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**AGRICULTURAL AND  
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**Australian Government**

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**Australian Pesticides and  
Veterinary Medicines Authority**

The *Agricultural and Veterinary Chemical Code Act 1994* (the Act) commenced on 15 March 1995. The Agricultural and Veterinary Chemicals Code (the Agvet Code) scheduled to the Act requires notices to be published in the *Gazette* containing details of the registration of agricultural and veterinary chemical products and other approvals granted by the Australian Pesticides and Veterinary Medicines Authority. The Agvet Code and related legislation also requires certain other notices to be published in the *Gazette*. A reference to Agvet Codes in this publication is a reference to the Agvet Code in each state and territory jurisdiction.

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## GENERAL INFORMATION

The *APVMA (Australian Pesticides and Veterinary Medicines Authority) Gazette* is published fortnightly and contains details of the registration of agricultural and veterinary chemicals products and other approvals granted by the APVMA, notices as required by the Agricultural and Veterinary Chemicals Code (the Agvet Code) and related legislation and a range of regulatory material issued by the APVMA.

Pursuant to section 8J(1) of the Agvet Code, the APVMA has decided that it is unnecessary to publish details of applications made for the purpose of notifying minor variations to registration details. The APVMA will however report notifications activity in quarterly statistical reports.

## DISTRIBUTION AND SUBSCRIPTION

The *APVMA Gazette* is published in electronic format only and is available from the APVMA website,

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## Regulatory Decisions for the Reconsideration of Approvals and Registrations of Omethoate

The APVMA, in accordance with Part 2, Division 4, of the Agricultural and Veterinary Chemicals Code scheduled to the *Agricultural and Veterinary Chemicals Code Act 1994* (Agvet Code), has reconsidered the approvals of the active constituent omethoate, the registrations of products containing omethoate and the label approvals of those products. This notice is published in accordance with paragraph 34AC(1)(b) of the Agvet Code.

Omethoate is a systemic organophosphorus (OP) pesticide used to control insects and mites in the home garden, and in agricultural situations such as horticulture and broadacre cropping.

Omethoate active approvals, product registrations and associated label approvals (see Tables 1 and 2) were placed under reconsideration in April 2004 because of concerns about toxicology, occupational health and safety, dietary exposure to residues and trade.

### RECONSIDERATION DECISIONS

The APVMA has:

- under s.34(1)(a) affirmed the active constituent approvals of omethoate outlined in Table 1
- in accordance with s.34A(1)(a) and (b), varied the relevant particulars of the label approvals, and affirmed the omethoate product registrations and varied label approvals as listed in Table (2).

The variations to the relevant particulars of label approvals include:

- deletion of all horticultural, pasture, grain legume, cereal and home garden uses, that may result in residues of omethoate on edible crops or crops consumed by food producing animals
- retention of the use of omethoate on ornamental plants
- retention of the use of omethoate as a barrier spray against red-legged earth mite around broad-acre crops
- amendments to the safety directions and first aid instructions for all product labels
- addition of re-entry periods to protect workers re-entering treated areas.

For details, see Omethoate review decisions report (available at [apvma.gov.au/node/12661](http://apvma.gov.au/node/12661)).

### REASONS FOR THE AFFIRMATION OF APPROVALS AND REGISTRATIONS

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, 5C and 5D 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, and
- would not unduly prejudice trade or commerce between Australia and places outside Australia.

Thus, for affirming the approvals and registrations, the APVMA must be satisfied that the safety criteria under section 5A, the trade criteria under section 5C and the labelling criteria under section 5D are met.

After consideration of all data and information, and submissions from industry and the public, the APVMA determined that:

- The instructions for use for products containing omethoate do not adequately protect workers involved in mixing / loading and spraying of omethoate because the estimated exposure of workers exceeds the established safe levels for use with open mixing/loading systems for boom spray and aerial equipment, application by air blast, application by boom spray (open cabs), application by equipment carried on the back of the user and aerial application at the higher rates used on eucalypts
- The approved use patterns for citrus, apples, pears, bananas (bell injection) and potatoes were likely to result in consumers being exposed to omethoate at levels exceeding the health based guidance values
- There is insufficient residues data for the APVMA to be satisfied that the approved use for bananas (throat spray), onion, legume crops (pulses), oilseeds, and fodder crops would meet the safety criteria.
- The use patterns on the label of the home garden product included use on crops identified above as having unacceptable dietary risk or with insufficient residues data to affirm their safety.

