

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 exemption in this action, 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. As a result, this action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, EPA 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, EPA 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 EPA’s 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).

## V. 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: February 23, 2018.

**Richard Keigwin, Jr.,**

*Director, 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 § 180.1353 to subpart D to read as follows:

### § 180.1353 Lipochitooligosaccharide (LCO) SP104; exemption from the requirement of a tolerance.

Residues of the biochemical pesticide Lipochitooligosaccharide (LCO) SP104 (which has been used in accordance with label directions and good agricultural practices) are exempt from the requirement of a tolerance in or on all food commodities.

[FR Doc. 2018–04534 Filed 3–5–18; 8:45 am]

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## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 180

[EPA–HQ–OPP–2016–0519; FRL–9972–96]

### Kasugamycin; Pesticide Tolerances

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes tolerances for residues of kasugamycin in or on the cherry subgroup 12–12A and walnut. The Interregional Research Project Number 4 (IR–4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

**DATES:** This regulation is effective March 6, 2018. Objections and requests for hearings must be received on or

before May 7, 2018, 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–2016–0519, 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 L. Goodis, Director, 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 Printing Office’s e-CFR site at [http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab\\_02.tpl](http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl).

To access the OCSPP test guidelines referenced in this document

electronically, please go to <http://www.epa.gov/ocspp> and select "Test Methods and Guidelines."

### 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-2016-0519 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 May 7, 2018. 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-2016-0519, 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 8, 2017 (82 FR 26641) (FRL-9961-14), 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 6E8450) by IR-4, Rutgers,

The State University of New Jersey, 500 College Road East, Suite 201W, Princeton, NJ 08540. The petition requested that 40 CFR 180.614 be amended by establishing tolerances for residues of the fungicide kasugamycin, (3-*O*-[2-amino-4-[(carboxyimino-methyl)amino]-2,3,4,6-tetra-deoxy- $\alpha$ -D-arabino-hexopyranosyl]-D-*chiro*-inositol, in or on fruit, stone, subgroup 12-12A at 0.6 parts per million (ppm) and walnut at 0.04 ppm. That document referenced a summary of the petition prepared by Arysta LifeScience North America, LLC, the registrant, which is available in the docket, <http://www.regulations.gov>. There were no comments received in response to the notice of filing.

In accordance with EPA's significance figures policy, as discussed in Unit IV.C., the established tolerance for cherry subgroup 12-12A is adjusted slightly from the petition request.

## 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 kasugamycin including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with kasugamycin 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.

Kasugamycin is an aminoglycoside antibiotic pesticide with limited activity against some plant bacterial and fungal pathogens. There are no human or veterinary therapeutic applications due to low efficacy, but at one time was used clinically in Japan to treat *Pseudomonas* kidney infections in humans (Shuworth *et al.* (2006) *Nat. Struct. Mol. Biol.* 13(10):879-886). The mode of action is distinct from other aminoglycosides such as streptomycin, which also has pesticidal uses. Kasugamycin inhibits formation of the 30S ribosomal subunit at initiation of protein synthesis by perturbing the mRNA-tRNA codon/anticodon interaction; other aminoglycoside antibiotics bind to the 30S ribosomal subunit, but disrupt translation of mRNA at later stages of initiation.

The primary target organs identified for kasugamycin were the testes and kidney. These effects were seen at higher dose levels, generally at the highest dose tested (HDT). In the rat combined chronic toxicity/carcinogenicity study, an increased incidence and severity of testicular tubular atrophy was observed at histopathological evaluations at 6, 12 and 24 months. Testicular degeneration and atrophy were also observed in adult F1 males in the rat reproductive toxicity study at the highest dose. Testicular tubular dilatation and degeneration were observed in the subchronic mouse study at a dose that exceeded the limit dose, but not in the mouse carcinogenicity study, which tested at much lower doses. In the dog chronic toxicity study, testicular inflammation was reported at the high dose, but was not accompanied by atrophic or degenerative changes, and was not considered a treatment-related adverse effect.

Kidney toxicity is often associated with exposure to aminoglycoside antibiotics. In the rat reproductive toxicity study, kidney dilatation and increased incidence of chronic progressive nephropathy were observed in F1 males. In the subchronic rat study, increased incidence of eosinophilic bodies (slight severity) in the renal proximal tubular cells was reported in males at several dose levels. These effects were considered treatment-related but not adverse due to the low severity and lack of associated findings.

