Australian Government

Australian Pesticides and Veterinary Medicines Authority

**CHEMICAL REVIEW PROGRAM**

**Exposure and Risk Assessment**

**Including**

**Occupational Health and Safety Assessment**

**of**

# Dimethoate

***This Report was prepared for the APVMA by***

**The Office of Chemical Safety**

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## PREFACE

The APVMA began a review of dimethoate in 2004 because of potential human health concerns related to the usage of this chemical.

The Office of Chemical Safety (OCS) has prepared this review of dimethoate for the Australian Pesticides and Veterinary Medicines Authority (APVMA).

# EXECUTIVE SUMMARY

Dimethoate has been identified for priority reconsideration under the APVMA Chemicals Review Program because of toxicological concerns. The review commenced in April 2004 with the release of the Dimethoate and Omethoate Review Scope Documents. Additional toxicology data and data related to occupational exposure were received from industry. These data, together with all previously submitted registration data and relevant published data, have been assessed in detail.

Dimethoate has been registered for use as an insecticide and acaricide in Australia for over 30 years. The current review considered the 8 approved sources of dimethoate active constituent, and 21 registered products as determined at the start of this review. Products containing dimethoate are registered for more than 200 use patterns and to control more than 80 insect pest species. In agriculture, dimethoate is used both as a pre-harvest and post-harvest insecticide in orchard and fruit crops. It is applied by ground boom, airblast, backpack sprayer and as a fruit dip. In the home garden dimethoate products are normally applied by hand spray and were used to control many common insect pests on a wide range of vegetables, flowers and fruit crops, as well as on ornamentals.

Dimethoate is a contact and systemic organophosphate pesticide and its major toxicological endpoint in animals and humans is the inhibition of acetylcholinesterase (ChE) activity. A toxicology report prepared by OCS in 2010 provides information on the mammalian toxicology of dimethoate and recommends updated health standards. The toxicology report should be considered in conjunction with this exposure and risk assessment, which evaluates the risk to the public and workers during, and subsequent to, the use of dimethoate products.

There are no toxicology concerns regarding the ongoing registration of the home/garden aerosol product Garden King Rogor Garden Insect Spray (APVMA No. 52673), containing 0.3 g/kg dimethoate. The OCS has recommended Safety Directions for this product, together with a revised First Aid Instruction. The Scheduling of this product may be reconsidered.

The ongoing registration of dimethoate 100-400 g/L EC products for use in the home garden is not supported on toxicological grounds. These products are not appropriate for home garden use on the basis of their high acute oral toxicity and moderate-severe skin and eye irritation potential. On that basis, continued registration is not supported for home garden use of 100 – 400 g/kg dimethoate products.

The dimethoate 400 g/L EC products, while acceptable for commercial use, do not conform to criteria for domestic use. Therefore, the review recommends that pack sizes of these dimethoate 400 g/L EC products should be limited to volumes greater than 1 L to prevent home garden use.

The review evaluated the occupational risks associated with the dimethoate 400 g/L EC products used by farmers and contract workers. In the absence of adequate worker exposure studies specific for dimethoate products, surrogate exposure data (the Pesticide Handler Exposure Database, PHED) were used to estimate exposure during mixing/loading and application by boom spraying, airblast spraying, aerial spraying and hand spraying (vehicle-mounted and backpack). A short-term NOEL of 0.2 mg/kg bw/d based on inhibition of blood ChE activity in a 14-57 day human study was used for the OHS assessment. A dermal absorption factor of 5.1% from an *in vitro* study with human epidermis, and a default value of

100% inhalation absorption were used. A margin of exposure (MOE) $\geq$ 10 was considered acceptable. Qualitative assessment was conducted on other use patterns, which included misting machine, seed treatment, trunk injection, pre-planting dipping and post harvest dipping (including quarantine treatment). Personal protective equipment (PPE) was revised based on the OHS risk assessment.

The review identified that the following uses: outdoor and indoor application by fogging or misting; seed treatment; and trunk injection, of dimethoate should be deleted from product labels unless supported by additional exposure studies or detailed information on work rates and handling practices.

The US Occupational Post-Application Risk Assessment Calculator was used to quantify the post application risks. Based on the MOE values obtained, re-entry intervals (REI) of 0 (until the spray has dried) to 9 days are considered necessary to carry out various crop management activities safely. PPE including cotton overalls buttoned to the neck and wrist (or equivalent clothing) and chemical resistant gloves were recommended for re-entry during these periods.

The information provided on the products and considered in this review justifies the revised safety directions, precautionary statements and re-entry statements recommended. Furthermore, the proposed uses of those dimethoate products supported by this review will not be an undue health hazard to humans in accordance with the criteria stipulated in Section 14 (5)(e) criteria of the AgVet Code Act of 1994.

Further characterisation of risks for certain unsupported applications may be possible should further data be made available.

Revised safety directions and current first aid instructions should be included on the labels of dimethoate products that are supported for ongoing registration.

# RECOMMENDATIONS TO THE APVMA

## Approval Status

There is no objection on toxicological and occupational health and safety grounds to the ongoing approval of dimethoate and dimethoate manufacturing concentrate from the existing sponsors and manufacturers.

## Impurity Limits

It is recommended that the existing upper limit for the impurity O,O,S-trimethyl phosphorodithioate (5 g/kg) should be revised downwards to 3 g/kg, based on the levels of this impurity which were present in the active ingredient administered in the study used to establish the ADI. It is recommended that impurity limits of 2 g/kg for omethoate and 3 g/kg for isodimethoate be established on the basis of toxicological concerns, and current practically achievable levels.

The following revised impurity limits for the active constituent dimethoate are recommended based on toxicological grounds:

| **Chemical** | **Standard** |
|---|---|
| O,O,S-trimethyl phosphorodithioate | Maximum 3 g/kg |
| omethoate | Maximum 2 g/kg |
| isodimethoate | Maximum 3 g/kg |

## Product Registration

*HG EC products*

The ongoing registration of dimethoate 100-400 g/L EC products for use in the home garden is not supported on toxicological grounds. These products do not comply with the APVMA Agricultural Manual of Requirements and Guidelines (MORAG) requirements that "*household, home garden and domestic animal pesticide products must be relatively harmless or capable of causing only mild illness if accidental poisoning occurs… Any domestic pesticide formulations that may be ingested should not be expected to be acutely toxic to a child at doses up to 1,500 mg/kg bodyweight…The irritancy to skin and eyes of domestic products should be low*".

EC products containing 100–300 g/L dimethoate are not appropriate for home garden use on the basis of their high acute oral toxicity and moderate-severe skin and eye irritation potential. On that basis, continued registration of products containing 100–300 g/L dimethoate for home garden use is not supported.

Pack sizes of dimethoate 400 g/L EC products should be limited to volumes greater than 1 L to prevent home garden use. These dimethoate 400 g/L EC products are acceptable for commercial use.

*HG AE products*

There are no toxicology concerns regarding the ongoing registration of the home/garden aerosol product Amgrow Systemic Insect and Mite Spray (APVMA No. 52673), containing 0.3 g/kg dimethoate. The OCS has recommended Safety Directions for this product, together with a revised First Aid Instruction (see below), and that the Scheduling of this product may be reconsidered, as described below.

*Specific non-HG use patterns*

Based on the likelihood of an unacceptable risk to operators, the following uses of dimethoate should be deleted from product labels unless supported by additional exposure studies or detailed information on work rates and handling practices:

- Outdoor and indoor application by fogging or misting.
- Seed treatment
- Trunk injection

Amendments to first-aid instructions, precautionary statements, safety directions and re-entry statements (see below) should be incorporated onto labels of those dimethoate products supported for ongoing registration.

**First Aid Instructions and Poisons Scheduling**

A provisional recommendation has been made that a new First Aid Instruction be specified for dimethoate aerosol products containing 0.3 g/kg dimethoate (0.03%), for use in the home garden. It is considered appropriate to refer this proposed amendment of the First Aid Instructions for dimethoate to the Scheduling Delegate, together with a recommendation to establish a cut off to Schedule 5 for dimethoate in pressurised spray packs containing 0.03 per cent or less dimethoate.

| | |
|---|---|
| Dimethoate · in 0.03 percent pressurised spray packs | a,o |
| Dimethoate · in other preparations | m |

| | |
|---|---|
| a, o | If poisoning occurs, contact a doctor or Poisons Information Centre. Phone Australia 131126, New Zealand 0800 764 766. If sprayed on skin, wash thoroughly. If sprayed in mouth, rinse mouth with water. |
| m | If swallowed, splashed on skin or in eyes, or inhaled, contact a Poisons Information Centre (Phone Australia 131126) or a doctor at once. Remove any contaminated clothing and wash skin thoroughly. If swallowed, activated charcoal may be advised. Give atropine if instructed. |

## Safety Directions

The following changes in safety directions are recommended:

*Deleted entries*

Given that the home/garden use of dimethoate EC products is no longer supported, the safety directions for HG EC 100 g/L or less in cyclohexanone should be deleted from the FAISD handbook.

There are no registered dimethoate WP products, therefore the entry for WP 88 g/kg or less should be deleted from the FAISD handbook.

*Amended safety directions*

**Amended safety directions**

| **EC 400 g/L or less with cyclohexanone** | |
|---|---|
| 130 131 132 133 190 207 211 180 210 211<br><br>279 280 281 290 292 293 294c 296 298<br><br>279 282 (spray) (or dip *for preplant and post harvest dipping*) 290 294c<br>289 420 (*vehicle mounted low pressure equipment)* 290 292b 294c 300 307<br><br>330 332 340 342 340 343 351 360 361 362 364 366 | Poisonous if absorbed by skin contact, inhaled or swallowed. Repeated minor exposure may have a cumulative poisoning effect. Will damage eyes and skin. Repeated exposure may cause allergic disorders. Avoid contact with eyes and skin.<br><br>When opening the container and preparing spray wear cotton overalls buttoned to the neck and wrist, a washable hat, a PVC or rubber apron, elbow-length chemical resistant gloves, a face shield and impervious footwear.<br><br>When using the prepared spray (or dip *for preplant and post harvest dipping*) wear elbow-length chemical resistant gloves.<br><br>If applying by hand by *vehicle mounted low pressure equipment* wear cotton overalls buttoned to the neck and wrist, elbow-length chemical resistant gloves and a half face-piece respirator with organic vapour/gas cartridge or canister<br><br>If clothing becomes contaminated with product remove clothing immediately. If product on skin, immediately wash area with soap and water. If product in eyes, wash it out immediately with water. Wash hands after use. After each day's use wash gloves, face-shield, respirator and contaminated clothing. |

***Important Note: there are daily restrictions on the amount of product that can be applied by hand (see section 5.2.4). Labels will require amending to reflect these reduced application rates***

| **HG AE 0.3 g/kg** | |
|---|---|
| 160 162 163 164 210 211 220 223 340 343 340 342 351 | May irritate eyes, nose, throat and skin. Avoid contact with eyes and skin. Do not inhale spray mist. If product in eyes wash it out immediately with water. If product on skin, immediately wash area with soap and water. Wash hands after use. |

## Precautionary statements

The following precautionary statement should appear on all registered product labels that include airblast spray application:

"Do not apply with airblast spray equipment unless operators are protected by engineering controls such as enclosed cabs fitted with appropriate air filters."

Hand application of dimethoate products is only supported at low or intermediate application rates as specified on the label.

OCS recommends that upper label application rates are amended as follows:

Vehicle-mounted *high pressure* handwand: max application of 1.6 kg ai/d or 4L product/d (400 mL product /100 L)
Vehicle-mounted *low pressure* handwand: max application of 0.6 kg ai/d or 1.5L product/d (150 mL product /100L)
Knapsack/backpack application: max application of 0.03 kg ai/d or 0.075L product (75 mL product /100 L)

**Re-entry and re-handling statements**

*HG AE product*

Based on a re-entry risk assessment, it is considered appropriate to include a label precaution against hand harvesting for 7 days after application. The following re-entry statement should appear on the label of dimethoate products for use in the home garden:

"Do not pick fruit or vegetables for 7 days after spraying[1]".

*EC products – acute toxicity*

The following re-entry statement is recommended on the basis of low to moderate acute inhalation toxicity:

"For glasshouses and other confined areas, do not re-enter until spray deposits have dried and areas has been thoroughly ventilated."

*EC products – repeat exposure*

Some hand-harvested crops have withholding periods that are shorter than the re-entry interval. This means that hand harvesters of dimethoate-treated food crops including apples, pears and citrus crops will be required to wear personal protective equipment including cotton overalls buttoned to the neck and wrist (or equivalent clothing) and gloves, in order to achieve suitable margins of exposure.

The following re-entry statements are recommended:

<u>Corn, sunflowers, sorghum</u>

"Do not allow entry into treated areas for irrigation, scouting, weeding mature/full foliage plants until the spray has dried. Do not allow entry into treated areas for 9 days for sweetcorn

[1] This statement is currently not available as ALL uses of this product on fruits or vegetables were suspended in October 2011

hand harvesting or detasseling. If prior entry is required, wear cotton overalls buttoned to the neck and wrist (or equivalent clothing) and gloves. Clothing must be laundered after each day's use."

Deciduous trees

"Do not allow entry into treated areas for 9 days for harvesting, pruning or training, and for 16 days for thinning. If prior entry is required, wear cotton overalls buttoned to the neck and wrist (or equivalent clothing) and gloves. Clothing must be laundered after each day's use."

Evergreen trees

"Do not allow entry into treated areas for 4 days for irrigation, scouting, or hand weeding, and for 12 days for pruning or tying. Do not allow entry into treated areas for 19 days for hand harvesting or thinning. If prior entry is required, wear cotton overalls buttoned to the neck and wrist (or equivalent clothing) and gloves. Clothing must be laundered after each day's use."

Vine/trellis (pole beans, blackberries, highbush blueberries, grapes, kiwi, raspberries)

"Do not allow entry into treated areas for scouting, hand harvesting, leaf pulling, thinning, pruning, or training/tying until the spray has dried. Do not allow entry into treated areas for 5 days for grape girdling or cane turning. If prior entry is required, wear cotton overalls buttoned to the neck and wrist (or equivalent clothing) and gloves. Clothing must be laundered after each day's use."

For all other crops

"Do not enter treated areas until the spray has dried, unless wearing cotton overalls buttoned to the neck and wrist (or equivalent clothing) and chemical resistant gloves. Clothing must be laundered after each day's use."

The following rehandling statement is recommended:

For post-harvest dipping of fruit and vegetables, and for pre-plant dipping of plants

"Do not handle treated fruit, vegetable or plant until the product solution has dried. If prior handling is required, wear elbow-length chemical resistant gloves."

# ACRONYMS AND ABBREVIATIONS

**Chemistry and haematology terminology**

| | |
|---|---|
| **CAS number** | Chemical Abstract Service number. This identifies a compound |
| **ChE** | Cholinesterase |
| **GC** | Gas chromatography |
| **HPLC** | High pressure liquid chromatography |
| **RBC** | Red blood cell |

**General terminology**

| | |
|---|---|
| **ADI** | Acceptable daily intake |
| **AE** | Aerosol |
| **ai** | Active Ingredient |
| **APPL** | Application |
| **ARfD** | Acute Reference dose |
| **ChE** | Cholinesterase |
| **CRP** | Chemical review program |
| **DASA** | Days after second application |
| **DFR** | Dislodgeable foliar residue |
| **EC** | Emulsifiable concentrate |
| **GD** | Gestational day – a measure of the stage of a pregnancy |
| **GI** | Gastrointestinal |
| **GLP** | Good laboratory practice |
| **HG** | Home garden |
| **$LD_{50}$** | Lethal Dose 50 – Median Lethal Dose |
| **LOD** | Limit of detection |
| **LOEL** | Lowest observed effect level |
| **LOQ** | Limit of quantification |
| **MOE** | Margin of exposure |
| **MRL** | Maximum residue limit |
| **NOEL** | No observed effect level |
| **OHS** | Occupational health and safety |
| **O,O,S-TMP** | O,O,S-trimethyl phosphorodithioate |
| **OP** | Organophosphorus pesticide |
| **PHED** | Pesticide handlers' exposure database |
| **POEM** | Predictive operator exposure model |
| **PPE** | Personal protective Equipment |
| **PVC** | Polyvinyl chloride |
| **QA** | Quality Assurance |
| **R** | Correlation coefficient |
| **$R^2$** | Regression coefficient |
| **REI** | Re-entry interval |
| **S** | Poisons schedule |
| **SCBA** | Self Contained Breathing Apparatus |
| **SD** | Safety directions |
| **SD** | Standard Deviation |

| | |
|---|---|
| **TC** | Transfer Coefficient |
| **TGAC** | Technical Grade Active Constituent |
| **UCL** | Upper Confidence Limit |
| **UV** | Ultraviolet |
| **WHP** | Withholding period |
| **WP** | Wettable Powder |

**Organisations & publications**

| | |
|---|---|
| **ACCS** | Advisory Committee on Chemicals Scheduling |
| **APVMA** | Australian Pesticides and Veterinary Medicines Authority |
| **DPSSC** | Drugs and Poisons Schedule Standing Committee |
| **EU** | European Union |
| **FAO** | Food and Agriculture Organization of the UN |
| **FAISD** | First Aid Instructions & Safety Directions |
| **FSANZ** | Food Standards Australia New Zealand |
| **JMPR** | Joint Meeting on Pesticide Residues |
| **NDPSC** | National Drugs and Poisons Scheduling Committee Now known as Advisory Committee on Chemicals Scheduling (ACCS) |
| **NOHSC** | National Occupational Health & Safety Commission |
| **OCS** | Office of Chemical Safety, Department of Health and Ageing |
| **NTP** | National Toxicology Program |
| **SUSMP** | Standard for the Uniform Scheduling of Medicines and Poisons |
| **SUSDP** | Standard for the Uniform Scheduling of Drugs and Poisons (Now known as Standard for the Uniform Scheduling of Medicines and Poisons SUSMP) |
| **SWA** | Safe Work Australia |
| **TGA** | Therapeutic Goods Administration |
| **US EPA** | United States Environmental Protection Agency |
| **WHO** | World Health Organization |

# PART 1 RISK ANALYSIS REPORT

# 1 BACKGROUND

## 1.1 History of use of dimethoate

Dimethoate is an organophosphate insecticide. It has both direct and systemic action against a broad range of insect pests in various crops and pastures, and in the home garden. As with other organophosphorus chemicals, the mode of action of dimethoate is through inhibition of cholinesterase (ChE) activity.

Omethoate, an oxygen analogue metabolite of dimethoate, appears to play a dominant role in the toxicity of dimethoate for insects and mammals. Omethoate itself is also used as an active constituent in five products registered in Australia. A human health risk for omethoate is being assessed separately.

Dimethoate was introduced in 1956 and has been used as an insecticide in Australia for more than 30 years. At the commencement of this review, dimethoate was the active constituent in 21 registered products in Australia. The approvals of the active constituents and the registrations of products are being reconsidered based on concerns related to toxicology, occupational and health and safety, residues and trade.

## 1.2 Reason for the review of dimethoate

The current review of dimethoate was undertaken under the auspices of the APVMA's Chemical Review Program. Dimethoate was classified as an active constituent of high priority by the Department of Health and Ageing because of concerns over potentially unacceptable dietary exposure risks resulting from post harvest dipping of fruit and vegetables. In addition, assessments performed by the JMPR in 1997 and 2002, and the US EPA in 1999, indicated that there were a number of studies that may impact on the human health risk assessment that had not previously been evaluated by the OCS.

The toxicological database for dimethoate is extensive and consists of unpublished reports generated by industry, as well as numerous studies in the published literature. Since the toxicological database for dimethoate was last reviewed in 1988, new information considering a range of toxicological endpoints have become available. In particular, there are now behavioural studies that quantify the extent of functional (task performing) impairment in rats following exposure to dimethoate, as well as reproductive and dermal toxicity studies.

# 2 HAZARD CHARACTERISATION

A comprehensive discussion of the toxicity of dimethoate is included in the toxicology component of this review (OCS , 2010a).

## 2.1 Standards relevant to human health risk assessment

### 2.1.1 Selection of a NOEL for occupational risk assessment

Workers may be exposed to dimethoate through dermal contact with the undiluted product, the spray mixture or treated vegetation. In addition, exposure may occur via inhalation of spray mist. Therefore, a dermal NOEL and an inhalation NOEL are the ideal basis for the worker risk assessment of dimethoate. However, repeat dose dermal and inhalation studies with dimethoate are not available, and oral studies have been used instead.

The most sensitive toxicological endpoint for dimethoate in adult laboratory animals following repeated dosing was the inhibition of plasma and RBC ChE activity and this endpoint is the most appropriate toxicological endpoint for OHS risk assessment purposes. In reproductive and developmental studies in rats, there was an increase in postnatal deaths in pups treated both indirectly *in utero* and via lactation and treated directly following weaning. These effects were concurrent with decreased RBC ChE activity, but were seen at higher doses ($\geq$0.5 mg/kg bw/d) than decreased whole blood ChE activity in the human study (Table 1). The human NOEL (0.2 mg/kg bw/d) is therefore considered likely to be protective of effects (seen in pups) in the developmental study. Taken into consideration with the uncertainties associated with interspecies extrapolation, the human study is considered by OCS to be more applicable to occupational risk assessment.

Regarding duration of exposure, the inhibition of plasma ChE activity does not change significantly over short to medium term dosing. Therefore, repeat dose studies ranging from weeks to months are appropriate for establishing NOELs for OHS risk assessment purposes, as this is consistent with the expected exposure pattern. Table 1 summarises the NOELs/LOELs in laboratory animal and human studies deemed suitable for OHS risk assessment purposes.

**Table 1: Summary of oral NOELs relevant for OH&S assessment**

| Species | Study Type | NOEL (mg/kg bw/d) | LOEL (mg/kg bw/d) | Effect | Reference |
|---|---|---|---|---|---|
| **Short term studies** | | | | | |
| Rat | 4 w dietary | 0.83/0.85 M/F | 2.48/2.60 M/F | Erythrocyte/brain ChE | Kaspers *et al.*, (2004) [GLP, QA] |
| Dog | 4 w dietary | 0.43 | 2.20 | Erythrocyte/brain ChE | Harling *et al.*, (1989) [GLP, QA] |
| **Subchronic studies** | | | | | |
| Rat | 13 w dietary | 0.06/0.08 M/F | 3.2/3.8 M/F | Erythrocyte ChE | Lamb (1994) [GLP, QA] |
| **Human studies** | | | | | |
| Human | Repeat dose | 0.2 (39-day dosing) | 0.42 | Whole blood ChE | Edson *et al.*, |

| | | | | | |
|---|---|---|---|---|---|
| | (14-57 days) | | | | (1967) |

***NOEL for assessing risk from repeated dermal exposure***

Occupational use of products containing dimethoate is expected to result in some systemic uptake following dermal exposure. Dermal repeat-dose studies form the optimal basis for setting a NOEL for risk assessment purposes, however, dermal repeat-dose studies were not available in either humans or animals. A human oral study is available in which volunteers did not show any effect when treated five days/week with dimethoate at up to 0.2 mg/kg bw/day for 39-days (Edson *et al*., 1967). In this human study, dosing was carried out only 5 days per week followed by a recovery period of 2 days, and a steady state of the drug level in the plasma might not be maintained. However, this pattern of administration is similar to that of worker exposure, i.e. 6-8 hour/day, 5 days/week. Therefore, the NOEL of 0.2 mg/kg bw/day in this repeat dose oral study in humans is selected for the occupational risk assessment.

Route-to-route extrapolations usually involve a consideration of the internal dose. In the case of oral-to-dermal extrapolation, this consideration takes account of the extent of absorption across the GI tract following oral administration. Absorption of dimethoate across the GI tract was estimated to be 89-95% of the administered dose, taking its biliary excretion into account. Therefore, no correction to the NOEL used for OHS risk assessment was required.

***NOEL for assessing risk from repeated inhalation exposure***

Inhalational exposure to dimethoate in an agricultural setting would mostly arise from inhalation of spray mist. The pattern and frequency of exposure would similar to dermal exposure. Repeat dose inhalation studies with dimethoate are not available, and therefore, it is necessary to perform the assessment using studies carried out by oral administration. The most suitable study for estimation of occupational risks via the inhalation route is that of a 14-57-day oral study in humans (Edson *et al*., 1967) in which the NOEL was 0.2 mg/kg bw/day. This value was therefore used for risk assessment of professional users by inhalation during mixing/loading and application.

***NOEL for re-entry period calculation***

As re-entry exposure is expected to be of short durations and intermittent, the NOEL of 0.2 mg/kg bw/day derived from the 14-57-day oral study in humans (Edson *et al*., 1967) was used for the re-entry risk assessment.

### 2.4.3 Absorption factors relevant to occupational risk assessment

***Dermal absorption factor***

An *in vitro* study comparing absorption of dimethoate (from a 400 g/L EC formulation or 1/200 aqueous dilution thereof) through human and rat epidermal membranes, showed that absorption was considerably faster through rat epidermis than through human epidermis for all applications of the concentrate and dilution (Davies DJ, 1999). Small amounts (0.60% of the concentrate dose and 5.1% of the diluted dose) were absorbed through human epidermis while larger amounts (9% and 76%, respectively) were absorbed at a higher rate by rat skin. That is, only 5.1% of the applied diluted dose was absorbed by human epidermis compared to

76% by rat epidermis. Based on the results from this study, a dermal absorption factor of 5.1% was selected for the risk assessment.

***Inhalation absorption factor***

No chemical specific studies are available on the inhalation absorption of dimethoate. In the absence of information on inhalation absorption, a default value of 100% absorption through the inhalation route is used in the risk assessment.

## 2.2 Acute toxicity of products

The toxicological characteristics of products containing dimethoate (Table 2) have been extrapolated on the basis of all ingredients in the products. Further details on this extrapolation, including details of the excipients in the formulations, are shown in Appendix VIII.

*EC products containing dimethoate at a concentration of 400 g/L*

Dimethoate 400 g/L EC products are expected to be of moderate acute oral toxicity, and low to moderate dermal and inhalational toxicity. Dimethoate 400 g/L EC products are expected to be moderate to severe skin and eye irritants, and possible skin sensitizers. The skin and eye irritation potential of the products is due primarily to the presence of cyclohexanone in the formulation.

*EC products containing dimethoate at a concentration of 300 g/L and 100 g/L.*

Dimethoate EC formulations containing 100-300 g/L dimethoate are expected to be of moderate acute oral toxicity, and low to moderate dermal and inhalational toxicity, and be moderate to severe skin and eye irritants, and possible skin sensitizers. The skin and eye irritation potential of the products is due primarily to the presence of cyclohexanone in the formulation.

*AE products containing dimethoate at a concentration of 0.3 g/kg*

It is expected that the aerosol product Garden King Rogor garden insect spray is likely to be of low oral, dermal and inhalational toxicity, a moderate irritant to the skin and eye, and is unlikely to cause skin sensitization. The irritation potential is driven primarily by the excipients in the aerosol formulation.

**Table 2. Summary of acute toxicity of dimethoate products***

| Toxicity end point | 400 g/L EC products | 100 and 300 g/L EC products | 0.3 g/kg AE product |
|---|---|---|---|
| Oral | Moderate toxicity | Moderate toxicity | Low toxicity |
| Dermal | Moderate toxicity | Moderate toxicity | Low toxicity |
| Inhalational | Moderate toxicity | Moderate toxicity | Low toxicity |
| Skin irritation | Moderate to severe irritant | Moderate to severe irritant | Moderate irritant |
| Eye irritation | Moderate to severe irritant | Moderate to severe irritant | Moderate irritant |
| Skin sensitisation | Possible sensitiser | Possible sensitiser | Possible sensitiser |

* based on the toxicological profile of all ingredients in the product – see Appendix VIII

# 3 PRODUCTS AND THEIR USE

Dimethoate is a broad use systemic organophosphate insecticide/acaricide. In Australia, products containing dimethoate are registered for a broad range of agricultural and home garden situations. Products are registered for more than 200 use patterns and to control more than 80 insect pest species. In agriculture, dimethoate is used both as a pre-harvest and post-harvest insecticide in orchard and fruit crops. It is applied by ground boom, airblast, backpack sprayer and as a fruit dip. In the home garden dimethoate products are normally applied by hand spray used to control many common insect pests on a wide range of vegetables, flowers and fruit crops, as well as on ornamentals.

## 3.1 Registered products and pack sizes

As of March 2011, there were 22 dimethoate products registered in Australia according to the APVMA PUBCRIS database. Ten of these products were registered after the current review on dimethoate products was commenced (seven 400 g/L, one 300 g/L and two 100 g/L products) and, therefore, are not included in this review report (although all registered products are subject to the regulatory outcome of the Review). The 21 registered dimethoate products at the start of this review report are listed in Table 3.