Accordingly, the APVMA was not satisfied that the active constituent and product met the safety criteria under sections 5A(1)(a) and (b), and that the labels met the labelling criteria under s.5D.

However, the APVMA determined that if the instructions for use for products containing omethoate are varied in the following manner, then the use of products would meet the safety criteria under s. 5A(1)(a) and (b), and labelling criteria under s.5D.

- Delete the use patterns for citrus, apples, pears, bananas (bell injection and throat spray), potatoes, onion, legume crops (pulses), oilseeds, and fodder crops so that use of the product would not be an undue hazard to people using anything containing its residues.
- The exposure of workers during mixing / loading and application can be reduced to acceptable levels for the remaining use patterns by using closed mixing / loading systems for certain use patterns, prohibiting certain application methods, wearing personal protective equipment (PPE) and using engineering controls such as a closed cab tractor;
- The exposure of workers re-entering treated areas can be reduced to acceptable levels if the re-entry periods and instructions for prior entry recommended for inclusion on the varied labels were followed.

- The remaining use patterns recommended for inclusion on the varied labels (barrier spraying for red-legged earth mites and use on ornamentals) are acceptable from a residues perspective as they should not result in residues on food commodities.

The APVMA, accordingly, varied the relevant particulars of the label approvals to reflect the above.

The APVMA has determined that the varied labels contain adequate instructions as specified in section 5D of the Agvet Code.

The original basis of reconsideration of omethoate did not include concerns over harmful effects on animals, plants or things or to the environment 5A(1)(c), or efficacy 5(B) because at that time, there was no information to suggest this might be the case; and no new information has become available since the commencement of the reconsideration indicate that this position needs to be changed.

#### **Affirmation of active constituent approvals**

The APVMA has determined that the use of the active constituent omethoate, in accordance with any instructions approved or to be approved by the APVMA, is not, or would not be, an undue hazard to the safety of people exposed to it during its handling or people using anything containing its residues and is not or would not be, likely to have an effect that is harmful to human beings. The APVMA has, therefore, affirmed the active constituent approvals of omethoate.

The reasons for this decision are that:

- the Toxicology Report of November 2011 concluded that there were no toxicological grounds to object to the ongoing approval of the active constituent omethoate
- health based guidance values (ADI and ARfD) have been established in the Toxicology Report for both long and short term dietary exposure to omethoate respectively and
- safe occupational exposure limits for short to medium term occupational exposure to omethoate have been established.

#### **Affirmation of product registrations following variation of the instructions for use of products**

The APVMA has affirmed the registrations of omethoate products following the variation of the instruction for use. The reasons for this decision are:

- the conclusions in the OHS report that the exposure of workers during mixing / loading and application of products according to the new instructions for use will not exceed safe occupational exposure limits
- the conclusions in the OHS report that the exposure of workers re-entering treated areas according to the new instructions for use will not exceed safe occupational exposure limits
- the conclusions in the residues report that remaining use patterns on the varied labels (barrier spraying for red-legged earth mites and use on ornamentals) should not result in residues on food commodities or be likely to result in significant residues on any crop that may be fed to animals and therefore do not pose any significant risk to trade .

The APVMA has also determined that use of the product, in accordance with the new instructions will not, unduly prejudice trade or commerce between Australia and places outside Australia because:

- the proposed varied instructions for the use of products should not result in residues on any food commodities or be likely to result in significant residues on any crop that may be fed to animals.

#### **Affirmation of new varied labels**

The APVMA determined that the labels could be varied so that they would contain adequate instructions as specified in section 5D of the Agvet Code. The APVMA has varied the relevant label particulars (namely the instructions for use of products) of the labels of omethoate products and has affirmed the approvals of those labels as varied.

#### **FURTHER DETAILS**

Further details can be found in the [omethoate regulatory decision report](#). Copies of the report or further information can be obtained from the APVMA website, [www.apvma.gov.au](http://www.apvma.gov.au) or by request to the Chemical Review Contact Officer on +02 6210 4749 or [chemicalreview@apvma.gov.au](mailto:chemicalreview@apvma.gov.au)

#### **SUPPLY OF PRODUCT BEARING PREVIOUSLY APPROVED LABELS**

The APVMA has determined that subsection 81(3) of the Agvet Code is to apply in respect of the earlier approved version of labels that have been varied as a result of this reconsideration and that supply may take place no later than 12 months after 1 December 2016. After that period, ending 1 December 2017, all product that is supplied should bear the varied approved label.

