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AUSTRALIA

CHEMICAL REVIEW PROGRAM

OCCUPATIONAL HEALTH AND SAFETY ASSESSMENT

OF

OMETHOATE

PREPARED BY THE

OFFICE OF CHEMICAL SAFETY

of the

Department of Health

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GLOSSARY OF TERMS AND ABBREVIATIONS

ai	Active Ingredient
bw	body weight
g	gram
h	hour
ha	hectare
iv	intravenous
kg	kilogram
L	litre
m	metre
m^2	square metre
m^3	cubic metre
µg	microgram
mg	milligram
mg/kg bw/day	mg/kg bodyweight/day
mL	millilitre
min	minute
mo	month
ng	nanogram
ppb	parts per billion
ppm	parts per million
s	second
te	Tonne
Wk	Week
d	day

AC	Aqueous concentrate
AE	Aerosol
ACPH	Advisory Committee on Pesticides and Health
APVMA	Australian Pesticides and Veterinary Medicines Authority
ChE	Cholinesterase
CRP	Chemical Review Program
DDVP	2,2-dichlorovinyl dimethyl phosphate (Omethoate)
DFR	Dislodgeable Foliar Residue
DMP	Dimethylphosphate
DoH	Department of Health
EC	Emulsifiable Concentrate
GC	Gas Chromatography
HG	Home Garden
LC	Liquid concentrate
LD	Liquid
LD_{50}	Lethal Dose 50 – Median Lethal Dose
LOEL	Lowest Observed Effect Level
LOD	Limit of Detection
LOQ	Limit of Quantification
MOE	Margin of Exposure
NHMRC	National Health and Medical Research Council
NOEC	No Observed Effect Concentration

NOEL	No Observed Effect Level
NOHSC	National Occupational Health and Safety Commission
OCS	Office of Chemical Safety
OHS	Occupational Health and Safety
OP	Organophosphorus pesticide
PCO	Pest Control Operator
PHED	Pesticide Handlers Exposure Database
PPE	Personal Protective Equipment
PVC	Polyvinyl chloride
R	Correlation Coefficient
RBC	Red blood cell
REI	Re-entry interval
RHI	Re-handling interval
SL	Soluble concentrate
SUSMP	Poisons Schedule
TC	Transfer Coefficient
TWA	Time Weighted Average
USEPA	United States Environment Protection Agency
WHP	Withholding period

EXECUTIVE SUMMARY

Omethoate has a long history of use in Australia as a direct and systemic insecticide and acaricide in both commercial and home garden situations. Currently, there are eighteen omethoate-containing professional use products registered in Australia. These professional products, aqueous concentrate (AC), liquid concentrate (LC) or soluble concentrate (SL) formulations, contain either 290 g/L or 800 g/L omethoate and are the subject of this OHS review. Omethoate is an organophosphorus pesticide, and along with other pesticides of this class, its mode of insecticidal action is through inhibition of cholinesterase (ChE) activity. Omethoate and its products are being reviewed because of their toxicity and occupational health and safety concerns, as well as matters related to residues and trade. Omethoate exists as a pesticide in its own right, but is also a toxic metabolite of dimethoate. The OHS review of omethoate has therefore been conducted in conjunction with the dimethoate review.

Omethoate has high acute oral toxicity and moderate dermal and inhalational toxicity in rats. It is not a skin irritant but a slight eye irritant and a skin sensitiser. For omethoate, the inhibition of plasma, RBC and brain ChE activity was the most sensitive toxicological endpoint following repeated oral or dermal exposure in mammals. Since mixing/loading and spraying the product will result in exposure via the skin and via inhalation, NOELs for ChE inhibition derived from short-term dermal and inhalation studies in rats were used for the risk assessment.

No chemical specific exposure data was available. Based exclusively on PHED surrogate exposure modelling, the risk assessment suggests that the label prescribed PPE is insufficiently protective for workers involved in mixing/loading and spraying of omethoate products. However, exposure can be reduced to acceptable levels by using closed mixing/loading systems and the PPE and engineering controls which have been assigned in this report.

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

1. INTRODUCTION

Omethoate is an organophosphorus chemical used in domestic and agricultural situations. Applications for omethoate include crop protection and pest control in domestic and commercial farming areas. Omethoate is one of the 80 agricultural and veterinary chemicals identified for priority review under the APVMA's Chemical Review Program (CRP). Omethoate was nominated for review because of concerns over its high acute toxicity and its potential to cause chronic effects on human health.

This occupational health and safety (OHS) review (as updated in June 2015), is based on information obtained from the following sources: data submitted by industry, published studies, and the Review of the Mammalian Toxicology and Metabolism/Toxicokinetics of omethoate, prepared by the Office of Chemical Safety (OCS) in October 2005 and updated in November 2011.

Only the agricultural products with the potential for occupational exposure have been considered in this assessment.

2. OMETHOATE PRODUCTS AND THEIR USE PATTERNS

There are currently eighteen omethoate products registered by APVMA for agricultural use (see below). An additional product, a 350 g home garden (HG) aerosol product, containing 2 g/kg omethoate, has no commercial application and has been assessed for risks posed by label uses in the draft OCS Review of Mammalian Toxicology and Metabolism/Toxicokinetics (DoH, 2011) and remain appropriate.

The omethoate product types are shown in the following table:

Product type	Number of registered products	Omethoate Conc.
Home garden (HG AE)	1	2 g/kg
Horticultural and broadacre uses (LC/SL)	4	800 g/L
Broadacre uses (AC/LC/SL)	14	290 g/L

AC = aqueous concentrate, LC = liquid concentrate, SL = soluble concentrate, AE = aerosol, HG = home/garden

Product Labels

800 g/L products (LC/SL)

The 800 g/L products are used in the control of certain pests on cotton, apples, bananas, citrus, lupins, onions, pears, potatoes and ornamentals (see Table 1). The products are intended for application by boom spray, airblast, hand-held equipment or by aircraft. The products are applied as a dilute spray at 50-75 mL/100L (0.4-0.6% omethoate active) or as a concentrated spray at no greater than 5 times the dilute spraying rate to various crops when pests are first seen, and to be repeated if required. For dilute spraying, where spray volumes per hectare are not indicated on the product label, the OCS used default spray volumes of 2500 L/ha for pome fruits and 5000 L/ha for citrus based on information provided by the APVMA. For concentrate spraying, the label rate is 500 L/ha, applied at 225 mL/100 L of the spray (0.06% of the active omethoate).

For bananas, the product may be applied by bell injection at 50 mL/5L (30-40 mL/bell) or as an individual plant treatment at 125 mL/100L (throat treatment, 500 mL/plant). For these methods, a hand gun on retractable hose (bike mounted) or a knapsack using a long pole with

a sharp needle nozzle attachment are used. These applications will be once in a year and may be repeated if required. Use patterns for 800 g/L products are listed in Table 1.

Table 1. Use patterns for 800 g/L products

Crop	***Pest***	***Application rate (product)***	***Working strength of the active constituent***	***Comments***
Apples Pears	Two spotted mites European red mite Woolly aphid	75 mL/100L	0.06% 1500 g/ha (2500 L/ha) (if 30 ha; 45 kg a.c/day)	Spray thoroughly by airblast at beginning of mite build up. Repeat at beginning of renewed mite activity.
Citrus	California red scale Aphids	50 mL/100L	0.04% 2000 g/ha(5000 L/ha) (If 30ha; 60 kg a.c./day)	Apply thoroughly by airblast as a full cover spray between January and early March
Glen Retreat mandarins	California red scale	65 mL/100L	0.05% 2600 g/ha(5000 L/ha) (If 30 ha; 78 kg a.c./day)	Apply thoroughly by airblast as a full cover spray. Apply two sprays one in early December and one in late January
Cotton	Thrips Mirids Aphids Jassids	140-280 mL/ha	224 g/ha, maximum (Boom spray 120 ha 26.88 kg active) (Aerial 1200 ha; 268.8 kg a.c./day)	Apply by boomspray or aircraft
Bananas	Corky scab caused by flower thrips	Bell injection 50 mL/5 L Individual plant treatment 125 mL/100L	40 g/5 L (up to 80 g/day) 100 g/100L (1000 plants; 500 g a.c./day)	Apply to the emerging bell Apply 500 mL of spray mix to the throat of the plant at the bunch leaf stage (flower thrips activity time) By handheld or knapsack equipment
Lupins	Blue green aphid, cowpea aphid, green peach aphid (WA only)	250 mL/ha	200 g/ha (Boom spray 50 ha; 10kg a.c./day)	Can be applied ULV in water
Onions	Thrips	700 mL/ha	560 g/ha (Boom spray and handheld 30 and 3 ha, 16.8 kg active and 1.68 kg a.c./day)	Apply thoroughly as a full cover spray
	Lucerne flea	35 mL/ha	28 g/ha (Boom spray and handheld 30 and 3 ha, 0.84 kg active and 0.084	