**Table 3. Dimethoate products registered at the start of this review**

| APVMA Product Code | Product Name | Product Registrant | Product Description | Content & formulation type |
|---|---|---|---|---|
| 32953 HG | Chemspray Rogor Insecticide | Envirogreen Pty Ltd | For control of fruit fly, aphids, thrips, leaf miners, bean fly & other pests on fruit trees, vegetables, potatoes & ornamentals. | 300 g/L EC |
| 32962 | Nufarm Dimethoate Systemic Insecticide | Nufarm Australia Limited | For control of a wide range of pests on fruit, vegetables, pastures, cotton, lucerne, peanuts & ornamentals. | 400 g/L EC |
| 32963 HG | Garden King Rogor 100 Systemic Insecticide | Envirogreen Pty Ltd | Controls aphids, fruit fly, jassids, two-spotted mite & thrips in the home garden. | 100 g/L EC |
| 39239 | Farmoz Dimethoate 400 Systemic Insecticide | Farmoz Pty Limited | For the control of certain insects (including aphids, thrips, jassids, lucerne flea, red-legged earthmite, Queensland fruit fly, leaf hoppers & wingless grasshopper) in field crops, fruit crops, oilseed & fibre crops, vegetables, ornamentals, forest trees. To use as a post harvest fruit dip & as seed dressing for lupins, peas, sub-clover, lucerne, linseed & canola. | 400 g/L EC |
| 41070 HG | CRG Systex Insecticide | Chemical Recovery Co Pty Ltd | For the control of aphids, thrips & other suckling insects in ornamentals, beans & vegetables. | 300 g/L EC |
| 48956 HG | Richgro Garden Products Rogor Insecticide | A Richards Pty Ltd T/A Richgro Garden Products | For the control of fruit fly, aphids, thrips, leaf miners, bean fly & other insects on fruit trees, vegetables, potatoes & ornamentals. | 100 g/L EC |

| APVMA Product Code | Product Name | Product Registrant | Product Description | Content & formulation type |
|---|---|---|---|---|
| 49167 | Summit Dimethoate Systemic Insecticide | Summit Agro Australia Pty Ltd | Controls pests including Queensland fruit fly, redlegged earthmite, thrips, jassids, lucerne flea, leaf hoppers wingless grasshoppers. | 400 g/L EC |
| 49600 | Saboteur Systemic Insecticide | Crop Care Australasia Pty Ltd | For control of insect pests on fruit, vegetables, citrus, pastures, cotton, lucerne, peanuts & ornamentals. | 400 g/L EC |
| 51545 | Chemag Dimethoate Insecticide | Chemag Pty Ltd | For control of pests on bananas, berry fruits, cereals, citrus, cotton, grapes legume crops, lucerne & medic pastures, peanuts, pome & stone fruits, oil seeds, ornamentals, tropical fruit & vegetables. Product can be used as a seed treatment for certain crops & as post harvest dip for quarantine purposes. | 400 g/L EC |
| 51658 | Sipcam Rogor Systemic Insecticide | Sipcam Pacific Australia Ltd | For control of pests on fruits & vegetable crops, pastures, cotton, lucerne, oil seed crops & ornamentals. | 400 g/L EC |
| 52673 HG | Garden King Rogor Garden Insect Spray | Envirogreen Pty Ltd | Controls aphids, thrips, mealy bug, azalea lace bug, fruit fly & other insect pests on fruit trees, vegetables & ornamental plants in the home garden. | 0.3 g/kg AE |
| 53045 | Agcare Biotech Dimethoate 400 EC Systemic Insecticide | Agcare Biotech Pty Ltd | For the control of a wide range of pests on fruit, vegetables, pastures, cotton, lucerne, peanuts & ornamentals. | 400 g/L EC |
| 55272 HG | Superway Dimethoate 300 Systemic Insecticide | Superway Garden Products Pty Ltd | For the control of fruit fly, aphids, thrips, leaf miners, bean fly and other pests on fruit trees, vegetables, potatoes and ornamentals in the home garden. | 300 g/L EC |
| 55441 | 4 Farmers Dimethoate 400 Systemic Insecticide | 4 Farmers Pty Ltd | For control of pests on fruit, vegetables, citrus, pastures, cotton, lucerne, peanuts & ornamentals. | 400 g/L EC |
| 55495 | Superway Dimethoate 400 Systemic Insecticide | Superway Garden Products Pty Ltd | For control of insect pests on fruits, vegetables, pastures, cotton, lucerne, oil seed crops, peanuts & ornamentals. | 400 g/L EC |
| 55704 | Conquest Dimethoate 400 Systemic Insecticide | Conquest Agrochemicals Pty Ltd | For the control of pests on some fruit, vegetables, citrus, pastures, cotton, lucerne, peanuts & ornamentals. | 400 g/L EC |
| 56454 | Danadim Insecticide | Cheminova Australia Pty Limited | For the control of a wide range of insect pests on fruit trees, vegetables, citrus, pastures, cotton, lucerne, peanuts & ornamentals. | 400 g/L EC |
| 56887 | United Farmers Unidime 400 Insecticide | United Farmers cooperative Company Ltd | For control of pests on some fruit, vegetables, citrus, pastures, cotton, lucerne, peanuts & ornamentals. | 400 g/L EC |
| 57860 | Halley Dimethoate 400 Systemic Insecticide | Halley International Enterprise (Australia) Pty Ltd | For control of insect pests on fruits & vegetable crops, pastures, cotton, lucerne, oil seed crops, peanuts & ornamentals. | 400 g/L EC |

Of the 21 products registered prior to the review, 6 were registered as home garden (HG) products. Of the six home garden products, five were emulsifiable concentrate (EC) products containing 100-300 g/L dimethoate and the other was an aerosol (AE) product containing 0.3 g/kg dimethoate. The other 15 (all 400 g/L EC formulations) were intended for use by farmers and/or contract workers in the agricultural sector, although some of these were available in pack sizes equal to or less than 1L which could potentially be made available for home garden use. The pack sizes for each of the products considered in the current review report are shown in Table 4.

**Table 4. Pack sizes of dimethoate products**

| | | |
|---|---|---|
| **HG AE products containing dimethoate at a concentration of 0.3 g/kg** | | |
| APVMA No.52673 | Garden King Rogor Garden Insect Spray | 300 g |
| **EC products containing dimethoate at a concentration of 100 g/L** | | |
| APVMA No.32963 | Garden King Rogor 100 Systemic Insecticide | 200 mL |
| APVMA No.48956 | Richgro Garden Products Rogor Insecticide | 250 mL |
| **EC products containing dimethoate at a concentration of 300 g/L** | | |
| APVMA No. 32953 | Chemspray Rogor Insecticide | 100 mL, 500 mL |
| APVMA No. 41070 | CRG Systex Insecticide | 100 mL, 200 mL, 500 mL |
| APVMA No.55272 | Superway Dimethoate 300 Systemic Insecticide | 125 mL, 250 mL, 500 mL, 1 L |
| **EC products containing dimethoate at a concentration of 400 g/L** | | |
| APVMA No. 32962 | Nufarm Dimethoate Systemic Insecticide | 500 mL, 5 L, 20 L |
| APVMA No. 39239 | Farmoz Dimethoate 400 Systemic Insecticide | 5 L, 20 L, 200 L |
| APVMA No. 49167 | Summit Dimethoate Systemic Insecticide | 5 L, 20 L, 200 L |
| APVMA No. 49600 | Saboteur Systemic Insecticide | 20 L, 200 L |
| APVMA No. 51545 | Chemag Dimethoate Insecticide | 10, 20, 200, 500, 1000 L |
| APVMA No. 51658 | Sipcam Rogor Systemic Insecticide | 500 mL, 5L, 20 L |
| APVMA No. 53045 | Agcare Biotech Dimethoate 400 EC Systemic Insecticide | 500 mL, 5L, 20 L |
| APVMA No. 55441 | 4 Farmers Dimethoate 400 Systemic Insecticide | 20 L, 200 L |
| APVMA No. 55495 | Superway Dimethoate 400 Systemic Insecticide | 500 mL, 1 L, 2.5 L, 5 L, 10 L, 20 L |
| APVMA No. 55704 | Conquest Dimethoate 400 Systemic Insecticide | 5 L, 20 L, 200 L |
| APVMA No. 56454 | Danadim Insecticide | 5 L, 20 L, 200 L |
| APVMA No. 56887 | United Farmers Unidime 400 Insecticide | 5 L, 20 L, 200 L |
| APVMA No. 57860 | Halley Dimethoate 400 Systemic Insecticide | 500 mL, 1 L, 2.5 L, 5 L, 10 L, 20 L, 100 L, 200 L |

## 3.2 Use pattern

## 3.3 Existing label restrictions and withholding periods

The withholding periods for different crops, as stipulated on labels of the products considered in the current review report are presented in Table 5.

**Table 5: Withholding periods for different crops at the commencement of this review**

| CROP | WHP (Harvesting) |
|---|---|
| Cereals, maize, sorghum, tobacco | 28 days |
| Adzuki beans, cowpea, navy bean*, mung beans*, pigeon pea, peanuts*, grain legume, cotton , oil seed, sunflower*, fibre crops (mustard, linseed, poppy, canola, safflower), sesame | 14 days |

| | |
|---|---|
| Bananas, beans, soybeans, peas, peanuts*, leafy vegetables (cole crops, silverbeet, lettuce, celery), root vegetables (potatoes, onions, carrots, beetroot, parsnips), litchi, tomatoes, legumes, lentils, fruit trees and vine crops, berry fruits, and sunflower, blueberries*, lupins, capsicum*, mung beans, navy beans | 7 days |
| Capsicum, mangoes | 3 days |
| Blueberries, strawberries, cucurbits and lucerne. | 1 day |
| oil tea tree | 5 Months |
| **WHP for grazing:**<br>1 day for cereals, lucerne, leucaena, maize, sorghum, peas and pastures;<br>7 days for lucerne and pasture if >250 mL/ha product is applied. | |

* Some crops have two different WHPs based on different application rates for different insect pests or due to state regulations, e.g. 7 and 14 days for sunflower, cowpea, mung beans and navy beans; 3 and 7 days for capsicum, 1 and 7 days for blueberries.

The product labels advise workers to apply ~20 m wide spray band around the crop areas to be protected from certain insect pests (eg: wingless grasshopper). All product labels for 400 g ai/L EC formulations, except one (APVMA no: 49167), include the following restraint statement:

**Restraint:** Do not apply to any non-food tree crop or plantation (including Eucalyptus spp.) by air.

One product label (55441: 4 Farmers Dimethoate 400 Systemic Insecticide) recommends the following re-entry statement. No re-entry statements appear on the labels of other registered products.

**Re-entry period:** Do not allow entry into treated areas until the spray deposits have dried. When prior entry is necessary, wear cotton overalls buttoned to the neck and wrist and elbow-length PVC gloves. Clothing must be laundered after each day's use. For glasshouses and other confined areas, do not re-enter until spray deposits have dried and areas has been thoroughly ventilated.

# 4 EXPOSURE ESTIMATION

## 4.1 Public exposure

The majority of dimethoate products considered in the current review report are intended for use in the agricultural sector, however some products are intended for use in the home garden. In addition there could be exposure to the public from residues of dimethoate on food, and bystander exposure following application in agricultural situations.

### 4.1.1 Residues in food

Assessment of the exposure of the Australian population to residues of agricultural and veterinary chemicals in food crops and target animals is performed by the APVMA, with the support of, and using the procedures and databases provided by Food Standards Australia New Zealand (FSANZ).

### 4.1.2 Home garden products

Dimethoate products are also available for use in the home garden, for the control of insect pests on fruit trees, vegetables, potatoes and ornamental plants. The home garden products considered in the current review report instruct the user to apply the insecticide once per season, or at 10-14 day intervals. An assessment of the exposure and risks arising from the use of home garden products has been conducted in Section 6.

## 4.2 Occupational exposure

### 4.2.1 Exposure during production/reformulation

Formulators, laboratory staff and packers handle the active constituent and/or the products and can be exposed to dimethoate during the process of formulation and packaging. Individual premises, manufacturing/formulation processes and exposure control measures may vary within workplaces. However, they are expected to follow good manufacturing practices and have adequate quality control and monitoring facilities as required by the Commonwealth / State / Territory occupational health and safety legislations. Transport workers, storemen retailers and warehouse workers may also be exposed to the products if packaging is breached and spillage occurs.

### 4.2.2 Exposure during application – worker studies

Use of dimethoate products by farmers/contract sprayers may vary greatly depending on the insect pest species and the crop type to be treated. Workers may become contaminated with the product/spray when opening the containers, mixing/loading, applying spray, cleaning up spills, and maintaining equipment. The most likely potential routes of exposure to the product/spray would be dermal and inhalation. Ocular exposure to the spray mist may also occur during air-assisted or hand spraying.

Studies measuring exposure of workers to dimethoate during product application have been described in Section 11.3 of the toxicology part of this review (OCS, 2010a). The study in enclosed areas (plastic houses) was not relevant to Australian use pattern, and the second was of inadequate quality and design. These studies were therefore not used in the risk assessment. Instead, exposure study data from the Pesticides Handler Exposure Database (PHED) were used to estimate exposure.

### 4.2.3 Exposure during application – models and assumptions

Dimethoate products considered in the current review report are applied in field crops, vegetables, strawberries, lucerne and pastures using ground boom equipment. Air-assisted spray is used in tree crops and vines. Hand application is used in ornamentals and smaller areas of other crops, for example citrus. Aerial application is indicated on product labels for cereals, oilseed crops, lucerne and pasture. The labels indicate misting machine use in tomatoes.

Very limited chemical specific exposure data are available for dimethoate. In the absence of adequate worker exposure data, the OCS used the PHED Surrogate Exposure Database and Guide (1998) to estimate worker exposure.

Considering the vast variety of crops included on product labels and the possibility of using various application methods, the OCS grouped the crops according to the possible application methods (Table 7). The highest application rate recommended on each product label for each application method was used in the exposure assessment to estimate worker exposure to dimethoate.

The PHED Surrogate Exposure Guide (1998) does not take into consideration the container size or spray volume. Exposure to the chemical is estimated based on the amount of chemical handled per day. This parameter varies with the application equipment used. In the absence of specific work rate information for dimethoate products, the OCS used the following default work rates based on previously available information:

Exposure to a worker was estimated in an 8 h working day that included a 6 h application period. The number of hectares treated per day varies with the application method. The following assumptions are made with regard to the number of hectares treated by each application method:

For ground boom application = 50 ha/day

For air-assisted application = 30 ha/day

For vehicle-mounted handwand application = 1000 L/day

For knapsack/backpack application = 100 L/day

For aerial application = 1200 ha/day

The following assumptions have been applied (Table 6).

**Table 6: List of assumptions used in exposure and risk assessment**

| | | |
|---|---|---|
| Bodyweight | 70 kg | US EPA (1997) |
| Body surface area (adult) | 1.94 $m^2$ | Derelanko (2000) |
| Ventilation rate (light activities) | 1.0 $m^3$/h | US EPA (1997) |
| Normal workday | 8 h with an application period of 6 h | |
| Penetration through overalls | 10% | Stamper *et al*. (1989) |
| Penetration through chemical-resistant full body clothing | 5% | Thongsinthusak *et al*. (1993) |
| Penetration through chemical-resistant gloves | 10% | Thongsinthusak *et al*. (1993) |
| Protection afforded by half face-piece respirator with gas/dust cartridges | 90% | Thongsinthusak *et al*. (1993) |
| Protection afforded by full face-piece respirator with gas/dust cartridges | 98% | Thongsinthusak *et al*. (1993) |
| Protection afforded by supplied air respirator (air-hose respirator or SCBA) | 100% | |

The following scenarios from the PHED Surrogate Exposure Guide were used to estimate worker exposure based on each application method.

***PHED scenarios used to estimate exposure***

*Ground boom application*

The following PHED scenarios were used:

*PHED surrogate scenario 3*: All liquids, open mixing and loading (MLOD)
[High confidence data for dermal exposure (AB grade): 53 hand replicates without gloves; and 59 hand replicates with gloves; High confidence data for inhalation exposure without any protective equipment (AB grade): 85 replicates]

*PHED surrogate scenario 13*: Ground boom, open cab application (APPL)
[High confidence data for dermal exposure without gloves (AB grade): 29 hand replicates, medium confidence data for dermal exposure with gloves (ABC grade): 21 hand replicates; High confidence data for inhalation exposure without any protective equipment (AB grade): 22 replicates].

*PHED surrogate scenario 14*: Ground boom, closed cab application (APPL)
[Medium confidence data for dermal exposure without gloves (AB grade): 16 hand replicates, low confidence data for dermal exposure with gloves (ABC grade): 12 hand replicates; High confidence data for inhalation exposure without any protective equipment (AB grade): 16 replicates].

As the amount of chemical handled per day is used in PHED scenarios to estimate worker exposure, dimethoate products were grouped according to the calculated maximum use rates per day (Table 7):

**Table 7: Highest application rates used in ground boom application**

| Product* | Crop | Product dilution rate and/or application rate | Product % (dimethoate %) in spray** | Maximum product (dimethoate) use per day |
|---|---|---|---|---|
| **49833: Rotam Romethoate Systemic Insecticide;**<br>**51545: Chemag Dimethoate Insecticide;**<br>**55441: 4 Farmers Dimethoate 400 Systemic Insecticide** | Tomatoes | 75 mL/100 L or 850 mL/ha | 0.075% (0.03% ai) or 0.07% (0.03% ai) | 45 L (18 kg ai)[#] |
| **32962: Nufarm Dimethoate Systemic Insecticide;**<br>**39239: Farmoz Dimethoate 400 Systemic Insecticide** | Field crops | 800 mL/ha | 0.07% (0.03% ai) | 40 L (16 kg ai)[##] |
| **49600: Saboteur Systemic Insecticide;**<br>**50342: Dimethomax Systemic Insecticide;**<br>**51658: Sipcam Rogor Systemic Insecticide** | Vegetables, beans, peas and berry fruits<br>Legume crops, vegetables, sunflower | 75 mL/100 L or 800 mL/ha | 0.075% (0.03% ai) or 0.07% (0.03% ai) | 45 L (18 kg ai) [#] |
| **53045: Agcare Biotech Dimethoate 400 EC Systemic Insecticide;**<br>**55495: Superway Dimethoate 400 Systemic Insecticide;**<br>**55704: Conquest Dimethoate 400 Systemic Insecticide;**<br>**56454: Danadim Insecticide;**<br>**56887: United Farmers Unidime 400 Insecticide;**<br>**57860: Halley Dimethoate 400 Systemic Insecticide** | Grain legumes, vegetables, sunflower | 75/85 mL/100 L or up to 800 mL/ha | 0.075/0.085% (0.03/0.034% ai) or 0.07% (0.03% ai) | 51 L (20.4 kg ai)[#] |
| **49167: Summit Dimethoate Systemic Insecticide** | Vegetables, berry fruits, lucerne and pastures | 750 mL/ha | 0.06% (0.03% ai) | 37.5 L (15 kg ai) [##] |

* Containing 400 g/L dimethoate unless indicated differently.

** To estimate the spray strength/dilution, if spray volumes or mixing rates are not indicated on the product label for the particular crop (with recommended highest application rate), the OCS used 1200 L/ha as the default application rates for vegetables, based on information from the APVMA.

[#] Based on dilution rate (e.g. 75 mL / 100 L), default application rate (1200 L/ha) and work rate (50 ha/d) for ground boom application (e.g. 75/100 * 1200 * 50 / 1000 = 45 L /day)

[##] Based on the application rate (e.g. 800 mL/ha) and the default work rate of 50 ha/d for ground boom application (e.g. 800 * 50 / 1000 = 40 L / day)

The amount of dimethoate (ai) used per day by groundboom spraying is 15-20.4 kg. The maximum rate (20.4 kg/d) allowable in the label is used as the worst case scenario for the risk assessment.

*Air-assisted (airblast) application*

The following PHED scenarios were used:

*PHED surrogate scenario 3*: All liquids, open mixing and loading (MLOD)
[High confidence data for dermal exposure (AB grade): 53 hand replicates without gloves and 59 hand replicates with gloves; High confidence data for inhalation exposure without any protective equipment (AB grade): 85 replicates]

*PHED surrogate scenario 11*: Airblast application, open cab (APPL)
[High confidence data for dermal exposure (AB grade): 22 hand replicates without gloves; High confidence data for dermal exposure (AB grade): 18 hand replicates with gloves (AB grade); High confidence data for inhalation exposure without any protective equipment (AB grade): 47 replicates]

*PHED surrogate scenario 12*: Airblast application, closed cab (APPL)
[Low confidence data for dermal exposure (AB grade): 0 hand replicates without gloves; High confidence data for dermal exposure (AB grade): 20 hand replicates with gloves (AB grade); Low confidence data for inhalation exposure without any protective equipment (ABC grade): 9 replicates]

As the amount of chemical handled per day is used in PHED scenarios to estimate worker exposure, dimethoate products were grouped according to the calculated maximum use rates per day (Table 8):

**Table 8: Highest application/mixing rates indicated for airblast/air-assisted application**

| **Product*** | **Crop** | **Product application rate** | **Product & active % in spray**** | **Maximum amount of product (dimethoate)/d***** |
|---|---|---|---|---|
| **32962: Nufarm Dimethoate Systemic Insecticide; 51658: Sipcam Rogor Systemic Insecticide; 53045: Agcare Biotech Dimethoate 400 EC Systemic Insecticide[§§]; 55441: 4 Farmers Dimethoate 400 Systemic Insecticide[§]; 55495: Superway Dimethoate 400 Systemic Insecticide; 55704: Conquest Dimethoate 400 Systemic Insecticide; 56454: Danadim Insecticide; 56887: United Farmers Unidime 400 Insecticide; 57860: Halley Dimethoate 400 Systemic Insecticide** | Trees (eucalyptus, kurrajong, flame and umbrella) | 25 mL/8 L | 0.3125% (0.125% ai) | 140.6 L (56.25 kg ai) |
| | Citrus<br>pome fruit | 75 – 150 mL/100 L | 0.075 - 0.15% (0.03 – 0.06 % ai) | 225 L (90 kg ai) |
| | Fruit trees including stone fruit, pawpaw, passionfruit and grapes;<br>Bananas (minimum spray volume 1000 L/ha);<br>Wild flowers, proteas and duboisia | 75 mL/100 L | 0.075% (0.03% ai) | 56.25 L (22.5 kg ai) |

**Table 8 (continued)**

| Product* | Crop | Product application rate | Product & active % in spray** | Maximum amount of product (dimethoate)/d*** |
|---|---|---|---|---|
| **39239: Farmoz Dimethoate 400 Systemic Insecticide** | Citrus | 75 – 150 mL/100 L | 0.075 - 0.15% (0.03 – 0.06 % ai) | 225 L (90 kg ai) |
| | Fruit trees including stone and pome fruit, pawpaw, passionfruit and grapes; Bananas (minimum spray volume 1000 L/ha) | 75 mL/100 L | 0.075% (0.03% ai) | 56.25 L (22.5 kg ai) |
| | Wild flowers, proteas and duboisia, ornamental shrubs | 75 – 100 mL/100 L or 750 mL/ha | 0.075 – 0.1 % (0.03 – 0.04% ai) | 22.5 L (9 kg ai) |
| | Ornamental farm and forest trees | 75-400 mL / 100 L | 0.075 – 0.4 % (0.03 – 0.16% ai) | 300 L (120 kg ai) |
| **49167: Summit Dimethoate Systemic Insecticide** | Citrus Pome fruit | 75 – 150 mL/100 L | 0.075 - 0.15% (0.03 – 0.06 % ai) | 225 L (90 kg ai) |
| | Fruit trees including stone fruit, litchi, pawpaw, passionfruit and grapes; Bananas (minimum spray volume 1000 L/ha); Wild flowers, proteas and duboisia | 75 mL/100 L | 0.075% (0.03% ai) | 56.25 L (22.5 kg ai) |
| **49600: Saboteur Systemic Insecticide; 49833: Rotam Romethoate Systemic Insecticide** | Trees (eucalyptus, kurrajong, flame and umbrella) | 25 mL/8 L | 0.3125% (0.125% ai) | 140.6 L (56.25 kg ai) |
| | Apples, pears, quinces | 75 – 150 mL/100 L | 0.075 - 0.15% (0.03 – 0.06 % ai) | 112.5 L (45 kg ai) |
| | Fruit trees, pawpaw, passionfruit and grapes; Bananas (minimum spray volume 1000 L/ha) | 75 mL/100 L | 0.075% (0.03% ai) | 56.25 L (22.5 kg ai) |
| | Stone fruit and citrus | 75 mL/100 L or 750 mL/ha | 0.075 % (0.03% ai) | 22.5 L (9 kg ai) |

**Table 8 (continued)**

| Product* | Crop | Product application rate | Product & active % in spray** | Maximum amount of product (dimethoate)/d*** |
|---|---|---|---|---|
| **50342: Dimethomax Systemic Insecticide; 51545: Chemag Dimethoate Insecticide** | Trees (eucalyptus, kurrajong, flame and umbrella) | 25 mL/8 L | 0.3125% (0.125% ai) | 140.6 L (56.25 kg ai) |
| | Pome and stone fruit and citrus | 75 – 150 mL/100 L | 0.075 - 0.15% (0.03 – 0.06 % ai) | 225 L (90 kg ai) |
| | Fruit trees, pawpaw, passionfruit and grapes; Bananas (minimum spray volume 1000 L/ha) Wild flowers, proteas and duboisia | 75 mL/100 L | 0.075% (0.03% ai) | 56.25 L (22.5 kg ai) |

*Containing 400 g/L dimethoate unless indicated otherwise.
**Calculated based on product concentrations and use patterns.
***Considering a default work rate of 30 ha/d for air-assisted application. Where spray volumes per hectare are not indicated on the product label, the OCS used default spray volumes of 2500 L/ha for stone/pome fruits and 5000 L/ha for citrus based on information from the APVMA, and an average default spray volume of 1500 L per hectare for other crops.
§ This product label indicated the mixing rate for concentrated spraying. All other product labels indicate the same mixing rate for dilute spraying or not specified. If not specified, the OCS considered the mixing rate as for dilute spraying.
§§ This product label advises not to use a concentrate spray rate greater than 5 times the dilute spray rate indicated (75 mL x 5 in 100 L = 375 mL/100 L; 0.375% product and 0.15% active in spray).

The amount of dimethoate used per day by air-assisted spraying is 9.0-135 kg. The maximum rate (135 kg/d) allowable in the label is used as the worst case of scenario for the risk assessment.

*Hand application – vehicle-mounted handwand*

The following PHED scenarios were used:

*PHED surrogate scenario 3*: All liquid, open mixing and loading (MLOD)
[High confidence data for dermal exposure (AB grade): 53 hand replicates without gloves and 59 hand replicates with gloves; High confidence data for inhalation exposure without any protective equipment (AB grade): 85 replicates]

*PHED surrogate scenario 18*: Low pressure handwand application (APPL)
[Low confidence data for dermal exposure (BC grade): 9 hand replicates without gloves; Low confidence data for dermal exposure (BC grade): 4 hand replicates with gloves; Low confidence data for inhalation exposure without any protective equipment (ABC grade): 13 replicates]

*PHED surrogate scenario 19*: High pressure handwand application (APPL)
[Low confidence data for dermal exposure (All grades): 2 hand replicates without gloves; Low confidence data for dermal exposure (All grades): 9 hand replicates with gloves; Low

confidence data for inhalation exposure without any protective equipment (All grades): 11 replicates]

As the amount of chemical handled per day is used in PHED scenarios to estimate worker exposure, dimethoate products were grouped according to the calculated maximum use rates per day (Table 9):

**Table 9: Highest application rates used in handwand application**

| Product* | Crop | Product application rate | Product % (dimethoate %) in spray** | Maximum product (dimethoate) use per day*** |
|---|---|---|---|---|
| **39239: Farmoz Dimethoate 400 Systemic Insecticide** | Ornamental farms | 75 – 400 mL/100 L | 0.075 – 0.4% (0.03 – 0.16% ai) | 4 L (1.6 kg ai) |
| **49167: Summit Dimethoate Systemic Insecticide** | Ornamentals | 75 mL/100 L | 0.075% (0.03% ai) | 0.75 L (0.3 kg ai) |
| **Rest of the products: (Product Nos: 2962, 49600, 49833, 50342, 51545, 51658, 53045, 55441, 55495, 55704, 56454, 56887, 57860)** | Ornamentals (excluding chrysanthemum, begonia, liquid amber and gloxinias) | 75 mL/100 L | 0.075% (0.03% ai) | 0.75 L (0.3 kg ai) |

* Containing 400 g/L dimethoate unless indicated differently.
** To estimate the maximum product use, the OCS used a maximum default spray volume of 600 L/ha for hand spraying in ornamentals.
*** Considering a default work rate of 1000 L/d for hand application via handwand.

