BIOPESTICIDES REGISTRATION ACTION DOCUMENT

(E,Z)-7,9-Dodecadien-1-yl acetate
PC Code 011471

EUROPEAN GRAPE VINE MOTH

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

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I. EXECUTIVE SUMMARY:

This Biopesticides Registration Action Document (BRAD) presents EPA's risk assessment and regulatory decision on the new biochemical pesticide active ingredient (E,Z)-7,9-Dodecadien-1-yl acetate. (E,Z)-7,9-Dodecadien-1-yl acetate is a technical grade synthetic straight-chained lepidopteran pheromone (SCLP) that is structurally similar to and mimics the naturally occurring pheromone produced by the female European Grapevine moth (*Lobesia botrana)* (EGVM) to attract males for mating. The synthetic active ingredient (Isomate-EGVM) is intended to mitigate the effects of the EGVM by disrupting the normal mating cycle of the EGVM in vineyards. Isomate-EGVM will be contained in a twist-tie dispenser that consists of a polyethylene plastic tube parallel to an associated aluminum wire. The pheromone slowly diffuses from the inside of the tube to the surface where it volatilizes in microgram amounts. Each twist tie dispenser will be tied directly on the plant or trellis wires, and will slowly release infinitesimal amounts of pheromone into the atmosphere. This formulation is **not** randomly distributed by a mechanical device, nor is it sprayed into the air.

The EGVM feeds on both the flower and the fruit of the grapevine, and poses a risk of serious harm to vineyards. If the moth attacks mature grape clusters, the berries can become further damaged through infection by the fungus *botrytis cinerea* – a condition known as bunch rot. While the EGVM is established in many parts of the world, it has not previously been observed in the United States. But, in 2009, Napa Valley winegrape growers suffered serious crop loss and damage from EGVM. Approximately 30 properties have been officially identified as having the pest present, and it is believed that the pest will be found on many more properties once delimitation trapping is conducted in the spring of 2010.

In response to an infestation of the European Grape Vine Moth in the Napa Valley Area that is anticipated to occur during the 2010 growing season, the EPA received a request from the U.S. Department of Agriculture's Animal Plant Health Inspection Service (APHIS) for expedited consideration of the registration application for Isomate-EGVM. APHIS requested expedited consideration of the registration application so that the product would be available for mating disruption efforts immediately during the time the insects emerge from diapause.

EPA has considered the Isomate-EGVM registration application on an expedited basis and has determined to grant a registration for Isomate-EGVM under Section 3(c)(5) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). EPA has determined that registration and use of this pesticide in accordance with label directions will not cause unreasonable adverse effects to the environment. In addition, EPA has determined that there is a reasonable certainty of no harm from dietary exposure to residues of Isomate-EGVM.

Product chemistry data requirements for both the technical grade active ingredient (TGAI) and the end-use product (EP) were satisfied by acceptable guideline studies. EPA's regulations at 40 CFR 158.2050(a)(2) and 158.2060(a)(2) exempt straight chain lepidopteran pheromones from human health, non-target organism, and environmental fate data requirements. EPA has concluded that use of SCLPs in accordance with approved labels does not pose a risk to human health based on the low toxicity in animal testing and the expected low exposure to humans. Thus, given that these compounds present both low hazard and low exposure, we have determined that, when used as directed, they present low risk to both humans and non-target organisms (and, in actuality, they present low toxicological risk to the target organism).

Pursuant to FIFRA Section 3(c)(4), EPA provided notice of receipt of an application to register the biochemical pesticide Isomate-EGVM, which contains an active ingredient not included in any previously registered pesticide products, and opportunity for comment. The notice included a profile of the product and the active ingredient, and a preliminary risk assessment. In addition, given the urgent circumstances of a potential EGVM infestation, and the need to begin mating disruption efforts as soon as possible after insect emergence, EPA noted its intent to register Isomate-EGVM – provided no contrary information was received during the comment period. During that 30-day comment period, EPA did not receive any substantive comments that provided data or information calling into question EPA's risk assessment. EPA received 12 comments in support of registration of Isomate-EGVM as soon as possible. All comments have been included in the docket.

On October 1, 2009, EPA announced a new policy to provide a more meaningful opportunity for the public to comment on significant registration decisions prior to the Agency's final decision. According to this new policy, EPA intends to provide a public comment period in advance of making a registration decision for, at minimum, the following types of applications: new active ingredients, first food use, first outdoor use, first residential use, and any registration action for which the Agency believes there may be substantial public interest.

