

Proposed Acceptability for Continuing Registration

Re-evaluation of Methyl Nonyl Ketone

The purpose of this document is to inform the registrants, pesticide regulatory officials and Canadian public that the Pest Management Regulatory Agency (PMRA) has completed a re-evaluation of methyl nonyl ketone. The PMRA has determined that methyl nonyl ketone is acceptable for continued registration provided that the proposed mitigation measures are adopted and the data requirements are addressed.

This Proposed Acceptability for Continuing Registration (PACR) document provides a rationale for the proposed regulatory decision for methyl nonyl ketone. The PMRA will accept written comments on this proposal up to 45 days from the date of publication of this document. Please forward all comments to the Publications Coordinator at the address below.

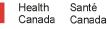
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1.0 Background

The PMRA is re-evaluating all pesticides, both active ingredients and formulated end-use products, that were registered prior to 31 December 1994 to ensure that their continued acceptability is examined using current scientific approaches. Regulatory Directive DIR2001-03, *PMRA Re-evaluation Program*, presents the details of the re-evaluation activities and program structure.

Methyl nonyl ketone has been re-evaluated by the PMRA under Re-evaluation Program 1 as described in DIR2001-03. Under Program 1, the PMRA relies as much as possible on foreign reviews, typically United States Environmental Protection Agency (USEPA) Reregistration Eligibility Decision (RED) documents, to assess Canadian pest control products. For products to be re-evaluated under Program 1, there must exist a suitable foreign review that meets the following conditions:

- it covers the main science areas that are necessary for Canadian regulatory decisions;
- it addresses the active ingredient itself and its main formulation types registered in Canada; and
- it is relevant to registered Canadian uses.

Based on the outcome of the USEPA review, the PMRA will propose, under Program 1, a regulatory decision and appropriate mitigation measures for Canadian uses of an active ingredient.

The USEPA conducted a re-evaluation of methyl nonyl ketone and concluded, on the basis of a health and environmental risk assessment, that it was eligible for reregistration with implementation of mitigation measures. PMRA conclusions on the methyl nonyl ketone re-evaluation were based on the USEPA RED document (USEPA 1995)¹ for methyl nonyl ketone, with consideration of the Canadian use pattern and Canadian issues (e.g., the Canadian Toxic Substance Management Policy [TSMP]).

The USEPA RED document for methyl nonyl ketone is available from the Chemical Status List on the Office of Pesticide Programs Web site at <u>www.epa.gov/pesticides/reregistration</u>

2.0 Re-evaluation of methyl nonyl ketone

Active substance:	Methyl nonyl ketone
Common name:	Methyl nonyl ketone
Chemical name:	2-undecanone
CAS number:	112-12-9
Chemical structure:	
Empirical formula:	$C_{11}H_{22}O$
Molecular weight:	170
Technical registrant:	McLaughlin Gormley King Co.
Purity of technical:	95.0% (minimum)

Methyl nonyl ketone was first registered in 1968. It is an animal repellent used in indoor and outdoor domestic settings. It is used as a deterrent for dogs and cats in order to prevent soiling of indoor and outdoor domestic sites such as furniture, carpets, flower beds, shrubs, lawns, patios and garbage cans. Canadian products containing methyl nonyl ketone registered as of 31 December 2003 are listed in Appendix I.

Canadian registered use sites, application rates, application methods and formulation types are also registered in the United States, and the USEPA assessment described in the RED document for methyl nonyl ketone is considered to be an adequate basis for the proposed Canadian re-evaluation decision. The details of the health and environmental risk assessments conducted by the USEPA are outlined in the USEPA RED for methyl nonyl ketone.

The federal TSMP² and Regulatory Directive DIR99-03³ were taken into consideration during the review of methyl nonyl ketone and it was determined that methyl nonyl ketone is not a TSMP Track 1 substance. The technical product is not expected to contain impurities of toxicological concern as identified in DIR98-04 or TSMP Track 1 substances as identified in Appendix II of DIR99-03.

3.0 Proposed re-evaluation decision

The USEPA published a RED document for methyl nonyl ketone that addressed the main science areas necessary for Canadian regulatory decisions, i.e., human health and the environment. This document addressed uses of methyl nonyl ketone that are also registered in Canada. Based on the USEPA RED and Canadian use patterns, the PMRA has determined that methyl nonyl ketone is acceptable for continued registration provided that the mitigation measures specified below are adopted and the data requirements outlined in this document are addressed.

It should be noted that end-use products containing several active ingredients under re-evaluation will not be considered acceptable for continued registration until the re-evaluation of all of the active ingredients is complete.

The PMRA will accept written comments on this proposal up to 45 days from the date of publication of this document to allow interested parties an opportunity to provide input into the proposed re-evaluation decision for these products.

4.0 Proposed regulatory action

Based on the USEPA RED, in consideration of the Canadian use pattern and basic hygiene practices, Canadian end-use product labels should be amended to include the following statements.

- (a) All end-use product labels
 - (i) In the "Directions for Application" section:
 - "Apply only in areas adjacent to buildings. Do not apply in wildlife habitat areas (e.g., parklands, forested lands)."