The amount of dimethoate (active) used per day for application via handwand is 0.3 - 1.6 kg. The maximum rate (1.6 kg/d) allowable in the label is used as the worst case of scenario for the risk assessment.

*Hand application – knapsack/backpack*

The following PHED scenarios were used:

*PHED surrogate scenario 3*: All liquid, open mixing and loading (MLOD)
[High confidence data for dermal exposure (AB grade): 53 hand replicates without gloves and 59 hand replicates with gloves; High confidence data for inhalation exposure without any protective equipment (AB grade): 85 replicates]

*PHED surrogate scenario 20*: Backpack application (APPL)
[Low confidence data for dermal exposure (AB grade): 69 dermal replicates without clothing: 90% protection factor applied to derive exposure with single layer; 60 hand replicate without gloves: 90% protection factor applied to derive exposure with gloves; High confidence data for inhalation exposure without any protective equipment (AB grade): 40 replicates]

As the amount of chemical handled per day is used in PHED scenarios to estimate worker exposure, dimethoate products were grouped according to the calculated maximum use rates per day (Table 10):

**Table 10: Highest application rates used in knapsack application**

| Product* | Crop | Product application rate | Product % (dimethoate %) in spray** | Maximum product (dimethoate) use per day*** |
|---|---|---|---|---|
| **39239: Farmoz Dimethoate 400 Systemic Insecticide** | Ornamental farms | 75 – 400 mL/100 L | 0.075 – 0.4% (0.03 – 0.16% ai) | 0.4 L (0.16 kg ai) |
| **49167: Summit Dimethoate Systemic Insecticide** | Ornamentals | 75 mL/100 L | 0.075% (0.03% ai) | 0.075 L (0.03 kg ai) |
| **Rest of the products: (Product Nos: 2962, 49600, 49833, 50342, 51545, 51658, 53045, 55441, 55495, 55704, 56454, 56887, 57860)** | Ornamentals (excluding chrysanthemum, begonia, liquid amber and gloxinias) | 75 mL/100 L | 0.075% (0.03% ai) | 0.075 L (0.03 kg ai) |
| All products | Citrus | 75 – 150 mL/100 L | 0.075 - 0.15% (0.03 – 0.06 % ai) | 0.15 L (0.06 kg ai) |

* Containing 400 g/L dimethoate unless indicated differently.
** To estimate the maximum product use, the OCS used a maximum default spray volume of 600 L/ha for hand spraying in ornamentals.
*** Considering a default work rate of 100 L/d for hand application via knapsack.

The amount of dimethoate (active) used per day by hand-held spraying is 0.03 - 0.16 kg. The maximum work rate (0.16 kg/d) as per the label is used as the worst case of scenario for the risk assessment.

*Aerial application*

The following PHED scenarios were used:

*PHED surrogate scenario 3*: All liquids, open mixing and loading (MLOD)
[High confidence data for dermal exposure (AB grade): 53 hand replicates without gloves and 59 hand replicates with gloves; High confidence data for inhalation exposure without any protective equipment (AB grade): 85 replicates]

*PHED surrogate scenario 6:* All liquids, closed mixing and loading (MLOD)
[High confidence data for dermal exposure (AB grade): 31 hand replicates with gloves; Low confidence due to lack of "no glove" hand replicates; High confidence data for inhalation exposure without any protective equipment (AB grade): 27 replicates].

Total dermal exposure for this PHED scenario was based on a combination of 15% exposure to head and neck, 19% exposure to hands and 66% exposure to other body parts (upper and lower arms, chest, back, thigh and lower leg). Exposure without gloves was estimated by back calculating the exposure with gloves (100% exposure to hands).

*PHED surrogate scenario 7*: Aerial fixed wing, enclosed cockpit; liquid application (APPL), [Medium confidence data for dermal exposure with a single layer of clothing and no gloves (AB grade): 34 hand replicates; Low confidence data for dermal exposure with a single layer of clothing with gloves, (All grades): 7 hand replicates; Medium confidence data for inhalation exposure without any protective equipment (ABC grade): 23 replicates].

It is expected that large areas of cereal crops, oilseed crops and pastures will be treated by aerial application. The lowest and highest application rates for aerial application are 340 and 800 mL product per ha, respectively and a default maximum work load is 1200 hectares per day. Both minimum and maximum rates of 163 kg and 384 kg dimethoate /day are used as the best and worst case scenario for the risk assessment for mixing/loading and application by aerial spraying.

*Misting machine use*

The product is applied in tomatoes using misting machines at a rate of 850 mL/ha with 70 L water/ha (1.2% product and 0.486% dimethoate in the mist). Assuming that 30 hectares can be treated in one day (similar to that of air-assisted spraying), the amount of dimethoate applied per day by misting would be 10.2 kg. The PHED Surrogate Exposure Guide (PHED, 1998) has no scenarios to estimate worker exposure during misting machine use. The OCS has no other models or databases to use for estimating worker exposure during misting. Prediction of operator exposure from outdoor application of dimethoate by misting is difficult because these operations may be performed with a variety of equipment (i.e., hand-held foggers or backpack misters, semi-portable misters mounted on utility vehicles or trailers, or stationary misters), and will be affected by variables including the size, type and topography of the misting site, the wind speed and direction, and the ambient temperature. Operator exposure is likely to be greater when using portable or vehicle-mounted equipment than stationary equipment, but even in the latter case, exposure may occur if the operator remains on site to supervise application.

Considering the relatively high concentrations of the product and the active constituent in the mist and the anticipated repeated use of the product in tomatoes, exposure to dimethoate is likely to be very high, particularly from inhalation exposure for which the presumed absorption rate is 100%.

As there is no data available to estimate exposure during misting, a qualitative risk assessment has been conducted in Section 5.

*Seed treatment*

For seed treatment, the recommended mixing rate with the maximum concentration of the product is 300 mL in 900 mL of water (33% product and 13.2% dimethoate in treatment slurry) per 50 kg seed of lupins, peas, clover, lucerne, linseed and canola/rapeseed.

Labels direct the user to mix the slurry and seeds thoroughly in a drum or cement mixer. This indicates that at least some of the seed treatment will be performed by farmers on-site, using relatively open systems. Exposure to dimethoate is possible when preparing the slurry, loading the prepared slurry, during the mixing process, and when bagging treated seed. There is no appropriate model to estimate exposure during these processes.

In Australia, professional seed treaters mostly treat seed in enclosed systems. Bulk containers of dimethoate product are connected via an inlet pipe or lance to the application equipment. The mechanical treaters measure the required amount of product and dilute it with water to the required volume. Seed to be treated is loaded into a hopper for treatment within the machine. Dry treated seed emerges from the machine through a funnel into sacks, which are sealed either mechanically or by hand. At some seed-treating facilities, grain is treated in a coarse shielded spray as it comes on a conveyor belt for storage. There is the potential for worker exposure when opening containers, connecting pipes and fittings, cleaning equipment, and bagging treated seed.

The PHED scenario for closed mixing/loading (*PHED surrogate scenario 6:* All liquids, closed mixing and loading) have been used to estimate worker exposure when carrying out those tasks. As there is no data available to estimate exposure during seed treatment, a qualitative risk assessment has been conducted in Section 5.

*Pre-planting dipping*

Preplant dipping is mostly carried out for lychee plants. Before transferring to the ground, the seedlings are dipped in a solution containing 0.03% dimethoate (75 mL product/100 L water) for one minute and then drained. The seedlings are immediately planted thereafter. Although details of the dipping procedure are not available, it is expected that plant dipping is performed manually.

As there is no data available to estimate exposure during pre-plant dipping, a qualitative risk assessment has been conducted in Section 5.

*Post harvest dipping (including quarantine treatment)*

Fruit and vegetable dipping is mainly performed by mechanical methods where containers carrying the fruit are lowered into solution tanks and removed a few minutes later. The working solution is expected to contain low amounts of dimethoate, as a maximum 150 mL product is added to 100 L water (0.06% dimethoate). Workers prepare large volumes of the dip solution in big containers. The solution is charged periodically with the product to maintain the required levels of dimethoate in the solution.

As there is no data available to estimate exposure during post-harvest dipping, a qualitative risk assessment has been conducted in Section 5.

*Trunk injection*

A mixture of 1 part product with 1 part water (50% product and 20% dimethoate) is used for tree trunk injections in eucalyptus, kurrajong, flame trees, umbrella trees. Downward angled holes of 5 cm are drilled into the sapwood of the tree trunk at 15 – 30 cm apart, around the trunk at waist height. The amount of mixture required is calculated by multiplying the tree diameter by 3, i.e. a 3 mL of the mixture per cm diameter is injected, and holes are plugged with putty or mastic filler and paint over with bitumen sealer. The trees are treated once every 12 months.

As there is no data available to estimate exposure during trunk injection, a qualitative risk assessment has been conducted in Section 5.

### 4.2.3 Exposure during application – PHED estimates

Table 11 provides PHED exposure data (dermal and inhalation exposure) for various application methods. These exposure values, given as exposure per unit quantity of chemical handled, were adjusted for the total active ingredient handled per day (kg ai/day) for each application method to estimate exposure for that application method.

Table 12 provides dermal and inhalation exposure estimates for each application method. Where exposure data or exposure model for some application methods (e.g. fruit dipping) were not available, a qualitative risk of occupational exposure was undertaken.

**Table 11: Dermal and inhalation exposure estimates**

| Exposure Scenario Equipment | Dermal Unit Exposure (mg/kg ai handled) (body+hands) | Dermal Replicates | Hand Replicates | Inhalation Unit Exposure (mg/kg ai handled) | Inhalation Replicates |
|---|---|---|---|---|---|
| **Mixer/Loader** | | | | | |
| Scenario 3: Open mixing/loading (no gloves) | 6.39 | 72-122 | 53 | 0.0026 | 85 |
| Scenario 3: Open mixing/loading (gloves) | 0.05 | 72-122 | 59 | 0.0026 | 85 |
| Scenario 6: Closed mixing/loading (no gloves) | (0.015) | 16-22 | 0 | 0.0002 | 27 |
| Scenario 6: Closed mixing/loading (gloves) | 0.019 | 16-22 | 31 | 0.0002 | 27 |
| **Applicator** | | | | | |
| **Boomspray application** | | | | | |
| Scenario 13: Applicator, open cab (no gloves) | 0.03 | 23-42 | 29 | 0.0016 | 22 |
| Scenario 13: Applicator, open cab (gloves) | 0.03 | 23-42 | 21 | 0.0016 | 22 |
| Scenario 14: Applicator, closed cab (no gloves) | 0.011 | 20-31 | 16 | 0.0001 | 16 |
| Scenario 14: Applicator, closed cab, (gloves) | 0.011 | 10-31 | 12 | 0.0001 | 16 |
| **Airblast application** | | | | | |
| Scenario 11: Applicator, open cab (no gloves) | 0.79 | 32-49 | 22 | 0.0016 | 47 |
| Scenario 11: Applicator, open cab (gloves) | 0.53 | 31-49 | 18 | 0.0016 | 47 |
| Scenario 12: Applicator, closed cab (no gloves) | (0.013) | 20-30 | 0 | 0.0001 | 9 |
| Scenario 12: Applicator, closed cab, (gloves) | 0.041 | 20-30 | 20 | 0.0001 | 9 |
| **Hand application – vehicle-mounted handwand** | | | | | |
| Scenario 18: Low pressure hand wand (no gloves) | 26.4 | 13 | 9 | 2.07 | 13 |
| Scenario 18: Low pressure hand wand (gloves) | 15.6 | 13 | 4 | 2.07 | 13 |
| Scenario 19: High pressure hand wand (no gloves) | 3.97 | 9-11 | 2 | 0.17 | 11 |
| Scenario 19: High pressure hand wand (gloves) | 1.41 | 9-11 | 9 | 0.17 | 11 |
| **Hand application - knapsack** | | | | | |
| Scenario 20: Backpack (no gloves) | 1064* | 0* | 60 | 0.73 | 40 |
| Scenario 20: Backpack (gloves) | (517) | 0* | 0 | 0.73 | 40 |
| **Aerial application by fixed-wing aircraft** | | | | | |
| Scenario 7: Aerial fixed wing (no gloves) | 0.011 | 24-28 | 34 | 0.00015 | 23 |
| Scenario 7: Aerial fixed wing (gloves) | 0.0048 | 24-28 | 7 | 0.00015 | 23 |

For all exposure measurements, workers wore a single layer of clothes (long pants and long sleeve shirt) with or without gloves for dermal exposure, and no protective equipment for inhalation exposure.

For mixing/loading estimates, subsets for all types of liquids were used, as this provided large number of hand replicates.

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

* This dermal unit exposure value was obtained by assuming the standard 50% protection factor (Keigwin, 1998) for the “no clothing” exposure value, as no “single layer” data is available for this PHED scenario

**Table 12: Exposure estimates for workers using dimethoate products**

| ***Estimate*** | *Gloves* | **Systemic exposure to dimethoate (mg/kg bw/d)** | | | | | |
|---|---|---|---|---|---|---|---|
| | | *Mixer/ Loader Dermal* | *Applicator Dermal* | *Total Dermal exposure* | *Mixer/ Loader Inhalation* | *Applicator Inhalation* | *Total inhalation exposure* |
| **Ground boom application** | | | | | | | |
| Open cab (20.4 kg ai/day) **Scenario 3 and 13** | N | 0.0950 | 0.0004 | 0.0954 | 0.0008 | 0.0005 | 0.0013 |
| | Y | 0.0007 | 0.0004 | 0.0011 | 0.0008 | 0.0005 | 0.0013 |
| Closed cab (20.4 kg ai/day) **Scenario 3 and 14** | N | 0.0950 | 0.0002 | 0.0952 | 0.0008 | 0.0000 | 0.0008 |
| | Y | 0.0007 | 0.0002 | 0.0009 | 0.0008 | 0.0000 | 0.0008 |
| **Airblast/air-assisted application** | | | | | | | |
| Open cab (120 kg ai/day) **Scenario 3 and 11** | N | 0.554 | 0.0684 | 0.621 | 0.0044 | 0.0027 | 0.0071 |
| | Y | 0.0043 | 0.0458 | 0.050 | 0.0044 | 0.0027 | 0.0071 |
| Closed cab (120 kg ai/day) **Scenario 3 and 12** | N | 0.554 | (0.0012) | 0.554 | 0.0044 | 0.00017 | 0.0046 |
| | Y | 0.0043 | 0.0035 | 0.0079 | 0.0044 | 0.00017 | 0.0046 |
| **Hand application using vehicle-mounted low pressure handwand** | | | | | | | |
| **Scenario 3 and 18** (1.6 kg ai/day) | N | 0.0074 | 0.0308 | 0.0382 | 0.0001 | 0.0473 | 0.0474 |
| | Y | 0.0001 | 0.0182 | 0.0183 | 0.0001 | 0.0473 | 0.0474 |
| **Scenario 3 and 18** (0.6 kg ai/day) | N | 0.0028 | 0.0115 | 0.0143 | 0.0001 | 0.0178 | 0.0179 |
| | Y | 0.0001 | 0.0068 | 0.0069 | 0.0001 | 0.0178 | 0.0179 |
| **Scenario 3 and 18** (0.3 kg ai/day) | N | 0.0014 | 0.0058 | 0.0072 | 0.0001 | 0.0089 | 0.0090 |
| | Y | 0.0001 | 0.0034 | 0.0035 | 0.0001 | 0.0089 | 0.0090 |
| **Hand application using vehicle-mounted high pressure handwand** | | | | | | | |
| **Scenario 3 and 19** (1.6 kg ai/day) | N | 0.0073 | 0.0046 | 0.012 | 0.0001 | 0.0040 | 0.0041 |
| | Y | 0.0001 | 0.0016 | 0.0017 | 0.0001 | 0.0040 | 0.0041 |
| **Hand application using knapsack** | | | | | | | |
| **Scenario 3 and 20** (0.16 kg ai/day) | N | 0.0007 | 0.124 | 0.125 | 0.00001 | 0.0017 | 0.00171 |
| | Y | 0.00001 | 0.0603 | 0.0603 | 0.00001 | 0.0017 | 0.00171 |
| **Scenario 3 and 20** (0.06 kg ai/day) | N | 0.003 | 0.0465 | 0.0495 | 0.00001 | 0.0001 | 0.00011 |
| | Y | 0.00001 | 0.0226 | 0.0226 | 0.00001 | 0.0001 | 0.00011 |
| **Scenario 3 and 20** (0.03 kg ai/day) | N | 0.0015 | 0.0233 | 0.0248 | 0.00001 | 0.00005 | 0.00006 |
| | Y | 0.00001 | 0.0113 | 0.0113 | 0.00001 | 0.00005 | 0.00006 |
| **Aerial application (high rate) by fixed-wing aircraft (open mixing/loading)** | | | | | | | |
| **Scenario 3 and 7** (384 kg ai/day) | N | 1.76 | 0.0031 | 1.76 | 0.0145 | 0.0008 | 0.0153 |
| | Y | 0.0142 | 0.0013 | 0.0155 | 0.0145 | 0.0008 | 0.0153 |
| **Aerial application (high rate) by fixed-wing aircraft (closed mixing/loading)** | | | | | | | |
| **Scenario 6 and 7** (384 kg ai/day) | N | 0.0148 | 0.0031 | 0.0179 | 0.001 | 0.0008 | 0.0018 |
| | Y | 0.0053 | 0.0013 | 0.0066 | 0.001 | 0.0008 | 0.0018 |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| **Aerial application (low rate) by fixed-wing aircraft (open mixing/loading)** | | | | | | | |
| **Scenario 3 and 7** (163 kg ai/day) | N | 0.748 | 0.0013 | 0.749 | 0.0062 | 0.0003 | 0.0065 |
| | Y | 0.006 | 0.0006 | 0.0066 | 0.0062 | 0.0003 | 0.0065 |
| **Aerial application (low rate) by fixed-wing aircraft (closed mixing/loading)** | | | | | | | |
| **Scenario 6 and 7** (163 kg ai/day) | N | 0.0063 | 0.0005 | 0.0068 | 0.0004 | 0.0001 | 0.0005 |
| | Y | 0.0022 | 0.0002 | 0.0024 | 0.0004 | 0.0001 | 0.0005 |

For all exposure measurements, workers wore a single layer of clothes (long pants and long sleeve shirt) with or without gloves for dermal exposure, and no protective equipment for inhalation exposure.
Dermal and inhalation exposures from PHED (mg/kg ai handled) are adjusted for total active ingredient handled per day (kg ai/day) for each application method, applicators body weight (70 kg), 5.1% dermal absorption and 100% inhalation absorption for dimethoate.
Values in parentheses represent estimates where observations on hand contamination in PHED database were not available. Exposure for the combined task (mixing/loading/application) was obtained by adding exposures during mixing/loading and application. Total exposure (dermal + inhalation) is not shown in the Table.

### 4.2.4 Post-application exposure

Post application worker exposure is expected when workers re-enter treated areas to carry out crop management activities such as irrigation, weeding, pruning, thinning and harvesting and when handling treated seeds/plants/fruits/vegetables. The type of crop management activities, duration and frequency of activities vary with different crops. Potential worker exposure varies with the amount of chemical used/applied, interval between spraying and re-entry, nature and duration of the particular re-entry activity, density of crop foliage, spacing of crops and environmental factors that affect the breakdown of residues.

Harvesting of agricultural crops may be by either manual (by hand) or by mechanical means. No worker exposure is expected during mechanical harvesting of crops. Hand harvesting results in dermal and probably inhalation exposure, and will depend on the quantities of chemical residues present on the crop at the time of harvesting.

***Measured post-application exposure studies***

No measured post application worker exposure studies were provided.

***Dislodgeable foliar residue studies***

Three dislodgeable foliar residues studies on apples, tomatoes and leaf lettuce were provided for assessment. These studies are summarised below:

**Prochaska LM (1999) Dissipation of dimethoate and its metabolite omethoate dislodgeable foliar residues on apples treated with Clean Crop Dimethoate 400. Stewart Agricultural Research Services, Inc., Macon, Missouri 63552 (Field project identifier: SARS-97-21) and Wildlife International Ltd., Easton, Maryland 21601 (Analytical project identifier: 232-118), Study completion date: 5 March 1999**.

The levels of dislodgeable dimethoate and omethoate residues were measured in apple foliage surfaces treated with two sequential applications of an EC formulation containing 400 g/L dimethoate. The study was conducted according to the requirements of the US EPA Occupational and Residential Exposure Test Guidelines, OPPTS 875-2100 Foliar Dislodgeable Residue Dissipation and US EPA GLP and QA standards.

*Test method:* Three trials were conducted in three different locations, Michigan, New York and Washington. The test plots were between 357–642 $m^2$ and the control plots were between 71 – 321 $m^2$. The buffer areas between the control and the treated plots were not less than 73 m.

Two spray applications were made in test plots using ground air blast equipment at 8 – 10 day intervals. The maximum label application rate of 1.12–1.13 kg ai/ha was used with the minimum spray dilution (937.74 – 1023.98 L/ha spray volume). Details of the trials are included in Table 13.

**Table 13: Trial details**

| | Michigan | | New York | | Washington | |
|---|---|---|---|---|---|---|
| | First application | Second application | First application | Second application | First application | Second application |
| Application rate (kg ai/ha) | 1.13 | 1.12 | 1.12 | 1.12 | 1.12 | 1.13 |
| Spray volume (L/ha) | 986.47 | 1023.98 | 938.02 | 937.74 | 946.44 | 950.18 |
| Crop stage | 5 cm diameter fruit | 5.4 cm diameter fruit | 3.8 – 5.1 cm diameter fruit | 3.8 - 5.1 cm diameter fruit | 8 - 9 cm diameter fruit | 8 - 9 cm diameter fruit |
| Crop height (m) | 2.7 – 3.7 | 2.7 – 3.7 | 5 | 5 | 4 | 4 |
| Crop width (m) | 3.7 – 4.3 | 3.7 – 4.3 | 2 - 3 | 2 - 3 | 3 | 3 |
| Air temperature ($^{o}$C) | 27 | 13 | 24 | 18 | 31 | 20 |
| Relative humidity (%) | 47 | 88 | 80 | 75 | 34 | 80 |
| Total rainfall during the test period* (cm) | 15.2 | | 11.2 | | 1.27 | |
| Monthly average minimum temperature range ($^{o}$C) | 3 - 19 | | 2.9 – 19.6 | | 5.1 – 17.2 | |
| Monthly average maximum temperature range ($^{o}$C) | 16 - 28 | | 13.2 – 30.9 | | 17.9 – 35.1 | |

* Rainfall occurred within 1 – 3 days after last application at each site.

The treatment plot was divided into three subplots with two replicate samples taken from each of the subplot at each sampling interval. The foliage was sampled randomly using a Birkestrand leaf punch sampler, before (-T) and after each application (as soon as possible when spray has dried but within 4 h of application) and on days 0.5 (12 h after application), 1, 2, 3, 5, 7, 10, 14, 21, 28 and 35 after last application. The samples were taken from dry, viable leaves only. A minimum of 40 random leaf disc samples (each with 2.54 cm diameter) were taken from at least ten plants per sample per sampling interval (equivalent to a total of 405 $cm^2$ sample area per sample, counting both sides of the leaf disc). A separate leaf punch sample apparatus was used in sampling the control and treated plots.

The dissipation was measured by dislodging the foliar residues twice with a 0.01% solution of Aerosol OT-75 in the field. Control leaf punch samples were obtained and dislodged using the same dislodging procedure as used on the residue samples. The dislodged samples were analysed for dimethoate by gas chromatography with a flame photometric detector and for omethoate with high pressure liquid chromatography (HPLC) with a UV detector operating at 205 nm.

The field fortification samples were analysed concurrently with the field samples for all three field trials. The field fortification samples (dislodging solution) were spiked with pre-prepared dimethoate or omethoate spiking solutions at levels of 0.01, 0.10 or 10.0 µg ai/mL at 1, 14 and 28 day sampling intervals and then treated in the same manner as for the corresponding residue samples.

The limit of quantification (LOQ) was 0.004 µg/cm$^2$ and the limit of detection (LOD) was 0.002 µg/cm$^2$ for both dimethoate and omethoate. A value of 0.002 µg/cm$^2$ was used in the regression calculation for all residues less than the calculated LOQ of 0.00395 µg/cm$^2$.

The dissipation of dislodgeable foliar residue (DFR) of dimethoate (includes both the conversion of dimethoate to omethoate and dissipation of other mechanisms such as plant uptake) was estimated using the following:

$$\frac{dC}{dt} = -kC$$

$C$ = *DFR at time t*
$k$ = *first-order rate constant*

$$C = C_o exp(-kt)$$

$C_o$ = Initial concentration
$t_{1/2}$ = Half-life (the time when the concentration equals half the initial concentration)

$$t_{1/2} = \frac{0.693}{k}$$

Dissipation curves were fit directly to the first-order kinetic equation in order to determine the first-order rate constant and initial concentration. Data from individual replicates were used (as opposed to mean values) to quantify the uncertainty of the parameter estimates. A nonlinear curve fitting program (SAS, procedure NLIN) was used to fit the data directly to the first-order decay equation.

However, omethoate (the metabolite of dimethoate) dissipation is more complicated as the amount of omethoate residues over time is dependent on the concentration of dimethoate, the rate of conversion of dimethoate to omethoate and the decomposition of omethoate. If the amount of omethoate that dissipates is less than the amount of omethoate formed by dissipation of dimethoate, it is expected that the omethoate concentration will first rise and then begin to dissipate after the dimethoate dissipates. Therefore, the time for omethoate to reach peak concentration was determined by DFR data.

*Results:* The highest dimethoate residues were observed in the samples obtained immediately (within 4 h) after the second spray application (2.006, 2.178 and 2.461 µg/cm$^2$ at Michigan, New York and Washington, respectively; Table 14, Table 15, Table 16). Dimethoate residues continued to decline for the remainder of the test period with lowest residue levels on day 35 (0.005, 0.048 and 0.197 µg/cm$^2$ at Michigan, New York and Washington, respectively).

**Table 14: Dimethoate and omethoate residues on apple leaves in the Michigan trial**

| Dimethoate | | | | | Omethoate | | | |
|---|---|---|---|---|---|---|---|---|
| **Sample interval (days after treatment** | **DFR Arithmetic mean (µg/cm$^2$)** | **Log mean (µg/cm$^2$)** | **S.D. (µg/cm$^2$)** | **C.V. (%)** | **DFR Arithmetic mean (µg/cm$^2$)** | **Log mean (µg/cm$^2$)** | **S.D. (µg/cm$^2$)** | **C.V. (%)** |
| -T1 | 0.002 | -6.2146 | 0.0 | 0.0 | 0.002 | -6.2146 | 0.0 | 0.0 |
| T1, 4h | 1.709 | 0.5359 | 0.147 | 8.6 | 0.002 | -6.2146 | 0.0 | 0.0 |
| -T2 | 0.296 | -1.2174 | 0.037 | 12.5 | 0.010 | -4.6052 | 0.001 | 10.0 |
| T2, 4h | 2.006* | 0.6961 | 0.270 | 13.5 | 0.010 | -4.6052 | 0.001 | 10.0 |
| T2, 12h | 1.436 | 0.3619 | 0.108 | 7.52 | 0.013 | -4.3428 | 0.001 | 7.69 |
| D 1 | 1.404 | 0.3393 | 0.109 | 7.76 | 0.014 | -4.2687 | 0.001 | 7.14 |
| D 2 | 1.046 | 0.0450 | 0.143 | 13.7 | 0.013 | -4.3428 | 0.001 | 7.69 |
| D 3 | 0.899 | -0.1065 | 0.076 | 8.45 | 0.014 | -4.2687 | 0.001 | 7.14 |
| D 5 | 0.725 | -0.3216 | 0.145 | 20.0 | 0.012 | -4.4228 | 0.001 | 8.33 |
| D 7 | 0.354 | -1.0385 | 0.038 | 10.7 | 0.015* | -4.1997 | 0.002 | 13.3 |
| D 10 | 0.230 | -1.4697 | 0.063 | 27.4 | 0.013 | -4.3428 | 0.003 | 23.1 |
| D 14 | 0.144 | -1.9379 | 0.024 | 16.7 | 0.010 | -4.6052 | 0.001 | 10.0 |
| D 21 | 0.065 | -2.7334 | 0.024 | 36.9 | 0.006 | -5.1160 | 0.001 | 16.7 |
| D 28 | 0.030 | -3.5066 | 0.023 | 76.7 | 0.003 | -5.8091 | 0.001 | 33.3 |
| D 35 | 0.005 | -5.2983 | 0.006 | 120 | 0.002 | -6.2146 | 0.0 | 0.0 |

* Maximum dimethoate or omethoate DFR level

T1: 1$^{st}$ treatment; T2: 2$^{nd}$ treatment.

