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Omethoate: residues and dietary risk assessment report

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

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EXECUTIVE SUMMARY

Introduction

This residues assessment for the review of omethoate was undertaken by the APVMA Residues section. The dietary risk assessment follows the recommended revision of the Acceptable Daily Intake (ADI) from 0.0003 mg/kg/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 Office of Chemical Safety as part of its assessment of the toxicology of omethoate for the APVMA review of omethoate.

Recommendations

Acute dietary exposure concerns

For the following use patterns the available residue data were insufficient for MRL establishment or assessment of acute dietary exposure. On the basis of the available data an acute dietary risk has been identified. 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
- use on potatoes.

Insufficient residue data provided

For the following use patterns residues data were requested but were not provided 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

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.

Use patterns that remain acceptable from a residues (human health) perspective

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.

MRL recommendations:

The following amendments are recommended to the MRL Standard.

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

COMPOUND		FOOD	MRL (mg/kg)
Omethoate			
DELETE:	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
ADD:		*Appropriate MRLs as recommended in the review of dimethoate*	

Table 2: Recommended amendments to Table 4 of the MRL Standard

COMPOUND		ANIMAL FEED COMMODITY	MRL (mg/kg)
Omethoate			
DELETE:	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
ADD:		*Appropriate MRLs as recommended in the review of dimethoate*	

It is noted that the current omethoate MRLs that have been recommended for deletion will not be removed from the MRL Standard until the dimethoate review has been finalised and appropriate omethoate MRLs have been recommended to cover the dimethoate only uses.

1 REPORT

1.1 INTRODUCTION

Omethoate was nominated for review in 1995 as part of the Existing Chemicals Review Program (ECRP). Omethoate is the oxygen analogue of dimethoate and is also a metabolite of dimethoate. Omethoate was nominated for review because of concerns over toxicology, occupational health and safety, residues and trade. Omethoate 800 g/L products are registered for use in several crops including cotton, pome fruit, bananas, citrus, lupins, onions, potatoes and flowers. Omethoate 290 g/L products are also registered for the control of mites and aphids in pasture, cereals, oilseeds, poppies and legume crops.

A toxicological assessment has been undertaken for omethoate as part of the review. The acceptable daily intake (ADI) for omethoate prior to the review was 0.0003 mg/kg bw/d, based on a no observed (adverse) effect level (NOEL) of 0.025 mg/kg bw/d for inhibition of erythrocyte (RBC) cholinesterase (ChE) activity in a 1-year gavage study in dogs, applying a safety factor of 100. The new toxicological assessment recommended that the ADI be revised to 0.0004 mg/kg bw/d, based on a NOEL of 0.04 mg/kg bw/d for inhibition of ChE activity in a 2-year rat dietary study, applying a safety factor of 100. Prior to this review, an acute reference dose (ARfD) for omethoate had not been established. An ARfD has now been established at 0.003 mg/kg bw, based on a NOEL of 0.25 mg/kg bw for inhibition of RBC ChE activity in an acute oral neurotoxicity study in rats, using a safety factor of 100.

The revision of the ADI for omethoate and the establishment of an ARfD requires a contemporary assessment of dietary exposure associated with approved uses.

1.2 Labels and maximum treatment regime

Food producing uses under permit and on label are summarised below. Uses on ornamental crops are not considered in this report.

Table 3: A. Tree and vine crops (omethoate 800 g/L EC)

Crop	Pest controlled	Application instructions	WHP days	Comments
Apples, Pears	Two spotted mite, European red mite, woolly aphid	65–75 mL/100 L	7	Spray thoroughly at beginning of mite build up. Repeat at beginning of renewed mite activity. Do not apply during flowering. Not compatible with integrated mite control programs.
Citrus	California red scale, aphids	50–75 mL/100 L	7	Apply thoroughly as a full cover spray timed according to previous schedule, eg between January and early March. Do not apply to Meyer Lemon or Seville orange.
Glen retreat mandarins	California red scale	65 mL/100 L	7	Apply thoroughly as a full cover spray. Apply two sprays—one in early December to coincide with peak hatching and one in late January

Table 4: A. Non tree/vine crops (omethoate 800 g/L EC)

