



**Australian Government**  
**Australian Pesticides and  
Veterinary Medicines Authority**



MAY 2016

## **Omethoate: proposed regulatory decisions**

The reconsideration of the active constituent omethoate, registration of products containing omethoate and approvals of their associated labels

© Australian Pesticides and Veterinary Medicines Authority 2016

ISBN 978-1-925390-32-2 (electronic)

### **Ownership of intellectual property rights in this publication**

Unless otherwise noted, copyright (and any other intellectual property rights, if any) in this publication is owned by the Australian Pesticides and Veterinary Medicines Authority (APVMA).

### **Creative Commons licence**

With the exception of the Coat of Arms and other elements specifically identified, this publication is licensed under a Creative Commons Attribution 3.0 Australia Licence. This is a standard form agreement that allows you to copy, distribute, transmit and adapt this publication provided that you attribute the work.



A summary of the licence terms is available from [www.creativecommons.org/licenses/by/3.0/au/deed.en](http://www.creativecommons.org/licenses/by/3.0/au/deed.en). The full licence terms are available from [www.creativecommons.org/licenses/by/3.0/au/legalcode](http://www.creativecommons.org/licenses/by/3.0/au/legalcode).

The APVMA's preference is that you attribute this publication (and any approved material sourced from it) using the following wording:

*Source: Licensed from the Australian Pesticides and Veterinary Medicines Authority (APVMA) under a Creative Commons Attribution 3.0 Australia Licence.*

In referencing this document the Australian Pesticides and Veterinary Medicines Authority should be cited as the author, publisher and copyright owner.

### **Use of the Coat of Arms**

The terms under which the Coat of Arms can be used are set out on the Department of the Prime Minister and Cabinet website (see [www.dPMC.gov.au/pmc/publication/commonwealth-coat-arms-information-and-guidelines](http://www.dPMC.gov.au/pmc/publication/commonwealth-coat-arms-information-and-guidelines)).

### **Comments and enquiries regarding copyright:**

Director Public Affairs and Communication  
Australian Pesticides and Veterinary Medicines Authority  
PO Box 6182  
KINGSTON ACT 2604 Australia

Telephone: +61 2 6210 4988

Email: [communications@apvma.gov.au](mailto:communications@apvma.gov.au)

This publication is available from the APVMA website: [www.apvma.gov.au](http://www.apvma.gov.au).

# CONTENTS

---

FOREWORD	1
SUBMISSIONS FROM THE PUBLIC ARE INVITED	2
<b>Preparing your comments for submission</b>	<b>2</b>
<hr/>	
EXECUTIVE SUMMARY	4
<b>Introduction</b>	<b>4</b>
<b>Proposed regulatory decisions</b>	<b>4</b>
<hr/>	
<b>1 INTRODUCTION</b>	<b>6</b>
<b>1.1 Current regulatory status of omethoate in Australia</b>	<b>6</b>
<b>1.2 APVMA reconsideration of omethoate</b>	<b>7</b>
Submissions received for the reconsideration of omethoate	7
Next steps for this reconsideration	7
<b>1.3 Regulatory context</b>	<b>8</b>
<hr/>	
<b>2 INTERNATIONAL REGULATORY STATUS</b>	<b>10</b>
United States	10
Canada	10
Europe	10
New Zealand	10
FAO/WHO Joint Meeting on Pesticide Residues (JMPR)	11
<hr/>	
<b>3 SUMMARY OF ASSESSMENTS AND PROPOSED FINDINGS</b>	<b>12</b>
<b>3.1 Toxicology</b>	<b>12</b>
Toxicology assessment	12
Summary of findings and outcomes	13
Approval status	13
Acceptable Daily Intake (ADI)	13
Acute Reference Dose (ARfD)	14
Poisons schedule	14
Warning statements and first aid instructions	14
Safety directions for use of the home garden product	14
<b>3.2 Occupational Health and Safety (OHS)</b>	<b>15</b>
Summary of findings	15
Scope of the OHS assessment	15
Safety directions	16
Precautionary statements	18
Re-entry statements	19
<b>3.3 Residues, dietary risk assessment and trade</b>	<b>20</b>
Supported uses of omethoate	21
Uses of omethoate that are not supported	21
Insufficient residue data provided	22
Home garden use on food producing plants is not supported	23
Residue-related aspects of trade	23

MRL recommendations	23
<hr/>	
<b>4 PROPOSED RECONSIDERATION DECISIONS</b>	<b>24</b>
<b>4.1 Affirm approvals of the active constituent</b>	<b>24</b>
<b>4.2 Vary particulars of label approvals, and affirm products with varied labels</b>	<b>24</b>
<b>4.3 Supported uses</b>	<b>24</b>
<b>4.4 Unsupported uses</b>	<b>24</b>
<b>4.5 Label instructions</b>	<b>24</b>
<b>4.6 Phase-out periods</b>	<b>25</b>
<hr/>	
<b>5 PROPOSED AMENDMENTS TO STANDARDS</b>	<b>26</b>
<b>5.1 Active constituent standards</b>	<b>26</b>
<b>5.2 Public health standards</b>	<b>26</b>
Acceptable daily intake (ADI)	26
Acute reference dose (ARfD)	26
Poisons schedule	26
First aid instructions, warning statements and safety directions including personal protective equipment (PPE)	26
<b>5.3 Residues definition</b>	<b>26</b>
<b>5.4 MRL Standards</b>	<b>27</b>
<hr/>	
<b>APPENDIX A—SUMMARY OF PROPOSED DIRECTIONS FOR USE FOR PRODUCTS CONTAINING OMETHOATE</b>	<b>29</b>
<b>Proposed changes to the directions for use 2 g/L aerosol home garden product</b>	<b>29</b>
Use patterns to be deleted	29
Use patterns to remain on the label	29
First aid instructions 2 g/L home garden product	29
Safety directions 2 g/L home garden product	29
<b>Proposed changes to the directions for use 290 g/L agricultural products</b>	<b>30</b>
Use patterns to be deleted	30
Use patterns to remain on the label	30
First aid instructions	30
Safety directions	30
Precautions	31
Re-entry intervals	31
Withholding periods	31
<b>Proposed changes to the directions for use for 800g/L agricultural products</b>	<b>32</b>
Use patterns to be deleted	32
Use patterns to remain on the label	33
First aid instructions	33
Safety directions	33
Precautions	34
Re-entry intervals	34
Withholding periods	34
<hr/>	
<b>APPENDIX B—LIST OF ACTIVE CONSTITUENTS, PRODUCT REGISTRATIONS AND LABEL APPROVALS</b>	<b>35</b>
<b>Active approvals to be affirmed</b>	<b>35</b>
<b>Product registrations to be affirmed following variation of approved labels</b>	<b>35</b>

Also label approvals to be varied	35
<b>Active approvals and product registrations initially included in the reconsideration—now discontinued</b>	<b>37</b>
No further regulatory action required as these approvals and registrations no longer in force	37
<hr/>	
APPENDIX C—RECOMMENDED AMENDMENTS TO TABLE 1 AND TABLE 4 OF THE APVMA MRL STANDARD	38
APPENDIX D—ADDITIONAL RE-ENTRY INTERVAL CALCULATIONS FOR NURSERY, GREENHOUSE AND FORESTRY SITUATIONS	39
ABBREVIATIONS	41

## LIST OF TABLES

Table 1: Currently registered omethoate products	6
Table 2: Recommended first aid instructions	14
Table 3: Recommended safety directions—home garden product	15
Table 4: Recommended safety directions 290 g/L products	17
Table 5: Recommended safety directions 800 g/L products	18
Table 6: Summary of NESTI calculations for existing omethoate uses with unacceptable dietary risks	22
Table 7: Uses proposed for deletion from the 2 g/L home garden product	29
Table 11: Uses proposed for deletion from the labels of 800 g/L agricultural products	32
Table 12: Uses proposed to remain on labels of 800 g/L agricultural products	33
Table 13: Active approvals to be affirmed	35
Table 14: Product registrations to be affirmed following variation of approved labels	35
Table 15: Active approvals included in the reconsideration that were discontinued- no further regulatory action required	37
Table 16: Product registrations approvals that were included in the reconsideration that are no longer registered- no further regulatory action required	37
Table 17: Recommended amendments to Table 1 of the APVMA MRL Standard	38
Table 18: Recommended amendments to Table 4 of the APVMA MRL Standard	38
Table 19: Calculated re-entry periods for ornamental crops	39

## FOREWORD

The Australian Pesticides and Veterinary Medicines Authority (APVMA) is an independent statutory authority with responsibility for the regulation of agricultural and veterinary chemicals in Australia up to the point of retail sale. Its statutory powers are provided in the Agvet Codes scheduled to the *Agricultural and Veterinary Chemicals Code Act 1994*.

