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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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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.

Distribution and subscription

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Diazinon reconsideration – proposed decisions on reconsideration

- 1) The Australian Pesticides and Veterinary Medicines Authority (APVMA) is proposing to make regulatory decisions in relation to the reconsideration of diazinon active constituent approvals, product registrations, and label approvals being conducted under Part 2, Division 4 of the Agricultural and Veterinary Chemicals Code scheduled to the *Agricultural and Veterinary Chemicals Code Act 1994* (Agvet Code).
- 2) This notice is issued under section 34AB of the Agvet Code and relates to the reconsideration of diazinon active constituent approvals, product registrations and label approvals listed in Attachment A of this notice. This reconsideration extends to compliance with any requirement prescribed by the regulations for those approvals and registrations listed in Attachment A.
- 3) The Draft Statement of Reasons for the proposed decisions is included as Attachment B of this notice.
- 4) The information on which the reasons are based is set out in Attachment C of this notice.
- 5) Pursuant to section 34A(1) of the Agvet Code, the APVMA proposes to:
 - a. vary the conditions of the active constituent approvals listed in Table 1 in Attachment A of this notice in the manner set out in paragraph 6 of the Draft Statement of Reasons in Attachment B of this notice to allow affirmation under section 34(A)1 of the Agvet Code;
 - b. vary the relevant particulars and conditions of the chemical product registrations listed in Table 1 in Attachment A of this notice in the manner set out paragraphs 20), 30), of the Draft Statement of Reasons in Attachment B of this notice, to allow affirmation under section 34(A)1 of the Agvet Code; and
 - c. vary the relevant particulars of the label approvals listed in Table 1 in Attachment A of this notice in the manner set out in paragraph 43) of the Draft Statement of Reasons in Attachment B, and as reflected in the proposed sample labels in Attachment D, to allow affirmation under section 34(A)1 of the Agvet Code.
- 6) Pursuant to section 34AA(1) of the Agvet Code, the APVMA proposes to:
 - a. cancel the diazinon active constituent approval listed in Table 2 in Attachment A of this notice, as the APVMA is not satisfied that the relevant particulars or conditions of approval can be varied to allow the approval to be affirmed;
 - b. cancel the chemical product registrations listed in Table 2 in Attachment A of this notice, as the APVMA is not satisfied that the relevant particulars or conditions of the registrations can be varied in such a way as to allow the registrations to be affirmed; and
 - c. cancel the label approvals listed in Table 2 in Attachment A of this notice, as the APVMA is not satisfied that the relevant particulars or conditions of the approvals can be varied in such a way as to allow the approvals to be affirmed.

Written submissions are invited

- 7) The APVMA invites written submissions on the proposed course of action. All submissions will be considered by the APVMA prior to finalisation of this reconsideration.

8) Submissions or requests for further information can be sent to:

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

Phone: +61 2 6770 2400

Email: chemicalreview@apvma.gov.au

Please note: Submissions will be published on the APVMA website, unless you have asked for the submission to remain confidential (see [public submission coversheet](#)).

- Please lodge your submission with a public submission coversheet, which provides options for how your submission will be published.
- Note that all submissions received are subject to legislative requirements, including the *Freedom of Information Act 1982*, the *Privacy Act 1988* and the Agvet Code. In providing your submission to the APVMA, you agree to the APVMA publicly disclosing your submission in whole or summary form. The APVMA confirms that if your submission includes confidential commercial information or protected information as defined in the Agvet Code, such information will be subject to the relevant provisions of the Agvet Code including relevant limitations on use and disclosure by the APVMA.

9) The closing date for submissions is 11 June 2024.

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: 12 March 2024

Attachments

Note: The below Attachments form part of this Notice.

Attachment A: Active constituent approval(s), product registration(s) and approved label(s) placed under reconsideration.

Attachment B: Draft Statement of Reasons

Attachment C: Information on which the reasons are based.

Attachment D: Proposed sample labels for diazinon chemical products.

Contact information

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Attachment A: Active constituent approval(s), product registration(s) and label approval(s) under reconsideration

Table 1: Active constituent approval(s), product registration(s) and associated label approval(s) placed under reconsideration that the APVMA is proposing to vary to allow affirmation

Type	Approval or registration number	Name	Holder	Label approval number(s) associated with the product
Active constituent	46132	Diazinon	Nippon Kayaku Co Ltd	N/A
Active constituent	92520	Diazinon	Sanonda (Australia) Pty Ltd	N/A
Product	49876	Nucidol 200 EC Insecticide and Acaricide	Zagro Animal Health Pte Ltd	49876/01, 49876/0498, 48976/0509
Product	50007	Barmac Diazinon Insecticide	Amgrow Pty Ltd	50007/0598, 50007/57614
Product	59707	Farmoz Diazol 800 Insecticide	Adama Australia Pty Ltd	59707/0605, 59707/0609
Product	68534	Accensi Diazinon 800 Insecticide	Accensi Pty Ltd	68534/58536
Product	88946	AC Dizzy 800 Insecticide	Axichem Pty Ltd	88946/122991

Table 2: Active constituent approval(s), product registration(s) and associated label approval(s) placed under reconsideration that the APVMA is proposing to cancel

Type	Approval or registration number	Name	Holder	Label approval number(s) associated with the product
Active constituent	44033	Diazinon	Adama Australia Pty Ltd	N/A
Product	39572	WSD Diazinon For Sheep, Cattle, Goats And Pigs	WSD Agribusiness Pty Ltd	39572/0614
Product	39573	WSD Fly Strike Powder To Control Flystrike And For Wound Dressing For Animals	WSD Agribusiness Pty Ltd	39573/0614
Product	39574	WSD Mulesing Powder Wound Dressing Following Mules Operation General Wound Dressing For Sheep, Cattle And Goats	WSD Agribusiness Pty Ltd	39574/0614
Product	46231	Coopers Fly Strike Powder Insecticide	Intervet Australia Pty Limited	46231/0614
Product	46406	Y-TEX Optimizer Insecticidal Cattle Ear Tags	Nutrien Ag Solutions Limited	46406/01, 46406/0503, 46406/5283, 46406/111798, 46406/119795

Type	Approval or registration number	Name	Holder	Label approval number(s) associated with the product
Product	51290	Eureka Gold Op Spray-On Off-Shears Sheep Lice Treatment	Zagro Animal Health Pte Ltd	51290/0614
Product	51524	Y-TEX Warrior Insecticidal Cattle Ear Tags	Nutrien Ag Solutions Limited	51524/0202, 51524/0303, 51524/0999, 51524/50285, 51524/106701, 51524/111799, 51524/119797
Product	53910	Patriot Insecticide Ear Tag For Cattle	Elanco Australasia Pty Ltd	53910/0507, 53910/0702, 53910/0801, 53910/130969
Product	60662	Co-Ral Plus Insecticide Cattle Ear Tag	Elanco Australasia Pty Ltd	60662/0710, 60662/130564
Product	62353	Coopers Diazinon Sheep Blowfly Dressing And Cattle, Goat And Pig Spray	Intervet Australia Pty Ltd	62353/0614
Product	68253	Nucidol Gold Op Spray-On Off-Shears Sheep Lice Treatment	Zagro Animal Health Pte Ltd	68253/0614
Product	86308	Coopers Erase Gold Spray-On Off-Shears Sheep Lice Treatment	Intervet Australia Pty Limited	86308/115392
Product	86314	Coopers Gold Spray-On Off-Shears Sheep Lice Treatment	Intervet Australia Pty Ltd	86314/115408, 86314/119067
Product	87681	Imtrade Diazinon 800 EC Insecticide	Imtrade Australia Pty Ltd	87681/118969, 87681/128623
Product	92828	BFD Blowfly Dressing	Abbey Laboratories Pty Ltd	92828/136822

Attachment B: Statement of Reasons

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Material findings of fact and reasons for the proposed decisions

Active constituents

- 1) 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 (section 5A), and
 - b) complies with any requirement prescribed by the Agricultural and Veterinary Chemicals Code Regulations 1995 (Agvet Regulations).
- 2) 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.
- 3) The APVMA has decided to reconsider all matters covered by subsection 34(1) in relation to the reconsideration of diazinon active constituent approvals.