Crop	Pest controlled	Application instructions	WHP days	Comments
Cotton	Thrips, Mirids, Aphids, Jassids	140–280 mL/ha	21 days	Apply by ground rig or air. Aircraft may use double track spacing with a reliable cross wind for thrips only. Use higher rate for longer residual control of thrips or where mirid population exceed 1/m of row.
Banana	Corky scab caused by flower thrips	Bell injection 50 mL/5 L	6 weeks	At bunch emergence. Apply 40 to 60 mL of mix while the emerging bell is still upright by injecting into the bell about ¼ of its length from the upright tip. Inject to a depth of 30–50 mm so as not to damage the bunch stem. Use the higher rate for large bunches.
		Individual plant treatment 125 mL/100 L	4 days	Apply 500 mL of spray mix to the throat of the plant at the bunch leaf stage during the period of flower thrips activity.
Lupins	Blue green aphid, cow pea aphid, green peach aphid (suppression only)	250 mL/ha	14 days	Can be applied ULV in water using 20% anti-evaporative oil
Onions	Thrips, Lucerne flea	35–700 mL/ha or 65 mL/100 L	14 days	Apply thoroughly as a full cover spray. Add wetting agent. (Lower rate of 35 mL/ha is used for Lucerne flea).
Potatoes	Aphids	75 mL/100 L	7 days	Spray when pest are first seen and repeat when necessary.

Table 5: A. Non tree / vine crops (omethoate 290 g/L products)

Crop	Pest controlled	Application instructions	WHP days	Comments
Pastures, cereals, oilseeds and legume crops	Red legged earth mite, blue oat mite,	100–120 mL/ha	1 day (grazing)	AUTUMN/WINTER: Spray 2–5 weeks after opening rains when mites have hatched to prevent seedling damage or loss. SPRING: Spray mite infested pastures and legumes to prevent damage, yield loss and to reduce infestation pressure in the following autumn
	Lucerne flea, Pasture mite			Spray on appearance and before damage occurs. If second hatching occurs a follow up spray may be required (for 100 mL/ha application rate)
Pasture legumes, lucerne, faba bean, vetch	Blue green aphid, cowpea aphid	100–200 mL/ha	1 day (grazing)	Spray when aphids start to build up. Use the higher rate when faster knockdown is required.
Pasture	Spotted clover aphid	100 mL/ha	1 day (grazing)	Apply at first sign of aphid activity
Barrier spraying	Red legged earth mite	300 mL/ha	1 day (grazing)	To prevent invasion, spray bare earth outside crop as well as weeds along the fence line using an offset jet. Note: Rain will reduce the efficacy of the bare earth treatment but leave an effective barrier on the weeds
Poppy	Red legged earth mite	100 mL/ha	1 day (grazing)	Spray on appearance and before damage occurs.

Table 6: A. Home garden (omethoate 2 g/kg aerosol)

Crop	Pest controlled	Application instructions	WHP days	Comments
Vegetables, herbs	Aphids, thrips, whiteflies, caterpillars (eg cabbage white butterfly, cabbage moth)	Foliar spray	7	Spray foliage thoroughly from a distance of 30 cm when insects are first seen or if insects reappear. Spray underneath the leaves to kill pests which may be hiding out of sight. For best results spray in the morning when there is little or no wind and little direct heat from the sun and when plants and conditions are dry. Do not spray if it is raining or about to rain. Apples/codling moth—spray every 14 to 21 days from petal fall until 7 days before harvest.
Citrus	Citrus leaf miner, aphids, mealybug, thrips, bronze orange bug	Foliar spray	7	
Apples	Thrips, woolly aphid, mites, codling moth	Foliar spray	7	

1.3 MRLs and current uses

The Australian residue definition for omethoate is: *Omethoate.*

Current entries in Table 1 and Table 4 of the MRL Standard for omethoate are summarised below. There are no entries for omethoate in Table 5 of the MRL Standard.

Table 7: Current entries in Table 1 of the MRL Standard

COMPOUND	FOOD	MRL (mg/kg)
Omethoate		
GC 0080	Cereal grains	*0.05
MO 0105	Edible offal (Mammalian)	*0.05
PE 0112	Eggs	*0.05
	Fruits	2
VD 0545	Lupin (dry)	0.1
MM 0095	Meat [mammalian]	*0.05
ML 0106	Milks	*0.05
SO 0088	Oilseed	0.05
VO 0445	Peppers, Sweet [capsicums]	1
PO 0111	Poultry, Edible offal of	*0.05
PM 0110	Poultry meat	*0.05
VO 0448	Tomato	1
	Vegetables [except lupin; peppers, sweet; tomato]	2

Table 8: Current entries in Table 4 of the MRL Standard

COMPOUND		ANIMAL FEED COMMODITY	MRL (mg/kg)
Omethoate			
	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

1.4 Metabolism

No omethoate metabolism studies were provided for review. The JMPR (1971) postulated that the metabolic route of omethoate would follow that observed for dimethoate in plants and animals, though the rates of individual reactions may vary between the two compounds. Metabolism studies on various plants, including wheat and potatoes, were considered as part of the dimethoate review. For animals, dimethoate studies on lactating goats and laying hens were considered previously.

