Pest Management Regulatory Agency
Agence de réglementation de la lutte antiparasitaire

Proposed Acceptability for Continuing Registration

PACR2004-40

Re-evaluation of Acephate

The purpose of this document is to inform registrants, pesticide regulatory officials and the Canadian public that the Pest Management Regulatory Agency (PMRA) has completed an assessment of acephate pursuant to Section 19 of the Pest Control Products (PCP) Regulations. This Proposed Acceptability for Continuing Registration (PACR) document provides a summary of the data and information reviewed, and the rationale for the proposed interim regulatory decision.

The PMRA has determined that the uses of acephate and its end-use products (EPs) do not entail an unacceptable risk to human health and the environment, provided that the proposed mitigation measures are implemented.

By way of this document, the PMRA is soliciting comments from interested parties on the proposed interim regulatory decision for acephate. The PMRA will accept written comments on this proposal and additional information up to 60 days from the date of publication of this document to allow interested parties an opportunity to provide input into the proposed decision. Please forward all comments to the Publications Coordinator at the address below.

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Foreword

The re-evaluation of the available information on the active ingredient acephate and its associated EPs registered for use as a broad spectrum insecticide on food and non-food areas, has been completed by the PMRA. The registrant of the technical grade active ingredient (TGAI) is Arysta LifeScience Corporation.

The PMRA announced in June 1999 that products containing organophosphate (OP) active ingredients, including acephate, were subject to re-evaluation under authority of Section 19 of the PCP Regulations.[1]

Arysta LifeScience Corporation newly acquired this product from Tomen Corporation and is now the primary data provider. All uses of acephate included on the label are being supported by the registrant. There are no Domestic class products containing acephate.

The PMRA has carried out an assessment of available information and has found it sufficient, to allow a determination of the safety, merit and value of acephate and associated end-uses. In the assessment, the PMRA has concluded that the use of acephate and its end-uses do not entail an unacceptable dietary or drinking water risk to human health or risk to the environment, provided that the proposed mitigation measures described in the document are implemented and the data requirements are addressed. The major residual concern is for post-application workers wherein the estimated margins of exposure (MOEs) for workers re-entering the treated areas are less than the target MOEs. The estimated exposures are considered to represent conservative assessments, and the PMRA is requesting the registrant to submit, within 24 months of the finalization of the re-evaluation document, information to refine post-application worker exposure assessment and demonstrate that MOEs for workers re-entering the treated areas meet the targets. This will include data such as those currently being developed by an industry lead task force. The risk estimates for workers will be revised using the submitted data and further measures will be considered during that time (e.g., longer restricted entry intervals [REIs], cancellation of uses), as necessary, to address any remaining issues.

In the interim, the PMRA proposes the following measures to mitigate exposure and risk to the greatest extent possible:

1. maximum agronomically feasible REIs;

2. protective clothing for re-entry workers, including clothes and gloves; and

3. a product stewardship program to minimize re-entry worker exposure that includes double notification of REIs for post-application activities.

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[1] See Re-evaluation Document REV99-01, *Re-evaluation of Organophosphate Pesticides*

It is important to note that while estimated MOEs are less than the target based on the current conservative assessment, the implementation of the proposed mitigation measures will substantially reduce exposure and risk. This interim strategy is considered acceptable until the risk can be more accurately characterized.

By means of this document, the PMRA wishes to consult on the feasibility of these risk mitigation measures, including lengthening these interim REIs and preharvest intervals (PHIs) for certain crops, prior to the finalization of this interim decision.

The PMRA will accept written comments on this proposal up to 60 days from the date of this document to allow interested parties an opportunity to provide input into the proposed re-evaluation decision for these products.

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1.0 Purpose

This PACR document describes the outcome of the PMRA re-evaluation of available data and information on the insecticide acephate and its associated end-uses. It includes assessments on human health and environment as well as information on the value of acephate to pest management in Canada. By way of this document, the PMRA is soliciting comments from interested parties on the decisions and mitigation measures proposed for acephate.

2.0 General background on re-evaluation

The PMRA is re-evaluating all pesticides, both active ingredients (a.i.) and formulated EPs, that were registered prior to 31 December 1994 to ensure that their continued acceptability in relation to human health and the environment is examined using current and modern scientific approaches. Regulatory Directive DIR2001-03, *PMRA Re-evaluation Program*, presents the re-evaluation activities and the program structure.

Acephate is under re-assessment in the United States as a result of the *Food Quality Protection Act*; therefore, the PMRA is re-evaluating acephate under Program 3. The following components are addressed and considered in this re-evaluation.

Risk to human health
The initial focus of the re-evaluation of a pest control product in Program 3 is the risk to human health. As indicated in Regulatory Directive DIR2001-03, a reassessment in Program 3 focuses specifically on the following:

- pest control products with a common mechanism of toxicity;
- aggregate exposure to a pesticide arising from its residues in food and drinking water, and from non-occupational exposure, such as from treatments in and around homes; and
- susceptibility and exposure of infants and children that may be different from that of adults during critical developmental stages.

Upon the completion of the non-occupational assessments of all individual OPs, a cumulative assessment of all the remaining uses will be conducted.

The re-evaluation of risks to human health also includes a re-examination of the acceptability of risks resulting from occupational exposure. Occupational risk assessments follow an internationally accepted tiered approach as described in the Organisation for Economic Co-operation Development document *Guidance Document for the Conduct of Occupational Exposure to Pesticides During Agricultural Application.*

The tiered approach involves increasing levels of refinement through consideration of additional data such as dermal absorption, chemical-specific use-pattern information and biological monitoring data.

For most of the OP compounds, there are often insufficient data available to the PMRA to refine occupational exposure assessments to higher tiers. These refined assessments are now required for some OPs, due in part to the PMRA's policy to apply additional safety factors for workers as required to further ensure their protection. It is important to note that the current re-evaluations of OPs were not preceded by a data call-in. As a result, in many cases, the PMRA does not have the types of information required to conduct more refined and higher tiered occupational exposure assessments. Therefore, the PMRA has conducted lower tier reviews based on conservative approaches in these cases.

However, the Agricultural Handlers Exposure Task Force and the Agricultural Re-entry Task Force (ARTF) are developing additional proprietary generic databases that will enhance the PMRA's ability to conduct more refined assessments. Other additional data that could be used to refine estimates include residue, dermal absorption, biomonitoring and actual compound-specific use-pattern data (e.g., typical minimum versus maximum rates, typical number of applications). These data could also be used in a probabilistic assessment to provide additional refinement. Currently, there is an international project (International Life Sciences Institute) to develop guidance on probabilistic techniques for worker assessment.

Based on an assessment of the data and information available to the PMRA, the following courses of action may be proposed for OPs where the MOEs are less than the target for workers.

1) Where estimated MOEs indicate significant concern, even with maximum feasible mitigation, a phase-out or cancellation of the active ingredient would be proposed.

2) Where estimated MOEs are less than the target but where exposure estimates could be refined with additional data, continuing registration of the active ingredient for a limited term will be granted on a conditional basis upon submission of those required data. As an interim measure, maximum feasible personal protective equipment (PPE), engineering controls and REIs will be implemented pending finalization of the decision document. These measures will substantially reduce exposure and risk. The risk estimates for workers will then be revisited before a final re-evaluation decision is made using the submitted data.

Risk to the environment

The environmental assessments will be tiered, with refined environmental risk assessments being conducted only for those active ingredients, products or uses that pass the cumulative health risk assessment or, for unique mechanisms of toxicity, that are acceptable from a human health perspective. At the first tier, based on an identification of hazards to non-target organisms, measures to reduce environmental exposure will be

implemented where warranted. These measures may include removing uses that are obsolete, reducing the number of applications, requiring buffer zones to protect sensitive habitats and taking regulatory action against uses that have been determined to be extremely high risk to organisms in the environment. In general, uses that remain after the first tier assessment will be revisited when the results of refined environmental assessments are available.

Value
The PMRA seeks to understand, as early as possible in the re-evaluation process, the current uses of the products under review and their importance for pest management in agriculture, the nursery trades, forestry and public health. The PMRA relies to a great extent on provincial and territorial government input. Registrants and users are also an important source of these information. Government agencies including Environment Canada, the Department of International Trade, the Canadian Food Inspection Agency, and Agriculture and Agri-Food Canada are also contacted during the re-evaluation process, as needed, for information specific to their areas of expertise.

Consultation regarding proposed regulatory decisions
The outcome of the re-evaluation of a pesticide, including proposed risk mitigation measures, will be published in a consultation document at the end of the aggregate human health risk assessment and the first tier environmental assessment. In some cases, the PMRA will implement changes in regulatory status of products prior to public consultation, especially where the PMRA considers risk mitigation ineffective or impractical, or where registrants have opted for voluntary discontinuation of sale of the products.

3.0 Re-evaluation of acephate

Acephate is one of the 27 OP pesticides subject to re-evaluation in Canada. The re-evaluation of acephate was announced in Re-evaluation Document REV99-01, *Re-evaluation of Organophosphate Pesticides.* Acephate is a broad spectrum, OP pesticide that inhibits the enzyme acetylcholinesterase. It works by ingestion action and is a systemic insecticide. Acephate, also known by the trademark "Orthene™", has been used in registered pest control products in Canada since 1977 when the Commercial class product "Orthene 75% Soluble Powder Systemic Insecticide" (Registration Number 14225, *Pest Control Products Act)* was registered. Currently registered Canadian products containing acephate are listed in Appendix I.

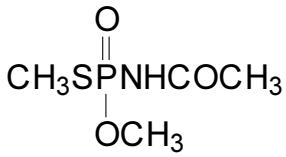
Much of the scientific information used by the PMRA in its assessment of acephate came from United States Environmental Protection Agency (USEPA) reviews. The USEPA Interim Reregistration Eligibility Decision (IRED) document for acephate, dated September 2001, can be referenced for further details regarding scientific studies used by the PMRA. This document, as well as other information on the regulatory aspect of acephate in the United States, can be found at the USEPA's web site at http://www.epa.gov/pesticides/op/status.htm.

3.1 Chemical identification

Chemical name: O,S-dimethyl acetylphosphoramidothioate

Molecular formula: $C_4H_{10}NO_3PS$

Structural formula:



3.2 Description of registered uses

3.2.1 Type of pesticide

Acephate is an organophosphate insecticide with a systemic mode of action.

Formulation types registered
The formulation types of end use products registered are soluble powder (registration numbers 14225 and 15559, *Pest Control Products Act*), and soluble powder contained in solid implant cartridges (Registration Number 21568, *Pest Control Products Act*).

3.2.2 Summary of use sites

Food crops	Brussels sprouts, cabbage, cauliflower, celery, field crisphead lettuce, seed and sweet corn, bell peppers, potatoes, field tomatoes, cranberries
Other agricultural sites	tobacco, non-bearing Saskatoon berries
Outdoor ornamentals	numerous flowers, shrubs and trees
Greenhouse grown ornamentals	roses
Forest and woodlots	Christmas tree plantations, farm woodlots, tree nurseries, shelterbelts, shade trees, right of ways and municipal parks (excluding national and provincial parks)

3.2.3 Summary of target pests

NOTE: Not all pests are registered on all use sites

True bugs	aphids (green peach aphid, potato aphid, woolly elm aphid and others), whiteflies (greenhouse and others), scales (lecanium scales, cottony maple scales, hemlock scale, oystershell scale, cottony cushion scale), psyllids, mealybugs, meadow spittlebug, potato leafhopper, tarnished plant bug, lace bug
Thrips	flower thrips, western flower thrips, gladiolus thrips and others
Flies	rose midge, root maggots (pepper maggot and others), cone maggots
Moths and butterflies	cabbage looper, diamondback moth larvae, imported cabbageworm, omnivorous leafroller, European corn borer, blackheaded fireworm, darksided cutworm, tomato hornworm, cutworms, fall webworm, leafminers, bagworms, gypsy moth, tent caterpillars (eastern, forest), armyworms (fall, beet, yellowstriped), cankerworms (fall, spring), tobacco budworm, obliquebanded leafroller, spruce coneworm, western spruce budworm, sunflower moth, oak leafshredder, pine needleminer, Nantucket pine tip moth, casebearer, Tussock moth, yellownecked caterpillar, poplar tentmatter
Beetles	wireworms, flea beetles (potato flea beetle, elm leaf beetle, willow leaf beetle and others), Colorado potato beetle
Ants, bees, wasps and sawflies	sawflies (open feeders), birch leafminer, pearslug (pear sawfly larvae)
Mites	spider mites (two spotted and others), bladder gall mite

3.2.4 Method and rates of application

3.2.4.1 Equipment

Acephate is usually applied to field food crops using conventional ground application equipment, except for transplant water application to tomatoes. It may be applied to tobacco using conventional ground application equipment or as a transplant water treatment. Non-bearing Saskatoon berries are treated by soil injection. Acephate is applied to ornamentals using a hydraulic sprayer or mist blower. Trees may also be treated by drilling holes into which acephate implants are inserted.

3.2.4.2 Rates and Timing

The rate of ground application to food crops and tobacco ranges from 563 to 825 g a.i./ha. The rate in transplant water for tomatoes is 900 g a.i./ha. The rate in transplant water for tobacco is 563–1125 g a.i./ha before planting or 1125 g a.i./ha after planting. The rate of soil injections to Saskatoon berries (non-bearing) is 2550 g a.i./ha. Hydraulic sprayer applications to ornamentals are applied at 638 g a.i./1000 L, while mist blower applications are applied at 1275 g a.i./1000 L. Tree implants are applied at a rate of 0.85 g per 10.16 cm around the tree trunk. Timings vary with site and target pests.

4.0 Effects having relevance to human health

4.1 Toxicology summary

The toxicology data base supporting acephate is primarily based on studies available from the registrant. In laboratory animals, acephate was slightly or moderately acutely toxic to rats or rabbits via the oral route, but highly toxic to mice. Low acute toxicity was observed via the dermal or inhalation route. It was mildly irritating to eyes and skin and was not found to be a skin sensitizer. Acute toxic signs induced by acephate via the oral route are consistent with signs of cholinesterase intoxication and include tremors, salivation, ataxia, depression, bloody tears, lacrimation, decreased motor activity, loss of coordination, laboured breathing and death. With oral exposure, acephate was readily absorbed and rapidly eliminated with little tissue retention. Excretion occurred primarily in the urine and was predominantly characterized as unchanged acephate. A minor amount (< 2% of administered dose) is converted to methamidophos by intestinal microorganisms.

Following both single and repeated dosing, the most sensitive indicator of toxicity was the inhibition of acetylcholinesterase, an enzyme necessary for the proper functioning of the nervous system. Acetylcholinesterase was affected by oral, dermal and inhalation routes with no appreciable species or gender differences. Duration of oral exposure had little effect on toxicity in rats (subchronic to chronic exposure) based on no observed adverse effect levels/lowest observed adverse effect levels (NOAELs/LOAELs). Cholinergic signs of toxicity, reduced body weight gain and food consumption (mice, rats and rabbits) were also observed at higher doses. Changes in liver weight and liver pathology were also recorded at high doses after repeated or chronic exposure (mice, rabbits and dogs). In acute and subchronic oral neurotoxicity studies in rats, no treatment-related neuropathy was evident although neurological signs of toxicity were demonstrated. No histopathological findings of neuropathy were evident in the remainder of the database in rodents.

