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Re-evaluation Note

REV2018-16

# Re-evaluation Project Plan for p-Menthane- 3,8-diol

*(publié aussi en français)*

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## Background

In Canada, p-Menthane-3,8-diol is under re-evaluation by Health Canada's Pest Management Regulatory Agency (PMRA). The PMRA re-evaluates registered pesticides to determine whether the use of these products continues to be acceptable in terms of value, human health and the environment according to current standards.

The active ingredient p-Menthane-3,8-diol is a synthetic analogue of a compound derived from the lemon eucalyptus plant. It is registered as a skin-applied personal insect repellent against mosquitos and blackflies. As of 16 October 2018, a total of three products containing p-Menthane-3,8-diol are registered in Canada, including one technical grade active ingredient and two domestic-class end-use products.

Under the authority of section 16 of the *Pest Control Products Act*, the registrant of p-Menthane-3,8-diol was notified of the initiation of the re-evaluation of p-Menthane-3,8-diol. Following this, the registrant of p-Menthane-3,8-diol technical grade active ingredient in Canada indicated support of all uses included on the labels of end-use products in Canada.

The re-evaluation project plan below outlines the timeline, the anticipated areas of focus for the risk assessments, and the data requirements for the re-evaluation of p-Menthane-3,8-diol.

## Re-evaluation Project Plan

### Anticipated Re-evaluation Timeline

The re-evaluation of p-Menthane-3,8-diol is defined as a Category 1 as described in Regulatory Directive DIR2016-04, *Management of Pesticides Re-evaluation Policy*. For this re-evaluation, 980 calendar days are required between re-evaluation initiation and publication of the proposed decision. Currently, a proposed re-evaluation decision for p-Menthane-3,8-diol is anticipated to be published for consultation by October 2020. The re-evaluation timeline may be updated if, during the risk assessment, the PMRA identifies additional areas of focus that should be considered.

### Human Health Risk Assessment

New assessments will be conducted for toxicology, occupational exposure and residential exposure in order to be consistent with Regulatory Directive DIR2017-02, *Essential Oil-based Personal Insect Repellents (EOPIR)*.

### Environmental Risk Assessment

Existing assessments with minor updates are considered to be adequate to support the re-evaluation of p-Menthane-3,8-diol.

## **Value**

The value of p-Menthane-3,8-diol will be considered. The viability of alternatives will be examined for certain uses if risks of concern requiring mitigation are identified.

## **Data Requirements**

The PMRA has identified the need for the technical registrant to provide data for p-Menthane-3,8-diol related to chemistry, toxicology and occupational and/or bystander exposure. Available data have been submitted to the PMRA. A summary of the data call-in is found in the PMRA's Public Registry. For a list of data categories that have been required, see Appendix I.

## **Additional Information**

PMRA documents can be found in the Pesticides section of Canada.ca. PMRA documents are also available through the Pest Management Information Service:

Phone:	1-800-267-6315	within Canada, or
	1-613-736-3799	outside Canada (long distance charges apply)
Fax:	1-613-736-3798	
E-mail:	hc.pmra.info-arla.sc@canada.ca	

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**Appendix I Data Required Under Subsection 19(1) of the *Pest Control Products Act* for the Re-evaluation of p-Menthane-3,8-diol****I. Chemistry Data**

<b>DACO</b>	<b>Title</b>
2.11	Manufacturing Methods
2.13.3	Batch Data
2.13.4	Impurities of Toxicological Concern

**II. Toxicology Data**

<b>DACO</b>	<b>Title</b>
4.5.14	Developmental Neurotoxicity
4.8	Other Studies/Data/Reports
12.5.4	Foreign Reviews of Toxicology

**III. Exposure (Occupational and/or Bystander) Data**

<b>DACO</b>	<b>Title</b>
5.8	Dermal Absorption (in vivo)