



ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2016-0661; FRL-9974-42]

Chlormequat Chloride; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of chlormequat chloride in or on multiple commodities which are identified and discussed later in this document. Taminco US LLC, a subsidiary of Eastman Chemical Company 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-2016-0661, 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 Printing 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-2016-0661 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-2016-0661, 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 7, 2017 (82 FR 9555) (FRL-9956-86), 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 6E8495) by Taminco US LLC, a subsidiary of Eastman Chemical Company, Two Windsor Plaza, Suite 400, 7540 Windsor Dr., Allentown, PA 18195. The petition requested that 40 CFR part 180 be amended by establishing tolerances for residues of the plant regulator chlormequat chloride in or on barley grain at 3 parts per million (ppm); bovine, sheep, goat-fat at 0.06 ppm; bovine, sheep, goat-kidney at 0.5 ppm; bovine, sheep, goat-liver at 0.15 ppm; bovine, sheep, goat-muscle at 0.2 ppm; cattle-milk at 0.5 ppm; eggs at 0.1 ppm; oat grain at 15

ppm; poultry-fat at 0.03 ppm; poultry-liver at 0.1 ppm; poultry-muscle at 0.04 ppm; swine-fat at 0.02 ppm; swine-kidney at 0.5 ppm; swine-liver at 0.15 ppm; swine-muscle at 0.2 ppm; and wheat grain at 4 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>. Comments were received on the notice of filing. EPA's response to these comments is discussed in Unit IV.C.

Based upon review of the data supporting the petition, EPA has modified the levels at which some of the tolerances are being established as well as the commodities for which tolerances are being established. 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 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 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 tolerances established by this action. EPA's assessment of exposures and risks associated with chlormequat chloride follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

Decreases in body weight and signs of neurotoxicity (e.g. ataxia, salivation, decreased body temperature) were consistently observed in the available oral repeat dosing studies in rats, mice, and dogs. Dogs appear to be the most sensitive species with clinical signs of toxicity (salivation, vomiting, and diarrhea) at 10 mg/kg/day in the chronic dog study. Decreased body weights and/or decreased food consumption were the only effects observed in the 90-day dietary rat study (190 mg/kg/day), and in the chronic toxicity and carcinogenicity studies in rats (125 mg/kg/day) and mice (363 mg/kg/day). The prenatal developmental rat study (gavage), however, produced clinical signs such as salivation and chromorhinorrhea, as well as decreased food consumption at 90 mg/kg/day. One or more of these clinical signs were observed in the dams typically within one hour after the single oral dose on gestational day six (GD6). In the prenatal developmental toxicity study in rabbits, there were no adverse effects noted up to the highest dose tested (12 mg/kg/day). In the rat two-generation reproduction study, reproductive and offspring effects occurred at doses higher than those causing parental toxicity.

There was no quantitative or qualitative susceptibility observed in the offspring compared to the adult animals in the rat and rabbit developmental studies and the rat two-generation reproduction study.

No systemic toxicity was observed in the 21-day dermal study in rabbits when tested up to the limit dose. Dermal irritation and histopathological lesions of the treated skin (acanthosis, subacute inflammation and edema) was observed at 345 mg/kg/day in female rabbits only. No immunotoxicity study was available; however, no evidence of immunotoxicity was observed in the chlormequat chloride database.

Carcinogenicity studies in mice and rats did not demonstrate potential signs of carcinogenicity and chlormequat chloride was non-mutagenic in four genotoxicity studies. Therefore, chlormequat chloride is classified as “Not Likely to be a Carcinogen to Human” based on the lack of evidence of carcinogenicity.

Specific information on the studies received and the nature of the adverse effects caused by chlormequat chloride as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies 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*” on pages 20-22 in docket ID number EPA-HQ-OPP-2016-0661.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide’s toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the

toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level - generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD) - and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see <http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/assessing-human-health-risk-pesticides>.

A summary of the toxicological endpoints for chlormequat chloride used for human risk assessment is shown in Table 1 of this unit.