1.5 Analytical methods

No specific omethoate analytical methods were provided for this review. Validated methods for the determination of omethoate in both plant and animal commodities were provided for the dimethoate review. For plant commodities in the overseas trials (see appendixes 4–7 of the Dimethoate Residues Review Report), the following methodology was generally utilised. Residues were extracted with acetone and partitioned into dichloromethane, followed by clean up on a celite/activated carbon column or by gel permeation chromatography for oily samples. Residues were quantified by gas chromatography with a flame photometric detector in the phosphorus mode. In some cases quantification was by LC-MS. The LOQ for plant commodities was generally 0.01 mg/kg for omethoate. Method recoveries are given with the individual report summaries in Appendixes 4–7 of the dimethoate residues review report.

For the Australian dimethoate residue trials provided by HAL for the dimethoate review, samples were homogenised and sub-samples extracted into an organic solvent using high power ultrasonication and mechanical shaking. The solvent was evaporated under vacuum and the aqueous residue partitioned against dichloromethane. The dichloromethane extracts were combined and evaporated under vacuum to dryness before redissolving in acetone. An aliquot was filtered before determination of dimethoate and omethoate by GC-MSMS. The LOQ for the method was 0.01 mg/kg for omethoate. Method recoveries are given with the individual report summaries in Appendix 8 of the dimethoate residues review report.

Methods for animal commodities were also provided as part of the review of dimethoate. Samples were initially extracted with acetone or acetonitrile followed by a protease treatment of the dried post extraction solids. The combined extract and enzyme hydrolysate were partitioned with dichloromethane. The organic layer was subjected to several steps including solid phase extraction and evaporation and re-suspension in benzene. Analysis was by GC-FPD. The method's limit of quantitation was 0.001 mg/kg for milk and eggs, and 0.01 mg/kg for tissues. Recoveries of omethoate from fortified samples of milk, eggs and tissues were generally within acceptable limits, except for the recovery of omethoate from egg whites fortified at 0.001 mg/kg (mean recovery 64%).

1.6 Residue definition

The current residue definition for omethoate for enforcement and dietary exposure assessment is omethoate. No omethoate metabolism studies were provided for review. However, the metabolic route of omethoate would follow that observed for dimethoate in plants and animals. Adequate plant and animal

metabolism data were provided for dimethoate as part of the dimethoate review. Adequate analytical methodology is available for the determination of omethoate residues in plant and animal matrices. Based on the review of the available metabolism data and the most recent toxicology assessments of omethoate it is considered that the current residue definition remains appropriate for both enforcement and dietary exposure risk assessment.

1.7 Residues in foods and animal feeds

MRLs associated with dimethoate use patterns only

A number of MRLs for omethoate will be recommended as part of the dimethoate review for those residues of omethoate that arise from the permitted uses of dimethoate use patterns only. Those residues will be considered in the residues assessment for the review of dimethoate to be published on the APVMA website.

Citrus

Omethoate is registered for the pre-harvest use on citrus and Glen retreat mandarins as summarised below.

Table 9: Omethoate use on citrus crops

Crop	Treatment	Rate (omethoate)	WHP (days)	Critical comments
Citrus	Pre-harvest/omethoate	60 g ai/100 L	7	Spray when pests are seen
Glen retreat mandarins	Pre-harvest/omethoate	52 g ai/100 L	7	Apply two sprays—one in early December to coincide with peak hatching and one in late January

The uses are covered by the omethoate fruits MRL of 2 mg/kg.

Residue data covering the pre-harvest application of omethoate to citrus are available from the 1990 JMPR as summarised in Table 10 overleaf.

The available data for citrus do not closely match Australian good agricultural practice (GAP) which allows application at 60 g ai/100 L in conjunction with a 7 day withholding period (WHP). For a spray volume of 3000 L/ha this corresponds to an application rate of 1.8 kg ai/ha. In the trial involving application at 2.25 kg ai/ha (which is within 25% of GAP) the residue in the pulp at 28 DAT was 0.41 mg/kg. This would give unacceptable acute dietary exposure estimates for both children and the general population (430 and 140% of the ARfD, respectively).

- The pre-harvest treatment of citrus and Glen retreat mandarins with omethoate is no longer supported as appropriate residue data are not available. The available data indicate unacceptable acute dietary exposure even at 28 days after application.

