

Evaluation Report for Category B, Subcategory 2.2 Application

Application Number: 2017-2586
Application: Changes to End-Use Product Chemistry – Form of Technical Active Ingredient
Product: PiActive Insect Repellent Lotion
Registration Number: 33411
Active ingredient (a.i.): Icaridin
PMRA Document Number: 2966810

Purpose of Application

The purpose of this application was to register a new personal insect repellent lotion, containing the active ingredient, icaridin, for protection from mosquitos, ticks and blackflies.

Chemistry Assessment

PiActive Insect Repellent Lotion is formulated as an emulsifiable concentrate containing icaridin at a concentration of 20%. This end-use product has a density of 0.984-1.004 g/mL and pH of 4.9-6.4. The required chemistry data for PiActive Insect Repellent Lotion have been provided, reviewed and found to be acceptable.

Health Assessments

Piactive Insect Repellent Lotion is of low acute toxicity to rats via the oral and dermal routes of exposure, is mildly irritating to the eyes and non-irritating to the skin of rabbits, and is not considered to be a dermal sensitizer in guinea pigs. A waiver has been granted for the requirement for an acute inhalation study based upon the fact that the formulation is a cream and that the physical form is prohibitive of conducting such a study. Therefore, no acute inhalation hazard is expected from use of this product.

The exposure and risk to individuals applying PiActive Repellent Lotion was assessed. No risks of concern are expected from the use, provided individuals follow the 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

The value information and rationale provided were sufficient to support use of this product for protection from mosquitoes and ticks for 12 hours, and protection from black flies for 10 hours.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided and has found the information sufficient to support the registration of PiActive Insect Repellent Lotion.

References

PMRA Document Number	Reference
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2765446	2008, Description of Starting Materials, DACO: 3.2.1 CBI
2765447	2016, Description of Starting Materials, DACO: 3.2.1 CBI
2765448	2008, Validation of the analytical method M01166-01 for the determination of the Active Ingredient Icaridin in the formulation KBR 3023 All Family Repellent Cream 20 %, DACO: 3.4.1
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2765450	1997, Acute Oral Toxicity Study with R140/102 KBR 3023 Repellent Cream in Rats., DACO: 4.6.1
2765451	1997, Acute Oral, DACO: 4.6.1 CBI
2765455	1996, Acute Dermal Toxicity Study with R140/102 KBR 3023 Repellent Cream in Rats, DACO: 4.6.2
2765456	1996, Acute Dermal, DACO: 4.6.2 CBI
2765458	1997, Primary Eye Irritation Study in Rabbits with R140/102 (KBR 3023 Repellent Cream)., DACO: 4.6.4
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2765460	1997, Primary Dermal Irritation Study in Rabbits with R140/102 (KBR 3023 Repellent Cream)., DACO: 4.6.5
2765461	1997, Primary Dermal Irritation, DACO: 4.6.5 CBI
2765462	1997, Dermal Sensitization Study with R140/102 KBR 3023 Repellent Cream in Guinea Pigs, DACO: 4.6.6
2765463	1997, Dermal Sensitization, DACO: 4.6.6 CBI
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2765469	2010, Efficacy Test of KBR 3023 (Picaridin; Icaridin)-based personal insect repellents (20% Cream and 20% Spray) with black flies under field conditions., DACO: 10.2.3.3(C)

- 2765470 2010, Efficacy Test of KBR 3023 (Picaridin; Icaridin)-based personal insect repellents (20% Cream and 20% Spray) with ticks under laboratory conditions., DACO: 10.2.3.2(C)
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