



Australian Government
**Australian Pesticides and
Veterinary Medicines Authority**



Malathion
Final Review Technical Report
May 2024

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Comments and enquiries regarding copyright:

Assistant Director, Communications
Australian Pesticides and Veterinary Medicines Authority
GPO Box 3262
Sydney NSW 2001 Australia

Telephone: +61 2 6770 2300

Email: communications@apvma.gov.au.

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Preface

The Australian Pesticides and Veterinary Medicines Authority (APVMA) is an independent statutory authority which administers the National Registration Scheme for Agricultural and Veterinary Chemicals. The APVMA evaluates, registers and regulates agricultural and veterinary (agvet) chemicals up to the point of sale. The states and territories are responsible for control of use. Its statutory powers are provided in the Agricultural and Veterinary Chemicals Code (the Code), which is scheduled to the *Agricultural and Veterinary Chemicals Code Act 1994*.

The APVMA has legislated powers to reconsider the approval of an active constituent, registration of a chemical product or approval of a label at any time after it has been registered. The reconsideration process is outlined in sections 29L to 34AF of Part 2, Division 4 of the Agvet Codes. The Code provides for the suspension and cancellation of approvals and registrations if it appears to the APVMA that the criteria for approval or registration are not, or are no longer, satisfied (s 41 and s 44 of Part 2, Division 5).

A reconsideration may be initiated when new research or evidence has raised concerns about the use or safety of a particular chemical, a product containing that chemical, or its label. The scope of each reconsideration can cover a range of areas including human health (toxicology, public health, work health and safety), the environment (environmental fate and ecotoxicology), residues and trade, chemistry, efficacy or target crop or animal safety. However, the scope of each reconsideration is determined on a case-by-case basis reflecting the specific issues raised by the new research or evidence.

The reconsideration process includes a call for data from a variety of sources, a scientific evaluation of that data and, following public consultation, a regulatory decision about the ongoing use of the chemical or product. The data required by the APVMA must be generated according to scientific principles. The APVMA conducts scientific and evidence-based risk analysis with respect to the matters of concern by analysing all the relevant information and data available.

About this document

This Technical Report is intended to provide an overview of the assessments that have been conducted by the APVMA. It has been deliberately presented in a manner that is likely to be informative to the widest possible audience, thereby encouraging public comment.

This document contains a summary of the assessment reports generated in the course of the chemical review of an active ingredient, including the registered product and approved labels. The document provides a summary of the APVMA's assessment, which may include details of:

- the chemistry of the active constituent
- the toxicology of both the active constituent and product
- the residues and trade assessment
- occupational exposure aspects
- environmental fate, toxicity, potential exposure and hazard
- efficacy and target crop or animal safety.

Introduction

Maldison is the Australian common name for the chemical also referred to as malathion, a synthetic organophosphorus chemical insecticide and acaricide used in domestic, agricultural and veterinary situations. The APVMA commenced its review of maldison in 2003 due to human health concerns. In April 2016, the APVMA published the chemistry report for maldison.

The APVMA typically adopts Australian common names for pesticides as specified in the Australian standard 'AS 1719–1994 – Recommended common names for pesticides' established by Standards Australia (1994), therefore the chemical was originally referred to as maldison. However, AS 1719–1994 is no longer being updated and this active constituent is now more widely referred to by the internationally accepted ISO common name specified in the International Standards Organisation (ISO) standard 'ISO 1750:1981–Pesticides and other agrochemicals – Common names' (ISO, 1981) – malathion. Further, it is noted that 'malathion' is the Australian Approved Name for therapeutic ingredients (and hence the name used on therapeutic goods labels such as head lice treatments), as well as being the primary listing in the Poisons Standard. Hereafter, the APVMA will use the ISO common name 'malathion'.

Purpose of review

The APVMA began its review of the active constituent malathion and all products containing malathion due to human health concerns including the potential formation of toxicologically significant impurities, metabolites and degradants in active constituents and products, after opening and during storage, and the potential adverse effects of these on human health.

The original scope of the review included the following assessments:

- Toxicology of active constituents and products containing malathion, including impurities specified for malathion in the [Agricultural and Veterinary Chemicals Code \(Agricultural Active Constituents\) Standards 2022](#).
- Chemical stability of approved malathion active constituents and registered products.
- Occupational health and safety including risk to people mixing, loading and applying malathion, risk to worker/public on re-entry to treated areas and adequacy and suitability of first aid and safety directions on product labels.

In addition to these assessments, the APVMA has completed contemporary assessments of potential dietary exposure through residues in food and has reviewed the product labels for consistency with current APVMA policies and guidelines, including the [APVMA Spray Drift Policy July 2019](#).

Mode of action, product claims and use patterns

Malathion is a group 1b (organophosphorus) insecticide and anticholinesterase chemical used in domestic, agricultural and veterinary situations. Malathion containing products are available in a variety of formulation types including emulsifiable concentrates (EC), ready to use baits (RB), oil in water emulsions (EW), ultra-low volume

(UL), dustable powder (DP), vapour releasing (VP)¹ and topical solutions for veterinary use. Malathion is used for the control of a wide range of insect pests on various commercial food crops, pastures, eucalypt forests, grain storage facilities and other buildings and equipment, ornamental plants, livestock and domestic pets, bowling and golf greens, mosquito breeding areas and on home garden, fruit vegetables and ornamentals.

¹ See the [APVMA section 6A guideline on formulation types for agricultural chemical products](#) and the [CIPAC list of formulation codes](#) for full listings of formulation type codes.

Chemistry

Active constituent

Table 1: Nomenclature and structural formula of the active constituent malathion

Common name (ISO):	Malathion (ISO 1750-1981)
Other common names:	Maldison (AS 1719-1994) Mercaptothion (Republic of South Africa) Carbofos (Russia) Mercaptotian (Argentina) Malthon (Japan)
IUPAC name:	Diethyl (2 <i>RS</i>)-2-[(dimethoxyphosphorothioyl)(sulfanyl)]butanedioate or diethyl [(dimethoxyphosphinothioyl)thio]succinate
CAS name:	Diethyl 2-[(dimethoxyphosphinothioyl)thio]butanedioate
CAS registry number:	121-75-5
EC number:	204-497-7
Molecular formula:	C ₁₀ H ₁₉ O ₆ PS ₂
Molecular weight:	330.36 g mol ⁻¹
Structural formula:	<p>The structural formula of Malathion is shown as a skeletal structure. It features a central chiral carbon atom (C*) bonded to a hydrogen atom (H) with a wavy bond, a methyl group (H₃C), a succinate group (CH₂-C(=O)-O-CH₂-CH₃), and a phosphorothioate group (S-P(=S)(OCH₃)₂). The phosphorus atom is double-bonded to a sulfur atom and single-bonded to two methoxy groups (OCH₃).</p>
Chemical family	Organophosphate compound

Table 2: Key physiochemical properties of active constituent malathion

Parameters	Properties
Colour	Clear amber
Odour	Mercaptan (thiol)-like
Physical state	Liquid
Melting point	2.85°C
Boiling point	156 to 157°C at 0.7 mmHg
Density	1.23 (25°C)
Partition coefficient (log K _{ow})	2.75
Henry constant	1.21× 10 ⁻² Pa· m ³ ·mol ⁻¹ (calc.)
Vapour pressure	5.3 mPa (30°C)
Solubility	In water: 145 mg/L (25°C) Miscible with most organic solvents e.g. alcohols, esters, ketones, ether, aromatic hydrocarbons. Slightly soluble in petroleum ether and some types of mineral oil. In heptane 65 to 93 g/L
Stability	Relatively stable in neutral, aqueous media. Decomposed by strong acids and alkalis.

There are currently 3 active constituent approvals for malathion, these are listed in Table 3.

Table 3: Current active approvals for malathion

Approval number	Approval holder
44350	FMC Australasia Pty Ltd
46160	Gulmohar Chemicals Pty Ltd
87713	Tagros Chemicals India Private Limited

The current APVMA active constituent standard specifies a minimum purity of 950 g/kg and the following toxicological impurities:

- Isomalathion: 2 g/kg maximum
- Malaaxon: 1 g/kg maximum, O,O,S-trimethylphosphorothioate (CAS No. 152-20-5): 5 g/kg maximum and O,S,S-trimethylphosphorodithioate (CAS No.22608-53-3): 0.1 g/kg maximum.

Formulated products

There are currently 19 registered products containing malathion as the active constituent. Eleven of these are agricultural products including 3 designated as home garden products, 3 are rodent bait products that contain malathion as an excipient and 5 are veterinary chemical products, these are listed in Table 4. One product (Hy-mal Insecticide) has been voluntarily cancelled by the holder since the publication of the proposed regulatory decision.

The products are formulated as emulsifiable concentrates (EC), emulsion – oil in water (EW), dustable powders (DP), ultra low volume (UL), bait (ready for use) (RB)², vapour releasing products (VP), topical dust and topical solution/suspensions.

Table 4: Malathion products under reconsideration

APVMA product number	Product name	Holder	Formulation type
Agricultural products			
42035	David Grays Malathion Garden Spray	David Gray & Co Pty Ltd	Emsulsifiable concentrate (EC)
42727	Q Fly Wick	Bugs For Bugs Pty Ltd	Vapour Releasing Product (VP)
49539	Fyfanon ULV Insecticide	FMC Australasia Pty Ltd	Ultra-low volume (UL)
50110	David Grays Malathion Grain Dust Insecticide	David Gray & Co Pty Ltd	Dustable powder (DP)
50589	Searles Fruit Fly Wick Attractant and Insecticide	JC & AT Searle Pty Ltd	Vapour releasing product (VP)
51150	Fyfanon 440 EW Insecticide	FMC Australasia Pty Ltd	Emulsion – oil in water (EW)
58968	David Grays Malathion and White Oil Insecticide	David Gray & Co Pty Ltd	Emsulsifiable concentrate (EC)
62194	Fyfanon 1000 EC Insecticide	FMC Australasia Pty Ltd	Emsulsifiable concentrate (EC)
62242	David Grays Fruit Fly Garden Spray	David Gray & Co Pty Ltd	Emsulsifiable concentrate (EC)
63032	Eco-Lure Male Qld Fruit Fly Wick	Duluxgroup (Australia) Pty Ltd	Vapour releasing product (VP)
69529	Fyfanon Premium Insecticide	FMC Australasia Pty Ltd	Emulsion – oil in water (EW)

² Containing malathion as an excipient which is included in the Poisons Standard and must be declared on the label.

APVMA product number	Product name	Holder	Formulation type
Agricultural chemical products – zinc phosphide baits containing malathion as an excipient			
60832	ZP Mouse Zinc Phosphide Bait	Bell Laboratories Inc	Bait (ready for use) (RB)
60890	ZP Rat Zinc Phosphide Bait	Bell Laboratories Inc	Bait (ready for use) (RB)
66869	Genfarm Zinc Phosphide Mouse Bait	Nutrien Ag Solutions Limited	Bait (ready for use) (RB)
Veterinary products			
33021	Pharmachemical Maldison 50 Insecticide	Bocko P/L & Flexsky P/L In Partnership	Topical solution/suspension
37201	Inca Malaban Wash Concentrate	Inca (Flight) Co Pty Ltd	Topical solution/suspension
42267	David Grays Poultry Dust	David Gray & Co Pty Ltd	Topical dust/powder
54285	Bob Martin Since 1892 Flea & Tick Control for Dogs, Cats & Aviaries Malawash	Bob Martin (Australia) Pty Ltd	Topical solution/suspension
63456	Saint Bernard Petcare Maldison Wash Insecticide	Vet Med IP Pty Ltd	Topical solution/suspension

There are currently no standards for malathion end use products. The introduction of standards for malathion products is recommended and discussed in detail in the [chemistry assessment report](#), which was published in 2016. It is recommended that an APVMA product standard be established for malathion products based on the APVMA product specifications for the assessment of storage stability data as outlined in Table 5.

The 3 ready to use bait products for control of rodents are grain-based products and contain malathion as an excipient at a concentration of 0.11 g/kg. It is proposed that the standard and conditions of registration for products containing malathion would not apply to products where malathion is an excipient at concentration of 0.11 g/kg or less.

Recommendations

Amendment of active constituent statements

It is recommended that the active constituent statements for malathion products be amended according to the requirements set out in the [Agricultural and Veterinary Labelling Codes](#).

Amendment of Australian common name

It is recommended that the Australian pesticides common name for maldison is changed to malathion to harmonise with the common name specified in ISO 1750-1981.

The amendment to the name will require changes to the relevant APVMA Standards, the register and product labels.

Date controlled status for malathion products

Prolonged storage may increase the concentration of impurities (especially isomalathion), to concentrations that do not comply with the recommended APVMA specifications outlined in Table 5. Therefore, it is recommended that malathion products be made date-controlled products, with a shelf life of no more than two years after manufacture. Product labels would therefore include an expiry date for the product.

Proposed amendment to the APVMA Standard for malathion active constituents

The current APVMA standard in the [Agricultural and Veterinary Chemicals Code \(Agricultural Active Constituents\) Standards 2022](#) (the Active Standards) states the material shall consist of maldison together with related manufacturing impurities and shall be a clear, colourless to light amber liquid, free from visible extraneous matter and added modifying agents and the minimum purity specified is 950 g/kg.

The current standard indicates the following acceptable levels of impurities:

- Isomalathion (CAS no. 3344-12-5): 2 g/kg maximum
- Malaoxon (CAS no. 1634-78-2): 1 g/kg maximum
- O,O,S-trimethylphosphorothioate (MeOOSPO) (CAS no. 152-20-5): 5 g/kg maximum
- O,S,S-trimethylphosphorodithoate (MeOSSPO) (CAS no. 22608-53-3): 0.1 g/kg maximum

It is recommended that the common name in the Active Standards be changed from maldison to malathion.

It is recommended that for the malathion active constituent, the acceptable levels for isomalthion are amended to the following in the Active Standards:

- 2 g/kg maximum within 30 days of manufacture
- 4 g/kg maximum (as measured after accelerated storage, or after 2 years storage at ambient temperature)

In addition, it is recommended that for the malathion active constituent the following additional acceptable levels of impurities should be included in the Active Standards:

- O,O,S-trimethylphosphorodithoate (MeOOSPS) (CAS no. 2953-29-9): 15 g/kg maximum
- O,O,O-trimethylphosphorothioate (MeOOOPS) (CAS no. 152-18-1): 5 g/kg maximum

The rationale behind the recommended amendments is based on the data evaluated indicating that the isomalathion concentration in active constituents increased during storage, from approximately 2 g/kg prior to

storage to 4 g/kg after 2 years storage. In addition, although the 2 trimethyl impurities currently included in the FAO but not the Australian standard (MeOOSPS & MeOOOPS) are less toxic than the 2 specified in the current APVMA Standard for malathion active constituent (MeOOSPO and MeOSSPO), the APVMA concluded that they should be added to the APVMA active constituent standard to harmonise the Australian standard Food and Agriculture Organization of the United Nations (FAO) as laid out in the FAO specifications for malathion (FAO, 2020).

Proposed APVMA standard for malathion products

It is recommended that the APVMA makes a standard for malathion products based on the APVMA product specifications for the assessment of storage stability data as indicated in Table 5. The submitted data and supporting information FAO (2020) for isomalathion in products containing malathion indicate that isomalathion has the potential to exceed acceptable concentrations after prolonged storage or storage at elevated temperatures. Hence the APVMA considers that all future registrations of malathion products require storage stability data for isomalathion, and all currently registered products must demonstrate they comply with compositional requirements outlined in Table 5.

Table 5: Compositional requirements of the APVMA condition of approval for products containing malathion

Chemical	Formulation type			
	UL and VP	EW	EC ¹	DP
Malathion ²	Active constituent concentration	Active constituent concentration	Active constituent concentration	Active constituent concentration ³
Malaoxon	Max. 0.1%	Max. 0.8%	Max 0.1%	Max 0.1%
Isomalathion	Max. 0.4%	Max. 0.6%	Max 0.8%	Max. 2.5%
MeOOSPO	Max. 0.5%	Max. 0.5%	Max. 0.5%	Max. 0.5%
MeOSSPO	Max. 0.01%	NR ⁴	NR4	NR4

Concentration percentages for all impurities in products are relative to the weight of active in the product.

¹ Compositional requirements for EC products will also be applicable to veterinary products which are specified as topical solutions.

² Allowable ranges of malathion concentrations in products are as specified in the Agricultural and Veterinary Chemicals Code Regulations 1995 and FAO specifications, with the exception of DP products as outlined below.

³ For a DP formulation, a tolerance range for declared contents between 25 and 100 g/kg is -10% to +25% instead of the usual $\pm 10\%$. The +25% tolerance used in this assessment reflects an allowable variation required to offset a significant degradation that may occur in freshly formulated material after storage.

⁴ NR = not required – because of analytical limitations, testing for MeOSSPO is not required for EW, EC and DP products.

Storage of product containers

All product containers should contain a storage statement indicating the product is to be stored below 30°C.

Approval and registration status

Active constituents and registered products should be subject to conditions of approval or registration that require them to meet the required specifications. Registrants and holders should be required to demonstrate that they meet the specifications for continuation of registration or approval.

Toxicology

The toxicology database available for malathion was considered to be of sufficient breadth and quality to determine its toxicology profile and to characterise the risk to humans for risk assessment purposes. The data included metabolism studies, acute toxicity studies, short-term toxicity studies, genotoxicity studies, neurotoxicity studies, carcinogenicity studies, reproduction studies, studies on metabolites, degradants and impurities, and other information to address the human safety criteria.

From these studies the APVMA derived health-based guidance values that underpin further risk assessments of residues and trade, spray drift, and worker health and safety.

Evaluation of toxicology

Biochemical aspects

Malathion is well absorbed following oral dosing. Accordingly, an oral absorption factor of 100% was considered appropriate for risk assessment purposes. No specific inhalation absorption data was available, and therefore the default inhalation absorption factor of 1 (100%) was considered appropriate for risk assessment. Based on studies in humans a dermal absorption factor of 8% was considered appropriate for risk assessment (Feldmann and Maibach 1974; Maibach et al. 1971, Schraf et al. 2008, Wester et al. 1983).

Malathion and its metabolites are widely and rapidly distributed in the body. However, since rapid metabolism of malathion occurs in some tissues but not in others, the distribution of malathion and its metabolites is complex.

No human-specific metabolites of risk assessment concern were identified. Following oral dosing in rats ¹⁴C-malathion was extensively metabolised via desulfuration, oxidation, hydrolysis and dealkylation and demethylation reactions. CYP1A2 and CYP2B6 catalysed oxidative desulfuration of malathion to malaoxon is an important metabolic pathway. CYP3A4 catalysis can also occur at high malathion concentrations (Burattie et al. 2005). In rats, malathion-derived radioactivity was excreted rapidly with the majority (up to 90%) excreted in urine within 24 hours. There was no evidence of accumulation of malathion-derived radioactivity in any tissue. The major urinary metabolites of ¹⁴C-malathion (greater than 80% of urine radioactivity) were: (a) α - and β -malathion monocarboxylic acids (MMAs; weak inhibitors of acetylcholinesterase), and (b) malathion dicarboxylic acid (DCA) (inactive against acetylcholinesterases). MMAs and DCA are used for biomonitoring of malathion exposure.

Trans-mammary malathion exposure of the human infant is unlikely when malathion-containing products are used as directed. While malathion was detected in human hindmilk at a concentration of 0.086 mg/L following consumption of contaminated food crops (Sanghi et al. 2003), it has not been detected in human milk from women exposed following normal aerial application practices (Lonnerdal and Asquith 1982).