**Table 15: Dimethoate and omethoate residues on apple leaves in the New York trial**

| Dimethoate | | | | | Omethoate | | | |
|---|---|---|---|---|---|---|---|---|
| **Sample interval (days after treatment** | **DFR Arithmetic mean (µg/cm$^2$)** | **LN of mean (µg/cm$^2$)** | **S.D. (µg/cm$^2$)** | **C.V. (%)** | **DFR Arithmetic mean (µg/cm$^2$)** | **LN of mean (µg/cm$^2$)** | **S.D. (µg/cm$^2$)** | **C.V. (%)** |
| -T1 | 0.002 | -6.2146 | 0.0 | 0.0 | 0.002 | -6.2146 | 0.0 | 0.0 |
| T1, 4h | 1.789 | 0.5817 | 0.272 | 15.2 | 0.002 | -6.2146 | 0.0 | 0.0 |
| -T2 | 0.418 | -0.8723 | 0.034 | 8.13 | 0.007 | -4.9618 | 0.001 | 14.3 |
| T2, 4h | 2.178* | 0.7784 | 0.303 | 13.9 | 0.010 | -4.6052 | 0.001 | 10.0 |
| T2, 12h | 2.046 | 0.7159 | 0.376 | 18.4 | 0.013 | -4.3428 | 0.002 | 15.4 |
| D 1 | 2.056 | 0.7208 | 0.166 | 8.07 | 0.016 | -4.1352 | 0.002 | 12.5 |
| D 2 | 1.174 | 0.1604 | 0.171 | 14.6 | 0.009 | -4.7105 | 0.001 | 11.1 |
| D 3 | 1.309 | 0.2693 | 0.181 | 13.8 | 0.012 | -4.4228 | 0.001 | 8.33 |
| D 5 | 1.041 | 0.0402 | 0.190 | 18.3 | 0.014 | -4.2687 | 0.002 | 14.3 |
| D 7 | 0.611 | -0.4927 | 0.093 | 15.2 | 0.015 | -4.1997 | 0.004 | 26.7 |
| D 10 | 0.485 | -0.7236 | 0.095 | 19.6 | 0.016 | -4.1352 | 0.002 | 12.5 |
| D 14 | 0.286 | -1.2518 | 0.057 | 19.9 | 0.016 | -4.1352 | 0.003 | 18.8 |
| D 21 | 0.228 | -1.4784 | 0.076 | 33.3 | 0.017* | -4.0745 | 0.002 | 11.8 |
| D 28 | 0.082 | -2.5010 | 0.021 | 25.6 | 0.009 | -4.7105 | 0.001 | 11.1 |
| D 35 | 0.048 | -3.0366 | 0.021 | 43.8 | 0.005 | -5.2983 | 0.003 | 60.0 |

* Maximum dimethoate or omethoate DFR level

T1: 1$^{st}$ treatment; T2: 2$^{nd}$ treatment.

**Table 16: Dimethoate and omethoate residues on apple leaves in the Washington trial**

| Dimethoate | | | | | Omethoate | | | |
|---|---|---|---|---|---|---|---|---|
| **Sample interval (days after treatment** | **DFR Arithmetic mean (µg/cm$^2$)** | **Log mean (µg/cm$^2$)** | **S.D. (µg/cm$^2$)** | **C.V. (%)** | **DFR Arithmetic mean (µg/cm$^2$)** | **Log mean (µg/cm$^2$)** | **S.D. (µg/cm$^2$)** | **C.V. (%)** |
| -T1 | 0.002 | -6.2146 | 0.0 | 0.0 | 0.002 | -6.2146 | 0.0 | 0.0 |
| T1, 4h | 1.866 | 0.6238 | 0.214 | 11.5 | 0.002 | -6.2146 | 0.0 | 0.0 |
| -T2 | 0.628 | -0.4652 | 0.194 | 30.9 | 0.010 | -4.6052 | 0.0 | 0.0 |
| T2, 4h | 2.461* | -0.9006 | 0.246 | 10.0 | 0.010 | -4.6052 | 0.001 | 10.0 |
| T2, 12h | 2.239 | 0.8060 | 0.080 | 3.57 | 0.014 | -4.2687 | 0.001 | 7.14 |
| D 1 | 2.289 | 0.8281 | 0.252 | 11.0 | 0.016 | -4.1352 | 0.002 | 12.5 |
| D 2 | 1.779 | 0.5761 | 0.274 | 15.4 | 0.018* | -4.0174 | 0.002 | 11.1 |
| D 3 | 1.527 | 0.4233 | 0.131 | 8.58 | 0.018* | -4.0174 | 0.002 | 11.1 |
| D 5 | 1.215 | 0.1947 | 0.161 | 13.3 | 0.016 | -4.1352 | 0.001 | 6.25 |
| D 7 | 0.826 | -0.1912 | 0.131 | 15.9 | 0.015 | -4.1997 | 0.002 | 13.3 |
| D 10 | 0.710 | -0.3425 | 0.077 | 10.8 | 0.015 | -4.1997 | 0.001 | 6.67 |
| D 14 | 0.353 | -1.0413 | 0.064 | 18.1 | 0.013 | -4.3428 | 0.001 | 7.69 |
| D 21 | 0.299 | -1.2073 | 0.079 | 26.4 | 0.012 | -4.4228 | 0.002 | 16.7 |
| D 28 | 0.242 | -1.4188 | 0.076 | 31.4 | 0.010 | -4.6052 | 0.001 | 10.0 |
| D 35 | 0.197 | -1.6245 | 0.030 | 15.2 | 0.009 | -4.7105 | 0.001 | 11.1 |

* Maximum dimethoate or omethoate DFR level
T1: 1$^{st}$ treatment; T2: 2$^{nd}$ treatment.

Omethoate residues were comparatively low (0.015, 0.017 and 0.018 µg/cm$^2$ being the highest at Michigan, New York and Washington, respectively) compared to dimethoate residues throughout the study. The time for omethoate to reach peak concentration was 7, 21 and 2 – 3 days at Michigan, New York and Washington, respectively.

**Table 17: Summary of dimethoate DFR dissipation**

| **Parameter** | **Michigan** | **New York** | **Washington** |
|---|---|---|---|
| Predicted initial DFR (µg/cm$^2$) | 1.794 | 2.163 | 2.431 |
| Predicted rate constant | 0.222 | 0.164 | 0.135 |
| R squared | 0.977882 | 0.96877 | 0.984168 |
| No: of observations | 72 | 72 | 72 |
| Degree of freedom | 70 | 70 | 70 |
| Half-life (days) | 3.12 | 4.23 | 5.13 |

**Table 18: Summary of omethoate DFR dissipation**

| Parameter | Michigan | New York | Washington |
|---|---|---|---|
| Time to peak concentration (days) | 7 | 21 | 3 |
| Predicted initial DFR ($\mu g/cm^2$) | 0.015 | 0.017 | 0.017 |
| Predicted rate constant | 0.067 | 0.092 | 0.020 |
| R squared | 0.977337 | 0.977191 | 0.992059 |
| No: of observations | 36 | 18 | 48 |
| Degree of freedom | 34 | 16 | 46 |
| Half-life (days) | 10.3 | 7.53 | 34.6 |

The calculated dimethoate half-lives for Michigan, New York and Washington are 3.12, 4.23 and 5.13 days, respectively. The calculated omethoate half-lives for Michigan, New York and Washington are 10.3, 7.53 and 34.6 days, respectively.

*Conclusion*

Dimethoate dissipated with a half-life of 3.12, 4.23 and 5.13 days at Michigan, New York and Washington, respectively (Table 17). Omethoate (the metabolite of dimethoate) dissipated with a half-life of 10.3, 7.53 and 34.6 days at Michigan, New York and Washington, respectively (Table 18). Omethoate occurred at relatively low levels compared to dimethoate, throughout the study at each test site.

The study concluded that dissipation of dimethoate and omethoate occurred regardless of the geographical location of the field test plots, the effects of weather, the effects of regional agronomic practices or other variables associated with the use of the products according to normal agricultural practices.

The OCS noted that there is a considerable difference in dissipation rate of omethoate in Washington (34.6 days half-life), compared to the other two locations (7.53 – 10.3 days half-life), and this may be due to the low rainfall received during the trial period in Washington (1.27 cm) compared to the other two locations (11.2 and 15.2 cm).

**Bookbinder MG (1998) Dissipation of foliar dislodgeable residues of dimethoate (O,O-dimethyl S-[N-[methylcarbamoyl] methyl] phosphorodithioate) and its metabolite omethoate (O,O-dimethyl S-[2-(methylamino)-2-oxoethyl] phosphorothioate) after application of Clean Crop Dimethoate 400 Insecticide to tomato plants. Crop Management Strategies, Inc., Hereford, PA and EN-CAS Laboratories, Winston-Salem, NC 27107 (Study ID number: Bookbinder MGB 97002 and EN-CAS 97-0023, Study completion date: 30 October 1998).**

The dislodgeable foliar residues (DFR) of dimethoate and its metabolite, omethoate were measured after two applications of dimethoate insecticide to tomato plants. Tomato plants were selected as the test system, since tomato cultivation and harvest are generally considered to be activities producing the 'worst-case' foliar contact and re-entry exposure. The study was conducted according to the requirements of the US EPA Occupational and Residential Exposure Test Guidelines, OPPTS 875-2100 Foliar Dislodgeable Residue Dissipation and US EPA GLP and QA standards.

*Test method:* The study was conducted at three different locations, California (CA), Florida (FL) and Pennsylvania (PA). Two plots were established at each site and one was used as the control (not treated). The test plots were between 0.02 – 0.03 acres (~0.008 – 0.012 ha) and the control plots were between 0.02 – 0.04 acres (~0.008 – 0.016 ha). The buffer areas between the control and the treated plots were >1000 ft (> 304 m) in CA, 181 ft (55.17 m) in FL and 150 ft (45.72 m) in PA.

The product used in the study was an emulsifiable concentrate (EC) formulation containing dimethoate at 42.9% (Clean Crop Dimethoate 400). The spray application in tomatoes was carried out using $CO_2$-powered backpack boom equipment in FL and tractor-mounted, PTO-powered ground-boom equipment in CA and PA. The application rate used was between 0.56 – 0.60 kg ai/ha with a spray volume of 192.68 – 213.26 L/ha. The treatment plots received two spray applications at 7 – 8 days interval. No other compounds that could interfere with dimethoate/omethoate analysis were applied to test sites during the course of the study (Table 19).

**Table 19: Application rates & spray volumes used**

| Location | CA | | FL | | PA | |
|---|---|---|---|---|---|---|
| | **First application** | **Second application (after 7 days)** | **First application** | **Second application (after 8* days)** | **First application** | **Second application (after 7 days)** |
| Application rate (kg ai/ha) | 0.56 | 0.57 | 0.58 | 0.60 | 0.59 | 0.59 |
| Spray volume (L/ha) | 195.49 | 198.3 | 196.43 | 193.62 | 192.68 | 213.26 |

* The second FL application was delayed 1 day due to high winds at the test site.

Each treated plot was divided into three equal-area subplots for sampling. Leaf disc samples were collected randomly using a Birkestrand leaf punch sampler, from the untreated and treated subplots prior to first application, immediately after the first application (as soon as the spray had dried), immediately before the second application, immediately after the second application (as soon as the spray had dried: day 0), and on 1, 2, 3, 5, 7, 10, 14, 21, 28 and 35 days after the second application (DASA). On each sampling date, a single sample was collected from each control plot and duplicate samples were collected from each treated subplot. Each leaf sample consisted of 40, 2.54 cm diameter discs mechanically cut from mature tomato leaves of randomly selected plants in 1 – 2 rows of the treated subplots (each sample totalling ~ 400 $cm^2$ of leaf surface using two sides of leaf discs). When rain occurs on a sampling day, samples were collected as soon as the foliage has dried.

Samples were processed at the field sites by shaking two times with dislodging solution (DS), consisting of 0.004% dioctyl sulfosuccinate in water. Each sample was analysed by GC using a DB-5 column and flame photometer detector operating in phosphorus mode. The LOQ for dimethoate and omethoate in DS was 0.01 ppm.

On each of 1, 14 and 28 DASA, fresh DS samples (200 mL) were prepared for field fortification. DS samples were fortified by adding either dimethoate or omethoate at 0.10, 25 or 100 ppm concentrations (2 samples per concentration/sampling). Two DS samples per fortification sampling time remained as controls. Since the PA tomato trial was conducted simultaneously with leaf lettuce trial, separate field controls were not prepared for this trial. The data reported herein for PA field fortifications were derived from the lettuce trial.

The raw ppm residue levels determined for each leaf-disc sample was adjusted for the recovery of that analyte in appropriate field-fortified sample (eg: 0.039 ppm dimethoate in the 1 DASA leaf sample, mean % recovery of dimethoate from 1 DASA field fortified sample = 96.7%, adjusted residue level = 0.039/0.967 = 0.040 ppm). If a sample contained non-quantifiable residues (< 0.01 ppm), it was assigned a value of 50% of the LOQ (or 0.005 ppm). No adjustments were made for samples when their associated field spike recoveries were 100% or higher.

Adjusted residue levels were converted into µg/cm$^2$ leaf surface values (eg: Dimethoate 0.040 ppm x 200 mL/sample = 8 µg dimethoate /sample; Dimethoate µg/cm$^2$ leaf area = (8 µg/sample) ÷ (400 cm$^2$/sample) = 0.020 µg/cm$^2$).

The DFR means were plotted against the time after the second application to obtain a residue decline curve for dimethoate and omethoate. The rate of dissipation was calculated using the same formulas as described in the previous study.

*Results:* Percentage recoveries from lab-fortified samples were between 80 – 114% for dimethoate (mean = 97.4%, SD = 9.7) and 62 – 125% for omethoate (mean = 90.8%, SD = 14.8) at 0.01 – 100 ppm. Dimethoate and omethoate DFR levels from treated tomato foliage are provided in Table 20 & Table 21.

**Table 20a: Mean DFR levels (µg/cm$^2$) on tomato leaf surfaces**

| Analyte | Trial | Days before second application | | | |
|---|---|---|---|---|---|
| | | **-9** | **-8** | **-1** | **0** |
| Dimethoate | FL | 0.003 | 1.706 | 0.003 | 1.111* |
| | CA | 0.003 | 0.930 | 0.010 | 0.572* |
| | PA | 0.003 | 0.723 | 0.003 | 0.597* |
| Omethoate | FL | 0.003 | 0.017 | 0.003 | 0.033* |
| | CA | 0.003 | 0.008 | 0.005 | 0.013 |
| | PA | 0.004 | 0.030 | 0.004 | 0.034* |

Table 20**b: Mean DFR levels (µg/cm$^2$) on tomato leaf surfaces**

| Analyte | Trial | Days after second application | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | **0** | **1** | **2** | **3** | **5** | **6** | **7** | **10** | **14** |
| Dimethoate | FL | 1.111* | 0.049 | 0.019 | 0.006 | 0.003 | NS | 0.003 | 0.003 | 0.003 |
| | CA | 0.572* | 0.401 | 0.079 | 0.088 | 0.055 | NS | 0.032 | 0.008 | 0.005 |
| | PA | 0.597* | 0.073 | 0.031 | 0.014 | NS | 0.003 | 0.003 | 0.002 | 0.002 |
| Omethoate | FL | 0.033* | 0.023 | 0.023 | 0.020 | 0.003 | NS | 0.003 | 0.003 | 0.003 |
| | CA | 0.013 | 0.030* | 0.011 | 0.023 | 0.020 | NS | 0.016 | 0.010 | 0.008 |
| | PA | 0.034* | 0.010 | 0.008 | 0.005 | NS | 0.004 | 0.004 | 0.003 | 0.003 |

Day -9 = prior to first application; day -8 = immediately after the first application (as soon as the spray has dried); day -1 = immediately before the second application; day 0 = immediately after the second application (as soon as the spray has dried); NS = Not sampled
* Highest DFR value

**Table 21: Daily air temperature (between the first application date and last sampling date) and total rainfall recorded during the test period**

| Location | Mean minimum temperature ($^o$C) | Mean maximum temperature ($^o$C) | Total rainfall (mm) |
|---|---|---|---|
| CA | 14.6 | 31.2 | 0.25 |
| FL | 20.5 | 31.0 | 248.16 |
| PA | 15.7 | 30.8 | 210.06 |

Dimethoate DFR declined over time at all sites, with half-lives of 0.23, 1.12 and 0.34 days at FL, CA and PA, respectively (Table 22). Residues were below the LOQ in all samples collected 10 DASA in FL and PA. Samples collected after 14 DASA were not analysed because residues had dropped below the limit of quantitation (LOQ) by that time. The least residue decline was on foliage from the CA site, which received the least rainfall and at which the relative humidity level never exceeded 80%. Residues declined more rapidly on foliage from the FL and PA sites, at which local relative humidity reached 90 – 100% almost daily during the sampling period.

**Table 22: Half-lives of dimethoate and omethoate**

| Analyte | Trial site | Predicted initial DFR (µg/cm$^2$) | Predicted rate constant (1/day) | Half-life (days) | Half-life LCL (days) | Half-life UCL (days) |
|---|---|---|---|---|---|---|
| Dimethoate | FL | 1.11 | 3.08 | 0.23 | 0.19 | 0.29 |
| | CA | 0.59 | 0.62 | 1.12 | 0.83 | 1.68 |
| | PA | 0.60 | 2.01 | 0.34 | 0.32 | 0.38 |
| Omethoate | CA | 0.023 | 0.12 | 6.4 | 4 | 16 |
| | PA | 0.033 | 0.85 | 0.81 | 0.64 | 1.1 |

LCL = lower 95% confidence limit
UCL = upper 95% confidence limit

Omethoate residues declined with half-lives of 0.81 in PA and 6.4 days in CA. Omethoate dissipation is considerably greater than the production rate of omethoate from dimethoate dissipation. Omethoate levels on foliage peaked at 0 and 1 DASA in PA and CA, respectively, and could be modelled by first-order decay. Omethoate levels on FL foliage declined to < LOQ by 5 DASA, but in a manner that could not be fit to a first-order kinetics curve.

*Conclusion*

Dimethoate DFR on tomato leaves were highest soon after the spray has dried (0.572 – 1.706 µg/cm$^2$), and declined over time at all sites with half-lives of 0.23 to 1.11 days. Residues were below the LOQ (0.01 ppm) in all samples collected 10 DASA in FL and PA. Residues in CA samples approached the LOQ by day 14. The least residue decline was on foliage from the CA site, which received the least rainfall and at which the relative humidity level never exceeded 80%.

Omethoate residues declined with half-lives of 0.81 in PA and 6.4 days in CA. Omethoate residue levels on FL foliage reached < LOQ by 5 DASA, but the decline did not fit a first-order kinetics curve.

**Bookbinder MG (1998) Dissipation of foliar dislodgeable residues of dimethoate (O,O-dimethyl S-[N-[methylcarbamoyl] methyl] phosphorodithioate) and its metabolite omethoate (O,O-dimethyl S-[2-(methylamino)-2-oxoethyl] phosphorothioate) after application of Clean Crop Dimethoate 400 Insecticide to leaf lettuce. Crop Management Strategies, Inc., Hereford, PA and EN-CAS Laboratories, Winston-Salem, NC 27107 (Study ID number: Bookbinder MGB 97001 and EN-CAS 96-0068, Study completion date: 30 October 1998).**

The dislodgeable foliar residues (DFR) of dimethoate insecticide and its metabolite, omethoate were measured after two applications to leaf lettuce. The study was conducted according to the requirements of the US EPA Occupational and Residential Exposure Test

Guidelines, OPPTS 875-2100 Foliar Dislodgeable Residue Dissipation and US EPA GLP and QA standards.

*Test method:* The study was conducted at three different locations, California (CA), Florida (FL) and Pennsylvania (PA). Two plots were established at each site and one was used as the control (not treated). The test plots were 0.02 acres (~0.008 ha) and the control plots were between 0.02 – 0.04 acres (~0.008 – 0.016 ha). The buffer areas between the control and the treated plots were >1000 ft (> 304 m) in CA, 347 ft (105.77 m) in FL and 150 ft (45.72 m) in PA.

The product used in the study was an emulsifiable concentrate (EC) formulation containing dimethoate at 42.9% (Clean Crop Dimethoate 400). The spray application in lettuce was carried out using $CO_2$-powered backpack boom equipment in FL and tractor-mounted, PTO-powered ground-boom equipment in CA and PA. The application rate used was between 0.28 – 0.30 kg ai/ha with a spray volume of 195.49 – 222.62 L/ha (Table 23). The treatment plots received two spray applications at 7 – 8 days interval. No other compounds that could interfere with dimethoate/omethoate analysis were applied to test sites during the course of the study.

**Table 23: Application rates and spray volumes used**

| Location | CA | | FL | | PA | |
|---|---|---|---|---|---|---|
| | **First application** | **Second application (after 7 days)** | **First application** | **Second application (after 8* days)** | **First application** | **Second application (after 7 days)** |
| Application rate (kg ai/ha) | 0.28 | 0.28 | 0.30 | 0.29 | 0.29 | 0.30 |
| Spray volume (L/ha) | 200.63 | 195.58 | 202.04 | 195.49 | 202.04 | 222.62 |

* The second FL application was delayed 1 day due to thunderstorms at the test site.

Each treated plot was divided into three equal-area subplots for sampling. Leaf disc samples (each sample consisted of 40, 2.54 cm diameter leaf discs totalling ~ 400 $cm^2$ of surface using two sides of the discs) were collected randomly using a Birkestrand leaf punch sampler, from the untreated and treated subplots prior to first application, immediately after the first application (as soon as the spray had dried), immediately before the second application, immediately after the second application (as soon as the spray had dried: day 0), and on 1, 2, 3, 5, 7, 10, 14, 21, 28 and 35 days after the second application (DASA). An additional sampling was performed at the CA site 49 DASA. On each sampling date, a single sample was collected from each control plot and duplicate samples were collected from each treated subplot. Each leaf sample was mechanically cut from mature lettuce leaves of randomly selected plants in 1 – 2 rows of the treated subplots.

Samples were processed at the field sites by shaking two times with dislodging solution (DS), consisting of 0.004% dioctyl sulfosuccinate in water. Each sample was analysed by GC using a DB-5 column and flame photometer detector operating in phosphorus mode. The LOQ for dimethoate and omethoate in DS was 0.01 ppm.

On each of 1, 14 and 28 DASA, fresh DS samples (200 mL) were prepared for field fortification. DS samples were fortified by adding either dimethoate or omethoate at 0, 10, 25 or 100 ppm concentrations (2 samples per concentration/sampling). Two DS samples per fortification sampling time remained as controls.

The raw ppm determined for each leaf-disc sample was adjusted for the recovery of that analyte in appropriate field-fortified sample (eg: 0.063 ppm dimethoate in 1 DASA leaf sample, mean % recovery of dimethoate from 1 DASA field spikes = 77.3%, adjusted residue level = 0.063/0.773 = 0.082 ppm). If a sample contained non-quantifiable residues (< 0.01 ppm), it was assigned a value of 50% of the LOQ (or 0.005 ppm). No adjustments were made for samples when their associated field spike recoveries were 100% or higher.

Adjusted residue levels were converted into µg/cm$^2$ leaf surface values (eg: Dimethoate 0.082 ppm x 200 mL/sample = 16.4 µg dimethoate /sample; Dimethoate µg/cm$^2$ leaf area = (16.4 µg/sample) ÷ (400 cm$^2$/sample) = 0.041 µg/cm$^2$).

The DFR means were plotted against the time after the second application to obtain residue decline curves for dimethoate and omethoate.

The rate of dissipation was calculated using the same formulas as described previously in section 18.1.2.

*Results:* Percentage recoveries from lab-fortified samples were between 75 – 120% for dimethoate (mean = 98%, SD = 9.7) and 63 – 112% for omethoate (mean = 90.4%, SD = 13.7) at 0.01 – 100 ppm. Dimethoate and omethoate DFR levels from treated lettuce foliage are provided in Table 24.

**Table 24: Mean DFR levels (µg/cm$^2$) on lettuce leaf surfaces**

| Analyte | Trial | Days after second application (DASA) | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | **-9** | **-8** | **-1** | **0** | **1** | **2** | **3** | **5** | **7** | **10** | **14** |
| Dimethoate | FL | 0.003 | 0.424* | 0.003 | 0.129 | 0.034 | 0.010 | 0.007 | 0.003 | 0.003 | 0.002 | 0.002 |
| | CA | 0.003 | 0.410 | 0.008 | 0.610* | 0.410 | 0.202 | 0.203 | 0.063 | 0.036 | 0.019 | 0.003 |
| | PA | 0.003 | 0.187 | 0.003 | 0.348* | 0.059 | 0.042 | 0.003 | n/c | 0.003 | 0.002 | 0.002 |
| Omethoate | FL | 0.003 | 0.003 | 0.003 | 0.003 | 0.003 | 0.003 | 0.003 | 0.003 | 0.003 | 0.003 | 0.003 |
| | CA | 0.003 | 0.003 | 0.005 | 0.010 | 0.011 | 0.011 | 0.021* | 0.020 | 0.018 | 0.011 | 0.003 |
| | PA | 0.004 | 0.004 | 0.004 | 0.004 | 0.004 | 0.004 | 0.004 | n/c | 0.004 | 0.003 | 0.003 |

Day -9 = prior to first application; day -8 = immediately after the first application (as soon as the spray has dried); day -1 = immediately before the second application; day 0 = immediately after the second application (as soon as the spray has dried); n/c = Not collected due to adverse weather.
* Highest DFR value

Dimethoate levels were highest immediately after the second application had dried (except in FL where the highest levels were recorded immediately after the first application), and declined in all test plots to < LOQ by 14 DASA (Table 25).

**Table 25: Daily air temperature (between the first application date and last sampling date) & total rainfall recorded during the test period**

| Location | Mean minimum temperature ($^o$C) | Mean maximum temperature ($^o$C) | Total rainfall (mm) |
|---|---|---|---|
| CA | 14.6 | 31.2 | 0.0 |
| FL | 20.5 | 31.0 | 362.97 |
| PA | 15.7 | 30.8 | 210.06 |

The calculated half-lives of dimethoate shown in Table 26 which demonstrates that dissipation of DFR was faster in FL and PA sites. The major difference in weather parameters between the CA site and those in FL and PA was noted as relative humidity. There was also no rainfall during the test period in CA, compared to FL and PA.

**Table 26: Half-lives of dimethoate & omethoate**

| Analyte | Trial site | Predicted initial DFR (µg/cm$^2$) | Predicted rate constant (1/day) | Half-life (days) | Half-life LCL (days) | Half-life UCL (days) |
|---|---|---|---|---|---|---|
| Dimethoate | FL | 0.13 | 1.29 | 0.54 | 0.49 | 0.6 |
| | CA | 0.61 | 0.44 | 1.58 | 1.36 | 1.89 |
| | PA | 0.35 | 1.6 | 0.43 | 0.38 | 0.51 |
| Omethoate | CA | 0.023 | 0.12 | 5.9 | 4.0 | 11.3 |

LCL = lower 95% confidence limit
UCL = upper 95% confidence limit

Omethoate levels were below LOQ in all samples of FL or PA foliage. Omethoate levels in CA samples rose through 3 DASA and declined thereafter to levels close to LOQ at 14 DASA. Therefore, the calculations of half-life in CA were based on omethoate values beginning 3 DASA. Change of omethoate concentration over time is dependent on the concentration of dimethoate, the rate of conversion of dimethoate to omethoate, and the decomposition of omethoate. From the study data available, it is not possible to calculate all three of these quantities. The results indicate that the omethoate dissipation is considerably greater than the production rate of omethoate from dimethoate dissipation.

*Conclusion*

Dimethoate DFR on leaf discs declined over time at all sites, with half-lives of 0.43 to 1.58 days. Residues were below the LOQ (0.1 ppm) in all samples collected 14 days after the second application. The least residue decline was on foliage from the CA site, which received no rainfall during the sampling period, and at which the relative humidity level never exceeded 80%. Residues declined more rapidly on foliage from the FL and PA sites, at which local relative humidity reached 90 – 100% almost daily during the sampling period.

DFR of omethoate, a metabolite of dimethoate, were <LOQ in all samples collected in FL and PA between the second application and 14 days later. In CA samples, omethoate levels reached maximum at 3 DASA and then started to decline with a half-life of 11.3 days.

