

Evaluation Report for Category B, Subcategory 2.1, 3.4 Application

Application Number: 2014-1774
Application: New/Changes EP or MA Product Chemistry – Guarantee; New or changes to Product Labels-Application Method
Product: Semios OFM
Registration Number: 31718
Active ingredients (a.i.): Z-8-dodecenyl acetate , E-8-dodecenyl acetate, Z-8-dodecenol
PMRA Document Number : 2495717

Purpose of Application

The purpose of this application was to register the end-use product, Semios OFM, used for control of oriental fruit moth in tree fruits by mating disruption.

Chemistry Assessment

Semios OFM is formulated as a pressurized product containing Z-8-dodecenyl acetate at a nominal concentration of 10.59%, E-8-dodecenyl acetate at a nominal concentration of 0.96% and Z-8-dodecenol at a nominal concentration of 0.15%. This end-use product has a density of 0.81 g/mL. The chemistry requirements for Semios OFM have been fulfilled.

Health Assessments

Waivers were granted for acute oral, dermal, and inhalation toxicity, based on low toxicity and the minimal exposure expected when label precautions are observed. A waiver was also granted for dermal sensitization, based on available information which demonstrated that none of the components of the end-use product, Semios OFM, were dermal sensitizers.

Based on the dermal and ocular irritation of each component in the formulation, Semios OFM is expected to be a mild skin irritant and a moderate eye irritant.

Because of the placement of the dispensers, the timing of the applications (overnight), the volatility and degradability of the components of Semios OFM, and the rate of application being comparable to background levels of the pheromones, the potential risk due to exposure of individuals involved in loading, clean-up, maintenance/repair of the dispenser units, post application activities, and bystander exposure is expected to be negligible.

Maximum Residue Limit

As part of the assessment process prior to the registration of a pesticide, Health Canada must determine that the consumption of the maximum amount of residues that are expected to remain on food products when a pesticide is used according to label directions will not be a concern to human health. This maximum amount of residues expected is then legally specified as a

maximum residue limit (MRL) under the *Pest Control Products Act* (PCPA) for the purposes of adulteration provision of the *Food and Drugs Act* (FDA). Health Canada specifies science-based MRLs to ensure the food Canadians eat is safe.

The dietary risks from food and drinking water are expected to be negligible given the low toxicity and the exposure (most likely negligible) of individuals to Semios OFM. Consequently, the specification of an MRL under the PCPA is not being recommended.

Incident Reports

Since April 26, 2007, registrants have been required by law to report incidents, including adverse effects to health and the environment, to the Pest Management Regulatory Agency (PMRA) within a set time frame. Information on the mandatory reporting of incidents can be found on the PMRA website. Incidents were searched and reviewed for the active ingredients Z-8-dodecenyl acetate, E-8-dodecenyl acetate, and Z-8-dodecenol. As of November 19, 2014, there were no incident reports submitted to the PMRA.

Environmental Assessment

It is not expected that the use of this product would result in any significant environmental exposure. The product contains active ingredients that are part of a group of chemicals called straight chain lepidopteran pheromones. This is a well-defined chemical group and available information has demonstrated that straight chain lepidopteran pheromones pose minimal risk to the environment at volumes similar to naturally occurring concentrations. In addition, the product is released in a controlled manner, which minimised the amount used. Any potential environmental concerns have also been mitigated through adequate statements on the product label.

Value Assessment

Three operational trials demonstrated that Semios OFM controlled oriental fruit moth by mating disruption in apple orchards. Oriental fruit moths infest pome fruit and various stone fruit. The canopy structure of pome fruit and stone fruit trees are similar and oriental fruit moth causes similar damage to these crops. Therefore, Semios OFM was supported to control oriental fruit moth by mating disruption in pome and stone fruits. The supported density of automated aerosol dispensers was 2.5-5 per hectare. The dispensers emit a 40 mg product (4.68 mg pheromones) puff every 15 minutes for up to 12 hours (5 pm to 5 am). No more than 375 g active ingredient may be applied per hectare per year.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided, and has found the information sufficient to support the registration of the end-use product Semios OFM.

References

A. List of Studies/Information Submitted by Registrant

- 2455745 2014, Value Summary for registration of Semios OFM aerosol mating disruption formulation for oriental fruit moth (*Grapholita molesta*). 10.1,10.2,10.3,10.4,10.5
- 2455750 2004, Fact Sheet: Mating Disruption for Management of Oriental Fruit Moth in Stone and Pome Fruit. 10.1,10.2,10.3,10.4,10.5
- 2455754 2009, Oriental Fruit Moth (OFM). 10.1,10.2,10.3,10.4,10.5
- 2455756 2006, Notes on Apple Insects, Oriental Fruit Moth. 10.1,10.2,10.3,10.4,10.5
- 2426237 2014, DACO 3.1 PRODUCT IDENTIFICATION, DACO: 3.1,3.1.1,3.1.2, 3.1.3,3.1.4
- 2426238 2013, Product Chemistry: Group A, DACO: 3.2,3.2.2,3.2.3,3.3.1 CBI
- 2426239 2013, Enforcement analytical method, DACO: 3.4,3.4.1 CBI
- 2426240 2013, Product Chemistry: Group B, DACO: 3.5,3.5.11,3.5.2,3.5.6,3.5.9 CBI
- 2426241 2014, DACO 3.5 Chemical and physical properties (part 2), DACO: 3.5,3.5.1, 3.5.3,3.5.4,3.5.5,3.5.7
- 2490551 2014, Application for Registration of Semios OFM - Physical and Chemical Characteristics: Storage Stability and Corrosion Characteristics, DACO: 3.5.10,3.5.14
- 2426242 2014. Toxicity data requirements for Semios OFM Scientific rationales to fulfill certain toxicity requirements Part 1. Technology Science Group Inc. Washington, DC, DACO: 4.6.1
- 2426243 2014. Toxicity data requirements for Semios OFM Scientific rationales to fulfill certain toxicity requirements Part 2. Technology Science Group Inc. Washington, DC, DACO: 4.6.2
- 2426245 2014. Toxicity data requirements for Semios OFM Scientific rationales to fulfill certain toxicity requirements Part 3. Technology Science Group Inc. Washington, DC, DACO: 4.6.3
- 2426246 2014. Toxicity data requirements for Semios OFM Scientific rationales to fulfill certain toxicity requirements Part 4. Technology Science Group Inc. Washington, DC, DACO: 4.6.4
- 2426247 2014. Toxicity data requirements for Semios OFM Scientific rationales to fulfill certain toxicity requirements Part 5. Technology Science Group Inc. Washington, DC, DACO: 4.6.5
- 2426248 2014. Toxicity data requirements for Semios OFM Scientific rationales to fulfill certain toxicity requirements Part 6. Technology Science Group Inc. Washington, DC, DACO: 4.6.6
- 2426249 2014. Exposure (Occupational and/or Bystander) Summary for Semios OFM Aerosol. SemiosBIO Technologies Inc. Vancouver, BC, DACO: 5.2

B. Additional Information Considered

i) Published Information

2.0 Human and Animal Health

- 2485776 Beroza, Morton, et al. 1975. Acute Toxicity Studies with Insect Attractants. Toxicology and Applied Pharmacology, 31: 421-429, DACO: 4.6.1, 4.6.2, 4.6.3, 4.6.4, and 4.6.5

2485778 1998, Technical Report No. 48 (2) Eye Irritation, DACO 4.6.4
2485780 1986, G.A. Jacobs and Martens, OECD Skin Irritation Tests on Three Alcohols,
DACO 4.6.5

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