In vivo germinal cell, somatic cell, chromosome aberration, sister chromatid exchange and micronucleus assays showed that acephate was not genotoxic, but a positive or weakly positive response was observed in some in vitro assays (bacteria, yeast and cultured mammalian cells). The negative findings from the in vivo assays lessen the

concern for a potential mutagenic hazard. No carcinogenicity was evident in a two-year chronic toxicity and carcinogenicity study in rats. However, a mouse study showed an increase in the incidence of hepatocellular carcinomas in female mice at the highest dose tested. As this effect was confined to a single species, a single sex, a single site (liver) at a dose exceeding the maximum tolerated dose only with no dose-response, the evidence of carcinogenicity was considered limited.

The developmental toxicity studies in rats and rabbits showed no evidence of teratogenic effects and no additional sensitivity of the fetus following in utero exposure to acephate. Developmental effects in rats (decreased fetal weight) were observed only in the presence of maternal toxicity. A report in the literature identified additional developmental effects in mice that included decreased numbers of live fetuses and fetal weight as well as increased early resorptions and external or skeletal abnormalities, but only at a dose level showing severe maternal toxicity. In the three-generation reproductive toxicity study in rats, no sensitivity of the young was demonstrated at the levels tested. Decreased mating performance, litter size and pup viability were observed at parentally toxic dose levels of 25 mg/kg bw/day (NOAEL of 2.5 mg/kg bw/day).

Reference doses have been set based on NOAELs for the most sensitive indicator of toxicity, namely acetylcholinesterase inhibition. These reference doses incorporate various uncertainty factors to account for extrapolating between laboratory animals and humans as well as for variability within the human population. Additional safety factors have been used, where necessary, to protect for the severity of endpoint (decreased mating performance, litter size and pup viability).

The toxicology endpoints used in the risk assessment of acephate are summarized in Appendix II.

4.2 Occupational and residential risk assessment

4.2.1 Occupational and residential toxicological endpoints

For short-term dermal risk assessment, the NOAEL of 50 mg/kg bw/day (the highest dose tested) from the rat three-week dermal toxicity study was selected. This NOAEL was supported by inhibition of brain cholinesterase observed at the dose of 60 mg/kg bw/day in a second three-week dermal toxicity study with rats. This study was selected as the route and duration of exposure are considered appropriate and the endpoint affected (cholinesterase inhibition) is consistent with the remainder of the database. Although this study did not address some of the endpoints of concern identified in the oral route database, it was considered relevant in that it demonstrated low dermal absorption potential. A target MOE of 300 is required; this accounts for interspecies extrapolation (10×) and intraspecies variability (10×), and applies an additional safety factor of 3× to account for the severity of endpoints noted in the reproductive toxicity study (decreased mating performance, litter size and pup viability at maternally toxic levels).

For short-term inhalation risk assessment, the NOAEL of 0.001 mg/L (equal to 0.26 mg/kg bw/day) from a 28-day inhalation toxicity study in rats was selected. This NOAEL was based on the brain and erythrocyte cholinesterase inhibition observed at the next higher dose level (0.003 mg/L). This study was selected as the route and duration of exposure are considered appropriate and the endpoint affected is consistent with the remainder of the database. Although this study did not address some of the endpoints of concern identified in the oral route database, it demonstrated comparable toxicity to the oral route of exposure; moreover, the NOAEL was lower than the NOAEL of 2.5 mg/kg bw/day from the reproductive study. Hence, no additional safety factor was required since the selected NOAEL was inherently protective of the endpoints of concern. A target MOE of 100 is required to account for interspecies extrapolation (10×) and intraspecies variability (10×).

4.2.2 Occupational mixer/loader/applicator exposure and risk assessment

There are potential exposures to mixers, loaders, applicators or other handlers. Based on typical use patterns, the major scenarios identified were as follows:

- mixing/loading soluble powder for application to terrestrial field crops, trees and ornamentals;
- applying soluble powder as sprays to field crops or ornamentals by groundboom;
- applying soluble powder as sprays to trees, ornamentals and cranberries by airblast sprayer;
- mixing/loading soluble powder for soil injection application;
- mixing/loading/applying soluble powder to trees and ornamentals by high-pressure handwand;
- mixing/loading/applying soluble powder to trees and ornamentals by low-pressure handwand;
- mixing/loading/applying soluble powder to trees and ornamentals by backpack sprayer; and
- applying implant cartridges to trees.

The PMRA estimated handler exposure based on different levels of protection as follows:

- Baseline: Long-sleeved shirt + long pants + shoes + socks + chemical-resistant gloves;
- Minimum PPE: Baseline + cotton coveralls + respirator;

- Maximum PPE: Baseline + chemical-resistant coveralls + respirator; and

- Engineering controls: Water-soluble packaging and chemical-resistant gloves for mixing/loading and closed tractor cab (no gloves) for application.

No chemical-specific handler exposure data were submitted for acephate; therefore, daily dermal and inhalation exposure was estimated for the various application methods using the Pesticide Handlers Exposure Database Version 1.1 (PHED). The PHED is a compilation of generic mixer/loader applicator passive dosimetry data with associated software that facilitates the generation of scenario-specific exposure estimates, based on formulation type, application equipment, mix/load systems and level of PPE. Exposure (mg/kg bw/day) is calculated as the product of the PHED unit exposure for a given scenario, the label application rate(s) and the area treated per day for a specific crop divided by body weight.

In most cases, the PHED did not contain appropriate data sets to estimate exposure of workers wearing cotton coveralls, chemical-resistant coveralls or a respirator. This was estimated by incorporating a 75% clothing protection factor for cotton coveralls, 90% protection factor for chemical-resistant coveralls and a 90% protection factor for a respirator into the unit exposure data.

Mixer, loader and applicator exposure estimates are based on the best available data at this time. The assessment might be refined with exposure data more representative of modern spray equipment and engineering controls.

Based on the acephate use pattern, mixer/loader/applicator exposure scenarios were considered to be short term (< 30 days).

Occupational risk is estimated by comparing a calculated MOE to a target MOE incorporating safety factors protective of the most sensitive sub-population. Since MOEs could not be calculated for combined dermal and inhalation exposure (different NOAELs and target MOEs), an aggregate risk index (ARI) was calculated. ARIs greater than or equal to 1 do not require risk mitigation. Dermal and inhalation MOEs and ARIs for mixing, loading and applying acephate are summarized in Appendix III.

No data were available for estimating exposures from application by soil injection. However, handler risks for this type of application should be similar to other application scenarios with the use of appropriate PPE. Exposure from application of implant cartridges is expected to be minimal.

In summary, ARIs for occupational handlers were greater than 1 for most scenarios provided the product is packaged in water-soluble packaging and chemical-resistant gloves are worn. For custom application (or treating > 65 ha/day), a closed cab is required to mitigate exposure. For airblast application to trees and ornamentals, the ARI was greater than 1 at a diluted volume of 1000 L/ha, or at a higher dilution rate with a closed

cab. For high-pressure handwand application to ornamentals, the ARI was less than 1, even with water-soluble packaging (surrogate data using liquid formulation), chemical-resistant coveralls and respirator (for mixers/loaders and applicators). It is not possible to have a closed application system for hand-held equipment. However, the ARI was greater than 1 when the diluted volume handled is limited to 1500 L/day.

4.2.3 Occupational post-application exposure and risk assessment

The post-application occupational risk assessment considered exposures to workers who re-enter treated sites to conduct agronomic activities involving foliar contact (e.g., pruning, thinning, harvesting or scouting). Acephate degrades into methamidophos, another OP insecticide; therefore, both chemicals are considered in the post-application risk assessment. Based on the acephate use pattern, there is potential for short-term (< 30 days) post-application exposure by the dermal route to acephate and methamidophos residues.

Potential exposure to re-entry workers was estimated using activity specific transfer coefficients (TCs) and dislodgeable foliar residue (DFR) studies. The TC is a measure of the relationship between exposure and DFRs for individuals engaged in a specific activity, and is calculated from the data generated in field exposure studies. The registrant is not a member of the ARTF, so generally conservative generic default transfer coefficients were used, except in cases where the default numbers were less conservative than the refined ARTF studies.

Post-application risk is managed by establishing an REI for specific tasks. Pesticide residues dissipate and/or breakdown over time and an REI is the length of time required for the dislodgeable pesticide residues to dissipate to such a level that entry into a treated area does not result in an unacceptable exposure.

Potential post-application exposure for re-entry workers performing any activity results in calculated MOEs that do not meet the target MOE (i.e., MOE < 300) based on current label REIs and use pattern. Based on the currently available data, most REIs would need to be significantly increased in length to achieve the target MOEs. Calculated REIs for selected re-entry activities and a target MOE of 300 are shown in Table 2 of Appendix IV. Many of these REIs are not practical for growers. Table 3 in Appendix IV shows calculated MOEs for REIs considered agronomically feasible by the PMRA.

With these agronomically feasible REIs, which range from 3 to 13 days for most crops, target MOEs are not met for any scenarios. However, the post-application exposure estimates include a number of conservative inputs, such as the assumptions that workers:

- are exposed to residues following the maximum number of applications at the maximum rate; and

- are performing activities for up to 30 days a year that involve foliar contact during the acephate post-application window.

The assessments could be refined with the following data:

- enhanced information on the acephate use pattern, including typical rates and number of applications per season;
- survey information on critical worker activities that typically take place for each crop during the use season and the timing of these activities with respect to crop growth and applications of acephate;
- passive dosimetry or biological monitoring exposure data, additional DFR data, refined transfer coefficients such as those being developed by the ARTF; or
- a probabilistic assessment using the full distribution of all available data.

With these additional data and information, it is expected that estimated exposure and risk would decrease.

The registrant is required to submit data that will allow exposure estimates to be refined. To minimize exposure in the interim, the following measures are proposed:

- implement maximum agronomically feasible REIs;
- reduce application rates;
- limit the number of applications per season;
- implement a product stewardship program to minimize re-entry worker exposure that includes double notification of REIs for post-application activities;
- ensure the availability of wash stations for all re-entry workers; and
- wear PPE (chemical-resistant gloves, long-sleeved shirt and long pants) for all critical post-application activities performed by a worker within 30 days of acephate application.

4.2.4 Residential exposure and risk assessment

There are no domestic class products for acephate; thus, a homeowner applicator assessment is not required. Acephate is applied solely by commercial applicators. Exposure to commercial applicators is discussed in Section 4.2.2.

The residential post-application risk assessment considered exposures to individuals re-entering ornamentals (trees, shrubs, and flowers) treated with a foliar spray. Both adults and youths were considered in the assessment. Young children are not expected to be exposed. The dermal MOEs are summarized in Table 4 of Appendix IV. All of the calculated MOEs exceeded the target MOEs; thus, post-application contact with commercially treated ornamentals in a residential environment does not pose a health concern.

4.3 Dietary exposure and risk assessment

In a dietary exposure assessment, the PMRA determines how much of a pesticide residue, including residues in milk and meat, may be ingested with the daily diet. These dietary assessments are age specific and incorporate the different eating habits of the population at various stages of life. For example, the assessments take into account differences in children's eating patterns, such as food preferences and the greater consumption of food relative to their body weight when compared to adults. Dietary risk is then determined by the combination of the exposure and the toxicity assessments. High toxicity may not indicate high risk if the exposure is low. Similarly, there may be risk from a pesticide with low toxicity if the exposure is high.

Acute and chronic dietary exposure and risk estimates were generated using Dietary Exposure Evaluation Model (DEEM®) software and updated consumption data from the United Sates Department of Agriculture's Continuing Survey of Food Intakes by Individuals 1994–1998.

Acute dietary risk is calculated considering food consumption and food residue values. A probabilistic statistical analysis allows all possible combinations of consumption and residue levels to be combined to estimate a distribution of the amount of acephate residue that might be eaten in a day. A value representing the high end (99.9^{th} percentile) of this distribution is compared to the acute reference dose (ARfD), which is the dose at which an individual could be exposed on any given day and expect no adverse health effects. When the expected intake from residues is less than the ARfD, the expected intake is not considered to be of concern.

To estimate acute dietary risk (1 day), the NOAEL of 0.5 mg/kg bw from a range-finding acute neurotoxicity study in rats was selected. This NOAEL was established based on inhibition of brain cholinesterase in females at the next highest dose of 2.5 mg/kg bw. An overall uncertainty factor of 100 is required to account for interspecies extrapolation (10×) and intraspecies variability (10×). The ARfD was calculated to be 0.005 mg/kg bw (0.5 mg/kg bw ÷100). This value was considered to be protective of all populations, including infants and children.

The acute dietary exposure was assessed in a mixed tier probabilistic assessment, using anticipated residue data from feeding studies, available monitoring data and percent crop treated as refinements for commodities on which acephate is registered in the United

States and in Canada. The acute potential daily intake (PDI) accounted for < 58% (99.9th percentile) of the ARfD for all subpopulations. Therefore, the acute dietary risk from acephate is not considered to be of concern.

The chronic dietary risk was calculated by using the average consumption of different foods, and the average residue values on those foods, over a 70-year lifetime. This expected intake of residues was compared to the acceptable daily intake (ADI), which is the dose at which an individual could be exposed over the course of a lifetime and expect no adverse health effects. When the expected intake from residues is less than the ADI, the expected intake is not considered to be of concern.

To estimate dietary risk from the repeat or chronic exposure, the LOAEL of 0.12 mg/kg bw/day from the 13-week dietary toxicity study in rats was selected. The effect observed at this dose level was a slight inhibition of brain cholinesterase, which was believed to be close to the threshold of a NOAEL due to the shallow dose-response noted at higher dose levels. The available toxicology database suggests that increased duration of oral exposure (subchronic to chronic) would not significantly increase toxicity of acephate. A 100-fold uncertainty factor is required to account for interspecies extrapolation (10×) and intraspecies variability (10×). Although a safety factor is applied to the reference dose for the lack of a NOAEL, no additional uncertainty factor was considered necessary since the LOAEL was considered to represent a threshold NOAEL. The ADI was calculated to be 0.0012 mg/kg bw/day (0.12 mg/kg bw/day ÷ 100). This value was considered to be protective of all populations, including infants and children.

The chronic dietary exposure was assessed using anticipated residue data from feeding studies, available monitoring data and percent crop treated as refinements for commodities on which acephate is registered in the United States and in Canada. The chronic PDI accounted for < 4 % of the ADI for all population subgroups. Therefore, the chronic dietary risk from acephate is not considered to be of concern.

