BIOPESTICIDES REGISTRATION ACTION DOCUMENT

Lavandulyl senecioate
PC Code 036005

U.S. Environmental Protection Agency
Office of Pesticide Programs
Biopesticides and Pollution Prevention Division

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This document is for informational purposes only and is representative of the Agency's justification in registering products containing this active ingredient. This is not a legal document.

TABLE OF CONTENTS

I. EXECUTIVE SUMMARY: 5

II. ACTIVE INGREDIENT OVERVIEW 6

III. REGULATORY BACKGROUND 6

A. Classification 6

B. Food Clearances and Tolerances 6

IV. RISK ASSESSMENT 6

A. Active Ingredient Characterization 6

B. Human Health Assessment 7
1. Toxicology 7
2. Dose Response Assessment 8
3. Food Quality Protection Act (FQPA) Consideration ……..... 8
4.. Occupational, Residential, School and Day Care Exposure and Risk Characterization 8
5 Cumulative Effects 9
6 Risk Characterization 9

C. ENVIRONMENTAL ASSESSMENT 9
1. Ecological Hazards 9
2. Environmental Fate and Ground Water Data 9
3. Ecological Exposure and Risk Characterization 9
4. Endangered Species Assessment……. 10

D. EFFICACY DATA 10

V. RISK MANAGEMENT DECISION 10

A. Determination of Eligibility for Registration 10

B. Regulatory Decision 11

C. Environmental Justice 13

VI. ACTIONS REQUIRED BY REGISTRANTS 11

A. Reporting Adverce Effects 13

B. Reporting of Hypersensitivity Incidents 11

VII. APPENDIX A. Product Specific Information……..…14

VIII. APPENDIX B. Product Specific Information……..…15

IX. APPENDIX C. References..... 14

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I. EXECUTIVE SUMMARY:

The new active ingredient Lavandulyl Senecioate, also known as 5-methyl-2-(1-methylethenyl)-4-hexenyl 3-methyl-2-butonate, is a technical grade synthetic arthropod pheromone. This pheromone is structurally similar to and mimics a naturally occurring pheromone produced by the female vine mealybug (*Planococcus ficus*) to attract the males for mating. Lavandulyl Senecioate is intended for use in polymeric dispensers to disrupt the normal mating cycle of vine mealybug on table and wine grapes. Accordingly, EPA is considering the approval of a registration for Lavandulyl Senecioate under Section 3(c)(5) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).

The Biopesticides and Pollution Prevention Division (BPPD) has reviewed the data required to support the registration of this biochemical active ingredient, under Section 3(c)(5) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). Product chemistry data requirements were satisfied by acceptable guideline studies. Adequate mammalian toxicology data/information was submitted to support registration of Lavandulyl Senecioate. Acceptable acute toxicity guideline studies were submitted, and data waivers were granted by the Agency for the remaining toxicity requirements based on the lack of toxicity of the active ingredient. Ecological effects data requirements for are waived because of the use of this pheromone in retrievable, polymeric dispensers.

Based on the data available to the Agency, it has been determined that no unreasonable adverse effects to the U.S. population and the environment will result from the use of the active ingredient when label instructions are followed and good agricultural practices are employed. Laboratory studies indicate that the active ingredient is not toxic following oral, inhalation or dermal exposure. Moreover, the pesticidal usage of this biochemical in polymeric dispensers, will not have any harmful environmental effects

Due to the negligible risk concerns when used as mating disrupter, Lavandulyl Senecioate meets the criteria as specified in §3(c)(5) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, and is thus eligible for unconditional registration. It was determined that the data/information submitted adequately satisfy applicable data requirements at 40 C.F.R. Subpart U §158.2000.

II. ACTIVE INGREDIENT OVERVIEW

Common Name: Lavandulyl Senecioate

Chemical Names: 5-methyl-2-(1-methylethenyl)-4-hexenyl 3-methyl-2-butonate

Trade & Other Names: Lavandulyl Senecioate

CAS Registry Number: 23960-07-8

OPP Chemical Code: 036005

Type of Pesticide: Mating disrupter for vine mealybug

Application rates and methods vary depending on the product. For specific information regarding the product*(s)* refer to Appendix B.

