Proposed Re-evaluation Decision PRVD2022-19

Verbenone and Its Associated End-use Products

Consultation Document

(publié aussi en français)

6 September 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: H113-27/2022-19E (print)
H113-27/2022-19E-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 verbenone, 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.

Verbenone is an anti-aggregation pheromone registered as an outdoor insect repellent. Verbenone is a naturally occurring semiochemical produced by yeast in the gut of the mountain pine beetle, *Dendroctonus ponderosae*. When used in pest control products, verbenone can protect pine stands and individual pine trees by repelling adult mountain pine beetle, preventing the laying of eggs on the protected trees. Two commercial-class products and one domestic-class product containing verbenone are formulated as slow-release generators packaged in pouches. Verbenone end-use products are nailed or stapled to pine tree trunks and slowly release verbenone into the atmosphere through evaporation. Currently registered products containing verbenone are listed in Appendix I.

Verbenone is a naturally occurring substance with a non-toxic mode of action that has value in providing a pest management solution. Based on the current use pattern of verbenone, dietary (food and water) exposure to verbenone is not anticipated. The potential risks to human health (occupational, residential, and bystander) and environment are considered to be acceptable when products containing verbenone are used according to the proposed updated label directions. As a result of re-evaluation, updates to label statements as per current labelling standards are proposed (Appendix II).

Under the authority of the *Pest Control Products Act* and based on an evaluation of currently available scientific information, products containing verbenone (Appendix I) are being proposed for continued registration in Canada, with the proposed labelling updates (Appendix II).

All products containing verbenone 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 registrant 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 the 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 verbenone (based on the Science Evaluation of PRVD20xx-xx). 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

Verbenone is an anti-aggregation pheromone registered as an outdoor insect repellent. Products containing verbenone are formulated as slow-release generators packaged in pouches. Verbenone end-use products are nailed or stapled to pine tree trunks at the handler's maximum reach of 2–3 m, and the active is slowly released into the atmosphere through evaporation. The expected life span of the pouch is 60–120 days, weather dependent.

1.0 Human health assessment

Verbenone is a naturally occurring substance. It has a non-toxic, species-specific mode of action. Health Canada has not established toxicological reference values for risk assessment and has used a qualitative approach to assess risks to human health. The available data in the PMRA database indicates that verbenone is considered to be slightly acutely toxic by the oral exposure route, of low acute toxicity by dermal and inhalation exposure routes, mildly irritating to the eyes, non- to minimally irritating to the skin, and is a potential skin sensitizer. See Evaluation Reports for further details (Canada, 2010a and 2011a). Updates to signal words on the principal display panel and precautionary statements are being proposed for all products containing verbenone (Appendix II); changes reflect current standards for users to be alerted with caution for eye irritation and potential skin sensitization. The USEPA also used a qualitative approach for the verbenone review (USEPA, 2009 and 2018).

There is a potential for occupational exposure as a result of workers handling and attaching the commercial-class end-use products to trees. Occupational exposure is expected to be primarily via the inhalation route, with possible dermal exposure from punctured or improperly sealed pouches. Precautionary statements are present on all currently registered product labels, including "DO NOT puncture pouches or handle their contents", "Avoid inhaling fumes; open storage bags outdoors prior to use and allow to vent for 10 minutes before removing pouches", and "Avoid contact with skin or clothing. Wash skin and clothing thoroughly with soap and water after handling." Current labels require workers to wear suitable protective clothing including chemical resistant gloves and eye protection when handling dispensers; updates are being proposed to meet current label standards, "Wear a long-sleeved shirt, long pants, chemical-resistant gloves, protective eyewear (goggles or face shield), and socks and shoes when handling the dispensers." (Appendix II). Pesticidal applications of verbenone are made at application rates that fall within naturally occurring background levels found in coniferous forests. Furthermore, the commercial products are not intended for residential use.

Workers can be exposed when entering a treated site to tend trees or to remove the dispensers. Postapplication inhalation exposure is not expected to exceed ambient levels of pheromone that would be produced by the natural mountain pine beetle populations during an infestation. Furthermore, because dispensers are placed at an operator's maximum reach 2–3 m, exposure to workers or bystanders at ground level is expected to be low.

Occupational exposure is considered to be acceptable when the commercial products containing verbenone are used according to the label directions; label updates are proposed to meet current standards (Appendix II). See Evaluation Reports for summary of detailed reviews (Canada, 2011b and 2012b).

