



Australian Pesticides &
Veterinary Medicines Authority

**The Reconsideration of Approvals and Registrations
Relating to Dimethoate and Omethoate**

REVIEW SCOPE DOCUMENT

APRIL 2004

**Australian Pesticides &
Veterinary Medicines Authority**

**Canberra
Australia**

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This scope document for the reviews of dimethoate and omethoate is published by the Australian Pesticides and Veterinary Medicines Authority. For further information about this review or the Pesticides Review Program, contact:

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Review Scope Document Dimethoate and Omethoate

SUMMARY

The APVMA has initiated its reconsideration of the approvals of the active constituent dimethoate, the registrations of products containing dimethoate and the approvals of associated labels. The APVMA has similarly initiated its reconsideration of the approvals of the active constituent omethoate, the registrations of products containing omethoate and the approvals of associated labels. The reconsideration of each of these related chemicals will be undertaken in conjunction as the reasons for review relate to similar concerns, as both chemicals have similar chemistry and the review scopes are the same. This document defines the scope of the matters of concern to the APVMA, outlines the kind of information the APVMA requires to conduct comprehensive scientific assessments of dimethoate and omethoate and invites submissions from the public.

Approvals of the active constituents dimethoate and omethoate are being reconsidered because of toxicological concerns. Products containing dimethoate and products containing omethoate and all associated labels are being reviewed because of toxicological, occupational health and safety and residue concern.

The decision from the reconsiderations will be made after the APVMA assesses all the data and other information provided to it for this purpose – the assessment process is hereafter referred to as ‘review’

The APVMA will review the following aspects of the active constituent approvals, product registrations and label approvals for each of dimethoate and omethoate:

- a) Toxicology:
 - the potential for acute and chronic toxicity, that could have an effect that is harmful to human beings;
 - b) Occupational Health and Safety:
 - the potential for short and intermediate term occupational exposure to hazards to human safety; and
 - c) Trade:
 - the potential for residues in export commodities that exceed the tolerances of importing countries, that could unduly prejudice trade or commerce between Australia and places outside Australia; and
 - d) Residues:
 - assess dietary exposure and determine maximum residue limits, that could pose an undue hazard to the safety of people exposed to it during its handling or people using anything containing its residues.
- The APVMA will also consider whether product labels carry adequate instructions and warning statements.

A decision on the reconsideration will be made after the APVMA has reviewed all of the data and other information provided to it for this purpose

1 INTRODUCTION

Section 31 the Agvet Codes, authorises the APVMA to reconsider:

- (a) the approval of an active constituent for a proposed or existing chemical product;
- (b) the registration of a chemical product; and
- (c) the approval of a label for containers for a chemical product.

The APVMA has decided to reconsider the approvals of the active constituents dimethoate and omethoate, the registrations of products containing dimethoate and omethoate and the approvals of associated labels, based on concerns related to toxicology, occupational health and safety, residues and trade.

2 REGULATORY STATUS AND USE PATTERNS OF DIMETHOATE AND OMETHOATE IN AUSTRALIA

2.1 Active Constituent and Products

At the commencement of the review, there were:

- two (2) approvals of omethoate active constituent (Attachment 1, Table 1)
- four (4) registered products containing the active constituent omethoate, (Attachment 1, Table 2); and
- Nine (9) approvals of dimethoate active constituent and two (2) manufacturing concentrates (Attachment 2, Table 1); and
- 24 registered products containing the active constituent dimethoate (Attachment 2, Table 2).

Formulations of registered products of dimethoate and omethoate include two home garden products in aerosol form, with the remainder emulsifiable concentrates (EC). The products are registered in all Australian states. These active constituent approvals and product registrations are subject to this review. It should be noted that any active constituent approvals and product registrations that occur after the commencement of the review would be made subject to the outcomes of the review.

