



Health  
Canada Santé  
Canada

Your health and  
safety... our priority.

Votre santé et votre  
sécurité... notre priorité.

Proposed Re-evaluation Decision

PRVD2021-13

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

*Consultation Document*

*(publié aussi en français)*

**20 December 2021**

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: [canada.ca/pesticides](https://canada.ca/pesticides)  
[pmra.publications-arla@hc-sc.gc.ca](mailto:pmra.publications-arla@hc-sc.gc.ca)  
Facsimile: 613-736-3758  
Information Service:  
1-800-267-6315 or 613-736-3799  
[pmra.info-arla@hc-sc.gc.ca](mailto:pmra.info-arla@hc-sc.gc.ca)

**Canada** 

ISSN: 1925-0959 (print)  
1925-0967 (online)

Catalogue number: H113-27/2021-13E (print)  
H113-27/2021-13E-PDF (PDF version)

© Her Majesty the Queen in Right of Canada, as represented by the Minister of Health Canada, 2021

All rights reserved. No part of this information (publication or product) may be reproduced or transmitted in any form or by any means, electronic, mechanical, photocopying, recording or otherwise, or stored in a retrieval system, without prior written permission of Health Canada, Ottawa, Ontario K1A 0K9.

## Table of Contents

Proposed re-evaluation decision .....	1
Next steps.....	2
Additional scientific information .....	2
Science evaluation .....	3
1.0    Human health assessment .....	3
2.0    Environmental assessment.....	4
3.0    Value assessment .....	5
4.0    Incident reports .....	5
Appendix I    Registered products containing Octadec-9-enoic Acid, Methyl Ester and Octadec-9-enoic Acid, Ethyl Ester .....	6
Table 1    Registered products containing Octadec-9-enoic Acid, Methyl Ester and Octadec-9-enoic Acid, Ethyl Esterl .....	6
Appendix II    Proposed label amendments.....	7
References.....	8

## Proposed re-evaluation decision

Under 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 continue to meet current health and environmental standards and continue to have value. The re-evaluation considers data and information from pesticide manufacturers, published scientific reports, and other regulatory agencies. 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. There are currently three commercial end-use products registered containing octadec-9-enoic acid, methyl ester and octadec-9-enoic acid, ethyl ester, formulated as emulsifiable concentrates (Appendix I). Octadec-9-enoic acid, methyl ester and octadec-9-enoic acid, ethyl ester are also used as formulants<sup>1</sup> (List 4B) in other pesticide products and are listed as inert ingredients<sup>2</sup> 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.

This document presents the proposed regulatory decision for the re-evaluation of the following adjuvants:

Adjuvant	CAS. No.
Octadec-9-enoic acid, methyl ester	112-62-9
Octadec-9-enoic acid, ethyl ester	111-62-6

When the current label directions are followed, potential risks to human health (occupational, dietary and bystander) and the environment (aquatic and terrestrial organisms) are considered to be acceptable. However, label updates are proposed to meet the current labelling standards (Appendix II). Updates to standard label statements related to human health (wording for using the most restrictive precautions of the tank-mix labels) and environment (wording for using the most restrictive precautions and avoiding contamination of aquatic habitats and drinking water) are proposed.

---

<sup>1</sup> Regulatory Directive DIR2006-02, *Formulants Policy and Implementation Guidance Document*.

<sup>2</sup> as listed in the United States Code of Federal Regulations, 40 CFR Protection of Environment, Subpart D, Sections 180.910, 180.920, and 180.930.

Under the authority of the *Pest Control Products Act* and based on the evaluation of currently available scientific information, products containing octadec-9-enoic acid, methyl ester and octadec-9-enoic acid, ethyl ester listed in Appendix I have value and are being proposed for continued registration in Canada.

Registered pesticide product labels include specific directions for use. Directions include risk mitigation measures to protect human health and the environment that must be followed by law. As a result of the re-evaluation of octadec-9-enoic acid, methyl ester and octadec-9-enoic acid, ethyl ester, no further risk mitigation measures for the adjuvant product labels are being proposed.

All products containing octadec-9-enoic acid, methyl ester and octadec-9-enoic acid, ethyl ester registered in Canada are subject to this proposed re-evaluation decision. This document is subject to a public consultation,<sup>3</sup> during which written comments and additional information may be submitted to [the PMRA](#). The final re-evaluation decision will be published taking into consideration the comments and information received during consultation.

## **Next steps**

The public, including the registrants and stakeholders, are encouraged to submit comments and additional information during the 90-day public consultation period upon publication of this proposed re-evaluation decision.

