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Re-evaluation Note

REV2017-22

# Re-evaluation Project Plan for 1,3- bis(hydroxymethyl)-5,5- dimethylhydantoin and 1- or 3-monomethylol-5,5- dimethylhydantoin

*(publié aussi en français)*

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This document is published by the Health Canada Pest Management Regulatory Agency. For further information, please contact:

Publications  
Pest Management Regulatory Agency  
Health Canada  
2720 Riverside Drive  
A.L. 6607 D  
Ottawa, Ontario K1A 0K9

Internet: [pmra.publications@hc-sc.gc.ca](mailto:pmra.publications@hc-sc.gc.ca)  
[healthcanada.gc.ca/pmra](http://healthcanada.gc.ca/pmra)  
Facsimile: 613-736-3758  
Information Service:  
1-800-267-6315 or 613-736-3799  
[pmra.infoserv@hc-sc.gc.ca](mailto:pmra.infoserv@hc-sc.gc.ca)

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## Background

In Canada, 1,3-bis(hydroxymethyl)-5,5-dimethylhydantoin and 1- or 3-monomethylol-5,5-dimethylhydantoin are 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.

1,3-bis(hydroxymethyl)-5,5-dimethylhydantoin and 1- or 3-monomethylol-5,5-dimethylhydantoin are registered as antimicrobial active ingredients used for the preservation of various products such as liquid detergents, soft soaps, room deodorizers, polymer emulsions and water-based gels for household and industrial products. As of 24 May 2017, there are two technical grade products and five end-use products containing these active ingredients registered for use in Canada.

Under the authority of section 16 of the *Pest Control Products Act*, all registrants of 1,3-bis(hydroxymethyl)-5,5-dimethylhydantoin and 1- or 3-monomethylol-5,5-dimethylhydantoin were notified of the initiation of the re-evaluation. Following this, the registrant of these technical grade active ingredients in Canada indicated their support of all uses included on the labels of end use products in Canada.

The re-evaluation project plan below outlines the timeline for review, summarizes the anticipated areas of focus for the risk assessments, and lists the data requirements for this re-evaluation.

## Re-evaluation Project Plan

### Anticipated Re-evaluation Timeline

The re-evaluation of 1,3-bis(hydroxymethyl)-5,5-dimethylhydantoin and 1- or 3-monomethylol-5,5-dimethylhydantoin is defined as a Category 1, as described in Regulatory Directive DIR2016-04, *Management of Pesticides Re-evaluation Policy*. However, because this re-evaluation was initiated prior to the publication of DIR2016-04, the proposed re-evaluation decision for 1,3-bis(hydroxymethyl)-5,5-dimethylhydantoin and 1- or 3-monomethylol-5,5-dimethylhydantoin is anticipated to be published for consultation by August 2019. 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 assessments.

## **Environmental Risk Assessment**

Existing assessments with minor updates are considered to be adequate to support the re-evaluation of 1,3-bis(hydroxymethyl)-5,5-dimethylhydantoin and 1- or 3-monomethylol-5,5-dimethylhydantoin for most review areas.

### **Value**

The value of 1,3-bis(hydroxymethyl)-5,5-dimethylhydantoin and 1- or 3-monomethylol-5,5-dimethylhydantoin will be considered. The viability of alternatives will be examined for certain uses if risks of concern which require mitigation are identified.

### **Data Requirements**

The PMRA has identified the need for the technical registrant to provide data for 1,3-bis(hydroxymethyl)-5,5-dimethylhydantoin and 1- or 3-monomethylol-5,5-dimethylhydantoin related to toxicology, occupational exposure and environment. Relevant data/studies have been requested from the technical registrant. A summary of the data call-in is found in the PMRA's Public Registry found online at <https://www.canada.ca/en/health-canada/services/consumer-product-safety/pesticides-pest-management/public/protecting-your-health-environment/public-registry.html>. For a list of data categories that have been requested from the technical registrant, see Appendix I.

### **Additional Information**

The PMRA documents can be found in the Pesticides and Pest Management portion of the Canada.ca website at <https://www.canada.ca/en/health-canada/services/consumer-product-safety/pesticides-pest-management.html>. The 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:	pmra.infoserv@hc-sc.gc.ca	

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**Appendix I Data Required Under Subsection 19(1) of the *Pest Control Products Act* for the Re-evaluation of 1,3-bis(hydroxymethyl)-5,5-dimethylhydantoin and 1- or 3-monomethylol-5,5-dimethylhydantoin**

**I. Toxicology**

- DACO 4.1 Summary of toxicological studies
- DACO 4.2.1 Acute Oral
- DACO 4.2.2 Acute Dermal
- DACO 4.2.3 Acute Inhalation
- DACO 4.2.4 Primary Eye Irritation
- DACO 4.2.5 Primary Dermal Irritation
- DACO 4.2.9 Other Acute Studies (rat and rabbit)
- DACO 4.3.1 Short-term Oral (90-day rodent)
- DACO 4.3.4 Short-term Dermal (90-day)
- DACO 4.5.2 Prenatal Developmental Toxicity (rodent)
- DACO 4.5.3 Prenatal Developmental Toxicity (non-rodent)
- DACO 4.5.8 Other Genotoxicity Studies (DNA synthesis assay)
- DACO 6.4 Other Studies/Data/Reports (absorption/distribution/metabolism and excretion)

**II. Occupational Exposure**

- DACO 5.4 Mixer/Loader/Applicator- Passive Dosimetry Data
- DACO 5.5 Mixer/Loader/Applicator-Biological Monitoring Data
- DACO 5.6 Post Application - Passive Dosimetry Data
- DACO 5.7 Post Application - Biological Monitoring Data
- DACO 5.9 Dislogeable Residues (Foliar, Soil and Surface)

**III. Environment**

- DACO 8.2.3.2 Hydrolysis
- DACO 8.2.3.3.2 Phototransformation - Water