[Federal Register Volume 86, Number 25 (Tuesday, February 9, 2021)]

[Rules and Regulations]

[Pages 8707-8710]

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

[FR Doc No: 2021-02511]

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

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2016-0067; FRL-10017-52]

Streptomycin; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

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

SUMMARY: This regulation establishes tolerances for residues of

streptomycin in or on the fruit, citrus, group 10-10 and fruit, citrus,

group 10-10, dried pulp. Geo Logic Corporation requested these

tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective February 9, 2021. Objections and

requests for hearings must be received on or before April 12, 2021, 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-2016-0067, 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.

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, 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](mailto: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-2016-0067 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

April 12, 2021. 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-2016-0067, 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.

[[Page 8708]]

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 April 25, 2016 (81 FR 24044) (FRL-9944-

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

5F8427) by Geo Logic Corporation, P.O. Box 3091, Tequesta, FL 33409.

The petition requested that 40 CFR 180.245 be amended by establishing

tolerances for residues of streptomycin in or on citrus fruit, crop

group 10-10 at 0.5 ppm and citrus, dried pulp at 3.5 ppm and by

removing the existing tolerances for grapefruit.

In addition, in the Federal Register of September 5, 2014 (79 FR

53009) (FRL-9914-98), 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 4E8236) by Interregional Research Project No. 4 (IR-4),

500 College Road East, Suite 201W, Princeton, NJ 08540. The petition

requested the establishment of tolerances for residues of streptomycin

in or on grapefruit at 0.15 ppm, grapefruit, dried pulp at 0.63 ppm,

and fruit, pome, group 11-10 at 0.25, as well as several amendments to

the existing tolerances in 40 CFR 180.245 as follows: (1) Moving the

existing tolerances for streptomycin on celery, pepper, and tomato from

paragraph (a)(2), and potato from paragraph (a)(3) to the table in

paragraph (a)(1); (2) modifying the existing tolerance for tomato from

0.25 ppm to 0.5 ppm; (3) removing the existing time-limited tolerances

for grapefruit and grapefruit, dried pulp in paragraph (b) upon

establishment of the permanent tolerances for grapefruit and

grapefruit, dried pulp; (4) removing the existing tolerance for fruit,

pome, group 11 upon establishment of the tolerance for fruit, pome,

group 11-10; and (5) modifying the tolerance expression and creating a

single paragraph and table under Sec. 180.245(a) to provide that in

general tolerances are established for residues of the fungicide

streptomycin, including its metabolites and degradates, in or on the

commodities in the table to the paragraph. Compliance with the

tolerance levels specified in the table is to be determined by

measuring only streptomycin (O-2-Deoxy-2-(methylamino)-a-

Lglucopyranosyl-(1-2)-O-5-deoxy-3-Cformyl-a-L-lyxofuranosyl-(1-4)-N,N'-

bis(aminoiminomethyl)-D-streptamine) in or on the commodity.

The documents referenced summaries of the petitions prepared by the

petitioners, which are available at [http://www.regulations.gov](http://www.regulations.gov/). in the

following dockets: EPA-HQ-OPP-2016-0067 for PP 5F8427 and EPA-HQ-OPP-

2014-0134 for PP 4E8236. No comments were received in response to the

notice of filing for PP 5F8427; eighteen comments were submitted in

response to the notice of filing for PP 4E8236 although none were

relevant to the streptomycin tolerance.

Based upon review of the data supporting the petitions, EPA is

establishing the tolerances at different levels than requested. The

reasons for these changes are 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 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 streptomycin including exposure

resulting from the tolerances modified by this action. EPA's assessment

of exposures and risks associated with streptomycin follows.

In an effort to streamline its publications in the Federal

Register, EPA is not reprinting sections that repeat what has been

previously published for tolerance rulemakings of the same pesticide

chemical. Where scientific information concerning a particular chemical

remains unchanged, the content of those sections would not vary between

tolerance rulemakings and republishing the same sections is

unnecessary; EPA considers referral back to those sections as

sufficient to provide an explanation of the information EPA considered

in making its safety determination for the new rulemaking.

