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Methiocarb review update to occupational health and safety assessment

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

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EXECUTIVE SUMMARY

Methiocarb is a carbamate pesticide that has been registered for use in Australia for over 30 years. It kills insects, slugs and snails by interfering with the activity of acetylcholinesterase, an enzyme in the nervous system.

In Australia, methiocarb is currently registered for use in the control of snails, slugs and wireworms in a range of agricultural and home garden situations. At present methiocarb is available only as bait granules (BA 20 g/kg methiocarb) formulation. Previously it was available in wettable powder and suspension concentrate formulations, but those formulations are no longer registered.

The reconsideration of the active constituent methiocarb, products containing methiocarb and associated labels includes public health, occupational health and safety (OHS), residues in food and possible risks to Australian trade and the environment.

After assessing all the available data, the Australian Pesticides and Veterinary Medicines Authority (APVMA) published the toxicology, OHS, environment, and residues and trade assessment reports along with the Preliminary Review Findings (PRF) in 2005. These reports, and the updated 2013 toxicology assessment are available via the publication archive tab on the methiocarb reconsideration webpage.

This document is an update of the 2005 OHS report. It contains revised first aid instructions and safety directions (FAISD) for bait and wettable powder products, as well as the OHS risk assessment for wettable powder (WP) use in poppies (as the 2005 OHS report did not address WP use on poppies).

For bait products the 2005 OHS assessment was revised and updated to remove the recommendation that cotton overalls be worn over normal clothing during hand or mechanical distribution of pellets. The present recommendation requires only the additional use of gloves for workers applying methiocarb baits by hand distribution. This is reflected in the updated safety directions for bait products.

The registration of the wettable powder product ceased after this revision to the 2005 OHS assessment had commenced, and therefore there are no regulatory actions recommended as a result of this assessment. However, the consideration of any future application to register or renew the registration of wettable powder products should take into account the recommendations in this report.

This assessment concluded that the 2005 safety directions for wettable powder use require a few comparatively minor amendments and changes of the wording, to match the current standard phrases in the FAISD handbook and to take into account the findings of this poppy use OHS assessment for the WP formulation.

A rehandling period of 28 days has been recommended for the soil drench and ornamental foliar-application uses of the wettable powder products.

The respiratory protection for mixing and loading wettable powder (WP) has been more clearly specified as a disposable dust mask to cover the mouth and nose. The requirement for a washable hat has been removed, and

the reference to PVC gloves has been replaced with one to chemical resistant gloves. For application by hand, it is now additionally specified that the chemical resistant clothing should be buttoned to the neck and wrist.

The APVMA has also revised[1] the safety directions for the bait products and wettable powder products. These are also presented in this report, in chapter 4.

Lastly, this assessment recommends some amendments and clarifications to the findings of the 2005 OHS report. These amendments and clarifications are presented in chapter 5 of this report.

[1] Based on advice from the Office of Chemical Safety [OCS], which ceased operation on 30 June 2016.

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 was nominated for reconsideration (review) because of concerns over public health, occupational health and safety, residues in food, and possible risks to Australian trade and the environment. There were also some adverse experience reports relating to domestic animals inadvertently consuming pellets of methiocarb products.

The Australian Pesticides and Veterinary Medicines Authority (APVMA) published the Preliminary Review Findings (PRF) and associated assessment reports in 2005. These are available on the APVMA website via the 'Publication Archive' tab on the methiocarb reconsideration webpage.

This document presents amendments and updates to the Occupational Health and Safety assessment published in 2005. These include:

- revised first aid instructions and safety directions (FAISD) for bait products and wettable powder products
- an OHS risk assessment for wettable powder (WP) use in poppies
- some amendments and clarifications of the findings of the 2005 OHS assessment.

Note that wettable powder products are not currently registered. However, this updated OHS report has been published for transparency, and to provide useful information should anyone seek to register wettable powder products in the future.

2 TOXICOLOGICAL ENDPOINTS FOR THE OHS RISK ASSESSMENT

The revision of the first aid and safety directions for bait and WP products and the OHS risk assessment for use of WP products on poppies, took into consideration the following toxicological findings and endpoints (below). A more detailed discussion of these endpoints is available in the 2005 OHS report and the 2013 toxicology report.

2.1 Acute toxicity

In acute toxicity 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 new toxicological studies were made available to the APVMA review, on WP or pellet bait methiocarb products, prior to this OHS update report. 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 NOAELs relevant for an OHS risk assessment. Based on a consideration of the likely duration and routes of worker exposure (ie. dermal and inhalation), this OHS risk assessment update used NOAELs derived from a 3–week dermal study and a 3–week inhalational study in rabbits and rats respectively. These are shown in Table 1.

Table 1: Methiocarb—Summary of NOAELs relevant to the OHS assessment

Species and route	Duration of study/ treatment	NOAEL (mg/kg bw/day, unless otherwise stated)	LOAEL and toxic effects
Rat, inhalation Thyssen & Mohr (1983)[2]	3 weeks	6 mg/m^3 (males) [1.6 mg/kg bw/day]**	Inhibition of ChE* activity in the plasma and brain at higher exposure levels (23 mg/m^3 for males, 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]	3 weeks	60	Decreased food consumption and weight gain and plasma ChE inhibition at 150 mg/kg bw/day; NOAEL for RBC and brain ChE >375 mg/kg bw/day

* *ChE = cholinesterase*

** *The NOAEC (6 mg/m^3) was converted to a daily systemic exposure 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

The NOAEL, based on cholinesterase inhibition and decreased food consumption and weight gain, was 60 mg/kg bw/day for dermal exposure whereas for inhalational exposure with the same toxicological endpoint the NOAEL was 6 mg/m^3 (Procter, 1988; Thyssen & Mohr, 1983) [converted to a systemic exposure 1.6 mg/kg bw/day].

