



Health
Canada Santé
Canada

Your health and
safety... our priority.

Votre santé et votre
sécurité... notre priorité.

Special Review Decision

SRD2020-01

Special Review Decision: Acephate

Final Decision Document

(publié aussi en français)

3 April 2020

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 hc.pmra.info-arla.sc@canada.ca

Internet: canada.ca/pesticides
hc.pmra.publications-arla.sc@canada.ca
Facsimile: 613-736-3758
Information Service:
1-800-267-6315 or 613-736-3799

Canada 

ISSN: 2561-6269 (online)

Catalogue number: H113-17/2020-1E (print version)
H113-17/2020-1E-PDF (PDF version)

© Her Majesty the Queen in Right of Canada, as represented by the Minister of Health Canada, 2020

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.

Special Review Decision

Pursuant to subsection 17(2) of the *Pest Control Products Act*, Health Canada's Pest Management Regulatory Agency (PMRA) initiated a special review of all registered pest control products containing acephate, based on the 2003 European Commission regulatory decision to prohibit all uses of acephate in European Union member countries due to human health and environmental concerns (Canada, 2013). The aspects of concern identified for the special review are acute dietary exposure, potential risk to non-target terrestrial invertebrates, birds and mammals, and, potential risk to aquatic organisms.

Health Canada evaluated the aspects of concern that prompted the special review in accordance with subsection 18(4) of the *Pest Control Products Act*. The proposed special review decision was published for consultation in the Re-evaluation Note REV2016-16, *Special Review of Acephate: Proposed Decision for Consultation* (Canada, 2016a). No comments were received during the consultation period.

In addition to the consultation on REV2016-16, Health Canada consulted on a proposed re-evaluation decision of acephate in 2016 (PRVD2016-01), and subsequently in 2019, an updated environmental risk assessment using revised end-points (PRVD2019-04). The updated environmental assessment was related to pollinators, birds and mammals, and aquatic buffer zones (PRVD 2019-04) which are relevant to the special review of acephate. Comments and information were received during the consultations of PRVD2016-01 and PRVD2019-04.

While no comments were received during consultation of the proposed special review decision of acephate, Health Canada, for the final special review decision considered the comments and information received as part of the re-evaluation, as well as the updated environmental risk assessment related to the aspects(s) of concern (PRVD2019-04). The outcome of the assessment of the aspects of concern, based on the consideration of additional information and updated environmental assessment following the consultation of the REV2016-16 is outlined below:

- Acute dietary exposure assessment: No changes required to the proposed special review decision.
- Potential risk to non-target terrestrial invertebrates, birds, and mammals: Following consultation of the REV2016-16, Health Canada updated the assessments with revised end-points for pollinators, birds and mammals (PRVD2019-04 and RVD2020-07), and for updating the aquatic buffer zones. Based on the updated assessment of the aspects of concern related to the environment, revised risk reduction measures are required as compared to REV2016-16 (Appendix I).

Details on the revised assessment on terrestrial invertebrates, birds and mammals and aquatic organisms, and associated risk reduction measures are in PRVD2019-04 and RVD2020-07.

Following an evaluation of the aspects of concern, Health Canada has determined that continued registration of products containing acephate is considered to be acceptable with the revised risk reduction measures (Appendix I). Therefore, Health Canada, under the authority of the *Pest Control Products Act*, is confirming the current registration of pest control products containing acephate in Canada, with revised label directions. As the label amendments related to the aspects of concern are included in RVD2020-07 (Canada, 2020), they are not listed in detail in this decision document. However, a summary of the required label amendments for the special review are included in Appendix I.

All pest control products containing acephate that are registered in Canada are subject to this special review decision. Currently registered products containing acephate are listed in Appendix II.

This document presents the final regulatory decision¹ for the special review of acephate. To comply with this decision, the required label changes related to the aspects of concern included in RVD2020-07 must be implemented on all product labels sold by registrants no later than 24 months after the publication date of this document. Registrants of the products containing acephate will be informed of the specific requirements affecting their product registration(s) and of the regulatory options available to them.