Table 10: Residues of omethoate in citrus (1990 JMPR)

Crop	Country	Application rate ai/ha or concentration (formulation)	No. of applications	Portion analysed	Days after last application	Residue (mg/kg)	
						Range	Average
Grapefruit	Israel	12 kg/ha (500 EC)	1	peel	32 60	1.9 0.55	
				pulp	32 60	0.15 0.1	
				whole fruit	32 60	0.62 0.22	
Oranges	Israel	9.6 kg/ha (500 EC)	1–2	peel	30 60-62	n.d. – 2.5 n.d. – 0.9	1.25 (n =2) 0.45 (n =2)
				pulp	30 60-62	n.d. – 0.7 n.d. – 0.5	0.35 (n =2) 0.25 (n =2)
				whole fruit	30 60-62	n.d. – 1.25 n.d. – 0.6	0.6 (n =2) 0.3 (n =2)
Oranges	Italy	0.75 kg/ha (500 EC)	1	peel	7 39 66	0.7 0.14 0.05	
				pulp	7 39 66	0.04 0.10 0.03	
				whole fruit	7 39 66	0.25 0.11 0.03	
Oranges	Spain	2.25 kg/ha (500 SL)	2	pulp	0 28	0.30 0.41	
				peel	0 28	9.3 4.6	
				Whole fruit	28	1.6	
				Marmalade Raw juice Juice	28 28 28	0.37 0.27 0.23	

Pome fruits

Omethoate is registered for use on apples and pears pre-harvest. The application rate is 75 mL/100 L (60 g ai/100 L) and a 7 day withholding period applies.

Table 11: Omethoate use on pome fruits

Crop	Treatment	Rate (omethoate)	WHP (days)	Critical comments
Apples, Pears	Pre-harvest (omethoate)	60 g ai/100 L	7	Spray thoroughly at beginning of mite build up. Repeat at beginning of renewed mite activity.

The uses are covered by the omethoate fruit MRL of 2 mg/kg. Residue data for omethoate on apples and pears are available from the 1990 JMPR as summarised in Table 12 below.

Table 12: Residues of omethoate in apples and pears (1990 JMPR)

Crop	Country	Application rate ai/ha or concentration (formulation)	No. of applications	Days after last application	Residue (mg/kg)	
					Range	Average
Apples	FRG	0.75 g/tree (300 EC)	1	0 7 14 21	0.66–1.0 0.16–0.4 0.04–0.2 0.01–0.14	0.8 (n = 3) 0.3 (n = 3) 0.1 (n = 3) 0.07 (n = 3)
	FRG	0.1% form (500 EC)	3	0 7 14 21 28 35	1.55–2.07 0.32–0.6 0.12–0.17 0.10–0.11 0.07–0.09 <0.05	1.75 (n = 3) 0.45 (n = 3) 0.15 (n = 3) 0.11 (n = 3) 0.08 (n = 3) <0.05 (n = 3)
	FRG	1.35 kg/ha (500 EC)	2–3	21	1.0–1.9	1.45 (n = 2)
	FRG	1.35 kg/ha (500 EC)	2	0 13/14 20/21 27/28 34/35 41/42	3.3–5.2 1.1–2.35 0.75–1.3 0.5–1.4 0.5–1.05 0.25–0.85	3.75 (n = 3) 1.62 (n = 5) 1.02 (n = 5) 0.87 (n = 5) 0.70 (n = 4) 0.51 (n = 5)
	S. Africa	0.08% form. (800 EC)	1	0 7 14 21 28	3.3 1.9 1.6 1.2 0.4	
	Chile	1.0–1.5 kg/ha (1000 EC)	3 2	14 28	0.38 0.15	
	Italy	1.0 kg/ha (500 SL)	3 3 2 2	37 64 81 108	2.3 0.46 0.36 0.07	

Crop	Country	Application rate ai/ha or concentration (formulation)	No. of applications	Days after last application	Residue (mg/kg)	
					Range	Average
Apple fruit	Italy	0.75 kg/ha (500 SL)	2	0 21 30 45	0.57 0.15 0.17 0.08	
Process fractions: Fruit, washed Raw puree Puree Raw juice Juice Pomace Rinse water				 30 30 30 30 30 30 30	 0.11 0.08 0.07 0.23 0.16 0.11 <0.02	
Pears	S. Africa	0.08% form. (800 EC)	1	0 7 14 21 28	2.13 1.97 1.43 1.05 0.92	
	FRG	1.35–1.65 kg/ha (500 EC)	2-3	0 7 14 21/22 28	2.4–6.7 2.2–3.8 1.4 – 1.5 1.3 – 1.6 0.8 – 1.3	4.05 (n = 3) 3.0 (n = 2) 1.45 (n = 2) 1.5 (n = 4) 1.05 (n = 2)
	FRG	1.35 kg/ha (500 EC)	2	0 13/14 20/21 27/28 34/35 41/42	4.05–6.4 1.7–3.05 0.5–2.25 0.35–1.3 0.17–1.1 0.16–1.1	5.5 (n = 4) 2.2 (n = 6) 1.1 (n = 6) 0.88 (n = 6) 0.57 (n = 6) 0.41 (n = 6)
Pears, fruit	Italy	0.75 kg/ha	1	0 21 30 45	0.92 0.14 0.09 0.02	
Process fractions: Fruit, peeled Preserve Waste peel				 30 30 30	 0.05 0.03 0.09	