Consideration of whether active constituents meet the safety criteria

- 4) 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)).
- 5) 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 matters 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 respect of the toxicity of diazinon and its residues:
 - Studies examining the absorption, metabolism and excretion of diazinon in animal models as described in the *Diazinon Review Technical Report*
 - Studies on the toxicological effects of diazinon, including the toxicological mode of action, acute and chronic toxicity, genotoxicity, reproductive and developmental toxicity in animal models as described in the *Diazinon Review Technical Report*

- Studies on the acute toxicological effects of diazinon on human volunteers as described in the *Diazinon Review Technical Report*
 - Studies on the presence and formation of impurities of toxicological concern during manufacture and storage of diazinon active constituents as described in the *Diazinon Review Technical Report*
 - The specifications for diazinon active constituents in Agricultural and Veterinary Chemicals Code (Agricultural Active Constituents) Standards 2022 (Active Constituents Standard 2022) and the Food And Agriculture Organization Of The United Nations (FAO) Specifications for Plant Protection Products
 - Environmental toxicity studies as detailed in the *Diazinon Review Technical Report*
 - The APVMA's records of approval of diazinon active constituents for use in agricultural and veterinary chemical products.
 - Information submitted in response to notices issued under section 33 of the Agvet Code.
- II. The APVMA has concluded that the following health based guidance values for diazinon are applicable, as set out in the *Diazinon Review Technical Report*:
- The acceptable daily intake (ADI¹) for diazinon should remain at 0.001 mg of diazinon per kilogram body weight per day (mg/kg bw/day) established on a no observed adverse effect level (NOAEL) of 0.02 mg/kg bw/day in a 37 – 43 day human volunteer study, and based on inhibition of plasma cholinesterase activity at the next higher dose. The ADI incorporates a 20-fold uncertainty factor to account for any intra-species variations in sensitivity.
 - The acute reference dose (ARfD²) for diazinon should remain at 0.01 mg/kg of body weight, based on a NOAEL of 0.2 mg/kg body weight (mg/kg bw) in an acute dose human volunteer study. The ARfD incorporates a 20-fold uncertainty factor to account for any intra-species variation in sensitivity.
- III. The APVMA has identified acceptable worker exposure levels for diazinon as detailed in the *Diazinon Review Technical Report* as follows:
- For a single exposure to diazinon, applying a 20 fold margin of exposure (MOE) to a point of departure of 0.2 mg/kg bw.
 - For short term repeated occupational exposure to diazinon, applying a 20 fold MOE to a point of departure of 0.02 mg/kg bw/day for short term repeated oral exposure.
- IV. As detailed in the *Diazinon Review Technical Report* the APVMA concluded that:
- a residue definition for diazinon cannot be established for the purposes of risk assessment for plant commodities treated with diazinon chemical products based on the information available

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.

- a residue definition of diazinon *per se* is suitable for enforcement for Maximum Residue Limits (MRLs) for plant commodities based on the information available
- a residue definition for diazinon cannot be established for the purposes of risk assessment or compliance with the MRLs for animal commodities treated with diazinon chemical products based on the information available
- use of chemical products containing diazinon as an active constituent is not supported for use on any crop or animal intended for human consumption on the basis that an appropriate residue definition for risk assessment could not be established.

V. The APVMA's chemistry assessment described in the *Diazinon Review Technical Report* concluded that:

- two impurities of toxicological concern, O,O,O',O'-tetraethyl dithiopyrophosphate (S,S-TEPP) and O,O,O',O'-tetraethyl thiopyrophosphate (O,S-TEPP), may be present in diazinon active constituent as a result of manufacturing processes or degradation during storage, particularly in the presence of trace amounts of water without adequate levels of water scavenging additive
- the APVMA's Active Constituents Standard 2022 and the FAO specifications for diazinon specify maximum levels of the impurities of toxicological concern of 2.5 g/kg for S,S-TEPP and 0.02 g/kg for O,S-TEPP, and maximum quantity of 0.6 g/kg water and 0.3 g/kg for acidity calculated as equivalents of H₂SO₄
- the available information was sufficient to conclude that the active constituents listed in Table 1 of Attachment A meet the specifications in the APVMA's Active Constituents Standard 2022 and the FAO specifications and will not contain unacceptable levels of impurities of toxicological concern
- the available information was not sufficient to determine whether the active constituents listed in Table 2 of Attachment A meet the specifications in the APVMA's Active Constituents Standard 2022 and the FAO specifications and whether the active constituent will contain unacceptable levels of impurities of toxicological concern.

VI. The APVMA's assessment of environmental toxicology concluded that exposure of non-target species to diazinon below regulatory acceptable levels detailed in the *Diazinon Review Technical Report* is not likely to have an unintended effect that is harmful to animals, plants, things or the environment.

b) Section 5A(2)(a)(ii) of the Agvet Code – the method by which the constituent is, or is proposed to be, manufactured.

- I. The APVMA has considered information submitted in response to notices issued under section 33 of the Agvet Code and in the original applications for active constituent approval regarding the method of manufacture for each approved diazinon active constituent.
- II. The available information demonstrates that the method by which each diazinon active constituent approval listed in Table 1 in Attachment A of this notice is manufactured is expected to result in diazinon active constituents that comply with the APVMA's Active Constituents Standard 2022 and the FAO specifications as relevant.

- III. The available information for the diazinon active constituent number 44033 listed in Table 2 in Attachment A, is not sufficient to assess the potential presence of impurities, including impurities of toxicological concern, water and acidity noted in paragraph 5)a)V above.
- 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 each approved diazinon active constituent will contain impurities as detailed in the *Diazinon Review Technical Report*.
- Information submitted in response to notices issued under section 33 of the Agvet Code and in the original applications for active constituent approval including Declarations of Composition and Certificates of Analysis.
 - The FAO specification for diazinon established in 1988.
 - The standard for diazinon in the Agricultural Active Constituents Standard 2022.
- II. The APVMA's assessment concluded that the active constituents listed in Table 1 of Attachment A will contain impurities below the limit specified in Agricultural Active Constituents Standards 2022 or the FAO specification for Diazinon as applicable, as detailed in the *Diazinon Review Technical Report*.
- III. The APVMA's assessment concluded that the available information for the diazinon active constituent number 44033 listed in Table 2 of Attachment A is not sufficient to determine the extent that the active constituent will contain impurities as detailed in the *Diazinon Review Technical Report*.
- 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 that were submitted and assessed by the APVMA as part of the original approval for each approved diazinon active constituent and in response to notices issued under section 33 of the Agvet Code in 2023.
- II. The APVMA's assessment of the batch analyses for active constituents listed in Table 1 of Attachment A concluded that the chemical composition of those diazinon active constituents is compliant with the Agricultural Active Constituents Standards 2022 or the FAO specifications for Diazinon as applicable, as detailed in the *Diazinon Review Technical Report*.
- III. The APVMA's assessment of the information available for the diazinon active constituent number 44033, listed in Table 2 concluded that the information was inadequate for the APVMA to determine whether the active constituent meets the Agricultural Active Constituents Standards 2022 or FAO specifications for Diazinon.
- e) Section 5A(2)(a)(v) of the Agvet Code – any conditions to which its approval is, or would be, subject.
- I. The APVMA has had regard to the conditions prescribed by the Agvet Regulations in accordance with section 23(1)(a) of the Agvet Code and to the conditions imposed by the APVMA in accordance with section 23(1)(b) of the Agvet Code and entered in the record for each diazinon active constituent approval.

