



Evaluation Report for Category B, Subcategories 2.3, 2.4, 2.5, 3.4 Application

Application Number: 2018-6221
Application: New EP Product Chemistry-Identity of Formulants, Proportion of Formulants, Formulation Type, Application Method
Product: OFF! Familycare Botanicals Insect Repellent Pump Spray
Registration Number: 33948
Active ingredient (a.i.): p-menthane-3,8-diol
PMRA Document Number: 3162213

Purpose of Application

The purpose of this application was to register a new personal insect repellent product containing p-menthane-3,8-diol, to repel mosquitoes, black flies, ticks, and biting midges from human skin.

Chemistry Assessment

OFF! Familycare Botanicals Insect Repellent Pump Spray is formulated as a solution containing p-menthane-3,8-diol at a concentration of 10%. This end-use product has a density of 0.984 g/mL and pH of 8.17 (1% aqueous solution). The required chemistry data for OFF! Familycare Botanicals Insect Repellent Pump Spray have been provided, reviewed and found to be acceptable.

Health Assessments

OFF! Familycare Botanicals Insect Repellent Pump Spray is of low acute toxicity by the oral, dermal, and inhalation routes, is mildly irritating to the eyes, is not irritating to the skin, and is not a dermal sensitizer.

Exposure to residential users handling OFF! Familycare Botanicals Insect Repellent Pump Spray is not expected to result in health risks of concern when the product is used according to label directions.

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

A dietary exposure assessment was not required for this application.

Environmental Assessment

An environmental assessment was not required for this application.

Value Assessment

Value information reviewed in support of claims for OFF! Familycare Botanicals Insect Repellent Pump Spray included one laboratory trial testing the product against four species of mosquitoes, nine trials testing other 10% p-menthane-3,8-diol formulations against various pests, and a scientific rationale to extrapolate performance of OFF! Familycare Botanicals Insect Repellent Pump Spray from information provided on other formulations. Trials on other formulations included both field and laboratory trials that tested the efficacy of those formulations against *Culicoides* (biting midge) species (five field trials), black flies (five field trials), mosquitoes (four field trials), and ticks (two laboratory trials).

Based on the submitted trials and rationale to extrapolate from both registered and other 10% p-menthane-3,8-diol formulations, a claim that OFF! Familycare Botanicals Insect Repellent Pump Spray will repel mosquitoes, biting midges, and ticks for two hours and black flies for five hours was supported.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided, and has found it sufficient to support the registration of OFF! Familycare Botanicals Insect Repellent Pump Spray.

References

PMRA

Document

Number	Reference
2937939	2018, Description of the Formulation Process_CBI Reference Document, DACO: 3.2.2 CBI
2937940	2018, Discussion of the Formation of Impurities of Toxicological Concern, DACO: 3.2.3
2937945	2012, Enforcement Analytical Method_CBI Reference Document, DACO: 3.4.1 CBI
2937947	2013, Chemical and Physical Properties, DACO: 3.5 CBI
2937951	2018, Formulation Type, DACO: 3.5.4
2937952	2018, Container Material and Description, DACO: 3.5.5
2937958	2014, Storage Stability Data_CBI Reference Document, DACO: 3.5.10 CBI
3113697	2020, Analytical method study, DACO: 3.4.1 CBI
3113698	2020, Analytical Method Chromatogram, DACO: 3.4.1 CBI
3113699	2020, Analytical Method Rationale, DACO: 3.4.1 CBI
3113700	2020, Storage Stability Rationale, DACO: 3.5.10 CBI
2937966	2018, Acute Oral Toxicity, Data Numbering Code: 4.6.1
2937967	2018, Acute Dermal Toxicity, Data Numbering Code: 4.6.2
2937968	2018, Acute Inhalation Toxicity, Data Numbering Code: 4.6.3
2937969	2013, Primary Eye Irritation, Data Numbering Code: 4.6.4
2937970	2013, Primary Skin Irritation, Data Numbering Code: 4.6.5
2937971	2018, Skin Sensitization, Data Numbering Code: 4.6.6
2937973	2018, Use Description/Scenario, Data Numbering Code: 5.2
2937974	2018, Value Summary, DACO: 10.1
2937975	2018, Mode of Action, DACO: 10.2.1
2937976	2018, Description of Pest Problem, DACO: 10.2.2
2937977	2018, Efficacy Summary - CBI Removed, DACO: 10.2.3.1
2937978	2018, Efficacy Summary - CBI Reference Document, DACO: 10.2.3.1 CBI
2937980	2001, Efficacy Trials - Lab - Ticks, DACO: 10.2.3.2
2937981	2001, Efficacy Trials - Lab - Ticks, DACO: 10.2.3.2
2937982	2018, Efficacy Trials - Lab - Mosquitoes, DACO: 10.2.3.2
2937983	1998, Efficacy Trials - Field - Gnats, Biting Flies, Mosquitoes, DACO: 10.2.3.3
2937984	2001, Efficacy Trials - Field - Gnats, Biting Flies, DACO: 10.2.3.3
2937986	2001, Efficacy Trials - Field - Gnats, Biting Flies, Mosquitoes, DACO: 10.2.3.3

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