The APVMA has legislated powers to reconsider the approval of an active constituent, registration of a chemical product or approval of a label at any time after it has been registered. The reconsideration process is outlined in sections 29 to 34 of Part 2, Division 4 of the Agvet Codes.

A reconsideration may be initiated when credible new information raises concerns about the use or safety of a particular chemical, a product containing that chemical, or its label.

The reconsideration process includes a call for data from a variety of sources, a scientific evaluation of that data and, following public consultation, a regulatory decision about the ongoing use of the chemical or product. The data required by the APVMA must be generated according to scientific principles. The APVMA conducts science and evidence-based risk analysis with respect to the matters of concern, analysing all the relevant information and data available.

In undertaking reconsiderations, the APVMA works in close cooperation with advisory agencies including the Office of Chemical Safety (OCS) within the Department of Health, Food Standards Australia New Zealand (FSANZ), the Department of the Environment and the state departments of agriculture, as well as other expert advisers as appropriate.

This document sets out the proposed regulatory decisions (PRD) relating to the active constituent omethoate and products containing omethoate when used in accordance with current approved label instructions.

This PRD and supporting technical reports on omethoate are available from the [APVMA website](#).

The technical reports are:

- the [Review of the mammalian toxicology and metabolism/toxicokinetics of omethoate](#)
- the [Occupational health and safety assessment of omethoate](#)
- the [Omethoate residues and dietary risk assessment report](#).

## SUBMISSIONS FROM THE PUBLIC ARE INVITED

This proposed regulatory decision report:

- outlines the APVMA reconsideration process
- advises interested parties how to respond to the reconsideration
- summarises the technical assessments
- outlines the proposed regulatory decisions to be taken in relation to the continued approvals and registrations of omethoate in Australia.

The APVMA invites written comments on this report. All comments on this report will be assessed by the APVMA prior to finalisation of the reconsideration and publication of the final regulatory decision report.

### Preparing your comments for submission

When making your comments:

- clearly identify the issue and clearly state your point of view
- give reasons for your comments, supporting them, if possible, with relevant information and indicating the source of the information you have used
- suggest to the APVMA any alternative solution you may have for the issue.

Please structure your comments in point form, referring each point to the relevant section in the report.

All submissions to the APVMA will be acknowledged in writing via email or by post.

When making a submission please include:

- contact name
- company or group name (if relevant)
- postal address
- email address (if available)
- the date you made the submission.

Note that all submissions received are subject to the *Freedom of Information Act 1982*, the *Privacy Act 1988* and the Agvet Code. All personal and confidential commercial information (CCI) material contained in submissions will be treated confidentially. (A full definition of 'confidential commercial information' is contained in the [Agvet Code](#)).

**The closing date for submissions is 5pm Thursday 4 August 2016.**

Submissions can be sent to:

Director, Chemical Review  
Australian Pesticides and Veterinary Medicines Authority  
PO Box 6182  
KINGSTON ACT 2604

Telephone: +61 2 6210 4749  
Facsimile: +61 2 6210 4776  
Email: [chemicalreview@apvma.gov.au](mailto:chemicalreview@apvma.gov.au)  
Website: [www.apvma.gov.au](http://www.apvma.gov.au)

## EXECUTIVE SUMMARY

### Introduction

Omethoate (O,O-dimethyl S-methylcarbamoylmethyl phosphorothioate) is a systemic organophosphorus (OP) insecticide and acaricide used to control insects and mites in horticulture and agriculture, as well as in the home garden. Omethoate has been registered in Australia for over 40 years.

Along with other pesticides of this class, its mode of action is through inhibition of the enzyme acetylcholinesterase. This inhibition results in the over-stimulation of those parts of the nervous system that use acetylcholine to transmit nerve impulses. The APVMA began its reconsideration of omethoate together with that of the related chemical, dimethoate in April 2004.

The scope of the reconsideration includes the following aspects of active constituent approvals, product registrations and label approvals for omethoate:

- toxicology
- Occupational Health and Safety (OHS)
- residues including dietary exposure and trade.

As part of the toxicology assessment for omethoate, public health standards for acceptable exposure to omethoate have been amended or established:

- the acceptable daily intake (ADI) has been amended from 0.0003 to 0.0004 mg/kg bw
- an acute reference dose (ARfD) for omethoate of 0.003 mg/kg bw has been established.

There have been no changes recommended to the approval status of the active constituent or to the current poisons schedule of omethoate.

As part of the OHS assessment, amendments to the first aid instructions and safety directions for the agricultural products and the one home garden product have been recommended. New re-entry intervals and additional precautions have been set for the agricultural products.

The residues and dietary assessment did not support any uses of omethoate that could result in residues on food commodities. The remaining supported uses are:

- barrier spraying (not in-crop) for red legged earth mite
- use on ornamentals.

### Proposed regulatory decisions

After consideration of all data and assessments, the APVMA proposes the following regulatory actions:

- affirm active constituent approvals for omethoate

- vary all label approvals for products containing omethoate to remove the instructions for use on food producing plants and to upgrade the safety directions (as listed in Appendix B)
- affirm these product registrations once the necessary label variations have been made.

# 1 INTRODUCTION

## 1.1 Current regulatory status of omethoate in Australia

Omethoate (O,O-dimethyl S-methylcarbamoylmethyl phosphorothioate) is a systemic organophosphorus (OP) insecticide and acaricide used to control insects and mites in horticulture and agriculture, as well as in the home garden. Along with other pesticides of this class, its mode of action is through inhibition of acetylcholinesterase activity.

Omethoate has been registered in Australia for over 40 years.

As of March 2016 there were 4 active constituent approvals for omethoate and 22 registered products containing omethoate. One product is registered for home garden use and 21 for agricultural use. The home garden product (an aerosol product—AE) is currently approved for use in the home garden to control insect pest of citrus, herbs, apples, vegetables, flowers and ornamentals.

There are two types of products registered for use in agricultural crops and can be applied by ground boom, airblast, handheld sprayers or backpack sprayer. The 800 g/L products are approved for the control of a variety of insect or mite pests of cotton, pome fruit, bananas, citrus, lupins, onions, potatoes and flowers. The 800 g/L products are formulated either as liquid concentrates (LC) or soluble concentrates (SC).

The 290 g/L products are approved for the control of aphids and mites in pastures and some field crops. These products are formulated as aqueous concentrates (AC), liquid concentrates (LC) or soluble concentrates (SC).

Omethoate is in Schedule 7 of the Poisons Standard (the SUSMP<sup>1</sup>) with a cut-off to Schedule 6 at 30 per cent or less, or to Schedule 5 in pressurised spray packs containing 0.2 per cent or less of omethoate.

**Table 1: Currently registered omethoate products**

Product type	Number of products	Concentration of omethoate	Schedule	Formulation types
Home garden product	1	2.0 g/L	Schedule 5	Aerosol (AE)
Agricultural products	18	290 g/L	Schedule 6	Aqueous concentrate (AC) Liquid concentrate (LC) Soluble concentrate (SC)
	3	800 g/L	Schedule 7	Liquid concentrate (LC) Soluble concentrate (SC)

<sup>1</sup> [www.tga.gov.au/publication/poisons-standard-susmp](http://www.tga.gov.au/publication/poisons-standard-susmp)

## 1.2 APVMA reconsideration of omethoate

In October 1994, the APVMA invited the public to nominate active constituents, chemical products or labels for reconsideration. Of the 600 chemical nominations, 80 were prioritised for reconsideration, one of which was dimethoate.

In considering the scope of the reconsideration of dimethoate, the APVMA received advice from the OCS and APVMA Residue Program noting the need to also reconsider the oxygen analogue of dimethoate, omethoate. Omethoate is used as a pesticide in its own right and can also be formed as a breakdown product of dimethoate. Omethoate is known to be considerably more toxic than dimethoate.

APVMA began its reconsideration of omethoate together with that of dimethoate in April 2004 and released the [Reconsideration of approvals and registrations relating to dimethoate and omethoate—review scope document](#), which outlined the reasons and scope of the reconsideration and included a call for public submissions.

The scope of the reconsideration included the following aspects of active constituent approvals, product registrations and label approvals for omethoate:

- toxicology
- Occupational Health and Safety
- residues including dietary exposure and trade.

### Submissions received for the reconsideration of omethoate

During the three month consultation period after publication of the scope of the reconsideration of omethoate, the APVMA received a submission of data and use pattern information from the holder of the active approvals and product registrations. Most of the public submissions were relevant only to the dimethoate review. However the NSW Farmers Federation (30 June 2004) submission noted the importance of omethoate for the control of a range of insects and mites in horticultural, cereal and field crops as well as in pastures.

