Re-evaluation Decision

RVD2023-08

Octadec-9-enoic Acid, Methyl Ester and Octadec-9-enoic Acid, Ethyl Ester

Final Decision

(publié aussi en français)

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$\hbox{$\mathbb O$}$ His Majesty the King in Right of Canada, as represented by the Minister of Health Canada, 2023

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Re-evaluation decision for octadec-9-enoic acid, methyl ester and octadec-9-enoic acid, ethyl ester

Under the authority of the *Pest Control Products Act*, all registered pesticides must be regularly re-evaluated by Health Canada's Pest Management Regulatory Agency (PMRA) to ensure that they continue to meet health and environmental standards and continue to have value. The re-evaluation considers information from various sources such as data and information from pesticide manufacturers 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.

Octadec-9-enoic acid, methyl ester and octadec-9-enoic acid, ethyl ester are esterified fatty acids made from vegetable oil. In Canada, these two substances are registered as adjuvants and are always co-formulated. Octadec-9-enoic acid, methyl ester and octadec-9-enoic acid, ethyl ester are also used as formulants (List 4B) in other pesticide products and are listed as inert ingredients by the United States Environmental Protection Agency (USEPA).

Octadec-9-enoic acid, methyl ester and octadec-9-enoic acid, ethyl ester are considered activator or spray modifier adjuvants which are intended to improve the efficacy or enhance the biological performance of the pest control product with which they are tank mixed, by modifying or enhancing physical or chemical characteristics. Octadec-9-enoic acid, methyl ester and octadec-9-enoic acid, ethyl ester are registered for use as a tank mix with a variety of herbicides and insecticides. Application directions of these adjuvants will vary based upon the pest control products with which they are tank-mixed. Refer to the registered adjuvant product labels for the tank mix partners. For specific details of uses, application rates and methods, precautions, restrictions, and personal protective equipment requirements, refer to the associated product label. Currently registered products containing octadec-9-enoic acid, methyl ester and octadec-9-enoic acid, ethyl ester can be found in the Pesticide Product Information Database and in Appendix I.

The Proposed Re-evaluation Decision PRVD2021-13, *Octadec-9-enoic Acid, Methyl Ester and Octadec-9-enoic Acid, Ethyl Ester* ¹ underwent a 90-day consultation period ending on 20 March 2022. PRVD2021-13 proposed continued registration of octadec-9-enoic acid, methyl ester and octadec-9-enoic acid, ethyl ester products for sale and use in Canada, with label updates to meet current labelling standards (Appendix II).

No comments were received during the consultation period. Therefore, this decision is consistent with the proposed re-evaluation decision stated in PRVD2021-13, which lists all information used as the basis for the re-evaluation decision.

[&]quot;Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

This document presents the final re-evaluation decision² for the re-evaluation of octadec-9-enoic acid, methyl ester and octadec-9-enoic acid, ethyl ester, including the label updates required to meet the current labelling standards. All products containing octadec-9-enoic acid, methyl ester and octadec-9-enoic acid, ethyl ester that are registered in Canada are subject to this re-evaluation decision.

Re-evaluation decision for octadec-9-enoic acid, methyl ester and octadec-9-enoic acid, ethyl ester

Health Canada has completed the re-evaluation for octadec-9-enoic acid, methyl ester and octadec-9-enoic acid, ethyl ester. Under the authority of the *Pest Control Products Act*, Health Canada has determined that continued registration of products containing octadec-9-enoic acid, methyl ester and octadec-9-enoic acid, ethyl ester is acceptable with the label updates (Appendix II). An evaluation of available scientific information found that uses of octadec-9-enoic acid, methyl ester and octadec-9-enoic acid, ethyl ester products meet current standards for protection of human health and the environment and have acceptable value under the current conditions of use.

Risk mitigation measures

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 octadec-9-enoic acid, methyl ester and octadec-9-enoic acid, ethyl ester, are summarized below. Refer to Appendix II for details.

Human health

Label improvements to meet current standards:

• Update to standard label statements (health precautions)

Environment

Label improvements to meet current standards:

• Updates to standard label statements (environmental precautions)

[&]quot;Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

Next steps

To comply with this decision, the required label amendments 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 objection³ regarding this decision on octadec-9-enoic acid, methyl ester and octadec-9-enoic acid, ethyl ester 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 Canada.ca (Request a Reconsideration of Decision) or contact the PMRA's Pest Management Information Service.

The relevant confidential test data on which the decision is based (as referenced in PRVD2021-13) are available for public inspection, upon application, in the PMRA's Reading Room. For more information, please contact Health Canada's Pest Management Information Service.

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

Appendix I Registered products containing octadec-9-enoic acid, methyl ester and octadec-9-enoic acid, ethyl ester in Canada

Table 1 Products requiring label amendments¹

Registration number	Marketing class	Registrant	Product name	Formulation type	Active ingredient (%, g/L)
27420	Commercial	Victorian Chemical Co Pty Ltd	HASTEN Spray Adjuvant	Emulsifiable Concentrate	OCC – 17.3% OCD – 60.1%
28277	Commercial	Victorian Chemical Co Pty Ltd	HASTEN NT Spray Adjuvant	Emulsifiable Concentrate	OCC/OCD – 71.44 %
31760	Commercial	Victorian Chemical Co Pty Ltd	HASTEN NT Ultra Spray Adjuvant	Emulsifiable Concentrate	OCC/OCD - 75.2 %

OCC: Octadec-9-Enoic acid, Methyl Ester; OCD: Octadec-9-Enoic Acid, Ethyl Ester

¹As of 6 December 2022, excluding discontinued products or products with a submission for discontinuation.

Appendix II Required label updates for products containing octadec-9enoic Acid, methyl ester and octadec-9-enoic acid, ethyl ester

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

The following statements must be updated for all products to meet current labelling standards:

On the principal display panel, replace "GUARANTEE" with "ACTIVE INGREDIENT".

Add the following statement before the Precautions section:

• "Read and observe all label directions, including directions for use, precautions, restrictions, environmental precautions and spray buffer zones for each product used in the tank mix. In cases where these requirements differ between the tank mix partner labels, the most restrictive label must be followed."

Under Environmental Precautions include the statements:

• "DO NOT contaminate irrigation or drinking water supplies or aquatic habitats by cleaning of equipment or disposal of wastes."