Registration Decision RD2013-12

DWB Pheromone Technical

(publié aussi en français)

16 July 2013

This document is published by the Health Canada Pest Management Regulatory Agency. For further information, please contact:

Publications
Pest Management Regulatory Agency
Health Canada
2720 Riverside Drive
A.L. 6604-E2
Ottawa, Ontario K1A 0K9

Internet: pmra.publications@hc-sc.gc.ca
healthcanada.gc.ca/pmra
Facsimile: 613-736-3758
Information Service:
1-800-267-6315 or 613-736-3799
pmra.infoserv@hc-sc.gc.ca

Canada

ISSN: 1925-0932 (print)
1925-0940 (online)

Catalogue number: H113-25/2013-12E (print version)
H113-25/2013-12E-PDF (PDF version)

© Her Majesty the Queen in Right of Canada, represented by the Minister of Health Canada, 2013

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.

Registration Decision for DWB Pheromone Technical

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is granting full registration for the sale and use of Isomate DWB, containing the technical grade active ingredient DWB Pheromone Technical, which contains the following four active compounds: (Z,Z)-3,13-octadecadien-1-yl acetate, (E,Z)-2,13-octadecadien-1-yl acetate, (Z,Z)-3,13-octadecadien-1-ol, and (E,Z)-2,13-octadecadien-1-ol. Isomate DWB is registered as a mating disruptor of the dogwood borer (*Synathedon scitula*) on pome fruits, stone fruits, tree nut, highbush blueberry, and woody ornamental nursery crops.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

These products were first proposed for registration in the consultation document[1] PRD2012-19, *DWB Pheromone Technical*. This Registration Decision[2] describes this stage of the PMRA's regulatory process for DWB Pheromone Technical and summarizes the Agency's decision and the reasons for it. The PMRA received no comments on PRD2012-19. This decision is consistent with the proposed registration decision stated in PRD2012-19.

For more details on the information presented in this Registration Decision, please refer to PRD2012-19, which contains a detailed evaluation of the information submitted in support of this registration.

What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable[3] if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its conditions of registration. The Act also requires that products have value[4] when used according to label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (for example, children) as well as organisms in the environment (for example, those

1 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act.*

2 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act.*

3 "Acceptable risks" as defined by subsection 2(2) of *Pest Control Products Act.*

4 "Value" as defined by subsection 2(1) of *Pest Control Products Act* "...the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (*a*) efficacy; (*b*) effect on host organisms in connection with which it is intended to be used; and (*c*) health, safety and environmental benefits and social and economic impact".

most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the Pesticides and Pest Management portion of Health Canada's website at healthcanada.gc.ca/pmra.

What Is DWB Pheromone Technical?

DWB Pheromone Technical is a mixture of straight chain lepidopteran pheromones, containing 84.03% (Z,Z)-3,13-octadecadien-1-yl acetate, 5.75% (E,Z)-2,13-octadecadien-1-yl acetate, 1.58% (Z,Z)-3,13-octadecadien-1-ol, and 0.28% (E,Z)-2,13-octadecadien-1-ol. The combination of these four compounds constitutes the sex pheromone of the dogwood borer. In nature, this sex pheromone is produced by female moths and attracts male moths for mating.

Health Considerations

Can Approved Use of DWB Pheromone Technical Affect Human Health?

DWB Pheromone Technical, containing the straight chain lepidopteran pheromones (Z,Z)-3,13-octadecadien-1-yl acetate, (E,Z)-2,13-octadecadien-1-yl acetate, (Z,Z)-3,13-octadecadien-1-ol, and (E,Z)-2,13-octadecadien-1-ol, is used to formulate the end-use product Isomate DWB, which is unlikely to affect human health when it is used according to label directions.

Exposure to DWB Pheromone Technical may occur when handling Isomate DWB, which has a registered commercial use as a mating disruptor of the dogwood borer. When assessing health risks, two key factors are considered: the levels where no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers). Only uses for which the exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

DWB Pheromone Technical is of low acute toxicity via the oral, dermal and inhalation routes. It is non to minimally irritating to eyes, mildly irritating to skin, and is not considered a dermal sensitizer.

Dermal exposure is possible for workers handling Isomate DWB during placement of the dispensers. The precautionary measures including personal protective equipment and cautionary statements alerting users to the potential for skin irritation are required on the technical grade active ingredient and end-use product labels to mitigate such exposure concerns. The potential for bystander exposure is expected to be minimal.

Residues in Water and Food

Dietary risks from food and water are not of concern.

The use of Isomate DWB formulated with DWB Pheromone Technical is not expected to result in unacceptable dietary risks when the product is used according to label directions. In addition, as the active ingredients are enclosed in a polymeric dispenser, and the dispensers will be attached to trees, exposure to the technical grade active ingredient in drinking water is not expected to occur. The PMRA has also determined that a maximum residue limit (MRL) is not required for Isomate DWB.

Occupational Risks From Handling Isomate DWB

Occupational risks are not of concern when Isomate DWB is used according to label directions, which include protective measures.

Occupational exposure to individuals handling Isomate DWB is not expected to result in unacceptable risk when the product is used according to label directions.

Precautionary and hygiene statements on the label (for example, wearing of personal protective equipment) are considered adequate to protect individuals from any unnecessary risk due to occupational exposure.

Environmental Considerations

What Happens When DWB Pheromone Technical Is Introduced Into the Environment?

DWB Pheromone Technical is released into the environment through passive vaporization into air from Isomate DWB fixed dispensers. The straight chain lepidopteran pheromone components of DWB Pheromone Technical are a group of chemicals that are naturally-based and are well known to break down rapidly in the environment. Through this use pattern, and because of the inherent nature of the chemicals, limited environmental exposure is expected.

Value Considerations

What Is the Value of Isomate DWB?

Isomate DWB has value in disrupting the mating of dogwood borers, thus reducing the production of larvae that would otherwise damage woody plants, including fruit and nut trees, highbush blueberries, and various ornamentals.

Application of Isomate DWB slow-release dispensers containing DWB Pheromone Technical in fruit or nut orchards, highbush blueberry fields, or nurseries for woody ornamentals produces numerous artificial sources of sex pheromone. This interferes with the ability of male moths to find females for mating and unmated females cannot lay fertile eggs; therefore, the next generation of larvae is reduced, limiting the damage the larvae would otherwise cause. Dogwood

borer larvae tunnel under the bark of a wide variety of tree species and other woody plants, seriously weakening them and killing smaller trees or plants by girdling.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law.

The key risk-reduction measures on the label of Isomate DWB to address the potential risks identified in this assessment are as follows.

Human Health

The signal words 'CAUTION – SKIN IRRITANT' and the statements 'May irritate skin' and 'Avoid contact with skin' are required on the principal and secondary display panels, respectively.

The personal protective equipment for all users includes chemical-resistant gloves and eye protection.

Environment

No environmentally-related mitigative measures are required.

Other Information

The relevant test data on which the decision is based (Proposed Registration Decision PRD2012-19, *DWB Pheromone Technical)* are available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa). For more information, please contact the PMRA's Pest Management Information Service by phone (1-800-267-6315) or by e-mail (pmra.infoserv@hc-sc.gc.ca).

Any person may file a notice of objection[5] regarding this registration decision within 60 days from the date of publication of this Registration Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the Pesticides and Pest Management portion of the Health Canada's website (Request a Reconsideration of Decision, www.hc-sc.gc.ca/cps-spc/pest/part/protect-proteger/publi-regist/index-eng.php#rrd) or contact the PMRA's Pest Management Information Service.

[5] As per subsection 35(1) of the *Pest Control Products Act.*