



BILLING CODE 6560-50-P

## **ENVIRONMENTAL PROTECTION AGENCY**

### **40 CFR Part 180**

**[EPA-HQ-OPP-2019-0128; FRL-10009-93]**

### **Oxathiapiprolin; Pesticide Tolerances**

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

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes tolerances for residues of oxathiapiprolin in or on multiple commodities which are identified and discussed later in this document. The Interregional Project Number 4 (IR-4) and the registrant, Syngenta Crop Protection 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-2019-0128, is available at <http://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 is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805.

Please note that due to the public health emergency, the EPA Docket Center (EPA/DC) and Reading Room was closed to public visitors on March 31, 2020. Our EPA/DC staff will continue to provide customer service via email, phone, and webform. For further information on EPA/DC services, docket contact information and the current status of the EPA/DC and Reading Room, please visit <https://www.epa.gov/dockets>.

**FOR FURTHER INFORMATION CONTACT:** Michael Goodis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; main telephone number: (703) 305-7090; email address: [RDFRNotices@epa.gov](mailto: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 Government Publishing Office's e-CFR site at [http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab\\_02.tpl](http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl).

### *C. How Can I File an Objection or Hearing Request?*

Under FFDCFA section 408(g), 21 U.S.C. 346a, 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-2019-0128 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).

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-2019-0128, by one of the following methods:

- *Federal eRulemaking Portal*: <http://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 <http://www.epa.gov/dockets>.

## **II. Summary of Petitioned-For Tolerance**

In the **Federal Register** of August 2, 2019 (84 FR 37818) (FRL-9996-78), 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 9E8755) by IR-4, Rutgers, The State University of New Jersey, 500 College Road East, Suite 201W, Princeton, NJ 08540. The petition requested that 40 CFR 180.685 be amended by establishing tolerances for residues of the fungicide oxathiapiprolin, 1-[4-[4-[5-(2,6-difluorophenyl)-4,5-dihydro-3-isoxazolyl]-2-thiazolyl]-1-piperidinyl]-2-[5-methyl-3-(trifluoromethyl)-1H-pyrazol-1-yl]-ethanone, in or on the following commodities: Berry, low growing, subgroup 13-07G, except cranberry at 0.4 parts per million (ppm); Hop, dried cones at 5 ppm; Tropical and subtropical, medium to large fruit, smooth, inedible peel, subgroup 24B at 0.1 ppm; individual crops of proposed crop subgroup 6-18B: Edible podded pea legume vegetable subgroup including: Chickpea, edible podded at 1 ppm; Dwarf pea, edible podded at 1 ppm; Edible podded pea at 1 ppm; Grass-pea, edible podded at 1 ppm; Green pea, edible podded at 1 ppm; Lentil, edible podded at 1 ppm; Pigeon pea, edible podded at 1 ppm; Snap pea, edible podded at 1 ppm; Snow pea, edible podded at 1 ppm; and Sugar snap pea, edible podded at 1 ppm; and individual crops of proposed crop subgroup 6-18D: Succulent shelled pea subgroup including: Chickpea, succulent shelled at 0.05 ppm; English pea, succulent shelled at 0.05 ppm; Garden pea, succulent shelled at 0.05 ppm; Green pea, succulent shelled at 0.05 ppm; Lentil,

succulent shelled at 0.05 ppm; and Pigeon pea, succulent shelled at 0.05 ppm. In addition, IR-4 requested removal of the following existing tolerances upon establishment of the above tolerances for residues of the fungicide oxathiapiprolin, 1-[4-[4-[5-(2,6-difluorophenyl)-4,5-dihydro-3-isoxazolyl]-2-thiazolyl]-1-piperidinyl]-2-[5-methyl-3-(trifluoromethyl)-1H-pyrazol-1-yl]-ethanone, in or on Pea, edible-podded at 1.0 ppm and Pea, succulent shelled at 0.05 ppm.

In the **Federal Register** of June 7, 2019 (84 FR 26630) (FRL-9993-93), 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 9F8736) by Syngenta Crop Protection, LLC, P.O. Box 18300, Greensboro, NC 27419, that requested to establish tolerances in 40 CFR part 180.685 for residues of the fungicide oxathiapiprolin (1-[4-[4-[5-(2,6-difluorophenyl)-4,5-dihydro-3-isoxazolyl]-2-thiazolyl]-1-piperidinyl]-2-[5-methyl-3-(trifluoromethyl)-1H-pyrazol-1-yl]-ethanone), in or on bushberry crop subgroup 13-07B, except lowbush blueberry, at 0.5 ppm; tree nuts, crop group 14-12 at 0.01 ppm; and almond hulls at 0.05 ppm.

These documents referenced a summary of the petition prepared by Syngenta Crop Protection, LLC, the registrant, which is available in the docket, <http://www.regulations.gov>. One comment was received on the notice of filings. EPA's response to this comment is discussed in Unit IV.C.