The available data for apples and pears do not closely match Australian GAP which allows application at 60 g ai/100 L with a 7 day PHI. For a spray volume of 2000 L/ha this would correspond to a rate of 1.2 kg ai/ha. Omethoate residues in apples at 7 days after application at 0.8% (80 g ai/100 L, 1.3×) were 1.9 mg/kg. It is noted that residues were higher at 14 days after the last application at 1.35 kg ai/ha (1.1×) at 2.35 mg/kg suggesting the current fruit MRL may not be appropriate to cover residues in apples. For pears the highest residue at 7 days after application at 0.8% (80 g ai/100 L, 1.3×) was 1.97 mg/kg.

Based on omethoate residues of 1.9 mg/kg in apples and 1.97 mg/kg in pears the acute dietary exposure estimates are unacceptable for both children and the general population (2100–2400 and 690–720% of the ARfD, respectively).

- The approved pre-harvest treatment of apples and pears with omethoate is no longer supported as sufficient residue data are not available to support the use pattern, noting that the available data indicate unacceptable acute dietary exposure.

Assorted tropical and sub-tropical fruits, inedible peel

Bananas

Omethoate is registered for use on bananas either by bell injection or by throat spray as summarised below.

Table 13: Omethoate use on bananas

Crop	Treatment	Rate (omethoate)	WHP	Comments
Banana	Bell injection (omethoate)	40 g ai/5 L	6 weeks	At bunch emergence. Apply 40 to 60 mL of mix while the emerging bell is still upright by injecting into the bell about ¼ of its length from the upright tip. Inject to a depth of 30—50 mm so as not to damage the bunch stem. Use the higher rate for large bunches.
	Throat spray (omethoate)	100 g ai/100 L	4 days	Apply 500 mL of spray mix to the throat of the plant at the bunch leaf stage during the period of flower thrips activity

The uses are covered by the omethoate fruits MRLs at 2 mg/kg respectively.

Two Australian trials were provided to support a 6 week WHP for application of omethoate to bananas by bell injection (for product 33055). At the 6 week WHP omethoate residues in bananas were 1.4 and 1.5 mg/kg after bell injection at the label rate, below the current omethoate MRL of 2 mg/kg for fruits (includes bananas).

An omethoate high residue (HR) of 1.5 mg/kg following bell injection only would give an unacceptable intake of 1165% of the ARfD for children (2–6) and 319% for the general population. Data are not available to indicate the omethoate residue in the edible portion after bell injection so this use cannot be supported at this time.

Australian residue data for the foliar treatment of bananas are available from the 1990 JMPR. However, no residue data are available for the omethoate throat spray. This use is therefore also not supported.

- The treatment of bananas with omethoate by bell injection is no longer supported due to unacceptable acute dietary exposure risks for children and the general population.
- The treatment of bananas with omethoate by throat spray is not supported as residue data are not available to allow an assessment of dietary exposure.

Bulb vegetables

Omethoate is currently registered in Australia for use on onions as summarised below.

Table 14: Omethoate use on onions

Crop	Treatment	Rate (omethoate)	WHP (days)	Comments
Onion	Pre-harvest (omethoate)	560 g ai/ha or 52 g ai/100 L	14	Apply thoroughly as a full cover spray. Add wetting agent.

The uses are covered by the omethoate vegetable MRL at 2 mg/kg. Australian residue data from a single trial for use of omethoate on onions are available from the 1990 JMPR. The data are summarised below.

Table 15: Residues of omethoate in onions from Australian trials

Crop, location, year	Formulation	Application rate (kg ai/ha)	No. of applications (interval, days)	Days after last application	Omethoate (mg/kg)
Onions, Australia, 1980	800 g/L	0.56 (high vol.)	2 (7)	1 4 7 10 11	6.0 4.4 3.7 1.2 0.3
	800 g/L	0.56 (aerial low vol.)	1	95	0.24†

†The JMPR noted that an interference of 0.2 mg/kg apparent omethoate was reported in the controls for the method used in this trial.

The available residue trials did not determine residues in onions after a 14 day post-harvest interval (PHI). At 11 days after 2 applications at the registered rate, omethoate residues in onions were 0.3 mg/kg. An omethoate residue of 0.3 mg/kg gives an acute exposure estimate which is 101% of the ARfD for children.

- The continued use of omethoate on onions is not supported as insufficient data are available for MRL establishment.

Legumes (vegetable)

Omethoate is registered for use on legume crops at 120 mL/ha (34.8 g ai/ha). A repeat application may be made and a 1 day grazing withholding period applies. No harvest withholding period is specified.