- II. Regulation 17C(1) of the Agvet Regulations prescribes conditions to which the approval of an active constituent for a proposed or existing chemical product is subject.
- III. The APVMA has imposed conditions on the approval of diazinon active constituents in accordance with section 23(1)(a) of the Agvet Code, and in accordance with the Agricultural and Veterinary Chemicals Code (Conditions of Approval or Registration) Order 2021 (Conditions of Approval or Registration Order). and through the condition referred to as the *Agricultural Active Constituents Quality Assurance Requirements* which is reproduced below.
- *“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. The APVMA is not satisfied that the current condition referred to as the ‘Active constituent Quality Assurance Requirements’ remains appropriate, as it references the “APVMA Standard” and

indicates this is published on the APVMA Website. The “APVMA Standard” has been replaced by the legislative instrument named the Agricultural and Veterinary Chemicals Code (Agricultural Active Constituents) Standards 2022 (Agricultural Active Constituents Standards 2022). The condition also references a ‘registrant’ which is not defined within the Agvet Code or related legislation, rather than referring to the ‘holder’.

- V. The APVMA is satisfied that the conditions imposed by the Conditions of Approval or Registration Order in conjunction with the conditions prescribed by the Agvet Regulations are appropriate.
- f) Section 5A(2)(a)(vi) of the Agvet Code – any relevant particulars that are, or would be, entered in the Record for the constituent.
- I. The relevant particulars recorded for each approved diazinon active constituent have been reviewed. Section 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:
 - If a name is given to the active constituent by the International Union of Pure and Applied Chemistry – that name.
 - If no name is given to the active constituent by the International Union of Pure and Applied Chemistry – the name given to the active constituent in the standard prescribed in respect of the active constituent for the purposes of paragraph 87(1)(a) of the Code.
 - The name of the active constituent.
 - The composition and purity of the active constituent.
 - The name of the manufacturer of the active constituent.
 - The address of each site at which the active constituent is manufactured by the manufacturer.
 - Identifying information for the holder of the approval of the active constituent.
 - The date of entry of these particulars in the Record of Approved Active Constituents.
 - Identifying information for any nominated agent for the approval.
 - II. The APVMA is satisfied that the relevant particulars entered into the Record for diazinon active constituents approvals are correct.
- g) Section 5A(2)(a)(via) of the Agvet Code – 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 was made under section 6E(1) of the Agvet Code for active constituents used in agricultural chemical products, including diazinon.
 - II. The APVMA has considered the information described in paragraphs 5(a) to 5(d) above and concluded that each diazinon active constituent listed in Table 1 conforms to the Agricultural Active Constituents Standards 2022 as outlined in the *Diazinon Review Technical Report*.

- III. The APVMA has considered the information described in paragraphs 5)a) to 5)d) and is not satisfied the diazinon active constituent number 44033 listed in Table 1 of Attachment A conforms to the Agricultural Active Constituents Standards 2022 as outlined in the *Diazinon Review Technical Report*.
- h) Section 5A(2)(a)(vii) of the Agvet Code – any matters prescribed by the regulations.
- I. Regulation 8AA of the Agvet Code Regulations prescribes the method of analysis (if any) of the chemical composition of the active constituent concerned.
- II. The APVMA has had regard to information about the method of analysis of the chemical composition of the active constituent submitted as part of the original applications for approval and in response to notices issued under section 33 of the Agvet code, as discussed in the Diazinon Review Technical Report.
- There were no concerns identified for the method(s) of analysis used to determine the purity of diazinon for each approved source of the active constituent listed in Table 1. The APVMA is satisfied of the method of analysis of the chemical composition of each approved diazinon active constituent listed in Table 1 of Attachment A.
 - The available information for the diazinon active constituent approval number 44033 as listed in Table 2 of Attachment A, was not sufficient to assess whether the analytical methodology used to assess the chemical composition of the active constituent is adequate. Therefore, the APVMA is not satisfied of the method of analysis of the chemical composition of the diazinon active constituent listed in Table 2 of Attachment A.
- 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 diazinon active constituents meet the safety criteria.
- 6) Having had regard to the matters described above, the APVMA is not satisfied that diazinon active constituents meet the safety criteria set out in section 5A of the Agvet Code.

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

- 7) Section 34A(1) 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.
- 8) The APVMA has considered whether active constituent approvals can be varied in such a way as to meet the safety criteria set out in Section 5A(1) as follows:
- I. To address concerns identified in paragraph 5)e)III which relate to the conditions of approval of diazinon active constituents, as set out in section 5A(2)(a)(v) of the Agvet Code, the APVMA proposes to vary the conditions referred to as the 'Active Constituent Quality Assurance Requirements' so as to substitute the reference to the "APVMA standard" with "Agricultural and Veterinary Chemicals Code (Agricultural Active Constituents) Standards 2022 (Agricultural Active Constituents Standards 2022)" in the first instance and "Agricultural Active Constituents Standards 2022" in subsequent instances.

- 9) For the purposes of section 34(A)(1)(b), the APVMA is satisfied that the relevant particulars or conditions of the active constituent approvals listed in Table 1 in Attachment A of this notice can be varied in the ways set out in paragraph 8), to allow the approval of those active constituents to be affirmed.
- 10) For the purposes of section 34(A)(1)(b), the APVMA is not satisfied that the relevant particulars or conditions of approval for the diazinon active constituent number 44033 as listed in Table 2 of Attachment A, can be varied to allow the approval to be affirmed.

Consideration of whether active constituents comply with any requirement 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 requirements prescribed by the regulations.
- a) There are no other requirements prescribed by the regulations for active constituents that have not already been considered above.

Chemical products

- 12) 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 regulations.
- 13) 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.
- 14) The APVMA has decided to reconsider all matters covered by subsection 34(1) in relation to the reconsideration of diazinon chemical product registrations except where those matters relate to an active constituent other than diazinon.

Consideration of whether registered chemical products meet the safety criteria

- 15) 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 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)(l)).

