PART B

OCCUPATIONAL HEALTH AND SAFETY

1 INTRODUCTION

Methiocarb is an anticholinesterase carbamate chemical with insecticidal, acaricidal and molluscicidal activity used for commercial crop protection and in home garden products. It has no registered veterinary uses. Commercial uses include crop protection and home garden use.

Methiocarb was one of the agricultural and veterinary chemicals identified as candidates for priority review under the Australian Pesticides and Veterinary Medicines Authority (APVMA) Chemical Review Program.

In addition to the hazard assessment, the Occupational Health and Safety (OHS) Review, is based on information obtained from: Industry submissions, APVMA Performance Questionnaires (PQs) (initiated as part of the review of methiocarb), APVMA Agriculture Report on methiocarb, published literature and overseas reviews.

2 HAZARD OVERVIEW

2.1 Acute toxicity

In lethal-dose studies, the oral LD_{50} for methiocarb in rats ranged from 9 to 135 mg/kg bw (moderate to high). The acute inhalation LC_{50} of methiocarb in rats was moderate (433-1208 mg/m^3; head only, 4 hr exposure). The acute dermal toxicity in rats and rabbits was low (LD_{50} > 2000 mg/kg bw). The effects of acute methiocarb intoxication were consistent with those seen for other carbamates and included salivation, lacrimation, vomiting, diarrhoea, muscular tremors, restlessness, convulsions, and paralysis. Methiocarb was non-irritant to rabbit eyes or skin and was non-sensitising to guinea pig skin.

No studies were available on methiocarb products currently registered in Australia (wettable powder containing 750 g/kg active ingredient or baits containing 20 g/kg active ingredient). The acute toxicity of other formulations containing methiocarb was generally consistent with that seen for the technical grade active constituent. LD_{50} values in rats ranged from 23 to 140 mg/kg bw for formulations containing 75% methiocarb. The acute oral LD_{50} of products containing 4% methiocarb ranged from 848 to 945 mg/kg bw, and the value for pellets containing 2% methiocarb was in excess of 2648 mg/kg bw in rats. The formulations were of moderate to low dermal toxicity. Based on the proportions of non-active ingredients in the registered products, the wettable powder is expected to exhibit slight dermal and ocular irritation, whilst the baits are expected to exhibit eye but no dermal irritation.

2.2 Repeat dose toxicity

A number of repeat dose animal studies were considered suitable to establish NOELs relevant for an OHS risk assessment. These are shown in Table 1.

Table 1: Methiocarb - Summary of NOELs relevant to the OHS assessment

Species and route	**Duration of study/ treatment**	**NOEL (mg/kg bw/day, unless otherwise stated)**	2.2.1.1 LOEL and toxic effects
Rat, inhalation Thyssen & Mohr (1983)	3 weeks	6 mg/m^3 (males) 23 mg/m^3 (females)	Inhibition of ChE activity in the plasma and brain at higher exposure levels (23 mg/m^3 for males, 96 23 mg/m^3 for females); depressed RBC ChE (18% in males) and depressed body weight (both sexes) at 96 mg/m^3
Rabbit, dermal occluded Procter (1988)	3 weeks	60	Decreased food consumption and weight gain and plasma ChE inhibition at 150 mg/kg bw/day; NOEL for RBC and brain ChE >375 mg/kg bw/day

ChE – cholinesterase

Based on a consideration of the likely duration and routes of worker exposure, ie. dermal and inhalation, the OHS risk assessment, used NOELs derived from 3-week dermal study and a 3-week inhalational study in rabbits and rats respectively. The NOEL, based on cholinesterase inhibition, was 60 mg/kg bw/day for dermal exposure whereas for inhalational exposure with the same toxicological endpoint the NOEL was 6 mg/m^3 (Procter, 1988; Thyssen & Mohr, 1983). Since these studies were performed using the routes of exposure which are relevant for occupational use, dermal and inhalation absorption factors are not necessary.

2.3 Human Studies

One human study was available in the literature. In this study, Kimmerle (1960) investigated the irritancy of technical grade methiocarb when applied to the forearm of 8 subjects. A cotton wool compresses containing methiocarb (source, purity and the dose not specified) in dry form or moistened with oil (type not specified) or water were applied to each subject's forearm for 8 and 24 h respectively. The compresses were held in position with adhesive bandages.

The study results showed the test compound to be an irritant to human skin. However, the study was not considered suitable for regulatory purposes due to lack of information regarding the chemical identity of the vehicle (oil) and therefore its contribution to the observed irritancy.

2.4 Carcinogenicity classification

Methiocarb is not classified as carcinogenic on the NOHSC List of Designated Hazardous Substances (NOHSC, 1999) and is not listed in the NOHSC Exposure Standards for Atmospheric Contaminants in the Occupational Environment (NOHSC, 1995a).

Methiocarb has not been evaluated by the International Agency for Research on Cancer (IARC).

3 Health effects related to occupational exposure

There are no published reports of illness or poisonings associated with the use of methiocarb in Australia.

However, an occupational medical experience statement was provided by the sponsor (Faul, 1993). Annual medical check-ups and regular blood ChE testing (at four-week intervals) of 250 formulation plant workers showed no evidence of chemical-related health effects. These workers handled a number of different crop-protection agents in addition to methiocarb.

A case study reported a dermatological effect of methiocarb (98.2%, 0.5% petrolatum, product or constituents not identified) in a 35-year old carnation grower (Willems, 1997). The man presented acute severe hand eczema, which did not respond to several topical corticosteroids. The dermatitis failed to improve when contact with methiocarb was minimised . A series of skin patch test using allergens from the European Standard Series were found to be positive for potassium dichromate, wool wax alcohols and a methiocarb-based product (Mesurol, 0.5% petrolatum), but were negative with 11 other pesticide formulations. This single case study was considered to be of limited value in determining the skin sensitising potential of methiocarb because other constituents in the product may have contributed to the observed reaction. Information on previous exposure to the chemical/chemical mixtures or length of exposure was not provided.

4 USE PROFILE

Two formulations of methiocarb are currently registered in Australia. They include a wettable powder (**WP**) containing 750 g active ingredient (ai) per kg and baits (**BA**) containing 20 g/kg ai. A summary of formulation and packaging types is provided in Table 2.

Table 2: Formulation types and packaging sizes for methiocarb products registered for agricultural use

Formulation type	Code*	Packaging size and type**
WP 750 g/kg	**75 WP**	400 g
BA 20 g/kg	**2 BA**	250 g, 500 g, 600 g, 1 kg, 1.5 kg, 5 kg, 10 kg, 25 kg and 150 kg

WP – wettable powder, **BA** – bait
* these codes are used henceforth in the report
Source: APVMA and product labels
** information provided on labels

Technical methiocarb is imported into Australia where it is reformulated into pellet and wettable powder formulations. There is currently only one Australian registrant of methiocarb products.

This assessment does not address worker exposure and risk during manufacture/formulation. However, Australian manufacturers/formulators have a legal requirement to follow good manufacturing practices, and to have adequate quality control and monitoring facilities.

4.1 Use patterns

Information on the Australian use pattern of methiocarb was obtained from registered product labels, APVMA Agriculture Report and PQs obtained through the APVMA covering Large Scale Users (PQ No.1), Small Scale Users (PQ No.2) and State Chemical Co-ordinators (PQ No. 4). This information is summarised in Table 3.

Methiocarb is used in a limited number of registered and off-label agricultural and domestic situations. There are also a number of current permits for this chemical. This review considered registered uses of commercial methiocarb products only. These uses are summarised in Table 3.

Table 3: Use pattern of registered methiocarb products

Crop/ Situation	Product: application rate/dilution	Alternative chemicals/ strategies used*	Comments/ label instructions	Application methods
Grapevines	**75 WP**: 100 g/100 L or 200 g/100 L	N/A	Applied at or before flowering	Boom or air mist Orchard type spraying equipment**
Oranges	**75 WP**: 100 g/100 L	Metaldehyde (citrus)	Apply as a cover spray when pests become apparent	Although this is a label use, most applications to orchards (including oranges) are expected to be by hand distribution of pellets (**2 BA**)**
Hibiscus	**75 WP**: 100 g/100 L	N/A	Spray when beetles are first seen and 3 days later to control beetles in tight buds	Cover spray**
Ornamentals	**75 WP**: 300 g/100 L or 200 g/100 L	N/A	Higher rate applied as a soil drench (Ag report specifies an application volume of 2 L/m^2), lower rate applied as a cover spray	Cover or spot spray** Hand wand connected to mobile powered spray equipment **
Poppies	**75 WP**: 5.5 kg/ha	N/A	Applied at seedling stage as a "thorough spray"	Cover spray**
Gardens	**2 BA**: 100 pellets per m^2	N/A	Sprinkle evenly onto ground. Heaping is unnecessary and wasteful	Assumed to be applied by hand**
Berry crops, cereals, gardens, nurseries, oilseed crops, orchards, pastures, vegetable crops	**2 BA**: 5.5 kg/ha or 11-22 kg/ha	Metaldehyde (avocado, pulses, cereals, pasture)	Lower rate used for most infestations, higher rate for heavy infestations or tall/dense pasture Gloves should be worn when pellets are spread by hand	Applied by hand, fertiliser spinners, combines or sod seeders Hand distribution around vine butts or along the rows**
Sunflowers	**2 BA**: 2.5 kg/ha (10 pellets/m^2)	N/A	Scatter evenly on ground 1-3 days after sowing	Method not specified, assumed to be as above

Information derived from labels unless otherwise indicated
* Information provided by survey respondents
** Information provided by APVMA (Agricultural assessment)
N/A – not available

Duration and frequency of application

The frequency of application is not specified on product labels. Information from the APVMA suggests that methiocarb may not be required every season, however some agricultural practices (eg. conservation tillage systems) may increase the number and spread of slugs and snails into more areas.

Information from survey respondents suggests a range of application frequencies from less than once per year to 2 applications per year for all label situations. Although application frequencies are low, work is generally conducted on consecutive days to cover large treatment areas.

4.2 Label restrictions

The withholding periods (WHP) specified on methiocarb product labels are summarised in
Table 4.

Table 4: Label restrictions for methiocarb products

Crop	Product labels identifying WHP	WHP
Citrus	75 **WP**	Do not harvest for **6 weeks** after application
Grapes	75 **WP**	Do not harvest for **9 weeks** after application
Grapevine leaves	75 **WP**	Must not be used for human consumption
Edible crops	2 **BA**	Do not harvest for **7 days** after application
Treated areas	2 **BA**	Do not graze or cut for stock food for **7 days**

The label for **WP** formulation recommends the use of PVC gloves and a face shield during the preparation of spray. This information is contained in the safety directions. No other PPE are recommended for mixing/loading or application of **WP**.

The labels for commercial packs of **BA** formulation recommend the use of gloves during hand spreading when treating berry crops, cereals, gardens, nurseries, oilseed crops, orchards, pastures and vegetable crops. This recommendation is located in the Directions for Use table for one product only. The safety directions for **BA** products do not recommend gloves or any other PPE. There are no re-entry periods specified on any of the product labels.

5 OCCUPATIONAL EXPOSURE AND RISK ASSESSMENT

The occupational risk assessment takes into consideration the hazard of the chemical as determined by toxicology testing, its use pattern in Australia and worker exposure for each exposure situation.

In order to adequately determine the risk associated with the end use or post-application exposure to methiocarb, the MOE were calculated by comparing the most appropriate NOELs (described in Section 2) with exposure data obtained from end use exposure data (surrogate exposure studies, predictive modelling or exposure database estimates) or post-application

exposure data (measured exposure studies or dislodgeable foliar residue data) detailed in this section.
Where a NOEL, taken from a human study, is used to estimate risk a MOE of approximately 10 or more is considered to be acceptable to account for intra-species (10x) variability. For NOELs derived from animal data a MOE of 100 or more is considered to be acceptable. This MOE includes a consideration of the intra-species (10x) and inter-species (10x) variability. Since the methiocarb risk assessment relies on NOELs derived from animal data only, a MOE of 100 or more is considered to represent an acceptable risk.

Methiocarb exposure is usually associated with the inhibition of cholinesterase activity. As the extent of cholinesterase inhibition increases clinical effects, characteristic of carbamates, may be observed. To estimate methiocarb risk, short-term studies were considered the most appropriate, as most exposures are expected to be infrequent (one to two applications per year) with applications made on a small number of consecutive days. A rabbit dermal NOEL (60 mg/kg bw/day) was available to assess risk from dermal exposure, while a rat inhalational study was considered suitable to estimate risk from inhalation exposure (NOEC 6 mg/m^3). The NOEC (6 mg/m^3) was converted to a daily systemic dose by assuming that the respiratory volume/h and bodyweight of the rats was 0.01 m^3 and 0.23 kg respectively (ie. 6 mg/m^3 x 0.01 m^3/h x 6 h/day (exposure duration)/0.23 kg = 1.6 mg/kg bw/day).

In general, based on the presence of non-active ingredients, wettable powders containing methiocarb are expected to exhibit slight skin and eye irritation, but no skin sensitisation, while baits are expected to exhibit only eye irritation. These topical effects may occur in workers who come in contact with these products.

5.1 End use

Methiocarb products are used in a number of crop and garden situations. To facilitate the risk assessment, rather than consider each individual use situation separately, exposure scenarios were developed, coded and grouped where possible according to application method.

Methiocarb is available in two different formulation types to be used outdoors as a foliar spray, a soil drench or as a soil bait. The extent of exposure is dependent on the formulation type and method of application. On the whole, exposure is expected to be limited to inhalation and dermal exposure during mixing/loading (if applicable) and application.

The agricultural exposure scenarios identified for use of methiocarb are:

Scenario (1) Mixing/loading and application of **WP** by mechanical application
Scenario (2) Mixing/loading and application of **WP** by hand held application - soil drench
Scenario (3) Mixing/loading and application of **WP** by hand held application - cover spray
Scenario (4) Application of **BA** by mechanical applicator – orchard applications
Scenario (5) Application of **BA** by mechanical applicator – broadacre applications
Scenario (6) Application of **BA** by hand distribution - all situations

Mechanical applications of WP are in most cases conducted using orchard type equipment however the label also allows for the use of boom equipment or misters. Exposure estimates for scenario (1) are based on orchard type equipment only given that:

(i) airblast application is the only mechanical method indicated by survey respondents,
(ii) application parameters are only available for orchard applications, and
(iii) boom spray or misting is expected to result in equal or less exposure than orchard airblast.

Details of the use pattern parameters identified in the occupational exposure assessment are presented in Table 5.

