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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2015-0017; FRL-9930-16]

Lavandulyl Senecioate; 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 arthropod pheromone, lavandulyl senecioate, in or on all raw agricultural commodities when applied or used in microbeads/dispensers at a rate not to exceed 150 grams active ingredient/acre/year in accordance with good agricultural practices. Suterra, LLC 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 lavandulyl senecioate.

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-2015-0017, 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-2015-0017 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-2015-0017, 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 March 4, 2015 (80 FR 11611) (FRL-9922-68), 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 4F8292) by Suterra, LLC, 20950 NE Talus Place, Bend, OR 97701. The petition requested that 40 CFR part 180 be amended by establishing an exemption from the requirement of a tolerance for residues of lavandulyl senecioate in or on all raw agricultural commodities when applied to growing crops at a rate not to exceed 150 grams of active ingredient per acre per year. That document referenced a summary of the petition prepared by the petitioner Suterra, LLC, which is available in the docket via *http://www.regulations.gov*. No comments were received on 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 Lavandulyl Senecioate

Lavandulyl senecioate (5-methyl-2-(1-methylethenyl)-4-hexenyl 3-methyl-2-butonate) is a technical grade synthetic arthropod pheromone. This arthropod pheromone is structurally similar to and mimics a naturally occurring pheromone produced by the female vine mealybug (*Planococcus ficus*) to attract males for mating. This pheromone is used to disrupt the normal mating cycle of the vine mealybug and has a non-toxic mode of action.

As an arthropod pheromone, lavandulyl senecioate is exempt from the requirement of a tolerance when used in retrievably sized polymeric matrix dispensers in or on all raw agricultural commodities when applied to growing crops only at a rate not to exceed 150 grams active ingredient/acre/year in accordance with good agricultural practices (40 CFR 180.1124). The petitioner is requesting to apply this arthropod pheromone in an aqueous suspension of micro-bead/dispensers via normal spray equipment; therefore, the proposed new use of lavandulyl senecioate is not covered under the existing tolerance exemption listed in 40 CFR 180.1124. See the document entitled, "Federal Food, Drug, and Cosmetic Act (FFDCA) Considerations for Lavandulyl Senecioate" (June 30, 2015), available in the docket for this action.

B. Biochemical Pesticide Toxicology Data Requirements

All applicable mammalian toxicology data requirements supporting the petition to exempt residues of the arthropod pheromone, lavandulyl senecioate, from the requirement of a tolerance in or on all raw agricultural commodities when applied or used in microbeads/dispensers at a rate not to exceed 150 grams active ingredient/acre/year have been fulfilled. No significant toxicological effects were observed in any of the acute

toxicity studies. Three mutagenicity studies submitted indicate that lavandulyl senecioate is not a mutagen. There are no known effects on endocrine systems via oral, dermal, or inhalation routes of exposure.

In the preamble to the final rule that exempted arthropod pheromones from the requirement of a tolerance when used in retrievably sized polymeric matrix dispensers, the Agency indicated that it did not have a toxicology database for arthropod pheromones that addressed the potential risk of repeated, direct dietary exposure with sprayable formulations; therefore, at that time, the Agency limited the tolerance exemption to arthropod pheromones used in retrievably sized polymeric matrix dispensers with an annual rate limitation of 150 grams of active ingredient per acre. The Agency concluded that the limitations would not result in dietary exposure any greater than what may be found naturally as a result of heavy infestations of the pest arthropod. March 30, 1994 (59 FR 14757) (FRL-4761-9).

To address the subchronic and prenatal developmental toxicity data requirements for this exemption from the requirement of a tolerance for this arthropod pheromone, lavandulyl senecioate, the petitioner submitted scientific rationales that demonstrate that it is highly unlikely that there will be significant repeated exposure, including dietary exposure and exposure to female humans, to this pheromone when used as proposed based on the extremely low application rate, low emission rate, rapid volatilization after emission from the microbeads, and rapid biodegradation. Taking into account the petitioner's rationale, EPA has concluded that there is unlikely to be exposure that could result in subchronic and developmental effects and so has waived the requirements for subchronic and prenatal developmental testing.