Table 16: Omethoate use on legume crops

Crop	Treatment	Rate (omethoate)	WHP (days)	Comments
Legume crops	Omethoate	34.8 g ai/ha	1 (G)	Spray on appearance and before damage occurs

These uses are covered by the omethoate vegetable MRL at 2 mg/kg. Limited residue data for the treatment of bush beans with omethoate are available from the 1990 JMPR as summarised below:

Table 17: Residues of omethoate in beans

Crop, location, year	Formulation	Application rate (kg ai/ha)	No. of applications, (interval, days)	Days after last application	Omethoate (mg/kg)
Bush beans, Australia, 1979	800 g/L SC	7.2–12[a] (60 g ai/100 L)	3 (7)	7	1.9
Bush beans, Australia, 1982	2 g/kg AE	2.9[b]	3 (7)	7	0.4

[a] kg ai/ha estimate based on 12-20000 L high spray volume/ha reported (spray volume as reported by JMPR);

[b] kg ai/ha estimate based on 0.29 g ai/m^2 plot as reported. Aerosol application.

The available residue data do not match Australian GAP for legume vegetables and data are not available to undertake a robust dietary exposure assessment.

- The treatment of legume crops with omethoate is no longer supported as appropriate residue data to support the use pattern are not available.

Pulses (legumes dried)

Lupins

Omethoate is registered for use on lupins as summarised below.

Table 18: Omethoate use on lupins

Crop	Treatment	Rate (omethoate)	WHP (days)	Comments
Lupins	omethoate	200 g ai/ha	14	Can be applied ULV in water using 20% anti-evaporative oil

The use is covered by an MRL of 0.1 mg/kg for omethoate on VD 0545 Lupin (dry) and an MRL of 0.5 mg/kg for omethoate on AL 0545 Lupin forage dry.

No residue data are available to support the application of omethoate to lupins or to allow a robust dietary exposure assessment. It is therefore not appropriate to support the continuation of this use pattern.

- The approved use of omethoate on lupins is no longer supported as residue data to support the use pattern are not available.
- The MRLs for omethoate on lupins and lupin forage should be deleted.

Other pulse crops

There are also registered uses for 290 g/L omethoate on legume crops and faba beans at a lower rate of active per hectare than the lupin use. Harvest withholding periods are not specified.

Table 19: Omethoate use on other pulse crops (290 g/L products)

Crop	Treatment	Rate (omethoate)	WHP (days)	Comments
Legume crops	omethoate	34.8 g ai/ha	1 (G)	AUTUMN/WINTER: Spray 2–5 weeks after opening rains when mites have hatched to prevent seedling damage or loss. SPRING: Spray mite infested pastures and legumes to prevent damage, yield loss and to reduce infestation pressure in the following autumn Spray on appearance and before damage occurs. If second hatching occurs a follow up spray may be required (for 100 mL/ha application rate)
Faba beans	omethoate	58 g ai/ha	1 (G)	Spray when aphids start to build up

There is a registered use for omethoate 290 g/L products on faba beans at up to 200 mL/ha (58 g ai/ha). A 1 day grazing withholding period applies. Omethoate is also registered for use on legume crops at 120 mL/ha (34.8 g ai/ha). A repeat application may be made and a 1 day grazing withholding period applies.

These uses are covered by the omethoate vegetable MRL at 2 mg/kg which includes dried commodities.

No residue data are available to support the application of omethoate to legume crops or to allow a robust dietary exposure assessment. It is therefore not appropriate to support the continuation of this use pattern.

- The registered use of omethoate on faba beans or legume crops is also no longer supported.

Root and tuber vegetables

Omethoate is registered for use on potatoes as below.

Table 20: Omethoate use on potatoes

Crop	Treatment	Rate (omethoate)	WHP (days)	Comments
Potatoes	omethoate	60 g ai/100 L	7	Spray when pests are first seen and repeat when necessary

The use is covered by the omethoate vegetables MRL at 2 mg/kg. Residue data for omethoate on potatoes are available from the 1990 JMPR as summarised below:

Table 21: Residues of omethoate in potatoes (1990 JMPR)

Crop	Country	Application rate ai/ha or concentration (formulation)	No. of applications	Days after last application	Residue (mg/kg)	
					Range	Average
Potatoes	FRG	0.18 kg/ha (300 EC)	2	14	<0.02–0.21	0.10 (n = 6)
	FRG	0.16 – 0.24 kg/ha (200 EC)	3	0 28 35/40	n.d. n.d. n.d.	n.d. (n = 3) n.d. (n = 3) n.d. (n = 3)

The available data do not closely match Australian GAP which allows application at 60 g ai/100 L in conjunction with a 7 day WHP. For a spray volume of 1000 L/ha this would correspond to a rate of 0.6 kg ai/ha. The overseas trials therefore used much lower rates than approved in Australia and also did not determine residues after a 7 day withholding period. It is noted that the highest omethoate residue of 0.21 mg/kg at 14 days after last application (DALA) would give an unacceptable acute dietary exposure estimate for children (200% of the ARfD).