4.4 Drinking water exposure

Drinking water exposure was addressed by calculating drinking water levels of comparison (DWLOC). The DWLOCs can only be calculated if other relevant exposures are not of concern to the PMRA, as it simply expresses the difference between the reference dose and the non-drinking water exposure. The DWLOC values were compared to model estimates of potential water exposure.

The acute DWLOC values ranged from 33 µg/L for infants to 113 µg/L for the general population. The chronic DWLOCs ranged from 12 µg/L for infants, to 41 µg/L for the general population. These DWLOCs were compared to the maximum expected environmental concentrations (EECs) in water, which were calculated to be 38 and 2.1 µg/L for the acute and chronic settings, respectively. There were no concerns regarding chronic drinking water exposure as the chronic EEC did not exceed the chronic DWLOC. The acute EEC of 38 µg/L exceeded the DWLOC for children under the age of

6 years, which ranged from 33–36 µg/L. This exceedence is not of high concern to the PMRA based on the conservatism in the EEC and the low probability that high drinking water exposure will occur with high dietary exposure.

These chronic and acute aggregate risk assessments, which reflect potential exposure from the diet and drinking water, demonstrate that there were no dietary health concerns for any population subgroup in Canada, including infants, children, teenagers, adults and seniors. In addition no aggregate health concerns were evident for nursing or pregnant females, or based on gender in general.

4.5 Aggregate exposure and risk assessment

Aggregate risk assessment looks at the combined potential risk associated with exposures from food, drinking water and residential uses of a pesticide.

The short-term aggregate risk assessment encompassed potential short-term exposure to acephate residues on ornamentals treated in residential areas, dietary and drinking water exposure. The acute aggregate assessment considered dietary and drinking water exposure only (see Section 4.4) as it is improbable that an individual would be exposed to high end dietary and residential exposures on the same day. The chronic aggregate assessment was also restricted to considerations of dietary and drinking water exposure since residential exposure was not anticipated to occur on a chronic basis (see Section 4.4).

To assess short-term aggregate risk for acephate, exposures resulting from use of acephate on ornamental plants in residential areas were assumed to co-occur with background (chronic) dietary and drinking water exposure for adults and youths. As acephate has only commercial class registrations, co-occurrence with homeowner applicator exposure was not considered.

The relevant duration of exposure for this assessment would be a period of up to one month. As inhibition of brain cholinesterase was a common toxic effect among all routes of exposure, the most relevant studies are those that were selected for the ADI and short-term dermal scenarios outlined previously. Thus, an oral LOAEL of 0.12 mg/kg bw/day with a MOE of 100 was considered appropriate for use in the acephate aggregate risk assessment. It was not considered necessary to increase the MOE for the lack of a NOAEL since the LOAEL was considered to represent a threshold NOAEL. A dermal NOAEL of 50 mg/kg bw/day with a MOE of 300 was also used for the acephate aggregate risk assessment. These MOEs are considered to be protective of all populations. As the target MOEs are different, an ARI was generated by comparing the aggregate exposure values to the route-specific aggregate toxic endpoints. An ARI value above 1.0 is not considered to be of concern to the PMRA.

The ARIs of 2.05 and 2.27 for the adult and youth populations, respectively, were above the target ARI of 1.0 and, therefore, are not considered to be of concern. Aggregate DWLOCs calculated for the short-term aggregate risk assessment were 13.1 µg/L for

adults and 21.5 µg/L for youth. As the corresponding EEC (2.1 µg/L) did not exceed the DWLOCs, the aggregate drinking water exposure is not of concern.

As the ARI and the aggregate DWLOCs are acceptable for all populations and exposure durations, the aggregate risk of acephate through drinking water, food and residential exposure is not of concern.

5.0 Environmental assessment

This assessment is based mainly on the data from the PMRA Environmental Assessment of Orthene 75 SP (Acephate) Insecticide (April 1994 and February 1997), the USEPA registration eligibility decision for acephate [revised Environmental Fate and Effects Division (EFED) Risk Assessment, December 1998] and the USEPA IRED for acephate issued September 2001.

In characterizing the environmental risk of acephate, the PMRA utilized a deterministic approach that characterizes the risk by quotient method. In this method, a risk quotient (RQ) is calculated as the ratio of the EEC to the effects endpoint of concern. RQs less than one are considered as a low risk to non-target organisms, whereas, RQs greater than one indicate some degree of risk.

In the assessment, the EECs for aquatic and terrestrial ecosystems were based on the maximum recommended application rate (0.825 kg ai/ha) and one application/season. Toxicity endpoints (acute and/or chronic) were chosen for the most sensitive species and used as surrogates for the range of species which can potentially be exposed following the treatment with acephate.

5.1 Environmental fate

Available data indicate that acephate is non-persistent in the environment. In soil, biotransformation was an important route in the transformation of acephate. The half-life of acephate was two days in aerobic soil and less than seven days in anaerobic soil. In water, the half-life for hydrolysis was 60 days at pH 5–7; biotransformation was a more important route of transformation with the half-life of less than seven days. Acephate is stable to phototransformation in both water and soil.

Acephate is non-volatile from moist soil and water surface as indicated by Henry's law constant (4.9×10^{-13} atm·m^3/mole[1]). The log *n*-octanol–water partition coefficient (K_{ow}) is not available. However, based on the high solubility of acephate in water at 20ºC (820 g/L) and the low solubility in octanol, the K_{OW} is expected to be very small. This would indicate a low potential for bioaccumulation. Under field conditions, acephate is expected to be very highly mobile in soil (organic carbon partition coefficient [K_{oc}] = 2.7).

5.2 Environmental toxicology

Laboratory studies on the acute basis demonstrated that acephate is moderately to practically non-toxic to a wide variety of organisms, including birds, mammals, fish and aquatic invertebrates, but not bees.

Acephate is classified as highly toxic to honey bees (lethal dose [LD_{50}]) = 1.2 µg a.i./bee). Toxicity test determined that lethal concentration to 50% (LC_{50}) is greater than 10 000 mg ai/kg soil for earthworm. Acephate is slightly to moderately toxic to freshwater invertebrates (LC_{50} = 6.4–100 mg a.i./L), and slightly to practically non-toxic to fish (LC_{50} = 50–1000 mg a.i./L). It is slightly to moderately toxic to estuarine/marine organisms (LC_{50} = 3.8–22.9 mg a.i./L). Acephate is slightly to moderately toxic to algae (no observed effect concentration [NOEC] = 7.2–24 mg a.i./L). It is moderately toxic to birds (LD_{50} = 109–350 mg a.i./kg) on an acute basis and slightly to practically non-toxic (LC_{50} = 1280–5000 mg a.i./kg) on a dietary basis. Acephate is slightly to moderately toxic to mammals on an acute basis (LD_{50} = 321–945 mg a.i./kg). It has chronic adverse effects on mammals at levels greater than 50 mg a.i./kg, on freshwater invertebrates at levels greater than 0.15 mg a.i./L and on marine/estuarine invertebrates at levels greater than 0.58 mg a.i./L.

Methamidophos, the major transformation product of acephate, is very highly toxic to aquatic invertebrates (LC_{50} < 0.1 mg a.i./L), slightly toxic to freshwater fish on an acute basis (LD_{50} = 10–100 mg a.i./kg), and moderately toxic to estuarine/marine organisms (LC_{50} = 1–10 mg a.i./kg).

5.3 Concentrations in drinking water

Residues of acephate in drinking water sources in Canada were estimated in a refined assessment (Level 2) using the Leaching Estimation and Chemistry Model (LEACHM) and the combined Pesticide Root Zone Model/Exposure Analysis Modelling System (PRZM/EXAMS). LEACHM was used to estimate the residues in groundwater, whereas the residues in dugouts and reservoirs were estimated using PRZM/EXAMS. For residues in groundwater, the concentration was estimated to be 2.1 µg a.i./L (both acute and chronic exposure). For residues in reservoirs, the acute and chronic exposure concentrations were estimated to be 30.8 and 2.0 µg a.i./L, respectively. For dugouts, the acute and chronic exposure concentrations were estimated to be 38.0 and 2.0 µg a.i./L, respectively.

A search for Canadian acephate water monitoring data revealed that routine analysis for acephate is not conducted. The limited monitoring data available in the United States combined with the lack of monitoring data within Canada did not allow for an estimation of acephate residues in potential drinking water sources to be calculated through statistical analysis of monitoring data. At this time, therefore, the drinking water values used in the exposure risk assessment were estimated by modelling.

5.4 Terrestrial assessment

The results of this screening assessment identified various levels of risk to non-target terrestrial organisms exposed to acephate.

Bees and other beneficial insects may be exposed to acephate through spray deposit. Based on the acute contact toxicity (LD_{50} = 1.34 kg a.i./ha), moderate acute risk to bees is anticipated from the use of acephate, when use involves application to crops in blossom (RQ = 7). The foliar residue toxicity studies indicate that acephate is highly toxic to honey bees from 2 to 24 hours after the application of 560 g a.i./ha. Studies show that acephate can be transferred to honey bee queens from nurse bees that have fed on crops with surface residues of > 1 ppm acephate. In addition, acephate is taken up by plants, and honey bees can be exposed to acephate through nectar. Honey bee colonies that fed on honey dosed with acephate had their brood cycles broken, effectively killing the colony.

Birds could be exposed to acephate by drift or by consuming contaminated food (e.g., seeds, insects or grasses). Based on the acute oral toxicity of acephate to birds (LD_{50} = 109 mg a.i./kg; NOEL = 10.9 mg a.i./kg) and using standard PMRA exposure scenarios, it was determined that birds would have to consume contaminated food sources for 13 days for their population to be reduced by 50% (LD_{50}). For no-observable effects on a population, birds can consume contaminated food for up to 1.3 days (NOEL). As the number of feeding days required for adverse effect is greater than one, there is a negligible acute risk to birds consuming contaminated food sources. Assessment of chronic (reproduction) toxicity to birds resulted in RQ = 5.6. Based on this scenario, chronic toxicity of acephate is classified as moderate risk for birds.

Methamidophos, the major transformation product of acephate, is classified as very highly toxic to birds for oral acute, subacute dietary, dermal and inhalation exposures based on laboratory data. Acephate transforms quickly to methamidophos in the environment (dissipation time to 50% [DT_{50}] < 2 days); thus, methamidophos could be the main causative agent for avian mortality from acephate applications. Many field studies show that adverse effects from acephate do not occur at the time of application, rather they occur at one to two days after application. As a result, researchers interpreted that toxicity was due to the transformation product, methamidophos. Reported incidents and field studies have indicated that there is a high acute risk to birds. Data from field studies suggested that when acephate alone was applied, both acephate and methamidophos residues were found in animals and in their food items. Birds have been shown to have marked brain cholinesterase (ChE) inhibition for at least up to 33 days after acephate application at a rate as low as 560 g a.i./ha.

Wild mammals could be exposed to acephate by the ingestion of contaminated food (e.g, grass, seeds and leafy plants). Based on the acute oral toxicity of acephate to small mammals (LD_{50} = 351 mg a.i./kg; NOEL = 35.1 mg a.i./kg) and using standard PMRA exposure scenarios, it was determined that animals would have to consume contaminated

food sources for 4.6 days in order for their population to be reduced by 50% (LD_{50}). For no-observable effects on population, animals can consume contaminated food for up to 0.46 days (NOEL). Since the number of feeding days required for adverse effects is less than one, there is an acute risk to small mammals consuming contaminated food. Assessment of chronic (reproduction) toxicity to mammals resulted in an RQ of 8.3. Based on this scenario, chronic toxicity of acephate is classified as moderate risk for small mammals.

Based on laboratory data, methamidophos, the major transformation product of acephate, is classified as very highly toxic for oral acute, subacute dietary, dermal and inhalation exposures. Because acephate transforms quickly to methamidophos in the environment ($DT_{50} < 2$ days), methamidophos may be the main causative agent for mammalian mortality from acephate applications. Mammals are comparatively less sensitive to OP insecticides than birds; however, field studies do show mortality and depressed ChEs in mammals. Field studies show that squirrels and deer mice were adversely affected by acephate applications; brain ChEs were depressed 15% from acephate application at a rate as low as 100 g a.i./ha.

5.5 Aquatic assessment

The results of this screening assessment identified various levels of risk to non-target aquatic organisms exposed to acephate.

Aquatic organisms can be exposed to acephate that enters aquatic systems through spray drift. For the laboratory-derived data, RQ values were based on estimates of the acute NOEC for the most sensitive species (eg., 1/10 of the LC_{50}). The RQs for freshwater invertebrates (NOEC = 5 mg a.i./L), algae (NOEC = 7.2 mg a.i./L) and fish (NOEC = 5 mg a.i./L) were 0.4, 0.04 and 0.05, respectively. For the most sensitive estuarine invertebrates (NOEC = 0.38 mg a.i./L), the RQ was 0.7. The assessment concluded that for all aquatic invertebrates and plants, acute risks from the use of acephate was low. Acephate has chronic adverse effects on freshwater invertebrates at levels greater than 0.15 mg a.i./L and on marine/estuarine invertebrates and fish at levels greater than 0.58 mg a.i./L.

Methamidophos, the major transformation product of acephate, is very highly toxic to aquatic invertebrates ($LC_{50} < 0.1$ mg a.i./L).

5.6 Environmental assessment conclusions

Acephate poses a low risk to aquatic organisms. There is a low risk (RQ = 0.4–0.7) for aquatic invertebrates and there is no risk for fish (RQ = 0.05) and plants (RQ = 0.04).

For terrestrial organisms, there are low levels of acute risk to birds and mammals. However, there is moderate chronic risk for birds and mammals (RQ = 5.6 and 8.3, respectively) and a moderate acute risk for bees (RQ = 7).

The major transformation product of acephate, methamidophos, is very highly toxic for birds, mammals and aquatic invertebrates. Methamidophos may be the main causative agent of toxicity to non-target organisms from acephate applications.

5.7 Environmental risk mitigation

Mitigation of potential impacts on terrestrial ecosystems is difficult given that the non-target organisms frequent treated areas. In the case of bees, it may be possible to reduce the risk by restricting the application of acephate to a time when bees are not actively foraging.

Acephate does not pose a high risk to aquatic ecosystems. However, as acephate transforms quickly to methamidophos, which is more toxic to aquatic organisms, the buffer zones should be based on the amount of methamidophos entering the water with acephate application. Therefore, buffer zones were calculated using the molecular weight ratio of methamidophos to acephate (0.77) and that 25% of acephate is being transformed into methamidophos with the most sensitive toxicity endpoint for *Daphnia magna* (NOEC = 2.6 µg a.i./L), as shown in Table 5.7.1.

Table 5.7.1 Summary of buffer zones for application of acephate

Method of application	Buffer zone (metres) required for the protection of aquatic habitat with water depth of:		
	< 1 metre	1–3 metres	> 3 metres
Field sprayer *	10	5	0
Airblast **	15	5	0

* For field sprayers, buffer zones can be reduced by 70% when using shrouds or 30% when using cones.
** Timing of application was not indicated; thus, buffer zones were determined for early season application.