			kg a.c./day)	
Potatoes	Aphids	75 mL/100L	0.06% 900 g/ha (Aerial and boom spray, 300 and 30 ha, 270 kg active and 27 kg a.c./day)	Spray when pests are first seen and repeat when necessary
Ornamentals (including eucalyptus spp)	Aphids, lace bugs, mealy bugs, mites, thrips, whiteflies	75 mL/100L	0.06% 900 g/ha (0.9 kg/ha) (Handheld and knapsack 1 ha and 0.2 ha, 0.9 kg active and 0.18 kg a.c./day) (Aerial for eucalyptus spp. 1200 ha: 1080 kg a.c./day)	Apply thoroughly as a full cover spray Repeat at beginning of renewed pest activity

Information provided to OCS indicated that the 800 g/L products have relatively few uses in ornamentals and nursery production. The Safety Directions for 800 g/L AC products at the initiation of the review are as follows:

AC 500-800 g/L	
100 101	Very dangerous, particularly the concentrate
120 121 130 131 132 133	Product and spray are poisonous if absorbed by skin contact or inhaled or swallowed
180	Repeated exposure may cause allergic disorders
190	Repeated minor exposure may have a cumulative poisoning effect
181	Sensitive workers should use protective clothing
210 211 212	Avoid contact with eyes, skin and clothing
220 223	Do not inhale spray mist
279 281 290 292 294 296	When preparing the spray, wear cotton overalls buttoned to the neck and wrist and a washable hat, elbow length PVC gloves and face shield
340 342	If product on skin, immediately wash area with soap and water
350	After use and before eating, drinking or smoking, wash hands, arms and face thoroughly with soap and water
360 361 362 366	After each day's use, wash gloves, face shield and contaminated clothing.

290 g/L products (AC/LC/SL)

The 290 g/L products are used for the control of redlegged earth mite, blue oat mite and lucerne flea on pastures, cereals, oilseed and legume crops, and bluegreen aphid and cowpea aphid, on pasture legumes, lucerne, faba beans and vetch. They are applied by boom spray or by aircraft. Use patterns for 290 g/L products are listed in Table 2.

Table 2. Use patterns for 290 g/L products

Crop	*Pest*	*Application rate (product)*	*Working strength of the active constituent*	*Comments*
Pastures, cereals, oilseed and legume crops	Redlegged earth mite Blue oat mite	100 mL/ha to 120 mL/ha	29 to 34.8 g/ha (Boom spray 50 ha 1.74 kg active) (Aerial 1200 ha; 41.76kg a.c./day)	Spray mite infested pastures and legumes to prevent damage, yield loss and to reduce infestation pressure in the following autumn, product may be added to pasture herbicides
	Lucerne flea			Spray on appearance and before damage occurs. If second hatching occurs a follow up spray may be required
	Pasture mite			Spray on appearance and before damage occurs
Pasture, legumes, Lucerne, Faba beans, Vetch	Bluegreen aphid	100 ml or 200 mL/ha	29 to 58 g/ha (Boom spray 50 ha 2.9 kg active) (Aerial 1200 ha; 69.6 kg a.c./day)	Spray when aphids stars to build up
	Cowpea aphid	200 mL/ha	58 g/ha (Boom spray 50 ha 2.9 kg active) (Aerial 1200 ha; 69.6 kg a.c./day)	
Pasture	Spotted clover aphid	100 mL/ha	29 g/ha (Boom spray 50 ha 1.45 kg active) (Aerial 1200 ha; 34.8 kg a.c./day)	Apply at first sign of aphid activity
Barrier spraying	Redlegged earth mite	300 mL/ha	87 g/ha (Boom spray 50 ha 2.9 kg active)	To prevent invasion, spray bare earth outside crop as well as weeds along the fence line
Poppy	Redlegged earth mite	100 mL/ha	29 g/ha (Boom spray 50 ha 1.45 kg active)	Spray on appearance and before damage occurs

The Safety Directions for 290 g/L AC products, at the initiation of this review are as follows:

AC 290 g/L or less	
120 121	Product and spray are poisonous if absorbed by skin contact, inhaled or swallowed
130 131 132 133	
161 162	Will irritate the eyes
180	Repeated exposure may cause allergic disorders
190	Repeated minor exposure may have a cumulative poisoning effect
210 211	Avoid contact with eyes and skin
220 223	Do not inhale spray mist
279 281 282 290 292 294 296 (293 298 (seed dressing only)	When preparing and using the spray, wear cotton overalls buttoned to the neck and wrist and a washable hat, elbow length PVC gloves and face shield (PVC or rubber apron and impervious footwear, seed dressing only)
330 332	If clothing becomes contaminated with product, remove clothing immediately
340 342	If product on skin, immediately wash area with soap and water
340 343	If product in eyes, wash it out immediately with water
350	After use and before eating, drinking or smoking, wash hands, arms and face thoroughly with soap and water
360 361 362 366	After each day's use, wash gloves, face shield and contaminated clothing.

Label restrictions

The following withholding periods for 800 g/L products are specified on the product labels

Crops	**WHP**
Lupins, onions	Do not harvest for 14 days after application
Cotton	Do not harvest for 21 days after application
Bananas (bell injection)	Do not harvest for 6 weeks after application
Bananas (throat spray)	Do not harvest for 4 days after application
Other edible crops	Do not harvest for 7 days after application

For the 290 g/L products, Do not graze or cut for stock food for 1 day after application (Withholding period).

Re-entry interval

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

"Do not allow entry into treated areas for 1 day after treatment. When prior entry is necessary, wear cotton overalls buttoned to the neck and wrist and a washable hat, chemical resistant gloves and impervious footwear. Clothing must be laundered after each day's use".

There are no re-entry statements on the 290 g/L product labels.

3. TOXICOLOGICAL HAZARDS OF OMETHOATE

Acute toxicity

Omethoate acts by inhibiting cholinesterase (ChE) enzymes in the blood and central and peripheral nervous systems. In lethal-dose studies, the oral LD_{50} for omethoate in rats ranged from 25 to 65 mg/kg bw in rats (high toxicity). In mice, the oral LD_{50} was 36 mg/kg bw. The dermal LD_{50} was from >250 and <500 mg/kg bw in rats. The dermal study that most closely approximated modern guidelines (Flucke, 1978 as cited in the OCS Tox report), resulted in an LD_{50} of 865 mg/kg bw in female rats following 24 h exposure under semi-occlusive dressings, with females slightly more sensitive than males. In rats, the acute inhalational LC_{50} was 220-425 mg/m^3 and in mice, the LC_{50} was 140 mg/m^3 for 4-hour exposure. The effects of acute omethoate intoxication were consistent with those seen for other organophosphorus insecticides, and included lacrimation, tremors, muscle spasms, laboured breathing and behavioural disturbances. Omethoate was a slight eye irritant but not a skin irritant, and was a skin sensitiser in guinea pigs.

Reproductive toxicity/carcinogenicity

As described in the OCS review of mammalian toxicology of omethoate there are no carcinogenicity or reproductive toxicity endpoints of concern (DoH, 2011).

Dose levels relevant for OHS risk assessment

The most sensitive toxicological endpoint for omethoate in laboratory animals following repeated dosing was the inhibition of plasma and RBC ChE activity and is therefore the most appropriate toxicological endpoint for OHS risk assessment purposes. In terms of duration of exposure, the inhibition of plasma ChE activity is maximal within days to weeks of dosing. Therefore repeat dose studies ranging from weeks to months are the most appropriate for establishing NOELs for OHS risk assessment purposes. Chronic studies are likely to generate conservative NOELs due to the dose selection rather than any difference in toxicokinetics with shorter exposures. The following Table summarises the NOELs/LOELs in laboratory studies deemed suitable for OHS risk assessment purposes (noting that there were no human studies available for assessment).

