

Evaluation Report for Category B, Subcategory B.2.1, B.2.3, B.2.4, B.2.5, B.3.11, B.3.9 Application

Application Number: 2015-1060
Application: New EP Product Chemistry: Guarantee; Identity of Formulants; Proportion of Formulants; Formulation Type
New Product Labels: New Pests; Level of Control
Product: Orange Guard Home Pest Control Refill
Registration Number: 32431
Active ingredients (a.i.): d-limonene
PMRA Document Number: 2663873

Background

The active ingredient d-limonene was first registered in 2010 as a botanical insecticide in commercial and domestic end-use products intended to kill certain insects and arthropods through direct contact.

Purpose of Application

The purpose of this application was to register a new end-use product, Orange Guard Home Pest Control Refill, which contains d-limonene as its active ingredient. The product is intended for use in and around the home to kill ants, flies, fleas, and cockroaches.

Chemistry Assessment

Orange Guard Home Pest Control Refill is formulated as a solution containing d-limonene at a nominal concentration of 5.8%. This end-use product has a density of 0.993 g/cm³ and pH of 7.41. The required chemistry data for Orange Guard Home Pest Control Refill have been provided, reviewed and found to be acceptable.

Health Assessments

The submitted toxicology studies for the end-use product indicate that Orange Guard Home Pest Control Refill is of low acute toxicity by the oral, dermal, and inhalation routes, minimally irritating to eyes and skin and is not a skin sensitizer. The sensitization potential of hydroperoxides and other oxidation products of d-limonene formed on exposure to the air have been reported as potential contact allergens in animal studies. Based on the sensitization potential of d-limonene, it is likely that repetitive dermal contact to the end-use product may result in dermal sensitization. Therefore, Orange Guard Home Pest Control Refill is considered a potential skin sensitizer.

There is no concern anticipated from the domestic use of Orange Guard Home Pest Control Refill because of its low toxicity, low irritation potential, and the low exposure from its approved uses. Moreover, the labels have adequate precautionary and hygiene statements to mitigate exposure.

There are no food uses for this end-use product and the label has the necessary precautionary statements to prevent food and drinking water contamination. As dietary and drinking water exposure is therefore not expected, a maximum residue limit for d-limonene has not been specified and will not be required for the uses approved for Orange Guard Home Pest Control Refill.

Environmental Assessment

Because the approved use pattern is limited to cracks and crevices in and around the house for use as a domestic structural insecticide and insect repellent, exposure of non-target organisms in the environment to the product is not expected to be significant. Therefore, the approved uses of Orange Guard Home Pest Control Refill are not expected to pose risks of concern to non-target organisms in the environment.

Value Assessment

Value information in the form of five efficacy trials, scientific publications, and rationales demonstrated that Orange Guard Home Pest Control Refills kills ants, fleas, house flies, cluster flies and cockroaches located inside homes and apartments buildings, as well as on the outside of the structure. Orange Guard Home Pest Control Refills is a new domestic class option for management of these pests.

Conclusion

The PMRA has assessed the information provided in support of the new end-use product, Orange Guard Home Pest Control Refill, and determined it to be sufficient for its registration.