Table 5: Use pattern parameters used in exposure assessment

Situation	Scenario number and description	Product application rate, spray volume and concentration of ai in spray	Work rate	Total ai handled per day
ornamentals (nurseries, cut flowers, greenhouses, poppies, hibiscus) vineyards orchards (including oranges)	**Scenario (1)*** Mixing/loading and application of **WP** by mechanical application	150 g/100 L 2000 L/ha (2.25 kg ai/ha) 0.11%[1]	12 ha/6 hr/day[2]	27 kg
	Scenario (2)* Mixing/loading and application of **WP** by hand held application - soil drench	300 g/100 L 2 L/m^2 (45 kg ai/ha) 0.23%[3]	0.1 ha/6 hr/day (vehicle mounted spray tank)[4]	4.5 kg
			0.02 ha/6 hr/day (knapsack tank)**	0.9 kg
	Scenario (3)* Mixing/loading and application of **WP** by hand held application - cover spray	200 g/100 L 2000 L/ha (3 kg ai/ha) 0.15%[5]	0.5 ha/3 hr/day (vehicle mounted spray tank)[6]	1.5 kg
			0.2 ha/6 hr/day (knapsack tank)**	0.6 kg
gardens broadacre crops (cereals, sunflower, oilseeds, pasture) ornamentals (nurseries, cut flowers, greenhouses) orchards (including oranges) vegetable crops berry crops	**Scenario (4)** Application of **BA** by mechanical applicator – orchard applications	5.5 kg/ha[7]	5 ha/2 hr/day[8]	0.55 kg
	Scenario (5) Application of **BA** by mechanical applicator – broadacre applications	17 kg/ha[9]	5 ha/2 hr/day[10]	1.7 kg
	Scenario (6) Application of **BA** by hand distribution - all situations	5.5 kg/ha[11]	2 ha/2 hr/day[12]	0.22 kg

* open mixing and loading using non-water soluble 400 g packs
** area to be treated is limited by total spray volume achievable using knapsack per day: 400 L (default maximum used in UK Predictive Operator Exposure Model)
[1] mean label rate; spray volume based on APVMA advice (airblast application in cherries); equivalent to 3 kg product/ha
[2] based on survey information; crop areas ranged from 1-50 ha for orchards
[3] label rate for soil drench; spray volume based on APVMA advice for application by soil drench
[4] based on survey information for nurseries and greenhouses; average crop area 1 ha; soil area to be treated expected to be a fraction of total crop area, assume to be 10%
[5] label rate for cover spray; spray volume based on volume for mechanical applications
[6] based on survey information for flowers (cut flowers, gerberas, roses); most ornamentals grown in small areas (~1 ha), poppies grown in larger areas (over 50 ha)
[7] label rates for most orchard infestations
[8] based on survey information for orchards; crop areas ranged from 1-50 ha for orchards
[9] mean label rate for tall/dense pasture (11-22 kg/ha)
[10] based on survey information for applications by fertilizer spreaders; broadacre crop area ~200 ha
[11] application rate for the majority of label situations
[12] based on survey information for hand applications; APVMA advice suggests up to 50 ha of vegetable crops are treated by hand, mean vegetable farm size reported in survey ~30 ha

Exposure estimates represent the exposure of a worker after all protection provided by clothing, protective clothing or engineering controls.

Workers applying **WP** are assumed to wear their own clothing (one layer) and gloves during mixing/loading and application (justification provided in Section 5.1.3.1.

Workers applying **BA** are assumed to wear their own clothing (one layer) for all application methods except hand distribution, during which they are assumed to also wear gloves (justification provided in Section 4.1.3.2).

The following other assumptions are used in the exposure assessment:

10% penetration (90% protection) through coveralls/overalls or equivalent clothing ie. long-sleeved shirt and long pants – Thongsinthusak et al. (1993)

10% penetration (90% protection) through PVC gloves - Thongsinthusak et al. (1993)

90% protection afforded by half face-piece respirator with cartridges - Thongsinthusak et al. (1993)

100% absorption of inhaled dose (default) –Thongsinthusak et al. (1993)

average human body weight = 70 kg

5.1.1 Methiocarb exposure studies

No chemical specific worker exposure data was provided for assessment and there were no relevant studies located in the literature.

5.1.2 Predicted exposure

Predicted exposure – Sponsor provided estimates

Diesing L and Schrader J (1997) Assessment of the potential risk that may result during application of mesurol WP 50 in high cultures in the field and in high and low cultures in greenhouses, Bayer AG, Study number 2 (unpublished report).

The sponsor provided the above study, which utilised modelling data to derive exposure estimates during field applications as well as surrogate measured exposure data to estimate exposure during knapsack application to greenhouse plants. The modelled and surrogate exposure data are discussed separately below.

Modelled data

Exposure modelling was conducted to estimate mixer/loader and applicator exposure during field applications of WP formulation by broadcast air assisted sprayers or by hand held sprayers.

Modelling was conducted using the German Model :

Uniform Principles for Safeguarding the Health of Applicators of Plant Protection Products (Uniform Principles for Operator Protection); Mitteilungen aus Biologischen Bundesanstalt für Land- und Forstwirtschaft, Berlin-Dahlem, no. 277, 1992.

The following parameters and assumptions were used in the German modelling:

Inhalation absorption	100%
Average body weight	70 kg
Dermal NOAEL	150 mg/kg bw/day based on RBC and brain ChE inhibition in a 3-week dermal exposure study in rabbits (Procter, 1988).
Inhalation NOAEL	1.62 mg/kg bw/day
Formulation type	50 WP
Application rate	1.5 kg ai/ha
Work rate (tractor mounted equipment)	8 ha/day
Work rate (hand held equipment)	1 ha/day
Spray volume	not provided
PPE	gloves during mixing/loading, standard protective garment (equivalent to one layer of clothing) during mixing/loading and application
Packaging type	not provided

Table 6: Mixer/loader/applicator exposure during 50 WP application to high field crops based on the German Model:

Situation	PPE		Application rate, work rate (amount ai handled)	Actual exposure							
				(mg/kg bw/day)						(mg/person/ kg ai handled)*	
				M/L		Appl		M/L/A		M/L/A	
				Dermal	Inh	Dermal	Inh	Dermal	Inh	Dermal	Inh
High crops, tractor mounted equipment	no protective clothing	no gloves	1.5 kg ai/ha, 8 ha/day (12 kg ai/day)	1.030	0.012	1.972	0.003	3.002	0.015	17.5	0.088
		Gloves during M/L		0.010				1.982		11.6	
	protective clothing	no gloves		1.030		0.408		1.438		8.4	
		gloves during M/L		0.010				0.418		2.4	
High crops, hand held equipment	no protective clothing	no gloves	1.5 kg ai/ha, 1 ha/day (1.5 kg ai /day)	1.071	0.017	0.866	0.006	1.937	0.023	90.4	1.07
		gloves during M/L		0.011				0.877		40.9	
	protective clothing	no gloves		1.071		0.357		1.428		66.6	
		gloves during M/L		0.011				0.368		17.2	

All estimates assume 1% transmittance through gloves (worn during M/L only) and 5% transmittance through protective clothing (worn during both M/L and application, however model does not consider dermal body exposure during M/L)
*Calculation based on 70 kg body weight/person
Inh – inhalation; M/L - mixing/loading; Appl – applicator; M/L/A - mixer/loader/applicator

Comments:

The concentration of methiocarb in the product (500 g/kg) used in this model was appreciably less than the product currently available for use in Australia (750 g/kg). Furthermore, the cab type, spray volume and packaging type used in the model were not reported. Therefore this data will not be considered for methiocarb exposure estimation.

Surrogate data

Exposure estimates for greenhouse workers following applications of dichlofluanid, fenpropathrin and triforine were used to predict exposure of greenhouse workers during application of methiocarb. The surrogate data reported in this study are summarised from the following, more comprehensive, study:

Burhenne S and Mich G (1996) Operator Exposure in Greenhouses During Practical Use of Plant Protection Products, Bayer AG, Study number EF 94-02-03 (unpublished report)

Potential dermal body exposure was measured from external dermal patches and glove rinsings. Actual dermal body exposure was measured from analysing whole body underwear and hand rinsings. Actual dermal head exposure was estimated from a patch fitted to each operator's hat. Inhalation exposure was measured from personal air samplers located at each operator's breathing zone.

The table below summarises the relevant report data from both studies.

Table 7: Mixer/loader/applicator exposure during WP application to greenhouse crops based on surrogate estimates:

Situation	PPE	Actual exposure (mg ai/person/kg ai handled)					
		Mixer/loader		Applicator		Mixer/loader/applicator	
		Dermal	Inhalation	Dermal	Inhalation	Dermal	Inhalation
Mixing/loading* and knapsack application of low cultures on tables**	Cotton or Gore-Tex overalls (half the replicates wore each) Nitrile gloves (mixer/loaders and applicators) Cotton cap and dust mask (mixer/loaders only) Respirator (applicators only)	0.6865 (Hd: 0.5319; Hs: 0.0090; B; 0.1456)	0.8946	0.6709 (Hd: 0.4393; Hs: 0.0089; B: 0.2227)	0.3985	1.3574	1.2931
Mixing/loading* and knapsack application of high cultures (roses, height up to 1.8 m) **		0.6865 (Hd: 0.5319; Hs: 0.0090; B; 0.1456)	0.8946	1.7973 (Hd: 1.5619; Hs: 0.0075; B: 0.2279)	0.1084	2.4838	1.0030

All estimates are geometric means of 12 replicates,
Hd: head exposure (based on external patch on hat)
Hs: hands exposure (based on hand rinsings, gloves worn during both mixing/loading and application)
B: body exposure (based on whole body underwear analyses)
Inhalation exposure is based on breathing zone air concentrations (it is assumed that potential inhalation exposure is equivalent to actual exposure for workers not wearing a respirator); although applicators wore respirators the authors estimated potential inhalation exposure for all workers
* twelve mixer loaders each handled 63.88 g ai when mixing dichlofluanid as a 50% WP using open mixing techniques (5 operations per replicate, each operation involving the mixing of 10 L and transferring into a 17 L knapsack tank, average replicate time was 17 min)
** applicator exposure estimates were pooled following applications of three different actives using a spray gun attached to a pressurised hose sprayer; the details of the separate applications are tabulated as follows:

Situation	Number of replicates	Product	Average application rate and spray volume	Final concentration of ai in spray	Total ai applied per replicate	Average application time per replicate
Low crops	4	Dichlofluanid (50% **WP**)	3.1 kg ai/ha; 2423 L/ha	0.127%	63.9 g	19 min
	4	Fenpropathrin (10% EC)	0.15 kg ai/ha; 2771 L/ha	0.005%	2.58 g	
	4	triforine (19% EC)	0.51 kg ai/ha; 2490 L/ha	0.020%	9.75 g	
High crops	4	Dichlofluanid (50% **WP**)	6.8 kg ai/ha; 5333 L/ha	0.127%	230 g	41 min
	4	Fenpropathrin(10% EC)	0.30 kg ai/ha; 5545 L/ha	0.005%	9.27 g	
	4	triforine (19% EC)	0.87 kg ai/ha; 4245 L/ha	0.020%	35.1 g	

Discussion

This study provided risk assessments based on the estimated exposure data, however due to differences in the application parameters and assumptions, these results were not considered suitable for inclusion in this review.

Burhenne and Mich (1996) also reported greenhouse air concentrations following application of the three test substances for up to 120 minutes. These results are not considered in this review as the relative dissipation rates of the surrogate substances and methiocarb are not known. In addition the results from this part of the study were not conclusive with most of the values below detection level.

The results from surrogate greenhouse applications will be used to assess risk during **Scenario (3)** (Mixing/loading and application of WP by hand held application - cover spray). The study results have been standardised to the Australian situation in the table below.

Table 8: Surrogate greenhouse exposures standardised for Australian end users applying 75 WP:

Exposure Scenario	Study situation	Australian application rate, spray concentration, total ai applied per day Australian PPE/clothing	Study application rate, total ai applied per day* Study PPE/clothing	Operation	Exposure*	
					Actual dermal exposure (mg/kg bw/day)	Inhalation dose** (mg/kg bw/day)
Scenario (3) Mixing/loading and application of **WP** by hand held application - cover spray	Knapsack, greenhouse low cultures	3 kg ai/ha, 0.15%, 6 kg ai/day One layer clothing and gloves during M/L/A	0.15-6.8 kg ai/ha, 0.05-0.127% 0.026-0.23 kg ai/day Protective clothing + gloves during M/L/A, dust mask during M/L, respirator during Appl	M/L	0.00588	0.00768
				Appl	0.00576	0.00342
				M/L/A	0.0116	0.0111
	Knapsack, greenhouse high cultures			M/L	0.00588	0.00768
				Appl	0.0154	0.000928
				M/L/A	0.0213	0.0086

* standardised to Australian use pattern (amount ai handled per day); PPE as per study assumptions

** assuming 100% inhalation absorption; authors did not account for dust mask or respirator use, inhalation exposure was estimated from breathing zone samples with no correction for the use of such devices

Risk estimated from the standardised exposure estimates above are presented in Table 13 (Section 4.1.3).

Predicted exposure – UK Predictive Operator Exposure Model

In the absence of relevant worker exposure data, the UK Predictive Operator Exposure Model (POEM) was used to assess uses of methiocarb wherever possible.

POEM is a descriptive model based on databases of operator exposure field studies. POEM provides surrogate exposure values, which are derived from the levels determined in several field studies for each of several different scenarios. Exposure calculations are divided into two parts; contamination from handling the concentrated product and contamination during actual application of the dilute spray. The model assumes that the level and distribution of potential dermal contamination are mainly dependent on the handling techniques used during preparing the pesticide product for use, the type of application equipment employed and the work practices of the individual operator.

In this model, exposure during mixing/loading, is assumed to be confined to the hands only, and no respiratory exposure is assumed to occur during mixing/loading. Dermal (hands, trunk and legs) and inhalation exposure is assumed during spray application.

In using POEM, it is necessary to make assumptions in order to estimate the actual exposure from potential exposure. These assumptions may be based on laboratory or field data, but in the absence of data conservative estimates have to be made.

The use of exposure values derived from predictive models (such as POEM), involve the use of conservative assumptions for unknowns and a range of values for a particular method of

spraying. Such modelling is internationally accepted as the first step in a tiered risk assessment (Tier 1). There is no POEM model suitable for the estimation of exposure during the application of pelleted (BA) methiocarb.

POEM was suitable for the estimation of mixer/loader and applicator exposure to WP methiocarb for a number of end use situations. These estimates are provided in Appendix 1. The end use parameters, resultant exposure estimates and risk assessment for each end use scenario are presented and discussed under the designated scenario numbers in

Table 5 and in the end use risk assessment section (Section 4.1.3).