- The registered use of omethoate on potatoes is not supported as appropriate residue data are not available to support the use pattern, noting that the available residue data indicate acute dietary exposure concerns for children.

Cereals

Omethoate (290g/L) is registered for the control of various pests on cereals. The critical use pattern is summarised below.

Table 22: Omethoate use on cereals

Crop	Treatment	Rate (omethoate)	WHP (days)	Comments
Cereals	Omethoate	34.8 g ai/ha	1 (grazing)	Spray on appearance and before damage occurs.

These uses are covered by the omethoate cereal grains MRL of *0.05 mg/kg. There are also Table 4 entries for omethoate on the straw, fodder (dry) and hay of cereal grains and other grass-like plants and miscellaneous fodder and forage crops [Fresh weight] each at 20 mg/kg.

Limited residue data for omethoate on wheat are available from the 1990 JMPR as summarised below:

Table 23: Residues of omethoate in wheat (1990 JMPR)

Crop, location, year	Formulation	Application rate (kg ai/ha)	No. of applications, (interval, days)	Days after last application	Omethoate (mg/kg)
Wheat (early dough), Australia, 1978	800 EC	0.056	1	44	0.05
Wheat, grain, UK	500 EC	0.56–0.75	1	169/187	n.d., 0.16
Wheat straw, UK				169/187	n.d., <0.05

The available data do not match Australian GAP which allows application at 34.8 g ai/ha in conjunction with a 1 day grazing withholding period and no specified harvest withholding period.

- The use of omethoate on cereals is also not supported as appropriate omethoate residue trials are not available.
- The current omethoate cereal grains MRL at *0.05 mg/kg should remain in place to cover the use of dimethoate on cereals.

Oilseeds

Omethoate (800 g/L) is currently registered for use on cotton with other formulations (290 g/L) registered for use on oilseeds generally and poppies as summarised below.

Table 24: Omethoate use on oilseed crops

Crop	Treatment	Rate (omethoate)	WHP (days)	Comments
Cotton	Omethoate	up to 224 g ai/ha	21	Apply by ground rig or air

Crop	Treatment	Rate (omethoate)	WHP (days)	Comments
Oilseeds	Omethoate	up to 34.8 g ai/ha	1 (grazing)	Spray on appearance and before damage occurs
Poppies	Omethoate	29 g ai/ha	1 (grazing)	Spray on appearance and before damage occurs

The omethoate MRL for oilseed is 0.05 mg/kg.

- The approved uses of omethoate on cotton, poppies and other oilseeds are no longer supported as residue data are not available to allow an assessment of dietary exposure.
- The omethoate oilseeds MRL of 0.05 mg/kg should remain in the MRL Standard to cover the dimethoate uses on oilseeds.

Uses on pasture, pasture legumes, lucerne and vetch

Omethoate is registered for use on pasture and pasture legumes. The maximum approved treatment rates are summarised below.

Table 25: Omethoate use on pasture, pasture legumes, lucerne and vetch

Crop	Treatment	Rate (omethoate)	WHP (days)	Comments
Pastures, legume crops	Omethoate	34.8 g ai/ha	1 (grazing)	Spray on appearance and before damage occurs.
Pasture legumes, Lucerne, vetch	Omethoate	58 g ai/ha	1 (grazing)	Spray when aphids start to build up

Table 4 entries are currently established for omethoate on:

- legume animal feeds [fresh weight]
- straw, fodder (dry) and hay of cereal grains and other grass-like plants
- miscellaneous fodder and forage crops [fresh weight] each at 20 mg/kg.

As no data are available to support the use of omethoate on pastures, lucerne or vetch, these uses should not continue.

Other uses

Home garden uses – omethoate

Omethoate is registered for use in the home garden on vegetables, herbs, citrus and apples. As limited residue trials for omethoate on these crops are available and acute dietary exposure concerns have been

identified, it is not appropriate to support the continued use of omethoate in the home garden in food producing situations.

Animal commodities

No omethoate uses on animal feed commodities continue to be supported, hence no animal commodity MRLs are required to support the use of omethoate.

An increase to the omethoate MRL for MO 0105 Edible offal (mammalian) from *0.05 to 0.1 mg/kg was recommended as part of the dimethoate residues review evaluation. The remaining omethoate animal commodity MRLs were expected to remain appropriate with respect to dimethoate use patterns and will be confirmed as part of the dimethoate review.