Consistent with the new policy of making registration actions more transparent, Isomate EGVM Pheromone is subject to a 30 day comment period as a “new active ingredient” whose registration would result in a “first outdoor use”. While a final decision on registration is contingent upon review and consideration of public comments, EPA presently believes that based on the preliminary risk assessment and information submitted in support of the registration of Isomate EGVM Pheromone that it is in the best interests of the public and the environment to issue the registration for Isomate EGVM Pheromone without delay. Consistent with the Agency’s new policy for making these registration actions more transparent, however, EPA is issuing this registration with an initial period of one-year and, concurrent with its issuance, providing a 30-day public comment period on the time-limited registration. EPA is registering this product as a time-limited registration, with the understanding that public comments could bring to light new information or concerns that could inform EPA’s initial decision. Therefore, EPA is granting a time-limited one year registration for Isomate-EGVM.

II. ACTIVE INGREDIENT OVERVIEW

Common Name: EGVM Pheromone

Chemical Names: (E,Z)-7,9-Dodecadien-1-yl Acetate

Trade & Other Names: EGVM Pheromone

OPP Chemical Code: 011471

Type of Pesticide: Mating disrupter for European grapevine moth

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 16, 2009, Pacific Biocontrol Corporation, submitted an application for the registration of the end use product (EP) Isomate® - EGVM, containing 75.68% of the active ingredient E,Z)-7,9-Dodecadien-1-yl acetate. A notice of receipt of the application for registration of EGVM Pheromone as a new active ingredient was published in the Federal Register on February 01, 2010 (75 FR 5077), with a 30-day comment period. In addition to providing notice of receipt of the application, the notice included a profile of the product and the active ingredient, a preliminary risk assessment, a description of the urgent circumstances of a potential EGVM infestation and the need to begin mating disruption efforts as soon as possible after insect emergence, and EPA's inclination to register Isomate-EGVM – provided no contrary information was received during the comment period. EPA received a total of thirteen comments on the notice of receipt. Twelve comments supported immediate registration of Isomate-EGVM. One comment opposed the registration of Isomate-EGVM, but did not provide any substantive basis supporting that position. That comment also did not provide any data or information calling into question EPA's risk assessment. All comments have been included in the docket.

Consistent with the new policy of making registration actions more transparent, Isomate EGVM Pheromone is subject to a 30 day comment period as a “new active ingredient” whose registration would result in a “first outdoor use”. While a final decision on registration is contingent upon review and consideration of public comments, EPA presently believes that based on the preliminary risk assessment and information submitted in support of the registration of Isomate EGVM Pheromone that it is in the best interests of the public and the environment to issue the registration for Isomate EGVM Pheromone without delay. Consistent with the Agency’s new policy for making these registration actions more transparent, however, EPA is issuing this registration with an initial period of one-year and, concurrent with its issuance, providing a 30-day public comment period on the time-limited registration. EPA is registering this product as a time-limited registration, with the understanding that public comments could bring to light new information or concerns that could inform EPA’s initial decision. Therefore, EPA is granting a time-limited one year registration for Isomate-EGVM.

The public comment period was closed on April 4, 2010, and no comments were received during this period. As a result, EPA issued a final unconditional registration of the product containing

Isomate-EGVM.

A. Classification

EGVM Pheromone is a synthetic Straight-chained Lepidopteran Pheromone (SCLP) and is classified as a biochemical pesticide.

B. Food Clearances/Tolerances

Straight-chained Lepidopteran Pheromones are exempt from the requirement of a tolerance in or on all raw agricultural commodities when applied to growing crops at a rate not to exceed 150 grams of active ingredient/acre/year in accordance with good agricultural practices and indoor post-harvest treatment in or on all stored food commodities when applied/used at a rate not to exceed 3.5 grams active ingredient (AI)/1,000 square feet/year (equivalent of 150 grams AI/acre/year) in accordance with good agricultural practices use practices (40 CFR 180.1153). Pheromones are ubiquitous in the environment, and are not considered to be air pollutants. During the season where moths and/or butterflies appear, they normally emit pheromones and therefore, humans are naturally exposed to numerous pheromones without adverse reactions.

IV. RISK ASSESSMENT

A. Active Ingredient Characterization

EGVM Pheromone, is a technical grade synthetic straight-chained lepidopteran pheromone (SCLP). This pheromone is structurally similar to and mimics a naturally occurring pheromone produced by the female European grapevine moth (*Lobesia botrana),* to attract males for mating.

