Health Canada Santé Canada

Evaluation Report for Category B, Subcategory 2.1 Application

Application Number: 2020-5657
Application: Changes to End-Use Product (Product Chemistry) – Guarantee
Product: Semios OFM Plus
Registration Number: 31718
Active ingredients (a.i.): Z-8-dodecenyl acetate, E-8-dodecenyl acetate and Z-8-dodecenol
PMRA Document Number: 3272248

Purpose of Application

The purpose of this application was to change the source of active ingredients in Semios OFM Plus to one that is registered for use in Canada, amend the formulation, and add an alternate formulating site.

Chemistry Assessment

Semios OFM Plus is formulated as a pressurized aerosol containing Z-8-dodecenyl acetate at 10.59 %, E-8-dodecenyl acetate at 0.96 %, and Z-8-dodecenol at 0.15 %. This end-use product has a density of 0.80 – 0.83 g/mL. The required chemistry data for the amendment of Semios OFM Plus have been provided, reviewed and found to be acceptable.

Health Assessments

The human health and safety database for this end-use product was considered complete and no additional toxicological information was required. E-8-dodecenyl acetate, Z-8-dodecenol and Z-8-dodecenyl acetate are of low acute toxicity by the oral, dermal and inhalation routes. No developmental or reproductive effects or evidence of carcinogenicity have been identified (See PRVD2017-05, *E-8-dodecenyl acetate, Z-8-dodecenol and Z-8-dodecenyl acetate*).

As the uses, application rates and application methods for Semios OFM Plus remain the same, the potential for dietary and occupational exposure is unchanged and the associated risks are considered acceptable (see PRVD2017-05, *E-8-dodecenyl acetate, Z-8-dodecenol and Z-8-dodecenyl acetate*). Therefore, no additional exposure information was required.

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.

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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 acceptable given the low toxicity and exposure level of individuals to Semios OFM Plus. Consequently, the specification of an MRL under the PCPA is not being recommended.

Environmental Assessment

The environmental risks associated with the use of Semios OFM Plus are acceptable when the product is used according to the label directions.

Value Assessment

Value assessment was not required for this application.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided, and has found the information sufficient to support the amendment of Semios OFM Plus.

References

PMRA Document Number	Reference
2426238	2013, Product Chemistry: Group A, DACO: 3.2.1, 3.2.2, 3.2.3, 3.3.1 CBI
2426240	2013, Product Chemistry: Group B, DACO: 3.5, 3.5.11, 3.5.2, 3.5.6, 3.5.9 CBI
2490551	2014, Application for Registration of Semios OFM - Physical and Chemical Characteristics: Storage Stability and Corrosion Characteristics, DACO: 3.5.10, 3.5.14 CBI
3176761	2020, DACO 3.5 Chemical and physical properties (part 2), DACO: 3.5.1, 3.5.3, 3.5.4, 3.5.5, 3.5.7
3176762	2013, GC Method Of Analysis For Semios CM & OFM Pheromones, DACO: 3.4.1
3176764	2020, Application for Registration of Semios OFM Plus Physical and Chemical Characteristics Group B Physical Tests, DACO: 3.5.1, 3.5.10, 3.5.11, 3.5.14, 3.5.2, 3.5.3 CBI
3176765	2020, Additional Product Chemistry for Semios OFM Plus, Reg. No. 31718, DACO: 3.5.12, 3.5.13, 3.5.15, 3.5.8
3187903	2021, Response for Study ECS302-21 OFM Plus Query, DACO: 3.5.10, 3.5.14