6.0 Value

6.1 Evaluation method

6.1.1 Agricultural uses of acephate

The importance of acephate EPs for managing specific pests on specific crops in Canada was evaluated based on the availability of registered pesticides that are potential alternatives. The use of acephate in agriculture in recent years in Canada was assessed by surveying crop production specialists, provincial agricultural officials, growers' associations and other stakeholders about acephate use.

Uses of acephate were classified into two value classes as follows:

Key uses
Some uses of acephate were considered "key uses" because they matched one or more of the following criteria:

- a User Requested Minor Use Label Expansion (URMULE) was granted in the last two years and there are no registered alternatives; or
- there was reported use of > 5% on the given crop and there are no registered alternatives; or
- there was reported use of at least 10% on the given crop and there are registered alternatives; however, acephate is the primary active ingredient for control of the pest; or
- maintaining registration was considered key for resistance management and/or plays an important role in integrated pest management programs; or
- the use site is of great importance to the economy of Canada.

Non-key uses
Uses of acephate were considered to be "non-key uses" either because they did not match the "key use" criteria or because the information available to the PMRA indicated little or no use in Canada.

6.1.2 Non-agricultural uses of acephate

Information regarding the extent of non-agricultural use of acephate was obtained from consultation with provincial governments and crop protection specialists. The following discussion is based on the information available to the PMRA. These uses were also categorized into "key uses" and "non-key uses" based on the above criteria.

6.2 Evaluation results

6.2.1 Agricultural sites with key uses of acephate

The following uses were identified as being "key uses" of acephate:

Saskatoon berries (non-bearing)—for control of woolly elm aphid
Soil injections of acephate are applied to Saskatoon berries to kill woolly elm aphid, which feed on underground roots. Acephate is the only insecticide registered in Canada for this use. Treatments are applied only to non-fruiting plants during the first three years of growth.

Tomatoes (field)—for control of wireworms
Fresh and processing tomato crops are treated with acephate to prevent wireworm damage. Acephate is the only insecticide registered in Canada for this use.

Tobacco—for control of root maggots, thrips and wireworms
Acephate is applied to tobacco to control thrips, root maggots, and wireworms. Acephate is the only insecticide registered in Canada for controlling thrips and wireworms on tobacco. Diazinon and chlorpyrifos are registered alternatives to control root maggots on tobacco; however, both active ingredients are currently under re-evaluation.

6.2.2 Agricultural sites with non-key uses of acephate

The following agricultural sites were identified as having no "key uses" of acephate: Brussels sprouts, sweet peppers (bell), cabbage, cauliflower, celery, corn (seed and sweet), cranberries, head lettuce and potatoes.

6.2.3 Non-agricultural sites with key uses of acephate

There were no non-agricultural uses identified as being a "key use".

6.2.4 Non-agricultural sites with non-key uses of acephate

Outdoor ornamentals
Abelia, alder, alyssum, arborvitae, ash, aspen, aster, azalea, barberry, birch, bloodleaf (Iresine), Boston ivy, bottlebrush, boxwood, calendula, camellia, cedar, cockspur thorn, cotoneaster, cypress, dahlia, daisy, daylily, deutzia, dusty miller, elm (Chinese or Siberian), Euonymus, fir, flowering almond, flowering cherry, flowering plum, flowering quince, forsythia, fruitless mulberry, gazania, geranium, gladiolus, hackberry, hawthorn, hemlock, hibiscus, holly, honey locust, hydrangea, ivy, juniper, lantana, larch, laurel, ligustrum, lilac, linden, locust, magnolia, mahonia, maple, marigold, mock orange, mountain ash, nandina, oak, pachysandra, petunia, phlox, photinia, pincherry, pine, pittosporum, poplar, primrose, pyracantha, red oak, rhododendron, rose, rose of Sharon, salvia, shade trees, silver maple, slippery elm, snapdragon, spirea, spruce, sumac, staghorn sumac, sweet gum, sycamore, tulip, viburnum, wild cherry, white oak, willow, wisteria, yew (taxus), yucca, and zinnia

Greenhouses
Roses

Forest and woodlots
Christmas tree plantations, farm woodlots, tree nurseries, shelterbelts, shade trees, right of ways and municipal parks (excluding national and provincial parks)

7.0 Other assessment considerations

7.1 Toxic Substances Management Policy

During the review of acephate, the PMRA has taken into account the federal TSMP[2] (Toxic Substances Management Policy) and has followed its Regulatory Directive DIR99-03[3]. It has been determined that this active ingredient does not meet the TSMP Track 1 criteria for the following reasons:

- it does not meet the criteria for persistence. Its values for half-life in water (≤ 7 days, anaerobic conditions), soil (≤ 2 days) and sediment (≤ 7 days) are below the TSMP Track 1 cut-off criteria for water (≥ 182 days), soil (≥ 182 days) and sediment (≥ 365 days).

- it is not bioaccumulative. The log K_{ow} was not provided; however, based on high solubility of acephate in water and low solubility in octanol, the log K_{ow} is expected to be very small.

- its technical grade does not contain any by-products or microcontaminants that meet the TSMP Track 1 criteria. Impurities of toxicological concern are not expected to be present in the raw materials nor are they expected to be generated during the manufacturing process.

- the formulated product does not contain any formulants that are known to contain TSMP Track 1 substances.

7.2 Formulant issues

Identity of relevant impurities of toxicological, environmental and/or other significance

Methamidophos, which is also currently registered as a TGAI, is the only impurity present in the TGAI acephate. Based on the starting materials used, the reaction conditions, the reaction intermediates and the chemical structure of the active ingredient acephate, the TGAI is not expected to contain TSMP Track 1 substances as identified in DIR99-03, Appendix II.

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2 The federal Toxic Substances Management Policy is available through Environment Canada's web site at www.ec.gc.ca/toxics

3 Regulatory Directive DIR99-03, *The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy*, is available through the Pest Management Information Service. Phone: 1 800 267-6315 within Canada or (613) 736-3799 outside Canada (long distance charges apply); Fax: (613) 736-3798; E-mail: pmra_infoserv@hc-sc.gc.ca; or through our web site at www.pmra-arla.gc.ca

Identity of formulants in EPs

- There are no List 1 formulants in the EPs containing the acephate.
- All formulants have been adequately identified to PMRA.

8.0 Proposed regulatory action

The PMRA has determined that the dietary and drinking water risks, residential post-application risk, worker risks during mixing, loading and application and risks to the environment are acceptable, provided that the mitigation measures listed in Section 8.1 are implemented and the supporting data identified in Section 9.0 are provided. The one residual concern is for post application workers; calculated MOEs for workers re-entering treated areas at agronomically feasible REIs do not meet target MOEs, but it is expected that exposure and risk estimates could be refined with the provision of additional data. At this stage of the re-evaluation process, the PMRA requests the registrant to submit data needed to refine the post-application worker exposure assessment and demonstrate acceptable MOEs for workers re-entering the treated areas (as outlined in Section 9.1) within 24 months of the finalization of the current re-evaluation decision. Registrants of other OP pesticides may wish to cooperate in the development of further generic data (e.g., use-pattern data). This re-evaluation assessment and decision will be revisited in light of the additional information that is received.

8.1 Proposed mitigation measures and label changes

8.1.1 Toxicological information

A. Labels of pesticide products carry statements regarding symptoms of poisoning and treatment, which are especially important for those who may be overexposed when working with the product in a commercial or industrial setting (e.g., mixers/loaders who handle more concentrated forms). Based on the toxicological assessments, the label text of the acephate-containing products should be expanded and/or standardized, as follows:

Toxicological 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.

B. For those products that contain greater than 10% petroleum distillates, the following text should also be added to the Toxicological Information section (placed at the end of the paragraph presented above), as an additional aid to the attending physician:

NOTE: Product contains a petroleum distillate solvent.

8.1.2 Proposed measures to protect mixers/loaders/applicators

A. Mixing and loading in all agricultural scenarios

- closed mixing/loading systems are required (i.e., water-soluble packaging for soluble powder formulation)
- mixers/loaders must wear a long-sleeved shirt, long pants and chemical-resistant gloves

Although calculated MOEs exceed target MOEs for some low acreage and/or low application rate scenarios, closed mixing/loading systems are still warranted for all ground applications. This is consistent with the mitigation measures listed in the USEPA IRED for acephate.

Mixers and loaders using water-soluble packets must not open or puncture the bag. They must also have additional PPE immediately available for use in emergency (such as broken package, spill or equipment breakdown). These PPE include chemical-resistant coveralls and a respirator.

B. Applying using groundboom equipment

- applicators must use a closed cab when applying to areas larger than 65 ha in one day
- applicators must wear a long-sleeved shirt, long pants and chemical-resistant gloves when applying to areas smaller than 65 ha

Calculated MOEs exceed target MOEs for farmers applying pesticides to their own farm. However, target MOEs are not met for custom applicators, who apply to larger areas per day, unless engineering controls are used.

The closed cab must have a non-porous barrier that totally surrounds the occupant and prevents contact with pesticides outside the cab. Applicators must have immediately available PPE for use in case of an emergency (i.e., a broken package, spill or equipment breakdown), such as chemical-resistant coveralls, chemical-resistant gloves and a respirator.

C. Applying using airblast equipment

- workers must use a closed cab

To mitigate both dermal and inhalation exposures, closed cabs are required for all airblast applications. The only possible exception is if airblast equipment is used for cranberries because the application rate for cranberries (0.56 kg ai/ha) is much lower than the application rate for ornamentals and trees (2.62 kg ai/ha).

The closed cab must have a non-porous barrier that totally surrounds the occupant and prevents contact with pesticides outside the cab. Applicators must have immediately available PPE for use in case of an emergency (i.e., a broken package, spill, or equipment breakdown), such as chemical-resistant coveralls, chemical-resistant gloves, chemical-resistant head gear and a respirator.

D. Applying using hand held equipment

- closed mixing/loading systems are required (water-soluble packaging, as discussed above)

- mixers/loaders/applicators must wear maximum PPE (chemical-resistant coveralls over a long-sleeved shirt and long pants, a respirator and chemical-resistant gloves)

- mixers/loaders/applicators must not handle more than 1500 L/day of diluted product

The calculated MOEs for high-pressure handwand are above the target MOEs for both inhalation and dermal exposure, with water-soluble packaging and maximum PPE during application, only when a smaller diluted amount is used per day (1500 L).

E. Mixing, loading and applying using soil injection

- mixers/loaders/applicators must wear PPE listed in sections A and B

For soil injection, only the mixing/loading portion of exposure was assessed. No data are available for estimating exposures from application. However, the applicator mitigation measures outlined in Section B (groundboom) should be implemented.

F. Applying encapsulated implants

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

No data are available to estimate exposure to workers who use encapsulated implants, but applicator exposure should be minimal if gloves are worn.

8.1.3 Proposed interim measures to minimize exposure to workers re-entering the treated areas

Post-application occupational risks consider exposures to acephate and its degraded, methamidophos. In some instances, methamidophos residues resulting from acephate applications increase the post-application risks. Methamidophos is also an OP insecticide, currently registered for use on broccoli, Brussels sprouts, cabbages, cauliflowers, lettuce, potatoes and canola (rapeseed).

Both acephate and methamidophos should not be used on the same crop in the same season. The following statement should be added to the labels of all products containing either methamidophos or acephate:

- Residues that result from the use of acephate and methamidophos are similar. Brussels sprout, cabbage, cauliflower, celery, lettuce and potato crops may only be treated with one end-use product containing either acephate **or** methamidophos in the same season.

The registrant must design, submit to the PMRA for approval, and implement a specific product stewardship plan to ensure that field worker post-application exposure is minimized. This would include ensuring that field workers are provided with double notification (i.e., written notice on posted signs and verbal notification to those re-entering a field) that the area has been treated with acephate and that they may be exposed to acephate and methamidophos, both of which are cholinesterase inhibitors. This should include a brief description of the signs and symptoms of cholinesterase inhibition and ways to minimize exposure.

Furthermore, the registrant must implement a number of mitigative measures to increase the margins of safety for agricultural workers as follows:

- longer intervals before workers may re-enter treated areas (i.e., maximum agronomically feasible REIs);
- availability of wash stations for all re-entry workers;
- reducing the application rate;
- limiting the number of applications per season; and
- requiring PPE (chemical-resistant gloves, long sleeved shirt) for all critical post-application activities performed by worker within 30 days of acephate application.

The following agronomically feasible REIs (days) are proposed:

Brussels sprouts – 5
cabbage – 5
cauliflower – 5
celery – 5
corn – 5
cranberries – 3
lettuce – 5
peppers – 3
potatoes – 5
Saskatoon berries – 3
tobacco – 3
tomatoes – 3
ornamentals – 3
trees (plantations, nurseries, etc.) – 13

8.1.4 Proposed measures to protect adults and youth re-entering treated residential areas

The use of acephate on residential and recreational ornamentals does not result in unacceptable MOEs for individuals re-entering these areas. The label should specify the following:

- Restrict the number of applications on residential outdoor ornamentals to two applications per year.

8.1.5 Dietary risk assessment

- The residue of concern for acephate is currently described as the parent compound, *O,S*-dimethyl acetylphosphoramidothioate.

- Residues of methamidophos can occur following the use of acephate. Methamidophos is also registered as a pest control product and Table 8.1.6.1, Division 15 of the Food and Drug Regulations (FDR) lists maximum residue limits (MRLs) for methamidophos separately. These values will be reconsidered as part of the re-evaluation of methamidophos. Similarly, exposure to methamidophos which results from the use of acephate will be addressed in the risk assessment for methamidophos.

- Based on the available residue data and label uses, it is recommended that the preharvest intervals (PHIs) on cranberries and peppers be increased from 0 to 75 days, and from 7 to 21 days, respectively, to ensure that the residues on treated commodities do not exceed the MRL.

- Both acephate and methamidophos should not be used on the same crop during the same season, as indicated in Section 8.1.3.

8.1.6 Maximum residue limits of acephate in food

In general, when the re-evaluation of a pesticide has been completed, the PMRA intends to update Canadian MRLs following the evaluation of requested data, and to remove MRLs that are no longer supported. If petitions are received to request MRLs for imported agricultural commodities or to support an expansion of use, MRLs will be established if the PMRA determines that the requested MRLs are needed and would not result in unacceptable health risks. These refinements ensure that the Canadian food supply continues to be protected by the highest standards.

As indicated in Table 8.1.6.1, the FDR specifies MRLs for acephate residues at 5 ppm on celery; 2 ppm on cauliflower and peppers; 1.5 ppm on Brussels sprouts; 1 ppm on lettuce; 0.5 ppm on corn, cranberries and potatoes; 0.3 ppm on cabbage and 0.05 ppm on milk. Import MRLs are established at 1 ppm on beans and 0.5 ppm on soybeans. Residues in all other agricultural commodities, including those approved for treatment in Canada but without a specified MRL (i.e., Saskatoon berries, tomatoes and animal commodities other than milk), must not exceed 0.1 ppm, a general MRL specified in subsection B.15.002(1) of the FDR. Changes to this general MRL may be implemented in the future, as indicated in Discussion Document DIS2003-01, *Revocation of the 0.1 ppm General Maximum Residue Limit for Food Pesticide Residues [Regulation B.15.002(1)]*.

