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Re-evaluation Decision

RVD2020-07

# Acephate and Its Associated End-use Products

*Final Decision*

*(publié aussi en français)*

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## Re-evaluation Decision

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 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. PMRA applies internationally accepted risk assessment methods as well as current risk management approaches and policies.

Acephate is a systemic organophosphate insecticide registered to control a broad spectrum of insect pests on a wide variety of crops and use sites, including forest and woodlots, terrestrial food and feed crops, and outdoor ornamentals. Currently registered products containing acephate can be found in the Pesticide [Label Search](#) and in Appendix I. A proposed re-evaluation decision for acephate was published in 2016 (PRVD2016-01, *Acephate*) and an updated environmental risk assessment in 2019 (PRVD2019-04, *Acephate and Its Associated End-use Products, Updated Environmental Risk Assessment*). Both consultation documents underwent 90-day consultation periods.

The proposed regulatory decision pertaining to human health was presented in PRVD2016-01 in which a prohibition of foliar application in residential areas, the cancellation of uses on potatoes, and the replacement of the soluble powder formulation with a soluble granule formulation were proposed. PRVD2019-04 describes the complete environmental risk assessment with additional proposed mitigation measures including the cancellation of all airblast/outdoor mistblower applications, restrictions in application timing relative to blooming periods, and limiting applications in farm woodlots, shelter belts, rights of way and municipal parks to spot treatments with hand-held equipment. Updated label statements were also proposed to inform users of ways to reduce potential environmental risks.

Health Canada received comments and information relating to the health and environmental assessments. Refer to Appendix II for a list of respondents, and summarized comments with responses by Health Canada. The comments and information resulted in some revisions to the risk assessments (see Science Evaluation Update) and changes to the proposed regulatory decision as described in PRVD2016-01. Reference lists for the information used in the proposed re-evaluation decisions are found in PRVD2016-01 and PRVD2019-04. Appendix VI of this document lists additional information used in the final re-evaluation decision.

This document presents the final regulatory decision<sup>1</sup> for the re-evaluation of acephate, including required risk mitigation measures to protect human health and the environment and label amendments to bring labels up to current standards. All products containing acephate that are registered in Canada are subject to this re-evaluation decision.

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

## **Outcome of Science Evaluation**

Based on information received during the comment period for the proposed re-evaluation decision, Health Canada has made revisions to certain aspects of the health and environmental risk assessments. The following uses, which had been proposed for cancellation in PRVD2016-01, are now considered to be acceptable:

- Greenhouse cut flowers (based on stakeholder comments on feasibility)
- Outdoor cut flowers (based on lower rates resulting from environmental mitigation measures)

With some exceptions, health and environmental risks have been shown to be acceptable for uses of acephate and its associated end-use products when revised label directions and other mitigation measures are followed. Uses for which risks have not been shown to be acceptable are being cancelled.

## **Regulatory Decision for Acephate**

Health Canada has completed the re-evaluation of acephate. Under the authority of the *Pest Control Products Act*, Health Canada has determined that continued registration of certain products containing acephate is acceptable. An evaluation of available scientific information found that most uses of acephate products meet current standards for protection of human health and the environment when used according to revised label directions, which include new mitigation measures. Certain uses and application methods for acephate are being cancelled to address potential risks of concern to human health and the environment. Label amendments, as summarized below and listed in Appendix III, are required. No additional data are required at this time.

## **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 revised label statements and mitigation measures required as a result of the re-evaluation of acephate are summarized below. Refer to Appendix III for details.

## **Human Health**

### **Label improvements to meet current standards:**

- Updated toxicological information with additional information about symptoms and treatment for overexposed individuals.

## **Risk mitigation:**

To protect human health, the following risk-reduction measures are required for continued registration of acephate in Canada:

- 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 the 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, which include 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**

To protect the environment, the following risk-reduction measures are required:

- 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, rights-of-way and municipal parks.
- Restriction of foliar applications in farm woodlots, shelter belts, and rights-of-way 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.

## Next Steps

To comply with this decision, the required mitigation measures must be implemented on all product labels sold by registrants no later than 24 months after the publication date of this decision document. Refer to Appendix I for specific products impacted by this decision. Products that are cancelled will be phased out according to the following implementation timeline:

- One (1) year of sale by registrant from the publication date of this decision document, followed by;
- One (1) year of sale by retailer from the last date of sale by registrant, followed by;
- One (1) year of permitted use from the last date of sale by retailer.

## Other Information

Any person may file a notice of objection<sup>2</sup> regarding this decision on acephate 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 the Canada.ca website (Request a Reconsideration of Decision) or contact the PMRA's Pest Management Information Service by phone (1-800-267-6315) or by e-mail (hc.pmra.info-arla.sc@canada.ca).

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

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



# Science Evaluation Update

## 1.0 Revised Health Risk Assessment

### 1.1 Toxicology Summary

Details of the toxicological assessment can be found in PRVD2016-01. No comments were received on the toxicological assessment of acephate during the consultation period; thus, no changes were made to reference values. Label changes related to the toxicity of acephate are outlined in Appendix III.

### 1.2 Dietary Exposure and Risk Assessment

The dietary assessment for acephate was previously conducted and published in PRVD2016-01. One comment was received during the consultation process (see Appendix II), which did not result in any changes to the dietary assessment. Label and maximum residue limit (MRL) revisions related to the dietary assessment proposed in PRVD2016-01 remain unchanged. Refer to Appendix III for details on required label changes. MRL revisions, described in Appendix IV, will be made through a corresponding MRL process that includes the publication of proposed changes in a separate document (PMRL).

### 1.3 Residential Exposure and Risk Assessment

With the removal of airblast/mistblower applications from the label due to environmental concerns, the resulting lower maximum label rate of 0.637 kg a.i./ha for ornamentals, trees, and flowers was used in an updated postapplication residential assessment. All other inputs for the residential postapplication assessment remained consistent with PRVD2016-01. The results of the risk assessment are summarized in Appendix V, Table 4. Target margins of exposure (MOEs) and aggregate risk indexes (ARIs) were not met and risks were not shown to be acceptable for all age groups, including children, due to residential postapplication exposure following foliar application to ornamentals (trees, shrubs and flowers), even at the lower application rate. Therefore, commercial foliar application of acephate products in outdoor residential areas will not be permitted.

### 1.4 Occupational Exposure and Risk Assessment

The occupational assessment for acephate was previously conducted and published in PRVD2016-01. The assessment was revised based on the comments received, consideration of more updated exposure task force data, and environmental risk mitigation measures.

As a result of these revisions, certain mitigation measures proposed in PRVD2016-01 have changed, as described below. See Appendix III for revised label amendments.

## **Mixer, Loader and Applicator Exposure and Risk Assessment**

There is potential for exposure to acephate in occupational scenarios from workers handling acephate products during mixing/loading and application activities. Exposure scenarios, inputs and calculations used in the previous Mixer, Loader and Applicator Exposure and Risk Assessment are described in PRVD2016-01. Following PRVD2016-01, the assessment was updated to account for new available information and changes in use pattern resulting from required mitigation measures. Updates to the assessment are detailed in Appendix V along with a summary of the results.

Results of the final risk assessment did not significantly change the mitigation measures for mixer, loader and applicator exposure that were proposed in PRVD2016-01. The only update is the addition of a label statement requiring head protection during overhead spraying with handheld equipment. This is to address a concern stemming from the removal of all airblast and groundboom applications for environmental mitigation (proposed in the updated environmental risk assessment; PRVD2019-04), leaving only handheld equipment for application to trees, which may require overhead spraying.

## **Postapplication Worker Exposure and Risk Assessment**

There is potential for exposure to acephate in occupational scenarios from workers who enter treated sites to conduct agronomic activities involving foliar contact. Exposure scenarios, inputs and calculations used in the previous Postapplication Worker Exposure and Risk Assessment are described in PRVD2016-01. Following PRVD2016-01, the assessment was updated to account for new available information and changes in use pattern resulting from required mitigation measures. Updates to the assessment are detailed in Appendix V along with a summary of the results.

REIs are similar to, or shorter than those proposed in PRVD2016-01, with the exception of bell peppers and tobacco, which increased slightly due to rate changes.

The use on greenhouse cut flowers was proposed for cancellation due to post-application worker risk, as the REI of 2 days for some tasks was considered to be agronomically unfeasible. Comments were received from Flowers Canada indicating that the 2-day REI is indeed feasible (see Appendix II – Comments Related to Occupational Exposure). Cancellation of acephate use on greenhouse cut flowers is therefore no longer required. The REIs of 2 days for hand harvesting, disbudding and hand pruning, and of 12 hours for all other tasks, are to be added to the label.

In PRVD2016-01, the use on outdoor cut flowers was proposed for cancellation due to postapplication worker risk with an REI of 11 days for some tasks, which was considered agronomically unfeasible. However, when the reduction in rate for this use resulting from environmental risk mitigation is assessed, the REI decreases to 7 days. Health Canada considers this REI to be agronomically feasible for some varieties of outdoor cut flowers.

Consequently, cancellation of acephate use on outdoor cut flowers is not required in light of updated environmental risk mitigation. REIs of 7 days for hand harvesting, disbudding and hand pruning, and 12 hours for all other tasks are to be added to the label.

### **1.5 Aggregate Exposure and Risk Assessment**

Details of the aggregate assessment can be found in PRVD2016-01. As there were no changes to the risk conclusions of the residential assessment and no changes to the dietary assessment, the outcome of the aggregate assessment is also unchanged.

### **2.0 Revised Environmental Risk Assessment**

The registrant provided comments and information aimed at retaining airblast/outdoor mist blower applications for acephate. One comment pointed to the small size of sites being treated using these application methods. Another proposed a lower application rate for airblast/outdoor mist blower uses (a reduction of approximately 51%). Other comments suggested that the risk assessment for birds is too conservative and does not represent what would happen under actual field exposure conditions.

These comments are presented in Appendix II with responses (Comments and Responses Related to the Environment). The information provided in these comments, including a suggested reduction in rate (637 g a.i./ha) for airblast/outdoor mist blower applications, did not alter the conclusions of the environmental assessment as the risk to birds and mammals associated with the lower rate still was not shown to be acceptable. Details of this risk assessment conducted to verify the viability of the suggested changes is presented in Appendix II.

Health Canada has concluded that after consideration of all information received during the consultation process, the overall risk conclusions and proposed mitigation measures remain consistent with those presented in PRVD2019-04.

### **3.0 Value Assessment**

Comments received in response to PRVD2019-04 did not result in a change in the value assessment. Therefore, the value assessment and conclusions are consistent with the proposed re-evaluation decision stated in PRVD2016-01 and PRVD2019-04.

### **4.0 Conclusion of Science Evaluation**

Acephate offers an effective, alternative mode of action to non-organophosphate insecticides to control a wide variety of insect pests. This allows users the option to rotate insecticide modes of action, and as such contributes to resistance management.

With some exceptions, the human health risks for most uses from the current acephate use pattern were shown to be acceptable with proposed risk mitigation measures. The following uses, however, were not shown to have acceptable risk and will be cancelled:

- Potato (due to potential dietary risks)
- Foliar use on trees and ornamentals in residential areas (due to potential residential risks including to children)
- All uses of the soluble powder formulation (due to potential occupational risk)

Following revisions to the risk assessment based on information received during the comment period, the following uses, which had been proposed for cancellation in PRVD2016-01, are now considered to be acceptable:

- Greenhouse cut flowers (based on stakeholder comments on feasibility)
- Outdoor cut flowers (based on lower rates resulting from environmental mitigation measures)

With respect to the environment, with some exceptions, the risks associated with the use of acephate and its associated end-use products are acceptable when used in accordance with revised label directions and the risk mitigation measures presented in PRVD2019-04.

The following uses, however, were not shown to have acceptable environmental risk and will be cancelled:

- Airblast/outdoor mist blower applications which are currently registered for use on various trees and ornamentals, and in Christmas tree plantations, farm woodlots, nurseries, shelter belts, rights-of-way and municipal parks.

All revised label directions and risk mitigation measures are presented in Appendix III of this document.

