Pest Management Regulatory Agency
Agence de réglementation de la lutte antiparasitaire

Re-evaluation Decision Document RRD2004-05

Azinphos-methyl

The purpose of this Re-evaluation Decision Document (RRD) is to notify registrants, pesticide regulatory officials and the Canadian public that the re-evaluation of azinphos-methyl is now complete.

Based on a review of the available information, the Pest Management Regulatory Agency (PMRA) has determined that all uses of azinphos-methyl are to be phased out. The decision and time frames to phase out uses in Canada are similar to the decisions reached for this chemical in the United States.

This RRD contains comments made to the PMRA in response to Proposed Acceptability for Continuing Registration document PACR2003-07, *Re-evaluation of Azinphos-methyl*, published on 31 March 2003. This document also provides the PMRA's response to the comments and presents the regulatory decisions resulting from the re-evaluation of azinphos-methyl.

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Publications Coordinator
Pest Management Regulatory Agency
Health Canada
2720 Riverside Drive
A.L. 6605C
Ottawa, Ontario
K1A 0K9

Internet: **pmra_publications@hc-sc.gc.ca**
www.hc-sc.gc.ca/pmra-arla/
Information Service:
1-800-267-6315 or (613) 736-3799
Facsimile: (613) 736-3798

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1.0 Introduction

A re-evaluation of the active ingredient azinphos-methyl has been completed by the Pest Management Regulatory Agency (PMRA).

2.0 Background

In June 1999, the PMRA announced[1] that organophosphate active ingredients, including azinphos-methyl, were subject to re-evaluation under authority of Section 19 of the Pest Control Products (PCP) Regulations. The purpose of this RRD is to notify registrants, pesticide regulatory officials and the Canadian public that the re-evaluation of azinphos-methyl is now complete.

On 31 March 2003, the PMRA published PACR 2003-07, *Re-evaluation of Azinphos-methyl*, which presented the outcome of the assessments and the proposed risk management decision for azinphos-methyl. The PMRA received 17 responses to PACR2003-07 from provincial governments, grower organizations and registrants of azinphos-methyl products.

This RRD presents a summary of these comments and the PMRA's response to these comments. This document also outlines the regulatory decisions resulting from the re-evaluation of azinphos-methyl.

3.0 Regulatory Decision

The PMRA has reviewed the comments received in response to the Agency's proposed re-evaluation decision for azinphos-methyl presented in PACR2003-07. A summary of the comments received and the PMRA's response to these comments is presented in Appendix I. No information was received that resulted in substantive changes to the human health and environmental risk assessments summarized in PACR2003-07.

Based on a review of the available information, the PMRA has concluded that the use of azinphos-methyl and its associated end-use products in accordance with the current label directions entails an unacceptable risk of harm to agricultural workers pursuant to Section 20 of the PCP Regulations. Environmental concerns have also been identified. As a result, the PMRA has determined that all uses for azinphos-methyl are to be phased-out as outlined below.

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

A. Uses on alfalfa, clover, rye, quince, potatoes, tomatoes, rutabagas, turnips, cabbages (including tight heading varieties of Chinese cabbage), broccoli, Brussels sprouts, cauliflowers, cucumbers, strawberries, boysenberries, loganberries, walnuts, melons, pumpkins, blueberries, outdoor ornamentals, nursery plants, forest trees and shade trees (i.e., uses for which alternatives exist)

The sale and use of azinphos-methyl products labelled for the uses presented above, uses for which alternatives exist, are to be phased out as follows:

- Last date of sale by registrants: 31 August 2004
- Last date for use of product: 31 December 2005

In order to minimize carry-over of product with the current label, sales of currently labelled product by registrants for the 2004 season (up to 31 August 2004) will be limited to the average annual sales for each product by registrants over the past 5 years. After 31 August 2004, remaining azinphos-methyl end-use products sold by registrants must conform with the conditions described in Subsection B below.

The decision to phase out these uses of azinphos-methyl is similar to the decision reached for this chemical in the United States.

B. Uses on apples, crab apples, apricots, blackberries, cherries, cranberries, grapes, pears, peaches, plums, prunes, raspberries (i.e., uses that are part of an established IPM program and uses for which no alternatives exist)

Between 31 August 2004 and 31 August 2005, registrants may continue to sell azinphos-methyl end-use products for the uses presented above, provided that the labels are amended to limit use to only these crops. In addition, mitigative measures must be implemented to increase the margins of safety for agricultural workers and to protect environmentally sensitive aquatic areas. Use limitations and restrictions are described in Appendix II. Sale and use of all azinphos-methyl products labelled for these uses are to be phased out as follows:

- Last date of sale by registrants: 31 August 2005
- Last date of sale by retailers: 31 August 2006
- Last date of use of product by users: 31 December 2006

The United States Environmental Protection Agency (USEPA) has reached an agreement with registrants of products containing azinphos-methyl to phase out the registration of all uses by 31 October 2005 (all product use will end by 31 October 2006), unless additional data to refine the risk assessment for agricultural workers are provided in support of some key uses. The primary data provider for the re-evaluation of azinphos-methyl, Bayer CropScience, has

indicated its intention to generate further data to address some of the worker concerns identified by the PMRA and the USEPA. The PMRA would also be prepared to revisit the assessment for azinphos-methyl in light of new data, if requested by the registrant. The registrations for these uses will, in effect, expire on 31 December 2006, unless the registrant requests and the PMRA grants a renewal of the registrations.

Registrants are required to provide the PMRA with a plan for communicating to retailers and users the new label requirements and mitigation measures to be implemented for these crop uses until the registrations expire on 31 December 2006.

In addition, registrants must design and implement a product stewardship plan to ensure 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 azinphos-methyl and that azinphos-methyl is a cholinesterase inhibitor. This must include a brief description of the signs and symptoms of cholinesterase inhibition as well as ways to minimise exposure.

C. Use in Prince Edward Island (P.E.I.)

All registrants of azinphos-methyl products have informed the PMRA that they have ceased marketing azinphos-methyl products for sale in P.E.I. Azinphos-methyl use in P.E.I. is governed by a provincial permitting system implemented to mitigate the risk of fish kills from specific pest control products. This decision by the registrants, together with the permitting system administered by the province of P.E.I., reflects the unique geography of and agronomic practices in P.E.I., and is seen as a prudent measure to address concerns regarding use of azinphos-methyl in that province.