Table 1. Summary of Toxicological Doses and Endpoints for Chlormequat Chloride for Use in Human Health Risk Assessment

Exposure/Scenario	Point of Departure and Uncertainty/Safety Factors	RfD, PAD, LOC for Risk Assessment	Study and Toxicological Effects
Acute dietary	NOAEL = 100 mg/kg/day $UF_A = 10x$	Acute RfD = 1 mg/kg/day	Prenatal Developmental-Rat and acute neurotoxicity-rat

(all populations)	$UF_H = 10x$ FQPA SF = 1x	$aPAD = 1$ mg/kg/day	1-Day oral LOAEL 180 mg/kg/day, based on overt toxicity signs (tremors, ataxia) within an hour after a single oral dose in dams (GD 6).
Chronic dietary (All populations)	NOAEL= 5 mg/kg/day $UF_A = 10x$ $UF_H = 10x$ FQPA SF = 1x	Chronic RfD = 0.05 mg/kg/day $cPAD = 0.05$ mg/kg/day	Chronic Toxicity-Dog LOAEL (mg/kg/day): 10 mg/kg/day, based on salivation (1-week post-dosing, both sexes), vomiting (females), diarrhea (males), and decreased body weight gain (males).
Cancer (Oral, dermal, inhalation)	Classification: "Not Likely to be Carcinogenic to Humans" based on the lack of carcinogenic potential in the available studies.		

FQPA SF = Food Quality Protection Act Safety Factor. LOAEL = lowest-observed-adverse-effect-level. NOAEL = no-observed-adverse-effect-level. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies).

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to chlormequat chloride, EPA considered exposure under the petitioned-for tolerances. EPA assessed dietary exposures from chlormequat chloride in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure.

Such effects were identified for chlormequat chloride. In estimating acute dietary exposure, EPA used food consumption information from the U.S. Department of Agriculture's National Health and Nutrition Examination Survey, What We Eat in America, (NHANES/WWEIA). As to residue levels in food, EPA assumed tolerance-level residues and 100 percent crop treated (PCT).

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA's NHANES/WWEIA. As to residue levels in food, EPA assumed tolerance-level residues and 100 PCT.

iii. *Cancer.* Based on the data summarized in Unit III.A., EPA has concluded that chlormequat chloride does not pose a cancer risk to humans. Therefore, a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

iv. *Anticipated residue and percent crop treated (PCT) information.* EPA did not use anticipated residue or PCT information in the dietary assessment for chlormequat chloride. Tolerance-level residues and 100 PCT were assumed for all food commodities.

2. *Dietary exposure from drinking water.* The Agency used screening-level water exposure models in the dietary exposure analysis and risk assessment for chlormequat chloride

in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of chlormequat chloride. A total toxic residue approach that assumes all uncharacterized extractable residues are of equal toxicity to chlormequat chloride was used to estimate exposure. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at <http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/about-water-exposure-models-used-pesticide>.

Based on the First Index Reservoir Screening Tool (FIRST) and Screening Concentration in Ground Water (SCI-GROW) models, the estimated drinking water concentrations (EDWCs) of chlormequat chloride for acute exposures are estimated to be 2574 parts per billion (ppb) for surface water and 24 ppb for ground water and for chronic exposures are estimated to be 91 ppb for surface water and 24 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For the acute dietary risk assessment, the water concentration value of 2574 ppb was used to assess the contribution to drinking water. For the chronic dietary risk assessment, the water concentration of value 91 ppb was used to assess the contribution to drinking water.

3. *From non-dietary exposure.* The term “residential exposure” is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets).

Chlormequat chloride is not registered for any specific use patterns that would result in residential exposure.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider “available information” concerning the cumulative effects of a particular pesticide's residues and “other substances that have a common mechanism of toxicity.”

EPA has not found chlormequat chloride to share a common mechanism of toxicity with any other substances, and chlormequat chloride does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that chlormequat chloride does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at <http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/cumulative-assessment-risk-pesticides>.

D. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(C) of FFDCA 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 Food Quality Protection Act Safety Factor (FQPA SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* There was no quantitative or qualitative susceptibility observed in the offspring compared to the adult animals in the rat and rabbit developmental studies and the rat two-generation reproduction study.

3. *Conclusion.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1x. That decision is based on the following findings:

- i. The toxicity database for chlormequat chloride is complete.
- ii. Although a subchronic neurotoxicity study is not available, evidence of neurotoxicity was observed in the acute neurotoxicity, developmental rat, two-generation reproduction and chronic dog studies. However, there is a low degree of concern for the potential neurotoxic effects of chlormequat chloride because clear no observed adverse effect levels (NOAELs) were identified for the neurotoxic effects, and the endpoints chosen for risk assessment are protective of any potential neurotoxicity.
- iii. There is no evidence that chlormequat chloride results in increased susceptibility in *in utero* rats or rabbits in the prenatal developmental studies or in young rats in the 2-generation reproduction study.
- iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100 PCT and tolerance-level residues. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to chlormequat chloride in drinking water. These assessments will not underestimate the exposure and risks posed by chlormequat chloride.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to chlormequat chloride will occupy 49% of the aPAD for all infants less than 1-year-old, the population group receiving the greatest exposure.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to chlormequat chloride from food and water will utilize 86% of the cPAD for children 1-2 years old, the population group receiving the greatest exposure. There are no residential uses for chlormequat chloride.