The following assumptions are common for all POEM estimates.

Inhalation absorption:	100% (default value)
Hand contamination:	0.01 g per operation (consistent with POEM estimate for small packs)
PPE worn by operators:	One layer clothing during application plus gloves during mixing/loading/application

All other parameters are as per use pattern parameters in

Table 5.

The POEM models chosen to represent each spray scenario are described in the table below.

Table 9: POEM models for Australian end users mixing/loading and applying methiocarb:

Exposure Scenario	POEM Model used and reason
Scenario (2) Mixing/loading and application of **WP** by hand held application – soil drench [(2)]	*Hand Held Outdoors Hydraulic Nozzles (H-Nozzle)* Droplet size not important for soil drench, therefore hydraulic nozzles will be appropriate for both vehicle mounted spray tanks and for knapsack spraying
Scenario (3) Mixing/loading and application of **WP** by hand held application – cover spray	*Hand Held Outdoors Hydraulic Nozzles (H-Nozzle)* Model appropriate for hand applications from vehicle mounted spray tanks, depending on the height of the crop; *H-Nozzle* appropriate for knapsack applications

The resulting exposure estimates are summarised in the table below.

Table 10: POEM estimates for Australian end users applying 75 WP:

Exposure Scenario	POEM estimate number (POEM model)	Product application rate, spray volume, final spray and concentration (% ai)	Application equipment Work rate	Operation	Exposure (mg/kg bw/day) *	
					Actual dermal exposure	Inhalation dose
Scenario (2) Mixing/loading and application of **WP** by hand held application - soil drench [(2)]	Estimate 1 (H-Nozzle)	300 g/100 L; 2 L/m^2; (45 kg ai/ha); 0.23%	Vehicle mounted spray tank 0.1 ha/6 hr/day	M/L**	0.016	not measured
				Appl	1.59	0.0039
				M/L/A	1.61	0.0039
	Estimate 2 (H-Nozzle)		Knapsack sprayer 0.02 ha/6 hr/day	M/L***	0.029	not measured
				Appl	1.59	0.0039
				M/L/A	1.62	0.0039
Scenario (3) Mixing/loading and application of **WP** by hand held application - cover spray	Estimate 3 (H-Nozzle)	200 g/100 L; 2000 L ha; (3 kg ai/ha); 0.15%	Vehicle mounted spray tank 0.5 ha/3 hr/day	M/L**	0.0053	not measured
				Appl	0.530	0.0013
				M/L/A	0.54	0.0013

* dermal or inhalation exposure (mg/day) divided by 70 kg body weight; assumes 100% inhalation absorption
** number of transfer operations during mixing/loading into vehicle mounted spray tanks (including orchard sprayer) = total product applied per day (kg) ÷ 0.4 kg product pack size
*** number of transfer operations during mixing/loading into knapsack tanks = 27: total volume applied per day (400 L POEM maximum) ÷ default knapsack tank size (15 L)
M/L- mixing loading
Appl - application
M/L/A - mixing/loading/application

Predicted exposure – Pesticide Handlers Exposure Database

In the absence of relevant worker exposure data, the Pesticide Handlers Exposure Database (PHED) Version 1.1 was used to support other modelled or surrogate data.

PHED is a generic database containing measured exposure data for pesticide users during handling and application. Exposure records are included in one of the four files in PHED: mixer/loader, applicator; combined mixer/loader/applicator and flaggers. To generate estimates of exposure the user selects the use pattern, which is the most applicable and chooses the multiple variables in the database. Estimated exposure can be normalised as mg/kg ai handled or mg/hr. In order for the database to be used effectively, accurate subsetting and interpretation of exposure scenarios and values is required.

The most suitable application method to estimate exposure to WP formulation during mechanical application was considered to be orchard sprayer. A number of PHED files contained data suitable for this application method. Data available on mixing/loaders who also applied the product were limited, therefore separate estimates for mixer/loaders (applying by any method) and applicators (applying WP formulation from other packaging types) were also used as a source of exposure estimates. The subsetting parameters used are summarised in

Table 11 under Scenario (1).

For hand held applications of WP formulation, the only studies suitable were for low pressure hand wand applications in indoor settings (eg ornamentals). The spray tanks involved were small enough to be carried by hand or worn on the back. These studies can therefore be used to represent knapsack applications by soil drench or cover spray. Again data in the mixer/loader/applicator file were limited therefore relevant data in the mixer/loader and applicator files are also used. The subsetting parameters used are summarised in

Table 11 under Scenario (2) and Scenario (3).

Exposure during application of BA formulation could be estimated based on PHED studies involving solid broadcast applications of granules or hand distribution of baits. PHED data were available for mechanical application of granules using either tractor-mounted applicators (such as drop type granular applicators or seed planters) or hand pulled/pushed applicators (such as fertiliser spreaders). Both types of mechanical applicators were considered relevant for Australian orchard and broadacre applications. Data were obtained from both the mixer/loader/applicator and applicator data sets where appropriate. The subsetting parameters used are summarised in under Scenario (4) and Scenario (5).

Estimates of exposure during hand application of BA formulation was possible using data from one PHED study, which measured exposure following hand distribution of baits to a residential site. The subsetting parameters used for this situation are summarised in Table 11 under Scenario (6).

Table 11: PHED data used to estimate exposure to Australian end users of methiocarb:

<table>
<tr><th></th><th colspan="2">PHED File (subset name) and subsetting parameters</th></tr>
<tr><td>Scenario (1)
Mixing/loading and application of WP by mechanical application</td><td colspan="2">Orchard sprayer

MIXLD.FILE (M1.MLOD)
WP ≥ 50%; packaging type: bags; mixing procedure: open; location: outdoor

APPL.FILE (M2.APPL)
WP; application method: airblast; cab type: open

MLAP.FILE (M3.MLAP)
WP ≥ 50%; packaging type: bags; mixing procedure: open; application method: airblast; cab type: open</td></tr>
<tr><td>Scenario (2)
Mixing/loading and application of WP by hand held application - soil drench (2)</td><td colspan="2" rowspan="2">Knapsack

MIXLD.FILE (M4. MXLOD)
WP ≥ 50%; packaging type: bags; mixing procedure: open; location: indoor

APPL.FILE (M5.APPL)
WP; application method: low pressure hand wand; location: indoor

MLAP.FILE (M6.MLAP)
WP ≥ 50%; packaging type: bags; mixing procedure: open; application method: low pressure hand wand; location: indoor</td></tr>
<tr><td>Scenario (3)
Mixing/loading and application of WP by hand held application - cover spray</td></tr>
<tr><td>Scenario (4)
Application of BA by mechanical applicator - orchard applications</td><td rowspan="2">Tractor-mounted equipment *

MIXLD.FILE (M7. MXLOD)
Granule ≤ 20%; packaging type: bags; mixing procedure: open; location: outdoor; without study codes: 1004, 0448 **

APPL.FILE (M8.APPL)
Granule ≤ 20%; application method: solid broadcast spreader (tractor/truck/AG uses); cab type: closed

APPL.FILE (M9.APPL)
Granule ≤ 20%; application method: solid broadcast spreader (tractor/truck/AG uses); cab type: open</td><td rowspan="2">Hand operated equipment ***

MIXLD.FILE (M7. MXLOD)
Granule ≤ 20%; packaging type: bags; mixing procedure: open; location: outdoor; without study codes: 1004, 0448 **

MLAP.FILE (M10.MLAP)
Granule ≤ 20%; application method: solid broadcast spreader (belly grinder) or solid broadcast spreader (Scotts type residential)</td></tr>
<tr><td>Scenario (5)
Application of BA by mechanical applicator - broadacre applications</td></tr>
<tr><td>Scenario (6)
Application of BA by hand distribution - all situations</td><td colspan="2">Hand distribution

APPL.FILE (M11.APPL)
Study code: 0520 ****</td></tr>
</table>

* the MLAP. FILE was not used as it contains only inhalation data for this application method
** these two studies were not considered relevant as the mixing/loading was conducted for aerial applications; all other studies in this subset were for application by solid broadcast spreader
*** the APPL.FILE was not used as it contains no data for this application method
**** this is the only study in any PHED file that involves hand distribution of a granular formulation; in this study a 2% bait was used to treat one residential site

The resulting exposure estimates are summarised in Table 12.

Table 12: PHED estimates for Australian end users of methiocarb

Exposure Scenario	**Australian use parameters**		**PHED subset name**	**Operation***	**Exposure (mg/kg ai handled) *(mg/kg bw/day)* ****	
	Product application rate, spray volume, final spray concentration (% ai) **Work rate** ***Total ai handled***	**Application equipment**			**Actual dermal exposure**	**Inhalation dose *****
Scenario (1) Mixing/ loading and application of **WP** by mechanical application	150 g/100 L; 2000 L/ha; (2.25 kg ai/ha); 0.11% 12 ha/6 hr/day *27 kg ai/day*	**Orchard sprayer**	M1.MLOD	M/L	0.265 ***0.102***	0.020 ***0.0077***
			M2.APPL	Appl	0.660 ***0.255***	0.00466 ***0.00180***
			M1.MLOD + M2.APPL	M/L/A	***0.357***	***0.0095***
			M3.MLAP	M/L/A	6.133 ***2.37***	0.054 ***0.021***
Scenario (2) Mixing/ loading and application of **WP** by hand held application - soil drench	300 g/100 L; 2 L/m^2; (45 kg ai/ha); 0.23% 0.02 ha/6 hr/day *0.9 kg ai/day*	**Knapsack sprayer** (Indoor)	M4.MLOD	M/L	1.024 ***0.0132***	0.064 ***0.00082***
			M5.APPL	Appl	0.600 ***0.0077***	0.0590 ***0.00076***
			M4.MLOD + M5.APPL	M/L/A	***0.0209***	***0.00158***
			M6.MLAP	M/L/A	19.745 ***0.253***	2.093 ***0.0270***
Scenario (3) Mixing/ loading and application of **WP** by hand held application - cover spray	200 g/100 L; 2000 L ha; (3 kg ai/ha); 0.15% 0.2 ha/6 hr/day *0.6 kg ai/day*	**Knapsack sprayer** (Indoor)	M4.MLOD	M/L	1.024 ***0.00878***	0.064 ***0.00055***
			M5.APPL	Appl	0.600 ***0.0051***	0.0590 ***0.00051***
			M4.MLOD + M5.APPL	M/L/A	***0.0139***	***0.00106***
			M6.MLAP	M/L/A	19.745 ***0.169***	2.093 ***0.0179***

* all estimates for workers wearing long pants, long sleeved shirt plus gloves

** dermal or inhalation exposure (mg/kg ai handled, geometric mean) x kg ai handled per day ÷ by 70 kg body weight

*** assumes 100% inhalation absorption

M/L- mixing loading

Appl - application

M/L/A - mixing/loading/application

Table 12: PHED estimates for Australian end users of methiocarb (continued)

Exposure Scenario	Australian use parameters		PHED subset name	Operation*	Exposure (mg/kg ai handled) *(mg/kg bw/day)* **	
	Product application rate, spray volume, final spray concentration (% ai) **Work rate** ***Total ai handled***	**Application equipment**			**Actual dermal exposure**	**Inhalation dose *** **
Scenario (4) Application of **BA** by mechanical applicator - orchard applications	5.5 kg/ha 5 ha/2 hr/day *0.55 kg ai/day*	**Tractor-mounted equipment**	M7.MLOD	M/L	0.0802 ***0.00063***	0.00159 ***0.000013***
			M8.APPL	Appl (closed cab)	0.00528 ***0.000042***	0.000381 ***0.000003***
			M9.APPL	Appl (open cab)	0.0219 ***0.00017***	0.00236 ***0.000019***
			M7.MLOD + M8.APPL	M/L/A (closed cab)	***0.00067***	***0.000016***
			M7.MLOD + M9.APPL	M/L/A (open cab)	***0.00080***	***0.000031***
		Hand operated equipment	M7.MLOD	M/L	0.0802 ***0.00063***	0.00159 ***0.000012***
			M10.MLAP	M/L/A	12.60 ***0.0990***	0.0650 ***0.00051***
Scenario (5) Application of **BA** by mechanical applicator - broadacre applications	17 kg/ha 5 ha/2 hr/day *1.7 kg ai/day*	**Tractor-mounted equipment**	M7.MLOD	M/L	0.0802 ***0.00195***	0.00159 ***0.000039***
			M8.APPL	Appl (closed cab)	0.00528 ***0.00013***	0.000381 ***0.000009***
			M9.APPL	Appl (open cab)	0.0219 ***0.00053***	0.00236 ***0.000057***
			M7.MLOD + M8.APPL	M/L/A (closed cab)	***0.00208***	***0.00005***
			M7.MLOD + M9.APPL	M/L/A (open cab)	***0.00248***	***0.00010***
		Hand operated equipment	M7.MLOD	M/L	0.0802 ***0.00195***	0.00159 ***0.00004***
			M10.MLAP	M/L/A	12.60 ***0.306***	0.0650 ***0.00158***
Scenario (6) Application of **BA** by hand distribution - all situations	5.5 kg/ha 2 ha/2 hr/day *0.22 kg ai/day*	**Hand distribution**	M11.APPL	Appl (+ gloves)****	157 ***0.493***	0.890 ***0.00280***
				Appl (coveralls + gloves)	20.3 ***0.0638***	0.890 ***0.00280***

* all estimates for workers wearing long pants, long sleeved shirt an no gloves unless otherwise stated
** dermal or inhalation exposure (mg/kg ai handled, geometric mean) x kg ai handled per day ÷ by 70 kg body weight
*** assumes 100% inhalation absorption
**** no data available for hand exposure without gloves (hand exposure was estimated under gloves)
M/L- mixing loading
Appl - application
M/L/A - mixing/loading/application

5.1.3 Risk from end use exposure

No measured exposure data were available for methiocarb products, however worker exposure during end use could be quantified to some extent using surrogate or modelled data. Each of the data sources was used only as a guide, with some sources (POEM and PHED) being considered more reliable than others (German model, surrogate study).

Risk estimated from the surrogate/modelled data (Section 4.1.2) was estimated and is summarised in Table 13. The results of the risk assessment are discussed by formulation type and scenario number following the table.