Appendix I Comments and Responses

The PMRA received 17 responses to PACR2003-07 from provincial governments, grower organizations and registrants of azinphos-methyl products. The PMRA has consolidated and summarized these comments, and provides responses below.

1.0 Comments Pertaining to the Human Health Assessment

1.1 Comment

The registrant requested that the acute reference dose (ARfD) be revisited using a proposed extrapolation method for determining the no observed adverse effect level (NOAEL).

PMRA response

It is not PMRA policy to extrapolate NOAELs from study data that show a lowest observed adverse effect level (LOAEL) at the lowest dose tested. However, PMRA would entertain a discussion of the extrapolation method used by the registrant to determine a NOAEL for the purpose of setting their ARfD for azinphos-methyl. Therefore, the registrant was asked to submit an outline of their extrapolation methodology in writing.

The information in the document the registrant provided to the PMRA makes the assumption that a (log) linear dose–response relationship exists between the middle and lowest dose groups in the study. However, no data are provided to substantiate this assumption. As such, it remains conjecture and not fact. The registrant is, in essence, fitting a straight line between two points. More importantly, this assumed relationship is used to extrapolate outside the range of the observable data. This is, by default, not advised by Health Canada statisticians and again no data are provided to substantiate this extrapolation. Therefore, the PMRA is not convinced that a NOAEL of 1 mg/kg bw can be assumed for male rats in this study.

1.2 Comment

A registrant's study reports a no observed effect level (NOEL) in humans, therefore 3× and 10× uncertainty factors should not be used. The toxicity endpoints need to be revisited.

PMRA response

For risk assessments, the PMRA does not use toxicity studies in which humans are intentionally dosed with pesticides for the purpose of identifying a human NOAEL. The human studies of this nature that have been brought to the PMRA's attention have been used solely in a supplementary manner to confirm that the animal model is an appropriate surrogate for assessment purposes.

Therefore, after careful consideration of comments from the registrant, the PMRA's assessment of the ARfD for azinphos-methyl remains as stated in PACR2003-07.

1.3 Comment

It is unclear if the PMRA is requesting a new dislodgeable foliar residue (DFR) study for azinphos-methyl on grapes or a copy of a previously conducted DFR study for azinphos-methyl on grapes (Bayer Report No. 98401 [05 NOV 1988]).

PMRA response

The requested study is Bayer Report No. 98401 (05 NOV 1988). This study was received by the PMRA. After consideration of this information, a re-entry interval (REI) of 28 days will be retained for grapes during the phase-out period.

1.4 Comment

After 45 years of use of this product in Canada, there was no use made of Canadian field data to justify the concerns about undue worker exposure. An American model and observations should not substitute for Canadian experience.

PMRA response

The handler exposure assessment was based on the Pesticide Handler's Exposure Database (Version I.I), a database of generic exposure studies. This database was developed jointly by the PMRA and the USEPA, and is relevant to both American and Canadian scenarios.

The PMRA regularly uses worker exposure data generated in the United States when Canadian-generated studies are not available. Since it is assumed that applicator exposure is a function of the application rate and the area treated for a given application method, the location of the worker exposure study is not considered relevant. For postapplication exposure studies, where DFRs dissipate as a function of weather, studies conducted in the United States are used if they are conducted in agricultural zones relevant to Canada, or where no alternative data are available. Thus, the PMRA considers the American data to be relevant to Canada where use scenarios are comparable.

1.5 Comment

The PMRA states that no chemical-specific mixer/loader/applicator data were submitted to support the operator exposure risk assessment in the re-evaluation of azinphos-methyl. Additional studies will be conducted by Bayer CropScience as part of the data call-in for azinphos-methyl in the United States. The planned worker exposure studies, to be conducted in 2003-2004, will be submitted to the USEPA and the PMRA upon their completion.

PMRA response

The PMRA is prepared to consider these data if they are made available by the registrant.

1.6 Comment

The PMRA appears to rely on USEPA transfer coefficients (TCs) but states that data being generated by the Agricultural Re-entry Task Force (ARTF) and additional DFR data might permit refinement of the assessment. The USEPA did not appear to use the most recent TCs reported by the ARTF clusters. Therefore, there is considerable uncertainty regarding the appropriate TCs that should be used in the assessment. The registrant requests that the PMRA review the data available through the ARTF and refine their assessments based on those data.

PMRA response

The PMRA attempts to harmonize its assessments with those of the USEPA whenever possible. However, the PMRA may, in some instances, review data and arrive at slightly different conclusions. The USEPA used a TC value of 3000 cm^2/hr for thinning and harvesting apples, whereas the ARTF reported a TC of 1555 cm^2/hr for these activities. Recently, the PMRA reviewed some of the ARTF data and concluded that a TC of 1500 cm^2/hr is appropriate for harvesting tree fruit, but the TC for thinning should remain at 3000 cm^2/hr. The uncertainty in the TC does not change the original assessment since the harmonization with the USEPA provided REIs much shorter than those calculated on the basis of the dissipation in the DFR studies identified in the USEPA Interim Reregistration Eligibility Decision (IRED) for azinphos-methyl.

1.7 Comment

The model of exposure for DFR used 3 to 4 applications, in direct contravention of the guidance for rotation of use between families of insecticides. It is false to assume that pruning, for example, occurs after such a use pattern, since much of the pruning occurs early in the season. Likewise, for tomatoes, use is limited and would never be 3 to 4 applications.

PMRA response

DFRs following multiple applications of azinphos-methyl were used in the assessment because the registered use pattern (i.e., label) permits multiple applications. DFR studies were used if they were conducted in agricultural zones relevant to Canada. The studies respected the application intervals identified on the labels. The timing of agronomic practices was considered in assessing postapplication exposures and in the development of risk management options. However, given the persistent nature of azinphos-methyl and the potential for multiple applications, most postapplication activities are expected to incur significant exposure.

1.8 Comment

The following comments pertain to the proposed action on maximum residue limits (MRLs).