16) For the purposes of being satisfied that diazinon chemical products meet the safety criteria, the APVMA has had regard to the criteria set out in section 5A(3)(a) of the Agvet Code 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 relation to the toxicity of diazinon chemical products and their residues:
 - Information on the toxicity of diazinon and its residues, as set out in paragraph 5)a) and the *Diazinon Review Technical Report* and the references therein, including the diazinon health based guidance values and regulatory acceptable levels for exposure of non-target species.
 - Studies on the presence and formation of impurities of toxicological concern during manufacture and storage of diazinon chemical products as described in the *Diazinon Review Technical Report*.
 - The status of agricultural chemical products containing diazinon as date-controlled chemical products.
 - The APVMA's records of registration of diazinon agricultural and veterinary chemical products.
 - The impact of any excipients in the chemical products on the toxicity of the diazinon chemical products to relevant organisms and ecosystems, including human beings as detailed in the *Diazinon Review Technical Report*.
 - Environmental toxicity studies on the effects of formulated diazinon products on non-target species, as detailed in the *Diazinon Review Technical Report*.
 - II. The APVMA concluded that an ADI of 0.001 mg/kg bw/day and an ARfD of 0.01 mg/kg bw for diazinon are appropriate, as set out in the *Diazinon Review Technical Report* and paragraph 5)a)II above.
 - III. The APVMA's worker exposure assessment detailed in *Diazinon Review Technical Report* identified acceptable levels of occupational exposure to for a single exposure to diazinon, applying a 20-fold MOE of to a point of departure of 0.2 mg/kg bw.
 - IV. The APVMA's worker exposure assessment detailed in *Diazinon Review Technical Report* identified acceptable levels of short term repeated occupational exposure to diazinon, applying a 20-fold MOE of to a point of departure of 0.02 mg/kg bw/day for short term repeated oral exposure.
 - V. The APVMA's environmental assessment concluded that exposure of non-target species to diazinon below the regulatory acceptable levels set out in the *Diazinon Review Technical Report* is not likely to have an unintended effect that is harmful to animals, plants or things or to the environment.
 - VI. The APVMA's residue assessment detailed in the *Diazinon Review Technical Report* and discussed in paragraph 5)a)IV concluded that:

- a residue definition for diazinon cannot be established for the purposes of risk assessment for plant commodities treated with diazinon chemical products based on the information available
 - a residue definition of diazinon *per se* is suitable for enforcement for plant commodity MRLs based on the information available
 - a residue definition for diazinon cannot be established for the purposes of risk assessment or compliance with the MRLs for animal commodities treated with diazinon chemical products based on the information available
 - the APVMA is unable to approve diazinon MRLs for any plant or animal commodity intended for human consumption on the basis that an appropriate residues definition for risk assessment could not be established
 - uses of chemical products containing diazinon as an active constituent is not supported for use on any crop or animal intended for human consumption.
- VII. The APVMA's chemistry assessment concluded that the diazinon chemical products formulated as emulsifiable concentrate (EC) have the potential to form the toxicologically significant impurities S,S-TEPP and O,S-TEPP during storage. The available information indicates that the products listed in Table 1 and 2 of Attachment A, except for product number 87681, the formulation of the products to include an adequate amount of water scavenging material and other parameters is sufficient such that the expected level of impurities would not be harmful to relevant organisms and ecosystems, including human beings, provided that the recommended shelf-life is not exceeded as discussed in the *Diazinon Review Technical Report*. Therefore, the APVMA is satisfied that diazinon products, except product number 87681, are not expected to form unacceptable levels of toxicologically significant impurities, provided the recommended shelf-life is not exceeded.
- 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. Diazinon is listed in Schedule 5 of the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) in dust preparations containing 2% or less of diazinon.
 - II. Diazinon is listed in Schedule 6 of the SUSMP, except when included in Schedule 5.
 - III. The APVMA is satisfied that agricultural and veterinary chemical products listed in schedule 5 or schedule 6 of the SUSMP can be used safely according to instructions issued by the APVMA for the purposes of section 5A(1) of the Agvet Code.
- c) Section 5A(3)(a)(iii) of the Agvet Code – how the product is formulated.
- I. The APVMA has considered the existing registration records and information submitted in response to notices issued under section 33 of the Agvet Code during 2023 in having regard to how registered chemical products containing diazinon are formulated.
 - II. Registered diazinon chemical products are formulated as:
 - Emulsifiable concentrate (EC) formulation containing 800 g/L diazinon (agricultural chemical products)

- Topical solution/suspension (emulsifiable concentrate formulation applied after dilution in water to form an emulsion) containing 3 g/L diazinon
 - Topical solution/suspension (emulsifiable concentrate formulation applied after dilution in water to form an emulsion) containing 93.3 g/L diazinon
 - Topical solution/suspension (emulsifiable concentrate formulation applied after dilution in water to form an emulsion) containing 200 g/L diazinon
 - Ear tag containing 200 g/kg diazinon
 - Ear tag containing 400 g/kg diazinon
 - Ear tag containing 300 g/kg diazinon and 100 g/kg chlorpyrifos
 - Ear tag containing 200 g/kg diazinon and 200 g/kg coumaphos
- III. As indicated in paragraph 16)a)VII above, products formulated as emulsifiable concentrates have the potential to form impurities of toxicological concern unless adequate water scavenging material is present and other parameters, as outlined in the *Diazinon Review Technical Report*, are met. All diazinon EC products except product number 87681 as listed in Table 2 were found to meet all parameters required with respect to product formulation.
- IV. Diazinon products formulated as ear tags or powders did not have any concerns related to their formulation identified.
- 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 the existing registration records and information provided in response to notices issued under section 33 of the Agvet Code during 2023 in respect of the composition and form of the constituents of the chemical products containing diazinon, including the Declaration of Composition for the active constituent, certificates of analysis for the formulated products and the manufacturer's specification of other constituents.
- II. The APVMA is satisfied that the composition and form of the constituents of the diazinon products remain acceptable.
- e) Section 5A(3)(a)(v) of the Agvet Code – any conditions to which a product's registration is, or would be, subject.
- I. The APVMA has had regard the existing registration records for diazinon chemical products and the relevant provisions in the Agvet Code and Agvet Regulations in considering the conditions to which diazinon chemical products are or would be subject.
- II. Product registrations are currently subject to the conditions prescribed by items 1, 2, 3, 4, 5, 6, and 7 of the table in regulation 17C(2) of the Agvet Regulations.

Note: Regulation 17C(3)) specifies that Items 3 and 4 of regulation 17C(2) do not apply to any agricultural chemical product as these are prescribed under regulation 59(1)(a) for the purposes of section 120A of the Agvet Code.