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. The production process was adequately described. The packaging was also adequately described and quality control/quality assurance procedures were discussed. The formation of potential impurities in the product was adequately described. Acceptable results were provided regarding the preliminary analysis of five batches of the product. The physical/chemical characteristics were adequately presented. In addition, the applicant submitted acceptable updated storage stability data that included values at the 6 month interval.

B. Human Health Assessment

1. Toxicology Assessment

Isomate-EGVM has a low application rate (not to exceed 150 grams active ingredient/acre/year) and expected exposure to humans is low. Adequate information and data waiver rationales to address all toxicity requirements for this product was submitted by the applicant. The product consists of two polymer tubes, one filled with a wire, and the other filled with the pheromone formulation. This twist-tie dispenser precludes concerns for toxicity via the dermal, ocular, oral, and inhalation routes of exposure. Label requirements indicate that the product must be applied while wearing chemical resistant gloves and protective eyewear. In addition, with no direct contact with food or feed crops, there is no chance to develop skin sensitization through the oral route and inhalation exposure is negligible. Also, the inerts in this product are all cleared for

food-use and SCLP's are exempt from the requirement of a tolerance. In summary, no risk to human health is expected from the use of Isomate-EGVM.

2. Dose Response Assessment

Isomate-EGVM contains 191.79 mg of (E,Z)-7,9-Dodecadien-1-yl acetate. Given the maximum label use-rate of no more than 200 twist ties per application, the calculated grams of active ingredient (AI) per acre of application equals 38.358 g. 782 twist ties per acre may be used for the entire calendar year. Assuming a worst case misuse scenario of 782 dispensers used in a single application, this would result in an emission of 149.798 g AI/acre/year. Assuming a year-round application of 782 twist ties per acre, an approximated daily application rate would be 410 mg AI/acre/day. Comparing this to typical natural exposure, codling moths during the calling period are estimated to release an approximate 240 ng pheromone/hr,* resulting in total pheromone release of 6-2184mg pheromone/acre/day. Thus, worst case year-round application of Isomate-EGVM via twist ties would be in the lower range of natural release by a living lepidopteran. Thus, given that expected emissions of (E,Z)-7,9-Dodecadien-1-yl acetate in Isomate-EGVM is comparable to naturally occurring emissions of pheromones during an infestation, we conclude that it will have no impact on human health, non-target organisms, or the environment.

3. Food Quality Protection Act (FQPA) Consideration

a. Dietary Exposure and Risk Characterization

In accordance with 40 CFR 180.1153, SCLPs such as Isomate-EGVM are exempt from the requirement of a tolerance. Moreover, notwithstanding this exemption, exposure to this pheromone is expected to be minimal due to its use in point source dispensers, from which it is released in infinitesimal quantities. Restricting the use of the EGVM Pheromone to retrievably sized twist ties dispensers, will significantly limit the possibility of dietary exposure to the pheromone. As discussed above regarding the human health assessment, Isomate-EGVM poses negligible toxicological hazard, including dietary hazard. Therefore, given the negligible dietary hazard and the limited possibility of dietary exposure, we conclude that there will be very low risk associated with dietary exposure to Isomate-EGVM.

We note that this is consistent with the determination of the OECD, which has determined that consumption of food containing residues of SCLPs presents no risk (OECD- Guidance for Registration Requirements for Pheromones and Other Semiochemicals Used for Pest Control (http://www.epa.gov/pesticides/biopesticides/regtools/index.htm).

b. Drinking Water Exposure and Risk Characterization

No significant drinking water exposure or residues are expected to result from the pesticidal usage of EGVM Pheromone. 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

* OECD Series on Pesticides No. 12: Guidance for Registration Requirements for Pheromones and Other Semiochemicals Used for Arthropod Pest Control, dated 02/26/2002 (citing data from EPA's Pheromone White Paper, by J. G. Touhy)

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

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

a. Occupational Exposure and Risk Characterization

As discussed above, Isomate-EGVM acts via a non-toxic mode of action to target specific pests. Low oral, dermal, and inhalation toxicity have been demonstrated by the data summarized above. The end-use product will be applied via polymeric-twist tie dispensers placed in trees. As discussed above, the potential for dermal, eye, and inhalation exposure to EGVM Pheromone 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 EGVM Pheromone. 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 SCLPs.

5. Cumulative Effects

Section 408(b)(2)(D)(v) of the FFDCA requires the Agency to consider the cumulative effects of exposure to (E,Z)-7,9-Dodecadien-1-yl acetate and to other substances that have a common mechanism of toxicity. These considerations include the possible cumulative effects of such residues on infants and children. (E,Z)-7,9-Dodecadien-1-yl acetate has a non-toxic mode of action. Thus, there is no indication or any evidence to suggest that this biochemical pesticide shares any common mechanisms of toxicity with other substances. Therefore, cumulative exposure concerns are not anticipated for the product Isomate-EGVM.