- The PMRA and the USEPA should harmonize decisions on maintaining or withdrawing uses of azinphos-methyl. Otherwise, changes in residue tolerances/MRLs could become trade irritants between the countries.
- It is unfair to allow produce treated with pesticides that Canadians are not allowed to use to be imported into Canada.

PMRA response

While the PMRA has made significant progress in harmonizing pesticide data requirements and assessment methods with other countries that are members of the Organisation for Economic Co-operation and Development (OECD), harmonization of registration decisions may not always be possible because of differences in interpretation of the data and/or differences in decision-making policies or legislative authority. In the case of azinphos-methyl, both the PMRA and the USEPA have decided that all uses of azinphos-methyl are to be phased out, based on assessments of the available data. However, the PMRA has decided on different phase-out dates than those decided on in the United States for some crops due to Canadian considerations as presented in Section 8.0 of PACR2003-07.

In general, when the re-evaluation of a pesticide has been completed, the PMRA intends to recommend amendments to Table II of the Food and Drugs Regulations to prohibit the sale of food with quantifiable residues of the pesticide for any agricultural commodity not approved for continued treatment in Canada. Proposed amendments to the Food and Drugs Regulations reflecting these MRLs will be published in the Canada Gazette and international suppliers of foods will be notified through the World Trade Organization. MRLs for import purposes will be considered if sufficient data are provided by interested parties to allow an assessment of those residues. Other OECD-member countries have policies similar to the PMRA's in this area.

For azinphos-methyl, the PMRA is prepared to consider requests from parties interested in supporting MRLs to allow imports of specific commodities treated with azinphos-methyl because the decision to phase out all use is based on non-dietary concerns. In the United States, the USEPA has indicated it will not change existing azinphos-methyl MRLs at this time as the registrants require them for import purposes. This decision was made despite the eventual discontinuation of the product within its borders.

Parties interested in supporting an MRL to allow imports of specific commodities treated with azinphos-methyl should contact the PMRA as soon as possible to discuss the appropriate data requirements.

2.0 Comments Pertaining to the Environmental Assessment

2.1 Comment

Several respondents commented on the proposed buffer zone of 78 metres for airblast application.

- The proposed buffer zone is unrealistic (equivalent to 13 to 26 rows of trees) and would be prohibitive.
- The proposed buffer zone is greater than that required by the USEPA.
- A buffer zone of 20 to 30 metres was suggested by a grower organization from Quebec.

PMRA response

The buffer zone applies only to those situations where aquatic habitats are adjacent to the treatment area (orchards) and to distances that are downwind from the point of application. A buffer zone is not applicable when the aquatic habitat is upwind from the point of application.

The PMRA uses exposure scenarios and spray drift models that are different from those used by USEPA for estimating buffer zones in field crops and orchards. The USEPA has recommended buffer zones for young/dormant orchards. These buffer zones range from 18 to 58 metres (60 to 190 feet). It is not clear why the USEPA did not recommend buffer zones for mature/foliated orchards. For other uses, the USEPA recommends the observance of no-spray buffer zones around water bodies, yet actual buffer zone distances are not provided. The PMRA is generally recommending a higher level of protection for bodies of water (compared to the USEPA) as buffer zones are proposed for all uses of azinphos-methyl.

The PMRA has revised the buffer zones for azinphos-methyl to take into account early- and late-season scenarios in orchards and water bodies of various depths. The revised buffers zones for protection of aquatic habitat are as follows.

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*	50	40	30
Airblast (early season)	75	60	50
Airblast (late season)	65	50	40

* With the use of shrouds or cones on field sprayers (for reducing drift), buffer zones can be reduced by 70% (shrouds) or 30% (cones).

The basis for a respondent's recommendation of a 20 to 30 metre zone is unclear and not substantiated by data. It was indicated that this buffer zone is recommended for buildings protected under the new Pesticides Management Code in Quebec. The buffer zones for azinphos-methyl relate to protection of aquatic habitat. Therefore, the proposal from the respondent was not accepted.

2.2 Comment

The following comments pertain to the assessment of effects on non-target organisms.

- Surveys on non-target organisms should be conducted and used as basis for decisions.
- Data regarding effects on non-target organisms are not conclusive and need to be re-examined.

PMRA response

With the exception of the incident data mentioned in PACR2003-07, the PMRA is not aware of any toxicity data on non-target species that are likely to occur in areas where azinphos-methyl is used. Consistent with the assessment methods of pesticide regulatory agencies from other OECD-member countries, the PMRA uses standard test species as surrogates for non-target species that may be present in these areas. Also, no available data indicate that these "non-target" species are more or less sensitive than the surrogate test species. On this basis, surveys of non-target organisms without toxicological data would not refine the current environmental risk assessment.

The PMRA did cite incident data (Canada and the United States) indicating that indirect bird kills were attributed to feeding on dead or dying fish exposed to azinphos-methyl; also, azinphos-methyl was detected in bird tissue. The PMRA is not aware of any surveys of bird mortality in all the regions of Canada where azinphos-methyl is used.

2.3 Comment

The following comments pertain to the drinking water assessment.

- The source of data for drinking water assessment should be provided.
- Drinking water residue data should be re-examined as conflicting results are given for different studies. On-farm water source surveys done in Ontario (> 3000 wells) found no residues of azinphos-methyl.

PMRA response

The sources of monitoring data used in the PMRA's drinking water assessment are listed below. No further drinking water data were made available to the PMRA. Study reports of the on-farm water source surveys reported by one respondent were not provided to the PMRA. The PMRA would consider any such information if submitted.

Sources of monitoring data:

Berryman, D. and I. Giroux (1994). La contamination des cours d'eau par les pesticides dans les régions de culture intesive de maïs au Québec. Campagnes d'échantillonnage de 1992 et 1993. Ministère de l'Environnement et de la Faune du Québec.

Blundell, G. and J. Harman (2000). A Survey of the Quality of Municipal supplies of Drinking Water from Groundwater Sources in Prince Edward Island. Sierra Club of Canada, Eastern Canada Chapter, University of Waterloo, Department of Earth Sciences.

