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Proposed Re-evaluation Decision

PRVD2022-07

(Z)-9-Tricosene and Its Associated End-use Products

Consultation Document

(publié aussi en français)

26 April 2022

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

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ISSN: 1925-0959 (print)
1925-0967 (online)

Catalogue number: H113-27/2022-XXE (print)
H113-27/2022-XXE-PDF (PDF version)

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Proposed Re-evaluation Decision

Under the *Pest Control Products Act*, all registered pesticides must be re-evaluated regularly by Health Canada's Pest Management Regulatory Agency (PMRA) to ensure that they continue to meet health and environmental safety standards and continue to have value. The re-evaluation considers data and information from various sources such as information from pesticide manufacturers, incident reports, and other regulatory agencies. Health Canada applies internationally accepted risk assessment methods, risk management approaches and policies to all re-evaluations.

This document presents the proposed regulatory decision for the re-evaluation of (Z)-9-tricosene, including any proposed amendments (risk mitigation measures) to protect human health and the environment, as well as the science evaluation on which the proposed decision is based.

(Z)-9-tricosene, also known as muscalure, is used for the control of flies and acts as a fly attractant. It is a semiochemical that is produced by the female house fly, *Musca domestica*. (Z)-9-tricosene commercial end-use products are registered for use in and around animal/livestock housing or in residential/commercial structures and inside transport vehicles. The commercial class end-use products are co-formulated with conventional insecticides and are available as bait stations, sprays or brushable paint. The domestic class end-use product is not co-formulated with any other insecticide and is registered for outdoor use around residential and farm buildings to reduce fly populations using physical traps. Currently registered products containing (Z)-9-tricosene are listed in Appendix I.

(Z)-9-tricosene has a non-toxic mode of action and has value in providing a pest management solution. Based on the current use pattern of (Z)-9-tricosene, dietary exposure is not anticipated. The potential risks to human health (occupational, residential, and bystander) and environment (terrestrial and aquatic organisms) are considered to be acceptable when products containing (Z)-9-tricosene are used according to label directions. As a result of re-evaluation, no additional mitigation measures are proposed, however, updates to labels as per current labelling standards are proposed (Appendix II).

Under the authority of the *Pest Control Products Act* and based on the evaluation of currently available scientific information, products containing (Z)-9-tricosene (Appendix I) are proposed for continued registration in Canada, with the proposed updates to label directions (Appendix II).

All products containing (Z)-9-tricosene registered in Canada are subject to this proposed re-evaluation decision. This document is subject to a public consultation,¹ during which written comments and additional information may be submitted to PMRA Publications. The final re-evaluation decision will be published taking into consideration the comments and information received during the consultation period.

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

Next steps

The public, including the registrants and stakeholders, are encouraged to submit written comments and additional information during the 90-day public consultation period upon publication of this proposed re-evaluation decision.

All comments received during the 90-day public consultation period will be taken into consideration in preparation of re-evaluation decision document,² which could result in revised risk mitigation measures. The re-evaluation decision document will include the final re-evaluation decision, the reasons for it and a summary of comments received on the proposed re-evaluation decision with Health Canada's responses.

Other information

When Health Canada makes its re-evaluation decision, it will publish a Re-evaluation Decision on (Z)-9-tricosene (based on the Science evaluation of PRVD2022-07. In addition, the test data referenced in this consultation document will be available for public inspection, upon application, in the PMRA's Reading Room.

Additional scientific information

Additional scientific data are not required at this time.

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

Science evaluation

1.0 Human health assessment

Semiochemicals generally present a very low potential risk to human health, because of their mode of action (in other words, behavioural changes of the pest in response to volatile chemical signals), a rapid rate of dissipation, and the quantities used, which often reflect concentrations that occur in nature during an outbreak of the pest. (Z)-9-tricosene showed no significant signs of acute toxicity via the oral, dermal and inhalation routes, however, there was slight eye and dermal irritation. (Z)-9-tricosene has been identified as a moderate dermal sensitizer, therefore, product labels currently include “POTENTIAL SKIN SENSITIZER” on the primary panel. Health Canada has not established toxicological reference values for risk assessment.

There is potential for occupational exposure to (Z)-9-tricosene as a result of application of products containing (Z)-9-tricosene as follows:

- applying granular formulation by hand using shaker cans,
- mixing wettable granules into solution for use in bait stations (for example, jug traps),
- mixing wettable granules into solution and applying using low-pressure spray applicators,
- mixing wettable granules into solution and applying as a brushable paint, and/or
- re-entering treated sites (in other words, postapplication).

Due to the absence of toxicological concerns, no quantitative risk assessments were required for (Z)-9-tricosene. The potential risk to occupational workers (mixing/loading/applying) is considered acceptable under the current conditions of use (the commercial-class product labels currently require workers to wear personal protective equipment consisting, at a minimum, of a long-sleeved shirt and long pants, and chemical-resistant gloves during mixing, loading, application, clean-up and repair activities). Postapplication risk of workers entering sites treated with (Z)-9-tricosene is considered acceptable under the current conditions of use. No additional mitigation measures are proposed. Label updates to human health precautionary statements are proposed to meet standards set out in PMRA Guidance Document, Structural Pest Control Products: Label Updates (Appendix II).