3. *Short- and intermediate-term risk.* Short- and intermediate-term aggregate exposure takes into account short- and intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

Short- and intermediate-term adverse effects were identified; however, chlormequat chloride is not registered for any use patterns that would result in either short- or intermediate-term residential exposure. Short- and intermediate-term risk is assessed based on short- and intermediate-term residential exposure plus chronic dietary exposure. Because there is no short- or intermediate-term residential exposure and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess short-term risk), no further assessment of short- or intermediate-term risk is

necessary, and EPA relies on the chronic dietary risk assessment for evaluating short- and intermediate-term risk for chlormequat chloride.

4. *Aggregate cancer risk for U.S. population.* Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, chlormequat chloride is not expected to pose a cancer risk to humans.

5. *Determination of safety.* Based on these risk assessments, 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 chlormequat chloride residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Plant: 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. The HPLC/MS/MS method determines residues as the chlormequat cation. The limit of quantitation (LOQ) is 0.05 ppm for plant commodities other than straw and 0.1 ppm for straw.

Animal: 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 LOQ is 0.01 ppm for meat, kidney, fat, milk, and egg, and 0.05 ppm for liver. A method description, method validation data, and an independent laboratory validation have been submitted to support the proposed enforcement method.

The method 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 chlormequat chloride in or on the commodities referenced in this document at the same levels as the tolerances established for chlormequat chloride in this rule.

C. Response to Comments

Two comments were received in response to the notice of filing. One noted that “these are of a highly technical nature and should be written in a format that the layperson can understand.” The other comment stated that “there should not be ANY residue of chlormequat chloride on ANY commodity, ever.”

The first comment does not materially impact this establishment of these tolerances. Concerning the second comment, 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 these chlormequat chloride tolerances are safe. The commenter has provided no information supporting a contrary conclusion.

D. Revisions to Petitioned-For Tolerances

The petitioner requested tolerances for several animal commodities in addition to the barley, oat, and wheat grain tolerances. The Agency has determined that tolerances are only needed on meat and meat byproducts to cover the liver and kidney tissues. In addition, based on residue data and using the Organisation for Economic Cooperation and Development calculator, the Agency is establishing tolerances for the barley, oat, and wheat grain commodities at levels that harmonize with Codex MRLs. In addition, EPA is revising the commodity terminology used by the petitioner to be consistent with the commodity vocabulary EPA uses for establishing tolerances.

V. Conclusion

Therefore, tolerances are established for residues of chlormequat chloride, in or on barley, grain at 2.0 ppm; cattle, meat byproduct at 0.50 ppm; cattle, meat at 0.20 ppm; egg at 0.10 ppm; goat, meat byproduct at 0.50 ppm; goat, meat at 0.20 ppm; hog, meat byproduct at 0.50 ppm; hog, meat at 0.20 ppm; milk at 0.50 ppm; oat, grain at 10 ppm; poultry, meat

byproduct at 0.10 ppm; poultry, meat at 0.04 ppm; sheep, meat byproduct at 0.50 ppm; sheep, meat at 0.20 ppm; and wheat, grain at 3.0 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. 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: April 6, 2018,

Michael L. 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. Add § 180.698 to subpart C to read as follows:

§ 180.698 Chlormequat chloride; tolerances for residues.

(a) *General.* Tolerances are established for the residues of the plant regulator chlormequat chloride, including its metabolites and degradates in or on food commodities in the table below. Compliance with the tolerance levels specified below is to be determined by measuring only chlormequat chloride [(2-chloroethyl) trimethylammonium chloride in or on the following commodities:

Commodity	Parts per million
Barley, grain ¹	2.0
Cattle, meat byproduct ¹	0.50
Cattle, meat ¹	0.20
Egg ¹	0.10
Goat, meat byproduct ¹	0.50
Goat, meat ¹	0.20

Hog, meat byproduct ¹	0.50
Hog, meat ¹	0.20
Milk ¹	0.50
Oat, grain ¹	10
Poultry, meat byproduct ¹	0.10
Poultry, meat ¹	0.04
Sheep, meat byproduct ¹	0.50
Sheep, meat ¹	0.20
Wheat, grain ¹	3.0

¹ There are no US registrations for this commodity as of [insert date of publication in the *Federal Register*].

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

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