



BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2019-0297; FRL-10008-50]

Chlormequat Chloride; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation amends a tolerance for residues of chlormequat chloride in or on oat grain. Taminco US LLC, a subsidiary of Eastman Chemical Company, requested this amendment 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-2019-0297, 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 review the visitor instructions and additional information about the

docket available at <http://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-2019-0297 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-2019-0297, 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 June 28, 2019 (84 FR 30976) (FRL-9995-27), 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 9F8758) by Taminco US LLC, a subsidiary of Eastman Chemical Company, 200 S Wilcox Drive, Kingsport, TN 37660-5147. The petition requested that 40 CFR 180.698 be amended by modifying the tolerance for residues of the plant regulator, chlormequat chloride, in or on the raw agricultural commodity oat, grain from 10 parts per million (ppm) to 30.0 ppm. That document referenced a summary of the petition prepared by Taminco US LLC, the registrant, which is available in the docket, <http://www.regulations.gov>. A comment was received in response to the notice of filing. EPA's response to this comment is discussed in Unit IV.C.

Based upon review of the data supporting the petition, EPA has modified the level to which the tolerance is being amended. 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 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 FFDCFA 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 FFDCFA 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 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 chlormequat chloride including exposure resulting from the tolerance modified by this action. EPA's assessment of exposures and risks associated with chlormequat chloride follows.

On April 25, 2018, EPA published in the **Federal Register** a final rule establishing tolerances for residues of chlormequat chloride in or on barley, grain; cattle, meat byproduct; cattle, meat; egg; goat, meat byproduct; goat, meat; hog, meat byproduct; hog, meat; milk; oat, grain; poultry, meat byproduct; poultry, meat; sheep, meat byproduct; sheep, meat; and wheat, grain based on the Agency's conclusion that aggregate exposure to chlormequat chloride is safe for the general population, including infants and children. *See* 83 FR 17925 (FRL-9974-42). That document contains a summary of the toxicological profile and points of departure, assumptions for exposure assessment, and the Agency's determination regarding the children's safety factor, which have not changed.

EPA's dietary exposure assessments have been updated to include the potential additional exposure from the increased tolerance of chlormequat chloride on oat grain, *i.e.*, reliance on tolerance-level residues for all crops, and an assumption of 100 percent crop treated (PCT). EPA's aggregate exposure assessment incorporated this additional assumed dietary exposure, as well as exposure in drinking water and from residential sources, although those latter exposures are not impacted by the increased tolerance on oat grain and thus have not changed since the last assessment. Further information about EPA's risk assessment and determination of safety supporting the tolerances established in the April 25, 2018 **Federal Register** action, as well as

the amended chlormequat chloride tolerance, can be found at <http://www.regulations.gov> in the document titled, “Chlormequat Chloride. Human-Health Risk Assessment to Support Establishment of a Tolerance Without U.S. Registration on Wheat, Barley, and Oats,” dated February 27, 2018 in docket ID number EPA-HQ-OPP-2016-0661 and the document titled, “Chlormequat Chloride. Human Health Risk Assessment to Support Tolerance Amendment for Residues in/on Imported Oat Grains,” dated April 14, 2020 in docket ID number EPA-HQ-OPP-2019-0297.

Acute aggregate dietary risks (food and water) are below the Agency’s level of concern of 100% of the acute population adjusted dose: 52% of the aPAD at the 95th percentile of exposure for all infants less than 1-year old, the population subgroup with the highest exposure estimate. Chronic dietary risks are below the Agency’s level of concern of 100% of the chronic population adjusted dose (cPAD): 72% of the cPAD for children 1 to 2 years old, the population subgroup with the highest exposure estimate. There are no residential uses for chlormequat chloride; therefore, no aggregate short- or intermediate-term assessment was necessary.

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 chlormequat chloride residues. More detailed information on the subject action to modify the oat grain tolerance can be found in the document entitled, “Chlormequat Chloride. Human Health Risk Assessment to Support Tolerance Amendment for Residues in/on Imported Oat Grains” 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-2019-0297.

IV. Other Considerations

A. Analytical Enforcement Methodology

An adequate high-performance liquid chromatography method with tandem mass spectrometry detection (HPLC/MS/MS), BASF Method No. 530/0, is available for the determination of residues of chlormequat chloride in/on plant commodities. An adequate LC/MS/MS method, BASF Method No. 397/0 is available for the determination of residues of chlormequat chloride in livestock commodities for enforcement purposes.

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 FFDC 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, FFDC section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

There is an established Codex MRL for chlormequat chloride in/on oat grains at 4 ppm. Based on the oat grain residue from the field trials (40 ppm), harmonization with the Codex

MRL is not possible.

C. Response to Comments

One comment was received to the notice of filing that stated in part that “this should [sic] be denied. it should [sic] be disapproved.”

Although the Agency recognizes that some individuals believe that pesticides should be banned on agricultural crops, the existing legal framework provided by section 408 of the Federal Food, Drug and Cosmetic Act (FFDCA) authorizes EPA to establish tolerances when it determines that the tolerance is safe. Upon consideration of the validity, completeness, and reliability of the available data as well as other factors the FFDCA requires EPA to consider, EPA has determined that this chlormequat chloride tolerance is safe. The commenter has provided no information supporting a contrary conclusion.

D. Revisions to Petitioned-For Tolerances

The petitioner requested the oat, grain tolerance be amended from 10 ppm to 30.0 ppm. The analytical method detected chlormequat cation; therefore, the residues were converted to chlormequat chloride equivalents using a molecular weight conversion factor (MWCF) of 1.29. The petitioner-proposed tolerances on oat grains are without the MWCF; therefore, the Agency has determined that the tolerance needs to be higher. Additionally, the Agency is harmonizing the tolerance level with the MRL that is currently being established by Canada.

V. Conclusion

Therefore, the tolerance for residues of chlormequat chloride in or on oat, grain is amended from 10 ppm to 40 ppm.

VI. Statutory and Executive Order Reviews

This action amends a tolerance 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 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. 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, 2020.

Michael Goodis,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended 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 § 180.698, revise the entry for “Oat, grain” and the footnote in paragraph (a) to read as follows:

§ 180.698 Chlormequat chloride; tolerances for residues.

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Commodity	Parts per million
* * * * *	* * *
Oat, grain ²	40
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² There are no U.S. registrations for this commodity.

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