Currie, R.S. and D.A. Williamson (1995). An Assessment of Pesticide Residues in Surface Waters of Manitoba Canada. Water Quality Management Section. Manitoba Environment. Report #95-08.

Data Management Unit of the Environmental Protection Branch (2002). Saskatchewan Environment and Research Management.

Giroux, I. (1995). Contamination de l'eau souterraine par les pesticides et les nitrates dans les régions de culture de pommes de terre. Campagnes d'échantillonnage 1991-1992-1993. Ministère de l'Environnement et de la Faune. *During the summers of 1991, 1992 and 1993, 72 wells were sampled less than 50 m from the location of potato farms.*

Giroux, I (1998). Suivi environnemental des pesticides dans des régions de vergers de pommiers. Rapport d'échantillonnage de petits cours d'eau et de l'eau souterraine au Québec en 1994, 1995 et 1996. Ministère de l'Environnement et de la Faune.

Giroux, I. (1998b). Impact de l'utilisation des pesticides sur la qualité de l'eau des bassins versants des rivières Yamaska, L'Assomption, Chaudière et Boyer. Volet assainissement agricole. Direction des écosystèmes aquatiques. Ministère de l'Environnement et de la Faune.

Giroux, I., M. Duchemin and M. Roy (1997). Contamination de l'eau par les pesticides dans les régions de culture intensive du maïs au Québec. Campagnes d'échantillonnage de 1994 et 1995. Ministère de l'Environnement et de la Faune.

Giroux, I (1999). Contamination de l'eau par les pesticides dans les régions de culture de maïs et de soya : 1996, 1997, 1998. Service des pesticides, Direction du secteur agricole, Ministère de l'Environnement du Québec

McLean, J (2002). Pesticide Management Program, Alberta Environment.

NAWQA (2002). GW: USGS summary data for pesticide occurrence and concentrations in ground water from agricultural and urban wells. These samples do not represent drinking water directly, and some of the wells in the survey are shallow "monitoring wells". As part of the sampling method, all samples are filtered prior to analysis.

NAWQA (2002). SW: The National Water Quality Assessment Program (NAWQA) USGS data of residue detections from 31 integrator sites on large rivers and streams. Thes samples do not represent drinking water directly. All samples analyzed in this program are filtered prior to analysis.

Smith, R (2001). Ministry of Health, British Colombia.

Somers *et. al.* (1999). Envirodat database compiled by the Atlantic Region of Environment Canada.

3.0 Comments Pertaining to Value

3.1 Comment

The registrant questioned the reason for the removal of rutabaga and turnip, since in 1999 the PMRA requested that these crops be maintained on the Canadian label.

PMRA response

Use of azinphos-methyl on rutabaga and turnip was maintained at that time as an interim measure due to uncertainty regarding the future availability, as a result of re-evaluation, of insecticides (primarily organophosphates) for control of cabbage maggot. This use of azinphos-methyl does not meet the criteria for the longer phase-out since, as an outcome of re-evaluation, an alternative for this use (chlorpyrifos) has been found acceptable for continuing registration.

3.2 Comment

Crab apples are often planted within apple orchards for pollination purposes. It would be impossible to avoid spraying the crab apple trees. These crab apples will not be used as a food crop.

PMRA response

The PMRA agrees that crab apples (for purpose of pollination in commercial apple orchards) should be retained on the label for the duration of the longer phase-out.

3.3 Comment

Several respondents commented on the value of azinphos-methyl for control of various pests of crops.

PMRA response

The value of azinphos-methyl as a pest management tool for various crops was acknowledged in PACR2003-07. However, not all uses meet the criteria for the longer phase-out as defined in Section 8.0 of PACR2003-07.

The following table lists the active ingredients registered in Canada to control the pests mentioned in the responses to PACR2003-07. However, as pointed out by many respondents, only azinphos-methyl is registered in Canada for the control of European apple sawfly on apples, cranberry tipworm on cranberries, and grasshoppers and crickets on tomatoes. The uses for control of European apple sawfly on apples and cranberry tipworm on cranberries meet the criteria for the longer phase-out period. In the case of grasshoppers and crickets on tomatoes, the Ontario Ministry of Agriculture and Food suggests in its *Vegetable Production Recommendations 2002-2003* that growers control weeds in and around tomato fields; if there is no food near the tomato plants for these insects it is unlikely that they will move long distances from other food sources into tomato fields in search of food.

The PMRA notes that azinphos-methyl is not registered in Canada to control spanworms on apples and pears, or elm bark beetles on elms.

No insecticides are registered in Canada for the control of raspberry bud moth. Yet, as stated by one respondent, it is a very minor pest usually suppressed by sanitation and insecticides applied to control other pests.

Active ingredients registered in Canada (as of 14 July 2003) to control pests mentioned in responses to PACR2003-07 are as follows:

Site	Pest	Registered Active Ingredients (resistance-management group number)[1, 2]
grape	grape berry moth	**carbaryl** (1A) azinphos-methyl (1B) **diazinon** (1B) **phosalone** (1B) **phosmet** (1B) cypermethrin (3) permethrin (3) grape berry moth pheromone (-)
caneberry	crown borer (also known as raspberry root borer)	azinphos-methyl (1B) — blackberry, boysenberry, loganberry, raspberry **diazinon** (1B) — blackberry, loganberry, raspberry **dimethoate** (1B) — non-bearing loganberry
	root weevil	**carbofuran** (1A) — root weevils azinphos-methyl (1B) — obscure root weevil on blackberry, boysenberry, loganberry, raspberry **malathion** (1B) — bud weevil (also known as root weevil) on raspberry
	leafroller	**carbaryl** (1A) — all leafrollers on blackberry, boysenberry, dewberry, loganberry, raspberry azinphos-methyl (1B) — all leafrollers on blackberry, boysenberry, loganberry, raspberry Bacillus thuringiensist (11) — obliquebanded leafroller on red raspberry