[2] Thyssen J & Mohr U (1983) H 321 (Mesurol Active Ingredient) Subacute inhalation study with rats. Institute of Toxicology, Bayer AG, Wuppertal-Elberfel, Germany. Report No. 12120. Unpublished.

[3] Procter BG (1988) A 21-day dermal toxicity study of Mesurol technical in Albino rabbits. Bio-research Laboratories Ltd., 87 Sennville Road, Sennville, Quebec H9X 3R3, Canada. Report No. 1084. Unpublished.

3 OHS RISK ASSESSMENT FOR WP-USE IN POPPIES

A suspension concentrate (SC) containing 500 g active ingredient (ai) per litre and a wettable power (WP) containing 750 g ai per kg were the only formulations that were used in poppies.

The SC was first registered in January 2011, became a stopped product on 1 July 2013 and a fully unregistered product on 30 June–2015. Hence no review-related OHS assessment was done on this formulation, and it was subsequently unnecessary, given its un-registered status when this OHS update commenced.

The WP was first registered in January 1980 (under the previous state based system), became a stopped product on 1 July 2014 and a fully unregistered product on 30 June-2015.

The only reasons for this OHS update of the WP, is that a WP-assessment was published in 2005, which omitted the use in poppies. This update is purely for transparency and completeness.

3.1 Use pattern

Information on the Australian WP's poppy use pattern was obtained from the last-approved product label, APVMA Agriculture Report and performance questionnaires (PQs) covering methiocarb users, and State Chemical Co-ordinators. This information is summarised in Table 2.

Table 2: Use pattern of methiocarb WP-product in poppies

Crop/ Situation	Product: application rate/dilution	Alternative chemicals/ strategies used*	Comments/ label instructions	Application methods
Poppies	**75 WP**: 5.5 kg/ha (4.125 kg-ai/ha)	N/A	Applied at seedling stage as a 'thorough spray'	Cover spray** (via boom spray)

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 to poppies is not specified on the WP product label, though it implies a single application, given the application timing is very specific (seedling stage). Information received by the APVMA, from industry, 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 future poppy fields, potentially increasing the number of seasons when treatment is necessary.

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 areas.

Label restrictions

Withholding period

There was no withholding period (WHP) specified on the methiocarb WP product label, for use in poppies.

This is not unusual, given the very early crop-stage at time of application (seedlings), which would restrict residue accumulation in plant tissues (and in poppy seed), given that harvesting occurs 3 to 5 months after sowing. Further, the huge increase in plant biomass after application would significantly dilute any residues from the seedling stage.

Also the alkaloids extracted from treated poppies are not consumed by humans (the rationale behind WHPs), and the extraction processes are likely to destroy any minute methiocarb residues in harvested plants.

Safety directions

Up to approximately 2005, the label for the **WP** formulation recommended the use of PVC gloves and a face shield during the preparation of the spray. No other personal protective equipment [PPE] were recommended for mixing/loading or application of **WP**.

However, as a result of the 2005 OHS assessment for the APVMA review, a subsequent label for **WP** formulation reflected the more stringent PPE from that assessment, as below:

> Upon opening the container and preparing the spray, elbow length PVC gloves and dust mask covering mouth and nose were recommended. For application, wearing of cotton overalls (over normal clothing) buttoned to the neck and wrist were recommended, together with a washable hat, elbow length PVC gloves and a face shield. Further, if applied by hand, the label recommended wearing of chemical resistant clothing buttoned to the neck and wrist, together with a washable hat, elbow length PVC gloves and a face shield.

This information was contained in the safety directions section of the label.

Re-entry interval (REI)

The WP label did not specify a re-entry period for treated areas. Note though that the 2005 report did recommend a 28 day REI for the WP, which was also reflected in the SC label of 2013. There has been no change in this REI for the WP, since the 2005 report. Note that this proposed REI reflected the worst case situations on the label (such as high rates applied to plant foliage [eg citrus or grapevines], and hence significant dislodgeable leaf residues that may transfer onto workers).

In the case of poppies, worker contact with treated foliage would be negligible, given the application at seedling stage and most field tasks at that stage are via mechanical means. In short, there would be minimal brushing against treated foliage by workers.

Hence the most appropriate REI statement for the poppy use-pattern would be that there be no re-entry until the spray has dried.

3.2 Occupational exposure and risk assessment

The occupational risk assessment for use of methiocarb products in poppies took into consideration the toxicity of the chemical, its use pattern in Australia and worker exposure for each use-pattern.

In order to adequately determine the risk associated with the end use or post-application exposure to methiocarb, the margin of exposure [MOE] were calculated by comparing the most appropriate NOAELs (described in Section 2) with exposure data obtained from end use exposure (surrogate exposure studies, predictive modelling or exposure database estimates), or post-application exposure data (measured exposure or dis-lodgeable foliar residue data) detailed in this section.