EPA has previously published a tolerance rulemaking for

streptomycin, in which EPA concluded, based on the available

information, that there is a reasonable certainty that no harm would

result from aggregate exposure to streptomycin and established

tolerances for residues of that chemical. EPA is incorporating

previously published sections from those rulemakings as described

further in this rulemaking, as they remain unchanged.

Toxicological Profile. There are no guideline toxicity studies

available to assess pesticidal uses of streptomycin. The toxicity of

streptomycin was assessed using the extensive published literature on

drug use of streptomycin in humans and in animals, as well as with

several toxicity summaries provided by the FDA. Injections of

streptomycin as a drug (up to a gram), at doses much higher than

expected from dietary or residential routes of exposure to pesticidal

uses, can cause inner ear toxicity resulting in vestibular problems

with loss of balance or equilibrium. Injections also sometimes cause

hearing loss and mild, reversible kidney toxicity. Children born to

mothers treated with streptomycin injections have sometimes had hearing

loss. No teratogenic effects were noted in a non-guideline rabbit

developmental study. In a non-guideline 2-year rat feeding study, the

only adverse effect noted was reduced body weight in males; an increase

in treatment-related tumors was not reported. The acute oral toxicity

for streptomycin is very low; the LD50 was 9,000 mg/kg in

both rats and mice.

Toxicological Points of Departure/Levels of Concern. For a summary

of the Toxicological Points of Departure/Levels of Concern used for the

safety assessment, see Unit IV.A. of the March 15, 2017 rulemaking (82

FR 13759) (FRL-9957-65).

Exposure Assessment. EPA's dietary exposure assessments for the

permanent tolerances on the citrus fruit crop group 10-10 and dried

citrus pulp relied on

[[Page 8709]]

tolerance-level residues for all crops and an assumption of 100 percent

crop treated (PCT). EPA's aggregate exposure assessment incorporated

this assumed dietary exposure, as well as exposure in drinking water

and from residential sources, which have not changed since the last

assessment. The assessment also considered aggregate risk as a result

of the pharmaceutical uses of streptomycin. For a description of the

rest of the EPA approach to and assumptions for the exposure

assessment, see Unit IV.B. of the March 15, 2017 rulemaking.

Safety Factor for Infants and Children. EPA continues to conclude

that there is reliable data to support the reduction of the Food

Quality Protection Act (FQPA) safety factor. See Unit IV.C. of the

March 15, 2017 rulemaking for a discussion of the Agency's rationale

for that determination.

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 population adjusted dose

(aPAD) and chronic PAD (cPAD). 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 margin of exposure (MOE) exists. For linear cancer risks, EPA

calculates the lifetime probability of acquiring cancer given the

estimated aggregate exposure.

No acute effects were identified in the toxicological studies for

streptomycin; therefore, acute risk is not expected. Chronic dietary

risks are below the Agency's level of concern of 100% of the cPAD: They

are 91% of the cPAD for all infants less than 1 year old, the

population subgroup with the highest exposure estimate. The short-term

MOE is greater than the Agency's level of concern of 100: It is 260 for

adults, the population group of concern. Intermediate-term or long-term

residential exposures are not expected. Lastly, because the pesticide

exposure has no more than a minimal impact on the total dose to a

pharmaceutical user, EPA believes that there is a reasonable certainty

that the potential dietary pesticide exposure will result in no harm to

a user being treated therapeutically with streptomycin.

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 streptomycin residues. More detailed information

about the Agency's analysis can be found at [http://www.regulations.gov](http://www.regulations.gov/)

in the document titled ``Streptomycin. Section 3 Registration for

Citrus Fruits Crop Group 10-10'' in docket ID number EPA-HQ-OPP-2016-

0067.

IV. Other Considerations

A. Analytical Enforcement Methodology

A high-performance liquid chromatography method with tandem mass

spectrometry detection (LC/MS/MS) is available for tolerance

enforcement.

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](mailto: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 has not established any MRLs for streptomycin.