Site	Pest	Registered Active Ingredients (resistance-management group number)[1, 2]
caneberry (cont'd)	raspberry bud moth	no active ingredients registered
blueberry, cranberry	cranberry fruitworm	**carbaryl** (1A) azinphos-methyl (1B) **diazinon** (1B) — cranberry only **malathion** (1B)
cranberry	cranberry tipworm	azinphos-methyl (1B)
	sparganothis fruitworm	azinphos-methyl (1B) **diazinon** (1B) tebufenozide (18)
stone fruit (cherry, nectarine, peach, plum)	plum curculio	**carbaryl** (1A) — not nectarine azinphos-methyl (1B) — not nectarine **malathion** (1B) — not nectarine **phosalone** (1B) — not nectarine or plum **phosmet** (1B) — not nectarine or sweet cherry cyhalothrin-lambda (3) — not nectarine or peach cypermethrin (3) — plum only permethrin (3) — not cherry
cherry	cherry fruit fly	azinphos-methyl (1B) **diazinon** (1B) **dimethoate** (1B) **phosmet** (1B) — sour cherry only imidacloprid (4) — British Columbia and Ontario only
apricot, peach	peach twig borer	**carbaryl** (1A) azinphos-methyl (1B) **diazinon** (1B) **endosulfan** (2)

Site	Pest	Registered Active Ingredients (resistance-management group number)[1, 2]
apple	apple maggot	**carbaryl** (1A) azinphos-methyl (1B) **diazinon** (1B) **dimethoate** (1B) **phosalone** (1B) **phosmet** (1B) cypermethrin (3) permethrin (3)
	European apple sawfly	azinphos-methyl (1B)
	leafroller	**carbaryl** (1A) — pale apple, redbanded and fruittree leafrollers **methomyl** (1A) — obliquebanded leafroller **oxamyl** (1A) — non-bearing trees azinphos-methyl (1B) — fruittree, obliquebanded, pale apple and redbanded leafrollers **diazinon** (1B) — fruittree leafroller **malathion** (1B) — redbanded and fruittree leafrollers **phosalone** (1B) — redbanded leafroller **phosmet** (1B) — obliquebanded leafroller cyhalothrin-lambda (3) — fruittree, obliquebanded and pale apple leafrollers cypermethrin (3) — pale apple leafroller deltamethrin (3) — fruittree, obliquebanded and pale apple leafrollers permethrin (3) — leafrollers in general pyrethrins (3) + soap (-) — leafrollers in general spinosad (5) — obliquebanded, threelined, fruittree and European leafrollers *Bacillus thuringiensis* (11) — obliquebanded, European, fruittree and threelined leafrollers tebufenozide (18) — obliquebanded and threelined leafrollers mineral oil (-) — leafroller eggs paraffinic base oil (-) — eggs of fruittree and redbanded leafrollers leafroller pheromone (-) — obliquebanded, threelined, Pandemis and redbanded leafrollers
pear	leafroller	**carbaryl** (1A) — apple, redbanded and fruittree leafrollers azinphos-methyl (1B) — fruittree, obliquebanded, pale apple and redbanded leafrollers **diazinon** (1B) — fruittree leafroller malathion (1B) — leafrollers in general **phosalone** (1B) — redbanded leafroller **phosmet** (1B) — obliquebanded and redbanded leafrollers pyrethrins (3) + soap (-) — leafrollers in general spinosad (5) — obliquebanded, threelined, fruittree and European leafrollers *Bacillus thuringiensis* (11) — obliquebanded, European, fruittree and threelined leafrollers tebufenozide (18) — obliquebanded and threelined leafrollers petroleum oil (-) — leafroller eggs paraffinic base oil (-) — fruittree leafroller eggs

Site	Pest	Registered Active Ingredients (resistance-management group number)[1, 2]
apple, pear	plum curculio	**carbaryl** (1A) azinphos-methyl (1B) **malathion** (1B) phosalone (1B) phosmet (1B) cyhalothrin-lambda (3) — apple only cypermethrin (3) permethrin (3) — apple only
	spanworms	**phosmet** (1B) pyrethrins (3) + soap (-)
apple, pear	green fruitworm	**carbaryl** (1A) azinphos-methyl (1B) **diazinon** (1B) — apple only **phosmet** (1B) cypermethrin (3) permethrin (3) pyrethrins (3) + soap (-) *Bacillus thuringiensis* (11)
	bud moth	**carbaryl** (1A) azinphos-methyl (1B) **diazinon** (1B) **malathion** (1B) — apple only cypermethrin (3) — apple only deltamethrin (3) — apple only permethrin (3) — apple only pyrethrins (3) + soap (-) spinosad (5)
	codling moth	**carbaryl** (1A) **methomyl** (1A) — apple only azinphos-methyl (1B) **diazinon** (1B) **dimethoate** (1B) — apple only **malathion** (1B) **phosalone** (1B) **phosmet** (1B) **endosulfan** (2) cyhalothrin-lambda (3) cypermethrin (3) deltamethrin (3) — apple only permethrin (3) pyrethrins (3) + soap (-) acetamiprid (4) tebufenozide (18) pheromone (-) *Cydia pomonella* granulovirus (-) — apple only

Site	Pest	Registered Active Ingredients (resistance-management group number)[1, 2]
curcubit vegetables (cucumber, squash, melons, pumpkin)	cucumber beetle	**carbaryl** (1A) azinphos-methyl (1B) — not squash **diazinon** (1B) — not pumpkin **malathion** (1B) **endosulfan** (2)
broccoli, Brussels sprouts, cabbage, cauliflower	cabbage maggot	azinphos-methyl (1B) chlorpyrifos (1B) **diazinon** (1B)
tight-heading varieties of Chinese cabbage	cabbage maggot	azinphos-methyl (1B) chlorpyrifos (1B)
potato	Colorado potato beetle	**carbaryl** (1A) **carbofuran** (1A) oxamyl (1A) azinphos-methyl (1B) chlorpyrifos (1B) **diazinon** (1B) **malathion** (1B) **methamidophos** (1B) **naled** (1B) **phosmet** (1B) **endosulfan** (2) cyhalothrin-lambda (3) cypermethrin (3) deltamethrin (3) permethrin (3) imidacloprid (4) spinosad (5) *Bacillus thuringiensis* (11)