### Next steps for this reconsideration

In this PRD report certain regulatory decisions are proposed based on the assessments conducted by the APVMA and its partner agencies.

Persons and organisations are invited to submit their comments and related information relevant to these proposed decisions directly to the APVMA. This consultation period continues for three months ending on Thursday 4 August 2016.

At the end of the consultation period the APVMA will publish the submissions, assess the information received and will determine the final regulatory actions for this reconsideration.

### 1.3 Regulatory context

The basis for a reconsideration of the approvals and registrations of a chemical is whether the APVMA is satisfied that the safety, efficacy and trade criteria listed in sections 5A, 5B and 5C of the Agvet Codes for continued registration and approval are being met. The requirements that are relevant to the scope of this reconsideration (toxicology, occupational health and safety, residues and trade) are that the use of the product, in accordance with instructions approved, or to be approved, by the APVMA for the product or contained in an established standard:

- would not be an undue hazard to the safety of people exposed to it during its handling or people using anything containing its residues
- would not be likely to have an effect that is harmful to human beings
- would not unduly prejudice trade or commerce between Australia and places outside Australia.

The APVMA also considers whether labels for containers for chemical products containing omethoate meet the labelling criteria as defined in section 5D of the Agvet Code which requires that labels have adequate instructions relating to:

- the circumstances in which the product should be used
- how the product should be used
- the times when the product should be used
- the frequency of the use of the product
- the re-entry period after use of the product
- the withholding period after the use of the product
- disposal of the product and its container
- safe handling of the product and first aid in the event of an accident
- any matters prescribed by the regulations.

There are three possible outcomes to the reconsideration of the active constituent omethoate, registration of products containing omethoate and all associated label approvals. Based on the information reviewed the APVMA may be:

- satisfied under that the active constituent approvals, product registrations and associated label approvals continue to meet the safety and labelling criteria and therefore affirms the registrations and approvals
- not satisfied under that the approvals and registrations meet the safety and labelling criteria but is satisfied that the relevant particulars or conditions of those registrations or approvals can be varied in such a way as to allow the approval or registration to be affirmed
- not satisfied that the relevant particulars or conditions of those registrations or approvals can be varied in such a way as to allow the approval or registration to be affirmed and thus suspends or cancels the registration and/or approvals.

It is proposed in this PRD that the APVMA should affirm the active constituent approvals, vary the label particulars for all label approvals associated with products containing omethoate to remove use on food producing plants and affirm the registrations of products once those labels have been varied.

## 2 INTERNATIONAL REGULATORY STATUS

Omethoate is currently not approved for use in Canada, the USA, the European Union or New Zealand.

### United States

Omethoate was not registered as a pesticide in the US and as such has not been reviewed separately. However the toxicity of omethoate has been considered in the US EPA's Reregistration Eligibility Decision (RED) review of dimethoate as it is a metabolite of dimethoate.

### Canada

Omethoate is not listed in the *Pesticide Product Information Database* for Canada. There is no available re-evaluation decision report for omethoate. The toxicity of omethoate has been considered as part of the review of diemthoate because omethoate is a break down product of dimethoate (*Re-evaluation Decision RVD2015-04, Dimethoate*).

### Europe

Omethoate is not approved for plant protection products or as a biocide in the European Union. It was removed from the list of approved plant protection substances by the European Union in 2002. This committed member States to withdraw all authorisations for plant protection products containing omethoate by 25 July 2003 with an exception for products used only on ornamental plants in Austria (which could continue until June 2007).

As omethoate is a metabolite of dimethoate, its toxicity was considered by the European Food Safety Authority (EFSA) as part of the assessment of dimethoate in 2013<sup>2</sup>.

### New Zealand

Omethoate is not approved for use as a plant protection product in New Zealand. In September 2011<sup>3</sup> it was noted that omethoate was not included in any registered plant protection products in New Zealand.

---

<sup>2</sup> European Food Safety Authority, 2013. *Conclusion on the peer review of the pesticide risk assessment of confirmatory data submitted for the active substance dimethoate*. [EFSA Journal 2013;11\(7\):3233, 36 pp. doi:10.2903/j.efsa.2013.3233](https://doi.org/10.2903/j.efsa.2013.3233).

<sup>3</sup> Environmental Protection Authority NZ Sept 2011, *Call for information: Potential reassessment of selected organophosphates and carbamates*, [www.epa.govt.nz/Publications/Call%20for%20info%20on%20potential%20reassessment%20of%20some%20OPCs.pdf](http://www.epa.govt.nz/Publications/Call%20for%20info%20on%20potential%20reassessment%20of%20some%20OPCs.pdf)

**FAO/WHO Joint Meeting on Pesticide Residues (JMPR)**

The toxicology of omethoate was evaluated by the JMPR in 1971, 1975, 1978, 1979, 1981, 1985, and 1996.

In the 1996 toxicological assessment of dimethoate, omethoate and formothion, the previous ADI of 0.0003 mg/kg bw for omethoate was withdrawn. This was because the primary manufacturer was no longer producing omethoate and toxicological data was not available to the meeting.

The 2003 toxicological assessment of dimethoate included omethoate as a significant metabolite but did not establish a separate ADI for omethoate.

The most recent residues assessment was completed in 1990 with limited residues information for omethoate included in the 1998 assessment of dimethoate.

## 3 SUMMARY OF ASSESSMENTS AND PROPOSED FINDINGS

### 3.1 Toxicology

In February 2012, the APVMA published the [Review of the mammalian toxicology and metabolism/toxicokinetics of omethoate](#) (completed November 2011). This assessment was conducted by the OCS. The OCS assessed toxicology data submitted at the commencement of the reconsideration, together with all previously submitted registration data and relevant published data.

#### Toxicology assessment

The toxicology assessment included:

- hazard identification—the identification of the type and nature of adverse effects that a substance can potentially cause in an organism, animal species or human.
- hazard characterisation (often referred to as the dose response characterisation)—the qualitative and, wherever possible, quantitative description of the inherent property of a substance having the potential to cause adverse effects. This should, where possible, include a dose–response assessment and its attendant uncertainties.
- identification of a threshold (the No Observed Adverse Effect Level—NOAEL) below which no adverse effects occur following short-, medium or long-term exposure to the chemical. As part of the assessment the OCS also sets (or confirms) the public health standards for exposure to that substance. These are the acceptable daily Intake (for long term exposure) and if single or short term exposure is of concern, the Acute Reference Dose (ARfD). These standards are used in any subsequent residues and dietary risk assessment.

In common with all organophosphate compounds, the primary mode of action of omethoate is via the inhibition of an important enzyme, acetylcholinesterase (AChE). This inhibition of AChE results in the over-stimulation of those parts of the nervous system that use acetylcholine to transmit nerve impulses. Signs of intoxication at high doses are consistent with acetylcholinesterase inhibition and include inactivity, salivation (drooling), difficulty breathing, flaccid paralysis (weakness), vomiting, and diarrhoea. If intoxication is severe, muscle twitching, loss of reflexes, convulsions and death can eventuate. Signs of intoxication at low doses noted in animal studies include changes to pupillary reflexes and reduced grip strength and activity.

In the toxicology assessment it was confirmed that the inhibition of cholinesterase enzyme (ChE) in either red blood cells or the brain was the most sensitive endpoint to measure any effects of omethoate.

## Summary of findings and outcomes

During the course of this reconsideration the OCS has:

- revised the acceptable daily intake (ADI) from 0.0003 to 0.0004 mg/kg bw
- established a new acute reference dose for omethoate of 0.003 mg/kg bw.

The OCS has recommended to the APVMA:

- no changes to the approval status of the active constituent
- amendments to the safety directions for the agricultural products and the remaining home garden product<sup>4</sup>.
- that the current Scheduling of omethoate is appropriate and no changes are required
- a maximum impurity limit of 20 g/kg for the impurity O,O,S-trimethyl phosphorothioate in omethoate active ingredient.

## Approval status

The OCS assessment concluded that there is no objection on toxicological grounds to the ongoing approval of omethoate from the existing sponsors and manufacturers.

The OCS also conducted an assessment of the risks of O,O,S-trimethyl phosphorothioate (O,O,S-TMP) which can be present as an impurity in omethoate. They considered both its intrinsic toxicity as well as the risk of it increasing the toxicity of omethoate through possible inhibition of detoxification pathways. As a result of this assessment they recommended that the maximum limit of the impurity O,O,S-TMP could be increased from 5 g/kg ai to 20 g/kg ai.

The APVMA Standard for omethoate active constituent currently specifies a maximum of 5 g/kg ai of O,O,S-trimethyl phosphorothioate. The APVMA has considered the OCS recommendation and decided to maintain the impurity level at the current level of 5 g/kg, which is consistent with good manufacturing practice and will be protective of human health.

