Proposed Re-evaluation Decision PRVD2024-05

3-Methyl-2-cyclohexen-1-one and Its Associated End-use Products

Consultation Document

(publié aussi en français)

24 September 2024

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

Publications
Pest Management Regulatory Agency
Health Canada
2 Constellation Drive
8th floor, A.L. 2608 A
Ottawa, Ontario K1A 0K9

Internet: canada.ca/pesticides
pmra.publications-arla@hc-sc.gc.ca

Information Service:
1-800-267-6315
pmra.info-arla@hc-sc.gc.ca

Canada

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

Catalogue number: H113-27/2024-5E (print)
H113-27/2024-5E-PDF (PDF version)

Proposed re-evaluation decision for 3-methyl-2-cyclohexen-1-one and associated end use products

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 3-methyl-2-cyclohexen-1-one (also referred to as methylcyclohexenone), 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.

Methylcyclohexenone is an anti-aggregation pheromone (semiochemical) registered as an insect repellent to deter Douglas-fir beetle, *Dendroctonus pseudotsugae*, and spruce beetle, *Dendroctonus rufipennis*, from attacking Douglas-fir trees and spruce trees, respectively. Methylcyclohexenone is a naturally occurring pheromone produced by beetles (*Dendroctonus sp.),* and released after they successfully attack a host tree.

There are three commercial class end-use products containing methylcyclohexenone registered in Canada which are formulated as slow-release generators contained in individual bubble caps or dispensers. The product is applied at least two weeks prior to the expected attack flight of beetles by manually stapling individual bubble caps/dispensers to trees and stumps at a minimum height of 2.5 metres above ground. Currently registered products containing methylcyclohexenone can be found in the Pesticide Product Information Database and in Appendix I.

Methylcyclohexenone has a non-toxic mode of action and is of value in providing a pest management solution. Based on the current use pattern of methylcyclohexenone, dietary exposure (food and drinking water) to methylcyclohexenone is not anticipated. The potential health (occupational, residential, and bystander) and environmental risks are considered to be acceptable when products containing methylcyclohexenone are used according to the current label directions. As a result of re-evaluation, no additional mitigation measures are proposed, however, updates to standard label statements as per current labelling standards are proposed (Appendix II).

Key risk-reduction measures

Human health

- Update personal protective equipment to current standards.

Environment

- Update environmental precautions for aquatic environment and disposal.

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

This proposed re-evaluation decision is a consultation document and is subject to a 90-day public consultation period.[1] Please forward any comments to PMRA Publications. All products containing methylcyclohexenone that are registered in Canada are subject to this proposed re-evaluation decision.

Refer to Appendix I for details on specific products impacted by this proposed decision.

Next steps

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

Health Canada will accept written comments on this proposal up to 90 days from the date of publication of this document. Before making a re-evaluation decision on methylcyclohexenone, the comments received during the consultation period will be taken into consideration in preparation of re-evaluation decision document, which could result in revised risk mitigation measures. A science-based approach will be applied in making a final decision on methylcyclohexenone. Health Canada will then publish a final re-evaluation decision document, which will include the decision, the reasons for it, a summary of comments received on the proposed re-evaluation decision, and Health Canada's response to these comments.

Other information

When Health Canada makes its re-evaluation decision, it will publish a Re-evaluation Decision on 3-methyl-2-cyclohexen-1-one (based on the Science evaluation of PRVD2024-05). 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.

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

Science evaluation

Methylcyclohexenone is a naturally occurring pheromone released by *Dendroctonus sp.* beetles after they successfully attack a host tree. Methylcyclohexenone acts by affecting the behaviour of the target pest. The pheromone serves to prevent too many beetles from attacking the same tree, which would result in reproductive failure due to excessive competition among the beetles for the limited resources within the tree (Canada, 2010a).

Methylcyclohexenone is a biopesticide registered as an insect repellent to deter Douglas-fir beetle and spruce beetle from attacking Douglas-fir trees and spruce trees, respectively, including standing and fallen trees and stumps, individually and forests/woodlots, stands containing Douglas-fir or spruce trees, and log storage decks. Methylcyclohexenone end-use products are formulated as slow-release generators encased in a plastic matrix (individual bubble caps or dispensers).

1.0 Human health assessment

Health Canada has not established toxicology reference values for risk assessment and has used a qualitative approach to assess risks to human health (Canada, 2010a, Canada, 2010c & Canada, 2018).