Table 13: Methiocarb end use exposure and risk assessment

Exposure Scenario	Data source/model (Estimate No) (Number of replicates)		Australian application rate, spray concentration, total ai applied per day Study/Model PPE	Operation	Exposure*		MOE**		
					Actual dermal exposure (mg/kg bw/day)	Inhalation dose (mg/kg bw/day)	Dermal	Inhalation	Dermal + inhalation ***
Scenario (1) Mixing/loading and application of **WP** by mechanical application	PHED Subset	M1.MLOD (72 replicates)	27 kg ai/day Long pants, long sleeve shirt, gloves	M/L	0.102	0.0077	588	208	154
		M2.APPL (40 replicates)		Appl	0.255	0.00180	235	889	189
		M1.MLOD + M2.APPL		M/L/A	0.357	0.0095	168	168	83
Scenario (2) Mixing/ loading and application of **WP** by hand held application - soil drench	POEM Estimate 1 Model: H-Nozzle (Vehicle mounted spray tank)		45 kg ai/ha; 0.23%; 4.5 kg ai/6 hr day One layer clothing during Appl plus gloves during M/L/A	M/L	0.016	not measured	3750	not measured	3750
				Appl	1.59	0.0039	38	410	36
				M/L/A	1.61	0.0039	37	410	35
	POEM Estimate 2 Model: H-Nozzle (Knapsack sprayer)		45 kg ai/ha; 0.23%; 0.9 kg ai/6 hr day One layer clothing during Appl plus gloves during M/L/A	M/L	0.029	not measured	2069	not measured	2069
				Appl	1.59	0.0039	38	410	36
				M/L/A	1.62	0.0039	37	410	35
	PHED Subset (Indoor knap-sack)	M4.MLOD (4 replicates)	0.9 kg ai/day Long pants, long sleeve shirt, gloves	M/L	0.0132	0.00082	4545	1951	1429
		M5.APPL (4 replicates)		Appl	0.0077	0.00076	7792	2105	1667
		M4.MLOD + M5.APPL		M/L/A	0.0209	0.00158	2871	1012	770
		M6.MLAP (16 replicates)		M/L/A	0.253	0.0270	237	59	48

* standardised to Australian use pattern (amount ai handled per day)

** MOE = NOEL ÷ Exposure; dermal NOEL = 60 mg/kg bw/day) Procter (1988); inhalation NOEL = 1.6 mg/kg bw/day , Thyssen & Mohr (1983); unacceptable MOE (ie MOE less than 100) are highlighted

*** total MOE = 1 ÷ (1 ÷ dermal MOE + 1 ÷ inhalation MOE)

M/L – mixing/loading

Appl – application

M/L/A – mixing/loading/application

Table 13: Methiocarb end use exposure and risk assessment (continued)

Exposure Scenario	Data source/model (Estimate No)	Australian application rate, spray concentration, total ai applied per day Study/Model PPE	Operation	Exposure*		MOE**		
				Actual dermal exposure (mg/kg bw/day)	Inhalation dose (mg/kg bw/day)	Dermal	Inhalation	Dermal + inhalation ***
Scenario (3) Mixing/ loading and application of **WP** by hand held application - cover spray	Sponsor information - Surrogate data Burhenne & Mich (1996) – indoor knapsack, low cultures	3 kg ai/ha, 0.15%, 0.6 kg ai/day Protective clothing + gloves during M/L/A (potential inhalation exposure reported although dust mask worn during M/L and respirator worn during Appl)	M/L	0.00588	0.00768	10204	208	200
			Appl	0.00576	0.00342	10416	468	500
			M/L/A	0.0116	0.0111	5172	144	143
	Sponsor information - Surrogate data Burhenne & Mich (1996) – indoor knapsack, high cultures		M/L	0.00588	0.00768	10204	208	200
			Appl	0.0154	0.000928	3896	1778	1111
			M/L/A	0.0213	0.0086	2817	186	167

* standardised to Australian use pattern (amount ai handled per day)
** MOE = NOEL ÷ Exposure; dermal NOEL = 60 mg/kg bw/day Procter (1988); inhalation NOEL = 1.6 mg/kg bw/day , Thyssen & Mohr (1983); unacceptable MOE (ie MOE less than 100) are highlighted
*** total MOE = 1 ÷ (1 ÷ dermal MOE + 1 ÷ inhalation MOE)
M/L – mixing/loading
Appl – application
M/L/A – mixing/loading/application

Table 13: Methiocarb end use exposure and risk assessment (continued)

Exposure Scenario	Data source/model (Estimate No) (Number of replicates)		Australian application rate, spray concentration, total ai applied per day Study/Model PPE	Operation	Exposure*		MOE**		
					Actual dermal exposure (mg/kg bw/day)	Inhalation dose (mg/kg bw/day)	Dermal	Inhalation	Dermal + inhalation ***
Scenario (3) Mixing/ loading and application of **WP** by hand held application - cover spray	POEM Estimate 3 Model: H-Nozzle (Vehicle mounted spray tank)		3 kg ai/ha; 0.15%; 1.5 kg ai/3 hr day One layer clothing during Appl plus gloves during M/L/A	M/L	0.0053	not measured	11320	not measured	11320
				Appl	0.530	0.0013	113	1230	104
				M/L/A	0.54	0.0013	111	1230	102
	PHED Subset (Indoor knap-sack)	M4.MLOD (4 replicates)	0.6 kg ai/day Long pants, long sleeve shirt, gloves	M/L	0.00878	0.00055	6834	2909	2040
		M5.APPL (4 replicates)		Appl	0.0051	0.00051	11764	3137	2500
		M4.MLOD + M5.APPL		M/L/A	0.0139	0.00106	4316	1509	1111
		M6.MLAP (16 replicates)		M/L/A	0.169	0.0179	355	89	71

* standardised to Australian use pattern (amount ai handled per day)

** MOE = NOEL ÷ Exposure; dermal NOEL = 60 mg/kg bw/day Procter (1988); inhalation NOEL = 1.6 mg/kg bw/day , Thyssen & Mohr (1983), unacceptable MOE (ie MOE less than 100) are highlighted

*** total MOE = 1 ÷ (1 ÷ dermal MOE + 1 ÷ inhalation MOE)

M/L – mixing/loading

Appl – application

M/L/A – mixing/loading/application

Table 13: Methiocarb end use exposure and risk assessment (continued)

Exposure Scenario	Data source/model (Estimate No) (Number of replicates)		Australian application rate, spray concentration, total ai applied per day Study/Model PPE	Operation	Exposure*		MOE**		
					Actual dermal exposure (mg/kg bw/day)	Inhalation dose (mg/kg bw/day)	Dermal	Inhalation	Dermal + inhalation ***
Scenario (4) Application of **BA** by mechanical applicator - orchard applications	PHED Subset (Tractor-mounted equipment)	M7.MLOD	5.5 kg product/ha; 0.55 kg ai/2 hr day Long pants, long sleeved shirt, no gloves	M/L	0.00063	0.000013	95238	160000	62500
		M8.APPL		Appl (closed cab)	0.000042	0.000003	1500000	533333	416666
		M9.APPL		Appl (open cab)	0.00017	0.000019	352941	84210	66666
		M7.MLOD + M8.APPL		M/L/A (closed cab)	0.00067	0.000016	89552	100000	50000
		M7.MLOD + M9.APPL		M/L/A (open cab)	0.00080	0.000031	75000	51612	33333
	PHED Subset (Hand operated equipment)	M7.MLOD		M/L	0.00063	0.000012	95238	133333	55555
		M10.MLAP		M/L/A	0.0990	0.00051	606	3137	526

* standardised to Australian use pattern (amount ai handled per day)

** MOE = NOEL ÷ Exposure; dermal NOEL = 60 mg/kg bw/day Procter (1988); inhalation NOEL = 1.6 mg/kg bw/day , Thyssen & Mohr (1983); unacceptable MOE (ie MOE less than 100) are highlighted

*** total MOE = 1 ÷ (1 ÷ dermal MOE + 1 ÷ inhalation MOE)

M/L – mixing/loading

Appl – application

M/L/A – mixing/loading/application

Table 13: Methiocarb end use exposure and risk assessment (continued)

Exposure Scenario	Data source/model (Estimate No) (Number of replicates)		Australian application rate, spray concentration, total ai applied per day Study/Model PPE	Operation	Exposure*		MOE**		
					Actual dermal exposure (mg/kg bw/day)	Inhalation dose (mg/kg bw/day)	Dermal	Inhalation	Dermal + inhalation ***
Scenario (5) Application of **BA** by mechanical applicator - broadacre applications	PHED Subset (Tractor-mounted equipment)	M7.MLOD (51 replicates)	17 kg product/ha; 1.7 kg ai/2 hr day Long pants, long sleeved shirt, no gloves	M/L	0.00195	0.000039	30769	41025	20000
		M8.APPL (45 replicates)		Appl (closed cab)	0.00013	0.000009	461538	177777	131578
		M9.APPL (5 repicates)		Appl (open cab)	0.00053	0.000057	113207	28070	22222
		M7.MLOD + M8.APPL		M/L/A (closed cab)	0.00208	0.00005	28846	32000	16666
		M7.MLOD + M9.APPL		M/L/A (open cab)	0.00248	0.00010	24193	16000	10000
	PHED subset (Hand operated equipment)	M7.MLOD		M/L	0.00195	0.00004	30769	40000	16666
		M10.MLAP (60 replicates)		M/L/A	0.306	0.00158	196	1012	167
Scenario (6) Application of **BA** by hand distribution - all situations	PHED subset (Hand distribution)	M11.APPL (16 replicates)	5.5 kg product/ha; 0.22 kg ai/2 hr day Long pants, long sleeved shirt, plus gloves	Appl	0.493	0.00280	121	571	100
			5.5 kg product/ha; 0.22 kg ai/2 hr day Coveralls plus gloves	Appl	0.0638	0.00280	938	571	333

* standardised to Australian use pattern (amount ai handled per day)

** MOE = NOEL ÷ Exposure; dermal NOEL = 60 mg/kg bw/day Procter (1988); inhalation NOEL = 1.6 mg/kg bw/day , Thyssen & Mohr (1983); unacceptable MOE (ie MOE less than 100) are highlighted

*** total MOE = 1 ÷ (1 ÷ dermal MOE + 1 ÷ inhalation MOE)

M/L – mixing/loading

Appl – application

M/L/A – mixing/loading/application

WP Formulation

The current safety directions for **WP** formulation recommend the use of PVC gloves and a face shield during the preparation of spray mixture. The exposure assessment however assumes the wearing of gloves during both mixing/loading and application but no mask during mixing/loading. The reason for this is that mixer/loader and applicator PPE is standardised together in the PHED mixer/loader/applicator database file. In addition the PHED database does not allow for standardisation for respiratory protection. In order to keep all exposure estimates consistent, POEM estimates presented in this report are also for workers wearing gloves during both mixing/loading and application.

Hand exposure is expected to occur during hand spraying and also during mechanical application when equipment needs attention. To avoid possible topical effects, a recommendation of gloves during the preparation and application of **WP** formulation would be warranted irrespective of the risk assessment outcome.

Scenario (1) Mixing/loading and application of **WP** by mechanical application

Mechanical application of **WP** methiocarb as a cover spray is expected to be limited. The label suggests grapevines and oranges may be treated this way, however most growers prefer to use methiocarb baits instead. Mechanical application of **WP** involves workers mixing the product with water and applying the final spray mixture by orchard sprayer.

Exposure estimates for this scenario are based on applications by orchard sprayer. Applications by boom spray or mister are indicated on the label but are uncommon and unlikely to result in any additional exposure.

The exposure assessment for this scenario relied on PHED data. The risk assessment results showed similar MOE for mixer/loader or applicators based on PHED with a value of 154 and 189 respectively. The majority of exposure occurred during application, with dermal exposure contributing the most to risk. Exposure during mixing/loading was also significant, with the majority of the risk associated with inhalation exposure. The use of a face shield is recommended on the current safety directions. However, since preparing a **WP** formulation involves handling a powder there is the potential to form dust. A face shield is unlikely to adequately protect mixers against this type of exposure and therefore a dust mask is proposed.

The overall conclusion is that mixer/loader/applicators applying **WP** formulation by mechanical application will not be adequately protected when using the product according to current label instructions (including safety directions: face shield and PVC gloves during spray preparation).

The risk assessment indicated that these workers will be protected if they wear cotton overalls, gloves and a dusk mask during both mixing/loading and substitute a face shield for the dust mask during application. It is anticipated that the face shield will minimise exposure to respirable droplets in the breathing zone during application.

Scenario (2) Mixing/loading and application of **WP** by hand held application - soil drench

Methiocarb **WP** formulation will be applied as a soil drench to ornamentals including nurseries, cut flowers, greenhouses, poppies and hibiscus. Applications are expected to be made either with a vehicle-mounted spray gun or for smaller areas by knapsack sprayer.

The exposure assessment for this scenario relied on OCS generated model data (POEM) and database data (PHED). The POEM data represent outdoor applications while the PHED data represent indoor applications.

Outdoor knapsack and vehicle-mounted applications

POEM showed unacceptable risk for workers using methiocarb as a soil drench by either knapsack or vehicle-mounted spray gun.

POEM data were used to estimate knapsack exposure. Estimates 1 and 2 (Appendix 1) show that hand exposure contributed 15% (1.25 ml/hr) to the total actual dermal exposure during application (8.25 ml/hr). The remaining 85% is due to torso and leg exposure. To reduce applicator exposure to acceptable levels chemical resistant clothing is required, however this does not include mixer/loader inhalation exposure.

The overall conclusion is that mixer/loader/applicators applying **WP** formulation outdoors by soil drench will not be adequately protected when using the product according to current label instructions (including safety directions: face shield and PVC gloves during spray preparation).

In order to reduce risk to an acceptable level workers should wear cotton overalls, dust mask and gloves during mixing/loading. During application a face shield should replaced the dusk mask and wear chemical resistant overalls and gloves.

Indoor knapsack applications

PHED data showed unacceptable risk for workers using methiocarb as a soil drench by knapsack. There was however a large discrepancy between data generated from individual mixer/loader and applicator data sets compared to data generated from the combined mixer/loader/applicator data set.

The data estimated from the mixer/loader/applicator subset (M6.MLAP) resulted in an MOE of 71, with the majority of the risk associated with the inhalation route (MOE 111). Exposure estimates from the other data sets (subsets M4.MLOD and M5.APPL) resulted in much higher MOE (at least 10 fold higher). Given the uncertainty of the PHED data the more conservative estimates will be used. These estimates indicate the need to reduce inhalation exposure in order to reach an overall acceptable risk level.

The use of a face shield is recommended on the current safety directions for mixer/loaders only. As the relative contributions of inhalation exposure during mixing/loading or application cannot be determined, applicator inhalation exposure should also be minimised as much as possible.

The overall conclusion is that mixer/loader/applicators applying **WP** formulation indoors by soil drench will not be adequately protected when using the product according to current label

instructions (including safety directions: face shield and PVC gloves during spray preparation).