For all commodities specified, residue data were available to indicate that existing MRLs should not be exceeded if acephate is used according to good agricultural practice, as described by the current product labels. In most cases, however, the existing residue data were insufficient to meet our current standards as described in Regulatory Directive DIR98-02, *Residue Chemistry Guidelines*. The registrant is requested to provide confirmation that residue field trial data for all commodities meet contemporary standards by submitting the appropriate data and/or USEPA Data Evaluation Reports.

The general MRL of 0.1 ppm will apply for enforcement purposes with respect to the residues of acephate in food for all other commodities, including Saskatoon berries, tomatoes, meat, poultry and eggs. Parties interested in supporting an import MRL for residues of acephate on other commodities should contact the PMRA during the comment period of this document to discuss the submission of appropriate data.

Table 8.1.6.1 Acephate MRLs, for commodities approved for treatment in Canada and imports with specified MRLs

Commodity	MRLs (ppm)
Beans*	1.0
Brussels sprouts	1.5
Cabbage	0.3
Cattle, hog, sheep (fat, meat, meat by products)	0.1**
Cauliflower	2.0
Celery	5.0
Corn	0.5
Cranberries	0.5
Eggs	0.1**
Lettuce	1.0
Milk	0.05
Peppers	2.0
Potatoes	0.5
Poultry (fat, meat, meat by products)	0.1**
Saskatoon berries	0.1**
Soybeans*	0.5
Tomatoes	0.1**

* MRL for import purposes; use not registered in Canada
** FDR B.15.002(1)

8.2 Proposed regulatory action relating to environment

Label amendments

Environmental hazards
This product is toxic to bees exposed to direct treatment or residues on blooming crops or weeds. Do not apply this product or allow it to drift to blooming crops or weeds if bees are foraging in the treatment area. Warn beekeepers to protect bees from treated areas for one week after treatment.

Toxic to aquatic organisms. Observe buffer zones as specified under Directions for Use.

This product is toxic to birds and wild mammals. Applications may adversely affect birds and wildlife visiting the treatment area.

This product has the potential to leach through soils to groundwater. It is recommended that this product not to be used on coarse textured soils or in areas where the water table may be high. This product should not be applied if rainfall is expected within 48 hours after application and treatment areas should not be irrigated for at least 48 hours after application to minimize the potential for leaching and surface run-off.

Directions for use
Overspray or drift to sensitive habitats should be avoided. Buffer zones, as specified in Table 5.7.1, are required between the downwind point of direct application and the closest edge of sensitive aquatic habitats including lakes, rivers, sloughs, ponds, prairie potholes, creeks, marshes, streams, reservoirs and wetlands. Do not contaminate these habitats when cleaning and rinsing spray equipment or containers.

Do not apply during periods of dead calm or when winds are gusty.

When a tank mixture is used, consult the label of the tank-mix partners and observe the largest (most restrictive) buffer zone of the products involved in the tank mixture.

9.0 Additional data requirements

9.1 Information required to refine the occupational exposure assessment

The registrant is required to provide, within 24 months of the finalization of the current re-evaluation decision, information that demonstrates calculated MOEs exceed target MOEs for re-entry workers. The PMRA will revisit the re-evaluation assessment and decision on acephate in light of data that are received. If no data are received within the given time, the PMRA will consider appropriate measures (e.g., longer REIs, cancellation of uses) to address these concerns. The type of data needed to refine the exposure assessment could include, but are not limited to, the following:

- typical rate and number of applications per season;
- critical worker activities and their timing with respect to the stage of growth of the crop and application of acephate;
- refined transfer coefficients such as those being developed by the ARTF (registrant would need to join ARTF);
- passive dosimetry or biological monitoring exposure data;
- additional DFR data;
- data to support lower rate of application;
- data to support longer REIs;
- data supporting the feasibility of additional protective clothing and/or other; and
- mitigation measures selected for post-application worker activities.

9.2 Data requirements relating to toxicology

The following confirmatory data would be required to support the continued registration of acephate and to support any expansion of acephate use:

- A delayed neurotoxicity study with neuropathy target esterase measurements (triggered by the delayed neurotoxic potential identified with methamidophos, a metabolite of acephate) (DACO 4.5.10)
- A developmental neurotoxicity study (DACO 4.5.14)

Although not critical to the current acephate re-evaluation, the registrant has indicated that the following data are being generated; thus, these confirmatory data should be submitted when available:

- A rat metabolism study (DACO 4.5.9)
- A subchronic, repeat-dose neurotoxicity study (DACO 4.5.13)

9.3 Data requirements relating to food residue exposure

a) The following confirmatory data are required to support the continued registration of acephate or any expansion of use:
   - An acceptable confined crop rotation study (DACO 7.4.3) and relevant USEPA DERs are required to determine the nature and amount of residue uptake that may occur after the harvest of a treated crop.

b) Although not critical to the determination of risks in the current re-evaluation, the following data gap was identified and must be filled:
   - Confirmation that residue field trial data for all commodities meet contemporary standards, as per DIR98-02, *Residue Chemistry Guidelines*.

9.4 Data requirements relating to environmental risks

This study was identified as a data gap. Note that upon review of newly submitted data, the PMRA may request further data on the following:

- Aerobic aquatic biotransformation (DACO 8.2.3.5.2)

10.0 Re-evaluation conclusion

By way of this document, the PMRA is soliciting comments from interested parties on the proposed interim regulatory decision for acephate. In particular, the PMRA is soliciting comments on the feasibility of lengthening the proposed interim REIs and PHIs for certain crops prior to finalizing this interim document. The PMRA will accept written comments on this proposal up to 60 days from the date of publication of this document.

List of abbreviations

ADI	acceptable daily intake
a.i.	active ingredient
ARfD	acute reference dose
ARI	aggregate risk index
ARTF	Agricultural Re-entry Task Force
atm	atmospheres
bw	body weight
CAS	Chemical Abstracts Service
ChE	cholinesterase
cm	centimetre(s)
d	day(s)
DACO	data code
DEEM™	Dietary Exposure Evaluation Model
DER	Data Evaluation Report
DFR	dislodgeable foliar residue
DT_{50}	dissipation time to 50%
DWLOC	drinking water level of comparison
EEC	expected environmental concentration
EFED	Environmental Fate and Effects Division (USEPA)
EXAMS	Exposure Analysis Modeling System
EP	end-use product
FDR	Food and Drug Regulations
g	gram(s)
ha	hectare
IRED	Interim Reregistration Eligibility Decision
kg	kilogram(s)
K_{oc}	organic carbon partition coefficient
K_{ow}	*n*-octanol–water partition coefficient
L	litre(s)
LEACHM	Leaching Estimation and Chemistry Model
LC_{50}	lethal concentration to 50%
LD_{50}	lethal dose to 50%
LOAEL	lowest observed adverse effect level
LOEL	lowest observed effect level
m	metre(s)
m^3	metre(s) cubed
max	maximum
min	minimum
min	minute(s)
mg	milligram(s)
mm	millimetre(s)
mm Hg	millimetre mercury
MOE	margin of exposure
MRL	maximum residue limit

NOAEL	no observed adverse effect level
NOEC	no observed effect concentration
NOEL	no observed effect level
nm	nanometre(s)
OP	organophosphate insecticide
PACR	Proposed Acceptability for Continuing Registration
PCP	pest control product
PDI	potential daily intake
PHI	preharvest interval
pH	-log10 hydrogen ion concentration
PHED	Pesticide Handlers Exposure Database
PMRA	Pest Management Regulatory Agency
PPE	personal protective equipment
ppm	parts per million
PRZM	Pesticide Root Zone Model
RED	Reregistration Eligibility Decision
REI	Restricted Entry Interval
RQ	risk quotient
SP	soluble powder
TC	transfer coefficient
TGAI	technical grade active ingredient
UDS	Unscheduled DNA synthesis
URMULE	User Requested Minor Use Label Expansion
U.S.	United States
USEPA	United States Environmental Protection Agency
WSP	water-soluble powder

Appendix I Registered products containing acephate in Canada as of 31 December 2003

Registrant	Registration number	Guarantee	Product name	Class
Arvesta Corporation	14225	75.0%	Orthene 75% Soluble Powder Systemic Insecticide	Commercial
Arysta LifeScience Corporation	15559	75.0%	Orthene Tree and Ornamental Spray	Commercial
Arysta LifeScience Corporation	21568	97.0%	Acecap 97 Systemic Insecticide Implants	Commercial
Arysta LifeScience Corporation	22109	99.78%	Orthene Technical	Technical

Appendix II Toxicology endpoints for health risk assessment for acephate

Exposure scenario	Dose (mg/kg bw/day)	Endpoint	Study	UF/SF or MOE[b]
Acute dietary	NOAEL = 0.5	Brain cholinesterase inhibition	Range-finding acute neurotoxicity— rat	100
	ARfD = 0.005 mg/kg bw			
Chronic dietary	LOAEL = 0.12 (close to threshold of a NOAEL)	Brain cholinesterase inhibition (slight)	13-week oral toxicity—rat	100
	ADI = 0.0012 mg/kg bw/day			
Short-term[a] dermal	Dermal NOAEL = 50	Brain cholinesterase inhibition	3-week dermal toxicity—rat	300
Short-term[a] inhalation	Inhalation NOAEL = 0.26	Brain and erythrocyte cholinesterase inhibition	4-week inhalation toxicity—rat	100
Aggregate[a]	Oral LOAEL = 0.12 (close to threshold of a NOAEL) Dermal NOAEL = 50	Brain cholinesterase inhibition	13-week oral toxicity—rat 3-week dermal toxicity—rat	100 (Oral) 300 (Dermal)

[a] Duration of exposure is 1–30 days.

[b] UF/SF refers to total of uncertainty and/or safety factors for dietary assessments; MOE refers to desired margin of exposure for occupational or residential assessments.

Appendix III Occupational risk estimates for acephate

Table 1 Route specific MOEs for mixers/loaders and applicators

(Shading in table indicates calculated MOEs that are less than target MOEs)

Crop	Application method	Rate (kg ai/ha)	Area treated (ha/day)	Dermal MOEs[a]				Inhalation MOEs[b]		
				Baseline[f]	Min PPE[g]	Max PPE[h]	EC[i]	Baseline	Respirator	EC
Mixer/Loader/Applicator										
vegetables	groundboom	0.56	32	345	496	543	5954	18	177	4213
		0.83	32	235	338	370	4059	12	121	2872
corn, sweet & seed	groundboom	0.56	80	138	198	217	2381	7	71	1685
		0.83	80	94	135	148	1625	5	48	1149
		0.56	140	79	113	124	1361	4	40	963
		0.83	140	54	77	85	928	3	28	657
cranberries	groundboom	0.56	32	346	498	546	5980	18	178	4232
	mist blower (airblast)[j]	0.56	16	357	455	481	6165	33	328	2673
potatoes	groundboom	0.56	65	170	244	268	2931	9	87	2074
		0.83	65	116	166	182	1998	6	59	1414
		0.56	300	37	53	58	635	2	19	449
		0.83	300	25	36	40	433	1	13	306
Saskatoon berries	soil injection[c]	2.55	32	81	116	126	1985	4	40	1239
tobacco	groundboom	0.56	32	345	496	543	5954	18	177	4213
		0.83	32	235	338	370	4059	12	121	2872
		1.13	32	172	248	272	2977	9	88	2106
		1.28	32	152	219	240	2627	8	78	1859
tomatoes	groundboom	0.90	32	216	310	340	3721	11	111	2633
ornamentals (outdoor and greenhouse)	mist blower (airblast)[j]	2.62	16	76	97	103	1318	7	70	571
	low-pressure handwand[d]	1.31 g ai/L	150 L/day	902	1540	1793	18881	65	651	2049
	high-pressure handwand[e]	1.31 g ai/L	3800 L/day	N/A	N/A	N/A	126	N/A	N/A	24
	groundboom	1.28	32	152	218	239	2616	8	78	1851
	backpack[e]	1.31 g ai/L	150 L/day	N/A	N/A	N/A	3271	N/A	N/A	1491

Crop	Application method	Rate (kg ai/ha)	Area treated (ha/day)	Dermal MOEs[a]				Inhalation MOEs[b]		
				Baseline[f]	Min PPE[g]	Max PPE[h]	EC[i]	Baseline	Respirator	EC
trees	mist blower (airblast)[j]	2.62	16	76	97	103	1318	7	70	571
	low-pressure handwand[d]	1.31 g ai/L	150 L/day	902	1540	1793	18881	65	651	2049
	high-pressure handwand[e]	1.31 g ai/L	1500 L/day	N/A	N/A	N/A	319	N/A	N/A	61

[a] Dermal MOE = dermal NOAEL / dermal exposure. The dermal NOAEL is 50 mg/kg bw/day. The target dermal MOE is 300.

[b] Inhalation MOE = inhalation NOAEL / inhalation exposure. The inhalation NOAEL is 0.26 mg/kg bw/day. The target inhalation MOE is 100.

[c] Exposure estimates are for mixing/loading only. The PHED does not contain application data for applying by soil injection.

[d] EC for low-pressure handwand is based on liquid formulation, single layer and chemical-resistant gloves (for mixing/loading and applying) because there is no data for water-soluble packaging. Closed cab does not apply to this method of application.

[e] There is no data to estimate mixing/loading a soluble powder for high-pressure handwand or backpack. As such, exposure for baseline, minimum PPE and maximum PPE could not be estimated. For engineering control values, mixing/loading a liquid was considered representative of water-soluble packaging for a wettable powder. In this scenario, mixers/loaders and applicators are wearing a single layer of clothing plus chemical-resistant gloves.

[f] Baseline: long-sleeved shirt + long pants + shoes + socks + chemical-resistant gloves

[g] Min PPE = minimum PPE = baseline + cotton coveralls + respirator

[h] Max PPE = maximum PPE = baseline + chemical-resistant coveralls + respirator

[I] EC = engineering controls;
mixing/loading EC = water-soluble packaging, single layer plus chemical-resistant gloves;
applying EC = closed cab and single layer clothing.

[j] EC values for applicators included chemical-resistant gloves because data for closed cab, no gloves were not available for airblast.

Table 2 Summary of aggregate risk index for mixers/loaders and applicators

NOTE: Since MOEs could not be calculated for combined dermal and inhalation exposure (different NOAELs and target MOEs), an aggregate risk index (ARI) was calculated using the following equation:

$$ARI = \frac{1}{\frac{\text{target dermal MOE}}{\text{dermal MOE}} + \frac{\text{target inhalation MOE}}{\text{inhalation MOE}}}$$

If the ARI exceeds 1, there is no concern.

