



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



TRADE ADVICE NOTICE

on Dimethoate in the Product Danadim Insecticide

APVMA Product Number 56454

JUNE 2015

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This publication is available from the APVMA website: www.apvma.gov.au.

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PREFACE

The Australian Pesticides and Veterinary Medicines Authority (APVMA) is an independent statutory authority with responsibility for assessing and approving agricultural and veterinary chemical products prior to their sale and use in Australia.

In undertaking this task, the APVMA works in close cooperation with advisory agencies, including the Department of Health and Aging, Office of Chemical Safety and Environmental Health (OCSEH), Department of the Environment, Water, Heritage and the Arts (DEWHA), and State Departments of Primary Industry.

The APVMA has a policy of encouraging openness and transparency in its activities and of seeking stakeholder involvement in decision making. Part of that process is the publication of Trade Advice Notices for all proposed extensions of use for existing products where there may be trade implications.

The information and technical data required by the APVMA to assess the safety of new chemical products and the methods of assessment must be undertaken according to accepted scientific principles. Details are outlined in regulatory guidance published on the APVMA website.

About this document

This is a Trade Advice Notice.

It indicates that the Australian Pesticides and Veterinary Medicines Authority (APVMA) is considering an application to vary the use of an existing registered agricultural or veterinary chemical. It provides a summary of the APVMA's residue and trade assessment.

Comment is sought from industry groups and stakeholders on the information contained within this document.

Any advice the APVMA receives through this consultation which it relies on to grant this application will be noted in a subsequent Advice Summary.

Advice Summaries can be found on the APVMA website: www.apvma.gov.au

Making a submission

The APVMA invites any person to submit a relevant written submission as to whether the application to vary the registration of Danadim Insecticide should be granted. Submissions should relate only to matters that the APVMA is required by legislation to take into account in deciding whether to grant the application. These grounds relate to the trade implications of the extended use of the product. Submissions should state the grounds on which they are based. Comments received outside these grounds cannot be considered by the APVMA.

Submissions must be received by the APVMA by close of business on 22 July 2015 and be directed to the contact listed below. All submissions to the APVMA will be acknowledged in writing via email or by post.

Relevant comments will be taken into account by the APVMA in deciding whether to grant the application and in determining appropriate conditions of registration and product labelling. A summary of relevant comments and the APVMA's response will be published on the APVMA website.

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.

All personal and confidential commercial information (CCI)¹ material contained in submissions will be treated confidentially.

Written submissions on the APVMA's proposal to grant the application for registration that relate to the grounds for registration should be addressed in writing to:

Scientific Assessment and Chemical Review
Residues and Trade
Australian Pesticides and Veterinary Medicines Authority
PO Box 6182
Symonston ACT 2609

Phone: +61 2 6210 4701
Fax: +61 2 6210 4776
Email: enquiries@apvma.gov.au

Further information

Further information can be obtained via the contact details provided above.

Further information on public release summaries can be found on the APVMA website: www.apvma.gov.au

¹ A full definition of 'confidential commercial information' is contained in the Agvet Code.

1 INTRODUCTION

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application from Cheminova Australia Pty Ltd, to vary the registration of Danadim Insecticide to confirm/amend the use pattern for canola, mustard, linseed and poppy and also for pastures. It is proposed that the maximum rate for these crops will be reduced from that which was allowed previously. The withholding period for canola, mustard, linseed and poppy will be reduced from 14 to 7 days. The proposed grazing withholding period for pasture is 7 days.

Prior to the dimethoate review the grazing WHP for pasture was 1 day. An outcome of APVMA *Dimethoate Residues and Dietary Risk Assessment Report* Published in August 2011 was that these uses would be phased out as data were not available to the review to address to human health and safety, and to trade, associated with these uses. New data was provided to the APVMA to address the issues related to oilseeds and pastures that were raised in the dimethoate review.

