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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2015-0811; FRL-9949-03]

Natamycin; Exemption from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of the biochemical pesticide natamycin [6,11,28-Trioxatricyclo [22.3.1.05'7]octacosa-8,14,16,18,20-pentaene-25-carboxylic acid, 22-[(3-amino-3,6-dideoxy-p-Dmannopyranosyl)oxy]-1,3,26-trihydroxy-12-methyl-10-oxo-, (1R,3S,5R,7R,8E,12R,14E,16E,18E,20E,22R,24S,25R,26S)-] in or on citrus, pome, stone fruit crop groups, avocado, kiwi, mango and pomegranates when used in accordance with label directions and good agricultural practices. DSM Food Specialties, B.V., P.O. Box 1, 2600 MA Delft, The Netherlands (c/o Keller and Heckman, LLP, 1001 G St., NW., Washington, DC 20001) submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of natamycin in or on citrus, pome, stone fruit crop groups, avocado, kiwi, mango and pomegranate when used in accordance with label directions and good agricultural practices.

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-2015-0811, 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: Robert McNally, Biopesticides and Pollution Prevention Division (7511P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; main telephone number: (703) 305-7090; email address: *BPPDFRNotices@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 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-2015-0811 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-2015-0811 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. Background and Statutory Findings

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 tolerance petition (PP 5F8407) by Keller and Heckman, LLP, 1001 G St., NW., Washington, DC 2001 on behalf of DSM Food Specialties, B.V., P.O. Box 1, 2600 MA Delft, The Netherlands. The petition requested that 40 CFR part 180 be amended by establishing an exemption from the requirement of a tolerance for residues of natamycin in or on citrus, pome, stone fruit crop groups, avocado, kiwi, mango, and pomegranates, when used in facilities as a post-harvest fungistat to control certain fungal diseases. That document referenced a summary of the petition prepared by the petitioner, DSM Food Specialties, which is available in the docket, *http://www.regulations.gov*. There were no comments received in response to the notice of filing.

Section 408(c)(2)(A)(i) of FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the exemption is "safe." Section 408(c)(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. Pursuant to FFDCA section 408(c)(2)(B), in establishing or maintaining in effect an exemption from the requirement of a tolerance, EPA must take into account the factors set forth in FFDCA section 408(b)(2)(C), which require 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.... " Additionally, FFDCA section 408(b)(2)(D) requires that 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 performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of pesticides. Second, EPA examines exposure to the pesticide through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings.

III. Toxicological Profile

Consistent with FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action and considered its validity, completeness and reliability, and the relationship of this information 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.

A. *Overview of Natamycin*

Natamycin is a naturally occurring compound derived from the common soil microorganisms *Streptomyces natalensis, Streptomyces lydicus,* and *Streptomyces chattanoogensis.* Natamycin was originally discovered in *Streptomyces natalensis* in South Africa

in the early 1950s, and was subsequently discovered to also occur naturally in North America in *Streptomyces lydicus* and *Streptomyces chattanoogensis.* It is commercially produced by a submerged oxygen-based fermentation of *Streptomyces natalensis, Streptomyces lydicus,* or *Streptomyces chattanoogensis.* Natamycin has been used as a food preservative worldwide for over 40 years and is approved as a food additive/preservative by the European Union, the World Health Organization, and individual countries including New Zealand and Australia for use as a fungistat to suppress mold on cheese, meats and sausage. In the United States, natamycin is approved by the Food and Drug Administration (FDA) as a direct food additive/preservative for the inhibition of mold and yeast on the surface of cheeses (21 CFR 172.155) and as an additive to the feed and drinking water of broiler chickens to retard the growth of specific molds (21 CFR 573.685). Natamycin is also FDA approved for use as a treatment to suppress fungal eye infections such as blepharitis, conjunctivitis, and keratitis.

As a biochemical pesticide active ingredient, natamycin is already approved for use as a fungistat to prevent and control the germination of mold and yeast spores in the growth media of mushrooms produced in enclosed mushroom production facilities (77 FR 29543), and to control fungal growth post-harvest on pineapples treated indoors (79 FR 75068). Natamycin has a non-toxic mode of action, has no effects on fungal mycelia, and development of antibiotic resistance to natamycin has not been reported during its entire history of use. See the document entitled, "Federal Food, Drug, and Cosmetic Act (FFDCA) Considerations for Natamycin" (June 16, 2016), available in the docket for this action.

B. Biochemical Pesticide Toxicology Data Requirements

All applicable mammalian toxicology data requirements supporting the petition to amend the existing tolerance exemption by adding use as a fungicide post-harvest, indoors, on citrus, pome, stone fruit crop groups, avocado, kiwi, mango, and pomegranates have been

fulfilled. No toxic endpoints were established, and no significant toxicological effects were observed in any of the acute toxicity studies. In addition, studies submitted indicate that natamycin is not genotoxic, has no subchronic toxic effects, and is not a developmental toxicant. There are no known effects on endocrine systems via oral, dermal, or inhalation routes of exposure. For a summary of the data upon which EPA relied, and its human health risk assessment based on that data, please refer to the document entitled, "Federal Food, Drug, and Cosmetic Act (FFDCA) Considerations for Natamycin" (June 16, 2016). This document, as well as other relevant information, is available in the docket for this action as described under **ADDRESSES**.

