



BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

EPA-HQ-OPP-2019-0384; FRL-10012-78

Indoxacarb; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of the insecticide indoxacarb in or on Almond, hulls at 8 parts per million (ppm) and Nut, tree, group 14-12 at 0.08 ppm. FMC Corporation requested tolerances for these commodities 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-2019-0384, 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.

Due to the public health concerns related to COVID-19, the EPA Docket Center (EPA/DC) and Reading Room is closed to visitors with limited exceptions. The staff continues to provide remote customer service via email, phone, and webform. For the latest status information on EPA/DC services and docket access, visit <https://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Marietta Echeverria, Acting Director, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Avenue, NW., Washington, DC 20460-0001; main telephone number: (703) 305-7090; 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 Government Publishing Office's e-CFR site at 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 FFDCA section 408(g), 21 U.S.C. section 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-2019-0384 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 section 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-2019-0384, 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 <http://www.epa.gov/dockets/contacts.html>. 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 February 11, 2020 (85 FR 7708) (FRL-10005-02), EPA issued a document pursuant to FFDCFA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 9F8774) by FMC Corporation, 2929 Walnut Street, Philadelphia, PA 19104. The petition requested that 40 CFR 180.564 be amended by establishing tolerances for residues of the insecticide indoxacarb, [(S)-methyl 7-chloro-2,5-dihydro-2-[[[(methoxycarbonyl)[4-(trifluoromethoxy)phenyl]amino]carbonyl]indeno[1,2e][1,3,4]oxadiazine-4a(3H)-carboxylate], and its R-enantiomer [(R)-methyl 7 chloro-2,5-dihydro-2[[[(methoxycarbonyl)[4-(trifluoromethoxy)phenyl]amino]carbonyl]indeno [1,2-e][1,3,4]oxadiazine-4a(3H)-carboxylate], in or on Almond, hulls at 9 parts per million (ppm) and Nut, tree, group 14-12 at 0.07 ppm. That document referenced a summary of the petition prepared by FMC Corporation, the registrant, which is available in the docket, <http://www.regulations.gov>. No public comments were received in response to the notice of filing.

Based upon review of the data supporting the petition and in accordance with its authority under FFDCFA section 408(d)(4)(A)(i), EPA is establishing tolerances that vary from what the petitioners sought. The reasons for these changes are explained in detail in Unit IV.C.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of the FFDCFA 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 the 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 the 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 indoxacarb in or on almond, hulls and nut, tree, group 14-12.

In the *Federal Register* on December 8, 2017 (82 FR 57860) (FRL-9970-39), EPA published a final rule establishing a tolerance for residues of the insecticide indoxacarb in or on corn, field, forage; corn, field, grain; and corn, field, stover based on the Agency’s determination that aggregate exposure to indoxacarb is safe for the U.S. general population, including infants and children. Because certain elements of EPA’s assessment of exposures and risks associated with indoxacarb have not changed since the 2017 rule was published, EPA is incorporating the following portions of the 2017 rule as part of this rulemaking: the toxicological profile and points of departure/levels of concern.

A. Exposure assessment

EPA has updated the exposure assessments of indoxacarb to estimate exposures that will

result from the current and proposed new uses of indoxacarb in or on almond, hulls and nut, tree, group 14-12, as described below. Based on the current and proposed uses of indoxacarb, exposures can occur both from dietary sources (food + water) and in residential settings. An updated 2020 drinking water assessment utilized a total residue modeling approach to account for the environmental fate and transport of indoxacarb plus its degradation products of concern. Notwithstanding the updated 2020 drinking water assessment, the exposure estimates generated in the 2017 drinking water assessment are protective of the estimates generated from the proposed use of indoxacarb on tree nuts. Surface water estimated drinking water concentrations (EDWCs) were lower than the corresponding ground water EDWCs (acute EDWC of 131 parts per billion (ppb) and a chronic EDWC of 123 ppb), which were used in the partially refined acute probabilistic and chronic dietary exposure assessments of indoxacarb, respectively. In addition, for food commodities, residue distribution files were constructed from field trial residues for the probabilistic acute dietary exposure assessment as appropriate, and average residues were computed for blended commodities and for the chronic dietary exposure assessment.

An updated occupational and residential exposure assessment found no residential handler risk estimates of concern and there are no proposed changes to the use pattern which will impact the residential exposure or aggregate assessments for indoxacarb. For the currently registered products of indoxacarb: (1) residential handler inhalation MOEs are ≥ 92 (LOC = 30) and are not of concern; and (2) there is potential for residential post-application exposure for individuals entering an environment previously treated with indoxacarb and/or contact with treated pets; however, residential post-application MOEs are ≥ 170 (LOC = 100) and are not of concern.

B. Safety factor for infants and children

Section 408(b)(2)(C) of the FFDCFA 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 FQPA Safety Factor (SF). In applying this provision, EPA either retains the default value of 10 times, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

EPA determined reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1x because: (1) the hazard and exposure databases are complete; (2) there is no susceptibility in fetuses or offspring in any of the *in utero* or postnatal toxicity studies; (3) there are no residual uncertainties with regard to pre- and/or postnatal toxicity; (4) the acute neurotoxicity, subchronic neurotoxicity, and developmental neurotoxicity studies are available and all endpoints used in this risk assessment are protective of neurotoxic effects; and (5) exposure estimates will not underestimate actual exposures.

