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The *Agricultural and Veterinary Chemical Code Act 1994* (the Act) commenced on 15 March 1995. The Agricultural and Veterinary Chemicals Code (the Agvet Code) scheduled to the Act requires notices to be published in the *Gazette* containing details of the registration of agricultural and veterinary chemical products and other approvals granted by the Australian Pesticides and Veterinary Medicines Authority. The Agvet Code and related legislation also requires certain other notices to be published in the *Gazette*. A reference to Agvet Codes in this publication is a reference to the Agvet Code in each state and territory jurisdiction.

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

Email: communications@apvma.gov.au

Website: apvma.gov.au

General information

The APVMA Gazette is published fortnightly and contains details of the registration of agricultural and veterinary chemicals products and other approvals granted by the APVMA, notices as required by the Agricultural and Veterinary Chemicals Code (the Agvet Code) and related legislation and a range of regulatory material issued by the APVMA.

Pursuant to section 8J(1) of the Agvet Code, the APVMA has decided that it is unnecessary to publish details of applications made for the purpose of notifying minor variations to registration details. The APVMA will however report notifications activity in quarterly statistical reports.

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APVMA contacts

For enquiries regarding the publishing and distribution of the APVMA Gazette: Telephone: +61 2 6770 2300.

For enquiries on APVMA Gazette content, please refer to the individual APVMA contacts listed under each notice.

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Notice of decision on reconsideration under section 34AC of the Agricultural and Veterinary Chemicals Code – affirmations for malathion reconsideration

I, Sheila Logan, Executive Director, Risk Assessment Capability, pursuant to section 34AC(1)(b) of the Agricultural and Veterinary Chemicals Code scheduled to the *Agricultural and Veterinary Chemicals Code Act 1994* (Agvet Code) hereby publish notice that I, Sheila Logan, Executive Director, Risk Assessment Capability, have varied and affirmed all malathion active constituent approvals, product registrations and label approvals listed in Attachment A of this notice.

A statement of reasons for the variation and affirmation is included in Attachment B of this notice.

Sheila Logan
Executive Director, Risk Assessment Capability

With the delegated authority under sections 11, 32 and 44 of the *Agricultural and Veterinary Chemicals (Administration) Act 1992*

Date: 2 May 2024

Attachments

Note: The below Attachments form part of this Notice.

- Attachment A: Active constituent approvals, product registrations and label approvals that the APVMA has varied and affirmed
- Attachment B: Statement of Reasons

Contact information

For any enquiries or further information about this matter, please contact:

Chemical Review
Australian Pesticides and Veterinary Medicines Authority
GPO Box 3262
Sydney NSW 2001

Phone: +61 2 6770 2400

Email: chemicalreview@apvma.gov.au

Attachment A: Active constituent approvals, product registrations and label approvals that the APVMA has varied and affirmed

Approval or registration number	Name	Holder	Affirmed label approval number associated with the registered product
Active constituents			
44350	Maldison	FMC Australasia Pty Ltd	N/A
46160	Maldison	Gulmohar Chemicals Pty Ltd	N/A
87713	Malathion	Tagros Chemicals India Private Limited	N/A
Agricultural chemical products			
42035	David Grays Malathion Garden Spray	David Gray & Co. Pty Limited	42035/RV24
42727	Q Fly Wick	Bugs For Bugs Pty Ltd	42727/RV24
49539	Fyfanon ULV Insecticide	FMC Australasia Pty Ltd	49539/RV24
50110	David Grays Malathion Grain Dust Insecticide	David Gray & Co. Pty Limited	50110/RV24
50589	Searles Fruit Fly Wick Attractant and Insecticide	J C & A T Searle Pty Ltd	50589/RV24
51150	Fyfanon 440 EW Insecticide	FMC Australasia Pty Ltd	51150/RV24
58968	David Grays Malathion and White Oil Insecticide	David Gray & Co. Pty Limited	58968/RV24
62194	Fyfanon 1000 EC Insecticide	FMC Australasia Pty Ltd	62194/RV24
62242	David Grays Fruit Fly Garden Spray	David Gray & Co. Pty Limited	62242/RV24
63032	Eco-Lure Male Qld Fruit Fly Wick	Duluxgroup (Australia) Pty Ltd	63032/RV24
69529	Fyfanon Premium Insecticide	FMC Australasia Pty Ltd	69529/RV24
Agricultural chemical products containing malathion as an excipient			
60832	ZP Mouse Zinc Phosphide Bait	Bell Laboratories, Inc.	60832/54449
60890	ZP Rat Zinc Phosphide Bait	Bell Laboratories, Inc.	60890/111240
66869	Genfarm Zinc Phosphide Mouse Bait	Nutrien Ag Solutions Limited	66869/55942
Veterinary chemical products			
33021	Pharmachem Maldison 50 Insecticide	Pharmachem Australia Pty Ltd	33021/RV24
37201	Inca Malaban Wash Concentrate	Inca (Flight) Co Pty Ltd	37201/RV24
42267	David Grays Poultry Dust	David Gray & Co. Pty Limited	42267/RV24
54285	Bob Martin Since 1892 Flea & Tick Control for Dogs, Cats & Aviaries Malawash	Bob Martin (Australia) Pty Ltd	54285/RV24
63456	Saint Bernard Petcare Maldison Wash Insecticide	Vet Med Ip Pty Ltd	63456/RV24

Attachment B: Statement of Reasons

Note: In this Statement of Reasons, references to the APVMA are referring to Sheila Logan, Executive Director Risk Assessment Capability as the APVMA delegate.

- 1) The APVMA has reconsidered the malathion active constituent approvals, chemical product registrations containing malathion and associated label approvals under Part 2, Division 4 of the Agvet Code to determine whether the:
 - a) active constituents meet the safety criteria (section 5A of the Agvet Code),
 - b) chemical products meet the safety criteria (section 5A of the Agvet Code), the trade criteria (section 5C of the Agvet Code), and the efficacy criteria (section 5B of the Agvet Code),
 - c) labels meet the labelling criteria (section 5D of the Agvet Code), and
 - d) active constituents, chemical products and labels comply with the requirements prescribed by the Agvet Regulations.

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Material findings of fact and reasons for the decisions

Active constituents

- 2) Section 34(1) of the Agvet Code provides that the APVMA must affirm the approval of an active constituent if, and only if, it is satisfied that the constituent:
 - a) meets the safety criteria, and
 - b) complies with any requirement prescribed by the Agvet Regulations.
- 3) Section 34(2) of the Agvet Code provides that subsection 34(1) applies only to the extent that the APVMA decides to reconsider matters covered by this subsection.
- 4) The APVMA has reconsidered all matters covered by subsection 34(1) in relation to the reconsideration of malathion active constituent approvals.

Consideration of whether active constituents meet the safety criteria

- 5) Section 5A(1) of the Agvet Code provides that an active constituent meets the safety criteria if use of the active constituent, in accordance with any instructions approved or to be approved by the APVMA for the constituent or contained in an established standard:
 - a) is not, or would not be, an undue hazard to the safety of people exposed to it during its handling or people using anything containing its residues (section 5A(1)(a))
 - b) is not, or would not be, likely to have an effect that is harmful to human beings (section 5A(1)(b))
 - c) is not, or would not be, likely to have an unintended effect that is harmful to animals, plants or things or to the environment (section 5A(1)(c)).
- 6) For the purposes of being satisfied that the active constituents meet the safety criteria as described in section 5A(1)(a) to (c) of the Agvet Code, the APVMA has had regard to the criteria set out in section 5A(2)(a) of the Agvet Code as follows:
 - a) Section 5A(2)(a)(i) of the Agvet Code - the toxicity of the constituent and its residues, including metabolites and degradation products in relation to relevant organisms and ecosystems, including human beings.
 - I. The APVMA has considered the following information in having regard to the toxicity of the constituent malathion and its residues, as detailed in the *Malathion Final Review Technical Report*:
 - acute toxicity, short-term toxicity, chronic toxicity, genotoxicity, neurotoxicity, carcinogenicity, reproduction toxicity, developmental toxicity and immunotoxicity studies,
 - metabolism studies and studies on malathion metabolites, degradants and impurities,
 - the impact of the impurities of toxicological concern. As set out in the *2016 Maldison Chemistry Report*, impurities in malathion can increase (potentiate) the toxicity of malathion itself and the most significant potentiators of malathion toxicity are MeOSSPO, isomalathion and MeOOSPO.

- II. The APVMA has considered relevant toxicity studies and has retained the malathion health-based guidance values, as detailed in the *Malathion Final Review Technical Report*:
- The acceptable daily intake (ADI¹) is 0.02 mg/kg bw/d based on a no observable adverse effect level (NOAEL) of 2 mg/kg bw/d and an uncertainty factor of 100, derived from a 2-year dietary study in rats.
 - The acute reference dose (ARfD²) is 1.5 mg/kg bw based on a NOAEL of 15 mg/kg bw/d and an uncertainty factor of 10, derived from an acute oral human study.
- III. The APVMA is satisfied that the scheduling for malathion in the *Therapeutic Goods (Poisons Standard—February 2024) Instrument 2024* remains appropriate based on the malathion toxicological database, as set out in the *Malathion Final Review Technical Report*.
- IV. The APVMA is satisfied that there is sufficient information to assess the role of the toxicity of the constituent malathion and its metabolites in relation to relevant organisms and ecosystems, including human beings, for both agricultural and veterinary products. Details of the assessment are provided in the *Malathion Final Review Technical Report*.
- V. The worker exposure assessment detailed in the *Malathion Final Review Technical Report* identified acceptable levels of occupational exposure to malathion, applying a margin of exposure of 100 to a no observed adverse effect level of 50 mg/kg bw/day.
- VI. The residues assessment detailed in the *Malathion Final Review Technical Report* has confirmed that the acute and chronic dietary exposure calculated using the National Estimated Dietary Intake calculation are acceptable based on the ADI of 0.02 mg/kg bw/d and ARfD of 1.5 mg/kg bw.
- b) Section 5A(2)(a)(ii) of the Agvet Code - the method by which the constituent is, or is proposed to be, manufactured.
- I. There were no concerns identified for the method by which each approved source of the malathion active constituent is manufactured. The APVMA is satisfied that the method by which each approved source of the malathion active constituent is manufactured remains appropriate.
- c) Section 5A(2)(a)(iii) of the Agvet Code - the extent to which the constituent will contain impurities.
- I. The APVMA has considered the following information with respect to the extent to which the constituent malathion will contain impurities, as detailed in the *Malathion Final Review Technical Report*.
- Information submitted to the APVMA as part of the original approval and during the course of the reconsideration, including minimum purity and maximum impurity level requirements listed in the source-specific Declaration of Composition, batch analyses and stability data.
 - The specifications for malathion active constituents in the Food and Agriculture Organization of the United Nations (FAO) Specifications for Pesticides established in 2022 and associated evaluations.
- II. The chemistry assessment detailed in the *Malathion Final Review Technical Report* has concluded that the following minimum purity and maximum impurity levels for malathion active constituents are appropriate,

¹ ADI – acceptable daily intake (for humans): a level of intake of a chemical (expressed mg/kg bw/day; milligrams per kilogram of body weight per day) that can be ingested daily over an entire lifetime without any appreciable risk to health.

² ARfD – acute reference dose (for humans): the amount of a substance in food or drinking-water, (expressed as mg/kg of body weight), that can be ingested or absorbed over 24 hours or less, without appreciable health risk.

based on the data evaluated and the malathion specification in FAO Specifications for Pesticides and associated evaluations:

- Malathion: 950 g/kg minimum
 - Isomalathion: 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)
 - Malaoxon: 1 g/kg maximum
 - O,O,S-trimethylphosphorothioate (MeOOSPO) (CAS no. 152-20-5): 5 g/kg maximum
 - O,S,S-trimethylphosphorodithioate (MeOSSPO) (CAS no. 22608-53-3): 0.1 g/kg maximum
 - O,O,S-trimethylphosphorodithioate (MeOOSPS) (CAS no. 2953-29-9): 15 g/kg maximum.
 - O,O,O-trimethylphosphorothioate (MeOOOPS) (CAS no. 152-18-1): 5 g/kg maximum
- III. The APVMA is satisfied that the minimum purity and maximum impurity levels for each approved source of malathion active constituent, as set out in the Declarations of Composition, comply with the requirements set out in paragraph 6)c)II. above.
- d) Section 5A(2)(a)(iv) of the Agvet Code – whether an analysis of the chemical composition of the constituent has been carried out and, if so, the results of the analysis.
- I. The APVMA has considered the batch analyses and stability data that were submitted and assessed by the APVMA as part of the original approval for each approved source of malathion active constituent and submitted to the APVMA during the course of the reconsideration.
- II. The APVMA is satisfied that the batch analyses and stability data for malathion active constituent approval demonstrate that the chemical composition of these malathion approvals are appropriate.
- e) Section 5A(2)(a)(v) of the Agvet Code - any conditions to which its approval is, or would be, subject.
- I. Section 23(1)(a) of the Agvet Code provides that the approval of an active constituent is subject to the conditions prescribed by the regulations (whether or not the conditions are prescribed at the time the constituent is approved).
- The table-items under Regulation 17C of the Agvet Regulations prescribes the following:
 - The active constituent must be manufactured in accordance with the composition and purity entered for that source of active constituent in the Record in accordance with paragraph 15(1)(d) of the Agvet Regulations.
 - The active constituent must be manufactured by the manufacturer whose name is entered for the active constituent in the Record in accordance with paragraph 15(1)(e) of the Agvet Regulations.
 - The active constituent must be manufactured at the site of manufacture entered for the active constituent in the Record in accordance with paragraph 15(1)(f) of the Agvet Regulations.

- The identifying information for the holder of the approval and the nominated agent (if any), of the active constituent must be the identifying information for the holder and nominated agent (if any) entered for the active constituent in the Record.
- II. Section 23(1)(b) of the Agvet Code provides that the approval of an active constituent is also subject to any conditions imposed on the approval as the APVMA thinks appropriate.
- III. In determining whether malathion active constituents meet the safety criteria, the APVMA has had regard to the following conditions imposed by the APVMA in accordance with section 23(1)(b) of the Agvet Code referred to as the Agricultural Active Constituents Quality Assurance Requirements.
- *'Agricultural Active Constituents must meet Quality Assurance Requirements*
 - *A person must not Supply the Active Constituent, or cause it to be supplied, unless the Active Constituent:*
 - *complies with the APVMA Standard for the Active Constituent; and*
 - *was manufactured at a site of manufacture listed in the Record of Approved Active Constituents.*
 - *A person must at the time of Supply of a Batch of the Active Constituent to another person also supply details of the Batch Number of the Active Constituent to the person to whom the active constituent was supplied.*
 - *For the purposes of these conditions a constituent complies with the APVMA Standard if the constituent, when measured using a validated analytical method:*
 - *does not contain less than the minimum purity and/or content of the constituent as set out in the APVMA Standard; and*
 - *does not contain more than the maximum level of any impurity as set out in the APVMA Standard*
 - *Definitions and Interpretation - in these conditions the following words have the following meanings:*
 - *'APVMA Standard' means the standard determined by the APVMA to which a constituent must comply and which is published on the APVMA website;*
 - *'Batch' means a defined quantity of material produced in a single series of operations;*
 - *'Batch Number' means that a distinctive combination of numbers and/or letters that specifically identifies a Batch and from which the production history can be determined;*
 - *'Supply' has the same meaning as given to it in Section 3 of the Agvet Codes and includes the doing of those things through, or pursuant to an arrangement with another person.'*
- IV. In determining whether active constituents meet the safety criteria, the APVMA has also had regard to conditions imposed on active constituents by the *Agricultural and Veterinary Chemicals Code (Conditions of Approval or Registration) Order 2021* (Conditions of Approval or Registration Order).

- V. The APVMA is satisfied that the current conditions of approval prescribed by the Agvet Regulations and the conditions of approval imposed on the approval or by the Registration Order are appropriate and that the holder of the approvals can comply with these conditions.
 - VI. The APVMA is **not satisfied** that the current condition referred to as the Agricultural Active Constituents Quality Assurance Requirements is appropriate, as it references the 'APVMA Standard' and indicates that this is published on the APVMA Website. The APVMA Standard has been replaced by the legislative instrument, the *Agricultural and Veterinary Chemicals Code (Agricultural Active Constituents) Standards 2022* (Agricultural Active Constituents Standards).
- f) Section 5A(2)(a)(vi) - any relevant particulars that are, or would be, entered in the Record for malathion.
- I. The relevant particulars entered in the Record for each approved source of the malathion active constituent have been reviewed. Sections 3 and 19(c) of the Agvet Code provide that the relevant particulars are the distinguishing number, any instructions for use and any other particulars prescribed by the regulations. Regulation 15(1) prescribes the following particulars for the purposes of section 19(c) of the Agvet Code: the name of the active (including the common name and the IUPAC name), the composition and purity of the active, the name of the manufacturer, the address of each site at which the active constituent is manufactured, the holder of the approval, the date of entry of these particulars and, if relevant, the nominated agent.
 - II. The APVMA is **not satisfied** that the common name entered in the Record for all active constituents remains appropriate. The Australian pesticides common name 'maldison' is not used outside Australia, nor is it used for Australian therapeutic goods. The common name 'malathion' is specified in ISO 1750-1981.
 - III. The APVMA is **not satisfied** that the information entered into the Record accurately reflects the composition of the malathion active constituents, as specified in the current Declarations of Composition submitted to the APVMA as part of the original approval or submitted to the APVMA during the course of the reconsideration. The information entered into the Record does not include limits for all relevant impurities listed in paragraph 6)c)II. above.
 - IV. The APVMA is satisfied that all other relevant particulars entered into the Record for malathion active constituent approvals remain appropriate.
- g) Section 5A(2)(a)(via) – whether the constituent conforms, or would conform, to any standard made for the constituent under section 6E to the extent that the standard relates to matters covered by subsection 5A(1).
- I. The Agricultural Active Constituents Standards 2022 is made under section 6E(1) of the Agvet Code for active constituents used in agricultural chemical products, including malathion.
 - II. The chemistry assessment recommended that the Standard for malathion active constituents in the Active Constituents Standard 2022 be amended to the requirements set out in paragraph 6)c)II. above, as outlined in the *Malathion Final Review Technical Report*. It is noted that the process for varying a Standard made under 6E(1) of the Agvet Code is set out in regulation 8AF of the Agvet Regulations and will be undertaken separately to this regulatory decision.
 - III. The APVMA is satisfied that each approved source of malathion active constituent listed in Attachment A conforms to the current requirements set out in the Agricultural Active Constituents Standards 2022 and will also conform to the proposed revised malathion standard.
- h) Section 5A(2)(a)(vii) of the Agvet Code – any matters prescribed by the regulations.

- I. Regulation 8AA – the method of analysis (if any) of the chemical composition of the active constituent concerned.
 - There were no concerns identified for the method(s) of analysis used to determine the purity of malathion for each approved source of the active constituent. The APVMA is satisfied that the method(s) of analysis of the chemical composition of each approved source of the malathion active constituent remain appropriate.
- i) Section 5A(2)(b) of the Agvet Code – such other matters as the APVMA thinks relevant.
 - I. There are no other matters that the APVMA thinks relevant regarding whether malathion active constituents meet the safety criteria.
- 7) Having had regard to the matters and findings set out above, the APVMA is **not satisfied** that the use of the malathion active constituent in Attachment A of this notice meets the safety criteria as defined in section 5A of the Agvet Code for the following reasons
 - a) that the current condition referred to as the ‘Agricultural Active Constituents Quality Assurance Requirements’ is no longer appropriate, as it references the ‘APVMA Standard’ and indicates that this is published on the APVMA Website. The APVMA Standard has been replaced by the legislative instrument Agricultural Active Constituents Standards 2022; and
 - b) that the common name entered in the Record for all active constituents **is no longer** appropriate as the Australian pesticides common name ‘maldison’ is not used outside Australia, nor is it used for Australian therapeutic goods. The common name ‘malathion’ is specified in ISO 1750-1981; and
 - c) that the information entered into the Record **does not** accurately reflect the composition of the malathion active constituents, as specified in the current Declarations of Composition submitted to the APVMA as part of the original approval or submitted to the APVMA during the course of the reconsideration. The information entered into the Record does not include limits for all relevant impurities listed in paragraph 6)c)II. above

Consideration of whether active constituents can be varied to meet the safety criteria

- 8) Section 34A(1) of the Agvet Code provides that if the APVMA is **not satisfied** under section 34(1) but is satisfied that the relevant particulars or conditions of the approval can be varied in such a way as to allow the approval to be affirmed, the APVMA must vary the relevant particulars or conditions.
- 9) The APVMA has considered whether the relevant particular or conditions of the active constituent approvals can be varied in such a way as to meet the safety criteria as defined in section 5A of the Agvet Code and has determined that the relevant particular and conditions can be varied as follows:
 - a) To address concerns identified in paragraph 6)e) that the current condition referred to as the ‘Agricultural Active Constituents Quality Assurance Requirements’ is no longer appropriate, the APVMA has varied this condition so as to substitute the reference to the ‘APVMA Standard’ with the ‘Active Constituent Standard 2022’ as follows:
 - I. *‘Agricultural Active Constituents must meet Quality Assurance Requirements*
 - *A person must not Supply the Active Constituent, or cause it to be supplied, unless the Active Constituent:*

- *complies with the Agricultural and Veterinary Chemicals Code (Agricultural Active Constituents) Standards 2022 (Active Constituent Standard 2022); and*
 - *was manufactured at a site of manufacture listed in the Record of Approved Active Constituents.*
 - *A person must at the time of Supply of a Batch of the Active Constituent to another person also supply details of the Batch Number of the Active Constituent to the person to whom the active constituent was supplied.*
 - *A constituent complies with the Active Constituent Standard 2022; if the constituent, when measured using a validated analytical method:*
 - *does not contain less than the minimum purity and/or content of the constituent as set out in the Active Constituent Standard 2022; and*
 - *does not contain more than the maximum level of any impurity as set out in the Active Constituent Standard 2022.*
 - *Definitions and interpretation: In these conditions the following words have the following meanings:*
 - *'Batch' means a defined quantity of material produced in a single series of operations;*
 - *'Batch Number' means that a distinctive combination of numbers and/or letters that specifically identifies a Batch and from which the production history can be determined;*
 - *'Supply' has the same meaning as given to it in section 3 of the Agvet Code.'*
- b) To address concerns identified in paragraph 6)f) that the common name entered into the Record for all active constituents is no longer appropriate and that the information entered into the Record does not accurately reflect the composition of the active constituents, the APVMA has varied the following relevant particulars
- I. the name of the approved active constituents in the Record to 'malathion' to harmonise with the common name specified in ISO 1750-1981.
 - II. the composition of each approved source of active constituent in the Record to include maximum levels of all impurities listed in paragraph 6)c)II. above, in line with the current Declaration of Composition for each approved source of active constituent.
- 10) In accordance with section 34A(1) of the Agvet Code, the APVMA is satisfied that the relevant particulars and conditions of the malathion active constituent approvals in Attachment A of this notice as varied in the ways set out in paragraph 9) meet the safety criteria defined in section 5A of the Agvet Code.

Consideration of whether active constituents comply with any requirements prescribed by the regulations

- 11) Section 34(1)(d) of the Agvet Code provides that the APVMA must affirm an active constituent approval only if it is satisfied that the constituent complies with any requirement prescribed by the regulations.
- a) there are no other requirements prescribed by the regulations for active constituent that have not already been considered above.

Conclusion for active constituents

- 12) For the purposes of sections 34(1) and 34A(1) of the Agvet Code, the APVMA is satisfied that the particulars and conditions of the malathion active constituent approval listed in Attachment A can be varied in such a way as to meet the safety criteria and allow the active constituent approvals to be affirmed. Accordingly, pursuant to section 34A(1) of the Agvet Code, the APVMA has varied the relevant particulars and conditions of malathion active constituent approvals listed in Attachment A of this notice, in the manner set out in paragraph 9) of the statement of reasons, and affirmed the approval of these active constituents under section 34(1) of the Agvet Code

Agricultural chemical products

- 13) Section 34(1)(b) and (d) of the Agvet Code provides that the APVMA must affirm the registration for a chemical product if, and only if, it is satisfied that the product:
- a) meets the safety criteria (section 5A),
 - b) meets the efficacy criteria (section 5B),
 - c) meets the trade criteria (section 5C), and
 - d) complies with any requirement prescribed by the Agvet Regulations.
- 14) Section 34(2) of the Agvet Code provides that subsection 34(1) applies only to the extent that the APVMA decides to reconsider matters covered by the subsection.
- 15) The APVMA reconsidered all matters covered by subsection 34(1) in relation to the reconsideration of malathion agricultural chemical product registrations subject to the following limitations.
- a) The environmental risk assessment was limited to the toxicity of malathion to aquatic species, pollinators and vegetation and the adequacy of instructions; and
 - b) The residues and trade risk assessment was limited to the consideration of malathion maximum residue limits, dietary exposure based on the maximum residue limits and the adequacy of instructions.
 - c) For agricultural chemical products containing a combination of active constituents, the matters were reconsidered only to the extent that the product contains the active constituent malathion. The impact of the second active constituent 4-(p-acetoxyphenyl)-2-butanone or petroleum oil on relevant chemical product registrations was based on previous assessments of these active constituents.
 - d) For agricultural chemical products containing malathion as an excipient, the matters were reconsidered only to the extent that the product contains the excipient malathion. The impact of the active constituent zinc phosphide and other formulation excipients was based on previous assessments of the products.

Consideration of whether agricultural chemical products meet the safety criteria

- 16) Section 5A(1) of the Agvet Code provides that a chemical product meets the safety criteria if use of the product, in accordance with any instructions approved or to be approved by the APVMA for the constituent or product or contained in an established standard:
- a) is not, or would not be, an undue hazard to the safety of people exposed to it during its handling or people using anything containing its residues (section 5A(1)(a)).

- b) is not, or would not be, likely to have an effect that is harmful to human beings (section 5A(1)(b)).
- c) is not, or would not be, likely to have an unintended effect that is harmful to animals, plants or things or to the environment (section 5A(1)(c)).
- 17) For the purpose of being satisfied that the malathion agricultural chemical products meet the safety criteria, the APVMA has had regard to the criteria set out in section 5A(3)(a) as follows:
- a) Section 5A(3)(a)(i) - the toxicity of the product and its residues, including metabolites and degradation products, in relation to relevant organisms and ecosystems, including human beings.
- I. The APVMA has considered the following information in having regard to the toxicity of malathion chemical products and their residues, as detailed in the *Malathion Final Review Technical Report*:
- Information on the toxicity of the constituent malathion and its residues, as set out in paragraph 6)a) and the references therein, including the malathion health-based guidance values.
 - The toxicity of malathion to non-target species, including aquatic species, pollinators and vegetation.
 - The impact of impurities of toxicological concern in formulated agricultural chemical products. As set out in the *2016 Malathion Chemistry Report*, impurities can increase (potentiate) the toxicity of malathion itself and the most significant potentiators of malathion toxicity are MeOSSPO, isomalathion and MeOOSPO.
 - The impact of any relevant formulation excipients, and where relevant the active constituents 4-(p-acetoxyphenyl)-2-butanone, petroleum oil or zinc phosphide, on the toxicity of the malathion agricultural chemical products to relevant organisms and ecosystems, including human beings.
- II. The APVMA has set health-based guidance values for the constituent malathion and have assessed the following to be adequately protective of human health, as set out in the *Malathion Final Review Technical Report*.
- an ADI of 0.02 mg/kg bw/d based on a NOAEL of 2 mg/kg bw/d and an uncertainty factor of 100, and
 - an ARfD of 1.5 mg/kg bw based on a and NOAEL of 15 mg/kg bw/d and an uncertainty factor of 10.
- III. The APVMA is satisfied the following is adequately protective for use of malathion chemical products occupational handlers or non-professionals, as set out in the *Malathion Final Review Technical Report*.
- applying a margin of exposure of 10 to a point of departure of 15 mg/kg bw (single oral exposure) based on a NOEL of ≥ 15 mg/kg bw,
 - applying a margin of exposure of 100 to a point of departure of 9 mg/kg bw/d (short term repeated oral exposure) based on inhibition of erythrocyte cholinesterase,
 - applying a margin of exposure of 100 to a point of departure of 50 mg/kg bw/d (short term repeated dermal exposure, re-entry exposure) based on the NOEL, and
 - applying a margin of exposure of 1000 to a point of departure of 23 mg/kg bw/d (short and intermediate term repeated dermal inhalation) based on the LOAEL.

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- IV. The APVMA is satisfied that there is sufficient information on the toxicity of malathion to non-target species, including aquatic species, pollinators and vegetation, to assess the adequacy of the instructions for use for malathion agricultural chemical products.
- V. The APVMA is satisfied that exposure to malathion through spray drift below the spray drift regulatory acceptable levels set out in the *Malathion Final Review Technical Report* is not likely to have an effect that is harmful to human beings and is not likely to have an unintended effect that is harmful to animals, plants or things or to the environment.
- VI. The APVMA is satisfied that there is sufficient information on the toxicity of the impurities of toxicological concern, and the origin of these impurities in both technical malathion and formulated agricultural products, to establish appropriate specifications for agricultural chemical products containing malathion, as set out in the *Malathion Final Review Technical Report*.
- VII. The APVMA is satisfied that there is sufficient information to assess the impact of formulation excipients, and where relevant the active constituents 4-(p-acetoxyphenyl)-2-butanone, petroleum oil or zinc phosphide, on the toxicity of the malathion agricultural chemical products to relevant organisms and ecosystems, including human beings, as set out in the *Malathion Final Review Technical Report*.
- VIII. The APVMA is therefore satisfied that the toxicity of malathion agricultural chemical products and their residues, including metabolites and degradation products, are sufficiently defined to allow assessment of the risks to relevant organisms and ecosystems, including human beings, and the adequacy of the instructions for use for malathion agricultural chemical products.
- b) Section 5A(3)(a)(ii) of the Agvet Code – the relevant poison classification of the product under the law in force in this jurisdiction.
- I. Malathion is listed in the following schedules of the *Therapeutic Goods (Poisons Standard—February 2024) Instrument 2024*:
- Schedule 5 for preparations containing 1% or less of malathion except: for human therapeutic use; or in dust preparations containing 2% or less of malathion.
 - Schedule 6 for preparations containing malathion except: when included in Schedule 5; for human therapeutic use; or in dust preparations containing 2% or less of malathion.
- II. The APVMA is satisfied that the current scheduling remains appropriate based on the assessment of available toxicology data, as outlined in the *Malathion Final Review Technical Report*.
- c) Section 5A(3)(a)(iii) – how the product is formulated.
- I. The APVMA has considered the existing registration records in having regard to how the chemical products containing malathion are formulated. Agricultural chemical products containing malathion are formulated as follows:
- 1169 g/ L of malathion as an ultra-low volume liquid,
 - 1000 g/L of malathion as an emulsifiable concentrate,
 - 500 g/L of malathion as an emulsifiable concentrate,

- 100 g/L of malathion as an emulsifiable concentrate,
 - 420 g/L of malathion as an oil-in-water emulsion,
 - 320g/L of malathion as an oil-in-water emulsion,
 - 20 g/kg of malathion as a dustable powder,
 - 205 g/kg of malathion as vapour releasing product,
 - 306 g/kg of malathion as vapour releasing product, and
 - 0.11 g/kg of malathion as a bait (ready to use).
- II. The APVMA has also considered the levels of toxicological impurities that may be present in formulated agricultural products containing malathion. As further discussed in the *Maldison chemistry report* and the *Malathion Final Review Technical Report*:
- the concentration of the impurities (in particular, isomalathion) can increase significantly during storage of malathion products, especially at elevated temperatures.
 - products formulated as fruit fly lures and baits contain less than 0.3 g of malathion per wick or block and were assessed as being low risk to people who prepare and use them.
- III. The APVMA is satisfied that how the product is formulated remains appropriate when there is sufficient batch analysis and stability data to demonstrate that relevant impurities of toxicological concern will not exceed acceptable levels for a 2-year period, or if the product is formulated in a way that is considered low risk.
- IV. If there is not sufficient information to demonstrate that impurities of toxicological concern will not exceed acceptable levels, and the product is not a low-risk product, the APVMA is **not satisfied** that how the agricultural chemical product containing malathion is formulated remains appropriate.
- d) Section 5A(3)(a)(iv) of the Agvet Code – the composition and form of the constituents of the product.
- I. The APVMA has considered existing registration records for the excipients and Declarations of Composition submitted by the relevant holders for the approved active constituents when having regard to the composition and form of the constituents of agricultural chemical products containing malathion.
- II. Based on the assessment of this information, the APVMA is satisfied that the composition and form of constituents in the agricultural products are appropriate.
- e) Section 5A(3)(a)(v) of the Agvet Code – any conditions to which its registration is, or would be, subject.
- I. In accordance with section 23(1)(a) of the Agvet Code, the agricultural product registrations are currently subject to the conditions prescribed in items 1, 2, 5, 6 and 7 of the table in regulation 17C(2) of the Agvet Regulations.
- Note: Items 3 and 4 of this do not apply to agricultural product registrations as these are prescribed under regulation 59(1) for the purposes of section 120A of the Agvet Code (see regulation 17C(3)).