Site	Pest	Registered Active Ingredients (resistance-management group number)[1, 2]
potato (cont'd)	potato leafhopper, tarnished plant bug	**carbaryl** (1A) **carbofuran** (1A) **methomyl** (1A) — leafhopper only **oxamyl** (1A) **acephate** (1B) azinphos-methyl (1B) **diazinon** (1B) — leafhopper only **dimethoate** (1B) **malathion** (1B) — leafhopper only **methamidophos** (1B) **naled** (1B) — leafhopper only **phosmet** (1B) — leafhopper only **endosulfan** (2) cyhalothrin-lambda (3) cypermethrin (3) deltamethrin (3) permethrin (3) imidacloprid (4) — leafhopper only
tomato	Colorado potato beetle	**carbaryl** (1A) **acephate** (1B) azinphos-methyl (1B) **malathion** (1B) **endosulfan** (2) cyhalothrin-lambda (3) cypermethrin (3) deltamethrin (3) permethrin (3) acetamiprid (4) imidacloprid (4) spinosad (5) *Bacillus thuringiensis* (11)
	grasshoppers, crickets	azinphos-methyl (1B)
elm	European elm scale	**carbaryl** (1A) **acephate** (1B) — immature scale azinphos-methyl (1B) paraffinic base oil (-) — immature scale
	elm bark beetle	chlorpyrifos (1B) permethrin (3)

[1] Resistance-management groups are described in PMRA Regulatory Directive DIR99-06.

[2] Bold text indicates that the active ingredient is under re-evaluation in Canada and a Proposed Acceptability for Continuing Registration document has not yet been published.

4.0 Comments Pertaining to the Use Standard

The following comments were received regarding the interim label requirements for azinphos-methyl products.

4.1 Comment

The statement under Use Limitations “USE OF THIS PRODUCT IN GREENHOUSES OR ENCLOSED AREAS IS PROHIBITED” is redundant as the crops on the labels are grown outdoors.

PMRA response

The statement prohibiting use in greenhouses, though seemingly redundant, reinforces the notion that this product must only be used outdoors.

4.2 Comment

Specifying the applicator must wear socks is very condescending and should be removed as it will not achieve the desired result. However, it could be left in the section on re-entry requirements.

PMRA response

The suggestion that label statements requiring socks are condescending and would not achieve the desired result is not clear since it is also suggested that the statement could be left in the section on re-entry requirements. The Worker Protection Standard in the United States includes socks in the description of personal protective equipment. Since it is expressly spelled out that socks must be worn with chemical resistant footwear, remaining silent on the matter in other instances would imply that socks are not required. The explicit statement that socks must be worn avoids any ambiguity created by assuming that all pesticide handlers wear socks.

4.3 Comment

Most orchard airblast spraying in British Columbia is not carried out in closed cabs.

PMRA response

The PMRA recognizes that not all applicators have closed cabs at this time. Thus, the Use Standard identifies the personal protective equipment applicators must wear if not in fully enclosed cabs.

4.4 Comment

Select a different title than “Engineering Controls” as it is not a common term for applicators.

PMRA response

Engineering controls eliminate or reduce exposure to a chemical or physical hazard through the use or substitution of engineered machinery or equipment. Thus, the title “Engineering Controls” heads the section where protective measures are brought to the packaging or the application equipment rather than added to the section pertaining to the handler.

4.5 Comment

Consider adding a note for wettable powder formulations: “Do not break open water soluble packages”.

PMRA response

The statement “Do not break open water soluble packages” is appropriate for wettable powder formulations in water soluble packaging and will be required on the label.

4.6 Comment

Re-entry Interval (REI) — The statement “Workers performing activities that involve foliar contact following the REI must wear clean long sleeved shirts and protective gloves” should provide a time frame.

PMRA response

The stated protective equipment is required following the REI and for the remainder of the growing season. The calculated postapplication risks to re-entry workers exceed the level of concern based on current REIs and label use patterns. To achieve margins of exposure that are not a concern for post-application workers based on the current use pattern, most REIs would need to be significantly increased in length. The revised REIs and use pattern reduction identified in Appendix II further mitigate worker exposure during the phase-out period. The requirement that workers performing activities that involve foliar contact following the REI must wear clean long sleeved shirts and protective gloves is in place to address uncertainties in the revised REIs.

4.7 Comment

Separate TOXICOLOGICAL INFORMATION into two sections: (1) Poisoning Symptoms, and (2) Information for medical personnel. Growers need to be able to quickly find the poisoning symptoms.

PMRA response

The wording of this section conforms to that outlined in the *Registration Handbook* and is consistent for all organophosphate pesticide labels.

4.8 Comment

Several suggestions were made for alternate wording of label language proposed in Appendix II of PACR2003-07.

PMRA Response

These comments were considered and the label language has been revised accordingly, as reflected in Appendix II of this document.

Appendix II Use standard for RESTRICTED class products containing azinphos-methyl for the interim period until phase-out of all uses at the end of 2006

NOTE: The information in this appendix summarizes the uses, limitations and precautions for the restricted class products containing azinphos-methyl, but does not identify all label requirements for such products. Registrants are referred to the PMRA *Registration Handbook* for further guidance on label requirements for pest control products.

COMMON NAME: azinphos-methyl

CHEMICAL NAME: *S*-(3,4-dihydro-4-oxobenzo [*D*]-[1,2,3] triazin-3-ylmethyl) *O*,*O*-dimethyl phosphorodithioate

FORMULATION TYPE: WP: wettable powder
EC: emulsifiable concentrate

SITE CATEGORY: USC# 14, Terrestrial Food Crops

NOTE: All uses of azinphos-methyl fall under RESTRICTED classification.

NATURE OF RESTRICTION

This product is to be stored, displayed and distributed in the manner authorized. Provincial and federal regulations are in effect.

USE LIMITATIONS

Do not use on other crops used for food or forage. Use only according to label directions. Application at rates above those shown may result in illegal crop residues. Do not graze livestock in treated orchards or groves for 21 days after treatment. Use of this product in greenhouses or enclosed areas is prohibited. Backpack and handwand spraying is prohibited.

TOXICOLOGICAL INFORMATION

Azinphos-methyl 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. 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 products that contain more 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."

