



BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2020-0338; FRL-10013-94]

Kasugamycin; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes time-limited tolerances for residues of kasugamycin in or on almonds. This action is in response to EPA's granting of an emergency exemption under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizing use of the pesticide on almond trees. This regulation establishes maximum permissible levels for residues of kasugamycin in or on this commodity. The time-limited tolerances expire on December 31, 2023.

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-2020-0338, 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.

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, Acting 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.

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 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 section 408(g) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 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-2020-0338 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-2020-0338, 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 <https://www.epa.gov/dockets/where-send-comments-epa-dockets>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

II. Background and Statutory Findings

EPA, on its own initiative, in accordance with FFDCA sections 408(e) and 408(l)(6), 21 U.S.C. 346a(e) and 346a(1)(6), is establishing time-limited tolerances for residues of kasugamycin, (3-O-[2-amino-4-[(carboxyimino-methyl)amino]-2,3,4,6-tetrahydroxy- α -D-arabino-hexopyranosyl]-D-chiro-inositol), in or on Almond at 0.04 parts per million (ppm); and Almond, hulls at 0.4 ppm. These time-limited tolerances expire on December 31, 2023.

Section 408(l)(6) of FFDCA requires EPA to establish a time-limited tolerance or exemption from the requirement for a tolerance for pesticide chemical residues in food that will result from the use of a pesticide under an emergency exemption granted by EPA under FIFRA section 18. Such tolerances can be established without providing notice or period for public comment. EPA does not intend for its actions on FIFRA section 18 related time-limited tolerances to set binding precedents for the application of FFDCA section 408 and the safety standard to other tolerances and exemptions. Section 408(e) of FFDCA allows EPA to establish a tolerance or an exemption from the requirement of a tolerance on its own initiative, i.e., without having received any petition from an outside party.

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. . . .”

Section 18 of FIFRA authorizes EPA to exempt any Federal or State agency from any provision of FIFRA, if EPA determines that “emergency conditions exist which require such exemption.” EPA has established regulations governing such emergency exemptions in 40 CFR part 166.

III. Emergency Exemption for Kasugamycin on Almond Trees

According to the California Department of Pesticide Regulation (CDPR), the California almond industry has been experiencing frequent frost events with concurrent wetness and temperatures below 0°C in the last several years, specifically from 2013 to 2019. In recent seasons (2017, 2018, and 2019), early-spring cold spells have resulted in a high incidence of bacterial blast in almond buds and blossoms in several almond production areas in California. CDPR claims that these freeze events caused direct crop losses in the form of blasted flowers, dropped fruit, and shoot dieback affecting future fruiting wood on the tree. CDPR claims that frost injury has been described as one of the main limiting factors to crop production in many locations in California. Some plants’ frost injuries have been shown to involve an interaction of

certain leaf surface bacteria and low temperature stress. Some epiphytic bacteria such as *P. syringae* cause frost-sensitive plants to become more susceptible to freeze damage by initiating the formation of ice that results in frost injury. Many pathovars of *P. syringae* are active in ice nucleation and are the most common ice nucleation active bacteria found on plants in the United States.

After having reviewed the submission, EPA determined that an emergency condition exists for this State, and that the criteria for approval of an emergency exemption were met. EPA has authorized a specific exemption under FIFRA section 18 for the use of kasugamycin on almond trees for control of bacterial blast in almonds in California.

As part of its evaluation of the emergency exemption application, EPA assessed the potential risks presented by residues of kasugamycin in or on almonds. In doing so, EPA considered the safety standard in FFDCFA section 408(b)(2), and EPA decided that the necessary tolerance under FFDCFA section 408(l)(6) would be consistent with the safety standard and with FIFRA section 18. Consistent with the need to move quickly on the emergency exemption in order to address an urgent non-routine situation and to ensure that the resulting food is safe and lawful, EPA is issuing this tolerance without notice and opportunity for public comment as provided in FFDCFA section 408(l)(6). Although these time-limited tolerances expire on December 31, 2023, under FFDCFA section 408(l)(5), residues of the pesticide not in excess of the amounts specified in the tolerance remaining in or on almond after that date will not be unlawful, provided the pesticide was applied in a manner that was lawful under FIFRA, and the residues do not exceed a level that was authorized by these time-limited tolerances at the time of that application. EPA will take action to revoke these time-limited tolerances earlier if any experience with, scientific data on, or other relevant information on this pesticide indicate that

the residues are not safe.

Because these time-limited tolerances are being approved under emergency conditions, EPA has not made any decisions about whether kasugamycin meets FIFRA's registration requirements for use on almonds or whether permanent tolerances for this use would be appropriate. Under these circumstances, EPA does not believe that this time-limited tolerance decision serves as a basis for registration of kasugamycin by a State for special local needs under FIFRA section 24(c). Nor does this tolerance by itself serve as the authority for persons in any State other than California to use this pesticide on the applicable crops under FIFRA section 18 absent the issuance of an emergency exemption applicable within that State. For additional information regarding the emergency exemption for kasugamycin, contact the Agency's Registration Division at the address provided under **FOR FURTHER INFORMATION CONTACT**.

