the OPP Docket is (202) 566–1744. Please review the visitor instructions and additional information about the docket available at *https://www.epa.gov/.*

**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; 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//.*

### *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 docket ID number EPA–HQ–OPP–2022–0887 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 July 9, 2024. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA–HQ–OPP–2022–0887, 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/.*

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *https://www.epa.gov/.*

## II. Summary of Petitioned-For Tolerance

In the **Federal Register** of February 23, 2023 (88 FR 11401) (FRL–10579–01–OCSPP), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of pesticide petition (PP 2E9030) by the Interregional Research Project No. 4 (IR–4), North Carolina State University, 1730 Varsity Drive, Venture IV, Suite 210, Raleigh, NC 27606. The petition requests to amend 40 CFR 180.677 by establishing tolerances for residues of cyflumetofen (2-methoxyethyl α-cyano-α-[4-(1,1-dimethylethyl)phenyl]-β-oxo-2-(trifluoromethyl)benzenepropanoate), including its metabolites and degradates, in or on the following raw agricultural commodities: berry, low growing, subgroup 13–07G at 0.6 parts per million (ppm); fruit, small, vine climbing, except fuzzy kiwifruit, subgroup 13–07F at 0.6 ppm; and vegetable, cucurbit, group 9 at 2 ppm. Upon the establishment of these tolerances, IR–4 requested that EPA remove the existing tolerances in 40 CFR 180.677 for residues of cyflumetofen (2-methoxyethyl α-cyano-α-[4-(1,1-dimethylethyl)phenyl]-β-oxo-2-(trifluoromethyl)benzenepropanoate) in or on cucumber at 0.3 ppm; grape at 0.60 ppm; and strawberry at 0.6 ppm. That document referenced a summary of the petition prepared by IR–4, which is available in the docket at *https://www.regulations.gov.* One comment was received in response to the notice of filing. EPA's response to the comment is discussed in Unit IV.C.

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 one tolerance at a different level than petitioned-for. The reason for this change is explained in Unit IV.D.

## 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 cyflumetofen including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with cyflumetofen 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 cyflumetofen in which EPA concluded, based on the available information, that there is a reasonable certainty that no harm would result from aggregate exposure to cyflumetofen 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.

*Toxicological profile.* For a discussion of the Toxicological Profile of cyflumetofen, see Unit III.A. of the final rule published in the **Federal Register** of May 8, 2019 (84 FR 20037) (FRL–9990–60).

*Toxicological points of departure/Levels of concern.* A summary of the toxicological endpoints for cyflumetofen used for human health risk assessment is discussed in Unit III.B. of the May 8, 2019, rulemaking.

*Exposure assessment.* EPA's dietary exposure assessments have been updated to include the additional exposures from the petitioned-for tolerances. No acute dietary exposure and risk analyses were performed since there were no appropriate toxicological effects attributable to a single dose observed in available toxicity studies for either the general population or for females 13 to 49 years of age. The chronic dietary (food and drinking water) exposure and risk assessment for cyflumetofen was conducted using the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (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). An unrefined chronic dietary (food and drinking water) analysis was conducted using tolerance-level residues, default processing factors, empirical processing factors, and 100% crop treated assumptions.

*Drinking water exposure.* EPA has revised the cyflumetofen drinking water assessment (DWA) since the May 8, 2019, final rule and the final rule published in the **Federal Register** of December 6, 2021 (86 FR 68915) (FRL–9234–01–OCSPP). The DWA provides updated estimated drinking water concentrations (EDWCs) for cyflumetofen residues of concern in surface water and groundwater. The use patterns for current and proposed uses were modeled using new pesticide in water calculator scenarios. The updated EDWCs for use in human health risk assessment are 0.59 µg/L for acute exposures, 0.11 µg/L for non-cancer chronic exposures and 0.10 µg/L for cancer exposures generated from exposure in surface water.

*Non-occupational exposure.* There are no new proposed residential (non-occupational) uses for cyflumetofen at this time; however, there are registered uses of cyflumetofen on commercial vegetable gardens and ornamental plants. EPA's residential exposure assessment has changed since the May 8, 2019, final rule based on a revised practice. Because all current cyflumetofen labels require handlers to wear personal protective equipment, EPA assumes that cyflumetofen is applied by professional applicators, not residential (homeowner) applicators. Therefore, the current assessment does not consider exposure to residential handlers or exposure from direct homeowner applications to ornamentals or home gardens.