Based upon review of the data supporting the petition, EPA is correcting many of the commodity definitions. The reasons for these changes are 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 FFDCCA 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 FFDCCA section 408(b)(2)(D), and the factors specified in FFDCCA section 408(b)(2)(D), 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 oxathiapiprolin including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with oxathiapiprolin follows.

As indicated in the **Federal Register** for previous tolerances established for residues of oxathiapiprolin (see 81 FR 87463, FRL-9954-69, December 6, 2016), the toxicity database for oxathiapiprolin supports a decision to conduct a qualitative risk assessment, due to the lack of treatment-related effects and limited toxicity. While dietary exposure to oxathiapiprolin may occur through food and drinking water, no risks of concern are anticipated due to the lack of toxicity at anticipated human exposure levels. While residential post-application exposures may occur through the registered uses on turf and ornamentals, no risks of concern are anticipated due to the lack of toxicity at anticipated human exposure levels. While dietary and residential exposures may occur through the registered and proposed uses for oxathiapiprolin, no aggregate risks of concern are anticipated due to the lack of toxicity at anticipated human exposure levels.

Therefore, based on the lack of toxicity at anticipated human exposure levels, 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 oxathiapiprolin residues. More detailed information on the subject action to establish tolerances in or on the range of commodities can be found in the document entitled, “Oxathiapiprolin. Human Health Risk Assessment to Support the Registration for Use on Bushberry Crop Subgroup 13-07B (Except Lowbush Blueberry), Hops, Low Growing Berry Crop Subgroup 13-07G (Except Cranberry), Tree Nut Crop Group 14-12, and Tropical and Subtropical Medium to Large Fruit with Smooth Inedible Peel Crop Subgroup 24B, as well as Tolerance Translations” dated May 15, 2020 by going to <http://www.regulations.gov>. The referenced document is available in the docket established by this action, which is described under **ADDRESSES**. Locate and click on the hyperlink for docket ID number EPA-HQ-OPP-2019-0128.

#### **IV. Other Considerations**

##### *A. Analytical Enforcement Methodology*

Analytical method DuPont-30422, Supplement 1 is a high performance liquid chromatography with tandem mass spectrometry (HPLC-MS/MS) method available for the quantitation of oxathiapiprolin residues in plant matrices. Analytical method DuPont-31138 is an HPLC-MS/MS method available for the analytical enforcement of oxathiapiprolin residues in livestock commodities.

The methods may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755-5350; telephone number: (410) 305-2905; email address: *residuemethods@epa.gov*.

### *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 established MRLs for oxathiapiprolin in/on peas (pods and succulent-immature seeds) at 1 ppm and in/on peas, shelled (succulent seeds) at 0.05 ppm. The U.S. tolerances for the corresponding commodities are harmonized with these Codex MRLs. The Codex has not established MRLs for oxathiapiprolin on any of the other requested crops or crop groups.

### *C. Response to Comments*

One relevant comment was received from a private citizen who opposed approval of this active ingredient due to combination with other chemicals and not testing toxic pollutants. The existing legal framework provided by section 408 of the FFDCa states that tolerances may be set when persons seeking such tolerances or exemptions have demonstrated that the pesticide meets the safety standard imposed by that statute. This comment appears to be directed at the

underlying statute and not EPA's implementation of it; the comments provide no information relevant the Agency's safety determination.

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

The Agency corrected the commodity definitions for: Almond, hulls; Bushberry subgroup 13-07B, except lowbush blueberry; Nut, tree, group 14-12; Pea, dwarf, edible podded; Pea, edible podded; Pea, English, succulent shelled; Pea, garden, succulent shelled; Pea, grass, edible podded; Pea, green, edible podded; Pea, green, succulent shelled; Pea, pigeon, edible podded; Pea, pigeon, succulent shelled; Pea, snap, edible podded; Pea, snow, edible podded; and Pea, sugar snap, edible podded.

#### **V. Conclusion**

Therefore, tolerances are established for residues of oxathiapiprolin, 1-[4-[4-[5-(2,6-difluorophenyl)-4,5-dihydro-3-isoxazolyl]-2-thiazolyl]-1-piperidiny]-2-[5-methyl-3-(trifluoromethyl)-1H-pyrazol-1-yl]-ethanone, in or on Almond, hulls at 0.05 ppm; Berry, low growing, subgroup 13-07G, except cranberry at 0.4 ppm; Bushberry subgroup 13-07B, except lowbush blueberry at 0.5 ppm; Chickpea, edible podded at 1 ppm; Chickpea, succulent shelled at 0.05 ppm; Hop, dried cones at 5 ppm; Lentil, edible podded at 1 ppm; Lentil, succulent shelled at 0.05 ppm; Nut, tree, group 14-12 at 0.01 ppm; Pea, dwarf, edible podded at 1 ppm; Pea, edible podded at 1 ppm; Pea, English, succulent shelled at 0.05 ppm; Pea, garden, succulent shelled at 0.05 ppm; Pea, grass, edible podded at 1 ppm; Pea, green, edible podded at 1 ppm; Pea, green, succulent shelled at 0.05 ppm; Pea, pigeon, edible podded at 1 ppm; Pea, pigeon, succulent shelled at 0.05 ppm; Pea, snap, edible podded at 1 ppm; Pea, snow, edible podded at 1 ppm; Pea, sugar snap, edible podded at 1 ppm; Tropical and subtropical, medium to large fruit, smooth inedible peel, subgroup 24B at 0.1 ppm. Upon the establishment of the above tolerances, the