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## List of Abbreviations

a.i.	active ingredient
ACP	acephate
ARI	Aggregate Risk Index
ARTF	Agricultural Reentry Task Force
ASAE	American Society of Agricultural Engineers
BMDL <sub>10</sub>	benchmark dose lower bound
bw	body weight
CFIA	Canadian Food Inspection Agency
cm	centimeter
d	day
DA	dermal absorption
DFR	dislodgeable foliar residues
EDE	estimated daily exposure
g	gram
ha	hectare
hr	hour
kg	kilogram
L	litre
LD <sub>50</sub>	lethal dose 50%
LOAEL	lowest observed adverse effect level
LOC	level of concern
LOD	limit of detection
LOEL	lowest-observed-effect level
m	meter
max	maximum
mg	milligram
Min	minimum
MOE	margin of exposure
MOM	methamidophos
MRL	maximum residue limit
N	number of samples
NOEL	no-observed-effect level
NPos	number of positive results
PHI	post-harvest interval
PMRA	Pest Management Regulatory Agency
PPE	personal protection equipment
ppm	parts per million
PRVD	proposed re-evaluation decision document
Reg.No	registration number
REI	restricted-entry interval
RQ	risk quotient
RVD	re-evaluation decision
TC	transfer coefficient
µg	microgram

## Appendix I 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 Being Cancelled**

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%

## Appendix II Comments and Responses

In response to the consultation for the proposed acephate re-evaluation decision, written comments were received. These comments were considered during the final decision phase of this re-evaluation. Health Canada's responses to the comments are provided below.

### Respondents and affiliations for comments submitted in response to PRVD2016-01 and PRVD2019-04

Category	Respondent
Registrant	Arysta LifeScience Canada, Inc.
Governmental organizations	New Brunswick Minor Use Coordinator
	Service des grands parcs, du verdissement et du Mont-Royal / Ville de Montréal
Agricultural and trade associations	BC Cranberry Growers Association
	Nova Scotia Cranberry Growers Association
	Canadian Cranberry Growers Coalition
	The Cranberry Institute
	Ontario Cranberry Growers Association
	Cranberry Association of Newfoundland and Labrador
	Canadian Nursery Landscape Association
	Flowers Canada Growers Inc.

## 1.0 Comments Related to the Health Risk Assessment

### Comments Related to Dietary Exposure

**Comment:** A comment was submitted by the City of Montreal regarding concerns about the potential contamination of acephate in honey, which could affect dietary exposure and risk.

**Health Canada's Response:** Monitoring data from the Canadian Food Inspection Agency (CFIA) were available for acephate and its major transformation product, methamidophos, in honey. There were no detectable residues of acephate or methamidophos in any domestic and imported honey samples tested. Generally, Health Canada will include honey in the dietary assessment if empirical data indicates the potential for exposure. In the case of acephate and methamidophos, the evidence does not indicate any potential for dietary exposure and risk from honey. Refer to Table 1 and Table 2 for details on the CFIA data.

**Table 1 Acephate CFIA 2010-2014**

Commodity	N	NPos	Min	Max	LOD (ppm)	Origin
Honey	376	0	-	-	0.007	Domestic
Honey	256	0	-	-	0.007	Imported

**Table 2 Methamidophos 2010-2014**

Commodity	N	NPos	Min	Max	LOD (ppm)	Origin
Honey	887	0	-	-	0.004	Domestic
Honey	429	0	-	-	0.004	Imported

CFIA: Canadian Food Inspection Agency; N: number of samples; NPos: number of positive results; LOD: limit of detection

### Comments Related to Occupational Exposure

**Comment:** Use information regarding application equipment used most frequently for cranberries was submitted by cranberry associations.

**Health Canada's Response:** This information was considered in this risk assessment. With the exception of chemigation, the application equipment assessed in PRVD2016-01 reflects this information. Although chemigation was assessed in PRVD2016-01, the assessment was removed from the current RVD. As per Regulatory Directive DIR93-13, *Chemigation*, this use must be identified on labels in conjunction with appropriate label directions. This use is not included on any acephate label, and thus, is not a registered use for acephate.

**Comment:** Another comment from cranberry associations indicated that there are no harvest, raking or pruning activities for cranberries within the 75 day pre-harvest interval (PHI) for cranberries.

**Health Canada's Response:** The label does not indicate a PHI for cranberries. The use instructions indicate a pre-bloom application with a possibility of a second application postbloom. The REIs for harvest, raking and pruning cranberries will remain on the label to protect the workers in situations where a second late application is applied.

**Comment:** Cranberry associations submitted information on scouting activities for cranberries.

**Health Canada's Response:** This information was considered in the updated risk assessment. The proposed scouting REI in PRVD2016-01 was re-calculated based on information received during the comment period and other information considered. The recalculated REI is 12 hrs for cranberry scouting, which is considered to be feasible for cranberry growers.

**Comment:** Flowers Canada Growers Inc. commented that the default transfer coefficient (TC) used for hand harvesting cut flowers (Gcf, 4000cm<sup>2</sup>/hr) and default DFR data assumptions often contribute to the regulatory decisions that identify occupational concerns for cut flowers.

**Health Canada's Response:** For the acephate assessment, default DFR values were not required, since a chemical-specific DFR study for greenhouse roses was submitted and used in the assessment. Standard TCs were used for all postapplication tasks as there was no chemical-specific exposure study available for acephate. More information on estimating worker postapplication exposure is available in Health Canada's Regulatory Proposal PRO2014-02, *Updated Agricultural Transfer Coefficients for Assessing Occupational Postapplication Exposure to Pesticides*. For specific information regarding the cut flower TC, refer to the response to the related comment below.



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**Comment:** Flowers Canada Growers Inc. commented that a 2 day REI for greenhouse grown cut flowers is feasible for growers. Many growers apply pest management tools over a weekend and do not re-enter the crop until the start of the next work week.

**Health Canada's Response:** This information has been considered in the revised risk assessment for cut flowers. Refer to Appendix III for the final REIs. Based on this comment, cancellation of acephate use on greenhouse cut flowers is no longer required. REIs of 2 days for hand harvesting, disbudding and hand pruning, and of 12 hours for all other tasks will be added to the label.

**Comment:** Flowers Canada Growers Inc. commented that Health Canada should consider that workers do utilize personal protection equipment (PPE) after pesticide application when harvesting cut flowers.

**Health Canada's Response:** Studies that are used currently to estimate postapplication worker exposure are based on workers wearing long-sleeved shirts, long pants, socks and footwear. It is also understood that many postapplication workers may wear gloves for their own personal comfort. However, there is no reliable data to indicate the degree of protection that various types of gloves may provide to postapplication workers, or conversely, the extent that gloves may enhance exposure under certain conditions (see below).

Before Health Canada can estimate risk to workers wearing gloves or other PPE, worker exposure studies comparable to those currently used by Health Canada are required. Studies that are currently used are discussed in the Regulatory Proposal PRO2014-14, *Updated Agricultural Transfer Coefficients for Assessing Occupational Postapplication Exposure to Pesticides*. Most, if not all, studies conducted by the ARTF, submitted by registrants, or available in the scientific literature that are used to determine Health Canada's TCs do not include gloves as a basis to estimate exposure. Gloves may have been worn in some of the studies; however, they were used as dosimeters to measure hand exposure without gloves, rather than exposure with protection from the gloves. While one limited study showed significant reduction in hand exposure when wearing gloves during tomato harvesting (Rech et al., 1989), a number of other available studies suggest that exposure may actually increase when gloves are worn (Brouwer, 2000; Boman et al., 2005; Garrigou et al., 2011; Graves et al., 1995; Keifer, 2000; Rawson et al., 2005).

Health Canada is currently participating in a working group that includes grower and industry representatives. The purpose of the working group is to a) investigate the potential use of PPE (specifically gloves) as a risk mitigation option for postapplication workers in pesticide treated areas and b) to investigate more efficient ways to gather postapplication worker information to ensure that risk assessments are kept up-to-date in reflecting activities that occur in the field. The scope of this information gathering includes both agricultural crops and ornamentals. The role of Health Canada on this working group is to provide regulatory advice and direction for any proposals suggested by the working group to meet the project goals. Currently, the working group is considering conducting studies to estimate the degree of protection offered by chemical-resistant gloves while performing activities in various crops for the purpose of determining a default protection factor of gloves for postapplication workers. Based on the outcome of these studies, Health Canada may consider gloves as a mitigation measure for postapplication workers in the future. Presently, such data are not available.

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**Comment:** Flowers Canada Growers Inc. commented that Health Canada should consider financially assisting the study of the accuracy of the default TCs and DFR data presently used in risk assessments. A study of floriculture TCs in Canada would be of considerable value to farmers, regulators, workers and the public.

**Health Canada's Response:** In order to support the registration of a currently registered pesticide, companies intending to sell a pest control product in Canada are responsible for generating and submitting detailed information for evaluation by Health Canada. Companies must provide all the scientific studies necessary for Health Canada to determine whether the risk from the use of the product is acceptable to human health. Health Canada uses the best available data to conduct the re-evaluations of pesticides and makes regulatory decisions accordingly. Pesticide companies are encouraged to contact Health Canada for direction on the generation of data to support a pesticide registration.

**Comment:** Flowers Canada Growers Inc. commented that the crops studied in Brouwer et al. 1992, and Schneider et al. 2002, Carnation, Carnation & Rose respectively, are largely not grown in Canada. A review of TCs on the harvest of currently produced cut flowers may differ considerably.

**Health Canada's Response:** Health Canada's TC for harvesting cut flowers (cluster Gcf) was based on data from three available studies (Brouwer et al., 1992; Schneider, et al., 2002; and ARF055). These three studies represent a number of cut flower crops, and active ingredients, thus capturing a range of variables. This is the best data currently available to determine postapplication exposure for cut flowers. As noted in the comment above, pesticide companies have the option of generating more specific or relevant data.

**Comment:** The Canadian Nursery Association expressed concern with Health Canada's proposal to cancel all residential uses of this product. Acecap 97 Systemic Insecticide Implants (Reg.No. 21568) is still an important tool in the management of hard to control invasive pests such as Emerald Ash Borer and Gypsy Moth which do not respect the boundaries between agricultural, forestry and residential lands. Acecap is applied to the inside of a mature tree via a drilled and sealed hole which significantly reduces worker and environmental exposure concerns.

**Health Canada's Response:** As proposed in PRVD2016-01 and confirmed in the current RVD, Health Canada will prohibit applications as a foliar spray method to trees and ornamentals in residential areas based on risk to human health from postapplication exposure. All treatments to trees and ornamentals using implant cartridges, and various methods of tree trunk injection that do not result in direct application to foliage are, however, acceptable for continued registration in residential areas. A label statement to clarify this point will be added.

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## 2.0 Comments Related to the Updated Environmental Risk Assessment (PRVD2019-04)

**All comments related to the cancellation of airblast applications were received from the registrant.**

**Comment:** Comments suggested that airblast application for foliar application in trees and ornamentals, Christmas tree plantations, tree nurseries, shelter belts, right-of-ways should be kept because these are small area farms with limited exposure off-field.

**Health Canada's Response:** The size of the treated area is not currently a parameter used by Health Canada to refine the estimate of potential exposure of non-target organisms. It is assumed that the size of the area being treated will vary within and between different types of use sites. Therefore, the assessment is general in nature to cover various scenarios of pesticide use at different sites across Canada. Potential off-field exposure is considered for all use sites when risks have been identified for a direct spray on the treated site. Off-field exposure includes an area directly adjacent to the treated field. Trees, ornamentals, Christmas tree plantations, tree nurseries, shelter belts, and rights-of-way may constitute habitats for many birds where they roost, feed and raise their young.

**Comment:** In order to retain airblast applications, the registrant proposed a reduction of the maximum airblast application rate to trees, ornamentals, Christmas tree plantations, tree nurseries, shelter belts and rights-of-way, from 1312 g a.i./ha to 637 g a.i./ha and that the assessment should use a late season application scenario.

The registrant suggested that airblast/out door mistblower applications on Christmas tree plantations, shelter belts, and rights-of-way are best modeled using late season applications because of the types of trees grown (evergreen) and the location where the product is applied (into forested areas), two factors that would limit drift into off-field areas.

**Health Canada's Response:** A bird and mammal risk assessment was conducted for the use of acephate applied by airblast/outdoor mist blower equipment at a rate of 637 g a.i./ha to verify the viability of the registrant's proposal. The assessment was conducted for acephate and its major transformation product, methamidophos, separately. Based on empirical concentrations of the two active substances in various plant tissues, it was assumed that 95% of applied acephate converts to methamidophos, leading to peak methamidophos molar concentration equal to 40% of the peak acephate molar concentration. The exposure scenario included mean residue levels in food items and maximum predicted levels. Additionally, risk was calculated for the lowest-observed-effect level (LOEL) as well as the no-observed-effect level (NOEL) for birds.

Based on a 'late season' application, the off-field assessment assumed that 59% of the acephate application was deposited 1 m downwind from the target area. 'Late season' applications are considered when the presence of fully emerged foliage on target plants/crops are present to intercept sprayed product. This model was considered to be appropriate in this case because of the amount of foliage expected at the time of application.

