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Re-evaluation Decision

RVD2022-11

p-Menthane-3,8-diol and Its Associated End-use Products

Final Decision

(publié aussi en français)

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Re-evaluation decision for p-Menthane-3,8-diol and associated end-use products

Under the authority of the *Pest Control Products Act*, all registered pesticides must be re-evaluated by Health Canada's Pest Management Regulatory Agency (PMRA) to ensure that they meet current health and environmental standards and have value. The re-evaluation considers data and information from pesticide manufacturers, published scientific reports and other regulatory agencies, as well as comments received during public consultations. Health Canada applies internationally accepted risk assessment methods as well as current risk management approaches and policies.

p-Menthane-3,8-diol is a synthetic analogue of a compound derived from the lemon eucalyptus plant. Products containing p-menthane-3,8-diol are applied as personal insect repellents and repel mosquitoes, biting midges, blackflies and ticks following application. Currently registered products containing p-menthane-3,8-diol can be found in the Pesticide Product Information Database and in Appendix I.

The Proposed Re-evaluation Decision PRVD2021-14, *p-Menthane-3,8-diol* containing the evaluation of p-menthane-3,8-diol and proposed decision, underwent a 90 day consultation period ending on 20 March 2022. PRVD2021-14 proposed continued registration of all uses of p-menthane-3,8-diol and associated end-use products registered for sale and use in Canada.

Health Canada received comments relating to the health assessment. Commenters are listed in Appendix II. These comments are summarized in Appendix III along with the responses by Health Canada. These comments did not result in revisions to the health assessment, but did result in changes to the cumulative assessment wording of the proposed re-evaluation decision as described in PRVD2021-14.

A reference list of information used as the basis for the proposed re-evaluation decision is included in PRVD2021-14. There was no further information used in the re-evaluation decision. Therefore, the reference list of all information used in the proposed re-evaluation decision, set out in PRVD2021-14, represents the complete reference of information used in this final re-evaluation decision.

This document presents the final re-evaluation decision¹ for the re-evaluation of p-menthane-3,8-diol. All products containing p-menthane-3,8-diol that are registered in Canada are subject to this re-evaluation decision.

Re-evaluation decision for p-Menthane-3,8-diol

Health Canada has completed the re-evaluation of p-menthane-3,8-diol. Under the authority of the *Pest Control Products Act*, Health Canada has determined that continued registration of products containing p-menthane-3,8-diol is acceptable. An evaluation of available scientific

¹ "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

information found that the uses of p-menthane-3,8-diol products meet current standards for protection of human health and the environment and have acceptable value when used according to conditions of registration.

Other information

Any person may file a notice of objection² regarding this decision on p-menthane-3,8-diol within 60 days from the date of publication of this Re-evaluation Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the Pesticides section of the Canada.ca website (Request a Reconsideration of Decision) or contact Health Canada's Pest Management Information Service.

The relevant confidential test data on which the decision is based (as referenced in PRVD2021-14) are available for public inspection, upon application, in Health Canada's Reading Room. For more information, please contact Health Canada's Pest Management Information Service.

² As per subsection 35(1) of the *Pest Control Products Act*.

Appendix I Registered products containing p-Menthane-3,8-diol in Canada

Table 1 Products containing p-Menthanol-3,8-diol that do not require label amendments¹

Registration number	Class	Registrant	Product name	Formulation type	Guarantee
27193	Technical	S. C. Johnson and Son, Ltd.	p-Menthane-3,8-diol Technical	Dust or powder	p-Menthane-3,8-diol 99 %
27194	Domestic	S. C. Johnson and Son, Ltd.	OFF! Botanicals Insect Repellent 1	Emulsifiable concentrate or emulsion	p-Menthane-3,8-diol 10 %
29313	Domestic	S. C. Johnson and Son, Ltd.	OFF!® Familycare Botanicals Insect Repellent Lotion	Emulsifiable concentrate or emulsion	p-Menthane-3,8-diol 10 %
33948	Domestic	S. C. Johnson and Son, Ltd.	OFF!® Familycare® Botanicals® Insect Repellent Pump Spray	Solution	p-Menthane-3,8-diol 10 %
34004	Domestic	S. C. Johnson and Son, Ltd.	OFF!® Botanicals Insect Repellent Spritz	Solution	p-Menthane-3,8-diol 10 %
34008	Domestic	S. C. Johnson and Son, Ltd.	OFF!® Botanicals Insect Repellent Lotion	Emulsifiable concentrate or emulsion	p-Menthane-3,8-diol 10 %

¹ as of 28 April 2022, excluding discontinued products or products with a submission for discontinuation

Appendix II List of commenters to PRVD2021-14

List of commenters' affiliations for comments submitted in response to PRVD2021-14

Category	Commenter
Other registrant	Citrefine International Ltd.

Appendix III Comment(s) and response(s)

Health Canada received two comments during the public consultation for the p-menthane-3,8-diol proposed re-evaluation decision. Commenters' affiliations are listed in Appendix II. These comments were considered during the final decision phase of this re-evaluation. Summarized comments and Health Canada's responses to them are provided below.

1.0 Comment(s) related to the health risk assessment

1.1 Toxicology

1.1.1 Comment

Comments related to toxicology were received from Citrefine International Ltd.

The registrant is requesting that wording in the cumulative assessment be clarified to indicate that p-Menthane-3,8-diol can be derived from the lemon eucalyptus plant to account for both natural and synthetic sources and to correct the name of a referenced active to "oil of lemon eucalyptus, hydrated, cyclized".

Health Canada response

The registrant's changes are accepted and the following paragraph represents the updated version of the cumulative assessment.

The *Pest Control Products Act* requires that the PMRA consider the cumulative exposure to pesticides with a common mechanism of toxicity. Accordingly, an assessment of a potential common mechanism of toxicity with other pesticides was undertaken. p-Menthane-3,8-diol can be derived from the lemon eucalyptus plant. Although there is another registered pesticide derived from the same plant, oil of lemon eucalyptus, hydrated, cyclized, given that both active ingredients are registered uniquely as a personal insect repellent, co-exposure is unlikely. Therefore, a cumulative assessment for p-menthane-3,8-diol is not required at this time.