Plant metabolites of human health risk assessment relevance

Metabolites occurring in plants were also identified in mammalian toxicology studies, where they were not regarded as a human health concern.

Environmental metabolites and degradants of human health risk assessment relevance

Malathion rapidly photo-oxidises to malaoxon, which rapidly degrades in agricultural environments. The toxicology of malaoxon is well elaborated and no additional human health concerns relating to environmental exposure have been identified.

Malathion impurities and degradants of human health risk assessment relevance

A range of toxic impurities have been identified in malathion, including isomalathion, malaoxon, and a number of trimethyl phosphorothioate manufacturing impurities. For the protection of human health maximum levels for these impurities have been stipulated (see Table 5, compositional requirements of the APVMA condition of approval for products containing malathion).

Major toxicological mode(s) of action and key events

As frequently observed with other organophosphorus cholinesterase insecticides the most sensitive known effects following acute and repeated exposures to malathion are the inhibition of blood and neuronal cholinesterases. At higher systemic exposure levels the key adverse effects reflect the associated cholinergic crisis. Based on current knowledge, inhibition of blood cholinesterases are generally more sensitive (and accessible) biomarkers of toxicity compared with the inhibition of neuronal cholinesterase (the key adverse event).

Acute toxicity

The acute oral (gavage) LD₅₀ of malathion in rodents range from about 1,600 to over 8,000 mg/kg, depending on the level of impurities and degradants present. The acute oral toxidrome was consistent with a cholinergic crisis. The acute dermal LD₅₀ of malathion in rats and rabbits was >2,000 mg/kg even under exaggerated exposure conditions (skin abrasion). Death occurred after dermal exposure of rabbits at ≥8,000 mg/kg. The acute inhalation LC₅₀ of malathion was >5,200 mg/m³.

Some sources of malathion are slight skin and eye irritants in rabbits. Rare instances of malathion-associated skin irritancy have been reported in children (Schanker et al 1992).

Malathion was not a skin sensitizer in a guinea-pig Buehler test, in the mouse local lymph node assay or in the mouse epicutaneous delayed hypersensitivity assay (Cushman and Street 1983). However, malathion was a weak skin sensitizer in the guinea-pig maximisation test. Rare cases of allergic contact sensitivity to malathion have been reported in humans (Milby and Epstein 1964, Schafey et al. 1999, Schanker et al. 1992, Sharma and Kaur 1990). Malathion is therefore considered to be a weak contact sensitiser.

Under normal conditions of use the risk of serious anaphylactoid reactions to malathion in humans is very low. Rare cases of IgE-mediated Type I hypersensitivity to malathion characterised by urticaria, angioedema and nonspecific skin rash have been reported in humans (Schanker et al 1992). Under strongly immunogenic conditions cutaneous anaphylaxis-associated malathion-specific IgE can be induced in rodents (Cushman and Street 1983).

Acute oral toxicity in humans

A high quality, GLP and GCP compliant, randomised, double blind, ascending single oral (gelatine capsule) dose study in humans was available for review. No effects on blood cholinesterases occurred in either sex at doses up to 15 mg/kg bw. No adverse effects occurred at any dose. The NOEL for the study was ≥ 15 mg/kg bw (OCS, 2005).

Repeat dose toxicity

A range of repeat dose studies in laboratory animals were assessed (OCS, 2005). The key effects identified across species were the inhibition of blood and brain cholinesterases. In mice and rats, damage to nasal tissue was seen at high doses (167 mg/kg bw/day in female mice in an 18-month dietary study, 458 mg/kg bw/day in rats in a 28-day dietary study, and 360 mg/kg bw/day in rats in a 24-month study). A NOAEL of 17 mg/kg bw/day based on inhibition of blood cholinesterases was identified in an 18-month dietary mouse study. In rats, NOAELs based on inhibition of blood cholinesterases were identified in a 28-day study (9 mg/kg bw/day), in a 90-day study (7 mg/kg bw/day), and in a two-year study (of 2 mg/kg bw/day). Across all rat studies erythrocyte cholinesterase activity was more sensitive to inhibition by malathion cf. brain cholinesterases. In dogs, a one-year capsule study did not identify a NOAEL; the LOAEL was 62.4 mg/kg bw/day based on inhibition of blood cholinesterases. Due to toxicity to the nasal epithelium, inhalation studies (2 week and 13 week in adult rats) did not identify a NOAEL; the LOAEL in the 13 week study was 100 mg/m³.

In dermal studies in rabbits, malathion was a cumulative skin irritant at all tested doses. A NOAEL of 50 mg/kg bw/day based on erythrocyte cholinesterase inhibition was identified in a 21-day study.

Genetic toxicology

The outcomes of the pivotal genotoxicity studies submitted for review are summarised in Table 6.

Table 6: Key findings of the pivotal genotoxicity studies (IARC, 2015, JMPR 2016)

Study type	Number of independent studies	Notes
In vitro		
Bacterial reverse mutation assay	8	All studies were negative with or without metabolic activation. 7 studies were conducted in accordance with GLP. 6 studies were conducted in accordance with OECD test guideline 471. Sufficient strains and concentrations were tested.
Mammalian cell forward mutation	1	Mouse lymphoma L5178Y (TK+/-). Based on the current OECD test guideline 490 unacceptably low cell relative survival was associated with positive findings at high concentrations. At acceptable levels of cell relative survival the results were negative.
Unscheduled DNA synthesis in primary rat hepatocytes	2	Negative.

Study type	Number of independent studies	Notes
Chromosomal aberration in primary human lymphocytes	1	Positive in the absence of metabolic activation when present at cytotoxic concentrations.
In vivo		
Mouse micronucleus	2	Negative
Mouse chromosomal aberration	1	Negative
Rat chromosomal aberration	2	One out of 2 positive. The positive study was associated with intraperitoneal injection of malathion. This route of exposure is not considered to be relevant to the human health risk assessment of malathion when used in accordance with the label directions
Rat micronucleus	1	Negative
Rat leukocyte comet assay	1	Negative
Rat hippocampus and peripheral blood comet assay	1	Negative

Based on the weight of evidence presented in Table 6 malathion is unlikely to be directly genotoxic.

There is a large body of published literature on the potential genotoxicity of malathion. Most of these studies lacked adequate descriptions of the experimental methods, controls and the source, concentrations and purity of test articles. Accordingly, most of these the studies were not compliant with accepted international best practices and regulatory requirements.

There is also considerable published evidence that exposure of mammalian systems to high doses/concentrations of malathion results in the adverse generation of reactive oxygen species and oxidative damage to (IARC 2015). As noted by WHO JMPR (2016), malathion-induced genotoxicity is associated with high doses/concentrations and oxidative DNA damage. This mode of action exhibits a threshold dose response. Based on the available body of evidence, the relevant points of departure for human health risk assessment shown in Table 7 are adequately protective against such malathion-induced redox effects *in vivo*.

Overall, malathion is unlikely to be genotoxic at the concentrations and routes of exposure encountered when malathion-containing products are used in accordance with their label directions.

Carcinogenicity

In one 18-month dietary study in mice, an increased incidence of hepatocellular adenomas in males occurred at doses ($\geq 8,000$ ppm in the diet) that exceeded the maximum tolerated dose. It is noted that these did not progress to carcinomas; however were accompanied by an increased incidence of pre-neoplastic altered eosinophilic foci. In rats, an increased incidence of hepatocellular adenomas, which did not progress to carcinomas, occurred in females at a high dose of 12,000 ppm in the diet. This exceeded the maximum tolerated dose. Given that benign hepatocellular neoplasia in rodents only occurred at excessive dose levels that exceeded the maximum tolerated

dose³ lacked a dose response and did not progress to hepatocellular carcinomas the relationship between these cancers and treatment with malathion is uncertain. Malathion is unlikely to result in human hepatic neoplasia at the levels of exposure associated with the use of malathion- containing products in accordance with their label directions.

At 6,000 ppm in the diet, a small increase in the number of nasal adenomas was seen accompanied by damage to the surface of the nasal and respiratory tissues characterised by epithelial hyperplasia, inflammation and ineffective repair. This implies a non-genotoxic, threshold neoplastic mode of action. The NOAEL of 2 mg/kg bw/day is considered to be adequately protective for these effects.

Reproduction studies

While there is limited, non-regulatory quality evidence that malathion can produce target organ toxicity in the rat male and female reproductive tract these findings were not supported in a regulatory quality 2-generation reproductive study in rats, nor in any of the repeat dose toxicology studies in this species. The key parental effect observed in the multigenerational study was reduced body weight gain, with a NOAEL of 245 mg/kg bw/day. The key offspring effect observed in the multigenerational study was reduced body weight, with a NOAEL of 80 mg/kg bw/day (JMPR, 2016).

Developmental studies

In rats, no effects on fetuses were seen at 800 mg/kg bw/day whereas reduced body weight gain occurred in the dams at this dose. A maternal NOAEL of 400 mg/kg bw/day and a foetal NOAEL of 800 mg/kg bw/day were established (JMPR, 1997). In rabbits, a maternal NOAEL of 25 mg/kg bw/day was established based on reduced body weight gain at higher doses, while no adverse foetal effects were seen at the high dose (100 mg/kg bw/day) (JMPR, 1997).

Special studies

Acute neurotoxicity

Based on a non-pivotal acute oral gavage dosing range finding study in rats cholinergic clinical signs occurred at doses greater than or equal to 800 mg/kg body weight (peak incidence of clinical signs at 15 minutes after dosing). Inhibition of blood cholinesterases was not detected following dosing at up to and including 10 mg/kg bw. In a pivotal acute oral gavage neurotoxicity study no effects on general neurological and neuromuscular performance were detected following doses of up to and including 1000 mg/kg bw. Cholinergic neurotoxic effects, inhibition of erythrocyte acetylcholinesterase and deaths occurred following dosing at 2000 mg/kg bw.

³ Treatment at excessively high doses does not distinguish between compound-induced carcinogenic effects or carcinogenesis due to non-chemical specific effects.

Acute organophosphate-induced delayed polyneuropathy

Oral exposure of hens to doses of malathion (exceeded the acute oral LD₅₀) did not induce clinical or micro-anatomic signs of organophosphate-induced delayed polyneuropathy (JMPPR, 1997). Rare cases of organophosphate-induced delayed polyneuropathy manifesting as a demyelinating sensory-motor axonopathy have been reported after massive suicidal ingestions or injection of malathion by humans (Das et al 2013, Ergun et al 2009 and Komori et al 1991). In all cases, malathion-associated organophosphate-induced delayed polyneuropathy occurred at doses that were non-survivable without treatment and were not caused by contamination with isomalathion (Jianmongkol et al 1996). Provided malathion products are used according to their label directions the risk of malathion-induced organophosphate-induced delayed polyneuropathy is negligible.

Developmental effects on blood and brain cholinesterases

Overall, the results of these studies demonstrated that rat fetuses exposed trans-placentally to malathion and rat pups were no more susceptible to inhibition of blood and brain cholinesterases cf. female adults. Overall, the NOAEL for inhibition of blood cholinesterases for rat fetuses at gestational day 20, rat pups postnatal days 11 to 21 of age, pregnant dams at gestational day 20 and young adult rats was 5 mg/kg bw/day. Across the same populations the NOAEL for inhibition of brain cholinesterases was 50 mg/kg bw/day.

Developmental neurotoxicity

In rats the maternal NOAEL was 50 mg/kg bw/day, due to the increased incidence of salivation following dosing at 150 mg/kg bw/day. The NOAEL for developmental neurotoxicity was also 50 mg/kg bw/day due to transient, and reversible, effects on the righting reflex in females at 150 mg/kg bw/day on post-natal day 11.

Immunotoxicology

No effects on T-cell mediated antibody responses resulted from oral malathion dosing of female mice at up to 1,216 mg/kg bw/day.

Endocrine disruption

Based on a rat prostate cytosol test malathion had equivocal androgen receptor binding at concentrations up to 10⁻³ M. In an *in vitro* estrogen receptor transcriptional activation assay malathion did not induce more than 4% transcriptional activation relative to positive control. The no observed effect concentration (NOEC) in this assay was 10⁻⁵ M. Based on these findings, malathion is not classified as a human estrogen receptor alpha agonist. Malathion at concentrations up to 10⁻⁴ M was an equivocal modulator of steroidogenesis *in vitro*. Likewise, malathion at concentrations up to 10⁻³ M was an equivocal inhibitor of aromatase *in vitro*.

Malathion at dose up to 1,000 mg/kg bw/day did not induce estrogenic effects in a female rat uterotrophic bioassay, did not induce any androgenic effects in a male rat Hershberger bioassay and did not produce effects on the androgen, estrogen and thyroid hormone systems in a rat pubertal development and thyroid function study.

Based on weight of evidence malathion is not a human-relevant endocrine disruptor at the levels of exposure associated with the use of malathion-containing products in accordance with their label directions.

High throughput screening data

A large body of high throughput bioactivity screening data is available and was evaluated as part of the APVMA chemical review. The high throughput bioactivity screening data are consistent with the overall findings of the malathion toxicology assessment.

Studies on metabolites

Acute toxicity

The acute oral LD₅₀ for malathion monocarboxylic acid and malathion dicarboxylic acid were >2,000 mg/kg bw in rats. The acute oral LD₅₀ of the malaoxon ultimate toxicant derived from malathion was 50 mg/kg bw in rats

Repeat dose toxicity

The NOAEL for malaoxon administered in the diet in a non-pivotal 14-day repeat daily dose ranging study in rats was 3 mg/kg bw/day based on inhibition of plasma cholinesterase following dosing at 12 mg/kg bw/day.

In a 24-month repeat daily dose study in rats the NOAEL for malaoxon was 1 mg/kg bw/day based on the inhibition of blood and brain cholinesterases and damage to the nasal mucosa. Near life-time dietary exposure to malaoxon was not associated with neoplasia in rats.

Health-based guidance values

Table 7: Points of departure for human health risk assessment

	Study type	Key effect	Point of departure	Reference
Single dose exposure				
Single oral dose	Single oral (capsule) ascending dose study; human	No effects	NOEL ≥15 mg/kg bw	(OCS, 2005. JMPR 1997). (Gillies and Dickson, 2000, Aston, 2005)
Repeat dose exposure				
Short term oral exposure	28-day oral (dietary) repeat dose; rat (adult)	Inhibition of erythrocyte cholinesterase	NOEL 9 mg/kg bw/day	(OCS, 2005. JMPR 1997) (Barnett 2012b)
Intermediate term oral exposure	90-day oral (dietary) repeat dose; rat (adult)	Inhibition of erythrocyte cholinesterase	NOEL 7 mg/kg bw/day	(OCS, 2005. JMPR 1997) (Daly, 1993)
Long term oral exposure	2-year oral (dietary) repeat dose; rat (adult)	Inhibition of plasma, erythrocyte and brain cholinesterase	NOEL 2 mg/kg bw/day	(OCS, 2005. JMPR 1997) (Daly, 1996a)

	Study type	Key effect	Point of departure	Reference
Short term inhalation exposure	2-week inhalation (respirable aerosol, whole body exposure, 6 hours per day, five days per week) repeat exposure; rat (adult)	Inhibition of plasma cholinesterases Inhibition of erythrocyte cholinesterase Toxicity to the olfactory epithelium	LOAEL 500 mg/m ³	(OCS 2005, Beattie, 1993)
Intermediate term inhalation exposure	13-week inhalation (respirable aerosol, whole body exposure, 6 hours per day, five days per week) repeat exposure; rat (adult)	Toxicity to the olfactory epithelium Toxicity to the laryngeal epithelium	LOAEL 100 mg/m ³	(OCS 2005, Beattie, 1994)
Short term dermal exposure	21-day occlusive dermal repeat dose; rabbit (adult)	Inhibition of erythrocyte cholinesterase Inhibition of brain cerebellum cholinesterase Skin irritancy	NOEL (systemic effects) 50 mg/kg bw/day LOAEL (local effects in the skin) 50 mg/kg bw/day	((OCS, 2005. JMPR 1997) (Moreno, 1988))
Carcinogenicity				
Near life-time exposure carcinogenesis study	24-month repeat daily oral exposure study in rats	Increased incidence of nasal adenomas (mode of action: hyperplastic ineffective repair+ inflammation; threshold mode of action)	LOAEL 739 mg/kg bw/day NOAEL 29 mg/kg bw/day	(OCS, 2005. JMPR 1997) Daly, 1996a
Reproduction and development				
Reproduction	Two-generation reproduction study; rat	Parents: reduced body weight gain Offspring: reduced body weight	Parental: NOAEL 245 mg/kg bw/day Offspring: NOAEL 80 mg/kg bw/day	(OCS, 2005. JMPR 1997) Schroeder, 1990
Development				
Maternal toxicity	Developmental toxicity study; rabbit	Reduced body weight gain	NOEL 25 mg/kg bw/day	(OCS, 2005. JMPR 1997) Siglin 1985b
Foetal development	Developmental toxicity study; rat	No effects at the highest dose tested	≥800 mg/kg bw/day	(OCS, 2005. JMPR 1997) Lochry 1989

The acceptable daily intake (ADI) is that quantity of a chemical that can safely be consumed on a daily basis for a lifetime and the acute reference dose (ARfD) is the maximum quantity of a chemical that can safely be consumed over a short period of time, usually in one meal or during one day. Based on the evaluation of the available toxicological database the current APVMA ADI (Table 8) and ARfD (Table 9) for malathion will be retained.

Table 8: Acceptable daily intake for malathion

Chemical	ADI mg/kg bw/day	NOEL	Date	Study	Comments
Malathion	0.02	2	12 April 2005	2-year dietary rat study; a NOAEL of 2 mg/kg bw/day was based on inhibition of RBC cholinesterase activity at the next higher dose.	Acceptable margin of exposure ≥ 100 .

Table 9: Acute reference dose for malathion

Chemical	ARfD mg/kg bw/day	NOEL	Date	Study	Comments
Malathion	1.5	15	12 April 2005	Acute oral human study; NOEL of ≥ 15 mg/kg bw due to lack of effects at the maximum dose tested.	Test article contained 0.24% isomalathion which slightly exceeds the recommended APVMA limit for this impurity (0.2%). However this does not decrease the reliability of the ARfD. Acceptable margin of exposure ≥ 10 .

Poisons scheduling

No changes to poisons scheduling are required. A summary of the current poison scheduling for malathion is shown in Table 10.

Table 10: Poison scheduling for malathion

Chemical schedule	Description
Schedule 3	Malathion in preparations for human external use except in preparations containing 2 % or less of malathion.
Schedule 4	Organophosphorus compounds with anticholinesterase activity for human therapeutic use except a) when separately specified in these Schedules or b) in preparations containing 2% or less of malathion for external use.
Schedule 5	Malathion in preparations containing 10% or less of malathion except a) for human therapeutic use or b) in dust preparations containing 2% or less of malathion.
Schedule 6	MALATHION except a) when included in Schedule 5, b) for human therapeutic use or c) in dust preparations containing 2% or less of malathion.

Recommendations

The toxicological component of the Review Technical Report considered the hazards identified in acute, short-term, chronic, reproduction and developmental toxicity studies, genotoxicity, carcinogenicity and neurotoxicity studies of malathion, its degradants, metabolites and impurities.