6. Risk Characterization

(E,Z)-7,9-Dodecadien-1-yl acetate is a synthetic semiochemical that acts via a non-toxic mode of action on a specific insect pest. Givent the low toxicity of lepidopteran pheromones in animal testing, and the expected low exposure to humans, no risk to human health is expected from use of the product Isomate-EGVM. The Agency has considered the various routes of exposure and potential risks of the product and determined that the proposed use of the active ingredient does not pose significant risk to all populations, including infants and children.

C. ENVIRONMENTAL ASSESSMENT

1. Ecological Hazards

According to 40 CFR 158.2060(a)(2), SCLPs 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 address non-target toxicity data requirements. Isomate-EGVM is a synthetic pheromone that is subject to section 180.2060(a)(2). This compound acts on a select group of insects and has a non-toxic mode of action.

2. Environmental Fate and Ground Water Data

Environmental fate data are not required for this active ingredient because it is an SCLP 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

EGVM pheromone is intended for use in polymeric twist-tie dispensers to disrupt the normal mating cycle of European grapevine moth on table and wine grapes. As a result, no toxicology or environmental fate and effects data were deemed necessary for registration.

4. Endangered Species Assessment

Given that Isomate-EGVM has a non-toxic mode of action, that it is not toxic to any species (i.e., target or non-target organisms), and that its use pattern requires application via retrievable twist tie dispensers, placed directly in the vineyards, EPA determines that it will "No Effect" on current listed threatened or endangered species and 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.g., 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 EGVM Pheromone. 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, EGVM Pheromone is eligible for registration for the labeled uses.

B. REGULATORY DECISION

As set forth above, EPA has determined that Isomate-EGVM presents no issues of toxicological, ecological, or environmental concern. Accordingly, EPA is granting a time-limited registration for Isomate-EGVM under Section 3(c)(5) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). On October 1, 2009, EPA announced a new policy to provide a more meaningful opportunity for the public to comment on major registration decisions in advance of EPA's final decision. According to this new policy, EPA intends to provide a public comment period prior to making a registration decision for, at minimum, the following types of applications: new active ingredients; first food use; first outdoor use; first residential use; and any registration decision for which the Agency believes there may be substantial public interest.

Notwithstanding that the current action on Isomate-EGVM qualifies as a "new active ingredient" under the new policy, EPA believes that it is in the best interests of the public and the environment to issue the registration for Isomate-EGVM without delay. As discussed above, acute toxicity data for Isomate-EGVM demonstrate that it is either toxicity category III or IV. Isomate-EGVM 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 Isomate-EGVM in accordance with approved label directions. EPA has not identified any toxic endpoints for non-target mammals, birds, plants, aquatic, or soil organisms. There are no concerns for any threatened or endangered species. Thus, given that Isomate-EGVM 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 Isomate-EGVM without delay. Consistent with the Agency's new policy for making these registration actions more transparent, EPA issued a registration with an initial period of one-year and, concurrent with its issuance, providing a 30-day public comment period on the time-limited registration. EPA registered this product as a time-limited registration, with the understanding that public comments could bring to light new information or concerns that could inform EPA's initial decision. The public comment period was closed on April 4, 2010, and no comments were received during this period. As a result, EPA issued a final unconditional registration of the product containing Isomate-EGVM.

We note that, pursuant to FIFRA Section 3(c)(4), we have provided notice of the receipt of the application to register Isomate-EGVM, and opened a 30-day comment period on the receipt of the application. In addition, the notice included a profile of the product and the active ingredient, and a preliminary risk assessment. In addition, given the urgent circumstances of a potential EGVM infestation, and the need to begin mating disruption efforts as soon as possible after insect emergence, EPA noted its intent to register Isomate-EGVM – provided no contrary information was received during the comment period. EPA received a total of thirteen comments on the notice of receipt. Twelve comments supported immediate registration of Isomate-EGVM. One comment opposed the registration of Isomate-EGVM, but did not provide any substantive basis supporting that position. That comment also did not provide any data or information calling into question EPA's risk assessment. All comments have been included in the docket.

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 EGVM Pheromone, 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 EGVM Pheromone 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 REQUIREMENTS (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.

Waiver Requests: MRID Number 4791181-00

Product Chemistry Data: MRID Number 479118-01