## Acceptable Daily Intake (ADI)

The ADI for humans is the level of intake of a chemical that can be ingested daily over an entire lifetime without appreciable risk to health. It is established by dividing the overall NOAEL for the most sensitive, relevant adverse effect from a suitable study by an appropriate safety factor—the magnitude of the safety factor is selected to account for uncertainties in extrapolation of animal data to humans, intraspecies variation and the completeness of the toxicological database.

The previous ADI for omethoate of 0.0003 mg/kg bw/d was established in February 1989. It was based on a NOAEL of 0.025 mg/kg bw/d for the inhibition of RBC ChE activity in a 12-month gavage study in dogs (Hoffmann and Schilde, 1984) and using a 100-fold safety factor. Based on the work done in this reconsideration, the OCS

---

<sup>4</sup> A second 50 g/L omethoate products was registered at the start of the reconsideration and was included in this assessment. The OCS recommended that it is not suitable for home garden use. It is no longer registered and therefore no further action is required.

has revised the ADI to 0.0004 mg/kg bw/d, based on a NOAEL of 0.04 mg/kg bw/d for inhibition of ChE activity in a two-year rat dietary study and using a 100-fold safety factor.

### Acute Reference Dose (ARfD)

The ARfD is the estimate of the amount of a substance in food or drinking water, expressed on a milligram per kilogram body weight basis, that can be ingested over a short period of time, usually one meal or one day, without appreciable health risk to the consumer on the basis of all known facts at the time of the evaluation.

Prior to the commencement of this reconsideration there was no Australian ARfD value for omethoate. An ARfD of 0.003 mg/kg bw has now been established based on a NOAEL of 0.25 mg/kg bw for inhibition of ChE activity in an acute oral neurotoxicity study in rats, incorporating a safety factor of 100.

### Poisons schedule

The OCS noted that omethoate is in Schedule 7 of the SUSMP with a cut-off to Schedule 6 at 30 per cent or less, or to Schedule 5 in pressurised spray packs containing 0.2 per cent or less of omethoate. The information provided for this reconsideration did not raise any concerns regarding scheduling and therefore the OCS has advised that the current poisons schedule of omethoate remains appropriate.

### Warning statements and first aid instructions

The OCS has recommended that the current first aid instructions (as amended in 2008<sup>5</sup>) are appropriate for products containing omethoate:

Table 2: Recommended first aid instructions

	Codes	Text
in 0.2 per cent pressurised spray packs	o	If sprayed on skin, wash thoroughly. If sprayed in mouth, rinse mouth with water
	a	If poisoning occurs, contact a doctor or Poisons Information Centre. Phone Australia 131126, New Zealand 0800 764 766
in other preparations	m	If swallowed, splashed on skin or in eyes, or inhaled, contact a Poisons Information Centre (phone Australia 131 126) or a doctor at once. Remove any contaminated clothing and wash skin thoroughly. If swallowed, activated charcoal may be advised. Give atropine if instructed.

### Safety directions for use of the home garden product

The 2011 Toxicology report also recommended safety directions for all products. The recommendations for agricultural products have since been updated in the 2015 [Occupational health and safety assessment of](#)

<sup>5</sup> In 2008, the FSAID Handbook was amended to remove references to the use of atropine tablets, which are no longer available.

[omethoate](#) and are listed in the next section of this report. The recommended safety directions for the 0.2 per cent aerosol home garden product are listed below:

Table 3: Recommended safety directions—home garden product

Codes	Text
Product type: 0.2 per cent pressurised spray packs	
161, 162, 160, 164	Will irritate the eyes. May irritate the skin
210, 211, 180	Avoid contact with eyes and skin. Repeated exposure may cause allergic disorders
340, 342, 340, 343	If product on skin, immediately wash area with soap and water. If product in eyes, wash it out immediately with water.
351	Wash hands after use

## 3.2 Occupational Health and Safety (OHS)

### Summary of findings

In 2015, the APVMA published the [Occupational health and safety assessment of omethoate](#) which considered the risks to workers mixing or loading omethoate or re-entering crops treated with omethoate. The assessment recommended that the APVMA cannot be satisfied that the use of omethoate according to its existing label directions will not be a risk to workers and recommended changes to the current label instructions for use, safety directions, warnings and re-entry periods. These recommended changes are:

- that the application of 800 g/L omethoate products by the following methods should no longer be allowed
  - airblast equipment
  - equipment carried on the back of the user
  - aerial application to eucalypts<sup>6</sup> (aerial application to potatoes or cotton was assessed as acceptable)
- amendments and additions to the safety directions including personal protection equipment
- amendments and additions to the re-entry periods for all crops.

### Scope of the OHS assessment

The OHS assessment considered the:

- potential exposure during handling or use of the product by professional users
- potential post-application exposure, during re-entry to treated crops.

<sup>6</sup> Based on the potentially large treated area (and therefore usage of omethoate) per day. Aerial application to potatoes or cotton was assessed as acceptable based on the lower treated area per day.

The occupational risk during mixing/loading/application and post-application is determined by the Margin of Exposure (MOE), which compares the estimated occupational exposure to a chemical to the No-Observed-Effect-Level (NOEL) for the critical effect of that chemical (as observed in a suitable laboratory animal or human study). The larger the MOE the lower the risk.

Based on the risk assessment, risk management measures are then recommended to reduce human exposures to an acceptable level. Those measures include engineering controls, safety directions (including for personal protective equipment), use restraints, re-entry intervals, and scheduling recommendations.

As user exposure to these products is expected to be of short duration and intermittent, the NOEL of 2.5 mg/kg bw/day in a three week dermal study in rats and the NOEC of 0.96 mg/m<sup>3</sup> (equivalent to a systemic dose of 0.26 mg/kg bw/day) in a three week inhalation study in rats, were used for the dermal and inhalational exposure aspects of the occupational risk assessment, respectively. As both the NOEL and the NOEC were derived from laboratory animals, a MOE of 100 or more was considered acceptable. This MOE takes into account inter- (10x) and intra-species (10x) variability.

No chemical specific exposure data were available. Based exclusively on PHED surrogate exposure modelling, the risk assessment suggests that the label prescribed PPE do not adequately protect workers involved in mixing/loading and spraying of omethoate products. The OCS advised that exposure can be reduced to acceptable levels by using closed mixing/loading systems, wearing PPE and using engineering controls.

Following application to crops, workers may be exposed to omethoate foliar residues when undertaking post-application (re-entry) activities. The OCS recommended that workers should wear PPE until the residues dissipate to acceptable levels. Re-entry intervals (REI) have been assigned for all label crops in this report.

### **Safety directions**

The following safety directions were recommended by the OCS for the two types of omethoate agricultural product.

Table 4: Recommended safety directions 290 g/L products

Codes	Text
<b>Product type: 290 g/L products AC, LC or SL</b>	
120 121 130 131 132 133	Product and spray are poisonous if absorbed by skin contact or inhaled or swallowed.
161 162	Will irritate the eyes.
180, 181	Repeated exposure may cause allergic disorders. Sensitive workers should use protective clothing.
190	Repeated minor exposure may have a cumulative poisoning effect.
210 211 212	Avoid contact with eyes and skin and clothing.
220 223	Do not inhale spray mist.
279 280 281 290 292b 291 294c 298b 299	When opening the container and preparing spray, wear cotton overalls buttoned to the neck and wrist (or equivalent clothing), elbow-length chemical resistant gloves, water resistant footwear and face shield or goggles.
279 282 290 292b 294c	When using the prepared spray, wear cotton overalls buttoned to the neck and wrist (or equivalent clothing) and elbow-length chemical resistant gloves.
330 331 332	If clothing becomes contaminated with product or wet with spray remove clothing immediately.
340 342	If product on skin, immediately wash area with soap and water.
340 343	If product in eyes, wash it out immediately with water.
350	After use and before eating, drinking or smoking, wash hands, arms and face thoroughly with soap and water.
360 361 365 366	After each day's use, wash gloves and face shield or goggles and contaminated clothing

