Proposed Re-evaluation Decision

PRVD2022-08

Methyl Nonyl Ketone and Its Associated Enduse Products

Consultation Document

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Proposed re-evaluation decision

Under the *Pest Control Products Act*, all registered pest control products, including animal repellents, must be regularly re-evaluated 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 methyl nonyl ketone 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.

Methyl nonyl ketone is registered in Canada for use as an animal repellent against cats and dogs in a wide range of indoor and outdoor domestic settings such as on furniture, carpets, flowerbeds, lawns, patios and garbage cans. It can be applied as a spray (indoor and outdoor), or by spreading the granular product by hand or with a fertilizer spreader (outdoor). It acts by confusing the animal's sense of smell and discouraging it from visiting the treated area. Currently registered products containing methyl nonyl ketone can be found in Appendix I.

Registered pest control product labels include specific instructions, including risk mitigation measures to protect human health and the environment, which must be followed by law. When the current label directions are followed, these products were shown to have value in providing a pest management solution, and potential risks to human health (residential and bystander) and the environment (aquatic and terrestrial organisms and their habitats) are considered to be acceptable. Based on the current use pattern, occupational and dietary exposure are not expected. As a result of the re-evaluation of methyl nonyl ketone, no additional risk mitigation measures are proposed by Health Canada. However, updates to precautionary label statements are proposed as per current labelling standards.

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

All products containing methyl nonyl ketone registered in Canada are subject to this proposed reevaluation decision. This document is subject to a public consultation, during which written comments and additional information may be submitted to <u>PMRA Publications</u>. The final reevaluation decision will be published taking into consideration the comments and information received during the consultation period.

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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 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 PMRA's responses.

Other information

When Health Canada makes its re-evaluation decision, it will publish a Re-evaluation Decision on methyl nonyl ketone (based on the Science Evaluation of PRVD2022-08). 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.

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

Science Evaluation

Methyl nonyl ketone is registered for use as an animal repellent against cats and dogs in a wide range of indoor and outdoor domestic settings such as on furniture, carpets, flowerbeds, lawns, patios and garbage cans.

1.0 Human health

Methyl nonyl ketone is a natural substance produced by many plants, and is not expected to present a toxicological concern. Natural background exposures are not associated with any known hazards to humans. Health Canada did not establish toxicological reference values for human health risk assessment and used a qualitative approach to the human health assessment.

Methyl nonyl ketone is not registered for use on food or feed crops, and drinking water contamination is considered unlikely. Therefore, dietary exposure from the registered uses of methyl nonyl ketone is not anticipated.

There are no commercial-class products containing methyl nonyl ketone registered in Canada and domestic-class products are not anticipated to be used in occupational settings. Therefore, occupational exposure is not anticipated under current conditions of use.

Based on the registered use patterns of methyl nonyl ketone, there is potential for dermal and inhalation exposure for residential handlers, specifically during the application of granular products by hand and by lawn spreaders, and of liquid sprays to ornamentals, furniture and rugs. Postapplication exposure is possible when individuals in residential settings come in contact with treated surfaces; however, postapplication risk is not expected to be significant.

Methyl nonyl ketone is considered to be of low toxicity to humans and animal repellent uses are not expected to result in significant human exposures. Therefore, the potential risk resulting from domestic use of methyl nonyl ketone is expected to be acceptable under current conditions of use. For good hygiene practices, the current product labels recommend that users wear gloves during applications. No additional mitigation measures are proposed. However, as per current labelling standards, the label statement should be updated to recommend users wear waterproof gloves.

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). Exposure to methyl nonyl ketone from food and drinking water is not expected. Although there is potential for residential exposure, since methyl nonyl ketone is considered to be of low toxicity to humans, there is no residential risk of concern. Therefore, an aggregate risk assessment is not required.

The *Pest Control Products Act* requires that Health Canada considers the cumulative exposure to pesticides with a common mechanism of toxicity. For the current re-evaluation, Health Canada has not identified information indicating that methyl nonyl ketone shares a common mechanism of toxicity with other pest control products. Therefore, a cumulative risk assessment is not required at this time.

2.0 Environment

Methyl nonyl ketone is soluble in water, but is stable to hydrolysis. In soil, it degrades rapidly through aerobic biotransformation. Its vapour pressure and Henry's law Constant indicate a potential for volatilization from moist soil and water. Methyl nonyl ketone has a low potential to leach into groundwater. Its octanol-water partition coefficient indicates a potential to bioaccumulate; however, it is not persistent in the environment. Therefore, accumulation in biota is not expected to occur. Methyl nonyl ketone does not meet all Track 1 criteria, and is not considered a Track 1 substance.³ Based on the use pattern, environmental releases of methyl nonyl ketone are expected to be negligible.

Methyl nonyl ketone is practically non-toxic to birds, moderately toxic to fish, and highly toxic to aquatic invertebrates.

The potential risk to the environment (aquatic and terrestrial) from the use of methyl nonyl ketone, as a cat and dog repellent in residential settings, is considered acceptable under the current conditions of use. For consistency between product labels, precautionary label statements are proposed to be included to advise users that the products are not to be applied to pets or in wildlife habitat areas (for example, parklands, forested areas). No additional mitigation measures are proposed.

3.0 Value

Methyl nonyl ketone is an animal repellent used against cats and dogs in a wide range of indoor and outdoor domestic settings such as on furniture, carpets, flowerbeds, lawns, patios, and garbage cans. It is used as a deterrent to stop undesirable habits such as sleeping on furniture and soiling outdoor flowerbeds. Label updates are proposed to meet the current labelling standards and to provide clarity on the use of the products (Appendix II).

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PMRA Regulatory Directive DIR99-03, The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy.