- III. Section 23(1)(a) of the Agvet Code, in conjunction with Regulation 18 of the Agvet Regulations also prescribe conditions for registration of chemical products relating to containers for chemical products.
- IV. In accordance with section 23(1)(a) of the Agvet Code, all registered chemical products are also subject to the conditions of registration imposed by the APVMA in the Agricultural and Veterinary Chemicals Code (Conditions of Approval or Registration) Order 2021.
- V. In accordance with section 23(1) of the Agvet Code, all veterinary chemical products are also subject to the conditions imposed by the APVMA in the Agricultural and Veterinary Chemicals Code (Manufacturing Principles) Determination 2014.
- VI. The APVMA is satisfied that the conditions detailed above can be met by the registered chemical products containing diazinon.
- VII. Agricultural chemical 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.*

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- *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.”*

VIII. The APVMA is **not satisfied** that the current condition referred to as ‘Agricultural Products Quality Assurance Requirements’, to which each agricultural chemical 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 Agricultural and Veterinary Chemicals Code (Agricultural Active Constituents) Standards 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 required to be entered in the Register for a chemical product are set out by section 20(1)(c) of the Agvet Code and prescribed by Regulation 16 of the Agvet Regulations as:
 - the distinguishing number; any instructions for the use of the product
 - the distinguishing name of the chemical product
 - the constituents of the chemical product
 - the concentration of each constituent of the chemical product

- if possible, the composition and purity of each active constituent of the chemical product
 - the formulation type for the chemical product; the net contents of the chemical product
 - identifying information for the holder of the registration for the chemical product
 - the name of each manufacturer of the chemical product
 - the address of each site at which the chemical product is manufactured by the manufacturer
 - the date of entry of these particulars in the Register of Chemical Products
 - and identifying information for any nominated agent for the registration.
- II. The APVMA has considered the relevant particulars entered in the Register for each of the products listed in Tables 1 and 2 of Attachment A.
- III. The APVMA is satisfied that all relevant particulars that are entered in the Register for diazinon chemical products, except for the instructions for use of the product, remain acceptable.
- IV. The APVMA has concluded that the use of diazinon chemical products according to the instructions for use entered in the register do not meet the safety criteria in the following situations for the reasons indicated.
- All instructions for use of diazinon chemical products on crops or animals intended for human consumption will result in human exposure to diazinon residues and toxicologically relevant metabolites at levels that are unable to be estimated based on currently available information. Therefore, the APVMA is **not satisfied** that the use of diazinon on crops or animals intended for human consumption 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; and is not, or would not be, likely to have an effect that is harmful to human beings.
 - Instructions for use of diazinon for professional use for mosquito control in permanent water bodies, pineapple sprays and pre-plant dips, banana butt treatments, onions, garlic, cauliflower and broccoli treatment, and Argentine ant control in lawns (turf) and pasture is expected to result in exposure to non-target species that exceeds the regulatory acceptable levels as described in the *Diazinon Review Technical Report*. Therefore, the APVMA is **not satisfied** that the use of diazinon in the situations above is not, or would not be, likely to have an unintended effect that is harmful to animals, plants or things or to the environment.
 - Instructions for use of diazinon products in the home and home garden, including for external treatment of horses is likely to result in exposure of people mixing and applying the product or re-entering treated areas that does not meet an acceptable margin of exposure (MOE) relative to the applicable point of departure for the assessment type, as described in the *Diazinon Review Technical Report*. Therefore, the APVMA is **not satisfied** that the use of diazinon in the home and home garden or other domestic settings 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; and is not, or would not be, likely to have an effect that is harmful to human beings. and

- V. The APVMA has concluded that the use of diazinon products by appropriately trained applicators in the following situations would not exceed the relevant regulatory acceptable levels for non-target species or acceptable MOEs for human exposure, provided that the instructions on the approved label once varied as discussed in paragraph 43) below, and reflected in the proposed labels in Attachment D of this notice, are followed:
- Space and surface spray in farm buildings and sheds
 - Space and surface spray in refuse areas, garbage containers, ant trails and nests
 - Mosquito control in temporary water pools (puddles)
 - Pre-plant dip of nursery plants
 - Skin and hide treatment
 - Mechanically pressurised hand spray treatment of horses not for human consumption
- 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.
- II. The APVMA has had regard to Declarations of Composition and Certificates of Analysis for diazinon chemical products supplied as part of the original registration applications and in response to notices issued under section 33 of the Agvet code during 2023. The APVMA is satisfied that all registered diazinon chemical products conform to the Agricultural and Veterinary Chemicals Code (Allowable Variation in Concentrations of Constituents in Agricultural Chemical Products) Standard 2022.
- 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 in having regard to the method of analysis of the chemical composition and form of the constituents of diazinon chemical products. The APVMA is satisfied of the method of analysis.
- 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.

- The APVMA has considered existing veterinary chemical product registration records and is satisfied that the registered veterinary chemical products containing diazinon comply with the requirements of regulations 8AB(1)(b) and (c) of the Agvet Regulations.
 - In accordance with regulation 8AB(2), regulations 8AB(1)(b) and (c) of the Agvet Regulations does 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) of the Agvet Regulations do not apply to diazinon chemical products based on the use patterns of diazinon products.
- 17) 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 has determined that the acceptable daily intake for diazinon is 0.001 mg/kg bw/day.
- 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* because a residue definition for risk assessment could not be established as set out in paragraph 17)c)I below.
- 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. The APVMA has concluded that the available information is not sufficient to determine a residue definition for diazinon that adequately accounts for all metabolites and breakdown products as described in the *Diazinon Review Technical Report* and in paragraphs 5)a)IV and 16)a)VI above.
- II. The APVMA is therefore **not satisfied** that sufficient trials or laboratory experiments have been carried out to assess the level of diazinon and its residues that will remain following use of diazinon on plant or animal commodities intended for human consumption, and accordingly, it is not possible for the APVMA to approve an acceptable residue limit.
- d) Section 5A(3)(b)(iv) of the Agvet Code – the stability of the product.
- I. All products containing diazinon are defined as date controlled chemical products by Regulation 4 of the Agvet Regulations.
- II. The information considered by the APVMA's chemistry assessment described in the *Diazinon Review Technical Report* and paragraph 16)a)VII above demonstrated that diazinon chemical products have the potential to form impurities of toxicological concern during storage.

- III. The available information is sufficient to allow the APVMA to determine limitations on the storage shelf-life for all Emulsifiable Concentrate products, except product number 87681 as set out in Table 2 of Attachment A, such that those diazinon products are expected to remain stable within the shelf life applied to the product if stored according to label directions.
 - IV. Solid diazinon product formulations, topical dusts/powders and ear tags, currently have shelf-life limits which are considered to be adequate based on the available stability information.
- e) Section 5A(3)(b)(v) of the Agvet Code – the specifications for containers for the product.
- I. The specifications for containers for diazinon chemical products have been assessed as described in the *Diazinon Review Technical Report*.
 - II. The APVMA is satisfied that the containers for diazinon chemical products meet the conditions set out in Regulation 18 of the Agvet Regulations. The APVMA is also satisfied that the containers are sufficient to prevent contamination of the products by unacceptable levels of water, except for the container for product number 87681.
 - III. The APVMA is **not satisfied** that the specifications for the container for product number 87681 are sufficient to prevent contamination of the products by unacceptable levels of water.
- f) Section 5A(3)(b)(vi) of the Agvet Code – such other matters as it thinks relevant.
- I. The APVMA has not identified any other relevant matters to consider.
- 18) Having had regard to the matters and findings set out above, the APVMA is **not satisfied** that the use of chemical products containing diazinon, in accordance with instructions approved by the APVMA for the products meet the safety criteria as defined in section 5A of the Agvet Code.

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

- 19) 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 registration can be varied in such a way as to allow the registration to be affirmed, the APVMA must vary the relevant particulars or conditions.
- 20) The APVMA has considered whether registered diazinon chemical products can be varied in such a way as to meet the safety criteria set out in Section 5A(1) as follows:
- a) To address concerns identified in paragraphs 16)a)VII and 16)c) when considering criteria related to the toxicity of the product and its residues and metabolites and degradation products set out in section 5A(3)(a)(i) the Agvet Code:
 - I. The APVMA is satisfied that the maximum shelf-life of the emulsifiable concentrate products listed in Table 1 of Attachment A can be varied such that the product is not expected to develop unacceptable levels of toxicologically significant impurities.
 - II. The APVMA is **not satisfied** that product number 87681 listed in Table 2 of Attachment A can be varied to meet the safety criteria, as there is not sufficient information to determine the level of toxicologically significant impurities that may be present at any given time after manufacture of the product.