III. REGULATORY BACKGROUND

On November 07, 2008, Suterra LLC, submitted an application for the registration of the end use product (EP) CheckMate® VMB Dispenser (56336- LA) containing 5.91% Lavandulyl Senecioate, and CheckMate VMB Technical Pheromone (56336-LL) containing 97.66% Lavandulyl Senecioate. A notice of receipt of the application for registration of Lavandulyl Senecioate as a new active ingredient was published in the Federal Register on February 18, 2009 (74 FR 7601), with a 30-day comment period. No comments were received following this publication.
Consistent with the Agency's new policy for making pesticide registration actions more transparent, EPA provided a 30-day public comment period on the decision to register Lavandulyl Senecioate. No comments were received during the 30 day public comment period

A. Classification

The Biochemical Classification Committee determined that Lavandulyl Senecioate is a biochemical pesticide because this pheromone has a non toxic mode of action, and is structurally similar to and mimics a naturally occurring pheromone produced by the female vine mealybug.

B. Food Clearances/Tolerances

Arthropod pheromones are exempt from the requirement of a tolerance in or on raw agricultural commodities when used in retrievable, polymeric matrix dispensers, and when the pheromone is applied to growing crops at a rate not to exceed 150 grams active ingredient per acre per year in accordance with good agricultural practices (40 CFR §180.1124).

IV. RISK ASSESSMENT

A. Active Ingredient Characterization

Lavandulyl Senecioate is a synthetic compound that mimics the naturally occurring pheromone

substance produced by female vine mealybug. This compound is a yellow liquid with a slightly burnt oily smell.

The descriptions of the product formulation and production process, as well as the formation of impurities, were examined by the Agency and found to meet current standards. A preliminary analysis was conducted to identify Lavandulyl Senecioate in five batches of the product, and the results were determined to be acceptable by the Agency. The analytical method used to determine the content of the active ingredient is also acceptable. Physical and chemical properties were submitted for the active ingredient and are adequate. Refer to Table 1 in Appendix A for a summary of product chemistry data requirements. Refer to Table 2 in Appendix A for the summary of physical and chemical characteristics for Lavandulyl Senecioatel. All product chemistry data requirements for registration of Lavandulyl Senecioate have been satisfied.

B. Human Health Assessment

1. Toxicology

Toxicity categories are assigned based on the hazard(s) identified from studies and/or information on file with the Agency. An active ingredient is classified into Toxicity Category I, II, III or IV, in which Toxicity Category I indicates the highest toxicity and Toxicity Category IV indicates the lowest toxicity.

Adequate mammalian toxicology data/information is available to support registration of Lavandulyl Senecioate. All toxicology data requirements for Lavandulyl Senecioate have been satisfied.
Lavandulyl Senecioate is a naturally occurring arthropod pheromone with a non-toxic mode of action. Arthropod pheromones are generally effective at very low rates and are used in point source applications such as retrievable polymeric dispensers. The Agency recognizes the low toxicity, negligible expected exposure, and lack of expected adverse effects on humans and nontarget organisms of arthropod pheromones when used in polymeric dispensers. Moreover, published subchronic studies on compounds similar in structure to arthropod pheromones have been submitted indicating these compounds have no significant human health effects. As a result only acute mammalian toxicology data were required for this registration.

a. Acute Toxicity

Acute toxicity testing is required to 1) determine systemic toxicity from acute exposure via the dermal, inhalation and oral routes, 2) determine irritant effects from exposure to the eyes and 3) determine the potential for skin sensitization (allergic contact dermatitis).

Tier I toxicity data submitted and reviewed showed that Lavandulyl Senecioate is a toxicity category IV (low toxicity) compound via acute oral, acute dermal, eye irritation, and acute inhalation routes of exposure. Lavandulyl Senecioate is in Toxicity Category III (slightly toxic) for primary dermal irritation. Lavandulyl Senecioate is not an eye or skin irritant. No additional toxicity data are required to support usage of this biochemical.

For more information regarding the acute toxicity data requirements, refer to Table 3 in Appendix A.

2. Dose Response Assessment

No meaningful toxicological endpoints were identified on Lavandulyl Senecioate when used as a pesticide; therefore, a dose response assessment was not required.

3. Food Quality Protection Act (FQPA) Consideration

a. Dietary Exposure and Risk Characterization

According to 40 CFR 180.1124, arthropod pheromones are exempt from the requirement of a tolerance, and thus a dietary assessment is not required.

