



## Evaluation Report for Category B, Subcategories 2.1, 2.3, 2.4, 2.5 Application

**Application Number:** 2021-1393  
**Application:** New EP Product Chemistry-Guarantee; Identity of Formulants;  
Proportion of Formulants; Formulation Type  
**Product:** OFF!® Botanicals Insect Repellent  
**Registration Number:** 34594  
**Active ingredient (a.i.):** p-menthane-3,8-diol  
**PMRA Document Number:** 3380470

### Purpose of Application

The purpose of this application was to register the new domestic class product OFF!® Botanicals Insect Repellent, for application to skin to repel mosquitoes, biting midges, ticks and black flies.

### Chemistry Assessment

OFF!® Botanicals Insect Repellent is formulated as a pressurized product containing p-menthane-3,8-diol at a concentration of 10%. This end-use product has a density between 0.9037 and 0.9251 g/mL and pH between 6.10 and 8.11. The required chemistry data for OFF!® Botanicals Insect Repellent have been provided, reviewed and found to be acceptable.

### Health Assessments

OFF!® Botanicals Insect Repellent is of low acute toxicity by the oral, dermal, and inhalation routes, moderately irritating to the eyes, non-irritating to the skin, and is not a dermal sensitizer.

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 exposure assessment was not required for this application.

### Value Assessment

Extrapolation from a similar registered product supported the use of OFF!® Botanicals Insect Repellent to repel mosquitoes, biting midges and ticks for 2 hours and black flies for 5 hours.

## **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!® Botanicals Insect Repellent.

## References

### PMRA

#### Document

Number	Reference
3217074	2021, type, DACO: 3.5.4
3217075	2021, material, DACO: 3.5.5
3317620	2022, Storage Stability, DACO: 3.5.10 CBI
3237398	2021, physchem, DACO: 3.5 CBI
3217058	2021, form, DACO: 3.2.2 CBI
3263807	2021, Manufacturing Process memorandum, DACO: 3.2 CBI
3217059	2021, disclosure, DACO: 3.2.3
3368020	2022, Process Instructions, DACO: 2.11.3 CBI
3217067	2021, enforcement method, DACO: 3.4.1 CBI
3263806	2021, Analytical method memorandum, DACO: 3.4.1 CBI
3317620	2022, Storage Stability, DACO: 3.5.10 CBI
3217098	2021, Use Description, DACO: 5.2

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