2 TRADE CONSIDERATIONS

2.1 Commodities exported

Canola seed (including its derived oil and meal) is considered to be a major export commodity, as are animal commodities from livestock fed on treated pasture. However, no changes are required to the animal commodity MRLs for dimethoate and omethoate as a result of the supported uses. The risk to trade in animal commodities will not be considered further, noting also that the supported use in pasture is more restrictive than that which was registered prior to the dimethoate review.

2.2 Destination and value of exports

In 2013–14 Australia exported 3,194.39 kt of canola seed, 151.68 kt of canola oil and 42.23 kt of canola meal (Agricultural Commodity Statistics 2014, ABARES).

Major export markets for canola seed in 2013–14 were China (946.92 kt), Belgium (660.04 kt), Pakistan (214.43 kt), Japan (179.30 kt) and the Netherlands (119.99 kt).

Major export markets for canola oil in 2013–14 were Malaysia (41.89 kt), Korea (37.37 kt), China (20.93 kt) New Zealand (18.47 kt) and Japan (2.56 kt).

The major market for canola meal in 2013–14 was New Zealand (42.23 kt). Major export markets for canola meal in 2012–13 were Vietnam (18.83 kt), New Zealand (7.67 kt) and Taiwan (2.17 kt).

2.3 Proposed Australian use-pattern

Table 1: Proposed use pattern

DANADIM INSECTICIDE (400 G/L DIMETHOATE)

CROP	PEST	STATE	RATE	WHP (DAYS)	CRITICAL COMMENTS
Pastures, Pasture Seed and Forage Crops (inc. Clover, Medics, Cereals, Lucerne, Legumes for animal feed)	Blue oat mite	NSW, WA only	90 mL/ha (36 g ai/ha)	7 (G)	DO NOT graze or cut for stock feed for 7 days after application. Apply 3-5 weeks after the commencement of autumn rains or when outbreak occurs. Use the higher rate in NSW and in cold weather and/or for heavy infestations in other States. DO NOT spray on bare ground. Allow the crop to emerge before application. Boom spray: apply in 50-100 L of water/ha. Aircraft and misting machines: apply in 20-40 L/ha
	Lucerne Flea, Redlegged Earth Mite	NSW, Vic, Tas, SA, WA only	55–85 mL/ha (22–34 g ai/ha)		
	Redlegged Earth Mite		250 mL/ha (100 g ai/ha)		
	Pangola Aphid	Qld, WA only	190 mL/ha (76 g ai/ha)		
	Spotted Alfalfa Aphid, Blue Green Aphid	WA only	150–225 mL/ha (60–90 g ai/ha)		
		Qld, NSW, Vic only	150 mL/ha (60 g ai/ha)		
		Tas only	375 mL/ha (150 g ai/ha)		
	Blue green aphid	NSW only	150 mL/ha (60 g ai/ha)		
		SA, WA only	375 mL/ha (150 g ai/ha)		
	Leucaena	Leucaena Psyllid	Qld, WA only		