There are registered uses of cyflumetofen to commercially treat garden vegetables that could be subsequently purchased at a retail location for transplant into a residential setting and treated ornamental plants that can be purchased by consumers. EPA considers post-application exposure resulting from this scenario to be negligible because residues are

expected to decline significantly during the time from application in a commercial setting to consumer purchase at a retail location. Also, there is no dermal hazard for cyflumetofen since no systemic effects were observed in the dermal study up to the limit dose. Therefore, a quantitative residential post-application dermal risk assessment is not required.

*Cumulative exposures.* 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 cyflumetofen and any other substances and cyflumetofen does not appear to produce a toxic metabolite produced by other substances. For the purposes of this action, therefore, EPA has not assumed that cyflumetofen 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 from 10X to 1X. See Unit III.D. of the May 8, 2019, rulemaking for a discussion of the Agency's rationale for that determination.

*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 chronic population adjusted dose (cPAD). Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated total food, water, and residential exposure to the appropriate points of departure (PODs) to ensure that an adequate margin of exposure (MOE) exists.

An acute dietary risk assessment was not conducted as toxicological effects attributable to a single dose were not identified. Therefore, cyflumetofen is not expected to pose an acute risk. Chronic dietary risks are below the Agency's level of concern of 100% of the cPAD; the chronic dietary exposure estimate for all infants, the most highly exposed population subgroup, is 7.6% of the cPAD. Because EPA has determined that there are no residential exposures, the chronic dietary risk is the same as the overall chronic aggregate risk for cyflumetofen and is not of concern.

As stated in Unit III.A. of the May 8, 2019, final rule, EPA concluded that the nonlinear approach for assessing potential cancer risk is appropriate. The chronic risk resulting from aggregate exposure to cyflumetofen is below the Agency's level of concern; therefore, the Agency concludes that there is not a cancer risk of concern from exposure to cyflumetofen.

Therefore, based on the risk assessments and information described above, 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 cyflumetofen residues. More detailed information on this action can be found in the document titled ''Cyflumetofen. Human Health Risk Assessment for the Proposed New Use on Vegetable, Cucurbit, Group 9, Label Amendment for Vegetable, Fruiting, Group 8–10, and Crop Group Expansion of Berry, Low Subgroup 13–07G and Fruit, Small, Vine Climbing, Except Fuzzy Kiwifruit, subgroup 13–07F.'' in docket ID number EPA–HQ–OPP–2022–0887.

## IV. Other Considerations

### *A. Analytical Enforcement Methodology*

For a discussion of the available analytical enforcement method, see Unit IV.A. of the final rule published in the **Federal Register** of July 1, 2020 (85 FR 39491) (FRL–10009–25).

### *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 an MRL for residues of cyflumetofen in or on cucurbit vegetable group 9, bell pepper or non-bell pepper. Codex has established MRLs for residues of cyflumetofen in or on strawberry at 0.6 ppm and in or on grape, table and grape, wine at 0.6 ppm. The U.S. tolerances for berry, low growing, subgroup 13–07G and fruit, small, vine climbing, except fuzzy kiwifruit, subgroup 13–07F are being established at 0.6 ppm and are harmonized with the relevant Codex MRLs.

### *C. Response to Comments*

One comment was received on the notice of filing. The comment is an inquiry from the People's Republic of China, requesting that EPA explain the reasons for removing the existing tolerances for strawberries and grapes and establishing new crop group tolerances for berry, low growing, subgroup 13–07G and fruit, small, vine climbing, except fuzzy kiwifruit, subgroup 13–07F, thus expanding tolerance coverage for these crops. The commenter also requested that the Agency provide the test data used for risk assessment of the relevant fruits.

Under FFDCA section 408, EPA is authorized to establish tolerances for pesticide chemical residues in food. EPA establishes tolerances for each pesticide based on data on the pesticide residues and assesses the potential risks to human health posed by that pesticide. A tolerance is the maximum permissible residue level established for a pesticide in raw agricultural commodities and processed foods. The crop group regulations currently in 40 CFR 180.40 and 180.41 enable the establishment of tolerances for a group of crops based on residue data for certain crops that are representative of the group. Strawberry is a representative crop for the crop subgroup 13–07G, and grape is a representative crop for the crop subgroup 13–07F.