References

List of Studies/Information Submitted by the Registrant

PMRA Document Number	References
2306047	2011, Enforcement Analytical Method. DACO: 3.2.1,3.4,3.4.1 CBI
2480991	2013, Applicants Name and office. DACO: 3.1.1,3.1.2,3.1.3,3.1.4,3.2.1,3.2.2,3.5.4,3.5.5
2480997	1991, Establishing Certified Limits. DACO: 3.3.1,3.4.1,3.5.1,3.5.11,3.5.13,3.5.14,3.5.2,3.5.3,3.5.4,3.5.5,3.5.6,3.5.7,3.5.8,3.5.9
2481006	2011, Storage Stability Data. DACO: 3.5.10
2630813	2016, Daco 3.4.1 Rationale. DACO: 3.4.1
2630814	2016, Chemical and Physical Properties Rationale. DACO: 3.5
2644452	2016, Density. DACO: 3.5.11,3.5.6,3.5.7,3.5.9
2650801	2011, Determination of Limonene. DACO: 3.4 CBI
2481008	1993, Acute Oral Toxicity Study. DACO: 4.6.1
2481009	1993, Acute Dermal Toxicity Study. DACO: 4.6.2
2481010	1993, Acute Inhalation Toxicity Study. DACO: 4.6.3
2481011	1993, Primary Eye Irritation Study. DACO: 4.6.4
2481012	1993, Primary Dermal Irritation Study. DACO: 4.6.5
2481013	1993, Dermal Sensitization Study. DACO: 4.6.6
2481016	2014, Value Summary. DACO: 10.1
2481018	2013, Description of Pest Problem, DACO: 10.2.2
2481019	2013, Efficacy and Value Summary, DACO: 10.2.3.1
2481020	1997, Laboratory Evaluation of d-Limonene Applied as a Contact Insecticide to Cat Fleas, <i>Ctenocephalides felis</i> , DACO: 10.2.3.2(C)
2481022	1997, Laboratory Evaluation of d-Limonene Applied as a Contact Insecticide to Argentine Ants, <i>Iridomyrmex humilis</i> , DACO: 10.2.3.2(C)
2481023	1997, Summary of Preliminary Evaluations of Repellency of Orange Guard against the Argentine Ant, DACO: 10.2.3.2(C)
2481024	Hink, W.F. and B.J. Feel, 1986, Toxicity of D-Limonene, The Major Component of Citrus Peel Oil, To All Life Stages of the Cat Flea, <i>Ctenocephalides Felis</i> (Siphonaptera: Pulicidae), J. Med. Entomol 23:400-404(5)DACO: 10.2.3.2(C)
2481025	2005. Control of Common Housefly, <i>Musca domestica</i> (Linn.) with Natural Pest controls. DACO: 10.2.3.2(C)
2481026	Palacios S.M., A. Bertoni, Y. Rossi, R. Santander and A. Urza, 2009, Efficacy of Essential Oils from Edible Plants as Insecticides Against the House Fly, <i>Musca domestica</i> L., Molecules 14:1938-1947, DACO: 10.2.3.2(C)
2481027	1997, Efficacy:Small-scale Trials (simulating proposed use sites). DACO: 10.2.3.3
2481028	1994, Adverse Effects on Use Site Summaries. DACO: 10.3.1
2560795	2015, Value Summary. DACO: 10.1
2560796	2015, Efficacy: Small Scale Trials/Laboratory Trials 10.1 Ants. DACO: 10.2.3.3

2560797	2015, Efficacy: Small Scale Trials/Laboratory Trials 10.2- Fly Repel. DACO: 10.2.3.3
2560798	2015, Efficacy: Small Scale Trials/Laboratory Trials 10.3- Cockroaches. DACO: 10.2.3.3
2560799	2015, Efficacy: Small Scale Trials/Laboratory Trials 10.4 Kills Fleas. DACO: 10.2.3.3
2560800	2015, Efficacy: Small Scale Trials/Laboratory Trials 10.5- Fly Kill. DACO: 10.2.3.3
2560801	2015, Efficacy: Small Scale Trials/Laboratory Trials 10.6- Repels. DACO: 10.2.3.3
2560802	2003, Efficacy: Small Scale Trials/Laboratory Trials 10.1 Ants Pest Management Alliance Project Final Report Ag. No. 01-0190C. DACO: 10.2.3.3
2560803	2015, Efficacy: Small Scale Trials/Laboratory Trials 10.1 Ants- Fire Ants in Mississippi. DACO: 10.2.3.3
2560804	2015, Efficacy: Small Scale Trials/Laboratory Trials 10.1 Ants Evaluation of QRD as an individual mound treatment for red imported fire ant. DACO: 10.2.3.3
2560805	1993, Efficacy: Small Scale Trials/Laboratory Trials 10.2- Repels Flies Efficacy Review. DACO: 10.2.3.3
2560806	2015, Efficacy: Small Scale Trials/Laboratory Trials 10.2- Repels Flies Fly Study. DACO: 10.2.3.3
2560807	1999, Efficacy of Orange Guard (d-Limonene) Against Red Imported Fire Ants. DACO: 10.2.3.3
2560808	2007, APVMA Orange Guard Decision (Australian Decision). DACO: 10.2.3.3
2560809	2015, APVMA Label search on Orange Guard. DACO: 10.2.3.3

B. Additional Information Considered

Published Information

PMRA Document Number	References
2674948	International Programme On Chemical Safety, 1998, Concise International Chemical Assessment Document No. 5: Limonene, 32pp. DACO: 4.8

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