

Proposed Special Review Decision

PSRD2020-02

Special Review for Metaldehyde and Its Associated End-use Products

Consultation Document

(publié aussi en français)

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1.0 Introduction

Pursuant to subsection 17(2) of the *Pest Control Products Act*, Health Canada's Pest Management Regulatory Agency (PMRA) has initiated a special review of metaldehyde (Canada, 2018) based on the decision taken by Norway to prohibit the use of metaldehyde due to environmental concerns (Rotterdam Convention, 2018; PIC Circular XLVII).

Pursuant to subsection 18(4) of the *Pest Control Products Act*, the PMRA has evaluated the aspect of concern that prompted the special review of pest control products containing metaldehyde. The aspect of concern for this special review is relevant to the environment.

2.0 Uses of Metaldehyde in Canada

Metaldehyde is a molluscicide used to control snails and slugs in a wide variety of use areas, including agricultural crops and home gardens, such as fruit and vegetable crops, and greenhouse and outdoor ornamentals. Metaldehyde is formulated as granular or liquid bait form and is applied by band treatment for commercial class products or by hand spray or dispersal for domestic class products to soil surfaces. All currently registered products containing metaldehyde (Appendix I) are considered in this special review.

3.0 Aspects of the Pest Control Product that Prompted the Special Review

Based on the review of the Norwegian decision (Rotterdam Convention, 2018; PIC Circular XLVII), the PMRA identified the aspect of concern that prompted the special review of metaldehyde as:

• Potential risk to birds and mammals.

4.0 Evaluation of the Aspect of Concern that Prompted the Special Review

In order to evaluate the aspect of concern, the PMRA has considered all currently available relevant scientific information, which includes existing reviews (Canada, 2008a; Canada, 2008b), and other relevant information (for example, incident reports, Norwegian decision, and relevant information published by the European Union (European Commission, 2011) and the United States Environmental Protection Agency (USEPA) (US EPA, 2006).

Following the initiation of the special review, the PMRA requested information related to the aspect of concern from provinces and other relevant federal government departments and agencies in accordance with subsection 18(2) of the *Pest Control Products Act*. No information was received.

4.1 Potential Risk to Birds and Mammals

The PMRA assessed potential acute risks to birds and mammals resulting from application of metaldehyde (Canada, 2008a, Canada, 2008b).

Metaldehyde is moderately toxic to mammals (LD₅₀ of 398 mg/kg) and slightly to moderately toxic to birds (LD₅₀ of 181 mg/kg) on an acute exposure basis (US EPA, 2006). Birds and mammals could be exposed to metaldehyde through direct ingestion of metaldehyde granules applied to the soil. Exposure estimates for terrestrial wildlife were based on the assumption that 100% of the applied granules were present on the surface of the soil following application. The screening level risk assessment showed that small- and medium-size avian and mammalian species are at risk from acute exposure to metaldehyde granules (RQs \leq 13) (Canada, 2008a, USEPA, 2006).

To reduce the potential exposure of metaldehyde to non-target organisms (birds and mammals), several mitigation measures are currently included on product labels (Canada, 2008b, 2016a, 2016b).

For example, broadcast and foliar applications of all metaldehyde products are prohibited. Only soil application as a barrier around gardens or individual plants is permitted. In addition, application is prohibited unless domestic animals can be excluded from the treated areas from the time of application until the applied product is no longer visible. All granular products are formulated so pellet size is small (>35 pellets/gram) to avoid products being mistaken for pet foods/wildlife forage items.

For domestic uses, exposure to non-target organisms is minimized when pellets are covered once applied to soil or mulch (Canada, 2016a, 2016b). Currently, this requirement is included on several domestic product labels. For consistency, this requirement is proposed for all domestic uses. To avoid attracting domestic animals, a bittering agent, such as denatonium benzoate,¹ has been added to all domestic class products to deter ingestion. Most granular product labels indicate that piling of pellets should be avoided and all labels require spilled pellets to be removed.

Warnings of the dangers to domestic animals as well as instructions on treatment if the product were ingested are on all commercial and domestic class end-use product labels. Label statements informing users of the toxicity of metaldehyde to birds and mammals are also currently included on all labels (Canada, 2008b).

Several labels have cultural controls that provide supplemental controls of slugs and snails which may reduce the damage and possibly decrease the need for metaldehyde use. Cultural controls include hand-picking, removing of plant debris that can shelter slugs and snails, and watering in the morning rather than in the evening (snails and slugs favour damp conditions and feed at night) (USEPA, 2006).

As part of the special review, the PMRA incident reporting database was searched for incident reports related to the identified aspect of concern for metaldehyde. No incident reports involving birds and granivorous mammals exposed to metaldehyde were submitted to the PMRA. However, there are 92 incident reports, including 86 domestic animal reports, in the PMRA database. Most cases (80 reports) involving domestic animals occurred in the United States

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Registered trademark as Bitrex of Macfarlene Smith Limited.

The six (6) Canadian incidents had minor or moderate effects. The subset of serious American. incidents indicates a potential for life-threatening effects including death in animals (involving mainly dogs) via ingestion when applied granular metaldehyde products are accessible to animals.

An USEPA review of domestic animal incidents conducted in 2015 indicated a decrease in the number of metaldehyde animal poisoning cases over time. A similar pattern is also observed in the number of serious American incidents submitted to the PMRA database. The observed decrease in serious American incidents may be due to the mitigation strategies that were implemented in the United States following the 2006 RED for metaldehyde. As the use pattern in the United States encompasses Canadian uses, the PMRA (as part of the re-evaluation of metaldehyde in 2008), adopted similar risk reduction measures, such as, prohibiting broadcast applications and adding a bittering agent to all domestic products (Canada, 2008a). Hence, no additional mitigation measures relevant to the current aspect of concern are being proposed following the incident report review.