Based on a reproductive endpoint, risks to birds and mammals were again identified both on-field and off-field for the application rate of 637 g a.i./ha, particularly for small and medium sized insectivorous birds. For birds, using the acephate endpoints (Table 1), the screening level risk quotients (RQs) exceed the level of concern (LOC) for acute and reproductive effects (RQ = 5 and 118, respectively). For mammals, RQs for acute and reproductive effects also exceeded the LOC (RQ = 1.8 and 1.06, respectively; data not presented in table). The screening RQs exceeded the LOC for acute and reproductive methamidophos endpoints (Table 2, for birds, RQ = 47 and 119, respectively; for mammals, 32.5 and 85, respectively). The acute and reproductive risks to birds still exceeded the LOC at the rate of 637 g a.i./ha when it was assumed that only 1–2% of the diet of small insectivorous birds comes from sites treated with acephate (in consideration that birds seek food from various sources).

The foliar applications using airblast/outdoor mist blower equipment results in important on-field potential exposure and off-target drift and deposition onto habitats that are attractive to and used by birds and mammals. As such, when acephate is used with airblast and other mist blower equipment outdoors, risks for birds and wild mammals are a concern.

Using mean residues on food items with acephate endpoints, the LOC for small insectivore birds is exceeded from off-field acute and reproductive effects (RQ = 2 and 48, respectively). For mammals, RQs from off-field acute and reproductive effects of acephate do not exceed the LOC. However, for methamidophos, RQs for mammals are 7 and 18 for the highest acute and reproductive endpoints, respectively. For birds, RQs for off-field acute and reproductive endpoints are 19 and 48, respectively. All of these RQs exceed the LOC for methamidophos.

**Table 1 Expanded risk assessment for birds and mammals associated with late-season use of acephate applied by outdoor mist-blower/airblast equipment at a rate of 637 g a.i./ha**

Acephate on Ornamentals: 637 g a.i./ha. Airblast/outdoor mist blower - on-field and off-field (59% deposition downwind)										
Toxicity (mg a.i./kg bw/d)	Food Guild (food item)	Maximum nomogram residues				Mean nomogram residues				
		On-field		Off-field (59% drift)		On-field		Off-field (59% drift)		
		EDE (mg a.i./kg bw)	RQ	EDE (mg a.i./kg bw)	RQ	EDE (mg a.i./kg bw)	RQ	EDE (mg ai / kg bw)	RQ	
<b>Small Bird (0.02 kg)</b>										
Acute LD50 / 10	10.90	Insectivore	51.87	<b>4.8</b>	30.60	<b>2.8</b>	35.82	<b>3.29</b>	21.13	<b>1.94</b>
		Granivore (grain and seeds)	8.03	0.7	4.74	0.4	3.83	0.35	2.26	0.21
		Frugivore (fruit)	16.06	<b>1.5</b>	9.47	0.9	7.66	0.70	4.52	0.41
Dietary LD50 / 10	7.48	Insectivore	51.87	<b>6.9</b>	30.60	<b>4.1</b>	35.82	<b>4.79</b>	21.13	<b>2.83</b>
		Granivore (grain and seeds)	8.03	<b>1.1</b>	4.74	0.6	3.83	0.51	2.26	0.30
		Frugivore (fruit)	16.06	<b>2.1</b>	9.47	<b>1.3</b>	7.66	<b>1.02</b>	4.52	0.60
Reproduction NOEL / 1	0.44	Insectivore	51.87	<b>117.9</b>	30.60	<b>69.6</b>	35.82	<b>81.40</b>	21.13	<b>48.03</b>
		Granivore (grain and seeds)	8.03	<b>18.2</b>	4.74	<b>10.8</b>	3.83	<b>8.70</b>	2.26	<b>5.13</b>
		Frugivore (fruit)	16.06	<b>36.5</b>	9.47	<b>21.5</b>	7.66	<b>17.40</b>	4.52	<b>10.27</b>

Acephate on Ornamentals: 637 g a.i./ha. Airblast/outdoor mist blower - on-field and off-field (59% deposition downwind)										
Toxicity (mg a.i./kg bw/d)		Food Guild (food item)	Maximum nomogram residues				Mean nomogram residues			
			On-field		Off-field (59% drift)		On-field		Off-field (59% drift)	
			EDE (mg a.i./kg bw)	RQ	EDE (mg a.i./kg bw)	RQ	EDE (mg a.i./kg bw)	RQ	EDE (mg ai / kg bw)	RQ
Reproduction LOAEL / 1	2.03	Insectivore	51.87	<b>25.6</b>	30.60	<b>15.1</b>	35.82	<b>17.64</b>	21.13	<b>10.41</b>
		Granivore (grain and seeds)	8.03	<b>4.0</b>	4.74	<b>2.3</b>	3.83	<b>1.89</b>	2.26	<b>1.11</b>
		Frugivore (fruit)	16.06	<b>7.9</b>	9.47	<b>4.7</b>	7.66	<b>3.77</b>	4.52	<b>2.23</b>
<b>Medium Sized Bird (0.1 kg)</b>										
Acute LD50 / 10	10.90	Insectivore	40.48	<b>3.7</b>	23.88	<b>2.2</b>	27.95	<b>2.56</b>	16.49	<b>1.51</b>
		Granivore (grain and seeds)	6.26	0.6	3.70	0.3	2.99	0.27	1.76	0.16
		Frugivore (fruit)	12.53	<b>1.1</b>	7.39	0.7	5.98	0.55	3.53	0.32
Dietary LD50 / 10	7.48	Insectivore	40.48	<b>5.4</b>	23.88	<b>3.2</b>	27.95	<b>3.74</b>	16.49	<b>2.20</b>
		Granivore (grain and seeds)	6.26	0.8	3.70	0.5	2.99	0.40	1.76	0.24
		Frugivore (fruit)	12.53	<b>1.7</b>	7.39	1.0	5.98	0.80	3.53	0.47
Reproduction NOEL / 1	0.44	Insectivore	40.48	<b>92.0</b>	23.88	<b>54.3</b>	27.95	<b>63.53</b>	16.49	<b>37.48</b>
		Granivore (grain and seeds)	6.26	<b>14.2</b>	3.70	<b>8.4</b>	2.99	<b>6.79</b>	1.76	<b>4.01</b>
		Frugivore (fruit)	12.53	<b>28.5</b>	7.39	<b>16.8</b>	5.98	<b>13.58</b>	3.53	<b>8.01</b>
Reproduction LOAEL / 1	2.03	Insectivore	40.48	<b>19.9</b>	23.88	<b>11.8</b>	27.95	<b>13.77</b>	16.49	<b>8.12</b>
		Granivore (grain and seeds)	6.26	<b>3.1</b>	3.70	<b>1.8</b>	2.99	<b>1.47</b>	1.76	0.87
		Frugivore (fruit)	12.53	<b>6.2</b>	7.39	<b>3.6</b>	5.98	<b>2.94</b>	3.53	<b>1.74</b>
<b>Large Sized Bird (1 kg)</b>										
Acute LD50 / 10	10.90	Insectivore	11.82	<b>1.1</b>	6.97	0.6	8.16	0.75	4.81	0.44
		Granivore (grain and seeds)	1.83	0.2	1.08	< 0.1	0.87	< 0.1	0.51	< 0.1
		Frugivore (fruit)	3.66	0.3	2.16	0.2	1.74	0.16	1.03	< 0.1
		Herbivore (short grass)	26.15	<b>2.4</b>	15.43	<b>1.4</b>	9.29	0.85	5.48	0.50
		Herbivore (long grass)	15.97	<b>1.5</b>	9.42	0.9	5.21	0.48	3.08	0.28
		Herbivore (Broadleaf plants)	24.19	<b>2.2</b>	14.27	<b>1.3</b>	8.00	0.73	4.72	0.43
Dietary LD50 / 10	7.48	Insectivore	11.82	<b>1.6</b>	6.97	0.9	8.16	<b>1.09</b>	4.81	0.64
		Granivore (grain and seeds)	1.83	0.2	1.08	0.1	0.87	0.12	0.51	< 0.1
		Frugivore (fruit)	3.66	0.5	2.16	0.3	1.74	0.23	1.03	0.14
		Herbivore (short grass)	26.15	<b>3.5</b>	15.43	<b>2.1</b>	9.29	<b>1.24</b>	5.48	0.73
		Herbivore (long grass)	15.97	<b>2.1</b>	9.42	<b>1.3</b>	5.21	0.70	3.08	0.41
		Herbivore (Broadleaf plants)	24.19	<b>3.2</b>	14.27	<b>1.9</b>	8.00	<b>1.07</b>	4.72	0.63

Acephate on Ornamentals: 637 g a.i./ha. Airblast/outdoor mist blower - on-field and off-field (59% deposition downwind)										
Toxicity (mg a.i./kg bw/d)	Food Guild (food item)	Maximum nomogram residues				Mean nomogram residues				
		On-field		Off-field (59% drift)		On-field		Off-field (59% drift)		
		EDE (mg a.i./kg bw)	RQ	EDE (mg a.i./kg bw)	RQ	EDE (mg a.i./kg bw)	RQ	EDE (mg ai / kg bw)	RQ	
Reproduction NOEL / 1	0.44	Insectivore	11.82	<b>26.9</b>	6.97	<b>15.8</b>	8.16	<b>18.55</b>	4.81	<b>10.94</b>
		Granivore (grain and seeds)	1.83	<b>4.2</b>	1.08	<b>2.5</b>	0.87	<b>1.98</b>	0.51	<b>1.17</b>
		Frugivore (fruit)	3.66	<b>8.3</b>	2.16	<b>4.9</b>	1.74	<b>3.97</b>	1.03	<b>2.34</b>
		Herbivore (short grass)	26.15	<b>59.4</b>	15.43	<b>35.1</b>	9.29	<b>21.11</b>	5.48	<b>12.45</b>
		Herbivore (long grass)	15.97	<b>36.3</b>	9.42	<b>21.4</b>	5.21	<b>11.85</b>	3.08	<b>6.99</b>
		Herbivore (Broadleaf plants)	24.19	<b>55.0</b>	14.27	<b>32.4</b>	8.00	<b>18.18</b>	4.72	<b>10.72</b>
Reproduction LOAEL / 1	2.03	Insectivore	11.82	<b>5.8</b>	6.97	<b>3.4</b>	8.16	<b>4.02</b>	4.81	<b>2.37</b>
		Granivore (grain and seeds)	1.83	0.9	1.08	0.5	0.87	0.43	0.51	0.25
		Frugivore (fruit)	3.66	<b>1.8</b>	2.16	<b>1.1</b>	1.74	0.86	1.03	0.51
		Herbivore (short grass)	26.15	<b>12.9</b>	15.43	<b>7.6</b>	9.29	<b>4.57</b>	5.48	<b>2.70</b>
		Herbivore (long grass)	15.97	<b>7.9</b>	9.42	<b>4.6</b>	5.21	<b>2.57</b>	3.08	<b>1.52</b>
		Herbivore (Broadleaf plants)	24.19	<b>11.9</b>	14.27	<b>7.0</b>	8.00	<b>3.94</b>	4.72	<b>2.32</b>

**Table 2 Risk assessment for birds and mammals exposed to methamidophos associated with late-season use of acephate applied by outdoor mist-blower/airblast equipment at a rate of 637 g a.i./ha**

Methamidophos on Ornamentals: 1 × 466 <sup>1</sup> g a.i./ha. Airblast/outdoor mist blower - on-field and off-field (59% deposition downwind)										
Toxicity (mg a.i./kg bw/d)	Food Guild (food item)	Maximum nomogram residues				Mean nomogram residues				
		On-field		Off-field (59% drift)		On-field		Off-field (59% drift)		
		EDE (mg a.i./kg bw)	RQ	EDE (mg a.i./kg bw)	RQ	EDE (mg a.i./kg bw)	RQ	EDE (mg ai / kg bw)	RQ	
<b>Small Bird (0.02 kg)</b>										
Acute LD50 / 10	0.8	Insectivore	37.93	<b>47.4</b>	22.38	<b>28</b>	26.19	<b>32.74</b>	15.45	<b>19.31</b>
		Granivore (grain and seeds)	5.87	<b>7.3</b>	3.46	<b>4.3</b>	2.8	<b>3.5</b>	1.65	<b>2.06</b>
		Frugivore (fruit)	11.74	<b>14.7</b>	6.93	<b>8.7</b>	5.6	<b>7</b>	3.3	<b>4.13</b>
Reproduction NOEL / 1	0.3 2	Insectivore	37.93	<b>118.5</b>	22.38	<b>69.9</b>	26.19	<b>81.84</b>	15.45	<b>48.28</b>
		Granivore (grain and seeds)	5.87	<b>18.3</b>	3.46	<b>10.8</b>	2.8	<b>8.75</b>	1.65	<b>5.16</b>
		Frugivore (fruit)	11.74	<b>36.7</b>	6.93	<b>21.6</b>	5.6	<b>17.5</b>	3.3	<b>10.32</b>