2.2 Current use patterns

Dimethoate (*O,O*-dimethyl *S*-methylcarbamoylmethyl phosphorodithioate) is a broad use, systemic organophosphate insecticide/acaricide. Products containing dimethoate are registered for use in a broad range of agricultural and home garden situations. Products are registered for more than 200 use patterns and to control more than 80 insect pest species. In agriculture dimethoate is used both as a pre-harvest and post-harvest insecticide in orchard and field crops. It is applied by ground boom, airblast, backpack sprayer and as a fruit dip. In the home garden dimethoate products are normally applied by hand spray used to control many common insect pests in a wide range of vegetables, flowers and fruit crops, as well as on ornamentals.

Omethoate (*O,O*-dimethyl *S*-methylcarbamoylmethyl phosphorothioate) is the oxygen analogue of dimethoate. It is a broad use systemic organophosphate insecticide and acaricide. Products containing omethoate are used to control a range of insects and mites in horticultural, cereal and field crops and pastures, as well as in the home garden. There are four registered products containing the active constituent omethoate. Two products are used in the home garden to control insect pest of citrus, herbs, apples, vegetables, flowers and ornamentals. Of

these two home garden products one is applied as an aerosol and the other is applied by hand spray.

There are two products registered for use in agricultural crops. One product is registered for control of a variety of insect pests of cotton, pome fruit, bananas, citrus, lupins, onions, potatoes and flowers. The other product is only for the control of aphids and mites in pastures and some field crops. Both of the agricultural products can be applied by ground boom, airblast or backpack sprayer.

3 REASONS FOR REVIEW

In October 1994 the APVMA invited the public to nominate active constituents, chemical products or labels for consideration for review. Of the 600 chemical nominations, 80 were prioritised for review, one of which was dimethoate. Community groups, individual citizens and government agencies nominated dimethoate for review, on the basis concerns relating to toxicology and residues.

In considering the scope of the review of dimethoate, the APVMA received advice from the Office of Chemical Safety (OCS) and APVMA Chemistry and Residue Program (CRP) of the need to review 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. As omethoate is considerably more toxic than dimethoate it is necessary to take account of these omethoate residues in order to determine the health risk posed by dimethoate.

The reviews of dimethoate and omethoate are being considered in conjunction, as both active constituents have similar chemistry, with omethoate being the oxygen analogue of dimethoate. The scope of the review for both chemicals is the same, with both OCS and CRP advising that both chemicals need to be considered together.

The details of the concerns that have been raised can be found in Sections 5 - 7 of this report.

4 SCOPE OF THE REVIEW

The scope of the review has been defined taking into consideration the reasons for the nomination of dimethoate and omethoate, the information already available on these chemicals and the way in which they are registered for use in Australia.

In light of concerns raised by:

- Office of Chemical Safety (OCS), as detailed in Section 5;
- National Occupational Health and Safety Commission (NOHSC), detailed in Section 6; and
- APVMA Chemistry and Residues Program (CRP) detailed in Section 7;

it does not appear that the APVMA can be satisfied that the continued use of or any other dealing with, the active constituents dimethoate and omethoate or products containing dimethoate and omethoate in accordance with the approved instructions for use:

- 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/or
- would not be likely to have an effect that is harmful to human beings; and /or
- may unduly prejudice trade or commerce between Australia and places outside Australia.

It also appears that labels for products containing dimethoate and omethoate may not contain adequate instructions and warning statements.

On the basis of these concerns, it is appropriate that the registrations and approvals of dimethoate and omethoate be reconsidered under Part 2, Division 4, of the Agvet Codes.

The APVMA will therefore review the following aspects of active constituent approvals, product registrations and label approvals for each of dimethoate and omethoate:

- a) Toxicology:
 - the potential for acute and chronic toxicity, that could have an effect that is harmful to human beings;
- b) Occupational Health and Safety:
 - the potential for short and intermediate term occupational exposure to hazards to human safety; and
- c) Trade:
 - the potential for residues in export commodities that exceed the tolerances of importing countries, that could unduly prejudice trade or commerce between Australia and places outside Australia; and
- d) Residues:
 - the potential for dietary exposure and determine maximum residue limits, that could pose an undue hazard to the safety of people exposed to it during its handling or people using anything containing its residues.

The APVMA will also consider whether product labels carry adequate instructions and warning statements. The requirements for such instructions include:

- 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 withholding period after the use of the product;
- the disposal of the product and its container;
- the safe handling of the product.