Studies Relevant for OHS risk assessment purposes

Species	Study type	NOEL	LOEL	Toxicological endpoint	Reference
Rabbits	3-week dermal	2.5 mg/kg bw/day	20 mg/kg bw/day	Plasma, RBC and brain ChE inhibition	Flucke and Luckhaus (1979)
Rats	3-week inhalational	0.96 mg/m^3 (0.26 mg/kg bw/day)*	2.3 mg/m^3 (0.63 mg/kg bw/day)*	Plasma, RBC and brain ChE inhibition	Thyssen, (1979)

*mg/kg bw/day = mg/m^3/1000 (mg/L) x 0.141 (L/min, respiratory rate of rat) x 60 (min) x 6 (hr/day)/0.19kg (weight of rats in the study)

4. TOXICOLOGICAL ENDPOINTS FOR THE OHS RISK ASSESSMENT

Omethoate products intended for professional use are most likely to be applied by farmers and horticulturalists. Depending on pest activity, farmers may use omethoate products on few days during the working week. Potential routes of exposure would be dermal contact and inhalation

of omethoate vapour when handling undiluted products and/or inhalation of omethoate spray mist during application of diluted product.

Dermal and inhalation NOELs are considered appropriate for assessment of occupational exposure, using data generated over timescales appropriate to the likely frequency and duration of exposure. In order to perform an occupational risk assessment, careful consideration needs to be given to the selection of the appropriate toxicological endpoint and duration of dosing. The most relevant toxicological end-point for both dermal and inhalation occupational exposure to omethoate is plasma and RBC ChE inhibition.

4.1 Dermal NOEL

Normal occupational use of products containing omethoate is expected to result in some systemic uptake following dermal exposure. As user exposure to these products is expected to be of short duration and intermittent, the NOEL of 2.5 mg/kg bw/day in a 3-week dermal study in rats will be used for the occupational risk assessment.

4.2 Inhalation NOEC

Inhalational exposure to omethoate in an agricultural setting would most probably arise from inhalation of spray mist. The pattern and frequency of exposure would be the same as for dermal exposure.

As user exposure to these products is expected to be of short duration and intermittent, the NOEC of 0.96 mg/m^3 (equivalent to a systemic dose of 0.26 mg/kg bw/day) in a 3-week inhalation study in rats, will be used for the occupational risk assessment.

4.3 NOEL for re-entry interval calculation

As re-entry exposure is expected to be of short duration and intermittent, the NOEL of 2.5 mg/kg bw/day in a 3-week dermal study in rats will be used for the re-entry risk assessment.

5. ASSESSMENT OF OCCUPATIONAL EXPOSURE AND RISKS DURING PRODUCT USE

5.1 Evaluation of exposure studies

There are no exposure studies available.

5.2 PHED estimation of occupational exposure

The main route of occupational exposure to omethoate is expected to be by skin contamination during mixing/loading/spraying or applying the AC/LC/SL products. Inhalation of spray mist may occur during spray application. Occupational exposure for the following agricultural scenarios was assessed using the Pesticide Handlers Exposure Database (PHED, US EPA, 1999).

Scenario (1) Mixing and loading AC/LC/SL formulations (800 g/L and 290 g/L omethoate)

Scenario (2) Outdoor application of AC/LC/SL formulations by boom spray (800 g/L and 290 g/L omethoate)

Scenario (3) Outdoor application of LC/SL formulation by airblast (800 g/L omethoate)

Scenario (4) Application of AC/LC/SL formulation by aircraft (800 g/L and 290 g/L omethoate)

Scenario (5) Application of LC/SL formulation to bananas and ornamentals (800 g/L omethoate)

Scenario (1): Mixing and loading AC/LC/SL formulations (800 g/L and 290 g/L Omethoate)

Mixing and loading of products containing 800 g/L and 290 g/L omethoate, are used for the following application methods. The maximum quantities of omethoate active used per day are:

Boom spray:	50 ha (27 kg of omethoate) for 800 g/L and 290 g/L products (note up to 120 ha for cotton <28 kg a.c./day).
Airblast spray:	30 ha (78 kg of omethoate) for 800 g/L products only.
Aerial application:	Field crops: 1200 ha (69.6 kg omethoate) (information from the data provider) for 290 g/L products only. Cotton: 1200 ha (268.8 kg omethoate) (information from APVMA) for 800 g/L products only Potatoes: 300 ha (270 kg omethoate) 800g/L product Eucalyptus: 1200 ha (1080 kg omethoate) (information from APVMA) for 800 g/L products only
Handheld high pressure spray:	Flowers: (0.9 kg of omethoate) or on bananas, 1000 trees (0.5 kg of omethoate) for 800 g/L products only.
Knapsack spray:	Ornamentals: 0.2 ha (0.18 kg of omethoate) for 800 g/L products only.

Scenario (2) Outdoor application of AC/LC/SL formulations by boom spray

The 800 g/L products may be applied as dilute or concentrate spray by boom spray. The 290 g/L products can also be applied by boom spray. The maximum quantity of omethoate active used is 50 ha (27 kg of omethoate).

Scenario (3) Outdoor application of LC/SL formulation by airblast

The 800 g/L products may be applied as dilute or concentrate spray by airblast. The maximum quantity of omethoate active used is 30 ha (78 kg of omethoate).

Scenario (4) Application of AC/LC/SL formulations by aircraft

The 290 g/L products may be applied by aircraft to broadacre crops. The maximum quantities of omethoate active used are 69.6 kg (1200 ha).

Additionally, the 800g/L products can be applied by air (potatoes or forestry eucalypts) at a rate of 75 mL/100 L. Maximum quantities of omethoate active used are 1080 kg (1200 ha) for eucalyptus, and 270 kg for cotton and potatoes (300 ha/day).

Scenario (5) Application of LC/SL formulation by hand held equipment

The 800 g/L products are applied to bananas by two methods. In the first method, bell injection, 50 mL (40 g of omethoate) of the product are mixed into 5 L of water and 40-60 mL (around 0.4 g of omethoate) of this mixture is injected into the bell using a long pole with a sharp needle nozzle attachment (to a depth of 30-50 mm). This scenario cannot be modelled using PHED surrogate data.

The second method of application involves use of a hand gun fitted with a flat fan nozzle attached to a retractable hose (bike mounted/knapsack) (information supplied by the data provider). For this method, individual plant treatment is carried out by mixing 125 mL (100 g of omethoate) of the product in 100 L of water and 500 mL (0.5 g of omethoate, 0.5 kg for 1000 trees) and applying to the throat of the plant at the bunch leaf stage. This scenario can be modelled using PHED high pressure handheld method of application.

For ornamentals, products are applied by the high pressure handheld method (0.9 kg of omethoate).

For scenarios 1-5, PHED was used to estimate dermal and inhalational exposure for workers using both omethoate products. PHED does not have data to estimate exposure by bell injection in bananas, but for individual plant treatment (application to the throat of the plant) PHED was used to estimate exposure from high pressure handheld and knapsack application.

The following information gives the default number of hectares treated and the quantities of omethoate used for boomspray and airblast methods of application. For aerial spray and handheld methods, information is obtained from the data provider.

Area(s) treated per scenario for omethoate

Exposure scenario and equipment/usage value units

Mixer/Loader

Scenario 1 - Mixing/loading liquids for:

a) Groundboom spray - 50 ha/day - 120 ha/day (for cotton)

b) Airblast spray - 30 ha/day

c) High pressure handheld spray – 1 ha/day

d) Knapsack spray – 0.2 ha/day

e) Aerial spray – 300 ha/day (potatoes) - 1200 ha/day (Eucalyptus)

Applicators

Scenario 2 - Applying sprays

a) Groundboom spray - 50 ha/day - 120 ha/day (for cotton)

b) Airblast spray - 30 ha/day

c) High pressure handheld spray – 1 ha/day

d) Knapsack spray – 0.2 ha/day

e) Aerial spray – 300 ha/day (potatoes) - 1200 ha/day (Eucalyptus)

The following parameters and assumptions were used for PHED.

Formulation type = All liquid formulations.

Mixing/loading = Open and closed mixing/loading for mechanical ground and aerial spraying.