<b>Methamidophos on Ornamentals: 1 × 466<sup>1</sup> g a.i./ha. Airblast/outdoor mist blower - on-field and off-field (59% deposition downwind)</b>										
<b>Toxicity (mg a.i./kg bw/d)</b>		<b>Food Guild (food item)</b>	<b>Maximum nomogram residues</b>				<b>Mean nomogram residues</b>			
			<b>On-field</b>		<b>Off-field (59% drift)</b>		<b>On-field</b>		<b>Off-field (59% drift)</b>	
			<b>EDE (mg a.i./kg bw)</b>	<b>RQ</b>	<b>EDE (mg a.i./kg bw)</b>	<b>RQ</b>	<b>EDE (mg a.i./kg bw)</b>	<b>RQ</b>	<b>EDE (mg ai /kg bw)</b>	<b>RQ</b>
Reproduction LOAEL / 1	0.5 3	Insectivore	37.93	<b>71.6</b>	22.38	<b>42.2</b>	26.19	<b>49.41</b>	15.45	<b>29.15</b>
		Granivore (grain and seeds)	5.87	<b>11.1</b>	3.46	<b>6.5</b>	2.8	<b>5.28</b>	1.65	<b>3.12</b>
		Frugivore (fruit)	11.74	<b>22.2</b>	6.93	<b>13.1</b>	5.6	<b>10.56</b>	3.3	<b>6.23</b>
<b>Medium Sized Bird (0.1 kg)</b>										
Acute LD50 / 10	0.8	Insectivore	29.6	<b>37</b>	17.46	<b>21.8</b>	20.44	<b>25.55</b>	12.06	<b>15.07</b>
		Granivore (grain and seeds)	4.58	<b>5.7</b>	2.7	<b>3.4</b>	2.18	<b>2.73</b>	1.29	<b>1.61</b>
		Frugivore (fruit)	9.16	<b>11.5</b>	5.41	<b>6.8</b>	4.37	<b>5.46</b>	2.58	<b>3.22</b>
Reproduction NOEL / 1	0.3 2	Insectivore	29.6	<b>92.5</b>	17.46	<b>54.6</b>	20.44	<b>63.87</b>	12.06	<b>37.68</b>
		Granivore (grain and seeds)	4.58	<b>14.3</b>	2.7	<b>8.4</b>	2.18	<b>6.83</b>	1.29	<b>4.03</b>
		Frugivore (fruit)	9.16	<b>28.6</b>	5.41	<b>16.9</b>	4.37	<b>13.65</b>	2.58	<b>8.06</b>
Reproduction LOAEL / 1	0.5 3	Insectivore	29.6	<b>55.8</b>	17.46	<b>32.9</b>	20.44	<b>38.56</b>	12.06	<b>22.75</b>
		Granivore (grain and seeds)	4.58	<b>8.6</b>	2.7	<b>5.1</b>	2.18	<b>4.12</b>	1.29	<b>2.43</b>
		Frugivore (fruit)	9.16	<b>17.3</b>	5.41	<b>10.2</b>	4.37	<b>8.24</b>	2.58	<b>4.86</b>
<b>Large Sized Bird (1 kg)</b>										
Acute LD50 / 10	0.8	Insectivore	8.64	<b>10.8</b>	5.1	<b>6.4</b>	5.97	<b>7.46</b>	3.52	<b>4.4</b>
		Granivore (grain and seeds)	1.34	<b>1.7</b>	0.79	<b>1</b>	0.64	<b>0.8</b>	0.38	<b>0.47</b>
		Frugivore (fruit)	2.67	<b>3.3</b>	1.58	<b>2</b>	1.28	<b>1.59</b>	0.75	<b>0.94</b>
		Herbivore (short grass)	19.12	<b>23.9</b>	11.28	<b>14.1</b>	6.79	<b>8.49</b>	4.01	<b>5.01</b>
		Herbivore (long grass)	11.67	<b>14.6</b>	6.89	<b>8.6</b>	3.81	<b>4.76</b>	2.25	<b>2.81</b>
		Herbivore (Broadleaf plants)	17.69	<b>22.1</b>	10.44	<b>13</b>	5.85	<b>7.31</b>	3.45	<b>4.31</b>
Reproduction NOEL / 1	0.3 2	Insectivore	8.64	<b>27</b>	5.1	<b>15.9</b>	5.97	<b>18.65</b>	3.52	<b>11</b>
		Granivore (grain and seeds)	1.34	<b>4.2</b>	0.79	<b>2.5</b>	0.64	<b>1.99</b>	0.38	<b>1.18</b>
		Frugivore (fruit)	2.67	<b>8.4</b>	1.58	<b>4.9</b>	1.28	<b>3.99</b>	0.75	<b>2.35</b>
		Herbivore (short grass)	19.12	<b>59.7</b>	11.28	<b>35.3</b>	6.79	<b>21.22</b>	4.01	<b>12.52</b>
		Herbivore (long grass)	11.67	<b>36.5</b>	6.89	<b>21.5</b>	3.81	<b>11.91</b>	2.25	<b>7.03</b>
		Herbivore (Broadleaf plants)	17.69	<b>55.3</b>	10.44	<b>32.6</b>	5.85	<b>18.27</b>	3.45	<b>10.78</b>
Reproduction LOAEL / 1	0.5 3	Insectivore	8.64	<b>16.3</b>	5.1	<b>9.6</b>	5.97	<b>11.26</b>	3.52	<b>6.64</b>
		Granivore (grain and seeds)	1.34	<b>2.5</b>	0.79	<b>1.5</b>	0.64	<b>1.2</b>	0.38	<b>0.71</b>
		Frugivore (fruit)	2.67	<b>5</b>	1.58	<b>3</b>	1.28	<b>2.41</b>	0.75	<b>1.42</b>
		Herbivore (short grass)	19.12	<b>36.1</b>	11.28	<b>21.3</b>	6.79	<b>12.81</b>	4.01	<b>7.56</b>

<b>Methamidophos on Ornamentals: 1 × 466<sup>1</sup> g a.i./ha. Airblast/outdoor mist blower - on-field and off-field (59% deposition downwind)</b>										
Toxicity (mg a.i./kg bw/d)	Food Guild (food item)	Maximum nomogram residues				Mean nomogram residues				
		On-field		Off-field (59% drift)		On-field		Off-field (59% drift)		
		EDE (mg a.i./kg bw)	RQ	EDE (mg a.i./kg bw)	RQ	EDE (mg a.i./kg bw)	RQ	EDE (mg ai /kg bw)	RQ	
	Herbivore (long grass)	11.67	22	6.89	13	3.81	7.19	2.25	4.24	
	Herbivore (Broadleaf plants)	17.69	33.4	10.44	19.7	5.85	11.03	3.45	6.51	
<b>Small Mammal (0.015 kg)</b>										
Acute LD50 / 10	1.3	Insectivore	21.81	16.8	12.87	9.9	15.06	11.59	8.89	6.84
		Granivore (grain and seeds)	3.38	2.6	1.99	1.5	1.61	1.24	0.95	0.73
		Frugivore (fruit)	6.75	5.2	3.98	3.1	3.22	2.48	1.9	1.46
Reproduction NOEL / 1	0.5	Insectivore	21.81	43.6	12.87	25.7	15.06	30.12	8.89	17.77
		Granivore (grain and seeds)	3.38	6.8	1.99	4	1.61	3.22	0.95	1.9
		Frugivore (fruit)	6.75	13.5	3.98	8	3.22	6.44	1.9	3.8
Reproduction LOAEL / 1	1.6 5	Insectivore	21.81	13.2	12.87	7.8	15.06	9.13	8.89	5.39
		Granivore (grain and seeds)	3.38	2.046	1.99	1.2	1.61	0.98	0.95	0.58
		Frugivore (fruit)	6.75	4.1	3.98	2.4	3.22	1.95	1.9	1.15
<b>Medium Sized Mammal (0.035 kg)</b>										
Acute LD50 / 10	1.3	Insectivore	19.12	14.7	11.28	8.7	13.2	10.2	7.79	6
		Granivore (grain and seeds)	2.96	2.3	1.75	1.3	1.41	1.1	0.83	0.6
		Frugivore (fruit)	5.92	4.6	3.49	2.7	2.82	2.2	1.67	1.3
		Herbivore (short grass)	42.31	32.5	24.96	19.2	15.03	11.6	8.87	6.8
		Herbivore (long grass)	25.83	19.9	15.24	11.7	8.44	6.5	4.98	3.8
		Herbivore (forage crops)	39.15	30.1	23.1	17.8	12.94	10	7.63	5.9
Reproduction NOEL / 1	0.5	Insectivore	19.12	38.2	11.28	22.6	13.2	26.4	7.79	15.6
		Granivore (grain and seeds)	2.96	5.9	1.75	3.5	1.41	2.8	0.83	1.7
		Frugivore (fruit)	5.92	11.8	3.49	7	2.82	5.6	1.67	3.3
		Herbivore (short grass)	42.31	84.6	24.96	49.9	15.03	30.1	8.87	17.7
		Herbivore (long grass)	25.83	51.7	15.24	30.5	8.44	16.9	4.98	10
		Herbivore (Broadleaf plants)	39.15	78.3	23.1	46.2	12.94	25.9	7.63	15.3
Reproduction LOAEL / 1	1.6 5	Insectivore	19.12	11.6	11.28	6.8	13.2	8	7.79	4.7
		Granivore (grain and seeds)	2.96	1.8	1.75	1.1	1.41	0.9	0.83	0.5
		Frugivore (fruit)	5.92	3.6	3.49	2.1	2.82	1.7	1.67	1
		Herbivore (short grass)	42.31	25.6	24.96	15.1	15.03	9.1	8.87	5.4



<b>Methamidophos on Ornamentals: 1 × 466<sup>1</sup> g a.i./ha. Airblast/outdoor mist blower - on-field and off-field (59% deposition downwind)</b>										
Toxicity (mg a.i./kg bw/d)	Food Guild (food item)	Maximum nomogram residues				Mean nomogram residues				
		On-field		Off-field (59% drift)		On-field		Off-field (59% drift)		
		EDE (mg a.i./kg bw)	RQ	EDE (mg a.i./kg bw)	RQ	EDE (mg a.i./kg bw)	RQ	EDE (mg ai /kg bw)	RQ	
	Herbivore (long grass)	25.83	<b>15.7</b>	15.24	<b>9.2</b>	8.44	<b>5.1</b>	4.98	<b>3</b>	
	Herbivore (broadleaf plants)	39.15	<b>23.7</b>	23.1	<b>14</b>	12.94	<b>7.8</b>	7.63	<b>4.6</b>	
<b>Large Sized Mammal (1 kg)</b>										
Acute LD50 / 10	1.3	Insectivore	10.22	<b>7.9</b>	6.03	<b>4.6</b>	7.06	<b>5.4</b>	4.16	<b>3.2</b>
		Granivore (grain and seeds)	1.58	<b>1.2</b>	0.93	0.7	0.75	0.6	0.44	0.3
		Frugivore (fruit)	3.16	<b>2.4</b>	1.87	<b>1.4</b>	1.51	<b>1.2</b>	0.89	0.7
		Herbivore (short grass)	22.61	<b>17.4</b>	13.34	<b>10.3</b>	8.03	<b>6.2</b>	4.74	<b>3.6</b>
		Herbivore (long grass)	13.8	<b>10.6</b>	8.14	<b>6.3</b>	4.51	<b>3.5</b>	2.66	<b>2</b>
		Herbivore (broadleaf plants)	20.92	<b>16.1</b>	12.34	<b>9.5</b>	6.91	<b>5.3</b>	4.08	<b>3.1</b>
Reproduction NOEL / 1	0.5	Insectivore	10.22	<b>20.4</b>	6.03	<b>12.1</b>	7.06	<b>14.1</b>	4.16	<b>8.3</b>
		Granivore (grain and seeds)	1.58	<b>3.2</b>	0.93	<b>1.9</b>	0.75	<b>1.5</b>	0.44	0.9
		Frugivore (fruit)	3.16	<b>6.3</b>	1.87	<b>3.7</b>	1.51	<b>3</b>	0.89	<b>1.8</b>
		Herbivore (short grass)	22.61	<b>45.2</b>	13.34	<b>26.7</b>	8.03	<b>16.1</b>	4.74	<b>9.5</b>
		Herbivore (long grass)	13.8	<b>27.6</b>	8.14	<b>16.3</b>	4.51	<b>9</b>	2.66	<b>5.3</b>
		Herbivore (Broadleaf plants)	20.92	<b>41.8</b>	12.34	<b>24.7</b>	6.91	<b>13.8</b>	4.08	<b>8.2</b>
Reproduction LOAEL / 1	1.6 5	Insectivore	10.22	<b>6.2</b>	6.03	<b>3.7</b>	7.06	<b>4.3</b>	4.16	<b>2.5</b>
		Granivore (grain and seeds)	1.58	1	0.93	0.6	0.75	0.5	0.44	0.3
		Frugivore (fruit)	3.16	<b>1.9</b>	1.87	<b>1.1</b>	1.51	0.9	0.89	0.5
		Herbivore (short grass)	22.61	<b>13.7</b>	13.34	<b>8.1</b>	8.03	<b>4.9</b>	4.74	<b>2.9</b>
		Herbivore (long grass)	13.8	<b>8.4</b>	8.14	<b>4.9</b>	4.51	<b>2.7</b>	2.66	<b>1.6</b>
		Herbivore (broadleaf plants)	20.92	<b>12.7</b>	12.34	<b>7.5</b>	6.91	<b>4.2</b>	4.08	<b>2.5</b>

<sup>1</sup>Estimated by multiplying the proposed acephate application rate (637 g a.i./ha) by the methamidophos/acephate molecular weight ratio (77%) and by an assumed 95% conversion rate of acephate into methamidophos.

