



Evaluation Report for Category B, Subcategory 4.1 Application

Application Number: 2008-2533
Application: B.4.1 Conversion to full registration without consultation
Product: Verbenone Pouch (7g load)
Registration Number: 28645
Active ingredients (a.i.): Verbenone (PMB)
PMRA Document Number : 2009613

Purpose of Application

The purpose of this application was to convert the registration status of the non-conventional end-use product, Verbenone Pouch (7g load) (Registration Number. 28645) from conditional to full.

Chemistry Assessment

Verbenone Pouch (7g load) is formulated as a slow release generator containing Verbenone Technical at a nominal value of 7g per pouch. This end-use product has a density of 0.98 g/cm³. The chemistry requirements are complete.

Health Assessments

A food exposure assessment was not required and no additional occupational exposure information was required for this application.

The data requirements were waived for the end-use product, Verbenone Pouch (7g load) (Verbenone at 96%), on the basis that the active ingredient, Verbenone Technical (Registration Number 28259), would be used instead of the toxicological information required for the end-use product.

The acute oral toxicity of Verbenone Technical was slight, having an LD₅₀ of 1700 mg/kg bw in female rats. The acute dermal toxicity of Verbenone Technical was low, with an LD₅₀ > 2000 mg/kg bw in rabbits, and a waiver was granted for the acute inhalation of its toxicity. The primary eye irritation of Verbenone Technical was mildly irritating in rabbits. With respect to skin irritation, it was minimally irritating in rabbits. The need for dermal sensitization information for Verbenone Technical was waived since positive results were not found in public literature. However, Verbenone is ubiquitous in areas containing conifer stands.

The precautionary label statements and directions for product placement in the field (maximum reach) adequately address any potential risk due to exposure of the mixer, loader, applicator, and/or bystander to the end-use product.

This is a non-food/feed application. Therefore, a food residue exposure assessment was not performed and a Maximum Residue Limit was not proposed.

Environmental Assessment

This pheromone will pose negligible risk to terrestrial or aquatic organisms. The chemical is released from fixed dispensers (pouches) at a rate where air concentrations will remain low and will have minimal effects on terrestrial organisms. Minimal exposure to aquatic systems is expected since the pheromone will not readily dissolve in water while in a gaseous state. Ingestion of the pouch containing Verbenone Technical by terrestrial organisms (e.g., birds or squirrels) is not likely to occur as it is too large for most animals to consume.

Value Assessment

No further value data was required for the conversion of this product to full registration.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided in support for the product, Verbenone Pouch (7g load), and has found the information sufficient to convert the registration status from conditional to full.

References

<i>PMRA Number</i>	<i>Title</i>
1046642	1987, Verbenone: Acute Oral Toxicity, Acute Dermal Toxicity, Primary Skin Irritation and Primary Eye Irritation., DACO: 4.2.1,4.2.2,4.2.3,4.2.4,4.2.5
1046644	Verbenone: Acute Oral Toxicity, Acute Dermal Toxicity, Primary Skin Irritation and Primary Eye Irritation - reformatted report. reformatted;, DACO: 4.2.1
1046645	Memorandum from R. Garner to A. Bryceland re: status of acute toxicity studies/ purity of Verbenone. Date of memo: March 13 2003. Comments: confirms purity of material used, DACO: 4.2.1
1046646	Acute Inhalation - Request for waiver. Comments: 4.2.1 /02 is a reference cited, DACO: 4.2.3
1046647	Dermal Sensitization - Request for waiver. Comments: 4.2.1 /02 is a reference cited, DACO: 4.2.6
1159350	Flake Test. A summary of a non-GLP/QA/QC study prepared by Wildlife International Ltd. 4 pp DACO 9.3.2
1159351	2006, Waiver request for DACO 9.5.2, 9.5.2.1, 9.5.2.2 (Fish)
1159352	2006, Waiver request for DACO 9.6.2, 9.6.2.1, 9.6.2.2(Birds)
1335377	2006, Company specifications for Verbenone Pouch (7g load), DACO: 3.5.5 CBI
1401817	2007, Confidential Attachment- Verbenone Pouch (7g load), DACO: 3.2,3.4.1 CBI

1613355 M. Chiariello, G. Campana, G. Dettanti and D. Codogno, 1986, Platelet aggregation induced by arachidonic acid, ADP, thrombin. Study of the antiaggregating effects of verbenone and indomethacin, DACO: 4.8

1613356 2008, Enforcement Analytical Method for the determination of the active ingredient Verbenone and Storage Stability Study, DACO: 3.4.1,3.5.10 CBI

1784035 Tetradecane, DACO: 3.4.1 CBI

1784036 Blank Verbenone Pouch (7g load) Extract, DACO: 3.4.1 CBI

1784037 Verbenone Standard, DACO: 3.4.1 CBI

ISSN: 1911-8082

© Her Majesty the Queen in Right of Canada, represented by the Minister of Public Works and Government Services Canada 2012

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 the Minister of Public Works and Government Services Canada, Ottawa, Ontario K1A 0S5.