However, in female rats, increased epithelial cells in the urinary sediment, along with decreased urine pH (also seen in males), was considered evidence of possible kidney toxicity. Slight lipofuscin deposition in the rat combined chronic toxicity/carcinogenicity study was not considered adverse due to the lack of other related findings (this study tested up to the NOAEL of the subchronic study). The rat metabolism study indicated higher levels of radioactivity in the kidneys than other tissues. In the subchronic mouse study, minimal to severe basophilia/hyperplasia in the renal *pars recta* in females was observed. No renal effects were seen in the mouse carcinogenicity study or in the dog.

Kasugamycin caused decreased body weight and/or weight gain in subchronic studies in the rat, mouse and dog. The chronic studies, which tested at lower doses, did not show body weight effects. Decreased body weight was also observed in developmental and reproductive studies in the rat and the range-finding study for the rabbit developmental study. Body weight effects in the mouse immunotoxicity study were observed only at a dose exceeding the limit dose.

Kasugamycin appears to be irritating to the oral and gastrointestinal tract mucosa. Anal lesions and perianal/perigenital staining were observed in the subchronic mouse study. Red and swollen skin around the anal opening, and inflammation and ulceration of the rectum, were noted in male and female rats of both generations in the 2-generation reproduction study. In the rat developmental toxicity study, distention of the large intestine with stool in the cecum, and an increased incidence of loose stool, were reported. Similar findings were seen in the rabbit developmental range-finding study among females that died or were sacrificed *in extremis*. These effects may be related to the acidity (or other irritant property) of the active ingredient, which is primarily excreted unabsorbed and un-metabolized in the feces. In the dog, tongue and mouth lesions were reported at the highest dose tested in the subchronic toxicity study (but not the chronic study, which tested at a lower dose). Systemic effects were not observed in the rat 21-day dermal study at doses up to the limit dose, but local dermal irritation was observed.

The available studies, including rat acute and subchronic neurobehavioral screening studies, did not show evidence of neurotoxicity. A 28-day mouse immunotoxicity study did not

show evidence of immune system effects.

There was no evidence of increased quantitative or qualitative susceptibility in rat or rabbit developmental toxicity studies, or in the rat reproductive study. No developmental effects were seen in the rat developmental study up to doses causing maternal toxicity (decreased body weight gain, food consumption, and feed efficiency). No maternal or developmental toxicity was observed in the main rabbit developmental toxicity study, in the dose range-finding study, but maternal weight loss, reduced food consumption during dosing and abortions (GD 18 or later) were observed at higher doses. Fetal weight was decreased at the maternally toxic dose, but could not be evaluated at higher doses due to maternal death and abortions. In the rat reproductive toxicity study, parental toxicity included decreased body weight/weight gain. No offspring toxicity was observed. Reproductive toxicity at the highest dose tested (above the parental LOAEL) included testicular atrophy, decreased fertility and fecundity in the F1 parents for both litters, and an increased pre-coital interval during the F2b litter mating period.

Kasugamycin is classified as “not likely to be carcinogenic to humans,” based on lack of evidence of carcinogenicity in rat and mouse carcinogenicity studies. There was no evidence of genotoxicity.

Specific information on the studies received and the nature of the adverse effects caused by kasugamycin 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 “Kasugamycin. Human Health Risk Assessment for the Proposed Section 3 Registration of New Uses of the Antibiotic Fungicide on Cherry Subgroup 12–12A and Walnuts” on pages 30–39 in docket ID number EPA–HQ–OPP–2016–0519.

#### *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 kasugamycin used for human risk assessment is discussed in Unit III.B of the final rule published in the **Federal Register** of August 29, 2014 (79 FR 51492) (FRL–9911–57).

#### *C. Exposure Assessment*

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to kasugamycin, EPA considered exposure under the petitioned-for tolerances as well as all existing kasugamycin tolerances in 40 CFR 180.614. EPA assessed dietary exposures from kasugamycin 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.