The weather conditions such as rainfall and relative humidity affect the dissipation rate of both dimethoate and omethoate, but the effect was more significant on omethoate dissipation.

# 5 RISK ASSESSMENT AND MANAGEMENT – OCCUPATIONAL

## 5.1 Acute hazards

For occupational use, dimethoate is available in EC formulations containing between 100-400 g/L dimethoate. These products are expected to be of moderate acute oral toxicity, and low to moderate dermal and inhalational toxicity, and be moderate to severe skin and eye irritants, and possible skin sensitizers. The skin and eye irritation potential of the products arises primarily from the presence of cyclohexanone in the formulation.

These acute hazards pose a risk to workers during mixing and loading products, and will require PPE to be established to minimise exposure via the dermal, ocular and inhalation routes. During mixing/loading, workers will be required to wear cotton overalls buttoned to the neck and wrist, a washable hat, elbow-length chemical resistant gloves, impervious footwear, and a faceshield. Safety directions based on acute hazards have been derived as shown in Table 27.

The diluted spray, when prepared for agricultural use as per the label instructions, will contain less than 1% of the product, and in most cases less than 0.1% of the product. As such, the dilute spray is not expected to pose acute hazards during application.

**Table 27. Derivation of Safety Directions based on acute hazards**

| Acute or Repeat Exposure Risk | Safety Direction | Code |
|---|---|---|
| | ***HAZARDS*** | |
| Moderate acute oral, dermal and inhalation toxicity | Poisonous if absorbed by skin contact, inhaled or swallowed. | 130 131 132 133 |
| Organophosphate chemical | Repeated minor exposure may have a cumulative poisoning effect. | 190 |
| Severe skin and eye irritation | Will damage eyes and skin. | 207 211 |
| Skin sensitisation | Repeated exposure may cause allergic disorders | 180 |
| | ***PRECAUTIONS*** | |
| Severe skin and eye irritation | Avoid contact with eyes and skin. | 210 211 |
| | ***MIXING OR USING*** | |
| Moderate acute dermal and inhalation toxicity, and severe skin and eye irritation (product) | When opening the container and preparing spray wear cotton overalls buttoned to the neck and wrist, a washable hat, a PVC or rubber apron, elbow-length chemical resistant gloves, a face shield and impervious footwear | 279 280 281 290 292 293 294c 296 298 |
| Severe skin irritation | If clothing becomes contaminated with product remove clothing immediately. If product on skin, immediately wash area with soap and water. | 330 332 340 342 |
| Severe eye irritation | If product in eyes, wash it out immediately with water. | 340 343 |
| | ***AFTER USE*** | |
| | Wash hands after use | 351 |
| | After each day's use wash gloves and contaminated clothing | 360 361 366 |

## 5.2 Repeated exposure risks assessed using PHED data

The risks associated with groundboom, airblast, aerial and hand application are discussed below. Exposure for these application methods was modelled using PHED, and the modelled exposure compared with the NOEL to obtain a margin of exposure (MOE). Other application methods, for which PHED models were not available, are addressed in Section 5.3.

### 5.2.1 Dermal and inhalation margins of exposure (MOEs)

Potential ***daily exposure*** is calculated using the following formula:

*Daily exp. (mg ai/day) = Unit exp. (mg ai/kg ai) x Max. appl. rate (kg ai/ha) x max. area treated (ha/day)*

The ***daily dose*** is calculated using the following formula:

*Daily dose (mg ai/kg bw/day) = Daily exp. (mg ai/day) x Dermal absorption / bodyweight (kg)*

The ***MOE*** is calculated using the following formula:

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

Table 28 summarises the MOEs calculated from combined dermal and inhalation exposures to dimethoate during mixing/loading and application of dimethoate products by various methods. These MOEs are based on the PHED exposure estimates in Table 12, and the NOELs derived in Section 2.

The main adverse health effect of dimethoate exposure is cholinesterase inhibition applicable to both inhalation and dermal risk assessments. Since dermal and inhalation exposures may occur simultaneously, exposure from the two routes were added together to obtain a total exposure, which was used to estimate occupational risk.

Considering that the NOEL used in the OHS risk assessment was established in humans, an MOE of 10 or more was considered acceptable, to account for possible intra-species (10x) variability.

**Table 28: MOE estimates for workers using dimethoate products**

| Estimate | Gloves # | MOE* for workers using dimethoate | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | Dermal | | | Inhalation | | | |
| | | *Mixer/Loader Dermal MOE* | *Applicator Dermal MOE* | *Total Dermal MOE* | *Mixer/Loader Inhalation MOE* | *Applicator Inhalation MOE* | *Total Inhalation MOE* | *Total MOE* |
| **Ground boom application** | | | | | | | | |
| Open cab (20.4 kg ai/day) **Scenario 3 and 13** | N | 2.1 | 450 | 2.1 | 260 | 430 | 160 | 2.1 |
| | Y | 270 | 450 | 170 | 260 | 430 | 160 | 83 |
| Closed cab (20.4 kg ai/day) **Scenario 3 and 14** | N | 2.1 | 1200 | 2.1 | 260 | 6900 | 250 | 2.1 |
| | Y | 270 | 1200 | 220 | 260 | 6900 | 250 | 120 |
| **Airblast/air-assisted application** | | | | | | | | |
| Open cab (120 kg ai/day) **Scenario 3 and 11** | N | 0.36 | 2.9 | 0.32 | 45 | 73 | 28 | 0.32 |
| | Y | 46 | 4.3 | 3.9 | 45 | 73 | 28 | 3.5 |
| Closed cab (120 kg ai/day) **Scenario 3 and 12** | N | 0.36 | (180) | 0.36 | 45 | 1130 | 43 | 0.35 |
| | Y | 46 | 56 | 25 | 45 | 1130 | 43 | 16 |

**Table 28 (Continued)**

| Estimate | Gloves # | Dermal | | | Inhalation | | | |
|---|---|---|---|---|---|---|---|---|
| | | *Mixer/Loader Dermal MOE* | *Applicator Dermal MOE* | *Total Dermal MOE* | *Mixer/Loader Inhalation MOE* | *Applicator Inhalation MOE* | *Total Inhalation MOE* | *Total MOE* |
| **Hand application using vehicle-mounted *low pressure* handwand** | | | | | | | | |
| **Scenario 3 and 18** (1.6 kg ai/day) | N | 27 | 6.5 | 5.2 | 3400 | 4.2 | 4.2 | 2.3 |
| | Y | 3400 | 11 | 11 | 3400 | 4.2 | 4.2 | 3.1 |
| | Y + respirator[@] | 3400 | 11 | 11 | 3400 | 42 | 42 | 8.7 |
| **Scenario 3 and 18** (0.6 kg ai/day) | N | 73 | 17 | 14 | 8820 | 11 | 11 | 6.2 |
| | Y | 9031 | 29 | 29 | 8820 | 11 | 11 | 8.0 |
| | Y + respirator[@] | 9031 | 29 | 29 | 8820 | 113 | 113 | 23 |
| **Scenario 3 and 18** (0.3 kg ai/day) | N | 145 | 35 | 28 | 17640 | 23 | 23 | 12.5 |
| | Y | 18062 | 59 | 59 | 17640 | 23 | 23 | 16.5 |
| | Y + respirator[@] | 18062 | 59 | 59 | 17640 | 225 | 225 | 46 |
| **Hand application using vehicle-mounted *high pressure* handwand** | | | | | | | | |
| **Scenario 3 and 19** (1.6 kg ai/day) | N | 27 | 43 | 17 | 3300 | 50 | 50 | 13 |
| | Y | 3400 | 122 | 122 | 3300 | 50 | 50 | 35 |
| **Hand application using knapsack/backpack** | | | | | | | | |
| **Scenario 3 and 20** (0.16 kg ai/day) | N | 270 | 1.6 | 1.6 | >10000 | 120 | 120 | 1.6 |
| | Y | >10000 | 3.3 | 3.3 | >10000 | 120 | 120 | 3.2 |
| | Y + respirator[@] | >10000 | 3.3 | 3.3 | >10000 | 1200 | 1200 | 3.3 |
| **Scenario 3 and 20** (0.06 kg ai/day) | N | 727 | 4 | 4 | >10000 | 320 | 320 | 4 |
| | Y | >10000 | 9 | 9 | >10000 | 320 | 320 | 9 |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | Y + respirator[@] | >10000 | 9 | 9 | >10000 | 3210 | 3210 | 9 |
| **Scenario 3 and 20** (0.03 kg ai/day) | N | 1453 | 9 | 9 | >100000 | 640 | 640 | 8.5 |
| | Y | >100000 | 18 | 18 | >100000 | 640 | 640 | 17.5 |
| | Y + respirator[@] | >100000 | 18 | 18 | >100000 | 6415 | 6415 | 18 |
| **Aerial application (high rate) by fixed-wing aircraft (open mixing/loading)** | | | | | | | | |
| **Scenario 3 and 7** (384 kg ai/day) | N | 0.11 | 65 | 0.11 | 14 | 243 | 13 | 0.11 |
| | Y | 14 | 149 | 13 | 14 | 243 | 13 | 6.5 |
| **Aerial application (high rate) by fixed-wing aircraft (closed mixing/loading)** | | | | | | | | |
| **Scenario 6 and 7** (384 kg ai/day) | N | 13.5 | 65 | 11 | 199 | 343 | 111 | 10 |
| | Y | 38 | 149 | 30 | 199 | 343 | 111 | 24 |
| **Aerial application (low rate) by fixed-wing aircraft (open mixing/loading)** | | | | | | | | |
| **Scenario 3 and 7** (163 kg ai/day) | N | 0.27 | 153 | 0.27 | 32 | 573 | 30 | 0.27 |
| | Y | 33 | 350 | 31 | 32 | 573 | 30 | 15 |
| **Aerial application (low rate) by fixed-wing aircraft (closed mixing/loading)** | | | | | | | | |
| **Scenario 6 and 7** (163 kg ai/day) | N | 32 | 153 | 29 | 469 | 1450 | 370 | 27 |
| | Y | 89 | 350 | 83 | 469 | 1450 | 370 | 68 |

# PHED estimates assume workers wearing long pants and long sleeved shirt.
Exposure values were converted to systemic doses based on 70 kg person, 5.1% dermal absorption and 100% inhalation absorption for dimethoate.
[*] Based on an oral NOEL of 0.2 mg/kg bw/d for dimethoate.
Dermal MOE = NOEL (0.2 mg/kg bw/d)/total dermal dose. Inhalation MOE = NOEL (0.2 mg/kg bw/d)/total inhalation dose.
Total MOE were calculated by using formula 1/Total MOE = 1/Dermal MOE + 1/Inhalation MOE
Exposures for the combined task (mixing/loading/application) were obtained by adding exposures during mixing/loading and application.
Values in parentheses represent estimates where observations on hand contamination in PHED database were not available.
Shaded values (for total exposures) indicate an unacceptable MOE (ie $\underline{>}$10). All values have been rounded to 2 significant figures.
[@] A half-facepiece respirator is considered to provide a 90% reduction in inhalation exposure.

### 5.2.2 Mixing and loading only

For mixing/loading only, the MOEs calculated using exposure estimates from PHED indicate that:

- The risks from **inhalation exposure** (without inhalational PPE) are acceptable during both open and closed mixing/loading up to 384 kg ai/day for all application methods.

- The risks of **dermal exposure** are acceptable for mixing/loading smaller amounts of a product (< 2 kg ai, for hand application) with or without gloves.

- The risks from **dermal exposure** are acceptable for workers mixing/loading quantities $\underline{\geq}$ 5 kg ai/d) only if gloves are worn. Gloves are not required for mixing/loading using closed systems for aerial application (up to 384 kg ai/day).

In summary, the risks from repeated exposure during mixing/loading are acceptable for all application methods, as long as gloves are worn. However, additional PPE is required during mixing and loading based on the acute hazards of the undiluted product (These additional PPE are set out in Table 28).

### 5.2.3 Groundboom, airblast and aerial application of the diluted product

For workers conducting application of the diluted products which contain up to 0.31% product or 0.125% dimethoate, and assuming that gloves are worn during mixing/loading:

- For ground boom application, the risks are acceptable for workers with or without gloves (during application) using either open or closed cabs. The MOE for combined exposure (i.e. the same worker performs both mixing/loading and application activities) is ≥83.

- For airblast/air assisted application, the risks from dermal exposure are unacceptably high (MOE <10) for workers conducting airblast spray with open cabs. Hence, only closed cabs fitted with air filters are recommended to reach an acceptable risk, (combined MOE of 16).

- Both dermal and inhalation risks are low during aerial application by fixed-wing aircraft. However combined dermal and inhalation risk (open mixing mixing/loading and application) provide unacceptable MOEs (even with gloves) at the highest label application rate of 384 kg ai/day.

In summary, when applying diluted dimethoate products, closed cabs are recommended for airblast/air-assisted application, and are preferred for ground boom application. The diluted spray, when prepared for agricultural use as per the label instructions, will contain less than 1% of the product, and in most cases less than 0.1% of the product. As such, the dilute spray is not expected to pose acute hazards during application. No additional PPE are required to protect workers (other than a single layer of clothing) during application using groundboom, airblast (enclosed cab) and aerial application.

Airblast application using open cabs is not supported. The following precautionary statement should appear on product labels: "Do Not apply using airblast equipment unless the operator is protected within an enclosed cab".

For ***aerial application***, mixer/loaders are expected to handle large quantities (up to 384 kg ai/day) of the product and potential exposure during mixing and loading can be high. However, since all aerial application facilities in Australia reportedly use closed mixing/loading systems and exposure for aerial applicators is low, PHED estimates indicated acceptable exposure risk for the combined task of mixing/loading and aerial application, even without gloves. The pilot will be protected from direct contact with the spray during aerial spraying.

### 5.2.4 Hand application of the diluted product

For hand application, the risks arising from vehicle-mounted *low pressure* handwand are unacceptable at the highest application rate (1.6 kg ai/d) even when gloves and a respirator are used. At the intermediate rate of 0.6 kg ai/d, risks are acceptable with gloves and respirator and at the lowest application rate of 0.3 kg ai/d, risks are acceptable wearing only single layer of clothes.

For vehicle-mounted *high pressure* handwand, the reported MOE for no gloves is marginally above an acceptable level at the highest application rate of 1.6 kg ai/d. As this PHED scenario is comprised of low confidence data, with only 9 hand replicates with gloves (all grades) and 11 replicates for inhalation exposure (all grades), there is insufficient confidence in these estimates for OCS to be satisfied that workers can safely apply dimethoate via vehicle-mounted high pressure handwand without the use of gloves.

Risks from knapsack/backpack application are unacceptable (MOE <10) even when gloves are used for application rates at and above 0.06 kg ai/d. A respirator is not required as dermal exposure is the main determinant of the MOE values. An acceptable combined exposure risk was determined for the low application rate of 0.03 kg ai/d, with the use of gloves.

In summary, OCS supports the use hand application equipment as follows: lowest rate only for knapsack/backpack (with gloves); low (single layer clothing) and intermediate (with gloves and respirator) rates for low pressure vehicle-mounted handwand and highest rate (with gloves) for high pressure handwand.

## 5.3 Repeated exposure risks for other use patterns

Qualitative risk assessments were conducted for the following methods of application: misting machine, dipping, seed treatment, and trunk injection The PHED Surrogate Exposure Guide does not contain worker exposure data for these activities. There are no other models/databases available to the OCS to estimate worker exposure during these activities.

### 5.3.1 Misting machine use

For mixing/loading only, there is not expected to be an appreciable repeat-dose risk to workers as long as gloves are worn. The risk assessment for airblast application demonstrates an acceptable MOE for workers mixing/loading up to 135 kg ai/day using open systems

(provided gloves are worn), and it is not expected that misting machine use would exceed this amount of active ingredient each day. Acute hazards expected from exposure to the concentrate are addressed in Section 5.1.

In tomatoes the product is applied using misting machines at a rate of 850 mL/ha with 70 L water/ha (1.2% product and 0.486% dimethoate in the mist). Acute hazards which may arise from exposure to the mist are eye irritation and skin sensitisation at this concentration.

Prediction of operator exposure from outdoor application of dimethoate by misting is difficult because these operations may be performed with a variety of equipment (i.e., hand-held foggers or backpack misters, semi-portable misters mounted on utility vehicles or trailers, or stationary misters), and will be affected by variables including the size, type and topography of the misting site, the wind speed and direction, and the ambient temperature. Operator exposure is likely to be greater when using portable or vehicle-mounted equipment than stationary equipment, but even in the latter case, exposure may occur if the operator remains on site to supervise application.

Considering the relatively high concentrations of the product and the active constituent in the mist and the anticipated repeated use of the product in tomatoes, exposure to dimethoate may be relatively high, particularly from inhalation exposure for which the presumed absorption rate is 100%.

Therefore, continued use of misting in tomatoes is not recommended unless supported by suitable data. This could include exposure data from operators under in-use conditions, and/or more detailed information on work rates and handling practices.

### 5.3.2 Pre-planting dips and post harvest/quarantine dipping of fruit and vegetables

For mixing/loading only, there is not expected to be an appreciable repeat-dose risk to workers as long as gloves are worn. The risk assessment for airblast application demonstrates an acceptable MOE for workers mixing/loading up to 135 kg ai/day using open systems (provided gloves are worn), and it is not expected that dipping use would exceed this amount of active ingredient each day. Acute hazards expected from exposure to the concentrate are addressed in Section 5.1.

For all post harvest/quarantine dips (including top-up solutions) and pre-plant dips, a solution of 50 – 150 mL/100 L is used which contains 0.05 – 0.15% product and 0.02 – 0.06% dimethoate. Dermal exposure to the dipping solution is possible when workers perform dipping activities, remove items for draining, and during planting. At these concentrations, acute hazards are not expected from exposure to the treatment solution.

In the absence of worker exposure data, a qualitative risk assessment was undertaken to address risks during dipping. Based on the concentration of dimethoate in the dipping solution (for plant or fruit dipping), the risk from acute exposure is expected to be low. However the activity can be repetitive.

It is appropriate to determine whether the repeated daily exposure is likely to exceed a tolerable exposure value. The NOEL for use in occupational risk assessment is 0.2 mg/kg bw/d. Using a BW of 70 kg, a dermal absorption value of 5.1%, and a MOE of 10, the tolerable daily dermal exposure for dimethoate is 27.5 mg/day (0.2 x 70 / 0.051 / 10). The most concentrated solution used for dipping is 0.06% dimethoate (0.6 mg/mL), so a worker

who is dermally exposed to less than 46 mL/day (27.5 / 0.6) of dipping solution would not exceed a tolerable exposure value.

Post-harvest dipping is generally a relatively low exposure activity, with whole bins of picked fruit being dipped and allowed to dry, followed by a partially or totally automated washing process. As such, a worker wearing gloves is unlikely to be exposed dermally to greater than 46 mL of dipping solution per day.

In summary, to address repeat-dose risks, workers using dimethoate products for plant (including lychee plant) or fruit dipping will need to wear elbow-length chemical resistant gloves.

**Table 29. Derivation of the Safety Directions**

| Acute or Repeat Exposure Risk | Safety Direction | Code |
|---|---|---|
| | ***MIXING OR USING*** | |
| Systemic toxicity (during preplant and post harvest dipping) | *(for preplant and post harvest dipping)* When using the prepared dip wear elbow-length chemical resistant gloves. | *(for preplant and post harvest dipping)* 279 282 290 294c |

### 5.3.3 Seed treatment

For seed treatment the recommended maximum mixing rate is 330 mL product in 1 L water (33% product; 13.2% dimethoate) per 50 kg of seed. Acute hazards expected from exposure to slurry are severe eye and skin irritation and skin sensitisation. Acute hazards expected from exposure to the concentrate are addressed in Section 5.1.

Seed treatment may be conducted on a large scale (commercial seed treatment), or can be conducted on a small scale by farmers (on-site seed treatment). These have been considered separately.

*Commercial seed treatment*

Commercial-scale seed treatment is likely to occur using mechanical systems, wherein dimethoate product containers are connected via an inlet pipe to the application equipment. Data held by OCS indicates that up to 100 tons of seed can be treated each day via mechanical processes, involving 4-6 workers. Therefore, each worker may handle up to 165 L of product, containing 66 kg dimethoate/day.

There is no appropriate model to estimate exposure during mechanical seed treatment. Workers may have dermal or inhalation exposure to dimethoate when opening containers, during closed loading, during mechanical agitation of the slurry and seeds, when cleaning equipment, and when bagging treated seed. Although the total exposure cannot be modelled with PHED, it is possible to estimate exposure during closed loading using the relevant PHED scenario for liquids, closed mixing/loading.

*PHED surrogate scenario 6:* All liquids, closed mixing and loading (MLOD)
[High confidence data for dermal exposure (AB grade): 31 hand replicates with gloves; Low confidence due to lack of "no glove" hand replicates; High confidence data for inhalation exposure without any protective equipment (AB grade): 27 replicates].

For this PHED scenario, the dermal unit exposure for a worker wearing gloves is 0.019 mg/kg ai handled and the inhalation unit exposure is 0.0002 mg/kg ai handled (see Table 11). Therefore, a worker handing 66 kg dimethoate per day would have a combined dermal and inhalation exposure of 1.3 mg dimethoate/day, or 0.018 mg/kg bw/d for a 70 kg worker. Comparing this exposure to the NOEL of 0.2 mg/kg bw/d gives an MOE of 11.

This assessment did not consider the additional exposure which may occur during mechanical agitation of the slurry and seeds, when cleaning equipment, and when bagging treated seed. Data held by OCS indicates that exposure during mechanical bagging of treated seed is similar to exposure during mixing/loading. Bagging is often conducted by the same workers involved in mixing/loading, and as a result the combined MOE for closed mixing/loading and mechanical bagging is likely to be less than 10.

Based on the available evidence the OCS concludes that the MOE for workers mixing/loading and bagging treated seeds is unacceptable.

*On-site seed treatment*

Labels direct the user to mix the slurry and seeds thoroughly in a drum or cement mixer. This indicates that at least some seed treatment will be performed by farmers on-site, using relatively open systems. Exposure to dimethoate is possible when opening containers, preparing the slurry, loading the prepared slurry, during the mixing process, and when bagging treated seed. There is no appropriate model to estimate exposure during these processes. Considering the relatively high concentrations of the product and the active constituent in the seed treatment slurry, exposure to dimethoate may be relatively high.

It is appropriate to determine whether exposure during seed treatment using open systems is likely to exceed a tolerable exposure value. As described (in Section 5.3.2), the tolerable daily dermal exposure for dimethoate is 27.5 mg/day. The seed treatment slurry contains 13.2% dimethoate (132 mg/mL), so a worker who is dermally exposed to more than 0.21 mL/day of slurry would exceed a tolerable exposure value. This is equivalent to around four drops of the seed slurry (0.05 mL/drop).

It is considered likely that dermal exposure would exceed 0.21 mL/day of slurry for workers conducting on-site seed treatment using relatively open systems, even if PPE were to be applied. Therefore, based on the available information, the OCS cannot conclude that there will not be an unacceptable exposure to workers using open systems for seed treatment.

*Conclusion*

Based on the available data, OCS does not support the use of dimethoate products for seed treatment, either on-site treatment by farmers or bulk treatment using mechanical systems, due to a high likelihood of unacceptable exposure to workers conducting these activities. Seed treatment is not recommended unless supported by suitable data. This could include exposure

data from operators under in-use conditions, and/or more detailed information on work rates and handling practices.

### 5.3.4 Trunk injection

For mixing/loading only, there is not expected to be an appreciable repeat-dose risk to workers as long as gloves are worn. The risk assessment for airblast application demonstrates an acceptable MOE for workers mixing/loading up to 135 kg ai/day using open systems (provided gloves are worn), and it is not expected that trunk injection would exceed this amount of active ingredient each day. Acute hazards expected from exposure to the concentrate are addressed in Section 5.1.

For tree injection the product is diluted 1:1 with water, and therefore the injection solution contains 50% product and 20% dimethoate. Acute hazards expected from exposure to this solution are severe eye and skin irritation and skin sensitisation. Based on the application method, hand and body exposure to the injection solution is possible during mixing/loading and when injecting into tree trunks. Inhalation exposure is also likely.

It is appropriate to determine whether workers conducting trunk injection are likely to exceed a tolerable exposure value. As described above, the tolerable daily dermal exposure for dimethoate is 27.5 mg/day. The trunk injection mixture contains 20% dimethoate (200 mg/mL), so a worker who is dermally exposed to more than 0.14 mL/day of injection mixture would exceed a tolerable exposure value. This is equivalent to around three drops of the injection solution (0.05 mL/drop).

It is considered likely that dermal exposure would exceed 0.14 mL/day of injection mixture for workers conducting trunk injection, even if PPE were to be applied. Therefore, based on the available information, the OCS cannot conclude that there will not be an unacceptable exposure to workers during trunk injection.

In conclusion, based on the available data, OCS does not support the use of dimethoate products for trunk injection, due to a high likelihood of unacceptable exposure to workers conducting these activities. Continued use of dimethoate products for trunk injection is not recommended unless supported by suitable data. This could include exposure data from operators under in-use conditions, and/or more detailed information on work rates and handling practices.

### 5.3.5 FAISD Entry for Wettable Powder (WP 88 g/kg or less)

There are no currently registered dimethoate products in the form of wettable powders. Therefore, this entry should be deleted from the FAISD.

## 5.4 Re-entry or re-handling

The main routes of exposure for workers entering treated areas or handling treated fruits and vegetables/plants/seeds are dermal and inhalational.

### 5.4.1 Exposure and risks for re-entry situations in crops

*Inhalation exposure*

Dimethoate products containing 100-400 g/L of dimethoate are of low to moderate inhalation toxicity. Therefore, the following re-entry statement should apply to address the risk of acute inhalation toxicity:

For glasshouses and other confined areas, do not re-enter until spray deposits have dried and areas has been thoroughly ventilated.

*Dermal exposure*

Workers can be exposed to dimethoate residues and its degradation products when undertaking crop management activities such as, irrigation and scouting in all crops, thinning and harvesting in orchard crops, tying and training in vine crops and, harvesting and pruning in ornamental crops.

According to the foliar residue studies provided on apples, tomatoes and lettuce, the half-life of dimethoate varied from 0.23 days in Florida to 5.13 days in Washington. The difference was mainly due to the relative humidity and rainfall received during the trials at different locations. The half-life was shortened when relative humidity was over 80% and with more rainfall. Considering Australian weather conditions (relative humidity rarely goes above 80%), the longest half-life obtained in the residue trials (5 days) was selected for use in the re-entry risk assessment for dimethoate.

The metabolite of dimethoate, omethoate has a longer half-life (up to 34.6 days on apple foliage in Washington) compared to dimethoate (5.13 days on apple foliage in Washington). However, in the DFR studies described above, omethoate occurred at relatively very low levels compared to dimethoate, after each application. In general the levels of omethoate residues remained at a level which was less than 10% of the levels of dimethoate residues. The maximum post-day 0 omethoate residues were 0.023 µg/cm$^2$ on day 3 following application to tomatoes (Table 20), and similar values were obtained on day 3 for lettuce (Table 24). An MOE was calculated[2] using this maximum residue level, and the highest transfer coefficients for these crop types (1500 for lettuce). The MOE for re-entry exposure to omethoate is 380, and is therefore acceptable (>100) at the maximum measured residue level. Based on the calculated MOE, the degradation and half-life of omethoate were not considered further in the current dimethoate post application risk assessment.

For the re-entry risk assessment in apples, tomatoes and lettuce, the mean highest DFR value obtained soon after the second spray has dried (highest from the three trials for each crop) as the worst scenario was selected and standardised for the Australian application rate as indicated on product labels, as shown in Table 30.

[2] Omethoate dermal exposure = 0.023(DFR)*2500(TC)*8(T) /70(BW) /1000 = 0.0066 mg/ kg bw. The dermal NOEL for omethoate is 2.5 mg/kg bw/day (from a dermal study in rabbits so no adjustment for dermal absorption is required). The MOE is therefore 380 (2.5 / 0.0066) compared with an acceptable MOE of 100.

**Table 30: Comparison of dimethoate products use rates between the US and Australia**

| | | **The US (DFR studies)*** | **Australia (standardised)** |
|---|---|---|---|
| Apples | Application rate (kg ai/ha) | 1.13 | 0.9 – 1.8<br>(2.25 – 4.5 L product/ha) |
| | DFR (μg/cm$^2$) | 2.461 (Washington trial) | 1.96 – 3.9 |
| Tomatos | Application rate (kg ai/ha) | 0.6 | 0.3-0.34<br>(750-850 mL product/ha) |
| | DFR (μg/cm$^2$) | 1.111 (Florida trial) | 0.63 |
| Lettuce | Application rate (kg ai/ha) | 0.28 | 0.32<br>(800 mL product/ha) |
| | DFR (μg/cm$^2$) | 0.610 (California trial) | 0.697 |

* for each crop type, the highest DFR was chosen (at 4 h after second application) from three trial sites.