The malathion toxicology component of the Review Technical Report concludes that the:

- active constituents and registration of products containing malathion would not be an undue health hazard to the safety of people exposed to it during its handling or people using anything containing its residues
- active constituents and registration of products containing malathion would not be likely to have an effect that is harmful to human beings
- ADI for malathion should remain at 0.02 mg of malathion per kilogram body weight per day based on a no observed adverse effect level of 2 mg/kg bw/day in a 2-year rat dietary study, based on inhibition of RBC cholinesterase activity at the next higher dose. The ADI incorporates a 100-fold uncertainty factor to account for inter- and intra-species variation in sensitivity
- ARfD for malathion should remain at 1.5 mg of malathion per kg body weight based on a no observed adverse effect level of 15 mg per kilogram body weight in an acute human study. The ARfD incorporates a 100-fold uncertainty factor to account for inter- and intra-species variation in sensitivity
- scheduling for malathion in the Standard for the Uniform Scheduling of Medicines and Poisons remain unchanged.
- signal heading on the labels of malathion fruit fly bait products containing a concentration of malathion of >10% should be changed from 'CAUTION' to 'POSION' to align with the current poison schedule.

Work health and safety

The risks associated with the use of products containing malathion have been assessed, in accordance with the [APVMA human health risk assessment manual](#), and a summary of the evaluation is presented.

Points of departure and margins of exposure for risk characterisation

The points of departure (POD) and margins of exposure (MOE) used for risk characterisation are shown in Table 11.

Table 11: Points of departure and margins of exposure used for risk characterisation

Form of exposure	Point of departure	Required margin of exposure	Study and comments
Single exposure	15 mg/kg bw (oral route)	10	Acute oral human study; NOEL of ≥ 15 mg/kg bw due to lack of effects at the maximum dose tested. (Gillies and Dickson, 2000, Aston, 2000)
Short term repeated oral exposure	9 mg/kg bw/day	100	28-day oral (dietary) repeat dose; rat (adult). NOEL based on inhibition of erythrocyte cholinesterase (Barnett 2012b) (OCS, 2005. JMPR 1997)
Short term repeated dermal exposure Re-entry exposures	50 mg/kg bw/day (NOEL)	100	21-day repeat daily occlusive dermal exposure in rabbits. Note that, at this dose, local irritation effects were observed. (Moreno, 1988) (OCS, 2005) (JMPR 1997)
Short and intermediate term repeated inhalation exposure	100 mg/m ³ POD _{Adj} \approx 23 mg/kg bw/day* (LOAEL)	1,000	90-day repeat inhalation (respirable aerosol, whole body exposure, 6 hours per day, five days per week) exposure study in rats. (Beattie, 1994)

* POD_{Adj} is the POD in rats adjusted to an 8-hour working day using Haber's law

Use patterns and parameters of the risk assessment

Currently registered products are set out in Table 4.

Companion animal external parasiticide exposure, non-professional use surrogate exposure scenario evaluations

The methods and parameters used in the exposure evaluation are shown in Table 12. These methods were applied to the non-professional application of liquid and dust preparations to companion/domestic horses, dogs, cats and poultry. Handler application and post application exposures were assessed using the US EPA Residential Exposure Standard Operating Procedures. Default assumptions include handlers being over 16 years of age and wearing short-sleeved shirts and shorts. Application methods included dips (rinse or pour) and sponge for cats,

dogs and horses, trigger pump spray for domestic poultry and shaker can for domestic poultry and companion birds. The use of products on cattle and pigs have not been assessed in this category as these species are not considered to be companion animals.

Table 12: Parameters used in the companion animal external parasiticide exposure, non-professional use surrogate exposure scenario evaluation

Parameters	Value
Number of animals treated per day	2 (large)
Application rate of 6.25 g malathion/L liquid	Horse – 2 L (12,500 mg) Dog – 200 mL to 500 mL (1,250 to 3,125 mg/dog) Cat – 100 mL to 200 mL (625 to 1,250 mg/cat)
Application rate of 2.5 g malathion/L liquid	Domestic poultry – 50 mL (125 mg)/bird
Application rate of 20 g malathion/kg dust	125 mg/bird
Exposure population characteristics	Handler – 16 years or over, body weight 70 kg Children – 1- to 2-year-old, body weight 11 kg
Exposure pattern	Acute exposure, with minimum re-treatment interval of 7 days
NOAEL	15 mg/kg bw – acute human study
Margin of exposure (MOE)	10
Fraction of malathion removable from animal surface	0.02%

Based on the above parameters and using the default values and calculators in the US Residential Exposure Standard Operating Procedures, exposures associated with mixing, application and post-application exposure resulting from the non-professional use of liquid and dust formulations of malathion for the treatment of external parasites on companion horses, dogs, cats and domestic poultry were assessed. All uses were acceptable (MOE >10), however animals treated with liquid preparations should be allowed to dry for at least one hour before petting and re-handling by children.

Companion animal housing and bedding non-professional treatment surrogate exposure scenario evaluations

A similar approach was taken to assess exposure resulting from companion animal housing and bedding. These exposure scenarios apply to the non-professional use of malathion-containing products for the treatment of bird aviaries (walls, cracks and crevices, roosts, nesting boxes, litter etc.), domestic poultry facilities (walls, cracks and crevices, roosts, nesting boxes, litter), dog and cat bedding, dog and cat living areas, yards and kennels, horse stables. Application methods for liquid treatments include trigger pump sprayers, manually pressured trigger sprayers, hand wands, paint sprayers and airless sprayers. Dust formulations were assessed for application via a shaker can. The parameters used in the exposure evaluation are shown in Table 13.

Table 13: Methods and parameters used in the companion animal housing and bedding non-professional treatment surrogate exposure scenario evaluation

Parameters	Value
Application rate of 6.25 g malathion/L liquid	Trigger pump and manually pressurized trigger sprayers – 2 L (0.0125 kg malathion) per day Manually pressurized hand wand, paint (including manually pressurised sprayer) and airless sprayer – 4 L (0.025 kg malathion) per day
Application rate of 20 g malathion/kg dust	Shaker can – 1 kg (0.02 kg malathion) per day
Exposure population characteristics	Handler – 16 years or over, body weight 70 kg Children – 1- to 2-year-old, body weight 11 kg
Exposure pattern	Acute exposure, with minimum re-treatment interval of 7 days
NOAEL	Acute – 15 mg/kg bw – acute human study Post-application – repeated exposure – 9 mg/kg bw/day (rat)
Margin of exposure (MOE)	10 (acute) 100 (repeat)

Based on the parameters shown in Table 13 and using the defaults and calculations in the US EPA Residential Exposure Standard Operational Procedures, exposures associated with mixing, application and immediate post-application exposure of adults (but not children) resulting from the non-professional use of liquid and dust formulations of malathion for the treatment of companion animal housing and bedding is acceptable (MOE >10). It is good practice to allow animal housing and bedding treated with liquid preparations to dry before re-entering/re-handling. Children must not be allowed to enter into treated animal housing or handle treated animal bedding for 3 full days post-application (re-entry/re-handling permissible on the 4th post-application day, MOE >100).

Non-professional home and garden use surrogate exposure scenario evaluations

The methods and parameters used in the exposure evaluation are shown in Table 14. These exposure scenarios apply to the non-professional use of malathion-containing products for home garden fruit fly, fly and mosquito control and as an insecticide in home garden fruit trees, ornamentals and vegetables.

Table 14: Non-professional home and garden use surrogate exposure scenario evaluations

Assessment method	Application methods	Parameters
Handler application exposure: RESOP*	<ul style="list-style-type: none"> • Trigger pump spray and manually pressurised trigger sprayers 	Application rates and amount handled per day
		Garden size 111.5 m ² **12
Post application exposure: RESOP	<ul style="list-style-type: none"> • Manually pressurised hand wand 	Maximum concentration ac used 3.125 g/L
		Liquids
	<ul style="list-style-type: none"> • Hose-end sprayer 	Trigger pump sprayers and manually pressurised trigger sprayers 7.6 L/d** x3.125 g/L= 23.75 g/d
	<ul style="list-style-type: none"> • Sprinkler can 	Manually pressurised hand wand 18.9 L/d** x3.125 g/L= 59.1 g/d
	<ul style="list-style-type: none"> • Backpack sprayer 	Hose-end sprayer 41.6 L/d** x3.125 g/L= 130 g/d
		Sprinkler can 18.9 L/d**= 51.9 g/d
		Backpack sprayer 18.9 L/d** x3.125 g/L= 51.9 g/d
		Exposure population characteristics
		Handlers Adult (≥ 16 years of age, body weight 70 kg**)
		Post-application Adult (≥ 16 years of age, body weight 70 kg**) Children (6 < 11 years old; body weight 32 kg**)
		Exposure pattern
		Acute (single exposure) based on minimum re-treatment interval of 7 days. Based on the biochemical data the elimination of malathion and its metabolites is essentially complete at one to 2 days following exposure.
		Based on the biochemical data the elimination of malathion and its metabolites is essentially complete at one to 2 days following exposure. Accordingly the acute POD (systemic)= 15 mg/kg bw (acceptable MOE= 10) was regarded as appropriate. Based on agricultural data surface malathion residues declined to about 3% of the initial values within 2 days of application, an approximate t _{1/2} = 12 hours. Accordingly an FD of 0.75 has been used. Since post-application exposure of children involves repeated daily exposures the short-term POD (systemic) of 9 mg/kg bw/day, acceptable MOE= 100 has been used.
		Handler*** mixing and application unit exposures (UES) and algorithm

Assessment method	Application methods	Parameters			
		Formulation	Application method	Dermal unit exposure mg/kg ac**	Inhalation unit exposure mg/kg ac**
		Liquid	Trigger pump sprayers and manually pressurised trigger sprayers	187.613	0.134
			Manually pressurised hand wand	138.891	0.040
			Hose-end sprayer	127.868	0.003
			Sprinkler can	127.868	0.003
			Backpack sprayer	286.601	0.309
		Exposure mg/day= UEx amount handled/day (kg/d)			
		Post-application dermal exposure factors and algorithm			
		DFRt ($\mu\text{g}/\text{cm}^2$)**	15		
		CF1 ($\text{mg}/\mu\text{g}$)**	0.001		
		TC (cm^2/h)**	Adult: 8400 Children 6 < 11 years old: 4600		
		ET (h)**	Adult: 2.2 Children 6 < 11 years old: 1.1		
		E= DFRt x CF1 x TC x ET			
		Post-application hand-to-mouth exposure: not required**			

* RESOP = US EPA Residential Exposure Standard Operational Procedures

** RESOP default

*** Handler = person who mixes and applies the material. By RESOP default handlers are assumed to be adult (≥ 16 years of age) and wearing short-sleeved shirt, shorts and no chemical-resistant gloves.

Based on the methods and parameters shown in Table 14, exposures associated with mixing, application and post-application exposure resulting from the non-professional use of liquid formulations of malathion for home garden fruit fly, fly and mosquito control and as an insecticide in home garden fruit trees, ornamentals and vegetables is acceptable (MOE >10). It is good practice not to re-enter treated areas until the spray is dry. Withholding periods for consumption of home-grown foods treated with malathion may apply.

Professional occupational agricultural and veterinary use surrogate exposure scenario evaluations

The exposure scenarios are based on the [US EPA Occupational Pesticide Handler Exposure Data](#) (OPHED) and [Occupational Pesticide Post-application Exposure Data](#) (OPPED). The exposure modelling parameters, assumptions, exposure situations and use rates evaluated are shown in Table 15. The outcomes of the exposure risk assessments for the various exposure situations are shown in Table 16. Bystander exposure was assessed based on the [APVMA spray drift risk assessment tool](#).

Table 15: Exposure situations and modelling parameters

Parameters	Value
Bodyweight	70 kg
Body surface area (adult)	1.94 m ²
Ventilation rate (light activities)	1.0 m ³ /h
Normal workday	8 h with an application period of 6 h
Average size of house	Area 170 m ² , volume 430 m ³
Average size of greenhouse	Area 150 m ² , volume 375 m ³
Average industrial building	Area 2500 m ² , volume 12,500 m ³
Average office building	Area 7500 m ² , volume 18,000 m ³
Penetration through overalls	10%
Penetration through chemical-resistant full body clothing	5%
Penetration through chemical-resistant gloves	10%
Protection afforded by half face-piece respirator with gas/dust cartridges	90%
Protection afforded by full face-piece respirator with gas/dust cartridges	98%
Protection afforded by supplied air respirator (air-hose respirator or SCBA)	100%
Container neck width	Narrow
Dermal absorption factor	
Concentrate	8%
Dilution	8%
Inhalation absorption factor	100%
Oral absorption factor	100%
Re-entry exposure assessment parameters	

Parameters	Value
Initial dislodgeable foliar residues (DFR)	20% of the ac applied
Dissipation rate/day	10%
Adult exposure duration	8 h/day

Exposure situations

Situation 1: Mixing and loading EC formulations (500 g/L malathion)

	Dilution of product for application	Application rate
Dilute Spray	200 mL/100 L water	1,500 L/ha
Concentrate spray	600 mL/100 L water	
Eucalypts – dilute spray	300 mL/100 L	
Eucalypts – concentrate spray	900 mL/100 L	
Cereals and pastures	1.2 – 2.2 L product in 110 L	1.2 to 2.2 L/ha
Bait	250 – 500 mL with 10/20 kg kibbled grain	
	2.4 L/100 L water	1 L/1 tonne grain
Treating stored grain facilities	5L /100L water	10 L/200 m ² surface
Dairies, stables, factories, pig	6L /100L water	

Products are also used for mosquito control and will be mixed with a suitable diluent and applied by fogging machines. These rates are also applicable for the 440 g/L EW formulation. These products will also be used as bait. 250 to 500 mL of product will be mixed in a cement mixer in 10 to 20 kg kibbled grain to be applied by a spreader. For grain protection, the maximum amount of product used is 2.4 L/100 L water using 1 L of the mixed solution for treating 1 tonne of grain. For treating stored grain facilities, the product is diluted at 5 L/100L water and used at 10 L of prepared spray/200 m² surface. For treating dairies, stables, factories, pig sheds and animal quarters, maximum 6 L of the products will be mixed in 100 L of water.

Situation 2: Mixing and loading ULV and EC formulations (1180/1150 g/L malathion)

These products will be used for the control of a wide range of insect pests in a variety of crops, and eucalypts, as well as for mosquito control. For crops and eucalypts, they will be applied undiluted from aircraft or misting machines at up to 900 mL/ha, and for mosquito control they will be mixed with a suitable diluent and applied by fogging machines. Repeated applications may be carried out if required. The ultra-low volume products contain no excipients, consisting entirely of the active constituent, malathion.

Situation 3: Outdoor application of EC/ULV formulation by boomspray

These products will be applied by boomspray for the control of a range of insect pests in field crops, pastures, vegetable crops, tobacco and ornamentals.

Situation 4: Outdoor application of EC/ULV formulation by airblast

These products are for the control of a wide range of insect pests in a variety of crops, and eucalypt. They are applied at the rate of generally up to 1.5 kg active/ha, however for EC formulations, the rate may be up to 2.8 kg active/ha, different concentrations will be mixed depending on the formulation used. The product with the highest application rate

Parameters	Value
	of 2.8 kg active/ha (to be applied to apples) includes information from the registrant that a work rate of 15 hectares per day is anticipated for this product.
Situation 5: Outdoor application of 500 EC formulation as a mist	
	The EC formulations will be applied using 1.2 L to 2.2 L product in 2.5 L water/ha. The ULV formulations will be applied after mixing 280 mL of the product with a kerosene/diesel distillate ratio of 1 L to 8 L for mosquito control by using a fogger.
Situation 6: Outdoor application of ULV/EC formulation by aircraft	
	The product will be applied without diluting in the range of 225 mL to 900 mL/ha by aircraft.
Situation 7: Application of EC formulation on stored grain	
	Dust formulation for use on grains is registered only in WA, for the protection of stored grain from weevil attack. This dust will be applied at the rate of 600 g of dust to 1000 kg of grain and will be mixed thoroughly.
Situation 8: Application for Fruit Fly lure control	
	These products are for the monitoring of the presence of the male Queensland Fruit fly in orchards. Traps containing blocks or wicks impregnated with the chemical lure and malathion are hung in trees. Presentation of the product varies. Two include a trap, and require minimal assembly, while the other two products require that the wick or block be placed into a trap contrasted by the user. The potential for dermal exposure exists when assembling traps and during subsequent inspections (daily). The amount of the active, malathion present in the wick, or the block is minimal, for example one of the products, Q Fly Wick contains 0.1 mL malathion per wick. Traps containing Q Fly Wick are placed around the orchard perimeter to indicate source direction of flies entering the orchard and one or 2 traps are placed in the centre of the orchard to indicate the efficacy of the control program. Q Fly Wicks will attract male flies from up to 400 meters. They are replaced after 3 months if needed.
Situation 9: Application to animal housing facilities	
	The products are applied to animal houses such as stables, kennels, bedding with hand-held spray or knapsack equipment, using 1 L of diluted spray, (10 mL/L) per 20 m ² of area. The highest use rate however is for control of hide beetle in pig and poultry sheds where up to 6.8 L/100L (of a 440 g/L malathion product) is recommended, therefore using 1 L of diluted spray, (68 mL/L) per 20 m ² of area.
Situation 10: Application for mosquito control	
	These products are applied at a rate of 600 mL to 1L/ha by using handheld pressure spray or a misting machine. When applied by a mister, 280 mL/ha of ULV products are diluted with a kerosene/diesel mixture of 1 L or 8 L respectively.
Situation 11: Application as a bait	
	For application as a bait, for ULV products, 110 mL of the product will be mixed with 10 kg of whole or kibbled grain for application/ha for the control of immature crickets or 110 to 22 mL/10 to 20 kg of whole or kibbled grain/ha for the control of mature crickets.
Situation 12: Dust application to poultry	
	For the treatment of various infestations in poultry application is to the feathers of birds, and to roost and crevices of buildings, with repeated application where necessary. Details for the application method are not provided on the registered label.
Situation 13: Liquid parasiticide application to livestock and companion animals (professional use)	
	A 500 g/L product is recommended for the control of a wide range of insect pests in dogs, cats, poultry, pigs, horses and cattle. The product will be diluted in water to malathion concentrations of 2.5 to 10 g/L, for the control of external pests on animals, 0.6 to 6.25 g/L for fly control. 0.5 to 1 L/ha of the product is used for mosquito control, diluted with water as required. The product Inca Malaban Wash Concentrate (200 g/L malathion) is also for the control of fleas, lice and adult brown ticks on dogs and cats, and in dog kennels. It is also for the control of Sarcoptic mange and mites on

Parameters	Value
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dogs and cats, and aids in the control of mites in aviaries and lofts. For most applications, the product will be diluted 15 mL in 1 L of water (30 mL/L for treating dogs for Sarcoptic Mange and ticks), resulting in malathion concentrations of 3 to 6 g/L. Dogs and cats will be swabbed with the dilute solution, and aviaries and lofts sprayed.