- II. In accordance with section 23(1)(a) of the Agvet Code, products are also subject to the conditions of registration prescribed in section 6 of the Conditions of Approval or Registration Order. Section 6 of this Order prescribes the following conditions:
- The chemical product must not be supplied if the manufacture of the chemical product contravenes, or fails to comply with, any manufacturing law of the country, or part of the country, in which it is manufactured.
 - The holder of the registration must, on written request by the APVMA and within 28 days after the request is given, provide the APVMA with written evidence that the manufacture of the chemical product does not contravene, or fail to comply with, any manufacturing law of the country, or part of the country, in which it is manufactured.
- III. The APVMA is satisfied that holders of malathion agricultural chemical products can comply with the conditions prescribed by the Agvet Regulations and the Conditions of Approval or Registration Order.
- IV. Agricultural product registrations are also subject to the additional conditions imposed by the APVMA under section 23(1)(b) of the Agvet Code referred to as the 'Agricultural Products Active Constituent Quality Assurance Requirements' as follows:
- *'Agricultural Products must meet the Agricultural Products Active Constituent Quality Assurance Requirements*
 - *Manufacture of active constituent – the registrant must not supply the chemical product, or cause it to be supplied, unless the active constituent contained in the chemical product:*
 - *complies with the APVMA Standard for that active constituent; and*
 - *was manufactured at a site of manufacture listed in the Record of approved active constituents.*
 - *Analysis results – the registrant must not supply the chemical product or cause it to be supplied unless the registrant has in its possession prior to the supply of each batch of the chemical product, batch analysis results that show:*
 - *the active constituent contained in the chemical product complied with the APVMA Standard for that active constituent;*
 - *if there is an APVMA Standard for a constituent in the chemical product that is not an active constituent, the constituent complied with the APVMA Standard for that constituent; and*
 - *the batch number of the active constituent contained in the chemical product.*
 - *Records – the registrant must, at or prior to the supply of a batch of the chemical product by the registrant or by another person on behalf of the registrant, make or have in its possession, a record that contains the following information:*
 - *The name of the chemical product.*
 - *The APVMA product number of the chemical product.*

- *If the chemical product was imported into Australia by another person on behalf of, or pursuant to an arrangement with the registrant, the name and address of that person.*
- *If the chemical product was manufactured in Australia by another person on behalf of, or pursuant to an arrangement with the registrant, the name and address of that person.*
- *The date of importation into, or manufacture in, Australia as the case may be.*
- *The batch number of the chemical product from which the supply was made.*
- *The quantity of the chemical product that constitutes the batch*
- *The batch number, and name and address of the manufacturer of the active constituent contained in the chemical product*
- *The registrant must produce, or cause to be produced, to the APVMA any batch analysis results or record within 10 working days of the request having been made by the APVMA, or other such period as determined by the APVMA.*
- *The registrant must keep, or cause to be kept, any batch analysis results or record for 2 years after any batch analysis results or record is made.*
- *Possession of batch analysis results and records – for the purposes of these conditions, batch analysis results or records are in the possession of the registrant if batch analysis results or records are:*
 - *in the possession of the registrant; or*
 - *in the possession of another person pursuant to an arrangement with the registrant.*
- *Compliance with the Standard – for the purposes of these conditions, a constituent complies with the APVMA Standard if the constituent, when measured using a validated analytical method does not contain:*
 - *less than the minimum purity and/or content of the constituent as set out in the APVMA Standard for the Constituent*
 - *more than the maximum level of any impurity as set out in the APVMA Standard.*
- *Definitions and Interpretation – in these conditions the following words have the following meanings:*
 - *'APVMA Standard' means the standard determined by the APVMA to which a constituent contained in chemical products must comply and which is published on the APVMA website.*
 - *'Batch' means a defined quantity of material produced in a single series of operations.*
 - *'Batch number' means that a distinctive combination of numbers and/or letters that specifically identifies a batch and from which the production history can be determined.*

- *'Batch analysis results' means the results of analysis from each batch of the constituent that include:*
 1. *the name of the manufacturer and the manufacturing site address*
 2. *the date of the analysis*
 3. *the batch number and date of manufacture of the batch*
 4. *the analysis result(s) for the constituent purity and/or content and/or isomer ratio and/or the specified impurities as per the APVMA Standard for the constituent*
 5. *full details and validation data for the analytical method(s) used for the determination of the constituent purity (linearity and precision) and/or the content and/or the isomer ratio and/or the specified impurities (linearity, precision, accuracy and limit of quantitation if relevant).*
 6. *If analytical methods and validation data have been previously provided to the APVMA, a reference to that submission will suffice.*
 - *'Record' means a document in written or electronic form that contains the particulars set out in paragraph (3) and which is readily accessible for the purposes of Part 9 of the Agvet Code (Enforcement).*
 - *'Supply' has the same meaning as given to it in section 3 of the Agvet Code and includes the doing of those things through, or pursuant to an arrangement with, another person.'*
- V. The APVMA is **not satisfied** that the current condition referred to as 'Agricultural Products Quality Assurance Requirements', to which each agricultural product registration is subject, remains appropriate, as the condition references the 'APVMA Standard' available on the APVMA Website. The 'APVMA Standard' has been replaced by the legislative instrument 'Active Constituents Standard 2022'. The condition also references a 'registrant' which is not defined within the Agvet Code or related legislation, rather than referring to the 'holder'.
- f) Section 5A(3)(a)(vi) of the Agvet Code – any relevant particulars that are, or would be, entered in the Register for the product.
- I. The relevant particulars on the record for each malathion agricultural chemical product have been reviewed. Sections 3 and 20(1)(c) of the Agvet Code provide that the relevant particulars are the distinguishing number, any instructions for use and any other particulars prescribed by the regulations. Regulation 16 of the Agvet Regulations prescribes the following particulars for the purposes of section 20(1)(c) of the Agvet Code: the distinguishing name, the constituents, the concentration of each constituent, the composition and purity of each active constituent (if possible), the formulation type, the net contents, the holder of the registration, the name of each manufacturer, the address of each site at which the chemical product is manufactured, the nominated agent and identifying information of the nominated agent (if relevant) and the date of entry of these particulars.
 - II. The APVMA is **not satisfied** that when used according to the instructions for use, malathion agricultural chemical products would not pose an undue hazard to the safety of people exposed to it during its handling or people using anything containing its residues based on the following findings set out in the *Malathion Final Review Technical Report*.

- There are insufficient instructions for use (including safety directions, re-entry periods and restraints) to prevent unacceptable exposure to people who mix, load and/or apply malathion agricultural chemical products or re-enter areas treated with malathion agricultural chemical products.
 - The application of malathion agricultural products using the following application equipment is not supported as it may result in unacceptable exposure to mixer/loaders or applicators:
 - backpack ULV or backpack foggers,
 - open mixing and loading for aerial application, and
 - open cab equipment for airblast application.
- III. The APVMA is **not satisfied** that use of malathion agricultural chemical products in accordance with instructions for use would not be likely to have an unintended effect that is harmful to non-target species, based on the following findings set out in the *Malathion Final Review Technical Report*:
- Malathion has high toxicity to aquatic species and there are insufficient instructions for use (including protection statements and spray drift restraints) to prevent unacceptable exposure to aquatic species. Further, malathion agricultural products cannot be safely applied to aquatic areas for control of mosquito larvae.
 - Malathion is toxic to pollinators (including honeybees) and there are insufficient instructions for use (including protection statements and spray drift restraints) to prevent unacceptable exposure to pollinators.
 - The application of malathion agricultural products by ultra-low volume by aircraft in the following situations is not supported as it may result in unacceptable exposure to sensitive areas, as a mandatory no-spray buffer zone cannot be established.
 - use on peas at a rate equal to or greater than 625 g ac/ha (62194), and
 - use on linseed, maize, peas, cereal crops, maize, pastures, pasture seed crops, rice and sorghum at a rate equal to or greater than 642.95 g ac/ha (49539).
- IV. The APVMA is **not satisfied** that when used according to the instructions for use, commercial malathion agricultural chemical products formulated as an emulsifiable concentrate, ultra-low volume liquid and oil-in-water emulsion would not be likely to have an effect that is harmful to human beings, based on the following findings set out in the *Malathion Final Review Technical Report*:
- for products 49539, 51150, 62194, 69529, there are insufficient instructions for use (specifically, spray drift restraints) to prevent unacceptable exposure of livestock to malathion residues.
 - for products 49539, 51150, 62194, there are insufficient instructions for use (specifically, harvest withholding periods) for the control of insect pests on broadacre crops.
 - for products 49539, 51150, 62194, there are insufficient instructions for use (specifically, instructions of the number of applications permitted per season) in certain situations.
- V. The APVMA is satisfied that use of malathion agricultural products in accordance with instructions for use would not have an unintended effect that is harmful to target crops, based on a history of sale and use of

the products and that no reports of crop damage have been received by the Adverse Experience Reporting Program of the APVMA, as further detailed in the *Malathion Final Review Technical Report*.

- VI. The APVMA is satisfied that all relevant particulars that are entered in the Register for malathion agricultural chemical products, excluding the instructions for use of the product, remain acceptable.
- g) Section 5A(3)(a)(via) of the Agvet Code – whether the product conforms, or would conform, to any standard made for the product under section 6E to the extent that the standard relates to matters covered by subsection (1).
- I. The *Agricultural and Veterinary Chemicals Code (Allowable Variation in Concentrations of Constituents in Agricultural Chemical Products) Standard 2022* prescribes the maximum allowable variation of the concentration of constituents in registered chemical products from the nominal quantities recorded in the Register for active constituents and non-active constituents. The APVMA is satisfied that agricultural chemical products containing malathion conform to the requirements listed in this Standard.
- II. The APVMA is proposing to make a standard under section 6E for malathion chemical products as an outcome of the reconsideration, which includes limits on relevant impurities, as set out in the *Malathion Final Review Technical Report*. It is noted that the process for making a Standard made under section 6E(1) of the Agvet Code is set out in regulation 8AF of the Agvet Regulations and will be undertaken separately to this final regulatory decision.
- h) Section 5A(3)(a)(vii) of the Agvet Code – any matters prescribed by the regulations.
- I. Regulation 8AB(1)(a) of the Agvet Regulations prescribes the method of analysis (if any) of the chemical composition and form of the constituents of the chemical product.
- The APVMA has considered the existing registration records and data submitted during the course of the reconsideration in having regard to the method of analysis of the chemical composition and form of the constituents of agricultural malathion chemical products. The APVMA is satisfied that the methods of analysis are appropriate to analyse relevant physicochemical properties and determine the concentration of the malathion active constituent and relevant impurities.
- II. Regulations 8AB(1)(b) and (c) of the Agvet Regulations prescribe, respectively, that for a product manufactured in Australia—whether each step in the manufacture of the product complies, or will comply, with the manufacturing principles and the Australian GMP Code, and for a product manufactured outside Australia—whether each step in the manufacture of the product complies, or will comply, with a standard that the APVMA has determined is comparable to the manufacturing principles and the Australian GMP Code.
- In accordance with regulation 8AB(2), regulations 8AB(1)(b) and (c) of the Agvet Regulations do not apply to agricultural chemical products as these are prescribed under regulation 59(1) for the purposes of section 120A of the Agvet Code.
- III. Regulations 8AB(1)(d), (e) and (f) do not apply based on the use patterns of malathion agricultural chemical products.
- 18) Under section 5A(3)(b) of the Agvet Code, the APVMA may have regard to one or more of the following matters in determining whether a chemical product meets the safety criteria:
- a) Section 5A(3)(b)(i) of the Agvet Code – the acceptable daily intake of each constituent contained in the product.

- I. The APVMA considered the toxicity of malathion, as set out in the *Malathion Final Review Technical Report*, and is satisfied that the acceptable daily intake of 0.02 mg/kg bw/d remains appropriate.
- b) Section 5A(3)(b)(ii) of the Agvet Code – any dietary exposure assessment prepared under subsection 82(4) of the *Food Standards Australia New Zealand Act 1991* as a result of any proposed variation notified under section 82(3) of that Act in relation to the product, and any comments on the assessment given to the APVMA under section 82(4) of that Act.
 - I. There has not been a dietary exposure assessment prepared under subsection 82(4) of the *Food Standards Australia New Zealand Act 1991*.
- c) Section 5A(3)(b)(iii) of the Agvet Code – whether any trials or laboratory experiments have been carried out to determine the residues of the product and, if so, the results of those trials or experiments and whether those results show that the residues of the product will not be greater than limits that the APVMA has approved or approves.
 - I. In considering whether any trials or laboratory experiments have been carried out to determine the residues of malathion agricultural products and, if so, the results of those trials or experiments and whether those results show that residues will not be greater than limits that the APVMA has approved, the APVMA has had regard to existing product records and information submitted as part of the reconsideration, as outlined in the *Malathion Final Review Technical Report*.
 - II. There are currently no entries in Table 4 of the *Agricultural and Veterinary Chemicals (MRL Standard for Residues of Chemical Products) Instrument 2023* (MRL Standard) for the use of malathion agricultural chemical products in crops that may be used as animal feed, including pastures, forage crops, orange pulp and grape pomace. The APVMA is satisfied that sufficient trials or experiments have been carried out to determine the residues of malathion agricultural products in these situations, as outlined in the *Malathion Final Review Technical Report*. It is noted that there is a separate process for updating the MRL Standard, which will be undertaken separately to this final regulatory decision.
- d) Section 5A(3)(b)(iv) of the Agvet Code – the stability of the product.
 - I. In considering the stability of malathion agricultural chemical products, the APVMA has had regard to information submitted as part of the original registration and during the course of the reconsideration, including product-specific stability data.
 - II. The consideration of that information indicates that concentrations of impurities of toxicological concern (in particular isomalathion) have the potential to significantly increase during prolonged storage or storage at elevated temperatures, as further discussed in the *Malathion chemistry report* and the *Malathion Final Review Technical Report*.
 - III. For agricultural chemical products containing malathion as the active constituent, the APVMA is **not satisfied** that the concentration of impurities of toxicological concern will not exceed acceptable concentrations in the products after prolonged storage or storage at elevated temperature.
- e) Section 5A(3)(b)(v) of the Agvet Code – the specifications for containers for the product.
 - I. In considering the specification for containers of malathion agricultural chemical products, the APVMA has had regard existing product records on the stability of the product in the proposed containers and the integrity of the container during storage of the product. Additionally, there were no concerns identified in relation to the specifications for containers for malathion agricultural chemical products.

- II. Malathion agricultural chemical product registrations are also subject to the conditions of registration prescribed under regulation 18(2), which the APVMA is satisfied that the holders can comply with.
 - III. The APVMA is satisfied that the specifications for containers for products are appropriate.
- f) Section 5A(3)(b)(vi) of the Agvet Code – such other matters as it thinks relevant.
- I. The APVMA has conducted a dietary exposure assessment for malathion chemical products and is satisfied that the acute and chronic dietary exposure to malathion calculated using the National Estimated Dietary Intake calculation will not exceed the ADI and ARfD and is not likely to have an effect that is harmful to human beings, as set out in the *Malathion Final Review Technical Report*.
- 19) Having had regard to the matters and findings set out above, the APVMA is **not satisfied** that the use of malathion agricultural chemical products meets the safety criteria as defined in section 5A of the Agvet Code for the following reasons:
- a) If there is not sufficient information to demonstrate that impurities of toxicological concern will not exceed acceptable levels, and the product is not a low-risk product, the way in which the agricultural chemical product containing malathion is formulated may not be appropriate. Further, in relation to the stability of the agricultural chemical products, the concentration of impurities of toxicological concern may increase and exceed acceptable concentrations after prolonged storage of the products or storage of the products at elevated temperature.
 - b) The current condition referred to as 'Agricultural Products Quality Assurance Requirements', to which each agricultural product registration is subject, is no longer appropriate. The condition references the 'APVMA Standard' available on the APVMA Website which has been replaced by the legislative instrument 'Active Constituents Standard 2022'. The condition also references a 'registrant' which is not defined within the Agvet Code or related legislation, rather than referring to the 'holder'.
 - c) the use of malathion agricultural chemical products in accordance with the instructions for use may pose an undue hazard to the safety of people exposed to it during its handling or people using anything containing its residues, may have an unintended effect that harmful to non-target species and may have an effect that is harmful to human beings.

Consideration of whether agricultural chemical products can be varied to meet the safety criteria

- 20) The APVMA has considered whether the relevant particular or conditions of the registration of malathion agricultural chemical products can be varied in such a way as to meet the safety criteria set out in Section 5A(1) and has determined that the relevant particular and conditions can be varied as follows:
- a) To address concerns identified in paragraphs 17)c) and 18)d) in relation to the levels of impurities of toxicological concern, the APVMA has varied the particulars and conditions as follows:
 - I. The storage instructions for all agricultural chemical products that contain malathion as an active constituent have been varied to include the instruction 'Store below 30 °C (room temperature). 'to prevent the formation of toxicologically significant impurities at elevated temperatures.
 - II. For agricultural products that contain malathion as an active constituent, where the APVMA has sufficient information to be satisfied that toxicologically significant impurities will not exceed acceptable levels within 2 years, the APVMA has varied the conditions of registration to add the following shelf-life condition of registration:

- *'This product can only be supplied if the approved label contains an expiry date not greater than 24 months after the date of manufacture of the product when stored below 30°C (room temperature).'*
- III. For agricultural products that contain malathion as an active constituent, where the APVMA does not have sufficient information to be satisfied that toxicologically significant impurities will not exceed acceptable levels, the APVMA has varied the conditions of registration to add the following conditions (including a shelf-life condition of registration):
- *'On or before DD/MM/YYYY (which is 1 year from the date of the APVMA affirming the registration of this product), you are required to provide storage stability data and validation data to enable the APVMA to determine and establish an appropriate shelf life.'*
 - For the purposes of this condition, the storage stability data and validation data required would include:
 - Results from accelerated storage (before and after storage for 14 days at 54 °C in the designated packaging) that includes the content of the impurity isomalathion and is generated in accordance with the APVMA guideline 'Generation of storage stability data for agricultural chemical products' available at apvma.gov.au/registrations-and-permits/data-requirements/agricultural-data-guidelines/chemistry-manufacture-part-2/storage-stability.
 - Details of the analytical method(s) and validation data generated in accordance with the APVMA guideline 'Validation of analytical methods for active constituents and agricultural products', available at apvma.gov.au/registrations-and-permits/data-requirements/agricultural-data-guidelines/chemistry-manufacture-part-2/validation.
 - *'This product can only be supplied if the approved label contains an expiry date not greater than 12 months after the date of manufacture of the product when stored below 30°C (room temperature).'*
- b) To address concerns identified in paragraph 17)e), the APVMA has varied the conditions referred to as the 'Agricultural Products Active Constituent Quality Assurance Requirements' so as to substitute the reference to the 'APVMA standard' with the 'Active Constituent Standard 2022' and 'registrant' with 'holder' as follows:
- I. *'Agricultural Products must meet the Agricultural Products Active Constituent Quality Assurance Requirements*
- *Manufacture of active constituent – the holder must not supply the chemical product, or cause it to be supplied, unless the active constituent contained in the chemical product:*
 - *complies with the Agricultural and Veterinary Chemicals Code (Agricultural Active Constituents) Standards 2022 (Active Constituent Standard 2022) for that active constituent; and*
 - *was manufactured at a site of manufacture listed in the Record of approved active constituents.*
 - *Analysis results – the holder must not supply the chemical product or cause it to be supplied unless the holder has in its possession prior to the supply of each batch of the chemical product, batch analysis results that show:*
 - *the active constituent contained in the chemical product complied with the Active Constituent Standard 2022 for that active constituent;*

- *if there is a standard for a constituent in the chemical product that is listed in the Active Constituent Standard 2022, that the constituent complies with the Active Constituent Standard 2022 for that constituent; and*
 - *the batch number of the active constituent contained in the chemical product.*
- *Records – the holder must, at or prior to the supply of a batch of the chemical product by the holder or by another person on behalf of the holder, make or have in its possession, a record that contains the following information:*
 - *The name of the chemical product.*
 - *The APVMA product number of the chemical product.*
 - *If the chemical product was imported into Australia by another person on behalf of, or pursuant to an arrangement with the holder, the name and address of that person.*
 - *If the chemical product was manufactured in Australia by another person on behalf of, or pursuant to an arrangement with the holder, the name and address of that person.*
 - *The date of importation into, or manufacture in, Australia as the case may be.*
 - *The batch number of the chemical product from which the supply was made.*
 - *The quantity of the chemical product that constitutes the batch*
 - *The batch number, and name and address of the manufacturer of the active constituent contained in the chemical product*
- *The holder must produce, or cause to be produced, to the APVMA any batch analysis results or record within 10 working days of the request having been made by the APVMA, or other such period as determined by the APVMA.*
- *The holder must keep, or cause to be kept, any batch analysis results or record for 2 years after any batch analysis results or record is made.*
- *Possession of batch analysis results and records – for the purposes of these conditions, batch analysis results or records are in the possession of the holder if batch analysis results or records are:*
 - *in the possession of the holder; or*
 - *in the possession of another person pursuant to an arrangement with the holder.*
- *Compliance with the Standard – for the purposes of these conditions, a constituent complies with the Active Constituent Standard 2022 if the constituent, when measured using a validated analytical method does not contain:*
 - *less than the minimum purity and/or content of the constituent as set out in the Active Constituent Standard 2022 for the Constituent; and*
 - *more than the maximum level of any impurity as set out in the Active Constituent Standard 2022.*

- *Definitions and Interpretation – in these conditions the following words have the following meanings:*
 - *'Batch' means a defined quantity of material produced in a single series of operations.*
 - *'Batch number' means that a distinctive combination of numbers and/or letters that specifically identifies a batch and from which the production history can be determined.*
 - *'Batch analysis results' means the results of analysis from each batch of the constituent that include:*
 - *the name of the manufacturer and the manufacturing site address*
 - *the date of the analysis*
 - *the batch number and date of manufacture of the batch*
 - *the analysis result(s) for the constituent purity and/or content and/or isomer ratio and/or the specified impurities as per the Active Constituent Standard 2022 for the constituent*
 - *full details and validation data for the analytical method(s) used for the determination of the constituent purity (linearity and precision) and/or the content and/or the isomer ratio and/or the specified impurities (linearity, precision, accuracy and limit of quantitation if relevant).*
 - *If analytical methods and validation data have been previously provided to the APVMA, a reference to that submission will suffice.*
 - *'Record' means a document in written or electronic form that contains the particulars set out in paragraph (3) and which is readily accessible for the purposes of Part 9 of the Agvet Code (Enforcement).*
 - *'Supply' has the same meaning as given to it in section 3 of the Agvet Code and includes the doing of those things through, or pursuant to an arrangement with, another person.'*
- c) To address concerns identified in paragraph 17)f), the APVMA has varied the instructions for use of malathion agricultural chemical products as follows, as further detailed in the *Malathion Final Review Technical Report*:
- I. The safety directions for each agricultural chemical product containing malathion as the active constituent have been varied, as set out in paragraph 49)a)VII. of this statement of reasons.
 - II. Spray drift restraints and buffer zones have been added to relevant malathion agricultural chemical products (49539, 51150, 62194, 69529) to protect sensitive areas from exposure exceeding the regulatory acceptable levels (RALs), as set out in the *Malathion Final Review Technical Report*.
 - III. The following re-entry periods have been added to the instructions for use of relevant malathion agricultural chemical products:
 - for all uses where malathion is applied as a spray (49539, 51150, 62194 and 69529) – *'DO NOT enter treated areas until spray has dried.'*
 - for use on fruiting vegetable crops (49539, 51150, 6219–) - *'DO NOT enter for 1 day after application for irrigation, scouting, thinning and weeding.'*

- for use on leafy vegetable crops (49539, 51150, 6219–) - *'DO NOT enter for 1 day after application for irrigation and scouting mature plants, hand harvesting and pruning.'*
 - for use on field crops (low) (49539, 51150, 6219–) - *'DO NOT enter for 2 days after application for hand-set irrigation. DO NOT enter for 1 day after application for scouting, thinning and weeding.'*
 - for use on grapes (51150, 62194) *'Grapes: DO NOT enter for 1 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.'*
 - for use of products 49539, 51150 and 62194 on apples – *'DO NOT enter for 1 day after application for hand pruning, training, scouting, training, transplanting, orchard maintenance, propping and hand weeding. DO NOT enter for 8 days after application for hand harvesting. DO NOT enter for 17 days after application for thinning fruit.'*
 - for use of product 69529 on apples – *'DO NOT enter for 1 day after application for hand pruning, training, scouting, training, transplanting, orchard maintenance, propping and hand weeding. DO NOT enter for 8 days after application for hand harvesting. DO NOT enter for 17 days after application for thinning fruit.'*
 - For treatment of animal housing (51150) – *'DO NOT allow entry into treated animal housing or handle treated animal bedding until spray has dried. Children must not be allowed to enter into treated animal housing or handle treated animal bedding for 3 full days post-application.'*
- IV. The following restraints have been added to the instructions for use relevant malathion agricultural chemical products (49539, 51150, 62194) – *'DO NOT use open mixing and loading systems for aerial application (use closed mixing and loading only). DO NOT use open cabs for air blast application. DO NOT use backpack ULV misters/cold foggers. DO NOT apply directly to water.'*
- V. The following environmental protection statements have been added to the instructions for use for relevant malathion agricultural chemical products:
- for all commercial agricultural products (42727, 49539, 50110, 50589, 51150, 62914, 63032, 69529) – *'Very toxic to aquatic life. DO NOT contaminate wetlands or watercourses with this product or used containers.'*
 - for commercial agricultural products that can be applied as a spray and are approved for mosquito control (49539, 51150, 62194) – *'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 the other commercial agricultural products that can be applied as a spray (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.'*

- for commercial agricultural products formulated as dusts (50110) or solids (42727, 50589 and 63032) – *Toxic to bees. However, the use of this product as directed is not expected to have adverse effects on bees.*
- for all home garden agricultural products (42035, 58968 and 62242) – *Toxic to aquatic life. DO NOT allow the product, chemical containers or spray to get into drains, sewers, streams or ponds. Toxic to bees. DO NOT spray if bees are feeding on flowering plants.*

VI. The following harvest withholding periods have been added to the instructions for use of relevant malathion agricultural chemical products:

- for use on cereals crops (including maize, rice and sorghum) grain legumes and/or linseed (49539, 51150, 62194) – *DO NOT HARVEST FOR 1 DAY AFTER APPLICATION.*
- for use in canola (rapeseed), safflower and/or sunflower crops (49539, 51150, 62194) – *DO NOT HARVEST FOR 3 DAYS AFTER APPLICATION.*

VII. For products 49539, 51150 and 62194, *“DO NOT apply more than 4 applications per season.”* has been added to the instructions (i.e. critical comments) for use patterns where the number of applications has not already been specified, excluding use patterns which are unlikely to result in residues in food (including use in baits for the control of fruit flies and uses on ornamental plants).

21) In accordance with section 34A(1) of the Agvet Code, the APVMA is satisfied that the relevant particulars and conditions of the malathion agricultural chemical products listed in Attachment A of this notice as varied in the ways set out in paragraph 20) meet the safety criteria.

Consideration of whether agricultural chemical products meet the efficacy criteria

22) Section 5B(1) of the Agvet Code provides that a chemical product meets the efficacy criteria if use of the product, in accordance with instructions approved, or to be approved, by the APVMA for the product or contained in an established standard, is, or would be, effective according to criteria determined by the APVMA by legislative instrument.

a) Malathion chemical products are not contained in an established standard.

b) The criteria for determining the efficacy of agricultural chemical products are specified in Part 2 of the legislative instrument, the *Agricultural and Veterinary Chemicals Code (Efficacy Criteria) Determination 2014* and are:

- criteria based on type of product, as set out in clause 3; and
- criteria based on demonstrated effectiveness, as set out in clause 4.

23) For the purpose of being satisfied that the malathion agricultural chemical products meet the efficacy criteria, the APVMA has had regard to the criteria set out in section 5B(2) of the Agvet Code as follows:

- Section 5B(2)(a) - whether any trials or laboratory experiments have been carried out to determine the efficacy of the product and, if so, the results of those trials or experiments.
 - The APVMA has considered the assessments of previously submitted information for the registration and variation of agricultural chemical products containing malathion. The APVMA is satisfied that this information continues to support the efficacy of these chemical products.

- b) Section 5B(2)(b) - any conditions to which its registration is, or would be, subject;
 - I. The APVMA has considered the conditions of registration which apply to chemical products containing malathion. The APVMA is satisfied that no additional conditions of registration are required to satisfy the efficacy criteria.
- c) Section 5B(2)(c) - any relevant particulars that are, or would be, entered in the Register for the product;
 - I. The APVMA has considered the relevant particulars that are entered in the Register for agricultural chemical products containing malathion, the variations to the instructions for use that are set out in paragraphs 20) and 31) of this statement of reasons and a submission received in response to the proposed decisions for the reconsideration of malathion.
 - II. The variations to the instructions for use set out in paragraphs 20) and 31) are within existing use patterns. The APVMA is satisfied that these variations will not impact the efficacy of the agricultural products, as discussed in the *Malathion Final Review Technical Report*.
 - III. The submission received from the National Working Party on Grain Protection raised concerns of the efficacy against certain stored grain pests where a general claim for insects in grain (referred to by the common term weevils) was made. As a result, the APVMA is **not satisfied** the use on product 50110 in accordance with current instructions for the protection of stored grain remains efficacious.
 - IV. The APVMA is satisfied that all remaining relevant particulars entered in the Register remain appropriate with regards to the efficacy of the agricultural chemical products containing malathion.
- d) Section 5B(2)(ca) - whether the product conforms, or would conform, to any standard made for the product under section 6E to the extent that the standard relates to matters covered by subsection (1);
 - I. There are no standards made under section 6E that are relevant to the efficacy of agricultural chemical products containing malathion.
- e) Section 5B(2)(d) any matters prescribed by the regulations.
 - I. There are no regulations which are relevant to the efficacy of malathion agricultural chemical products.