In order to reduce risk to an acceptable level workers should wear cotton overalls, gloves and respiratory protection during mixing/loading and application.

> **Scenario (3)** Mixing/loading and application of **WP** by hand held application - cover spray

Methiocarb **WP** formulation will also be applied to ornamentals as a cover spray. As with soil drench applications, either vehicle-mounted spray guns or knapsack sprayers will be used. The product is applied at a much lower application rate and lower final spray concentration than in scenario (2) and this is reflected in the lower estimated risks.

The exposure assessment for this scenario relied on sponsor supplied surrogate data as well as NOHSC generated model (POEM) and database (PHED) data. Outdoor applications are represented by the POEM data. Indoor applications are represented by surrogate and PHED data.

Outdoor applications using vehicle-mounted spray guns and knapsack

POEM data were the only source available for this situation. Vehicle mounted spray tank with H-nozzle was considered relevant for this exposure estimation (as this is a worst case scenario, this can be used for outdoor knapsack application also). It showed acceptable risk for workers wearing their own clothing and gloves during mixing/loading and application.

The overall conclusion is that mixer/loader/applicators applying **WP** formulation as a cover spray using vehicle-mounted spray guns will not be adequately protected when using the product according to current label instructions (including safety directions: face shield and PVC gloves during spray preparation).

In order to reduce risk to an acceptable level workers should wear cotton overalls and gloves during mixing/loading and application.

Indoor knapsack applications

The sponsor provided surrogate data showed acceptable risk for workers applying **WP** formulation to high or low crops in greenhouses by knapsack, while wearing protective clothing and gloves.

The same PHED data subsets were used for scenario (2) and (3), the standardised exposure estimates showed an unacceptable risk for this method of application. It is noted that the lowest MOE is 71 for combined dermal and inhalation exposure.

Given the uncertainties associated with the sponsor provided data, the overall risk assessment relies more on PHED data.

The overall conclusion is that mixer/loader/applicators applying **WP** formulation as a cover spray by knapsack will not be adequately protected when using the product according to

current label instructions (including safety directions: face shield and PVC gloves during spray preparation).

Given that PHED data indicate significant inhalation exposure relative to total exposure, inhalation exposure during both mixing/loading and application should be minimised as much as possible.

In order to reduce risk to an acceptable level workers should wear cotton overalls, dust mask and gloves during mixing/loading and substitute a face shield for the dusk mask during application.

BA formulation

The exposure assessment of **BA** formulations relied on PHED data only. No other data were available in the literature or provided by the sponsor. Additionally, POEM was not suitable for this product or application type.

The safety directions for **BA** products do not recommend gloves or any other PPE. PHED data generated for workers using mechanical application equipment was estimated for workers wearing normal work clothing and no gloves. PHED data for workers applying bait by hand were estimated for workers wearing normal clothing and gloves. This was done because there were no data available for workers without gloves. The data are considered relevant because gloves are currently recommended on the product labels for hand application, although the recommendation is not located in the safety directions. Given that the risk assessment relied only on one data source, exposure for workers wearing protective clothing and gloves was also estimated and served as a comparison.

Baits containing methiocarb will be applied to gardens, broadacre crops (cereals, sunflower, oilseeds and pasture) ornamentals (nurseries, cut flowers and greenhouses) orchards (including oranges) vegetable crops and berry crops. All of these crops may be treated by either mechanical applicator (sod seeder, combine, fertiliser spreader) or by hand distribution. The mechanical applications are separated into two scenarios based on different application rates for different crops (scenario (4) and (5)). These two scenarios cover exactly the same application methods and therefore rely on the same PHED data for their exposure estimates. The third scenario (scenario (6)) covers the application of bait by hand application to any of the label crops.

Scenario (4) Application of **BA** by mechanical applicator - orchard applications

and

Scenario (5) Application of **BA** by mechanical applicator - broadacre applications

PHED estimates for workers applying methiocarb baits by tractor mounted equipment or hand held/pulled equipment showed acceptable risk to workers wearing long pants, long sleeved shirt and no gloves. Australian workers are expected to wear similar clothing during the working day, although there may be exceptions. Tractors with open cabs showed greater risk to applicators than tractors with closed cabs, but in both cases risk was very low.

The lowest MOE was 150, obtained for operators using hand operated equipment and applying product at the higher application rate (scenario (5)). This level of risk suggests that workers wearing less clothing than that specified above could be exposed to unsafe levels of product.

The overall conclusion is that the risk during mechanical applications of bait is acceptable provided workers' clothing is appropriate. Label safety directions should be amended to recommend the use of cotton overalls (ie one layer of protection).

Scenario (6) Application of **BA** by hand distribution - all situations

PHED estimates for workers applying methiocarb baits by hand distribution showed unacceptable risk (MOE 93) to workers wearing long pants, long sleeved shirt and gloves. An estimate based on workers wearing protective coveralls and gloves showed acceptable risk (MOE 453).

Label safety directions should be amended to recommend the use of cotton overalls and gloves during hand distribution of pellets.

5.2 Post-application

The potential for exposure will exist during worker re-occupation of treated crops. The level of exposure will be dependent on a number of factors, including the amount of active applied, the timing of the post-application activity, the nature and duration of the work done, as well as ambient (atmospheric) conditions.

Limited information was available to estimate re-entry worker exposure following methiocarb use. Measured re-entry exposure, dislodgeable residue and dissipation data which are relevant for the assessment of re-entry exposure are described below.

5.2.1 Measured post-application exposure studies and dislodgeable foliar residues

The following literature study was provided by the sponsor.

Zweig G, Heffingwell JT and Popendorf W (1985) The relationship between dermal pesticide exposure by fruit harvesters and dislodgeable foliar residues, Journal of Environmental Science and Health, Part B20(1), 27-60.

Four test substances were evaluated in this study. Only the methiocarb results are discussed here.

Blueberry harvesters (25) were monitored on three separate days of a spray application of bird repellent containing methiocarb. The blueberry variety used in the study grows in bushes four to six feet high.

Subjects wore specially supplied T-shirts under their own clothing, which was usually denim jeans and long-sleeved cotton shirts. The authors stated that some subjects may have removed their shirt on hot days but did not identify which subjects they were.

Dermal patches (gauze pads with impervious backing) were attached to each subject at the following body locations: the head (fastened to a head band or brim of a cap), chest, back and upper arms (stapled to tightly fitting T-shirt), lower arms and lower legs (fastened to skin with surgical tape). Cotton gloves served as hand dosimeters. Dermal exposure was presented as mg/hr for a 50-percentile man. The exposure estimates represent actual dermal exposure.

Foliar and soil samples were also collected for the determination of dislodgeable residues. The results following methiocarb applications are presented in Table 14.

Table 14: Dislodgeable leaf residues and re-entry exposure following methiocarb application to blueberries

Re-entry interval (days post-application)	Actual dermal exposure (mg/hr)	Actual dermal exposure (mg/kg bw/day)**	Dislodgeable foliar residues ($\mu g/cm^2$) ***	Transfer coefficient (cm^2/hr)****
3	6.037	0.69	7.83	771
4	3.80	0.44	2.42	1570
6*	1.06	0.12	0.59	1802

Application rate: 1.65 kg ai/ha
* heavy rainfall on day-5 post application; the authors stated that a significant amount of active may have been washed off the dosimeters as well as the leaf surfaces
**standardised by NOHSC based on 8 hour day and 70 kg body weight
*** the half-life was reported to be 1.7 days
**** estimate based on exposure (mg/hr) ÷ dislodgeable residues ($\mu g/cm^2$) × 1000 µg/mg

The anatomical distribution of methiocarb contamination was reported. Blueberry harvesters showed most of the contamination to be on the hands and lower arms on days 4 and 5 post application. The distribution was shown to be different for row harvesters (strawberry pickers) who showed little contamination on the lower arms. The authors expected a different distribution again for tree harvesters.

Based on the ratio of dermal exposure rate and dislodgeable foliar residues reported in this study (16 observations, strawberries and blueberries) as well as from Popendorf and Leffingwell (1983) (23 observations, including citrus) a generic transfer coefficient of 5000 cm^2/hr was proposed.

Comments:

The results from this study were considered suitable for the estimation of post-application exposure of workers harvesting fruit from orchards and vineyards treated with methiocarb as a surface spray. Although the formulation type used in the study was not specified, the application rate used (1.65 kg ai/ha) is similar to the Australian rate for application by orchard sprayer (2.25 kg ai/ha) and is also relevant for extrapolation to Australian crops treated by cover spray using hand held sprayers (3 kg ai/ha).

The exposure estimates from this study are used to estimate risk to harvesters. The risk estimates are presented in Section 5.2.3.

5.2.2 Surrogate post-application exposure and dislodgeable foliar residues

The following study was provided by the sponsor.

Knarr RD (1987) Re-entry interval for methiocarb: Calculation from generic data, Mobay Corporation, Kansas City, Missouri, Study number 95095 (unpublished report).

This study contains no new data. Generic transfer coefficients derived in an earlier study (Mobay Study No. 95090) and the published literature, were used in combination with methiocarb dislodgeable foliar residue data (Mobay Report No. 69347) and a dermal rat NOEL for RBC cholinesterase inhibition, to estimate a re-entry interval for blueberry and cherry workers.

Generic transfer coefficients were determined following foliar applications of azinphos-methyl, oxydemeton-methyl, disulfoton and anilazine to four crop groups including blueberries and cherries. The report provided a transfer coefficient of 1800 cm^2/hr for blueberry workers and 1900 cm^2/hr for cherry workers. Raw data were not provided for these estimates and the work practices were not described (eg re-entry activity: picking, thinning, or pruning; clothing/gloves worn during activity). An average of these two transfer coefficients was used to estimate exposure for re-entry workers.

Dislodgeable foliar residue data were available for methiocarb, as well as the metabolites methiocarb sulfoxide and methiocarb sulfone, following three applications of 75 **WP** to grape vines (Pinot Blanc). In a dermal study which was assessed and reported in the Toxicology Section, both methiocarb and methiocarb sulfoxide caused significant inhibition of RBC ChE activity at administration rates of 800 and 640 $\mu g/cm^2$ respectively (Knaak et al, 1981). As the dose of parent compound and metabolite which caused significant ChE inhibition was similar, the dermal exposure risk can be calculated using the NOEL from a dermal methiocarb study and combining the dislodgeable residues for both compounds. The application rate was 3.36 kg ai/ha (48 oz ai/acre). Raw data as well as sampling and analytical procedures were provided in appendices.

The results are summarised in Table 15.

Table 15: Dislodgeable residues of methiocarb and methiocarb sulfoxide on vine leaf surfaces

Days after application	Dislodgeable residues		*Actual dermal exposure (mg/kg bw/day)** (combined for both, methiocarb and methiocarb sulfoxide)
	Methiocarb dislodgeable residues (µg/cm^2)	Methiocarb sulfoxide dislodgeable residues (µg/cm^2)	
0.04	16.88	0.46	*3.67*
0.4	17.68	0.57	*3.86*
1	19.44	0.75	*4.27*
2	18.96	0.62	*4.14*
5	9.68	0.75	*2.21*
7	9.52	1.72	*2.38*
14	10.72	1.82	*2.65*
21	3.50	0.50	*0.85*
28	2.66	0.56	*0.68*

All estimates are averages of triplicate analyses (3 separate application days, 3 samples of 100 leaf discs for each day)
Residues of methiocarb sulfone were relatively low ($\leq$ 0.06 µg/cm^2) and are not included in this table
* Estimate based on transfer coefficient of 1850 cm^2/hr, 8 hr day and body weight of 70 kg (ie, dislodgeable residues (µg/cm^2) × transfer coefficient (cm^2/hr) × 8 hr ÷ 70 kg ÷1000 µg/mg)

Comments:

The results from this study are considered suitable for the estimation of exposure to Australian grape and orchard harvesters. The methiocarb formulation applied to the study vineyards is similar to the Australian product (75 compared to 70%, respectively) and the application rates are also comparable (3.36 kg ai/ha in the study, 2.25 kg ai/ha for Australian applications by orchard sprayer and 3 kg ai/ha by hand held surface spray).

Although the transfer coefficients used in this study are based on surrogate data, they are similar to those estimated for methiocarb by Zweig et al. (1985) in the previous section (Section 5.2.1).

The authors of this study calculated a re-entry interval (REI) of 6 days based on a ED10 value of 24.1 µg/cm^2 from a single 24 h dermal application study in rats (Knaak et al, 1981). The endpoint was the inhibition of RBC cholinesterase activity. While this study can be used to calculate an appropriate re-entry interval some of the assumptions made in the calculations used to derive the proposed 6-day REI are not. In particular the use of a 10-fold uncertainty factor (or safety factor) instead of the usual 100-fold for extrapolating from an animal study to humans is not usual practice in risk assessment. Furthermore since methiocarb and methiocarb sulfoxide have been shown to be almost equipotent and methiocarb sulfoxide is a degradation product formed from methiocarb under normal field conditions no consideration was given to the contribution of methiocarb sulfoxide in determining an appropriate re-entry period.

The dermal exposures estimated from this study are used to estimate risk to grape harvesters. The risk estimates are presented in Section 5.2.3.

5.2.3 Risk from post-application exposure

Worker exposure estimates presented in Section 5.2.1 and Section 5.2.2 were used to estimate risk to re-entry workers. MOE estimated using these data are presented in Table 16 and discussed, where relevant, by re-entry situation.

Table 16: Re-entry risk following methiocarb use

Re-entry situation (data source)	Re-entry time	PPE/clothing	† Study dermal exposure estimates (mg/kg bw/day)	Standardised dermal exposure estimates * (mg/kg bw/day)	MOE**
Blueberries Measured post-application exposure (Zweig et al., 1985)	3 days	Denim jeans, long sleeved cotton shirt	0.69	0.94-1.25	48-64
	4 days		0.44	0.60-0.80	75-100
	6 days		0.12	0.16-0.22	273-375
Grapevines Measured foliar dislodgeable residues (vine leaves), surrogate transfer factors (Knarr, 1987)	0.04	One layer of clothing and no gloves (assumed for surrogate transfer factors)	3.67	3.26	18
	0.4		3.86	3.43	18
	1		4.27	3.8	16
	2		4.14	3.69	16
	5		2.21	1.96	31
	7		2.38	2.12	28
	14		2.65	2.36	25
	21		0.85	0.76	79
	28		0.68	0.61	98

* Standardised to Australian application rate of 2.25-3 kg ai/ha (study application rates: 1.65 kg ai/ha (Zweig et al., 1985); 3.36 kg ai/ha (Knarr, 1987)); † Combined methiocarb and methiocarb sulfoxide residues.
** MOE = NOEL ÷ Exposure; Dermal NOEL = 60 mg/kg bw/day (Procter, 1988); Unacceptable MOE (ie. MOE less than 100) are highlighted.

