

Evaluation Report for Category B, Subcategory 2.3, 2.4 Application

Application Number: 2017-0867
Application: Changes EP Product Chemistry-Identity and proportion of Formulants
Product: Insect Repellent Moisturizing Milk Citronella Essential Oil
Registration Number: 25447
Active ingredients (a.i.): Citronella oil, Citronella terpene
PMRA Document Number : 2768186

Purpose of Application

The purpose of this application was to modify the formulation of the end-use product Insect Repellent Moisturizing Milk Citronella Essential Oil. The label for the product, including the use pattern information, and all hazard and precautionary statements, has not changed.

Chemistry Assessment

Insect Repellent Moisturizing Milk Citronella Essential Oil is formulated as an emulsifiable concentrate containing citronella oil at a nominal concentration of 10% and citronella terpenes at a nominal concentration of 5%. This end-use product has a density of 1 g/mL and pH of 5.5-6.5. The required chemistry data for Insect Repellent Moisturizing Milk Citronella Essential Oil have been provided, reviewed and found to be acceptable.

Health Assessments

Based on analyses conducted by Health Canada in 2015 and 2016, the citronella oil-based personal insect repellent Insect Repellent Moisturizing Milk Citronella Essential Oil (Registration No. 25447) was determined to contain a contaminant of concern for human health risks at a concentration exceeding a limit previously established by PMRA.

Subsequently, the formulation has been amended, including using a new source of the citronella oil active ingredient and removing two formulants. The registrant has also committed to not release any lots of the product unless they comply with the PMRA limit for the contaminant of concern. As a result of the changes, the revised formulation is expected to comply with the PMRA limit for the contaminant of concern. Taking into consideration the changes made to the formulation and the unchanged use pattern for the product, the revised formulation is not anticipated to increase user or bystander exposures and human health risks compared to the previously registered formulation for the product.

Environmental Assessment

An environmental assessment was not required for this application.

Value Assessment

The minor formulation change was not expected to impact product performance, and is acceptable from a value perspective.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided, and has found the information sufficient to support the formulation change of Insect Repellent Moisturizing Milk Citronella Essential Oil.

References

PMRA Document Number	Reference Title
2733452	2016, Developpement de methode d analyse de [CBI Removed], DACO: 2.13.1
2733441	2017, Value Dossier, DACO: 10.1

ISSN: 1911-8082

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