24) Having had regard to the matters and findings set out above, the APVMA is:

- a) **not satisfied** that the use of the malathion agricultural chemical product 50110 in accordance with current instructions for the protection of stored grain meets the efficacy criteria; and
- b) satisfied that the use of all other registered malathion agricultural chemical products meets the efficacy criteria.

Consideration of whether the agricultural chemical product can be varied to meet the efficacy criteria

- 25) The APVMA has considered whether malathion agricultural chemical product 50110 can be varied in such a way as to meet the efficacy criteria set out in Section 5B(1) and has determined as follows:
- a) To address concerns identified in paragraph 23)c), the APVMA has varied the instructions for use for product 50110 to remove the general claim for insects in grain (referred to by the common term weevils) and specified that the following pests are controlled '*Stored grain pests (except Lesser Grain Borer). Including: Indian meal moth, Rice Weevil, Rust-red flour beetle, Saw-toothed grain beetle and Tropical warehouse moth*'.

- 26) In accordance with section 34A(1) of the Agvet Code, the APVMA is satisfied that the relevant particulars of the malathion agricultural product 50110 as varied in the ways set out in paragraph 25) meet the efficacy criteria.

Consideration of whether agricultural chemical products meet the trade criteria

- 27) Section 5C(1) of the Agvet Code provides that a product meets the trade criteria if use of the product, in accordance with instructions approved, or to be approved, by the APVMA or contained in an established standard, does not, or would not, unduly prejudice trade or commerce between Australia and places outside Australia.
- 28) Section 5C(3) of the Agvet Code provides that for the purposes of the operation of this Code in relation to a particular chemical product, the APVMA is required to have regard to the matters set out in subsections (1) and (2) only to the extent prescribed by the regulations; or if there are no such regulations—to the extent that the APVMA thinks the matters are relevant.
- a) For the purposes of subsection 5C(3) of the Agvet Code, Regulation 8AD(2) of the Agvet Regulations provides that if it can be reasonably expected that a chemical product will be used in relation to a crop or animal, a product of which might be provided to a place outside Australia; or a crop that will be fed to animals a product of which might be provided to a place outside Australia then the APVMA must have full regard to the matters set out in sections 5C(1) and (2) of the Agvet Code.
- I. Certain commercial agricultural chemical products containing malathion (49539, 50110, 51150, 62194 and 69529) are approved for use on crops that are considered a major export commodity including canola, cereal grains (including stored grain), citrus fruit, grapes, pome fruit, pulses and/or stone fruit. It is therefore reasonably expected that a product of these crops might be provided to a place outside of Australia.
 - II. Certain commercial agricultural chemical products containing malathion (49539, 51150, 62194 and 69529) are approved for use on pastures, forage and fodder crops that can be used as stock feed for mammalian and poultry animals, in addition to being approved for use on crops where by-products may be used for stock feed (almonds, citrus, grapes, pome fruit and tomatoes). Mammalian and poultry animals and their products (including cattle, cattle dairy products, pigs, sheep, goats, poultry and eggs) are considered major export commodities. It is therefore reasonably expected that a product of these animals might be provided to a place outside of Australia.
 - III. Certain commercial agricultural chemical products containing malathion, which are formulated as vapour releasing baits for fruit flies (42727, 50589, 63032), may be use in crops that are considered a major export commodity such as citrus fruit, grapes and stone fruit. It is therefore reasonably expected that a product of these crops might be provided to a place outside of Australia.
 - IV. Certain commercial agricultural chemical products containing malathion, which are formulated as an emulsifiable concentrate (62194), ultra-low volume liquid (49539) or oil-in-water emulsion (51150 and 69529), are approved for use as a spray in situations where spray may drift into livestock areas. As mammalian livestock and their products are considered major export commodities, it is expected that a product of these animals might be provided to a place outside of Australia.
 - V. Home garden agricultural chemical products containing malathion (42035, 58969 and 62242) are approved for use on fruit trees. However, given that these products are registered for home garden use and have a limited pack size, it is not anticipated that a product from these fruit trees might be provided to a place outside of Australia, nor would a by-product of these fruit trees be used as feed for animals where a product of these animals might be provided to a place outside Australia.

- 29) For the purposes of being satisfied that the malathion agricultural chemical products meet the trade criteria as described in section 5C(1) of the Agvet Code, the APVMA has considered the criteria set out in section 5C(2) for the use patterns listed in paragraph 28) and has determined as follows:
- a) Section 5C(2)(a) - any conditions to which its registration is, or would be, subject.
- I. The APVMA has considered the conditions of registration which apply to agricultural chemical products containing malathion. The APVMA is satisfied that no additional conditions of registration are required to satisfy the trade criteria.
- b) Section 5C(2)(b) - any relevant particulars that are, or would be, entered in the Register for the product.
- I. The relevant particulars entered in the Register for each registered agricultural chemical product containing malathion have been reviewed, including the instructions for use for the chemical products.
- II. The APVMA is **not satisfied** that, for a sub-set of commercial agricultural chemical products containing malathion (49539, 51150, 62194 and 69529), use in accordance with the instructions entered into the Register will not unduly prejudice trade or commerce between Australia and places outside Australia, based on the following findings set out in the *Malathion Final Review Technical Report*:
- for products 49539, 51150, 62194 and 69529, there are insufficient instructions for use (specifically, spray drift restraints) to prevent unacceptable exposure of livestock to malathion residues.
 - for products 49539, 51150 and 62194, there are insufficient instructions for use (specifically, harvest withholding periods) for the control of insect pests on broadacre crops.
 - for products 49539, 51150 and 62194, there are insufficient instructions for use (specifically, instructions of the number of applications permitted per season) in certain situations.
 - for products 49539, 51150 and 69529, there is insufficient trade advice regarding treated crop commodities destined for export markets.
- III. The APVMA is satisfied that use of fruit fly baits (42727, 50589, 63032) in accordance with approved instructions will not result in any finite residues on crops and will not unduly prejudice trade or commerce between Australia and places outside Australia.
- IV. The APVMA is satisfied that all remaining relevant particulars for malathion agricultural chemical products entered in the Register remain appropriate with regards to the risk to trade or commerce between Australia and places outside Australia.
- c) Section 5C(2)(ba), whether the product conforms, or would conform, to any standard made for the product under section 6E to the extent that the standard relates to matters covered by subsection (1);
- I. There are no standards made under section 6E that are relevant to the risk to trade or commerce between Australia and places outside Australia.
- d) Section 5C(2)(c), any matters prescribed by the regulations.
- I. The APVMA has had regard to Regulation 8AD, as outlined in paragraph 28)a) above, in considering the risk to trade or commerce between Australia and places outside Australia, posed by the use of agricultural chemical products containing malathion.

30) Having had regard to the matters and findings set out above, the APVMA is:

- a) **not satisfied** that the use of malathion agricultural chemical products 49539, 51150, 62194 and 69529, in accordance with instructions approved for major export commodities, does not, or would not, unduly prejudice trade or commerce between Australia and places outside Australia.
- b) satisfied that the use of malathion agricultural chemical products 42035, 42727, 50110, 50589, 58968, 60832, 60890, 62242, 63032 and 66869, in accordance with instructions approved, does not, or would not, unduly prejudice trade or commerce between Australia and places outside Australia.

Consideration of whether the commercial agricultural chemical products can be varied to meet the trade criteria

31) The APVMA has considered whether the instructions for use for malathion agricultural chemical products 49539, 51150, 62194 and 69529 can be varied in such a way as to meet the trade criteria defined by section 5C(1) of the Agvet Code as follows:

- a) To address concerns identified in paragraph 29)b), the APVMA has varied the instructions for use of commercial agricultural chemical products containing malathion as follows, as detailed in the *Malathion Final Review Technical Report*:
 - I. Spray drift restraints and buffer zones have been added to relevant malathion agricultural chemical products (49539, 51150, 62194, 69529) to protect sensitive areas (including livestock areas) from exposure exceeding the regulatory acceptable levels (RALs).
 - II. The following harvest withholding periods have been added to the instructions for use of relevant malathion agricultural chemical products:
 - for use on cereals crops (including maize, rice and sorghum) grain legumes and/or linseed (49539, 51150, 62194) – *‘DO NOT HARVEST FOR 1 DAY AFTER APPLICATION.’*
 - for use in canola (rapeseed), safflower and/or sunflower crops (49539, 51150, 62194) – *‘DO NOT HARVEST FOR 3 DAYS AFTER APPLICATION.’*
 - III. For products 49539, 51150 and 62194, *‘DO NOT apply more than 4 applications per season.’* has been added to the instructions for use patterns where the number of applications has not already been specified, excluding the use patterns which are unlikely to result in residues in food (including use in baits for the control of fruit flies and uses on ornamental plants).
 - IV. The following trade advice statement has been added to the instructions for use of relevant malathion agricultural chemical products (49539, 51150, 69529) – *‘Treated crop commodities destined for export may require extra time between application and harvest to be accepted in some export markets. Before you use this product, you are advised to contact [company name] and/or your industry body about any potential trade issues and their management.’*

32) In accordance with section 34A(1) of the Agvet Code, the APVMA is satisfied that the relevant particulars of malathion agricultural chemical products 49539, 51150, 62194 and 69529 as varied in the ways set out in paragraph 31) above meet the trade criteria.

Consideration of whether agricultural chemical products comply with any requirement prescribed by the regulations

- 33) Regulation 16 of the Agvet Regulations prescribes the particulars of a chemical product which must be recorded in the Register pursuant to section 20(1)(c) of the Agvet Code:
- a) The APVMA has had regard to the particulars recorded in the Register for each agricultural chemical product containing malathion and is satisfied that the particulars prescribed by regulation 16 of the Agvet Regulations and recorded in the Register for malathion products remain appropriate.
- 34) Regulation 17C of the Agvet Regulations prescribes conditions to which the registration of a chemical product is subject:
- a) The APVMA is satisfied that holders of malathion agricultural chemical products can comply with the conditions prescribed by regulation 17C of the Agvet Regulations.
- 35) Regulation 18 of the Agvet Regulations prescribes conditions of registration relating to the containers for chemical products.
- a) The APVMA is satisfied that malathion agricultural chemical products comply with the conditions prescribed by regulation 18 of the Agvet Regulations.
- 36) Regulation 42(3) of the Agvet Regulations prescribes standards for chemical products to which chemical products must conform in accordance with section 87(1)(a) of the Agvet Code. In accordance with Regulation 42(3)(b):
- a) The APVMA has made the legislative instrument, the Active Constituents Standard 2022 under section 6E(1) of the Agvet Code. The APVMA is satisfied that the approved malathion active constituents listed in Attachment A of this notice conform to the malathion entry in the Active Constituents Standard 2022.
 - b) The APVMA has made the legislative instrument, the *Agricultural and Veterinary Chemicals Code (Allowable Variation in Concentrations of Constituents in Agricultural Chemical Products) Standard 2022* under section 6E of the Agvet Code. The APVMA is satisfied that agricultural chemical products containing malathion listed in Attachment A of this notice conform to the requirements listed in the *Agricultural and Veterinary Chemicals Code (Allowable Variation in Concentrations of Constituents in Agricultural Chemical Products) Standard 2022*.
- 37) Having had regard to the matters and findings set out above, the APVMA is satisfied that malathion agricultural chemical products meet the requirements prescribed by the regulations.

Conclusion of considerations of agricultural chemical products

- 38) The APVMA is satisfied that malathion agricultural chemical products listed in Attachment A of this notice comply with any requirements prescribed by the regulations, and that the relevant particulars and conditions can be varied so that they meet the safety criteria, efficacy criteria and trade criteria. Therefore, the APVMA has varied the relevant particulars and conditions as set out in paragraphs 20), 25) and 31) of this statement of reasons to allow the registration of these agricultural chemical products to be affirmed under section 34A(1) of the Agvet Code.

Labels for agricultural chemical products

- 39) Section 34(1)(c) and (d) of the Agvet Code provides that the APVMA must affirm the approval of a product label if, and only if, it is satisfied that the label:
- a) meets the labelling criteria
 - b) complies with any requirement prescribed by the regulations.

- 40) Subsection 34(2) of the Agvet Code provides that subsection 34(1) applies only to the extent that the APVMA decides to reconsider matters covered by this subsection.
- 41) The APVMA has decided to reconsider all matters covered by subsection 34(1) in relation to the reconsideration of malathion label approvals subject to the following limitations.
- a) The environmental risk assessment was limited to the toxicity of malathion to aquatic species, pollinators and vegetation and the adequacy of instructions.
 - b) The residues and trade risk assessment was limited to the consideration of malathion maximum residue limits, dietary exposure based on the maximum residue limits and the adequacy of instructions.
 - c) For labels of agricultural chemical products containing a combination of active constituents, the matters were reconsidered only to the extent that the product contains the active constituent malathion. The impact of the second active constituent 4-(p-acetoxyphenyl)-2-butanone or petroleum oil on relevant chemical product registrations will be based on previous assessments of this active constituent.
 - d) For labels of agricultural chemical products containing malathion as an excipient, the matters were reconsidered only to the extent that the product contains the excipient malathion. The impact of the active constituent zinc phosphide and other formulation excipients will be based on previous assessments of the product.

Consideration of whether approved labels for agricultural chemical products meet the labelling criteria and comply with any requirement prescribed by the regulations

- 42) Section 5D(1) of the Agvet Code provides that a label for containers for a chemical product 'meets the labelling criteria' if the label contains adequate instructions relating to the following as are appropriate:
- a) the circumstances in which the product should be used (section 5D(1)(a));
 - b) how the product should be used (section 5D(1)(b));
 - c) the times when the product should be used (section 5D(1)(c));
 - d) the frequency of the use of the product (section 5D(1)(d));
 - e) the withholding period after the use of the product (section 5D(1)(e));
 - f) the re-entry period after the use of the product (section 5D(1)(f));
 - g) the disposal of the product when it is no longer required (section 5D(1)(g));
 - h) the disposal of containers of the product (section 5D(1)(h));
 - i) the safe handling of the product and first aid in the event of an accident caused by the handling of the product (section 5D(1)(i));
 - j) any matters prescribed by the regulations (section 5D(1)(j)). In this regard, regulation 8AE(1) of the Agvet Regulations prescribes the following:
 - I. Regulation 8AE(1)(a) – for a chemical product that is a veterinary chemical product, the duration of the treatment.

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- II. Regulation 8AE(1)(b) – the prevention of undue prejudice to trade or commerce between Australia and places outside of Australia.
- III. Regulation 8AE(1)(c) – the appropriate signal words (if any) required by the current Poisons Standard.
- IV. Regulation 8AE(1)(d) – for a chemical product that is a date-controlled product, the storage of containers for the product.
- V. Regulation 8AE(1)(e) – any other matter determined by the APVMA CEO under regulation 8AE(2).
- 43) Regulation 17 of the Agvet Regulations prescribes the particulars of a label approval which must be recorded in the relevant APVMA file pursuant to sections 21(a) and 21(c)(iva) of the Agvet Code
- 44) Subdivision 2.1.6 of the Agvet Regulations (incorporating regulations 18B to 18J) prescribe the conditions of approval to which labels approvals are subject.
- 45) Section 5D(2) of the Agvet Code provides that for the purposes of being satisfied as to whether the current approved labels for containers for malathion agricultural chemical products meet the labelling criteria, the APVMA must have regard to the criteria set out in section 5D(2). The APVMA has considered these criteria as follows:
- a) Section 5D(2)(a) of the Agvet Code – any conditions to which its approval is, or would be, subject.
- I. The condition of approval prescribed by regulation 18E requires that if a labelling standard has not been made by the APVMA, and the product is an agricultural chemical product, then the label must comply with the requirements of the *Agricultural Labelling Code*.
- The APVMA has reviewed the current label approvals for agricultural chemical products containing malathion and is **not satisfied** that the approved labels have adequate instruction to comply with the current *Agricultural Labelling Code*.
- II. The APVMA is satisfied that labels approvals for malathion agricultural chemical products are compliant with all remaining conditions to which they are subject, including those prescribed by regulations 18B to 18D and 18F to 18J of the Agvet Regulations.
- III. As set out in paragraph 20)a) of this statement of reasons and the *Malathion Final Review Technical Report*, the APVMA has also varied the conditions of registration for certain agricultural chemical products to add a condition that requires an expiry date to be included on the relevant product label. A shelf-life is required for the APVMA to be satisfied that malathion agricultural chemical products (excluding low-risk bait products containing malathion as an excipient) meet the safety criteria as toxicologically significant impurities can form during prolonged storage.
- b) Section 5D(2)(b) of the Agvet Code – any relevant particulars and instructions that are, or would be, entered in the relevant APVMA file for the label.
- I. In relation to the circumstances in which the product should be used (section 5D(1)(a)):
- In general, the APVMA is satisfied that the crop/situation and pest statements in the instructions for use contained on the approved labels remain appropriate. However, the APVMA is **not satisfied** the pest statement on the label of product 50110 contains adequate information as detailed in paragraph 23)c) of this statement of reasons.

- In situations where there are no instructions for use that are specific for certain states or territories, the APVMA is satisfied that the uses are appropriate for all states and territories.
- II. In relation to how the product should be used (section 5D(1)(b)):
- The APVMA is **not satisfied** that the rate of application, application method, spray quality and environmental protection statements in the instructions for all uses on the approved labels remain appropriate, as detailed in *Malathion Final Review Technical Report* and paragraph 17(f) of this statement of reasons.
 - The APVMA is **not satisfied** that the instructions on how products 49539, 51150, 62194 and 69529 should be used, in relation to spray drift restraints (including mandatory no-spray buffer zones) and/or control of mosquitos in aquatic areas, are adequate as detailed in *Malathion Final Review Technical Report* and paragraph 17(f) of this statement of reasons.
 - The APVMA is **not satisfied** that the products approved for use as a prepared bait for the control of field crickets (49539, 51150, 62194) contain adequate instructions to prevent access to bait by non-target animals.
 - The APVMA is satisfied that that instructions on how the product should be used remains appropriate for agricultural products containing malathion as an excipient (60832, 60890, 66869).
- III. In relation to the times when the product should be used (section 5D(1)(c)):
- The APVMA is satisfied that the instructions on the times when products should be used contained on approved labels for all use patterns remain appropriate.
- IV. In relation to the frequency of the use of the product (section 5D(1)(d)):
- The APVMA is **not satisfied** that labels for products 49539, 51150 and 62194 contain sufficient instructions on the frequency of use, as the maximum number of applications permitted per season is not included in the instructions for use for all use patterns that involve direct application to crops.
 - The APVMA is satisfied that the instructions on the frequency of use of all other malathion agricultural products remain appropriate.
- V. In relation to the withholding period after the use of the product (section 5D(1)(e)):
- The APVMA is **not satisfied** that the labels for products 49539, 51150 and 62194 include appropriate harvest withholding periods for broad acre cereal crops, maize, rice, sorghum, legumes, linseed, canola (rapeseed), safflower and/or sunflower, as detailed in the *Malathion Final Review Technical Report*.
 - The APVMA is satisfied that the withholding periods for other malathion agricultural products remain appropriate.
- VI. In relation to the re-entry period after the use of the product (section 5D(1)(f)):
- The APVMA is **not satisfied** that the labels for products 49539, 51150, 62194 and 69529 include appropriate the re-entry period statements, as detailed in the *Malathion Final Review Technical Report*.

- The APVMA is satisfied that the re-entry period instructions for all other malathion agricultural products remain appropriate.
- VII. In relation to the disposal of the product when it is no longer required (section 5D(1)(g)):
- The APVMA is **not satisfied** that there are adequate instructions on the labels for disposal of product when it is no longer required, as detailed in the *Malathion Final Review Technical Report*.
- VIII. In relation to the disposal of containers for the product (section 5D(1)(h)):
- The APVMA is **not satisfied** that the instructions for disposal of containers on the labels for the product are adequate, as detailed in the *Malathion Final Review Technical Report*.
- IX. In relation to the safe handling of the product and first aid in the event of an accident caused by the handling of the product (section 5D(1)(i)).
- The APVMA is **not satisfied** that the current instructions for safe handling of the product on the labels remain appropriate (excluding ready to use baits containing malathion as an excipient), as outlined in the *Malathion Final Review Technical Report*.
 - The APVMA is satisfied that the instructions in relation to first aid in the event of an accident included on the labels are appropriate, as outlined in the *Malathion Final Review Technical Report*.
- X. In relation to any matters prescribed by the regulations (section 5D(1)(j)).
- Regulation 8AE(1)(a) of the Agvet Regulations – for a chemical product that is a veterinary chemical product, the duration of the treatment.
 - Regulation 8AE(1)(a) does not apply to agricultural chemical products containing malathion as it applies to veterinary products only.
 - Regulation 8AE(1)(b) of the Agvet Regulations – the prevention of undue prejudice to trade or commerce between Australia and places outside of Australia.
 - The APVMA is **not satisfied** that there are appropriate instructions relating to treated crop commodities destined for export on current label approvals of commercial agricultural products containing malathion (49539, 50110, 69529) to prevent undue prejudice to trade or commerce between Australia and places outside of Australia, as detailed in the *Malathion Final Review Technical Report*.
 - The APVMA is satisfied that there are appropriate instructions on current label approvals of all other malathion agricultural products in relation to the prevention of undue prejudice to trade or commerce between Australia and places outside of Australia.
 - Regulation 8AE(1)(c) of the Agvet Regulations – the appropriate signal words (if any) required by the current Poisons Standard.
 - The APVMA is **not satisfied** that the labels of fruit fly bait products that contain more than 10% malathion (42727, 50589, 63032) have the appropriate signal heading. In accordance with the Standard for the Uniform Scheduling of Medicines and Poisons No. 43, preparations containing

more than 1% malathion (except for human therapeutic use or dust preparations containing 2% or less of malathion) are Schedule 6 poisons and require the signal heading POISON.

- The APVMA is satisfied that all other malathion agricultural products which are Schedule 5 poisons have the appropriate signal heading CAUTION and products which are schedule 6 poisons include the signal heading POISON. All labels also include the cautionary phrase 'Keep out of reach of children' and, as all labels include safety directions, the statement 'Read safety directions before opening or using'.
 - Regulation 8AE(1)(d) of the Agvet Regulations – for a chemical product that is a date-controlled product, the storage of containers for the product.
 - As detailed in the *Malathion Final Review Technical Report*, due concerns raised in relation to the formation of toxic impurities during storage, the APVMA proposes to make agricultural products containing malathion as an active constituent date-controlled products. It is noted that there is a separate process for adding malathion products to Schedule 1 of the Agvet Regulations, which will be undertaken separately to this final regulatory decision.
 - It is also noted that the storage instruction '*Store below 30 °C (room temperature)*.' is required for malathion agricultural chemical products to meet the safety criteria, as toxicologically significant impurities can form at elevated temperatures, as set out in paragraph 20)a)i. of this statement of reasons and the *Malathion Final Review Technical Report*.
 - Regulation 8AE(1)(e) of the Agvet Regulations – any other matter determined by the APVMA CEO under regulation 8AE(2).
 - There are no other matters determined by the APVMA CEO under regulation 8AE(2) in relation to label approvals for agricultural chemical products containing malathion.
- c) Section 5D(2)(c) of the Agvet Code - whether the label conforms, or would conform, to any standard made for the label under section 6E to the extent that the standard relates to matters covered by subsection (1).
- I. There is no standard made for label approvals of agricultural chemical products containing malathion under section 6E.
- d) Section 5D(2)(d) of the Agvet Code – any matters prescribed by the regulations.
- I. Regulation 17 of the Agvet Regulations prescribes particulars for labels.
- The APVMA has reviewed the prescribed particulars for labels as defined by regulation 17 of the Agvet Regulations.
 - The APVMA is **not satisfied** that the name of the active constituent recorded in the APVMA file remains appropriate for labels of all agricultural products. The Australian pesticides common name 'maldison' is not used outside Australia, nor is it used for Australian therapeutic goods. The common name 'malathion' is specified in ISO 1750-1981.
 - The APVMA is **not satisfied** that the proportion of each active constituent recorded in the APVMA file and included in the constituent statement on labels for malathion fruit fly bait products (42727, 50589, 63032) is appropriate, as the APVMA file and labels do not include the weight per weight concentration (g/kg) of the liquid that coats the wick of these fruit fly bait products.

- The APVMA is satisfied that all other relevant particulars prescribed by regulation 17 of the Agvet Regulations recorded in the APVMA file remain appropriate.

II. The consideration of the conditions set out in subdivision 2.1.6 of the Agvet Regulations (incorporating regulations 18B to 18J) is detailed above in paragraphs 45)a)I. and 45)a)II. of this statement of reasons.

- 46) The APVMA is **not satisfied** that current approved labels for containers for malathion agricultural chemical products contain adequate instructions relating to the components set out in paragraph 42) above, excluding labels of agricultural products where malathion is an excipient (60832, 60890, 66869).
- 47) The APVMA is satisfied that, excluding the instructions contained on the label, the name of the active constituent and proportion of each active constituent, all other particulars that are recorded in the relevant APVMA file remain appropriate.
- 48) Having had regard to the matters and findings set out above, the APVMA is **not satisfied** that current approved labels for containers for malathion agricultural chemical products meet the labelling criteria as defined in section 5D of the Agvet Code, nor comply with any requirements prescribed by the regulations.

Consideration of whether approved labels for agricultural chemical products can be varied to meet the labelling criteria and comply with any requirement prescribed by the regulations

- 49) The APVMA has considered whether the labels for malathion agricultural chemical products can be varied in such a way as to meet the labelling criteria defined by section 5D(1) of the Agvet Code and comply with any requirement prescribed by the regulations as follows:
- a) To address concerns identified in paragraph 45)b), when considering the matters set out in sections 5D(1)(a) and 5D(2)(b) of the Agvet Code, the APVMA finds as follows:
- I. In relation to the concerns identified in paragraph 45)b)I. regarding the instructions for the circumstances in which a product should be used (section 5D(1)(a)):
- The APVMA has varied the pest statements for the protection of stored grain on the label of the relevant product (50110) to specify the pests *'Stored grain pests (except Lesser Grain Borer). Including: Indian meal moth, Rice Weevil, Rust-red flour beetle, Saw-toothed grain beetle and Tropical warehouse moth'*.
- II. In relation to the concerns identified in paragraph 45)b)II. regarding the instructions for how the product should be used (section 5D(1)(b)):
- To remove the option to use application methods that were not supported, the labels of relevant malathion agricultural products (49539, 51150, 62194) have been varied to include the restraints *'DO NOT use open mixing and loading systems for aerial application (use closed mixing and loading only). DO NOT use open cabs for air blast application. DO NOT use backpack ULV misters/cold foggers.'*
 - The instruction *'DO NOT apply by ultra-low volume aerial application'* has been added to the use patterns where an acceptable mandatory no-spray buffers zone cannot be established:
 - use on peas at a rate equal to or greater than 625 g ac/ha (62194), and
 - use on linseed, maize, peas, cereal crops, maize, pastures, pasture seed crops, rice and sorghum at a rate equal to or greater than 642.95 g ac/ha (49539).

- The labels of relevant malathion agricultural products (49539, 51150, 62194, 69529) have been varied to include spray drift restraints (including appropriate buffer zones) to protect sensitive areas from exposure exceeding the regulatory acceptable levels (RALs), as set out in the *Malathion Final Review Technical Report*.
 - The labels of malathion agricultural products that are approved for mosquito control (49539, 51150, 62194) have been varied to include the following restraint – *'DO NOT apply directly to water'*.
 - The labels of relevant malathion agricultural products have been varied to include the following environmental protection statements:
 - for commercial agricultural products that can be applied as a spray and are approved for mosquito control (48992, 49539, 62194) – *'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 remaining commercial agricultural products that can be applied as a spray (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.'*
 - for commercial agricultural products formulated as dusts (50110) or solids (42727, 50589, 63032) – *'Toxic to bees. However, the use of this product as directed is not expected to have adverse effects on bees.'*
 - for all home garden agricultural products (42035, 58968, 62242) – *'Toxic to bees. DO NOT spray if bees are feeding on flowering plants.'*
 - The labels of malathion agricultural products that are approved for use as a prepare bait for the control of field cricks (49539, 51150, 62194) have been varied to include the following instructions to prevent consumption of prepared bait by non-target animals, as required:
 - the critical comment – *'Prepared bait should be stored separate from stock feed and the containers clearly marked to indicate that the contents have been treated with [product name].'*
 - the environmental protection statement - *'DO NOT place treated grain bait for control of crickets in locations which are accessible which are accessible to domestic animals, livestock or birds. DO NOT feed treated grain to animals including poultry.'*
- III. In relation to the concerns identified in paragraph 45)b)IV. regarding the instructions for the frequency of the use of the product (section 5D(1)(d)):
- On labels of relevant agricultural products (49539, 51150 and 62194), the instruction *'DO NOT apply more than 4 applications per season'* has been added to the use patterns where the number of applications has not already been specified, excluding use patterns which are unlikely to result in residues in food (including use in baits for the control of fruit flies and uses on ornamental plants

- IV. In relation to the concerns identified in paragraph 45)b)V. regarding the instructions for the withholding period after the use of the product (section 5D(1)(e)), the following withholding periods have been added to the labels of relevant malathion agricultural products (49539, 51150, 62194):
- for use on cereals crops (including maize, rice and sorghum) grain legumes and/or linseed – *‘DO NOT HARVEST FOR 1 DAY AFTER APPLICATION.’*
 - for use in canola (rapeseed), safflower and/or sunflower crops – *‘DO NOT HARVEST FOR 3 DAYS AFTER APPLICATION.’*
- V. In relation to the concerns identified in paragraph 45)b)VI. regarding the instructions for the re-entry period after the use of the product (section 5D(1)(f)), the following re-entry have been added to the labels of relevant malathion agricultural products:
- for all uses where malathion is applied as a spray (49539, 51150, 62194 and 69529) – *‘DO NOT enter treated areas until spray has dried.’*
 - for use on fruiting vegetable crops (49539, 51150, 62194) - *‘DO NOT enter for 1 day after application for irrigation, scouting, thinning and weeding.’*
 - for use on leafy vegetable crops (49539, 51150, 62194) - *‘DO NOT enter for 1 day after application for irrigation and scouting mature plants, hand harvesting and pruning.’*
 - for use on field crops (low) (49539, 51150, 62194) - *‘DO NOT enter for 2 days after application for hand-set irrigation. DO NOT enter for 1 day after application for scouting, thinning and weeding.’*
 - for use on grapes (51150, 62194) *‘Grapes: DO NOT enter for 1 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.’*
 - for use of products 49539, 51150 and 62194 on apples – *‘DO NOT enter for 1 day after application for hand pruning, training, scouting, training, transplanting, orchard maintenance, propping and hand weeding. DO NOT enter for 8 days after application for hand harvesting. DO NOT enter for 17 days after application for thinning fruit.’*
 - for use of product 69529 on apples – *‘DO NOT enter for 1 day after application for hand pruning, training, scouting, training, transplanting, orchard maintenance, propping and hand weeding. DO NOT enter for 8 days after application for hand harvesting. DO NOT enter for 17 days after application for thinning fruit.’*
 - For treatment of animal housing (51150) – *‘DO NOT allow entry into treated animal housing or handle treated animal bedding until spray has dried. Children must not be allowed to enter into treated animal housing or handle treated animal bedding for 3 full days post-application.’*
- VI. In relation to the concerns identified in paragraphs 45)b)VII. and 45)b)VIII. regarding the instructions for the disposal of the product when it is no longer required (section 5D(1)(g)) and the disposal of containers for the product (section 5D(1)(h)):
- The labels of commercial malathion agricultural products have been varied as follows:

- for the disposal of the product when it is no longer required, the following instruction had been added – *'Dispose of any unused chemical in compliance with relevant local, state or territory government regulations.'*
 - the following disposal instructions have been added – *'Triple-rinse containers before disposal. Dispose of rinsate or any undiluted chemical according to state/territory legislative requirements. 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.'*
 - The following aquatic protection statement has been added – *'Very toxic to aquatic life. DO NOT contaminate wetlands or watercourses with this product or used containers.'*
 - The labels of home garden malathion agricultural products have been varied as follows:
 - the following disposal instructions has been added – *'Dispose of container by wrapping in paper, placing in plastic bag and putting in garbage.'*
 - the following aquatic protection statement has been added – *'Toxic to aquatic life. DO NOT allow the product, chemical containers or spray to get into drains, sewers, streams or ponds.'*
- VII. In relation to the concerns identified in paragraphs 45)b)IX. regarding the instructions for the safe handling of the product (section 5D(1)(i)), the safety directions on labels of relevant malathion agricultural products have been varied as follows:
- For malathion products formulated as ULV or EC 1200 g/L or less (49539, 62194) – *'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.'*
 - For malathion products formulated as EW 550 g/L or less (51150, 69529) – *'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.'*
 - For malathion products formulated as VP 100 g/Kg or less (42727, 50589, 63032) – *'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.'