WP formulation

Cover spray

The following crops will be treated with **WP** methiocarb as a cover spray:

vineyards

orchards (including oranges)

ornamentals (including nurseries, cut flowers, greenhouses, poppies and hibiscus)

There are no re-entry periods on the current label for **WP** formulation. The available studies indicate an unacceptable risk for workers handling treated foliage until 6 or 28 days

Vineyards and orchards

Based on label withholding periods, vineyards will not be harvested for **6 weeks** after application, while citrus orchards will not be harvested for **9 weeks** after application. Additionally, the label states that grapevine leaves are not permitted to be used for human consumption.

Under normal use situations significant foliar contact is not expected until harvest time. However to prevent any dermal contact during other activities (such as pruning or crop checking), a re-entry period of 28-days should be included on the label. Workers will be required to wear protective clothing and chemical resistant gloves if prior entry is required.

Inhalation exposure is not a significant concern for re-entry workers given that the chemical has low volatility and outdoor locations should have adequate natural ventilation.

Ornamentals

There is no withholding period for ornamentals. The APVMA has advised that methiocarb is used as a cover spray in nurseries and greenhouses for the control of Western flower thrips, while other pests are usually controlled with baits. Crop handling may be required soon after spraying and may be intensive, particularly in the cut flower industry.

The available information indicates an unacceptable risk for workers handling treated blueberry or grapevine foliage until 6 or 28 days after treatment, respectively (Table 16). In the absence of crop specific data, these results will be used as a rough estimate of dermal exposure to nursery workers handling treated ornamentals. Based on this information, a re-entry period of 28-days should be included on the label. Workers will be required to wear protective clothing and chemical resistant gloves if prior entry (or rehandling) is required.

Dermal exposure to soil could be significant during some nursery activities, such as plant re-potting. No information is available to assess the risk to workers handling treated soil. Given that most of the spray will be deposited on the foliage, the PPE requirements recommended above may be adequate to protect workers from dermal exposure to soil residues.

Workers entering treated greenhouses/glasshouses soon after application may be exposed to significant amounts of methiocarb in the air. However, given the chemical's low volatility air concentrations should not be significant after the enclosures have been ventilated.

Soil drench

Ornamentals are the main crops to be treated by soil drench. The application rate is much higher for this method compared to cover spray (15-20 times), however contact with plant foliage is unlikely.

Given that:

(i) there is potential for exposure to soil by nursery workers (eg during re-potting activities),

(ii) the application rate is high, and

(iii) no information is available to assess the risk to workers from treated soil,

However, as indicated above workers will be required to wear protective clothing and chemical resistant gloves if prior entry (or rehandling) is required.

BA formulation

Crops treated with **BA** formulations include berry crops, cereals, gardens, nurseries, oil seed crops, orchards, pastures, vegetable crops and sunflowers. The current **BA** labels advise that edible crops should not be harvested for **7 days** after application and treated areas should not be grazed or cut for stock food for **7 days** after application.

There are no data available to assess the post-application risk to workers following bait application to these crops. The application rate for **BA** formulations is similar to **WP** formulation (2.25-45 kg ai/ha and 5.5-17 kg ai/ha, respectively). However, as the product is not expected to come in contact with crop foliage, data from the sponsor studies cannot be extrapolated to this situation.

Given the method of application (bait distribution), most of the applied product will be present on or in the soil surrounding the plants. Shoes or boots worn by re-entry workers are expected to provide adequate protection in most situations. Exposure may however be significant during activities that involve direct contact with the soil, such as during manual harvest of vegetable crops (eg carrots) or during some nursery activities (re-potting of plants).

Most vegetables are harvested mechanically, however manual harvesting is also conducted when checking for optimal harvest times. In these situations relatively small sample sizes are involved. The withholding period for edible crops (7 days) is expected to provide adequate protection for workers involved in manual harvest.

There is no information available to estimate the risk to nursery workers during re-potting activities. However, as indicated above workers will be required to wear protective clothing and chemical resistant gloves if prior entry (or rehandling) is required. A re-entry statement is recommended for BA products in pack sizes greater than 1 kg on the basis that these packs would be used commercially. Methiocarb (BA) products in pack sizes under 1 kg currently do not require any safety directions.

5.3 International assessments

US EPA Registration Eligibility Decision review of Methiocarb, February 1994

When applied dermally to pregnant rabbits methiocarb caused developmental toxicity at 250 mg/kg bw/day in the presence of maternotoxicity. The US EPA utilized a rabbit developmental NOAEL of 50 mg/kg bw/day in their risk assessment.

For handlers of the **WP** using PPE according to the label, MOE indicated a level of concern. The agency recommended the use of additional PPE (coveralls) to achieve acceptable MOE, and a respirator to be worn by handlers during ventilation activities; a face shield must be worn while mixing/loading the **WP.**

The minimum PPE requirement for applicators and other handlers are: coveralls, gloves, footwear, headgear and apron when cleaning equipment, mixing or loading.

A 25-day restricted entry interval (REI) is recommended to protect workers entering areas treated with the **WP**. After 10 days, workers may enter treated areas to perform tasks, including hand labour tasks that involve contact with treated areas surfaces provided each worker spends no more than 3 hours in each 24-hour period performing such tasks. PPE is not required during the 3-hour work period. Data on estimation of dermal and inhalation exposure to handlers for the **WP** formulation is required.

For granular formulation use on commercial or research production of turfgrass, a 24-hour REI is required. The Worker Protection Standard for Agricultural pesticides converted the 24-hour re-entry interval (where re-entry with protective clothing is allowed) to a 24-hour restricted entry interval (where re-entry is prohibited except under the limited circumstances allowed under the Worker Protection Standards).

Data is required on soil dissipation and dermal exposure to assess the exposure to persons entering ornamental planting areas.

UK Department for Environment, Food and Rural Affairs Health and Safety Executive (Previously known as *Ministry of Agriculture, Fisheries and Food) (Source; Advisory Committee on Pesticides, Annual Report, 2002).*

The Acceptable Operator Exposure Level (AOEL) of 0.013 mg/kg bw/day was based on a NOAEL in a 90-day dog dietary study. The toxicological effect at the next highest dose was a reduction in erythrocyte and retinal cholinesterase activities and an increased incidence of vomiting. A dermal absorption factor of 5% was used in the OH&S risk assessment.

The PPE recommendations for professional uses included; protective gloves during loading and application for broadcast uses; protective gloves when loading at seed admixture plant, coveralls and gloves for calibration and cleaning at seed admixture plant and coveralls for bagging up. Operator exposure estimates were below the AOEL and therefore considered acceptable with appropriate PPE. Worker and bystander exposures were also acceptable.

6 REVIEW OUTCOMES

Methiocarb is registered for use in a number of agricultural situations as well as for use in the home garden. This review considers only the end uses and products that have potential for occupational exposure and which are included on current Australian labels.

Products containing methiocarb are available in two formulation types, WP or BA. WP formulation is mixed with water and applied as a cover spray or soil drench. BA is available in a ready-to-use form and is spread on the ground around crops to be protected. Most situations are outdoors, however indoor applications of either product may occur in greenhouses.

To assist in the risk assessment, end use situations were grouped into exposure scenarios, which were based largely on application method. A quantitative estimation of exposure for each of the scenarios was conducted using surrogate exposure data and/or predictive modelling and/or exposure database data. Measured re-entry exposure data and dislodgeable foliar residue data were used to quantify post-application risk.

6.1 End use

The end use risk assessment (Section 4.1.3) indicated that use of methiocarb products according to current label directions will result in **unacceptable** risk to workers in the following situations:

All uses of methiocarb wettable powder

hand distribution of methiocarb baits

Mechanical application of methiocarb baits was considered **acceptable** provided the workers own clothing covered their body adequately.

However, all registered end uses are considered to provide **acceptable** margins of exposure provided that:

(a) exposure mitigation methods specified in Section 6.1.1 are instituted where applicable

(b) the products are used in accordance with label instructions recommended in Section 6.3

(c) safe work practices are followed

The following table summarises all end use situations and the required regulatory action.

Table 16: Proposed regulatory action – end use

End use	Relevant mitigation method/label requirement
Mechanical application of **WP**	Cotton overalls, dust mask/face shield and gloves
Hand spraying of **WP** as a soil drench or cover spray	Cotton overalls, gloves, dust mask during mixing/loading and chemical resistant overalls, face shield and gloves during application.
Mechanical application of **BA**	Cotton overalls
Hand distribution of **BA**	Cotton overalls and gloves

6.2 Labelling requirements

6.2.1 Re-entry statements

*The following re-entry statements must be included on **wettable powder** product labels and ba products:*

RE-ENTRY TO TREATED AREA: DO NOT PERMIT re-entry until 28 days after application. If prior entry is required, wear cotton overalls buttoned to the neck and wrists and elbow length PVC gloves. Clothing must be laundered after each day's use.

7 RECOMMENDATIONS

The OCS recommends that the APVMA NOT be satisfied that the continued use of methiocarb and methiocarb products (wettable powder (WP) and bait (BA) in accordance with current label instructions, would NOT be an undue hazard to the safety of workers.

The OCS recommends however, that if the label instructions are varied, then APVMA can be satisfied that the continued use of methiocarb and methiocarb products in accordance with the following amended label instructions, would NOT be an undue hazard to the safety of workers.

7.1 Recommendations to mitigate risks during mixing/loading and application

WP formulations (750 g/kg)

Safety Directions

Mixer/loader: When opening the container and preparing spray, wear cotton overalls buttoned to the neck and wrist, a washable hat, dust mask and elbow length PVC gloves

Applicator: When using the prepared spray wear cotton overalls buttoned to the neck and wrist, a washable hat, face shield and elbow length PVC gloves, and if applying by hand wear chemical resistant clothing, a washable hat, face shield and elbow-length PVC gloves and if applying in enclosed areas wear cotton overalls buttoned to the neck and wrist, a washable hat, elbow length PVC gloves and a face shield
After each day's use, wash gloves, contaminated clothing and face shield.

Bait (20 g/kg in packs over 1 kg)

Safety Directions

Applicator: When using the product, wear cotton overalls buttoned to the neck and wrist, a washable hat and if dispensing by hand also wear elbow-length PVC gloves.

After each day's use, wash gloves, and contaminated clothing.

7.2 Re-entry statements (for all WP products and BA products in packs over 1 kg)

RE-ENTRY TO TREATED AREA: DO NOT PERMIT re-entry until 28 days after application. If prior entry is required, wear cotton overalls buttoned to the neck and wrists and elbow length PVC gloves. Clothing must be laundered after each day's use.

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OCCUPATIONAL HEALTH AND SAFETY ASSESSMENT

ATTACHMENTS

ACTIVE INGREDIENT: Methiocarb

ATTACHMENTS:

APPENDIX I	POEM estimates
APPENDIX II	PHED subsets
APPENDIX III	Sponsor provided studies noted but not included in review
APPENDIX IV	Overseas regulatory information
APPENDIX V	Risk control measures

APPENDIX I

POEM estimates

Estimate 1

Scenario (2) Mixing/loading and application of **WP** by hand held application - soil drench

Hand Held Outdoors Hydraulic Nozzles (H-Nozzle)
PREDICTIVE OPERATOR EXPOSURE MODEL (POEM)

A. PRODUCT DATA

1. Product name	75 **WP**			
2. Active ingredient	methiocarb			
3. Concentration	750	mg/g		
4. Formulation type	**WP**			
5. Maximum in-use ai concentration	2.250	mg/ml		

B. EXPOSURE DURING MIXING AND LOADING

1a. Container size	0.4	kg		
1b. Hand contamination/operation	0.01	g		
2. Application dose	60	kg product/ha	4.5	kg ai/day
3. Work rate	0.1	ha/day		
4. Number of operations	15	/day		
5. Hand contamination	0.15	g/day		
6. Protective clothing	**NONE**		**GLOVES**	
7. Transmission to skin	100		1	%
8. Dermal exposure to formulation	0.15		0.0015	g/day
9. Concentration of ai	750		750	mg/g
10. Dermal exposure to ai	**112.500**		**1.125**	**mg/day**

C. EXPOSURE DURING SPRAY APPLICATION

1. Application technique - Knapsack hydraulic nozzles low level outdoor					
2. Application volume	20000	spray/ha			
3. Volume of surface contamination	50	ml/h			
4. Distribution	Hands	Hands	Trunk	Legs	
	25	25	25	50	%
5. Clothing	NONE	GLOVES	PERMEABLE	PERMEABLE	
6. Penetration	100	10	20	18	%
7. Dermal exposure	10	1.25	2.5	4.5	ml/h
8. Duration of exposure	6	h			

PPE	**NONE**	**GLOVES**	
9. Total dermal exposure to spray	102	49.5	ml/day
10a. Concentration of ai	2.250	2.250	mg/ml
10b. Dermal exposure to ai	**229.500**	**111.375**	**mg/day**

E. INHALED EXPOSURE DURING SPRAY APPLICATION

1. Inhalation exposure	0.02	ml/h
2. Duration of exposure	6	h
3. Concentration of ai	2.250	mg/ml
4. Inhalational exposure to ai	**0.270**	**mg/day**

Estimate 2

Scenario (2) Mixing/loading and application of **WP** by hand held application - soil drench

Hand Held Outdoors Hydraulic Nozzles (H-Nozzle)
PREDICTIVE OPERATOR EXPOSURE MODEL (POEM)

A. PRODUCT DATA

1. Product name	75 **WP**			
2. Active ingredient	methiocarb			
3. Concentration	750	mg/g		
4. Formulation type	**WP**			
5. Maximum in-use ai concentration	2.250	mg/ml		

B. EXPOSURE DURING MIXING AND LOADING

1a. Sprayer tank size	15	kg		
1b. Hand contamination/operation	0.01	g		
2. Application dose	60	kg product/ha	0.9	kg ai/day
3. Work rate	0.02	ha/day		
4. Number of operations	27	/day		
5. Hand contamination	0.27	g/day		
6. Protective clothing	**NONE**		**GLOVES**	
7. Transmission to skin	100		1	%
8. Dermal exposure to formulation	0.27		0.0027	g/day
9. Concentration of ai	750		750	mg/g
10. Dermal exposure to ai	**202.500**		**2.025**	**mg/day**