CROP	PEST	STATE	RATE	WHP (DAYS)	CRITICAL COMMENTS	
Lucerne	Spotted Alfalfa Aphid, Blue Green Aphid	WA only	150–225 mL/ha (60–90 g ai/ha)		<p>DO NOT graze or cut for stock feed for 7 days after application.</p> <p>Apply when aphids begin to build up on the stem or apply at the same rate as soon as possible after cutting the lucerne stand if and when the infestation occurs. Repeat as necessary.</p> <p>VICTORIA: Spray when 20–40 aphids per stem on mature plants and 1–2 aphids per plant in seedlings are present. Spotted Alfalfa Aphids are resistant to some organophosphates in some areas. Consult your district agronomist before spraying.</p>	
		Qld, NSW, Vic only	150 mL/ha (60 g ai/ha)			
		Tas only	375 mL/ha (150 g ai/ha)			
	Blue Green Aphid	SA only				
	Leaf Hoppers (including Jassids)	Qld, Vic, Tas, SA, WA only	350 mL/ha (140 g ai/ha)			Apply when insects appear and repeat as necessary.
	Bean fly	Vic, Tas, SA, WA only	340 mL/ha (136 g ai/ha)			Apply when insects appear
	Blue oat mite	NSW, WA only	90 mL/ha (36 g ai/ha)			
	Pea aphid	NSW, Vic, WA only	150 mL/ha (60 g ai/ha)			Apply when Aphids begin building up on stems. VIC only: spray when 20–40 Aphids per stem or 1–2 per seedling.
	Lucerne Flea	NSW, Vic, Tas, SA, WA only	55–85 mL/ha (22–34 g ai/ha)			Apply 3–5 weeks after the commencement of autumn rains or when outbreak occurs. Use the higher rate in cold weather or on mature pastures. DO NOT spray on bare ground. Allow the lucerne to emerge before application. Boom spray: apply in 50–100 L of water/ha. Aircraft and misting machines: apply in 20–40 L/ha
	Redlegged Earth Mite	Vic, Tas, SA, WA only	55–85 mL/ha (22–34 g ai/ha)			
		NSW only	85 mL/ha (34 g ai/ha)			
	Wingless Grasshopper	All states	75 ml/100 L of water (30 g ai/100 L)			Apply when grasshoppers appear and re-apply as required. In addition to the infested area spray a band of about 20 metres around areas to be protected. Apply in a maximum spray volume of 500 L/ha

CROP	PEST	STATE	RATE	WHP (DAYS)	CRITICAL COMMENTS
Oil Seeds (Canola, Linseed, Mustard, Poppy)	Lucerne Flea	NSW, Vic, Tas, SA only	55–85 mL/ha (22–34 g ai/ha)	7	DO NOT harvest for 7 days after application DO NOT graze or cut for stock feed for 7 days after application. Apply 3–5 weeks after the commencement of autumn rains or when outbreak occurs. Use the higher rate in cold weather. DO NOT spray on bare ground. Allow the crop to emerge before application. Boom spray: apply in 50–100 L of water/ha. Aircraft and misting machines: apply in 20–40 L/ha
		WA only	40–55 mL/ha (16–22 g ai/ha)		
	Redlegged Earth Mite	Vic, Tas, SA, only	55–85 mL/ha (22–34 g ai/ha)		
		WA only	40–55 mL/ha (16–22 g ai/ha)		
		NSW only	85 mL/ha (34 g ai/ha)		
Leafhoppers (including Jassids), Green Vegetable Bug	All States	350 mL/ha (140 g ai/ha).	Apply when pests appear		

For pastures a minimum 21 day re-treatment interval is proposed. Use on canola, mustard, linseed and poppy will be restricted to one application per crop.

2.4 Results from residues trials presented to the APVMA

Canola, mustard, linseed, poppy

To support a continued use on oilseeds the applicant has supplied residue data for canola. This data is also considered in support of uses on mustard seed, poppy seed and linseed.

The applicant has supplied data from a GLP study conducted according to the proposed label directions on canola at 8 sites in Australia in 2011–12. Highest total dimethoate residues in canola seed at 7 or more days after application at 140 g ai/ha were <0.02, 0.02, 0.03, 0.04, 0.05, 0.05, 0.07 and 0.09 mg/kg. It is noted that the highest residue was observed at 21 days after application and was higher than the residue observed at 7 days at this site. The MRL for dimethoate on SO 0088 Oilseed except peanut at T0.1 mg/kg should be replaced with a permanent MRL at 0.2 mg/kg. Highest omethoate residues in canola seed at 7 or more days

after application were <0.01 (5), <0.02 (2) and 0.02 mg/kg. Based on this data the current MRL for omethoate on SO 0088 Oilseeds at *0.05 mg/kg should be changed to a finite MRL at 0.05 mg/kg.