- For malathion products formulated as DP 40 g/Kg or less (42267, 50110) – *'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'*
- For home garden malathion products formulated as EC 500 g/L or less (42035, 62242) – *'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.'*
- For home garden malathion products formulated as EC 100 g/L or less with petroleum oil 400 g/L or less (58968) – *'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.'*

VIII. In relation to the concerns identified in paragraph 45)b)X. regarding the prevention of undue prejudice to trade or commerce between Australia and places outside of Australia (regulation 8AE(1)(b)):

- The labels of relevant commercial malathion agricultural products (49539, 51150, 69529) have been varied to include the following trade advice statement – *'Treated crop commodities destined for export may require extra time between application and harvest to be accepted in some export markets. Before you use this product, you are advised to contact [company name] and/or your industry body about any potential trade issues and their management.'*

IX. In relation to the concerns identified in paragraph 45)b)X. regarding the appropriate signal words (if any) required by the current Poisons Standard (regulation 8AE(1)(c)):

- The signal heading for malathion fruit fly bait products which contain more than 10% of malathion (42727, 50589, 63032) has been varied from CAUTION to POISON.

b) To address concerns identified in paragraph 45)d), when considering the matters set out in Regulation 17 of the Agvet Regulations, the APVMA has:

- I. where required, varied the name of the active constituent recorded in the relevant APVMA file to 'malathion'.
- II. for malathion fruit fly bait products (42727, 50589, 63032), varied the proportion of each active constituent on the label to include the weight per weight concentration (g/kg) in addition to the weight or volume per wick concentration (g/wick or mL/wick).

c) In relation to concerns identified paragraph 45)a)III., the APVMA has added the following condition of label approval – *'The label must contain the expiry date of the chemical product'*.

- d) In relation to concerns identified when considering the criteria in sections 5D(2)(a) and 5D(2)(d) of the Agvet Code related to compliance with the *Agricultural Labelling Code*, the APVMA is satisfied that label approvals listed in Attachment A will comply with the *Agricultural Labelling Code* once varied in the ways set out in paragraph 49) above, and in the additional ways set out below:
- I. If it is not already included, add the required statement '*an anticholinesterase compound*' to the constituent statement in the label approval.
 - II. If not already included, add the instructions for storage of malathion agricultural chemical products '*Store in the closed, original container in a cool, well-ventilated area. DO NOT store for prolonged periods in direct sunlight.*'
 - III. Add the following instruction for re-entry into areas treated with malathion '*When prior entry is necessary, wear [list appropriate protective clothing]. Clothing must be washed after each day's use.*'
 - IV. For labels of commercial malathion agricultural products, if not already included, add the following mode of action statement 'Group 1B Insecticide and the insecticide resistance warning statement as set out in the *Agricultural Labelling Code*.

50) Section 34A(3) of the Agvet Code provides that if the variation would affect instructions for use on a label, the APVMA must not make the variation until it has consulted each co-ordinator designated for a jurisdiction and taken into account any recommendations made by the co-ordinators.

- a) The APVMA has consulted with each co-ordinator designated for a jurisdiction and taken into account any recommendations made prior to making this decision.

51) In accordance with section 34A(1) of the Agvet Code, the APVMA is satisfied that the relevant particulars of the label approvals for the agricultural products listed in Attachment A as varied in the ways set out in paragraph 49) contain adequate instructions relating to the components set out in paragraph 42), meet the labelling criteria and comply with any requirement prescribed by the regulations.

Conclusion on consideration of approved labels for agricultural chemical products

52) The APVMA is satisfied that the relevant particulars of the label approvals for containers for malathion agricultural chemical products listed in Attachment A can be varied to meet the labelling criteria and comply with any requirement prescribed by the regulations. Accordingly, the APVMA has varied the relevant particulars as set out in paragraph 49) of this statement of reasons to allow the approval of these labels for containers of agricultural chemical products to be affirmed under section 34A(1) of the Agvet Code.

Conclusion for agricultural chemicals

53) For the purposes of sections 34(1) and 34A(1) of the Agvet Code, and having regard to the matters set out above, the APVMA has determined that:

- a) Regarding malathion agricultural chemical product registrations, the APVMA is:
- I. **not satisfied** that the all malathion agricultural chemical product registrations meet the safety criteria, efficacy criteria or trade criteria
 - II. satisfied that all malathion agricultural chemical product registrations comply with any requirements prescribed by the regulations

III. satisfied that the relevant particulars and conditions of malathion agricultural chemical product registrations listed in Attachment A can be varied in such a way (as set out in paragraphs 20), 25) and 31) of the statement of reasons) to allow the chemical product registrations to be affirmed.

b) Regarding label approvals for containers for malathion agricultural chemical products, the APVMA is:

I. **not satisfied** that the label approvals meet the labelling criteria and comply with any requirement prescribed by the regulations

II. satisfied that the relevant particulars of label approvals for containers for malathion agricultural chemical products listed Attachment A can be varied in such a way (as set out in paragraph 49) of the statement of reasons) to allow the label approvals to be affirmed.

54) Consequently, pursuant to section 34A(1) of the Agvet Code, the APVMA has:

a) varied the relevant particulars and conditions of the malathion agricultural chemical product registrations listed in Attachment A in a manner set out in paragraphs 20), 25) and 31) of this statement of reasons and has affirmed the registration of these products under section 34(1) of the Agvet Code; and

b) varied the relevant particulars of the label approvals listed in Attachment A in the manner set out in paragraph 49) of this statement of reasons and affirmed the approval of these labels under section 34(1) of the Agvet Code.

Veterinary chemical products

55) Section 34(1)(b) and (d) of the Agvet Code provides that the APVMA must affirm the registration for a chemical product if, and only if, it is satisfied that the product:

a) meets the safety criteria (section 5A)

b) meets the efficacy criteria (section 5B)

c) meets the trade criteria (section 5C)

d) complies with any requirement prescribed by the regulations.

56) Section 34(2) of the Agvet Code provides that subsection 34(1) applies only to the extent that the APVMA decides to reconsider matters covered by the subsection.

57) The APVMA has decided to reconsider all matters covered by subsection 34(1) in relation to the reconsideration of malathion veterinary chemical product registrations subject to the following limitations:

a) The environmental risk assessment was limited to the toxicity of malathion to aquatic species, pollinators and vegetation and the adequacy of instructions.

b) The residues and trade risk assessment was limited to the consideration of malathion maximum residue limits, dietary exposure based on the maximum residue limits and the adequacy of instructions.

Consideration of whether veterinary chemical products meet the safety criteria

- 58) Section 5A(1) of the Agvet Code provides that a chemical product meets the safety criteria if use of the product, in accordance with any instructions approved or to be approved by the APVMA for the constituent or product or contained in an established standard:
- a) is not, or would not be, an undue hazard to the safety of people exposed to it during its handling or people using anything containing its residues (section 5A(1)(a)).
 - b) is not, or would not be, likely to have an effect that is harmful to human beings (section 5A(1)(b)).
 - c) is not, or would not be, likely to have an unintended effect that is harmful to animals, plants or things or to the environment (section 5A(1)(c)).
- 59) For the purpose of being satisfied that the malathion veterinary chemical products meet the safety criteria, the APVMA has had regard to the criteria set out in section 5A(3)(a) as follows:
- a) Section 5A(3)(a)(i) - the toxicity of the product and its residues, including metabolites and degradation products, in relation to relevant organisms and ecosystems, including human beings.
 - I. The APVMA has considered the following information in having regard to the toxicity of malathion chemical products and their residues, as detailed in the *Malathion Final Review Technical Report*:
 - Information on the toxicity of the constituent malathion and its residues, as set out in paragraph 6)a) and the references therein, including the malathion health-based guidance values.
 - The toxicity of malathion to non-target species, including aquatic species, pollinators and vegetation.
 - The impact of impurities of toxicological concern in formulated veterinary chemical products. As set out in the *2016 Malathion Chemistry Report*, impurities can increase (potentiate) the toxicity of malathion itself and the most significant potentiators of malathion toxicity are MeOSSPO, isomalathion and MeOOSPO.
 - The impact of any relevant formulation excipients on the toxicity of the malathion veterinary chemical products to relevant organisms and ecosystems, including human beings.
 - II. The APVMA has set health-based guidance values for the constituent malathion and have assessed the following to be adequately protective of human health, as set out in the *Malathion Final Review Technical Report*.
 - An ADI of 0.02 mg/kg bw/d based on a NOAEL of 2 mg/kg bw/d and an uncertainty factor of 100.
 - An ARfD of 1.5 mg/kg bw based on a and NOAEL of 15 mg/kg bw/d and an uncertainty factor of 10.
 - III. The APVMA is satisfied the following is adequately protective for use of malathion chemical products by occupational handles or non-professionals, as set out in the *Malathion Final Review Technical Report*.
 - applying a margin of exposure of 10 to a point of departure of 15 mg/kg bw (single oral exposure), based on a NOEL of ≥ 15 mg/kg bw
 - applying a margin of exposure of 100 to a point of departure of 9 mg/kg bw/d (short term repeated oral exposure), based on inhibition of erythrocyte cholinesterase

- applying a margin of exposure of 100 to a point of departure of 50 mg/kg bw/d (short term repeated dermal exposure, re-entry exposure), based on the NOEL
 - applying a margin of exposure of 1000 to a point of departure of 23 mg/kg bw/d (short and intermediate term repeated dermal inhalation), based on the LOAEL.
- IV. The APVMA is satisfied that there is sufficient information on the toxicity of malathion to non-target species, including aquatic species and pollinators, to assess the adequacy of the instructions for use for malathion veterinary chemical products.
- V. The APVMA is satisfied that there is sufficient information on the toxicity of the impurities of toxicological concern, and the origin of these impurities in both technical malathion and formulated veterinary products, to establish appropriate specifications for veterinary chemical products containing malathion, as set out in the *Malathion Final Review Technical Report*.
- VI. The APVMA is satisfied that there is sufficient information to assess the impact of relevant formulation excipients on the toxicity of the malathion veterinary chemical products to relevant organisms and ecosystems, including human beings, as set out in the *Malathion Final Review Technical Report*.
- VII. The APVMA is therefore satisfied that the toxicity of malathion veterinary chemical products and their residues, including metabolites and degradation products, are sufficiently defined to allow assessment of the risks to relevant organisms and ecosystems, including human beings, and the adequacy of the instructions for use for malathion veterinary chemical products.
- b) Section 5A(3)(a)(ii) of the Agvet Code – the relevant poison classification of the product under the law in force in this jurisdiction.
- I. Malathion is listed in the following schedules of the *Therapeutic Goods (Poisons Standard—February 2024) Instrument 2024*.
- Schedule 5 for preparations containing 1% or less of malathion except: for human therapeutic use; or in dust preparations containing 2% or less of malathion.
 - Schedule 6 for preparations containing malathion except: when included in Schedule 5; for human therapeutic use; or in dust preparations containing 2% or less of malathion.
- II. The APVMA is satisfied that the current scheduling remains appropriate based on the assessment of available toxicology data, as outlined in the *Malathion Final Review Technical Report*.
- c) Section 5A(3)(a)(iii) – how the product is formulated.
- I. The APVMA has considered the existing registration records in having regard to how the chemical products containing malathion are formulated. Veterinary chemical products containing malathion are formulated for topical application either as an emulsifiable concentrate or dustable powder.
- II. The APVMA has also considered the levels of toxicological impurities that may be present in formulated veterinary products containing malathion. As further discussed in the *Malathion chemistry report* and the *Malathion Final Review Technical Report*, the concentration of the impurities (in particular, isomalathion) can increase significantly during storage of malathion products, especially at elevated temperatures.

- III. The APVMA is satisfied that how the product is formulated remains appropriate when there is sufficient batch analysis and stability data to demonstrate that relevant impurities of toxicological concern will not exceed acceptable levels for a 2-year period.
- IV. If there is not sufficient information to demonstrate that impurities of toxicological concern will not exceed acceptable levels, the APVMA is **not satisfied** that how the veterinary chemical product containing malathion is formulated remains appropriate.
- d) Section 5A(3)(a)(iv) of the Agvet Code – the composition and form of the constituents of the product.
- I. The APVMA has considered existing registration records for the excipients and Declarations of Composition submitted by the relevant holders for the approved active constituents when having regard to the composition and form of the constituents of veterinary chemical products containing malathion.
- II. Based on the assessment of this information, the APVMA is satisfied that the composition and form of constituents in the veterinary products are appropriate.
- e) Section 5A(3)(a)(v) of the Agvet Code – any conditions to which its registration is, or would be, subject.
- I. Product registrations are currently subject to the conditions prescribed in items 1, 2, 3, 4, 5, 6 and 7 of the table in regulation 17C(2) of the Agvet Regulations. The APVMA is satisfied that holders of malathion veterinary chemical products can comply with the conditions prescribed by the Agvet Regulations.
- II. Under section 23(1)(b), the APVMA may also impose conditions on the approval or registration as the APVMA thinks appropriate.
- Each product is subject to a shelf-life condition imposed by the APVMA under section 23(1)(b). For each product, the condition states that the product can only be supplied if label includes an expiry date no greater than the shelf life of the product. The shelf life is determined by the APVMA for each product based on an assessment of product specific information and storage conditions.
 - As the concentration of the impurities (in particular, isomalathion) can increase significantly during storage of malathion products, especially at elevated temperatures, the APVMA is **not satisfied** that it has sufficient information to support the shelf-life included in the shelf-life condition of registration.
- f) Section 5A(3)(a)(vi) of the Agvet Code – any relevant particulars that are, or would be, entered in the Register for the product.
- I. The relevant particulars on the record for each malathion veterinary chemical product have been reviewed.
- II. The APVMA is **not satisfied** that when used according to the instructions for use, malathion veterinary chemical products would not pose an undue hazard to the safety of people exposed to it during its handling, or people using anything containing its residues based on the following findings as set out in the *Malathion Final Review Technical Report*.
- There are insufficient instructions for use (including safety directions and/or application equipment instructions) to prevent unacceptable exposure to people who use malathion veterinary chemical products.
 - There are insufficient instructions for use to prevent unacceptable exposure to people who re-enter areas or re-handle animals treated with malathion veterinary chemical products, in particular children.

- The veterinary malathion chemical product that contains xylene as a solvent (37201) cannot be safely used in domestic situations.
- III. The APVMA is **not satisfied** that the instructions for use of malathion veterinary chemical products would not be likely to have an unintended effect that is harmful to non-target species, based on the following findings as set out in the *Malathion Final Review Technical Report*.
- Malathion has high toxicity to aquatic species and there are insufficient instructions for use (specifically, environmental protection statements) to prevent unacceptable exposure of aquatic species. Further, malathion veterinary products cannot be safely applied to aquatic areas for control of mosquito larvae.
 - Malathion is toxic to pollinators (including honeybees) and there are insufficient instructions for use (specifically, environmental protection statements) for the veterinary malathion product approved for mosquito and fly control (63456) to prevent unacceptable exposure of pollinators. Further, there are insufficient instructions to prevent unacceptable exposure of non-target animals by run-off.
- IV. There were no concerns identified in relation to residues resulting from veterinary uses of malathion and the National Residues Survey data confirmed no detections of malathion residues in animal commodities over the past ten years, as set out in the *Malathion Final Review Technical Report*. Therefore, the APVMA is satisfied that the withholding periods and maximum residue limits previously established for malathion veterinary uses remain appropriate, and that use of malathion veterinary chemical products in food producing species would not be likely to have an effect that is harmful to human beings.
- V. The APVMA is satisfied that use of malathion veterinary products in accordance with instructions for use would not have an unintended effect that is harmful to target animals, based on a history of sale and use of the products and that no reports of adverse effects in target animals have been received by the Adverse Experience Reporting Program of the APVMA, as detailed in the *Malathion Final Review Technical Report*.
- VI. The APVMA is satisfied that all relevant particulars that are entered in the Register for malathion veterinary chemical products, excluding the instructions for use of the product, remain acceptable.
- g) Section 5A(3)(a)(via) of the Agvet Code – whether the product conforms, or would conform, to any standard made for the product under section 6E to the extent that the standard relates to matters covered by subsection (1).
- I. There are no standards made under section 6E which are relevant to the safety of veterinary chemical products containing malathion.
 - II. The APVMA is proposing to make a standard under section 6E for malathion chemical products as an outcome of the reconsideration, which includes limits on relevant impurities, as set out in the *Malathion Final Review Technical Report*. It is noted that the process for making a Standard made under section 6E(1) of the Agvet Code is set out in regulation 8AF of the Agvet Regulations and will be undertaken separately to this final regulatory decision.
- h) Section 5A(3)(a)(vii) of the Agvet Code – any matters prescribed by the regulations.
- I. Regulation 8AB(1)(a) of the Agvet Regulations prescribes the method of analysis (if any) of the chemical composition and form of the constituents of the chemical product.

- The APVMA has considered the existing registration records and data submitted during the course of the reconsideration in having regard to the method of analysis of the chemical composition and form of the constituents of veterinary malathion chemical products. The APVMA is satisfied that the methods of analysis are appropriate to analyse relevant physicochemical properties and determine the concentration of the malathion active constituent and relevant impurities.
 - II. Regulations 8AB(1)(b) and (c) of the Agvet Regulations prescribe, respectively, that for a product manufactured in Australia—whether each step in the manufacture of the product complies, or will comply, with the manufacturing principles and the Australian GMP Code, and for a product manufactured outside Australia—whether each step in the manufacture of the product complies, or will comply, with a standard that the APVMA has determined is comparable to the manufacturing principles and the Australian GMP Code.
 - There were no concerns identified in relation to the requirements prescribed by Regulations 8AB(1)(b) and 8AB(1)(c) of the Agvet Regulations. The APVMA is satisfied that products manufactured within Australia or outside Australia comply with the requirements set out in the relevant regulation.
 - III. Regulations 8AB(1)(d), (e) and (f) do not apply based on the use patterns of malathion veterinary chemical products.
- 60) Under section 5A(3)(b) of the Agvet Code, the APVMA may have regard to one or more of the following matters in determining whether a chemical product meets the safety criteria:
- a) Section 5A(3)(b)(i) of the Agvet Code – the acceptable daily intake of each constituent contained in the product.
 - I. The APVMA considered the toxicity of malathion, as set out in the *Malathion Final Review Technical Report*, and is satisfied that the acceptable daily intake of 0.02 mg/kg bw/d remains appropriate.
 - b) Section 5A(3)(b)(ii) of the Agvet Code – any dietary exposure assessment prepared under subsection 82(4) of the *Food Standards Australia New Zealand Act 1991* as a result of any proposed variation notified under section 82(3) of that Act in relation to the product, and any comments on the assessment given to the APVMA under section 82(4) of that Act.
 - I. There has not been a dietary exposure assessment prepared under subsection 82(4) of the *Food Standards Australia New Zealand Act 1991*.
 - c) Section 5A(3)(b)(iii) of the Agvet Code – whether any trials or laboratory experiments have been carried out to determine the residues of the product and, if so, the results of those trials or experiments and whether those results show that the residues of the product will not be greater than limits that the APVMA has approved or approves.
 - I. There were no concerns identified in relation to residues resulting from use of malathion veterinary chemical products and the National Residues Survey data also confirmed no detections of malathion residues in animal commodities over the past ten years, as set out in the *Malathion Final Review Technical Report*. Therefore, the APVMA is satisfied that the residues of malathion veterinary chemical products will not be greater than the approved maximum residue limits.
 - d) Section 5A(3)(b)(iv) of the Agvet Code – the stability of the product.
 - I. In considering the stability of malathion veterinary chemical products, the APVMA has had regard to information submitted as part of the original registration and during the course of the reconsideration,

including product-specific stability data. The APVMA has also reviewed the shelf-life condition of registration to which the malathion veterinary products are subject.

- II. The consideration of that information indicates that concentrations of impurities of toxicological concern (in particular isomalathion) have the potential to significantly increase during prolonged storage or storage at elevated temperatures, as further discussed in the *Maldison chemistry report* and the *Malathion Final Review Technical Report*.
- III. Where the shelf-life condition is for 2 years when stored at room temperature (30 °C), and APVMA has sufficient information to be satisfied that the product will remain within specifications when stored in accordance with this condition, the APVMA is satisfied of the stability of the product.
- IV. The APVMA is **not satisfied** of the stability of the product if there is insufficient information to demonstrate that the product will remain within specifications when stored in accordance with the current shelf-life condition of registration.

e) Section 5A(3)(b)(v) of the Agvet Code – the specifications for containers for the product.

- I. In considering the specification for containers of malathion veterinary chemical products, the APVMA has had regard existing product records on the stability of the product in the proposed containers and the integrity of the container during storage of the product. Additionally, there were no concerns identified in relation to the specifications for containers for malathion veterinary chemical products.
- II. Malathion veterinary chemical product registrations are also subject to the conditions of registration prescribed under regulation 18(2). The APVMA is satisfied that the holders can comply with these conditions.
- III. The APVMA is satisfied that the specifications for containers for products are appropriate.

f) Section 5A(3)(b)(vi) of the Agvet Code – such other matters as it thinks relevant.

- I. The APVMA has conducted a dietary exposure assessment for malathion chemical products and is satisfied that the acute and chronic dietary exposure to malathion calculated using the National Estimated Dietary Intake calculation will not exceed the ADI and ARfD and is not likely to have an effect that is harmful to human beings, as set out in the *Malathion Final Review Technical Report*.

61) Having regard to the matters and findings set out above, the APVMA is **not satisfied** that the use of malathion veterinary chemical products meets the safety criteria as defined in section 5A of the Agvet Code for the following reasons:

- a) if there is not sufficient information to demonstrate that impurities of toxicological concern will not exceed acceptable levels, the way in which the veterinary chemical product containing malathion is formulated may not be appropriate. Further, as the concentration of impurities of toxicological concern may increase and exceed acceptable concentrations after prolonged storage of the products or storage of the products at elevated temperature, the shelf-life condition of registration and stability of the product may also not be appropriate,
- b) the use of malathion veterinary chemical products in accordance with the instructions for use may pose an undue hazard to the safety of people exposed to it during its handling or people using anything containing its residues and may have an unintended effect that harmful to non-target species.

Consideration of whether veterinary chemical products can be varied to meet the safety criteria

62) The APVMA has considered whether the relevant particular or conditions of the registration of malathion veterinary chemical products can be varied in such a way as to meet the safety criteria set out in Section 5A(1) and has determined that the relevant particular and conditions can be varied as follows:

- a) To address concerns identified in paragraphs 59)c), 59)e) and 60)d) in relation to the levels of impurities of toxicological concern, the APVMA has varied the conditions of registration as follows:
- I. For products where the APVMA has sufficient information to be satisfied that toxicologically significant impurities will not exceed acceptable levels within 2 years, the APVMA has varied the shelf-life condition of registration to add the following:
 - *'This product can only be supplied if the approved label contains an expiry date not greater than 24 months after the date of manufacture of the product when stored below 30°C (room temperature).'*
 - II. For products where the APVMA does not have sufficient information to be satisfied that toxicologically significant impurities will not exceed acceptable levels, the APVMA has varied the shelf-life condition of registration and added conditions of registration as follows:
 - *'This product can only be supplied if the approved label contains an expiry date not greater than 12 months after the date of manufacture of the product when stored below 30°C (room temperature).'*
 - *'On or before DD/MM/YYYY (which is 1 year from the date of the APVMA affirming the registration of this product), you are required to provide storage stability data and validation data to enable the APVMA to determine and establish an appropriate shelf life.'*
 - For the purposes of this condition, the storage stability data and validation data required would include:
 - Storage stability data that includes the content of the active constituent malathion and the impurity isomalathion that is generated in accordance with either the:
 - APVMA agricultural guideline 'Generation of storage stability data for agricultural chemical products' available at apvma.gov.au/node/1042 (i.e. content before and after storage for 14 days at 54°C in the designated packaging to support a 2 year shelf-life); or
 - APVMA veterinary guideline 'Chemistry and manufacture of products (Part 2) — 7. Stability data' available at apvma.gov.au/registrations-and-permits/data-guidelines/veterinary-data-guidelines/chemistry-manufacture-part-2/products.
 - Details of the analytical method(s) and validation data generated in accordance with either the:
 - APVMA agricultural guideline 'Validation of analytical methods for active constituents and agricultural products', available at apvma.gov.au/node/1048; or
 - APVMA veterinary guideline 'Chemistry and manufacture of products (Part 2) — 8. Analytical method and validation data' available at apvma.gov.au/registrations-and-permits/data-guidelines/veterinary-data-guidelines/chemistry-manufacture-part-2/products.

and-permits/data-guidelines/veterinary-data-guidelines/chemistry-manufacture-part-2/products.

- b) To address concerns identified in paragraph 59)f), the APVMA has varied the instructions for use of malathion veterinary chemical products as follows, as further detailed in the *Malathion Final Review Technical Report*.
- I. The safety directions for each veterinary chemical product containing malathion as the active constituent have been varied, as set out in paragraph 86)a)V. of this statement of reason.
- II. The instructions for use for relevant malathion veterinary chemical products (33021, 63456) have been varied to specify the application equipment that was supported, as set out in the *Malathion Final Review Technical Report*:
- for use on cattle and pigs – ‘Apply with low pressure spray’ or ‘... using low pressure spray’.
 - for use on horses – ‘Apply 2 L prepared spray per horse using a trigger pump spray or sponge.’
 - for use on cats and dogs – ‘Saturate the animal using a sponge.’
 - for use on animal bedding – ‘... for spraying bedding etc. with a trigger pump spray’
 - for use on poultry – ‘Spray birds using a trigger pump spray...’
 - for treatment of poultry animal housing – ‘... with manually pressurised hand wand’
 - for mosquito and fly control (63456 only) – ‘Apply with manually pressurised handwand.’
- III. The following restraints have been added to the instructions for use of relevant malathion veterinary chemical products, as set out in the *Malathion Final Review Technical Report*:
- for veterinary malathion products approved for use on companion animals (33021, 37201, 42267 54285, 63456) – ‘DO NOT allow children to handle companion animals treated with malathion for one hour after application.’
 - for veterinary malathion products approved for use in animals housing and bedding (33021, 37201, 42267 54285, 63456) – ‘DO NOT allow children to enter treated animal housing or handle treated animal bedding for 3 full days after application.’
 - for veterinary malathion products approved for use as a spray in animals housing and bedding (33021, 37201, 54285, 63456) – ‘DO NOT allow entry into treated animal housing or handle treated animal bedding until spray has dried.’
 - for the veterinary malathion product approved for mosquito or fly control (63456) – ‘DO NOT allow entry into treated areas until spray has dried.’ and ‘DO NOT apply directly to water.’
 - for the veterinary malathion product that contains xylene as a solvent (37201) - ‘NOT SUITABLE FOR DOMESTIC USE’.
- IV. The instructions for use for relevant malathion veterinary chemical product have been varied to include the following environmental protection statements, as set out in the *Malathion Final Review Technical Report*:

- for all veterinary malathion products – *‘Very toxic to aquatic life. DO NOT contaminate wetlands or watercourses with this product or used containers.’*
- for the veterinary malathion product approved for mosquito or fly control (63456) – *‘Toxic to bees. DO NOT spray if bees are feeding on flowering plants.’*

V. The following instructions for use have been added to the veterinary malathion product approved for mosquito or fly control (63456) to prevent unacceptable exposure of children and non-target animals – *‘DO NOT apply past the point of run off. DO NOT apply to surfaces within reach of animals and/or children.’*

63) In accordance with section 34A(1) of the Agvet Code, the APVMA is satisfied that the relevant particulars and conditions of the malathion veterinary chemical products listed in Attachment A of this notice as varied in the ways set out in paragraph 62) meet the safety criteria.

Consideration of whether veterinary chemical products meet the efficacy criteria

64) Section 5B(1) of the Agvet Code provides that a chemical product meets the efficacy criteria if use of the product, in accordance with instructions approved, or to be approved, by the APVMA for the product or contained in an established standard, is, or would be, effective according to criteria determined by the APVMA by legislative instrument.

- a) Malathion products are not contained in an established standard.
- b) The criteria for determining the efficacy of veterinary chemical products are specified in Part 3 of the legislative instrument, the *Agricultural and Veterinary Chemicals Code (Efficacy Criteria) Determination 2014* and are:
 - I. criteria based on type of product, as set out in clause 5; and
 - II. criteria based on demonstrated effectiveness, as set out in clause 6.

65) For the purpose of being satisfied that the malathion veterinary chemical products meet the efficacy criteria, the APVMA has had regard to the criteria set out in section 5B(2) of the Agvet Code as follows:

- a) Section 5B(2)(a) - whether any trials or laboratory experiments have been carried out to determine the efficacy of the product and, if so, the results of those trials or experiments.
 - I. The APVMA has considered the assessments of previously submitted information for the registration and variation of veterinary chemical products containing malathion. The APVMA is satisfied that this information continues to support the efficacy of these chemical products.
- b) Section 5B(2)(b) - any conditions to which its registration is, or would be, subject;
 - I. The APVMA has considered the conditions of registration which apply to chemical products containing malathion. The APVMA is satisfied that no additional conditions of registration are required to satisfy the efficacy criteria.
- c) Section 5B(2)(c) - any relevant particulars that are, or would be, entered in the Register for the product;
 - I. The APVMA has considered the relevant particulars that are entered in the Register for veterinary chemical products containing malathion and the variations to the instructions for use that are set out in paragraph 62) of this statement of reasons.

- II. The variations to the instructions for use set out in paragraph 62) are within existing use patterns. The APVMA is satisfied that these variations will not impact the efficacy of these veterinary products, as discussed in the *Malathion Final Review Technical Report*.
 - III. The APVMA is satisfied that all relevant particulars entered in the Register remain appropriate with regards to the efficacy of the veterinary chemical products containing malathion.
- d) Section 5B(2)(ca) - whether the product conforms, or would conform, to any standard made for the product under section 6E to the extent that the standard relates to matters covered by subsection (1);
 - I. There are no standards made under section 6E that are relevant to the efficacy of veterinary chemical products containing malathion.
 - e) Section 5B(2)(d) - any matters prescribed by the regulations.
 - I. There are no regulations which are relevant to the efficacy of malathion veterinary chemical products.
- 66) Having had regard to the matters and findings set out above, the APVMA is satisfied that the use of malathion veterinary chemical products meets the efficacy criteria.