Open mixing/loading for high pressure handwand and knapsack spraying.

Spray application:

Ground (mechanical) application = Groundboom and airblast

Aerial application = Fixed wing aerial application.

Hand held application = High pressure hand wand and knapsack application

PHED does not take into consideration the container size or spray volume. Exposure to the chemical is estimated based on the amount of omethoate handled per day.

Amount of ai used/day for:

groundboom application is 27 kg [50 ha/day, cotton 120 ha/day].

airblast application is 78 kg [30 ha/day].

aerial spray is dependent on the concentration of the product and the daily application rate: For 290 g/L products: 69.6 kg [1200 ha]. For 800 g/L products: 270 kg [cotton, 1200 ha; potatoes, 300 ha] up to 1080 kg [eucalyptus, 1200 ha].

high pressure hand held application is 0.9 kg/day for flowers [1500 L spray/day] and 0.5 kg/500 mL/day for 1000 banana plants.

knapsack spray is 0.18 kg/day (for ornamentals) [0.2 ha/day].

Other input parameters used in PHED are included in the following table:

Adult bodyweight	70 kg	OCS default
Normal work day	8 h with an application period of 6 h	OCS default
Penetration through overalls	10%	Stamper et al. (1989)
Penetration through chemical-resistant full body clothing	5%	Thongsinthusak et al. (1993)
Penetration through chemical-resistant gloves	10%	Thongsinthusak et al. (1993)
Protection afforded by half face-piece respirator with gas/dust cartridges	90%	Thongsinthusak et al. (1993)
Protection afforded by full face-piece respirator with gas/dust cartridges	98%	Thongsinthusak et al. (1993)
Penetration through a washable hat (head and neck only)	10%	Thongsinthusak et al. (1993)

PHED estimates for dermal and inhalation exposure for various application methods are presented in the Table 3.

Table 3: Dermal and inhalation exposure estimates

Exposure Scenario Equipment	Dermal Unit Exposure (mg/kg ai) (body+hands)	Dermal Replicates	Hand Replicates	Inhalation Unit Exposure (mg/kg ai)	Inhalation Replicates
Mixer/Loader					
Open mixing/loading (no gloves)	6.39	72-122	53	0.0026	85
Open mixing/loading (gloves)	0.05	72-122	59	0.0026	85
Closed mixing/loading (no gloves)	(0.05)	16-22	0	0.0002	27
Closed mixing/loading (gloves)	0.019	16-22	31	0.0002	27
Applicator					
Boomspray application					
Applicator, open cab (no gloves)	0.03	23-42	29	0.0016	22
Applicator, open cab (gloves)	0.03	23-42	21	0.0016	22
Applicator, closed cab (no gloves)	0.011	20-31	16	0.0001	16
Applicator, closed cab, (gloves)	0.011	10-31	12	0.0001	16
Airblast application					
Applicator, open cab (no gloves)	0.79	32-49	22	0.0016	22
Applicator, open cab (gloves)	0.53	31-49	18	0.0016	22
Applicator, closed cab (no gloves)	(0.13)	20-30	0	0.0001	16
Applicator, closed cab, (gloves)	0.041	20-30	20	0.0001	16
Aerial application					
Aerial-fixed wing/enclosed cockpit (no gloves)	0.01	24-48	24	0.0002	23
Aerial-fixed wing/enclosed cockpit (gloves)	0.005	24-48	7	0.0002	23
Hand-held application					
High pressure hand wand (no gloves)	3.97	9-11	2	0.17	11
High pressure hand wand (gloves)	1.41	9-11	9	0.17	11
Knapsack application					
Backpack (no gloves)	1064.3	69	60	0.728	40
Backpack (gloves)	(516.7)	69	0	0.728	40

*Each study in PHED has been graded from "A" to "E" according to the quality of the study. PHED runs having any combination of A and B grade or A, B and C grade data are listed as 'Grade AB' or Grade ABC, respectively. Studies for mixing/loading, boomspray application and airblast application were of AB Grade and of medium to high confidence. Studies for handheld applications were of ABC Grade and low confidence.

Values in parentheses represent estimates where observations on hand contamination were not available.

For all exposure measurements, workers wore long pants and long sleeve shirt.

In the absence of measured exposure data, PHED was used to estimate worker exposure, using relevant exposure scenarios.

The PHED exposure data for mixing/loading and boom spray and airblast application were generally from high quality studies (AB grade and 15 or more replicates for each body part). However, for high pressure hand-held applications and for combined mixing/loading and application (for all application methods), PHED studies were of either medium or low quality grade and of low confidence (ABC grade and/or less than 15 replicates per body part). Exposure for the combined tasks (mixing/loading and application) were therefore estimated by adding exposure during mixing/loading and application carried out separately.

PHED does not contain surrogate exposure data for bell injection (in bananas). Exposure for this application method therefore could not be quantified. For this use pattern a qualitative exposure assessment was undertaken (discussed in the risk management section, 5.4).

5.3 Occupational Risk Characterization

The exposure estimates from PHED were used to generate the MOEs for omethoate each use scenario.

The MOE is calculated using the following formula:

MOE = NOEL (mg/kg bw/day) / Daily Dose (mg/kg bw/day)

Considering that the NOELs used in the risk assessment were established for the same toxicological end-point (i.e. plasma cholinesterase inhibition), MOEs were combined for both routes to obtain a total risk estimate for occupational exposure.

As both NOELs were derived from laboratory animals, a MOE of 100 or more is considered acceptable. This MOE takes into account inter- (10x) and intra-species (10x) variability.

Tables 4 to 9 summarise the MOEs for dermal and inhalation exposures to omethoate from mixing/loading and application exposures individually and combined for the various scenarios identified in section 5.2.

Table 4: Occupational exposure to omethoate estimated from PHED data-subsets, dermal MOE, inhalation MOE and total MOE for *ground boom application* of 290 g/L and 800 g/L products.

Scenarios	Exposure (mg/kg bw/day)		Dermal MOE	Inhalation MOE	Total MOE
	Dermal	Inhalation			
Mixer/loader					
Open M/L, no gloves	2.53	0.002	1	246	<1
Open M/L, gloves	0.02	0.002	125	246	82
Closed M/L (no gloves)	(0.021)	0.00008	(120)	3552	116
Closed M/L (gloves)	0.008	0.00008	330	3552	302
Applicator					
Open cab, no gloves	0.013	0.0007	199	398	133
Open cab, gloves	0.012	0.0007	202	398	134
Closed cab, no gloves	0.004	0.00004	565	6857	522
Closed cabs, gloves	0.004	0.00004	558	6857	516
Mixer/loader/applicator					
Closed M/L, open cabs; gloves	0.024	0.0011	101	237	71
Closed M/L, closed cabs; no gloves	0.025	0.0001	99	240	95
Closed M/L, closed cabs; gloves	0.012	0.00012	208	2340	191

M/L = mixing/loading
Dermal and inhalation exposures are adjusted for total active ingredient handled per day (27 kg).
Values in parentheses represent estimates where observations on hand contamination were not available.
Daily dermal or inhalation exposure (mg ai/kg bw/day) =arithmetic mean exposure obtained from PHED (mg/kg ai handled/day) x 27 kg ai÷70 kg (bw).
Dermal MOE = (Dermal NOEL (2.5 mg/kg bw/day)/total dermal dose) and Inhalation MOE = (inhalation NOEL (0.26 mg/kg bw/day)/total inhalation dose)
Total MOE were calculated by using formula 1/Total MOE = 1/Dermal MOE + 1/Inhalation MOE
Exposure for the combined task (mixing/loading/application) was obtained by adding exposures during mixing/loading and applications.
Unacceptable risk (MOE<100) are shaded.

Table 5: Occupational exposure to omethoate estimated from PHED data-subsets, dermal MOE, inhalation MOE and total MOE for *airblast application* of 800 g/L products.