PRECAUTIONS
KEEP OUT OF REACH OF CHILDREN. Poisonous if swallowed, inhaled, or absorbed through the skin. Do not get in eyes or on skin. Do not breathe fumes or spray mist. Spray operator should work to windward to stay out of drift or mist. Keep all unprotected persons out of the operating area or vicinity where there may be danger of drift. Do not contaminate feed or foodstuffs. Keep out of reach of children and domestic animals.

Personal Protective Equipment (PPE)
See Engineering Controls for additional requirements.

Mixers and loaders must wear the following during mixing, loading, clean-up and repair activities:
- Coveralls over long-sleeved shirt and long-legged pants
- Chemical-resistant gloves, such as barrier laminate or viton
- Chemical-resistant footwear plus socks
- Protective eyewear
- Chemical-resistant apron when mixing or loading
- Chemical-resistant headgear
- For exposure in enclosed areas, a respirator with either an organic vapour-removing cartridge with a prefilter approved for pesticides (MSHA/NIOSH approval number prefix TC-23C) or a canister approved for pesticides (MSHA/NIOSH approval number prefix TC-14G)
- For exposure outdoors, dust/mist filtering respirator (MSHA/NIOSH approval number prefix TC23-C)

Airblast applicators should be in fully enclosed cabs. If not in fully enclosed cabs, applicators must wear:
- Chemical-resistant coveralls over long-sleeved shirt and long-legged pants
- Chemical-resistant hood
- Full-face respirator or half-faced respirator with a face shield. Respirators can have either an organic vapour-removing cartridge with a prefilter approved for pesticides (MSHA/NIOSH approval number prefix TC-23C) or a canister approved for pesticides (MSHA/NIOSH approval number prefix TC-14G)
- Chemical-resistant footwear plus socks
- Chemical-resistant gloves

Applicators (other than airblast) must wear:
- Coveralls over long-sleeved shirt and long-legged pants
- Chemical-resistant gloves, such as barrier laminate or viton
- Chemical-resistant footwear plus socks
- Protective eyewear
- Dust/mist filtering respirator (MSHA/NIOSH approval number prefix TC23-C)

Ask dealers about suitable types of respirators.

Discard clothing and other absorbent materials if accidentally drenched or heavily contaminated with concentrated product. Do not reuse contaminated clothing. Follow manufacturer's instructions for cleaning/maintaining PPE. If there are no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

User safety recommendations
- Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet.
- Remove clothing immediately if pesticide gets inside. Then wash skin thoroughly and put on clean clothing.
- Remove PPE immediately after handling this product. Wash the outside of gloves before removing gloves or clothing. As soon as possible, wash skin thoroughly and change into clean clothing.

Engineering Controls
Liquid formulations: Mixers and loaders must use a fully closed mixing and loading system. The system must be capable of removing the pesticide from the shipping container and transferring it into mixing tanks and (or) application equipment. At any disconnect point, the system must be equipped with a dry disconnect or dry couple shut-off device that is warranted by the manufacturer to minimize drippage to not more than 2 ml per disconnect point. In addition, mixers and loaders must:
- wear the equipment required in the PPE section of this labelling for mixer/loaders; and
- wear protective eyewear if the system operates under pressure.

Wettable powder formulations: Wettable powder formulations are permitted only when marketed in water-soluble packages. Water-soluble packets qualify as a closed mixing/loading system when used correctly. Mixers and loaders using water-soluble packets must wear the personal protective equipment required above for mixers/loaders. Do not break open water soluble packages.

RE-ENTRY INTERVAL (REI)

Do not enter or allow worker entry into treated areas during the re-entry interval (REI) listed in the chart below.

Crop	REI	
apple, plum, prune, pear, apricot, peach	14 days	The following PPE is required for early entry to treated areas that involves contact with anything that has been treated, such as plants, soil or water. • Chemical-resistant coveralls over long-sleeved shirt and long pants • Chemical-resistant gloves • Chemical-resistant footwear plus socks • Protective eyewear • Chemical-resistant headgear for overhead exposure Following the REI and throughout the remainder of the growing season, workers must wear clean, long-sleeved shirts and protective gloves each time they perform activities that involve foliar contact. Notify workers of the pesticide application by warning them orally and by posting warning signs at entrances to treated areas. Wash stations must be available in the field for all re-entry workers. Do not apply this product in a way that will come into contact with workers or other persons, either directly or through drift. Only protected handlers may be in the area during application.
raspberry, cranberry, blackberry	7 days	
cherry (sweet and tart)	15 days	
grape	28 days	

Persons other than agricultural workers, such as members of the general public involved in "pick-your-own", "U-pick" or similar operations, are not permitted to enter a treated area for 30 days after application.

ENVIRONMENTAL HAZARDS

This pesticide is extremely toxic to fish and wildlife. Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water by cleaning equipment and container or disposing of waste. Drift and runoff from treated areas are hazardous to aquatic organisms in neighbouring areas. This product is highly toxic to bees exposed to direct treatment, drift, 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 visiting the treatment area. Protective information may be obtained from your local government extension specialist. When treating fruit during the bloom period, bee keepers should be warned well in advance to remove hives a safe distance from orchards to be treated.

Drift resulting from applications of azinphos-methyl is a hazard to aquatic ecosystems. Aquatic ecosystems consist of any permanent body of water, such as, but not limited to lakes, ponds, streams, rivers, creeks, sloughs, canals, coulees, prairie potholes, reservoirs, marshes or wetlands. For details on required buffer zones, refer to SPRAY DRIFT MANAGEMENT.

SPRAY DRIFT MANAGEMENT

General information

Only apply when there is minimal potential for drift to areas of human habitation or areas of human activity such as houses, cottages, schools and parks. Avoid overspray or drift onto water bodies or other environmentally sensitive habitat. Application equipment and weather affects spray drift. The applicator must consider wind speed, wind direction, temperature and sprayer settings when making application decisions.

Ground application

For minimizing drift, an appropriate buffer zone is required between the downwind point of direct application and the nearest boundary of sensitive aquatic habitats including lakes, ponds, streams, rivers, creeks, sloughs, canals, coulees, prairie potholes, reservoirs, marshes or wetlands.