Registrants and approval holders will be required to undertake certain actions aimed at securing relevant data that might address these matters. However, the public is invited to make submissions to the APVMA regarding any of the matters raised in the scope document (see Section 9).

5 TOXICOLOGICAL ISSUES

Dimethoate has been used as an insecticide in Australia for more than 30 years. More recently studies have been undertaken to assess the toxicity of dimethoate and omethoate. Omethoate is a metabolite of dimethoate. Due to the similarity in chemistry the OCS has recommended that the toxicological data of dimethoate be reviewed in conjunction with omethoate.

The Advisory Committee on Pesticides and Health (ACPH) reviewed dimethoate between 1962 – 1990, considering a number of issues. The National Drugs and Poisons Schedule Committee (NDPSC) has considered dimethoate on a number of occasions. In 1983 the NDPSC withdrew registration of dust formulations due to potential dermal exposure risks. In 1988 the NDPSC reviewed dimethoate and noted the moderate to high acute toxicity of dimethoate, adverse results in reproductive, developmental and carcinogenicity (rats and mice) studies and similar results from mutagenicity tests. The committee further considered dimethoate in 1990, 1992 and 1993, regarding safety directions.

Since the toxicological data base for dimethoate was last reviewed in Australia in 1988, new information which considered a range of toxicological endpoints that have either not previously been investigated or have now been studied more extensively, has become available. In particular there are studies that quantify the extent of functional (task performing) impairment in rats following exposure to known quantities of dimethoate. This is an important consideration for pesticides whose mode of action involves the inhibition of an enzyme involved in the transition of nerve impulses. A review of these studies and all other new data is considered important to determine whether the existing health standards that were established in 1988 to protect the general public and workers handling such products remain appropriate.

The OCS have advised the APVMA that no suitable studies have been submitted to adequately quantify functional activity impairment and determine the delayed neuropathy potential following exposure to dimethoate or omethoate. Since there has been considerable scientific debate surrounding cognitively deficiencies following long-term exposure to organophosphate compounds it is necessary to consider all new toxicological information.

The OCS has advised the APVMA that no Acute Reference Dose (ARfD) has been established in Australia for either dimethoate or omethoate. Therefore, the setting of an ARfD will be considered during the review process. OCS will also reconsider the current Acceptable Daily Intake (ADI).

Having regard to these matters the APVMA is concerned that dimethoate and omethoate might have an effect that is harmful to human beings.

6 OCCUPATIONAL HEALTH AND SAFETY ISSUES

The National Occupational Health and Safety Commission (NOHSC) has advised that products containing dimethoate and omethoate have not been assessed in accordance with new occupational health and safety (OH&S) standards. NOHSC have also advised that they have concerns regarding the appropriateness of Personal Protective Equipment (PPE) listed on product labels.

Having regard to these matters the APVMA is concerned that dimethoate and omethoate might pose an undue hazard to the safety of people exposed to it during its handling.

7 RESIDUE AND TRADE ISSUES

The APVMA Chemistry and Residues Program (CRP) have advised of concerns relating to the appropriateness of both pre and post harvest use patterns of dimethoate for fruit fly control. Agricultural practices relating to the use of dimethoate could potentially raise residue limits in fruit and have an impact on Australia's trade with other countries. CRP has also advised that they have concerns relating to dietary exposure. It is also necessary to determine and consider maximum residue limits for both dimethoate and omethoate.

Having regard to these matters the APVMA is concerned that dimethoate and omethoate might:

- pose an undue hazard to the safety of people using anything containing its residues; and
- be likely to unduly prejudice trade or commerce between Australia and places outside Australia.

8 INTERNATIONAL REGULATORY STATUS OF PRODUCTS CONTAINING DIMETHOATE AND OMETHOATE

United States

- The US EPA published the Re-registration Eligibility Decision Document (RED) for dimethoate in 1999. The final RED report is still to be completed.
- Initial outcomes have found that risk from dietary exposure to dimethoate is below the level of concern. The review has found that there are potential exposures to users from normal uses patterns of dimethoate and appropriate personal protective equipment (PPE) standards have been set.
- Omethoate is not registered as a pesticide in its own right in the US and as such is not included in the US EPA's Reregistration Eligibility Decision (RED) reviews of organophosphates.