All comments received during the 90-day public consultation period will be taken into consideration in preparation of re-evaluation decision document,<sup>4</sup> which could result in revised risk mitigation measures. The re-evaluation decision document will include the final re-evaluation decision, the reasons for it and a summary of comments received on the proposed re-evaluation decision with Health Canada's responses.

## **Additional scientific information**

No additional data are required.

---

<sup>3</sup> "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

<sup>4</sup> "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

## Science evaluation

### 1.0 Human health assessment

The toxicology database for the adjuvant products consists of acute toxicity studies of the end-use formulations to verify that labels have the appropriate signal words and hazard statements. The end-use formulations are of low acute toxicity via the oral, dermal and inhalation routes. They are minimally irritating to the eye, mildly irritating to the skin, and they are not considered to be dermal sensitizers. Based on acute toxicity studies, “CAUTION: SKIN IRRITANT” is currently present on the primary panel of all three end-use product labels. No further mitigation measures are required as a result of re-evaluation.

The three adjuvant products co-formulated with octadec-9-enoic acid, methyl ester and octadec-9-enoic acid, ethyl ester are always tank mixed with another registered pest control product (either an insecticide or herbicide). The tank mix is then applied as a foliar spray using either ground or aerial equipment, as indicated on the tank mix partner label.

Workers can be exposed to the adjuvant during mixing (that is, mixing the adjuvant with the herbicide or insecticide tank mix partner), loading the tank mix, application of the tank mix, clean-up, and repair as well as when entering a treated site that has been treated with the tank mix to perform tasks such as pruning, harvesting, scouting, and/or irrigation. Occupational handlers (for example, mixer/loader/applicator) and postapplication exposure is expected to vary depending on the pest control product to which the adjuvant is tank mixed.

Octadec-9-enoic acid, methyl ester and octadec-9-enoic acid, ethyl ester have an inherently low toxicity profile, and there are no toxicological concerns. Based on the acute toxicity (that is, mild skin irritant) the personal protective clothing listed on the current adjuvant product labels includes the wearing of a long-sleeved shirt, long pants and chemical resistant gloves during mixing, loading, application, clean-up and repair. In addition, because adjuvants are always tank mixed with other pesticides, the adjuvant labels state that the most stringent precautions when tank mixing must be followed, as well as all instructions on rates and restricted-entry intervals indicated on the tank mix partner labels.

There are no domestic class products that can be tank mixed with octadec-9-enoic acid, methyl ester and octadec-9-enoic acid, ethyl ester, therefore, direct residential exposure is not expected. Exposure to octadec-9-enoic acid, methyl ester and octadec-9-enoic acid, ethyl ester is expected to vary depending on the pest control product with which the adjuvant is tank mixed but commercial application to residential areas is not expected based on the associated tank mix partners as listed on the adjuvant product labels. Given the inherently low toxicity profile and when use directions on tank mix partner labels are followed, residential exposure to octadec-9-enoic acid, methyl ester and octadec-9-enoic acid, ethyl ester is not expected to be of concern. Bystander exposure to octadec-9-enoic acid, methyl ester and octadec-9-enoic acid, ethyl ester is also expected to be acceptable based on the low toxicity profile and when use directions on tank mix partner labels are followed.

Based on the above, occupational, bystander and residential risk from octadec-9-enoic acid, methyl ester and octadec-9-enoic acid, ethyl ester are considered acceptable when the most stringent tank mix label precautions and use directions are followed. Updates to the product labels are proposed based on the current precautionary label statements to follow the stricter tank mix instructions (Appendix II). No additional mitigation measures are proposed.

The potential impact on a pesticide residue from the addition of an adjuvant is evaluated in the context of the pesticide component with which it is tank mixed. As such, dietary risk (food + drinking water) from octadec-9-enoic acid, methyl ester and octadec-9-enoic acid, ethyl ester is considered acceptable when the label directions of the tank mix partner are followed. No additional mitigation measures are proposed.

Considering the inherently low toxicity profile, residential and dietary exposure to octadec-9-enoic acid, methyl ester and octadec-9-enoic acid, ethyl ester are not expected to be of concern when applied according to the tank mix partner label instructions. An aggregate exposure assessment is not required.

The *Pest Control Products Act* requires that the PMRA consider the cumulative exposure to pesticides with a common mechanism of toxicity. Accordingly, a cumulative health assessment was undertaken. While octadec-9-enoic acid, methyl ester and octadec-9-enoic acid, ethyl ester may share a common moiety with other fatty acid-based active ingredients, the potential health risks from cumulative exposure to octadec-9-enoic acid, methyl ester and octadec-9-enoic acid, ethyl ester, and other fatty acid-based pest control products are acceptable given the inherent low toxicity profile of octadec-9-enoic acid, methyl ester and octadec-9-enoic acid, ethyl ester.