Based on the above considerations, the PMRA concluded that the potential risk to birds and mammals are considered to be acceptable under the current conditions of use. However, for consistency, the following proposed risk reduction measures are proposed:

- Instructions on all commercial and domestic pellet products to avoid applying pellets in piles, and over applying.
- Instructions on all domestic pellet labels to moisten and cover pellets with boards, flat stone, etc.
- Recommend certain cultural practices that may reduce damage from snails and slugs to all products.

5.0 Proposed Special Review Decision for Metaldehyde

Evaluation of available information related to the aspect of concern indicates that the potential risk to birds and wild mammals are considered to be acceptable under current conditions of use. However, for consistency between product labels, label amendments are proposed to be included on product labels.

On this basis, Health Canada's Pest Management Regulatory Agency, pursuant to subsection 21(1) of the *Pest Control Products Act*, is proposing continued registration of metaldehyde products for sale and use in Canada with additional mitigation measures (for consistency). The proposed label amendments are summarized in Appendix II.

This proposed special review decision is a consultation document. The PMRA will accept written comments on this proposal up to 45 days from the date of publication of this document. All comments are to be directed to PMRA Publications (contact information on the cover page of this document).

6.0 Next Steps

Before making a final decision on the special review of metaldehyde, the PMRA will consider all comments received from the public in response to this consultation document. The PMRA will then publish a special review decision document, which will include the decision, the reasons for it, a summary of the comments received on the proposed decision, and the PMRA's response to these comments.

Appendix I Registered Products Containing Metaldehyde

Registration Number	Marketing Class	Registrant	Product Name	Guarantee
997	D	Matson LLC	Corry's Slug & Snail Death	2%
10304	D	Premier Tech Ltd	Wilson Slugout Pellets	2.75%
20785	D	Matson LLC	Corry's Liquid Slug & Snail Control	4%
22689	Т	Lonza Inc.	Meta-Metaldehyde Technical Molluscicide	98%
25908	D	Premier Tech Ltd	Wilson Slugout Meal	2%
26650	С	Amvac Chemical Corporation	Deadline M-PS	4%
28287	D	King Home & Garden Inc.	King Slug & Snail Pellets	2.75%
32149	С	Lonza Inc.	Axcela	3%
32150	D	Lonza Inc.	Xiren	3%
32392	Т	Sharda Cropchem Limited	Sharda Metaldehyde Technical	99.36%
32483	D	Sharda Cropchem Limited	Escar-go 3	3%
32484	D	Sharda Cropchem Limited	Escar-go 5	5%

C = Commercial; D = Domestic; T = Technical

Appendix II Label Amendments

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

APPLICATION DIRECTIONS

1. Add the following statement on the commercial-class product labels (Reg. Nos. 26650 and 32149)

"Avoid applying pellets in piles."

2. Add the following statement on all domestic and commercial class product labels (Reg. Nos. 997, 10304, 20785, 25908, 26650, 28287, 32149, 32150, 32483 and 32484)

"Do not over apply."

3. Add the following statement on the domestic-class product labels (Reg. Nos. 997, 10304 and 32150)

"Moisten pellets slightly and cover with boards, bricks, flat stones, etc."

4. Add the following statement on domestic-class product Reg. 25908:

"Moisten pellets slightly."

5. Add the following statements on domestic and commercial-class product labels (Reg. Nos. 10304, 25908, 26650, 32149, 32483 and 32484)

"Certain cultural practices may reduce damage from snails and slugs. These practices include:

- Eliminating hiding places by removing leave litter and debris in the garden;
- Removing slugs and snails during daylight hours from nearby leaf litter, mulch and other protected areas
- Watering in the morning to reduce humidity during the night when snails and slugs are active"

References

I) Information Considered in the Special Review not Supplied by Registrant

Published

PMRA Document	Reference
Number	
2677806	Canada. Pest Management Regulatory Agency. 2016a. Evaulation
	Report for Category B, Subcategory 2.3, 2.4 and 3.1 Application, Escar-
	go 3. Reference Number: 2015-3328. Registration Number: 32483.
2677803	Canada. Pest Management Regulatory Agency. 2016b. Evaluation
	Report for Category B, Subcategory 2.3, 2.4 and 3.1 Application, Escar-
	go 5. Reference Number: 2015-3330. Registration Number: 32484.
1601081	Canada. Pest Management Regulatory Agency. 2008a. Proposed Re- evaluation Decision PRVD2008-15, <i>Metaldehyde</i> , Consultation
	Document. 25 April 2008.
1668301	Canada. Pest Management Regulatory Agency. 2008b. Re-evaluation Decision Document RVD2008-34, <i>Metaldehyde</i> . 12 November 2008.
2930206	Canada. Pest Management Regulatory Agency. 2018. Section 18 (1)
	Announcement of Initiation of Re-evaluation: Metaldehyde. Reference
	Number: 2018-5174, 29 October 2018.
3092624	US EPA. 2006. Reregistration Eligibility Decision for Metaldehyde. 27 July 2006
3092623	European Commission, 2011. Review Report for the active substance
	Metaldehyde finalised in the Standing Committee on the Food Chain and
	Animal Health at its meeting on 11 March 2011 in view of the inclusion
	of metaldehyde in Annex I of Directive 91/414/EEC.
3092622	Rotterdam Convention, June 2018. PIC Circular XLVII (47).
3092621	Rotterdam Convention, 2018. Database of Notifications of Final
	Regulatory Action. Norway Final Regulatory Action, <i>Metaldehyde</i> . 12 June 2018.