

Evaluation Report for Category B, Subcategory 2.3, 2.4 Application

Application Number: 2020-0163

Application: New End-Use Product Chemistry – Identity and Proportion of

Formulants

Product: Semios OFM Eco

Registration Number: 34027

Active ingredients (a.i.): Z-8-Dodecen-1-yl acetate, E-8-Dodecen-1-yl acetate,

Z-8-Dodecen-1-ol

PMRA Document Number: 3183872

Purpose of Application

The purpose of this application was to register a new straight chain lepidopteran pheromone (SCLP) end-use product, Semios OFM Eco, for use as a mating disruptant to control oriental fruit moth in pome and stone fruits.

Chemistry Assessment

Semios OFM Eco is formulated as a pressurized product containing Z-8-dodecenyl acetate at 10.59%, E-8-dodecenyl acetate at 0.96%, and Z-8-dodecenol at 0.13%. This end-use product has a density of 0.794-0.801 g/mL and pH of 5.03 for a 1% dilution. The required chemistry data for Semios OFM Eco have been provided, reviewed and found to be acceptable.

Health Assessments

Semios OFM Eco is considered to be of low acute oral, dermal, and inhalation toxicity, moderately irritating to skin, mildly irritating to eyes, and not a dermal sensitizer.

Risk due to exposure of individuals involved in loading, clean-up, maintenance and repair of the dispenser units, and post application activities is acceptable when the product is used according to label directions. Precautionary and personal protective equipment statements on the product label aimed at mitigating worker exposure are considered adequate to protect individuals from any potential risk due to occupational exposure.

Risk to bystanders is acceptable when the product is used according to label directions.

Maximum Residue Limit

As part of the assessment process prior to the registration of a pesticide, Health Canada must determine whether 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 established as a maximum residue limit (MRL) under the Pest Control Products Act



(PCPA) for the purposes of the adulteration provision of the Food and Drugs Act (FDA). Health Canada sets science-based MRLs to ensure the food Canadians eat is safe.

The dietary risk from food and drinking water is acceptable given the low toxicity of the active ingredients, and given the product is not applied directly to food crops or drinking water. Consequently, the specification of an MRL under the PCPA is not required.

Environmental Assessment

As the proposed use pattern for Semios OFM Eco is within that currently registered for the precedent product, the registration of Semios OFM Eco on pome fruits and stone fruits for controlling oriental fruit moths by mating disruption is not expected to pose any additional environmental risks when used in accordance with label directions.

Value Assessment

The value of Semios OFM Eco was supported based on the similarity of the new formulation to that of the precedent product. The new formulation is intended to provide an alternative suitable for use in organic orchards.

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 Semios OFM Eco.

References

PMRA Document Number	References
3078244	2016, Product Identity and Composition, Description of Starting Materials, Production and Formulation Process, Discussion of Formation of Impurities, and Cartified Limits for Semios OFM Organia, DACO: 2.2.1.2.2.2.2.2.2.2.2.1
3078246	Certified Limits for Semios OFM Organic, DACO: 3.2.1,3.2.2,3.2.3,3.3.1 2016, Application for Registration of Semios OFM Organic, Product Identity and Composition, DACO: 3.5.1,3.5.10,3.5.11,3.5.14,3.5.2,3.5.3,3.5.6,3.5.7,3.5.9
3100231	2018, Application for Registration of Semios OFM Eco End Use Product Storage Stability and Corrosion Characteristics, DACO: 3.5.10,3.5.14 CBI
3104725	2020, Additional Product Chemistry for Semios OFM Eco - Revised, DACO: 3.1.1,3.1.2,3.1.3,3.1.4,3.5.13,3.5.15,3.5.5,3.5.8
3174183	2020, Enforcement analytical method - Response to DACO 3.4.1, DACO: 3.4.1 CBI
3100232	2020, Value Rationale for Semios OFM Eco, DACO: 10.1, 10.2.3.1, 10.2.3.3(D), 10.3.1, 10.3.2.

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