Scenarios	Exposure (mg/kg bw/day)		Dermal MOE	Inhalation MOE	Total MOE
	Dermal	Inhalation			
Mixer/loader					
Open M/L, no gloves	7.0166	0.0029	<1	288	<1
Open M/L, gloves	0.0565	0.0029	44	88	29
Closed M/L (no gloves)	0.0582	0.0002	43	1275	42
Closed M/L (gloves)	0.0211	0.0002	119	1275	109
Applicator					
Open cab, no gloves	0.3	0.004	8	65	7
Open cab, gloves	0.2	0.004	13	65	10
Closed cab, no gloves	0.3317	0.001	8	235	7
Closed cabs, gloves	0.0465	0.0001	54	235	44
Closed cab, gloves + PPE	0.033	<0.0001	75	2352	73
Mixer/loader/applicator					
Open M/L, closed cabs; gloves	0.103	0.004	24	64	18
Open M/L, closed cabs; gloves + PPE	0.054	0.0004	47	3207	46
Closed M/L, closed cabs; gloves	0.068	0.0013	37	199	31
Closed M/L, closed cabs; gloves + PPE	0.039	0.0001	64	1986	62

M/L = mixing/loading, NE = not estimated

PPE = Second layer of clothing over normal clothes and a washable hat plus a full face-piece respirator with gas/dust cartridges (During M/L and Application).

Dermal and inhalation exposures are adjusted for total active ingredient handled per day (78 kg).

Values in parentheses represent estimates where observations on hand contamination were not available.

Daily dermal or inhalation exposure (mg ai/kg bw/day) =arithmetic mean exposure obtained from PHED (mg/kg ai handled/day) x 78 kg ai÷70 kg (bw).

Dermal MOE = (Dermal NOEL (2.5 mg/kg bw/day)/total dermal dose).

Inhalation MOE = (inhalation NOEL (0.26 mg/kg bw/day)/total inhalation dose).

Total MOE were calculated by using formula 1/Total MOE = 1/Dermal MOE + 1/Inhalation MOE.

Exposure for the combined task (mixing/loading/application) was obtained by adding exposures during mixing/loading and applications.

Unacceptable risk (MOE<100) are shaded.

Table 6: Occupational exposure to omethoate estimated from PHED data-subsets, dermal MOE, inhalation MOE and total MOE for *aerial application* of 290 g/L products (cereals, legumes, lucerne, oilseeds, pasture and poppies).

Scenarios	Exposure (mg/kg bw/day)		Dermal MOE	Inhalation MOE	Total MOE
	Dermal	Inhalation			
Mixer/loader					
Open M/L, no gloves	6.2610	0.0026	<1	99	<1
Open M/L, gloves	0.0504	0.0026	50	99	33
Open M/L, gloves + PPE	0.0183	0.0001	137	4942	133
Closed M/L (no gloves)	0.0520	0.0002	48	1429	47
Closed M/L (gloves)	0.0188	0.0002	133	1429	122
Applicator					
Aerial, no gloves	0.0110	0.0001	228	1744	202

M/L = mixing/loading, NE = not estimated
PPE = Second layer of clothing over normal clothes and a washable hat plus a full face-piece respirator with gas/dust cartridges (During M/L).
Dermal and inhalation exposures are adjusted for total active ingredient handled per day (69.6 kg).
Values in parentheses represent estimates where observations on hand contamination were not available.
Daily dermal or inhalation exposure (mg ai/kg bw/day) =arithmetic mean exposure obtained from PHED (mg/kg ai handled/day) x 69.6 kg ai÷70 kg (bw).
Dermal MOE = (Dermal NOEL (2.5 mg/kg bw/day)/total dermal dose).
Inhalation MOE = (inhalation NOEL (0.26 mg/kg bw/day)/total inhalation dose).
Total MOE were calculated by using formula 1/Total MOE = 1/Dermal MOE + 1/Inhalation MOE.
Unacceptable risk (MOE<100) are shaded.

Table 7a: Occupational exposure to omethoate estimated from PHED data-subsets, dermal MOE, inhalation MOE and total MOE for *aerial applications* of 800 g/L products (eucalyptus).

Scenarios	Exposure (mg/kg bw/day)		Dermal MOE	Inhalation MOE	Total MOE
	Dermal	Inhalation			
Mixer/loader					
Open M/L, no gloves	97.1527	0.0408	<1	6	<1
Open M/L, gloves	0.7816	0.0408	3	6	2
Open M/L, gloves + PPE	0.2836	0.0008	9	318	9
Closed M/L (no gloves)	0.8061	0.0028	3	92	3
Closed M/L (gloves)	0.2918	0.0028	9	92	8
Closed M/L (gloves) + PPE	0.0806	0.0001	31	4605	31
Applicator					
Aerial, no gloves	0.1703	0.0023	15	112	13
Aerial, gloves	0.0743	0.0023	34	112	26
Aerial, gloves + second layer of clothing	0.0210	0.0023	119	112	58

M/L = mixing/loading, NE = not estimated
PPE = Second layer of clothing over normal clothes and a washable hat plus a full face-piece respirator with gas/dust cartridges (During M/L).
Dermal and inhalation exposures are adjusted for total active ingredient handled per day (1080 kg).
Values in parentheses represent estimates where observations on hand contamination were not available.
Daily dermal or inhalation exposure (mg ai/kg bw/day) =arithmetic mean exposure obtained from PHED (mg/kg ai handled/day) x 1080 kg ai÷70 kg (bw).
Dermal MOE = (Dermal NOEL (2.5 mg/kg bw/day)/total dermal dose).
Inhalation MOE = (inhalation NOEL (0.26 mg/kg bw/day)/total inhalation dose).
Total MOE were calculated by using formula 1/Total MOE = 1/Dermal MOE + 1/Inhalation MOE.
Unacceptable risk (MOE<100) are shaded.

Table 7b: Occupational exposure to omethoate estimated from PHED data-subsets, dermal MOE, inhalation MOE and total MOE for *aerial applications* of 800 g/L products (cotton and potatoes).

Scenarios	Exposure (mg/kg bw/day)		Dermal MOE	Inhalation MOE	Total MOE
	Dermal	Inhalation			
Mixer/loader					
Open M/L, no gloves	24.1802	0.0102	<1	26	<1
Open M/L, gloves	0.1945	0.0102	13	26	9
Open M/L, gloves + PPE	0.0706	0.0002	35	1280	34
Closed M/L (no gloves)	0.2006	0.0007	12	370	12
Closed M/L (gloves)	0.0726	0.0007	34	370	31
Closed M/L (gloves) + PPE	0.0201	0.0000	125	18501	124
Applicator					
Aerial, no gloves	0.0424	0.0006	59	452	52
Aerial, gloves	0.0185	0.0006	135	452	104

M/L = mixing/loading, NE = not estimated
PPE = Second layer of clothing over normal clothes and a washable hat plus a full face-piece respirator with gas/dust cartridges (During M/L).
Dermal and inhalation exposures are adjusted for total active ingredient handled per day (270 kg).
Values in parentheses represent estimates where observations on hand contamination were not available.
Daily dermal or inhalation exposure (mg ai/kg bw/day) =arithmetic mean exposure obtained from PHED (mg/kg ai handled/day) x 270 kg ai÷70 kg (bw).
Dermal MOE = (Dermal NOEL (2.5 mg/kg bw/day)/total dermal dose).
Inhalation MOE = (inhalation NOEL (0.26 mg/kg bw/day)/total inhalation dose).
Total MOE were calculated by using formula 1/Total MOE = 1/Dermal MOE + 1/Inhalation MOE.
Unacceptable risk (MOE<100) are shaded.

Table 8: Occupational exposure to omethoate estimated from PHED data-subsets, dermal MOE, inhalation MOE and total MOE for *high pressure handheld application* of 800 g/L products

Scenarios	Exposure (mg/kg bw/day)		Dermal MOE	Inhalation MOE	Total MOE
	Dermal	Inhalation			
Mixer/loader					
Open M/L, no gloves	0.081	0.00003	31	7644	31
Open M/L, gloves	0.0007	0.00003	3838	7644	2555
Applicator					
High pressure, no gloves	0.51	0.002	5	12	3
High pressure, gloves	0.18	0.002	14	12	6
High pressure, gloves +PPE	0.02	0.0004	127	581	104
Mixer/loader/applicator					
Open M/L, high Pressure; no gloves	0.59	0.002	4	12	3
Open M/L, high pressure; gloves	0.18	0.002	14	12	6
Open M/L, high pressure; gloves +PPE	0.02	0.0005	125	540	102

M/L = mixing/loading
PPE = Second layer of clothing over normal clothes and a washable hat (during M/L and Application) plus a full face-piece respirator with gas/dust cartridges (during application only)
Dermal and inhalation exposures are adjusted for total active ingredient handled per day (0.9 kg).
Values in parentheses represent estimates where observations on hand contamination were not available.
Daily dermal or inhalation exposure (mg ai/kg bw/day) =arithmetic mean exposure obtained from PHED (mg/kg ai handled/day) x 0.9 kg ai÷70 kg (bw).
Dermal MOE = (Dermal NOEL (2.5 mg/kg bw/day)/total dermal dose).
Inhalation MOE = (inhalation NOEL (0.26 mg/kg bw/day)/total inhalation dose).
Total MOE were calculated by using formula 1/Total MOE = 1/Dermal MOE + 1/Inhalation MOE.
Exposure for the combined task (mixing/loading/application) was obtained by adding exposures during mixing/loading and applications.
Unacceptable risk (MOE<100) are shaded.