Moreover, exposure to Lavandulyl Senecioate is expected to be minimal due to its use in point source dispensers, from which it is released in very small quantities. Restricting the use of the Lavandulyl Senecioate to retrievably sized dispensers will significantly limit the possibility of dietary exposure to the pheromone.

b. Drinking Water Exposure and Risk Characterization

No significant drinking water exposure or residues are expected to result from the pesticidal usage of Lavandulyl Senecioate. The active ingredient is intended for use in retrievable dispensers and not to be applied directly to water. If used in accordance with EPA-approved labeling, it is not likely to accumulate in drinking water

As a result, dietary and drinking water exposure to residues of Lavandulyl Senecioate are expected to be minimal.

4. Occupational, Residential, School and Day Care Exposure and Risk Characterization

a. Occupational Exposure and Risk Characterization

Lavandulyl Senecioate is a synthetic compound that is structurally identical to, and mimics, the naturally occurring pheromone of the female vine mealybug moth, and acts via a non-toxic mode of action to specific target pests. Low oral, dermal, and inhalation toxicity have been demonstrated by the data summarized above. The end-use product will be applied via polymeric-matrix dispensers placed in trees. The potential for dermal, eye, and inhalation exposure to Lavandulyl Senecioate for handlers is minimal and will be mitigated as long as products are used according to label directions. The Agency will require labels to include the appropriate signal word, re-entry interval, and precautionary statements.

b. Residential, School and Day Care Exposure and Risk Characterization

No indoor residential, school, or day care uses are currently approved for products containing Lavandulyl Senecioate. The Agency has concluded that the potential for pheromone residues is not a dietary hazard to the general population, including infants and children. This decision was based on the following criteria: 1) low acute and subchronic mammalian toxicity, 2) the known

metabolism; and 3) the history of safe use of similar arthropod pheromones. Also, for food uses of pheromones, the toxicity and residue data support the conclusion that an exemption from the requirement of a tolerance is appropriate and adequate to protect human health, including that of infants and children (40 CFR 180.1124)

5. Cumulative Effects

EPA has considered the potential for cumulative effects of Lavandulyl Senecioate and other substances in relation to a common mechanism of toxicity. Because of its low toxicity to mammalian systems, the Agency does not expect any cumulative or incremental effects from exposure to residues of Lavandulyl Senecioate when applied/used as directed on the label and in accordance with good agricultural practices.

6. Risk Characterization

The Agency considered human exposure to Lavandulyl Senecioate in light of the relevant safety factors in FQPA and FIFRA. A determination has been made that no unreasonable adverse effects to the U.S. population in general, and to infants and children in particular, will result from the use of Lavandulyl Senecioate when label instructions are followed.

C. ENVIRONMENTAL ASSESSMENT

1. Ecological Hazards

According to 40 CFR 158.2060 (a) (2), arthropod pheromones when applied at up to a maximum use rate of 150 grams active ingredient/acre/year, and that are not expected to available to avian species, are not required to provide non-target toxicity data. Lavandulyl Senecioate is a synthetic arthropod pheromone that is structurally similar to and mimics the pheromone produced by the female vine mealybug. This compound acts on a select group of insects and has a non-toxic mode of action. Lavandulyl Senecioate will be used in retrievably sized polymeric dispensers within traps at a rate not exceeding 150 gr / acre / year.

2. Environmental Fate and Ground Water Data

Environmental fate data are not required for this active ingredient because it is an arthropod pheromone applied at a maximum use rate of 150 grams active ingredient/acre/year, and that is not expected to available to avian species,. (40 CFR 158.2060)

3. Ecological Exposure and Risk Characterization

Lavandulyl Senecioate is a synthetic arthropod pheromone that is structurally identical to and mimics a naturally occurring pheromone produced by the female vine mealybybug moth. It acts on a select group of insects and has a non-toxic mode of action. Lavandulyl Senecioate is intended for use in retrievably sized polymeric dispensers within traps, which significantly limits the possibility of adverse effects on non-target avian, aquatic, or insect species. As a result, no toxicology or environmental fate and effects data were deemed necessary for registration.