Appendix I Registered products containing methyl nonyl ketone in Canada

Table 1 Registered products containing methyl nonyl ketone in Canada⁴

Registration number	Marketing class	Registrant	Product name	Formulation type	Guarantee (MNK)
21574	Т	McLaughlin Gormley King Company (MGK)	MGK Dog & Cat Repellent	Solution	99.7%
21575	M	McLaughlin Gormley King Company (MGK)	MGK Dog & Cat Repellent Emulsifiable F-1770	Emulsifiable Concentrate or Emulsion	66.67%
10403	D	Rolf C. Hagen Inc. (HAC)	Hagen Aerosol Indoor Cat Repellent	Pressurized Product	1.9%
12857	D	Premier Tech Ltd. (RMT)	Wilson Granular Dog & Cat Repellent	Granular	1.9%
20362	D	K-G Spray-Pak Inc. (KGS)	K-G Dog And Cat Repellent Pressurized Spray	Pressurized Product	1.9%
21733	D	King Home & Garden Inc. (KHG)	Get Off My Garden Dog & Cat Repellent	Liquid	1.9%
21791	D	King Home & Garden Inc. (KHG)	Get Off My Garden Dog & Cat Repellent Spray	Emulsifiable Concentrate or Emulsion	2.1%
22094	D	Rolf C. Hagen Inc. (HAC)	Hagen Indoor Repellent For Cats	Solution	1.9%
22095	D	Rolf C. Hagen Inc. (HAC)	Hagen Outdoor Repellent For Dogs & Cats	Solution	1.9%
22246	D	Rolf C. Hagen Inc. (HAC)	Hagen Indoor Repellent For Dogs	Solution	1.9%
22780	D	K-G Spray-Pak Inc. (KGS)	Spray-Pak Repellent For Dogs & Cats	Pressurized Product	1.9%
22781	D	Les Accesoires Hunter Brand Inc. (AHB)	Hunter's Repellent For Dogs & Cats	Pressurized Product	1.9%
25194	D	Rolf C. Hagen Inc. (HAC)	Sergeant's Shoo! Dog & Cat Repellent & Training Aid	Pressurized Product	1.9%
29043	D	753146 AB Ltd. O/A Ultrasol Industries (ULT)	Doktor Doom Indoor And Outdoor Dog And Cat Repellent	Pressurized Product	1.9%
30414	D	Business Helpers' Depot Inc. (BHD)	Sure Guard M-7	Pressurized Product	1.9%

As of 13 January 2022, excluding discontinued products or products with a submission for discontinuation.

Registration number	Marketing class	Registrant	Product name	Formulation type	Guarantee (MNK)
30982	D	Novella Brands Inc. (NVE)	Blaze Pro Animal Repellent	Pressurized Product	1.9%
31931	D	Woodstream Canada Corporation (SFR)	Chemfree Cat & Dog Repellent	Pressurized Product	1.9%

^{*} T = Technical, M = Manufacturing Concentrate, D = Domestic

Appendix II Label updates for end-use products containing methyl nonyl ketone

To meet current standards, the following label amendments are proposed:

I. The following statement under the PRECAUTIONS section:

Replace "gloves" with "waterproof gloves"

II. The following statements are proposed to be included under PRECAUTIONS section:

"Do not treat pets with this product.

Do not apply in wildlife habitat areas (e.g., Parklands, forested lands)."

- III. The principal display panel must reflect all the use locations stated in the DIRECTIONS FOR USE in the secondary panel of the label. For example, "Cat and Dog Repellent for use outdoors on shrubs and trees adjacent to buildings and on outdoor garbage cans".
- IV. The primary and secondary panel must clearly identify whether the product is "FOR INDOOR USE ONLY", "FOR OUTDOOR USE ONLY" and "FOR INDOOR OR OUTDOOR USE". Label instructions must be consistent with where the product is to be used throughout the label (for example, no references to outdoor uses if product is used indoors only).
- V. Locations of use must clearly be identified on a label and reflect the registered use-site category. Vague statements must be deleted or amended. This includes but is not limited to: "...forbidden areas of your home". General terms may be used in a statement that clearly identifies specific locations. For example, "Cat and Dog repellent for use on indoor building surfaces and furniture".
- VI. Directions for use must be clear for each site/pest combination and contain all information regarding the use of the product. For example, claims, location of use, timing and frequency of application and any limitations on its use.
- VII. Re-treatment intervals must include a statement that application of the product should not continue once the undesirable habits of your pet or stray animals has changed. For example, "Discontinue use once the behaviour of getting on the structure or furniture has stopped."
- VIII. Remove references to "retreat as necessary" or equivalent. A specific retreatment interval (for example, daily) must be stated.
- IX. For products applied outdoors, add: "DO NOT apply in areas where plants are grown for food or feed (e.g., vegetables, fruit, and herbs)."

- X. Where there is a potential of damage, non-safety adverse effects statements should be added such as "Users should test (treat) a small, inconspicuous area first to ensure there are no adverse effects such as staining or discolouration.", "Before spraying large areas, test the potential damage of the repellent by first treating a small inconspicuous area" and "It is advisable to treat a small portion of plants or lawns to determine if damage will occur."
- XI. Refer to the following PMRA regulatory policies and guidelines listed below for more details on the required labelling elements for pesticide products:

Checklist of Labelling Requirements for Pest Control Products.

LPS2011-02, Guidance to Improve Statements on Labels of Domestic Class Products.

References

Published information

PMRA	Reference
number	
748821	Canada, 2004. Proposed Acceptability for Continuing Registration. <i>Re-evaluation of</i>
	Methyl Nonyl Ketone. PACR2004-06. 21 April 2004.
830907	Canada, 2004. Re-evaluation Decision Document. Methyl Nonyl Ketone. RRD2004-
	17. 12 July 2004.