Methylcyclohexenone is considered to be of slight acute toxicity by the oral route, low acute toxicity by the inhalation route, mildly irritating to the eyes and skin and not a skin sensitizer (Canada, 2010a & Canada, 2018). Precautionary statements to avoid contact with eyes and skin are currently on all product labels.

Worker exposure to methylcyclohexenone may occur by the dermal and inhalation routes during handling (such as when attaching the dispensers to trees, as well as during retrieval of used or dislodged dispensers). Workers are required to wear chemical resistant gloves and eye protection when handling the products. In addition, label directions are currently included in the labels informing workers not to puncture bubble caps/reservoirs or handle their contents (enclosed liquid methylcyclohexenone), avoid inhaling fumes, and to open storage bags outdoors prior to use and vent for 10 minutes before removing dispensers. The methylcyclohexenone concentration released by the dispensers per day will not exceed naturally occurring levels of pheromone that would be produced by Douglas-fir and spruce beetle populations during an infestation. A dispenser is expected to have a field life of 50 to 90 days. Based on the current use pattern, potential risk from handling and post-application activities is considered acceptable when current label instructions are followed. However, an update to the personal protective equipment including long-sleeved shirt, long pants, chemical-resistant gloves, protective eyewear (goggles or face shield), socks and shoes when handling the product is proposed to meet current labelling standards (Appendix II).

There are no domestic class products registered containing methylcyclohexenone. Residential exposure is not expected since applications are limited to woodlots, forests and sawmill yards. Bystander exposure is expected to be negligible because dispensers must be properly affixed to the tree at a minimum height of 2.5 metres above the ground, out of reach of children and pets, and applications are not to be made near, or in, areas frequented by small children and companion animals (for example, residential lots, parks, camping sites, resorts).

Based on the current use pattern and that the concentrations of methylcyclohexenone released from the dispensers would be below natural background levels, risks to bystanders are considered acceptable when end-use products containing methylcyclohexenone are used according to the current label directions.

Pest control products containing methylcyclohexenone are not registered for food and feed uses, and contamination of drinking water sources is expected to be minimal. Therefore, dietary exposure to methylcyclohexenone 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, dietary (food and drinking water) and residential exposures are not expected, thus aggregate risk assessment is not required.

The *Pest Control Products Act* requires that the PMRA consider the cumulative non-occupational (food, drinking water and residential) exposure to pest control products with a common mechanism of toxicity, based on the likelihood that people may be exposed to more than one of these pesticides at the same time. Accordingly, an assessment of potential common mechanism of toxicity with other pesticides was undertaken. While methylcyclohexenone may be structurally similar to other registered semiochemical active ingredients and to components in pest control products containing cyclic ketones, 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. However, under the currently approved conditions of use, no dietary or residential exposure to methylcyclohexenone is anticipated; therefore, a cumulative health risk assessment is not required at this time.

2.0 Environment assessment

Methylcyclohexenone is highly volatile and insoluble in water, therefore, it is not expected to leach into ground water or be persistent in water or soil. Methylcyclohexenone is unlikely to bioaccumulate under neutral conditions. Methylcyclohexenone has no dissociable moieties (Canada, 2010a). However, being highly volatile, non-target organisms could be exposed in the air. Based on the slow release rate compared to the natural level occurring during an infestation of Douglas-fir beetle or spruce beetles, exposure of non-target organisms to methylcyclohexenone under typical conditions of use is considered to be negligible. Thus, the use of end-use products (slow-release generators) is not expected to pose a risk to non-target organisms, including beneficial arthropods.

There is potential of exposure to non-target terrestrial organisms from direct consumption of the content of the dispensers. Methylcyclohexenone caused some signs of neurotoxicity in birds in laboratory studies such as loss of coordination, weakness of the extremities, and decreased responsiveness to external stimuli. However, field observations showed that birds are not likely to peck, tamper with or eat the bubble caps (Canada, 2010a). In addition, as the product inside the dispenser is a liquid, any puncture in the packaging would cause the immediate loss of fluid, and the potential exposure to birds is not expected to occur. Therefore, the label statement, "This product is toxic to (wild) birds." currently included on MCH Bubble Cap and Beetle Block MCH is not required and proposed to be removed from end-use products containing methylcyclohexenone. Furthermore, the likelihood of mammals consuming the dispenser or its enclosed liquid methylcyclohexenone is unlikely, thus exposure to mammals is considered to be minimal.