Highest total dimethoate residues in canola fodder at 7 or more days after application at 140 g ai/ha were 0.85, 1.5, 1.9, 2.3, 2.7, 6.0, 8.0 and 8.8 mg/kg on a dry weight basis. Total dimethoate residues are therefore within the proposed primary feed commodities MRL of 40 mg/kg recommended below to cover the use on pasture. Highest omethoate residues in canola fodder at 7 or more days after application at 140 g ai/ha were 0.06, 0.07, 0.1 (2), 0.18, 0.19, 0.25 and 0.35 mg/kg on a dry weight basis. Residues will therefore be below the current MRL of 20 mg/kg for omethoate on miscellaneous fodder and forage crops [Fresh weight].

The canola residue trials did not determine residues in forage to cover a failed crop situation. However, uses on pasture at similar rates are supported with a 7 day withholding period (below). Given that some of the pasture trials involved application at early growth stages it is considered that the new primary feed commodities MRL (recommended below) will cover the fail crop situation.

In a safflower processing study, residues in refined oil were <0.01 mg/kg when residues in the seed were 0.70 mg/kg. For meal, total dimethoate residues in safflower meal were at similar levels to that in the seed. Similar results were obtained in the cotton processing study, indicating that dimethoate does not concentrate significantly into oilseed meals. An oilseed meal MRL is not required as residues will be covered by the oilseeds MRL.

Pasture

The applicant has submitted a study that determined dimethoate residues in pastures after application of Danadim Insecticide in 2012–13. The study was conducted at 9 sites in Australia on pangola, forage sorghum, lucerne, oats, barley, sub-clover based, medic based and vetch pastures or fodder crops.

At 7 days after application at 150 g ai/ha total dimethoate residues in pasture were 0.27, 1.5, 2.2, 3.0, 5.6, 7.4, 11, 15 and 28 mg/kg on a dry weight basis. It is recommended that the current temporary MRL of T30 mg/kg for dimethoate on *Primary feed commodities* should be increased to 40 mg/kg to cover this use.

Omethoate residues in pasture at 7 days after application were 0.18, 0.33, 0.86, 0.87, 0.96, 1.6, 1.6, 2.9 and 3.7 mg/kg (on a dry weight basis). Residues were within the currently established MRLs for omethoate on *Legume animal feeds [Fresh weight]*, *Straw, fodder (dry) and hay of cereal grains and other grass-like plants* and *Miscellaneous fodder and forage crops [Fresh weight]* at 20 mg/kg. No changes will be made to these MRLs at this time, noting that they will be considered as part of the omethoate review (reconsideration).

2.5 Overseas registration and approved label instructions

The applicant did not supply any information on the overseas registrations for dimethoate products.

2.6 Codex alimentarius commission and overseas MRLs

The Codex Alimentarius Commission (Codex) is responsible for establishing Codex Maximum Residue Limits (CXLs) for pesticides. Codex CXLs are primarily intended to facilitate international trade, and accommodate differences in Good Agricultural Practice (GAP) employed by various countries. Some countries may accept Codex CXLs when importing foods. Dimethoate has been considered by Codex, however no Codex CXLs have been established for oilseeds. The following overseas MRLs have been established:

Table 2: Overseas MRLs

COUNTRY/STATUS	COMMODITY	TOLERANCE, mg/kg
EU	Oilseeds	*0.05
Japan	Sunflower seeds	1
	Sesame seeds	1
	Safflower seeds	1
	Cotton seeds	1
	Rapeseeds	1
	Other oilseeds	1
Korea	Cotton seed	0.1
USA	Cotton, undelinted seed	0.1
	Safflower, seed	0.1

No MRLs are set in Taiwan or China for dimethoate in canola. (China has established a dimethoate edible vegetable oil MRL at *0.05 mg/kg)