Table 9: Occupational exposure to omethoate estimated from PHED data-subsets, dermal MOE, inhalation MOE and total MOE for *knapsack application* of 800 g/L products

Scenarios	Exposure (mg/kg bw/day)		Dermal MOE	Inhalation MOE	Total MOE
	Dermal	Inhalation			
Mixer/loader					
Open M/L, no gloves	0.016	<0.00001	154	3820	154
Applicator					
Backpack, no gloves	2.74	0.002	1	139	1
Backpack, gloves	1.33	0.002	2	139	2
Backpack, gloves + PPE	0.27	<0.0001	9	6949	9
Mixer/loader/applicator					
Open M/L, backpack; gloves	1.33	0.002	2	138	2
Open M/L backpack; gloves + PPE	0.27	<0.0001	9	6924	9

M/L = mixing/loading, NE = not estimated
PPE = Second layer of clothing over normal clothes plus a full face-piece respirator with gas/dust cartridges (During M/L and Application).
Dermal and inhalation exposures are adjusted for total active ingredient handled per day (0.18 kg).
Values in parentheses represent estimates where observations on hand contamination were not available.
Daily dermal or inhalation exposure (mg ai/kg bw/day) =arithmetic mean exposure obtained from PHED (mg/kg ai handled/day) x 0.18 kg ai÷70 kg (bw).
Dermal MOE = (Dermal NOEL (2.5 mg/kg bw/day)/total dermal dose)
Inhalation MOE = (inhalation NOEL (0.26 mg/kg bw/day)/total inhalation dose)
Total MOE were calculated by using formula 1/Total MOE = 1/Dermal MOE + 1/Inhalation MOE
Exposure for the combined task (mixing/loading/application) was obtained by adding exposures during mixing/loading and applications.
Unacceptable risk (MOE<100) are shaded.

Mixer/loaders

Exposure to omethoate was estimated for workers mixing/loading the product for ground (boom, airblast, hand-held and knapsack spraying) and aerial application. The amount of product handled per day for the different application methods varies depending on the number of hectares treated by that particular method per day. The MOE calculated using exposure estimates from PHED indicated unacceptable risks even if gloves were worn during open mixing/loading except for high pressure handheld method where exposure was acceptable for open mixing loading when gloves were worn and for knapsack without the use of gloves. For boomspray and airblast methods of application, exposure was acceptable only for closed mixing/loading systems, when gloves were worn (Tables 4-9). Mixing/loading for aerial application is mostly by mechanical methods in a closed mixing/loading system and was acceptable for the 290 g/L products when wearing gloves. For the 800 g/L products, an acceptable MOE was achieved for mixing/loading for both cotton and potatoes, when wearing a second layer of clothing over normal clothes, chemical resistant gloves plus a full face-piece respirator with gas/dust cartridges. However, no acceptable MOE could be achieved for closed mixing/loading using full PPE for eucalyptus application.

Applicators

Exposure to omethoate when applying the diluted 800 g/L and 290 g/L products by boom spray provides an acceptable risk to workers using open cabs during application (Table 4). However, from the low MOE values for applicators without gloves using closed cab equipment, it is recommended that closed cabs be used for all ground boom applications.

For airblast application (using only for 800 g/L products), open cabs did not provide adequate protection to applicators. The MOE was low for workers with or without gloves (Table 5). Risks from could not be reduced to acceptable levels when the spray was applied using closed cab tractors. Even when extensive PPE were applied (gloves, a second layer of clothing and a full face-piece respirator) during application with closed cab, the MOE was still unacceptable (<100).

For aerial application, an acceptable MOE was achieved for the 290 g/L product (pasture, cereal and field legume uses) with an enclosed cockpit (Table 6). For 800 g/L products applied to potatoes and cotton an acceptable MOE was achieved with an enclosed cockpit and gloves (Table 7b). However, for the larger quantity of active constituent applied to eucalyptus, an acceptable MOE could not be achieved even with the use of gloves and a second layer of clothing (Table 7a).

Exposure to omethoate when applying with high-pressure hand wand provides unacceptable MOEs for workers, either with or without gloves (Table 8). An acceptable MOE (>100) was achieved with the use of a second layer of clothing, over normal clothing, and a full face-piece respirator with gas/dust cartridges.

For knapsack/backpack application, an unacceptable MOE was achieved for workers either with or without gloves (Table 9). No acceptable MOE could be achieved even with the use of a second layer of clothing and a full face-piece respirator.

Mixer/loader/applicators (combined tasks)

For combined M/L/A (same worker performing mixing/loading and application) for boom spray application, risks were acceptable for workers wearing gloves for closed mixing/loading only and using enclosed cabs with gloves during application (Table 4).

For combined M/L/A for airblast application, risks are unacceptable for both open and closed cab application (Table 5), even when a second layer of clothing, over normal clothing, and a full face-piece respirator are worn during both operations.

For high pressure hand-held M/L/A (Table 8), risks were acceptable when a second layer of clothing and gloves are worn during M/L and a second layer of clothing and gloves, together with a full face-piece respirator are worn during application. This is recommended for bell injection to bananas also, as similar quantities are used and exposure is expected to be similar to or less than high pressure handheld applications. It is therefore considered that the any risk mitigation recommendations for handheld applications would also be protective of bell injection.

For knapsack/backpack M/L/A, risks to workers were unacceptable (MOE <10) even with the use of a second layer of clothing and a full face-piece respirator during both mixing/loading and application (Table 9).

As different workers are involved in mixing/loading and application for aerial application of pesticides, combined M/L/A was not assessed.

5.4 Risk management for use of omethoate products

Operators who mix/load omethoate products are likely to have dermal and inhalational exposure. In the absence of worker exposure studies specific for omethoate products, surrogate data (PHED) were used to predict exposure during mixing/loading, boom spraying, airblast spraying, aerial spraying, high-pressure hand and knapsack spraying. Worker exposure resulting from both activities combined, that is, the same worker performing mixing/loading and application was also estimated. Default values from PHED used included various parameters like mixing and loading methods and equipment, open or closed cabs.

MOEs (Tables 4 to 9) showed that risks to workers mixing/loading products for all mechanical ground based applications (boom spray or airblast) were acceptable for closed mixing/loading wearing one layer of clothing (cotton overalls buttoned to the neck and wrist or equivalent clothing) and gloves. MOEs for mixing/loading for handheld applications were acceptable for open mixing/loading wearing one layer of clothing (cotton overalls buttoned to the neck and wrist or equivalent clothing) and gloves. MOEs for aerial application were acceptable for closed mixing/loading wearing one layer of clothing (cotton overalls buttoned to the neck and wrist or equivalent clothing) and gloves, for the 290 g/L products only.

MOEs were acceptable for workers applying the diluted products by boom spray using closed cabs. For combined M/L/A the use of boom spray for both 290 g/L and 800 g/L products is supported by the OCS for closed cabs plus closed mixing/loading wearing one layer of clothing (cotton overalls buttoned to the neck and wrist or equivalent clothing) and gloves.

For airblast application MOEs (800 g/L products) were unacceptable even with the use of an enclosed cab and extensive PPE. For combined M/L/A, MOEs were also unacceptable, even with closed mixing and loading and the use on an enclosed cab. Therefore the use of airblast equipment is not supported by the OCS.