- b) To address concerns identified in paragraph 16)e) when considering the conditions to which the product's registration is, or would be subject, as set out in section 5A(3)(a)(v) of the Agvet Code, the APVMA proposes to vary 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 "Agricultural and Veterinary Chemicals Code (Agricultural Active Constituents) Standards 2022" and to replace references to "registrant" with "holder".
- c) To address concerns identified in paragraph 16)f) when considering any relevant particulars that are, or would be, entered in the Register for the product as set out in section 5A(3)(a)(vi) of the Agvet Code:
- I. The APVMA proposes to vary the instructions for use of the diazinon chemical products listed in Table 1 of Attachment A to remove all uses on crops intended for human consumption, as set out in the *Diazinon Review Technical Report* and in the proposed labels in Attachment D of this notice. The APVMA is **not satisfied** that sufficient trials or laboratory experiments have been carried out to assess the level of diazinon and its residues that will remain on plant or animal commodities intended for human consumption following use of diazinon, and accordingly, it is not possible for the APVMA to approve an acceptable residue limit for the purposes of section 5A(3)(b)(iii) of the Agvet Code, as described in the *Diazinon Review Technical Report* and paragraph 17)c) above.
 - II. The APVMA proposes to vary the instructions for use of diazinon chemical products listed in Table 1 of Attachment A to remove the following uses, for which the risks to human beings through exposure during use of the products could not be adequately mitigated, as detailed in the *Diazinon Review Technical Report*.
 - All uses in the home garden, including:
 - sponge application to horses
 - spray treatment of animal sheds and stables
 - spray treatment of surfaces and spaces in and around houses and flats, refuse areas and garbage containers
 - spray treatment of lawns and around trees
 - treatment of ornamental and potted plants.
 - III. The APVMA proposes to vary the instructions for use of diazinon chemical products to remove the following uses, for which the risks to non-target species could not be adequately mitigated, as detailed in the *Diazinon Review Technical Report*.
 - instructions for professional use to treat permanent water bodies for mosquito control.
 - lawns (turf) and pastures for control of Argentine ant.
 - IV. The APVMA is **not satisfied** that the instructions for use of the registered chemical products containing diazinon listed in Table 2 in Attachment A of this notice can be varied to allow the product registrations to be affirmed because the instructions for use of these products all relate to use in food producing situations. The APVMA is **not satisfied** that sufficient trials or laboratory experiments have been carried out to assess the level of diazinon and its residues that will remain following use of diazinon on plant or animal commodities intended for human consumption, and

accordingly, it is not possible for the APVMA to approve an acceptable residue limit. Therefore as described in the *Diazinon Review Technical Report* and paragraph 17)c) above these uses are not supported.

- 21) The APVMA is therefore satisfied that the relevant particulars and conditions of the registered chemical products in Table 1 in Attachment A of this notice can be varied in the ways set out in paragraph 20), so that the use of the chemical products containing diazinon, in accordance with the instructions approved by the APVMA for the products meet the safety criteria as defined in section 5A of the Agvet Code.
- 22) The APVMA is **not satisfied** that the relevant particulars or conditions of the registered chemical products in Table 2 in Attachment A of this notice can be varied so that the use of the chemical products containing diazinon, in accordance with the instructions approved by the APVMA for the products meet the safety criteria as defined in section 5A of the Agvet Code.

Consideration of whether registered diazinon chemical products meet the efficacy criteria

- 23) 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) The criteria for agricultural chemical products and veterinary chemical products are listed in Part 2 and Part 3 of the Agricultural and Veterinary Chemicals Code (Efficacy Criteria) Determination 2014, respectively, including:
- I. criteria based on type of product, as set out in clauses 3 and 5 respectively; and
 - II. criteria based on demonstrated effectiveness, as set out in clauses 4 and 6 respectively.
- 24) Section 5B(2) of the Agvet Code provides that, for the purposes of being satisfied as to whether a chemical product meets the efficacy criteria, the APVMA must have regard to the following:
- 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 chemical products containing diazinon. 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 diazinon. 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 chemical products containing diazinon. The APVMA is satisfied that no changes to the relevant particulars entered in the Register are required to be satisfied of the efficacy these products.

- II. The variations to the instructions for use proposed to satisfy the safety criteria (as set out in paragraph 20) and trade criteria (as set out in paragraph 30) are within existing use patterns. The APVMA is satisfied that these variations will not alter the efficacy of these products.
 - 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 which are relevant to the efficacy of chemical products containing diazinon.
 - e) Section 5B(2)(d) any matters prescribed by the regulations.
 - I. There are no regulations which are relevant to the efficacy of chemical products containing diazinon.
- 25) The APVMA is satisfied that the use of chemical products containing diazinon meets the efficacy criteria as set out in section 5B of the Agvet Code and the Agricultural and Veterinary Chemicals Code (Efficacy Criteria) Determination 2014.

Consideration of whether registered diazinon chemical products meet the trade criteria

- 26) 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.
- a) 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. Chemical products containing diazinon are approved for use on crops that are considered a major export commodity, including cereal grains, oilseeds (including cotton), pulses (soybeans, field peas, beans), citrus, grapes, pome fruit, stone fruit, and sugarcane. It is therefore reasonably expected that a product of these crops might be provided to a place outside of Australia.
 - II. Chemical products containing diazinon are approved for use on crops that can be used as stockfeed for mammalian and poultry animals. Mammalian and poultry animals and their products (including 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. Chemical products containing diazinon are approved for use on cattle, pigs, sheep, goats, in forms including powders, topical solutions and ear tags. Cattle and dairy products, sheep, pigs, and goats 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.

27) For the purposes of being satisfied that the diazinon 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) 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 chemical products containing diazinon remain acceptable 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 product containing diazinon have been considered and the APVMA has concluded that all relevant particulars except for the instructions for use for the product remain acceptable with respect to the trade criteria.
 - II. The instructions for the use of chemical products containing diazinon on cereal grains, canola, cotton, pulses, citrus, grapes, pome fruit and stone fruit may result in finite residues of diazinon in products of these crops that exceed limit of detection which will be the maximum permissible level of residue of diazinon if the APVMA removes all diazinon MRLs as proposed in the *Diazinon Review Technical Report*.
 - III. The instructions for the use of chemical products containing diazinon on crops that may be fed to animals may result in finite residues of diazinon in mammalian and poultry animal commodities that exceed residue tolerance requirements for importing countries, as set out in the *Diazinon Review Technical Report*.
 - IV. The instructions for the use of chemical products containing diazinon on plants and animals intended for human consumption may result in finite residues of diazinon in plant and animal products that exceed residue tolerance requirements for importing countries, as set out in the *Diazinon Review Technical Report*.
 - V. The APVMA is **not satisfied** that the instructions for use entered in the Register for chemical products containing diazinon, approved for use on cereal grains, canola, cotton, pulses, citrus, grapes, pome fruit, stone fruit, cattle, sheep, pigs, goats, and crops that may be fed to animals, will not unduly prejudice 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. There are no matters prescribed by the regulations for the purposes of section 5C(2)(c) of the Agvet Code.