No such effects were identified in the toxicological studies for kasugamycin; therefore, a quantitative acute dietary exposure assessment is unnecessary.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the United States Department of Agriculture (USDA) National Health and Nutrition Examination Survey, What We Eat in America, (NHANES/WWEIA; 2003–2008). As to residue levels in food, EPA assumed tolerance level residues and 100% crop treated for all registered and proposed crops.

iii. *Cancer.* Based on the data summarized in Unit III.A., EPA has concluded that kasugamycin 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 kasugamycin. 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 kasugamycin in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of kasugamycin. 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 Pesticide Root Zone Model 5/Variable Volume Water Model (VWWM) and Pesticide Root Zone Model Ground Water (PRZM GW), the estimated drinking water concentrations (EDWCs) of kasugamycin for chronic exposures are estimated to be 1.63 parts per billion (ppb) for surface water and 41.71 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For chronic dietary risk assessment, the water concentration value of 41.71 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).

Kasugamycin 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 kasugamycin to share a common mechanism of toxicity with any other substances, and kasugamycin does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that kasugamycin 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 FQPA Safety Factor (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 evidence of increased quantitative or qualitative pre- and/or postnatal susceptibility in developmental toxicity studies in two species, or the rat 2-generation reproductive toxicity study. Abortions and a reduction in fetal body weight in the rabbit developmental toxicity range-finding study were considered secondary to maternal toxicity (weight loss, and decreased food consumption). No toxicity to offspring was observed in the rat reproductive toxicity 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 kasugamycin is complete.

ii. There is no indication that kasugamycin is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

iii. There is no evidence that kasugamycin 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 kasugamycin in drinking water. These assessments will not underestimate the exposure and risks posed by kasugamycin.

#### *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.* An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. No adverse effect resulting from a single oral exposure was identified and no acute dietary endpoint was selected. Therefore, kasugamycin is not expected to pose an acute risk.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to kasugamycin from food and water will utilize 4.2% of the cPAD for children 1–2 years old, the population group receiving the greatest exposure. There are no residential uses for kasugamycin.

3. *Short-term risk.* Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Because there are no residential uses, kasugamycin is not expected to pose a short-term risk.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Because there are no residential uses, kasugamycin is not expected to pose an intermediate-term risk.

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

6. *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 kasugamycin residues.

#### IV. Other Considerations

##### A. Analytical Enforcement Methodology

An approved tolerance enforcement method for crops is available for kasugamycin using a reverse-phase, ion pairing HPLC/UV method (Morse Laboratories Method #Meth-146, Revision #4) for collecting data and enforcing tolerances for kasugamycin in plant commodities. 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 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 not established a MRL for kasugamycin.

##### C. Revisions to Petitioned-For Tolerances

In establishing the tolerance for cherry subgroup 12-12A, EPA added a significant figure (0.60 ppm rather than the proposed 0.6 ppm). This is in order to avoid the situation where rounding of an observed residue to the level of precision of the tolerance expression would be considered non-violative (such as 0.64 ppm being rounded to 0.6 ppm).

#### V. Conclusion

Therefore, tolerances are established for residues of kasugamycin, (3-O-[2-amino-4-[(carboxyimino-methyl)amino]-2,3,4,6-tetrahydroxy- $\alpha$ -D-arabino-hexopyranosyl]-D-chiro-inositol), in or on cherry subgroup 12-12A at 0.60 ppm and walnut at 0.04 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); Executive Order 13045, entitled "Protection of Children from Environmental Health Risks and Safety Risks" (62 FR 19885, April 23, 1997); or Executive Order 13771, entitled "Reducing Regulations and Controlling Regulatory Costs" (82 FR 9339, February 3, 2017). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations" (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerances in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled "Federalism" (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled "Consultation and Coordination with Indian Tribal Governments" (65 FR 67249, November 9, 2000) do not apply

to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

#### VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a "major rule" as defined by 5 U.S.C. 804(2).

#### List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: February 23, 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. In § 180.614, add alphabetically the entries "Cherry subgroup 12-12A"; and "Walnut" to the table in paragraph (a) to read as follows:

#### § 180.614 Kasugamycin; tolerances for residues.

(a) \* \* \*

| Commodity                    | Parts per million |
|------------------------------|-------------------|
| Cherry subgroup 12-12A ..... | 0.60              |
| * * * * *                    |                   |
| Walnut .....                 | 0.04              |
| * * * * *                    |                   |

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