Omethoate products are also applied by aerial application method. Large areas (around 1200 ha) can be sprayed by this method requiring large amounts of product to be mixed. PHED estimates confirmed that the MOE was acceptable for workers wearing one layer of clothing (cotton overalls buttoned to the neck and wrist or equivalent clothing) and gloves for the 290 g/L products. For application on eucalyptus plants, MOEs were unacceptable for workers mixing/loading 800 g/L products in closed systems and with full PPE and for application (pilots) in enclosed cockpits, and thus this use is not supported. For aerial application to cotton or potato crops however, risks to workers mixing/loading products were acceptable for closed mixing/loading wearing a second layer of clothing over normal clothes and a washable hat plus a full face-piece respirator with gas/dust cartridges and for applicators wearing a single layer of clothing and chemical resistant gloves. Hence these uses are supported by the OCS.

For hand-held spraying using high-pressure equipment, the MOE (800 g/L products) was acceptable for open mixing/loading with a second layer of clothing, over normal clothes, and gloves. For application, MOEs were acceptable when a second layer of clothing, over normal clothes, gloves and a full face-piece respirator with gas/dust cartridges were worn. This PPE will also be protective for the bell injection method in bananas. Therefore the use of high-pressure handheld spraying and bell injection methods are supported by the OCS.

For knapsack/backpack application the MOE (800 g/L products) was unacceptable for application and open mixing/loading even with extensive PPE. Therefore the use of equipment carried on the back of the user is not supported by the OCS.

6. ASSESSMENT OF POST-APPLICATION EXPOSURE AND RISKS

6.1 Post-application exposure

Exposure to omethoate residues may occur in agricultural crops when workers re-enter treated crops to irrigate, weed, prune, thin or harvest crops. The type of activity, timing and frequency of re-entry activities is dependent on crop type. Potential worker exposure will be determined by factors such as the amount of chemical applied; interval between spraying and re-entry; nature and duration of the particular re-entry activity; density of foliage and spacing of crops and environmental factors that affect the breakdown of residues.

The main route of exposure on re-entering sprayed areas is expected to occur by dermal contact with treated foliage. Workers can be exposed to omethoate residues during re-entry situations such as, irrigation, scouting and other activities such as thinning and harvesting in broadacre and orchard crops.

In agricultural situations, omethoate is used in field/row crops (low and medium), bananas, oranges, ornamentals and deciduous trees (apple and pears). Foliar residues of omethoate may pose an unacceptable risk to workers engaged in post-treatment activities mentioned above. Safe re-entry intervals can be determined using the parameters, dislodgeable foliar residue (DFR) and transfer coefficient (TC) and application rates.

The DFR can potentially be dislodged from both surfaces of a leaf. The Transfer Coefficient (TC) is a "residue transfer index" and indicates the amount of DFR that can be transferred to workers as a function of "field work activity". An appropriate TC is used in order to estimate worker exposure from DFR.

Dermal exposure can be calculated using the following formula:

$$\text{Dermal exposure (mg/kg bw)} = \frac{\text{DFR } (\mu g/cm^2) \times \text{TC } (cm^2/hr) \times \text{T (hr)} / \text{BW (kg)}}{1000}$$

6.2 Post-application risks

No measured worker exposure data or dislodgeable foliar residue (DFR) data for omethoate were provided for assessment.

Therefore, re-entry intervals (REIs) for all current crops appearing on the labels of both 290 g/L and 800 g/L products were estimated using the US Occupational Post-Application Risk Assessment Calculator (US EPA, 2000) (regardless of whether the application method provided unacceptable risks in PHED modelling).

Default assumptions used in the US EPA Calculator are:

Initial dislodgeable foliar residues (DFR): 20% of the omethoate applied

Dissipation rate/day: 10%

Transfer coefficients (TC): Varies with crop and agronomic activities (US EPA, 2000), as follows:

Bananas: 1300 (Irrigation, scouting mature plants)

2000 (hand harvesting)

Field crop

(low height): 1500 (Irrigation scouting thinning, weeding mature plants)

2500 (hand harvesting, thinning, pruning, leaf pulling)

Apples, pears : 3000 (harvesting, pruning, training)

Cut flowers: 2500 (irrigation, scouting, thinning, weeding

7000 (hand harvesting, pruning, thinning)

Tree fruit: 1000 (irrigation, scouting)

3000 (harvesting, pruning)

Root vegetables: 1500 (irrigation and scouting)

These values are used to estimate exposure for workers re-entering treated areas for various agricultural activities for each day after application. The worker exposure data is compared to the dermal NOEL (2.5 mg/kg bw/day) to derive safe re-entry periods for carrying out those activities.

The results indicated the following re-entry periods for various crops and post application activities:

Crops*	**WHP**	**REI (irrigation, scouting)**	**REI (hand harvest)**
Onions	14 days	10 days	16 days
Cotton	21 days	10 days	N/A
Bananas (bell injection)	6 weeks	17 days	17 days^
Bananas (throat spray)	4 days	17 days	17 days^
Other edible crops	7 days	17 days (citrus)	apples, pears - 16 days; citrus - 27 days
Cut flowers	-	29 days	30 days
Lupins (800 g/L product)	14 days	10 days	N/A
Field crops (290 g/L products)	1 day	2 days	7 days

* regardless of whether use supported in PHED modelling. N/A = Not Applicable

^ REI for scouting used based on the information supplied by APVMA, hand harvesting occurs at a significant time after product application.

7. RECOMMENDATIONS TO THE APVMA

1. The OCS recommends that the APVMA can NOT be satisfied that existing label instructions for omethoate products provide an acceptable margin of exposure for all label uses. However the OCS recommends that the APVMA can be satisfied that omethoate

will not be a risk to human health for workers using omethoate based products in accordance with the revised label directions.

2. The OCS recommends that the APVMA can NOT be satisfied that omethoate will not be a risk to human health from use of the 800 g/L products by airblast equipment or by equipment carried on the back of the user and for aerial application to eucalyptus.

3. The following amended and new Safety Directions, which will be included in the FAISD Handbook, should be included on the product labels (Please note that formulations types have changed from the original AC only formulations to include LC and SL formulations, the updated SD now include these formulation types).

Safety Directions

Amended FAISD entry

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

After each day's use, wash gloves, respirator (and if rubber wash with detergent and warm water), face shield or goggles and contaminated clothing	360 361 364, 365 366

Amended FAISD entry

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

4. Re-entry statements

The following re-entry statements are recommended:

Root vegetables (onions, potatoes)

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

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

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

Field crops 800 g/L product (cotton, lupins)

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

Bananas (Bell-injected or throat sprayed)

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

Cut flowers

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

5. Precautionary statements

The following Precautionary statements are recommended:

"Do not apply by airblast equipment."

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

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

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

8. REFERENCES

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ANNEX I – SAFE WORK AUSTRALIA HAZARDOUS SUBSTANCE REGULATIONS

Hazard Classification

The active constituent omethoate (CAS: 1113-02-6) is listed in Safe Work Australia's (SWA) Hazardous Substances Information System (HSIS) Database (SWA, 2015) with the following risk phrases:

R25	Toxic if swallowed
R21	Harmful in contact with skin

The following cut-offs apply for the active constituent omethoate:

Conc. > 25 %	T; R25, R21
3 % < Conc. < 25 %	Xn; R22

The OCS recommends the following additions/amendments to the risk phrases for omethoate (CAS: 1113-02-6) on Safe Work Australia's HSIS Database (SWA, 2015), based on the following toxicology information:

Risk phrases	Toxicology information
Xn; R43: May cause sensitisation by skin contact.	Positive reaction in an skin sensitisation study in guinea pigs (Flucke 1984)*.

*Flucke W (1984) S 6876 (c.n. omethoate) Study for skin-sensitising effect on guinea pigs in the open epicutaneous test. Report No. 13084. Sponsor: Bayer AG, Institute of Toxicology, Wuppertal-Elberfeld. 29.11.1984. Unpublished. [BA; sub: 239, Vol. 3 of 9].

With the following cut-off concentration:

Conc. ≥ 1%	Xn; R43

Therefore, the amended risk phrases for omethoate (CAS: 1113-02-6) to be listed in Safe Work Australia's HSIS Database (SWA, 2015) are as follows:

R25	Toxic if swallowed
R21	Harmful in contact with skin
R43	May cause sensitisation by skin contact

The following cut-off concentrations apply for omethoate:

Conc. > 25 %	T; R25, R21, R43
3 % < Conc. < 25 %	Xn; R22, R43
1 % < Conc. < 3 %	Xn; R43

Exposure Standards

There is no Safe Work Australia exposure standard listed for omethoate.