Dimethoate products are used in almost all crop types and therefore, re-entry exposure needs to be estimated for workers entering all types of treated crop areas.

Dermal exposure to dimethoate residues when undertaking crop management activities (after the spray has dried) can be calculated using the following formula:

$$\text{Dermal exposure (mg/kg bw)} = \frac{\text{DFR (μg/cm}^2\text{) x TC (cm}^2\text{/h) x T (h) / BW (kg)}}{1000 \text{ (}\textit{to convert to mg/kg exposure}\text{)}}$$

The Transfer coefficient (TC) is the amount of treated foliage that a worker contacts while performing a specific activity in a given period of time (cm$^2$/h). TC varies with the crop and crop management activity. As Cheminova Agro A/S is in the US re-entry task force, the OCS used the following TC values and default parameters indicated in the US Occupational Post-Application Risk Assessment Calculator (US EPA Policy 003.1).

TC values (cm$^2$/h) used:

Berry crops (including low bush blueberries, cranberries, strawberries) -
Low 400 for irrigation, scouting, mulching, weeding, pruning, thinning
High 1500 for harvesting, hand pruning, pinching, training

Bananas, hops, tobacco -
Medium 1300 for irrigation and scouting mature plants
High 2000 for hand harvesting, thinning, topping, stripping, pruning

Field crops – low/medium (low to medium including beans, peas, canola, peanut, cotton) -
Medium 1500 for irrigation scouting thinning, weeding mature/high foliage plants
High 2500 for hand harvesting

Field crops - tall (tall including corn, sunflowers, sorghum) –
High 1000 for scouting, irrigation, weeding mature/full foliage plants
Very high 17000 for sweetcorn hand harvest or detasseling

Cut flowers (floriculture crops/ornamentals) -

| | |
|---|---|
| Low | 2500 for irrigation, scouting, thinning, weeding immature/low foliage plants |
| Medium | 4000 for irrigation, scouting mature/high foliage plants |
| High | 7000 for hand harvesting, pruning, thinning, pinching |

Deciduous trees (including apples, apricots, cherries, figs, nectarines, peaches, pears, plums/prunes, pomegranates, pome and stone fruit) -

| | |
|---|---|
| High | 3000 for harvesting, pruning, training |
| Very high | 8000 for thinning |

Evergreen fruit trees (including avocadoes, conifers, dates, grapefruit, lemons, oranges, papaya, citrus, pawpaw, mangoes) –

| | |
|---|---|
| Low | 1000 for irrigation, scouting, hand weeding |
| Medium | 3000 for pruning, tying |
| High | 8000 for hand harvesting, thinning |

Root vegetables (including table beets, carrots, onions, potatoes, turnips) -

| | |
|---|---|
| Medium | 1500 for irrigation and scouting mature plants |
| High | 2500 for hand harvesting |

Cucurbit vegetables (cantelope, cucumbers, gourds, pumpkins, squash, watermelon, zucchini)

| | |
|---|---|
| Medium | 1500 for irrigation and scouting mature plants |
| High | 2500 for hand harvesting, pulling, thinning, turning |

Fruiting vegetables (including eggplant, okra, bell and chili peppers, tomatoes) –

| | |
|---|---|
| Medium | 700 for irrigation and scouting mature plants |
| High | 1000 for hand harvesting, pruning, staking, tying |

Brassica (broccoli, brussel sprouts, cabbage, cauliflower)

| | |
|---|---|
| Medium | 4000 for scouting mature plants |
| High | 5000 for hand harvesting, pruning, topping, tying mature plants |

Leafy vegetables (bok choy, celery, collards, greens, kale, herbs, lettuce/romaine, napa, parsley, swiss chard, spinach, watercress) –

| | |
|---|---|
| Medium | 1500 for irrigation and scouting mature plants |
| High | 2500 for hand harvesting, pruning, thinning mature plants |

Stem and stalk vegetables (artichoke, asparagus, pineapple) –

| | |
|---|---|
| Medium | 500 for irrigation and scouting mature plants |
| High | 1000 for hand harvesting, pruning artichokes |

Vine and trellis crops (including polebeans, blackberries, highbush blueberries, grapes, kivi, raspberries) –

| | |
|---|---|
| Medium | 1000 for scouting, training, tying |
| High | 5000 for hand harvesting, leaf pulling, thinning, pruning, training/tying grapes |
| Very high | 10,000 for grape girdling and cane turning |

No TC value is available in the US Occupational Post-Application Risk Assessment Calculator (US EPA Policy 003.1) for pastures. Considering the post application activities expected in pastures (irrigation and scouting), the OCS used the same TC value as indicated

for leafy vegetables during irrigation and scouting (TC 1500). Only mechanical harvesting is expected for pastures and therefore, a higher TC value is not considered in the post application risk assessment.

According to the US Occupational Post-Application Risk Assessment Calculator (US EPA Policy 003.1), the following default parameters were used in the exposure estimates:

The initial dislodgeable foliar residues (DFR) for crops other than apples, tomatoes and lettuce is 20% of dimethoate application rate (eg: 0.2 kg/ha or 2 µg/cm$^2$ for an application rate of 1 kg ai/ha). The DFR values of dimethoate obtained from the three studies provided were standardised to Australian application rates and used in the re-entry risk assessment for workers entering apples orchards, tomato and lettuce fields (Table 31).

Duration of the re-entry activity (T) = 8 h

Body weight (BW) = 70 kg

For all cropping situations, the longest half-life of 5 days obtained from the dimethoate residue studies (section 4.2.4) was used to estimate the dissipation rate per day. Thus a daily dissipation rate of 13% was calculated for a half-life of 5 days[3].

Dermal exposure to workers carrying out crop management activities was calculated using the above formula and the absorbed dose was estimated using the dermal absorption factor of 5.1% for dimethoate.

Margins of exposure (MOE) for re-entry workers were estimated using an oral NOEL of 0.2 mg/kg bw/d from a 14-57 day study in humans (Table 31). MOE > 10 are regarded as acceptable to set a safe re-entry period for workers carrying out crop management activities. In some cases an unacceptable MOE was obtained for exposure on day 0. For these exposure scenarios, the MOE was calculated on successive days using the dissipation rate of 13%/day until an MOE > 10 was obtained (Table 32).

[3] Using the compounding formula $DFR_n=DFR_0(1+i)^n$ where $DFR_n$ is the DFR after $n$ days and $i$ is the daily dissipation rate; then $i=(DFR_n/DFR_0)^{1/n}-1$ or $i = (50/100)^{1/5}-1 = -12.95$.

**Table 31. Dimethoate re-entry exposure and day 0 MOEs for various crop types**

| Crop type | Activities | TC ($cm^2$/hr) | Dilution Rate (mL/100L)[1] | Spray Application Rate (L/ha)[2] | Maximum Product Application Rate[1] (mL/ha) | Maximum Dimethoate Application Rate (kg ai/ha) | DFR[3] (µg/$cm^2$) | Dermal Exposure[4] (mg/kg bw) | Systemic Exposure[5] (mg/kg bw) | Day 0 MOE[6] |
|---|---|---|---|---|---|---|---|---|---|---|
| Berry crops | Low | 400 | | | 800 | 0.32 | 0.64 | 0.029257 | 0.001492 | 130 |
| | High | 1500 | | | 800 | 0.32 | 0.64 | 0.109714 | 0.005595 | 36 |
| Bananas, hops, tobacco | Medium | 1300 | 75 | 1500 | 1125 | 0.45 | 0.9 | 0.133714 | 0.006819 | 29 |
| | High | 2000 | 75 | 1500 | 1125 | 0.45 | 0.9 | 0.205714 | 0.010491 | 19 |
| Field crops - Low and Medium | Medium | 1500 | | | 800 | 0.32 | 0.64 | 0.109714 | 0.005595 | 36 |
| | High | 2500 | | | 800 | 0.32 | 0.64 | 0.182857 | 0.009326 | 21 |
| Field crops - tall | High | 1000 | | | 800 | 0.32 | 0.64 | 0.073143 | 0.00373 | 54 |
| | Very high | 17000 | | | 800 | 0.32 | 0.64 | 1.243429 | 0.063415 | 3.2 |
| Cut flowers | Low | 2500 | 75 | 600 | 450 | 0.18 | 0.36 | 0.102857 | 0.005246 | 38 |
| | Medium | 4000 | 75 | 600 | 450 | 0.18 | 0.36 | 0.164571 | 0.008393 | 24 |
| | High | 7000 | 75 | 600 | 450 | 0.18 | 0.36 | 0.288 | 0.014688 | 14 |
| Deciduous trees | High | 3000 | | | NA | NA | 3.9 | 1.337143 | 0.068194 | 2.9 |
| | Very high | 8000 | | | NA | NA | 3.9 | 3.565714 | 0.181851 | 1.1 |
| Evergreen fruit trees | Low | 1000 | 150 | 5000 | 7500 | 3 | 6 | 0.685714 | 0.034971 | 5.7 |
| | Medium | 3000 | 150 | 5000 | 7500 | 3 | 6 | 2.057143 | 0.104914 | 1.9 |
| | High | 8000 | 150 | 5000 | 7500 | 3 | 6 | 5.485714 | 0.279771 | 0.7 |
| Root vegetables | Medium | 1500 | | | 750 | 0.3 | 0.6 | 0.102857 | 0.005246 | 38 |
| | High | 2500 | | | 750 | 0.3 | 0.6 | 0.171429 | 0.008743 | 23 |
| Cucurbit vegetables | Medium | 1500 | | | 750 | 0.3 | 0.6 | 0.102857 | 0.005246 | 38 |
| | High | 2500 | | | 750 | 0.3 | 0.6 | 0.171429 | 0.008743 | 23 |
| Fruiting vegetables | Medium | 700 | | | NA | NA | 0.63 | 0.0504 | 0.00257 | 78 |
| | High | 1000 | | | NA | NA | 0.63 | 0.072 | 0.003672 | 55 |

**Table 31 (continued)**

| Crop type | Activities | TC ($cm^2$/hr) | Dilution Rate (mL/100L)[1] | Spray Application Rate (L/ha)[2] | Maximum Product Application Rate[1] (mL/ha) | Maximum Dimethoate Application Rate (kg ai/ha) | DFR[3] (µg/$cm^2$) | Dermal Exposure[4] (mg/kg bw) | Systemic Exposure[5] (mg/kg bw) | Day 0 MOE[6] |
|---|---|---|---|---|---|---|---|---|---|---|
| Brassica | Medium | 4000 | | | 800 | 0.32 | 0.64 | 0.292571 | 0.014921 | 13 |
| | High | 5000 | | | 800 | 0.32 | 0.64 | 0.365714 | 0.018651 | 11 |
| Leafy vegetables | Medium | 1500 | | | NA | NA | 0.697 | 0.119486 | 0.006094 | 33 |
| | High | 2500 | | | NA | NA | 0.697 | 0.199143 | 0.010156 | 20 |
| Stem and stalk vegetables | Medium | 500 | | | 750 | 0.3 | 0.6 | 0.034286 | 0.001749 | 110 |
| | High | 1000 | | | 750 | 0.3 | 0.6 | 0.068571 | 0.003497 | 57 |
| Vine and trellis crops | Medium | 1000 | | | 800 | 0.32 | 0.64 | 0.073143 | 0.00373 | 54 |
| | High | 5000 | | | 800 | 0.32 | 0.64 | 0.365714 | 0.018651 | 11 |
| | Very high | 10000 | | | 800 | 0.32 | 0.64 | 0.731429 | 0.037303 | 5.4 |
| Pastures | Medium | 1500 | 75 mL/100L | 100L/ha | 750 | 0.3 | 0.6 | 0.102857 | 0.005246 | 38 |

NA: DFR obtained from residue study rather than derived from application rate.

[1] Values for maximum product/ha either taken directly from **Error! Reference source not found.**, or derived from application rates and dilution rates in **Error! Reference source not found.**.

[2] Default spray volumes of 5000 L/ha for citrus (evergreen fruit tree), 600 L/ha for ornamentals (cut flowers) and 1500 L/ha for other crops.

[3] The initial dislodgeable foliar residues (DFR) for crops other than apples (deciduous trees), tomatoes (fruiting vegetables) and lettuce (leafy vegetables) is 20% of dimethoate application rate.

[4] Dermal exposure = DFR (µg/$cm^2$) x TC ($cm^2$/h) x T (h) / BW (kg) / 1000; based on 8 hours/day re-entry exposure and 70 kg BW.

[5] Systemic exposure = Dermal exposure * 5.1% dermal absorption.

[6] The MOE is based on an oral NOEL of 0.2 mg/kg bw/d for dimethoate. MOEs have been rounded to 2 significant figures. Shaded values indicate an unacceptable MOE.

**Table 32. Dimethoate re-entry exposure after day 0 and MOEs for select crop types**

| | Field crops - tall | | Deciduous trees | | | | Evergreen fruit trees | | | | | | Vine and trellis crops | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Day** | **Very high** | | **High** | | **Very high** | | **Low** | | **Medium** | | **High** | | **Very high** | |
| | DFR | MOE* | DFR | MOE* | DFR | MOE* | DFR | MOE* | DFR | MOE* | DFR | MOE* | DFR | MOE* |
| 0 | 0.64 | 3.2 | 3.9 | 2.9 | 3.9 | 1.1 | 6 | 5.7 | 6 | 1.9 | 6 | 0.7 | 0.64 | 5.4 |
| 1 | 0.557 | 3.6 | 3.39 | 3.4 | 3.39 | 1.3 | 5.22 | 6.6 | 5.22 | 2.2 | 5.22 | 0.8 | 0.557 | 6.2 |
| 2 | 0.484 | 4.2 | 2.95 | 3.9 | 2.95 | 1.5 | 4.54 | 7.6 | 4.54 | 2.5 | 4.54 | 0.9 | 0.484 | 7.1 |
| 3 | 0.421 | 4.8 | 2.57 | 4.5 | 2.57 | 1.7 | 3.95 | 8.7 | 3.95 | 2.9 | 3.95 | 1.1 | 0.421 | 8.1 |
| 4 | 0.367 | 5.5 | 2.23 | 5.1 | 2.23 | 1.9 | 3.44 | 10.0 | 3.44 | 3.3 | 3.44 | 1.2 | 0.367 | 9.4 |
| 5 | 0.319 | 6.3 | 1.94 | 5.9 | 1.94 | 2.2 | | | 2.99 | 3.8 | 2.99 | 1.4 | 0.319 | 10.8 |
| 6 | 0.278 | 7.3 | 1.69 | 6.8 | 1.69 | 2.5 | | | 2.60 | 4.4 | 2.60 | 1.6 | | |
| 7 | 0.241 | 8.4 | 1.47 | 7.8 | 1.47 | 2.9 | | | 2.26 | 5.1 | 2.26 | 1.9 | | |
| 8 | 0.210 | 9.6 | 1.28 | 8.9 | 1.28 | 3.4 | | | 1.97 | 5.8 | 1.97 | 2.2 | | |
| 9 | 0.183 | 11.0 | 1.11 | 10.3 | 1.11 | 3.9 | | | 1.71 | 6.7 | 1.71 | 2.5 | | |
| 10 | | | | | 0.969 | 4.4 | | | 1.49 | 7.7 | 1.49 | 2.9 | | |
| 11 | | | | | 0.843 | 5.1 | | | 1.30 | 8.8 | 1.30 | 3.3 | | |
| 12 | | | | | 0.733 | 5.8 | | | 1.13 | 10.1 | 1.13 | 3.8 | | |
| 13 | | | | | 0.638 | 6.7 | | | | | 0.982 | 4.4 | | |
| 14 | | | | | 0.555 | 7.7 | | | | | 0.854 | 5.0 | | |
| 15 | | | | | 0.483 | 8.9 | | | | | 0.743 | 5.8 | | |
| 16 | | | | | 0.420 | 10.2 | | | | | 0.646 | 6.6 | | |
| 17 | | | | | | | | | | | 0.562 | 7.6 | | |
| 18 | | | | | | | | | | | 0.489 | 8.8 | | |
| 19 | | | | | | | | | | | 0.426 | 10.1 | | |

*MOE for day X calculated by dividing the NOEL (0.2 mg/kg bw/d) by the exposure ($DFR_{dayX}$ x TC x 8 hours x 5.1% / BW / 1000).

Based on the acceptable MOE values obtained (≥10) by using the US Occupational Post-Application Risk Assessment Calculator (US EPA Policy 003.1) for various crops and activities (Table 31, Table 32), the following re-entry periods (0 – 19 days) are considered necessary to carry out crop management activities safely (Table 33).

**Table 33: Re-entry intervals (REI) for different crops**

| CROP | REI (day) | Post-application activities |
|---|---|---|
| Field crops - tall<br>Corn, sunflowers, sorghum | 9 | sweetcorn hand harvest or detasseling |
| Deciduous trees | 9 | harvesting, pruning, training |
| Apples, apricots, cherries, figs, nectarines, peaches, pears, plums/prunes, pomegranates, pome and stone fruit | 16 | thinning |
| Evergreen fruit trees | 4 | irrigation, scouting, hand weeding |
| Avocadoes, conifers, dates, grapefruit, lemons, oranges, papaya, citrus, pawpaw, mangoes | 12 | pruning, tying |
| | 19 | hand harvesting, thinning |
| Vine and trellis crops<br>Polebeans, blackberries, highbush blueberries, grapes, kiwi, raspberries | 5 | Grape girdling and cane turning |
| All other crops | 0[@] | For all activities. |

@For REI 0 day: No entry until the spray has dried.

### 5.4.2 Conclusions for re-entry situations in crops

The labels recommend 1 - 28 days withholding periods (WHP) depending on the crop (Table 5). The OCS considered the recommended WHP on the product label for a particular crop, when recommending a re-entry period for harvesting. For some crops re-entry periods are longer than existing WHP.

Some hand-harvested crops have withholding periods that are shorter than the re-entry interval. Specifically, the withholding period for fruit trees is 7 days, however the re-entry period for deciduous tree (e.g. apples, pears) is 9 days and for evergreen fruit trees (e.g. citrus) is 19 days. This means that hand harvesters of dimethoate-treated food crops including apples, pears and citrus crops will be required to wear personal protective equipment including cotton overalls buttoned to the neck and wrist (or equivalent clothing) and gloves, in order to achieve suitable margins of exposure.

Based on the assessment, the following re-entry statements are recommended:

<u>Corn, sunflowers, sorghum</u>

Do not allow entry into treated areas for irrigation, scouting, weeding mature/full foliage plants until the spray has dried. Do not allow entry into treated areas for 9 days for sweetcorn hand harvesting or detasseling. If prior 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.

Deciduous trees

Do not allow entry into treated areas for 9 days for harvesting, pruning or training, and for 16 days for thinning. If prior 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.

Evergreen trees

Do not allow entry into treated areas for 4 days for irrigation, scouting, or hand weeding, and for 12 days for pruning or tying. Do not allow entry into treated areas for 19 day for hand harvesting or thinning. If prior 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.

Vine/trellis (pole beans, blackberries, highbush blueberries, grapes, kiwi, raspberries)

Do not allow entry into treated areas for scouting, hand harvesting, leaf pulling, thinning, pruning, or training/tying until the spray has dried. Do not allow entry into treated areas for 5 days for grape girdling or cane turning. If prior 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.

For all other crops

Do not enter treated areas until the spray has dried, unless wearing cotton overalls buttoned to the neck and wrist (or equivalent clothing) and chemical resistant gloves. Clothing must be laundered after each day's use.

### 5.4.3 Rehandling treated seed / fruits / vegetables

Workers handling treated seeds, fruits and vegetables and lychee plants may be exposed to dimethoate and its degradation products.

Farmers in the cropping process rehandle treated seed. Seed is transferred from bags or bulk containers to sowing (planting/drilling) equipment. There are no data to estimate inhalation exposure to the product dust from agitated dried seed during this process. Dimethoate products have moderate inhalation toxicity and skin and eye irritation. As the OCS does not support seed treatment, no rehandling statement for seed treatment has been recommended at this time.

The solutions for dipping fruits/vegetables and plants contain only a small amount of dimethoate products. However workers repeatedly handling fruit/vegetables or plants while they are still wet may be exposed to unacceptable amounts of dimethoate, and a rehandling statement is required to prevent handling dipped fruit/vegetables before the product solution has dried. Dermal exposure to wet plants is expected when planting treated lychee plants in the field, and the rehandling statement will recommend the use of gloves when performing this activity.

For cut flowers, marketers of the flowers and the public buying those flowers may be exposed to foliar residue, however this exposure is expected to be minimal. Workers involved in hand harvesting cut flowers have acceptable MOEs at Day 0 (Table 31) and it is not expected that marketers or the public will have higher exposure than workers involved in hand harvesting, as most of the foliage will be left on the plants. Therefore, the risk to marketers of the flowers and to the public buying those flowers is considered negligible.

The following rehandling statements are recommended:

For post-harvest dipping of fruit and vegetables, and for pre-plant dipping of plants

Do not handle treated fruit, vegetable or plant until the product solution has dried. If prior handling is required, wear elbow-length chemical resistant gloves.

## 5.5 Recommendations – occupational use

### 5.5.1 Product registration

Based on the likelihood of an unacceptable risk to operators, the following uses of dimethoate should be deleted from product labels unless supported by additional exposure studies or detailed information on work rates and handling practices:

- Outdoor and indoor application by fogging or misting.
- Seed treatment
- Trunk injection

### 5.5.2 Safety directions

The current safety directions prescribed in the FAISD handbook for professional products containing dimethoate are shown below.

**Existing Safety Directions**

| **EC 400 g/L and less** | |
|---|---|
| 120 130 131 132 133 190 210 211 220 223 279 280 281 290 292 294 296 298 279 282 290 292 294 298 300 303 340 342 350 360 361 362 364 366 | Product is poisonous if absorbed by skin contact or inhaled or swallowed. Repeated minor exposure may have a cumulative effect. Avoid contact with eyes and skin. Do not inhale spray mist. When opening the container and preparing spray, wear cotton overalls buttoned to the neck and wrist and a washable hat, elbow-length PVC gloves and face shield and impervious footwear. When using the prepared spray, wear cotton overalls buttoned to the neck and wrist and a washable hat, elbow-length PVC gloves and impervious footwear and a half facepiece respirator with combined dust and gas cartridge. 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, face shield, respirator (if rubber wash with detergent and warm water) and contaminated clothing. |
| **WP 88 g/kg or less** | |
| 120 130 131 132 133 190 210 211 220 221 | Product is poisonous if absorbed by skin contact or inhaled or |

| | |
|---|---|
| 223 279 280 281 290 292 294 296 298 279 282 290 292 294 298 300 303 340 342 350 360 361 362 364 366 | swallowed. Repeated minor exposure may have a cumulative effect. Avoid contact with eyes and skin. Do not inhale dust or spray mist. When opening the container and preparing spray wear cotton overalls buttoned to the neck and wrist and a washable hat, elbow-length PVC gloves and face shield and impervious footwear. When using the prepared spray wear cotton overalls buttoned to the neck and wrist and a washable hat, elbow-length PVC gloves and impervious footwear and a half facepiece respirator with combined dust and gas cartridge. 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, face shield, respirator (if rubber wash with detergent and warm water) and contaminated clothing. |

The recommended revised safety directions are shown below. Extrapolated toxicities of individual products are shown in Appendix V.

**Amended safety directions**

| **EC 400 g/L or less with cyclohexanone** | |
|---|---|
| 130 131 132 133 190 207 211 180 210 211<br><br>279 280 281 290 292 293 294c 296 298<br><br>279 282 (spray) (or dip *for preplant and post harvest dipping*) 290 294c<br>289 420 (*vehicle mounted low pressure equipment)* 290 292b 294c 300 307<br><br>330 332 340 342 340 343 351 360 361 362 364 366 | Poisonous if absorbed by skin contact, inhaled or swallowed. Repeated minor exposure may have a cumulative poisoning effect. Will damage eyes and skin. Repeated exposure may cause allergic disorders. Avoid contact with eyes and skin.<br><br>When opening the container and preparing spray wear cotton overalls buttoned to the neck and wrist, a washable hat, a PVC or rubber apron, elbow-length chemical resistant gloves, a face shield and impervious footwear.<br><br>When using the prepared spray (or dip *for preplant and post harvest dipping*) wear elbow-length chemical resistant gloves.<br><br>If applying by hand by *vehicle mounted low pressure equipment* wear cotton overalls buttoned to the neck and wrist, elbow-length chemical resistant gloves and a half face-piece respirator with organic vapour/gas cartridge or canister<br><br>If clothing becomes contaminated with product remove clothing immediately. If product on skin, immediately wash area with soap and water. If product in eyes, wash it out immediately with water. Wash hands after use. After each day's use wash gloves, face-shield, respirator and contaminated clothing. |

***Important Note: there are daily restrictions on the amount of product that can be applied by hand (see section 5.2.4). Labels will require amending to reflect these reduced application rates***

### *Entry for Wettable Powder (WP 88 g/kg or less)*

There are no currently registered dimethoate products in the form of wettable powders. Therefore, this entry should be deleted from the FAISD.

### 5.5.3 Re-entry and re-handling statements

The following re-entry statement is recommended on the basis of low to moderate acute inhalation toxicity:

For glasshouses and other confined areas, do not re-enter until spray deposits have dried and areas has been thoroughly ventilated.

Some hand-harvested crops have withholding periods that are shorter than the re-entry interval. This means that hand harvesters of dimethoate-treated food crops including apples, pears and citrus crops will be required to wear personal protective equipment including cotton overalls buttoned to the neck and wrist (or equivalent clothing) and gloves, in order to achieve suitable margins of exposure.

The following re-entry statements are recommended:

Corn, sunflowers, sorghum

Do not allow entry into treated areas for irrigation, scouting, weeding mature/full foliage plants until the spray has dried. Do not allow entry into treated areas for 9 days for sweetcorn hand harvesting or detasseling. If prior 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.

Deciduous trees

Do not allow entry into treated areas for 9 days for harvesting, pruning or training, and for 16 days for thinning. If prior 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.

Evergreen trees

Do not allow entry into treated areas for 4 days for irrigation, scouting, or hand weeding, and for 12 days for pruning or tying. Do not allow entry into treated areas for 19 day for hand harvesting or thinning. If prior 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.

Vine/trellis (pole beans, blackberries, highbush blueberries, grapes, kiwi, raspberries)

Do not allow entry into treated areas for scouting, hand harvesting, leaf pulling, thinning, pruning, or training/tying until the spray has dried. Do not allow entry into treated areas for 5 days for grape girdling or cane turning. If prior 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.

For all other crops

Do not enter treated areas until the spray has dried, unless wearing cotton overalls buttoned to the neck and wrist (or equivalent clothing) and chemical resistant gloves. Clothing must be laundered after each day's use.

The following rehandling statements are recommended:

For post-harvest dipping of fruit and vegetables, and for pre-plant dipping of plants

Do not handle treated fruit, vegetable or plant until the product solution has dried. If prior handling is required, wear elbow-length chemical resistant gloves.

### 5.5.4 Precautionary statements

Airblast application using open cabs is not supported. The following precautionary statement should appear on all registered product labels that include airblast spray application:

**"Do Not apply using airblast equipment unless the operator is protected within an enclosed cab".**

Hand application of dimethoate products is only supported at low or intermediate application rates as specified on the label.

OCS recommends that upper label application rates are amended as follows:

Vehicle-mounted *high pressure* handwand: max application of 1.6 kg ai/d or 4L product/d (400 mL product /100 L)
Vehicle-mounted *low pressure* handwand: max application of 0.6 kg ai/d or 1.5L product/d (150 mL product /100L)
Knapsack/backpack application: max application of 0.03 kg ai/d or 0.075L product (75 mL product /100 L)

## 5.6 Recommended hazard classification statements

Dimethoate is listed in the National Occupational Health and Safety Commission (NOHSC) Hazardous Substances Information System (SWA 2011) with the following risk and safety phrases:

Risk phrases

| | |
|---|---|
| R21 | Harmful in contact with skin |
| R22 | Harmful if swallowed |

Safety phrases

| | |
|---|---|
| S36 | Wear suitable protective clothing. |
| S37 | Wear suitable gloves |

The following cut-off concentrations apply for dimethoate products:

| | |
|---|---|
| Conc. ≥ 25% | R21/22 |

During the current review, the OCS has re-classified dimethoate as follows according to the toxicology data available and applying the NOHSC (SWA) approved criteria:

*Acute effects*
Based on the acute oral (LD50 25-200 mg/kg), dermal (LD50 50-400 mg/kg) and potential inhalation toxicity of dimethoate, the risk phrases R25 'Toxic if swallowed', R24 'Toxic in contact with skin' and R23 'Toxic by inhalation' should be included.