Table 5: Recommended safety directions 800 g/L products

Codes	Text
<b>Product type: 800 g/L products LC/SL</b>	
100 101	Very dangerous, particularly the concentrate
120 121 130 131 132 133	Product and spray are poisonous if absorbed by skin contact or inhaled or swallowed
161 162	Will irritate the eyes
180	Repeated exposure may cause allergic disorders
181	Sensitive workers should use protective clothing
190	Repeated minor exposure may have a cumulative poisoning effect
210 211 212	Avoid contact with eyes and skin and clothing
220 223	Do not inhale spray mist
279 280 281 289d 290 292d 294c 298b 301 303	When opening the container and preparing spray for aerial spraying equipment wear cotton overalls, over normal clothing, buttoned to the neck and wrist and a washable hat, elbow-length chemical resistant gloves, water resistant footwear and full face-piece respirator with gas/dust cartridges
279 280 281 289b 290 292b 294c 298b 299	When opening the container and preparing spray for boom spray equipment, wear cotton overalls buttoned to the neck and wrist (or equivalent clothing), elbow-length chemical resistant gloves, water resistant footwear and face shield or goggles
279 280 281 289f 290 292d 294c 298b 299	When opening the container and preparing spray for high pressure hand wand <sup>7</sup> , wear cotton overalls, over normal clothing, buttoned to the neck and wrist and a washable hat, elbow-length chemical resistant gloves, water resistant footwear and face shield or goggles
289b 290 292b 294c	If applying by boom spray equipment, wear cotton overalls buttoned to the neck and wrist (or equivalent clothing) and elbow-length chemical resistant gloves
289f 290 292d 294c 301 303	If applying by high pressure hand wand, wear cotton overalls, over normal clothing, buttoned to the neck and wrists (or equivalent clothing) and a washable hat, elbow-length chemical resistant gloves and full face-piece respirator with gas/dust cartridges
330 331 332	If clothing becomes contaminated with product or wet with spray remove clothing immediately
340 342	If product on skin, immediately wash area with soap and water
340 343	If product in eyes, wash it out immediately with water
350	After use and before eating, drinking or smoking, wash hands, arms and face thoroughly with soap and water

### Precautionary statements

The following precautionary statements are recommended for relevant product labels:

- 'do not apply by airblast equipment'

<sup>7</sup> Note that the OCS also recommended that these safety directions were also appropriate for bell injection of bananas.

- 'do not apply with boomspray equipment unless operators are protected by enclosed cabs'
- 'do not use open mixing/loading systems for boom spray and aerial equipment'
- 'do not apply by spray equipment carried on the back of the user'.

### **Re-entry statements**

The existing re-entry interval on the 800 g/L product labels as follows:

'Do not allow entry into treated areas for 1 day after treatment. When prior entry is necessary, wear cotton overalls buttoned to the neck and wrist and a washable hat, chemical resistant gloves and impervious footwear. Clothing must be laundered after each day's use'. There are no re-entry statements on the current 290 g/L product labels.

REIs for all crops appearing on the labels of both 290 g/L and 800 g/L products were estimated using the US Occupational Post-Application Risk Assessment Calculator (US EPA, 2000). The OCS recommended the following re-entry statements for omethoate products for agricultural use:

#### ***Field crops 290 g/L product (pasture, cereals, oilseed, legumes, lucerne, poppies and vetch)***

Do not allow entry into treated areas for 2 days for field crops (pasture, cereals, oilseed, legumes, lucerne, poppies and vetch). If prior entry is required, wear cotton overalls buttoned to the neck and wrist (or equivalent clothing) and gloves. Clothing must be laundered after each day's use.

#### ***Field crops 800 g/L products (cotton, lupins) <sup>8</sup>***

Do not allow entry into treated areas for 10 days for field crops (cotton and lupins). If prior entry is required, wear cotton overalls buttoned to the neck and wrist (or equivalent clothing) and gloves. Clothing must be laundered after each day's use.

#### ***Bananas (bell-injected or throat sprayed)***

Do not allow entry into treated areas for 17 days for bananas. If prior entry is required, wear cotton overalls buttoned to the neck and wrist (or equivalent clothing) and gloves. Clothing must be laundered after each day's use.

#### ***Root vegetables (onions, potatoes)***

Do not allow entry into treated areas for 9 days for root vegetables. If prior entry is required, wear cotton overalls buttoned to the neck and wrist (or equivalent clothing) and gloves. Clothing must be laundered after each day's use.

---

<sup>8</sup> The 800 g/L product use instructions for field crops have a higher maximum rate of ai/ha than the 290 g/L products.

### *Cut flowers*

Do not allow entry into treated areas for 30 days for cut flowers. If prior entry is required, wear cotton overalls buttoned to the neck and wrist (or equivalent clothing) and gloves. Clothing must be laundered after each day's use.

For orchard trees the OCS calculated re-entry periods of 17 days for irrigation and scouting in citrus and 16 – 27 days for hand harvesting. However as the OCS did not support continued use on orchard trees by airblast, a re-entry period was not recommended for these uses.

Following the publication of the OHS report in November 2015, the APVMA received comments from the nursery industry regarding the appropriate re-entry interval for nursery crops as opposed to hand-harvested cut flowers. The APVMA has taken these comments into consideration and is proposing a separate re-entry period of 9 days for nursery and greenhouse crops for all activities except hand harvesting of cut flowers. During this additional assessment the APVMA also noted that the supported use of 800 g/L omethoate products on ornamentals includes eucalyptus which may be grown in a forestry situation rather than as nursery plants. The APVMA proposes a re-entry period of 17 days for tree crops (forestry). The APVMA is proposing to amend the wording of the entry for cut flowers and to add additional re-entry intervals as follows:

### *Cut flowers hand harvesting*

Do not allow hand harvesting of cut flowers for 30 days. If prior entry is required for hand harvesting, wear cotton overalls buttoned to the neck and wrist (or equivalent clothing) and gloves. Clothing must be laundered after each day's use.

### *Floriculture nursery and greenhouse crops (ornamentals non-bearing) (except hand harvesting of cut flowers)*

Do not allow entry into treated areas for 9 days for nursery and greenhouse crops. If prior entry is required, wear cotton overalls buttoned to the neck and wrist (or equivalent clothing) and gloves. Clothing must be laundered after each day's use.

### *Tree crops (forestry)*

Do not allow entry into treated areas for 17 days for tree crops. If prior entry is required, wear cotton overalls buttoned to the neck and wrist (or equivalent clothing) and gloves. Clothing must be laundered after each day's use.

See Appendix D—additional re-entry interval calculations for nursery, greenhouse and forestry situations.

## **3.3 Residues, dietary risk assessment and trade**

The residue assessment for the reconsideration of omethoate was undertaken by the APVMA Residue team, which considered all the available and relevant information regarding residues of omethoate following treatment of crops

according to current label directions. This included residues data published in the 1990 JMPR report. The [Omethoate residues and dietary risk assessment report](#) (March 2016) is now available.

In conducting a dietary risk assessment, the exposures of different age groups within the population to omethoate are compared with the reference health standards set by the OCS, namely the ARfD<sup>9</sup> and the ADI<sup>10</sup>. Dietary exposures below these health standards are considered acceptable while those exceeding these health standards would be considered unacceptable. In evaluating the dietary exposure of omethoate residues to consumers, it was necessary to examine the intake of foods that would potentially contain residues of omethoate. The National Estimated Daily Intake (NEDI) and National Estimated Short-Term Intake (NESTI) calculations were undertaken in accordance with the World Health Organization (WHO)—United Nations Food and Agriculture Organization's (FAO) recommended guidelines as agreed with Food Standards Australia New Zealand (FSANZ).

The dietary risk assessment follows the revision of the Acceptable Daily Intake (ADI) from 0.0003 mg/kg/bw day to 0.0004 mg/kg bw/day and establishment of an Acute Reference Dose (ARfD) of 0.003 mg/kg bw for omethoate by the OCS.

### Supported uses of omethoate

The following use patterns remain acceptable from a residues (human health) perspective as they should not result in residues on food commodities:

- barrier spraying for red legged earth mite
- use on ornamentals.

### Uses of omethoate that are not supported

The following use patterns are not supported by the available residues data. It is proposed that these uses be deleted from labels.

### Acute dietary exposure concerns

For the following use patterns, unacceptable acute dietary risks have been identified on the basis of the available data. The APVMA cannot be satisfied that these uses would not be an undue hazard to the safety of people using anything containing its residues and they must be deleted:

- use on citrus and glen retreat mandarins
- use on apples and pears
- use on bananas by bell injection

---

<sup>9</sup>ARfD Acute Reference Dose. An estimate of the amount of a substance in food or drinking water, normally expressed on a body weight basis, that can be ingested in a period of 24 h or less without appreciable health risks to the consumer on the basis of all known facts at the time of the evaluation.

<sup>10</sup>ADI acceptable daily intake (for humans). a level of intake of a chemical that can be ingested daily over an entire lifetime without any appreciable health risks to the consumer on the basis of all known facts at the time of the evaluation

- use on potatoes.

The National Estimated Short Term Intake (NESTI) is used to calculate the estimated dietary risk. This is calculated separately for children (ages 2–6 years old) and the general population. Levels above 100 per cent of the ARfD are not acceptable. In some cases (such as bananas) the dietary risk is calculated on whole fruit residues as there were no residues data for the edible portion of the fruit.