following tolerances will be removed: Pea, edible-podded at 1.0 ppm and Pea, succulent shelled at 0.05 ppm.

The removal of the “pea, edible-podded” and “pea, succulent shelled” tolerances as part of this rulemaking will not result in any adulterated pea commodities. The individual pea tolerances being established in this rulemaking cover all the edible-podded and succulent-shelled versions of pea as defined in 40 CFR 180.1, which includes “Cajanus cajan (includes pigeon pea); Cicer spp. (includes chickpea and garbanzo bean); Lens culinaris (lentil); Pisum spp. (includes dwarf pea, garden pea, green pea, English pea, field pea, and edible pod pea).” To avoid confusion about the coverage of residues in or on pea commodities as a result of this rulemaking, EPA is clarifying the status of two commodities listed in section 180.1 for which an individual tolerance is not being established in this rulemaking: garbanzo bean and field pea. Garbanzo bean is the same commodity as chickpea, so residues on garbanzo bean are covered by chickpea tolerances. Field pea is not sold as an edible-podded or succulent shelled pea and thus is not covered by the existing tolerances for “pea, edible-podded” and “pea, succulent shelled”; removing those tolerances does not change the status of tolerance coverage for field pea and an individual tolerance is not necessary.

## **VI. Statutory and Executive Order Reviews**

This action establishes tolerances under FFDCFA section 408(d) in response to petitions 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), nor is it considered a regulatory action under Executive Order 13771, entitled “Reducing Regulations and Controlling Regulatory Costs” (82 FR 9339, February 3, 2017). 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 26, 2020.

**Michael Goodis,**

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

Therefore, for the reasons stated in the preamble, EPA amends 40 CFR chapter I as follows:

### **PART 180--[AMENDED]**

1. The authority citation for part 180 continues to read as follows:

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

2. In § 180.685, amend the table in paragraph (a) by

i. Adding in alphabetical order entries for “Almond, hulls”; “Berry, low growing, subgroup 13-07G, except cranberry”; “Bushberry subgroup 13-07B, except lowbush blueberry”; “Chickpea, edible podded”; “Chickpea, succulent shelled”; “Hop, dried cones”; “Lentil, edible

podded”; “Lentil, succulent shelled”; “Nut, tree, group 14-12”; “Pea, dwarf, edible podded”; “Pea, edible podded”; “Pea, English, succulent shelled”; “Pea, garden, succulent shelled”; “Pea, grass, edible podded”; “Pea, green, edible podded”; “Pea, green, succulent shelled”; “Pea, pigeon, edible podded”; “Pea, pigeon, succulent shelled”; “Pea, snap, edible podded”; “Pea, snow, edible podded”; “Pea, sugar snap, edible podded”; and “Tropical and subtropical, medium to large fruit, smooth inedible peel, subgroup 24B”; and

ii. Removing the entries for: “Pea, edible-podded”; and “Pea, succulent shelled”.

The additions read as follows:

**§ 180.685 Oxathiapiprolin; tolerances for residues.**

(a) \* \* \*

<b>Commodity</b>	<b>Parts per million</b>
Almond, hulls	0.05
* * * * *	
Berry, low growing, subgroup 13-07G, except cranberry	0.4
* * * * *	
Bushberry subgroup 13-07B, except lowbush blueberry	0.5
* * * * *	
Chickpea, edible podded	1
Chickpea, succulent shelled	0.05
* * * * *	
Hop, dried cones	5
* * * * *	
Lentil, edible podded	1
Lentil, succulent shelled	0.05
Nut, tree, group 14-12	0.01
* * * * *	
Pea, dwarf, edible podded	1
Pea, edible podded	1
Pea, English, succulent shelled	0.05
Pea, garden, succulent shelled	0.05
Pea, grass, edible podded	1
Pea, green, edible podded	1
Pea, green, succulent shelled	0.05
Pea, pigeon, edible podded	1
Pea, pigeon, succulent shelled	0.05
Pea, snap, edible podded	1

Pea, snow, edible podded	1
Pea, sugar snap, edible podded	1
* * * * *	
Tropical and subtropical, medium to large fruit, smooth, inedible peel, subgroup 24B	0.1
* * * * *	

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