**Comment:** One comment pointed to studies that indicate reduced feeding in birds due to acephate and methamidophos. This level of avoidance is so significant that the toxicology endpoints may represent the effects of anorexia in birds rather than actual direct toxic effects.

**Health Canada's Response:** In the current environmental risk assessment, the most sensitive avian endpoint was from a reproduction study with mallard duck in which adverse reproduction effects were observed in a treatment group for which food consumption was not significantly different from that of the control group.

**Comment:** The registrant asserted that birds in laboratory toxicity studies are faced with a “no choice” situation which artificially increase exposure levels relative to natural conditions in which they would switch to other food sources.

**Health Canada's Response:** Laboratory toxicity studies are required to determine toxicity endpoints and are not intended to mimic realistic environmental exposure. Avoidance behavior may reduce wildlife exposure under certain circumstances. For example, some animals may avoid food sources if these become unpalatable after being sprayed, or if they associate certain food sources with feeling sick. However, no information was submitted to demonstrate specifically that birds would avoid feeding on food treated with acephate or methamidophos. Furthermore, mortalities and sub-lethal effects (for example, reduced brain cholinesterase) have been reported in wild birds collected from areas sprayed with acephate, providing evidence of wildlife exposure in the environment (for example, Mineau, 2002).

**Comment:** The registrant suggested that the current risk assessment is based on a conservative assumption that birds feed exclusively on food sources from the treatment site. However, the treated sites only occupy a small area and they may not constitute good foraging habitats for insectivores since arthropods are controlled by the active ingredient.

**Health Canada's Response:** The re-evaluation for acephate included an assessment of the on-field and off-field risks to birds from spray drift. The percentage of diet required to reach the LOC is equal to the reciprocal of the RQ (that is,  $1/RQ$ ). Based on the reproduction NOEL, the RQ for small birds for on-field and off-field sites ranged from 81–118 and 48-70, respectively. Thus, the LOC for reproduction is exceeded when only 1–2% of the diet of small insectivorous birds comes from sites treated with acephate at the lower proposed application rate of 637 g a.i./ha or from adjacent off-field sites receiving spray drift deposition.

**Comment:** The registrant proposed that the following instructions be added to acephate labels to reduce drift from airblast applications in trees, ornamentals, Christmas tree plantations, tree nurseries, shelter belts, right-of-ways, and thereby mitigate risks to birds:

- Turn off the sprayer when there are no trees present.
- Keep the spray as close to the target as possible.
- Minimize the small droplet fraction; however, remember that the purpose of spraying is to control pests. Large droplets may not provide the control desired without increasing the application rate.
- Match the sprayer air jet (volume and direction) and nozzle system to the trees being sprayed.
- Use special techniques near sensitive areas, especially for the last few downwind/outer rows. These may include:
  - use large droplets;
  - use techniques to direct spray at targets better, such as a handgun;

- spray the last few rows upwind and inward only; 10 m buffer from inside the treated area to the outer edge to reduce off-target drift;
- wait and spray when the wind shifts

**Health Canada's Response:** Although some of these measures may reduce off-field drift, bird exposure is still expected to be too high as only 1% drift results in exceeding the LOC. These use sites (that is, trees, ornamentals, Christmas tree plantations, tree nurseries, shelter belts, and rights-of-way) are potentially important habitat for birds. Both on- and off-field risks from the use of acephate on these sites is a concern. Compared to ground boom applications, airblast/outdoor mist blower equipment is expected to lead to higher non-target exposure with higher off-field deposition. Application of acephate by ground boom (excluding airblast/outdoor mist blower) or hand-held application equipment to trees, ornamentals, in Christmas tree plantations and tree nurseries will be permitted. Uses in farm woodlots, shelter belts, and rights-of-way will be limited to spot treatments using hand-held equipment only.

### 3.0 Comments Related to the Value Assessment

#### [Comments in response to PRVD2016-01]

**Comment:** Comments received from cranberry associations pointed to the importance of acephate as an effective tool for resistance management for control of black headed fireworm.

**Health Canada's Response:** Health Canada acknowledges that acephate is of value in cranberry production to control black headed fireworm and to manage insecticide resistance, and notes that this use was not proposed for cancellation.

**Comment:** Agricultural and trade associations from the cranberry and ornamental sectors commented that uses from the soluble powder formulation should be transferred to the soluble granule formulation.

**Health Canada's Response:** A transfer of uses on the label from the soluble powder-formulated product to that of the soluble granule formulation (Orthene 97% Soluble Granule Systemic Insecticide) has been done under a separate submission.

**Comment:** Comments from cranberry associations indicated a desire to add chemigation as a method for use on labels.

**Health Canada's Response:** Since chemigation is considered to be a new application method, its addition for use on cranberry will require a separate pre-market application to Health Canada.

**Comment:** Cranberry associations commented that there is confusion regarding the active ingredient rate listed on the label. Users assumed that the active ingredient rate should be 75% of the 0.56 kg/ha value.

**Health Canada's Response:** The rate for cranberry in PRVD2016-01 is correct. The label in question (Reg.No. 14225) expresses the rate on the basis of active ingredient, that is, 562 g a.i./ha.

**Comment:** Comments received from the Canadian Nursery Landscape Association, Flowers Canada Growers Inc., and New Brunswick Department of Agriculture, Aquaculture and Fisheries pointed to the value of acephate as a pest control tool on field grown and greenhouse ornamentals, especially for hard to control pests.

**Health Canada's Response:** Health Canada acknowledges that acephate is an important component of pest management programs to manage pests in ornamentals. Under the re-evaluation decision, growers will still be able to use acephate in their spray program to control the listed pests on field and greenhouse ornamentals.

**[Comments in response to PRVD2019-04]**

**Comment:** The registrant asserted that: acephate is needed by growers to meet specific pest issues and is one of few organophosphates available today. It is used to “clean-up” populations of insects that have become unmanageable by other pest control methods, and is used in rotation with newer chemistries, which are prone to resistance. Typically, acephate is not applied as a broadcast across the entire growing area, but applied only where needed. Specific needs include black vine weevil, where other longer residual insecticides are no longer available, and for white pine weevil in spruce production since dimethoate is no longer used.

**Health Canada's Response:** Health Canada acknowledges that acephate controls a wide variety of insect pests, and is an effective organophosphate insecticide. Continued registration of acephate allows users to alternate between different insecticide modes of action, and as such contributes to effective resistance management practices. In Canada, acephate is not currently registered for use as a foliar spray for black vine weevil or white pine weevil.

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## Appendix III Label Amendments for Products Containing Acephate

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

**The commercial product, Orthene 75% Soluble Powder Systemic Insecticide (Reg.No. 14225) is being cancelled.**

### III.1 Amendments to Address Health Risk Assessment

**The following amendments apply to all commercial end use products containing acephate:**

**Text under ‘TOXICOLOGICAL INFORMATION’ should be expanded and/or standardized, as follows:**

#### **Toxicology Information**

Acephate is an organophosphate that is a cholinesterase inhibitor. Typical symptoms of overexposure to cholinesterase inhibitors include headache, nausea, dizziness, sweating, salivation, runny nose and eyes. This may progress to muscle twitching, weakness, tremor, incoordination, vomiting, abdominal cramps and diarrhea in more serious poisonings. A life-threatening poisoning is signified by loss of consciousness, incontinence, convulsions and respiratory depression with a secondary cardiovascular component. Treat symptomatically. If exposed, plasma and red blood cell cholinesterase tests may indicate degree of exposure (baseline data are useful). Atropine, only by injection, is the preferable antidote. Oximes, such as pralidoxime chloride, may be therapeutic if used early; however, use only in conjunction with atropine. In cases of severe acute poisoning, use antidotes immediately after establishing an open airway and respiration. With oral exposure, the decision of whether to induce vomiting or not should be made by an attending physician.

**The following amendments apply to soluble granule-formulated commercial end use product labels (Registration No. 29499):**

**Add the following precaution statements for spray applications:**

DO NOT apply as a foliar application in residential areas. Residential areas are defined as any use site where bystanders including children could be exposed during or after application. This includes in and around homes, schools, public buildings or any other areas where the general public including children could be exposed.

Apply only when the potential for drift beyond the area to be treated is minimal. Take into consideration wind speed, wind direction, temperature inversions, application equipment and sprayer settings.

**Include the following directions as appropriate:**

**Personal Protective Equipment**

**Mechanically-Pressurized Handgun**

Wear a long-sleeved shirt, long pants, chemical-resistant gloves, socks and shoes during mixing, loading, application, clean-up and repair. In addition, a respirator with a NIOSH-approved organic-vapour-removing cartridge with a prefilter approved for pesticides OR a NIOSH -approved canister for pesticides, **MUST** be worn.

**All other Equipment**

Wear a long-sleeved shirt, long pants, chemical-resistant gloves, socks and shoes during mixing, loading, application, clean-up and repair. Gloves are not required during application within a closed cab.

For handheld application when applying above waist height, including overhead, chemical resistant headgear must be worn. Chemical-resistant headgear includes Sou'Wester hat, chemical-resistant rain hat or large brimmed waterproof hat and hood with sufficient neck protection.

**Under 'DIRECTIONS FOR USE', the following will be added:**

DO NOT apply using handheld mistblowers/airblast or handheld fogging equipment.

DO NOT apply in greenhouses, except on ornamentals (including roses)

**Remove all potato uses and associated directions.**

**Revise labels to reflect required mitigation as follows:**

**Maximum application rates, maximum number of applications and minimum re-treatment intervals:** The label must be modified so that the maximum application rate, maximum number of applications, minimum retreatment interval and application directions on the label match those specified in Table 1 for each crop currently registered on the label.

**Table 1 Maximum Application Rates, Maximum Number of Applications per Year and Minimum Retreatment Application Intervals**

<b>Crop</b>	<b>Maximum Application Rate (kg a.i./ha)</b>	<b>Maximum Number of applications per Year</b>	<b>Minimum Retreatment Interval (days)</b>
Bell Peppers	0.825	2	14
Brussels Sprouts	0.56	2	14
Cabbage	0.56	2	14
Cauliflower	0.56	2	14
Head Lettuce	0.56	2	14

Crop	Maximum Application Rate (kg a.i./ha)	Maximum Number of applications per Year	Minimum Retreatment Interval (days)
Celery	0.56	2	14
Sweet Corn	0.56	2	14
Seed Corn	0.56	2	14
Ornamentals, trees and cut flowers (greenhouse and outdoors)	0.637	2	7

**Under precautions, add the following label statements and table:**

DO NOT enter or allow worker entry into treated areas to perform postapplication activities during the intervals specified in Table 2.