Where a NOAEL, taken from a human study, is used to estimate risk, a MOE of 10 or more is considered to be acceptable to account for intra-species (10x) variability. For NOAELs based on animal data a MOE of 100 or more is considered to be acceptable. This MOE includes a consideration of the intra-species (10x) variability and inter-species (10x) extrapolation. Since the methiocarb risk assessment relies on NOAELs 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 that are 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 NOAEL (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) [converted to 1.6 mg/kg bw/day for a daily systemic exposure] [Table 1]. For details of how these NOAELS were set, see page 184 of the 2005 OHS report.

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.

End use

With respect to use of the methiocarb WP formulation in poppies, exposure is expected to be limited to inhalation and dermal exposure during mixing/loading (if applicable) and application.

Application details of the **WP** use pattern parameters for poppies, are identified in the occupational exposure assessment and are presented in Table 3.

Table 3: Use pattern parameters used in this 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
Poppies (Tas only)	Mixing/loading and application of **WP** by mechanical application—**boom spray** (poppies only)*	5.5 kg/ha (4.125 kg ai/ha) Spray volume not specified**	30 ha/6 hr/day#	124 kg

***** *open mixing and loading using non-water soluble 400 g packs*

** *The SC label directions for application to poppies recommends 100 L-spray-mix per hectare.*

Based on survey information

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 (see Section 5.1.3.1 in the 2005 OHS report).

The following additional 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)[4]
- 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

No chemical specific worker exposure data was provided for assessment of application of **WP** by mechanical means and there were no relevant studies located in the open literature.

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 estimate occupational exposure to methiocarb.

The label specifies that mechanical application of the WP formulation to poppies should be a 'thorough cover spray' and accordingly, this assessment assumes that application to poppies is made by boom spray (as stated on the SC label for this poppy use). The basic PHED scenario for open mixing/loading of wettable powders, and the basic PHED scenario for open cab boom spray application were considered suitable to estimate

[4] Thongsinthusak T, Ross JH, Sanborn JR, Wang R, 1993b. Dermal Absorption of Pesticides in Animals and Humans. Worker Health and Safety Branch, Cal/EPA Department of Pesticide Regulation, HS-1676.

exposure for this label use. As the basic PHED scenarios were used (see Table 4), no sub-setting parameters were needed for this exposure-scenario.

Table 4: PHED files/scenario used to estimate exposure to Australian end users of methiocarb

Exposure-scenario	PHED File (subset name) and sub-setting parameters
Mixing/loading and application of WP by mechanical application—**boom spray**	Boom sprayer MIXLD.FILE (M1.MLOD) WP > 50%; packaging type: bags; mixing procedure: open; location: outdoor APPL Basic scenario 13 Application method: boom-spray; cab type: open MIXLD/APPL :M1.MLOD + APPL Basic scenario 13

The resulting exposure estimates are summarised in Table 5.

Table 5: PHED data used to estimate exposure to Australian end users of methiocarb

Exposure Scenario	Australian use parameters		PHED subset name	Operation*	Exposure (mg/kg bw/day) **	
	Product application rate (etc.),	Application equipment			Dermal	Inhalation ***
Mixing/ loading and application of **WP** by mechanical application	**Product appl. rate:** 5.5 kg/ha (= 4.125 kg ai/ha) **Spray volume:** 100 L spray-mix/ha **Work rate:** 30 ha/6-hr-day **Total ai handled**: 124 kg-ai/day	**Boom spray** Long pants, long sleeve shirt, gloves Open cab	M1.MLOD	M/L	0.468	0.035
			Scenario-13	Appl.	0.0547	0.0004
			M1.MLOD + Scenario-13	M/L/A	***0.532***	***0.035***

** 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

Risk from end use exposure

Risk from exposure for WP use in poppies is estimated from the surrogate/modelled data (see Section 5.1.1 of the 2005 OHS report) and is summarised in Table 6.

The results of the previous WP risk assessment were discussed in section 5.1.3.1 of the 2005 OHS report. The following discussion is in addition to that WP assessment.

Table 6: PHED data used to estimate margin-of-exposure (MOE) for Australian end users of methiocarb

Exposure Scenario	Data source/model (Estimate No) (Number of replicates)		Total ai applied per day Study/Model PPE	Operation	Exposure* (mg/kg bw/day)		MOE**		
					Dermal	Inhalation	Dermal	Inhalation	Dermal + inhalation ***
Mixing/loading and application of WP by mechanical application—**boom spray**	PHED subset and Basic PHED scenario	M1.MLOD (72 replicates)	124 kg ai/day Long pants, long sleeve shirt, gloves	M/L	0.468	0.035	128	45	33
		Basic PHED Scenario 13 Ground-boom, open cab APPL (medium confidence data)		Appl.	0.0547	0.0004	1096	4000	860
		M1.MLOD + Scenario 13		M/L/A	0.523	0.035	114	45	32

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

****** *MOE = NOAEL ÷ Exposure;* ***dermal NOAEL*** *= 60 mg/kg bw/day) Procter (1988);* ***inhalation NOAEL*** *= 1.6 mg/kg bw/day , Thyssen & Mohr (1983)* ***[converted from 6 mg/m^3]***

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

M/L—mixing/loading Appl—application M/L/A—mixing/loading/application

Unacceptable MOE (ie. MOE less than 100) are shaded

The safety directions for the **WP** formulation prior to the 2005 review, 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.