Consideration of whether veterinary chemical products meet the trade criteria

- 67) Section 5C(1) of the Agvet Code provides that a product meets the trade criteria if use of the product, in accordance with instructions approved, or to be approved, by the APVMA or contained in an established standard, does not, or would not, unduly prejudice trade or commerce between Australia and places outside Australia.
- 68) Section 5C(3) of the Agvet Code provides that for the purposes of the operation of this Code in relation to a particular chemical product, the APVMA is required to have regard to the matters set out in subsections (1) and (2) only to the extent prescribed by the regulations; or if there are no such regulations—to the extent that the APVMA thinks the matters are relevant.
- a) For the purposes of subsection 5C(3) of the Agvet Code, Regulation 8AD(2) of the Agvet Regulations provides that if it can be reasonably expected that a chemical product will be used in relation to a crop or animal, a product of which might be provided to a place outside Australia; or a crop that will be fed to animals a product of which might be provided to a place outside Australia then the APVMA must have full regard to the matters set out in section 5C(1) and (2) of the Agvet Code.
 - I. Commercial veterinary chemical products are approved for use on cattle, cats, dogs, horses, pigs and poultry and for animal housing treatment. Cattle, pigs, poultry, eggs and cattle dairy products are considered major export commodities. It is therefore reasonably expected that a product of these animals (cattle, pigs and poultry) might be provided to a place outside of Australia.
- 69) For the purposes of being satisfied that the malathion veterinary chemical products meet the trade criteria as described in section 5C(1) of the Agvet Code, the APVMA has considered the matters set out in section 5C(2) for the use patterns listed in paragraph 28) and has determined as follows:
- a) Section 5C(2)(a) - any conditions to which its registration is, or would be, subject.
 - I. The APVMA is satisfied that the conditions of registration currently applied to veterinary chemical products containing malathion remain appropriate with regards to the risk to trade or commerce between Australia and places outside Australia.

- b) Section 5C(2)(b) - any relevant particulars that are, or would be, entered in the Register for the product.
- I. The relevant particulars entered in the Register for each registered veterinary chemical product containing malathion have been reviewed, including the instructions for use for the chemical products.
 - The current withholding periods and maximum residue limits for poultry meat, eggs, livestock meat and milk remain appropriate for veterinary uses of malathion, as set out in the *Malathion Final Review Technical Report*, and no trade incidents have been reported to the APVMA related to veterinary uses of malathion. Therefore, the APVMA is satisfied and that use in accordance with the instructions would not pose a risk to trade or commerce between Australia and places outside Australia.
 - II. The APVMA is satisfied that all relevant particulars for malathion veterinary chemical products entered in the Register remain appropriate with regards to the risk to trade or commerce between Australia and places outside Australia.
- c) Section 5C(2)(ba), whether the product conforms, or would conform, to any standard made for the product under section 6E to the extent that the standard relates to matters covered by subsection (1);
- I. There are no standards made under section 6E that are relevant to the risk to trade or commerce between Australia and places outside Australia
- d) Section 5C(2)(c), any matters prescribed by the regulations.
- I. The APVMA has had regard to Regulation 8AD, as outlined in paragraph 68) above, in considering the risk to trade or commerce between Australia and places outside Australia posed by the use of veterinary chemical products containing malathion.
- 70) Having had regard to the matters and findings set out above, the APVMA is satisfied that the use of malathion veterinary chemical products, in accordance with instructions approved for major export commodities, meets the trade criteria

Consideration of whether veterinary chemical products meet any requirements prescribed by the regulations

- 71) Regulation 16 of the Agvet Regulations prescribes the relevant particulars of a chemical product which must be recorded in the Register pursuant to section 20(1)(c) of the Agvet Code:
- a) The APVMA has had regard to the relevant particulars recorded in the Register for each veterinary chemical product containing malathion and is satisfied that the particulars prescribed by regulation 16 of the Agvet Regulations and recorded in the Register for malathion products remain appropriate.
- 72) Regulation 17C of the Agvet Regulations prescribes conditions to which the registration of a chemical product is subject:
- a) The APVMA is satisfied that holders of malathion veterinary chemical products can comply with the conditions prescribed by regulation 17C of the Agvet Regulations.
- 73) Regulation 18 of the Agvet Regulations prescribes conditions of registration relating to the containers for chemical products.

- a) The APVMA is satisfied that holders of malathion veterinary chemical products can comply with the conditions prescribed by regulation 18 of the Agvet Regulations
- 74) Regulation 42 of the Agvet Regulations prescribes standards for chemical products to which chemical products must conform in accordance with section 87 of the Agvet Code. In accordance with Regulation 42(3)(b):
- a) The APVMA is satisfied that active constituent in malathion veterinary chemical products conforms to a standard prescribed by Regulation 42(3)(e) of the Agvet Regulations.

Conclusion of considerations of veterinary chemical products

- 75) The APVMA is satisfied that malathion veterinary chemical products listed in Attachment A of this notice meet the efficacy criteria, trade criteria and comply with any requirements prescribed by the regulations, and that the relevant particulars and conditions can be varied so that they meet the safety criteria. Therefore, the APVMA has varied the relevant particulars and conditions as set out in paragraph 62) to allow the registration of these veterinary chemical products to be affirmed under section 34A(1) of the Agvet Code.

Labels for veterinary chemical products

- 76) Section 34(1)(c) and (d) of the Agvet Code provides that the APVMA must affirm the approval of a product label if, and only if, it is satisfied that the label:
- a) meets the labelling criteria
 - b) complies with any requirement prescribed by the regulations.
- 77) Subsection 34(2) of the Agvet Code provides that subsection 34(1) applies only to the extent that the APVMA decides to reconsider matters covered by this subsection.
- 78) The APVMA has decided to reconsider all matters covered by subsection 34(1) in relation to the reconsideration of label approvals for malathion veterinary chemical products subject to the following limitations.
- a) The environmental risk assessment was limited to the toxicity of malathion to aquatic species, pollinators and vegetation and the adequacy of instructions.
 - b) The residues and trade risk assessment was limited to the consideration of malathion maximum residue limits, dietary exposure based on the maximum residue limits and the adequacy of instructions.

Consideration of whether approved labels for veterinary chemical products meet the labelling criteria

- 79) Section 5D(1) of the Agvet Code provides that a label for containers for a chemical product 'meets the labelling criteria' if the label contains adequate instructions relating to the components set out in paragraph 42) above.
- 80) Regulation 17 of the Agvet Regulations prescribes the relevant particulars of a label approval which must be recorded in the relevant APVMA file pursuant to sections 21(a) and 21(c)(iva) of the Agvet Code
- 81) Subdivision 2.1.6 of the Agvet Regulations (incorporating regulations 18B to 18J) prescribe the conditions of approval to which labels approvals are subject.

82) Section 5D(2) of the Agvet Code provides that for the purposes of being satisfied as to whether the current approved labels for containers for malathion veterinary chemical products meet the labelling criteria, the APVMA must have regard to the criteria set out in section 5D(2). The APVMA has considered these criteria as follows:

- a) Section 5D(2)(a) of the Agvet Code – any conditions to which its approval is, or would be, subject.
 - I. The condition of approval prescribed by regulation 18E requires that if a labelling standard has not been made by the APVMA, and the product is a veterinary chemical product, then the label must comply with the requirements of the *Veterinary Labelling Code*.
 - The APVMA has reviewed the current label approvals for veterinary chemical products containing malathion and is **not satisfied** that the approved labels have adequate instruction to comply with the current *Veterinary Labelling Code*.
 - II. The APVMA is satisfied that labels approvals for malathion veterinary chemical products are compliant with all remaining conditions to which they are subject, including those prescribed by regulations 18B to 18D and 18F to 18J of the Agvet Regulations.
- b) Section 5D(2)(b) of the Agvet Code – any relevant particulars and instructions that are, or would be, entered in the relevant APVMA file for the label.
 - I. In relation to the circumstances in which the product should be used (s5D(1)(a)):
 - The APVMA is **not satisfied** that there are adequate instructions on the circumstances in which the product should be used as follows:
 - due to the toxicity of the solvent xylene, uses of the malathion product that contains the solvent xylene (37201) is not safe to be used in domestic situations.
 - use in the '*Living areas*' of cats and dogs is not an adequate area description (54285).
 - The APVMA is satisfied that all other uses listed on approved veterinary chemical products containing malathion relating to the control of various ectoparasites on cats, dogs, cattle, horses, pigs and poultry and in animal housing remain appropriate.
 - II. In relation to how the product should be used (s5D(1)(b)):
 - The APVMA is **not satisfied** that the labels of malathion veterinary products formulated as 500 g/L EC (33021 and 63456) contain adequate information on how the product should be used, as outlined in the *Malathion Final Review Technical Report*.
 - The APVMA is satisfied that the instructions in relation to how the product should be used included on the labels of all other malathion veterinary products (37201, 42267, 54285) are appropriate.
 - III. In relation to the times when the product should be used (s5D(1)(c)):
 - The APVMA is satisfied that the current labels contain sufficient instructions on the times the product should be used. The products are to be applied to control pests when they are present which is appropriate for the nature of the pests.
 - IV. In relation to the frequency of the use of the product (s5D(1)(d)).

- The APVMA is satisfied that the current labels contain sufficient instructions on the frequency with which the product should be used.
- V. In relation to the withholding period after the use of the product (s5D(1)(e)):
- The APVMA is satisfied that the current labels contain appropriate withholding periods for situations when use of the product may result in residues in livestock.
- VI. In relation to the re-entry period after the use of the product (s5D(1)(f)):
- The APVMA is **not satisfied** that the current labels include sufficient information for re-entry into treated areas or re-handling of treated animals, as detailed in the *Malathion Final Review Technical Report*.
- VII. In relation to the disposal of the product when it is no longer required (s5D(1)(g)):
- The APVMA is **not satisfied** that there are adequate instructions on the labels for disposal of product when it is no longer required, as detailed in the *Malathion Final Review Technical Report*.
- VIII. In relation to the disposal of containers for the product (s5D(1)(h)):
- The APVMA is **not satisfied** that the instructions for disposal of containers on the labels for the product are adequate, as detailed in the *Malathion Final Review Technical Report*.
- IX. In relation to the safe handling of the product and first aid in the event of an accident caused by the handling of the product (s5D(1)(i)).
- The APVMA is **not satisfied** of the current instructions for safe handling of the product on the labels remain appropriate, as outlined in *Malathion Final Review Technical Report*.
 - The APVMA is satisfied that the instructions in relation to first aid in the event of an accident included on the labels are appropriate, as outlined in the *Malathion Final Review Technical Report*.
- X. In relation to any matters prescribed by the regulations (s5D(1)(j)).
- Regulation 8AE(1)(a) of the Agvet Regulations – for a chemical product that is a veterinary chemical product, the duration of the treatment.
 - The APVMA is satisfied that the instructions related to the duration of any treatment using the veterinary products remains appropriate.
 - Regulation 8AE(1)(b) of the Agvet Regulations – the prevention of undue prejudice to trade or commerce between Australia and places outside of Australia.
 - The APVMA is satisfied that labels for veterinary products to be used on animals which may be traded between Australia and places outside Australia include sufficient information to address the risk to trade.
 - Regulation 8AE(1)(c) of the Agvet Regulations – the appropriate signal words (if any) required by the current Poisons Standard.

- The APVMA is satisfied that the labels include the appropriate signal words required by the current Poisons Standard.
 - Regulation 8AE(1)(d) of the Agvet Regulations – for a chemical product that is a date-controlled product, the storage of containers for the product.
 - Malathion veterinary chemical products are date-controlled products. The APVMA is satisfied that the instructions for the storage of containers of each product is adequate.
 - Regulation 8AE(1)(e) of the Agvet Regulations – any other matter determined by the APVMA CEO under regulation 8AE(2).
 - There are no other matters determined by the APVMA CEO under regulation 8AE(2).
- c) Section 5D(2)(c) of the Agvet Code - whether the label conforms, or would conform, to any standard made for the label under section 6E to the extent that the standard relates to matters covered by subsection (1).
- I. There is no standard made for label approvals of veterinary chemical products containing malathion under section 6E.
- d) Section 5D(2)(d) of the Agvet Code – any matters prescribed by the regulations.
- I. Regulation 17 of the Agvet Regulations prescribes relevant particulars for labels.
- The APVMA has reviewed the prescribed relevant particulars for labels as defined by regulation 17 of the Agvet Regulations.
 - The APVMA is **not satisfied** that the name of the active constituent recorded in the APVMA file remains appropriate. The Australian pesticides common name 'maldison' is not used outside Australia, nor is it used for Australian therapeutic goods. The common name 'malathion' is specified in ISO 1750-1981.
 - The APVMA is satisfied that all other relevant particulars prescribed by regulation 17 of the Agvet Regulations recorded in the APVMA file remain appropriate.
- II. The consideration of the conditions set out in subdivision 2.1.6 of the Agvet Regulations (incorporating regulations 18B to 18J) is detailed above in paragraphs 82)a)I. and 82)a)II. of this statement of reasons.
- 83) The APVMA is **not satisfied** that current approved labels for containers for malathion veterinary chemical products contain adequate instructions relating to the components set out in paragraph 42) above.
- 84) The APVMA is satisfied that, excluding the instructions contained on the label and the name of the active constituent, all other particulars that are recorded in the relevant APVMA file remain appropriate.
- 85) Having had regard to the matters and findings set out above, the APVMA is **not satisfied** that current approved labels for containers for malathion veterinary chemical products meet the labelling criteria as defined in section 5D of the Agvet Code, nor comply with any requirements prescribed by the regulations.

Consideration of whether approved labels for veterinary chemical products can be varied to meet the labelling criteria and comply with any requirement prescribed by the regulations

86) The APVMA has considered whether the labels for malathion veterinary chemical products can be varied in such a way as to meet the labelling criteria defined by section 5D(1) of the Agvet Code and comply with any requirement prescribed by the regulations as follows:

a) To address concerns identified in paragraph 82)b), when considering the matters set out in section 5D(1)(a) and 5D(2)(b) of the Agvet Code, the APVMA finds as follows:

I. In relation to the concerns identified in paragraph 82)b)i. regarding the circumstances in which the product should be used (section 5D(1)(a)):

- For the veterinary malathion product that contains xylene as a solvent (37201), the instructions have been varied to include the restraint *'NOT SUITABLE FOR DOMESTIC USE'*.
- For the veterinary malathion product that is approved for use in *'Living areas'* of cats and dogs (54285), the area description has been varied to *'Animal housing and bedding'*.

II. In relation to the concerns identified in paragraph 82)b)ii. regarding the instructions for how the product should be used (section 5D(1)(b)):

- The critical comments for the following use patterns of relevant veterinary malathion products (33021, 63456) have been varied to specify the application equipment that was supported:
 - for use on cattle and pigs – *'Apply with low pressure spray'* or *'... using low pressure spray'*
 - for use on horses – *'Apply 2 L prepared spray per horse using a trigger pump spray or sponge.'*
 - for use on cats and dogs – *'Saturate the animal using a sponge.'*
 - for use on animal bedding – *'... for spraying bedding etc. with a trigger pump spray'*
 - for use on poultry – *'Spray birds using a trigger pump spray...'*
 - for treatment of poultry animal housing – *'... with manually pressurised hand wand'*.
- The instructions for the veterinary malathion product approved for mosquito and fly control (63456) has been further varied as follows:
 - the following environmental protection statement has been added – *'Toxic to bees. DO NOT spray if bees are feeding on flowering plants.'*
 - the following restraint has been added due to the high toxicity of malathion to aquatic species – *'DO NOT apply directly to water.'*
 - the critical comment has been added to specify the application equipment that was supported – *'Apply with manually pressurised handwand.'*
 - the following critical comment has been added for the fly control use pattern to restrict the area for application to areas out of reach of children and animals, including livestock – *'DO NOT apply past the point of run off. DO NOT apply to surfaces within reach of animals and/or children.'*

- III. In relation to the concerns identified in paragraph 82)b)VI. regarding the instructions for the re-entry period after the use of the product (section 5D(1)(f)), the following restraints have been added to the labels of relevant malathion veterinary products:
- for veterinary products approved for use on companion animals (33021, 37201, 42267 54285, 63456) – *‘DO NOT allow children to handle companion animals treated with malathion for one hour after application.’*
 - for veterinary products approved for use in animals housing and bedding (33021, 37201, 42267 54285, 63456) – *‘DO NOT allow children to enter treated animal housing or handle treated animal bedding for 3 full days after application.’*
 - for veterinary products approved for use as a spray in animals housing and bedding (33021, 37201, 54285, 63456) – *‘DO NOT allow entry into treated animal housing or handle treated animal bedding until spray has dried.’*
 - for veterinary products approved for mosquito or fly control (63456) – *‘DO NOT allow entry into treated areas until spray has dried.’*
- IV. In relation to the concerns identified in paragraphs 82)b)VII. and 82)b)VIII. regarding the instructions for the disposal of the product when it is no longer required (section 5D(1)(g)) and the disposal of containers for the product (section 5D(1)(h)):
- For the disposal of the product, the labels of all veterinary products containing malathion have been varied to include the instruction *‘Dispose of unused chemical in compliance with relevant local, state or territory government regulations.’*
 - The labels of all veterinary products containing malathion have been varied to include the aquatic protection statement *‘Very toxic to aquatic life. DO NOT contaminate wetlands or watercourses with this product or used containers.’*
 - The disposal instructions on the labels of malathion veterinary products for pack sizes less than or equal to 1 L or 1 kg have been varied to *‘Dispose of container by wrapping in paper and putting in garbage.’*, unless these instructions were already included on the label.
 - The disposal instructions on the labels of malathion veterinary products for pack sizes greater than 1 L or 1 kg has been varied to *‘Triple-rinse container and dispose of rinsate in compliance with relevant local, state or territory government regulations. DO NOT dispose of undiluted chemicals on-site. If recycling, replace cap and return clean container to recycler or designated collection point. If not recycling, break, crush, or puncture container and deliver 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.’* unless these instructions were already included on the label.
- V. In relation to the concerns identified in paragraphs 82)b)IX. regarding the instructions for the safe handling of the product (section 5D(1)(i)), the safety directions for on labels of relevant malathion veterinary products have been varied as follows:
- For the veterinary malathion product formulated as EC 200 g/L or less in xylene 700 g/L or less with surfactant 100 g/L or less (37201) – *‘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 gets in eyes, wash it out immediately with water. If product gets on skin, immediately wash area with soap and water. Wash hands after use. After each day's use, wash gloves, goggles and contaminated clothing.'

- For veterinary malathion products formulated as EC 500 g/L or less in liquid hydrocarbons 500 g/L or less with surfactant 60 g/L or less (33021, 63456) – *'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 gets in eyes, wash it out immediately with water. If product gets on skin, immediately wash area with soap and water. Wash hands after use. After each day's use, wash gloves, goggles and contaminated clothing.'*
 - For the veterinary malathion product formulated as DC containing 20 g/kg malathion or less (42267) – *'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 days use wash gloves and contaminated clothing.'*
 - For the domestic use malathion products (home veterinary products) formulated as EC 200 g/L or less (54285) – *'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.'*
- b) To address concerns identified in paragraph 82)d), when considering the matters set out in Regulation 17 of the Agvet Regulations, the APVMA is satisfied that the name of the active constituent recorded in the relevant APVMA file can be varied to 'malathion'.
- c) In relation to concerns identified when considering the criteria in sections 5D(2)(a) and 5D(2)(d) of the Agvet Code related to compliance with the *Veterinary Labelling Code*, the APVMA is satisfied that label approvals listed in Attachment A will comply with the *Veterinary Labelling Code* once varied in the ways set out in paragraph 86)a) above, and in the additional ways set out below:
- I. If not already included, add the required statement '*an anticholinesterase compound*' to the constituent statement in the label approval.
 - II. The statement '*Resistance may develop to any chemical.*' can be added to the claims statement in the label approval, consistent with the requirements of the *Veterinary Labelling Code* for parasiticides excluding ectoparasiticides for cats and dogs.

- III. If not already included, the heading for environmental protections statements can be varied to *'ENVIRONMENTAL PROTECTION'*.

- 87) Section 34A(3) of the Agvet Code provides that if the variation would affect instructions for use on a label, the APVMA must not make the variation until it has consulted each co-ordinator designated for a jurisdiction and taken into account any recommendations made by the co-ordinators.
- a) The APVMA has consulted with each co-ordinator designated for a jurisdiction and taken into account any recommendations made prior to making this decision.
- 88) In accordance with section 34A(1) of the Agvet Code, the APVMA is satisfied that the relevant particulars of the label approvals for the veterinary chemical products listed in Attachment A as varied in the ways set out in paragraph 86) contain adequate instructions relating to the components set out in paragraph 45), meet the labelling criteria and comply with any requirement prescribed by the regulations.

Conclusion on consideration of the approved labels for veterinary chemical product

- 89) The APVMA is satisfied that the relevant particulars of the label approvals for containers for malathion veterinary chemical products listed in Attachment A can be varied to meet the labelling criteria and comply with any requirement prescribed by the regulations. Accordingly, the APVMA has varied the relevant particulars as set out in paragraph 86) of this statement of reasons to allow the approval of these labels for containers of veterinary chemical products to be affirmed under section 34A(1) of the Agvet Code., of this statement of reasons.

Conclusion for veterinary chemicals

- 90) For the purposes of sections 34(1) and 34A(1)) of the Agvet Code, and having regard to the matters set out above, referring to veterinary chemical products, the APVMA has determined that:
- a) Regarding malathion veterinary chemical product registrations, the APVMA is:
- I. **not satisfied** that the malathion veterinary chemical product registrations meet the safety criteria
 - II. satisfied that malathion veterinary chemical product registrations meet the efficacy criteria, trade criteria and comply with any requirements prescribed by the regulations
 - III. satisfied that the particulars and conditions of malathion veterinary chemical product registrations listed in Attachment A can be varied in such a way (as set out in paragraph 62) of the statement of reasons) to allow the chemical product registrations to be affirmed.
- b) Regarding label approvals for containers for malathion veterinary chemical products, the APVMA is:
- I. **not satisfied** that the label approvals meet the labelling criteria and comply with any requirement prescribed by the regulations.
 - II. satisfied that the particulars of label approvals for containers for malathion veterinary chemical products listed in Attachment A can be varied in such a way (as set out in paragraph 86) of the statement of reasons) to allow the label approvals to be affirmed.
- 91) Consequently, pursuant to section 34A(1) of the Agvet Code, the APVMA has:

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- a) varied the relevant particulars and conditions of the malathion veterinary chemical product registrations listed in Attachment A in a manner set out in paragraph 62) of the statement of reasons and has affirmed the registration of these products under section 34(1) of the Agvet Code
 - b) varied the relevant particulars of the label approvals for containers for malathion veterinary chemical products listed in Attachment A in the manner set out in paragraph 86) of the statement of reasons and has affirmed the approval of these labels under section 34(1) of the Agvet Code

Sample varied labels for malathion chemical products

Agricultural chemical product sample labels

Label 1: Malathion 1000 g/L emulsifiable concentrate – 62194

Signal Heading:	POISON KEEP OUT OF REACH OF CHILDREN READ SAFETY DIRECTIONS BEFORE OPENING OR USING
Product Name:	Fyfanon 1000 EC Insecticide
Constituent Statement:	1000 g/L malathion An anticholinesterase compound
Mode of Action	Group 1B Insecticide
Statement of Claims	Controls adult mosquitoes, Queensland fruit fly and chewing and sucking insect pests of citrus, grape vines, lucerne, oilseed crops, ornamentals, pastures, peas, pome and stone fruits, tobacco and vegetables as specified in the Directions for use table.
Net Contents:	5 L, 20 L
Restraints:	DO NOT apply directly to water. DO NOT use open mixing and loading systems for aerial application (use closed mixing and loading only). DO NOT use open cabs for air blast application. DO NOT use backpack ULV misters/cold foggers. DO NOT apply to melons or cucumbers when wet. SPRAY DRIFT RESTRAINTS: [See below]
Directions for Use:	[See below]
Other Limitations:	
Withholding Period:	Cereals, rice, lucerne, pastures, forage crops: DO NOT GRAZE OR CUT FOR STOCK FOOD FOR 1 DAY AFTER APPLICATION. DO NOT HARVEST FOR 1 DAY AFTER APPLICATION. Canola (rapeseed), sunflower: DO NOT GRAZE OR CUT FOR STOCK FOOD FOR 3 DAYS AFTER APPLICATION. DO NOT HARVEST FOR 3 DAYS AFTER APPLICATION. Fruit, vegetables: DO NOT HARVEST FOR 3 DAYS AFTER APPLICATION.
Trade Advice:	EXPORT TRADE ADVICE – TREATED CROPS: Treated crop commodities destined for export may require extra time between application and harvest to be accepted in some export markets. Before you use this product, you are advised to contact FMC Australasia Pty Ltd and/or your industry body about any potential trade issues and their management.
General Instructions:	Fyfanon is a contact insecticide and only partial control will be achieved if insects are protected from spray by dense foliage or if spray coverage is inadequate. All vehicles should be removed from areas to be sprayed as paintwork may be damaged. MIXING When mixing this product with water, good tank agitation must be maintained throughout the mixing and spraying operation. APPLICATION For high volume application on vegetables and row crops apply approximately 1000 litres of water/ha. For tree crops apply approximately 2000 litres of water/ha. Apply in high volume, low volume or through mister or aircraft spray equipment. Thorough uniform coverage is essential for effective insect control. This product may be diluted with diesel distillate and used through thermal fogging machines, or it can be applied undiluted by aircraft or suitable ground equipment designed for ultra-low volume application. COMPATIBILITY This product is compatible with summer spraying oil which may be added at a rate of 1.3 L/100 litres of water when recommended.
Resistance Warning:	For insecticide resistance management Fyfanon 1000 EC Insecticide is a Group 1B insecticide.

	<p>Some naturally occurring insect biotypes resistant to Fyfanon 1000 EC Insecticide and other Group 1B insecticides may exist through normal genetic variability in any insect population. The resistant individuals can eventually dominate the insect population if Fyfanon 1000 EC Insecticide or other Group 1B insecticides are used repeatedly. The effectiveness of Fyfanon 1000 EC Insecticide on resistant individuals could be significantly reduced. Since occurrence of resistant individuals is difficult to detect prior to use, FMC Australasia Pty Ltd accepts no liability for any losses that may result from the failure of Fyfanon 1000 EC Insecticide to control resistant insects.</p> <p>Fyfanon 1000 EC Insecticide may be subject to specific resistance management strategies. For further information contact your local supplier, FMC Australasia Pty Ltd representative or local agricultural department agronomist.</p>
Precautions:	<p>RE-ENTRY PERIODS:</p> <p>DO NOT allow entry into treated areas until spray has dried.</p> <p>Fruiting vegetable crops: DO NOT enter for 1 day after application for irrigation, scouting, thinning and weeding.</p> <p>Leafy vegetable crops: DO NOT enter for 1 day after application for irrigation and scouting mature plants, hand harvesting and pruning.</p> <p>Field crops (low): DO NOT enter for 2 days after application for hand-set irrigation. DO NOT enter for 1 day after application for scouting, thinning and weeding.</p> <p>Grapes: DO NOT enter for 1 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.</p> <p>Apples: DO NOT enter for 1 day after application for hand pruning, training, scouting, training, transplanting, orchard maintenance, propping and hand weeding. DO NOT enter for 8 days after application for hand harvesting. DO NOT enter for 17 days after application for thinning fruit.</p> <p>When prior entry is necessary, wear cotton overalls buttoned to the neck and wrist and a washable hat and chemical resistant gloves. Clothing must be laundered after each day's use.</p>
Protection Statements:	<p>PROTECTION OF WILDLIFE, FISH, CRUSTACEANS AND ENVIRONMENT</p> <p>Very toxic to aquatic life. DO NOT contaminate wetlands or watercourses with this product or used containers.</p> <p>PROTECTION OF HONEYBEES AND OTHER INSECT POLLINATORS</p> <p>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.</p> <p>PROTECTION OF LIVESTOCK</p> <p>DO NOT place treated grain bait for control of crickets in locations which are accessible which are accessible to domestic animals, livestock or birds. DO NOT feed treated grain to animals including poultry.</p>
Storage and Disposal:	<p>Store below 30°C (room temperature). Store in the closed, original container in a dry, cool, well-ventilated area out of direct sunlight.</p> <p>Triple-rinse containers before disposal. Add rinsings to spray tank. DO NOT dispose of undiluted chemicals on site. Dispose of any unused chemical in compliance with relevant local, state or territory government regulations. If recycling, replace cap and return clean containers to recycler or designated collection point.</p> <p>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.</p>
Safety Directions:	<p>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.</p>
First Aid Instructions:	<p>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.</p>

DIRECTIONS FOR USE:

Crop/situation	Pest	Rate	WHP	Critical comments
Bowling and golf greens	Argentine stem weevil (<i>Hyperodes bonariensis</i>)	60 mL in 50 L water/100 m ²	1 day	Lightly water grass after application.
Canola	Rutherglen bug (<i>Nysius vinitor</i>)	550 mL/ha	3 days	Apply by aircraft or ground equipment when the pest first appears and repeat as necessary. DO NOT apply more than 4 applications per season.
Citrus	Rutherglen bug (<i>Nysius vinitor</i>) Thrips	60 mL/100 L water	3 days	Apply when pests first appear. DO NOT apply more than 4 applications per season.
	Bronze orange bug (<i>Musgraveia sulciventris</i>), Citrus aphid, Citrus butterfly, Spiny lemon bug, Tree hoppers			Apply when pests first appear. DO NOT apply more than 4 applications per season
	California red scale (<i>Aonidiella aurantii</i>)	100 mL/100 L+ 1.3 L summer oil per 100 L water		For use in NSW, Vic, SA, WA and NT only. Apply November to March. Two applications, the first November to January and the second February to early March gives best results. DO NOT spray under hot conditions or when trees are under drought stress.
	Purple scale (<i>Lepidosaphes beckii</i>), soft brown scale (<i>Coccus hesperidum</i>)			For use in SA, NSW, Vic, Tas, WA and NT only. Apply November to March. Two applications, the first November to January and the second February to early March gives best results. DO NOT spray under hot conditions or when trees are under drought stress.
	Pink wax scale (<i>Ceroplastes rubens</i>)			For use in SA, NSW, Vic, Tas, WA and NT only. Apply December to early January or when crawlers are active. DO NOT apply more than 4 applications per season.
Cucurbits	Pumpkin beetle (<i>Aulacophora hiliaris</i>)	60 to 100 mL/100 L water	3 days	DO NOT apply to melons or cucumbers when wet. In later growth stages of the crop increase rate and volume of cover. DO NOT apply more than 4 applications per season.
Fruit fly lure control routine	All fruit fly species EXCLUDING Mediterranean fruit fly	500 mL/100 L water	3 days	Use only in combination with the registered rate per 100 litres of water of a suitable product containing a yeast autolysate protein lure e.g. Pinnacle or Natflav. DO NOT apply mixtures of Fyfanon with the protein Flavax. DO NOT exceed the recommended rates of Fyfanon or these proteins as phytotoxicity may occur. Some crops may be prone to phytotoxicity induced by the proteins. The risk is increased during hot dry conditions and re-application of spray to the same parts of the plant. Apply bait within 4 hours of sunrise to avoid phytotoxicity. Apply the Fyfanon yeast autolysate lure to the foliage at the rate of 50 to 100 mL per tree using a coarse spray. Use the lower volume on smaller trees. Commence application at least 6 weeks before normal ripening of the fruit and repeat at 4 to 10-day intervals while fruit remains on trees. Use the longer spray interval when spraying during colder weather when fruit flies are less active. Heavy rain will wash the bait off foliage. Shorter application intervals will be necessary during warm wet weather. Spraying the mixture onto the foliage of other fruit trees in or around the orchard will assist in control. DO NOT apply bait to grass or other foliage. Avoid contact of the bait with fruit. DO NOT add other pesticides to the Fyfanon yeast autolysate protein mixture.