The data supporting the strawberry and grape tolerances were submitted to the Agency and were reviewed and reported in the document titled ''Cyflumetofen. Petition for the Establishment of Permanent Tolerances and Registration for Use on Citrus (Crop Group 10–10), Pome Fruits (Crop Group 11–10), Tree Nuts (Crop Group 14–12), Grape, Strawberry, and Tomato. Summary of Analytical Chemistry and Residue Data.'', D408531, D. Wilbur, 09-July-2013. In the current action, EPA is expanding the grape tolerance to fruit, small, vine climbing, except fuzzy kiwifruit, subgroup 13–07F and expanding the strawberry tolerance to berry, low growing, subgroup 13–07G as stated in the document ''Cyflumetofen. Proposed Section 3 Registration for the New Use on Vegetable Cucurbit, Group 9, Label Amendment for Vegetable, Fruiting, Group 8–10, and Crop Group Expansion of Berry, Low Subgroup 13–07G and Fruit, Small, Vine Climbing, Except Fuzzy Kiwifruit, Subgroup 13–07F. Summary of Analytical Chemistry and Residue Data'' and the document ''Cyflumetofen. Human Health Risk Assessment for the Proposed New Use on Vegetable, Cucurbit, Group 9, Label Amendment for Vegetable, Fruiting, Group 8–10, and Crop Group Expansion of Berry, Low Subgroup 13–07G and Fruit, Small, Vine Climbing, Except Fuzzy Kiwifruit, subgroup 13–07F.'' All three documents can be found in docket ID number EPA–HQ–OPP–2022–0887.

### *D. Revisions to Petitioned-For Tolerances*

EPA reviewed the available residue data and is establishing the tolerance for

resides of cyflumetofen in or on vegetable, cucurbit, group 9 at 0.3 ppm rather than at 2 ppm as IR–4 requested. IR–4 calculated the tolerance of 2 ppm by including the metabolite B–1 in the residue levels. However, the only residues included in the tolerance expression are for the parent compound, cyflumetofen. Using the residues for cyflumetofen but not metabolite B–1, EPA calculated the tolerance for resides of cyflumetofen in or on vegetable, cucurbit, group 9 to be 0.06 ppm, which is covered by the established tolerance of 0.3 ppm in or on cucumber. Therefore, EPA is establishing the tolerance for residues of cyflumetofen in or on vegetable, cucurbit, group 9 at 0.3 ppm.

## V. Conclusion

Therefore, tolerances are established for residues of cyflumetofen: (2-methoxyethyl α-cyano-α-[4-(1,1-dimethylethyl)phenyl]-β-oxo-2-(trifluoromethyl)benzenepropanoate), including its metabolites and degradates, in or on berry, low growing, subgroup 13–07G at 0.6 ppm; fruit, small, vine climbing, except fuzzy kiwifruit, subgroup 13–07F at 0.6 ppm; and vegetable, cucurbit, group 9 at 0.3 ppm. EPA is removing the established tolerances for strawberry at 0.6 ppm; grape at 0.60 ppm; and cucumber at 0.3 ppm as unnecessary upon the establishment of the new tolerances.

## VI. Statutory and Executive Order Reviews

This action establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled ''Regulatory Planning and Review'' (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled ''Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations'' (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerances in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or Tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or Tribal governments, on the relationship between the National Government and the States or Tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled ''Federalism'' (64 FR 43255, August 10, 1999), and Executive Order 13175, entitled ''Consultation and Coordination with Indian Tribal Governments'' (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

## VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

## List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: May 6, 2024.

**Charles Smith,**

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

Therefore, for the reasons stated 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 § 180.677, amend table 1 to paragraph (a) by:

■ a. Adding in alphabetical order an entry for ''Berry, low growing, subgroup 13–07G'';

■ b. Removing the entry for ''Cucumber'';

■ c. Adding in alphabetical order an entry for ''Fruit, small, vine climbing, except fuzzy kiwifruit, subgroup 13–07F'';

■ d. Removing the entries for ''Grape'' and ''Strawberry''; and

■ e. Adding in alphabetical order an entry for ''Vegetable, cucurbit, group 9''.

The additions read as follows:

**§ 180.677 Cyflumetofen; tolerance for residues.**

(a) * * *

TABLE 1 TO PARAGRAPH (a)

| Commodity | Parts per million |
|---|---|
| * * * * * | |
| Berry, low growing, subgroup 13–07G | 0.6 |
| * * * * * | |
| Fruit, small, vine climbing, except fuzzy kiwifruit, subgroup 13–07F | 0.6 |
| * * * * * | |
| Vegetable, cucurbit, group 9 | 0.3 |

* * * * *

[FR Doc. 2024–10187 Filed 5–9–24; 8:45 am]

BILLING CODE 6560–50–P