C. Aggregate risks and determination of safety

For aggregate risk assessment, risk estimates resulting from food, drinking water, and residential uses are combined. Acute, short- and intermediate-term, and long-term (chronic) aggregate assessments were performed for indoxacarb. Partially refined acute probabilistic and chronic dietary exposure assessments were conducted for all current and proposed new uses of indoxacarb and were found to not be of concern at the 99.9th percentile for the U.S. general population and all population subgroups: 54% of the acute population adjusted dose (aPAD) for

children 1 to 2 years old, the group with the highest exposure level; and 35% of the chronic population adjusted dose (cPAD) for all infants, the group with the highest exposure level. Moreover, there are no acute, short-, intermediate- or long-term (chronic) aggregate risk estimates of concern for adult or child aggregate exposures to indoxacarb as a result of the current and proposed new uses of indoxacarb. For children 1 to 2 years old, the group expected to be the most highly exposed, the short-term aggregate margin of exposure (MOE) is 120 and the intermediate-/long-term aggregate MOE is 260. Because EPA's LOC for indoxacarb is an MOE of 100 or below, these MOEs are not of concern.

Indoxacarb is classified as not likely to be carcinogenic to humans. Therefore, cancer risk is not a concern and cancer risks are not quantified.

Based on the risk assessments and information described above, EPA concludes there is a reasonable certainty that no harm will result to the U.S. general population, or to infants and children, from aggregate exposure to indoxacarb residues. More detailed information on the subject action to establish tolerances in or on almond, hulls and nut, tree, group 14-12 can be found at <http://www.regulations.gov> in the document entitled "Indoxacarb. Human Health Risk Assessment for Indoxacarb to Support the Proposed New Use on Almond Hulls and Tree Nut Group 14-12," dated August 20, 2020. This document can be found in docket ID number EPA-HQ-OPP-2019-0384.

IV. Other Considerations

A. Analytical enforcement methodology

Several adequate methods are available for enforcing indoxacarb tolerances on both plant and livestock commodities. Because these methods do not distinguish the indoxacarb enantiomers, they give a total measure of indoxacarb concentration. For the enforcement of

tolerances established on crops, two high-performance liquid chromatograph/ultraviolet detection (HPLC/UV) methods are available for use. The limits of quantitation (LOQs) for these methods range from 0.01 to 0.05 ppm for a variety of plant commodities. A third gas chromatograph/mass-selective detection (GC/MSD), DuPont method AMR 3493–95 Supplement No. 4, is also available for the confirmation of residues in plants. In addition, a liquid chromatograph/mass spectrometer/mass spectrometer (LC/MS/MS) method has been developed and is considered an improvement to the previously approved enforcement method, Method DuPont-AMR-2712-93. Method DuPont-36189 has been determined to be adequate for enforcing tolerances established on crops and is reported to provide an LOQ of 0.01 ppm.

These methods may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Road, 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 FFDCFA section 408(b)(4). Codex 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. Although EPA may establish a tolerance that is different from a Codex MRL, FFDCFA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established MRLs for residues of indoxacarb in or on almond hulls or

tree nuts.

C. Revisions to petitioned-for tolerances

The petitioned-for tolerance levels are different from those being established by EPA. These differences are attributable to the petitioned-for levels not being consistent with Organization for Economic Cooperation and Development (OECD) rounding class practice. The almond, hulls tolerance level is somewhat lower than the petitioned-for level due to the level calculated with the OECD MRL calculation procedures. As a result, EPA is establishing a lower tolerance for almond hulls at 8 ppm based on the FMC data, rather than the tolerance level of 9 ppm proposed by FMC Corporation.

A tolerance level of 0.07 ppm was proposed by FMC Corporation for the tree nut group. EPA is establishing a tolerance level for the tree nut group at 0.08 ppm based on the MRL calculated for pistachios. The submitted field trial data for the representative tree nut crops of almond and pecan also included a full dataset for pistachios, which yielded the highest MRL in comparison to the almond and pecan representative crop data. In this instance, EPA considers the pistachio data acceptable for setting the recommended crop group tolerance on tree nuts because pistachios are analogous to almonds and share the same weed and pest pressures, are grown in the same geographic regions as almonds, and are a leading tree nut production crop based on total acreage as reported in the 2017 USDA Census of Agriculture report.

V. Conclusion

Tolerances are established for residues of the insecticide indoxacarb in or on Almond, hulls at 8 parts per million (ppm) and Nut, tree group 14-12 at 0.08 ppm.

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), 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. section 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 tolerance 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. section 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. section 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. section 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. section 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. section 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: October 16, 2020.

Marietta Echeverria,

Acting 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 § 180.564 amend paragraph (a)(1) by designating the table as Table 1 paragraph (a)(1) and adding in alphabetical order to newly designated Table 1 to paragraph (a)(1) the entries “Almond, hulls” and “Nut, tree, group 14-12” to read as follows:

§ 180.564 Indoxacarb; tolerances for residues.

(a) * * * (1) * * *

Table 1 to paragraph (a)(1)

| Commodity | Parts per million |
|------------------------|-------------------|
| * * * * * | * |
| Almond, hulls | 8 |
| * * * * * | * |
| Nut, tree, group 14-12 | 0.08 |
| * * * * * | * |

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