

Evaluation Report for Category B Subcategory 2.1, 2.3, 2.4, 3.3 Application

Application Number: 2008-1614
Application: New Formulation and Change in Application Number
Product: Beetle Block - Verbenone
Registration Number: 29674
Active ingredients (a.i.): Verbenone (PMB)
PMRA Document Number (English PDF): 1989317

Purpose of Application

The purpose of this application was to register a new commercial end-use product, Beetle Block – Verbenone, containing the active ingredient verbenone for use on pine trees and in pine stands to reduce attack by the mountain pine beetle.

Chemistry Assessment

The chemistry requirements for Beetle Block – Verbenone have been satisfied.

Health Assessments

Verbenone is of slight acute toxicity by the oral route in Wistar rats and low acute toxicity by the dermal route in New Zealand white rabbits. The submitted inhalation toxicity study indicated low acute inhalation toxicity for verbenone, but the study was deficient as it did not follow the required guidelines and the methodology adopted was inadequate to establish the LC₅₀. Therefore, the inhalation toxicity study is acceptable only as a supplemental study. Since the anticipated exposure from Beetle Block - Verbenone use is not anticipated to be greater than naturally occurring levels of verbenone during mountain pine beetle infestation, and the product labels have adequate mitigative statements to protect human inhalational toxicity, no additional studies are required.

Verbenone was minimally irritating to the eyes and non-irritating to the skin in New Zealand white rabbits. Topical application of verbenone produced skin sensitization in guinea pigs; therefore, Beetle Block - Verbenone is a skin sensitizer. The principal and secondary display panels of the Beetle Block – Verbenone label should have the warning statement: POTENTIAL SKIN SENSITIZER.

Acceptable waivers based on the potential for exposure of an individual to the end use product were submitted for short-term toxicity, teratogenicity, immunotoxicity, and genotoxicity.

The cautionary statements recommended and that are already present on the label are considered to be sufficient to minimize any human health and safety concerns.

Exposure to verbenone may occur when handling and applying the product, as well as from accidental exposure to dislodged pouches. Pesticide applicators and workers handling and attaching pouches to pine trees can come in direct contact with verbenone on the skin and eyes resulting from punctured or improperly sealed pouches. The label statements adequately mitigate the concern of exposure to the applicators or workers.

Any potential for inhalation of verbenone while handling and applying the product is anticipated to be negligible if the precautionary statements are observed.

Accidental bystander exposure is possible in situations where the pouch has been dislodged from the tree and punctured by adults, children, and/or companion pets. Exposure is expected to be negligible if the precautionary label statements, “Keep out of reach of children and pets”, and “DO NOT puncture pouches or handle their contents” are observed, the pouch is properly affixed to the tree, and each individual pouch has its own abbreviated label.

The pouches are expected to be depleted of verbenone within 60 – 120 days of application. Removal of the spent pouches will not result in any significant post-application exposure to the worker.

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

Environmental Assessment

PMRA does not anticipate the registration of Beetle Block – Verbenone to pose an unacceptable risk to the environment.

Value Assessment

In addition to a quantity of published literature indicating the potential value of verbenone for pest management of the mountain pine beetle, results were submitted from five efficacy trials which provided support for the use claims for the Beetle Block – Verbenone product in particular and indicated that the performance of this product is comparable to that of the currently registered products containing verbenone.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided in support of this application and has found the information sufficient to support full registration of Beetle Block – Verbenone.

References

- PMRA# 1595526 DACO 10.2.3.2 Field Trials.
- PMRA# 1623096 10.1 Value Summaries, pp. 1-104.
- PMRA# 1623097 10.1 Value Summaries, pp. 105-253.
- PMRA 1623078 2008, Summary Toxicology Profile. DACO: 4.1
- PMRA 1595588 2004, Acute Oral Toxicity in Rats - CTI-73813-3, DACO: 4.2.1
- PMRA 1595589 2004, Acute Dermal Toxicity, DACO: 4.2.2
- PMRA 1595590 2004, Acute Inhalation Toxicity (LC50 Rats) Study, DACO: 4.2.3
- PMRA 1595591 2004, Acute Eye Irritation Study in Rats, DACO: 4.2.4
- PMRA 1595592 2004, Acute Dermal Irritation Study in Rabbits, DACO: 4.2.5
- PMRA 1595593 2004, Skin Sensitization in Guinea Pigs (Buehler Test), DACO: 4.2.6
- PMRA 1595595 2006, Response to EPA Letter Dated October 5, 2006, DACO: 4.2.6
- PMRA 1595596 2006, Request for Waivers for Specific Data Requirements, DACO: 9.6.2.2, 9.6.2.5
- PMRA 1595521 2000, Verbenone, Human Health and Ecological Risk Assessment, DACO: 5.14
- PMRA 1595522 APPL 5.2, DACO: 5.2
- PMRA 1780080 2009, Aldrich Verbenone Dispenser Storage Stability Study, DACO: 3.4.1 CBI
- PMRA 1780081 Corrosion Characteristics of End Use Product, DACO: 3.5.14
- PMRA 1868211 GC 0 Time Sample, DACO: 3.4.1 CBI
- PMRA 1868212 GC 12 Month Sample, DACO: 3.4.1 CBI
- PMRA 1868213 GC Verb & Tetradec, DACO: 3.4.1 CBI

PMRA 1868214 Analytical Method, DACO: 3.4.1

PMRA 1868216 Analytical Method, DACO: 3.4.1

PMRA 1868217 Analytical Method, DACO: 3.4.1

ISSN: 1911-8082

© Her Majesty the Queen in Right of Canada, represented by the Minister of Public Works and Government Services Canada 2011

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.