Hand exposure is expected to occur during mechanical application when equipment needs attention (not just during hand spraying). To avoid possible skin irritation, a recommendation of gloves during the preparation and application of **WP** formulation would be warranted irrespective of the risk assessment outcome.

The exposure assessment for this scenario relied on PHED subset data for open mixing/loading of wettable powders, and the basic PHED scenario for open cab boom spray application.

The risk assessment results show that there was low dermal and inhalational risk during application, while the MOE for mixer/loaders is 128 for dermal exposure and 45 for inhalational exposure. Inhalation exposure during mixing/loading presented the highest risk. 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 (boom spray) will not be adequately protected, when using the product according to the pre-2005 label instructions (where safety directions state face shield and PVC gloves during spray preparation).

The risk assessment indicates that these workers will be protected if they wear cotton overalls, gloves and a dust mask during mixing/loading, and cotton overalls and gloves during application[5].

Post-application

Workers can potentially be exposed to methiocarb when they enter treated poppy crops.

As such, no poppy-specific data was available to the review in 2005, to set re-entry intervals into treated crops. It is possible to estimate exposure risk from entering treated crops, using surrogate data.

However, setting a formal re-entry interval in poppies is not considered necessary for operations following treatment. Methiocarb is applied to poppy crops infrequently, from one year to another, and then only when they are in seedling stages. Usually, any farm operations that take place in the early stages of crop are mechanical operations. Thus, scope for brushing against treated plants is not expected to be significant or present risk from dislodgeable foliar residues.

[5] However, note that the safety directions (SDs) on a WP label would address the worst case OHS scenario, such as orchard sprayer application, and so the label's SDs would include a face shield for that form of mechanical application.

So whilst the 2005 OHS report recommended a 28 day Re-entry Interval (REI) be included on the WP label, based on other uses on it, this is not relevant to the poppy use. At most, workers should not enter the treated poppy crop until the spray has dried.

Recommendations/conclusions

The APVMA can NOT be satisfied that the continued use of methiocarb wettable powder (WP) products in poppies, in accordance with pre-2005 label instructions, would NOT be an undue hazard to the safety of workers.

However, with the label instructions varied as per the 2005 OHS report and updated for current standard statements, the APVMA concluded that the use of methiocarb WP in poppies, would NOT be an undue hazard to the safety of workers.

The updated safety directions based on the 2005 OHS report and this report are presented below,

The associated 2005 re-entry interval (REI) statements are repeated below, with slight amendments for current REI statements,

WP formulations (750 g/kg or less)

The main changes to PPE (personal protective equipment) in the safety directions are:

- the respiratory protection for mixing and loading has been more clearly specified as a disposable dust mask to cover the mouth and nose
- the requirement for a washable hat has been removed
- the reference to 'PVC gloves' has been replaced with one stating 'chemical resistant gloves'
- for application by hand, it is now additionally specified that the chemical resistant clothing should be buttoned to the neck and wrist.

Safety directions: PPE related statements

*Mixer/load*er: When opening the container and preparing spray, wear cotton overalls buttoned to the neck and wrist, disposable dust face mask covering mouth and nose and elbow length chemical resistant gloves.

279 280 281 290 292b 294c 306 (dust)

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

279 282 290 292b 294c 296 289 290 291b 294c 296 360 361 362 366

Re-entry interval [REI] statement for all WP products

The 2005 OHS report recommended a Re-Entry Interval (REI) for WP products. Whilst this poppy-use assessment does not change it, an amended form (using current standard statements) is presented for completeness.

> DO NOT PERMIT re-entry **for** 28 days after application. If prior **re-**entry is required wear cotton overalls buttoned to the neck and wrist **(or equivalent clothing)** and **chemical resistant** gloves. Clothing must be laundered after each day's use.

However, as stated above, this 28 days REI is not necessary for the poppy use.

Re-handling interval [RHI] statement for all WP products

Note that after the 2005 OHS report, a re-handling interval (RHI) statement was assessed[6] as necessary for treated soil (treated using the WP and BA formulations) and for sprayed ornamentals. This was to cover the situation where treated soil/compost is handled when potting plants, and sprayed ornamentals are harvested/handled (eg for the florist trade).

That RHI and associated discussion/argument is presented in the section 5 of this report, as it does not relate specifically to the poppy use being assessed here.

[6] Based on advice from the Office of Chemical Safety [OCS], which ceased operation on 30 June 2016.

4 FIRST AID INSTRUCTIONS AND SAFETY DIRECTIONS

4.1 Safety directions amendments

The safety directions[7] [SDs] in the 2013 toxicology report for methiocarb have been amended in light of the assessment of the wettable powder's poppy use pattern presented above, and other amendments as presented in the next section.

The safety directions for the home garden bait product have been amended to remove the warning 'Poisonous' (which has been confirmed as not being required for this product), and to add the use of disposable gloves if applying by hand, which has been confirmed as being required.

The changes outlined in this report also reflect current safety directions wording (such as the use of the words 'chemical resistant gloves' instead of 'PVC gloves' as a default[8]), discontinuation of the atropine statement requiring atropine tablets (373)[9] and an updated acute hazard profile for products, as determined by this update report.

Whilst the 750 g/kg wettable powder (WP) product is no longer registered, its SDs have been checked and recorded here, and should be taken into consideration if there is any future application to register a wettable powder.