There is potential for residential (handler) and bystander exposure to (Z)-9-tricosene as there is one registered domestic class product and currently one commercial class product available for use in structures with residential/commercial activities and inside transport vehicles. The domestic class product is registered for use in physical fly traps in which the product containing (Z)-9-tricosene, formulated as a wettable granule and packaged in a water soluble pouch to limit exposure, is mixed into a solution with water. The domestic class product is registered for outdoor use only around residential and farm buildings and traps can be placed on a flat surface or hung above ground. The domestic product labels includes directions to not use the product in locations accessible to children, pets, domestic animals or wildlife. In addition, the commercial product available for use in structures with residential/commercial activities and inside transport vehicles limits the use of the product to when people and pets are not present to avoid bystander exposure. The commercial products also currently include directions to limit use in areas inaccessible to children. No additional risk mitigation measures are proposed. Label updates to

human health precautionary statements are proposed to meet standards set out in PMRA Guidance Document, Structural Pest Control Products: Label Updates (Appendix II).

(Z)-9-tricosene is not registered in Canada for food or feed uses, and contamination of drinking water sources is not expected. The current labels require that application of (Z)-9-tricosene must be restricted to areas where food and feed are not present to ensure that dietary exposure does not occur. When the current label directions are followed, potential dietary exposure is not anticipated and the risk is considered to be acceptable. No additional mitigation measures are proposed.

Aggregate exposure is the total exposure to a single pesticide that may occur from food, drinking water, residential, and other non-occupational sources, and from all known or plausible exposure routes (oral, dermal, and inhalation). Aggregate exposure to (Z)-9-tricosene is considered to be acceptable as there is no anticipated dietary exposure, and the risk from residential and non-occupational (bystander) exposures is considered acceptable. No additional mitigation measures are proposed.

The *Pest Control Products Act* requires that Health Canada consider the cumulative exposure to pesticides with a common mechanism of toxicity. While (Z)-9-tricosene may share a common moiety with other semiochemical active ingredients, the potential risks from cumulative exposure are not of concern given the low toxicity profile and the limited exposure potential. Therefore there is no requirement for a cumulative assessment at this time.

2.0 Environment assessment

The major routes of dissipation in the environment is expected to be volatilization and microbial degradation. Environmental exposure to (Z)-9-tricosene is expected to be minimal as registered uses are either for indoor use, inside transport containers or outdoor use, on the exterior of a building. Product labels for granular formulations currently include directions to minimize exposure to birds (use of a bait station is required when used in areas accessible to birds to prevent birds from consuming the granules). For consistency, as there is one granular end-use product label missing the required statement, updates are proposed to include the mitigation measure to prevent birds from consuming bait is proposed to meet current standards (Appendix II). For end-use products used in solution and applied as a spray or brushable paint, exposure of (Z)-9-tricosene to the environment and non-target organisms is expected to be minimal based on the use pattern, which consists of indoor uses in agricultural buildings (barns, poultry houses etc.) or for outdoor structural uses.

Therefore, based on the use pattern of (Z)-9-tricosene there is minimal potential for environmental exposure, and environmental risk is considered acceptable when label directions are followed. (Z)-9-tricosene is not considered a Track 1 substance as it does not meet all the Track 1 criteria as per the Toxic Substances Management Policy (Canada, 2003).

3.0 Incident reports

3.1 Health incident reports

As of 20 May 2021, 7 human (6 United States, 1 Canada) and 99 domestic animal incidents involving 104 animals (85 United States, 19 Canada) involving (Z)-9-tricosene have been submitted to the PMRA. These incidents involved bait products containing (Z)-9-tricosene, as well as either methomyl or thiamethoxam.

Overall, two human reports were considered to be at least possibly related to the reported product exposure. Both incidents reported misuse of the bait product, either as intentional ingestion or incorrect handling of the product (mixing the product with a bare finger). The symptoms reported in both cases included respiratory depression, and in one case, muscle spasms and eye effects (blurred vision, eye closed) were also reported. These effects are likely attributable to the co-formulant, methomyl, as they are consistent with carbamate poisoning effects.

Most of the domestic animal incidents reported accidental ingestion of a bait product, either from unattended product placed or stored within range of the animal, or the animal chewing through the product container. Nearly all incidents involved a product co-formulated with methomyl. The most frequently reported symptoms, which include drooling, convulsion/tremor, vomiting, diarrhea, weakness, and difficulty breathing as well as death shortly after exposure are all highly consistent with methomyl poisoning.

Based on the low number of Canadian incidents involving (Z)-9-tricosene products, and the presence of sufficient precautionary statements and protective use directions on product labels to prevent human and domestic animal exposure, no additional mitigation measures are proposed as a result of the incident report review.