C. EXPOSURE DURING SPRAY APPLICATION

1. Application technique - Knapsack hydraulic nozzles low level outdoor

2. Application volume	20000	spray/ha			
3. Volume of surface contamination	50	ml/h			
4. Distribution	Hands	Hands	Trunk	Legs	
	25	25	25	50	%
5. Clothing	NONE	GLOVES	PERMEABLE	PERMEABLE	
6. Penetration	100	10	20	18	%
7. Dermal exposure	10	1.25	2.5	4.5	ml/h
8. Duration of exposure	6	h			

PPE	**NONE**	**GLOVES**	
9. Total dermal exposure to spray	102	49.5	ml/day
10a. Concentration of ai	2.250	2.250	mg/ml
10b. Dermal exposure to ai	**229.500**	**111.375**	**mg/day**

E. INHALED EXPOSURE DURING SPRAY APPLICATION

1. Inhalation exposure	0.02	ml/h
2. Duration of exposure	6	h
3. Concentration of ai	2.250	mg/ml
4. Inhalational exposure to ai	**0.270**	**mg/day**

Estimate 3

Scenario (3) Mixing/loading and application of **WP** by hand held application - cover spray

Hand Held Outdoors Hydraulic Nozzles (H-Nozzle)
PREDICTIVE OPERATOR EXPOSURE MODEL (POEM)

A. PRODUCT DATA

1. Product name	75 **WP**			
2. Active ingredient	methiocarb			
3. Concentration	750	mg/g		
4. Formulation type	**WP**			
5. Maximum in-use ai concentration	1.500	mg/ml		

B. EXPOSURE DURING MIXING AND LOADING

1a. Container size	0.4	kg		
1b. Hand contamination/operation	0.01	g		
2. Application dose	4	kg product/ha	1.5	kg ai/day
3. Work rate	0.5	ha/day		
4. Number of operations	5	/day		
5. Hand contamination	0.05	g/day		
6. Protective clothing	**NONE**		**GLOVES**	
7. Transmission to skin	100		1	%
8. Dermal exposure to formulation	0.05		0.0005	g/day
9. Concentration of ai	750		750	mg/g
10. Dermal exposure to ai	**37.500**		**0.375**	**mg/day**

C. EXPOSURE DURING SPRAY APPLICATION

1. Application technique - Knapsack hydraulic nozzles low level outdoor

2. Application volume	2000	spray/ha			
3. Volume of surface contamination	50	ml/h			
4. Distribution	Hands	Hands	Trunk	Legs	
	25	25	25	50	%
5. Clothing	NONE	GLOVES	PERMEABLE	PERMEABLE	
6. Penetration	100	10	20	18	%
7. Dermal exposure	10	1.25	2.5	4.5	ml/h
8. Duration of exposure	3	h			

PPE	**NONE**	**GLOVES**	
9. Total dermal exposure to spray	51	24.75	ml/day
10a. Concentration of ai	1.500	1.500	mg/ml
10b. Dermal exposure to ai	**76.500**	**37.125**	**mg/day**

E. INHALED EXPOSURE DURING SPRAY APPLICATION

1. Inhalation exposure	0.02	ml/h
2. Duration of exposure	3	h
3. Concentration of ai	1.500	mg/ml
4. Inhalational exposure to ai	**0.090**	**mg/day**

APPENDIX II

PHED subsets

PHED subset: M1.MLOD

SUMMARY STATISTICS FOR CALCULATED DERMAL EXPOSURES

SCENARIO: Long pants, long sleeves, gloves

PATCH LOCATION	DISTRIB. TYPE	MICROGRAMS PER KG AI MIXED Median	Mean	Coef of Var	Geo. Mean	Obs
HEAD (REAL)	Lognormal	43.9073	63.9318	82.4416	43.6883	9
NECK.FRONT	Lognormal	27.5828	88.2863	245.8012	24.4068	36
NECK.BACK	Other	11.6799	60.4731	265.2785	10.3333	36
UPPER ARMS	Lognormal	24.4106	104.8967	200.8239	34.0881	41
CHEST	Lognormal	30.1711	86.3887	179.9571	37.7865	38
BACK	Lognormal	30.1711	119.1788	211.0878	40.7786	38
FOREARMS	Lognormal	14.1567	29.851	143.4032	15.3501	41
THIGHS	Lognormal	21.0817	40.5311	139.0543	19.0678	31
LOWER LEGS	Lognormal		22.5916	107.7721	14.0022	30
FEET						0
HANDS	Lognormal	27.0812	45.1748	108.1352	25.181	20
TOTAL DERM:		266.0293	244.1651	661.304	264.6828	
INHALATION:			24.1755	114.5161	208.7629	20.0046	59
COMBINED:		266.0293	268.3406	775.8201	284.6874	

95% C.I. on Mean: Dermal: [-2570.5041, 3893.1121]

95% C.I. on Geo. Mean: Inhalation: [.2474, 1617.3108]

Inhalation Rate : 25 Liters/Minute
Number of Records: 72
Data File: MIXER/LOADER Subset Name: M1.MLOD

PHED subset: M2.APPL

SUMMARY STATISTICS FOR CALCULATED DERMAL EXPOSURES

SCENARIO: Long pants, long sleeves, gloves

PATCH LOCATION	DISTRIB. TYPE	MICROGRAMS PER KG AI SPRAYED Median	Mean	Coef of Var	Geo. Mean	Obs
HEAD (REAL)	Lognormal	614.5585	2050.8514	137.4145	490.8051	14
NECK.FRONT	Lognormal	3.9735	16.1049	172.4693	6.1225	19
NECK.BACK	~,ognormal	7.1634	18.3371	166.4271	6.3561	19
UPPER ARMS	Other	9.6358	137.957	165.7133	27.4669	33
CHEST	Other	43.8852	205.9675	136.9257	46.8066	23
BACK	Other	43.8852	194.5532	143.2291	45.0614	23
FOREARMS	Other	3.4724	47.4678	183.1176	8.7347	31
THIGHS	Other	12.649	51.3305	262.6783	18.1015	31
LOWER LEGS	Lognormal	5.7792	17.8881	120.0165	9.6086	21
FEET						0
HANDS	Lognormal	1.7673	5.2799	198.8502	.9305	18
TOTAL DERM:	627.3504	746.7695	2745.7373		659.9938	
INHALATION:	Other	6.1415	9.2338	111.504	4.6581	36
COMBINED:	633.4919	752.911	2754.9711		664.6519	

95% C.I. on Mean: Dermal: [-28932.7077, 34424.1823]

95% C.I. on Geo. Mean: Inhalation: [.2325, 93.3193]

Inhalation Rate : 25 Liters/Minute
Number of Records: 40
Data File: APPLICATOR Subset Name: M2.APPL

PHED subset: M3.MLAP

SUMMARY STATISTICS FOR CALCULATED DERMAL EXPOSURES

SCENARIO: Long pants, long sleeves, gloves

PATCH LOCATION	DISTRIB. TYPE	MICROGRAMS PER KG AI SPRAYED Median	Mean	Coef of Var	Geo. Mean	Obs
HEAD (REAL)	Lognormal	4548.2781	4734.621	49.1413	4233.7753	6
NECK.FRONT	Lognormal	254.1225	236.4735	67.6017	172.4369	6
NECK.BACK	Lognormal	180.1159	180.2576	25.3063	175.2698	6
UPPER ARMS						0
CHEST	Lognormal	327.1799	399.1464	48.7422	362.8294	6
BACK						0
FOREARMS	Lognormal	253.8863	306.3285	72.4632	253.8742	6
THIGHS	Lognormal	315.3819	433.4393	57.7182	382.7386	6
LOWER LEGS	Lognormal	174.4283	1726.2444	221.3547	321.1962	6
FEET						0
HANDS	Lognormal	348.2896	339.7285	60.9447	231.5733	6
TOTAL DERM:	6133.6937	6401.6826	8356.2391		6133.6936	
INHALATION:	Lognormal	54.9254	54.4881	18.4758	53.7159	6
COMBINED:	6187.4096	6456.6079	8410.7272		6187.4095	

95% C.I. on Mean: Dermal: [-68252.0646, 84964.5428]

95% C.I. on Geo. Mean: Inhalation: [37.3351, 77.2838]

Inhalation Rate : 25 Liters/Minute
Number of Records: 6
Data File: MIXER/LOADER/APPLICATOR Subset Name: M3.MLAP

PHED subset: M4.MLOD

SUMMARY STATISTICS FOR CALCULATED DERMAL EXPOSURES

SCENARIO: Long pants, long sleeves, gloves

PATCH LOCATION	DISTRIB. TYPE	MICROGRAMS PER KG AI MIXED Median	Mean	Coef of Var	Geo. Mean	Obs
HEAD (REAL)	Lognormal	131.5784	149.4426	91.7902	93.4786	4
NECK.FRONT	Lognormal	52.4338	48.2947	73.6848	32.2945	4
NECK.BACK	Lognormal	6.0706	6.5806	46.0852	6.0576	4
UPPER ARMS	Lognormal	184.6854	188.0578	34.6746	179.302	4
CHEST	Lognormal	153.2064	179.4592	77.3974	137.1419	4
BACK	Other	65.0442	65.0442	0	65.0442	4
FOREARMS	Lognormal	296.0894	424.8355	97.2022	292.4777	4
THIGHS	Lognormal	69.9912	109.6247	72.3077	94.0845	4
LOWER LEGS	Other	43.6071	43.6071	0	43.6071	4
FEET						0
HANDS	Lognormal	120.1249	113.5024	74.1589	80.5609	4
TOTAL DERM:	1024.049	1122.8313	1328.4488		1024.049	
INHALATION:	Lognormal	58.0119	168.315	150.2132	64.0768	4
COMBINED:	1088.1258	1180.8433	1496.7638		1088.1258	

95% C.I. on Mean: Dermal: [-8620.9024, 11277.7999]

95% C.I. on Geo. Mean: Inhalation: [2.6086, 1573.9611]

Inhalation Rate : 25 Liters/Minute
Number of Records: 4
Data File: MIXER/LOADER Subset Name: M4.MLOD

PHED subset: M5.APPL

SUMMARY STATISTICS FOR CALCULATED DERMAL EXPOSURES

SCENARIO: Long pants, long sleeves, gloves

PATCH LOCATION	DISTRIB. TYPE	MICROGRAMS PER KG AI SPRAYED Median	Mean	Coef of Var	Geo. Mean	Obs
HEAD (REAL)	Lognormal	35.872	59.7627	95.3133	44.4442	4
NECK.FRONT	Lognormal	11.0265	11.7219	48.4614	10.6735	4
NECK.BACK	Lognormal	10.1137	31.8649	154.0181	12.0121	4
UPPER ARMS	Lognormal	94.7517	94.7517	50.4938	85.2102	4
CHEST	Other	65.0442	65.0442	0	65.0442	4
BACK	Lognormal	97.9581	97.9581	38.798	92.2651	4
FOREARMS	Lognormal	115.1236	237.5258	134.3206	91.9082	4
THIGHS	Lognormal	117.6358	129.8631	55.412	114.7572	4
LOWER LEGS	Lognormal	43.6071	49.1236	22.4599	48.3079	4
FEET						0
HANDS	Lognormal	23.3627	56.4294	123.344	35.2252	4
TOTAL DERM:	599.8478	614.4951	834.0453		599.8477	
INHALATION:	Lognormal	68.9845	70.3625	62.4728	59.0322	4
COMBINED:	658.88	683.4797	904.4077		658.8799	

95% C.I. on Mean: Dermal: [-6432.0242, 8100.1147]

95% C.I. on Geo. Mean: Inhalation: [14.6685, 237.5712]

Inhalation Rate : 25 Liters/Minute
Number of Records: 4
Data File: APPLICATOR Subset Name: M5.APPL

PHED subset: M6.MLAP

SUMMARY STATISTICS FOR CALCULATED DERMAL EXPOSURES

SCENARIO: Long pants, long sleeves, gloves

PATCH LOCATION	DISTRIB. TYPE	MICROGRAMS PER KG AI SPRAYED Median	Mean	Coef of Var	Geo. Mean	Obs
HEAD (REAL)	Lognormal	2644.9117	5724.1073	164.5217	2894.0371	16
NECK.FRONT	Lognormal	314.0066	1789.9296	287.1376	403.9781	16
NECK.BACK	Lognormal	246.0188	345.5863	74.5325	250.7874	16
UPPER ARMS	Lognormal	1101.0464	1124.2927	34.0729	1057.3439	16
CHEST	Lognormal	1343.2009	1628.2099	81.0128	1376.9962	16
BACK	Lognormal	1253.8631	1400.3594	40.2863	1299.5486	16
FOREARMS	Lognormal	529.1413	1139.7338	159.2321	657.5166	16
THIGHS	Lognormal	3936.3709	12856.7667	167.0442	5573.6901	16
LOWER LEGS'	Lognormal	900.5121	1066.994	60.5758	938.0236	16
FEET						0
HANDS	Lognormal	6201.1985	8522.606	116.7584	5293.0848	15
TOTAL DERM:	19745.0064	18470.2702	35598.5857		19745.0064	
INHALATION:	Lognormal	1323.366	3762.5245	122.9986	2093.1265	16
COMBINED:	21838.1329	19793.6362	39361.1102		21838.1329	

95% C.I. on Mean: Dermal: [~237942.2465, 309139.41781

95% C.I. on Geo. Mean: Inhalation: [254.2297, 17233.15041

Inhalation Rate : 25 Liters/Minute
Number of Records: 16
Data File: MIXER/LOADER/APPLICATOR Subset Name: M6.MLAP

PHED subset: M7.MLOD

SUMMARY STATISTICS FOR CALCULATED DERMAL EXPOSURES

SCENARIO: Long pants, long sleeves, no gloves

PATCH LOCATION	DISTRIB. TYPE	MICROGRAMS PER KG AI MIXED Median	Mean	Coef of Var	Geo. Mean	Obs
HEAD (REAL)	Other	.8609	3.1029	202.0347	1.3274	32
NECK.FRONT	Lognormal	3.6921	3.8024	93.4398	1.6163	6
NECK.BACK	Lognormal	.4492	.7082	124.0337	.2444	6
UPPER ARMS	Lognormal	1.9272	2.3554	127.0853	1.6954	36
CHEST	Lognormal	2.351	2.9923	126.3593	2.166	33
BACK	Lognormal	2.351	2.9923	126.3593	2.166	33
FOREARMS	Lognormal	.8013	1.098	128.9505	.7503	36
THIGHS	Lognormal	1.6865	2.7086	100.8068	2.0086	33
LOWER LEGS	Lognormal	1.0508	1.7221	101.9997	1.2411	36
FEET						0
HANDS	Lognormal	62.9792	74.987	58.0077	67.0002	3
TOTAL DERM:	79.7492	78.1492	96.4691		80.2157	
INHALATION:	Other	1.8724	3.5695	146.679	1.5896	51
COMBINED:	81.6216	80.0216	100.0386		81.8053	