There is one domestic-class product containing verbenone that is registered in Canada, thus there is potential for residential exposure to verbenone as a result of users handling the domestic-class product. Users may be exposed to verbenone as they staple or nail pouches containing verbenone to the pine tree. Since the domestic-class product contains verbenone in a sealed pouch, dermal exposure is not anticipated when users follow the current precautionary statements, "DO NOT use punctured pouches". Inhalation exposure is not anticipated when products are used according to precautionary statements that are presently on the labels, "Avoid inhaling fumes; open storage bags outdoors prior to use and allow to vent for 10 minutes before removing pouches". Furthermore, user exposure to verbenone from the registered domestic use is not anticipated to exceed naturally occurring levels present in the environment during mountain pine beetle infestation. Label precaution also states for users to wear eye protection, protective clothing and gloves when handling dispensers; updates are being proposed to meet current label standards (Appendix II).

Similar to the commercial products, domestic dispensers are placed at the user's maximum reach of 2–3 m, and the application of verbenone is not anticipated to adversely affect users or bystanders at ground level. Bystander exposure is possible if a pouch is dislodged from a tree and subsequently punctured by people, and/or companion animals. Unnecessary risks due to such accidental exposures are adequately mitigated by precautionary statements on individual pouch labels of commercial products (for example, do not puncture pouches; keep out of reach of children and pets).

Based on the above considerations, risks to residential users, bystanders and individuals in residential areas (including children and pets) are considered to be acceptable when products are used according to the label directions (Appendix II). See Evaluation Reports for summary of detailed reviews (Canada, 2011b, 2012a and 2012b).

Verbenone is not registered in Canada for food or feed uses and contamination of drinking water sources is not expected. Therefore, dietary exposure to verbenone is not anticipated under the current conditions of use.

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). Under the current conditions of use, aggregate exposure to verbenone is considered to be acceptable as there are no concerns for dietary (food and drinking water) exposure and the risk from residential and bystander exposure is acceptable.

The *Pest Control Products Act* requires that Health Canada consider the cumulative exposure to pest control products with a common mechanism of toxicity. Accordingly, an assessment of potential common mechanism of toxicity with other pesticides was undertaken. While verbenone may be structurally similar to other registered semiochemical active ingredients and components

of essential oil-based pest control products, it is difficult to determine whether constituents share a common mechanism of action as it is often not possible to fully identify and characterize the constituent(s) responsible for toxicity. Under the currently approved conditions of use, no dietary exposure to verbenone is anticipated, and therefore only residential exposure was considered. Verbenone is a naturally occurring substance with a non-toxic, species-specific mode of action, and a qualitative approach was taken for the health assessment. Furthermore, exposure to verbenone from the registered method of application is not anticipated to exceed naturally occurring levels present in the environment during mountain pine beetle infestation. Based on these considerations, cumulative risks are acceptable.

2.0 Environment assessment

Verbenone is a naturally occurring substance produced by mountain pine beetle during an infestation. Highly volatile and biodegradable, verbenone is expected to dissipate and rapidly degrade through biological and chemical processes in the environment. It is not expected to bioaccumulate in plants and animals. See Evaluation Report for further details (Canada, 2010a–2011a). Verbenone is not considered as a Track 1 substance as it does not meet all of the criteria in accordance with the Toxic Substances Management Policy.

Verbenone is registered for use as a species-specific insect repellent targeting the mountain pine beetle, *Dendroctonus ponderosae*. Verbenone is slightly toxic to birds, mammals and aquatic organisms. Based on its formulations and use-pattern, however, verbenone will pose negligible risks to terrestrial or aquatic organisms. Verbenone is released slowly from dispensers (in other words, pouches) at a rate that generates low air concentrations. Ingestion of verbenone is expected to be negligible as the product is not likely an attractant for animals. Similarly, the occurrence of verbenone in aquatic systems is expected to be negligible as the product is placed only in pine trees, thereby, minimizing the possibility of aquatic exposure. Furthermore, to reflect current labelling standards for commercial and domestic products, additional precautionary statements are proposed to indicate the product is not to be applied to any body of water or used to control pests in aquatic systems (Appendix II). Under the current conditions of use, verbenone is not expected to adversely affect the environment. Refer to Evaluation Reports for details (Canada, 2010b, 2012a and 2012b).

Label updates are proposed to meet current standards for proper disposal of the domestic class product (Appendix II).

The USEPA registration review concluded that risks to the environment are not anticipated (USEPA, 2018). Specifically, verbenone is highly volatile, biodegradable and is not expected to persist. Furthermore, USEPA data indicate that verbenone is of low mammalian, insect and avian toxicity.

3.0 Incident reports

As of 22 April 2022, no incident reports involving Verbenone had been submitted to the PMRA.

4.0 Value assessment

Verbenone has value in providing a solution for pest control to protect pine trees from mountain pine beetle attacks. When used in integrated pest management programs, verbenone can play a valuable part in resistance management and may help reduce the need for conventional insecticides.

Updates to the general statements on all product labels are proposed to improve clarity and meet current label standards (Appendix II).