28) The APVMA is **not satisfied** that the use of chemical products containing diazinon, 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.

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

- 29) Section 34A(1) provides that if the APVMA is not satisfied under section 34(1) but is satisfied that the relevant particulars or conditions of the registration can be varied in such a way as to allow the registration to be affirmed, the APVMA must vary the relevant particulars or conditions.
- 30) The APVMA has considered whether the instructions for use for registered diazinon products can be varied in such a way as to meet the trade criteria set out in Section 5C(1) as follows:
- a) To address concerns identified in paragraph 27)b), when considering the criteria in section 5C(2)(b) of the Agvet Code, in relation to any relevant particulars that are, or would be, entered in the Register for the product:
 - I. The APVMA proposes to vary the instructions for use of chemical products containing diazinon to remove the uses on all crops intended for human consumption and for feed for animals intended for human consumption, and for use directly on animals intended for human consumption as set out in the *Diazinon Review Technical Report* and the proposed labels in Attachment D.
- 31) The APVMA is satisfied that if the instructions for use of chemical products containing diazinon that are recorded in the Register for the products listed in Table 1 of Attachment A of this notice are varied in the ways set out in paragraph 30)a)30) above, the use of chemical products containing diazinon would not unduly prejudice trade or commerce between Australia and places outside Australia and allow the APVMA to be satisfied that those products meet the Trade Criteria set out in 5D of the Agvet Code.
- 32) The APVMA is **not satisfied** that the relevant particulars or conditions of registration of the products listed in Table 2 of Attachment A can be varied to allow the APVMA to be satisfied that those products meet the Trade Criteria set out in 5D of the Agvet Code. If the APVMA varies the instructions for use to remove the instructions for use of chemical products containing diazinon in all food producing situations as proposed in paragraph 20)c) and 30)a)l there will be no remaining situations where these products are registered for use.

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

- 33) Regulation 42 of the Agvet Regulations prescribes standards for chemical products for the purposes of section 87 of the Agvet Code.
- a) Regulation 42(3)(b) prescribes: “for a product or constituent (other than a product or constituent to which paragraph (a) applies) in respect of which a standard has been made under section 6E of the Code – that standard”.
 - I. The APVMA has made 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.
 - II. The APVMA has concluded that registered agricultural chemical products containing diazinon will meet the specification for diazinon listed in the Agricultural and Veterinary Chemicals Code (Allowable Variation in Concentrations of Constituents in Agricultural Chemical Products) Standard 2022.

- b) Regulation 42(3)(f) prescribes: “for a product or constituent (other than a product or constituent to which paragraph (a), (b), (c), (d) or (e) applies) in respect of which a standard is specified in the FAO and WHO Specifications for Pesticides – that standard”.

- I. The APVMA has concluded that diazinon veterinary chemical products will meet the standard in the FAO specifications for diazinon chemical products.

- 34) The APVMA is satisfied that registered chemical products meet the requirements prescribed by regulation 42 of the Agvet Regulations for the purposes of section 87 of the Agvet Code.

Labels for chemical products

- 35) Section 34(1) and (d) of the Agvet Code provides that the APVMA must affirm the approval of a label if, and only if, it is satisfied that the label:

- a) meets the labelling criteria; and
- b) complies with any requirement prescribed by the regulations.

- 36) 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.

- 37) The APVMA has decided to reconsider all matters covered by subsection 34(1) in relation to the reconsideration of diazinon label approvals.

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

- 38) 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 such of the following as are appropriate:

- a) The circumstances in which the product should be used (5D(1)(a));
- b) How the product should be used (5D(1)(b));
- c) The times when the product should be used (5D(1)(c));
- d) The frequency of the use of the product (5D(1)(d));
- e) The withholding period after the use of the product (5D(1)(e));
- f) The re-entry period after the use of the product (5D(1)(f));
- g) The disposal of the product when it is no longer required (5D(1)(g));
- h) The disposal of containers of the product (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 (5D(1)(i));

j) Any matters prescribed by the regulations (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.
- 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).

39) Section 5D(2) of the Agvet Code provides that for the purposes of being satisfied as to whether a label meets the labelling criteria, the APVMA must have regard to the matters set out in section 5D(2). The APVMA has considered these matters as follows:

a) Section 5D(2)(a) of the Agvet Code – any conditions to which the label's approval is, or would be, subject.

- I. The APVMA is satisfied that the conditions to which label approvals are subject, as prescribed by regulations 18B to 18J of the Agvet Regulations, are appropriate for the labels for containers for products listed in Table 1 and Table 2 of Attachment A of this notice, and that no additional conditions of approval are required.

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 the instructions for use of diazinon chemical products for the crop/situation and pests contained on the approved labels of all diazinon products are adequate, as detailed in the *Diazinon Review Technical Report* and paragraphs 16)f)IV and 27)b) of this Draft Statement of Reasons, as the APVMA is not satisfied that use of diazinon in food producing crops or on animals intended for human consumption, or for use in domestic situations, including on lawns (turf) and pastures meets the safety criteria or trade criteria.

II. In relation to how the product should be used (s5D(1)(b)):

- The APVMA is **not satisfied** that the instructions for how products should be used (including application rate and method of application for all food producing situations) contained on approved labels for all diazinon products are adequate to prevent harm to people exposed to the products or their residues, as detailed in the *Diazinon Review Technical Report*.
- The APVMA is **not satisfied** that the instructions on how agricultural products should be used on lawns and turf, around trees and on crops contained on agricultural product's labels are

adequate to ensure the exposure of non-target species is mitigated, as detailed in the *Diazinon Review Technical Report*.

III. In relation to the times when the product should be used (s5D(1)(c)):

- The APVMA is **not satisfied** that the instructions in relation to the times when products should be used contained on approved labels for all diazinon products are adequate to prevent unintended harmful effects to non-target animals, plants or the environment, as detailed in the *Diazinon Review Technical Report*.

IV. In relation to the frequency of the use of the product (s5D(1)(d)).

- The APVMA is **not satisfied** that the instructions for the frequency of use of diazinon products in food producing situations are adequate to prevent unacceptable risk of exposure for people using things containing its residues as described in the *Diazinon Review Technical Report*.
- The APVMA is satisfied that the instructions regarding the frequency of use in non-food producing situations remain adequate, as detailed in the *Diazinon Review Technical Report* and the proposed labels in Attachment D of this notice.

V. In relation to the withholding period after the use of the product (s5D(1)(e)):

- If the instructions for use of diazinon products on food producing crops and animals are removed as proposed, no uses of diazinon that require withholding periods will remain approved.

VI. The re-entry period after the use of the product (s5D(1)(f)):

- The APVMA is not satisfied that the instructions regarding the re-entry period after use of the product are adequate as described in the *Diazinon Review Technical Report*.

VII. The disposal of the product when it is no longer required (s5D(1)(g)):

- The APVMA is **not satisfied** that instructions for disposal of the product when it is no longer required contained on approved labels are adequate, noting the best practice guides in the Agricultural Labelling Code and Veterinary Labelling Code, as applicable, and that it may be an offence to bury diazinon chemical products in some jurisdictions.