95% C.I. on Mean: Dermal: [-955.0577, 1147.9959]

95% C.I. on Geo. Mean: Inhalation: [.1013, 24.95571

Inhalation Rate : 25 Liters/Minute
Number of Records: 51
Data File: MIXER/LOADER Subset Name: M7.MLOD

PHED subset: M8.APPL

SUMMARY STATISTICS FOR CALCULATED DERMAL EXPOSURES

SCENARIO: Long pants, long sleeves, no gloves

PATCH LOCATION	DISTRIB. TYPE	MICROGRAMS PER KG AI SPRAYED Median	Mean	Coef of Var	Geo. Mean	Obs
HEAD (REAL)	Other	.287	.9278	294.5277	.3744	30
NECK.FRONT	Lognormal	.2318	.3709	108.3333	.1709	5
NECK.BACK	Lognormal	.0971	.1457	100	.0854	5
UPPER ARMS	Other	.6424	.6424	0	.6424	30
CHEST	Other	.7837	.7837	0	.7837	28
BACK	Other	.7837	.7837	0	.7837	28
FOREARMS	Other	.2671	.2947	50.4869	.2801	29
THIGHS	Other	.8433	.9369	28.8172	.9108	27
LOWER LEGS	Other	.5254	.5797	28.1036	.5645	29
FEET						0
HANDS	Lognormal	.5874	2.5987	247.8508	.6896	27
TOTAL DERM:	5.0785	5.0488	8.064		5.2854	
INHALATION:	Lognormal	.3155	.6457	134.906	.3812	45
COMBINED:	5.4597	5.3642	8.7097		5.6667	

95% C.I. on Mean: Dermal: [-48.2576, 64.3856]

95% C.I. on Geo. Mean: Inhalation: [.0595, 2.4414]

Inhalation Rate : 25 Liters/Minute
Number of Records: 45
Data File: APPLICATOR Subset Name: M8.APPL

PHED subset: M9.APPL

SUMMARY STATISTICS FOR CALCULATED DERMAL EXPOSURES

SCENARIO: Long pants, long sleeves, no gloves

PATCH LOCATION	DISTRIB. TYPE	MICROGRAMS PER KG AI SPRAYED Median	Mean	Coef of Var	Geo. Mean	Obs
HEAD (REAL)	Lognormal	1.1479	1.3775	82.5481	1.0055	5
NECK.FRONT	Other	.3642	.3642	0	.3642	1
NECK.BACK	Other	.5342	.5342	0	.5342	1
UPPER ARMS	Lognormal	2.5695	3.2119	92.7354	2.3272	5
CHEST	Lognormal	2.7428	4.1143	101.2394	2.7695	4
BACK	Lognormal	2.7428	4.1143	101.2394	2.7695	4
FOREARMS	Lognormal	1.0684	1.3355	92.7438	.9678	5
THIGHS	Lognormal	2.9514	3.5839	80.0801	2.7185	4
LOWER LEGS	Lognormal	2.1015	2.2066	70.2281	1.7684	5
FEET						0
HANDS	Lognormal	13.5998	13.8049	85.5667	6.7216	5
TOTAL DERM:		21.9464	29.8227	34.6475	21.9466	
INHALATION:	Lognormal	2.4141	3.4366	80.2479	2.3572	5
COMBINED:		24.3036	32.2369	38.0841	24.3038	

95% C.I. on Mean: Dermal: [-235.0823, 304.3772]

95% C.I. on Geo..Mean: Inhalation: [.2777, 20.0057]

Inhalation Rate : 25 Liters/Minute
Number of Records: 5
Data File: APPLICATOR Subset Name: M9.APPL

PHED subset: M10.MLAP

SUMMARY STATISTICS FOR CALCULATED DERMAL EXPOSURES

SCENARIO: Long pants, long sleeves, no gloves

PATCH LOCATION	DISTRIB. TYPE	MICROGRAMS PER KG AI SPRAYED Median	Mean	Coef of Var	Geo. Mean	Obs
HEAD (REAL)	Lognormal	2042.6932	4152.4693	188.0451	891.2185	29
NECK.FRONT	Lognormal	562.7483	1361.9673	132.1257	423.9706	29
NECK.BACK	Lognormal	348.5276	842.7682	150.5699	260.2574	29
UPPER ARMS	Lognormal	1081.7748	6263.866	171.0753	1048.9325	60
CHEST	Lognormal	1325.1766	9372.5208	192.6588	1526.0773	59
BACK	Lognormal	1319.6909	7642.6093	171.0417	1240.8386	60
FOREARMS	Lognormal	449.8102	4620.1254	353.8259	503.9492	60
THIGHS	Lognormal	757.6755	6255.3554	173.1987	1245.67	60
LOWER LEGS	Lognormal	457.0861	3084.1053	155.7371	578.2611	60
FEET						0
HANDS	Lognormal	8563.8309	10584.7018	114.4942	4881.7958	38
TOTAL DERM:	12600.971	16909.0141	54180.4887		12600.9711	
INHALATION:	Lognormal	52.1119	203.0938	125.1489	64.9587	58
COMBINED:	12665.9297	16961.126	54383.5826		12665.9298	

95% C.I. on Mean: Dermal: [-146827.219, 255188.1965]

95% C.I. on Geo. Mean: Inhalation: [2.1632, 1950.654]

Inhalation Rate : 25 Liters/Minute
Number of Records: 60
Data File: MIXER/LOADER/APPLICATOR Subset Name: M10.MLAP

PHED subset: M11.APPL

SUMMARY STATISTICS FOR CALCULATED DERMAL EXPOSURES

SCENARIO: Long pants, long sleeves, gloves

PATCH LOCATION	DISTRIB. TYPE	MICROGRAMS PER KG AI SPRAYED Median	Mean	Coef of Var	Geo. Mean	Obs
HEAD (REAL)	Lognormal	12795.2428	13050.472	65.7229	10217.7603	16
NECK.FRONT	Lognormal	1543.543	1740.1077	56.8973	1439.883	16
NECK.BACK	Lognormal	1082.6744	1104.2706	65.7229	864.5797	16
UPPER ARMS	Lognormal	28641.6589	29212.9792	65.7229	22872.0636	16
CHEST	Lognormal	34940.8554	35637.8269	65.7229	27902.3457	16
BACK	Lognormal	34940.8554	35637.8269	65.7229	27902.3457	16
FOREARMS	Lognormal	11909.4183	12146.9777	65.7229	9510.377	16
THIGHS	Lognormal	37598.3289	38348.3095	65.7229	30024.4958	16
LOWER LEGS	Lognormal	23425.1369	23892.4022	65.7229	18706.3614	16
FEET						0
HANDS	Lognormal	9842.4477	10038.8375	65.723	7859.8724	16
TOTAL DERM:	157300.0846	196720.1618	200810.0104		157300.0845	
INHALATION:	Lognormal	1138.8031	1155.3786	68.6837	890.2717	16
COMBINED:	158190.3563	197858.9649	201965.389		158190.3563	

95% C.I. on Mean: Dermal: [-323758.9921, 725379.0129]

95% C.I. on Geo. Mean: Inhalation: [185.9517, 4262.3109]

Inhalation Rate : 25 Liters/Minute
Number of Records: 16
Data File: APPLICATOR Subset Name: M11.APPL

PHED subset: M11.APPL

SUMMARY STATISTICS FOR CALCULATED DERMAL EXPOSURES

SCENARIO: Protective overall over no clothing, gloves

PATCH LOCATION	DISTRIB. TYPE	MICROGRAMS PER KG AI SPRAYED Median	Mean	Coef of Var	Geo. Mean	Obs
HEAD (REAL)	Lognormal	12795.2428	13050.472	65.7229	10217.7603	16
NECK.FRONT	Lognormal	1543.543	1740.1077	56.8973	1439.883	16
NECK.BACK	Lognormal	1082.6744	1104.2706	65.7229	864.5797	16
UPPER ARMS						0
CHEST						0
BACK						0
FOREARMS						0
THIGHS						0
LOWER LEGS						0
FEET						0
HANDS	Lognormal	9842.4477	10038.8375	65.723	7859.8724	16
TOTAL DERM:	20382.0954	25263.9079	25933.6879		20382.0954	
INHALATION:	Lognormal	1138.8031	1155.3786	68.6837	890.2717	16
COMBINED:	21272.3671	26402.711	27089.0664		21272.3671	

95% C.I. on Mean: Dermal: [-87645.3614, 139512.7371]

95% C.I. on Geo. Mean: Inhalation: [185.9517, 4262.3109]

Inhalation Rate : 25 Liters/Minute
Number of Records: 16
Data File: APPLICATOR Subset Name: M11.APPL

APPENDIX III

Sponsor provided studies noted but not included in review

Diesing L (1997) Propoxur 0.2% & methiocarb 0.2% AE - Toxicological risk assessment for indoor use, Bayer AG, Study number 597 (unpublished report).

This study provides a theoretical estimate of methiocarb and propoxur air concentrations following aerosol application of a combination product to living areas.

The study product type and application method are not considered relevant for the Australian situation. The only Australian indoor use is in glasshouses. In this situation **WP** product is applied as a soil drench, while pellets are scattered on the soil.

Heimann KG (1993) Assessment of potential operator risk when dressing seed corn with Mesurol 500, Bayer AG, Study number 4 (unpublished report).

This study estimates risk during seed treatment based on a theoretical dermal exposure estimate. A number of limitations preclude the use of this study in the ECRP review. Most importantly the derivation of the exposure estimate was not provided, the formulation type used in the study (Flowable Concentrate for Seed Treatment) is not registered in Australia and methiocarb is not registered for us as a seed dressing in Australia.

Brouwer DH, De Haan M and Van Hemmen JJ (1996) Modelling re-entry exposure estimates: Application technique and foliar surface area as critical parameters for dislodgeable foliar residue, Abstract of Paper (Paper number 156), American Clinical Society 211 (1-2).

Abstract only. No data or results discussed.

APPENDIX IV

OCCUPATIONAL CONTROLS

Hazard classification

Methiocarb is listed in the National Occupational Health and Safety Commission (NOHSC) List of Designated Hazardous Substances (NOHSC, 1999). Substances containing methiocarb are classified as hazardous at concentrations greater than or equal to 3%. The risk and safety phrases assigned to methiocarb are as follows:

Risk phrases

≥25%	R25	Toxic if swallowed.
≥3% and <25%	R22	Harmful if swallowed.

The **WP** formulation of methiocarb is determined to be a hazardous substance based on the concentration of active ingredient (75% w/w).

The National Model Regulations [NOHSC:1005(1994)] and National Code of Practice [NOHSC:2007(1994)] for the Control of Workplace Hazardous Substances (NOHSC, 1994a) apply to all hazardous substances, as defined in the national model regulations, and extend to all workplaces in which hazardous substances are used or produced and to all persons (consistent with the relevant Commonwealth/State/Territory occupational health and safety legislation) with potential for exposure to hazardous substances in those workplaces.

Safety directions

The Handbook of First Aid Instructions and Safety Directions (FAISD Handbook) contains the following safety directions for methiocarb formulations (Table 18):

Current methiocarb safety directions

WP 750 g/kg or less	120 130 131 133 210 211 220 221 223 279 281 290 294 296 340 342 350 360 361 362	Product is poisonous if absorbed by skin contact or swallowed. Avoid contact with eyes and skin. Do not inhale dust or spray mist. When preparing spray wear elbow-length PVC gloves and face shield. If product on skin, immediately wash area with soap and water. After use and before eating, drinking or smoking, wash hands, arms and face thoroughly with soap and water. After each day's use, wash gloves and face shield.
BA 20 g/kg or less	130 133 210 211 340 342 350 373	Poisonous if swallowed. Avoid contact with eyes and skin. If product on skin, immediately wash area with soap and water. After use and before eating, drinking or smoking, wash hands, arms and face thoroughly with soap and water. Obtain an emergency supply of atropine tablets 0.6mg.
BA 20 g/kg (1 kg pack or less)	Nil	

The above safety directions are consistent with those appearing on the product labels.

Any changes or additions to these safety directions indicated by this review are addressed under Label requirements (Section 7.3.2).

Information provision

Labels

Active constituent label

Technical grade methiocarb is determined to be a hazardous substance. Therefore, it must be labelled in accordance with the NOHSC Code of Practice for the Labelling of Workplace Substances (NOHSC, 1994b).

Product labels

All methiocarb product labels must include a reference to the MSDS for further information.

Refer to Section 5.4 for product labelling requirements arising from this review.

MSDS

The active ingredient and all registered methiocarb products require MSDS in accordance with the NOHSC Code of Practice for the Preparation of Material Safety Data Sheets (NOHSC, 1994c).

Occupational exposure monitoring

Atmospheric monitoring

An exposure standard has not been assigned for methiocarb by NOHSC or ACGIH.

O'Keefe and Pierce (1980) estimated a TLV (Tolerance Limit Value) for methiocarb of 0.3-0.5 mg/m^3 based on the oral and dermal toxicity of methiocarb relative to other carbamates (carbofuran and carbaryl). The relative dermal toxicities of these three carbamates suggest that absorption through the skin may be a significant source of exposure to methiocarb.

The sponsor provided information on engineering controls used at the formulation plant and details of PPE worn by the personnel. Atmospheric and personal monitoring is routinely conducted at the formulation plant. Employee's personal dust and vapour exposure is measured and analysed for methiocarb technical.

OCS does not recommend the establishment of an exposure standard at this point, given that:

(i) inhalation exposure of formulation workers should be minimal with the controls and monitoring techniques currently in place, and

(ii) inhalation exposure of end users and re-entry workers should be minimal provided they follow the controls and labelling requirements recommended by NOHSC in Section 6.

Health surveillance

Carbamates (including methiocarb) are not listed on the NOHSC Schedule for Health Surveillance (Schedule 3) [NOHSC 1994a]. The DoHA has assessed methiocarb as being of high acute oral toxicity, moderate inhalation toxicity and low dermal toxicity, with reversible cholinesterase inhibition identified as the critical effect in animals and humans.

Under current conditions of use in Australia, the risk of adverse effects in workers using methiocarb **WP** and hand distribution of methiocarb **BA** is unacceptable unless specified exposure mitigation methods are applied. As such, workers should have access to health surveillance in accordance with the NOHSC Control of Workplace Hazardous Substances (NOHSC, 1994a). Also, the sponsor has indicated that all staff at the formulation plant are monitored for blood cholinesterase levels on a monthly basis.