

Evaluation Report for Category B, Subcategory 7.0 Application

| Application Number: | 2023-0698 | |
|--------------------------------|---|--|
| Application: | Reinstatement of Registered Product | |
| Product: | Hilltech Canada Oleoresin of Red Pepper Technical | |
| Registration Number: | 29550 | |
| Active ingredients (a.i.): | Capsaicin and related capsaicinoids | |
| PMRA Document Number : 3636806 | | |

Purpose of Application

The purpose of this application was to reinstate the registration of Hilltech Canada Oleoresin of Red Pepper Technical.

Chemistry Assessment

| Common Name: IUPAC* Chemical Name: CAS† Chemical Names: | Capsaicin N-(4-hydroxy-3-methoxybenzyl)-8-methylnon-6-enamide N-[(4-hydroxy-3-methoxyphenyl)methyl]-8-methyl-6-noneamide 6-Nonenamide, N-[4-hydroxy-3-methoxyphenyl)methyl]-8-methyl-, (6 <i>E</i>)- |
|---|---|
| Common Name: | Dihydrocapsaicin |
| IUPAC* Chemical Name: | N -[(4-hydroxy-3-methoxyphenyl)methyl]-8-methylnonanamide |
| CAS† Chemical Name: | N/A |
| Common Name: | Nordihydrocapsaicin |
| IUPAC* Chemical Name: | N -[(4-hydroxy-3-methoxyphenyl)methyl]-7-methyloctanamide |
| CAS† Chemical Name: | N/A |

* International Union of Pure and Applied Chemistry

† Chemical Abstracts Service

| Property | Result |
|---------------------------|--|
| Colour and physical state | Clear red liquid |
| Nominal concentration | Capsaicin: 4.20%, Related capsaicinoids: 2.70% |
| Odour | Distinctive acrid aroma characteristic of capsicum odour |
| Specific gravity | 1.02-1.05 |
| Vapour pressure | < 1333.224 Pa |
| pН | N/A (The product is not soluble in water) |
| Solubility in water | Insoluble to slightly soluble in water |
| n-Octanol/water partition | N/A |
| coefficient | |

Hilltech Canada Oleoresin of Red Pepper Technical has the following properties:



The required chemistry data for Hilltech Canada Oleoresin of Red Pepper Technical have been provided, reviewed, and found to be acceptable.

Health Assessments

Capsaicin and related capsaicinoids are known to be of low acute oral toxicity. They are irritating to the skin, eyes and upper respiratory tract on contact and are potential sensitizers.

There are no food or drinking water exposure concerns for capsaicin and related capsaicinoids when the formulated products are used according to label directions.

An occupational exposure assessment was not required for this application.

Environmental Assessment

The risk is acceptable when Hilltech Canada Oleoresin of Red Pepper Technical is used in accordance with the label, which includes statements to mitigate risks to the environment.

Value Assessment

A value assessment was 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 support the reinstatement of the registration for Hilltech Canada Oleoresin of Red Pepper Technical. **References**

| PMRA | |
|----------|--|
| Document | |
| Number | Reference |
| 3438689 | 2022, 4010000076 Flow Chart Oleoresin Capsicum, DACO: 2.11,2.11.1 CBI |
| 3438690 | 2022, 2.13.3-1 Food Grade Certificate, DACO: 2.13,2.13.1 CBI |
| 3438691 | 2022, 2.13.3-2 Specification and Product Information Oleoresin Capsicum, |
| | DACO: 2.13,2.13.1 CBI |
| 3438692 | 2020, 2.13.3-3 SDS Oleoresin Capsicum, DACO: 2.13,2.13.1 CBI |
| 3438693 | 2020, 2.13.3-4 COA 421I214741, DACO: 2.13,2.13.1 CBI |
| 3438694 | 2020, 2.13.3-5 COA 421H223372, DACO: 2.13,2.13.1 CBI |
| 3438695 | 2020, 2.13.3-6 COA 421H211603, DACO: 2.13,2.13.1 CBI |
| 3438696 | 2020, 2.13.3-7 COA 421E214522, DACO: 2.13,2.13.1 CBI |
| 3438697 | 2020, 2.13.3-8 COA 421D223817, DACO: 2.13,2.13.1 CBI |
| 3438698 | 2023, 2.13.3-10 GC Raw Data, DACO: 2.13,2.13.1 CBI |
| 3438699 | 2023, 2.13.3-11 GC Raw Data, DACO: 2.13,2.13.1 CBI |
| 3438700 | 2023, 2.13.3-12 GC Raw Data, DACO: 2.13,2.13.1 CBI |
| 3438701 | 2023, 2.13.3-13 GC Raw Data, DACO: 2.13,2.13.1 CBI |

| 3438702 | 2023, 2.13.3-14 GC Raw Data, DACO: 2.13,2.13.1 CBI |
|---------|---|
| 3438703 | 2022, 2.13.4 [CBI Removed] Oleoresin Capsicum, DACO: 2.13.4 CBI |
| 3455802 | 2023, Flow Chart Oleoresin of Red Pepper 4010000076, DACO: |
| | 2.11,2.11.1,2.11.3 CBI |
| 3455803 | 2023, Request to Synthite Industries for Information, DACO: |
| | 2.11,2.11.1,2.11.2 CBI |
| 3455804 | 2023, Spec-E471, DACO: 2.11,2.11.1,2.11.2 CBI |
| 3455805 | 2023, Black Pepper Raw Material Specification, DACO: 2.11,2.11.1,2.11.2 |
| | CBI |
| 3455806 | 2023, Chili Raw Material Specification, DACO: 2.11,2.11.1,2.11.2 CBI |
| 3503124 | 2023, 2023-0698 Waiver Request and Approval DAS, DACO: |
| | 2.0,2.13.4,2.16 CBI |
| 3503125 | 2023, 2023-0698 Waiver Request and Approval Ergot, DACO: |
| | 2.0,2.13.4,2.16 CBI |
| 3503126 | 2023, 2023-0698 [CBI Removed], DACO: 2.0,2.13.4,2.16 CBI |
| 3527646 | 2023, 2.13.4 Completed Attestation Form for [CBI Removed] for |
| | Sub.No.2023-0698, DACO: 2.13.4 CBI |
| 3564280 | 2024, Certificate of Analysis - [CBI Removed] TGAI, DACO: 2.13.4 CBI |
| 3564281 | 2024, Certificate of Analysis - [CBI Removed] TGAI, DACO: 2.13.4 CBI |
| 3564282 | 2024, Certificate of Analysis - [CBI Removed] TGAI, DACO: 2.13.4 CBI |
| 3564283 | 2024, Certificate of Analysis - [CBI Removed] TGAI, DACO: 2.13.4 CBI |
| 3564284 | 2024, Certificate of Analysis - [CBI Removed] TGAI, DACO: 2.13.4 CBI |
| | |

© His Majesty the King in Right of Canada, as represented by the Minister of Health Canada, 2024

All rights reserved. No part of this information (publication or product) may be reproduced or transmitted in any form or by any means, electronic, mechanical, photocopying, recording or otherwise, or stored in a retrieval system, without prior written permission of Health Canada, Ottawa, Ontario K1A 0K9.