² The federal TSMP is available through Environment Canada's website at <u>www.ec.gc.ca/toxics</u>

³ The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy, Dir99-03, is available through the Pest Management Information Service. Phone: 1 800 267-6315 within Canada or (613) 736-3799 outside Canada (long distance charges apply); Fax: (613) 736-3798; E-mail: <u>pmra_infoserv@hc-sc.gc.ca</u> or through our Web site at <u>www.hc-sc.gc.ca/pmra-arla</u>

- (ii) In the "Precautions" section:
 - "Wear rubber gloves when applying this product by hand." "Do not apply this product in a way that it will contact any person or pet, either directly or through drift."
 - "Do not apply to food/feed crops or animals."
- (iii) In the "Environmental Hazards" section:
 - "Do not apply directly to aquatic habitats (such as lakes, rivers, sloughs, ponds, coulees, prairie potholes, creeks, marshes, streams, reservoirs or wetlands) or estuarine/marine habitats. DO NOT contaminate water by cleaning equipment or disposing of wastes."
- (b) Liquid formulation end-use product labels
 - (i) In the "Precautions" section:
 - "Do not allow persons or pets to enter the treated area until the spray has dried."

These label amendments do not include all label requirements for individual end-use products, such as first aid statements, disposal statements, precautionary statements and supplementary protective equipment. Additional information on labels for currently registered products should not be removed unless it contradicts these proposed label statements.

A submission to request label revisions is required within 90 days of finalization of the reevaluation decision.

5.0 Additional data requirements

The registrant of technical grade methyl nonyl ketone is required to submit the following within 24 months of finalization of the re-evaluation decision:

- all data (as they relate to Canadian use patterns) submitted to the USEPA in response to the data call-in in the United States prior to reregistration, and USEPA Data Evaluation Reports (DERs);
- a commitment and schedule to address Canadian requirements that are not addressed through submission of the data outlined above.

Science-based rationales to support submitted data waivers may be acceptable.

The aforementioned data and additional data may be required sooner if expansion of current uses of methyl nonyl ketone is requested.

Appendix I Canadian methyl nonyl ketone products currently registered (as of 31 December 2003)

Product name	Registrant	Registration number	Guarantee	Class*
MGK Dog and Cat Repellent	McLaughlin Gormley King Co.	21574	95%	Т
MGK Dog and Cat Repellent Emulsifiable F-1770	McLaughlin Gormley King Co.	21575	63.33%	М
Hartz Indoor No Repellent Pressurized Spray	Hartz Canada, Inc.	10153	1.9%	D
Hartz Help! Stay Off Training Aid Pressurized Spray	Hartz Canada, Inc.	10154	1.9%	D
Hagen Indoor Repellent for Cats	Hagen, Rolf C., Inc.	10403	1.9%	D
Wilson Repell Granular Dog and Cat Repellent	Nu-Gro IP, Inc.	12857	1.9%	D
CCL Dog and Cat Repellent Pressurized Spray	K-G Packaging	20362	1.9%	D
Wilson R.T.U. Repell Dog and Cat Repellent	Nu-Gro IP, Inc.	21453	1.9%	D
Get Off My Garden	King Home and Garden, Inc.	21733	1.9%	D
Get Off My Garden Indoor/Outdoor Dog and Cat Repellent	King Home and Garden, Inc.	21791	1.9%	D
Chemac Quick 'N Easy Dog and Cat Repellent	Chemac Industries, Inc.	21944	1.9%	D
Hagen Indoor Repellent for Dogs and Cats	Hagen, Rolf C., Inc.	22094	1.9%	D
Hagen Outdoor Repellent for Dogs and Cats	Hagen, Rolf C., Inc.	22095	1.9%	D
Hagen Indoor Repellent for Dogs and Cats	Hagen, Rolf C., Inc.	22246	1.9%	D
Spray-Pak Repellent for Dogs and Cats	Spray-Pak Industries, Inc.	22780	1.9%	D
Hunter's Repellent for Dogs and Cats	Accessoires Hunter Brand, Inc.	22781	1.9%	D

Product name	Registrant	Registration number	Guarantee	Class*
Avant Guard Granular Outdoor Dog and Cat Repellent	Avant Sales	23450	1.9%	D
Avant Guard Dog and Cat Training Aid and Repellent	Avant Sales	23465	1.9%	D
Hagen Outdoor Repellent for Dogs and Cats	Hagen, Rolf C., Inc.	23475	1.9%	D
Dex-Off Dog and Cat Repellent	Beaphar B.V.	24358	1.9%	D
Sergeant's Shoo Dog and Cat Repellent and Training Aid	Sergeant's of Canada	25194	1.9%	D
Active Dog and Cat Repellent	Hawco Products Ltd.	25659	1.9%	D
Later's Dog and Cat Repellent	Later Chemicals Ltd.	26234	1.9%	D
Hartz Help! Stay Off Training Aid Pet Repellent	Hartz Canada Inc.	26393	1.9%	D
Reppers Outdoor Repellent for Cats and Dogs	Beaphar B.V.	27028	7.6%	D

*T = Technical; M = Manufacturing Concentrate; D = Domestic