**Table 6: Summary of NESTI calculations for existing omethoate uses with unacceptable dietary risks**

Commodity	MRL or HR (mg/kg)	% of ARfD	
		2–6 years	2+ years
FC 004 Oranges	0.41 (HR)	430	140
FP 0226 Apple	1.9 (hr)	2100	690
FP 0230 Pear	1.97 (hr)	2400	720
FI 0327 Banana (bell injection)	1.5 (hr)	1200	320
VR 0589 Potato	0.21 (hr)	200	80

The NESTI calculations are made in accordance with the deterministic method used by the JMPR with 97.5th percentile food consumption data derived from the 1995 National Nutrition Survey of Australia. NESTI calculations are conservative estimates of acute exposure (24 hour period) to chemical residues in food.

Results of the NESTI calculations based on the available data for the omethoate only uses—are summarised in the residues assessment. As noted above, unacceptable acute dietary risk have been identified for residues of omethoate on crops arising from uses on citrus and glen retreat mandarins, apples and pears, bananas by bell injection and potatoes.

### ***Chronic dietary exposure concerns***

There were no use patterns for omethoate supported by this residues assessment therefore a chronic dietary assessment for residues arising from the use of omethoate was not required. It is noted that the dimethoate reconsideration is ongoing and exposure to omethoate residues arising from the use of dimethoate will be considered as part of that reconsideration.

### **Insufficient residue data provided**

For the following use patterns, sufficient residues data were not made available to the APVMA. The APVMA cannot be satisfied that these uses would not be an undue hazard to the safety of people using anything containing its residues and they must be deleted:

- use on bananas by throat spray
- use on onions
- use on legume crops, including lupins and faba beans
- use on cereals

- use on oilseeds, including cotton and poppies
- use on pasture and pasture legumes
- use on lucerne
- use on vetch.

### **Home garden use on food producing plants is not supported**

Omethoate is approved for use in the home garden on a number of crops. Owing to concerns over acute (short term) dietary exposure to omethoate residues identified in commercial situations, the following approved home garden uses can no longer be supported:

- citrus
- apples
- vegetables
- herbs.

### **Residue-related aspects of trade**

Use of products containing omethoate in accordance with the label instructions for the supported uses is unlikely to pose a risk to Australian trade as those uses should not result in residues on food commodities.

### **MRL recommendations**

It is recommended that all current MRLs associated with the current uses of omethoate be deleted from the MRL Standard.

It is noted that, because the use of dimethoate may result in residues of omethoate in crops, the current omethoate MRLs that have been recommended for deletion will not be removed from the MRL Standard until the reconsideration of dimethoate has been finalised and appropriate omethoate MRLs have been recommended to cover the dimethoate only uses.

See Appendix C for a list of the recommended amendments to Table 1 and Table 4 of the APVMA MRL Standard.

.

## 4 PROPOSED RECONSIDERATION DECISIONS

On the basis of the evaluation of the submitted data and information, the APVMA proposes to make the following decisions with regard to the continued approval of the active constituent omethoate registration of omethoate products and their associated label approvals in Australia.

### 4.1 Affirm approvals of the active constituent

The APVMA proposes to affirm the approval of currently approved active constituents as listed in Table 12 in Appendix B.

### 4.2 Vary particulars of label approvals, and affirm products with varied labels

The APVMA proposes to find that it is NOT SATISFIED that the products listed in Table 13 in Appendix B currently meet the safety criteria as defined in sections 5A of the Agvet Code when they are used according to their current instructions for use.

However the APVMA also proposes to find that the relevant particulars of the label approvals for these products can be varied in such a way to amend the instructions for use of products so that they meet the safety criteria when used according to those varied instructions.

Therefore the APVMA is proposing to VARY the current label approvals for these products as noted in Column 5 of Table 13.

These variations to label instructions would satisfy the requirements for continued registration of products and the APVMA proposes that product registrations listed be affirmed once labels have been varied.

### 4.3 Supported uses

Taking into consideration the finding of the assessments listed above, the following uses of omethoate are supported as they are not likely to result in residues on food commodities:

- barrier spraying for red legged earth mite—agricultural products
- use on ornamentals—home garden and agricultural products.

### 4.4 Unsupported uses

Taking into consideration the finding of the assessments listed above, all uses of omethoate on food producing crops are not supported.

### 4.5 Label instructions

The amendments to the proposed label instructions for each group of products are listed in Appendix A.

In addition to the removal of unsupported use patterns from the directions for use of the products listed, the APVMA also proposes to amend the first aid and safety directions for each product and add precautions and re-entry intervals appropriate to the remaining use patterns.

#### **4.6 Phase-out periods**

The APVMA also proposes to determine that subsection 81(3) is to apply in respect of the earlier approved version of labels that have been varied and to allow a period of one year for their continued supply. After that period all product that is supplied should bear the varied approved label.

## 5 PROPOSED AMENDMENTS TO STANDARDS

### 5.1 Active constituent standards

The APVMA considers that the current active constituent standard, including impurity limits for omethoate is appropriate and does not propose making any changes to this standard.

### 5.2 Public health standards

These are established and maintained by the OCS. The APVMA proposes to recommend the following actions to the OCS when this reconsideration is finalised.

#### Acceptable daily intake (ADI)

Based on the work done in this reconsideration, the OCS has revised the ADI to 0.0004 mg/kg bw/d, based on a NOAEL of 0.04 mg/kg bw/d for inhibition of ChE activity in a two-year rat dietary study, using a 100-fold safety factor.

#### Acute reference dose (ARfD)

Prior to the commencement of this reconsideration there was no Australian ARfD value for omethoate. An ARfD of 0.003 mg/kg bw has now been established based on a NOEL of 0.25 mg/kg bw for inhibition of ChE activity in an acute oral neurotoxicity study in rats, incorporating a safety factor of 100.

#### Poisons schedule

Omethoate is currently listed in Schedule 7 of the SUSMP with a cut-off to Schedule 6 at 30% or less, or to Schedule 5 in pressurised spray packs containing 0.2% or less of omethoate. The OCS has advised that current poisons schedule for omethoate is appropriate and there are no changes proposed by the APVMA.

#### First aid instructions, warning statements and safety directions including personal protective equipment (PPE)

The APVMA recommends that the OCS adds the first aid instructions, precautions and safety directions recommended for this reconsideration to the First Aid Instruction and Safety Directions (FAISD) Handbook when this reconsideration is finalised.

### 5.3 Residues definition

The APVMA is not proposing to change the current residues definition for omethoate.

## 5.4 MRL Standards

The APVMA is proposing to delete all current MRLs associated with the current uses of omethoate from the MRL Standard once any phase out period for the supply of varied labels has ended.

It is noted that, because the use of dimethoate may result in residues of omethoate in crops, the current omethoate MRLs that have been recommended for deletion will not be removed from the MRL Standard until the reconsideration of dimethoate has been finalised, appropriate omethoate MRLs have been recommended to cover the dimethoate only uses and any periods for the legal use of previous versions of varied labels has ended.

Appendix C includes the list of the recommended amendments to Table 1 and Table 4 of the APVMA MRL Standard.



APPENDIXES

## APPENDIX A—SUMMARY OF PROPOSED DIRECTIONS FOR USE FOR PRODUCTS CONTAINING OMETHOATE

### Proposed changes to the directions for use 2 g/L aerosol home garden product

#### Use patterns to be deleted

Table 7: Uses proposed for deletion from the 2 g/L home garden product

Crop	Pest	Rate	WHP	Changes proposed
<b>Food producing crops</b>				
Vegetables, herbs	Aphids, thrips, whiteflies, caterpillars (eg cabbage white butterfly, cabbage moth)	Spray foliage thoroughly from a distance of 30 cm	7 days	Delete
Citrus	Citrus leaf miner, aphids, mealybug, thrips, bronze orange bug			Delete
Apples	Thrips, woolly aphid, mites, codling moth			Delete

#### Use patterns to remain on the label

Table 8: Uses that may remain on the label of the 2 g/L home garden product

Crop	Pest	Rate	WHP	Changes proposed
<b>Use Type</b>				
Flowers, ornamental trees and shrubs	Aphids, thrips, caterpillars, bugs (eg lacebug), mealybugs, mites, whiteflies	Spray foliage thoroughly from a distance of 30 cm	N/A	Retain
Eucalyptus	Leaf eating beetles	Spray foliage thoroughly from a distance of 30 cm	N/A	Retain

#### First aid instructions 2 g/L home garden product

If sprayed on skin, wash thoroughly. If sprayed in mouth, rinse mouth with water. If poisoning occurs, contact a doctor or Poisons Information Centre. phone Australia 131 126, New Zealand 0800 764 766.

