

Evaluation Report for Category B, Subcategory 2.1, 2.3, 2.4, 3.2 Application

Application Number: 2015-6034
Application: New EP/Product Chemistry - Guarantee, Identity and Proportion of Formulants; New Product Label - Application Timing
Product: SuffOil-X
Registration Number: 33099
Active ingredient (a.i.): Mineral oil
PMRA Document Number: 2872598

Purpose of Application

The purpose of this application was to register an end-use product, SuffOil-X, for use against various arthropod and fungal pests on field-grown fruit and vegetable crops, outdoor ornamentals, Christmas trees, and greenhouse vegetable and ornamental crops.

Chemistry Assessment

SuffOil-X is formulated as an emulsifiable concentrate containing mineral oil at a concentration of 80%. This end-use product has a density of 0.84 g/mL and pH of 9.6. The required chemistry data for SuffOil-X have been provided, reviewed and found to be acceptable.

Health Assessments

Based on submitted toxicology studies for the end-use product, SuffOil-X is considered to be of low acute toxicity by the oral, dermal and inhalation routes; non- to minimally irritating to the eye; minimally irritating to the skin; and is not a dermal sensitizer. The end-use product contains a formulant which is a priority allergen, and is labelled accordingly.

Occupational exposure to workers during mixing, loading, application, clean-up and repair activities is not expected to result in health risks of concern 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.

Bystander and residential exposure is not expected to result in health risks of concern when the product is used according to label directions.

Food residue exposure including drinking water exposure resulting from the use of SuffOil-X is not expected to result in dietary risks of concern when the product is used according to label directions, and the specification of a maximum residue limit will not be required for mineral oil.

Environmental Assessment

Mineral oil is ubiquitous in terrestrial and aquatic environments, and is expected to undergo microbial degradation. Risk was identified for aquatic non-target organisms, and is mitigated with label statements and buffer zones to protect sensitive aquatic habitats from spray drift with the use of SuffOil-X.

Value Assessment

From a value perspective, support for registration of SuffOil-X was based on extrapolation from three precedent products.

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 SuffOil-X.

References

A. List of Studies/Information Submitted by Registrant

PMRA Document Number	Reference
2581132	2012, Evaluation of SuffOil-X (paraffinic oil) for the management of thrips in greenhouse ornamentals, DACO: 10.2.3.3
2581133	2012, Evaluation of SuffOil-X (paraffinic oil) for the management of thrips in greenhouse ornamentals, DACO: 10.2.3.3
2581134	2012, Evaluation of SuffOil-X (paraffinic oil) for the management of thrips in greenhouse ornamentals, DACO: 10.2.3.3
2826376	2016, Email from Applicant to AC re: removal of unsupported uses
2581536	1990, Acute toxicology testing Brandt chemical Saf-T-Side, DACO: 4.6.1,4.6.2,4.6.4,Document K,IIIA 7.1.1,IIIA 7.1.2,IIIA 7.1.5
2581537	2009, Acute inhalation toxicity study in rats - Limit tests, DACO: 4.6.3,Document K,IIIA 7.1.3
2581538	2009, Dermal sensitization study in Guinea pig (Buehler Method), DACO: 4.6.6,Document K,IIIA 7.1.6
2611833	2016, Exposure analysis of SuffOil, DACO: 5.2
2581523	2014, Total Petroleum Hydrocarbons, DACO: 8.2.4.2, Document K, IIA 7.4.1
2581493	2014, Determination of Physical Chemical Properties - Vapour Pressure, Solubility in Organic Solvents and Solubility in Water, DACO: 2.14.8, 2.14.9, Document K, IIA 2.3.1, IIA 2.7
2581494	2011, Henry's Law Calculation, DACO: 2.16, Document K,IIA 2.3.2
2581495	2011, UV-VIS-NIR Absorption Analysis, DACO: 2.14.12, Document K, IIA 2.5.1.1
2581497	2013, Physical and Chemical Characteristics: UV/Visible Absorption, DACO: 2.14.12, Document K, IIA 2.5.1.1
2581505	2014, M C.A. Solubility in Water: Assessment of Water Solubility, DACO: 2.14.7, Document K, IIA 2.6
2581509	2011, Estimation of the Log Kow, DACO: 2.14.11, Document K, IIA 2.8.1
2581510	2013, Physical and Chemical Characteristics: Octanol/Water Partition, DACO: 2.14.11, Document K, IIA 2.8.1
2581580	2014, CAS No. 64742-55-8 Document M-CA, Section 7 Fate and Behaviour in the Environment, DACO: 12.7, Document M
2581550	2010, Earthworm (<i>Eisenia foetida</i>), DACO: 9.2.8, Document K, IIIA 10.6.2
2581544	2011, Honey Bee Acute Oral Toxicity Limit Test OECD 213, DACO: 9.2.8, Document K, IIIA 10.4.2.1
2581545	2011, Honey Bee Acute Contact Toxicity Limit Test OECD 214, DACO: 9.2.8, Document K, IIIA 10.4.2.2
2581549	2013, A Fresh and Aged Residue Laboratory Study to Determine the Effects of TriTek (80 EO Paraffin Oil) on the Non-Target Arthropod, DACO: 9.2.8, Document K, IIIA 10.5.2
2581548	2013, Extended Laboratory Test on the Green Lacewing <i>Chrysoperla carnea</i> (<i>Neuroptera Chrysopidae</i>), DACO: 9.2.8, Document K, IIIA 10.5.2