With respect to the specific issue of whether a washable hat is required for mechanical application of the prepared spray of the WP (as in the 2005 report), this was subsequently assessed as not required. A check of the exposure values showed that a washable hat was not required for an acceptable MOE for mix/load/apply (M/L/A). The necessary PPE are a single layer (M/L/A) [no hat], gloves (M/L/A) and a dust mask (during M/L phase only).

The 500 g/L suspension concentrate (SC) product was first registered in 2011 which included the setting of safety directions at that time. As this product is no longer registered, and no new assessment was carried out for the purpose of the methiocarb review, this report has not recommended any changes to those SC safety directions.

[7] See pages 41 and 42 of the APVMA's methiocarb 2013 toxicology report.

[8] Also code **295** [Elbow-length (nominate other specific material) gloves, with 'chemical resistant' inserted for the material], was replaced with the new code of **294c [**Elbow-length chemical resistant gloves].

[9] Atropine tablets are no longer available for general purchase in Australia, therefore references to atropine tablets have been replaced in all anticholinesterase products.

4.2 Recommended safety directions for WP and bait pellet products

The previous safety directions for the WP and bait products in the 2013 review report (toxicology update) have been amended to align them with current FAISD Handbook standard statements and codes as follows:

Table 7: Recommended safety directions methiocarb BA 20 g/kg or less: >1 kg pack size [commercial product]

Codes	Text
Product type: Methiocarb Bait (BA) 20g/kg or less: >1 kg pack size [**commercial product**]	
129 133 160 162 210 211 250 252	Harmful if swallowed. May irritate the eyes. Avoid contact with eyes and skin. Do not touch bait. If on skin and after each baiting, wash thoroughly with soap and water
310 290 306 (dust) 289 290 294c	If dust is present wear disposable dust face mask covering mouth and nose. If applying by hand wear elbow length chemical resistant gloves
350 360 361	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

Table 8: Recommended safety directions methiocarb BA HG 20 g/kg or less, 1 kg pack or less

Codes	Text
Product type: Methiocarb Bait (BA), Home garden (HG) 20 g/kg or less, in packs of 1 kg or less	
129 133 160 162 210 211 250 277 279 290 321	Harmful if swallowed. May irritate the eyes. Avoid contact with eyes and skin. Do not touch bait except when wearing disposable gloves
310 290 306 (dust)	If dust is present wear disposable dust face mask covering mouth and nose
252	If on skin and after each baiting, wash thoroughly with soap and water
351	Wash hands after use

Table 9: Recommended safety directions methiocarb WP 750 g/kg products

Codes	Text
Product type: Methiocarb Wettable powder (WP) 750 g/kg or less	
100	Very dangerous
130 131 132 133	Poisonous if absorbed by skin contact or inhaled or swallowed
160 162 164 210 211	May irritate the eyes and skin. Avoid contact with eyes and skin
220 221 223	Do not inhale dust or spray mist
279 280 281 290 292b 294c 306 (dust)	When opening the container and preparing spray wear cotton overalls buttoned to the neck and wrist (or equivalent clothing) and elbow length chemical resistant gloves and disposable dust face mask covering mouth and nose
279 282 290 292b 294c 296	When using the prepared spray wear cotton overalls buttoned to the neck and wrist (or equivalent clothing) and elbow length chemical resistant gloves and face shield
289 290 291b 294c 296	If applying by hand wear chemical resistant clothing buttoned to the neck and wrist and washable hat and elbow length chemical resistant gloves and face shield
340 342 350 360 361 362 366	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 and contaminated clothing

5 OTHER (MINOR) AMENDMENTS TO THE 2005 OHS ASSESSMENT REPORT

The 2005 assessment report has been used to generate recommendations for the FSAID statements for the currently registered bait products with the following amendments to be noted. It may also be used to assess any future application for a wettable powder product registration as long as the following amendments to that assessment are noted. The page numbers in column-1 refer to the 2005 report.

Table 10: Other (minor) amendments to the 2005 OHS report

Reference to the 2005 report	2005 report text	Amended recommendations or clarifications
Page 199 Table 13 Scenario (1) 'Exposure scenario' column	Scenario (1) Mixing/loading and application of WP by mechanical application	Note that, as described in Table 11 of the 2005 OHS report, Scenario (1) applies to mechanical application by orchard sprayers **only**. A different PHED scenario was necessary to assess application by boom spray (presented in this report).
Page 200 Scenario (3) Mixing/ loading and application of WP by hand held application - **cover spray** 'Australian application rate (etc.)' column	Protective clothing + gloves during M/L/A (potential inhalation exposure reported although dust mask worn during M/L and respirator worn during Appl)	'Protective clothing' should be more explicit, as in 'Protective clothing (cotton or Goretex overalls and a cotton cap)'. FAISD statement should be amended to include this level of PPE

Reference to the 2005 report	2005 report text	Amended recommendations or clarifications
Page 203 Table 13 Scenario (5) Application of BA by mechanical applicator—**broad-acre** applications PHED Subset (Tractor-mounted equipment) 'Australia application rate' column	17 kg product/ha, 1.7 kg ai/2 hr day—appears to apply to both tractor mounted and hand-operated equipment, in this table	The '17 kg-product/ha, 1.7 kg-ai/2 hr day' **only** applies to hand-operated equipment. The work rate for mechanical application is 10 kg-product/ha, 4 kg-ai/6 hr day. However, the 2005 report's assessment for mechanical application was conducted on the correct work rate for this use pattern, so its exposure conclusions are correct.
Page 204 Scenario (1) Mixing/loading and application of WP by mechanical application	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 (2nd last paragraph of this section) 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 sub-title 'Scenario (1) Mixing/loading ……mechanical application' should have specified '- orchard sprayer', as Scenario (1) applies to application by orchard sprayer **only**. Hence the overall conclusion (in the adjacent column) does **not** apply to application by boom spray.