Maximum work rates

Equipment/use pattern	Area treated per day (ha)	kg ac/ha	kg ac handled/day
Airblast	30	1.5	45
Airblast (apples)	15 ^a	2.8	42 ^b
Boomspray	50	1.1	55
Aircraft	1,200	1.05	1,260
Misters	30	1.1	33
Hand-held applications	1	15 (1 L spray/20 m ²)	15
Backpack	0.2 (100 L dilute spray)	3	0.6
Foggers (vehicle-mounted)	30	0.8	24
ULV misters/cold foggers (hand-held)	1	0.8	0.8
Thermal foggers (hand-held)	1	0.35	0.35
Mechanical spreader	10	0.25	2.5
Treatment of grains	2,000 tonnes grain/day	1.2 kg ai/100 tonnes gain	24

^a Rate specified for registered product with specific use on apples

^b Total work rate covered by the general rate for airblast application

Table 16: Exposure assessment outcomes and risk characterisations

Exposure situation	Exposure assessment outcome and risk characterisation
Situations 1–6, 9 and 10*	<p>Mixing and loading only (a separate operator must apply):</p> <p>Aerial application open mixing and loading: MOE <100 irrespective of the level of personal protective equipment used. Accordingly this use is not acceptable.</p> <p>Aerial application closed mixing and loading: MOE >100 provided a single layer of clothing is used.</p> <p>Application only (a separate operator must mix and load):</p> <p>High-pressure handheld ULV misters/cold fogger application: MOE >100 provided a single layer of clothing is worn.</p> <p>Backpack ULV misters/cold fogger application: MOE <100 irrespective of the level of personal protective equipment used. Accordingly, this use is not acceptable.</p> <p>Treatment of grain using a coarse shielded spray: Grain is treated as a coarse shielded spray (1.2% malathion) as it comes into the silo on a conveyor belt for storage. Under normal operating conditions, workers are not expected to come in contact with the spray. Exposure during equipment setup and maintenance should be minimised by flushing/cleaning the equipment before such operations.</p> <p>Aerial application: MOE >100 provided a single layer of clothing is worn.</p> <p>Mixing, loading and application by a single operator:</p> <p>Hand-held fogging equipment: MOE >100 provided a single layer of clothing, gloves and eye protection are worn.</p> <p>Boomspray: MOE >100 provided a single layer of clothing and gloves are worn.</p> <p>Airblast: MOE > 100 provided a closed cab is used and a single layer of clothing and gloves are worn. Open cab application is not acceptable (MOE < 100).</p> <p>High pressure hand wand: provided a single layer of clothing and gloves are worn.</p> <p>Low pressure hand wand: MOE >100 provided a double layer of clothing and gloves are worn.</p> <p>Backpack application: MOE >100 provided a double layer of clothing, gloves and a PF10 mask are worn.</p> <p>Broadacre misters and vehicle mounted foggers: MOE >100 provided a single layer of clothing and gloves are worn.</p> <p>High-pressure handheld fogger application: MOE >100 provided a single layer of clothing is worn.</p> <p>Backpack ULV/cold fogger application: MOE <100 irrespective of the level of personal protective equipment used. Accordingly this use is not acceptable.</p> <p>Backpack thermal fogger application: MOE >100 provided a single layer of clothing, chemical resistant clothing, gloves and a washable hat are worn.</p> <p>Bystander exposures</p> <p>Buffer zones are not required (single layer of clothing is recommended based on good agricultural practice) for ≥fine droplet size. Note Health RAL is 3606 g ac/ha</p> <p>Re-entry exposures</p> <p>Fruiting vegetable crops: MOE >100 provided a 1-day re-entry restriction is applied for irrigation, scouting, thinning and weeding.</p> <p>Leafy vegetable crops: MOE >100 provided a 1-day re-entry restriction is applied for irrigation and scouting mature plants, hand harvesting and pruning.</p>

Exposure situation	Exposure assessment outcome and risk characterisation
	<p>Field crops (low): MOE >100 provided: (a) a 2-day re-entry restriction is applied for hand- set irrigation; and (b) a 1-day re-entry restriction is applied for scouting, thinning and weeding.</p> <p>Grapes: MOE >100 provided: (a) a 1-day re-entry restriction is applied for bird control, propagation, trellis repair and transplanting; (b) a 2-day re-entry restriction is applied for hand irrigation, hand pruning, hand weeding and scouting; (c) a 17-day restriction is applied for tying, training, leaf pulling and hand harvesting; and (d) a 24-day re-entry restriction is applied for girdling and turning.</p> <p>Apples: MOE >100 provided: (a) a 1-day re-entry restriction is applied for hand pruning, training, scouting, training, transplanting, orchard maintenance, propping and hand weeding; (b) an 8 day re-entry restriction is applied for hand harvesting; and (c) 17 days for thinning fruit. Noting that there is a harvest withholding period of 14 days on the label of product 69529, a re-entry of 14 days for hand harvesting will included to provide clarity on the product label.</p>
Situation 8*	Trap loading/assembly: MOE >100 provided a single layer of clothing and gloves are worn.
Situations 7 and 12*	Application: MOE >100 provided a single layer of clothing, gloves and disposable dust mask are worn.
Situation 11*	Mixing and loading: MOE >100 provided a single layer of clothing and gloves are worn Application: MOE >100 provided a single layer of clothing is worn
Situation 13*	Mixing and preparation: MOE >100 provided a single layer of clothing, gloves, eye protection and disposable mist mask are worn. Application: MOE >100 provided a single layer of clothing and gloves are worn.

*Additional personal protective equipment may be required based on the First Aid Instructions and Safety Directions.

First aid instructions

Based on the current risk assessments, no change to the first aid instruction entries is recommended for malathion. The statements remain as follows in Table 17.

Table 17: First aid instructions for malathion products

Concentration	Code	First aid instruction
Malathion ≤20%	a	If poisoning occurs, contact a doctor or Poisons Information Centre. Phone Australia 13 11 26, New Zealand 0800 764 766.
Malathion >20%	m	If swallowed, splashed on skin or in eyes, or inhaled, contact a Poisons Information Centre (Phone Australia 13 11 26, New Zealand 0800 764 766) 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

Following consideration of both the acute hazards and systemic risks of exposure to formulated products, safety directions have been amended or established. These safety directions must be included on the relevant product label.

EC and ULV products

- Fyfanon ULV Insecticide (49539) (1169 g/L malathion)
- Fyfanon 1000 EC Insecticide (62194) (1000 g/L malathion)

ULV or EC 1,200 g/L or less

Harmful if swallowed. Will irritate the eyes and skin. Avoid contact with eyes and skin. Repeated exposure may cause allergic disorders. Repeated minor exposure may have a cumulative poisoning effect. When opening the container, preparing the spray, wear cotton overalls buttoned to the neck and wrist (or equivalent clothing) and elbow length chemical resistant gloves and a face shield. When using the prepared spray, wear chemical resistant clothing buttoned to the neck and wrist and a washable hat, and elbow length chemical resistant gloves. 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 and contaminated clothing.

EW products

- Fyfanon 440 EW Insecticide (51150) (440 g/L malathion)
- Fyfanon Premium Insecticide (69529) (320 g/L malathion)

EW 550 g/L or less

May irritate the eyes and skin. Avoid contact with eyes and skin. Repeated exposure may cause allergic disorders. Repeated minor exposure may have a cumulative poisoning effect. When opening the container and preparing the product for use, wear cotton overalls buttoned to the neck and wrist and a washable hat and elbow length chemical resistant gloves. When using the prepared bait/spray, wear cotton overalls buttoned to the neck and wrist and a washable hat and elbow length chemical resistant gloves. If applying by low pressure hand wand, wear chemical resistant clothing buttoned to the neck and wrist and a washable hat and elbow length chemical resistant gloves. If applying by backpack sprayer, wear cotton overalls, over normal clothing buttoned to the neck and wrist and elbow length chemical resistant gloves and a half facepiece respirator. Wash hands after use. After each day's use, wash gloves, face shield and contaminated clothing.

Baits – vapour releasing products

- Eco-lure male QLD Fruit Fly wick (63032) (0.5 mL/wick malathion and 1 mL/wick 4-(p-hydroxyphenyl)-2-butanone)
- Q Fly Wick (42727) (0.5 mL/wick malathion, 1.0 mL/wick 4-(p-acetoxyphenol)-2-butanone)
- Searles Fruit Fly Wick Attractant and Insecticide (50589) (40 g/kg malathion, 122 g/kg 4-(p-acetoxyphenol)-2-butanone)

VP 306 g/kg or less

May irritate the eyes and skin. Avoid contact with eyes and skin. Repeated exposure may cause allergic disorders. Repeated minor exposure may have a cumulative poisoning effect. When using the product wear elbow-length chemical resistant gloves. Wash hands after use. After each day's use wash gloves and contaminated clothing.

Baits – grain baits

- ZP Mouse zinc phosphide bait (60832) (20 g/kg zinc phosphide, 0.11 g/kg malathion)
- ZP Rat zinc phosphide bait (60890) (20 g/kg zinc phosphide, 0.11 g/kg malathion)
- Genfarm zinc phosphide mouse bait (66869) (20 g/kg zinc phosphide, 0.11 g/kg malathion)

No change is required. The current safety directions for zinc phosphide (grain bait 40 g/kg or less, except where otherwise specified) are protective and remain appropriate for these products.

Dustable powders

- David Gray's Poultry Dust (42267) (20 g/kg malathion)
- David Gray's Malathion Grain Dust Insecticide (50110) (20 g/kg malathion)

DP or topical dust/powder 40 g/kg or less

May irritate the eyes and skin. Avoid contact with eyes and skin. Repeated exposure may cause allergic disorders. Repeated minor exposure may have a cumulative poisoning effect. When using the product wear elbow-length chemical resistant gloves and a disposable dust mask. Wash hands after use. After each day's use wash gloves and contaminated clothing.

Veterinary topical insecticide

- Inca Malaban Wash Concentrate (37201) (200 g/L malathion, 663 g/L xylene as solvent)

Topical solution/suspension 200 g/L or less in xylene 700 g/L or less with surfactant 100 g/L or less

Poisonous if swallowed. Will damage the eyes. Will irritate the nose, throat and skin. Avoid contact with eyes and skin. Do not inhale vapour. Repeated exposure may cause allergic disorders. Repeated minor exposure may have a cumulative poisoning effect. When opening the container and preparing the product for use, wear cotton overalls buttoned to the neck and wrist (or equivalent clothing) and a washable hat, elbow length chemical resistant gloves, goggles and a disposable mist mask. 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. After each day's use, wash gloves, goggles and contaminated clothing.

Note: This product, which is intended for both commercial and domestic use, is not appropriate for domestic situations. This is due to its high xylene content (663 g/L) >50% in the formulation, which causes a health risk from the use and would require wearing additional PPE that is not acceptable on home veterinary products. Therefore a restraint statement should be added to the product label as follows:

NOT SUITABLE FOR DOMESTIC USE

- Pharmacological Malathion 50 Insecticide (33021) Saint Bernard Petcare Malathion Wash Insecticide (63456) (500 g/L malathion, 493 g/L hydrocarbon liquid as solvent)

EC 500 g/L or less in liquid hydrocarbons 500 g/L or less with surfactant 60 g/L or less

Will damage the eyes. Will irritate the nose, throat and skin. Avoid contact with eyes and skin. Do not inhale vapour. Repeated exposure may cause allergic disorders. Repeated minor exposure may have a cumulative poisoning effect. When opening the container and preparing the product for use, wear cotton overalls buttoned to the neck and wrist (or equivalent clothing) and a washable hat, elbow length chemical resistant gloves, goggles and a disposable mist mask. If applying by low pressure hand wand wear cotton overalls, over normal clothing, buttoned to the neck and wrist and a washable hat and elbow length chemical resistant gloves. If applying by backpack sprayer, wear cotton overalls, over normal clothing buttoned to the neck and wrist and elbow length chemical resistant gloves and a half facepiece respirator. 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. After each day's use, wash gloves, goggles and contaminated clothing.

Home garden products

- David Gray's Malathion Garden Spray (42035) (500 g/L malathion)
- David Gray's Malathion Fruit Fly Garden Spray (62242) (500 g/L malathion)

HG EC 500 g/L or less

Harmful if swallowed. Will irritate the eyes and skin. Avoid contact with eyes and skin. When opening the container, preparing spray and using the prepared spray, wear rubber gloves. 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.

- David Gray's Malathion and White Oil Insecticide (58968) (100 g/L malathion)

HG EC 100 g/L or less with petroleum oil 400 g/L or less

Harmful if swallowed. Will irritate the eyes. Avoid contact with eyes. When opening the container, preparing spray and using the prepared spray, wear rubber gloves. 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.

Home veterinary products

- Bob Martin Since 1892 Flea & Tick Control for Dogs, Cats & Aviaries Malawash (54285) (200 g/L malathion)

HV topical solution/suspension 200 g/L or less

Harmful if swallowed. Will irritate the eyes. Avoid contact with eyes. Do not inhale spray mist. When opening the container, preparing spray and using the prepared spray, wear rubber gloves. 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.

Recommendations

The work health and safety assessment considered that the use of malathion does not present any unacceptable risk to users or the public when used in accordance with the following:

- Companion animals treated with malathion must not be handled by children for one hour after application.
- Following treatment of companion animal housing and bedding, children must not be allowed contact with the treated materials for 3 full days after application (day 4 after application).
- Areas treated with malathion must not be re-entered until spray is dry.
- Treated animal housing must not be re-entered and treated animal bedding must not be handled until spray has dried.
- Commercial use of malathion indicated on currently registered labels is acceptable, with the following exceptions:
 - Open mixing and loading for aerial application are not acceptable (MOE <100).
 - Closed mixing and loading is acceptable provided a single layer of clothing is worn.
 - The following restraint should be added to all malathion labels with use patterns applied by aerial application 'DO NOT use open mixing and loading systems for aerial application (use closed mixing and loading only).'
- Open cabs are not acceptable for airblast application. Closed cabs are acceptable, provided a single layer of clothing is worn.
- Backpack ULV misters/cold foggers are not acceptable.
- First Aid instructions for products containing malathion remain unchanged from current recommendations.
- Safety directions are amended from current recommendations for all products except ready to use bait formulations as specified in the Safety Directions section and should be included on the label.
- Restrictions/restraints to appear on the label of products containing xylene as a solvent are:
 - NOT SUITABLE FOR DOMESTIC USE
- Re-entry periods are applicable and should appear on the product labels as appropriate and as follows:
 - Fruiting vegetable crops: Do not enter for one day after application for irrigation, scouting, thinning and weeding.
 - Leafy vegetable crops: Do not enter for one day after application for irrigation and scouting mature plants, hand harvesting and pruning.
 - Field crops (low): Do not enter for 2 days after application for hand-set irrigation; Do not enter for one day after application for scouting, thinning and weeding.
 - Grapes: Do not enter for one day after application for bird control, propagation, trellis repair and transplanting; Do not enter for 2 days after application for hand irrigation, hand pruning, hand weeding and scouting; Do not enter for 17 days after application for tying, training, leaf pulling and hand harvesting; Do not enter for 24 days after application for girdling and turning.

- Apples: Do not enter for one day after application for hand pruning, training, scouting, training, transplanting, orchard maintenance, propping and hand weeding; For product 69529, do not enter for 14 days after application for hand harvesting; For products 51150, 62194 and 49539, do not enter for 8 days after application for hand harvesting; Do not enter for 17 days after application for thinning fruit.
- Treated animal housing: Children must not be allowed to enter into treated animal housing or handle treated animal bedding for 3 full days post-application (i.e. entry is permitted on Day 4).
- Amend the wording on the label of product 54285 from 'Living area' to 'Animal housing and bedding' to clarify where the products can be used.
- Specify application methods in critical comments on the labels of two veterinary products 33021 and 63456 as follows:
 - The directions for use for application to cattle and pigs can be varied on commercial labels to specify that the product should be applied by low pressure spray.
 - The directions for use for application to horses can be varied to specify that the product once diluted can be applied via sponging or trigger pump spray.
 - The direction for use cats and dogs can be varied to specify that the product should be applied by sponging.
 - The direction for use for application to poultry by spray can be varied to specify that the product should be applied by trigger pump spray.
 - The directions for use can be varied to specify that animal bedding is to be treated using a trigger pump spray.
 - The directions for use for treatment of animal housing can be varied to specify spray application by manually pressurised hand wand or trigger pump spray.
- The directions for use for treatment of mosquito and fly control can be varied to specify spray application by manually pressurised hand wand.

Residues and trade

Malathion is registered for use on a variety of broadacre, horticultural and vegetable crops in addition to having uses on stored grains, animal housing and veterinary uses. Although residues and trade were not formally within the scope of this reconsideration, a contemporary assessment of residues and trade was undertaken on available information, which considered current MRLs, dietary exposure based on the MRLs and the requirements for spray drift restraints to ensure regulatory acceptable levels (RALs) for livestock areas are not exceeded.

Residues definition

The current residues definition for malathion is 'maldison'. While the residues definition will remain as 'parent' the entry in the Agricultural and Veterinary Chemicals (MRL Standard for Residues of Chemical Products) Instrument 2023 (the MRL Standard) will be varied to be 'malathion' rather than maldison to be consistent with the move to the internationally accepted ISO common name and references made to maldison will be deleted.

Previous assessments

The original assessment of safety in relation residues in food was undertaken by the relevant states and territories prior to the establishment of the APVMA. The APVMA has received and assessed additional data which was provided to support new registrations and variations to existing products.

Veterinary products

A number of veterinary use patterns exist on the current labels. These uses were registered and MRLs were recommended prior to the establishment of the APVMA. Residues and trade were not formally within the scope for this reconsideration. The National Residues Survey data confirmed no detections of malathion residues in animal commodities over the past 10 years and that the APVMA is not aware of any residues or trade incidents occurring related to these uses. On this basis the APVMA remains satisfied of residues and trade in relation to veterinary products.

Agricultural products

A number of the use patterns on the current labels do not define the maximum number of applications per season. Following input from registrants and relevant grower groups the APVMA has included a critical comment which limits the number of applications per season to 4 for all use patterns where maximum number of applications per season is not already defined on the labels of agricultural products with the exception of use patterns on ornamentals, stored cereal grain and for fruit fly control.

Based on the current use patterns, the APVMA remains satisfied that the residues and implications to trade for horticultural, vegetable and stored grains is acceptable, however it was noted:

1. there are no current entries in Table 4 of the Australian MRL Standard to cover current uses in animal feed including pastures, forage crops, orange pulp and grape pomace
2. there are no harvest withholding periods for broad acre crops

3. there are no spray drift restraints for livestock exposure
4. a contemporary dietary exposure assessment should be undertaken which includes the above considerations.

Each of these issues is considered separately below.

Animal feed

Pasture and forage crops

There are currently no Table 4 entries for malathion to cover current uses on pasture or other forage crops.

The maximum application rate to pastures and forage crops is 1,100 g ai/ha. A one-day grazing withholding period applies. Studies on cereals (Bookbinder, M. G. 1994a) did not sample forage until 7 days after application. The study reported residues of malathion in grass of 2.0, 19, 10, 22, 25, 29, 30, 34, 38, 44, 55, 68 (2), 72, 74, 75, 80, 83, 130 and 190 mg/kg and in hay of 1.9, 4.0, 6.0, 24, 27, 30, 33, 34, 36, 42, 46, 54, 55, 58, 61, 66, 68, 100, 130 and 260 mg/kg at zero days after application at 1.0 to 1.4 kg ai/ha (up to 1.3x). Residues in clover forage/hay (Bookbinder, M. G. 1995a) at one day after application at 0.68 to 1.4 kg ai/ha were 2.2 to 96 mg/kg (HR in hay) and in alfalfa forage/hay (Bookbinder, M. G. 1995b) 0.55 to 95 mg/kg (HR in forage). Moisture contents for clover and alfalfa forage were reported to vary from 71–85%, with a mean of 81% for clover forage and 78% for alfalfa forage. The dry matter contents of clover and alfalfa hay and the grass samples were not recorded. Assuming a dry matter content of 25% for grass forage the HR in an animal feed is 760 mg/kg dry weight ($190 \div 0.25$). It is noted that the grass trials only sampled at a zero-day PHI but that a significant number of clover and alfalfa trials had residues at similar or even higher levels in the one-day sample compared to the zero-day sample. Therefore the day zero grass data is considered applicable to the current one-day grazing withholding period.

Based on the grass, clover and alfalfa data presented here and as assessed in the 1999 JMPR evaluation a Primary feed commodities MRL of 800 mg/kg (dry weight basis) is required for malathion to cover registered uses on pastures and other forage crops in conjunction with a one-day grazing withholding period.