(Shading in table indicates calculated MOEs that are less than target MOEs)

Crop	Application method	Rate (kg ai/ha)	Area treated (ha/day)	Aggregate risk index			
				Baseline[c] M/L + A	EC[e] M/L Baseline A	EC[e] M/L Max PPE[d] A	EC[e] M/L + A
vegetables	groundboom	0.56	32	0.15	5.10	11.16	13.49
		0.83	32	0.10	3.47	7.61	9.20
corn sweet & seed	groundboom	0.56	80	0.06	2.04	4.47	5.40
		0.83	80	0.04	1.39	3.04	3.68
		0.56	140	0.04	1.16	2.55	3.08
		0.83	140	0.02	0.79	1.74	2.10
cranberries	groundboom	0.56	32	0.15	5.12	11.21	13.60
	mist blower (airblast)[f]	0.56	16	0.26	1.35	2.40	11.60
potatoes	groundboom	0.56	65	0.08	2.51	5.50	6.64
		0.83	65	0.05	1.71	3.75	4.53
		0.56	300	0.02	0.54	1.19	1.44
		0.83	300	0.01	0.37	0.81	0.98
Saskatoon berries	soil injection[a]	2.55	32	0.03	4.31		
tobacco	groundboom	0.56	32	0.15	5.10	11.16	13.49
		0.83	32	0.10	3.47	7.61	9.20
		1.13	32	0.08	2.55	5.58	6.75
		1.28	32	0.07	2.25	4.93	5.95
tomatoes	groundboom	0.90	32	0.10	3.19	6.98	8.43
ornamentals (outdoor + greenhouse)	mist blower (airblast)[f]	2.62	16	0.05	0.29	0.51	2.48
	low-pressure handwand[b]	1.31 kg ai/1000 L	150 L/day	0.54	15.46	60.38	N/A
	high-pressure handwand[b]	1.31 kg ai/1000 L	3800 L/day	N/A	0.15	0.84	N/A
	groundboom	1.28	32	0.07	2.24	4.91	5.93
	backpack[b]	1.31 kg ai/1000 L	150 L/day	N/A	6.30	24.48	N/A

Crop	Application method	Rate (kg ai/ha)	Area treated (ha/day)	Aggregate risk index			
				Baseline[c] M/L + A	EC[e] M/L Baseline A	EC[e] M/L Max PPE[d] A	EC[e] M/L + A
trees	mist blower (airblast[f])	2.62	16	0.05	0.29	0.51	2.48
	low-pressure handwand[b]	1.31 kg ai/1000 L	150 L/day	0.54	15.46	60.38	N/A
	high-pressure handwand[b]	1.31 kg ai/1000 L	1500 L/day	N/A	0.39	2.12	N/A

[a] No data are available for the soil injection application scenario. Risk estimates include mixing and loading only.

[b] For low-pressure handwand, high-pressure handwand and backpack, the mixer/loader and applicator data are combined in the PHED. As such, any PPE would apply to both the mixer/loader and applicator.

Therefore, for these scenarios,

EC M/L—Baseline A = liquid formulation (for water-soluble powder [WSP]), single layer clothing, chemical-resistant gloves
EC M/L—Max PPE A = liquid formulation (for WSP), chemical-resistant coveralls and chemical-resistant gloves (for M/L and A).

For the EC ML + A scenario, there are no values because these methods cannot be applied with a closed cab. In addition, there is no baseline values for high-pressure handwand or backpack because there is no soluble powder data for these equipment in the PHED.

[c] Baseline = long-sleeved shirt + long pants + shoes + socks + chemical-resistant gloves

[d] Max PPE = maximum PPE = baseline + chemical-resistant coveralls + respirator

[e] EC = engineering controls; mixing/loading EC = water-soluble packaging and single layer plus chemical-resistant gloves; applying EC = closed cab and single layer clothing.

[f] EC values for applicators included chemical-resistant gloves because data for closed cab, no gloves were not available for airblast.

Appendix IV Post-application exposure estimates and REIs

Table 1 Margins of exposure for workers entering treated fields on the day of the last application

(Shading in table indicates calculated MOEs that are less than target MOEs)

Crop	Activity	TC (cm^2/hr)	MOE			
			Acephate		Methamidophos[a]	
			Low application rate	High application rate	Low application rate	High application rate
Brussels sprouts, cabbage, cauliflower	harvest	5000	423	285	63	43
	scout, irrigate	4000	529	357	79	53
celery, lettuce	harvest	2500	846	571	126	85
	scout, irrigate	1500	1410	952	211	142
peppers	harvest, stake/tie, scout, irrigate	4000	529	357	79	53
tobacco	harvest, stake/tie, scout, irrigate	4000	529	231	79	35
cranberries	harvest, stake/tie, scout, irrigate	4000	N/A	361	N/A	116
corn	harvest, duteously	17000	124	84	19	13
	stake/tie, scout, irrigate	4000	529	357	79	53
tomatoes	harvest	10000	N/A	90	N/A	29
	stake/tie, scout, irrigate	4000		224		73
potatoes	sort/pack	2500	846	571	126	85
ornamentals	cut/harvest	10000	54	27	39	19
	irrigate	4000	136	66	98	48
	sort/pack	2500	217	106	157	77
trees	transplant ball/burlap	10000	54	27	39	19
	irrigate	4000	136	66	98	48
	sort/pack	3000	181	88	131	64

[a] The dermal NOAEL of 0.75 mg/kg BW/day was used for the short-term dermal assessment of methamidophos with a target MOE of 300.

Table 2 REIs following the last of the maximum number of applications for some crop/activity combinations

Crop	Activity	PHI (days)[a]	REIs			
			Acephate		Methamidophos	
			Low application rate	High application rate	Low application rate	High application rate
Brussels sprouts, cabbage, cauliflower	harvest	28	0	1	18	23
	scout, irrigate		0	0	16	20
celery, lettuce	harvest	21	0	0	10	15
	scout, irrigate		0	0	5	9
peppers	harvest, stake/tie, scout, irrigate	7	0	0	16	20
tobacco	harvest, stake/tie, scout, irrigate	3	0	2	16	25
cranberries	harvest, scout, irrigate	0	N/A	0	N/A	9
corn	harvest, duteously	21	7	10	32	37
	scout, irrigate		0	0	16	20
tomatoes	harvest	Not specified	N/A	6	N/A	20
	stake/tie, scout, irrigate			2		13
potatoes	sort/pack	21	0	0	10	15
ornamentals	cut/harvest	N/A	8	11	14	19
	irrigate		4	7	8	13
	sort/pack		2	5	5	9
trees	transplant ball/burlap	N/A	8	11	14	19
	irrigate		4	7	8	13
	sort/pack		3	6	6	11

[a] The PMRA is recommending a PHI of 75 days for cranberries and 21 days for peppers (see Section 8.1.5).

[b] Tomatoes are treated with one application (2 to 3 weeks after transplanting), so a PHI is not required.

Table 3 MOEs for workers entering treated fields on the agronomically feasible REI

(Shading indicates calculated MOEs that are less than target MOEs)

Crop	Activity	REI	MOEs			
			Acephate		Methamidophos[a]	
			Low application rate	High application rate	Low application rate	High application rate
Brussels sprouts, cabbage, cauliflower	harvest	5	824	556	98	66
	scout, irrigate		1030	695	122	82
celery, lettuce	harvest	5	1648	1112	195	132
	scout, irrigate		2747	1853	325	219
peppers	harvest, stake/tie, scout, irrigate	3	789	532	102	69
cranberries	harvest, stake/tie, scout, irrigate	3	N/A	665	N/A	164
tobacco	harvest, stake/tie, scout, irrigate	3	789	345	102	45
corn	harvest, duteously	5	242	164	29	19
	stake/tie, scout, irrigate		1030	695	122	82
tomatoes	harvest	3	N/A	166	N/A	41
	stake/tie, scout, irrigate			414		103
potatoes	sort/pack	5	1648	1112	195	132
ornamentals	cut/harvest	3	109	53	62	30
	irrigate		271	133	154	75
	sort/pack		434	212	247	120
trees	transplant ball/burlap	13	1094	534	273	137
	irrigate		2735	1336	684	340
	sort/pack		3646	1781	911	456

[a] The dermal NOAEL of 0.75 mg/kg bw/day was used for the short-term dermal assessment of methamidophos with a target MOE of 300.

Table 4 Adult and youth short-term post-application exposure and risk assessments to residential ornamentals

Scenario	Formulation and rate (μg/cm²)	Duration (min)	Dermal [exposure] (μg/kg bw/day)	Dermal MOE[b]
Adult				
Acephate	Soluble powder 12.75	40	76.88	650
Methamidophos			1.59	473
Youth				
Acephate	Soluble powder 12.75	40	69	725
Methamidophos			1.42	527

[a] Dermal exposure = % DFR × rate × TC × duration (hours)/BW (70 kg for adults, 39 kg for youth). The DFRs for acephate and methamidophos are 6.3% and 0.13%, respectively, based on the rose DFR study (Lai 1999a). TCs are 10 000 cm^2/hr for adults and 5000 cm^2/hr for youths.

[b] Adult and youth short-term MOEs are based on a NOAEL of 50 mg/kg/day for acephate and a NOAEL of 0.75 mg/kg bw/day for methamidophos. The target MOE is 300 for both actives.

[c] Methamidophos is a breakdown product of acephate.

Appendix V Use standard for commercial class products containing acephate

(Note: The information in this appendix summarizes the acceptable uses, limitations and minimum personal protective equipment (PPE) for the commercial class products containing acephate resulting from this re-evaluation. This use standard does not identify all label requirements for individual end-use products such as first aid statements, disposal statements, precautionary statements, and supplementary PPE that may be required. Additional information on labels for currently registered products should not be removed unless it contradicts information in this use standard.)

COMMON NAME: acephate

CHEMICAL NAME: O,S-dimethyl acetylphosphoramidothioate

FORMULATION TYPES: Soluble powder
Implant cartridge

SITE CATEGORIES:

4	Forests and Woodlots
6	Greenhouse Non-food Crops
14	Terrestrial Food Crops
27	Ornamentals Outdoor

GENERAL LIMITATIONS: DO NOT APPLY BY AIR

TOXICOLOGICAL 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.

For those products that contain greater than 10% petroleum distillates, the following text should also be added to the Toxicological Information section (placed at the end of the paragraph presented above), as an additional aid to the attending physician:

"NOTE: Product contains a petroleum distillate solvent."

PRECAUTIONARY STATEMENTS:

PROTECTIVE CLOTHING AND EQUIPMENT:

Wettable powder formulations:

A. Mixing and loading in all agricultural scenarios

- closed mixing/loading systems are required (i.e., water-soluble packaging for soluble powder formulation)
- mixers/loaders must wear a long-sleeved shirt, long pants and chemical-resistant gloves

Mixers and loaders using water-soluble packets must not open or puncture the bag. They must also have additional PPE immediately available for use in emergency (such as broken package, spill or equipment breakdown). These PPE include chemical-resistant coveralls and a respirator.

B. Applying using groundboom equipment

- applicators must use a closed cab when applying to areas larger than 65 ha in one day
- applicators must wear a long-sleeved shirt, long pants and chemical-resistant gloves when applying to areas smaller than 65 ha

The closed cab must have a non-porous barrier that totally surrounds the occupant and prevents contact with pesticides outside the cab. Applicators must have immediately available PPE for use in case of an emergency (i.e., a broken package, spill or equipment breakdown), such as chemical-resistant coveralls, chemical-resistant gloves and a respirator.

C. Applying using airblast equipment

- workers must use a closed cab

The closed cab must have a non-porous barrier that totally surrounds the occupant and prevents contact with pesticides outside the cab. Applicators must have immediately available PPE for use in case of an emergency (i.e., a broken package, spill, or equipment breakdown), such as chemical-resistant coveralls, chemical-resistant gloves, chemical-resistant head gear and a respirator.

D. Applying using hand held equipment

- closed mixing/loading systems are required (water-soluble packaging as discussed above)
- mixers/loaders/applicators must wear maximum PPE (chemical-resistant coveralls over a long-sleeved shirt and long pants, respirator and chemical-resistant gloves)
- mixers/loaders/applicators must not handle more than 1500 L/day of diluted product

E. Mixing, loading and applying using soil injection

- mixers/loaders/applicators must wear PPE listed in sections A and B

Encapsulated implants:
- Applicators must wear a long-sleeved shirt, long pants, and chemical-resistant gloves

Post-application

Workers performing critical activities within 30 days of acephate application must wear:
- a long-sleeved shirt and long pants
- chemical-resistant gloves

Wash stations must be available for re-entry workers.

RESTRICTED ENTRY INTERVAL:

Field workers must be provided with double notification (i.e., written notice on posted signs and verbal notification to those re-entering a field) that the area has been treated with acephate and that they may be exposed to acephate and methamidophos, both of which are cholinesterase inhibitors. This should include a brief description of the signs and symptoms of cholinesterase inhibition and ways to minimize exposure.

The following restricted entry intervals (days) must be observed by workers re-entering the treated areas for these crops:

Brussels sprouts – 5
cabbage – 5
cauliflower – 5
celery – 5
corn – 5
cranberries – 3
lettuce – 5
peppers – 3
potatoes – 5
Saskatoon berries – 3
tobacco – 3
tomatoes – 3
ornamentals – 3
trees (plantations, nurseries, etc.) – 13

ENVIRONMENTAL HAZARDS:

TOXIC to bees exposed to direct treatment, drift or residues on flowering crops or weeds. DO NOT apply this product to flowering crops or weeds if bees are visiting the treatment area. Minimize the spray drift to reduce harmful effects on bees in habitats close to the application site.

TOXIC to birds and wild mammals. Applications may adversely affect birds and wildlife visiting the treatment area.

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

TOXIC to aquatic organisms. Observe buffer zones as specified under Directions for Use.

DIRECTIONS FOR USE:

Buffer zones:

The buffer zones specified in the table below are required between the point of direct application and the closest downwind edge of (1) sensitive freshwater habitats (such as lakes, rivers, sloughs, ponds, prairie potholes, creeks, marshes, streams, reservoirs and wetlands), and (2) estuarine or marine habitats.

Method of application	Buffer zone (metres) required for the protection of aquatic habitat with water depth of:		
	< 1 metre	1–3 metres	> 3 metres
Field sprayer*	10	5	0
Airblast (early growth stage)	15	5	0

* For field sprayers, buffer zones can be reduced by 70% when using shrouds or 30% when using cones.

ACCEPTABLE COMMERCIAL USES FOR ACEPHATE

General application instructions and limitations

Soluble powder:

DO NOT handle more than 1500 L of diluted spray solution per day when using hand-held spray equipment.

Food crops:
Mix thoroughly and spray entire plant covering both sides of foliage. Spray when insects are present or feeding injury is first noticed.
Repeat if re-infestation occurs.
All crops may only be treated with one end-use product containing either acephate **or** methamidophos in the same season.