Crop/situation	Pest	Rate	WHP	Critical comments
Fruit fly lure control routine (citrus only)		500 mL/100 L water or 15 to 20 L/ha		Mixing and spray timing as above. Apply as above OR at 15 to 20 L/ha total volume as a 30 cm band at skirt level of trees for area wide control. Some varieties of citrus may be susceptible to fruit damage from the spray and caution should be exercised prior to application to varieties not previously treated. As repetitive application to the same part of the tree may cause some phytotoxicity, alternate sides of the trees sprayed.
Fruit fly lure eradication only	All fruit fly species	990 mL/100 L water		Mixing as above. Apply 50 to 100 mL per tree for eradication purposes as a spot bait to every tree or every second tree in orchards in a fruit fly outbreak area. To avoid phytotoxicity bait should not be applied if the weather is excessively dry and hot. Where large fruit trees are treated it may be necessary to apply in several spots and up to 200 mL of bait per tree. Continue baiting for the period prescribed for the eradication in the Code of Practice for the Management of Queensland Fruit Fly or equivalent document (prepared for the eradication of other fruit fly species). In urban areas 8 trees per household block should be spot sprayed with 50 to 100 mL of bait. To achieve successful eradication non-fruit trees and shrubs may need to be sprayed in order to achieve at least 100 spots/ha.
Grapevines	Grape vine scale (<i>Parthenolecanium persicae</i>)	100 mL/100 L+ 1.3 L summer oil per 100 L water	3 days	For application during summer months if scale population increases. DO NOT apply more than 4 applications per season.
	Mealy bug	100 mL/100 L water		Apply when pest first appears. DO NOT apply more than 4 applications per season.
	Grapevine moth (<i>Phalaenoides glyciniae</i>)	60 mL/100 L water		
Lucerne	Black field cricket (<i>Teleogryllus commodus</i>)	Bait 125 mL/10 kg kibbled grain/ha Use clean wheat, barley or oats. DO NOT use dusty grain.	1 day	IMMATURE CRICKETS Mix in a drum or cement mixer. It is not necessary to leave treated grain standing to absorb Fyfanon as it is absorbed rapidly and can be used immediately after treatment. Prepared bait should be stored separate from stock feed and the containers clearly marked to indicate that the contents have been treated with Fyfanon 1000 EC Insecticide.
		Bait 125 to 250 mL per 10 to 20 kg kibbled grain/ha. Use clean wheat, barley or oats. DO NOT use dusty grain.		MATURE CRICKETS Mix in a drum or cement mixer. It is not necessary to leave treated grain standing to absorb Fyfanon as it is absorbed rapidly and can be used immediately after treatment. Treated grain remains active for 4 to 6 weeks. Any excess grain therefore will be available to kill moderate numbers of re-invading crickets. Higher baiting rates (20 kg/ha) should be used where populations are dense, where plentiful alternative feed exists, or when the extra expense is considered a small premium to pay for greater certainty of control. Spread late in the afternoon or evening when early in the season, and in the morning late in the season. Baiting may fail if large quantities of pasture seed are present. Prepared bait should be stored separate from stock feed and the containers clearly marked to indicate that the contents have been treated with Fyfanon 1000 EC Insecticide.

Crop/situation	Pest	Rate	WHP	Critical comments
	Black field cricket (<i>Teleogryllus commodus</i>)	Spray 700 mL in 25 to 50 L water		Apply in the evening. Pasture cover must be low so that the chemical will have direct contact with the crickets. The method may fail if cold weather keeps crickets below the ground for a day or 2, or if rain falls after application. DO NOT apply more than 4 applications per season.
	Lucerne flea (<i>Sminthurus viridis</i>)	70 to 150 mL/ha		Rates vary according to stages of growth. For low volume application use sufficient water to give adequate cover at 3 to 4-week intervals after opening rains. DO NOT apply more than 4 applications per season.
	Spotted alfalfa aphid	550 mL/ha		Apply when insect appears. Use sufficient water to give thorough coverage. DO NOT apply more than 4 applications per season.
Mosquito resting sites, breeding grounds	Adult mosquitoes	300 mL/ha	-	Apply preferably at dusk without dilution through aircraft (helicopter) using ULV spray application equipment.
		Fogging 200 to 300 mL/ha		For areas of sparse cover use the lower rate. For areas of dense cover use the higher rate. COLD FOGGERS (Leco, Beeco): Use undiluted. THERMAL FOGGERS (Pulsfog, Swingfog): Use 200 to 300 mL/10 L of diluent per hectare. Diluents: Diesel distillate or power kerosene. Dilution rate depends on machine output, speed and swath width. Consult the operator manual for further details.
Onions	Onion thrip (<i>Thrips tabaci</i>)	85 mL/100 L water	3 days	Apply at first sign of infestation. Repeat each 10 days or as necessary. DO NOT apply more than 4 applications per season.
Ornamentals (flowers and shrubs)	Aphids, azalea lace bug (<i>Stephanitis pyrioides</i>), caterpillars, thrips	60 mL/100 L water	-	Apply when pest first appears and repeat if necessary.
	Scale insects on hardy plants	100 mL/100 L+ 1.3 L summer oil per 100 L water		
Pastures (plus cereals and non-crop areas)	Black field cricket (<i>Teleogryllus commodus</i>)	Bait 125 mL/10 kg kibbled grain/ha. Use clean wheat, barley or oats. DO NOT use dusty grain.	1 day	IMMATURE CRICKETS: Mix in a drum or cement mixer. It is not necessary to leave treated grain standing to absorb Fyfanon as it is absorbed rapidly and can be used immediately after treatment. Prepared bait should be stored separate from stock feed and the containers clearly marked to indicate that the contents have been treated with Fyfanon 1000 EC Insecticide.
		Bait 125 to 250 mL per 10 to 20 kg kibbled grain/ha. Use clean wheat, barley or oats. DO NOT use dusty grain.		MATURE CRICKETS Mix in a drum or cement mixer. It is not necessary to leave treated grain standing to absorb Fyfanon as it is absorbed rapidly and can be used immediately after treatment. Treated grain remains active for 4 to 6 weeks. Any excess grain therefore will be available to kill moderate numbers of re-invading crickets. Higher baiting rates (20 kg/ha) should be used where populations are dense, where plentiful alternative feed exists, or when the extra expense is considered a small premium to pay for greater certainty of control. Spread late in the afternoon or evening when early in the season, and in the morning late in the season. Baiting may fail if large quantities of pasture seed are present. Prepared bait should be stored separate from stock feed and the containers clearly marked to indicate that the contents have been treated with Fyfanon 1000 EC Insecticide.

Crop/situation	Pest	Rate	WHP	Critical comments
		SPRAY 700 mL in 25 to 50 L water		Apply in the evening. Pasture cover must be low so that the chemical will have direct contact with the crickets. The method may fail if cold weather keeps crickets below the ground for a day or 2, or if rain falls after application. DO NOT apply more than 4 applications per season.
	Australian plague locust (<i>Chortoicetes terminifera</i>), Large hoppers	850 mL/ha		GROUND APPLICATION ONLY BOOM: Apply in 110 L water/ha MISTING: Apply in 2.5 L water/ha. Repeat application as necessary. DO NOT apply more than 4 applications per season.
		1.1 L/ha		
	Plague locust, Small hoppers	600 mL/ha		
		1.1 L/ha		
Pastures (medic)	Spotted alfalfa aphid (<i>Therioaphis trifolii</i>)	550 mL/ha	1 day	Apply when aphids appear. Use sufficient water to ensure thorough coverage. DO NOT apply more than 4 applications per season.
Field peas	Pea weevil (<i>Bruchus pisorum</i>)	625 mL/ha	3 days	Spray when first flowers begin to wither. DO NOT add water. Use undiluted through calibrated spray equipment designed for ultra-low volume application. DO NOT apply by ultra-low volume aerial application.
Pome fruit (apples and pears)	Apple leaf hopper (<i>Typhlocyba froggatti</i>), Codling moth (<i>Cydia pomonella</i>), Thrips, Woolly aphid (<i>Eriosoma lanigerum</i>)	60 mL/100 L water	3 days	Apply when pests first appear or apply every 10 to 14 days from 2 weeks after full bloom. Wet trees thoroughly. DO NOT apply more than 4 applications per season.
Rice	Rice bloodworm larvae (<i>Chironomus tepperi</i>)	300 mL/ha	1 day	Premix in at least an equal volume of water and apply the product in 10 to 30 litres of water per hectare by aircraft to rice bays at sowing time or within 24 hours of sowing or when infestations occur after the application of permanent water. DO NOT apply more than 4 applications per season.
Rice seed		Apply 300 mL to the quantity of seed required to sow one hectare.		Apply only to pregerminated rice seed prior to aerial sowing. Dilute the 300 mL of product in 750 mL to 1 litre of water. Just prior to sowing pour the diluted solution evenly over the pregerminated rice seed in the aircraft hopper or in the hopper of the aircraft loading auger. Ensure thorough mixing. DO NOT sow treated seed outside the boundaries of the flooded rice field. Treated seed must not be used for human and/or animal consumption.
Stone fruit	Black cherry aphid, Black peach aphid (<i>Brachycaudus persicae</i>), Green peach aphid (<i>Myzus persicae</i>), Oriental fruit moth (<i>Cydia molesta</i>)	60 mL/100 L water	3 days	Apply when pest first appears or apply every 10 to 14 days from blossoming. Wet trees thoroughly. DO NOT apply more than 4 applications per season.
Sunflower	Rutherglen bug (<i>Nysius vinitor</i>)	550 mL/ha	3 days	Spray at bud stage for sunflowers. Apply by aircraft or with suitable ground equipment. DO NOT apply more than 4 applications per season.
Tobacco (field, seed bed)	Small plague grasshoppers (<i>Austroicetes cruciata</i>) Vegetable weevil (<i>Listroderes obliquus</i>)	50 mL/100 L water	-	Apply when pest first appears and repeat if necessary. DO NOT apply more than 4 applications per season.
Tomatoes	Tomato russet mite (<i>Aculops lycopersici</i>)		3 days	Apply when pest first appears. Adequate coverage is essential in later growth stages of these crops and

Crop/situation	Pest	Rate	WHP	Critical comments
Vegetables (beans, cabbage, carrots, cauliflowers, celery, lettuce, tomatoes)	Aphids, Cabbage moth (<i>Plutella xylostella</i>), Cabbage white butterfly (<i>Pieris rapae</i>), Green vegetable bug (<i>Nezara viridula</i>), Jassids, Leaf hoppers, Rutherglen bug (<i>Nysius vinitor</i>), Thrips	60 to 100 mL/100 L water	3 days	rate and volume should be increased to give additional cover. DO NOT apply more than 4 applications per season.

NOT TO BE USED FOR ANY PURPOSE, OR IN ANY MANNER, CONTRARY TO THIS LABEL UNLESS AUTHORISED UNDER APPROPRIATE LEGISLATION.

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 buffer zones in the relevant buffer zone table/s below 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 1 to 2 hours before sunset and persist until 1 to 2 hours after sunrise.

Buffer zones for 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
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
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
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
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
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
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

Buffer zones for 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
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
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
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
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

Buffer zones for 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 '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 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

Buffer zones for ULV application (by Helicopter only)

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 fixed-wing aircraft' 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

Buffer zones for 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

Label 2: Malathion 1169 g/L ultra-low volume – 49539

Signal Heading:	POISON KEEP OUT OF REACH OF CHILDREN READ SAFETY DIRECTIONS BEFORE OPENING OR USING
Product Name:	Fyfanon ULV Insecticide
Constituent Statement:	1169 g/L malathion An anticholinesterase compound
Mode of Action:	Group 1B Insecticide
Statement of Claims:	An ultra-low volume formulation for the control of a wide range of insect pests in certain crops and eucalypts as shown under Directions for Use.
Net Contents:	20 L, 200 L
Restrains:	DO NOT apply directly to water. DO NOT use open mixing and loading systems for aerial application (use closed mixing and loading only). DO NOT use open cabs for air blast application. DO NOT use backpack ULV misters/cold foggers. DO NOT apply to melons or cucumbers when wet. SPRAY DRIFT RESTRAINTS [See below]
Directions for Use:	[See below]
Withholding Period:	Cereals, maize, rice, sorghum, grain legumes, linseed, lucerne, pastures, forage crops: DO NOT GRAZE OR CUT FOR STOCK FOOD FOR 1 DAY AFTER APPLICATION. DO NOT HARVEST FOR 1 DAY AFTER APPLICATION. Canola (rapeseed), safflower, sunflower: DO NOT GRAZE OR CUT FOR STOCK FOOD FOR 3 DAYS AFTER APPLICATION. DO NOT HARVEST FOR 3 DAYS AFTER APPLICATION. Fruit, vegetable: DO NOT HARVEST FOR 3 DAYS AFTER APPLICATION.
Trade Advice:	EXPORT TRADE ADVICE – TREATED CROPS: Treated crop commodities destined for export may require extra time between application and harvest to be accepted in some export markets. Before you use this product, you are advised to contact FMC Australasia Pty Ltd and/or your industry body about any potential trade issues and their management.
General Instructions:	Fyfanon is a contact insecticide and only partial control will be achieved if insects are protected from spray by dense foliage or if spray coverage is inadequate. All vehicles should be removed from areas to be sprayed as paintwork may be damaged. MIXING Fyfanon should be used undiluted except when fogging. When fogging for mosquito control, dilute with a kerosene/diesel distillate mixture of 1 L:8 L respectively. APPLICATION Apply by aircraft or mist spray using properly calibrated equipment designed for ultra-low volume application.
Resistance Warning:	For insecticide resistance management Fyfanon ULV Insecticide is a Group 1B insecticide. Some naturally occurring insect biotypes resistant to Fyfanon ULV Insecticide and other Group 1B insecticides may exist through normal genetic variability in any insect population. The resistant individuals can eventually dominate the insect population if Fyfanon ULV Insecticide or other Group 1B insecticides are used repeatedly. The effectiveness of Fyfanon ULV Insecticide on resistant individuals could be significantly reduced. Since occurrence of resistant individuals is difficult to detect prior to use, FMC Australasia Pty Ltd accepts no liability for any losses that may result from the failure of Fyfanon ULV Insecticide to control resistant insects. Fyfanon ULV Insecticide may be subject to specific resistance management strategies. For further information contact your local supplier, FMC Australasia Pty Ltd representative or local agricultural department agronomist.
Precautions:	Avoid contact with food, food utensils, or places where food is prepared or stored. RE-ENTRY PERIODS: DO NOT allow entry into treated areas until spray has dried. Fruiting vegetable crops: DO NOT enter for 1 day after application for irrigation, scouting, thinning and weeding. Leafy vegetable crops: DO NOT enter for 1 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 1 day after application for scouting, thinning and weeding.

	<p>Apples: DO NOT enter for 1 day after application for hand pruning, training, scouting, training, transplanting, orchard maintenance, propping and hand weeding. DO NOT enter for 8 days after application for hand harvesting. DO NOT enter for 17 days after application for thinning fruit.</p> <p>When prior entry is necessary, wear cotton overalls buttoned to the neck and wrist and a washable hat and chemical resistant gloves. Clothing must be laundered after each day's use.</p>
Protection Statements:	<p>PROTECTION OF WILDLIFE, FISH, CRUSTACEANS AND ENVIRONMENT</p> <p>Very toxic to aquatic life. DO NOT contaminate wetlands or watercourses with this product or used containers.</p> <p>PROTECTION OF HONEYBEES AND OTHER INSECT POLLINATORS</p> <p>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, 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.</p> <p>PROTECTION OF LIVESTOCK</p> <p>DO NOT place treated grain bait for control of crickets in locations which are accessible which are accessible to domestic animals, livestock or birds. DO NOT feed treated grain to animals including poultry.</p>
Storage and Disposal:	<p>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.</p> <p>Triple-rinse containers before disposal. Add rinsing's to spray tank. DO NOT dispose of undiluted chemicals on site. Dispose of any unused chemical in compliance with relevant local, state or territory government regulations. 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.</p>
Safety Directions:	<p>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 glove, face shields and contaminated clothing.</p>
First Aid Instructions:	<p>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.</p>

DIRECTIONS FOR USE:

Crop/situation	Pest	Rate	WHP	Critical comments
Cereal crops, pastures, pasture seed crops	Black Field Cricket	450 mL	1 day	Apply in the early morning when crickets are active or swarming. DO NOT apply more than 4 applications per season.
	Small Plague Grasshopper			Apply to infested areas. DO NOT apply more than 4 applications per season.
Cereals, pastures, non-crop areas	Black Field Cricket	Bait 110 mL/10 kg whole or kibbled grain/ha (Use clean wheat, barley or oats, not dusty grain)		Immature crickets: Mix in a drum or cement mixer. As treated grain absorbs Fyfanon rapidly, it is unnecessary to leave standing and grain can be used immediately. Prepared bait should be stored separate from stock feed and the containers clearly marked to indicate that the contents have been treated with Fyfanon ULV Insecticide.
		Bait 110 to 220 mL/10 to 20 kg whole or kibbled grain/ha (use clean wheat, barley or oats, not dusty grain)		Mature crickets: Mix in a drum or cement mixer. As treated grain absorbs Fyfanon rapidly, it is unnecessary to leave standing and grain can be used immediately. Excess grain will kill moderate numbers of re-invading crickets as treated grain remains active for 4 to 6 weeks. Use higher rate for heavy pest pressure, where plentiful alternative feed exists, or for certainty of control. Spread in late afternoon and evening early in the season, and morning late in the season. Baiting may be ineffective if large amounts of pasture seed are present. Prepared bait should be stored separate from stock feed and the containers clearly marked to indicate that the contents have been treated with Fyfanon ULV Insecticide.
Cereal crops, lucerne, pastures, pasture seed crops, grain, legume crops	Redlegged earth mite, Lucerne flea	225 mL		Apply after hatching, usually 3 to 4 weeks after opening rains. DO NOT apply more than 4 applications per season.
		275 mL		
Cereal crops, maize, pastures, pasture seed crops, rice, sorghum	Common armyworm	700 mL		Spray entire crop or pasture when infestation is widespread. Spray along the front when pests are moving as an army. DO NOT apply by ultra-low volume aerial application.
Crucifers, cucurbits, canola (rapeseed), safflower, sunflower	Rutherglen bug	450 to 900 mL	3 days	DO NOT apply to melons or cucumbers when wet. Use higher rate when plant growth is dense. Sunflowers: spray at bud stage. DO NOT apply more than 4 applications per season. DO NOT apply by ultra-low volume aerial application.
Linseed	Common armyworm	700 mL	1 day	Apply when armyworms are actively feeding, in the early morning or late afternoon. DO NOT apply by ultra-low volume aerial application.
Lucerne, pastures, pasture seed crops	Bluegreen aphid, Spotted aphid	450 mL	1 day	Apply at first sign of pest. Repeat as necessary. DO NOT apply more than 4 applications per season
	Wingless grasshopper			Apply to infested areas. To prevent re-invasion, spray a wide protective barrier around crop or pasture. DO NOT apply more than 4 applications per season
Maize, pasture, pasture seed crops, sorghum	Australian plague locust	700 mL		Apply in hopper bands directly onto locusts. DO NOT apply by ultra-low volume aerial application
Peaches	Oriental fruit moth	900 mL	3 days	Apply before trees are in full leaf at first sign of pest and repeat at signs of further moth flights.

Crop/situation	Pest	Rate	WHP	Critical comments
Field peas	Pea weevil	550 mL		Apply when first flowers begin to wither. DO NOT apply by ultra-low volume aerial application.
Pome fruit, stone fruit	Wingless grasshopper	450 mL		Apply to infested areas. DO NOT apply more than 4 applications per season
		560 mL		
Sorghum	Sorghum midge	450 mL	1 day	Apply at the flowering stage when adult pest numbers indicate likely damage. Repeat as necessary. DO NOT apply more than 4 applications per season.
	Rutherglen bug	450 to 900 mL		Use higher rate when plant growth is dense. DO NOT apply by ultra-low volume aerial application
Stone fruit			3 days	Use higher rate when tree growth is dense.
Eucalyptus forests	Phasmatid nymphs	450 mL	-	Apply at first sign of pest. Repeat as necessary. DO NOT apply more than 4 applications per season.
Mosquito breeding areas	Adult mosquitoes	280 mL		Apply when adults emerge. Repeat as necessary. When fogging, dissolve product in a suitable diluent. Dilution rate is dependent on output speed over ground and swath width of fogger (refer to General Instructions).

NOT TO BE USED FOR ANY PURPOSE, OR IN ANY MANNER, CONTRARY TO THIS LABEL UNLESS AUTHORISED UNDER APPROPRIATE LEGISLATION

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 buffer zones in the relevant buffer zone table/s below 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 1 to 2 hours before sunset and persist until 1 to 2 hours after sunrise.

Buffer zones for ULV application by fixed wing aircraft

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

- 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 (see 'Mandatory buffer zones' section of the table titled 'Buffer zones for ULV application by fixed-wing aircraft') are observed.

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

Buffer zones for misting or ULV (ground application only)

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

- 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

Label 3: Malathion 20 g/kg dustable powder – 50110

Signal Heading:	KEEP OUT OF REACH OF CHILDREN READ SAFETY DIRECTIONS BEFORE OPENING OR USING																	
Product Name:	David Grays Malathion Grain Dust Insecticide																	
Constituent Statement:	20 g/kg malathion An anticholinesterase compound																	
Mode of Action:	Group	1B	Insecticide															
Statement of Claims:	To control pests of stored grain																	
Net Contents:	15 kg																	
Restrains:																		
Directions for Use:	<div><div><div>DIRECTIONS FOR USE:</div><table><tr><th>Crop/ Situation</th><th>Pest</th><th>State</th><th>Rate</th><th>WHP</th><th>Critical Comments</th></tr><tr><td>Stored cereal grain</td><td>Stored grain insect pests (except Lesser grain borer) including: Indian meal moth, Rice weevil, Rust-red flour beetle, Saw-toothed grain beetle, Tropical warehouse moth</td><td>WA only</td><td>600 g / 1000 kg grain</td><td>Malathion level 8 ppm or 90 days</td><td>Mix evenly through grain.</td></tr></table></div><div>NOT TO BE USED FOR ANY PURPOSE, OR IN ANY MANNER, CONTRARY TO THIS LABEL UNLESS AUTHORISED UNDER APPROPRIATE LEGISLATION.</div></div>						Crop/ Situation	Pest	State	Rate	WHP	Critical Comments	Stored cereal grain	Stored grain insect pests (except Lesser grain borer) including: Indian meal moth, Rice weevil, Rust-red flour beetle, Saw-toothed grain beetle, Tropical warehouse moth	WA only	600 g / 1000 kg grain	Malathion level 8 ppm or 90 days	Mix evenly through grain.
Crop/ Situation	Pest	State	Rate	WHP	Critical Comments													
Stored cereal grain	Stored grain insect pests (except Lesser grain borer) including: Indian meal moth, Rice weevil, Rust-red flour beetle, Saw-toothed grain beetle, Tropical warehouse moth	WA only	600 g / 1000 kg grain	Malathion level 8 ppm or 90 days	Mix evenly through grain.													
Other Limitations:																		
Withholding Period:	Hold grain in store and DO NOT use for processing into food for human consumption or stock food until the malathion level has declined to 8 ppm or within 90 days after treatment.																	
Trade Advice:	EXPORT OF TREATED PRODUCE: Treated crop commodities destined for export may require extra time between application and harvest to be accepted in some export markets. Before you use this product, you are advised to contact David Gray Pty Ltd and/or your industry body about any potential trade issues and their management.																	
General Instructions:	For best results treat grain as near as possible to final storage in clean silos or sheds. Storage temperature should be less than 27 °C and the moisture content of the grain at treatment should be below 12%.																	
Resistance Warning:	For insecticide resistance management David Grays Malathion Grain Dust Insecticide is a Group 1B insecticide. Some naturally occurring insect biotypes resistant to David Grays Malathion Grain Dust Insecticide and other Group 1B insecticides may exist through normal genetic variability in any insect population. The resistant individuals can eventually dominate the insect population if David Grays Malathion Grain Dust Insecticide or other Group 1B insecticides are used repeatedly. The effectiveness of David Grays Malathion Grain Dust Insecticide on resistant individuals could be significantly reduced. Since the occurrence of resistant individuals is difficult to detect prior to use, David Gray Pty Ltd accepts no liability for any losses that may result from the failure of David Grays Malathion Grain Dust Insecticide to control resistant insects. David Grays Malathion Grain Dust Insecticide may be subject to specific resistance management strategies. For further information contact your local supplier, David Gray Pty Ltd representative or local agricultural department agronomist.																	
Precautions:																		
Protection Statements:	PROTECTION OF WILDLIFE, FISH, CRUSTACEANS AND ENVIRONMENT Very toxic to aquatic life. DO NOT contaminate wetlands or watercourses with this product or used containers. PROTECTION OF HONEYBEES AND OTHER INSECT POLLINATORS Toxic to bees. However, the use of this product as directed is not expected to have adverse effects on bees.																	
Storage and Disposal:	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. Keep away from foodstuff. Triple-rinse containers before disposal. Dispose of any unused chemical in compliance with relevant local, state or territory government regulations. 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.
Safety Directions:	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.
First Aid Instructions:	If poisoning occurs, contact a doctor or Poisons Information Centre. Phone Australia 13 11 26, New Zealand 0800 764 766.

Label 4a: Malathion fruit fly bait – 42727

Signal Heading:	POISON KEEP OUT OF REACH OF CHILDREN READ SAFETY DIRECTIONS BEFORE OPENING OR USING								
Product Name:	Q Fly Wick								
Constituent Statement:	1.0 mL/wick 4-(p-Acetoxyphenyl)-2-butanone, 0.43 mL/wick Malathion* OR 674 g/kg 4-(p-Acetoxyphenyl)-2-butanone, 306 g/kg Malathion* *An anticholinesterase compound								
Mode of Action:	Group 1B Insecticide								
Statement of Claims:	An attractant for the male Queensland fruit fly <i>Bactrocera (Dacus) tryoni</i> containing an insecticide.								
Net Contents:	2 g, 100 g (50 × 2g), 400 g (200 × 2 g)								
Restraints:									
Directions for Use:	<p>(2 g pack)</p> <p>DIRECTIONS FOR USE</p> <ol style="list-style-type: none"> 1. Push hook through hole in trap lid and into wick holder. 2. Hang in tree at head height. 3. Empty trap and record fly numbers weekly. <p>IMPORTANT: Q Fly Wicks are a monitoring tool only and should be used in conjunction with a routine baiting program or cover sprays (or a combination of both) to effect control of Queensland Fruit Fly. Regular monitoring of the crop for egg-laying activity by female flies should be employed in addition to the use of Q Fly Wicks.</p> <p>Hang trap containing Q Fly Wick within foliage of the host crop plant. Traps may be placed around the orchard perimeter to indicate source direction of flies entering the orchard. 1 or 2 traps in the centre of the orchard can be used to indicate the efficacy of the control program.</p> <p>Q Fly Wicks will attract male flies from up to 400 metres. Trap catches will vary depending on local sources of infestation and fruit fly population dynamics at the time. Local experience will help to determine the significance of trap catches.</p> <p>Q Fly Wicks should be replaced after 3 months.</p> <p>NOT TO BE USED FOR ANY PURPOSE, OR IN ANY MANNER, CONTRARY TO THIS LABEL UNLESS AUTHORISED UNDER APPROPRIATE LEGISLATION.</p> <p>(100 g and 400 g packs)</p> <p>DIRECTIONS FOR USE</p> <ol style="list-style-type: none"> 1. Insert hook. 2. Hang in tree at head height within the crop canopy. <p>This new fruit fly control method aims to reduce male fruit fly numbers as part of an area-wide strategy. Best results will be achieved if all the orchards in the area are using Q Fly Wicks.</p> <p>Q Fly Wicks will help reduce fruit fly pressure by targeting male flies in the population.</p> <p>Q Fly Wicks do not control female flies and it is important that protein baiting continues as usual. It is also a good idea to retain complete fruit fly traps for monitoring purposes, although counts will be reduced when Q Fly Wicks are used.</p> <p>Q Fly Wicks should be put out at 20 per hectare in the following situations:</p> <ul style="list-style-type: none"> • where the area to be covered is less than 50 Ha • in high-risk crops such as stone fruits and grapes • in early season susceptible crops (e.g. imperial mandarins) during warm weather. <p>In most other situations, 10 Q Fly Wicks per Ha will be sufficient. Q Fly Wicks keep indefinitely if refrigerated and are fully effective for 3 months once placed in the field.</p> <p>It is recommended that Q Fly Wicks be placed in the orchard 3 times per year. The wicks will hang in the orchard for 1 year. They are supplied in 3 colours and should be released as follows:</p> <table border="1"> <thead> <tr> <th>Colour</th><th>Time of the year</th></tr> </thead> <tbody> <tr> <td>Orange</td><td>August/September</td></tr> <tr> <td>Yellow</td><td>November/December</td></tr> <tr> <td>Pink</td><td>February/March</td></tr> </tbody> </table> <p>NOT TO BE USED FOR ANY PURPOSE, OR IN ANY MANNER, CONTRARY TO THIS LABEL UNLESS AUTHORISED UNDER APPROPRIATE LEGISLATION.</p>	Colour	Time of the year	Orange	August/September	Yellow	November/December	Pink	February/March
Colour	Time of the year								
Orange	August/September								
Yellow	November/December								
Pink	February/March								

Other Limitations:	
Withholding Period:	
Trade Advice:	
General Instructions:	
Resistance Warning:	<p>For insecticide resistance management Q Fly Wick is a Group 1B insecticide.</p> <p>Some naturally occurring insect biotypes resistant to Q Fly Wick and other Group 1B insecticides may exist through normal genetic variability in any insect population. The resistant individuals can eventually dominate the insect population if Q Fly Wick or other Group 1B insecticides are used repeatedly. The effectiveness of Q Fly Wick on resistant individuals could be significantly reduced. Since occurrence of resistant individuals is difficult to detect prior to use, Bugs for Bugs Pty Ltd accepts no liability for any losses that may result from the failure of Q Fly Wick to control resistant insects.</p> <p>Q Fly Wick may be subject to specific resistance management strategies. For further information contact your local supplier, Bugs for Bugs Pty Ltd representative or local agricultural department agronomist.</p>
Precautions:	
Protection Statements:	<p>PROTECTION OF WILDLIFE, FISH, CRUSTACEANS AND ENVIRONMENT</p> <p>Very toxic to aquatic life. DO NOT contaminate wetlands or watercourses with this product or used containers.</p> <p>PROTECTION OF HONEYBEES AND OTHER INSECT POLLINATORS</p> <p>Toxic to bees. However, the use of this product as directed is not expected to have adverse effects on bees.</p>
Storage and Disposal:	<p>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.</p> <p>Triple-rinse containers before disposal. Dispose of any unused chemical in compliance with relevant local, state or territory government regulations.</p> <p>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.</p>
Safety Directions:	<p>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</p>
First Aid Instructions:	<p>If poisoning occurs, contact a doctor or Poisons Information Centre. Phone Australia 13 11 26, New Zealand 0800 764 766.</p>

Label 4b: Malathion fruit fly bait – 50589

Signal Heading:	POISON KEEP OUT OF REACH OF CHILDREN READ SAFETY DIRECTIONS BEFORE OPENING OR USING
Product Name:	Searles Fruit Fly Wick Attractant and Insecticide
Constituent Statement:	781 g/kg 4-(p-Acetoxyphenyl)-2-butanone, 205 g/kg Malathion*, OR 0.2 g/wick 4-(p-Acetoxyphenyl)-2-butanone, 0.06 g/wick malathion* *An anticholinesterase compound
Mode of Action:	GROUP 1B Insecticide
Statement of Claims:	An attractant for the male Queensland fruit fly <i>Bactrocera (Dacus) tryoni</i> containing an insecticide.
Net Contents:	1 g
Restraints:	
Directions for Use:	DIRECTIONS FOR USE: Place Searles Fruit Fly Wick into a trap and place into the foliage of the plant you wish to monitor. Male fruit flies will be attracted from up to 500 metres away. Replace Searles Fruit Fly Wick every 3 months or when efficacy is reduced. To determine the source direction of male fruit flies, deploy traps around the perimeter of the orchard. To determine the efficacy of the control program, plant 1 or 2 traps in the centre of the orchard. IMPORTANT: Searles Fruit Fly Wicks should only be used as a monitoring tool and should be used in conjunction with routine spraying program for effective control. Remember to also monitor egg-laying female activity within the crop in addition to the use of Searles Fruit Fly Wicks. NOT TO BE USED FOR ANY PURPOSE, OR IN ANY MANNER, CONTRARY TO THIS LABEL UNLESS AUTHORISED UNDER APPROPRIATE LEGISLATION.
Other Limitations:	
Withholding Period:	
Trade Advice:	
General Instructions:	
Resistance Warning:	For insecticide resistance management Searles Fruit Fly Wick Attractant and Insecticide is a Group 1B insecticide. Some naturally occurring insect biotypes resistant to Searles Fruit Fly Wick Attractant and Insecticide and other Group 1B insecticides may exist through normal genetic variability in any insect population. The resistant individuals can eventually dominate the insect population if Searles Fruit Fly Wick Attractant and Insecticide or other Group 1B insecticides are used repeatedly. The effectiveness of Searles Fruit Fly Wick Attractant and Insecticide on resistant individuals could be significantly reduced. Since occurrence of resistant individuals is difficult to detect prior to use, JC & AT Searle Pty Ltd accepts no liability for any losses that may result from the failure of Searles Fruit Fly Wick Attractant and Insecticide to control resistant insects. Searles Fruit Fly Wick Attractant and Insecticide may be subject to specific resistance management strategies. For further information contact your local supplier, JC & AT Searle Pty Ltd representative or local agricultural department agronomist.
Precautions:	
Protection Statements:	PROTECTION OF WILDLIFE, FISH, CRUSTACEANS AND ENVIRONMENT Very toxic to aquatic life. DO NOT contaminate wetlands or watercourses with this product or used containers. PROTECTION OF HONEYBEES AND OTHER INSECT POLLINATORS Toxic to bees. However, the use of this product as directed is not expected to have adverse effects on bees.
Storage and Disposal:	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. Triple-rinse containers before disposal. Dispose of any unused chemical in compliance with relevant local, state or territory government regulations. 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.
Safety Directions:	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
First Aid Instructions:	If poisoning occurs, contact a doctor or Poisons Information Centre. Phone Australia 13 11 26, New Zealand 0800 764 766.