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**ATTACHMENT 1: ACTIVE CONSTITUENTS, PRODUCTS REGISTRATIONS AND LABEL APPROVALS INCLUDED IN THE RECONSIDERATION**

**Table 1: Active constituent approvals affirmed**

Approval no.	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

**Table 2: Omethoate product registrations and associated label approvals varied and then affirmed**

Product no.	Product name	Registrant	Label approvals that have been varied <sup>1</sup>	Current label approvals
33051	FOLIMAT GARDEN INSECTICIDE	ARYSTA LIFESCIENCE NORTH AMERICA LLC	1106	33051/RV1216
33055	FOLIMAT 800 INSECTICIDE SPRAY	ARYSTA LIFESCIENCE NORTH AMERICA LLC	01, 0499, 1099, 0701, 0803, 0706	33055/RV1216_01 33055/RV1216_02
45672	LE-MAT 290 SL INSECTICIDE	ARYSTA LIFESCIENCE NORTH AMERICA LLC	3975, /02, 02, 1297, 1099, 0103, 0706, 58076	45672/RV1216_01 45672/RV1216_02
59576	ALL-MITEY 290 SL INSECTICIDE	FMC AUSTRALASIA PTY LTD	0000, 0106, 0609	59576/RV1216
59872	CHEMAG SENTINEL 800 INSECTICIDE SPRAY	IMTRADE AUSTRALIA PTY LTD	0905	59872/RV1216
61682	MITE MASTER 290 INSECTICIDE	GROW CHOICE PTY LIMITED	0107	61682/RV1216
62022	4FARMERS OMETHOATE 290 INSECTICIDE	4 FARMERS AUSTRALIA PTY LTD	0509	62022/RV1216
63676	IMTRADE OMEN 290 INSECTICIDE	IMTRADE AUSTRALIA PTY LTD	0609, 102502	63676/RV1216
65414	FARMALINX OMETHO-MITE 290 SL INSECTICIDE	FARMALINX PTY LTD	50861	65414/RV1216
66938	MISSION OMETHOATE 290 INSECTICIDE	MISSION BELL HOLDINGS PTY LTD	54727	66938/RV1216

<sup>1</sup> These label approvals have been varied. These labels are therefore, no longer currently approved and are subject to a 12 month period of permitted supply.

Product no.	Product name	Registrant	Label approvals that have been varied <sup>1</sup>	Current label approvals
68169	FMC OMETHOATE 290 MITICIDE	FMC AUSTRALASIA PTY LTD	57680	68169/RV1216
69096	RAINBOW OMETHOATE 290 INSECTICIDE	SHANDONG RAINBOW INTERNATIONAL CO., LTD	59972	69096/RV1216
69166	SABAKEM OMETHOATE 290SL MITICIDE & INSECTICIDE	SABAKEM PTY LTD	60113	69166/RV1216
69703	CONQUEST OVID 290 INSECTICIDE	CONQUEST CROP PROTECTION PTY LTD	61468	69703/RV1216
69899	K-MITE 800 INSECTICIDE	SHANDONG RAINBOW INTERNATIONAL CO., LTD	62002	69899/RV1216
70131	APPARENT MATEY 290 INSECTICIDE	APPARENT PTY. LTD	62585, 102431	70131/RV1216
80532	GENFARM OMETHOATE 290 INSECTICIDE	LANDMARK OPERATIONS LIMITED	101058	80532/RV1216
80673	ORBIT 290 SL INSECTICIDE	ADAMA AUSTRALIA PTY LIMITED	101373	80673/RV1216
80778	AC OMETHOATE 290 INSECTICIDE	AXICHEM PTY LTD	101616	80778/RV1216
81882	RELYON OMETHON 290 INSECTICIDE	RURALCO HOLDINGS LIMITED	104335	81882/RV1216
82095	O-MAT 290 SL INSECTICIDE	ARYSTA LIFESCIENCE AUSTRALIA PTY LTD	104990	82095/RV1216