Health Surveillance Requirements

Safe Work Australia has not placed omethoate specifically on the Schedule for Health Surveillance (Schedule 3 Hazardous Substances for which Health Surveillance is required; NOHSC *Control of Workplace Hazardous Substances*; 1994a). However, all organophosphate pesticides (including omethoate) are listed as requiring the following to be monitored:

- Occupational and medical history
- Physical examination
- Baseline estimation of red cell and plasma cholinesterase activity levels by the Ellman or equivalent method
- Estimation of red cell and plasma cholinesterase activity towards the end of the working day

ANNEX II - Overseas Regulatory Assessments/Actions

There is no information available on omethoate. Most of the available information is on dimethoate.

Annex III: Australian registered products containing omethoate[1]

APVMA Product Code	Product Name	Product Registrant	Product Description	Content & formulation type
80532	Genfarm Omethoate 290 Insecticide	Landmark Operations Limited	For control of redlegged earth mite, blue oat or pea mite, bryobia mite, lucerne flea, bluegreen aphid, cowpea aphid] and spotted clover aphid on cereal, legume, pastures and poppy oilseed crops.	290 g/L AC
70131	Apparent Omethoate 290 Insecticide	Apparent Pty. Ltd	For control of redlegged earth mite, blue oat or pea mite, bryobia mite, lucerne flea, bluegreen aphid, cowpea aphid] and spotted clover aphid on cereal, legume, pastures and poppy oilseed crops.	290 g/L SL
69899	K-MITE 800 INSECTICIDE	SHANDONG RAINBOW INTERNATIONAL CO., LTD.	For control of european red mite, two spotted mite, woolly aphid, banana flower thrips, aphid, mealy bug, mite, sycamore lace bug, thrip, whitefly, aphid, california red scale, jassids, mirids, thrip, bluegreen aphid, cowpea aphid, green peach aphid, green peach aphid and lucerne flea.on fruit trees, vegetables, potatoes, forestry & ornamentals	800 g/L SL
69703	CONQUEST OVID 290 INSECTICIDE	CONQUEST CROP PROTECTION PTY LTD	For control of redlegged earth mite, blue oat or pea mite, bryobia mite, lucerne flea, bluegreen aphid, cowpea aphid] and spotted clover aphid on cereal, legume, pastures and poppy oilseed crops.	290 g/L SL
69636	FOKUS 800 INSECTICIDE	HEXTAR CHEMICALS PTY LTD	For control of european red mite, two spotted mite, woolly aphid, banana flower thrips, aphid, mealy bug, mite, sycamore lace bug, thrip, whitefly, aphid, california red scale, jassids, mirids, thrip, bluegreen aphid, cowpea aphid, green peach aphid, green peach aphid and lucerne flea on fruit trees, vegetables, potatoes, forestry & ornamentals	800 g/L LC
69166	SABAKEM OMETHOATE 290SL MITICIDE & INSECTICIDE	SABAKEM PTY LTD	For control of redlegged earth mite, blue oat or pea mite, bryobia mite, lucerne flea, bluegreen aphid, cowpea aphid] and spotted clover aphid on cereal, legume, pastures and poppy oilseed crops.	290 g/L SL
69096	RAINBOW OMETHOATE 290 INSECTICIDE	SHANDONG RAINBOW INTERNATIONAL CO., LTD.	For control of redlegged earth mite, blue oat or pea mite, bryobia mite, lucerne flea, bluegreen aphid, cowpea aphid] and spotted clover aphid on cereal, legume, pastures and poppy oilseed crops.	290 g/L SL
68169	FMC OMETHOATE 290 MITICIDE	FMC AUSTRALASIA PTY LTD	For control of redlegged earth mite, blue oat or pea mite, bryobia mite, lucerne flea, bluegreen aphid, cowpea aphid] and spotted clover aphid on cereal, legume, pastures and poppy oilseed crops.	290 g/L SL

[1] As at 29 April 2015.

66938	MISSION OMETHOATE 290 INSECTICIDE	MISSION BELL HOLDINGS PTY LTD	For control of redlegged earth mite, blue oat or pea mite, bryobia mite, lucerne flea, bluegreen aphid, cowpea aphid] and spotted clover aphid on cereal, legume, pastures and poppy oilseed crops.	290 g/L SL
65414	FARMALINX OMETHO-MITE 290 SL INSECTICIDE	FARMALINX PTY LTD	For control of redlegged earth mite, blue oat or pea mite, bryobia mite, lucerne flea, bluegreen aphid, cowpea aphid] and spotted clover aphid on cereal, legume, pastures and poppy oilseed crops.	290 g/L LC
63676	IMTRADE OMEN 290 INSECTICIDE	IMTRADE AUSTRALIA PTY LTD	For control of redlegged earth mite, blue oat or pea mite, bryobia mite, lucerne flea, bluegreen aphid, cowpea aphid] and spotted clover aphid on cereal, legume, pastures and poppy oilseed crops.	290 g/L SL
62022	4FARMERS OMETHOATE 290 INSECTICIDE	4 FARMERS AUSTRALIA PTY LTD	For control of redlegged earth mite, blue oat or pea mite, bryobia mite, lucerne flea, bluegreen aphid, cowpea aphid] and spotted clover aphid on cereal, legume, pastures and poppy oilseed crops.	290 g/L SL
61682	MITE MASTER 290 INSECTICIDE	GROW CHOICE PTY LIMITED	For control of redlegged earth mite, blue oat or pea mite, bryobia mite, lucerne flea, bluegreen aphid, cowpea aphid] and spotted clover aphid on cereal, legume, pastures and poppy oilseed crops.	290 g/L LC
61681	AW OMETHOATE 290 SL INSECTICIDE	AGRI WEST PTY LIMITED	For control of redlegged earth mite, blue oat or pea mite, bryobia mite, lucerne flea, bluegreen aphid, cowpea aphid] and spotted clover aphid on cereal, legume, pastures and poppy oilseed crops.	290 g/L LC
59872	CHEMAG SENTINEL 800 INSECTICIDE SPRAY	IMTRADE AUSTRALIA PTY LTD	For control of european red mite, two spotted mite, woolly aphid, banana flower thrips, aphid, mealy bug, mite, sycamore lace bug, thrip, whitefly, aphid, california red scale, jassids, mirids, thrip, bluegreen aphid, cowpea aphid, green peach aphid, green peach aphid and lucerne flea.on fruit trees, vegetables, potatoes, forestry & ornamentals	800 g/L LC
59576	ALL-MITEY 290 SL INSECTICIDE	CHEMINOVA AUSTRALIA PTY LIMITED	For control of redlegged earth mite, blue oat or pea mite, bryobia mite, lucerne flea, bluegreen aphid, cowpea aphid] and spotted clover aphid on cereal, legume, pastures and poppy oilseed crops.	290 g/L LC
45672	LE-MAT 290 SL INSECTICIDE	ARYSTA LIFESCIENCE NORTH AMERICA LLC	For control of redlegged earth mite, blue oat or pea mite, bryobia mite, lucerne flea, bluegreen aphid, cowpea aphid] and spotted clover aphid on cereal, legume, pastures and poppy oilseed crops.	290 g/L AC
33055	FOLIMAT 800 INSECTICIDE SPRAY	ARYSTA LIFESCIENCE NORTH AMERICA LLC	For control of european red mite, two spotted mite, woolly aphid, banana flower thrips, aphid, mealy bug, mite, sycamore lace bug, thrip, whitefly, aphid, california red scale, jassids, mirids, thrip, bluegreen aphid, cowpea aphid, green peach aphid, green peach aphid and lucerne flea.on fruit trees, vegetables, potatoes, forestry & ornamentals	800 g/L LC

33051	FOLIMAT GARDEN INSECTICIDE	ARYSTA LIFESCIENCE NORTH AMERICA LLC	For control of codling moth, mite, thrip, woolly aphid, aphid, bronze orange bug, citrus leafminer, mealy bug, leaf-eating beetle, bug, caterpillar, mealy bug, mite, sycamore lace bug, whitefly cabbage moth and cabbage white butterfly on fruit trees, vegetables, potatoes, herbs & ornamentals	2 g/kg HG AE