Label 4c: Malathion fruit fly bait – 63032

Signal Heading:	POISON KEEP OUT OF REACH OF CHILDREN READ SAFETY DIRECTIONS BEFORE OPENING OR USING
Product Name:	Eco-Lure Male Qld Fruit Fly Wick
Constituent Statement:	674 g/kg 4-(p-Acetoxyphenyl)-2-butanone, 306 g/kg Malathion*, OR 1.0 mL/wick 4-(p-Acetoxyphenyl)-2-butanone, 0.5 mL/wick malathion* *An anticholinesterase compound
Mode of Action:	GROUP 1B Insecticide
Statement of Claims:	An attractant for the male Queensland fruit fly <i>Bactrocera (Dacus) tryoni</i> containing an insecticide.
Net Contents:	1 g
Restraints:	
Directions for Use:	<p>DIRECTIONS FOR USE</p> <ol style="list-style-type: none"> 1. Push hook through hole in trap lid and into wick holder 2. Hang in tree at head height. 3. Empty trap and record fly numbers weekly. <p>Hang the eco-lure trap containing the eco-lure wick within foliage of the host crop plant. Traps may be placed around the orchard perimeter to indicate source direction of flies entering the orchard. 1 or 2 traps in the centre of the orchard can be used to indicate the efficacy of the control program.</p> <p>The wicks will attract male flies from up to 400 metres. Eco-lure Trap catches will vary depending on local sources of infestation and fruit fly population dynamics at the time. Local experience will help to determine the significance of trap catches. eco-lure wicks should be replaced after 3 months.</p> <p>IMPORTANT: eco-lure wicks are a monitoring tool only and should be used in conjunction with a routine baiting program or cover sprays (or a combination of both) to effect control of Queensland Fruit Fly.</p> <p>Regular monitoring of the crop for egg-laying activity by female flies should be employed in addition to the use of eco-lure wicks.</p> <p>NOT TO BE USED FOR ANY PURPOSE, OR IN ANY MANNER, CONTRARY TO THIS LABEL UNLESS AUTHORISED UNDER APPROPRIATE LEGISLATION.</p>
Other Limitations:	
Withholding Period:	
Trade Advice:	
General Instructions:	
Resistance Warning:	<p>For insecticide resistance management Eco-Lure Male Qld Fruit Fly Wick is a Group 1B insecticide.</p> <p>Some naturally occurring insect biotypes resistant to Eco-Lure Male QLD Fruit Fly Wick and other Group 1B insecticides may exist through normal genetic variability in any insect population. The resistant individuals can eventually dominate the insect population if Eco-Lure Male Qld Fruit Fly Wick or other Group 1B insecticides are used repeatedly. The effectiveness of Eco-Lure Male Qld Fruit Fly Wick on resistant individuals could be significantly reduced. Since occurrence of resistant individuals is difficult to detect prior to use, Duluxgroup (Australia) Pty Ltd accepts no liability for any losses that may result from the failure of Eco-Lure Male Qld Fruit Fly Wick to control resistant insects.</p> <p>Eco-Lure Male Qld Fruit Fly Wick may be subject to specific resistance management strategies. For further information contact your local supplier, Duluxgroup (Australia) Pty Ltd representative or local agricultural department agronomist.</p>
Precautions:	
Protection Statements:	<p>PROTECTION OF WILDLIFE, FISH, CRUSTACEANS AND ENVIRONMENT</p> <p>Very toxic to aquatic life. DO NOT contaminate wetlands or watercourses with this product or used containers.</p> <p>PROTECTION OF HONEYBEES AND OTHER INSECT POLLINATORS</p> <p>Toxic to bees. However, the use of this product as directed is not expected to have adverse effects on bees.</p>

Storage and Disposal:	<p>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.</p> <p>Triple-rinse containers before disposal. Dispose of any unused chemical in compliance with relevant local, state or territory government regulations.</p> <p>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.</p>
Safety Directions:	<p>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</p>
First Aid Instructions:	<p>If poisoning occurs, contact a doctor or Poisons Information Centre. Phone Australia 13 11 26, New Zealand 0800 764 766.</p>

Label 5: Malathion 320 g/L oil-in-water emulsion – 69529

Signal Heading:	POISON KEEP OUT OF REACH OF CHILDREN READ SAFETY DIRECTIONS BEFORE OPENING OR USING			
Product Name:	Fyfanon Premium Insecticide			
Constituent Statement:	320 g/L malathion An anticholinesterase compound			
Mode of Action:	GROUP	1B	Insecticide	
Statement of Claims:	For the control of certain insect pests in apples as per the Directions for Use.			
Net Contents:	1 to 1000 L			
Restraints:	DO NOT apply by aerial application. DO NOT apply by air blast application. DO NOT apply using spraying equipment carried on the back of the user. DO NOT apply by low pressure hand wand. See 'SPRAY DRIFT RESTRAINTS' sections.			
Directions for Use:	Crop	Pest	Rate mL/100 L	Critical Comments
	Apples	Apple leaf hopper, Thrips, Woolly aphid	350	Apply a maximum of 3 sprays per crop with a minimum interval of 14 days between applications. Apply at first sign of pest.
		Codling moth	350 – 450	Apply a maximum of 3 sprays per crop with a minimum interval of 14 days between applications. Apply at first sign of pest. Use higher rates as dictated by pest populations.
		European red mite	350	Apply a maximum of 3 sprays per crop with a minimum interval of 14 days between applications. Apply at first sign of pest
		Red spider mite		
NOT TO BE USED FOR ANY PURPOSE, OR IN ANY MANNER, CONTRARY TO THIS LABEL UNLESS AUTHORISED UNDER APPROPRIATE LEGISLATION.				
Other Limitations:				
Withholding Period:	APPLES: DO NOT HARVEST FOR 14 DAYS AFTER APPLICATION.			
Trade Advice:	EXPORT TRADE ADVICE – TREATED CROPS: Treated crop commodities destined for export may require extra time between application and harvest to be accepted in some export markets. Before you use this product, you are advised to contact FMC Australasia Pty Ltd and/or your industry body about any potential trade issues and their management.			
General Instructions:	MIXING/APPLICATION DILUTE SPRAYING Use a sprayer designed to apply high volumes of water up to the point of runoff and matched to the crop being sprayed. Set up and operate the sprayer to achieve even coverage throughout the crop canopy. Apply sufficient water to cover the crop to the point of run-off. Avoid excessive run-off. The required water volume may be determined by applying different test volumes, using different settings on the sprayer, from industry guidelines or expert advice. Add the amount of product specified in the Directions for Use table for each 100 L of water. Spray to the point of run-off. The required dilute spray volume will change unless otherwise specified and the sprayer set up and operation may also need to be changed, as the crop grows. CONCENTRATE SPRAYING (a) Use a sprayer designed and set up for concentrate spraying (that is a sprayer which applies water volumes less than those required to reach the point of run- off) and matched to the crop being sprayed. (b) Set up and operate the sprayer to achieve even coverage throughout the crop canopy using your chosen water volume.			

	<p>(c) Determine an appropriate dilute spray volume (See <i>Dilute spraying</i> above) for the crop canopy. This is needed to calculate the concentrate mixing rate.</p> <p>(d) The mixing rate for concentrate spraying can then be calculated in the following way: EXAMPLE ONLY</p> <p>(i) Dilute spray volume as determined above: For example, 1500 L/ha</p> <p>(ii) Your chosen concentrate spray volume: For example, 500 L/ha</p> <p>(iii) The concentration factor in this example is: $3 \times$ (i.e. $1500 \text{ L} \div 500 \text{ L} = 3$)</p> <p>(iv) If the dilute label rate is 10 mL/100 L, then the concentrate rate becomes 3×10, that is 30 mL/100 L of concentrate spray</p> <p>(e) The chosen spray volume, amount of product per 100 L of water, and the sprayer set up and operation may need to be changed as the crop grows.</p> <p>(g) For further information on concentrate spraying, users are advised to consult relevant industry guidelines, undertake appropriate competency training and follow industry Best Practices.</p> <p>MIXING</p> <p>Add the recommended quantity of this product to the required volume of water, mix thoroughly.</p>
Resistance Warning:	<p>For insecticide resistance management Fyfanon Premium Insecticide is a Group 1B insecticide. Some naturally occurring insect biotypes resistant to Fyfanon Premium Insecticide and other Group 1B insecticides may exist through normal genetic variability in any insect population. The resistant individuals can eventually dominate the insect population if Fyfanon Premium Insecticide or other Group 1B insecticides are used repeatedly. The effectiveness of Fyfanon Premium Insecticide on resistant individuals could be significantly reduced. Since occurrence of resistant individuals is difficult to detect prior to use, FMC Australasia Pty Ltd accepts no liability for any losses that may result from the failure of Fyfanon Premium Insecticide to control resistant insects.</p> <p>Fyfanon Premium Insecticide may be subject to specific resistance management strategies. For further information contact your local supplier, FMC Australasia Pty Ltd representative or local agricultural department agronomist.</p>
Precautions:	<p>Avoid contact with food, food utensils, or places where food is prepared or stored.</p> <p>RE-ENTRY PERIOD:</p> <p>DO NOT allow entry into treated areas until spray has dried.</p> <p>DO NOT enter for 1 day after application for hand pruning, training, scouting, training, transplanting, orchard maintenance, propping and hand weeding.</p> <p>DO NOT enter for 14 days after application for hand harvesting.</p> <p>DO NOT enter for 17 days after application for thinning fruit.</p> <p>When prior entry is necessary, wear cotton overalls buttoned to the neck and wrist and a washable hat and chemical resistant gloves. Clothing must be laundered after each day's use.</p>
Protection Statements:	<p>PROTECTION OF WILDLIFE, FISH, CRUSTACEANS AND ENVIRONMENT</p> <p>Very toxic to aquatic life. DO NOT contaminate wetlands or watercourses with this product or used containers.</p> <p>PROTECTION OF HONEYBEES AND OTHER INSECT POLLINATORS</p> <p>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.</p>
Storage and Disposal:	<p>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.</p> <p>Triple-rinse containers before disposal. Add rinsings to spray tank. DO NOT dispose of undiluted chemicals on site. Dispose of any unused chemical in compliance with relevant local, state or territory government regulations. 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.</p>
Safety Directions:	<p>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.</p>

First Aid Instructions:	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.
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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 buffer zones in the relevant buffer zone table/s 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 1 to 2 hours before sunset and persist until 1 to 2 hours after sunrise.

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 '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	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

Level 6: Malathion 440 g/L oil-in-water emulsion – 51150

Signal Heading:	POISON KEEP OUT OF REACH OF CHILDREN READ SAFETY DIRECTIONS BEFORE OPENING OR USING
Product Name:	Fyfanon 440 EW Insecticide
Constituent Statement:	440 g/L malathion An anticholinesterase compound
Mode of Action:	GROUP 1B Insecticide
Statement of Claims:	For the control of a wide range of insect pests in certain crops, eucalypts and wildflowers as shown under Directions for use
Net Contents:	1 to 1000 L
Restraints:	DO NOT apply directly to water. DO NOT use open mixing and loading systems for aerial application (use closed mixing and loading only). DO NOT use open cabs for air blast application. DO NOT use backpack ULV misters/ cold foggers. SPRAY DRIFT RESTRAINTS [See below].
Directions for Use:	[See below]
Other Limitations:	
Withholding Period:	Cereal crops, rice, lucerne, pasture: DO NOT GRAZE OR CUT FOR STOCK FOOD FOR 1 DAY AFTER APPLICATION. DO NOT HARVEST FOR 1 DAY AFTER APPLICATION. Canola (rapeseed): DO NOT GRAZE OR CUT FOR STOCK FOOD FOR 3 DAYS AFTER APPLICATION. DO NOT HARVEST FOR 3 DAYS AFTER APPLICATION. Fruit and vegetables except cucumbers: DO NOT HARVEST FOR 3 DAYS AFTER APPLICATION Cucumbers: DO NOT HARVEST FOR 1 DAY AFTER APPLICATION Stored cereal grain - 12 ppm: HOLD GRAIN IN STORE AND DO NOT USE FOR PROCESSING INTO FOOD FOR HUMAN CONSUMPTION OR STOCK FOOD UNTIL THE MALATHION LEVEL HAS DECLINED TO 8 ppm OR WITHIN 90 DAYS AFTER TREATMENT
Trade Advice:	EXPORT OF TREATED PRODUCE: Treated crop commodities destined for export may require extra time between application and harvest to be accepted in some export markets. Before you use this product, you are advised to contact FMC Australasia Pty Ltd and/or your industry body about any potential trade issues and their management.
General Instructions:	GENERAL INSTRUCTIONS MIXING/APPLICATION Add the recommended quantity of this product to the required volume of water, mix thoroughly. DILUTE SPRAYING (tree and vine crops only) Use a sprayer designed to apply high volumes of water up to the point of runoff and matched to the crop being sprayed. Set up and operate the sprayer to achieve even coverage throughout the crop canopy. Apply sufficient water to cover the crop to the point of run-off. Avoid excessive run-off. The required water volume may be determined by applying different test volumes, using different settings on the sprayer, from industry guidelines or expert advice. Add the amount of product specified in the Directions for use table for each 100 L of water. Spray to the point of run-off. The required dilute spray volume will change unless otherwise specified and the sprayer set up and operation may also need to be changed, as the crop grows. CONCENTRATE SPRAYING (tree and vine crops only) a) Use a sprayer designed and set up for concentrate spraying (that is a sprayer which applies water volumes less than those required to reach the point of run-off) and matched to the crop being sprayed. b) Set up and operate the sprayer to achieve even coverage throughout the crop canopy using your chosen water volume. c) Determine an appropriate dilute spray volume (see Dilute spraying above) for the crop canopy. This is needed to calculate the concentrate mixing rate. d) The mixing rate for concentrate spraying can then be calculated in the following way: EXAMPLE ONLY (i) Dilute spray volume as determined above: For example, 1500 L/ha (ii) Your chosen concentrate spray volume: For example, 500 L/ha

	<p>(iii) The concentration factor in this example is: $3 \times$ (i.e. $1500 \text{ L} \div 500 \text{ L} = 3$)</p> <p>(iv) If the dilute label rate is 10 mL/100 L, then the concentrate rate becomes 3×10, that is 30 mL/100 L of concentrate spray.</p> <p>e) The chosen spray volume, amount of product per 100 L of water, and the sprayer set up and operation may need to be changed as the crop grows.</p> <p>f) For further information on concentrate spraying, users are advised to consult relevant industry guidelines, undertake appropriate competency training and follow industry best practices.</p> <p>MIXING</p> <p>Add the recommended quantity of this product to the required volume of water, mix thoroughly.</p>
Resistance Warning:	<p>For insecticide resistance management Fyfanon 440 EW Insecticide is a Group 1B insecticide. Some naturally occurring insect biotypes resistant to Fyfanon 440 EW and other Group 1B insecticides may exist through normal genetic variability in any insect population. The resistant individuals can eventually dominate the insect population if Fyfanon 440 EW or other Group 1B insecticides are used repeatedly. The effectiveness of Fyfanon 440 EW on resistant individuals could be significantly reduced. Since the occurrence of resistant individuals is difficult to detect prior to use, FMC Australasia Pty Ltd accepts no liability for any losses that may result from the failure of Fyfanon 440 EW to control resistant insects. Fyfanon 440 EW may be subject to specific resistance management strategies. For further information contact your local supplier, FMC Australasia Pty Ltd representative or local agricultural department agronomist.</p>
Precautions:	<p>Avoid contact with food, food utensils, or places where food is prepared or stored.</p> <p>RE-ENTRY PERIODS:</p> <p>DO NOT allow entry into treated areas until spray has dried.</p> <p>Fruiting vegetable crops: DO NOT enter for 1 day after application for irrigation, scouting, thinning and weeding.</p> <p>Leafy vegetable crops: DO NOT enter for 1 day after application for irrigation and scouting mature plants, hand harvesting and pruning.</p> <p>Field crops (low): DO NOT enter for 2 days after application for hand-set irrigation. DO NOT enter for 1 day after application for scouting, thinning and weeding.</p> <p>Grapes: DO NOT enter for 1 day after application for bird control, propagation, trellis repair and transplanting.</p> <p>DO NOT enter for 2 days after application for hand irrigation, hand pruning, hand weeding and scouting.</p> <p>DO NOT enter for 17 days after application for tying, training, leaf pulling and hand harvesting.</p> <p>DO NOT enter for 24 days after application for girdling and turning.</p> <p>Apples: DO NOT enter for 1 day after application for hand pruning, training, scouting, training, transplanting, orchard maintenance, propping and hand weeding.</p> <p>DO NOT enter for 8 days after application for hand harvesting.</p> <p>DO NOT enter for 17 days after application for thinning fruit.</p> <p>Treated animal housing: DO NOT allow entry into treated animal housing or handle treated animal bedding until spray has dried. Children must not be allowed to enter into treated animal housing or handle treated animal bedding for 3 full days post-application.</p> <p>When prior entry is necessary, wear cotton overalls buttoned to the neck and wrist and a washable hat and chemical resistant gloves. Clothing must be laundered after each day's use.</p>
Protection Statements:	<p>PROTECTION OF WILDLIFE, FISH, CRUSTACEANS AND ENVIRONMENT</p> <p>Very toxic to aquatic life. DO NOT contaminate wetlands or watercourses with this product or used containers.</p> <p>PROTECTION OF HONEYBEES AND OTHER INSECT POLLINATORS</p> <p>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.</p> <p>PROTECTION OF LIVESTOCK</p> <p>DO NOT place treated grain bait for control of crickets in locations which are accessible which are accessible to domestic animals, livestock or birds. DO NOT feed treated grain to animals including poultry.</p>
Storage and Disposal:	<p>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.</p> <p>Disposable containers:</p> <p>Triple-rinse containers before disposal. Add rinsings to spray tank. DO NOT dispose of undiluted chemicals on site. Dispose of any unused product in compliance with relevant local, state or territory government regulations. 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.</p>

	<p>Refillable containers:</p> <p>Empty contents fully into application equipment. Close all valves and return to [point of supply/designated collection point/other specific collection details] for refill or storage.</p>
Safety Directions:	<p>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.</p>
First Aid Instructions:	<p>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.</p>

DIRECTIONS FOR USE:**1. Tree and vine crops**

This table shows rates for dilute spraying. For concentrate spraying, refer to the mixing/application section.

Crop	Pest	Rate	WHP	Critical comments
Apples, pears	Apple leaf hopper, Codling moth, Red spider mite, Thrips, Woolly aphid	140 mL/100 L	3 days	Apply at first sign of pest. DO NOT apply more than 4 applications per season.
	Apple leaf hopper, Codling moth, European red mite, Woolly aphid			
Citrus	Purple scale, Red scale, Soft brown scale	230 mL/100 L plus 1.3 L summer oil/100 L		Apply November-March. For best results apply twice; November-January and then early February. For use in NSW, ACT, Vic, SA, WA, NT only.
	Pink wax scale			Apply December-early January or when crawlers are active. DO NOT apply more than 4 applications per season. For use in NSW, ACT, Vic, SA, WA, NT only.
	Purple scale, Soft brown scale			Apply November-March, with 2 applications, the first November-January and the second in February. Early application gives best results. For use in Tas, WA only.
	Bronze orange bug, Citrus aphid, Citrus butterfly, Rutherglen bug, Spined citrus bug, Tree hopper, Thrips	140 mL/100 L		Apply as necessary. DO NOT apply more than 4 applications per season. For use in NSW, ACT, Vic, SA, WA only.
	Citrus aphid, Rutherglen bug, Tree hopper, Thrips			Apply as necessary. DO NOT apply more than 4 applications per season. For use in Tas, WA only.
Grapevines	Mealy bug	230 mL/100 L		Apply when pests appear and repeat if pest population increases. DO NOT apply more than 4 applications per season
	Vine moth	140 mL/100 L		
	Grape vine scale	230 mL/100 L plus 1.3 L summer oil/100 L		For application during summer months if scale population increases. DO NOT apply more than 4 applications per season. NSW, ACT, Vic, Tas, SA and WA only
Stone fruit	Black peach aphid, Green peach aphid, European red mite, Oriental fruit moth	140 mL/100 L		Apply at first sign of pest and repeat as necessary. DO NOT apply more than 4 applications per season Warning: Some green peach aphid populations may be resistant to organophosphate insecticides, and therefore WILL NOT be controlled by Fyfanon® 440 EW

2. Field crops and pasture

Crop/situation	Pest	Rate	WHP	Critical comments
Canola	Rutherglen bug	1.25 L/ha	3 days	Apply at first sign of pest, repeat every 7 to 10 days as necessary. DO NOT apply more than 4 applications per season
Cereals, non-crop areas, pastures	Plague locust, Small hoppers	1.4 L/ha	1 day	Ground application only Boom apply in 110 L water/ha Misting apply in 2.5 L water/ha. Repeat as necessary.
		2.5 L/ha		
	Large hoppers, Plague locust	1.9 L/ha		
		2.5 L/ha		
Cereals, non-crop areas, pastures continued	Field cricket (Teleogryllus commodus)	Bait 285 mL/10 kg kibbled grain/ha	1 day	Immature crickets Mix in a drum or cement mixer. It is not necessary to leave treated grain standing to absorb Fyfanon 440 EW Insecticide as it is absorbed rapidly and can be used immediately after treatment. Prepared bait should be stored separate from stock feed and the containers clearly marked to indicate that the contents have been treated with Fyfanon 440 EW Insecticide.
		Bait 285 to 570 mL/10 to 20 kg kibbled grain/ha		Mature crickets Use higher rate for heavy infestations. Mix in a drum or cement mixer and keep 24 hours before spreading. Spread in late afternoon and evening early in the season, and morning late in the season. Baiting may be ineffective if large amounts of pasture seed are present. Prepared bait should be stored separate from stock feed and the containers clearly marked to indicate that the contents have been treated with Fyfanon 440 EW Insecticide.
		Spray 1.6 L/25-50 L		Apply in evening. Ensure pasture cover is low so chemical will come into direct contact with crickets. Spraying may be ineffective if cold conditions keep crickets underground for 1-2 days, or if rain falls after application. DO NOT apply more than 4 applications per season.
Lucerne	Lucerne flea	160 to 340 mL/ha	1 day	Apply by low volume equipment with sufficient water to ensure good coverage at 3 to 4 weekly intervals after opening rains. Vary rate according to stage of growth. DO NOT apply more than 4 applications per season.
	Spotted alfalfa aphid	1.25 L/ha		Apply at first sign of pest. Use sufficient water to ensure thorough coverage. DO NOT apply more than 4 applications per season.
	Pea aphid			
	Field cricket (Teleogryllus commodus)	Bait 285 mL/10 kg kibbled grain/ha		Immature crickets Mix in a drum or cement mixer. It is not necessary to leave treated grain standing to absorb Fyfanon 440 EW Insecticide as it is absorbed rapidly and can be used immediately after treatment. Prepared bait should be stored separate from stock feed and the containers clearly marked to indicate that the contents have been treated with Fyfanon 440 EW Insecticide.
		Bait 285 to 570 mL/10 to 20 kg kibbled grain/ha		Mature crickets: Use higher rate for heavy infestations. Mix in a drum or cement mixer and keep 24 hours before spreading. Spread in late afternoon and evening early in the season, and morning late in the season. Baiting may be ineffective if large amounts of pasture seed are present. Prepared bait should be stored separate from stock feed and the containers clearly marked to indicate that the contents have been treated with Fyfanon 440 EW Insecticide.
		Spray 1.6 L/25 to 50 L		Apply in evening. Ensure pasture cover is low so chemical will come into direct contact with crickets. Spraying may be ineffective if cold conditions keep crickets underground for 1 to 2 days, or if rain falls after application. DO NOT apply more than 4 applications per season.

Crop/situation	Pest	Rate	WHP	Critical comments
Pastures	Spotted alfalfa aphid	1.25 L/ha	1 day	Apply at first sign of pest. Use sufficient water to ensure thorough coverage. DO NOT apply more than 4 applications per season
Rice	Rice bloodworm larvae	680 mL/10 to 30 L/ha	1 day	Apply by aircraft to rice bays at or within 24 hours of sowing, or when infestations occur after application of permanent water. DO NOT apply more than 4 applications per season
	Common armyworm	1.8 L/ha		When infestation is widespread, spray total crop. When infestation is moving as an army, spray the front. DO NOT apply more than 4 applications per season

3. Vegetable crops

Crop	Pest	Rate	WHP	Critical comments
Cucurbits	Pumpkin beetle	140 to 230 mL/100 L	3 days	DO NOT apply to cucumbers or melons when wet. Apply as necessary. DO NOT apply more than 4 applications per season
Tomatoes	Tomato russet mite			Apply at first sign of pest and repeat as necessary. DO NOT apply more than 4 applications per season
Vegetables (bean, cabbage, carrot, cauliflower, celery, cucurbit, lettuce, tomato)	Aphid, Green vegetable bug, Jassid, Leaf hopper, Red legged earth mite (not Tas), Rutherglen bug, Twenty-eight-spotted ladybird (not Tas)			Apply at first sign of pest. Ensure adequate coverage in later growth stages by increasing rate and volume. DO NOT apply more than 4 applications per season. WARNING Some Green peach aphid populations may be resistant to organophosphate insecticides, and therefore WILL NOT be controlled by Fyfanon®440 EW

4. Fruit and Vegetables

Crop	Pest	Rate	WHP	Critical comments
To effectively manage fruit fly, a multi- faceted approach should be used. Fyfanon® 440 EW assists in the management of fruit flies as part of an integrated program that includes other registered insecticides, baiting, trapping, pest monitoring, and orchard hygiene. The efficacy of the multi-faceted approach will be dependent upon the level of pest pressure during the season.				
Apples, pears	Fruit fly	140 – 230 mL/100 L	3 days	Apply treatment when fruit fly activity is initially observed, as determined by regular monitoring and fruit fly trapping. Apply as a thorough cover spray to the point of run-off. DO NOT spray on any plants in flower while bees are foraging. Strawberries, Blueberries, Rubus and Ribes Apply a maximum of 6 applications per season, with a minimum of 7 days between consecutive (repeat) sprays. Other crops Apply a maximum of 4 applications per season, with a minimum of 7 days between consecutive (repeat) sprays.
Citrus				
Grapevines				
Persimmons				
Stone fruit				
Strawberries blueberries, rubus and ribes				
Capsicum, tomato		295 mL/100 L	1 day	
Cucumbers				
Fruit trees	Fruit fly	Bait 700 mL to 100 L (308 g ai/100 L) plus a protein bait at recommended rates.	3 days	Apply as a lower pressure coarse foliar, spot or strip spray throughout the orchard or in fruit fly hot spots. For foliar and strip spraying apply in a volume of 5 – 20 L/ha of bait solution. For spot spraying, apply 100 to 150 spots/ha at 50 – 100 mL/spot of bait solution. Only apply to leaves, trunk and lower limbs of trees. Apply weekly from 6 weeks before harvest to 2 weeks after harvest. If rain occurs after application, reapply as soon as possible after the rain event. DO NOT apply directly to fruit. DO NOT spray trees when bees are foraging. DO NOT use the bait treatment as a broadcast or cover spray.
Blueberries, rubus and ribes and strawberries	Fruit fly	Bait 700 mL to 100 L plus a yeast autolysate or hydrolysate protein bait at recommended rates.	3 days	Apply only to perimeter non-crop vegetation and fruit fly resting sites. Apply as a low pressure coarse foliar, spot or strip spray. For foliar and strip spraying, apply in a volume of 5 to 20 L/ha of bait solution. For spot spraying, apply 100 to 150 spots/ha at 50 to 100 mL/spot of bait solution. Apply weekly from 6 weeks before harvest. If rain occurs after application, reapply as soon as possible after the rain event. DO NOT apply to plants or fruit directly. DO NOT spray plants when bees are foraging. DO NOT use the bait treatment as a broadcast or cover spray. DO NOT exceed recommended rates of Fyfanon 440 EW and yeast autolysate protein to avoid phytotoxicity.