#### Safety directions 2 g/L home garden product

Will irritate the eyes. May irritate the skin. Avoid contact with eyes and skin. Repeated exposure may cause allergic disorders. If product on skin, immediately wash area with soap and water. If product in eyes, wash it out immediately with water. Wash hands after use.

## Proposed changes to the directions for use 290 g/L agricultural products

### Use patterns to be deleted

Table 9: Uses proposed for deletion from the labels of 290 g/L agricultural products

Crop	Pest	Rate	WHP	Changes proposed
<b>Field crops</b>				
Pastures, cereals, oilseeds and legume crops	Redlegged earth mite	100 mL/ha	Graze or cut for stock food 1 day	Delete
	Blue oat mite		Harvest—no statement	
	Lucerne flea			
Pasture legumes, lucerne, faba bean, Vetch	Bluegreen aphid	100 to 200 mL/ha	Graze or cut for stock food 1 day	Delete
	Cowpea aphid		Harvest—no statement	
Pasture	Spotted clover aphid	300 mL/ha	Graze or cut for stock food 1 day Harvest—no statement	Delete
Poppy	Redlegged earth mite	100 mL/ha	Harvest—no statement	Delete

### Use patterns to remain on the label

Table 10: Uses proposed to remain on labels of 290 g/L agricultural product labels

Crop	Pest	Rate	WHP	Changes proposed
<b>Use Type</b>				
Barrier spraying	Redlegged earth mite	300 mL/ha	Graze or cut for stock food 1 day	Retain: note new safety directions and re-entry

### First aid instructions

If swallowed, splashed on skin or in eyes, or inhaled, contact a Poisons Information Centre (phone Australia 131 126) or a doctor at once. Remove any contaminated clothing and wash skin thoroughly. If swallowed, activated charcoal may be advised. Give atropine if instructed.

### Safety directions

Product and spray are poisonous if absorbed by skin contact or inhaled or swallowed. Will irritate the eyes. Repeated exposure may cause allergic disorders. Sensitive workers should use protective clothing. Repeated minor exposure may have a cumulative poisoning effect. Avoid contact with eyes and skin and clothing. Do not inhale spray mist.

When opening the container and preparing spray, wear cotton overalls buttoned to the neck and wrist (or equivalent clothing), elbow-length chemical resistant gloves, water resistant footwear and face shield or goggles.

When using the prepared spray, wear cotton overalls buttoned to the neck and wrist (or equivalent clothing) and elbow-length chemical resistant gloves.

If clothing becomes contaminated with product or wet with spray remove clothing immediately. If product on skin, immediately wash area with soap and water. If product in eyes, wash it out immediately with water. After use and before eating, drinking or smoking, wash hands, arms and face thoroughly with soap and water. After each day's use, wash gloves and face shield or goggles and contaminated clothing.

### **Precautions**

Do not apply with boomspray equipment unless operators are protected by enclosed cabs.

Do not use open mixing/loading systems for boom spray and aerial equipment.

Do not apply by spray equipment carried on the back of the user.

### **Re-entry intervals**

As appropriate for the remaining use as a barrier spray.

#### ***Field crops 290 g/L product (pasture, cereals, oilseed, legumes, lucerne, poppies and vetch)***

Do not allow entry into treated areas for two days. If prior entry is required, wear cotton overalls buttoned to the neck and wrist (or equivalent clothing) and gloves. Clothing must be laundered after each day's use.

### **Withholding periods**

Not applicable as the remaining uses should not result in residues on food commodities.

## Proposed changes to the directions for use for 800g/L agricultural products

### Use patterns to be deleted

Table 8: Uses proposed for deletion from the labels of 800 g/L agricultural products

Crop	Pest	Rate	WHP	Changes proposed
<b>Tree and vine crops</b>				
Apples, Pears	Two spotted mite, European red mite, Woolly aphid	65 mL /100L to 75 mL /100L	7 days	Delete:  Also note that on OHS grounds DO NOT apply by airblast
Citrus	California red scale, aphids	50 mL/100L to 75 mL/100L	7 days	Delete:  Also note that on OHS grounds DO NOT apply by airblast
Glen Retreat mandarins	California red scale	65 mL/100L	7 days	Delete:  Also note that on OHS grounds DO NOT apply by airblast
<b>Bananas</b>				
Banana	Corky scab caused by flower thrips	Bell injection 50mL/5L 40 to 60 mL of mix	6 weeks	Delete
		Individual plant treatment 125mL/100L 500ml of spray mix	4 days	Delete
<b>Field crops</b>				
Cotton	Thrips, mirids, aphids, jassids	140-280 mL/ha	21 days	Delete
Lupins WA only	Blue green aphid, cowpea aphid, green peach aphid (suppression only)	250 mL/ha	14 days	Delete
<b>Vegetables</b>				
Onions	Thrips,  Lucerne flea	700 mL/ha or 65 mL/100L  35 mL/ha	14 days	Delete
Potatoes	Aphids	75mL/100L	7 days	Delete

## Use patterns to remain on the label

Table 9: Uses proposed to remain on labels of 800 g/L agricultural products

Crop	Pest	Of	Rate	Changes proposed
<b>Ornamentals</b>				
Carnations, chrysanthemums, Pelargoniums, Roses, Callistemons, Eucalyptus spp., Grevillea spp., paperbarks, wattles	Aphids, lace bugs, mealybugs, mites, thrips, whiteflies		75 mL/100 L	Retain: note new safety directions and re-entry

## First aid instructions

If swallowed, splashed on skin or in eyes, or inhaled, contact a Poisons Information Centre (phone Australia 131 126) or a doctor at once. Remove any contaminated clothing and wash skin thoroughly. If swallowed, activated charcoal may be advised. Give atropine if instructed.

## Safety directions

Very dangerous, particularly the concentrate. Product and spray are poisonous if absorbed by skin contact or inhaled or swallowed. Will irritate the eyes. Repeated exposure may cause allergic disorders. Sensitive workers should use protective clothing. Repeated minor exposure may have a cumulative poisoning effect. Avoid contact with eyes and skin and clothing. Do not inhale spray mist.

When opening the container and preparing spray for aerial spraying equipment wear cotton overalls, over normal clothing, buttoned to the neck and wrist and a washable hat, elbow-length chemical resistant gloves, water resistant footwear and full face-piece respirator with gas/dust cartridges.

When opening the container and preparing spray for boom spray equipment, wear cotton overalls buttoned to the neck and wrist (or equivalent clothing), elbow-length chemical resistant gloves, water resistant footwear and face shield or goggles.

When opening the container and preparing spray for high pressure hand wand, wear cotton overalls, over normal clothing, buttoned to the neck and wrist and a washable hat, elbow-length chemical resistant gloves, water resistant footwear and face shield or goggles.

If applying by boom spray equipment, wear cotton overalls buttoned to the neck and wrist (or equivalent clothing) and elbow-length chemical resistant gloves.

If applying by high pressure hand wand, wear cotton overalls, over normal clothing, buttoned to the neck and wrists (or equivalent clothing) and a washable hat, elbow-length chemical resistant gloves and full face-piece respirator with gas/dust cartridges.

If clothing becomes contaminated with product or wet with spray remove clothing immediately. If product on skin, immediately wash area with soap and water. If product in eyes, wash it out immediately with water. After use and before eating, drinking or smoking, wash hands, arms and face thoroughly with soap and water.

### **Precautions**

Do not apply by airblast equipment.

Do not apply with boomspray equipment unless operators are protected by enclosed cabs.

Do not use open mixing/loading systems for boom spray and aerial equipment.

Do not apply by spray equipment carried on the back of the user.

### **Re-entry intervals**

#### ***Cut flowers hand harvesting***

Do not allow hand harvesting of cut flowers for 30 days. If prior entry is required for hand harvesting, wear cotton overalls buttoned to the neck and wrist (or equivalent clothing) and gloves. Clothing must be laundered after each day's use.

#### ***Floriculture, nursery and greenhouse crops (ornamentals non-bearing) (except hand harvesting of cut flowers)***

Do not allow entry into treated areas for 9 days for nursery and greenhouse crops. If prior entry is required, wear cotton overalls buttoned to the neck and wrist (or equivalent clothing) and gloves. Clothing must be laundered after each day's use.

#### ***Tree crops (forestry)***

Do not allow entry into treated areas for 17 days for tree crops. If prior entry is required, wear cotton overalls buttoned to the neck and wrist (or equivalent clothing) and gloves. Clothing must be laundered after each day's use.

### **Withholding periods**

Not applicable as the remaining uses should not result in residues on food commodities.