2.7 Current and proposed Australian MRLs for Dimethoate

Table 3: Current MRL Standard—Table1

COMPOUND	FOOD	MRL (mg/kg)
DIMETHOATE		
MO 0105	Edible offal (Mammalian)	0.1
PE 0112	Eggs	*0.05
MM 0095	Meat [mammalian]	*0.05
ML 0106	Milks	*0.05
SO 0088	Oilseed except peanut	T0.1
SO 0697	Peanut	T*0.05
PO 0111	Poultry, Edible offal of	*0.05
PM 0110	Poultry meat	*0.05
OMETHOATE		
MO 0105	Edible offal (Mammalian)	*0.05
PE 0112	Eggs	*0.05
MM 0095	Meat [mammalian]	*0.05
ML 0106	Milks	*0.05
SO 0088	Oilseed	*0.05
PO 0111	Poultry, Edible offal of	*0.05
PM 0110	Poultry meat	*0.05

CURRENT MRL STANDARD—TABLE4

COMPOUND	ANIMAL FEED COMMODITY	MRL (mg/kg)
DIMETHOATE		
	Cotton seed meal and hulls	T0.5
	Primary feed commodities	T30
OMETHOATE		
AL 0157	Legume animal feeds [Fresh weight]	20
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

Table 4: Proposed changes to MRL Standard—Table1 and Table 4

MRL STANDARD—TABLE1

COMPOUND	FOOD	MRL (mg/kg)
DIMETHOATE		
DELETE:		
SO 0088	Oilseed except peanut	T0.1
ADD:		
SO 0088	Oilseed except peanut	0.2
OMETHOATE		
DELETE:		
SO 0088	Oilseed	*0.05
ADD:		
SO 0088	Oilseed	0.05

MRL STANDARD - TABLE4

COMPOUND	ANIMAL FEED COMMODITY	MRL (mg/kg)
DIMETHOATE		
DELETE:		
	Primary feed commodities	T30
ADD:		
	Primary feed commodities	40

2.8 Potential risk to trade

Export of treated produce containing finite (measurable) residues of dimethoate may pose a risk to Australian trade in situations where (i) no residue tolerance (import tolerance) is established in the importing country or (ii) where residues in Australian produce are likely to exceed a residue tolerance (import tolerance) established in the importing country.

The risk to trade in canola seed and meal is considered to be less than that which has existed under previously registered uses. The maximum rate that can be used for canola has been reduced from 300 g ai/ha to 140 g ai/ha. The use will also be restricted to a single application per crop. Although an increase is proposed to the current oilseeds MRL to cover the highest residue, the STMR in the canola trials was 0.05 mg/kg, the same level as the EU MRL for oilseeds.

A summary of residue survey data for grains from July 2005 to November 2010 was provided for the dimethoate review by the NRS. In 540 samples of canola seed collected by the NRS between 2005 to 2008 dimethoate and omethoate were below the limit of reporting (0.05 mg/kg) in all samples. Similarly dimethoate

and omethoate were also below the LOR (0.01 mg/kg) in 524 samples of canola seed collected by the NRS between July 2008 to November 2010. Data for canola for 2013–14 from the NRS currently on the Department of Agriculture website indicates there were no detections of dimethoate or omethoate at greater than half the Australian standards (0.1 mg/kg for dimethoate, 0.05 mg/kg for omethoate) in 555 samples tested (the data does not specify if there were any detections at <half the Australian standards).

The risk to trade in canola oil is considered to be low as detectable residues of dimethoate are not expected to occur in refined oil, based on processing studies for other oilseeds evaluated as part of the initial APVMA Chemical Review of dimethoate.

3 CONCLUSIONS

Cheminova Australia Pty Ltd has made an application to vary the registration of Danadim Insecticide to confirm/amend the use pattern for canola. Use of the product in accordance with the proposed label instructions is unlikely to unduly prejudice Australian trade as the risk is unchanged or less than has existed under previously registered uses for canola.

Comment is sought on the potential for Danadim Insecticide to prejudice Australian trade when used on canola.