Ornamentals:
DO NOT make more than 2 applications per season to residential ornamental plants and trees.
Restricted Entry Interval for ornamental shrubs and flowers: 3 days
Restricted Entry Interval for trees: 13 days

Implant cartridge:

Use sites may include trees in Christmas tree plantations, seed orchards, high value stands, nurseries, golf courses, and residential or commercial landscape plantings where foliar sprays or soil applied systemic insecticide sprays are not desirable.
DO NOT implant into trees where fruit, nuts or syrup is to be used for sale or consumption.
DO NOT implant into trees having less than 7.5 cm trunk diameter.
DO NOT use implants on trees other than those listed on this label.
DO NOT use implants on trees entering dormancy.
DO NOT repeat implant treatments where tree has not shown the ability to adequately close over the prior treatment.
DO NOT remove cartridges previously implanted.
DO NOT break plastic gelatin.
DO NOT place implant too deep.

NUMBER OF IMPLANTS REQUIRED PER TREE: Determine the tree trunk diameter, multiply by 3.14 and divide by 10.16. Implant around the tree trunk base at 10.16 cm intervals. Drill 0.95 cm (⅜ inch) diameter implant holes at 10.16 cm spacing, spiralling up and around the tree trunk base. Holes should be drilled 3.2 cm deep into the tree trunk (i.e., from the cambium layer) to assure that the cartridge head can be implanted beneath the bark and cambium surface. Cartridges left extending through the bark layer will delay or inhibit wound closure.

Where lower branching occurs 1.5 metres from the ground, make certain the implants are placed directly beneath the lower branches. This will assure adequate distribution of chemical throughout the tree.

IN AREAS OF PUBLIC ACCESS: Ensure that implant holes are covered with a suitable tree wound dressing prior to leaving. treated trees.

Applications timed with maximum upward flow of tree sap produce the most successful results. This characteristic may vary with tree species, geographic area, time of day, individual tree vigour or light intensity at time of treatment. If soil moisture conditions are dry, a thorough deep root watering prior to or immediately following implant treatment will enhance chemical uptake.

It takes 4–7 days for the insecticide to attain effective levels in the foliage of the tree (as early as 2 days if trees are in a healthy vegetative growth condition). Maximum duration of control documented is 18 weeks. Optimum control of severe infestations is 10–12 weeks. When re-treatment is necessary, place the new implants in a spiral pattern between and above or below the previous treatment.

SITE(S)	PESTS	RATE (a.i.)	APPLICATION INSTRUCTIONS AND LIMITATIONS
cabbage, cauliflower, Brussels sprouts, head lettuce (crisp head type only)	cabbage looper, imported cabbageworm, diamondback moth, green peach aphid,	563–825 g/ha	**Soluble powder** Apply in 225 to 1650 L of water using conventional ground application equipment. Use the high rate only when heavy pest infestations are present. Do not feed trimmings to livestock or allow animals to graze on treated areas. Do not apply more than 4 applications per season. Restricted Entry Interval (REI): 5 days Preharvest Interval (PHI): 28 days (Brussels sprouts, cabbage, cauliflower); 7 days (lettuce).
celery	green peach aphid, tarnished plant bug	563–825 g/ha	**Soluble powder** Apply in 225 to 1650 L of water. Apply when insects reach economic threshold levels. Do not apply more than 4 applications per season. Restricted Entry Interval (REI): 5 days Preharvest Interval (PHI): 21 days
corn (seed and sweet)	European corn borer	563–825 g/ha	**Soluble powder** Apply in 220 to 1000 L of spray mix using conventional ground application equipment. Use the high rate only when heavy pest infestations are present. For European corn borer, apply when egg mass count indicates an economically damaging population. Do not feed corn fodder or forage from treated crop to livestock. Do not apply more than 4 applications per season. Restricted Entry Interval (REI): 5 days Preharvest Interval (PHI): 21 days
potato	green peach aphid, potato aphid, potato flea beetle, potato leafhopper, tarnished plant bug	563–825 g/ha	**Soluble powder** Apply in 225 to 1650 L of water per hectare using conventional ground application equipment. Use the high rate only when heavy pest infestations are present. Begin applications at first sign of insects and repeat on a 7 to 10 day schedule as necessary. Do not apply more than 4 applications per season. Restricted Entry Interval (REI): 5 days Preharvest Interval (PHI): 21 days
Saskatoon berries (non-bearing)	woolly elm aphid	637 mg/L 1275 mg/plant	**Soluble powder** Soil Injection Application: Provides control of woolly elm aphid in non-bearing Saskatoon berry plants. Can be used in first three years of establishment. Apply once per year in mid July or early August. Mix 637 mg a.i/L water (equivalent to 6.37 g a.i./10 L of water). Apply 2 litres of this solution per plant. The solution is injected with a probe; 3 to 5 injections for each plant to a depth of 12 cm. The injection should be made 15 cm from the stem of the plant. Restricted Entry Interval (REI): 3 days
sweet pepper (Bell type)	green peach aphid, pepper maggot	562 g/ha	**Soluble powder** Apply in 225 to 1650 L of water with conventional ground application equipment. Begin applications when eggs or insects appear. Maintain a 7 to 10 day spray schedule until insects have been reduced below economic levels. Do not apply more than 4 applications per season. Restricted Entry Interval (REI): 3 days Preharvest Interval (PHI): 21 days
	European corn borer	825 g/ha	

SITE(S)	PESTS	RATE (a.i.)	APPLICATION INSTRUCTIONS AND LIMITATIONS
tobacco (flue cured)	tomato hornworm, flea beetle, green peach aphid	563–825 g/ha	**Soluble powder** Apply in at least 100 L of water per hectare using conventional ground application equipment. Apply on a 7-day schedule or as needed. Use 825 g a.i./ha for control of established populations. Restricted Entry Interval (REI): 3 days Preharvest Interval (PHI): 3 days
	darksided cutworm (pre-plant)	563 g/ha (cover crop treatment) 1125 g/ha (soil treatment)	**Soluble powder** Treat either the rye or wheat cover crop or the soil using at least 200 L of water per hectare. Applications are most effective when applied late afternoon or early evening when temperatures are 13°C or higher. Apply soon after the cutworms have hatched (mid to late April, 4 to 5 days before plowing). Restricted Entry Interval (REI): 3 days
	darksided cutworm (post-plant)	1125 g/ha	**Soluble powder** Apply in sufficient water to give good coverage of seedlings. Apply in the late afternoon or evening. Restricted Entry Interval (REI): 3 days
tobacco	darksided cutworm, potato flea beetle, root maggots, green peach aphid, thrips	825–1275 g/ha	**Soluble powder** Transplant water treatment: Provides control for approximately 2 to 3 weeks after transplanting. Apply in a minimum of 1200 L of transplant water per hectare. Do not apply more than 1275 g a.i./ha as a transplant water application as some phytotoxicity may occur. Restricted Entry Interval (REI): 3 days
	wireworm	825 g/ha	**Soluble powder** Transplant water treatment: Apply in 1200 L of transplant water per hectare. Make one application per season at transplanting. Restricted Entry Interval (REI): 3 days
cranberry	blackheaded fireworm	562 g/ha	**Soluble powder** Apply one prebloom application to control the first generation of blackheaded fireworm where field scouting indicates insect numbers warrant treatment. Apply in 225 to 1650 L of water per hectare using conventional ground equipment. A second application may be made post bloom if insect numbers indicate it is required. Restricted Entry Interval (REI): 3 days Preharvest Interval (PHI): 75 days
tomato	cutworms, potato flea beetle, root maggots, wireworm, aphids, thrips, Colorado potato beetle	900 g/ha	**Soluble powder** Transplant water application: To provide control of listed pests for approximately 2 to 3 weeks after transplanting, apply in 2000 L of water per hectare. This rate is based on 14 000 plants per hectare. Restricted Entry Interval (REI): 3 days
abelia, forsythia, fruitless mulberry, laurel, magnolia	scale insect (crawlers: cottony maple, hemlock, oystershell, cottony cushion, lecanium)	mist blower: 1312 g/1000 L hydraulic sprayer: 637 g/1000 L	**Soluble powder** Mix thoroughly and spray entire plant covering both sides of foliage. Spray when insects are present or feeding injury is first noticed. Spray 2 times, 7 to 10 days apart.
alyssum, daisy	flower thrips		
bottlebrush, honey locust	spider mites (except twospotted)		

SITE(S)	PESTS	RATE (a.i.)	APPLICATION INSTRUCTIONS AND LIMITATIONS
camellia	greenhouse whitefly, mealybug, scale insect (crawlers: cottony maple, hemlock, oystershell, cottony cushion, lecanium), spider mites (except twospotted)		
daylily	flower thrips, twospotted spider mite	mist blower: 1312 g/1000 L hydraulic sprayer: 637 g/1000 L	**Soluble powder** Mix thoroughly and spray entire plant covering both sides of foliage. Spray when insects are present or feeding injury is first noticed. Spray 2 times, 7 to 10 days apart.
gladiolus	flower thrips, gladiolus thrips		
lantana	greenhouse whitefly		
pachysandra, phlox	twospotted spider mite		
yew (taxus)	mealybug		
yucca	flower thrips, scale insect (crawlers: cottony maple, hemlock, oystershell, cottony cushion, lecanium)		
alder	fall webworm, leafminer, psyllids,		**Soluble powder** Mix thoroughly and spray entire plant covering both sides of foliage. Spray when insects are present or feeding injury is first noticed. Repeat application once only, if re-infestation occurs.
ash	aphid, fall webworm, gypsy moth, lace bug, sawflies (open feeders: blackheaded ash), tent caterpillar (eastern and forest), tussock moth		
aspen, bloodleaf (Iresine), dusty miller, flowering almond, flowering quince, gazania, mock orange, photinia, pittosporum, tulip	aphid		
Boston ivy	potato leafhopper		
cedar	bagworm, gypsy moth		
cockspur thorn	cankerworm (spring and fall)		
deutzia	aphid, leafminer		
flowering plum	aphid, tent caterpillar (eastern and forest)		
hawthorn	aphid, cankerworm (spring and fall), gypsy moth, tent caterpillar (eastern and forest)		
larch	sawflies (open feeders: redheaded pine sawfly)		

SITE(S)	PESTS	RATE (a.i.)	APPLICATION INSTRUCTIONS AND LIMITATIONS
linden	aphid, bagworm, cankerworm (spring and fall), fall webworm, tussock moth, yellownecked caterpillar		
locust	leafminer		
poplar	aphid, fall webworm, gypsy moth, poplar tentmaker, tent caterpillar (eastern and forest), tussock moth	mist blower: 1312 g/1000 L hydraulic sprayer: 637 g/1000 L	**Soluble powder** Mix thoroughly and spray entire plant covering both sides of foliage. Spray when insects are present or feeding injury is first noticed. Repeat application once only, if re-infestation occurs.
rhododendron	lace bug		
silver maple	cankerworm (spring and fall)		
slippery elm	casebearers		
spirea	aphid, obliquebanded leafroller		
staghorn sumac	obliquebanded leafroller		
sumac	psyllids		
sweet gum	bagworm		
sycamore	aphid, bagworm, casebearers, fall webworm, lace bug, obliquebanded leafroller, tussock moth		
shadetrees, ornamentals, shelterbelts (such as cotoneaster, willow, mountain ash and pincherry)	pear slug (pear sawfly larvae)		
wild cherry	tussock moth		
Arborvitae	aphid, bagworm, spider mites (except twospotted)		**Soluble powder** Mix thoroughly and spray entire plant covering both sides of foliage. Spray when insects are present or feeding injury is first noticed. Repeat application once only, if re-infestation occurs. To control spider mites, spray 2 times, 7 to 10 days apart.
aster	aphid, armyworm, flower thrips, leafminer		**Soluble powder** Mix thoroughly and spray entire plant covering both sides of foliage. Spray when insects are present or feeding injury is first noticed. Repeat application once only, if re-infestation occurs. To control flower thrips, spray 2 times, 7 to 10 days apart.
azalea	aphid, greenhouse whitefly, lace bug, mealybug, scale insect (crawlers: cottony maple, hemlock, oystershell, cottony cushion, lecanium), spider mites (except twospotted)		**Soluble powder** Mix thoroughly and spray entire plant covering both sides of foliage. Spray when insects are present or feeding injury is first noticed. Repeat application once only, if re-infestation occurs. To control greenhouse whitefly, mealybug, scale insects and spider mites (other than twospotted), spray 2 times, 7 to 10 days apart.

SITE(S)	PESTS	RATE (a.i.)	APPLICATION INSTRUCTIONS AND LIMITATIONS
barberry, ligustrum, Mahonia	aphid, greenhouse whitefly	mist blower: 1312 g/1000 L hydraulic sprayer: 637 g/1000 L	**Soluble powder** Mix thoroughly and spray entire plant covering both sides of foliage. Spray when insects are present or feeding injury is first noticed. Repeat application once only, if re-infestation occurs. To control greenhouse whitefly, spray 2 times, 7 to 10 days apart.
boxwood, Euonymous, hibiscus, nandina, rose of Sharon	aphid, scale insect (crawlers: cottony maple, hemlock, oystershell, cottony cushion, lecanium)		**Soluble powder** Mix thoroughly and spray entire plant covering both sides of foliage. Spray when insects are present or feeding injury is first noticed. Repeat application once only, if re-infestation occurs. To control scale insects, spray 2 times, 7 to 10 days apart.
calendula	aphid, armyworm (fall, beet and yellowstriped), flower thrips, potato leafhopper, tobacco budworm		**Soluble powder** Mix thoroughly and spray entire plant covering both sides of foliage. Spray when insects are present or feeding injury is first noticed. Repeat application once only, if re-infestation occurs. To control flower thrips, spray 2 times, 7 to 10 days apart.
cotoneaster	aphid, lace bug, scale insect (crawlers: cottony maple, hemlock, oystershell, cottony cushion, lecanium)		**Soluble powder** Mix thoroughly and spray entire plant covering both sides of foliage. Spray when insects are present or feeding injury is first noticed. Repeat application once only, if re-infestation occurs. To control scale insects, spray 2 times, 7 to 10 days apart.
cypress	bagworm, scale insect (crawlers: cottony maple, hemlock, oystershell, cottony cushion, lecanium), spider mites		**Soluble powder** Mix thoroughly and spray entire plant covering both sides of foliage. Spray when insects are present or feeding injury is first noticed. Repeat application once only, if re-infestation occurs. To control scale insects and spider mite, spray 2 times, 7 to 10 days apart.
dahlia	armyworm (fall, beet and yellowstriped), potato leafhopper, twospotted spider mite		**Soluble powder** Mix thoroughly and spray entire plant covering both sides of foliage. Spray when insects are present or feeding injury is first noticed. Repeat application once only, if re-infestation occurs. To control twospotted spider mite, spray 2 times, 7 to 10 days apart.
elm (Chinese or Siberian)	armyworm (fall, beet and yellowstriped), on Chinese elm only), elm leaf beetle (larvae), tussock moth, scale insect (crawlers: cottony maple, hemlock, oystershell, cottony cushion, lecanium) on Chinese elm only		**Soluble powder** Mix thoroughly and spray entire plant covering both sides of foliage. Spray when insects are present or feeding injury is first noticed. Repeat application once only, if re-infestation occurs. To control scale insects, spray 2 times, 7 to 10 days apart.
geranium	tobacco budworm, scale insect (crawlers: cottony maple, hemlock, oystershell, cottony cushion, lecanium)		**Soluble powder** Mix thoroughly and spray entire plant covering both sides of foliage. Spray when insects are present or feeding injury is first noticed. Repeat application once only, if re-infestation occurs. To control scale insects, spray 2 times, 7 to 10 days apart.
hackberry	psyllids, scale insect (crawlers: cottony maple, hemlock, oystershell, cottony cushion, lecanium)		**Soluble powder** Mix thoroughly and spray entire plant covering both sides of foliage. Spray when insects are present or feeding injury is first noticed. Repeat application once only, if re-infestation occurs. To control scale insects, spray 2 times, 7 to 10 days apart.