Appendix I Registered products containing verbenone

Table 1 Registered products containing verbenone as of 24 June 2022

Registration number	Marketing class	Registrant	Product name	Formulation type	Guarantee
28259	T	ISCA Technologies, Inc.	Verbenone Technical	Liquid	97%
29675	T	Chemtica Internacional S.A.	Chemtica Verbenone Technical	Liquid	96%
28645	C	ISCA Technologies, Inc.	Verbenone Pouch (7G load)	Slow Release Generator	Verbenone 7 g/pouch
29674	C	Chemtica Internacional S.A.	Beetle Block - Verbenone	Slow Release Generator	Verbenone 6.75 g/pouch
28919	D	ISCA Technologies, Inc.	Verbenone Pouch Mountain Pine Beetle Repellent	Slow Release Generator	Verbenone 7 g/pouch

T = Technical grade; C = Commercial class; D = Domestic class

Appendix II Proposed label updates for products containing verbenone

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.

I. For all products containing verbenone:

i. General statements:

Change “GUARANTEE”
to “ACTIVE INGREDIENT”

ii. General statements:

Amend NOTICE TO USER section to include the following statement:
“This pest control product is to be used in accordance with the directions on the label. It is an offence under the Pest Control Products Act to use this product in a way that is inconsistent with the directions on the label.”

iii. Under the PRECAUTIONS section:

Remove:
“Only protected handlers may be in the area during application.”

II. For all commercial-class products containing verbenone:

i. On the Principal Display Panel:

Remove:
“EYE AND SKIN IRRITANT”

Replace with:
“CAUTION - EYE IRRITANT
POTENTIAL SKIN SENSITIZER”

ii. Under the PRECAUTIONS section:

Remove:
“Users must wear suitable protective clothing including chemical resistant gloves and eye protection when handling the dispensers.”

And Replace with:
"Wear a long-sleeved shirt, long pants, chemical-resistant gloves, protective eyewear (goggles or face shield), and socks and shoes when handling the dispensers.

iii. Under the PRECAUTIONS section:

Add:

"As this product is not registered for the control of pests in aquatic systems, DO NOT use to control aquatic pests."

III. For the domestic-class product containing verbenone:

i. On the Principal Display Panel:

Remove:
"EYE AND SKIN IRRITANT"

Replace with:
"CAUTION - EYE IRRITANT
POTENTIAL SKIN SENSITIZER"

ii. Under the PRECAUTIONS section:

Remove:

"Harmful if swallowed or absorbed through skin. Causes moderate eye irritation."

And Replace with:
"Harmful if swallowed. May irritate eyes. Avoid contact with eyes. Potential skin sensitizer."

iii. Under the PRECAUTIONS section:

Remove:
"Users must wear suitable protective clothing including chemical resistant gloves and eye protection when handling the dispensers."

And Replace with:
"Users must wear eye protection, protective clothing and waterproof gloves when handling dispensers."

iv. Under the DIRECTIONS FOR USE section:

Add
“DO NOT apply to any body of water.”
“DO NOT use punctured pouches.”

v. Under the DIRECTIONS FOR USE section:

Remove:
“Dispose in household garbage.”

And Replace with:
“Dispose of empty container with household garbage.”

References

PMRA#	Reference
1426928	Canada, 2007. Evaluation Report for Category B, Subcategory 1.1 Application. Application Number: 2006-3329. Verbenone. Registration Number: 28259
1837949	Canada, 2010a. New Source of Technical Grade Active Ingredient Evaluation Report for Category B, Subcategory 1.2 Application. Application Number: 2007-2599. Verbenone Technical. Registration Number: 29519
1837956	Canada, 2010b. Evaluation Report for Category B, Subcategory 2.1, 2.3, 2.4, 3.1, 3.4 Application. Application Number: 2007-2176. Hercon Disrupt Micro-Flake VBN. Registration Number: 29520
1989319	Canada, 2011a. Evaluation Report for Category B, Subcategory 1.2 Application. Application Number: 2008-1615. Chemtica Verbenone Technical. Registration Number: 29675.
1989317	Canada, 2011b. Evaluation Report for Category B, Subcategory 2.1, 2.3, 2.4, 3.3 Application. Application Number: 2008-1614. Beetle Block - Verbenone. Registration Number: 29674.
2009534	Canada, 2012a. Evaluation Report for Category B, Subcategory 4.1 Application. Application Number: 2008-2282. Verbenone Pouch Mountain Pine Beetle Repellent. Registration Number: 28919.
2009613	Canada, 2012b. Evaluation Report for Category B, Subcategory 4.1 Application. Application Number: 2008-2533. Verbenone Pouch (7g load). Registration Number: 28645.
3357415	US EPA, 2018. Verbenone Interim Registration Review Decision Case Number 6031. March 2018.