*Repeat dose effects*
The repeat dose oral LOEL was 0.23 mg/kg bw/d in rats and 0.4 mg/kg bw/d in humans (blood ChE inhibition & adverse effects). This would indicate that dimethoate meets the criteria for R48 'Danger of serious damage to health by prolonged exposure' (ie LOEL, rat < 5 mg/kg bw/d). There are no repeat dose dermal or inhalation studies available.

*Irritation*
The report concludes that dimethoate was not an irritant to the skin and only a slight eye irritant in rabbits. Therefore dimethoate does NOT meet the approved criteria for classification with R36 'Irritating to eyes' and R38 'Irritating to skin'.

*Skin sensitisation*
Although dimethoate did not cause skin sensitisation in a closed patch test (dimethoate as a paste in paraffin oil) in guinea pigs (Madison 1984), a positive result was obtained in guinea pigs in the Buehler test using a dimethoate product which is similar to that available on the Australian market (Bollen 2001). Also, omethoate (the main metabolite of dimethoate) was a sensitiser to guinea pig skin in the open epicutaneous test (OCS Chemical Review Programme report on omethoate). Hence, a recommendation is made for R43 'May cause sensitisation by skin contact' to be included in the NOHSC hazard classification.

The overall revised classification (for dimethoate) recommendation (to SWA) should be as follows:

| | |
|---|---|
| R23 | Toxic by inhalation |
| R24 | Toxic in contact with skin |
| R25 | Toxic if swallowed |
| R43 | May cause sensitisation by skin contact |
| R48/25 | Toxic: danger of serious damage to health by prolonged exposure if swallowed |

The following cut-off concentrations should apply for dimethoate products:

| | |
|---|---|
| ≥ 25% | R43, R23/R24/25, R48/25 |
| ≥ 10% conc < 25% | R43, R20/R21/22, R48/25 |
| ≥ 3% conc < 10% | R43, R20/R21/22, R48/22 |
| ≥ 1% conc < 3% | R43, R48/22 |

*All codes above translate into the following risk phrases:*

R20 Harmful by inhalation
R21 Harmful in contact with skin
R22 Harmful if swallowed
R23 Toxic by inhalation
R24 Toxic in contact with skin
R25 Toxic if swallowed
R36 Irritating to eyes
R38 Irritating to skin
R43 May cause sensitisation by skin contact
R48/22 Harmful: danger of serious damage to health by prolonged exposure if swallowed
R48/25 Toxic: danger of serious damage to health by prolonged exposure if swallowed

All formulations of dimethoate are classified as hazardous when they contain ≥ 1% dimethoate.

# 6 RISK ASSESSMENT AND MANAGEMENT - PUBLIC

## 6.1 Impurity limits in the technical grade active

An integral part of the safety assessment of an active constituent is a consideration of the chemical composition of the material. Technical-grade active constituents will contain measurable levels of impurities, which can arise during manufacture and/or from subsequent degradation during storage. The chemical identity of these impurities is generally well characterised. The impurities present in the technical-grade material are usually of no particular concern since health standards are established on the basis of toxicology studies conducted using the mixture. However, for those which have high acute toxicity, genotoxicity or teratogenic potential, concentration limits need to be set, so that the toxicological profile of the technical-grade active constituent does not appreciably alter in the event of slight changes in the proportions of the impurities.

The current minimum compositional standard for the active constituent dimethoate and the maximum level for a toxicologically significant impurity are as follows:

| **Chemical** | **Standard** |
|---|---|
| Active constituent | Minimum 950 g/kg |
| O,O,S-trimethyl phosphorodithioate | Maximum 5 g/kg |

### 6.1.1 O,O,S-trimethyl phosphorodithioate (O,O,S-TMP)

OCS has prepared a draft toxicology assessment of O,O,S-TMP (OCS, 2010b), which is a common impurity in organophosphate (OP) technical grade active constituents. There are two toxicological concerns regarding the presence of O,O,S-TMP as an impurity in OP pesticides. Firstly, O,O,S-TMP can potentiate the acute toxicity of OP pesticides. Secondly, O,O,S-TMP has intrinsic toxicity which should also be considered. These two concerns are addressed below.

*Potentiation of dimethoate toxicity by O,O,S-TMP*

O,O,S-TMP can potentiate the acute oral toxicity of some OP compounds by inhibiting a "safe" detoxification pathway (carboxylesterase-associated detoxification) and instead driving the formation of the oxon derivatives which are often of greater toxicity than the parent OP compound (see Figure 1).

Metabolism of certain OPs, such as dimethoate, occurs via initial hydrolysis of the C-N bond (catalysed by A-carboxylesterases) to yield carboxylic acid derivatives, with the increased polarity aiding excretion. An alternate pathway is oxidation to the oxon analogue, which in the case of dimethoate is omethoate (Figure 1). Inhibition of A-carboxylesterases would be expected to drive a greater proportion of dimethoate to the oxon analogue, omethoate, which is more toxic than dimethoate.

O,O,S-TMP has been shown to inhibit A-carboxylesterase activity. Addition of O,O,S-TMP at low relative concentration (0.2 – 1% of the technical grade active constituent [TGAC]) caused a dose-related increase in the acute oral toxicity (up to 4-fold increase) of the OP compounds malathion and phenthoate in mice and rats (Pellegrini *et al*, 1972; Umetsu *et al*, 1977). Malathion and phenthoate are both metabolised by A-carboxylesterase catalysed

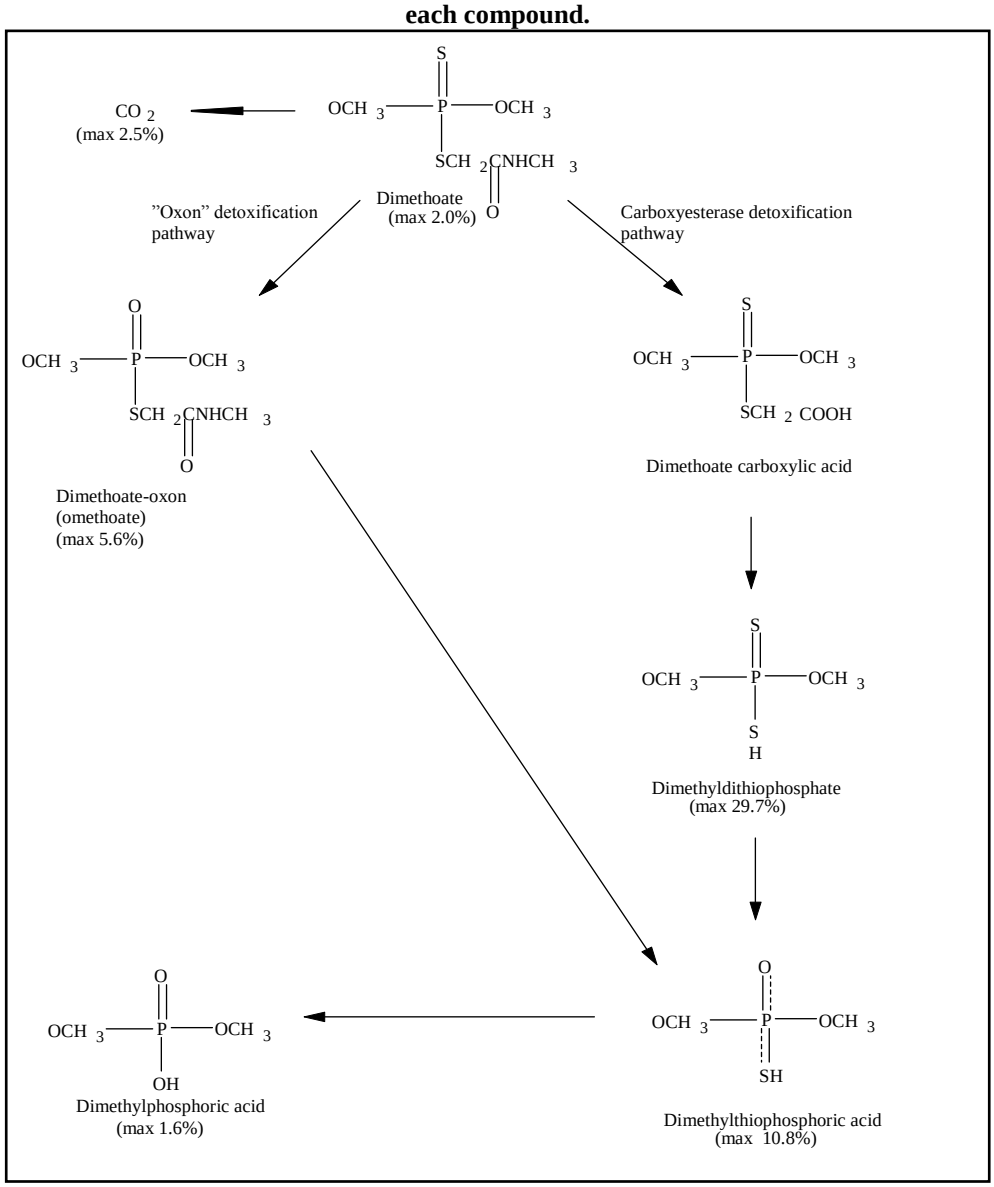
hydrolysis to carboxylic acid derivatives, and linear correlation was observed between the serum and liver carboxylesterase activities and the malathion lethality in mice following treatment with selected impurities (Toia *et al*., 1979, reported in Ambrus *et al*., 2003). Human poisonings, including deaths, have also been linked to the use of low-quality malathion. During the summer of 1976, thousands of cases of poisoning resulting from the use of malathion for malaria vector control were reported in Pakistan, resulting in at least five deaths. Although these poisoning cases were primarily attributable to poor safety practices and hygiene, there is evidence that increased toxicity of low-quality malathion also contributed to the poisonings. Toxicological evaluations revealed rat oral $LD_{50}$ values as low as 325 mg/kg for one of the malathion brands used. In contrast, the rat oral $LD_{50}$ of purified malathion has been reported to be as high as 12 500 mg/kg. The low-quality malathion used in Pakistan had an S-methyl isomer content of 3.1% as well as significant amounts of O,O,S-TMP (Baker *et al*., 1978, reported in Ambrus *et al*., 2003).

Based on the above findings, it is considered likely that O,O,S-TMP could potentiate the toxicity of dimethoate, and therefore O,O,S-TMP is considered a toxicologically significant impurity for which a maximum level should be established.

A maximum impurity limit may be established by using the levels of the impurity in the active ingredient which was used for toxicological testing. A number of studies were critical to the establishment of human health standards (see OCS 2010a). While no impurity profile was available for the oral study in humans (Edson et al., 1967) or the reproductive study in rats (Brooker *et al*., 1992), a declaration of composition was available for the batch of dimethoate which was used in the three developmental studies in rats (Mellert *et al*, 2003b; Myers, 2001b and Myers 2001c). The lowest NOEL for dimethoate, which was used to establish the ADI, was obtained from Myers (2001c). This NOEL of 0.1 mg/kg bw/d was established, based on AChE inhibition and increased pup mortality in a developmental neurotoxicity study in the rat.

Therefore, it is appropriate to use the level of O,O,S-TMP stated in the declaration of composition Myers (2001c) to establish a maximum impurity limit for O,O,S-TMP in dimethoate of 3g/kg.

**Figure 1. Proposed biotransformation pathway of dimethoate in rats, with maximum excreted dose for each compound.**




*Intrinsic toxicity of O,O,S-TMP*

O,O,S-TMP belongs to the organophosphorus class of chemicals, however, available data does not indicate its primary mode of action to be inhibition of AChE in the brain resulting in cholinergic effects. Instead, the available toxicological data indicate that the most sensitive endpoints of toxicity for O,O,S-TMP are immunotoxicity and pneumotoxicity in adults and foetotoxicity. These effects are described briefly below, and the relevant NOELs are included in Table 34.

Several studies in mice investigating immunotoxicity induced by O,O,S-TMP have been conducted. O,O,S-TMP has been demonstrated to cause a dose-related and statistically significant effect on humoral and cell-mediated immune responses of mice following single and repeat doses, in addition to associated pathological effects in the spleen and thymus.

Clinical manifestations of delayed pneumotoxicity (decreased respiration and laboured breathing) in addition to pathological effects in the lung (i.e. haemorrhaging) were observed in adult rodents in acute oral lethality studies Several studies investigating pneumotoxicity in rats induced by acute oral doses of O,O,S-TMP have demonstrated a dose-related effects in the lungs. Overall the results of the studies indicate that alveolar type I and type II cells are likely involved in the development of delayed pneumotoxicity in rats, with effects initiated early following treatment and increasing in severity with time. Studies also indicate that bronchiolar parameters (bronchiolar epithelium and Clara cells) are affected soon after treatment but appear to recover by day 7. The delayed pneumotoxic effects induced by O,O,S-TMP are similar to those induced by paraquat, although these effects are likely caused via separate modes of action.

Single doses of O,O,S-TMP to rats have been demonstrated to induce adverse pulmonary effects on the foetus. Foetuses from pregnant rats treated with a single doses of 7 mg/kg bw O,O,S-TMP or above on GD19 demonstrated delayed foetal pulmonary development in a dose-related fashion, characterised by biochemical/physiological immaturity observed on GD22, which were not apparent in foetuses from non-treated dams. A separate study demonstrated a dose-related pathological effects in the lungs of foetuses from dams treated with a single dose of 2.5 mg/kg bw O,O,S-TMP (on GD20) and cyanosis at higher doses, not observed in non-treated controls. Neonates from dams treated with single doses of 2.5 mg/kg bw O,O,S-TMP on GD20 demonstrated a dose-related and significant increase in mortality 72 hrs following birth in comparison to non-treated controls. A distribution study demonstrated that single oral doses of 2.5 mg/kg bw O,O,S-TMP or above on GD20 crossed the placental barrier and was present in the foetal lung, measured as the radioactive isotope (Koizumi *et al*, 1988). As such these effects are considered to be a direct result of exposure to O,O,S-TMP across the placenta.

In the absence of other data, the intrinsic toxicity of O,O,S-TMP (Table 34) could be used to establish a maximum impurity limit in technical grade dimethoate, by comparison with the intrinsic toxicity of dimethoate.

However, as described above, the declaration of composition is available from the developmental study in rats which was used to establish the ADI (Myers, 2001c), and the same batch of dimethoate was also used in a number of other developmental studies. These studies are considered adequate to characterise the toxicity of dimethoate containing the level of O,O,S-TMP impurity that was present in these studies. As such, the maximum impurity limit is recommended based on the levels of O,O,S-TMP in these studies.

**Table 34**: **Summary of O,O,S-TMP NOELs/LOELs relevant to human health risk assessment**

| **Study (study type)** | **NOEL** mg/kg bw/d | **LOEL** mg/kg bw/d | **Toxicological Endpoint** | **Reference** |
|---|---|---|---|---|
| ***Acute studies*** | | | | |
| Rats (acute developmental toxicity study) | 0.5 (dams) | 2.5 | Decreased food consumption and body-weight gain, and pneumotoxicity | Koizumi *et al*, 1988 |
| Rats (acute haemotoxicity study) | Not determined | 10 (single dose) | Adverse effects on blood clotting factors (additional effects not looked for) | Bezencon *et al* 1989 and Keadtisuke *et al*, 1990 |
| Mice (acute immunotoxicity study | Not determined | 1.0 (single dose) | Decrease in humoral and cell mediated immune response in the absence of pathological effects in other organs and clinical signs of toxicity | Rogers *et al*, 1986 |
| ***Repeat-dose studies*** | | | | |
| Mice (14-day immunotoxicity study) | 0.5* | 5 (highest dose tested) | Significant increase in spleen lymphocyte number | Rogers *et al*, 1985b |
| ***Developmental studies*** | | | | |
| Rats (acute developmental toxicity study) | 0.5 (foetus)* | 2.5 (foetus) | Morphological changes in foetal lung, delayed foetal lung development and increased neonatal mortality directly associated with exposure across the placenta | Koizumi *et al*, 1988 and Koizumi *et al*, 1989 |

*Due to the uncertainties arising as a result of the deficiencies in the study methodology, the use of this NOEL in an OHS risk assessment may require the use of an additional 2-fold safety factor in determining an acceptable MOE (see Section 3.3).

*Conclusion*

On toxicological grounds, it is appropriate to revise the maximum impurity limit for O,O,S-TMP from 5 to 3 g/kg. This is based on the levels of this impurity which were present in the active ingredient administered in the study which was used to establish the ADI (Myers (2001c).

### 6.1.2 Omethoate

Omethoate, the oxygen analogue of dimethoate, may be formed during manufacture or during storage of EC products, and is also a mammalian metabolite of dimethoate. The acute oral toxicity of omethoate was high with $LD_{50}$ values in the range of 22-28 mg/kg bw in rats (Flucke 1978, Krötlinger 1989a). Acute dermal studies in rats gave $LD_{50}$ values from approximately 145 mg/kg bw, up to ~1018 mg/kg bw (Flucke 1978, Krötlinger 1989b). For a 4 h exposure, the inhalation $LC_{50}$ value in rats was 287 mg/m$^3$ (Pauluhn 1989). Overall, deaths occurred in the acute studies within 24 h of dosing, up to day 4 post-dosing. Similar clinical signs (trembling, muscle spasms, red tears, breathing difficulties and behavioural disturbances) were common to exposure by all routes. These were usually rapid in onset (~1 h post-treatment), resolving in 1-12 days in survivors. In a study in rats to determine the effects of acute oral dosing with omethoate on ChE activity, brain ChE activity was the most sensitive to inhibition, followed by plasma, with minimal effects on erythrocyte ChE activity. Inhibition of brain ChE activity at 1.3 mg/kg bw/d was considered treatment-related, with a no-effect level of 0.6 mg/kg bw/d (Flucke 1978). Omethoate was also evaluated in a separate report by the OCS, and data contained within that evaluation indicated that in rabbits,

omethoate was not a skin irritant, but was a slight eye irritant. It was a skin sensitiser in guinea pigs according to the open epicutaneous test. Considering the toxicity of omethoate which is considerably higher than dimethoate, the impurity limit of omethoate should be set at the lowest practicable level. Declarations of Composition for dimethoate from all of the approved sources show omethoate concentrations of less than 2 g/kg. In accordance with this observation, the maximum impurity limit for omethoate (CAS No. 1113-02-6, CAS name O,O-dimethyl S-[2-(methylamino)-2-oxoethyl]phosphorothioate) in dimethoate technical material stipulated in the May 2005 FAO specifications was 2 g/kg.

*Conclusion*

The impurity limit for omethoate in dimethoate technical should be established at 2 g/kg.

### 6.1.3 Isodimethoate

Isodimethoate was identified as an impurity potentially formed during storage of dimethoate. The oral $LD_{50}$ for isodimethoate in rats was estimated to be in the range of 25-200 mg/kg bw (Dreher, 2001). In consideration of the slightly higher toxicity of isodimethoate compared to dimethoate, the impurity limit of isodimethoate should be set at the lowest practicable level. Declaration of Compositions (DOCs) for technical dimethoate support the recommendation that the impurity limit established on a practicable basis would be 0.3% or 3 g/kg for isodimethoate, which is specified as an upper limit for this impurity in a number of DOCs (see Appendix II). This value aligns with the value of 3 g/kg established in the May 2005 in the FAO specifications.

*Conclusion*

The impurity limit for isodimethoate should be established at 3 g/kg.

### 6.1.4 Recommendations

The current minimum compositional standard for the active constituent dimethoate and the maximum level for a toxicologically significant impurity are as follows:

| **Chemical** | **Standard** |
|---|---|
| Active constituent | Minimum 950 g/kg |
| O,O,S-trimethyl phosphorodithioate | Maximum 5 g/kg |

The following revised impurity limits for the active constituent dimethoate are recommended based on toxicological grounds:

| **Chemical** | **Standard** |
|---|---|
| O,O,S-trimethyl phosphorodithioate | Maximum 3 g/kg |
| omethoate | Maximum 2 g/kg |
| isodimethoate | Maximum 3 g/kg |

## 6.2 Residue definition

In the existing MRL Standard for Maximum Residue Limits in Food and Animal Feedstuff (APVMA, October 2006), the residue definition of dimethoate is defined as 'Sum of dimethoate and omethoate, expressed as dimethoate.' It appears that the toxicology studies of dimethoate and omethoate have adequately covered the potential toxicity of dimethoate metabolites that may be present as residues.

From a toxicological perspective, the current residue definition for dimethoate is considered appropriate.

## 6.3 Home garden EC products

### 6.3.1 Description of HG EC products

Two EC products contain dimethoate at a concentration of 100 g/L and with pack sizes of 250mL or less..

Two registered EC products with a dimethoate concentration of 300 g/L are available in pack sizes up to 1 L:

Four products containing 400 g/L dimethoate are available in pack sizes of less than or equal to 1 L. Although the label directions do not reflect that these products are intended for home garden use, it is expected that products of volume less than or equal to 1 L may be made available to the householder.

### 6.3.2 Acute hazards of HG EC products

The toxicological characteristics of EC products containing 100-400 g/L dimethoate, extrapolated on the basis of dimethoate concentration, and taking into consideration the excipients in the EC formulations, are shown along with the formulation details for each product in Appendix VIII.

EC products containing 100-400 g/L dimethoate were expected to be of moderate acute oral toxicity, and low to moderate dermal and inhalational toxicity. These products were expected to be moderate to severe skin and eye irritants, and possible skin sensitizers (see Table 2).

### 6.3.3 Suitability of EC products containing 100-400 g/L dimethoate for HG use

All existing dimethoate based EC formulations for use by householders are considered to be unacceptable on the grounds that these formulations do not conform to criteria established by the APVMA for domestic products.

The APVMA Agricultural Manual of Requirements and Guidelines (MORAG) states that "*household, home garden and domestic animal pesticide products must be relatively harmless or capable of causing only mild illness if accidental poisoning occurs… Any domestic pesticide formulations that may be ingested should not be expected to be acutely toxic to a child at doses up to 1,500 mg/kg bodyweight…The irritancy to skin and eyes of domestic products should be low*".

The acute toxicity of dimethoate EC formulations does not conform to these criteria. Dimethoate EC formulations containing 100-400 g/L dimethoate are expected to have oral $LD_{50}$ values of less than 1500 mg/kg bw. For example an EC formulation containing dimethoate at a concentration of 100 g/L would have an extrapolated acute oral toxicity range of 600-1700 mg/kg bw. These values are below the $LD_{50}$ of 1500 mg/kg bw recommended for any domestic pesticide formulations. At 100 g/L dimethoate, a 10 kg child would need to ingest only around 6 mL of this product to achieve a potentially fatal dose.

In addition, these dimethoate EC formulations are expected to be moderate to severe skin and eye irritants.

While dimethoate 100 g/L, 300 g/L and 400 g/L EC products may be acceptable for commercial use, with the appropriate PPE to protect the user, it is not reasonable to expect that items other than rubber gloves and clothing equivalent to long-sleeved overalls are available in the domestic situation.

### 6.3.4 Recommendations

The ongoing registration of dimethoate 100-400 g/L EC products for use in the home garden is not supported on toxicological grounds and do not comply with the APVMA Agricultural Manual of Requirements and Guidelines (MORAG) requirements (see 6.3.3).

Since dimethoate 100-400 g/L EC products do not conform to criteria established by the APVMA for pesticides intended for domestic use, pack sizes for these products should be limited to volumes greater than 1 L.

## 6.4 Home garden aerosol products

There is currently a single home garden aerosol product registered, Amgrow Systemic Insect & Mite Spray (APVMA No. 52673), containing 0.3 g/kg dimethoate. This product is estimated to be of low oral, dermal and inhalation toxicity. Although this product is expected to be a moderate skin, eye and respiratory tract irritant, the irritation potential is driven primarily by the excipients in the aerosol formulation, which are common in many other aerosol formulations used in the home garden.

As such, this product complies with the APVMA MORAG requirement that "*household, home garden and domestic animal pesticide products must be relatively harmless or capable of causing only mild illness*".

### 6.4.1 Use pattern

Amgrow Systemic Insect & Mite Spray (APVMA No. 52673) is an aerosol containing 0.3 g/kg dimethoate, and was originally registered for the control of aphids, thrips, mealy bug, azalea lace bug, fruit fly and other insect pests on fruit trees, vegetables, and ornamental plants in the Home garden.[4]

[4] Note that the current suspension instructions do not include the use of dimethoate products on food producing plants in the home garden

The label instructs the user to hold the can about 30 cm from plants and spray to just wet all surfaces. For stone fruit and tomatoes the instruction was to apply 4 and 2 weeks before harvest, and for apples, pears, quinces and citrus the instruction was to apply 7 and 5 weeks before harvest. For potatoes, ornamental flowers, vegetables and fruit trees the user was instructed to apply when pests appear, and to repeat application at 10-14 day intervals, or on reinfestation. The label instructions were "do not pick fruit or vegetables for 7 days after spraying".

There are three potentially significant routes of exposure to dimethoate following the use of this product: 1) exposure during use, 2) re-entry exposure and 3) exposure from intake of treated food from the home garden.

The third route of exposure, via intake of food, is considered to be dietary intake, and will not be further considered in this evaluation. Assessment of the exposure of the Australian population to residues of agricultural and veterinary chemicals in food crops and target animals is performed by the Australian Pesticides and Veterinary Medicines Authority (APVMA), with the support of, and using procedures and databases provided by, Food Standards Australia New Zealand (FSANZ).

### 6.4.2 Exposure during use

This product may be used in the home garden by a single user on a few occasions each year. There is the potential for dermal and inhalation exposure when using the product.

Although repeated daily exposure is not likely to occur, the primary endpoint of toxicity, cholinesterase inhibition, may occur following a single exposure. As such, the NOEL of 0.2 mg/kg bw/day from repeat dose oral study in humans is appropriate for use in this risk assessment. This NOEL of 0.2 mg/kg bw/d (for inhibition of ChE activity in whole blood from a 14-57 day human study) has been used to establish the ARfD for dimethoate, and as such it is the appropriate reference value for evaluating the risks posed by a single-day exposure which occurs relatively infrequently. Considering that this NOEL was established in humans, an MOE of 10 or more is considered acceptable, to account for possible intra-species (10x) variability.

There is no appropriate exposure data available for home garden use of this product. In the absence of adequate human exposure data, the OCS used the PHED Surrogate Exposure Database and Guide (1998) to estimate exposure during application of the HG AE product.

It is acknowledged that the PHED database is generally used to estimate exposure during occupational application of pesticides, however in this case it is the most appropriate data which is available.

When using PHED to estimate worker exposure, the amount of active ingredient handled each day is generally calculated based on an 8-hour workday. This approach is considered inappropriate for home garden use, and the estimate for home garden exposure is therefore based on application of a single 300 g can of the aerosol product per day.

Home garden human exposure was estimated using the following assumptions:

Bodyweight: 70 kg
Maximum amount of product handled per day: 300 g (one can)

Maximum amount of dimethoate handled per day: 90 mg/day (0.000090 kg/day)
Dermal absorption: 5.1%
Inhalation absorption: 100%
No protective equipment is worn (i.e. PHED scenario for no clothes, no gloves)
NOEL: 0.2 mg/kg bw/day

The following PHED scenario was used:
*PHED surrogate scenario 10*: Aerosol application (APPL)
[High confidence data for dermal exposure (AB grade): 15 hand replicates without gloves; High confidence data for inhalation exposure without any protective equipment (AB grade): 15 replicates]

For this scenario the dermal unit exposure is 1055 mg ai/kg ai handled (no clothing, no gloves) and the inhalation unit exposure is 2.87 mg ai/kg ai.

**Table 35: Exposure estimates and MOEs for home garden aerosol products**

| ***Estimate*** | **Systemic exposure (mg/kg bw/d) / MOEs for dimethoate** | | | | | |
|---|---|---|---|---|---|---|
| | *Mixer/ Loader Dermal* | *Applicator Dermal* | *Total Dermal exposure* | *Mixer/ Loader Inhalation* | *Applicator Inhalation* | *Total inhalation exposure* |
| **Exposure** | | | | | | |
| Aerosol (90 mg ai/day) **Scenario 10; no clothing, no gloves** | N/A | 0.0001 | 0.0001 | N/A | <0.0000 | <0.0000 |
| **MOEs** | | | | | | |
| Aerosol (90 mg ai/day) **Scenario 10; no clothing, no gloves** | N/A | 29000 | 29000 | N/A | >500000 | >500000 |

The above exposure estimate demonstrates that user exposure during application of a full can of the HG AE product results in a margin of exposure (MOE) in excess of 10000, which is well above the acceptable MOE of 10, and indicates no significant risk during application.