IV. Aggregate Risk Assessment and Determination of Safety

On March 6, 2018, EPA published in the **Federal Register** a final rule establishing tolerances for residues of kasugamycin in or on cherry subgroup 12-12A and walnut based on the Agency's conclusion that aggregate exposure to kasugamycin is safe for the general population, including infants and children. *See* (83 FR 9442) (FRL-9972-96). EPA is including the following portions of that document by reference here, as they have not changed in the Agency's current assessment of kasugamycin tolerances: the toxicological profile, assumptions for exposure assessment, and the Agency's determination regarding the children's safety factor, which have not changed. The Agency is also incorporating the toxicological points of departure that are referenced in that document and published in **Federal Register** published on August 29, 2014 (79 FR 51492) (FRL-9911-57), which have not changed.

EPA's exposure assessments have been updated to include the additional exposure from use of kasugamycin from use on almonds, assuming both tolerance-level residues and 100 percent crop treated.

An acute dietary endpoint was not identified for kasugamycin, as a result, acute dietary risk is not of concern and a separate acute dietary exposure analysis was not performed. Chronic dietary risk estimates for kasugamycin are below the Agency's level of concern of 100% of the chronic population adjusted dose (cPAD) for all population subgroups. The most highly exposed population subgroup, children 1-2 years old, had a risk estimate of 4.5% of the cPAD, while the general US population had a risk estimate of 1.3% of the cPAD. There are no dietary risk estimates of concern associated with the section 18 use of kasugamycin on almonds in California, when considered along with existing uses of the fungicide.

Since there are no residential uses of kasugamycin and no commercial uses that could result in residential exposure, aggregate risk estimates are equivalent to dietary risk estimates, which are not of concern.

Occupational handler exposures to kasugamycin were estimated assuming the maximum application rate, and label-recommended equipment and methods, and standard assumptions with respect to the area treated. In the absence of chemical-specific data to assess handler's exposure and risk, EPA relied on surrogate unit exposure data to estimate exposure and risk. The Agency assumed a single layer of clothing (baseline), without additional personal protective equipment (PPE). The resulting handler risk estimates, or margins of exposures, are all above 100, and are not of concern.

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 kasugamycin residues. More detailed information on the Agency's analysis to establish a time-limited tolerance in or almonds 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" dated September 27, 2017, in docket ID EPA-HQ-OPP-2016-0519 and the document titled, "Kasugamycin. 20CA01. Human Health Risk Assessment for the Proposed Section 18 Specific Exemption for Use on Almonds" dated April 15, 2020, in docket ID number EPA-HQ-OPP-2020-0338.

V. Other Considerations

A. Analytical Enforcement Methodology

An adequate enforcement methodology (a reverse-phase, ion pairing HPLC/UV method (Morse Laboratories Method #Meth-146, Revision #4)) is available 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.

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

The Codex has not established MRLs for kasugamycin.

VI. Conclusion

Therefore, time-limited tolerances are established for residues of kasugamycin, (3-O-[2-amino-4-[(carboxyimino-methyl)amino]-2,3,4,6-tetra-deoxy- α -D-arabino-hexopyranosyl]-D-chiro-inositol), in or on Almond at 0.04 ppm and Almond, hulls at 0.4 ppm. These tolerances expire on December 31, 2023.

VII. Statutory and Executive Order Reviews

This action establishes tolerances under FFDCFA section 408(l)(6) in response to an emergency exemption application 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 (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 in support of a FIFRA section 18 emergency exemption do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, but does not directly regulate 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 (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 (15 U.S.C. 272 note).

VIII. 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: August 25, 2020.

Marietta Echeverria,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, for the reasons stated in the preamble, the EPA amends 40 CFR chapter I as follows:

PART 180--TOLERANCES AND EXEMPTIONS FOR PESTICIDE CHEMICAL RESIDUES IN FOOD

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 paragraph (b) to read as follows:

§ 180.614 Kasugamycin; tolerances for residues.

* * * * *

(b) *Section 18 emergency exemptions.* Time-limited tolerances specified in the following table are established for residues of kasugamycin, including metabolites and degradates, in or on the specified agricultural commodities, resulting from use of the pesticide pursuant to FIFRA section 18 emergency exemptions. Compliance with the tolerance levels specified is to be determined by measuring only kasugamycin (3-O-[2-amino-4-[(carboxyimino-methyl)amino]-2,3,4,6-tetra-deoxy- α -D-arabino-hexopyranosyl]-D-chiro-inositol) in or on the commodity. The tolerances expire on the date specified in the table.

Commodity	Parts per million	Expiration date
Almond	0.04	December 31, 2023
Almond, hulls	0.4	December 31, 2023

* * * * *