Reference to the 2005 report	2005 report text	Amended recommendations or clarifications
Page 206 Scenario (2) Mixing/loading and application of WP by **handheld** application—soil drench Indoor Knapsack applications [soil drench] [Part of 'Risk from End-use Exposure: WP formulation']	*(at top of page 206)* In order to reduce risk to an acceptable level workers should wear cotton overalls, gloves and respiratory protection during mixing/loading and application.	With respect to 'respiratory protection', the more specific statement of a dust mask during mixing/loading, and a face shield during application, is now recommended. This gives clearer advice about the appropriate respiratory protection required at each stage of use.
Page 206 Scenario (3) Mixing/loading and application of WP by **handheld** application—cover spray Indoor Knapsack applications [greenhouses] [Part of 'Risk from End-use Exposure: WP formulation']	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.	Note that the sponsor provided surrogate data was checked, which confirmed that the workers involved were also wearing respiratory protection, in addition to gloves and protective clothing.

Reference to the 2005 report	2005 report text	Amended recommendations or clarifications
Page 208 Scenario (4) Application of BA by mechanical applicator—orchard applications and Scenario (5) Application of BA by mechanical applicator—broad acre applications [Part of 'Risk from End-use Exposure: BA formulation']	*(at top of page 208)* 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 recommend the use of cotton overalls (ie. one layer of protection).	Examination and rechecking of the MOE results in this table confirmed that the lowest MOE was actually an acceptable 167, obtained for operators using hand operated equipment and applying product at the higher application rate (scenario (5)). Therefore the use of overalls in addition to standard clothing is **not** required
Page 208 Scenario (6) Application of BA by hand distribution—all situations [Part of 'BA formulation [Risk from End-use Exposure]']	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.	Examination and rechecking of the MOE results in this table confirmed that the lowest MOE was actually at an acceptable risk (MOE 100), for workers wearing long pants, long sleeved shirt and gloves. Therefore there is no recommendation to require the use of overalls in addition to standard clothing. Label safety directions should be amended to just recommend the use of gloves during hand distribution of pellets.

Reference to the 2005 report	2005 report text	Amended recommendations or clarifications
Page 212 WP formulation [Risk from Post-application exposure]: Cover spray	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	(There are no changes to the original conclusion/recommendation of a re-entry period [REI] of 28 days. However it should be noted that the variability in the recommended re-entry periods from assessed studies, arises primarily due to differences in the measured dislodgeable foliar residues (DFR) between the two available studies. Zweig et. al. (1985)[10] reported a DFR of 8 µg/cm^2 on day 3, falling rapidly to 0.6 µg/cm^2 on day 6, following heavy rain. On the other hand, Knarr (1987)[11] reported a DFR of 20 µg/cm^2 on day 2, around 10 µg/cm^2 on days 5–14, falling below 3 µg/cm^2 on day 28. Given the variability of the data the more conservative estimates was be used.
Page 213 WP formulation [Risk from Post-application exposure]: 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, *(this paragraph was not finished)*	The missing part of the paragraph in the 2005 assessment was: 'it was not possible to directly calculate a re-entry/re-handling interval for potted plants. However, since the half-life of methiocarb residues in soil is apparently quite variable and possibly of a long duration, ie. 1.6 to 17.7 days (JMPR, 1999)[12], the recommended 28-day interval for re-entry into treated crops is also considered appropriate for handling soil in pot plants, which have been treated with methiocarb. Workers handling treated soil (or performing other activities such as harvesting) during this interval should also wear protective clothing and chemical resistant gloves. It is noted that the re-handling interval for treated soils could be re-considered if additional information on worker exposure becomes available.'

[10] 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.

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

[12] JMPR (1999) Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Core Assessment Group Rome, 20–29 September 1999. (JMPR/WHO report 1999)

<table>
<tr><th>Reference to the 2005 report</th><th>2005 report text</th><th>Amended recommendations or clarifications</th></tr>
<tr>
<td>Page 216
End Use [Review Outcomes]
Table 16: Proposed Regulatory action—end use</td>
<td>Table 16: Proposed regulatory action—end use
<table>
<tr><td>End use</td><td>Relevant mitigation method/label requirement</td></tr>
<tr><td>Mechanical application of BA</td><td>Cotton overalls</td></tr>
<tr><td>Hand distribution of BA</td><td>Cotton overalls and gloves.</td></tr>
</table>
</td>
<td>As noted above, overalls are not required for protection of workers applying baits by hand or by mechanical means. Additionally this table was misnumbered. Therefore this table should read:
Table 17: Proposed regulatory action—end use
<table>
<tr><td>End use</td><td>Relevant mitigation method/label requirement</td></tr>
<tr><td>Mechanical application of BA</td><td>None.</td></tr>
<tr><td>Hand distribution of BA</td><td>Gloves.</td></tr>
</table>
</td>
</tr>
</table>