United Kingdom

- Dimethoate was reconsidered by Pesticide Safety Directorate at their meeting in January 2001, as a result dimethoate products were suspended until the review can be finalised.
- Omethoate is not registered as a pesticide in its own right in the UK.

Europe

- Dimethoate is registered for use in a number of European countries.
- Omethoate is not registered as a pesticide in its own right in Europe except for Portugal.

Joint Meeting on Pesticide Residues (JMPR)

JMPR evaluated dimethoate for toxicological effects in 1963, 1965, 1967, 1984, 1987 and 1996. Omethoate was evaluated for toxicological effects by the JMPR in 1971, 1975, 1978, 1979, 1981, 1985, and 1996. The residue chemistry of dimethoate was reviewed by the JMPR in 1998.

9. SUBMISSIONS FROM THE PUBLIC INVITED

The formal review will now commence and will deal with the aspects outlined in this scope document.

Interested parties are requested to provide information and data addressing the issues raised in this scope document. These must reach the APVMA by no later than **2 July 2004**. Submissions can be sent either by email to chemrev@apvma.gov.au or by mail to:

Manager Pesticides Review
Australian Pesticides and Veterinary Medicines Authority
PO Box E240
KINGSTON ACT 2604
Telephone: (02) 62723213
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10 DATA ASSESSMENT AND POSSIBLE OUTCOMES

Office of Chemical Safety, National Occupational Health and Safety Commission and the APVMA Chemistry and Residues Program will conduct the technical assessment of data submitted for the review of dimethoate and omethoate. These agencies will advise the APVMA about the concerns raised in Sections 5, 6 and 7.

The data might lead to agencies that provide expert advice to the APVMA to consider setting appropriate public health standards, which in this case might involve:

- the OCS revising the Acceptable Daily Intake (ADI);
- the OCS establishing an acute reference dose (ARfD); and
- the NHMRC¹ revising the drinking water standard;
- the NDPSC² revising the existing poisons schedule.

The APVMA will have regard to the appropriate public health standards in its reconsideration of approvals and registrations.

Depending on the findings of the technical assessment, a review can result in one of three broad outcomes.

- The APVMA is satisfied that active constituents and products containing dimethoate or omethoate continue to meet the conditions to which registration or approval are currently subject and affirms the registration and approvals; or
- The APVMA is satisfied that the conditions to which the registration or approval is currently subject can be varied in such a way that the requirements for continued registration or approval will be complied with, and varies the conditions of approval or registration; or
- The APVMA is not satisfied that the conditions continue to be met and suspends or cancels the registration or approvals.

¹ National Health and Medical Research Council

² National Drugs and Poisons Scheduling Committee

11 CONSULTATION THROUGHOUT THE REVIEW PROCESS

From initiation of the review through to the implementation of the review outcomes, the APVMA will consult with relevant stakeholders and interested parties. Prior to finalisation of any report, comments from key stakeholders and the public will be sought.

The draft of the review summary along with proposed recommendations is intended to be made available to the stakeholders and public through the APVMA website or direct communication. A period will be allowed for the stakeholders and the public to comment on the draft.

ATTACHMENT 1**Table 1:** Active Constituent approvals for omethoate to be included in the reconsideration

Approval Number	Active Constituent	Registrant
44315	Omethoate	Bayer CropScience Pty Ltd
51857	Omethoate	Bayer CropScience Pty Ltd

Table 2: Registered products and label approvals for omethoate to be included in the reconsideration.

Product Number	Product Name	Registrant	Label Approval Numbers
33051	Folimate Garden Insecticide	Bayer CropScience	33051/01
33054	Folimate50 Garden Insecticide	Bayer CropScience	ψ
33055	Folimate 800 Insecticide Spray	Bayer CropScience	33054/01 33054/0499 33054/0701 33054/0803 33054/1099
45672	Le-Mat 290 SL Insecticide	Bayer CropScience	45672/02 45672/3975 45672/1297 45672/1099 45672/0103

ψ = Labels transitioned from the States and therefore not having an approval number

ATTACHMENT 2**Table 1:** Active Constituent approvals to be included in the review of dimethoate.

