



Evaluation Report for Category B, Subcategory 3.3 Application

Application Number: 2022-0660
Application: Changes to Product Labels-Application Number or Frequency (Best fit)
Product: OFF! Active Insect Repellent
Registration Number: 27474
Active ingredient (a.i.): DEET plus related active toluamides
PMRA Document Number: 3448673

Purpose of Application

The purpose of this application was to add a label claim that the registered insect repellent product OFF! Active Insect Repellent is sweat resistant.

Health Assessments

The addition of the sweat resistant claim to the OFF! Active Insect Repellent label was assessed. No risks of concern are expected from the use, provided that individuals follow the label directions.

Toxicology and dietary exposure assessments were not required for this application.

Value Assessment

To support a claim that OFF! Active Insect Repellent is sweat resistant, value information consisting of two small-scale field studies was reviewed. The submitted value information is acceptable to support a claim that OFF Active Insect Repellent is sweat resistant for up to 5 hours.

Chemistry and Environmental Assessments

Chemistry and environmental assessments were not required for this application.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided, and has found the information acceptable to amend the label of OFF! Active Insect Repellent to add the sweat resistant claim.

References

A. List of Studies/Information Submitted by Registrant

PMRA

Document

| Number | Reference |
|---------------|---|
| 3320635 | 2015, Field Testing of S.C. Johnson Personal Mosquito Repellent Products to Support Their Use of the EPA Repellency Awareness Graphic, DACO: 10.2.3.3 CBI |
| 3333138 | 2022, 10.2.3.1 Efficacy Summary, DACO: 10.2.3.1 CBI |
| 3333139 | 2022, 10.3.1 Adverse Effects on Use Site (Summaries), DACO: 10.3.1 |
| 3340028 | 2022, Value Dossier, DACO: 10.1 |

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