## APPENDIX B—LIST OF ACTIVE CONSTITUENTS, PRODUCT REGISTRATIONS AND LABEL APPROVALS

### Active approvals to be affirmed

Table 10: Active approvals to be affirmed

Approval number	Active constituent name	Approval holder
51857	Omethoate	Arysta Lifescience North America LLC
59132	Omethoate	Imtrade Australia Pty Ltd
69005	Omethoate	Agroserve Pty Ltd
69935	Omethoate	Arysta Lifescience North America LLC

### Product registrations to be affirmed following variation of approved labels

#### Also label approvals to be varied

Table 11: Product registrations to be affirmed following variation of approved labels

Product number	Product name	Registration holder	Label approvals to be varied
33051	Folimat Garden Insecticide	Arysta Lifescience North America LLC	1106
33055	Folimat 800 Insecticide Spray	Arysta Lifescience North America LLC	01, 0499, 1099, 0701, 0803,0706
45672	Le-Mat 290 SL Insecticide (Label names include Arysta O-Mat 290 SL Insecticide)	Arysta Lifescience North America LLC	3975, /02, 02, 1297, 1099, 0103, 0706, 58076,105622
59576	All-Mitey 290 SL Insecticide	Fmc Australasia Pty Ltd	0000, 0106,0609
59872	Chemag Sentinel 800 Insecticide Spray	Imtrade Australia Pty Ltd	0905
61681	AW Omethoate 290 SL Insecticide	Agri West Pty Limited	0107
61682	Mite Master 290 Insecticide	Grow Choice Pty Limited	0107
62022	4Farmers Omethoate 290 Insecticide	4 Farmers Australia Pty Ltd	0509
63676	Imtrade Omen 290 Insecticide	Imtrade Australia Pty Ltd	0609,102502
65414	Farmalinx Ometho-Mite 290 SL Insecticide	Farmalinx Pty Ltd	50861
66938	Mission Omethoate 290 Insecticide	Mission Bell Holdings Pty Ltd	54727

Product number	Product name	Registration holder	Label approvals to be varied
68169	FMC Omethoate 290 Miticide	FMC Australasia Pty Ltd	57680
69096	Rainbow Omethoate 290 Insecticide	Shandong Rainbow International Co., Ltd.	59972
69166	Sabakem Omethoate 290SL Miticide & Insecticide	Sabakem Pty Ltd	60113
69703	Conquest Ovid 290 Insecticide	Conquest Crop Protection Pty Ltd	61468
69899	K-Mite 800 Insecticide	Shandong Rainbow International Co., Ltd.	62002
70131	Apparent Matey 290 Insecticide	Apparent Pty. Ltd.	62585,102431
80532	Genfarm Omethoate 290 Insecticide	Landmark Operations Limited	101058
80673	Orbit 290 SL Insecticide	Adama Australia Pty Limited	101373
80778	AC Omethoate 290 Insecticide	Axichem Pty Ltd	101616
81882	Relyon Omethon 290 Insecticide	Ruralco Holdings Limited	104335
82095	O-Mat 290 SL Insecticide	Arysta Lifescience Australia Pty Ltd	104990

## Active approvals and product registrations initially included in the reconsideration—now discontinued

No further regulatory action required as these approvals and registrations no longer in force

Table 12: Active approvals included in the reconsideration that were discontinued- no further regulatory action required

Approval number	Active constituent name	Approval holder	
44315	Omethoate	Bayer Cropscience Pty Ltd	Approval voluntarily cancelled May 2010

Table 13: Product registrations approvals that were included in the reconsideration that are no longer registered- no further regulatory action required

Product number	Product name	Holder	Comment
33054	Folimat 50 Garden Insecticide	Arysta Lifescience North America Llc	Registration not renewed 30 June 2007

## APPENDIX C—RECOMMENDED AMENDMENTS TO TABLE 1 AND TABLE 4 OF THE APVMA MRL STANDARD

Table 14: Recommended amendments to Table 1 of the APVMA MRL Standard

Compound	Food	MRL (mg/kg)	
<b>Omethoate</b>			
<b>DELETE:</b>	MO 0105	Edible offal (mammalian)	*0.05
		Fruits	2
	VD 0545	Lupin (dry)	0.1
	VO 0445	Peppers, sweet [capsicums]	1
	VO 0448	Tomato	1
		Vegetables [except lupin; peppers, sweet; tomato]	2
<b>ADD:</b>	Appropriate MRLs as recommended in the review of dimethoate		

Table 15: Recommended amendments to Table 4 of the APVMA MRL Standard

Compound	Animal feed commodity	MRL (mg/kg)	
<b>Omethoate</b>			
<b>DELETE:</b>	AL 0157	Legume animal feeds [fresh weight]	20
	AL 0545	Lupin, forage	0.5
	AS 0161	Straw, fodder (dry) and hay of cereal grains and other grass-like plants	20
	AM 0165	Miscellaneous fodder and forage crops [fresh weight]	20
<b>ADD:</b>	Appropriate MRLs as recommended in the review of dimethoate		

## APPENDIX D—ADDITIONAL RE-ENTRY INTERVAL CALCULATIONS FOR NURSERY, GREENHOUSE AND FORESTRY SITUATIONS

Following the APVMA publication of the OHS report, comments were received questioning the suitability of the 30 day re-entry interval for the hand harvesting of cut flowers for all other nursery crops. The APVMA undertook to calculate an appropriate re-entry interval for all other (lower exposure) activities in floriculture, nursery and greenhouse crops. As omethoate may also be used on eucalyptus or other tree plantations a re-entry interval has also been calculated for tree crops (Forestry).

Table 16: Calculated re-entry periods for ornamental crops

Crop or situation as described on label	Specific situation	Relevant activities	REI
Carnations, chrysanthemums, Pelargoniums, Roses, Callistemons, Eucalyptus spp., Grevillea spp., paperbarks and wattles	Floriculture crops	Container moving, grafting, hand harvesting, hand pruning, scouting, hand weeding, transplanting, propagating, pinching, tying/training  (not hand harvesting)	9 days
	Nursery crop (ornamentals, non-bearing plants)	Container moving, grafting, hand harvesting, hand pruning, scouting, hand weeding, transplanting, propagating, pinching, tying/training	9 days
	Greenhouse crop (ornamentals, non-bearing plants)	Container moving, grafting, hand harvesting, hand pruning, scouting, hand weeding, transplanting, propagating, pinching, tying/training	9 days
	Tree crops (forestry)	Scouting	17 days

The US EPA calculator (US EPA 2013) default assumptions have been used for these estimations of REIs because there were no data provided regarding measured worker exposures or dislodgeable foliar residues (DFR) during or after the use of omethoate:

- initial dislodgeable foliar residues (DFR): 25% of the omethoate applied
- dissipation rate/day: 10%.

The application rates used were the equivalent of 0.9 kg ai/ha of treated foliage. For forestry this is equivalent to 1500 L/ha of a spray mix of 75 ml product/100 L. For floriculture, nursery and greenhouse crops this is equivalent to the treatment of 0.2 ha with 300 L of spray mix of 75 ml product/100 L.

The No Observable Adverse Effect Level (NOAEL) used was 2.5 mg/kg bw/day from a three week dermal exposure study in rabbits (Flucke and Luckhaus 1979) and an acceptable Margin Of Exposure (MOE) was 100 or more.

## ABBREVIATIONS

ADI	Acceptable daily intake (for humans) a level of intake of a chemical that can be ingested daily over an entire lifetime without any appreciable risk to health
AChE	Acetyl cholinesterase—an enzyme essential for the regulation of nerve tissue function
Agvet Code	Agricultural and Veterinary Chemicals Code, Schedule to the <i>Agricultural and Veterinary Chemicals Code Act 1994</i>
APVMA	Australian Pesticides and Veterinary Medicines Authority
ARfD	acute reference dose the estimated amount of a substance in food or drinking-water, (expressed on a body weight basis), that can be ingested or absorbed over 24 hours or less, without appreciable health risk
ChE	Cholinesterase
EC	Emulsifiable concentrate—a liquid formulation
EU	European Union
FAISD	First Aid Instruction and Safety Directions
GAP	good agricultural practice
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
MOE	Margin of exposure a measure of occupational exposure to a compound being the ratio of the no-observed effect-level to the estimated exposure dose
MRL	maximum residue limit
NEDI	National estimated daily intake (of chemical)
NESTI	National Estimated Short-Term Intake
NOAEL	no observable adverse effect level
NOEL	No Observed Effect Level
NOEC	No Observable Effect Concentration (applicable to inhalational studies)
OCS	Office of Chemical Safety within the Australian Government Department of Health
OHS	occupational health and safety
OP	organophosphorus pesticide
PPE	personal protective equipment such as gloves and overalls
SC	suspension concentrate
SUSMP	Standard for the Uniform Scheduling of Medicines and Poisons (formerly the Standard for the Uniform Scheduling of Drugs and Poisons)

---

US	United States
US EPA	US Environmental Protection Agency
WHO	World Health Organization

---