It is noted that an animal transfer study for malathion is not available and that this primary feed commodity MRL at 800 mg/kg is significantly higher than the feeding level in the available goat metabolism study (115 ppm) presented in the 1999 JMPR evaluation. No residues of parent malathion were detected (<0.05 mg/kg) in tissues or milk in the goat study when the offal and meat (fat) MRLs are established at 1 mg/kg, many times higher than the detection limit in the goat metabolism study. The current mammalian offal and meat (fat) MRLs were established in 1974 based on veterinary uses of malathion and there are products registered for direct treatment of cattle and pigs. In addition, these uses have been in place for many years without any known issues. Data published by the National Residue Survey indicates there have been no detections of malathion in beef or sheep products (fat) in the last 10 years (ending 2020–21, LOR 0.01 mg/kg after 2013–14 or 0.1 to 0.2 mg/kg prior to 2013–14).

Citrus pulp and grape pomace

There are uses currently approved uses on citrus but no Citrus pulp MRL and similarly there are approved uses on grapes but no MRL for grape pomace is established in Table 4.

Studies on processing from oranges to dried pulp (Bookbinder, M. G. 1994b), reported a processing factor of 10x for malathion. Applying this processing factor to the current MRL of 4 mg/kg for citrus fruits gives a maximum possible level of 40 mg/kg. An MRL of 40 mg/kg is recommended for malathion on AB 0001 Citrus pulp, dry. This is consistent with the findings of the 1999 JMPR report.

Studies on processing from whole grapes to dry pomace (Bookbinder, M. G. 1995c), reported a processing factor of 11x for malathion. Applying this processing factor to the current MRL of 8 mg/kg for malathion in grapes gives a maximum possible level of 88 mg/kg. An MRL of 90 mg/kg is recommended for malathion on AB 0269 Grape pomace, dry. This is consistent with the findings of the 1999 JMPR report.

Withholding periods

For use on broadacre crops (products 49539, 51150 and 62194) a grazing withholding period is specified on current labels for the pre-harvest use patterns with no clear harvest withholding period. A one-day harvest withholding period should apply to all broadacre crops that have only a one-day grazing withholding period specified. The crops include cereal crops (also including maize, rice and sorghum), grain legumes and linseed. For canola (rapeseed), safflower and sunflower a 3-day withholding period is specified in the directions for use table on the label of product 49539. A harvest and grazing withholding period statement should be added to this label specifying a 3-day withholding period for both harvest and grazing for these crops. This should also apply to other labels that have a canola use pattern with no clear withholding periods specified.

Spray drift (regulatory acceptable level)

A lactating goat metabolism study was evaluated by the 1999 JMPR. After dosing with malathion at 115 ppm in the feed for 5 days there were no detectable residues of parent in tissues or milk. Given the residue definition in Australia, Japan, USA (for animal commodities) and Codex is parent compound, the regulatory acceptable level (RAL) for the spray drift assessment for protection of international trade is 115 ppm, noting there are no Codex, Japanese or Taiwanese MRLs established for malathion in animal commodities and EU animal commodity MRLs are established at *0.02 mg/kg.

Dietary exposure assessment

The chronic dietary exposure to malathion is estimated by the National Estimated Daily Intake (NEDI) calculation encompassing all registered/temporary uses of the chemical and the mean daily dietary consumption data derived primarily from the 2011–12 National Nutritional and Physical Activity Survey. The NEDI calculation is made in accordance with WHO Guidelines and is a conservative estimate of dietary exposure to chemical residues in food. The NEDI for malathion is equivalent to <70% of the ADI. It is concluded that the chronic dietary exposure to malathion is acceptable.

The acute dietary exposure is estimated by the National Estimated Short-Term Intake (NESTI) calculation. The NESTI calculations are made in accordance with the deterministic method used by the JMPR with 97.5th percentile food consumption data derived primarily from the 2011–12 National Nutritional and Physical Activity Survey. NESTI calculations are conservative estimates of short-term exposure (24-hour period) to chemical

residues in food. The highest acute dietary intake was estimated at <15% of the ARfD. It is concluded that the acute dietary exposure is acceptable.

Recommended amendments to the Agricultural and Veterinary Chemicals (MRL Standard for Residues of Chemical Products) Instrument 2023

The amendments to the APVMA MRL Standard shown in Table 18 are recommended:

Table 18: Proposed changes to Table 1 of the MRL Standard

Compound	Food	MRL (mg/kg)
Delete:		
Maldison		
VD 0071	Beans (dry)	8
FB 0018	Berries and other small fruits {except Grapes; Strawberry}	10
VB 0040	Brassica (cole or cabbage) vegetables, head cabbages, flowerhead brassicas {except Cauliflower; Kohlrabi}	2
VL 0054	Brassica leafy vegetables {except Kale}	2
VR 0577	Carrot	0.5
VB 0404	Cauliflower	0.5
VS 0624	Celery	2
GC 0080	Cereal grains	8
FC 0001	Citrus fruits	4
VC 0424	Cucumber	3
DF 0167	Dried fruits	8
MO 0105	Edible offal (mammalian)	1
PE 0112	Eggs	1
VC 0045	Fruiting vegetables, cucurbits {except Cucumber}	2
VO 0050	Fruiting vegetables, other than cucurbits {except Peppers, sweet [capsicum]}	3
	Fruits {except Berries and other small fruits; Citrus fruits; Dried fruits; Stone fruits}	2
VP 0528	Garden pea (young pods)	0.5
FB 0269	Grapes	8

Compound	Food	MRL (mg/kg)
VL 0480	Kale	3
VB 0405	Kohlrabi	0.5
VA 0384	Leeks	2
VP 0060	Legume vegetables {except Garden pea}	2
VD 0533	Lentil (dry)	8
VL 0482	Lettuce, head	2
VL 0483	Lettuce, leaf	2
SO 0693	Linseed	10
MM 0095	Meat (mammalian) [in the fat]	1
ML 0106	Milks [in the fat]	1
VA 0385	Onion, bulb	2
VA 0387	Onion, Welsh	T0.1
VO 0445	Peppers, sweet [capsicum]	T5
PM 0110	Poultry meat [in the fat]	1
PO 0111	Poultry, edible offal of	1
VD 0070	Pulses {except Beans (dry); Lentils (dry)}	2
SO 0495	Rape seed [canola]	10
SO 0699	Safflower seed	10
VA 0388	Shallot	T0.1
VA 0389	Spring onion	T0.1
FS 0012	Stone fruits	5
FB 0275	Strawberry	1
SO 0702	Sunflower seed	10
TN 0085	Tree nuts	8
CM 0654	Wheat bran, unprocessed	20

Compound	Food	MRL (mg/kg)
Add:		
Malathion		
VD 0071	Beans (dry)	8
FB 0018	Berries and other small fruits {except Grapes; Strawberry}	10
VB 0040	Brassica (cole or cabbage) vegetables, head cabbages, flowerhead brassicas {except Cauliflower; Kohlrabi}	2
VL 0054	Brassica leafy vegetables {except Kale}	2
VR 0577	Carrot	0.5
VB 0404	Cauliflower	0.5
VS 0624	Celery	2
GC 0080	Cereal grains	8
FC 0001	Citrus fruits	4
VC 0424	Cucumber	3
DF 0167	Dried fruits	8
MO 0105	Edible offal (mammalian)	1
PE 0112	Eggs	1
VC 0045	Fruiting vegetables, cucurbits {except Cucumber}	2
VO 0050	Fruiting vegetables, other than cucurbits {except Peppers, sweet [capsicum]}	3
	Fruits {except Berries and other small fruits; Citrus fruits; Dried fruits; Stone fruits}	2
VP 0528	Garden pea (young pods)	0.5
FB 0269	Grapes	8
VL 0480	Kale	3
VB 0405	Kohlrabi	0.5
VA 0384	Leeks	2
VP 0060	Legume vegetables {except Garden pea}	2
VD 0533	Lentil (dry)	8
VL 0482	Lettuce, head	2
VL 0483	Lettuce, leaf	2

Compound	Food	MRL (mg/kg)
SO 0693	Linseed	10
MM 0095	Meat (mammalian) [in the fat]	1
ML 0106	Milks [in the fat]	1
VA 0385	Onion, bulb	2
VA 0387	Onion, Welsh	T0.1
VO 0445	Peppers, sweet [capsicum]	T5
PM 0110	Poultry meat [in the fat]	1
PO 0111	Poultry, edible offal of	1
VD 0070	Pulses {except Beans (dry); Lentils (dry)}	2
SO 0495	Rape seed [canola]	10
SO 0699	Safflower seed	10
VA 0388	Shallot	T0.1
VA 0389	Spring onion	T0.1
FS 0012	Stone fruits	5
FB 0275	Strawberry	1
SO 0702	Sunflower seed	10
TN 0085	Tree nuts	8
CM 0654	Wheat bran, unprocessed	20

Table 19: Proposed changes to Table 3 of the MRL Standard

Compound	Residues
Delete:	
Malathion	see Maldison
Maldison	Maldison
Add:	
Malathion	Malathion
Maldison	see Malathion

Table 20: Proposed changes to Table 4 of the MRL Standard

Compound	Animal feed commodity	MRL (mg/kg)
Delete:		
Maldison		
AB 0226	Apple pomace, dry	20
	Tomato pomace, dry	10
Add:		
Malathion		
AB 0226	Apple pomace, dry	20
	Tomato pomace, dry	10
AB 0001	Citrus pulp, dry	40
AB 0269	Grape pomace, dry	90
	Primary feed commodities	800

Environmental safety

A contemporary spray drift risk assessment was conducted to determine any necessary protection statements and restraints that would be required to align with current standards. Major formulation types relevant to the spray drift assessment were emulsifiable concentrates (EC), ultra-low volume (ULV) and emulsions – oil in water (EW). Regulatory acceptable levels (RALs) for natural aquatic areas, pollinator areas and vegetation areas are summarised below. The resulting buffer zones are summarised in Appendix A – spray drift restraints.

Aquatic areas

Malathion has high toxicity to fish (lowest LC₅₀ 22 µg/L, Gries et al. 2002) and daphnia (EC₅₀ 0.72 µg/L, Gries & Purghart 2001) in flow-through laboratory tests. A mesocosm study with high species diversity from different taxonomic groups also shows that Cladoceran species are the most sensitive group of invertebrates to malathion, for which an ecologically acceptable concentration of 30 µg/L was derived (Ebke 2002). Algae are far less sensitive to malathion than fish and daphnids (EC₅₀ 13 mg/L, Jenkins 1993).

Due to the high toxicity of malathion to fish and aquatic invertebrates, the following and protection statements are required for all commercial product labels (product nos. 33021, 37201, 42267, 42727, 49539, 50110, 50589, 51150, 54285, 62914, 63032, 63456 and 69529).

- Very toxic to aquatic life. DO NOT contaminate wetlands or watercourses with this product or used containers.

The following restraint should be applied to the following commercial product labels, which include use patterns for mosquito control (product nos. 49539, 51150, 62914 and 63456), to ensure that the products are not applied directly to aquatic areas.

- DO NOT apply to directly to water.

For home garden products (product nos. 42035, 58968 and 62242) the following protection statement is recommended.

- Toxic to aquatic life. DO NOT allow the product, chemical containers or spray to get into drains, sewers, streams or ponds.

Spray drift RAL

Because malathion has very low persistence in water (DT₅₀ 0.38 days, Knoch 2001), the RALs that are based on flow-through tests are adjusted by the time-weighted average (TWA) so that they can be directly compared to an initial exposure concentration suitable for a spray drift assessment. For example, the RAL of 2.2 µg/L for fish⁴ becomes RAL_{TWA} 16 µg ac/L when accounting for the 4-day exposure duration⁵. The acute fish RAL_{TWA} was the

⁴ RAL= LC₅₀ 22 µg/L / (assessment factor of 10)

⁵ RAL_{TWA} = RAL 2.2 µg/L / (1-EXP(4d*(-ln(2)/DT50 0.38d))) * (4d*ln(2)/ DT50 0.38d)

most conservative value derived for the risk assessment, and the RAL for the spray drift assessment was therefore set at 16 µg ac/L. Details of the spray drift assessment are included in the [Spray drift](#) section.

'Buffer zones' established for the purpose of the 'natural aquatic area' may also be used as the basis for the protection of 'aquacultural production' but as the buffer zones for 'natural aquatic areas' are based on survival at a population or ecosystem level, they may not be sufficient if yield loss or replacement cost within an aquaculture operation is the issue.

Pollinator areas

The acute contact LD₅₀ value for a representative EC formulation of malathion was found to be 0.15 µg ac/bee (Perina 1995), which indicates that malathion is toxic to honeybees. This value is considered a suitably conservative basis for risk assessment of the active constituent, and the products under evaluation.

Residual time to 25% mortality (RT25 values range from >8 to 154 hours at rates ranging between 1,400 to 1,800 g ac/ha (Hoxter & Jaber 1989, Sindermann et al. 2015). These values indicate that residues can remain toxic for several days after application. Therefore, malathion should not be applied to flowering crops and the following protection statements are recommended for commercial spray products (product nos. 62914 and 69529).

- Toxic to bees. DO NOT apply to crops from the onset of flowering until flowering is complete. DO NOT allow spray drift to flowering weeds or flowering crops in the vicinity of the treatment area. Before spraying, notify beekeepers to move hives to a safe location with an untreated source of nectar and pollen, if there is potential for managed hives to be affected by the spray or spray drift.

In considering the use of malathion for mosquito control (product nos. 49539, and 62194), it is noted that outdoor space spraying for knock-down and control of adult mosquitos may inevitably kill bees and other non-target arthropods that are flying at the same time as mosquitos (WHO 2011). The following protection statement is therefore recommended.

- Toxic to bees. DO NOT apply to crops from the onset of flowering until flowering is complete. Do not apply or allow spray drift to flowering weeds, plants or crops in the vicinity of the treatment area, except when applications are made to prevent or control a threat to public and/or animal health determined by the relevant state or territory authority. Before spraying, notify beekeepers to move hives to a safe location with an untreated source of nectar and pollen, if there is potential for managed hives to be affected by the spray or spray drift.

For stored grain dust (product no. 50110) and solid formulations (product nos. 42727, 50589 and 63032), the following protection statement is recommended based on negligible exposure.

- Toxic to bees. However, the use of this product as directed is not expected to have adverse effects on bees.

For home garden products (product nos. 42035, 58968 and 62242) and the veterinary products hand-applied for mosquito and fly control (product nos. 63456), the following protection statement is recommended.

- Toxic to bees. DO NOT spray if bees are feeding on flowering plants.

A pollinator protection statement is not required for the veterinary products that are not used for mosquito or fly control (product nos. 37201, 42267, 54285).

Spray drift RAL

Based on the acute contact LD₅₀ of 0.15 µg ac/bee, the RAL for the spray drift assessment is 25 g ac/ha⁶. Details of the spray drift assessment are included in the *Spray drift* section.

Vegetation areas

Due to the age of malathion, data on its toxicity to non-target terrestrial plants were not required at the time of its initial registration. Malathion is not known to have phytotoxic effects, and spray drift risks are considered to be acceptable on the basis of a lack of known effects on non-target terrestrial plants. No protection statements are required for non-target terrestrial plants.

Recommendations

The APVMA can be satisfied that malathion products meet the environmental safety criteria provided the recommended label restraints are followed for the protection of aquatic species and pollinators.

⁶ RAL (g/ha) = (contact LD₅₀ in µg/bee × LOC 0.4) / ExpE 2.4 × 1000

Efficacy and target safety

APVMA labelling recommendations made elsewhere in this technical report have the potential to change the way that malathion products are used. This may lead to changes in the effectiveness or safety of malathion products. No new efficacy, target crop or target animal safety information was submitted for consideration during the review, and this assessment has considered the history of use of these products, in conjunction with the likely effects of recommended label modifications.

Efficacy

The label variations recommended in this technical report are within the current application rates and intervals and application instructions for each use pattern. Therefore, the use of the malathion products when used according to label directions is expected to meet the efficacy criteria as described in the [Agricultural and Veterinary Chemicals Code \(Efficacy Criteria\) Determination 2014](#) based on previous assessments and a demonstrated history of effective use.

The APVMA received a submission from the National Working Party on Grain Protection in response to the public consultation on the proposed decision, which raised concerns about the potential for malathion resistance in certain stored grain pests. The APVMA agrees that the current directions for use on product 50110 does not adequately define the pests which would be controlled. This label should be varied to clearly identify the species and common names of the pests that are expected to be effectively controlled by malathion to ensure that the product meets the efficacy criteria.

Target crop safety

The label variations recommended in this technical report are within the current application rates, intervals and application instructions for each use pattern including the timing of application to specific crops. Based on the previous satisfaction that the uses would be safe to target crops and that the APVMA has not received any adverse experience reports in relation to in-crop damage or off target damage to plants from malathion products, the APVMA can be satisfied that the products will meet the safety criteria as they relate to target crop safety when used according to the proposed varied labels.

Mosquito control

Due to the high toxicity to aquatic organisms, products which are used for mosquito control are to include the restraint 'Do not apply directly to water' which precludes the general use of these products for control of mosquito larvae. Therefore, the use of the products for control of mosquito larvae is not supported. Instructions for control of adult mosquitoes remain appropriate and the products are expected to be effective within the limits of the pollinator and aquatic protection restraints which will apply.

Target animal safety

The label variations recommended in this technical report are within the current application rates, intervals and application instructions for each use pattern including the target animal developmental stage. Additionally, the

APVMA has received no adverse experience reports that were considered likely to be caused by a malathion product used according to label directions. Accordingly, the APVMA is satisfied that the products meet the safety criteria as they relate to target animal safety when malathion products are used according to the proposed labels.

Spray drift

A spray drift assessment was conducted according to APVMA's approach to spray drift management which specifies Regulatory Acceptable Levels (RALs) resulting from spray drift in bystander areas, livestock areas, natural aquatic areas, pollinator areas and vegetation areas.

The approved use patterns considered under the spray drift assessment included aerial application applications by airplane and helicopter, including ULV applications, and ground-based applications including boom spray, vertical spray, ULV applications, fogging and misting.

Regulatory acceptable levels

RALs are the maximum amount of spray drift exposure that is not expected to cause undue harm to sensitive areas. The derivation of these values is detailed under the assessments of each of the relevant risk areas (refer to previous sections of this document – [Work health and safety](#), [Residues and trade](#) and [Environmental safety](#)):

- Bystander areas: 3,606 g ac/ha
- Natural aquatic areas: 16 µg ac/L
- Pollinator areas: 25 g ac/ha
- Vegetation areas: not required
- Livestock areas: 115 mg ac/kg

These RALs have been used in conjunction with the appropriate standard deposition curves to generate appropriate buffer zones using the [Spray Drift Risk Assessment Tool](#) (SDRAT) as described in [Spray Drift Risk Assessment Manual](#).

Spray drift assessment

Spray drift buffer zones were calculated separately for each of the relevant use patterns using the SDRAT using standard deposition curves for ground applications by boom spray and vertical sprayers and aerial application by airplane and helicopter. The [Spray Drift Management Tool \(SDMT\)](#) was used to calculate buffer zones for a custom deposition curve was required as described in [Spray Drift Risk Assessment Manual](#).

Details of each assessment is provided below. Where a buffer zone was required to ensure that RALs are not exceeded, it is recommended that the product labels be varied to include the mandatory downwind buffer zones outlined below.

Emulsifiable concentrate (EC) and emulsion, oil-in-water (EW) products – ground boom, vertical sprayer and aerial application

The spray drift assessments considered a MEDIUM spray quality for boom sprayer, vertical sprayers and aerial application equipment. Spray drift buffer zones were calculated separately for each of the relevant use patterns

using the SDRAT using standard deposition curves. Use patterns where the recommended downwind buffer zones could not be generated as the label application rate exceeded the regulatory acceptable levels are not supported.