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

For application with ground spray booms, the buffer zones presented in Table 1 are required for protection of aquatic habitats (as indicated above).

Airblast application

Do not direct spray above trees/vines and turn off outward pointing nozzles at row ends and outer rows.

Do not apply during periods of dead calm, when winds are gusty or when wind speed is greater than 16 km/hour at the application site as measured outside of the orchard/vineyard on the upwind side.

For orchard airblast applications, the buffer zones presented in Table 1 are required for protection of aquatic habitats (as indicated above).

Table 1 Required buffer zones for protection of aquatic 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
Boom sprayer*	50	40	30
Airblast (early season)	75	60	50
Airblast (late season)	65	50	40

* With the use of shrouds or cones on field sprayers (for reducing drift), buffer zones can be reduced by 70% (shrouds) or 30% (cones).

DIRECTIONS FOR USE
NATURE OF RESTRICTION: This product is to be stored, displayed and distributed in the manner authorized — provincial and federal regulations are in effect.

DO NOT APPLY BY AIR.

SPRAYING
Work to windward. Protect sprayer operators from drift or mist. Additional information on spray drift management for ground application is provided in the SPRAY DRIFT MANAGEMENT section. When low volumes of spray are applied, complete coverage and thorough application are essential for most effective results. Schedule applications in accordance with local conditions. Consult your local agricultural authorities for specific use information.

Acceptable uses for azinphos-methyl until 31 December 2006

Site	Pests	Rate (g a.i.)	Application instructions and limitations
APPLE, PEAR, CRABAPPLE (for pollination in commercial apple orchards)	apple maggot, codling moth, eyespotted budmoth, Forbes scale, fruittree leafroller, green fruitworm, leafhoppers, mealybug, mullein bug (Campyloma), obliquebanded leafroller, oystershell scale, pear psylla, plum curculio, Putnam scale, redbanded leafroller, San José scale, stink bugs, tarnished plant bug, pale apple leafroller, winter moth, European apple sawfly	300–373.3 g a.i./ 1000 L Apply 1000–3000 L of water per hectare per spray. (Maximum application rate: 1120 g a.i./ha	Ground application only. Apply specified dose in sufficient water to ensure complete coverage. For control of plum curculio, apply as a border spray in sufficient water for thorough coverage. Up to 4480 g a.i. for apples and 3360 g a.i. for pears) may be applied per hectare per crop (4 applications for apples and 3 applications for pears per crop season). Allow at least 7 days between applications. If last application is less than 1120 g a.i./ha, allow at least 14 days between last application and harvest. If last application is equal to 1120 g a.i./ha allow 21 days between last application and harvest. Use during dormant season is prohibited. For airblast applications, turn off outward pointing nozzles at row ends and when spraying the outer two rows. Do not graze livestock in treated orchards.

Site	Pests	Rate (g a.i.)	Application instructions and limitations
APRICOT, PEACH	Cottony peach scale, European fruit lecanium, Forbes scale, Oriental fruit moth, oblique-banded leafroller, peach twig borer, *Platynota flavedana* leafroller, plum curculio, red-banded leafroller, San Jose scale, stink bug, tarnished plant bug, terrapin scale, walnut scale, white peach scale	300–333.3 g/1000 L	Ground application only. Apply specified dose in sufficient water to ensure complete coverage. For control of plum curculio, apply as a border spray in sufficient water for thorough coverage. Up to 2000 g a.i. maximum may be applied per hectare per crop season. Up to two applications per year. Allow at least 14 days between applications. Allow at least 21 days between last application and harvest. Use during dormant season is prohibited. For airblast applications, turn off outward pointing nozzles at row ends and when spraying the outer two rows. Do not graze livestock in treated orchards.
BLACKBERRY, RASPBERRY	raspberry crown borer	1125 g a.i./ha	Ground application only. Post-harvest application for control of raspberry crown borer, apply specified dosage per hectare to the lower portion of the canes and to soil beneath the plants in approximately 1600 L water. One application only.
CHERRY	cherry fruit fly, Forbes scale, eyespotted budmoth, fruittree leafroller, plum curculio, San José scale	300–1125 g a.i./1000 L	Ground application only. Apply specified dosage in 1000 L of water as a full coverage spray. Limit to two applications to a maximum of 1680 g a.i./ha per year. Allow at least 14 days between applications and at least 15 days between last application and harvest. Use during dormant season is prohibited. For airblast applications, turn off outward pointing nozzles at row ends and when spraying the outer two rows. Do not graze livestock in treated orchards.
	lesser peachtree borer	625 g a.i./1000 L	
CRANBERRY	cranberry fruitworms, *Sparganothis sulfureana*, tipworm	560–1125 g a.i./ha	Ground application only. Apply specified dosage in approximately 1600 L of water per hectare. A total of 2 applications may be made per crop season. Allow at least 14 days between applications and at least 21 days between last application and harvest.
	fireworm	1125 g a.i./ha	

Site	Pests	Rate (g a.i.)	Application instructions and limitations
GRAPE	grape berry moth, grape cane girdler, flea beetle, leafhoppers, leafrollers	312.5–625 g a.i./1000 L	Ground application only. Apply specified dosage in 1000 L of water as a full coverage border spray. A total of 2 applications is permitted per crop per season, regardless of rate. Use in an IPM program in conjunction with mating disruption pheromone technologies for control of grape berry moth. Allow at least 14 days between applications. Allow at least 28 days between last application and harvest.
PLUM, PRUNE	eyespotted budmoth, Forbes scale, fruittree leafroller, orange tortrix, peach twig borer, plum curculio, redbanded leafroller, San José scale, stink bug, tarnished plant bug, tussock moth	300–625 g a.i./ 1000 L	Ground application only. Apply in sufficient water for thorough coverage. For control of plum curculio, apply as a border spray. Up to 2000 g a.i. may be applied per hectare per crop season. Up to two applications per year. Allow at least 10 days between applications. Allow at least 15 days between last application and harvest. Use during dormant season is prohibited. For airblast applications, turn off outward pointing nozzles at row ends and when spraying the outer two rows. Do not graze livestock in treated orchards.
	American plum borer, lesser peachtree borer, peachtree borer	625 g a.i./1000 L	