Health Canada Santé Canada

Evaluation Report for Category B, Subcategory 2.1, 2.3, 2.4, & 2.5 Application

Application Number: 2015-7180
Application: New EP Product Chemistry – Guarantee, Identity of Formulants, Proportion of Formulants, Formulation Type
Product: ESD 12101
Registration Number: 32771
Active ingredients (a.i.): Metofluthrin
PMRA Document Number: 2771629

Purpose of Application

The purpose of this application was to register a domestic class product, ESD 12101, for use in residential outdoors as a mosquito area repellent. ESD 12101 is to be used in combination with a vaporizer device to repel mosquitoes.

Chemistry Assessment

ESD 12101 is formulated as a solution containing metofluthrin at a nominal concentration of 4.00%. This end-use product has a density of 0.796 g/mL and pH of 5.62. The required chemistry data for ESD 12101 have been provided, reviewed and found to be acceptable.

Health Assessments

ESD 12101 is of low acute toxicity to rats via the oral, dermal, and inhalation routes of exposure. It is non-irritating to the eye and slightly irritating to the skin of rabbits. It is not a dermal sensitizer in mice according to results of the Local Lymph Node Assay (LLNA) method.

The application and post-application exposures and risks from the use of ESD 12101 as an insect-repellent were assessed. No risks of concern are expected from these uses, provided the label directions are followed.

A dietary exposure assessment was not required for this application.

Environmental Assessment

The use of ESD 12101 is not expected to increase environmental risk when compared to products registered for similar uses. Environmental statements on the product label are sufficient to address environmental concerns.

Canada

Value Assessment

Three studies were submitted to support the claim that ESD 12101 will repel mosquitoes. All three trials were semi-field trials, conducted in walk-in screened tunnels with CO_2-baited traps. Mosquito species tested were *Aedes aegypti*, *Anopheles dirus,* and *Culex quinquefasciatus.* In addition to the efficacy trials, a laboratory study was submitted to demonstrate duration of efficacy. The efficacy trials demonstrated that ESD 12101 repels >90% of mosquitoes up to 1.8 m from the device. The laboratory study supported a claim that 45 ml of product provided up to 400 hours of repellency, 50 ml of product provided up to 455 hours of repellency, and 24 ml of product provided up to 216 hours of repellency.

Conclusion

The PMRA has reviewed the information available for this application and has determined that registration of the end-use product, ESD 12101, can be supported.

References

PMRA Document Number	Reference
2597208	2015, DACO 3.1_Product Identification, DACO: 3.1 CBI
2597209	2012, Product Identity and Composition of ESD12101 Oil Concentrate, DACO: 3.2.1,3.2.2,3.2.3 CBI
2597210	2012, Analysis and Certification of Product Ingredients of ESD12101 Oil Concentrate EPA Reg. No. 73049-XXX, DACO: 3.3.1,3.4.1,3.4.2 CBI
2597211	2012, Physical and Chemical Properties of ESD12101 Oil Concentrate, DACO: 3.5.1,3.5.11,3.5.12,3.5.13,3.5.2,3.5.3,3.5.6,3.5.7,3.5.8,3.5.9 CBI
2597212	2013, Shelf-Life Storage Stability and Corrosion Characteristics of ESD12101 Oil Concentrate (73049-XXX), DACO: 3.5.10,3.5.14 CBI
2597213	2015, DACO 3.5.15_Dielectric Breakdown Voltage, DACO: 3.5.15 CBI
2597214	2015, DACO 3.5.4_Formulation Type, DACO: 3.5.4 CBI
2597215	2015, DACO 3.5.5_Container Material and Description, DACO: 3.5.5 CBI
2597216	2015, Mosquito Repellent Cartridge, DACO: 3.5.5 CBI
2597202	2015, Value Summary for ESD 12101, DACO: 10.1
2597203	2013, 49102110 Quantifying the Formulation Evaluation Rate of ESD12101 LV Units During The Aging Process, DACO: 10.2
2597204	2015, Summary of Trials Evaluating ESD12101 (Metofluthrin 4.0%), DACO: 10.2.3.1
2597205	2013, 49102113_Semi-field Evaluation of the Repellent Efficacy of ESD12101 against adult female *Anopheles dirus* Mosquitoes in Thailand, DACO: 10.2.3.3
2597206	2013, 49102112_Semi-field Evaluation of the Repellent Efficacy of ESD12101 against *Culex* sp. Mosquitoes in Thailand, DACO: 10.2.3.3
2597207	2013, 49102111_Semi-field Evaluation of the Repellent Efficacy of ESD12101 Against *Aedes aegypti* Mosquitoes in Thailand, DACO: 10.2.3.3
2597219	2012, Acute Oral Toxicity Up and Down Procedure in Rats, DACO: 4.6.1
2597220	2012, Acute Dermal Toxicity Study in Rats - Limit Test, DACO: 4.6.2
2597221	2012, Acute Inhalation Toxicity Study in Rats - Limit Test, DACO: 4.6.3
2597222	2012, Primary Eye Irritation Study in Rabbits, DACO: 4.6.4
2597223	2012, Primary Skin Irritation Study in Rabbits, DACO: 4.6.5
2597224	2012, Local Lymph Node Assay (LLNA) in Mice, DACO: 4.6.6
2409268	2012, U.S. EPA Standard Operating Procedures for Residential Pesticide Exposure Assessment. EPA: Washington, DC.

ISSN: 1911-8082