1.8 Proposed MRL changes

It is recommended that the MRLs relating to omethoate use be deleted and replaced by appropriate MRLs for residues of omethoate arising from the permitted use of dimethoate, when the reviews have been finalised and any phase out periods for use completed:

Table 26: Recommended amendments to Table 1 of the APVMA MRL Standard

COMPOUND		FOOD	MRL (mg/kg)
Omethoate			
DELETE:	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
ADD:		*Appropriate MRLs as recommended in the review of dimethoate*	

Table 27: Recommended amendments to Table 4 of the APVMA MRL Standard

COMPOUND		ANIMAL FEED COMMODITY	MRL (mg/kg)
Omethoate			
DELETE:	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
ADD:		*Appropriate MRLs as recommended in the review of dimethoate*	

It is noted that the current omethoate MRLs that have been recommended for deletion will not be removed from the MRL Standard until the dimethoate review has been finalised and appropriate omethoate MRLs have been recommended to cover the dimethoate only uses.

1.9 Dietary exposure estimates

The following health standards have been recommended by the Office of Chemical Safety, Department of Health and Ageing.

Table 28: Recommended Health Standards

Compound	Dietary Standard, mg/kg bw		No Observable Effect Level (NOEL), mg/kg bw	Safety Factor
Omethoate	ADI	0.0004	0.04	100
	ARfD	0.003	0.25	100

1.10 Acute dietary exposure

Acute dietary exposure is estimated by the National Estimated Short Term Intake (NESTI) calculation. 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 below:

Table 29: Summary of NESTI calculations for existing omethoate uses

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
VA 0385 Onion	0.3 (HR)	101	50
VR 0589 Potato	0.21 (HR)	200	80
VD Pulses (except lupins)	2 (MRL)	180	80

Commodity	MRL or HR	% of ARfD	
VD 0545 Lupin	0.1 (MRL)[1]	10	<5

Commodity	MRL or HR (mg/kg)	% of ARfD	
		2–6 years	2+ years
GC Cereal grains	0.05 (MRL) [1]	20	<10
SO Oilseeds	0.05 (MRL) [1]	<5	<5
ML 0106 Milks	0.001 (HR)	<5	<5
MM 0095 Meat [mammalian]	0.001 (HR)	<1	<1
MO 0105 Edible offal (mammalian)	0.085 (HR)	<5	<10
PE 0112 Eggs	0.001 (HR)	<1	<1
PM 0110 Poultry meat	0.001 (HR)	<1	<1
PO 0111 Poultry, edible offal	0.001 (HR)	<1	<1

[1]Data are not available to confirm the MRL.

1.11 Chronic dietary exposure

The chronic dietary exposures to dimethoate and omethoate are estimated by the National Estimated Daily Intake (NEDI) calculation encompassing all registered/temporary uses of the chemical and the mean daily dietary consumption data derived from the 1995 National Nutrition Survey of Australia. The NEDI calculation is made in accordance with WHO Guidelines[1] and is a conservative estimate of dietary exposure to chemical residues in food.

There are no use patterns for omethoate supported by this residues assessment therefore a NEDI calculation for residues arising from the use of omethoate is not required. It is noted that the dimethoate review is ongoing and exposure to omethoate residues arising from the use of dimethoate will be considered as part of that review.

1 Guidelines for predicting dietary intake of pesticide residues, WHO, 1997.

2 CONCLUSIONS AND RECOMMENDATIONS

2.1 Acute dietary exposure concerns

For the following use patterns the available residue data were insufficient for MRL establishment or assessment of acute dietary exposure. On the basis of the available data an acute dietary risk has been identified. 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
- use on onions
- use on potatoes.

2.2 Insufficient residue data provided

For the following use patterns residues data were requested but were not provided 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 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.

2.3 Home garden use

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.

Use patterns that 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

ABBREVIATIONS

ADI	Acceptable Daily Intake
ai	active ingredient
APVMA	Australian Pesticides and Veterinary Medicines Authority
ARfD	Acute Reference Dose
ChE	Cholinesterase
EC	emulsifiable concentrate—a liquid formulation
GAP	good agricultural practice
GC-FPD	gas chromatography with flame photometric detector (measures and identifies chemicals)
GC-MSMS	gas chromatography–mass spectrometry (measures and identifies chemicals)
HAL	Horticulture Australia Limited
HR	high residue
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
LC-MS	liquid chromatography—mass spectrometry (to identify chemicals)
LOQ	Limit of Quantitation
MRL	maximum residue limit
NEDI	National estimated daily intake (of chemical from consumption of food and / or water)
NESTI	National Estimated Short-Term Intake
NOEL	No Observable Effect Level
OCS	Office of Chemical Safety within the Australian Government Department of Health
OP	organophosphorus pesticide
US	United States
WHO	World Health Organization