### 6.4.3 Re-entry exposure

The public may be exposed to dimethoate residues and degradation products when coming into contact with treated vegetation in the home garden. Gardening activities include weeding, pruning, tying and staking vegetables (e.g. tomatoes), and harvesting fruit and vegetables. Exposure will be mainly dermal, although ocular exposure may also occur.

Although home garden exposure is likely to be relatively infrequent as compared with occupational exposure, it is appropriate to use the same NOEL to evaluate the risk. This NOEL of 0.2 mg/kg bw/d (for inhibition of ChE activity in whole blood from a 14-57 day human study) has been used to establish the ARfD for dimethoate, and as such it is the appropriate reference value for evaluating the risks posed by a single-day exposure which occurs relatively infrequently. Considering that this NOEL was established in humans, an MOE of 10 or more is considered acceptable, to account for possible intra-species (10x) variability.

Dermal exposure to dimethoate residues when gardening (after the spray has dried) can be calculated using the following formula:

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

The Transfer coefficient (TC) is the amount of treated foliage that a person contacts while performing a specific activity in a given period of time ($cm^2$/h). TC varies with the crop and crop management activity. TC values specifically for home garden activities are not available, however occupational TC values were obtained from the US Occupational Post-Application Risk Assessment Calculator (US EPA Policy 003.1).

Maintenance activities:
Hand weeding (e.g. around citrus trees): 1000 $cm^2$/h
Pruning fruit trees (e.g. citrus, apples, pears, quinces): 3000 $cm^2$/h
Pruning, staking, tying of fruiting vegetables (e.g. eggplant, capsicum, tomato): 1000 $cm^2$/h

Harvesting:
Hand harvesting of fruit from deciduous trees (e.g. apples, pears): 3000 $cm^2$/h
Hand harvesting of fruit from evergreen trees (e.g. citrus): 8000 $cm^2$/h
Hand harvesting of fruiting vegetables (e.g. eggplant, capsicum, tomato): 1000 $cm^2$/h

The initial dislodgeable foliar residues (DFR) was derived using the same methodology as for the occupational exposure. The label for Garden King Rogor Garden Insect Spray instructs the user to “spray to just wet all surfaces”, and as such the initial DFR is likely to be similar to that used in the occupational exposure assessment. This assessment could be refined by DFR data specific for the use of this aerosol product.

Duration of the re-entry activity (T) = 1 h. This is approximately 10% of the time spent by workers conducting re-entry activities in an occupational setting, and is considered to be a reasonable worst-case estimation given that only a limited amount of foliage could be treated by using this product, given that the maximum size of the can is 300 g.

Body weight (BW) = 70 kg

Half-life: 5 days

Dermal exposure was calculated using the above formula and the absorbed dose was estimated using the dermal absorption factor of 5.1% for dimethoate.

As shown in Table 36, an unacceptable MOE (i.e. MOE < 10) is obtained for hand harvesting of fruit from evergreen trees (e.g. citrus). This assessment was based on the NOEL which was used to establish the ARfD, and as such addresses exposure in a single day.

The MOEs for hand harvesting were also calculated on day 7 following application, which reflects the current label directions. After 7 days, an acceptable MOE was obtained for hand harvesting of fruit from evergreen trees (e.g. citrus), and for all other uses.

On this basis, it is considered appropriate to include a label precaution against hand harvesting for 7 days after application. The following re-entry statement should appear on the label of dimethoate products for use in the home garden:

"Do not pick fruit or vegetables for 7 days after spraying" [5].

[5] Note that the current suspension instructions do not include the use of dimethoate products on food producing plants in the home garden

**Table 36. Dimethoate HG re-entry exposure**

| Activities | TC ($cm^2$/hr) | $DFR_{day0}$ (µg/$cm^2$) | $DFR_{day7}$ (µg/$cm^2$) | Dermal Exposure (mg/kg bw) [5] | Systemic Exposure (mg/kg bw) [6] | MOE[7] |
|---|---|---|---|---|---|---|
| Day 0 exposure and MOEs | | | | | | |
| Hand weeding (e.g. around citrus trees) | 1000 | 6 [1] | | 0.085714 | 0.004371 | 46 |
| Pruning fruit trees (e.g. citrus, apples, pears, quinces) | 3000 | 6 [1] | | 0.257143 | 0.013114 | 15 |
| Pruning, staking, tying of fruiting vegetables (e.g. eggplant, capsicum, tomato) | 1000 | 0.63 [2] | | 0.009 | 0.000459 | 440 |
| Hand harvesting of fruit from deciduous trees (e.g. apples, pears) | 3000 | 3.9 [3] | | 0.167143 | 0.008524 | 24 |
| Hand harvesting of fruit from evergreen trees (e.g. citrus) | 8000 | 6 [1] | | 0.685714 | 0.034971 | 5.7 |
| Hand harvesting of fruiting vegetables (e.g. eggplant, capsicum, tomato) | 1000 | 0.63 [2] | | 0.009 | 0.000459 | 440 |
| Day 7 exposure and MOEs | | | | | | |
| Hand harvesting of fruit from deciduous trees (e.g. apples, pears) | 3000 | | 1.47 [4] | 0.063055 | 0.003216 | 62 |
| Hand harvesting of fruit from evergreen trees (e.g. citrus) | 8000 | | 2.26 [4] | 0.258689 | 0.013193 | 15 |
| Hand harvesting of fruiting vegetables (e.g. eggplant, capsicum, tomato) | 1000 | | 0.238 [4] | 0.003395 | 0.000173 | 1200 |

[1] $DFR_{day0}$ for evergreen fruit trees (e.g. citrus) from Table 31
[2] $DFR_{day0}$ for fruiting vegetables (e.g. tomatoes) from Table 31
[3] $DFR_{day0}$ for deciduous fruit trees (e.g. apples, pears) from Table 31
[4] $DFR_{day7}$ derived from the relevant $DFR_{day0}$ using a dissipation rate of 13% / day.
[5] Dermal exposure = DFR (µg/$cm^2$) x TC ($cm^2$/h) x T (h) / BW (kg) / 1000; based on 3 hours/day re-entry exposure and 70 kg BW.
[6] Systemic exposure = Dermal exposure * 5.1% dermal absorption
[7] The MOE is based on an oral NOEL of 0.2 mg/kg bw/d for dimethoate. Shaded values indicate an unacceptable MOE

### 6.4.4 First Aid instructions

In the edition current to March 2011, the following standard statements for dimethoate are specified in the FAISD Handbook – *Handbook of First Aid Instructions, Safety Directions, Warning Statements and General Safety Precautions for Agricultural and Veterinary Chemicals.*

Dimethoate m

m If swallowed, splashed on skin or in eyes, or inhaled, contact a Poisons Information Centre (Phone Australia 131126) or a doctor at once. Remove any contaminated clothing and wash skin thoroughly. If swallowed, activated charcoal may be advised. Give atropine if instructed.

The APVMA Agricultural Manual of Requirements and Guidelines (MORAG) states that "*There should be appropriate directions for first aid measures to be taken, should poisoning occur in the household. Household, home garden and domestic animal products should not require specific antidotes or aggressive first aid measures*". Based on this MORAG requirement, a product with the First Aid Instruction "m" would not be appropriate for home garden use, as a requirement for a specific antidote is included on the label.

On the basis of the estimated acute toxicity of the home garden aerosol product, the First Aid Instruction "m" may not be necessary for the product Amgrow Systemic Insect & Mite Spray. The product contains 0.3 g/kg dimethoate, and the risk assessment during the use of this product (section 6.4.2) demonstrates that there is no significant risk that a worker using this product would exceed the MOE, even in the absence of specific clothing or gloves.

Therefore, a provisional recommendation has been made that a new First Aid Instruction be specified for dimethoate aerosol products containing 0.3 g/kg dimethoate (0.03%), for use on the home garden.

Dimethoate · in 0.03 percent pressurised spray packs a,o
Dimethoate · in other preparations m

a, o If poisoning occurs, contact a doctor or Poisons Information Centre. Phone Australia 131126, New Zealand 0800 764 766. If sprayed on skin, wash thoroughly. If sprayed in mouth, rinse mouth with water.

m If swallowed, splashed on skin or in eyes, or inhaled, contact a Poisons Information Centre (Phone Australia 131126) or a doctor at once. Remove any contaminated clothing and wash skin thoroughly. If swallowed, activated charcoal may be advised. Give atropine if instructed.

First Aid Instructions should appear on product labels when the substance is present in concentrations at which they would be scheduled as poisons in the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP). Dimethoate is currently included in the SUSMP in Schedule 6 with no cut-off concentration.

Precursor bodies to the Advisory Committee on Chemicals Scheduling (ACCS) have considered this home garden product.

At the May 1992 DPSSC meeting, proposed safety directions for a home garden aerosol product "Rogor Aerosol Garden Insecticide" (0.3 g/kg of dimethoate) were accepted with the addition of 223 ["spray mist"] after 219 ["avoid inhaling"]. However, the proposed SDs were not endorsed by the DPSSC until the status of the product as a HG product could be established (i.e. whether it conformed with the DPSSC guidelines for household pesticide products).

At the November 1993 DPSSC meeting, the committee agreed that a requirement to administer atropine was not usually appropriate for home garden products, and on that basis recommended that the SDs for dimethoate HG EC 100 g/L would need to be reviewed in the future. However, any discussion on the HG AE product was not recorded in the minutes.

As this matter has previously been considered by precursors to the Advisory Committee on Chemicals Scheduling, and as OCS has worked with the NDPSC in the past when considering emergency first-aid treatment of anticholinesterase pesticide poisoning (for example OCS, 2008), it is considered appropriate to refer this proposed amendment of the First Aid Instructions for dimethoate to the Scheduling Delegate, together with a recommendation to establish a cut off to Schedule 5 for dimethoate in pressurised spray packs containing 0.03 per cent or less dimethoate.

### 6.4.5 Safety directions

There is currently no entry in the FAISD handbook for the home garden aerosol product Amgrow Systemic Insect & Mite Spray (APVMA No. 52673). As noted above, the DPSSC accepted proposed safety directions for a home garden aerosol product in 1992, however, the proposed SDs were not endorsed until the status of the product as a HG product could be established (i.e. whether it conformed with the DPSSC guidelines for household pesticide products).

By extrapolation, the estimated acute toxicity of the product was low by oral, dermal, and inhalational exposure. It is expected to be a moderate skin and eye irritant and is unlikely to be a skin sensitizer. The product may also cause irritation to the nose and throat. The irritation potential is driven primarily by the excipients in the aerosol formulation, and would be similar to other aerosol formulations on the market (for example aerosol deodorisers, surface sprays or personal insect repellents). It would be appropriate to address on the label the potential risks of irritation to the skin, eye, nose and throat.

To address the acute hazards of this product, the following safety directions are recommended for HG AE 0.3 g/kg or less:

**Table 37. Derivation of the Safety Directions**

| Acute or Repeat Exposure Risk | Safety Direction | Code |
|---|---|---|
| | ***HAZARDS*** | |
| Skin, eye and respiratory tract irritation | May irritate eyes, nose, throat and skin | 160 162 163 164 |
| | ***PRECAUTIONS*** | |
| Skin and irritation | Avoid contact with eyes and skin. | 210 211 |
| Respiratory tract irritation | Do not inhale spray mist | 220 223 |
| | ***MIXING OR USING*** | |
| Eye irritation | If product in eyes wash it out immediately with water. | 340 343 |
| Skin irritation | If product on skin, immediately wash area with soap and water | 340 342 |
| | ***AFTER USE*** | |
| | Wash hands after use | 351 |

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**[Figures in square brackets are an Australian identification code and indicate the location of the submitted data.]**


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# APPENDICES

## APPENDIX I: Dimethoate toxicology data submission details – Sensitive Confidential Commercial Information

This data was considered by the OCS but is not for publication as it contains Sensitive Confidential Commercial Information.

## APPENDIX II: Composition of Active - Sensitive Confidential Commercial Information

This data was considered by the OCS but is not for publication as it contains Sensitive Confidential Commercial Information.

# APPENDIX III: Australian registered products containing dimethoate[6]

| APVMA Product Code | Product Name | Product Registrant | Product Description | Content & formulation type |
|---|---|---|---|---|
| 32953 HG | Chemspray Rogor Insecticide | Envirogreen Pty Ltd | For control of fruit fly, aphids, thrips, leaf miners, bean fly & other pests on fruit trees, vegetables, potatoes & ornamentals. | 300 g/L EC |
| 32962 | Nufarm Dimethoate Systemic Insecticide | Nufarm Australia Limited | For control of a wide range of pests on fruit, vegetables, pastures, cotton, lucerne, peanuts & ornamentals. | 400 g/L EC |
| 32963 HG | Garden King Rogor 100 Systemic Insecticide | Envirogreen Pty Ltd | Controls aphids, fruit fly, jassids, two-spotted mite & thrips in the home garden. | 100 g/L EC |
| 39239 | Farmoz Dimethoate 400 Systemic Insecticide | Farmoz Pty Limited | For the control of certain insects (including aphids, thrips, jassids, lucerne flea, red-legged earthmite, Queensland fruit fly, leaf hoppers & wingless grasshopper) in field crops, fruit crops, oilseed & fibre crops, vegetables, ornamentals, forest trees. To use as a post harvest fruit dip & as seed dressing for lupins, peas, sub-clover, lucerne, linseed & canola. | 400 g/L EC |
| 41070 HG | CRG Systex Insecticide | Chemical Recovery Co Pty Ltd | For the control of aphids, thrips & other suckling insects in ornamentals, beans & vegetables. | 300 g/L EC |
| 48956 HG | Richgro Garden Products Rogor Insecticide | A Richards Pty Ltd T/A Richgro Garden Products | For the control of fruit fly, aphids, thrips, leaf miners, bean fly & other insects on fruit trees, vegetables, potatoes & ornamentals. | 100 g/L EC |
| 49167 | Summit Dimethoate Systemic Insecticide | Summit Agro Australia Pty Ltd | Controls pests including Queensland fruit fly, redlegged earthmite, thrips, jassids, lucerne flea, leaf hoppers wingless grasshoppers. | 400 g/L EC |
| 49600 | Saboteur Systemic Insecticide | Crop Care Australasia Pty Ltd | For control of insect pests on fruit, vegetables, citrus, pastures, cotton, lucerne, peanuts & ornamentals. | 400 g/L EC |
| 49833 | Rotam Romethoate Systemic Insecticide | Rotam Australasia Pty Ltd | For control of pests on crops including bananas, berry fruits, cereals, citrus, cotton, legume crops and lucerne. | 400 g/L EC |
| 51545 | Chemag Dimethoate Insecticide | Chemag Pty Ltd | For control of pests on bananas, berry fruits, cereals, citrus, cotton, grapes legume crops, lucerne & medic pastures, peanuts, pome & stone fruits, oil seeds, ornamentals, tropical fruit & vegetables. Product can be used as a seed treatment for certain crops & as post harvest dip for quarantine purposes. | 400 g/L EC |
| 51658 | Sipcam Rogor Systemic Insecticide | Sipcam Pacific Australia Ltd | For control of pests on fruits & vegetable crops, pastures, cotton, lucerne, oil seed crops & ornamentals. | 400 g/L EC |

[6] At the commencement of the review.

| APVMA Product Code | Product Name | Product Registrant | Product Description | Content & formulation type |
|---|---|---|---|---|
| 52673 HG | Garden King Rogor Garden Insect Spray | Envirogreen Pty Ltd | Controls aphids, thrips, mealy bug, azalea lace bug, fruit fly & other insect pests on fruit trees, vegetables & ornamental plants in the home garden. | 0.3 g/kg AE |
| 53045 | Agcare Biotech Dimethoate 400 EC Systemic Insecticide | Agcare Biotech Pty Ltd | For the control of a wide range of pests on fruit, vegetables, pastures, cotton, lucerne, peanuts & ornamentals. | 400 g/L EC |
| 55272 HG | Superway Dimethoate 300 Systemic Insecticide | Superway Garden Products Pty Ltd | For the control of fruit fly, aphids, thrips, leaf miners, bean fly and other pests on fruit trees, vegetables, potatoes and ornamentals in the home garden. | 300 g/L EC |
| 55441 | 4 Farmers Dimethoate 400 Systemic Insecticide | 4 Farmers Pty Ltd | For control of pests on fruit, vegetables, citrus, pastures, cotton, lucerne, peanuts & ornamentals. | 400 g/L EC |
| 55495 | Superway Dimethoate 400 Systemic Insecticide | Superway Garden Products Pty Ltd | For control of insect pests on fruits, vegetables, pastures, cotton, lucerne, oil seed crops, peanuts & ornamentals. | 400 g/L EC |
| 55704 | Conquest Dimethoate 400 Systemic Insecticide | Conquest Agrochemicals Pty Ltd | For the control of pests on some fruit, vegetables, citrus, pastures, cotton, lucerne, peanuts & ornamentals. | 400 g/L EC |
| 56454 | Danadim Insecticide | Cheminova Australia Pty Limited | For the control of a wide range of insect pests on fruit trees, vegetables, citrus, pastures, cotton, lucerne, peanuts & ornamentals. | 400 g/L EC |
| 56887 | United Farmers Unidime 400 Insecticide | United Farmers cooperative Company Ltd | For control of pests on some fruit, vegetables, citrus, pastures, cotton, lucerne, peanuts & ornamentals. | 400 g/L EC |
| 57860 | Halley Dimethoate 400 Systemic Insecticide | Halley International Enterprise (Australia) Pty Ltd | For control of insect pests on fruits & vegetable crops, pastures, cotton, lucerne, oil seed crops, peanuts & ornamentals. | 400 g/L EC |

## APPENDIX IV:  Composition of Australian registered products – Sensitive Confidential Commercial Information

This data was considered by the OCS but is not for publication as it contains Sensitive Confidential Commercial Information.

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## APPENDIX V: List of clinical Chemistry, Haematology & Urinalysis Parameters

| Clinical Chemistry | Haematology | Urinalyses |
|---|---|---|
| Albumin<br>alkaline phosphatase<br>bilirubin (total)<br>calcium<br>chloride<br>cholesterol (total)<br>cholinesterase activity<br>creatinine (blood)<br>gamma-glutamyl transpeptidase<br>globulin<br>glucose (blood)<br>LDH (serum lactate dehydrogenase)<br>Phosphorus<br>potassium<br>protein (total)<br>SGPT (serum alanine aminotransferase)<br>SGOT (serum aspartate aminotransferase)<br>Sodium<br>triglycerides<br>urea nitrogen (blood)<br>CPK (creatinine phosphokinase) | Clotting parameters (clotting time, prothrombin time)<br>erythrocyte count<br>haematocrit (packed cell volume)<br>haemoglobin<br>leucocyte differential count<br>leucocyte total count<br>platelet count<br>reticulocyte count<br>MCH<br>MCHC<br>MCV<br>blood smear | appearance<br>specific gravity<br>glucose<br>ketones<br>sediment (microscopic)<br>occult blood<br>pH<br>protein<br>volume<br>bilirubin<br>urobilinogen |

## APPENDIX VI: Organs for weight determination and histopathological examination

| Organs Weighed | Tissues Examined | | |
|---|---|---|---|
| Adrenals | Adrenals | heart | prostate |
| Brain | aorta | ileum | rectum |
| Gonads | blood smear | jejunum | salivary gland |
| Heart | bone | kidneys | seminal vesicle |
| Kidneys | bone marrow | lacrimal gland | skin |
| Liver | brain (3 levels) | liver | spinal cord (cervical |
| Spleen | cecum | lungs | thoracic, lumbar) |
| Thyroid | colon | lymph nodes | spleen |
| (w/parathyroid) | duodenum | mammary gland | sternum |
| | epididymes | muscle (smooth) | stomach |
| | eyes | muscle (skeletal) | testes |
| | eyes (optic nerve) | nerve (peripheral) | thymus |
| | gall bladder | oesophagus | thyroid |
| | Harderian glands | ovaries | (w/parathyroid) |
| | head - 3 sections | pancreas | trachea |
| | (nasal cavity, para- | pituitary | urinary bladder |
| | nasal sinus, tongue, | | uterus |
| | oral cavity, naso- | | vagina |
| | pharynx, inner-ear) | | Zymbal's gland |
| | | | gross lesions |

# APPENDIX VII: Reproductive and Developmental Indices

$$\textbf{Male/female mating index } (\%) = \frac{\text{number of males/females with confirmed mating*}}{\text{number of males/females placed with females/males}} \times 100$$

* defined by females with vaginal sperm or that gave birth to a litter or with pups/fetuses in utero

$$\textbf{Male fertility index (\%)} = \frac{\text{number of males proving their fertility*}}{\text{number of males placed with females/males}} \times 100$$

* defined by a female giving bith to a litter or with pups/fetuses in utero

$$\textbf{Female fertility index (\%)} = \frac{\text{number of females pregnant*}}{\text{number of females mated**}} \times 100$$

* defined as the number of females that gave birth to a litter or with pup/fetuses in utero

** defined as the number of females with vaginal sperm or that gave birth to a litter or with pups/fetuses in utero

$$\textbf{Gestation index (\%)} = \frac{\text{number of females with live pups on the day of birth}}{\text{number of females pregnant*}} \times 100$$

* defined as the number of females that gave birth to a litter or with pups/fetuses in utero

$$\textbf{Live birth index (\%)} = \frac{\text{number of liveborn pups at birth}}{\text{total number of pups born}} \times 100$$

$$\textbf{Viability index (\%)} = \frac{\text{number of live pups on day 4* after birth}}{\text{number of liveborn pups on the day of birth}} \times 100$$

* before standardisation of litters (i.e. before culling)

$$\textbf{Lactation index (\%)} = \frac{\text{number of live pups on day 21 after birth}}{\text{number of live pups on day 4* after birth}} .$$

* after standardisation of litters (i.e. after culling)

$$\textbf{Sex ratio} = \frac{\text{number of live male or female pups on day 0/21}}{\text{number of live male and female pups on day 0/21}} \times 100$$

$$\textbf{Conception rate (\%)} = \frac{\text{number of pregnant animals}}{\text{number of fertilised animals}} \times 100$$

$$\textbf{Preimplantation loss (\%)} = \frac{\text{number of corpora lutea – number of implantations}}{\text{number of corpora lutea}} \times 100$$

$$\textbf{Postimplantation loss (\%)} = \frac{\text{number of implantations – number of live foetuses}}{\text{number of implantation}} \times 100$$

## APPENDIX VIII: Extrapolated toxicological characteristics of Australian registered products – Sensitive Confidential Commercial Information

This data was considered by the OCS but is not for publication as it contains Sensitive Confidential Commercial Information.

## APPENDIX IX: Formulation details for products used in acute and short term toxicity studies and dermal absorption studies – Sensitive Confidential Commercial Information

This data was considered by the OCS but is not for publication as it contains Sensitive Confidential Commercial Information.

## APPENDIX XI – Results of the Wilcoxon Signed Ranks Test on endpoints of ChE inhibition across dimethoate studies

The Wilcoxon matched pairs signed ranks test is a nonparametric test to compare two paired groups. Non-parametric methods provide an alternative series of statistical methods that require no or very limited assumptions to be made about the data. This allows for the use of small sample sizes as normal distribution does not need to be assumed. The Wilcoxon signed ranks test analyses the median of differences between the matched pairs and does not determine the magnitude of difference between matched groups (Motulsky, H, 1999). The differences between the LOEL for erythrocyte and brain ChE inhibition for each study was measured across dimethoate studies. If any observations are exactly equal they are ignored and dropped from the sample size. The Wilcoxon signed ranks test for the dimethoate studies is presented in appendix XII.

The Wilcoxon signed ranks test tests the null hypothesis that there are no systematic differences within pairs (LOELs for brain and erythrocyte ChE inhibition) when the test statistic ($W^-$) is a long way from its mean. The alternative hypothesis was that LOELs are systematically different between the 2 pairs (brain and erythrocyte ChE inhibition). The significance level chosen was 5% ($\alpha = 0.05$).

**Wilcoxon signed ranks test for matched pairs of erythrocyte and brain ChE endpoints**

| | **Brain LOEL** | **RBC LOEL** | **Difference** | **Absolute difference (bold = positive)** | **Order of absolute difference** | **Rank** | **Signed rank** |
|---|---|---|---|---|---|---|---|
| Rat 4 week (f) | 2.6 | 2.6 | 0 | 0 | NA | NA | NA |
| Dog 4 week | 2.2 | 2.2 | 0 | 0 | NA | NA | NA |
| 6 month rat study | 2.5 | 2.5 | 0 | 0 | NA | NA | NA |
| Dog 1 year (m) | 0.7 | 0.7 | 0 | 0 | NA | NA | NA |
| Dog 1 year (f) | 0.76 | 0.76 | 0 | 0 | NA | NA | NA |
| Repro rat 15 weeks (f) | 0.83 | 0.83 | 0 | 0 | NA | NA | NA |
| Rats 20 weeks repro (f) | 6.5 | 6.5 | 0 | 0 | NA | NA | NA |
| Rat 2 year (m) | 0.23 | 1.2 | -0.97 | 0.97 | 1 | 1 | -1 |
| Rat 2 year (f) | 1.5 | 0.3 | 1.2 | **1.2** | 2 | 2 | 2 |
| Rat 15 weeks repro (m) | 3.28 | 0.74 | 2.54 | **2.54** | 3 | 3 | 3 |
| Rat 13 week (m) | 8.1 | 3.2 | 4.9 | **4.9** | 4 | 4 | 4 |
| Rats 20 weeks repro (m) | 1 | 6.5 | -5.5 | 5.5 | 5 | 5 | -5 |
| Rat 13 week (f) | 9.9 | 3.8 | 6.1 | **6.1** | 6 | 6 | 6 |
| Rat 4 week (m) | 2.48 | 10.4 | -7.92 | 7.92 | 7 | 7 | -7 |

The statistical analysis has been performed using a two-tailed statistical test. The null hypothesis and alternative hypothesis are:

H0: LOELs have the same distribution between the 2 groups (brain and RBC) across all studies.
H1: LOELs are systematically different between the 2 groups.

The Wilcoxon's test statistic is calculated by summing the positive ranks (positive differences in bold) ($W^+$) and the negative ranks ($W^-$) and taking the minimum of the two.

$W^+ = 15$ and $W^- = 13$, the Wilcoxon test statistic = 13.

The sample size is 7 (discounting zero differences), n = 7

The mean of $W^-$ is = $\frac{n_1(n+1)}{4} = \frac{7(8)}{4} = 14$ and standard deviation = $\sqrt{\frac{n(n+1)(2n+1)}{24}} = \sqrt{\frac{7(8)(15)}{24}} = \sqrt{35} = 5.92$. A normal approximation using the mean and standard deviation can be employed to determine a p – value for statistical analysis. However, due to the small sample size n = 7, critical T values for Wilcoxon's Signed-Ranks and Matched-Pairs Signed-Ranks tests have been used to determine significance. The level of significance chosen for this analysis is significance > 95% ($\alpha = 0.05$).

**Table for critical values adapted from Sheskin, D, 2004**

**Critical Values for $T$ in the Wilcoxon Signed Mixed-Pairs Signed-Rank Test**

The values below are the approximate critical values of T for two-tailed tests at level P. For a signicant result, the calculated T must be less than or equal to the tabulated value.

(Values of P are halved for one-tailed tests using $R_-$ and $R_+$.)

| $n$ | $P = 0.10$ | $P = 0.05$ |
|---|---|---|
| 5 | 2 | - |
| 6 | 2 | 0 |
| 7 | 3 | 2 |
| 8 | 5 | 3 |
| 9 | 8 | 5 |
| 10 | 10 | 8 |
| 11 | 14 | 10 |
| 12 | 17 | 13 |
| 13 | 21 | 17 |
| 14 | 26 | 21 |
| 15 | 30 | 25 |
| 16 | 36 | 29 |
| 17 | 41 | 34 |
| 18 | 47 | 40 |
| 19 | 53 | 46 |
| 20 | 60 | 52 |
| 21 | 67 | 58 |
| 22 | 75 | 65 |
| 23 | 83 | 73 |
| 24 | 91 | 81 |
| 25 | 100 | 89 |

In order to be significant, the obtained Wilcoxon test statistic must be equal or less than the tabled critical T value at the prescribed level of significance (0.05). The Wilcoxon test statistic = 13. Figure 3 gives a critical value for n = 7 and $\alpha = 0.05$ of 2. Since 13 is greater than 2, the null hypothesis cannot be rejected at the 5% significance level.

In conclusion, there is not enough evidence at the 5% level to conclude that the distribution of erythrocyte and brain ChE inhibition LOELs is different across animal studies.