Reference to the 2005 report	2005 report text	Amended recommendations or clarifications
Page 216 Labelling requirements [Review Outcomes]: Re-entry statements	The following re-entry statements must be included on wettable powder product labels and bait 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.	The Re-Entry Interval (REI) statement should be reworded to conform to current standard statements: 'DO NOT PERMIT re-entry for 28 days after application. If re-entry is required wear cotton overalls buttoned to the neck and wrist (or equivalent clothing) and chemical resistant gloves. Clothing must be laundered after each day's use'. Additionally a re-handling interval (RHI) statement for treated soil was subsequently recommended, which was not included in the 2005 report. The proposed RHI is follows. **RE-HANDLING TREATED SOIL:** DO NOT RE-HANDLE treated soil for 28 days after application. If re-handling during this interval is required wear cotton overalls buttoned to the neck and wrists (or equivalent clothing) and chemical resistant gloves. Clothing must be laundered after each day's use. The RHI is related to treatment of soil, potting mix, compost and/or potted nursery stock (etc) [eg via a soil drench (WP)], and treated soil (etc.) is then handled or re-handled (eg for potting or re-potting). It also applies to handling sprayed ornaments, though the REI does address this. **NOTE**: the 2005 OHS report proposed the REI be placed on labels of both WP products and bait (BA) products. Further, the subsequent check of the 2005 report recommended that the RHI be applied to both WP and BA products. However, given the significant difference in rate compared to soil drenches using WP solution, versus bait application, the APVMA has not accepted that REI or RHI are required for the bait products. The rationale for this is presented below. First, there are no dislodgeable foliar residues (DFRs) from pellet application, which is the main reason for an REI: ie. an REI is not indicated. Secondly, with respect to an RHI, the pellet label has 110–440 g-ai/ha applied [~22 pellets/m^2 to 88 pellets/m^2] to nursery stock [etc.]. On a single square metre basis, this is 0.011–0.044 g-ai. In contrast, the WP uses a solution of 225 g-ai/100L as a soil drench. If 1L was used for a square metre of potting mix (of the same depth), then the rate of application is 2.25 g-ai/m^2. This is ~ 200 to 800 times higher than the pellet rate. That is, the rehandling exposure from pellet treated soil is approximately 200 to 800 times lower than from WP-soil-drench treated soil. **In short, specifying gloves when handling/re-handling pellet treated soil should be sufficient risk mitigation.** Inhalational risk would be negligible, given the nature of the pellet, so any standard respiratory protection when handling soil would be sufficient (eg dust mask).

Reference to the 2005 report	2005 report text	Amended recommendations or clarifications
Page 217 Recommendations to mitigate risks during mixing/loading and application : Bait (20 g/kg in packs over 1 kg) *[commercial product]* 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.	As noted above, cotton overalls and hat are no longer part of the required PPE for this use pattern, whether by hand or mechanical application. The previous reference to PVC gloves should also be replaced by chemical resistant gloves as the current standard for FAISD statements for hand application of the commercial product (and disposable gloves for the home-garden product). Hence the application statement for hand application of the commercial product should be: Applicator: If applying by hand wear chemical resistant gloves. After each day's use, wash gloves. 289 290 295 chemical resistant 360 361
Page 217 Re-entry statements (for all WP and BA products in packs over 1 kg) :	DO NOT PERMIT re-entry for 28 days after application. If re-entry is required wear cotton overalls buttoned to the neck and wrist and elbow length PVC gloves. Clothing must be laundered after each day's use'.	The Re-Entry Interval (REI) statement should be reworded to conform to current standard statements, including reference to chemical resistant gloves rather than PVC gloves. DO NOT PERMIT re-entry for 28 days after application. If re-entry is required wear cotton overalls buttoned to the neck and wrist (or equivalent clothing) and chemical resistant gloves. Clothing must be laundered after each day's use. There should also have been a re-handling interval (RHI) statement for treated soil (eg drenched with WP solution): RE-HANDLING TREATED SOIL: DO NOT RE-HANDLE treated soil for 28 days after application. If re-handling during this interval is required wear cotton overalls buttoned to the neck and wrists (or equivalent clothing) and chemical resistant gloves. Clothing must be laundered after each day's use. As detailed in 'Labelling statement Re-entry period' above, the REI and RHI only apply to the WP.
Page 238 APPENDIX IV : OCCUPATIONAL CONTROLS	Any changes or additions to these safety directions indicated by this review are addressed under Label Requirements (Section 7.3.2).	Note that this section should refer to Section 7.1.in the main text of the 2005 OHS report: 'Recommendations to mitigate risks during mixing/loading and application'