**Table 2 Restricted-Entry Intervals (REIs) and Pre-Harvest Intervals (PHI) for Acephate**

Crop	Postapplication Activity	REI and/or PHI
Cauliflower, Brussels Sprouts, Cabbage	Harvesting*	28 days
	All other activities	12 hrs
Celery	Harvesting*	21 days
	All other activities	12 hrs
Head lettuce	Harvesting*	7 days
	All other activities	12 hrs
Bell Peppers	Harvesting*	7 days
	Hand set/hand line irrigation related activities involving foliar contact	2 days
	All other activities	12 hrs
Cranberries	Hand harvesting-raking	5 days
	Mechanical harvesting	12 hrs
	All other activities	12 hrs
Seed corn	Hand detasseling	13 days
	All other activities	12 hrs
Sweet corn	Harvesting*	21 days
	All other activities	12 hrs
Saskatoon Berries	Harvesting*	11 months
	All other activities	12 hrs
Tobacco (seedlings)	All activities	12 hrs
Tobacco (mature plant)	Hand set/hand line irrigation related activities involving foliar contact	6 days
	Harvesting*	3 days
	All other activities	12 hrs
Tomato seedlings	All activities	12 hrs
Ornamentals, non-cut flowers (outdoors)	Hand set/hand line irrigation related activities involving foliar contact	11 days

Crop	Postapplication Activity	REI and/or PHI
	All other activities	12 hrs
Ornamentals grown for cut flowers (outdoors)	Hand harvesting, hand pruning (full foliage) disbudding	7 days
	All other activities (container moving, hand weeding, scouting, planting / transplanting, hand pruning (minimum foliage), pinching, plant support/staking, and hand set/hand line irrigation related activities involving foliar contact)	12 hrs
Trees (coniferous and deciduous) Foliar application	Hand set/hand line irrigation related activities involving foliar contact	7 days
	Harvesting (Christmas trees)	5 days
	All other activities	12 hrs
Ornamentals, non-cut flowers (greenhouse)	All activities	12 hrs
Ornamentals grown for cut flowers (greenhouse)	Hand harvesting, hand pruning (full foliage) disbudding	2 days
	All other activities (container moving, hand weeding, scouting, planting / transplanting, hand pruning (minimum foliage), pinching, plant support/staking)	12 hrs

\*Harvesting REI/PHI includes all methods of harvesting (i.e., hand, mechanically-assisted and mechanical)

### Add

“For non-crop areas, DO NOT enter or allow worker entry until sprays have dried”.

**REMOVE all label directions related to interim mitigation measures for mixer/loaders and applicators, and postapplication workers (REIs) required in REV2007-02.**

**REMOVE all label directions related to foliar treatment in Municipal Parks, as these fall under the criteria of residential areas.**

**The following amendments apply to all commercial end use products containing acephate that are formulated as implants:**

**Add the following PPE label directions as appropriate:**

Applicators must wear a long-sleeved shirt, long pants and chemical-resistant gloves.

#### **IN AREAS OF PUBLIC ACCESS**

Ensure that implant holes are covered with a suitable wound dressing prior to leaving the treated trees.

This product may be used in residential areas. Entry to treated areas by bystanders is restricted until all insecticide is injected into the trees.



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**Remove the following label text:**

“Do not apply by air”

**“Postapplication:**

- Do not enter or allow worker entry into treated areas during the re-entry intervals (REIs) as listed below:

Trees 3 days\*

\*Workers conducting activities that involve significant foliar contact must wear gloves and cotton covers for the following time after the REI:

Trees 1 week”

**III.2 Amendments to Address Environmental Risk Assessment**

**The following amendments are required for technical grade products containing acephate:**

**Add the following under the ENVIRONMENTAL PRECAUTIONS section:**

Toxic to aquatic organisms.

DO NOT discharge effluent containing this product into sewer systems, lakes, streams, ponds, estuaries, oceans or other waters.

**Under the DISPOSAL section, add the following:**

Canadian manufacturers should dispose of unwanted active ingredients and containers in accordance with municipal and provincial regulations. For additional details and clean up of spills, contact the manufacturer or the provincial regulatory agency.

**The following amendments are required for all commercial end use products containing acephate applied as a liquid:**

**Add the following under the ENVIRONMENTAL PRECAUTIONS section:**

Toxic to aquatic organisms. Observe buffer zones specified under DIRECTIONS FOR USE.

Toxic to birds and small wild mammals.

Toxic to bees. Bees may be exposed through direct treatment, spray drift, and residues on/in leaves, pollen and nectar in flowering crops and weeds. Minimize spray drift to reduce harmful effects on bees in habitats close to the application site. Avoid applications when bees are foraging in the treatment area in ground cover containing blooming weeds. To further minimize exposure to pollinators, refer to the complete guidance “Protecting Pollinators during Pesticide Spraying – Best Management Practices” on the Pesticides section of the Canada.ca website ([www.canada.ca/pollinators](http://www.canada.ca/pollinators)). Follow crop specific directions for application timing.

Toxic to certain beneficial arthropods (which may include predatory and parasitic insects, spiders, and mites). Minimize spray drift to reduce harmful effects on beneficial arthropods in habitats next to the application site such as hedgerows and woodland.

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For applications on crops that are highly attractive to pollinators (cranberry, and outdoor ornamentals excluding coniferous trees), or when using managed bees for pollination services:

DO NOT apply during the crop blooming period or during the 9-day period before the crop blooms.

For applications on all other crops:

Avoid application during the crop blooming period. If applications must be made during the crop blooming period, restrict applications to evening when most bees are not foraging.

To reduce runoff from treated areas into aquatic habitats avoid application to areas with a moderate to steep slope, compacted soil, or clay.

Avoid application when heavy rain is forecast. Contamination of aquatic areas as a result of runoff may be reduced by including a vegetative filter strip between the treated area and the edge of the water body.

The use of this product may result in contamination of groundwater particularly in areas where soils are permeable (for example, sandy soil) and/or the depth to the water table is shallow.

**Replace statements Under the DISPOSAL section with the following:**

1. Empty bag thoroughly into spray tank.
2. Make the empty bag unsuitable for further use.
3. Dispose of the bag in accordance with provincial requirements.

For further information on the disposal of unused, unwanted product contact the manufacturer or the provincial regulatory agency. Contact the manufacturer and the provincial regulatory agency in case of spills and for clean-up of spills.

**Add the following under STORAGE:**

Store this product away from food or feed.

**Add the following under DIRECTIONS FOR USE:**

As this product is not registered for the control of pests in aquatic systems, DO NOT use to control aquatic pests.

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

To protect pollinators, follow the instructions regarding bees in the Environmental Precautions section.

Field sprayer application: DO NOT apply during periods of dead calm. Avoid application of this product when winds are gusty. DO NOT apply with spray droplets smaller than the American Society of Agricultural Engineers (ASAE S572.1) fine classification. Boom height must be 60 cm or less above the crop or ground.

For outdoor uses, DO NOT apply with airblast or other mist-blower equipment.

DO NOT apply using aerial application equipment.

**Buffer zones:**

Spot treatments using hand-held equipment and soil drench or soil incorporation DO NOT require a buffer zone.

The buffer zones specified in the table below are required between the point of direct application and the closest downwind edge of sensitive freshwater habitats (such as lakes, rivers, sloughs, ponds, prairie potholes, creeks, marshes, streams, reservoirs and wetlands).

Method of application	Crop	Buffer Zones (metres) Required for the Protection of:	
		Freshwater Habitat of Depths:	
		Less than 1 m	Greater than 1 m
Field sprayer	Tobacco	1	0

For tank mixes, consult the labels of the tank-mix partners and observe the largest (most restrictive) buffer zone of the products involved in the tank mixture and apply using the coarsest spray (ASAE) category indicated on the labels for those tank mix partners.

**Repeat restrictions under the relevant specific crop use directions, as follows:**

**Under DIRECTIONS FOR USE ON FIELD CROPS:**

Toxic to bees: For cranberry: DO NOT apply during the crop blooming period or during the 9-day period before the crop blooms.

For all other crops: Avoid application during the crop blooming period. If applications must be made during the crop blooming period, restrict applications to evening when most bees are not foraging. When using managed bees for pollination services, DO NOT apply during the crop blooming period.

**Under DIRECTIONS FOR USE ON TREES AND ORNAMENTALS:**

DO NOT allow effluent or runoff from greenhouses containing this product to enter lakes, streams, ponds or other waters.

Toxic to bees: When used on outdoor ornamentals excluding coniferous trees (pine, fir, juniper, spruce, arborvitae, cedar, hemlock, cypress, yew, live Christmas trees), DO NOT apply during the crop blooming period or during the 9-day period before the crop blooms.

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**Under the DIRECTIONS FOR USE ON CHRISTMAS TREE PLANTATIONS, FARM WOODLOTS, TREE NURSERIES, SHELTER BELTS, RIGHTS OF WAY subsection:**

In farm woodlots, shelterbelts, and rights of way, acephate can ONLY be applied using hand-held application equipment for spot treatment.

Toxic to bees: When used on pollinator attractive trees DO NOT apply during the tree blooming/pollen shedding period, or the 9 days before the tree blooming/pollen shedding period. This restriction excludes coniferous trees: pine, fir, juniper, spruce, arborvitae, cedar, hemlock, cypress, yew, live Christmas trees.

**Under the TREE-INJECTION subsection:**

TOXIC to bees, birds and mammals. This product is systemic and is transported upwards through the tree. Bees, birds and mammals can be exposed to residues in floral pollen and/or nectar, fruits, seeds or sap resulting from tree injections. EXCEPT FOR CONIFEROUS TREES APPLICATION MUST BE MADE POST-BLOOM. Applying post-bloom reduces risk to pollinators.

**The following amendments are required for tree implants**

The following amendments are required for all commercial end use products containing acephate that are formulated as implants:

**Add the following under ENVIRONMENTAL PRECAUTIONS:**

Toxic to aquatic organisms, birds and small wild mammals. Toxic to bees, follow instructions in the DIRECTION FOR USE section.

**Remove under DIRECTIONS FOR USE:**

Do not apply by air.

**Add the following under the Application timing subsection:**

TOXIC to bees, birds and mammals. This product is systemic and is transported upwards through the tree. Bees, birds and mammals can be exposed to residues in floral pollen and/or nectar, fruits, seeds or sap resulting from tree injections. EXCEPT FOR CONIFEROUS TREES, APPLICATION MUST BE MADE POST-BLOOM. Applying post-bloom reduces risk to pollinators.

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

**Add the following under STORAGE:**

Store this product away from food or feed.

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**Move the following statement from STORAGE to DISPOSAL:**

Do not re-use the plastic implant cartridges; they are designed to be implanted and left in the tree. Do not re-use empty container or container wrappings.

**Add the following under DISPOSAL:**

Dispose of the container in accordance with provincial requirements.

For information on disposal of unused, unwanted product, contact the manufacturer or the provincial regulatory agency. Contact the manufacturer and the provincial regulatory agency in case of a spill, and for clean-up of spills.

**III.3 Amendments to address the value assessment and label improvements****The following amendments apply to all products containing acephate**

**On the front panel, replace: ‘Guarantee’ with: ‘Active ingredient’**

**The following amendments apply to all commercial end use products containing acephate**

Update the resistance management section of all acephate labels to include the resistance management statements as per Regulatory Directive DIR2013-04, *Pesticide Resistance Management Labelling Based on Target Site/Mode of Action*.

New pollinator protection measures prohibit tree trunk injection and encapsulated implant applications until after the blooming/pollen shedding period. Therefore, pest claims indicated for pre-bloom applications must be removed. These include all trunk injection/encapsulated application claims for the following host trees: cockspur hawthorn, flowering cherry, mountain-ash, pin cherry, wild cherry, basswood, beech, chestnut, hickory and walnut, and b) the following pest/host combinations: cankerworms/hawthorn, linden, and oak; tent caterpillars (including eastern)/ flowering plum, hawthorn, oak and willow; gypsy moth/hawthorn, oak, and willow; tussock moth/linden, oak, sycamore and willow; elm spanworm/ linden and oak; emerald ashborer/ash; oak leafshredder/oak; yellownecked caterpillar/linden; and obliquebanded leafroller/oak and sycamore.

Pest claims must be specific; vague claims or statements must be amended such that specific pests are identified. To this end, under the Directions for Use as Tree injections, replace ‘For use in ornamental deciduous and coniferous trees for control of sap sucking insects, leaf feeding insects and mites on non-flowering conifers, pine-like conifers and yew-like conifers’ with ‘For use by trunk injection and control of insect and mite pests of ornamental deciduous and coniferous trees, as listed on this label (refer to the table under DIRECTIONS FOR USE ON TREES AND ORNAMENTALS).

Replace minor use statements with the following (insert registrant name where indicated): “The DIRECTIONS FOR USE for the uses described in this section of the label were developed by persons other than [registrant name] under the User Requested Minor Use Label Expansion program.

For these uses, [Registrant name] has not fully assessed performance (efficacy) and/or crop tolerance (phytotoxicity) under all environmental conditions or for all crop varieties when used in accordance with the label. The user should test the product on a small area first, under local conditions and using standard practices, to confirm the product is suitable for widespread application.”

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## Appendix IV MRL Changes for Acephate and Methamidophos for the Protection of Human Health

The existing MRLs for acephate and methamidophos are listed in Table 1 of this appendix. MRL revocations and residue definition changes are indicated in PRVD2016-01 and in this document.

