Re-evaluation Decision RVD2024-07

Octenol and Its Associated End-use Products

Final Decision

(publié aussi en français)

28 June 2024

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

Publications
Pest Management Regulatory Agency
Health Canada
2 Constellation Drive
8th floor, A.L. 2608 A
Ottawa, Ontario K1A 0K9

Internet: canada.ca/pesticides
pmra.publications-arla@hc-sc.gc.ca

Information Service:
1-800-267-6315
pmra.info-arla@hc-sc.gc.ca

Canada

ISSN: 1925-1017 (print)
1925-1025 (online)

Catalogue number: H113-28/2024-7E (print version)
H113-28/2024-7E-PDF (PDF version)

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Re-evaluation decision for octenol 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 to all re-evaluations.

This document presents the final re-evaluation decision[1] for the re-evaluation of octenol, including the response to three comments received, and the required label updates. All products containing octenol regulated under the *Pest Control Products Act* in Canada are subject to this re-evaluation decision.

Octenol is a naturally occurring volatile alcohol, produced and released by many species of plants, animals and mushrooms. Octenol is registered as a mosquito attractant for outdoor use only in devices which trap and kill mosquitos. Octenol is a semiochemical which mimics a component of mammalian breath and is capable of attracting mosquitoes (Canada, 2006). There are only domestic end-use products registered containing octenol.

Currently registered technical grade active ingredient, and end-use products containing octenol can be found in the Pesticide Product Information Database and in Appendix I. The Proposed Re-evaluation Decision PRVD2023-05, *Octenol and Its Associated End-use Products*[2] containing the evaluation of octenol and proposed decision, underwent a 90 day consultation period ending on 4 March 2024. PRVD2023-05 proposed continued registration of octenol products in Canada, with updates to label directions and precautions to reflect the current labelling standards and to improve clarity (Appendix IV).

Health Canada received three (3) comments during the public consultation. Commenters are listed in Appendix II. The comments are summarized in Appendix III along with the responses by Health Canada. The comment did not result in changes to the proposed re-evaluation decision as described in PRVD2023-05. A reference list of information used as the basis for the proposed re-evaluation decision is included in PRVD2023-05.

Re-evaluation decision for octenol

Health Canada has completed the re-evaluation of octenol. Under the authority of the *Pest Control Products Act*, Health Canada has determined that continued registration of products containing octenol is acceptable.

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

An evaluation of available scientific information found that the use of octenol products meets current standards for protection of human health and the environment and have acceptable value when used according to revised conditions of registration which includes label amendments.

Risk mitigation measures

Registered pesticide product labels include specific directions for use. Directions include risk mitigation measures to protect human health and the environment and must be followed by law. The required updated label statements, as a result of the re-evaluation of octenol, are summarized below. Refer to Appendix IV for details.

Label improvements to meet current standards:

Human health

- Addition of standard first aid statements to all product labels;

Environment

- Update the storage statement on domestic-class end-use products and disposal statement for technical grade active ingredient to current standard.

Implementation of the re-evaluation decision

Regulatory Directive DIR2018-01, *Policy on Cancellations and Amendments Following Re-evaluation and Special Review* provides general timelines for implementation of post-market decisions. When an amendment to a registration is determined to be necessary, such as the need for additional risk mitigation measures, there will be an implementation period of up to two (2) years from the date of the decision to transition to selling and using the product with the newly amended labels, if risks during this period are considered acceptable. Potential risks (human health and the environment) from the use of products containing octenol are acceptable during the implementation period under the current label use conditions. Therefore, the required label updates will be implemented within 24 months following the publication of the re-evaluation decision document.

Next steps

To comply with this decision, the required amendments (label updates) must be implemented on all product labels no later than 24 months after the publication date of this decision document. Accordingly, both registrants and retailers will have up to 24 months from the date of this decision document to transition to selling the product with the newly amended labels. Similarly, users will also have the same 24-month period from the date of this decision document to transition to using the newly amended labels, which will be available on the Public Registry.

Refer to Appendix I for details on specific products impacted by this decision.

Other Information

Any person may file a notice of objection[3] regarding this decision on octenol and its associated end-use products 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 and Pest Management Section of the Canada.ca website (Public Engagement Portal - Public Engagement Forms - Notice of Objection) or contact PMRA's Pest Management Information Service.

The relevant confidential test data on which the decision is based (as referenced in PRVD2023-05) are available for public inspection, upon application, in PMRA's Reading Room. For more information, please contact the Pest Management Information Service.