Fogging, ultra-low volume and mister applications

Aerial – fixed wing (ULV only)

Risks from ultra-low volume application considered a VERY FINE spray quality for fixed wing aircraft and a maximum 4 metre release height using custom deposition curves generated using the AGDISP™ software, and the APVMA's SDMT.

Application of 1,000 g/L of malathion at a rate equal to or higher than 625 mL/ha by ultra-low volume by fixed wing aircraft is not supported as mandatory no-spray buffer zones protective of sensitive areas (natural aquatic areas, pollinators, livestock and human health) are not able to be established and should be removed from the label of product 62194. Use patterns which are not supported at a rate equal to or greater than 625 g ac/ha (1,000 g/L applied at 625 mL/ha) using aerial ULV application methods includes peas only, application by ground ULV at a rate equal to 625 g ac/ha (1,000 g/L applied at 625 mL/ha) is acceptable once the downwind buffer zones outlined in Appendix A are adhered to.

Application of 1,150 g/L of malathion at a rate equal to or higher than 550 mL/ha by ultra-low volume by fixed wing aircraft is not supported as mandatory no-spray buffer zones protective of sensitive areas (natural aquatic areas, pollinators, livestock and human health) are not able to be established. Use patterns which are not supported at a rate equal to or greater than 632.5 g ac/ha (1,150 g/L applied at 550 mL/ha) using aerial ULV application methods includes peas only, application by ground ULV at a rate equal to 632.5 g ac/ha (1,150 g/L applied at 550 mL/ha) is acceptable once the downwind buffer zones outlined in Appendix A are adhered to.

Application of 1,169 g/L of malathion at a rate equal to or higher than 550 mL/ha by ultra-low volume by fixed wing aircraft is not supported as mandatory no-spray buffer zones protective of sensitive areas (natural aquatic areas, pollinators, livestock and human health) are not able to be established and should be removed from the label of product 49539. Use patterns which are not supported at a rate equal to or greater than 642.95 g ac/ha (1,169 g/L applied at 550 mL/ha) using aerial ULV application methods include linseed, peaches, maize, peas, cereal crops, maize, pastures, pasture seed crops, rice, sorghum, application by ground ULV at a rate up to 1,052.1 g ac/ha (1,169 g/L applied up to 900 mL/ha) is acceptable once the downwind buffer zones outlined in Appendix A are adhered to.

Aerial – helicopter (ULV only)

Risks from ultra-low volume application considered a VERY FINE spray quality for helicopter and a maximum release height of 4 metres and a 120-metre maximum application site width. Custom deposition curves generated using the AGDISP™ software. The required downwind buffer zones were calculated using the APVMA's SDMT.

Ground based applications

Specific deposition curves for foggers, misters and ground ULV equipment are not available. Risks from these applications were considered using MISTER spray quality for ground application, a 2-metre release height and a

20 m maximum application site width. Custom deposition curves generated using the AGDISP™ software. The required downwind buffer zones were calculated using the APVMA's SDMT.

Home garden products, dust formulations and solid formulations

Mandatory buffer zones are not required for malathion home garden products, veterinary medicines used on animals and within animal housing, dust formulations, and solid formulations.

Recommendations

Fixed wing ULV aerial applications are not supported at application rates equal to or greater than 625 g ac/ha.

The recommended mandatory downwind buffer zones for use patterns which are supported are detailed in Appendix A.

Storage and disposal

Storage

As summarised in the [Chemistry](#) section and detailed in the [Maldison Chemistry Report \(2016\)](#), prolonged storage of the product and storage at high temperatures may increase the concentration of impurities (especially isomalathion), to concentrations that do not comply with the recommended APVMA specifications. It is recommended that malathion products be stored below 30°C and be made date-controlled products with a shelf life of no more than 2 years after manufacture.

For commercial containers or packaging of agricultural products which are impermeable to moisture (for example, steel drums with weather-proof labels), the following statement is required:

- Store below 30°C (room temperature). Store in the closed, original container in a cool, well-ventilated area. Do not store for prolonged periods in direct sunlight.

For other packaging types refer to the Agricultural Labelling Code. For home garden products:

- Store below 30°C (room temperature). Store in the closed, original container in a cool, dry place out of the reach of children. Do not store in direct sunlight.

The current storage statements on veterinary product labels remain appropriate.

All labels must also include an expiry date.

Storage of prepared bait for control of field crickets

When dispersed in field crops as a bait for crickets the APVMA has previously been satisfied that the use of a kibbled wheat bait prepared using malathion products is not a risk to off target animals. However, if the prepared bait is stored prior to use it may present a risk and it should be safely stored to ensure that it is not fed directly to livestock or mixed in stockfeed. If the kibbled grain bait is not to be used immediately following admixture it should be clearly labelled and kept separate from other feed stuffs until used as a bait. The use patterns should include the critical comment:

- If prepared bait is to be stored prior to use it should be clearly marked and kept separate from animal feed.

Disposal

Disposal of containers

Information on how to dispose of product containers must be included on the product label.

Commercial agricultural and veterinary chemical products

The most common packaging for commercial agricultural and veterinary chemical products is metal drums or plastic containers. The appropriate disposal statement for these containers is provided below.

- Triple-rinse containers before disposal. Add rinsings to spray tank. Do not dispose of undiluted chemicals on site. If recycling, replace cap and return clean containers to recycler or designated collection point.
- If not recycling, break, crush, or puncture and deliver empty packaging to an approved waste management facility. If an approved waste management facility is not available, dispose of empty container or unused product in compliance with relevant local, state or territory government regulations. Do not burn empty containers or product.

Agricultural home and garden products

- Dispose of empty container by wrapping in paper, placing in plastic bag and putting in garbage.

Veterinary products less than or equal to 1 L or 1 kg.

- Dispose of container by wrapping in paper and putting in garbage.

Disposal of unused chemical

Unused chemical should be disposed of in accordance with local government, state or territory legislation. All commercial product labels should include the statement:

- Dispose of unused chemical in compliance with local, state or territory government requirements.



Appendix

Appendix A – Spray drift restraints

General spray drift restraints

Spray drift restraints

Specific definitions for terms used in this section of the label can be found at apvma.gov.au/spraydrift

DO NOT allow bystanders to come into contact with the spray cloud.

DO NOT apply in a manner that may cause an unacceptable impact to native vegetation, agricultural crops, landscaped gardens and aquaculture production, or cause contamination of plant or livestock commodities, outside the application site from spray drift. The advisory buffer zones in the relevant buffer zone table/s below provide guidance but may not be sufficient in all situations. Wherever possible, correctly use application equipment designed to reduce spray drift and apply when the wind direction is away from these sensitive areas.

DO NOT apply unless the wind speed is between 3 and 20 kilometres per hour at the application site during the time of application.

DO NOT apply if there are hazardous surface temperature inversion conditions present at the application site during the time of application. These conditions exist most evenings one to 2 hours before sunset and persist until one to 2 hours after sunrise.

Spray drift restraints for EC 1,000 g/L malathion products

Boom sprayers

DO NOT apply by a boom sprayer unless the following requirements are met:

- Spray droplets not smaller than a MEDIUM spray droplet size category.
- Minimum distances between the application site and downwind sensitive areas (see 'Mandatory buffer zones' section of the following table titled 'Buffer zones for boom sprayers') are observed.

Buffer zones for boom sprayers

Application rate	Boom height above the target canopy	Mandatory buffer zones				
		Bystander areas	Natural aquatic areas	Pollinator areas	Vegetation areas	Livestock areas
Up to 6 L/ha	0.5 m or lower	0 metres	55 metres	55 metres	0 metres	0 metres
	1.0 m or lower	0 metres	160 metres	160 metres	0 metres	0 metres
Up to 1.1 L/ha	0.5 m or lower	0 metres	15 metres	15 metres	0 metres	0 metres
	1.0 m or lower	0 metres	50 metres	45 metres	0 metres	0 metres
Up to 850 mL/ha	0.5 m or lower	0 metres	10 metres	10 metres	0 metres	0 metres
	1.0 m or lower	0 metres	40 metres	40 metres	0 metres	0 metres
Up to 640 mL/ha	0.5 m or lower	0 metres	10 metres	5 metres	0 metres	0 metres
	1.0 m or lower	0 metres	30 metres	30 metres	0 metres	0 metres
Up to 600 mL/ha (85 mL/100L at 750 L/ha)	0.5 m or lower	0 metres	10 metres	5 metres	0 metres	0 metres
	1.0 m or lower	0 metres	30 metres	30 metres	0 metres	0 metres
Up to 150 mL/ha	0.5 m or lower	0 metres	0 metres	0 metres	0 metres	0 metres
	1.0 m or lower	0 metres	10 metres	10 metres	0 metres	0 metres
Up to 70 mL/ha	0.5 m or lower	0 metres	0 metres	0 metres	0 metres	0 metres
	1.0 m or lower	0 metres	0 metres	0 metres	0 metres	0 metres

Aircraft

DO NOT apply by aircraft unless the following requirements are met:

- Spray droplets not smaller than a MEDIUM spray droplet size category.
- For maximum release heights above the target canopy of 3 m or 25% of wingspan or 25% of rotor diameter whichever is the greatest, minimum distances between the application site and downwind sensitive areas (see 'Mandatory buffer zones' section of the following table titled 'Buffer zones for aircraft') are observed.

Buffer zones for aircraft

Application rate	Aircraft type	Mandatory buffer zones				
		Bystander areas	Natural aquatic areas	Pollinator areas	Vegetation areas	Livestock areas
Up to 550 mL/ha	Fixed wing	0 metres	120 metres	120 metres	0 metres	0 metres
	Helicopter	0 metres	90 metres	90 metres	0 metres	0 metres
Up to 300 mL/ha	Fixed wing	0 metres	75 metres	75 metres	0 metres	0 metres
	Helicopter	0 metres	60 metres	60 metres	0 metres	0 metres
Up to 150 mL/ha	Fixed wing	0 metres	40 metres	35 metres	0 metres	0 metres
	Helicopter	0 metres	40 metres	40 metres	0 metres	0 metres
Up to 70 mL/ha	Fixed wing	0 metres	15 metres	15 metres	0 metres	0 metres
	Helicopter	0 metres	20 metres	20 metres	0 metres	0 metres

Vertical sprayers

DO NOT apply by a vertical sprayer unless the following requirements are met:

- Spray is not directed above the target canopy.
- The outside of the sprayer is turned off when turning at the end of rows and when spraying the outer row on each side of the application site.
- For dilute water rates up to the maximum listed for each type of canopy specified, minimum distances between the application site and downwind sensitive areas (see the 'Mandatory buffer zones' section of the following table titled 'Buffer zones for vertical sprayers') are observed.

Buffer zones for vertical sprayers

Type of target canopy and dilute water rate	Mandatory buffer zones				
	Bystander areas	Natural aquatic areas	Pollinator areas	Vegetation areas	Livestock areas
100 mL/100 L in citrus					
2 metres tall and smaller, maximum dilute water rate of 1000 L/ha	0 metres	10 metres	10 metres	0 metres	0 metres
Taller than 2 metres (not fully foliated), maximum dilute water rate of 4000 L/ha	0 metres	40 metres	40 metres	0 metres	0 metres
Taller than 2 metres (fully foliated), maximum dilute water rate of 4000 L/ha	0 metres	30 metres	30 metres	0 metres	0 metres
100 mL/100 L in cucurbits, grapevines, ornamentals and vegetables					
All	0 metres	10 metres	10 metres	0 metres	0 metres
60 mL/100 L in pome fruit and stone fruit					
2 metres tall and smaller, maximum dilute water rate of 1000 L/ha	0 metres	5 metres	5 metres	0 metres	0 metres
Taller than 2 metres (not fully foliated), maximum dilute water rate of 1500 L/ha	0 metres	20 metres	20 metres	0 metres	0 metres
Taller than 2 metres (fully foliated), maximum dilute water rate of 1500 L/ha	0 metres	15 metres	15 metres	0 metres	0 metres
Up to 60 mL/100 L in cucurbits, grapevines, ornamentals, tomatoes, tobacco fields and vegetables					
All	0 metres	5 metres	5 metres	0 metres	0 metres

ULV application (by helicopter)

DO NOT apply by helicopter unless the following conditions are observed:

- A minimum droplet size of Very Fine.
- The release height is not greater than 4 metres above the ground.
- Minimum distances between the application site and downwind sensitive areas that appear in the 'Mandatory buffer zones' section of the table titled 'Buffer zones for ULV application by helicopter' below.

Buffer zones for ULV application (helicopter only)

Application rate	Mandatory buffer zones				
	Bystander areas	Natural aquatic areas	Pollinator areas	Vegetation areas	Livestock areas
300 mL/ha	0 metres	110 metres	105 metres	0 metres	0 metres

Foggers, misters and ULV (ground application)

DO NOT apply by foggers, misters or ground ULV equipment unless the following conditions are observed:

- The release height is not greater than 2 metres above the ground.
- Minimum distances between the application site and downwind sensitive areas that appear in the 'Mandatory buffer zones' section of the table titled 'Buffer zones for foggers (ground application)', 'Buffer zones for misters (ground application)' and 'Buffer zones for ULV (ground application)' below.

Buffer zones for foggers (ground application)

Application rate	Mandatory buffer zones				
	Bystander areas	Natural aquatic areas	Pollinator areas	Vegetation areas	Livestock areas
300 mL/ha	0 metres	40 metres	40 metres	0 metres	0 metres

Buffer zones for misting (ground application)

Application rate	Mandatory buffer zones				
	Bystander areas	Natural aquatic areas	Pollinator areas	Vegetation areas	Livestock areas
1100 mL/ha	0 metres	165 metres	160 metres	0 metres	0 metres
850 mL/ha	0 metres	130 metres	130 metres	0 metres	0 metres

Buffer zones for ULV (ground application)

Application rate	Mandatory buffer zones				
	Bystander areas	Natural aquatic areas	Pollinator areas	Vegetation areas	Livestock areas
625 mL/ha	0 metres	100 metres	95 metres	0 metres	0 metres

Spray drift restraints for EC 1150 g/L malathion products

Boom sprayers

DO NOT apply by a boom sprayer unless the following requirements are met:

- Spray droplets not smaller than a MEDIUM spray droplet size category.
- Minimum distances between the application site and downwind sensitive areas (see the 'Mandatory buffer zones' section of the following table titled 'Buffer zones for boom sprayers') are observed.

Buffer zones for boom sprayers

Application rate	Boom height above the target canopy	Mandatory buffer zones				
		Bystander areas	Natural aquatic areas	Pollinator areas	Vegetation areas	Livestock areas
Up to 5.5 L/ha	0.5 m or lower	0 metres	60 metres	60 metres	0 metres	0 metres
	1.0 m or lower	0 metres	170 metres	160 metres	0 metres	0 metres
Up to 950 mL/ha	0.5 m or lower	0 metres	15 metres	15 metres	0 metres	0 metres
	1.0 m or lower	0 metres	50 metres	45 metres	0 metres	0 metres
Up to 750 mL/ha	0.5 m or lower	0 metres	10 metres	10 metres	0 metres	0 metres
	1.0 m or lower	0 metres	40 metres	40 metres	0 metres	0 metres
Up to 560 mL/ha (75 mL/100 L at 750 L/ha)	0.5 m or lower	0 metres	10 metres	105 metres	0 metres	0 metres
	1.0 m or lower	0 metres	30 metres	30 metres	0 metres	0 metres
Up to 520 mL/ha	0.5 m or lower	0 metres	10 metres	10 metres	0 metres	0 metres
	1.0 m or lower	0 metres	30 metres	30 metres	0 metres	0 metres
Up to 130 mL/ha	0.5 m or lower	0 metres	0 metres	0 metres	0 metres	0 metres
	1.0 m or lower	0 metres	10 metres	10 metres	0 metres	0 metres
Up to 60 mL/ha	0.5 m or lower	0 metres	0 metres	0 metres	0 metres	0 metres
	1.0 m or lower	0 metres	0 metres	0 metres	0 metres	0 metres

Aircraft

DO NOT apply by aircraft unless the following requirements are met:

- Spray droplets not smaller than a MEDIUM spray droplet size category.
- For maximum release heights above the target canopy of 3 m or 25% of wingspan or 25% of rotor diameter whichever is the greatest, minimum distances between the application site and downwind sensitive areas (see the 'Mandatory buffer zones' section of the following table titled 'Buffer zones for aircraft') are observed.

Buffer zones for aircraft

Application rate	Aircraft type	Mandatory buffer zones				
		Bystander areas	Natural aquatic areas	Pollinator areas	Vegetation areas	Livestock areas
Up to 500 mL/ha	Fixed wing	0 metres	120 metres	120 metres	0 metres	0 metres
	Helicopter	0 metres	90 metres	90 metres	0 metres	0 metres
Rice						
Up to 260 mL/ha	Fixed wing	0 metres	75 metres	75 metres	0 metres	0 metres
	Helicopter	0 metres	60 metres	60 metres	0 metres	0 metres
Up to 130 mL/ha	Fixed wing	0 metres	40 metres	35 metres	0 metres	0 metres
	Helicopter	0 metres	40 metres	40 metres	0 metres	0 metres
Up to 60 mL/ha	Fixed wing	0 metres	15 metres	15 metres	0 metres	0 metres
	Helicopter	0 metres	20 metres	20 metres	0 metres	0 metres

Vertical sprayers

DO NOT apply by a vertical sprayer unless the following requirements are met:

- Spray is not directed above the target canopy.
- The outside of the sprayer is turned off when turning at the end of rows and when spraying the outer row on each side of the application site.
- For dilute water rates up to the maximum listed for each type of canopy specified, minimum distances between the application site and downwind sensitive areas (see the 'Mandatory buffer zones' section of the following table titled 'Buffer zones for vertical sprayers') are observed.

Buffer zones for vertical sprayers

Type of target canopy and dilute water rate	Mandatory buffer zones				
	Bystander areas	Natural aquatic areas	Pollinator areas	Vegetation areas	Livestock areas
435 mL/100 L in passionfruit					
2 metres tall and shorter, maximum dilute water rate of 1000 L/ha	0 metres	20 metres	20 metres	0 metres	0 metres
Taller than 2 metres (not fully foliated), maximum dilute water rate of 2000 L/ha	0 metres	55 metres	55 metres	0 metres	0 metres
Taller than 2 metres (fully foliated), maximum dilute water rate of 2000 L/ha	0 metres	45 metres	45 metres	0 metres	0 metres
435 mL/100 L in citrus, fruit fly control					
All, maximum dilute water rate of 20 L/ha	0 metres	0 metres	0 metres	0 metres	0 metres
90 mL/100 L in citrus					
2 metres tall and smaller, maximum dilute water rate of 1000 L/ha	0 metres	10 metres	10 metres	0 metres	0 metres
Taller than 2 metres (not fully foliated), maximum dilute water rate of 4000 L/ha	0 metres	40 metres	40 metres	0 metres	0 metres
taller than 2 metres (fully foliated), maximum dilute water rate of 4000 L/ha	0 metres	30 metres	30 metres	0 metres	0 metres
90 mL/100 L in cucurbits, grapevines, ornamentals and vegetables					
All	0 metres	10 metres	10 metres	0 metres	0 metres
55 mL/100 L in citrus					
2 metres tall and smaller, maximum dilute water rate of 1000 L/ha	0 metres	5 metres	5 metres	0 metres	0 metres
Taller than 2 metres (not fully foliated), maximum dilute water rate of 4000 L/ha	0 metres	30 metres	30 metres	0 metres	0 metres
Taller than 2 metres (fully foliated), maximum dilute water rate of 4000 L/ha	0 metres	25 metres	20 metres	0 metres	0 metres
55 mL/100 L in pome fruit and stone fruit					
2 metres tall and shorter, maximum dilute water rate of 1000 L/ha	0 metres	5 metres	5 metres	0 metres	0 metres

Type of target canopy and dilute water rate	Mandatory buffer zones				
	Bystander areas	Natural aquatic areas	Pollinator areas	Vegetation areas	Livestock areas
Taller than 2 metres (not fully foliated), maximum dilute water rate of 1500 L/ha	0 metres	20 metres	20 metres	0 metres	0 metres
Taller than 2 metres (fully foliated), maximum dilute water rate of 1500 L/ha	0 metres	15 metres	15 metres	0 metres	0 metres
Up to 55 mL/100 L in grapevines, table grapes, ornamentals, cucurbits, tobacco fields or seed beds and vegetables					
All	0 metres	5 metres	5 metres	0 metres	0 metres

ULV application (by helicopter)

DO NOT apply by helicopter unless the following conditions are observed:

- A minimum droplet size of Very Fine.
- The release height is not greater than 4 metres above the ground.
- Minimum distances between the application site and downwind sensitive areas that appear in the 'Mandatory buffer zones' section of the table titled 'Buffer zones for ULV application by helicopter' below.