## **2.0 Environmental assessment**

Octadec-9-enoic acid, methyl ester and octadec-9-enoic acid, ethyl ester are not expected to persist in the environment as they are readily biodegraded in aquatic and terrestrial environments. As adjuvants, octadec-9-enoic acid, methyl ester and octadec-9-enoic acid, ethyl ester do not have any inherent pesticidal properties. Octadec-9-enoic acid, methyl ester and octadec-9-enoic acid, ethyl ester are also used as formulants in other pesticide products and are not considered hazardous to the environment. The adjuvant product labels state that the most stringent precautions and use directions when tank mixing with other pesticides must be followed. When used as directed for associated tank mix pesticides, the risk to the environment from these adjuvants is considered acceptable. Updates to the product labels are proposed based on the current environmental label statements to avoid contamination of drinking water, and to follow the stricter tank mix instructions for environmental risk mitigation measures (Appendix II). No additional mitigation measures are proposed.

In accordance with the PMRA Regulatory Directive DIR99-03,<sup>5</sup> the assessment of octadec-9-enoic acid, methyl ester and octadec-9-enoic acid, ethyl ester against Track 1 criteria of Toxic Substances Management Policy (TSMP) under *Canadian Environmental Protection Act* was conducted. It determined that:

- Octadec-9-enoic acid, methyl ester and octadec-9-enoic acid, ethyl ester do not meet all the Track 1 criteria and are not considered Track 1 substances, as they are assumed to be relatively non-toxic, rapidly biodegrade and are not bioaccumulative in the environment.

### **3.0 Value assessment**

Octadec-9-enoic acid, methyl ester and octadec-9-enoic acid, ethyl ester are of value for increasing the efficacy of the associated herbicides and insecticides through altering the spray characteristics of the pest control product and its carrier. It acts as a penetrant allowing active ingredients to penetrate waxy coatings. It also increases the coverage of sprays by acting as a wetting agent.

### **4.0 Incident reports**

As of 17 May 2021, no human, domestic animal or environment incident reports involving octadec-9-enoic acid, methyl ester and octadec-9-enoic acid, ethyl ester were submitted to the PMRA.

---

<sup>5</sup> DIR99-03, The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy



## Appendix I Registered products containing Octadec-9-enoic Acid, Methyl Ester and Octadec-9-enoic Acid, Ethyl Ester

**Table 1 Registered products containing Octadec-9-enoic Acid, Methyl Ester and Octadec-9-enoic Acid, Ethyl Ester<sup>1</sup>**

Registration number	Registrant	Product Name	Formulation Type	Active Ingredient
27420	Victorian Chemical Co Pty Ltd	Hasten Spray Adjuvant	Emulsifiable Concentrate	OCC – 17.3% OCD – 60.1%
28277	Victorian Chemical Co Pty Ltd	Hasten NT Spray Adjuvant	Emulsifiable Concentrate	OCC/OCD 71.44 %
31760	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

<sup>1</sup> as of 31 August 2021, excluding discontinued products or products with a submission for discontinuation

## **Appendix II Proposed label amendments**

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”.

### **Human health**

Under Precautions include the statement:

- “Read and observe all label directions, including rates and restrictions for each product used in the tank-mix. Follow the more stringent label precautionary measures for mixing, loading and applying stated on both product labels.”

### **Environment**

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.”
- “Read and observe all label directions, including rates, use directions, and restrictions, such as buffer zones, for each product used in the tank-mix. Follow the more stringent label precautionary measures for applying stated on both product labels.”

---

## References

### Additional information considered

### Published information

<b>PMRA number</b>	<b>Reference</b>
2419952	Evaluation Report for Category B, Subcategory B.3.10 Application (New or Changes to Product Label - Tank Mixes), Submission No. 2013-6110
2511786	Evaluation Report for Category B, Subcategory 2.1, 2.3, 2.4 Application, Submission No. 2014-1995
2195396	Evaluation Report for Category C, Subcategory 3.10 Application, Submission No. 2012-1162
2161341	Evaluation Report for Category C, Subcategory C.3.1 Application (New or Changes to Product Label – Application Rate Decrease), Submission No. 2011-5702
2041588	Evaluation Report for Category C, Subcategory C.3.10 Application (New or Changes to Tank Mix), Submission No. 2011-0718
2039010	Evaluation Report for Category C, Subcategory C.3.10 Application (New or Changes to Tank Mix), Submission No. 2010-5919