IV. Aggregate Exposures

In examining aggregate exposure, FFDCA section 408 directs EPA to consider available information concerning exposures from the pesticide residue in food and all other non-occupational exposures, including drinking water from ground water or surface water and exposure through pesticide use in gardens, lawns, or buildings (residential and other indoor uses).

A. Dietary Exposure

The proposed use patterns may results in dietary exposure to natamycin, however, exposure is expected to be insignificant (see document entitled, "Federal Food, Drug, and Cosmetic Act (FFDCA) Considerations for Natamycin" (June 16, 2016), available in the docket for this action. No significant exposure via drinking water is expected; natamycin is applied indoors only. Some dietary exposure to natamycin might occur through other nonpesticidal sources as a result of its use as a food additive/preservative. Should exposure occur, however, minimal to no

risk is expected for the general population, including infants and children, due to the low toxicity of natamycin as demonstrated in the data submitted and evaluated by the Agency, as fully explained in the document entitled, "Federal Food, Drug, and Cosmetic Act (FFDCA) Considerations for Natamycin" (June 16, 2016), available in the docket for this action.

B. Other Non-Occupational Exposure

Other non-occupational exposure (other than dietary) from pesticidal use is not expected because natamycin is not approved for residential uses. The active ingredient is applied directly to commodities and degrades rapidly. There may be some exposure to natamycin as a result of its use as treatment of infections, but minimal to no risk is expected for the general population, including infants and children, due to the low toxicity of natamycin as demonstrated in the data submitted and evaluated by the Agency, as fully explained in the document entitled, "Federal Food, Drug, and Cosmetic Act (FFDCA) Considerations for Natamycin" (June 16, 2016), available in the docket for this action.

V. 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 natamycin to share a common mechanism of toxicity with any other substances, and natamycin does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that natamycin 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://www.epa.gov/pesticides/cumulative.*

VI. Determination of Safety for U.S. Population, Infants, and Children

FFDCA section 408(b)(2)(C) provides that, in considering the establishment of a tolerance or tolerance exemption for a pesticide chemical residue, EPA shall assess the available information about consumption patterns among infants and children, special susceptibly of infants and children to pesticide chemical residues, and the cumulative effects on infants and children of the residues and other substances with a common mechanism of toxicity. In addition, FFDCA section 408(b)(2)(C) 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 that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the Food Quality Protection Act (FQPA) Safety Factor. In applying this provision, EPA either retains the default value of 10X, or uses a different additional or no safety factor when reliable data are available to support a different additional or no safety factor.

As part of its qualitative assessment, EPA evaluated the available toxicity and exposure data for natamycin and considered it validity, completeness, and reliability, as well as the relationship of this information to human risk. EPA considers the toxicity database to be complete and has identified no residual uncertainty with regard to prenatal and postnatal toxicity or exposure. No hazard was identified based on the available studies, as fully explained in the document entitled, "Federal Food, Drug, and Cosmetic Act (FFDCA) Considerations for Natamycin" (June 16, 2016), available in the docket for this action. Based upon its evaluation, EPA concludes that there are no threshold effects of concern to infants, children, or adults when

natamycin is applied to mushrooms, in enclosed mushroom production facilities, and on pineapples, citrus, pome, stone fruit crop groups, avocado, kiwi, mango and pomegranates when used in accordance with label directions and good agricultural practices. As a result, EPA concludes that no additional margin of exposure (safety) is necessary.

VII. Other Considerations

An analytical method is not required for enforcement purposes since the Agency is establishing an exemption from the requirement of a tolerance without any numerical limitation. Further, residues are not expected on any other crops because natamycin will only be applied indoors to these particular crops.

VIII. Conclusions

Based on its assessment of natamycin, 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 natamycin. Therefore, an amendment to the exemption of a tolerance is established for residues of natamycin in or on citrus, pome, stone fruit crop groups, avocado, kiwi, mango and pomegranates.

The Agency is issuing the exemption for residues of natamycin in or on citrus, pome, stone fruit crop groups, avocado, kiwi, mango and pomegranates instead of limiting this exemption to post-harvest indoor applications to citrus, pome, stone fruit crop groups, avocado, kiwi, mango and pomegranates because the restrictions are not relevant to the FFDCA safety finding for natamycin. Those limitations are related to the use of the pesticide and regulated under FIFRA.

IX. Statutory and Executive Order Reviews

This final rule establishes 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, 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). 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 final rule 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).

X. 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: July 19, 2016.

Robert C. McNally,
Director, Biopesticides and Pollution Prevention 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. Revise § 180.1315 to read as follows:

§ 180.1315 Natamycin; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for the residues of natamycin in or on mushrooms, pineapples, citrus, pome, stone fruit crop groups, avocado, kiwi, mango, and pomegranates when used in accordance with label directions and good agricultural practices.

[FR Doc. 2016-20409 Filed: 8/24/2016 8:45 am; Publication Date: 8/25/2016]