5. Stored cereal grain

Crop/situation	Pest	Rate	WHP	Critical comments
Stored cereal grain, grain storage facilities and equipment	Stored grain insect pests (except Lesser Grain Borer) including Indian meal moth, Rice weevil, Rust-red flour beetle, Saw-toothed grain beetle, Tropical warehouse moth	5.7 L/100 L (10 L prepared spray/200 m ² surface)	Malathion level 8 ppm or 90 days	For use in WA only. Apply prepared spray to the walls, floors, roof structure, machinery, transport vehicles and areas surrounding storage facilities. Use as a routine hygiene procedure before grain is stored in any facility. Prevent surface contamination of grain. DO NOT apply more than at 2 monthly intervals in warm weather and 3 monthly intervals in winter.
		2.7 L/100 L (12 ppm) (1 L prepared spray/tonne grain)		For use in WA only. For up to 6 months protection apply to the grain as it is being transferred into storage. Ensure the use of suitable equipment to give an even coverage to the grain and which will adjust to the flow rate of the grain.
		56 mL/L (5 L prepared spray/100 m ²)		For use in WA only. At 3 monthly intervals apply to the surface of the stored grain.

6. Miscellaneous

Crop/situation	Pest	Rate	Critical comments
Animal quarters	Fleas, flies, ticks	11.5 mL/L (50 g sugar may be added per 1 L of spray as a bait for fly control)	Apply thoroughly to animal houses such as stables, kennels, and bedding using 1 L of diluted spray per 20 m ² of area. Good basic sanitation is necessary for a successful fly control program. Remove manure piles and other waste materials which act as breeding sites.
Dairies, stables, factories, homes	Flies	2.3 L/100 L	Treat surface where flies congregate such as walls, ceilings, stanchions, windows, etc out of reach of animals and children. Repeat as required.
Poultry and pig sheds	Common hide beetle (Dermestes maculatus)	6.8 L/100 L Spray 5 L of solution to 100 m ²	Ensure proper sanitation and run-off.
Eucalypts, natives	Autumn gum moth, Gumeaf skeletoniser, Leaf beetle, Spitfire Spring beetle	340 mL plus 125 mL activator/100 L	When mixing with alkaline water, use 500 mL of LI700 per 100 L instead of activator.
	Scale insects	195 mL plus 3.3 L white oil/100 L	Ensure thorough coverage.
Flowers, ornamentals	Aphid, Azalea lace bug, Mites	140 mL/100 L	Apply at first sign of pest, repeat every 7 to 10 days as necessary.
	Scale on hardy plants	230 mL/100 L plus 1.3 L summer oil/100 L	
Wildflowers, proteas	Aphid, Leaf hopper, Sucking bugs, Thrips	115 mL/100 L	Ensure thorough coverage.
	Grasshoppers	Spray 570 mL/100 L Bait 55 mL/1 kg bran	Mix bait in a plastic bag. Leave overnight. Spread thoroughly.
Mosquito breeding areas	Adults	680 mL/ha	Dilute with water as required. Apply by pressure spray. Apply at major emergence of adults.
Tobacco (seed bed, field)	Brown vegetable weevil, Springtails	115 mL/100 L	Apply the spray to tobacco in seedbed when the insects are present. Repeat application of the spray at 7- 10-day intervals if necessary to control the insects. Ensure thorough coverage.
	Small plague wingless grasshopper		

NOT TO BE USED FOR ANY OTHER PURPOSE OR IN ANY MANNER CONTRARY TO THIS LABEL UNLESS
AUTHORISED UNDER APPROPRIATE LEGISLATION

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 buffer zones in the relevant buffer zone table/s below 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 1 to 2 hours before sunset and persist until 1 to 2 hours after sunrise.

Buffer zones for 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
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
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
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
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
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
160 mL/ha	0.5 m or lower	0 metres	0 metres	0 metres	0 metres	0 metres

Application rate	Boom height above the target canopy	Mandatory buffer zones				
		Bystander areas	Natural aquatic areas	Pollinator areas	Vegetation areas	Livestock areas
	1.0 m or lower	0 metres	0 metres	0 metres	0 metres	0 metres

Buffer Zones for 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 3m 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 Aerial application

Application rate	Aircraft type	Mandatory buffer zones				
		Bystander areas	Natural aquatic areas	Pollinator areas	Vegetation areas	Livestock areas
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
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
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
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
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
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
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
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

Buffer Zones for 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 '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
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, rubus, ribes, 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
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, rubus, ribes, flowers ornamentals, tobacco field, wildflowers, and proteas					
All	0 metres	5 metres	5 metres	0 metres	0 metres

Buffer zones for 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
2.5 L/ha	0 metres	165 metres	160 metres	0 metres	0 metres
1.4 L/ha	0 metres	100 metres	95 metres	0 metres	0 metres
1.1 L/ha	0 metres	75 metres	70 metres	0 metres	0 metres
680 mL/ha	0 metres	40 metres	40 metres	0 metres	0 metres

Home garden agricultural chemical product sample labels

Label 7: Malathion 100 g/L emulsifiable concentrate – 58968

Signal Heading:	CAUTION KEEP OUT OF REACH OF CHILDREN READ SAFETY DIRECTIONS BEFORE OPENING OR USING		
Product Name:	David Grays Malathion and White Oil Insecticide		
Constituent Statement:	Active constituent: 100 g/L malathion (an anticholinesterase compound) 400 g/L petroleum oil Solvent: 357 g/L liquid hydrocarbon		
Statement of Claims:	For the control of scale, aphids, thrips, caterpillars, leafhoppers and other insects as indicated on vegetables, fruit trees and ornamentals in the home garden.		
Net Contents:	200 mL		
Restraints:			
How to Use:	How to use:		
	Crop	Insect pests	How to apply
	Fruit trees, ornamentals, vegetables	Scale, aphids, thrips, caterpillars, leafhoppers	Mix 10 mL in 2 litres of water and spray when pests first appear.
	Ornamentals, vegetables	Rutherglen bug, Green vegetable bug.	Repeat at 7 to 10-day intervals as necessary
	NOT TO BE USED FOR ANY PURPOSE, OR IN ANY MANNER, CONTRARY TO THIS LABEL UNLESS AUTHORISED		
Withholding Period:	DO NOT PICK EDIBLE PLANTS FOR 3 DAYS AFTER SPRAYING.		
How to Prepare:	Mix 10 mL in 2 litres of water DO NOT mix more than is needed. DO NOT store prepared spray. Compatibility: DO NOT mix with Bordeaux or any other alkaline mixtures.		
Caution Statements:	DO NOT allow entry into treated areas until spray has dried. Toxic to bees. DO NOT spray if bees are feeding on flowering plants. Toxic to aquatic life. DO NOT allow the product, chemical containers or spray to get into drains, sewers, streams or ponds.		
Storage and Disposal:	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. Dispose of empty container by wrapping in paper, placing in plastic bag and putting in garbage.		
Safety Directions	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.		
First Aid Instructions:	If poisoning occurs, contact a doctor or Poisons Information Centre. Phone Australia 13 11 26, New Zealand 0800 764 766.		

Label 8a: Malathion 500 g/L emulsifiable concentrate – 42035

Signal Heading:	POISON KEEP OUT OF REACH OF CHILDREN READ SAFETY DIRECTIONS BEFORE OPENING OR USING														
Product Name:	David Grays Malathion Garden Spray														
Constituent Statement:	Active constituent: 500 g/L malathion An anticholinesterase compound Solvent: 488 g/L hydrocarbon liquid														
Statement of Claims:	For the control of aphids, mites, scale, cabbage moth and loopers on ornamentals and vegetables, and fruit fly on fruit trees in the home garden.														
Net Contents:	200 mL, 500 mL														
Restraints:															
How to Use:	<p>How to use:</p> <table border="1"> <thead> <tr> <th>Plant</th><th>Pest</th><th>Rate</th><th>How to apply</th></tr> </thead> <tbody> <tr> <td>Ornamentals, vegetables</td><td>Aphids, mites, cabbage moth, scale, loopers.</td><td>5 mL per 2 litres of water.</td><td>Apply late in the day out of heat</td></tr> <tr> <td>Fruit trees</td><td>Fruit Fly</td><td>25 mL per 4 litres of water</td><td>To treat 20 trees, mix solution with 25 mL of protein or 200 g sugar.</td></tr> </tbody> </table> <p>NOT TO BE USED FOR ANY PURPOSE, OR IN ANY MANNER, CONTRARY TO THIS LABEL UNLESS AUTHORISED</p>			Plant	Pest	Rate	How to apply	Ornamentals, vegetables	Aphids, mites, cabbage moth, scale, loopers.	5 mL per 2 litres of water.	Apply late in the day out of heat	Fruit trees	Fruit Fly	25 mL per 4 litres of water	To treat 20 trees, mix solution with 25 mL of protein or 200 g sugar.
Plant	Pest	Rate	How to apply												
Ornamentals, vegetables	Aphids, mites, cabbage moth, scale, loopers.	5 mL per 2 litres of water.	Apply late in the day out of heat												
Fruit trees	Fruit Fly	25 mL per 4 litres of water	To treat 20 trees, mix solution with 25 mL of protein or 200 g sugar.												
Withholding Period:	DO NOT PICK EDIBLE PLANTS FOR 4 DAYS AFTER SPRAYING.														
How to Prepare:	<p>Pour the required quantity into a measuring cylinder and mix with water. Repeat if required and replace childproof cap.</p> <p>DO NOT mix more than is needed.</p> <p>DO NOT store prepared spray.</p>														
Caution Statements:	<p>DO NOT allow entry into treated areas until spray has dried.</p> <p>Toxic to bees. DO NOT spray if bees are feeding on flowering plants.</p> <p>Toxic to aquatic life. DO NOT allow the product, chemical containers or spray to get into drains, sewers, streams or ponds.</p>														
Storage and Disposal:	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. Dispose of container by wrapping in paper, placing in plastic bag and putting in garbage.														
Safety Directions	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.														
First Aid Instructions:	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.														

Label 8b: Malathion 500 g/L emulsifiable concentrate – 62242

Signal Heading:	POISON KEEP OUT OF REACH OF CHILDREN READ SAFETY DIRECTIONS BEFORE OPENING OR USING										
Product Name:	David Grays Fruit Fly Garden Spray										
Constituent Statement:	Active constituent: 500 g/L malathion An anticholinesterase compound Solvent: 488 g/L hydrocarbon liquid										
Statement of Claims:	For the control of fruit fly on fruit trees in the home garden.										
Net Contents:	200 mL, 500 mL										
Restraints											
How to Use:	<p>How to use</p> <table border="1"> <thead> <tr> <th>Plant</th><th>Pest</th><th>Rate</th><th>How to apply</th></tr> </thead> <tbody> <tr> <td>Fruit Trees</td><td>Fruit Fly</td><td>25 mL per 4 litres of water</td><td>To treat 30 trees, mix solution with 25 mL of Protein or 200 g sugar.</td></tr> </tbody> </table> <p>NOT TO BE USED FOR ANY PURPOSE, OR IN ANY MANNER, CONTRARY TO THIS LABEL UNLESS AUTHORISED</p>			Plant	Pest	Rate	How to apply	Fruit Trees	Fruit Fly	25 mL per 4 litres of water	To treat 30 trees, mix solution with 25 mL of Protein or 200 g sugar.
Plant	Pest	Rate	How to apply								
Fruit Trees	Fruit Fly	25 mL per 4 litres of water	To treat 30 trees, mix solution with 25 mL of Protein or 200 g sugar.								
Withholding Period:	DO NOT PICK EDIBLE PLANTS FOR 4 DAYS AFTER SPRAYING.										
How to Prepare:	<p>Pour the required quantity into a measuring cylinder and mix with water. Repeat if required and replace childproof cap.</p> <p>DO NOT mix more than is needed.</p> <p>DO NOT store prepared spray.</p>										
Caution Statements:	<p>DO NOT allow entry into treated areas until spray has dried.</p> <p>Toxic to bees. DO NOT spray if bees are feeding on flowering plants.</p> <p>Toxic to aquatic life. DO NOT allow the product, chemical containers or spray to get into drains, sewers, streams or ponds.</p>										
Storage and Disposal:	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. Dispose of container by wrapping in paper, placing in plastic bag and putting in garbage.										
Safety Directions:	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.										
First Aid Instructions:	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.										

Veterinary medicine sample labels

Label 9a: Malathion 200 g/L topical solution/suspension – 37201

Signal Heading:	POISON KEEP OUT OF REACH OF CHILDREN READ SAFETY DIRECTIONS BEFORE OPENING OR USING FOR ANIMAL TREATMENT ONLY
Product Name:	Inca Malaban Wash Concentrate
Constituent Statements:	Active constituent: 200 g/L malathion (an anticholinesterase compound) Also contains: 663 g/L Xylene (solvent)
Claims:	Controls fleas, lice and adult Brown Dog Ticks on dogs, cats, and in dog kennels. Also controls Sarcoptic Mange mites on dogs and cats and aids in control of Red Mites in aviaries.
Net Contents:	250 mL, 500 mL, 4 L
Directions for Use:	
Restraints:	NOT SUITABLE FOR DOMESTIC USE DO NOT allow children to handle companion animals treated with malathion for one hour after application. DO NOT allow entry into treated animal housing or handle treated animal bedding until spray has dried. DO NOT allow children to enter treated animal housing or handle treated animal bedding for 3 full days after application.
Contraindications:	DO NOT use on kittens and puppies under 3 months of age.
Precautions:	
Side Effects:	
Dosage and Administration:	<p>Dogs: Fleas (<i>Ctenocephalides spp.</i>) and Lice (<i>Trichodectes canis</i>): Mix 15 mL malaban wash with 1 litre of water and sponge animal. Repeat in 7 to 10 days if necessary. Saturate the kennel thoroughly, concentrating on cracks and crevices. Apply manually using pressurised hand wand or trigger pump spray. Remove animal until the kennel dries.</p> <p>Sarcoptic mange (<i>Sarcoptes scabiei</i>) and Ticks (<i>Rhipicephalus sanguineus</i>): Mix 30 mL malaban wash with 1 litre of water and sponge animal. Repeat in 7 to 10 days. Does not control paralysis tick (<i>Ixodes holocyclus</i>). In tick season daily searching for and removal of any ticks found is recommended. Search the animal thoroughly including between the toes and behind the ears.</p> <p>Cats: Fleas (<i>Ctenocephalides spp.</i>): Mix 15 mL malaban wash with 1 litre of water and sponge the animal. Repeat in 7 to 10 days if necessary.</p> <p>AVIARIES AND LOFTS: Red Mites (<i>Dermanyssus</i> and <i>Ornithonyssus spp</i>) and Lice (<i>Order Mallophaga</i>): Mix 15 mL malaban wash with 1 litre of water. Remove birds, then spray aviaries and lofts thoroughly including nesting boxes, litter and walls. Apply manually using pressurised hand wand or trigger pump spray. Return birds when aviaries etc. are dry. As total control of pests requires appropriate treatment of both the animal and its environment, also treat birds with a suitable registered insecticide.</p>
General Directions:	NOT TO BE USED FOR ANY PURPOSE, OR IN ANY MANNER, CONTRARY TO THIS LABEL UNLESS AUTHORISED UNDER APPROPRIATE LEGISLATION
Withholding Periods:	
Trade Advice:	
Safety Directions:	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 gets in eyes, wash it out immediately with water. If product gets on skin, immediately wash area with

	soap and water. Wash hands after use. After each day's use, wash gloves, goggles and contaminated clothing.
First Aid Instructions:	If poisoning occurs, contact a doctor or Poisons Information Centre, Phone Australia 13 11 26.
Additional User Safety:	Additional information is in the Material Safety Data Sheet.
Environmental Statements:	ENVIRONMENTAL PROTECTION Very toxic to aquatic life. DO NOT contaminate wetlands or watercourses with this product or used containers.
Disposal:	Dispose of any unused chemical in compliance with relevant local, state or territory government regulations. (250 mL, 500 mL containers) Dispose of container by wrapping in paper and putting in garbage. (4 L containers) Triple-rinse container into the medicated water. DO NOT dispose of undiluted chemicals on-site. If recycling, replace cap and return clean container to recycler or designated collection point. If not recycling, break, crush, or puncture container and deliver 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.
Storage:	Store below 30 °C (Room Temperature). Containers should be kept closed.

Label 9b: Malathion 200 g/L topical solution/suspension – 54285

Signal Heading:	POISON KEEP OUT OF REACH OF CHILDREN READ SAFETY DIRECTIONS BEFORE OPENING OR USING FOR ANIMAL TREATMENT ONLY				
Product Name:	Bob Martin Since 1892 Flea & Tick Control for Dogs, Cats & Aviaries Malawash				
Constituent Statements:	Active constituent: 200 g/L malathion (an anticholinesterase compound) Also contains: 640 g/L liquid hydrocarbons (solvent)				
Claims:	A concentrate wash for use on dogs, cats and in aviaries for the control of fleas, ticks, mites, lice and sarcoptic mange.				
Net Contents:	250 mL				
Directions for Use:					
Restraints:	DO NOT allow entry into treated animal housing or handle treated animal bedding until spray has dried. DO NOT allow children to handle companion animals treated with malathion for one hour after application. DO NOT allow children to enter treated animal housing or handle treated animal bedding for 3 full days after application.				
Contraindications	DO NOT use on kittens under 6 months or puppies under 3 months.				
Precautions:					
Side Effects:					
Dosage and Administration:	Animal/Area	Pest Controlled	Rate per 1L water	Critical Comments/Application	
				Direct application to animal	Animal Housing and Bedding
	Dogs over 4 months Cats over 6 months	Fleas (<i>Ctenocephalides spp.</i>) Lice (<i>Trichodectes canis</i> and <i>Felicola subrostratus</i>)	15 mL	Mix 15 mL of Malawash per litre of water and swab animal thoroughly. Repeat in 7 days if necessary.	Mix 15 mL of Malawash per litre of water and spray solution around the yard and bedding.
		Sarcoptic mange (<i>Sarcoptes scabiei</i>) Ticks (<i>Rhipicephalus sanguineus</i> and <i>Ixodes holocyclus</i>)	30 mL	Mix 30 mL of Malawash per litre of water and swab animal thoroughly. DO NOT immerse animal in the solution. Repeat in 7 Days if necessary. In Paralysis Tick areas, daily searching for removal of any ticks found is recommended	
	Aviaries	Red mites (<i>Dermanyssus gallinae</i>), ticks (<i>Argas spp.</i>), lice (<i>Menopon gallinae</i>)	50 mL	Remove birds and spray aviary thoroughly including nesting boxes, litter and walls with a mixture of 50 mL of Malawash per litre of water.	
General Directions:					
NOT TO BE USED FOR ANY PURPOSE, OR IN ANY MANNER, CONTRARY TO THIS LABEL UNLESS AUTHORISED UNDER APPROPRIATE LEGISLATION.					
Withholding Periods:					
Trade Advice:					
Safety Directions:					
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.					
First Aid Instructions:					
If poisoning occurs, contact a doctor or Poisons Information Centre, Phone Australia 13 11 26.					
Additional User Safety:					
Additional information is listed in the material safety data sheet.					

Environmental Statements:	ENVIRONMENTAL PROTECTION Very toxic to aquatic life. DO NOT contaminate wetlands or watercourses with this product or used containers.
Disposal:	Dispose of any unused product in compliance with relevant local, state or territory government regulations. Dispose of container by wrapping in paper and putting in garbage.
Storage:	Store below 30 °C (room temperature) in the closed original container. DO NOT store in direct sunlight. Tighten cap after use.

Label 10: Malathion 20 g/kg topical dust – 42267

Signal Heading:	CAUTION KEEP OUT OF REACH OF CHILDREN READ SAFETY DIRECTIONS BEFORE OPENING OR USING FOR ANIMAL TREATMENT ONLY
Product Name:	David Grays Poultry Dust
Constituent Statements:	Active constituent: 20 g/kg malathion (an anticholinesterase compound)
Claims:	Controls fleas (<i>Echidrophaga gallinacea</i>), flies (<i>Musca domestica</i> L), lice (<i>Manacanthus stramineus</i> and <i>Menocan gallinae</i> L), ticks (<i>Haemaphysalis spp.</i>), and mites (<i>Acarina</i>) on poultry. Resistance may develop to any chemical.
Net Contents:	400 g, 3 kg, 15 kg.
Directions for Use:	
Restraints:	DO NOT allow children to handle companion animals treated with malathion for one hour after application. DO NOT allow children to enter treated animal housing or handle treated animal bedding for 3 full days after application.
Contraindications:	
Precautions:	
Dosage and Administration:	Dust David Grays Poultry Dust between the feathers of birds and repeat where necessary. To prevent breeding of poultry parasites, apply Poultry Dust to roosts and crevices of buildings.
General Directions:	NOT TO BE USED FOR ANY PURPOSE, OR IN ANY MANNER, CONTRARY TO THIS LABEL UNLESS AUTHORISED UNDER APPROPRIATE LEGISLATION.
Withholding Periods:	Meat: DO NOT USE later than 7 days before slaughter for human consumption. Eggs: Zero (0) days.
Trade Advice:	
Safety Directions:	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.
First Aid Instructions:	If poisoning occurs, contact a doctor or Poisons Information Centre, Phone Australia 13 11 26.
Environmental Statements:	ENVIRONMENTAL PROTECTION Very toxic to aquatic life. DO NOT contaminate wetlands or watercourses with this product or used containers.
Disposal:	Dispose of any unused chemical in compliance with relevant local, state or territory government regulations. (400 g pack) Dispose of container by wrapping with paper and putting in garbage. (3 kg pack) Triple-rinse container and dispose of rinsate in compliance with relevant local, state or territory government regulations. If recycling, replace cap and return clean container to recycler or designated collection point. If not recycling, break, crush, or puncture container and deliver 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. (15 kg pack) Shake to empty contents from packaging. Do not dispose of undiluted chemicals on site. 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 in compliance with relevant local, state or territory government regulations. Do not burn empty packaging or product.
Storage:	Store in the closed original container in a dry, well-ventilated area out of direct sunlight. Store below 30 °C (room temperature).

Label 11a: Malathion 500 g/L emulsifiable concentrate – 33021

Signal Heading:	POISON KEEP OUT OF REACH OF CHILDREN READ SAFETY DIRECTIONS BEFORE OPENING OR USING FOR ANIMAL TREATMENT ONLY
Product Name:	Pharmachemical Maldison 50 Insecticide
Constituent Statement:	Active constituent: 500 g/L malathion (an anticholinesterase compound) Also contains: 493 g/L hydrocarbon liquid (solvent)
Claims:	For the control of a wide range of insect pests in dogs, poultry, pigs, horses and cattle and in animal housing. Resistance may develop to any chemical.
Net Contents:	250 mL, 500 mL, 5 L
Directions for Use:	
Restraints:	DO NOT allow entry into treated animal housing or handle treated animal bedding until spray has dried. DO NOT allow children to handle companion animals treated with malathion for one hour after application. DO NOT allow children to enter treated animal housing or handle treated animal bedding for 3 full days after application.
Contraindications:	
Precautions:	
Side Effects:	
Dosage and Administration:	See below
General Directions:	Dilute to recommended application strength with water before applying. Pharmachemical Maldison 50 Insecticide gives a spontaneous emulsion in water and may be added directly to the water in the spray vat with the agitators running. Mixes readily with hard or soft water. NOT TO BE USED FOR ANY PURPOSE, OR IN ANY MANNER, CONTRARY TO THIS LABEL UNLESS AUTHORISED UNDER APPROPRIATE LEGISLATION
Withholding Period:	Meat: DO NOT USE later than 7 days before slaughter for human consumption. MILK: Milk collected from cows within 5 hours following treatment MUST NOT BE USED or processed for human consumption or fed to bobby calves. Eggs: Zero (0) days.
Trade Advice:	EXPORT SLAUGHTER INTERVALS (ESI): This product does not have an ESI established. For advice on the ESI, please contact the manufacturer on (07) 3271 4411 before using this product.
Safety Directions:	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 gets in eyes, wash it out immediately with water. If product gets on skin, immediately wash area with soap and water. Wash hands after use. After each day's use, wash gloves, goggles and contaminated clothing.
First Aid Instructions:	If swallowed, splashed on skin or in eyes, or inhaled, contact a Poisons Information Centre (Phone Australia 13 11 26) or a doctor at once. Remove any contaminated clothing and wash skin thoroughly. If swallowed, activated charcoal may be advised. Give atropine if instructed.
Additional User Safety:	Additional information is listed in the Material Safety Data Sheet which can be obtained from the supplier.
Environmental Statements:	ENVIRONMENTAL PROTECTION Very toxic to aquatic life. DO NOT contaminate wetlands or watercourses with this product or used containers.
Disposal:	Dispose of any unused product in compliance with relevant local, state or territory government regulations. (250 mL, 500 mL containers) Dispose of container by wrapping in paper and putting in garbage. (5 L container)

	Triple-rinse container into the medicated water. DO NOT dispose of undiluted chemicals on-site. If recycling, replace cap and return clean container to recycler or designated collection point. If not recycling, break, crush, or puncture container and deliver 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.
Storage:	Store below 30°C (Room Temperature) in the closed original container. DO NOT store in direct sunlight.

Dosage and Administration

Animal situation	Pest	Dilution rate of product in water		Critical comments
		Spray/high volume	Alternative application	
Dogs over 3 months	Fleas and lice	–	50 mL/10 L	Saturate the animal using a sponge. Repeat in 7 days. Use the residue for spraying bedding etc with a trigger pump spray. DO NOT immerse the animal.
	Adult brown dog tick and sarcoptic mange		50 mL/5 L	
Poultry pests	Lice and mites (poultry houses)	–	500 mL/25 L	Thoroughly treat nesting boxes, litter and walls with spray with manually pressurised hand wand.
			500 mL/8 L	Paint onto roosts with paint brush. The above applications should be repeated 8-14 days later to destroy lice hatching from eggs present at the first treatment.
	Lice or tropical fowl mite	500 mL/100 L	–	Spray birds with a trigger pump spray at the rate of 50 L/1000 birds.
	Ticks	–	500 mL/8 L	Treat the walls, nesting boxes and roosts of poultry houses very thoroughly with a with manually pressurised hand wand, paying particular attention to cracks and crevices in timber where the lice hide.
Pigs	Pig lice and sarcoptic mange	–	250 mL/20 L	Thoroughly spray all pigs and sheds with a low-pressure spray.
Horses	Lice, ticks, sandflies	–	250 mL/20 L	Apply 2 L prepared spray per horse using a trigger pump spray or by sponge
Cattle	Lice	1 L/100 L	–	Spraying at the rate of 4.5 L per head is usually enough using a low-pressure spray.

Label 11b: Malathion 500 g/L emulsifiable concentrate – 63456

Signal Heading:	POISON KEEP OUT OF REACH OF CHILDREN READ SAFETY DIRECTIONS BEFORE OPENING OR USING FOR ANIMAL TREATMENT ONLY
Product Name:	Saint Bernard Petcare Maldison Wash Insecticide
Constituent Statements:	Active constituent: 500 g/L malathion (an anticholinesterase compound) Also contains: 493 g/L hydrocarbon liquid (solvent)
Claims:	For the control of a wide range of insect pests in dogs, cats, poultry, pigs, horses and cattle as per the Directions for Use Table. Resistance may develop to any chemical.
Net Contents:	250 mL
Directions for Use:	
Restraints:	DO NOT apply directly to water. DO NOT allow re-entry into treated areas until spray has dried. DO NOT allow entry into treated animal housing or handle treated animal bedding until spray has dried. DO NOT allow children to handle companion animals treated with malathion for one hour after application. DO NOT allow children to enter treated animal housing or handle treated animal bedding for 3 full days after application.
Contraindications:	
Precautions:	
Side Effects:	
Dosage and Administration:	[See below]
General Directions:	MIXING: Saint Bernard Petcare Maldison wash insecticide gives spontaneous emulsion in water and may be added directly to the water in the spray vat with the agitators running, mixes readily with hard or soft water. NOT TO BE USED FOR ANY PURPOSE, OR IN ANY MANNER, CONTRARY TO THIS LABEL UNLESS AUTHORISED UNDER APPROPRIATE LEGISLATION
Withholding Period:	Meat: DO NOT USE later than 7 days before slaughter for human consumption. Milk: Milk collected from cows within 5 hours following treatment MUST NOT BE USED or processed for human consumption or fed to bobby calves. Eggs: Zero (0) days.
Trade Advice:	EXPORT SLAUGHTER INTERVALS (ESI): This product does not have an ESI established. For advice on the ESI, please contact the manufacturer on (07) 3271 4411 before using this product.
Safety Directions:	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 gets in eyes, wash it out immediately with water. If product gets on skin, immediately wash area with soap and water. Wash hands after use. After each day's use, wash gloves, goggles and contaminated clothing.
First Aid Instructions:	If swallowed, splashed on skin or in eyes, or inhaled, contact a Poisons Information Centre (Phone Australia 13 11 26) or a doctor at once. Remove any contaminated clothing and wash skin thoroughly. If swallowed, activated charcoal may be advised. Give atropine if instructed.
Additional User Safety:	Additional information is listed in the Material Safety Data Sheet which can be obtained from the supplier.

Environmental Statements:	ENVIRONMENTAL PROTECTION Very toxic to aquatic life. DO NOT allow chemical containers or spray to get into drains, sewers, streams or ponds. PROTECTION OF HONEYBEES AND OTHER INSECT POLLINATORS Toxic to bees. DO NOT spray if bees are feeding on flowering plants.
Disposal:	Dispose of any unused chemical in compliance with relevant local, state or territory government regulations. Dispose of container by wrapping in paper and putting in garbage.
Storage:	Store below 30 °C (room temperature) in the closed original container. DO NOT store in direct sunlight.

Dosage and administration:

Animal/ situation	Pest	Dilution rate of product in water		Critical comments
		Spray/high volume	Alternative application	
Dogs over 3 months and cats over 6 months	Fleas and lice	–	50 mL/10 L	Saturate the animal using a sponge. Repeat in 7 days. Use the residue for spraying bedding etc with a trigger pump spray. DO NOT immerse the animal.
	Adult brown dog tick and sarcoptic mange		50 mL/5 L	
Poultry pests	Lice and mites (poultry houses)	–	500 mL/25 L	Thoroughly treat nesting boxes, litter and walls. Paint onto roosts. The above applications should be repeated 8-14 days later to destroy lice hatching from eggs present at the first treatment. Spray birds using a trigger pump spray at the rate of 50L/1000 birds. Treat the walls, nesting boxes and roosts of poultry houses very thoroughly with a manually pressurised hand wand, paying particular attention to cracks and crevices in timber where the lice hide.
			500 mL/8 L	
	Lice or tropical fowl mite	500 mL/100 L	–	
	Ticks	–	500 mL/8 L	
Pigs	Pig lice and sarcoptic mange	–	250 mL/20 L	Thoroughly spray all pigs and sheds using low pressure spray.
Horses	Lice, ticks, sandflies	–	250 mL/20 L	Apply 2 L prepared spray per horse using a trigger pump spray or by sponge
Cattle	Lice	1 L/100 L	–	Apply with low pressure spray. Spraying at the rate of 4.5 L per head is usually enough.
Fly control	–	500 mL/40 L	–	Apply with manually pressurised hand wand. The addition of sugar or molasses to the spray will result in a better kill. DO NOT apply past the point of run off. DO NOT apply to surfaces within reach of animals and/or children.
		–	25 mL/20 L	
Mosquito control	Adults	5 mL/100 m ²	–	Apply with manually pressurised hand wand. Dilute with water as required. Application should be timed for periods of major emergence of adults.