[3] As per subsection 35(1) of the *Pest Control Products Act*

Appendix I Registered products containing octenol in Canada

Table 1 Products containing octenol requiring (label) amendments[1]

Registration number	Class	Registrant	Product name	Formulation type	Active ingredient
28439	T	Bedoukian Research, Inc.	Bedoukian Octenol Technical	Liquid	99.7%
28440	D	Woodstream Canada Corporation	Mosquito Magnet Octenol Mosquito Attractant	Slow-release generator	1.66 g/lure
28446	D	Biosensory, Inc.	Biosensory Mosquito Lure	Slow-release generator	3.74 g/lure
28451	D	Mr. Bar-B-Q Products LLC	Skeeter Vac Fine Tune Mosquito Lure	Slow-release generator	3.74 g/lure
28456	D	Armatron International, Inc.	Flowtron Mosquito Attractant	Slow-release generator	1.66 g/lure
29062	D	Kaz Canada Inc., A Helen Of Troy Company	Nosquito By Stinger Mosquito Octenol Lure	Slow-release generator	0.735 g/lure
29217	D	Koolatron Inc.	Bite Shield™ Mosquito Lure By Koolatron	Solid	3.74 g/lure
30002	D	Koolatron Inc.	Bite Shield™ Mosquito Lure II By Koolatron	Solid	0.735 g/lure

[1] As of 6 June 2024, excluding discontinued products or products with a submission for discontinuation

T = Technical Grade Active Ingredient, D = Domestic

Appendix II List of commenters to PRVD2023-05

List of commenters' affiliations for comments submitted in response to PRVD2023-05

Category	Commenter
Public[1]	General public

[1] Three (3) different individuals

Appendix III Comment and response

Health Canada received one written comment during the public consultation for the octenol proposed re-evaluation decision. Commenter's affiliation is listed in Appendix II. The comment was considered during the final decision phase of this re-evaluation. The summarized comment and Health Canada's response is provided below.

1.0 Comment related to the environment and value assessment

1.1 Comment

A general comment was received from the public related to the health assessment of octenol; specifically concerns for the requirement of animal testing.

Health Canada response

With respect to animal testing, Health Canada requires information on the potential toxic effects of pesticides to protect human health and the environment from potential risks. Toxicity information typically includes, in part, animal testing data generated by pesticide manufacturers. These studies are conducted according to international testing protocols, which includes requirements to ensure protection of the welfare of laboratory animals. However, for the re-evaluation of octenol, the toxicology database was considered acceptable and Health Canada neither received nor requested additional animal studies.

While animal toxicity testing currently plays a critical role in assessing human health and environmental risks from exposure to pesticides, Health Canada supports the reduction of unnecessary animal testing where scientifically justified. To this end, Health Canada does consider requests from pesticide manufacturers to waive requirements for animal studies or to consider validated non-animal alternatives in hazard assessment whenever possible, provided that the same level of protection of human health or the environment is maintained. For example, Health Canada issued guidance for industry on the waiving of mammalian acute toxicity studies in 2013 (https://www.canada.ca/en/health-canada/services/consumer-product-safety/reports-publications/pesticides-pest-management/policies-guidelines/guidance-waiving-bridging-mammalian-acute-toxicity-tests-pesticides.html).

Health Canada is also an active participant in various international activities aimed at reducing animal testing while ensuring the protection of human health and the environment. Continued participation in these activities is important to encourage adoption of alternative approaches to animal testing.

Appendix IV Label amendments for products containing octenol

Information on labels of currently registered products should not be removed unless it contradicts the label statements provided below.

A. For all products:

1. On the primary display panel, replace "guarantee" with "active ingredient".

2. On the primary display panel, include the pictogram of the hazard symbol corresponding to "DANGER POISON":

3. All registered product labels must include the standard first aid statements as per the new PMRA Guidance Document, *First Aid Labelling Statement* (Canada, 2022), where applicable.

4. Add the following in a section titled NOTICE TO USER:
   "This pest control product is to be used only in accordance with the directions on the label. It is an offence under the *Pest Control Products Act* to use this product in a way that is inconsistent with the directions on the label."

B. For the technical grade active ingredient:

1. Under the DISPOSAL section MODIFY the following statement as follows:

   "Canadian ~~formulators~~ manufacturers ~~using this product~~ should dispose of unwanted active ingredients and containers in accordance with municipal ~~or~~ and provincial regulations."

C. For domestic-class end-use products:

1. Add the following under STORAGE:
   "Store this product away from food or feed."