6 GLOSSARY OF TERMS AND ABBREVIATIONS

AChE	Acetyl cholinesterase—an enzyme essential for the regulation of nerve tissue function
Agvet Code	Agricultural and Veterinary Chemicals Code, Schedule to the Agricultural and Veterinary Chemicals Code Act 1994
ai	Active ingredient
APVMA	Australian Pesticides and Veterinary Medicines Authority
ARfD	acute reference dose the estimated amount of a substance in food or drinking-water, (expressed on a body weight basis), that can be ingested or absorbed over 24 hours or less, without appreciable health risk
BA	Bait—a formulation type
bw	Body weight
ChE	Cholinesterase
cm^2	Square Centimetre
DFR	Dislodgeable Foliar Residues a measure of the amount of an applied pesticide that may be transferred to workers re-entering treated areas
g	Gram
FAISD	First Aid Instruction and Safety Directions
ha	Hectare
hr	Hour
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
kg	Kilogram
LC_{50}	Lethal concentration (to 50% of the tested population)
LD_{50}	Lethal dose (to 50% of the tested population)
LOAEL	Lowest Observable Adverse-Effect Level
m^2	Square metre
m^3	Cubic metre
mg	Milligram
ml	Millilitre
MOE	Margin of exposure a measure of occupational exposure to a compound being the ratio of the no-observed effect-level to the estimated exposure dose
NOHSC	National Occupational Health and Safety Commission

NOAEL	No Observed Adverse-Effect Level
NOAEC	No Observable Adverse-Effect Concentration (applicable to inhalational studies)
OCS	The previous Office of Chemical Safety within the Australian Government Department of Health (OCS ceased operation on 30 June 2016)
OHS	occupational health and safety
PHED	Pesticide Handlers Exposure Database, used to estimate levels of exposure to a chemical
PPE	personal protective equipment such as gloves and overalls
PRF	Preliminary Review Findings, an interim report published during a reconsideration
PVC	Polyvinylchloride, a type of plastic previously commonly used in gloves
RBC	Red blood cell
REI	Re Entry Interval
RHI	Re-Handling Interval
SC	Suspension concentrate a type of formulation of a product
SUSMP	Standard for the Uniform Scheduling of Medicines and Poisons (formerly the Standard for the Uniform Scheduling of Drugs and Poisons)
WHO	World Health Organization
WP	Wettable Powder, a type of formulation of a product
µg	Microgram

STOPPED PRODUCT:

A re-registration fee must be paid every year by 30 June, for a registered product to remain registered.

A stopped product is one where the annual registration fee is not paid by 30 June, and the product effectively becomes un-registered. However, existing wholesale, retail and on-farm stocks may possessed, transported, sold and used, under a deemed APVMA permit, for a period of 12 months.

Registration status can be restored by payment of the registration fee, within 3 months of registration lapse (ie. by 30 September). On rare occasions, this can occur up to 15 December of the same year that the registration lapsed.

If registration is not restored as described above, then once the 12 month period of the deemed-permit lapses (ie. on 30 June of the following year), the product is fully expired. It then cannot be possessed, transported, sold or used except by a successful permit application to the APVMA.

Note also that if the registration is not restored by 15 December, then registration can only be recovered by a successful product-registration application (with all its associated assessments)—effectively, a new product.

7 SUMMARY OF USE-PATTERNS ON 2010 WP LABEL

The WP was a 750 g/kg wettable powder formulation. The use-patterns below (Table 11) reflect the last approved label (33276/1209), which was approved in June 2010.

Table 11: Summary of use-patterns on 2010 WP label

Tree and vine crops

Crop	Pest	Rate	Critical comments	Most common Application Method
Grapevines (WA only)	White Italian snail	100 g/100 L	Apply before flowering as a cover spray when pests become apparent. For greater control spray where they harbour—eg damp, dark areas, dense foliage, compost heaps, fences etc.	Boom or air mist (Orchard type spraying equipment)
	Garden weevil	200 g/100 L	Wet vine thoroughly at or before flowering before foliage is established. Spray in the evening when the weevils are active. Use high volume equipment only. May require a second application 3 weeks after the first spray.	
Grapevines (butt treatment only)	White Italian snail (NSW, SA only)	100 g/100 L	Apply as a cover spray when pests become apparent. For greater control spray where they harbour—eg damp, dark areas, dense foliage, compost heaps, fences etc. Only spray butt of grapevines	Boom or air mist (Orchard type spraying equipment)
	Common garden snail *Bradybaena* spp. , Slugs (Qld, NSW, Tas, SA, WA only)			
Oranges	Common garden snail *Bradybaena* spp. , Slugs		Apply as a cover spray when pests become apparent. For greater control spray where they harbour—eg damp, dark areas, dense foliage, compost heaps, fences etc.	Boom or air mist (Orchard type spraying equipment)

Non-tree and vine crops

Crop	Pest	Rate	Critical comments	Most common Application Method
Hibiscus	Hibiscus Flower Beetle	100 g/100 L	Spray when beetles are first seen, particularly when flowers are present. Repeat spray 3 days later to control beetles in tight buds.	Hand wand connected to mobile powered spray equipment **or** knapsack sprayer.
Ornamentals	Common garden snail *Bradybaena* spp., Slugs	100 g/100 L	Apply as a cover spray when pests become apparent. Spray where they harbour—eg damp, dark areas, dense foliage, compost heaps, fences etc.	
	Glasshouse sciarids (fungus gnats)	300 g/100 L	Drench soil, potting mix or compost in which infested plants are growing. Apply when larvae are first seen.	
	Blackbirds, Sparrows, Starlings, Indian myna	200 g/100 L	Apply as a thorough cover spray when birds begin attacking plants.	
Poppies (Tas Only)	Slugs	5.5 kg/ha	Apply as a thorough spray to protect seedlings when slugs become apparent.	Horizontal Boom

Note the last use-pattern (on poppies) [shaded] was not addressed in the 2005 OHS report. Hence this supplementary report.