3.2 Environment incident reports

As of 20 May 2021, the PMRA has received one minor environmental incident based on the number of non-target organisms affected, involving (Z)-9-tricosene and methomyl. The incident occurred in the United States and involved the death of 6 mourning doves within two days of an outdoor bait station spill. Based on the presence of sufficient precautionary statements and protective use directions on product labels to prevent environmental exposure, no additional mitigation measures are proposed.

4.0 Value assessment

(Z)-9-tricosene acts as an attractant used in association with insecticides in baits or alone in physical fly traps, which are critical components for fly control programs. It is also an alternative to insecticidal sprays. General label updates are proposed for those products which require amendments to meet standards set out in PMRA Guidance Document, *Structural Pest Control Products: Label Updates* (Appendix II).

Appendix I Registered products containing (Z)-9-tricosene

Table 1 Registered products, excluding discontinued products or products with a submission for discontinuation, containing (Z)-9-tricosene as of 28 February 2022

Registration number	Marketing class*	Registrant	Product name	Formulation type	Guarantee
24957	T	Bedoukian Research, Inc.	Bedoukian Z-9-Tricosene Technical Pheromone	Liquid	Muscalure 93.48%
25312	T	Denka International B.V.	Technical Muscalure	Liquid	Muscalure 86.0%
15176	C	Wellmark International	Starbar Premium Fly Bait	Granular	Muscalure 0.049%; Methomyl 1.000%
24969	C	Troy Biosciences Inc.	Stimukil Fly Bait	Granular	Muscalure 0.025%; Methomyl 1.00%
28297	C	Elanco Canada Limited	Agita Fly Bait	Granular	Muscalure 0.10%; Thiamethoxam 1.0%
29428	C	Engage Animal Health Corporation	Fatal Attraction Fly Bait	Granular	Muscalure 0.025%; Methomyl 1.000%
30336	C	Elanco Canada Limited	Agita 10 WG	Wettable Granules	Muscalure 0.05%; Thiamethoxam 10%
32234	C	Bayer CropScience Inc.	QuickBayt Granular Fly Bait	Granular	Muscalure 0.09%; Imidacloprid 0.5%
32493	C	Bayer CropScience Inc.	Maxforce Fly Spot Bait	Granular	Muscalure 0.1%; Imidacloprid 10%
33305	C	Bayer CropScience Inc.	QuickBayt Spot Spray	Wettable Granules	Muscalure 0.1%; Imidacloprid 10%
33562	C	Sharda Cropchem Limited	SoFast Granular Fly Bait	Wettable Granules	Muscalure 0.1% Imidacloprid 10%
32124	D	Wellmark International	Starbar Fly Trap Attractant	Wettable Granules	Muscalure 1.0%

* T = Technical, C = Commercial, D = Domestic

Appendix II Proposed label updates for products containing (Z)-9-tricosene

The label amendments presented below do not include all label requirements for individual end-use products, such as first aid statements, disposal statements, precautionary statements, and supplementary protective equipment. Information on labels of currently registered products should not be removed unless it contradicts the label statements provided below.

General

For commercial and domestic end-use products:

- Labels with structural uses must be amended to reflect the revised definitions for application types outlined in the 2020 publication PMRA Guidance Document, Structural Pest Control Products: Label Updates.

Human health

For commercial and domestic end-use products:

- Labels with structural uses and surface or space application must be amended to reflect the standard human health precautionary statements outlined in the 2020 PMRA publication PMRA Guidance Document, Structural Pest Control Products: Label Updates.

Environment

For PCP No. 28297 (commercial end-use product with granular formulation), addition of the following under “Directions for Use”:

- “When used in areas accessible to birds, bait must be placed in a tamper- resistant bait station that prevents birds from consuming the bait.”

References

Published information

PMRA number	Reference
692324	Canada, 2003. Proposed Acceptability for Continuing Registration, PACR2003-12, Re-evaluation of (Z)-9-tricosene, October 24, 2003.
730052	Canada, 2004. Re-evaluation Decision Document, RRD2004-06, Re-evaluation of (Z)-9-tricosene, 30 March 2004.
2940510	Evaluation Report for Category B, Subcategory 3.4, 3.12 Application, Application Number: 2017-7671
2846584	Evaluation Report for Category B, Subcategory 3.12 Application, Application Number: 2017-3103
2674882	Evaluation Report for Category B, Subcategory B.2.1, B.2.3, B.2.4, B.2.6, B.3.1, B.3.4, B.3.12 Application, Application Number: 2015-2699
2579737	Evaluation Report for Category B, Subcategory 2.1, 2.3, 2.4, 2.5 Application, Application Number: 2015-1529
2574307	Evaluation Report for Category B, Subcategory 2.6, 3.1 and 3.11 Application, Application Number: 2014-3969
2119382	Evaluation Report for Category B, Subcategory 2.1, 2.3, 2.4, 3.1, 3.11, 3.12, 3.4 Application, Application Number: 2009-0746
1868858	Evaluation Report for Category B, Subcategory 4.1 Application, Application Number: 2008-3580