4. Endangered Species Assessment

Based on the fact that Lavandulyl Senecioate is not toxic to non-target organisms and on its use pattern in retrievable dispensers, EPA has determined it will have "No Effect" on any currently listed threatened or endangered species or any designated critical habitat

D. PRODUCT PERFORMANCE DATA (EFFICACY)

Submission of product performance data (OPPTS 810.3000) is listed as a requirement for all pesticide products. Customarily, the Agency requires efficacy data to be submitted for review only in connection with the registration of products directly pertaining to the mitigation of disease bearing human health organisms and certain designated quarantine pests, i.e., ticks, mosquitoes, fleas, Mediterranean fruit flies, gypsy moths, Japanese beetles. For a list of organisms considered by the Agency as “public health pests”, please refer to Pesticide Registration Notice 2002-1 (http://www.epa.gov/PR_Notices/pr2002-1.pdf).

V. RISK MANAGEMENT DECISION

A. DETERMINATION OF ELIGIBILITY FOR REGISTRATION

Section 3(c)(5) of FIFRA provides for the registration of a new active ingredient if it is determined that (A) its composition is such as to warrant the proposed claims for it; (B) its labeling and other materials required to be submitted comply with the requirements of FIFRA; (C) it will perform its intended function without unreasonable adverse effects on the environment; and (D) when used in accordance with widespread and commonly recognized practice it will not generally cause unreasonable adverse effects on the environment.

The four criteria of the Eligibility Determination for Pesticidal Active Ingredients are satisfied by the science assessments evaluating the subject registration application for products containing Lavandulyl Senecioate. Such products are not expected to cause unreasonable adverse effects on the environment, and are likely to provide protection as claimed when used according to label instructions. Therefore, Lavandulyl Senecioate is eligible for registration for the labeled uses.

B. REGULATORY DECISION

EPA has determined that Lavandulyl Senecioate presents no issues of toxicological, ecological, or environmental concern. As discussed above, acute toxicity data for Lavandulyl Senecioate demonstrate that it is either toxicity category IV or III. Lavandulyl Senecioate does not demonstrate subchronic or developmental toxicity, and it is not mutagenic or genotixic. EPA has no concerns for any non-target organisms exposed to Lavandulyl Senecioate in accordance with approved label directions. EPA has not identified any toxic endpoints for non-target mammals, birds, plants, aquatic, or soil organisms. Nor are there concerns for any threatened and endangered species. Thus, given that Lavandulyl Senecioate has very low toxicity and presents little if any risk to non-target organisms, EPA concludes that it is in the best interests of the public and the environment to issue the registration for Lavandulyl Senecioate.

Consistent with the Agency's new policy for making these registration actions more transparent, EPA has provided a 30-day public comment period on the decision to register Lavandulyl Senecioate. No comments were received during the 30 day public comment period.

The data submitted fulfill the requirements of registration of Lavandulyl Senecioate as a mating disrupter of mealybug moth on table and wine grapes, using retrievable polymeric dispensers, and at a rate not exceeding 150 grams / acre / year. Refer to Appendix B for product-specific information.

C. ENVIRONMENTAL JUSTICE

EPA seeks to achieve environmental justice, the fair treatment and meaningful involvement of all people, regardless of race, color, national origin, or income, in the development, implementation, and enforcement of environmental laws, regulations, and policies. To help address potential environmental justice issues, the Agency seeks information on any groups or segments of the population who, as a result of their location, cultural practices, or other factors, may have atypical, unusually high exposure to Lavandulyl Senecioate, compared to the general population. Please comment if you are aware of any sub-populations that may have atypical, unusually high exposure compared to the general population.

VI. ACTIONS REQUIRED BY REGISTRANTS

The Agency evaluated all of the data submitted in connection with the initial registration of Lavandulyl Senecioate and determined that these data are sufficient to satisfy current registration data requirements. No additional data are required to be submitted to the Agency at this time. For new uses and/or changes to existing uses, additional data may be required.

Not withstanding the information stated in the previous paragraph, it should be clearly understood that certain, specific, data are required to be reported to the Agency as a requirement for maintaining the Federal registration for a pesticide product. A brief summary of these types of data are listed below.

A. Reporting of Adverse Effects

Reports of all incidents of adverse effects to the environment must be submitted to the Agency under the provisions stated in FIFRA, Section 6(a)(2).

B. Reporting of Hypersensitivity Incidents

Additionally, all incidents of hypersensitivity (including both suspected and confirmed incidents) must be reported to the Agency under the provisions of 40 CFR Part 158.2050(d).

VII. APPENDIX A. DATA REQUIRMENTS (40 CFR Part 158-Subpart U)

*NOTE: MRID numbers listed in the following tables are representative of supporting data for the original registration of the product containing this active ingredient. Subsequent to this registration, there may be additional MRIDs that support registration of other products containing this active ingredient.