Buffer zones for ULV application (helicopter only)

Application rate	Mandatory buffer zones				
	Bystander areas	Natural aquatic areas	Pollinator areas	Vegetation areas	Livestock areas
300 mL/ha	0 metres	120 metres	115 metres	0 metres	0 metres

Foggers, misters and ULV (ground application)

DO NOT apply by foggers, misters or ground ULV equipment unless the following conditions are observed:

- The release height is not greater than 2 metres above the ground.
- Minimum distances between the application site and downwind sensitive areas that appear in the 'Mandatory buffer zones' section of the table titled 'Buffer zones for foggers (ground application)', 'Buffer zones for misters (ground application)' and 'Buffer zones for ULV (ground application)' below.

Buffer zones for foggers (ground application)

Application rate	Mandatory buffer zones				
	Bystander areas	Natural aquatic areas	Pollinator areas	Vegetation areas	Livestock areas
300 mL/ha	0 metres	50 metres	45 metres	0 metres	0 metres

Buffer zones for misting (ground application)

Application rate	Mandatory buffer zones				
	Bystander areas	Natural aquatic areas	Pollinator areas	Vegetation areas	Livestock areas
950 mL/ha	0 metres	160 metres	160 metres	0 metres	0 metres
750 mL/ha	0 metres	135 metres	130 metres	0 metres	0 metres

Buffer zones for ULV (ground application)

Application rate	Mandatory buffer zones				
	Bystander areas	Natural aquatic areas	Pollinator areas	Vegetation areas	Livestock areas
550 mL/ha	0 metres	100 metres	95 metres	0 metres	0 metres

Spray drift restraints for UL 1169 g/L malathion products

ULV application (by fixed wing aircraft)

Specific definitions for terms used in these conditions can be found at apvma.gov.au/spraydrift.

DO NOT allow bystanders to come into contact with the spray cloud.

DO NOT cause an unacceptable impact to native vegetation, agricultural crops, landscaped gardens and aquaculture production outside the application site from spray drift.

DO NOT cause contamination of plant or livestock commodities outside the application site from spray drift.

DO NOT apply unless the wind speed is between 3 and 20 kilometres per hour at the application site during the time of application.

DO NOT apply if there are hazardous surface temperature inversion conditions present at the application site during the time of application. Surface temperature inversion conditions exist most evenings one to two hours before sunset and persist until one to two hours after sunrise.

DO NOT apply by Fixed Wing Aircraft unless the following conditions are observed:

- A minimum droplet size of Very Fine.
- The release height is not greater than 4 metres above the ground.
- Minimum distances between the application site and downwind sensitive areas that appear in the 'Mandatory buffer zones' section of the table titled 'Buffer zones for ULV application by fixed-wing aircraft' below.

Buffer zones for ULV application (by fixed-wing aircraft only)

Application rate	Mandatory buffer zones				
	Bystander areas	Natural aquatic areas	Pollinator areas	Vegetation areas	Livestock areas
Up to 450 mL/ha	0 metres	750 metres	730 metres	0 metres	0 metres
Up to 280 mL/ha	0 metres	505 metres	490 metres	0 metres	0 metres
Up to 225 mL/ha	0 metres	420 metres	410 metres	0 metres	0 metres

Misting or ULV (ground application)

DO NOT apply by foggers, misters or ground ULV equipment unless the following conditions are observed:

- The release height is not greater than 2 metres above the ground.
- Minimum distances between the application site and downwind sensitive areas that appear in the 'Mandatory buffer zones' section of the table titled 'Buffer zones for foggers (ground application)', 'Buffer zones for misters (ground application)' and 'Buffer zones for ULV (ground application)' below.

Buffer zones for misting or ULV (ground application)

Application rate	Mandatory buffer zones				
	Bystander areas	Natural aquatic areas	Pollinator areas	Vegetation areas	Livestock areas
Up to 900 mL/ha	0 metres	160 metres	150 metres	0 metres	0 metres
Up to 700 mL/ha	0 metres	130 metres	120 metres	0 metres	0 metres
Up to 550 mL/ha	0 metres	100 metres	100 metres	0 metres	0 metres
Up to 450 mL/ha	0 metres	80 metres	80 metres	0 metres	0 metres
Up to 280 mL/ha	0 metres	80 metres	80 metres	0 metres	0 metres
Up to 225 mL/ha	0 metres	35 metres	30 metres	0 metres	0 metres

Buffer zones for foggers (ground application)

Application rate	Mandatory buffer zones				
	Bystander areas	Natural aquatic areas	Pollinator areas	Vegetation areas	Livestock areas
Up to 280 mL/ha	0 metres	80 metres	80 metres	0 metres	0 metres

Spray drift restraints for EW 320 g/L malathion labels

Vertical sprayers

DO NOT apply by a vertical sprayer unless the following requirements are met:

- Spray is not directed above the target canopy.
- The outside of the sprayer is turned off when turning at the end of rows and when spraying the outer row on each side of the application site.
- For dilute water rates up to the maximum listed for each type of canopy specified, minimum distances between the application site and downwind sensitive areas (see the 'Mandatory buffer zones' section of the following table titled 'Buffer zones for vertical sprayers') are observed.

Buffer zones for vertical sprayers

Type of target canopy and dilute water rate	Mandatory buffer zones				
	Bystander areas	Natural aquatic areas	Pollinator areas	Vegetation areas	Livestock areas
Up to 450 mL/100 L					
2 metres tall and smaller, maximum dilute water rate of 1000 L/ha	0 metres	10 metres	10 metres	0 metres	0 metres
Taller than 2 metres (not fully foliated), maximum dilute water rate of 1500 L/ha	0 metres	30 metres	30 metres	0 metres	0 metres
Taller than 2 metres (fully foliated), maximum dilute water rate of 1500 L/ha	0 metres	20 metres	20 metres	0 metres	0 metres

Spray drift restraints for EW 440 g/L malathion labels

Boom sprayers

DO NOT apply by a boom sprayer unless the following requirements are met:

- Spray droplets not smaller than a MEDIUM spray droplet size category.
- Minimum distances between the application site and downwind sensitive areas (see the 'Mandatory buffer zones' section of the following table titled 'Buffer zones for boom sprayers') are observed.

Buffer zones for boom sprayers

Application rate	Boom height above the target canopy	Mandatory buffer zones				
		Bystander areas	Natural aquatic areas	Pollinator areas	Vegetation areas	Livestock areas
Cereals, non-crop areas, pastures						
Up to 2.5 L/ha	0.5 m or lower	0 metres	15 metres	15 metres	0 metres	0 metres
	1.0 m or lower	0 metres	50 metres	45 metres	0 metres	0 metres
Up to 1.9 L/ha	0.5 m or lower	0 metres	10 metres	10 metres	0 metres	0 metres
	1.0 m or lower	0 metres	40 metres	40 metres	0 metres	0 metres
Up to 1.4 L/ha	0.5 m or lower	0 metres	10 metres	5 metres	0 metres	0 metres
	1.0 m or lower	0 metres	30 metres	30 metres	0 metres	0 metres
Up to 1.25 L/ha	0.5 m or lower	0 metres	5 metres	5 metres	0 metres	0 metres
	1.0 m or lower	0 metres	30 metres	30 metres	0 metres	0 metres
Up to 340 mL/ha	0.5 m or lower	0 metres	0 metres	0 metres	0 metres	0 metres
	1.0 m or lower	0 metres	10 metres	10 metres	0 metres	0 metres
Up to 160 mL/ha	0.5 m or lower	0 metres	0 metres	0 metres	0 metres	0 metres
	1.0 m or lower	0 metres	0 metres	0 metres	0 metres	0 metres

Aerial application

DO NOT apply by aircraft unless the following requirements are met:

- Spray droplets not smaller than a MEDIUM spray droplet size category.
- For maximum release heights above the target canopy of 3 m or 25% of wingspan or 25% of rotor diameter whichever is the greatest, minimum distances between the application site and downwind sensitive areas (see the 'Mandatory buffer zones' section of the following table titled 'Buffer zones for aircraft') are observed.

Buffer zones for aerial application

Application rate	Aircraft type	Mandatory buffer zones				
		Bystander areas	Natural aquatic areas	Pollinator areas	Vegetation areas	Livestock areas
Up to 2.5 L/ha	Fixed wing	0 metres	200 metres	190 metres	0 metres	0 metres
	Helicopter	0 metres	140 metres	140 metres	0 metres	0 metres
Up to 1.9 L/ha	Fixed wing	0 metres	160 metres	160 metres	0 metres	0 metres
	Helicopter	0 metres	120 metres	120 metres	0 metres	0 metres
Up to 1.8 L/ha	Fixed wing	0 metres	160 metres	150 metres	0 metres	0 metres
	Helicopter	0 metres	120 metres	110 metres	0 metres	0 metres
Up to 1.4 L/ha	Fixed wing	0 metres	130 metres	130 metres	0 metres	0 metres
	Helicopter	0 metres	95 metres	95 metres	0 metres	0 metres
Up to 1.25 L/ha	Fixed wing	0 metres	120 metres	120 metres	0 metres	0 metres
	Helicopter	0 metres	90 metres	90 metres	0 metres	0 metres
Up to 680 mL/ha	Fixed wing	0 metres	75 metres	75 metres	0 metres	0 metres
	Helicopter	0 metres	60 metres	60 metres	0 metres	0 metres
Up to 340 mL/ha	Fixed wing	0 metres	40 metres	35 metres	0 metres	0 metres
	Helicopter	0 metres	40 metres	40 metres	0 metres	0 metres

Application rate	Aircraft type	Mandatory buffer zones				
		Bystander areas	Natural aquatic areas	Pollinator areas	Vegetation areas	Livestock areas
Up to 160 mL/ha	Fixed wing	0 metres	15 metres	15 metres	0 metres	0 metres
	Helicopter	0 metres	20 metres	20 metres	0 metres	0 metres

Vertical sprayers

DO NOT apply by a vertical sprayer unless the following requirements are met:

- Spray is not directed above the target canopy.
- The outside of the sprayer is turned off when turning at the end of rows and when spraying the outer row on each side of the application site.
- For dilute water rates up to the maximum listed for each type of canopy specified, minimum distances between the application site and downwind sensitive areas (see the 'Mandatory buffer zones' section of the following table titled 'Buffer zones for vertical sprayers') are observed.

Buffer zones for vertical sprayers

Type of target canopy and dilute water rate	Mandatory buffer zones				
	Bystander areas	Natural aquatic areas	Pollinator areas	Vegetation areas	Livestock areas
700 mL/100 L in fruit trees, strawberries, blueberries, rubus and ribes					
All, maximum dilute rate of 20 L/ha	0 metres	15 metres	15 metres	0 metres	0 metres
570 mL/100 L wildflowers and proteas					
All	0 metres	10 metres	10 metres	0 metres	0 metres
340 mL/100 L in eucalypts and natives					
2 metres tall and smaller, maximum dilute water rate of 1000 L/ha	0 metres	10 metres	10 metres	0 metres	0 metres
Taller than 2 metres (not fully foliated), maximum dilute water rate of 2000 L/ha	0 metres	35 metres	35 metres	0 metres	0 metres
Taller than 2 metres (fully foliated), maximum dilute water rate of 2000 L/ha	0 metres	25 metres	25 metres	0 metres	0 metres
295 mL/100 L in capsicum, cucumber and tomatoes					
All	0 metres	10 metres	10 metres	0 metres	0 metres

Type of target canopy and dilute water rate	Mandatory buffer zones				
	Bystander areas	Natural aquatic areas	Pollinator areas	Vegetation areas	Livestock areas
230 mL/100 L in citrus					
2 metres tall and smaller, maximum dilute water rate of 1000 L/ha	0 metres	10 metres	10 metres	0 metres	0 metres
Taller than 2 metres (not fully foliated), maximum dilute water rate of 4000 L/ha	0 metres	40 metres	40 metres	0 metres	0 metres
Taller than 2 metres (fully foliated), maximum dilute water rate of 4000 L/ha	0 metres	30 metres	30 metres	0 metres	0 metres
230 mL/100 L in apples, pears, persimmons and stone fruit					
2 metres tall and smaller, maximum dilute water rate of 1000 L/ha	0 metres	10 metres	10 metres	0 metres	0 metres
Taller than 2 metres (not fully foliated), maximum dilute water rate of 1500 L/ha	0 metres	25 metres	25 metres	0 metres	0 metres
Taller than 2 metres (fully foliated), maximum dilute water rate of 1500 L/ha	0 metres	20 metres	20 metres	0 metres	0 metres
230 mL/100 L in cucurbits, vegetables (bean, cabbage, carrot, cauliflower, celery, cucurbit, lettuce, tomato), grapevines, strawberries, blueberries, <i>rubus</i>, <i>ribes</i>, flowers and ornamentals					
All	0 metres	10 metres	10 metres	0 metres	0 metres
195 mL/100 L in eucalypts and natives					
2 metres tall and smaller, maximum dilute water rate of 1000 L/ha	0 metres	10 metres	10 metres	0 metres	0 metres
Taller than 2 metres (not fully foliated), maximum dilute water rate of 4000 L/ha	0 metres	30 metres	30 metres	0 metres	0 metres
Taller than 2 metres (fully foliated), maximum dilute water rate of 4000 L/ha	0 metres	20 metres	20 metres	0 metres	0 metres
140 mL/100 L in citrus					
2 metres tall and smaller, maximum dilute water rate of 1000 L/ha	0 metres	5 metres	5 metres	0 metres	0 metres
Taller than 2 metres (not fully foliated), maximum dilute water rate of 4000 L/ha	0 metres	30 metres	30 metres	0 metres	0 metres

Type of target canopy and dilute water rate	Mandatory buffer zones				
	Bystander areas	Natural aquatic areas	Pollinator areas	Vegetation areas	Livestock areas
Taller than 2 metres (fully foliated), maximum dilute water rate of 4000 L/ha	0 metres	20 metres	20 metres	0 metres	0 metres
140 mL/100 L in apples, pears, persimmons and stone fruit					
2 metres tall and smaller, maximum dilute water rate of 1000 L/ha	0 metres	5 metres	5 metres	0 metres	0 metres
Taller than 2 metres (not fully foliated), maximum dilute water rate of 1500 L/ha	0 metres	20 metres	20 metres	0 metres	0 metres
Taller than 2 metres (fully foliated), maximum dilute water rate of 1500 L/ha	0 metres	15 metres	15 metres	0 metres	0 metres
Up to 140 mL/100 L in cucurbits, vegetables, grapevines, strawberries, blueberries, <i>rubus</i>, <i>ribes</i>, flowers, ornamentals, tobacco field, wildflowers, and proteas					
All	0 metres	5 metres	5 metres	0 metres	0 metres

Misters (ground application)

DO NOT apply by misters unless the following conditions are observed:

- The release height is not greater than 2 metres above the ground.
- Minimum distances between the application site and downwind sensitive areas that appear in the 'Mandatory buffer zones' section of the table titled 'Buffer zones for misters (ground application)' below.

Buffer zones for misting (ground application)

Application rate	Mandatory buffer zones				
	Bystander areas	Natural aquatic areas	Pollinator areas	Vegetation areas	Livestock areas
Up to 2.5 L/ha	0 metres	165 metres	160 metres	0 metres	0 metres
Up to 1.4 L/ha	0 metres	100 metres	95 metres	0 metres	0 metres
Up to 1.1 L/ha	0 metres	75 metres	70 metres	0 metres	0 metres
Up to 680 mL/ha	0 metres	40 metres	40 metres	0 metres	0 metres

Appendix B – public consultation

The APVMA received 3 submissions in response to the publication of the proposed regulatory decision. Details of the submissions are listed in Table 21 and the APVMA’s response is summarised below.

Table 21: Submissions in response to the proposed regulatory decisions on the reconsideration of malathion

Submitter	Comments
Summerfruit Australia	Support for the proposed decisions. Requested clarification on the number of spray applications permitted, mandatory buffer zones and label information.
National Working Party on Grain Protection	Support for proposed changes to relevant broadacre withholding periods and amending the common from “Maldison” to “Malathion”. Requested clarification on the efficacy and label directions of certain products with use patterns on stored grain.
Horticulture Innovation Australia Limited (Hort Innovation)	Support for retaining uses of malathion on horticultural crops and acknowledgement of the need to update current labels. Submission indicated that feedback received from industry indicated that the proposed changes should not negatively impact its use as an insecticide in the horticultural industry.

Summerfruit Australia

Summerfruit Australia commented on several proposed decisions, each of which is discussed individually below.

Summerfruit Australia requested that the number of cover sprays permitted be clearly articulated on the label.

APVMA: In relation to the number of applications permitted per season, the proposed decision indicated a maximum of 4 cover sprays will be permitted per season, this does not apply to bait spraying where the bait is applied to foliage only as it not expected to contribute to residues in food. In order to ensure all labels contain adequate instructions the following statement was proposed to be added to the directions for use table in other situations, where the maximum number of applications of a cover spray was not already defined, “*DO NOT apply more than 4 applications per season*”, to provide clarity to users.

Summerfruit Australia requested clarity on the scientific basis and justification for the proposed buffer zones detailed in the Malathion Review Technical Report. In addition, Summerfruit Australia commented that there appears to be no indication as to how growers may take actions to reduce these buffer zones.

APVMA: In relation to spray drift, the spray drift risk assessment was conducted in accordance with APVMA’s approach to spray drift management. The Regulatory Acceptable Levels (RALs) are the maximum amount of spray drift exposure that is not expected to cause undue harm to sensitive areas (bystander areas, livestock areas, natural aquatic areas, pollinator areas and vegetation areas). The derivation of these values is detailed in the [Malathion Review Technical report](#). The approved use patterns considered under the spray drift assessment included aerial application applications by airplane and helicopter, including ULV applications, and ground-based applications including boom spray, vertical spray, ULV applications, fogging and misting. Spray drift buffer zones

were calculated separately for each of the relevant use patterns using the [spray drift risk assessment tool](#) (SDRAT) using standard deposition curves for ground applications by boom spray and vertical sprayers and aerial application by airplane and helicopter. The [Spray drift management tool](#) (SDMT) was used to calculate buffer zones for a custom deposition curve as described in [Spray Drift Risk Assessment Manual](#). The variation of buffer zones is accounted for by use of different application rates and different application equipment, both the SDRAT and SDMT tools account for differences in the concentration of the active constituent in the product, the application rate, the target crop and the application equipment, these variable factors give rise to the buffer zone differences.