SITE(S)	PESTS	RATE (a.i.)	APPLICATION INSTRUCTIONS AND LIMITATIONS
hemlock	gypsy moth, scale insect (crawlers: cottony maple, hemlock, oystershell, cottony cushion, lecanium), spider mites (except twospotted)		**Soluble powder** Mix thoroughly and spray entire plant covering both sides of foliage. Spray when insects are present or feeding injury is first noticed. Repeat application once only, if re-infestation occurs. To control scale insects and spider mites (other than twospotted spider mite), spray 2 times, 7 to 10 days apart.
holly	leafminer, obliquebanded leafroller, psyllids, tussock moth, scale insect (crawlers: cottony maple, hemlock, oystershell, cottony cushion, lecanium), spider mites (except twospotted)	mist blower: 1312 g/1000 L hydraulic sprayer: 637 g/1000 L	**Soluble powder** Mix thoroughly and spray entire plant covering both sides of foliage. Spray when insects are present or feeding injury is first noticed. Repeat application once only, if re-infestation occurs. To control scale insects and spider mites (other than twospotted spider mite), spray 2 times, 7 to 10 days apart.
hydrangea, primrose	aphid, twospotted spider mite		**Soluble powder** Mix thoroughly and spray entire plant covering both sides of foliage. Spray when insects are present or feeding injury is first noticed. Repeat application once only, if re-infestation occurs. To control twospotted spider mites, spray 2 times, 7 to 10 days apart.
ivy	aphid, mealybug		**Soluble powder** Mix thoroughly and spray entire plant covering both sides of foliage. Spray when insects are present or feeding injury is first noticed. Repeat application once only, if re-infestation occurs. To control mealybugs, spray 2 times, 7 to 10 days apart.
juniper	bagworm, meadow spittlebug, spider mites (except twospotted)		**Soluble powder** Mix thoroughly and spray entire plant covering both sides of foliage. Spray when insects are present or feeding injury is first noticed. Repeat application once only, if re-infestation occurs. To control spider mites (other than twospotted spider mite), spray 2 times, 7 to 10 days apart.
lilac	aphid, leafminer, scale insect (crawlers: cottony maple, hemlock, oystershell, cottony cushion, lecanium)		**Soluble powder** Mix thoroughly and spray entire plant covering both sides of foliage. Spray when insects are present or feeding injury is first noticed. Repeat application once only, if re-infestation occurs. To control scale insects, spray 2 times, 7 to 10 days apart.
marigold	flower thrips, leafminer, sunflower moth, twospotted spider mite		**Soluble powder** Mix thoroughly and spray entire plant covering both sides of foliage. Spray when insects are present or feeding injury is first noticed. Repeat application once only, if re-infestation occurs. To control flower thrips and twospotted spider mites, spray 2 times, 7 to 10 days apart.
petunia	armyworm (fall, beet and yellowstriped), flower thrips, tobacco budworm		**Soluble powder** Mix thoroughly and spray entire plant covering both sides of foliage. Spray when insects are present or feeding injury is first noticed. Repeat application once only, if re-infestation occurs. To control flower thrips, spray 2 times, 7 to 10 days apart.
pyracantha	aphid, lace bug, yellownecked caterpillar, scale insect (crawlers: cottony maple, hemlock, oystershell, cottony cushion, lecanium)		**Soluble powder** Mix thoroughly and spray entire plant covering both sides of foliage. Spray when insects are present or feeding injury is first noticed. Repeat application once only, if re-infestation occurs. To control scale insects, spray 2 times, 7 to 10 days apart.

SITE(S)	PESTS	RATE (a.i.)	APPLICATION INSTRUCTIONS AND LIMITATIONS
rose (field grown)	aphid, armyworm (fall, beet and yellowstriped), flower thrips, meadow spittlebug, obliquebanded leafroller, rose midge, tussock moth, scale insect (crawlers: cottony maple, hemlock, oystershell, cottony cushion, lecanium), spider mites		**Soluble powder** Mix thoroughly and spray entire plant covering both sides of foliage. Spray when insects are present or feeding injury is first noticed. Repeat application once only, if re-infestation occurs. To control flower thrips, scale insects and spider mites, spray 2 times, 7 to 10 days apart.
salvia	aphid, flower thrips, greenhouse whitefly	mist blower: 1312 g/1000 L hydraulic sprayer: 637 g/1000 L	**Soluble powder** Mix thoroughly and spray entire plant covering both sides of foliage. Spray when insects are present or feeding injury is first noticed. Repeat application once only, if re-infestation occurs. To control flower thrips and greenhouse whitefly, spray 2 times, 7 to 10 days apart.
snapdragon	aphid, armyworm: (fall, beet and yellowstriped), flower thrips, tobacco budworm		**Soluble powder** Mix thoroughly and spray entire plant covering both sides of foliage. Spray when insects are present or feeding injury is first noticed. Repeat application once only, if re-infestation occurs. To control flower thrips, spray 2 times, 7 to 10 days apart.
viburnum	aphid, greenhouse whitefly, twospotted spider mite		**Soluble powder** Mix thoroughly and spray entire plant covering both sides of foliage. Spray when insects are present or feeding injury is first noticed. Repeat application once only, if re-infestation occurs. To control greenhouse whitefly and twospotted spider mite, spray 2 times, 7 to 10 days apart.
willow	aphid, bagworm, willow leaf beetle (larvae), fall webworm, gypsy moth, poplar tentmaker, psyllids, sawflies (open feeders: dusky birch), tent caterpillar (eastern and forest), tussock moth, scale insect (crawlers: cottony maple, hemlock, oystershell, cottony cushion, lecanium)		**Soluble powder** Mix thoroughly and spray entire plant covering both sides of foliage. Spray when insects are present or feeding injury is first noticed. Repeat application once only, if re-infestation occurs. To control scale insects, spray 2 times, 7 to 10 days apart.
wisteria	aphid, mealybugs, scale insect (crawlers: cottony maple, hemlock, oystershell, cottony cushion, lecanium)		**Soluble powder** Mix thoroughly and spray entire plant covering both sides of foliage. Spray when insects are present or feeding injury is first noticed. Repeat application once only, if re-infestation occurs. To control mealybugs and scale insects, spray 2 times, 7 to 10 days apart.
zinnia	flower thrips, greenhouse whitefly, lace bug, leafminer		**Soluble powder** Mix thoroughly and spray entire plant covering both sides of foliage. Spray when insects are present or feeding injury is first noticed. Repeat application once only, if re-infestation occurs. To control flower thrips and greenhouse whitefly, spray 2 times, 7 to 10 days apart.

SITE(S)	PESTS	RATE (a.i.)	APPLICATION INSTRUCTIONS AND LIMITATIONS
birch	aphid, cankerworm (spring and fall), fall webworm, gypsy moth, leafminer, sawflies (open feeders: dusky birch), tent caterpillar (eastern and forest), tussock moth, yellownecked caterpillar	mist blower: 1312 g/1000 L hydraulic sprayer: 637 g/1000 L	**Soluble powder** Mix thoroughly and spray entire plant covering both sides of foliage. Spray when insects are present or feeding injury is first noticed. Repeat application once only, if re-infestation occurs.
	aphid (green)	849 mg/cartridge 1 cartridge per 10.16 cm	**Implant cartridge** Apply when wingless forms are first noticed.
	birch leafminer		**Implant cartridge** Apply when insects first appear.
elm	wooly aphid	849 mg/cartridge 1 cartridge per 10.16 cm	**Implant cartridge** Apply only when heavy production of white waxy material becomes evident.
	elm leaf beetle		**Implant cartridge** Apply as eggs are hatching or larvae are first noticed.
fir	aphid, tussock moth, scale insect (crawlers: cottony maple, hemlock, oystershell, cottony cushion, lecanium), spider mites (except twospotted)	mist blower: 1312 g/1000 L hydraulic sprayer: 637 g/1000 L	**Soluble powder** Mix thoroughly and spray entire plant covering both sides of foliage. Spray when insects are present or feeding injury is first noticed. Repeat application once only, if re-infestation occurs. To control scale insects and spider mites (except twospotted spider mite), spray 2 times, 7 to 10 days apart.
	spruce coneworm	849 mg/cartridge 1 cartridge per 10.16 cm	**Implant cartridge** Apply immediately prior to or at budswell.
	western spruce budworm	849 mg/cartridge 1 cartridge per 10.16 cm	**Implant cartridge** Apply immediately prior to or at budswell.
flowering cherry	obliquebanded leafroller, tent caterpillar (eastern and forest)	mist blower: 1312 g/1000 L hydraulic sprayer: 637 g/1000 L	**Soluble powder** Mix thoroughly and spray entire plant covering both sides of foliage. Spray when insects are present or feeding injury is first noticed. Repeat application once only, if re-infestation occurs.
	eastern tent caterpillar	849 mg/cartridge 1 cartridge per 10.16 cm	**Implant cartridge** Apply when insects first appear.
maple	aphid, bagworm, cankerworm (spring and fall), gypsy moth, potato leafhopper, tent caterpillar (eastern and forest), tussock moth, scale insect (crawlers: cottony maple, hemlock, oystershell, cottony cushion, lecanium)	mist blower: 1312 g/1000 L hydraulic sprayer: 637 g/1000 L	**Soluble powder** Mix thoroughly and spray entire plant covering both sides of foliage. Spray when insects are present or feeding injury is first noticed. Repeat application once only, if re-infestation occurs. To control scale insects, spray 2 times, 7 to 10 days apart.
	bladder gall mites	849 mg/cartridge 1 cartridge per 10.16 cm	**Implant cartridge** Apply only if very high populations of galls develop on foliage.
	gypsy moth larvae		**Implant cartridge** Apply as eggs are hatching or when insects first appear.

SITE(S)	PESTS	RATE (a.i.)	APPLICATION INSTRUCTIONS AND LIMITATIONS
oak	aphid, cankerworm (spring and fall), fall webworm, gypsy moth, lace bug, leafminer, obliquebanded leafroller, oak leaf shredder (white and red oak only), tent caterpillar (eastern and forest), tussock moth, yellownecked caterpillar, scale insect (crawlers: cottony maple, hemlock, oystershell, cottony cushion, lecanium), spider mites (except twospotted)	mist blower: 1312 g/1000 L hydraulic sprayer: 637 g/1000 L	**Soluble powder** Mix thoroughly and spray entire plant covering both sides of foliage. Spray when insects are present or feeding injury is first noticed. Repeat application once only, if re-infestation occurs. To control scale insects and spider mites (other than twospotted spider mite), spray 2 times, 7 to 10 days apart.
	wooly aphid	849 mg/cartridge 1 cartridge per 10.16 cm	**Implant cartridge** Apply only when heavy production of white waxy material becomes evident.
	gypsy moth aphid		**Implant cartridge** Apply when eggs are hatching or when insects first appear.
	oak leafshredder		**Implant cartridge** Apply when insects first appear.
pine	bagworm, gypsy moth, Nantucket pine tip moth, sawflies (open feeders: redheaded pine, European pine sawfly), tussock moth, scale insect (crawlers: cottony maple, hemlock, oystershell, cottony cushion, lecanium), spider mites (except twospotted)	mist blower: 1312 g/1000 L hydraulic sprayer: 637 g/1000 L	**Soluble powder** Mix thoroughly and spray entire plant covering both sides of foliage. Spray when insects are present or feeding injury is first noticed. Repeat application once only, if re-infestation occurs. To control scale insects and spider mites (other than twospotted spider mite), spray 2 times, 7 to 10 days apart.
	wooly aphid	849 mg/cartridge 1 cartridge per 10.16 cm	**Implant cartridge** Apply when wingless forms are first noticed.
	pine needleminer		Implant cartridge Apply immediately prior to or at budswell.
	cone maggots		
spruce	gypsy moth, leafminer, sawflies (open feeders: redheaded pine, yellowheaded spruce sawfly), tussock moth, spider mites (except twospotted)	mist blower: 1312 g/1000 L hydraulic sprayer: 637 g/1000 L	**Soluble powder** Mix thoroughly and spray entire plant covering both sides of foliage. Spray when insects are present or feeding injury is first noticed. Repeat application once only, if re-infestation occurs. To control spider mites (other than twospotted spider mite), spray 2 times, 7 to 10 days apart.
	green aphid, wooly aphid	849 mg/cartridge 1 cartridge per 10.16 cm	**Implant cartridge** Apply when wingless forms are first noticed.
	spruce coneworm		**Implant cartridge** Apply immediately prior to or at budswell.
	western spruce budworm		
Greenhouse roses	aphid, flower thrips, omnivorous leafroller, rose midge, whitefly	637 g/1000 L	Spray to wet foliage completely.

SITE(S)	PESTS	RATE (a.i.)	APPLICATION INSTRUCTIONS AND LIMITATIONS
Christmas tree plantations, farm woodlots, tree nurseries, shelterbelts, right of ways, municipal parks (excluding national and provincial parks)	aphid, armyworm (fall, beet and yellowstriped), bagworm, cankerworm (fall and spring), casebearer, fall webworm, flower thrips, gladiolus thrips, greenhouse whitefly, gypsy moth, lace bug, leaf beetle larvae (elm and willow), leafminer, meadow spittlebug, mealybug, Nantucket pine tip moth, oak leafshredder, obliquebanded leafroller, psyllid, pear slug (pear sawfly larvae), poplar tentmaker, potato leafhopper, rose midge, scale insect (crawlers: cottony maple, hemlock, oystershell, cottony cushion, lecanium), sawflies (open feeders: dusky birch, blackheaded ash, redheaded pine, European pine, yellowheaded spruce sawfly), spider mites, sunflower moth, tent caterpillars (eastern and forest), tobacco budworm, tussock moth, yellownecked caterpillar	hydraulic sprayer: 637 g/1000 L mist blower: 1312 g/1000 L	Consult Canadian Forestry Service office or provincial forestry authority for information on timing of sprays and method of application. Do not apply to American elm, flowering crabapple, sugar maple, cottonwood, redbud and weigela, as foliage injury may occur. Before treating rare or unusual varieties, it is advisable to test it on a few plants before spraying large numbers.

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