TABLE 1. Product Chemistry Data Requirements for Lavandulyl Senecioate (40 CFR § 158.2030)

OPPTS Guideline No.	Study (MRID 475387-01)	Results
830.1550 to 830.1670	Product identity; Manufacturing process; Discussion of formation of unintentional ingredients	Submitted data satisfy the requirements for product identity, manufacturing process, and discussion of formation of impurities.
830.1700	Analysis of samples	Submitted data satisfy the requirements for analysis of samples.
830.1750	Certification of limits	Limits listed in the CSF are adequate / acceptable.
830.1800	Analytical method	Acceptable.

TABLE 2. Physical and Chemical Properties for CheckMate VMB Technical Pheromonea

Guideline Reference No./Property		Description of Result	Methods
830.6302	Color	Yellow	Visual inspection
830.6303	Physical State	Liquid	Visual inspection
830.6304	Odor	Slightly burnt, oily	Olfactory inspection
830.6313	Stability	To be conducted	
830.6314	Oxidation/Reduction: Chemical Incompatibility	N/A, the product does not contain any oxidizing/reducing agents	Product knowledge
830.6315	Flammability	134°C	JIS K 2265
830.6316	Explodability	N/A, product does not contain explosive ingredients	Product knowledge
830.6317	Storage Stability	To be conducted	
830.6319	Miscibility	N/A, the product is not an emulsifiable liquid.	
830.6320	Corrosion Characteristics	To be conducted	
830.6321	Dielectric Breakdown Voltage	Not required for TGAI/MP	
830.7000	pH	N/A, the product is not an aqueous solution or suspension	
830.7100	Viscosity	4.722 mPa at 20°C	JIS K 2283
830.7200	Melting Range	N/A, the product is a liquid	
830.7220	Boiling Range	106°C at 0.8 mm Hg	Distillation
830.7300	Density/Relative Density/Bulk Density	Density = 0.913 g/cm^3 at 20°C	JIS K 2249
830.7370	Dissociation Constant in Water	N/A	
830.7550	Partition Coefficient	5.57	OECD 117
830.7840	Water Solubility	8.0 µg/mL	OECD 105
830.7950	Vapor Pressure	0.000515 mmhg at25°C	

Table 3. Human Toxicology Data Requirements for Lavandulyl Senecioate (40 CFR § 158.2050)

Study Type/OPPTS Guideline	LD_{50}/LC_{50}/Results	Toxicity Category	MRID
Acute Oral Toxicity/OPPTS 870.1100	>5,000 mg/kg	IV	47595804
Acute Dermal Toxicity/OPPTS 870.1200	> 5,000 mg/kg	IV	47595804
Acute Inhalation Toxicity/OPPTS 870.1300	Info. to support tox data requirements submitted	Waived*	
Acute Eye Irritation/OPPTS 870.2400	Minimal effects clearing in less than 24 hours	IV	47595804
Acute Dermal Irritation/OPPTS 870.2500	Moderate irritation at 72 hours	III	47595804
Skin Sensitization/OPPTS 870.2600	Info. to support tox data requirements submitted	Waived*	
Bacterial Reverse Mutation Testing/OPPTS 870.5100	Must be addressed	Waived*	
In vitro Mammalian Cell Assay/OPPTS 870.5300	Must be addressed	Waived*	

* **Acute Inhalation Toxicity (OPPTS 870.1300)/ Skin Sensitization (OPPTS 870.2600)/ Bacterial Reverse Mutation Testing (OPPTS 870.5100)/ In vitro Mammalian Cell Assay (OPPTS 870.5300):** To address this data requirement, the applicant submitted a waiver request supported by credible rationale that shows minimal exposure to active ingredient. In fact the product is used a very dose and is enclosed in dispensers which precludes any significant exposure to the active ingredient.

VIII. APPENDIX B.

For product specific information, please refer to http://oaspub.epa.gov/pestlabl/ppls.home.

IX. APPENDIX C.

REFERENCES

1. Hinkens, D., McElfresh, J., Millar, J. 2001. *Identification and synthesis of the sex pheromone of the vine mealybug, Planococcus ficus*. Tetrahedron Letters, Vol. 42, Issue 9. Departments of Entomology and Chemistry, University of California, Riverside, CA.