- Methamidophos is a major metabolite of acephate and was registered independently as an active ingredient. Methamidophos MRLs were previously established for methamidophos uses. As all methamidophos uses are no longer registered, the MRLs for methamidophos will be modified to account for acephate uses only. Therefore, the residue definition for acephate for enforcement purposes will change to acephate and methamidophos with individual MRLs listed for each compound.
- The revocation of acephate and methamidophos MRLs on succulent beans is proposed to mitigate risk concerns and to account for the phase out of succulent bean use in the US. No change to the MRL on dry beans is required.
- The revocation of the methamidophos MRL on tomatoes is proposed to mitigate risk concerns. Quantifiable residues of acephate and methamidophos are not expected to be present on/in tomatoes as a result of the registered use pattern because acephate is only allowed for use during the transplanting period. The risk is driven by residues found on imported tomatoes.
- The revocation of the MRL on potatoes is proposed as the use on potatoes is being cancelled due to dietary risk concerns.
- The revocation of methamidophos MRLs on broccoli, cucumber, and eggplants is required to account for the discontinuation of methamidophos uses in Canada and the US, as acephate is not registered for use on these crops.
- The revocation of the MRLs for leaf lettuce and all varieties of corn except sweet and seed corn is required to reflect the use pattern for acephate in Canada. These crops are not registered on the acephate label. The label specifies use on head lettuce and sweet and seed corn.
- The revocation of the acephate MRL for milk is proposed, as crops treated with acephate are prohibited from being fed to livestock.

**Table 1 Proposed Acephate and Methamidophos MRL Changes**

Commodity	ACP MRL (ppm)	MOM MRL (ppm)	MRL Change	
			ACP	MOM
Beans <sup>1</sup>	1.0	0.3	Change to Dry Beans	Change to Dry Beans
Broccoli	-*	1.0	-	Revoke (will be subject to GMRL) – due to previous decision to phase-out of MOM
Brussels Sprout	1.5	1.0	-	-
Cabbages	0.3	0.5	-	-
Cauliflowers	2.0	0.5	-	-
Celery	5.0	0.5	-	-
Corn	0.5	-*	Change to Sweet Corn Kernels plus Cob with Husks Removed <sup>3</sup>	-
Cranberries	0.5	-*	-	-
Cucumbers	-*	0.5	-	Revoke MRL (will be subject to GMRL) – due to previous decision to phase-out of MOM
Eggplants	-*	0.5	-	Revoke MRL
Lettuce	1.0	1.0	Change to Head Lettuce	Change to Head Lettuce
Milk	0.05	-*	-	-
Peppers	2.0	1.0	-	-
Potatoes	0.5	0.1	Revoke MRL	Revoke MRL (will be subject to GMRL) – due to dietary risks
Saskatoon berries (juneberries)	0.03	-*	-	-
Soybeans	0.5	-*	-	-
Tomatoes <sup>2</sup>	-*	0.5	-	Revoke MRL (will be subject to GMRL) – due to previous decision to phase-out of MOM

ACP = acephate, MOM = methamidophos,

\* Regulated under Subsection B.15.002 (1) of the *Food and Drugs Act*. This requires that residues not exceed 0.1 ppm, which has been considered a general MRL for enforcement purposes.

<sup>1</sup> For import purposes

<sup>2</sup> Residues of methamidophos may potentially be present in tomatoes due to acephate use on tomatoes during transplanting. However, the residue level is expected to be low and below the general MRL of 0.1 ppm.

<sup>3</sup> The PRVD did not include the word “Removed” in the descriptor for Sweet Kernels plus Cob with Husks Removed. This is corrected for the RVD and associated PMRL document.



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## **Appendix V Occupational and Residential Exposure and Risk Estimates for Acephate**

The following updates were made to the occupational risk assessments since PRVD2016-01:

### **Mixer, Loader and Applicator Exposure and Risk Assessment**

- The soluble powder formulation was not included in the final assessment as it is being cancelled.
- The use on potatoes was proposed for cancellation in PRVD2016-01. As no new information was received to retain this use, it was not included in the updated assessment.
- Dietary scenarios, for which mitigation measures were proposed in PRVD2016-01 to address dietary risk, were updated using the revised rates only (see Table 1).
- Non-handheld airblast application scenarios were removed as a result of the environmental mitigation.
- Handheld airblast/mistblower equipment was assessed using unit exposures determined from two worker exposure studies (Testman 2015 and Thouvenin 2016).
- Right-of-way sprayer was included in this assessment, as it was identified as another type of application.
- Updated tobacco rates on the soluble granule label (Reg.No.29499) were used. The updated rates will be added to the product label.
- The airblast/mistblower rate is the highest rate on the label for ornamentals, trees and flowers. With the cancellation of airblast/mistblower applications as a mitigation measure to address environmental risk, the remaining maximum label rate for these crops is lower; that is, 0.637 kg a.i./day. Therefore, the lower rate was used in this assessment.
- All remaining scenarios were updated using current standards for body weight, agricultural areas treated per day, and AHETF open cab groundboom data.

### **Postapplication Worker Exposure and Risk Assessment**

- The use on potatoes was proposed for cancellation in PRVD2016-01. As no new information was received to retain this use, it was not included in the updated assessment.
- Dietary scenarios were updated using revised lower rates only (see Table 1)
- The task of 'moving irrigation pipes by hand' was removed from greenhouse scenarios, since it does not occur in greenhouses.
- Saskatoon berries were added to the REI table.
- The higher of the two label rates for bell peppers will be retained and the REI adjusted accordingly.
- Updated tobacco rates on the soluble granule label (Reg.No.29499) were used. The updated rates will be added to the product label.
- Transfer coefficients have been updated for sweet corn and seed corn based on new information provided by ARTF (Hand harvesting of sweet corn and hand detassling of seed corn changed from 17000 to 8800 cm<sup>2</sup>/hr),

- The airblast/mistblower rate is the highest rate on the label for ornamentals, trees and flowers. With airblast/mistblower applications removed from the label as a result of mitigation measures to address environmental risk, the maximum label rates for these crops are lower; that is, 0.637 kg a.i./day. Therefore, the lower rate was used in this assessment.
- The dislodgeable foliar residue (DFR) data for roses was re-examined for possible refinement and in consideration of comments submitted.
- Cranberry scouting was re-assessed based on information received during the comment period and other supporting information.
- All remaining scenarios were updated with current standard body weight for adults.

**Table 1 Maximum Application Rates, Maximum Number of Applications per Year and Minimum Retreatment Intervals For Mitigation of Dietary and Environmental Risk**

Crop	Maximum Application Rate (kg a.i./ha)	Maximum Number of applications per Year	Minimum Retreatment Interval (days)
Bell Peppers	0.825	2	14
Brussels Sprouts	0.563	2	14
Cabbage	0.563	2	14
Cauliflower	0.563	2	14
Head Lettuce	0.563	2	14
Celery	0.563	2	14
Sweet Corn	0.563	2	14
Seed Corn	0.563	2	14
Ornamentals, trees and cut flowers (greenhouse and outdoors) *	0.637	2	7

\*ornamental, tree and flower rate is based on airblast/mistblower removal as a result of environmental mitigation

**Table 2 Dermal and Inhalation MOEs for Mixing, Loading and Applying Acephate using the Soluble Granule Formulation<sup>a</sup>**

Crop	Application Method	Rate (kg ai /ha)	Area Treated per day (ha/day)	Dermal MOE <sup>b</sup>	Inhalation MOEs <sup>c</sup>		Combined MOEs <sup>d</sup> (dermal + inhalation)	
				Baseline PPE <sup>e</sup>	Without respirator	With respirator	Without respirator	With respirator
Vegetables <sup>f</sup>	Ground boom	0.563	26	4441	782	7825	665	2833
Sweet peppers	Ground boom	0.825	26	3031	534	5340	454	1933
Corn, sweet and seed	Ground boom	0.563	80	1443	254	2543	216	921
		0.563	140	825	145	1450	124	526
Cranberries	Ground boom	0.562	26	4441	782	7825	665	2833
	Handheld airblast/mistblower <sup>l</sup>		2	110	n/a	8	n/a	7
Saskatoon berries	Soil injection <sup>g</sup>	2.55	26	850	150	1497	127	542

Crop	Application Method	Rate (kg ai /ha)	Area Treated per day (ha/day)	Dermal MOE <sup>b</sup>	Inhalation MOEs <sup>c</sup>		Combined MOEs <sup>d</sup> (dermal + inhalation)	
				Baseline PPE <sup>c</sup>	Without respirator	With respirator	Without respirator	With respirator
Tobacco <sup>k</sup>	Ground boom	0.563	26	4441	782	7825	665	2833
		0.825		3031	534	5340	454	1933
		1.125		2223	392	3916	333	1418
		1.275		1961	346	3455	294	1251
Tomatoes	Ground boom	0.90	26	2778	489	4895	416	1251
Outdoor ornamentals, cut flowers and roses	Ground boom	0.637	26	3925	692	6916	588	2504
	Manually pressurized handwand	0.637 kg a.i./1000L	150 L/day	44376	4816	48161	4345	23095
	Mechanically pressurized handgun <sup>h</sup>		3800 L/day	296	57	569	48	195
	Backpack <sup>h</sup>		150 L/day	7687	3505	35054	2408	6305
	Handheld airblast/ mistblower		150 L/day	1284	n/a	89	n/a	84
Greenhouse ornamentals, cut flowers and roses	Automated spray equipment <sup>i</sup>	0.637	1 ha	173657	240096	2400960	100771	161944
	Manually pressurized handwand	0.637 kg a.i./1000L	150L/day	44376	4816	48161	4345	23095
	Mechanically pressurized handgun <sup>h</sup>		3800 L/day	296	57	569	48	195
	Backpack <sup>h</sup>		150 L/day	7687	3505	35054	2408	6305
	Handheld airblast/ mistblower		150 L/day	1284	n/a	89	n/a	84
Trees	Manually pressurized handwand	0.637 kg a.i./1000L	150 L/day	44376	4816	48161	4345	23095
	Mechanically pressurized handgun <sup>h</sup>		3800 L/day	296	57	569	48	195
	Backpack <sup>h</sup>		150 L/day	7687	3505	35054	2408	6305
	Handheld airblast/ mistblower		150 L/day	1284	n/a	89	n/a	84
	Right of way sprayer	0.637 kg a.i./1000L	3800 L/day	585	16731	1673	433	565
	Tree trunk	0.02 kg ai /	200 trees	35897	48212	482124	20576	33409

Crop	Application Method	Rate (kg ai /ha)	Area Treated per day (ha/day)	Dermal MOE <sup>b</sup>	Inhalation MOEs <sup>c</sup>		Combined MOEs <sup>d</sup> (dermal + inhalation)		
				Baseline PPE <sup>e</sup>	Without respirator	With respirator	Without respirator	With respirator	
	injection (pipette or syringe)	tree <sup>j</sup>							
	Cartridge implant	849 mg/ cartridge	1 cartridge /10.16 cm	No data available, but exposure is assumed to be minimal due to product packaging.					

<sup>a</sup> Mix/load exposure when using a soluble granule formulation of acephate was estimated using a submitted study (Bruce et al 2002).

For dermal exposure, the arithmetic mean including all three sites was used (36.13 ug/kg ai handled). For inhalation exposure the arithmetic mean including all three sites was used (0.136 ug/kg ai handled).

<sup>b</sup> Dermal MOE = (dermal NOAEL) / (dermal exposure). The dermal NOAEL is 50 mg/kg body weight/day. The target dermal MOE is 100. Dermal exposure ug/kg bw/day = (unit exposure × area treated × rate) / 80 kg bw

<sup>c</sup> Inhalation MOE = (inhalation NOAEL/ inhalation exposure). The inhalation NOAEL is 0.26 mg/kg body weight/day. The target inhalation MOE is 100.

<sup>d</sup> Combined (dermal and inhalation) MOE = 1/[1/dermal MOE + 1/inhalation MOE]. Target MOE is 100.

<sup>e</sup> Baseline PPE = long sleeves, long pants and gloves

<sup>f</sup> Vegetables: Brussels sprouts, cabbage, cauliflower, head lettuce, and celery

<sup>g</sup> PHED does not contain exposure data for applying by soil injection. It was assumed that exposure during application would be similar to application with ground boom. Therefore the unit exposure numbers of ground boom application were used as surrogate data to assess this scenario.

<sup>h</sup> PHED does not contain data for mechanically pressurized handwand and backpack using a soluble granule formulation. Exposure estimates are based on PHED liquid formulation for each use.

<sup>i</sup> PHED does not contain data for greenhouse automated spray equipment. Exposure estimates are based on an open mix/load soluble granule study (Bruce et al 2002).

<sup>j</sup> Rate calculated based on 24 injections per tree and 0.642 g a.i./injection.

<sup>k</sup> Tobacco rates: 0.563 kg a.i./ha (minimum rate for several pests and cover crop rate), 0.825 kg a.i./ha (maximum rate for several pests and minimum transplant water treatment rate), 1.125 kg a.i./ha (preplant and postplant soil treatment application rate for dark sided cutworm), 1.275 kg a.i./ha maximum transplant water treatment rate).

<sup>l</sup> Exposure estimates for handheld airblast/mistblower are based on 2 studies (Testman 2015 and Thouvenin 2016)

n/a = not applicable

Shaded cells are below the target MOE of 100.