PMRA Document Number	Reference
2581520	1981, Microbial Degradation of Petroleum Hydrocarbons: An Environmental Perspective, DACO: 8.2.3.4.2, Document K, IIA 7.1.1
2581521	1990, Microbial Degradation of Hydrocarbons in the Environment, DACO: 8.2.3.4.2, Document K, IIA 7.1.1
2581522	2014, Evaluation of a Novel Technology for the Bioremediation of Hydrocarbon Contaminated Materials, DACO: 8.2.3.4.2, Document K, IIA 7.1.1
2581525	2011, Atkinson Calculation, DACO: 8.2.3.3.3, Document K, IIA 7.10
2581547	2013, Aged Residue on <i>Aphidius rhopalosiphi</i> (Hym: Aphidiidae) Exposed to Maize Leaves (Limit Test), DACO: 9.2.8, Document K, IIIA 10.5.2
2581546	2013, Aged Residue Test on <i>Typhlodromus pyri</i> (Acari: Phytoseiidae) Exposed to Maize Plants (Limit Test), DACO: 9.2.8, Document K, IIIA 10.5.2
2581595	2014, TriTek Document M-CP, Section 7 Toxicological Studies on the Plant Protection Product, DACO: 12.7, Document M
2581541	2010, <i>Daphnia magna</i> 48-Hour Acute Test, DACO: 9.3.2, Document K, IIIA 10.2.2.2
2581539	2010, Rainbow Trout (<i>Oncorhynchus mykiss</i>) 96-hour Acute Test OECD 203, DACO: 9.5.4, Document K, IIIA 10.2.2.1
2581540	2010, Bluegill Sunfish (<i>Lepomis macrochirus</i>) 96-Hour Acute Test OECD 203, DACO: 9.5.4, Document K, IIIA 10.2.2.1
2581543	2010, <i>Selenastrum capricornutum</i> 72- Hour Algal Inhibition Test OECD Guideline 201, DACO: 9.8.2, 9.8.3, Document K, IIIA 10.2.2.3
2581524	2013, Biodegradability in the CO ₂ -Evolution Test According to OECD 301 B (July 1992), DACO: 8.2.3.5.2, 8.2.3.5.4, Document K, IIA 7.8.1

B. Additional Information Considered

Published Information

PMRA Document Number	Reference
2849755	Petry, T., et al., 2017. Review of data on the dermal penetration of mineral oils and waxes used in cosmetic applications. Toxicology Letters 280 pp 70-78. DACO 4.8.
2849754	Nash, J.F. et al., 1996. A toxicological review of topical exposure to white mineral oils. Food and Chemical Toxicology 34 (2) pp 213-25. DACO 4.8.
1621524	2006, Memorandum Describing the Environmental Fate and Effect Division's Ecological Risk Assessment on Aliphatic Oils (PC Codes 063502 and 063503) in Support of Reregistration Eligibility Decision, DACO: 12.5

PMRA Document Number	Reference
1913005	2006, Reregistration Eligibility Decision Exposure and Risk Assessment on Lower Risk Pesticide Chemicals Interim Reregistration Eligibility Decision (IREDD) Document for Aliphatic Solvents (Mineral Oil and Aliphatic Petroleum hydrocarbons) CASE: Aliphatic Solvents (3004) Active Ingredients: Mineral Oils (063502) & Aliphatic Petroleum Hydrocarbons (063503), DACO: 12.5, 4.8, 5.4
1913010	2007, US Environmental Protection Agency Office of Pesticide Programs Revised Reregistration Eligibility Decision for Aliphatic Solvents Exposure and Risk Assessment on Lower Risk Pesticide Chemicals CASE: Aliphatic Solvents (3004) Active Ingredients: Mineral Oil (063502) & Aliphatic Petroleum Hydrocarbons (063503), DACO: 12.5, 4.8, 5.4

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