Other Information

Any person may file a notice of objection² regarding this decision on acephate within 60 days from the date of publication of this special review decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the Pesticides section of the Canada.ca website (Request a Reconsideration of Decision) or contact the PMRA's Pest Management Information Service.

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

² As per subsection 35(1) of the *Pest Control Products Act*.

Appendix I Summary of the risk reduction measures related to the aspects of concern

Human Health:

- To protect mixer/loaders and applicators, cancellation of the soluble powder formulation product. Uses registered for this product have been transferred to the label of a soluble granule product. Additional mitigation measures identified in the present decision are to be added to this latest registered label of the soluble granule product.
- Prohibition of applications by handheld mist blower or handheld fogger.
- Revised restricted-entry intervals (REIs) to protect workers entering treated sites.
- Prohibition of foliar application to all trees and ornamentals in residential areas, including municipal parks.
- Cancellation of use on potatoes.
- Reduction in application rate, maximum number of applications per year, and increase in minimum application intervals for certain crops to address food and drinking water risk concerns.

Environment:

Following consultation of the REV2016-16, PMRA updated the assessments with revised endpoints for pollinators, birds and mammals and aquatic buffer zones (for details refer PRVD2019-04 and RVD2020-07). Based on the updated assessment of the aspects of concern related to the environment, the following revised risk reduction measures are required as compared to REV2016-16:

- Cancellation of airblast/outdoor mist blower applications and associated application rate, which are currently registered for use on various trees and ornamentals, and in Christmas tree plantations, farm woodlots, nurseries, shelter belts, and rights-of-way.
- Restriction of foliar applications in farm woodlots, shelter belts, rights-of-way and municipal parks to spot treatments using hand-held equipment only.
- Precautionary and hazard statements to inform users of the toxicity and potential risk of acephate to pollinators, beneficial arthropods, birds, mammals, and aquatic organisms.
- Prohibition of tree injection applications until after the blooming/pollen shedding period.
- Prohibition of applications during periods of bloom or during the 9-day period before crop bloom for crops that are attractive to pollinators (or for other crops when using managed bees for pollination services).
- A label statement directing users not to discharge acephate-contaminated effluent from greenhouses into aquatic environments.

Appendix II Registered Acephate Products in Canada as of December 2019

Table 1 Products Requiring Label Amendments

| Registration Number | Marketing Class | Registrant Name | Product Name | Formulation Type | Active Ingredient |
|---------------------|-----------------|---------------------------------------|--|------------------|-------------------------------|
| 21568 | Commercial | Arysta LifeScience North America, LLC | Acecap 97 Systemic Insecticide Implants | soluble powder | Acephate 0.773g per cartridge |
| 22109 | Technical | | Orthene Technical | soluble powder | Acephate 99.78% |
| 27917 | Technical | | Acephate Technical | soluble powder | Acephate 98.0% |
| 29499 | Commercial | | Orthene 97% Soluble Granule Systemic Insecticide | Soluble granule | Acephate 97% |

Table 2 Products Containing Acephate Cancelled Because of Re-evaluation

| Registration Number | Marketing Class | Registrant Name | Product Name | Formulation Type | Active Ingredient |
|---------------------|-----------------|---------------------------------------|---|------------------|-------------------|
| 14225 | Commercial | Arysta LifeScience North America, LLC | Orthene 75% Soluble Powder Systemic Insecticide | soluble powder | 75% |

References

Published Information

Reference

Canada, 2020. Re-evaluation Decision: Acephate. RVD2020-07.

Canada, 2019. Proposed Re-evaluation Decision: Acephate and Its Associated End-use Products, Updated Environmental Risk Assessment. PRVD2019-04.

Canada, 2016a. Special Review of Acephate: Proposed Decision for Consultation. REV2016-16.

Canada, 2016b. Proposed Re-evaluation Decision: Acephate. PRVD2016-01.

Canada, 2013. Re-evaluation Note: Special Review Initiation of 23 Active Ingredients. REV2013-06.