Methylcyclohexenone is insoluble in water and end-use products are not registered for use in aquatic habitats, therefore, exposure to aquatic organisms is expected to be minimal. Current labels include directions for use (including storage and disposal). Updates are proposed for the environmental precautions statements, for the aquatic habitat, to meet current labelling standards (Appendix II). No additional risk mitigation measures are proposed.

Methylcyclohexenone is not considered a Track 1 substance as it does not meet all of the criteria as per the Toxic Substance Management Policy.

3.0 Incident reports

As of 24 April 2024, no human, domestic animal or environmental incidents involving methylcyclohexenone as a pesticide have been reported to Health Canada's Incident Reporting program.

4.0 Value assessment

Methylcyclohexenone plays a role in Integrated Pest Management as it deters Douglas-fir beetle and spruce beetle from attacking Douglas-fir trees and spruce trees, respectively. No other pest control products are currently registered for use against either Douglas-fir beetle or spruce beetle to protect trees from attack.

Appendix I Registered products containing 3-Methyl-2-Cyclohexen-1-One in Canada

Table 1 Registered products containing 3-Methyl-2-Cyclohexen-1 One in Canada as of 16 July 2024[1]

Registration number	Marketing class*	Registrant	Product name	Formulation type	Guarantee
28638	T	Natural Resources Canada	MCH Technical	Liquid	98%
28637	C	Isca Technologies Inc.	MCH Bubble Cap	Slow-Release Generator	97%
29910	C	Chemtica Internacional S.A.	Beetle Block-MCH	Slow-Release Generator	97.5%
32922	C	Synergy Semiochemical Corporation	Synergy Shield MCH	Slow-Release Generator	97%

[1] As of 16 July 2024, excluding discontinued products or products with a submission for discontinuation.

* T = Technical Grade Active Ingredient; C = Commercial

Appendix II Proposed label updates for products containing 3-Methyl-2-Cyclohexen-1-One

Information on labels of currently registered products should not be removed unless it contradicts the label statements provided below.

For all products:

1. On the principal display, remove "Guarantee" and replace with "Active Ingredient".

For technical grade active ingredient:

2. Under DISPOSAL, update the following statement:

   "Canadian manufacturers should dispose unwanted active ingredient and containers in accordance with municipal or provincial regulations. For additional details and clean up of spills, contact the manufacturer or the provincial regulatory agency."

   With:

   "Canadian manufacturers should dispose of unwanted active ingredients and containers in accordance with municipal and provincial/territorial regulations. For additional details and cleanup of spills, contact the manufacturer and the provincial/territorial regulatory agency."

3. Under PRECAUTIONS, remove the following statement:

   "Do not contaminate irrigation water supplies or aquatic habitats by cleaning equipment or disposal of wastes."

For commercial class products:

4. Under PRECAUTIONS, update the personal protective equipment (PPE) with the following statement:

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

5. Update the following statement, and move to DIRECTIONS FOR USE:

   "Do not contaminate irrigation water supplies or aquatic habitats by cleaning equipment or disposal of wastes."

   With:

"DO NOT contaminate drinking water supplies or aquatic habitats by disposal of unused or used dispensers."

6. Replace "ENVIRONMENTAL HAZARDS" with "ENVIRONMENTAL PRECAUTIONS".

7. Under DIRECTIONS FOR USE, update the following statement:

   "DO NOT apply this product directly to freshwater habitats such as lakes, rivers, sloughs, ponds, prairie potholes, creeks, marshes, streams, reservoirs, ditches and wetlands, estuaries or marine habitats."

   With:

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

For PCP Reg Nos. 28637 and 29910:

8. Under ENVIRONMENTAL PRECAUTIONS, remove the following statement:

   "This product is toxic to (wild) birds."

References

PMRA No.	Reference
1929608	Canada, 2010a. Proposed Registration Decision, PRD2010-17
1952552	Canada, 2010b. Registration Decision, RD2010-19
1966290	Canada, 2010c. Evaluation Report for Category B, Subcategory 2.1, 2.3, 2.4, 3.1 Application, Application Number 2009-4950
2748147	Canada, 2018. Evaluation Report for Category B, Subcategory 3.1 Application, Application Number 2016-5734