There is currently no approved method to allow horticultural growers to take individual actions to reduce these buffer zones. It is a legal requirement that the buffer zones prescribed on the labels are adhered to when using a product unless a permit is granted for off-label use. The APVMA acknowledges the complexity of the spray drift restraints and buffer zone section on the labels and will review the proposed labels to determine if it is feasible to simplify the presentation of this section.

Summerfruit Australia questioned the basis for the inclusion of the following statement on the proposed label of product 51150 “Some Green Peach Aphid populations may be resistant to organophosphate insecticides, and therefore WILL NOT be controlled by Fyfanon® 440 EW”.

APVMA: In relation to the label statement “Some Green Peach Aphid populations may be resistant to organophosphate insecticides, and therefore WILL NOT be controlled by Fyfanon® 440 EW”, it is important to note efficacy was not within the initial scope of this reconsideration and this aspect of the label has not been reviewed, however it is noted that the Resistance Warning statement infers the same information. In this case the Registrant has chosen to specifically identify that there is currently organophosphate resistance in some Green Peach aphid populations.

National Working Party on Grain Protection

The National Working Party on Grain Protection commented on several parts of the proposed regulatory decisions, each comment is addressed separately below.

The National Working Party on Grain Protection commented on their support for amending the withholding period of certain broadacre crops and on their support for amending the common name of maldison to malathion.

APVMA: The APVMA acknowledges the support of the National Working Party on Grain Protection (NWPGP) for the variation of withholding holding periods for certain broadacre crops and the variation of common name from maldison to malathion, noting both proposed changes should not significantly impact industry.

The National Working Party on Grain Protection raised concerns in relation to the efficacy of malathion products for control of insect pests of stored cereal grain.

The APVMA also acknowledges the NWPGP’s concern in relation to the efficacy of malathion products for control of insect pests of stored cereal grain, a use pattern which is restricted to

Western Australia and appears on APVMA Product numbers 50110 and 51150. The efficacy of the product was not within the scope of the current reconsideration and as such, the APVMA has not further considered the efficacy of these products when used in accordance with the current label directions. However, the APVMA will further consider whether the label for product 50110 contains sufficient information around resistance management and whether the current details of the use pattern are appropriate given that it refers to controlling weevils, which is likely to be interpreted as a range of insect pests of grains (i.e. not limited to *Sitophilus* species).

The APVMA is satisfied that the label for product 51150 contains adequate information and that it would be appropriate to align the label for 50110 more closely with that of 51150 in terms of the insects controlled and commodities to be treated. Some of the differences between the two labels may be a result of the differences in data provided at the time of registration and the product formulation and formulation type.

The National Working Party on Grain Protection commented on the absence of a trade advice statement on the proposed label of product 51150.

The APVMA acknowledges there is no trade advice statement on the proposed label of product 51150 and will further consider whether a trade advice statement is required on this label as part of the reconsideration, as the use pattern is not clearly limited to domestic use for the treatment of seed grains.

Horticulture Innovation Australia Limited (Hort Innovation)

Horticulture Innovation Australia Limited (Hort Innovation) detailed their support for some of the proposed decisions, each outlined below:

Hort Innovation highlighted the importance of registered products containing malathion in the management of certain pest in horticultural crops and supported the proposed retention of these uses with variations to the labels as an outcome of the reconsideration.

The APVMA supports the continued registration of malathion products with registered use patterns on horticultural crops when the labels are varied as outlined in the malathion review technical report.

Acronyms and abbreviations

Shortened term	Full term
ADI	Acceptable daily intake (for humans)
ARfD	Acute reference dose
Bw	Bodyweight
D	Day
DAF	Dermal absorption factor
FAO	Food and Agriculture Organization of the United Nations
G	Gram
GCP	Good Clinical Practice
GLP	Good Laboratory Practice
Ha	Hectare
in vitro	Outside the living body and in an artificial environment
in vivo	In a living cell or organism
Kg	Kilogram
L	Litre
LD ₅₀	Dosage of chemical that kills 50% of the test population of organisms
LOAEL	Lowest observed adverse effect level
Mg	Milligram
mL	Millilitre
MRL	Maximum residue limit
NEDI	National Estimated Daily Intake
NESTI	National Estimated Short-Term Intake
NOEC/NOEL	No observable effect concentration level
NOAEL	No observed adverse effect level
OECD	Organisation for Economic Co-operation and Development
PHED	Pesticide Handler Exposure Database

Shortened term	Full term
PPE	Personal protective equipment
Ppm	Parts per million
RAL	Regulatory acceptable level
SDMT	Spray drift management tool
SDRAT	Spray drift risk assessment tool
TWA	Time-weighted average
µg	Microgram
WHO	World Health Organisation

References

Australian Pesticides and Veterinary Medicines Authority, [APVMA Risk Assessment Manual, Environment](#), APVMA website, 8 April 2019.

Australian Pesticides and Veterinary Medicines Authority, [APVMA Risk Assessment Manual, residues and trade](#), APVMA website, 22 March 2019.

Australian Pesticides and Veterinary Medicines Authority, [APVMA Risk Assessment Manual, chemistry and manufacture](#), APVMA website, 22 March 2019.

Australian Pesticides and Veterinary Medicines Authority, [Efficacy and target animal safety general guideline \(Part 8\)](#), APVMA website, 27 November 2013.

Australian Pesticides and Veterinary Medicines Authority, [Human Health Risk Assessment Manual](#), APVMA website, 4 October 2018.

Australian Pesticides and Veterinary Medicines Authority, [Spray drift](#), APVMA website, 24 June 2014.

Australian Pesticides and Veterinary Medicines Authority, [Spray drift risk assessment manual \(SDRAM\)](#), APVMA website 17 July 2019.

Australian Pesticides and Veterinary Medicines Authority, [Maldison Chemistry Report](#), APVMA website, 12 April 2016.

Aston L (2000) Determination of residues of malathion dicarboxylic acid (DCA), malathion monocarboxylic acid (MCA), dimethyl phosphate (DMP), dimethyl triphosphate (DMTP) and dimethyl dithiophosphate (DMDTP) in human urine. Project No. PTL 119801. Lab: Pacific Toxicology Laboratories, Woodland Hills, CA. Cheminova Doc. No. 299 FYF Amdt-5. Unpublished. 11.10.2000. [CA; sub: 12331, Vol. 72].

Barnett JF (2012b). Oral (Diet) Repeated Dose 28-Day Toxicity Study of Malathion Technical in Rats. Study No. TQC00065. Report No.: CHA Doc. No. 1108FYF. Unpublished. 05 April 2012

Beattie G (1993) A 2-week toxicity study of aerosolized malathion administered by whole body inhalation exposure to the albino rat. Project No. 90557. Lab: Bio-Research Laboratories Ltd. 87 Senneville Road, Senneville, Quebec H9X 3R3 Canada. Cheminova Doc. No. 228 FYF. 16.3.1994. Unpublished. [CA; sub 11743, Vol. 7].

Beattie G (1994) A 13-week toxicity study of aerosolized malathion administered by whole body inhalation exposure to the albino rat. Project No. 90729. Lab: Bio-Research Laboratories Ltd. 87 Senneville Road, Senneville, Quebec H9X 3R3 Canada. Cheminova Doc. No. 81 FYF. 16 March 1994. Unpublished. [CA; sub 11743, Vols 6-7].

Bookbinder, M.G. 1994a. Magnitude of the Residue of Malathion and its Metabolite Malaoxon in/on Grass Raw Agricultural Commodities harvested after Ground and Aerial Treatment, En-Cas Analytical Laboratories, Inc., Proj. No. AA920113, '92-0058, Unpublished Cheminova Agro A/S-report, CHA Doc. No. 123 FYFI.

- Bookbinder, M.G. 1994b. Magnitude of the Residue of Malathion and its Metabolite Malaoxon in Orange Processed Commodities, American Agricultural Services, Inc., EN-CAS Analytical Laboratories, Inc., Proj. No. AA920129, '92-0074, Unpublished Cheminova Agro A/S-report, CHA Doc. No. 118 FYF.
- Bookbinder, M.G. 1995a. Magnitude of the Residue of Malathion and Its Metabolite Malaoxon in/on Clover Raw Agricultural Commodities harvested after Ground and Aerial Treatment, American Agricultural Services, Inc., EN-CAS Analytical Laboratories, Inc., Proj. No. AA920107, '92-0044, Unpublished Cheminova Agro A/S-report, CHA Doc. No. 104 FYF.
- Bookbinder, M.G. 1995b. Magnitude of the Residue of Malathion and Its Metabolite Malaoxon in/on Alfalfa Raw Agricultural Commodities harvested after Ground and Aerial Treatment, American Agricultural Services, Inc., EN-CAS Analytical Laboratories, Inc., Proj. No. AA920101, '92-0031, Unpublished Cheminova Agro A/S-report, CHA Doc. No. 105 FYF.
- Bookbinder, M.G. 1995c. Magnitude of the Residue of Malathion and Its Metabolite Malaoxon in/on Grape Processed Commodities, American Agricultural Services, Inc., EN-CAS Analytical Laboratories, Inc., Proj. No. AA920133, '92-0073, Unpublished Cheminova Agro A/S-report, CHA Doc. No. 110 FYF.
- Buratti FM, D'Aniello A, Volpe MT, Meneguz A, Testai E. Malathion bioactivation in the human liver: the contribution of different cytochrome p450 isoforms. *Drug Metab Dispos.* 2005; 33(3):295-302. doi:10.1124/dmd.104.001693.
- Cui F, Li MX, Chang HJ, et al. Carboxylesterase-mediated insecticide resistance: Quantitative increase induces broader metabolic resistance than qualitative change. *Pestic Biochem Physiol.* 2015; 121:88-96. doi:10.1016/j.pestbp.2014.12.016.
- Cushman JR, Street JC. Allergic hypersensitivity to the insecticide malathion in BALB/c mice. *Toxicol Appl Pharmacol.* 1983; 70(1):29-42. doi:10.1016/0041-008x(83)90176-x.
- Daly IW (1993a) A 28-day study of malathion in the rat via dietary administration. Study No. 92-3806. Lab: Bio/dynamics, Inc. PO Box 2360, Mettlers Road, East Millstone, New Jersey 08875-2360. Cheminova Doc. No. 68 FYF. Unpublished. 9.3.1993.
- Daly IW (1993b) A subchronic (3-month) oral toxicity study of malathion in the rat via dietary administration. Project No. 92-3843. Lab: Bio/dynamics, Inc. PO Box 2360, Mettlers Road, east Millstone, New Jersey 08875-2360. Cheminova Doc. No. 70 FYF. Unpublished. 6.7. 1993.
- Daly IW (1996a) A 24-month oral toxicity/oncogenicity study of malathion in the rat via dietary administration: final report. Study No. 90-3641. Lab: Huntington Life Sciences, Mettlers Road, East Millstone, New Jersey USA. Cheminova Doc. No. 164 FYF. Unpublished. 27.2.1996.
- Das S, Chatterjee K, Sarkar N, Aich B, Dolui S. Cholinergic crisis, intermediate syndrome and delayed polyneuropathy following malathion poisoning. *J Pediatr Intensive Care.* 2013; 2(3):137-141. doi:10.3233/PIC-13063.
- Ebke KP, 2002. Evaluation of direct and indirect effects of a 440 g/l EW formulation of malathion on aquatic organisms in outdoor ponds. Cheminova unpublished report no. 379 FYF

Ebke KP, 2002. Evaluation of direct and indirect effects of a 440 g/l EW formulation of malathion on aquatic organisms in outdoor ponds. 379 FYF Amdt-1

Ergün SS, Oztürk K, Su O, Gürsoy EB, Uğurad I, Yüksel G. Delayed neuropathy due to organophosphate insecticide injection in an attempt to commit suicide. *Hand (N Y)*. 2009; 4(1):84-87. doi:10.1007/s11552-008-9126-y.

Food and Agriculture Organization of the United Nations, [FAO Specifications and Evaluations for Agricultural Pesticides – Malathion](#), FAO website.

Food and Agriculture Organization of the United Nations, [Pesticide residues in food – 2016: Toxicological evaluations](#), FAO website.

Food and Agriculture Organization of the United Nations, [Pesticide residues in food 2016 – Special Session of the Joint FAO/WHO Meeting on Pesticide Residues](#), FAO website.

Feldmann RJ, Maibach HI. Percutaneous penetration of some pesticides and herbicides in man. *Toxicol Appl Pharmacol*. 1974; 28(1):126-132. doi:10.1016/0041-008x(74)90137-9.

Gillies D, Dickson J (2000) A randomised double-blind ascending single oral dose study with malathion to determine the no effect level on plasma and RBC cholinesterase activity. Lab project ID: ICR 013177. Lab: Inveresk Research, Elphinstone Research Centre, Tranent EH33 2NE Scotland. Cheminova Doc. No. 299 FYF. Unpublished. 20.3.2000. [CA; sub 11743, Vols 69-71].

Gries T, Purghart V, 2001. Malathion technical: acute immobilisation test with daphnids (*Daphnia magna*) under flow-through conditions. Cheminova unpublished report no. 310 FYF

Gries T, van der Kolk J, Purghart V, 2002. Malathion technical: acute toxicity test with three-spined stickleback (*Gasterosteus aculeatus*) under flow-through conditions. Cheminova unpublished report no. 381 FYF

Hommen U, Shemotyuk L, 2016 MDD evaluation of a GLP mesocosm study with Malathion (CHA Doc. No. 379 FYF). 379 FYF Suppl-1

Hoxter KA, Jaber M. 1989. Cythion insecticide (AC 6601 57% EC) honey bee toxicity of residues on foliage – malathion (CL 6,601) and Malaoxon (CL 28,967) in alfalfa green forage and analysis of spray solutions. Cheminova unpublished report no.: 27 FYF

ISO (1981), ISO 1750:1981–Pesticides and other agrochemicals—Common names' (ISO, 1981). International Standards Organisation.

Jenkins CA, 1993. Fyfanon technical: determination of its EC₅₀ to *Selenastrum capricornutum*. Cheminova report no. 71 FYF.

Jianmongkol S, Berkman CE, Thompson CM, Richardson RJ. Relative potencies of the four stereoisomers of isomalathion for inhibition of hen brain acetylcholinesterase and neurotoxic esterase in vitro. *Toxicol Appl Pharmacol*. 1996; 139(2):342-348. doi:10.1006/taap.1996.0174.

- Kazen C, Bloomer A, Welch R, Oudbier A, Price H. Persistence of pesticides on the hands of some occupationally exposed people. *Arch Environ Health*. 1974; 29(6):315-318. doi:10.1080/00039896.1974.10666605.
- Knoch E, 2001. Degradability and fate of malathion in the aquatic environment (water/ sediment system). Cheminova unpublished report no. 337 FYF.
- Komori T, Yamane K, Nagayama T, Shibata K, Nozaki H, Takeuchi M. [A case of delayed myeloneuropathy due to malathion intoxication]. *No To Shinkei*. 1991; 43(10):969-974.
- Lochry, EA (1989) A development toxicity study with AC 6,601 in rats. Project No. 101-005. Cheminova Study No. 971-88-142. Lab: Argus Research Laboratories, Inc. 2025 Ridge Rd, Perkasie, Pennsylvania 18944. Cheminova Doc. No. 10 FYF. Unpublished. [CA; sub: 12331, Vol. 40].
- Lönnerdal B, Asquith MT. Malathion not detected in breast milk of women living in aerial spraying areas. *N Engl J Med*. 1982; 307(7):439. doi:10.1056/NEJM198208123070713.
- Maibach HI, Feldman RJ, Milby TH, Serat WF. Regional variation in percutaneous penetration in man. *Pesticides. Arch Environ Health*. 1971; 23(3):208-211. doi:10.1080/00039896.1971.10665987.
- Milby TH, EPSTEIN WL. Allergic Contact Sensitivity to Malathion. *Arch Environ Health*. 1964; 9:434-437. doi:10.1080/00039896.1964.10663862.
- Moreno OM (1988) 21-day dermal toxicity study with AC 6,601 in rabbits. Study No. MB 88-9191. Lab: MB Research Laboratories Inc. Cheminova Doc. No. 17 FYF. Unpublished. [CA; sub 12331, Vol 6].
- OCS (2005). APVMA Chemical Review Program. Review of the Mammalian Toxicology and Metabolims/toxicokinetics of Maldison prepared by the Office of Chemical Safety, Therapeutic Goods Administration of the Department of Health and Ageing, Canberra, April 2005.
- Perina VCF, 1995. Acute toxicity of Malatol 500EC to honeybee (*Apis mellifera mellifera* L.). Cheminova unpublished report no. 244 FYF.
- Saleh MA; El-Demerdash A; Jones J; Mohammed Z; Kamel A; Blancato JN; Dary C. 2000. Detection of malathion in dermally treated rats using electronic autoradiography and FT-IR microscopy. *J. Trace Microprobe Tech*. 2000; 18(1): 121-135.
- Sanghi R, Pillai MK, Jayalekshmi TR, Nair A. Organochlorine and organophosphorus pesticide residues in breast milk from Bhopal, Madhya Pradesh, India. *Hum Exp Toxicol*. 2003; 22(2):73-76. doi:10.1191/0960327103ht321oa.
- Schafey O., Sekereke HJ, Hughes BJ, et al. Surveillance for acute pesticide-related illness during the medfly eradication program — Florida, 1998. *Morbidity and Mortality Weekly Report. MMWR Morb Mortal Wkly Rep*. 1999; 48(44):1015-1027.
- Schanker HM, Rachelefsky G, Siegel S, et al. Immediate and delayed type hypersensitivity to malathion. *Ann Allergy*. 1992; 69(6):526-528.

Scharf JE, Johnson GT, Harbison SC, McCluskey JD, Harbison RD. Dermal absorption of a dilute aqueous solution of malathion. *J Emerg Trauma Shock*. 2008; 1(2):70-73. doi:10.4103/0974-2700.43182.

Sharma VK, Kaur S. Contact sensitization by pesticides in farmers. *Contact Dermatitis*. 1990; 23(2):77-80. doi:10.1111/j.1600-0536.1990.tb03227.x.

Siglin, JC (1985b) A teratology study with AC 6,601 in rabbits. Cheminova FDRL Study No. 8171. Lab: Food and Drug Research Laboratories, Inc. PO Box 106, Waverly, NY. 28.2.1985. Unpublished. [CA; sub 12331, Vol 41].

United States Environmental Protection Agency, [CompTox Chemicals Dashboard – Malathion](#), EPA website, 2020.

United States Environmental Protection Agency, [Occupational Pesticide Handler Exposure Data](#), EPA website, 10 August 2015.

United States Environmental Protection Agency, [Occupational Pesticide Post-Application Exposure Data](#), EPA website, 10 August 2015.

Wester RC, Maibach HI, Bucks DA, Guy RH. Malathion percutaneous absorption after repeated administration to man. *Toxicol Appl Pharmacol*. 1983; 68(1):116-119. doi:10.1016/0041-008x(83)90360-5.

WHO (World Health Organisation), 2011. Generic risk assessment model for indoor and outdoor space spraying of insecticides. WHO Pesticide Evaluation Scheme, February 2011.

World Health Organisation International Agency for Research on Cancer, [Some Organophosphate Insecticides and Herbicides – IARC Monographs on the Evaluation of Carcinogenic Risks to Humans Volume 112](#), IRAC website, 2017.

World Health Organisation International Agency for Research on Cancer, [Mode of Action Classification Scheme Version 10.3](#), June 2022.