C. Revisions to Petitioned-For Tolerances

The tolerances proposed by the petitioner for the citrus fruit crop

group 10-10 (0.50 ppm) and citrus dried pulp (3.5 ppm) are different

from those which are being established by this document. This is

primarily because the petitioner input the residue data differently

into the calculation procedures for determining the proposed crop group

tolerance (including all data for the representative crops into a

single calculation). As a result, the tolerances are being established

at 0.8 ppm for the fruit, citrus, crop group 10-10 and 3 ppm for fruit,

citrus, group 10-10, dried pulp. In addition, the commodity definitions

were corrected to reflect the crop group.

As a result of the IR-4 petition being withdrawn by the petitioner,

EPA is not granting the request to establish the requested tolerances

or to increase the tomato tolerance from 0.25 to 0.5 ppm. EPA is making

the editorial changes requested by IR-4, however, including

modifications to the tolerance expression and tables contained in

paragraph (a) and removal of expired grapefruit tolerances from

paragraph (b).

V. Conclusion

Therefore, tolerances are established for residues of streptomycin

in or on Fruit, citrus, group 10-10 at 0.8 ppm and Fruit, citrus, group

10-10, dried pulp at 3 ppm. In addition, existing tolerances in 40 CFR

180.245 are amended as follows: (1) Consolidating the subparagraphs and

tables in paragraph (a) into a single paragraph (a); (2) removing the

time-limited tolerances for grapefruit and grapefruit, dried pulp, as

they have expired; and (3) modifying the tolerance expression and

creating a single paragraph and table under Sec. 180.245(a) to provide

that in general tolerances are established for residues of the

fungicide streptomycin, including its metabolites and degradates, in or

on the commodities in the table to the paragraph. Compliance with the

tolerance levels specified in the table is to be determined by

measuring only streptomycin (O-2-Deoxy-2-(methylamino)-a-

Lglucopyranosyl-(1-2)-O-5-deoxy-3-Cformyl-a-L-lyxofuranosyl-(1-4)-N,N'-

bis(aminoiminomethyl)-D-streptamine) in or on the commodity.

VI. Statutory and Executive Order Reviews

This action establishes and 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

[[Page 8710]]

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: January 5, 2021.

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

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. Revise Sec. 180.245 to read as follows:

Sec. 180.245 Streptomycin; tolerances for residues.

(a) General. Tolerances are established for residues of the

fungicide streptomycin, including its metabolites and degradates, in or

on the commodities in Table 1 to this paragraph (a). Compliance with

the tolerance levels specified in Table 1 to this paragraph (a) is to

be determined by measuring only streptomycin (O-2-Deoxy-2-

(methylamino)-a-Lglucopyranosyl-(1-2)-O-5-deoxy-3-Cformyl-a-L-

lyxofuranosyl-(1-4)-N,N'-bis(aminoiminomethyl)-D-streptamine) in or on

the commodity.

Table 1 to Paragraph (a)

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

Parts per

Commodity million

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

Bean, dry, seed............................................ 0.5

Bean, succulent............................................ 0.5

Celery..................................................... 0.25

Fruit, citrus, group 10-10................................. 0.8

Fruit, citrus, group 10-10, dried pulp..................... 3

Fruit, pome, group 11...................................... 0.25

Pepper..................................................... 0.25

Potato..................................................... 0.25

Tomato..................................................... 0.25

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

(b) Section 18 emergency exemptions. Time-limited tolerances are

established for residues of streptomycin, in or on the agricultural

commodities, as specified in Table 2 to this paragraph (b), resulting

from use of the pesticide pursuant to FIFRA section 18 emergency

exemptions. Compliance with the tolerance levels listed in Table 2 to

this paragraph (b) is to be determined by measuring the levels of

streptomycin only, in or on the commodities listed in this Table 2

paragraph (b). The tolerances expire on the dates specified in Table 2

to this paragraph (b).

Table 2 to Paragraph (b)

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

Parts per Expiration

Commodity million date

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

Fruit, citrus, group 10-10.................... 2.0 12/31/22

Fruit, citrus, group 10-10, dried pulp........ 6.0 12/31/22

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

(c)-(d) [Reserved]

[FR Doc. 2021-02511 Filed 2-8-21; 8:45 am]

BILLING CODE 6560-50-P