Approval Number	Active Constituent	Registrant
44043	Dimethoate	Cheminova Australia Pty Limited
44127	Dimethoate	BASF Australia Ltd
44281	Dimethoate	BASF Australia Ltd
44442	Dimethoate	Isagro Australia Pty Ltd
44566	Dimethoate Manufacturing Concentrate	Cheminova Australia Pty Limited
45924	Dimethoate	Farmoz Pty Limited
48012	Dimethoate	National Resources Pty Ltd
48174	Dimethoate	Rotam Australasia Pty Ltd
49020	Dimethoate Manufacturing Concentrate	Farmoz Pty Limited
52285	Dimethoate	Nufarm Australia Limited
54320	Dimethoate	Cheminova Australia Pty Limited

Table 2: Registered products and label approvals for dimethoate to be included in the reconsideration.

Approval Number	Product Name	Registrant	Label Approval Numbers
32951	BASF Perfekthion EC 400 Systemic Insecticide	BASF Australia Ltd	32951/02 32951/03 32951/0301
32953	Chemspray Rogor Insecticide	Envirogreen Pty Ltd	49600/0598 49600/0702
32961	Hortico Rogor Sucking Insect Killer	Hortico (Aust) Pty Ltd	32961/0800
32962	Nufarm Dimethoate Systemic Insecticide	Nufarm Australia Limited	32962/0401 32962/0402 32962/0701 32962/0998 32962/1299
32963	Garden King Rogor 100 Systemic Insecticide	Envirogreen Pty Ltd	32963/01 32963/0700 32963/0802
39239	Farmoz Dimethoate 400 Systemic Insecticide	Farmoz Pty Limited	39239/0402 39239/0897 39239/4252
41070	CRG Systex Insecticide	Chemical Recovery Co Pty Ltd	41070/1002
48956	Richgro Garden Products Rogor Insecticide	A Richards Pty Ltd T/A Richgro Garden Products	48956/01
49167	Summit Dimethoate Systemic Insecticide	Summit Agro Australia Pty Ltd	49167/01 49167/0203 49167/1200
49600	Saboteur Systemic Insecticide	Crop Care Australasia Pty Ltd	49600/01 49600/0100 49600/0702
49833	Rotam Romethoate Systemic Insecticide	Rotam Australasia Pty Ltd	49833/01 49833/0300 49833/0499 49833/0603 49833/0699
50342	Dimethomax Systemic Insecticide	Nufarm Australia Limited	50342/0198 50342/0301 50342/0499 50342/0699 50342/0702
51545	Chemag Dimethoate Insecticide	Chemag Pty Ltd	51545/0203 51545/1100
51658	Sipcam Rogor Systemic Insecticide	Sipcam Pacific Australia Pty Ltd	51658/0299 51658/0501
52673	Garden King Rogor Garden Insect Spray	Envirogreen Pty Ltd	52673/0300 52673/0802
53045	Agcare Biotech Dimethoate 400 Ec Systemic Insecticide	Agcare Biotech Pty Ltd	48956/0600
53783	Yates Rogor Insecticide	Arthur Yates & Co Limited	53783/0202 53783/0501
55272	Superway Dimethoate 300 Systemic Insecticide	Superway Garden Products Pty Ltd	55272/0202
55441	4 Farmers Dimethoate 400 Systemic Insecticide	4 Farmers Pty Ltd	55441/0402
55495	Superway Dimethoate 400 Systemic Insecticide	Superway Garden Products Pty Ltd	55495/0103
55704	Conquest Dimethoate 400 Systemic Insecticide	Conquest Agrochemicals Pty Ltd	55704/0502
56454	Danadim Insecticide	Cheminova Australia Pty Limited	56454/0903
56887	United Farmers Unidime 400 Insecticide	United Farmers Cooperative Company Ltd	56887/0303
57860	Halley Dimethoate 400 Systemic Insecticide	Halley International Enterprise (Australia) Pty Ltd	57860/0603

