ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2019–0523; FRL–10010–91]

Quinclorac; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation amends the tolerance for residues of quinclorac in or on rice, grain. BASF Corporation requested this tolerance amendment under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective July 20, 2020. Objections and requests for hearings must be received on or before September 18, 2020, 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–2019–0523, 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.*

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. 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–2019–0523 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 September 18, 2020. 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–2019–0523, 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 October 28, 2019 (84 FR 57685) (FRL–10001–11), 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 9F8770) by BASF Corporation, 26 Davis Drive, Research Triangle Park, North Carolina 27709. The petition requested that 40 CFR part 180.463 be amended by raising the existing tolerance for residues of the herbicide quinclorac, in or on rice, grain to 10.0 parts per million (ppm). That document referenced a summary of the petition prepared by BASF Corporation, the registrant, which is available in the docket, *http://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 tolerances that vary from what was requested, by amending the tolerance of quinclorac in or on rice, bran to 30 ppm. The reason for this change is explained in Unit IV.C.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish or amend 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 or amending 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 in FFDCA 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 quinclorac including exposure resulting from the tolerance amended by this action. EPA's assessment of exposures and risks associated with quinclorac follows.

On December 4, 2017, EPA published in the **Federal Register** a final rule establishing tolerances for residues of quinclorac in or on several commodities based on the Agency's conclusion that aggregate exposure to quinclorac is safe for the general population, including infants and children. *See* 82 FR 57144 (FRL–9970–05). Because certain elements of EPA's safety assessment have not changed since that rulemaking, EPA is incorporating by reference portions of that rulemaking into this document—in particular, the toxicological profile and points of departure, cumulative risk statement, and the Agency's determination regarding the children's safety factor. In addition, because the residential exposures and drinking water exposures have not changed, those sections are also incorporated by reference, but the Agency did conduct updated dietary and aggregate risk assessments in order to incorporate the higher residues of quinclorac on rice.

The dietary exposure assessment was updated, assuming 100% crop treated (PCT), tolerance-level residues, an empirical processing factor (rapeseed oil, 1.5x) and HED's 2018 default processing factors, and the highest estimated drinking water concentrations (EDWCs) from acute/chronic ground water exposure. EPA's aggregate exposure assessment incorporated this revised dietary exposure, as well as exposure in drinking water and from residential sources, although those latter exposures are not impacted by the amended tolerance on rice, grain and thus have not changed since the last assessment.

Acute dietary risks are below the Agency's level of concern: 2.6% of the acute population adjusted dose (aPAD) for females age 13 to 49, the only population subgroup for which an acute endpoint was selected. Chronic dietary risks are below the Agency's level of concern: 11% of the chronic population adjusted dose (cPAD) for infants <1 year of age, the population subgroup with the highest exposure. Residential handler inhalation exposures for adults as well as post-application incidental oral exposures for children from registered uses of quinclorac in residential areas were assessed previously and no risks of concern were identified. Using the exposure assumptions described for short-term exposures, EPA has concluded the combined short-term food, water, and residential exposures result in aggregate margins of exposures above the level of concern of 100 for all scenarios assessed and are not of concern. There are no uses resulting in intermediate-term residential exposures.

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 quinclorac residues. Further information about EPA's risk assessment and safety analysis for residues of quinclorac can be found in the document entitled, ''Quinclorac: Human Health Risk Assessment for Rice Commodity Tolerance Increases'' 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–2019–0523.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate analytical methods (gas chromatography/electron capture detector (GC/ECD) and liquid chromatography with tandem mass spectrometry (LC/MS/MS)) are available for enforcing quinclorac tolerances on plant and livestock commodities.

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. Codex has established an MRL for quinclorac in or on rice at 10 ppm. This MRL is the same as the tolerance amended for quinclorac in the United States. Codex has not established an MRL for quinclorac in or on rice bran. Therefore, harmonization is not an issue for this commodity.

C. Revisions to Petitioned-For Tolerances

As a result of the tolerance increase on rice grain, the tolerance of the processed commodity rice, bran also needs to be increased. EPA used the highest average field trial value for rice reflecting the proposed foliar broadcast use, and the rice, bran processing factor to determine the needed tolerance of 30 ppm in or on rice, bran.

V. Conclusion

Therefore, tolerances are modified for residues of quinclorac in or on rice, grain to 10 ppm; and rice, bran to 30 ppm.

VI. Statutory and Executive Order Reviews

This action modifies 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. 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: June 12, 2020.

Michael Goodis,

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—[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 § 180.463 amend paragraph (a)(1) by designating the table and revising in newly designated Table 1 to paragraph (a)(1) the entries for ''Rice, bran'' and ''Rice, grain'' to read as follows:

§ 180.463180.463 Quinclorac; tolerances for residues.

(a)(1) * * *

TABLE 1 TO PARAGRAPH (a)(1)

Commodity	Parts per million
* * * * *	
Rice, bran	30
Rice, grain	10
* * * * *	

* * * * *

[FR Doc. 2020–14395 Filed 7–17–20; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2019–0571; FRL–10010–64]

Magnesium Sulfate; Exemption From the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes exemptions from the requirement of a tolerance for residues of magnesium sulfate anhydrous (CAS Reg. No. 7487–88–9); magnesium sulfate monohydrate (CAS Reg. No. 14168–73–1); magnesium sulfate trihydrate (CAS Reg. No. 15320–30–6); magnesium sulfate tetrahydrate (CAS Reg. No. 24378–31–2); magnesium sulfate pentahydrate (CAS Reg. No. 15553–21–6); magnesium sulfate hexahydrate (CAS Reg. No. 17830–18–1); and magnesium sulfate heptahydrate (CAS Reg. No. 10034–99–8), collectively referred to as magnesium sulfate, when used as an inert ingredient in antimicrobial pesticide formulations applied to food-contact surfaces in public eating places, dairy-processing equipment, and food-processing equipment and utensils at an end-use concentration not to exceed 4400 parts per million (ppm). Ecolab, Inc. submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting establishment of exemptions from the requirement of a tolerance for magnesium sulfate. This regulation eliminates the need to establish a maximum permissible level for residues of magnesium sulfate when used in accordance with these exemptions.

DATES: This regulation is effective July 20, 2020. Objections and requests for hearings must be received on or before September 18, 2020, 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–2019–0571, 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.

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I. General Information

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