**Table 3 Postapplication Short-term and Long-term Exposure Estimates, MOEs, ARIs and REIs for Mitigated Label Rates and Mitigated Number of Applications <sup>a</sup>**

Crop	App. Rate (kg a.i./ha) <sup>bl</sup>	Number of Apps. <sup>c</sup>	Activity <sup>d</sup>	TC <sup>e</sup> (cm <sup>2</sup> /hr)	Acephate		Methamidophos		Combined Risk (acephate + methamidiphos)	
					MOE on Day 0 <sup>f</sup>	Proposed REI <sup>g</sup>	MOE on Day 0 <sup>h</sup>	Proposed REI <sup>g</sup>	ARI on proposed REI <sup>i</sup>	Proposed REI <sup>g</sup>
Brussels sprouts, cauliflower, cabbage, celery, lettuce	0.563	2	All activities	230 - 5150	≥ 385	12 hrs	≥ 423	12 hrs	≥ 2.6	12 hrs
Peppers (bell)	0.83	2	Hand set irrigation	1750	527	12 hrs	250	<b>2 days</b>	3.3	<b>2 days</b>
			All other activities	70 - 1100	≥ 839	12 hrs	≥ 397	12 hrs	3.9	12 hrs
Tobacco – mature plants	0.825	3	Hand set irrigation	1750	947	12 hrs	183	<b>6 days</b>	4.4	<b>6 days</b>
			All other activities	90 - 800	≥ 2072	12 hrs	≥ 399	12 hrs	≥ 5.4	12 hrs
Tobacco – at transplant (seedling)	1.275	1	All activities	90 - 230	≥ 4663	12 hrs	≥ 889	12 hrs	≥ 12.1	12 hrs
Cranberries	0.562	2	Hand harvesting, raking	1100	219	12 hrs	182	<b>5 days</b>	1.8	<b>5 days</b>
			scouting	1100	438	12 hrs	365	12 hrs	2.6	12 hrs

Crop	App. Rate (kg a.i./ha) <sup>bl</sup>	Number of Apps. <sup>c</sup>	Activity <sup>d</sup>	TC <sup>e</sup> (cm <sup>2</sup> /hr)	Acephate		Methamidophos		Combined Risk (acephate + methomidiphos)	
					MOE on Day 0 <sup>f</sup>	Proposed REI <sup>g</sup>	MOE on Day 0 <sup>h</sup>	Proposed REI <sup>g</sup>	ARI on proposed REI <sup>i</sup>	Proposed REI <sup>g</sup>
			All other activities	70 - 230	≥ 1047	12 hrs	≥ 872	12 hrs	≥ 6.3	12 hrs
Saskatoon Berries			All activities	Not required						12 hrs
Corn (seed)	0.563	4	Hand de-tasseling	8800	154	12 hrs	73	<b>13 days</b>	4.2	<b>13 days</b>
			All other activities	70 - 1750	≥ 772	12 hrs	≥ 366	12 hrs	≥ 3.6	12 hrs
Corn (sweet)	0.563	4	Hand harvesting	8800	154	12 hrs	73	<b>13 days</b>	4.2	<b>13 days</b>
			All other activities	70 - 1750	≥ 772	12 hrs	≥ 366	12 hrs	≥ 3.6	12 hrs
Tomatoes (seedling)	0.9	1	All activities	70 - 1100	≥ 769	12 hrs	≥ 364	12 hrs	≥ 3.5	12 hrs
Outdoor Ornamentals (non-cut flowers)	0.637	2	Hand set irrigation	1750	121	12 hrs	101	<b>11 days</b>	2.3	<b>11 days</b>
			All other activities	230	≥ 923	12 hrs	≥ 770	12 hrs	≥ 5.6	12 hrs
Outdoor cut flowers	0.637	2	Hand harvesting, disbudding, hand pruning	4000	299	12 hrs	142	<b>7 days</b>	3.7	<b>7 days</b>
			All other activities <sup>k</sup>	230	≥ 683	12 hrs	≥ 324	12 hrs	≥ 3.4	12 hrs
Trees (coniferous, deciduous)	0.637	2	Hand set irrigation	1750	179	12 hrs	150	<b>7 days</b>	2.3	<b>7 days</b>
			Harvesting (Christmas trees)	1400	224	12 hrs	187	<b>5 days</b>	2.3	<b>5 days</b>
Foliar application			Scouting, shaping, hand pruning	580	≥ 541	12 hrs	≥ 451	12 hrs	≥ 3.3	12 hrs
			Transplanting, hand weeding, grading/tagging	100-230	≥ 1365	12 hrs	≥ 1138	12 hrs	≥ 8.2	12 hrs
Greenhouse ornamentals (non-cut flowers) (short term) <sup>j</sup>	0.637	2	All activities	230	6875	12 hrs	1463	12 hrs	19.1	12 hrs
Greenhouse cut flowers (short term) <sup>j</sup>	0.637	2	Hand harvesting, disbudding, hand pruning	4000	395	12 hrs	84	<b>2 days</b>	3.5	<b>2 days</b>
			All other activities <sup>k</sup>	230	6875	12 hrs	1463	12 hrs	19.1	12 hrs
Greenhouse ornamentals (non-cut flowers) (long term) <sup>j</sup>	0.637	2	All activities	230	43099	12 hrs	7622	12 hrs	24.0	12 hrs
Greenhouse cut flowers (long term) <sup>j</sup>	0.637	2	Hand harvesting, disbudding, hand pruning (full foliage)	4000	2478	12 hrs	438	12 hrs	1.4	12 hrs
			All other activities <sup>k</sup>	230	43099	12 hrs	7622	12 hrs	24.0	12 hrs

<sup>a</sup> Postapplication exposure was assumed to be the same for the soluble granule and soluble powder formulations.

<sup>b</sup> Maximum application rate as per current labels unless mitigation is noted in Table 1.

<sup>c</sup> Maximum number of applications permitted on the label, unless mitigation is noted in Table 1. Where a maximum is not stated a maximum was assumed based on registrant consultation.

<sup>d</sup> Activities are grouped as per common TC, or in some cases, "all other activities" is indicated where risk is acceptable at the minimum REI of 12 hrs.

<sup>e</sup> TCs are from the ARTF and can be found in PRO2014-02

<sup>f</sup> Acephate Dermal MOE = (dermal NOAEL) / (dermal exposure). The acephate dermal NOAEL is 50 mg/kg body weight/day. The target MOE is 100. The dermal exposure was calculated using DFR studies. See PRVD2016-01. Dermal Exposure = DFR × TC × 8 hr / 80 kg. Cranberry scouting has been adjusted to 4 hrs.

<sup>g</sup> REI = Restricted entry interval. Day at which the dermal exposure results in an ARI ≥ 1. Where target ARI was met at

- Day 0, a minimum REI of 12 hrs was specified.
- <sup>h</sup> Methamidophos Dermal MOE = (dermal NOAEL) / (dermal exposure). The methamidophos dermal NOAEL (from oral study) is 0.1 mg/kg bw/day. The target MOE is 300. The dermal exposure was calculated using DFR studies. See PRVD2016-01. Dermal Exposure = [DFR × TC × 8 hr / 80 kg] × DA
- <sup>i</sup> Dermal exposure from acephate and methamidophos co-occurs with a common adverse effect; therefore, an assessment of the combined exposure to multiple chemicals was conducted, using appropriate toxicological points of departure and exposure estimates for acephate and methamidophos. The calculated ARI (Aggregate Risk Index) is reported.  $ARI = 1 / [(ACP \text{ target MOE} / ACP \text{ MOE}) + (MOM \text{ target MOE} / MOM \text{ MOE})]$ . The acephate combined dermal NOAEL is 50 mg/kg body weight/day. The target MOE is 100. The methamidophos combined dermal BMDL<sub>10</sub> is 1.81 mg/kg bw/day. The target MOE is 100.
- <sup>j</sup> Greenhouse ornamentals were assessed for short and long term exposure to ensure that all possible exposure scenarios are covered. For long term exposure the DFR data was adjusted to a time weighted average of residues on Day 0 (or REI day) until day 30, as data permitted. Also, long term toxicology endpoints were used. The acephate long-term dermal NOAEL is the same as the short-term NOAEL at 50 mg/kg bw/day with a target MOE of 100. The methamidophos long term dermal NOAEL (from an oral study) is 0.05 mg/kg bw/day with a target MOE of 300. The combined long term risk assessment used the same toxicology endpoints as the individual long term risk assessment.
- <sup>k</sup> All other activities for cut flowers involves: container moving, hand weeding, scouting, planting/transplanting, hand pruning (minimum foliage), pinching, plant support/staking and hand set/hand line irrigation related activities involving foliar contact.
- <sup>l</sup> The airblast/mistblower rate is the highest rate on the label for ornamentals, trees and cut flowers. Since airblast/mistblower is removed from the label due to environmental concerns, the rates are lower for these crops. Trees and ornamentals changes from 1.31 kg a.i./ha to 0.637 kg a.i./1000 L (with a limitation of 1000 L/ha). Roses and cut flowers changes from 0.83 kg a.i./ha to 0.637 kg a.i./L (with a limitation of 1000 L/ha). Greenhouse remains the same as airblast is not used in greenhouses.
- n/a not applicable
- Shaded cells are either below the target MOE of 100 for acephate and 300 for methamidophos or the REIs may not be agronomically feasible

**Table 4 Postapplication short-, intermediate-term dermal exposure estimates, MOEs, and ARIs for Residential Gardening**

Activity	Sub-population <sup>a</sup>	TC (cm <sup>2</sup> /hr) <sup>b</sup>	Formulation <sup>c</sup>	Rate (kg a.i./ha) <sup>d</sup>	ACP MOE <sup>e</sup>	MOM MOE <sup>f</sup>	Combined Risk <sup>g</sup>		
							ACP MOE	MOM MOE	ARI (ACP+MOM)
<b>Number of Applications = 1</b>									
Residential Gardening <sup>h</sup>	Adults	8400	Soluble granule	0.637	106	745	106	1349	0.98
	Youth (11>16)	6900			92	646	92	1170	0.85
	Children (6>11)	4600			155	1089	155	1971	1.43
<b>Number of Applications = 2</b>									
Residential Gardening <sup>h</sup>	Adults	8400	Soluble granule	0.637	517	245	517	444	2.39
	Youth (11>16)	6900			449	213	449	385	2.07
	Children (6>11)	4600			756	358	756	648	3.49

Shaded cells are below the target MOE of 100 for acephate and 300 for methamidophos or below the target ARI of 1.0.

- <sup>a</sup> Subpopulations are described in the Revised EPA 2012 Standard Operating Procedures (SOPs) for Residential Exposure Assessments.
- <sup>b</sup> TC for residential gardening is a composite TC and is based on 4 studies (weeding, tying, harvesting, pinching). The TC was scaled for body surface area and typical clothing work in residential areas.
- <sup>c</sup> Soluble granule: previously referred to as the pelletized formulation
- <sup>d</sup> Rate is the maximum rate remaining on labels after taking into consideration environmental mitigation measures (removal of airblast/mistblower rate).
- <sup>e</sup> Acephate Dermal MOE = (dermal NOAEL)/(dermal exposure). The acephate dermal NOAEL is 50 mg/kg body weight/day. The target MOE is 100. The dermal exposure was calculated using the bean DFR study. See PRVD2016-01.
- <sup>f</sup> Methamidophos Dermal MOE = (dermal NOAEL) / (dermal exposure). The methamidophos dermal NOAEL (from an oral study) is 0.1 mg/kg bw/day. The target MOE is 300. The dermal exposure was calculated using the bean DFR study. See PRVD2016-01.

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- <sup>g</sup> Dermal exposure from acephate and methamidophos co-occurs with a common adverse effect; therefore, an assessment of the combined exposure to multiple chemicals was conducted, using the appropriate toxicological points of departure and exposure estimates for acephate and methamidophos. The calculated ARI (Aggregate Risk Index) is reported.  $ARI = 1 / [(ACP \text{ target} / ACP \text{ MOE}) + (MOM \text{ target} / MOM \text{ MOE})]$ . The acephate dermal NOAEL is 50 mg/kg body weight/day. The target MOE is 100. The methamidophos dermal  $BMDL_{10}$  is 1.81 mg/kg bw/day. The target MOE is 100. The target ARI is 1.
- <sup>h</sup> The daily duration of exposure for residential exposure is assumed to be 2.2 hours for adults and youth and 1.1 hrs for children. See PRVD2016-01

## Appendix VI References Considered Following Publication of PRVD2016-01 and PRVD2019-03

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1208120	Orthene Soil Metabolism- Laboratory Studies - Supplement, J.B. Leary, December 27, 1972 (741.10). DACO: 8.2.3.1
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