For a full discussion of the data and rationale upon which EPA relied, and its human health risk assessment based on that data and rationale, please refer to the document entitled, "Federal Food, Drug, and Cosmetic Act (FFDCA) Considerations for Lavandulyl Senecioate" (June 30, 2015). 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

In the preamble to the final rule, the Agency stated that limiting the exemption to applications of arthropod pheromones in retrievably sized dispensers would severely limit the possibility of direct dietary exposure. The Agency believed that restriction was necessary to protect public health due to a lack of data on repeat exposure but acknowledged that petitioners wanting to use other application methods or formulations could petition for an amendment by demonstrating that the new formulation did not increase the likely dietary exposure. For this tolerance exemption, based on the petitioner's submission concerning the proposed use, the Agency has determined that the proposed use (applying this arthropod pheromone in an aqueous suspension of micro-bead/dispensers via normal spray equipment with a limitation of 150 grams active ingredient/acre/year) will not result in detectable residues in or on all food commodities.

That use is unlikely to result in significant dietary exposure to lavandulyl senecioate based on the extremely low application rate, low emission rate, rapid volatilization after emission from the microbeads, and rapid biodegradation (see document entitled, "Federal Food, Drug, and Cosmetic Act (FFDCA) Considerations for Lavandulyl Senecioate" (June 30, 2015), available in the docket for this action). No significant exposure via drinking water is expected based on the previous information for dietary exposure and the fact that the arthropod pheromone is not to be applied directly to water. However, should any dietary and/or drinking water exposure occur, minimal to no risk is expected for the general population, including infants and children, due to the low toxicity of lavandulyl senecioate 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 Lavandulyl Senecioate" (June 30, 2015), available in the docket for this action.

B. Other Non-Occupational Exposure

Other non-occupational exposure (other than dietary) is not expected because the arthropod pheromone, lavandulyl senecioate, is not approved for residential uses.

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 lavandulyl senecioate to share a common mechanism of toxicity with any other substances, and lavandulyl senecioate does not appear to produce

a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that lavandulyl senecioate 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 susceptibility 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 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 on lavandulyl senecioate and considered its 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 Lavandulyl Senecioate" (June 30, 2015), available in the docket for this action. Based upon its evaluation, EPA concludes that there are no threshold effects of concern to infants or children when lavandulyl senecioate is applied or used in microbeads/dispensers in or on all raw agricultural commodities at a rate not to exceed 150 grams active ingredient/acre/year. As a result, EPA concludes that no additional margin of exposure (safety) is necessary.

Based on the available data, EPA determines that there is a reasonable certainty that no harm will result from aggregate exposure to lavandulyl senecioate to the general U.S. population, including infants and children when applied to growing crops using microbeads/dispensers at a rate not to exceed 150 grams active ingredient/acre/year. EPA concludes that an exemption from the requirement of a tolerance for residues of lavandulyl senecioate in or on raw agricultural commodities when applied to growing crops using microbeads/dispensers at a rate not to exceed 150 grams active ingredient/acre/year is safe.

VII. Other Considerations

A. Analytical Enforcement Methodology

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.

VIII. Conclusions

Therefore, an exemption is established for residues of the arthropod pheromone, lavandulyl senecioate, in or on all raw agricultural commodities when applied or used in microbeads/dispensers at a rate not to exceed 150 grams active ingredient/acre/year.

IX. Statutory and Executive Order Reviews

This action establishes an exemption from the requirement of 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 exemption 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).

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 31, 2015.

Robert McNally,
Director, Biopesticides and Pollution Prevention Division.

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 § 180.1332 to subpart D to read as follows:

§ 180.1332 Lavandulyl senecioate; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of the arthropod pheromone, lavandulyl senecioate (5-methyl-2-(1-methylethenyl)-4-hexenyl 3-methyl-2-butonate), in or on all raw agricultural commodities when applied or used in microbeads/dispensers at a rate not to exceed 150 grams active ingredient/acre/year in accordance with good agricultural practices.

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