[Federal Register Volume 85, Number 101 (Tuesday, May 26, 2020)]

[Rules and Regulations]

[Pages 31383-31386]

From the Federal Register Online via the Government Publishing Office [[www.gpo.gov](http://www.gpo.gov/)]

[FR Doc No: 2020-10331]

-----------------------------------------------------------------------

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 May 26, 2020. Objections and

requests for

[[Page 31384]]

hearings must be received on or before July 27, 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-2019-0297, is available at [http://www.regulations.gov](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

July 27, 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-2019-0297, by one of

the following methods:

 Federal eRulemaking Portal: [http://www.regulations.gov](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 FFDCA 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](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 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 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;

[[Page 31385]]

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](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](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 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.

 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 shoudl [sic] be denied. it shudl [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,

[[Page 31386]]

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]

0

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

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

0

2. In Sec. 180.698, revise the entry for ``Oat, grain'' and the

footnote in paragraph (a) to read as follows:

Sec. 180.698 Chlormequat chloride; tolerances for residues.

\* \* \* \* \*

------------------------------------------------------------------------

 Parts per

 Commodity million

------------------------------------------------------------------------

 \* \* \* \* \*

Oat, grain \2\.......................................... 40

 \* \* \* \* \*

------------------------------------------------------------------------

\2\ There are no U.S. registrations for this commodity.

\* \* \* \* \*

[FR Doc. 2020-10331 Filed 5-22-20; 8:45 am]

BILLING CODE 6560-50-P