VIII. The disposal of containers for the product (s5D(1)(h)):

- The APVMA is **not satisfied** that instructions for disposal of containers of diazinon chemical products contained on approved labels are adequate, noting the best practice guide in the Agricultural Labelling Code or Veterinary Labelling Code and that it may be an offence to bury containers of diazinon chemical products in some jurisdictions.

IX. 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 has considered the hazards and risks of exposure to diazinon in an accident caused by handling the product and is satisfied that the first aid instructions contained on the approved label of all products are adequate. and no changes are required.

- The APVMA is **not satisfied** that the instructions for safe handling of the product contained on approved labels for diazinon products are adequate to prevent undue exposure people handling the product as detailed in the *Diazinon Review Technical Report*.

X. 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 proposing to remove all veterinary treatments, except for spraying horses to control flies and lice on horses, as these uses on food producing animals will not meet the safety or trade criteria as discussed in the *Diazinon Review Technical Report* and paragraphs 16)f)IV and 27)b) of this Draft Statement of Reasons. The APVMA is satisfied that the instructions regarding the duration of treatment of horses are adequate.
- 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 adequate instructions to prevent undue prejudice to trade or commerce between Australia and places outside of Australia. The instructions for use on current labels for use of diazinon on major export commodities are expected to lead to finite residues exceeding limits accepted in the Codex MRL standard and other international jurisdictions, as detailed in the *Diazinon Review Technical Report* and paragraphs 27)b) of this Draft Statement of Reasons.
- Regulation 8AE(1)(c) of the Agvet Regulations – the appropriate signal words (if any) required by the current Poisons Standard.
 - The following signal words are required on labels by the current Poisons Standard:
 - Diazinon in dust preparations containing 2% or less of diazinon is listed in Schedule 5 of the SUSMP. The required signal word is “CAUTION” and the label requires the cautionary phrase “KEEP OUT OF REACH OF CHILDREN”.
 - Diazinon except when included in schedule 5 is listed in Schedule 6 of the SUSMP. The required signal word is “POISON” and the label requires the cautionary phrase “KEEP OUT OF REACH OF CHILDREN”.
 - As safety directions are required on all labels, the signal heading must also include the statement “READ SAFETY DIRECTIONS BEFORE OPENING OR USING”.
 - Veterinary chemical products only for the treatment of animals, must include the signal heading statement “FOR ANIMAL TREATMENT ONLY”
 - The APVMA is satisfied that the signal words required by the current Poisons Standard are included on approved labels.
- 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.

- Regulation 4 of the Agvet Regulations defines a date-controlled chemical product as “each veterinary chemical product and an agricultural chemical product specified in Schedule 1 to the Agvet Regulations”
 - All diazinon agricultural chemical products are listed in Schedule 1 to the Agvet Regulations
 - The APVMA is **not satisfied** that all labels for diazinon products contain adequate instructions for the storage of containers of diazinon products, as information about the duration of storage is not included.
 - 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 diazinon label approvals.
- 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 diazinon label approvals under section 6E.
- d) Section 5D(2)(d) of the Agvet Code – any matters prescribed by the regulations.
- I. Regulation 18E requires that if a labelling standard has not been made by the APVMA, then the label must comply with the requirements of either the Veterinary Labelling Code, if the product is a veterinary chemical product, or the Agricultural Labelling Code, if the product is an agricultural chemical product.
- The APVMA is **not satisfied** that the approved labels for diazinon veterinary chemical products comply with the current Veterinary Labelling Code and is **not satisfied** that the approved labels for diazinon agricultural chemical products comply with the current Agricultural Labelling Code for the reasons listed in paragraph 39)b) above related to the instructions for use of the products.
- II. The APVMA remains satisfied that diazinon labels approvals are compliant with all other matters prescribed by the regulations; specifically, the conditions to which label approvals are subject as prescribed by regulations 18B to 18J.
- 40) The APVMA is **not satisfied** that current approved labels for containers for diazinon chemical products contain adequate instructions relating to the matters set out in paragraph 39)b) above.
- 41) The APVMA is satisfied that all particulars, excluding the instructions contained on the label, that are recorded in the relevant APVMA file remain appropriate.

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

- 42) Section 34A(1) 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.
- 43) The APVMA has considered whether the labels approved for containers for diazinon chemical products can be varied in such a way as to meet the labelling criteria and comply with any requirement prescribed by the regulations as follows. Labels for products listed in Table 2 of Attachment A have not been considered for variation as the APVMA is proposing not to be satisfied that those products meet the safety or trade criteria as set out in the *Diazinon Review Technical Report* and paragraphs 20)c) and 30)a)I30)a)I of this statement of reasons.
- a) To address concerns identified in paragraph 39)b)39)b)39)a), when considering the matters in section 5D(2)(b) of the Agvet Code:
- i. In relation to the concerns identified in paragraph 39)b)I regarding the circumstances in which a product should be used (s5D(1)(a)):
- The APVMA is satisfied that the label approvals listed Table 1 in Attachment A of this notice can be varied to remove the crop/situation and pest statements, and all other associated instructions, for uses in food producing crops and animals intended for human consumption where the safety and trade risks could not be adequately mitigated, as set out in the *Diazinon Review Technical Report* and paragraphs 20) and 30)of this statement of reasons and in the proposed labels in Attachment D of this notice.
 - The APVMA also proposes to remove the instructions for use in the following domestic or residential situations as the risks to human exposure cannot be adequately mitigated as described in the *Diazinon Review Technical Report* and paragraph 20) above.
 - sponge application to horses
 - spray treatment of animal sheds and stables
 - spray treatment of surfaces and spaces in and around houses and flats, refuse areas and garbage containers
 - spray treatment of lawns and around trees
 - treatment of ornamental and potted plants.
 - The APVMA proposes to, where relevant, vary the approved labels listed in Table 1 in Attachment A of this notice to include the following statement of claims and restraints, as set out in in the proposed labels in Attachment D of this notice:
 - Statement of claims – “*THIS PRODUCT IS TOO HAZARDOUS FOR USE BY HOUSEHOLDERS*”
 - Restraints – “*DO NOT use in areas accessible to children*”

- II. In relation to the concerns identified in paragraph 39)b)II39)b)II and 39)b)III regarding the instructions for how the product should be used (s5D(1)(b)) and the times when the products should be used (s5D(1)(c)), respectively:
- The APVMA proposes to vary the approved labels listed in Table 1 in Attachment A of this notice to include the following additional restraints as applicable to each product indicated in the proposed labels in Attachment D of this notice.
 - For agricultural chemical products used in commercial and industrial areas and that include instructions for use in pre-plant dipping of nursery plants :
 - *DO NOT use in areas accessible to children*
 - *DO NOT spray water or feed troughs*
 - *DO NOT treat farm buildings and animal sheds by fog or spray in the presence of animals. Wait until chemical clears after treatment, then thoroughly ventilate treated area, before allowing re-entry of animals.*
 - *DO NOT treat outdoor areas if rain is expected within 24 hours*
 - *DO NOT plant treated material if heavy rains or storms are forecast within 3 days*
 - For veterinary chemical products that include uses on horses and on animal sheds:
 - *DO NOT use on horses that may be used for human consumption*
 - *DO NOT use in areas accessible to children*
 - The APVMA proposes to vary the approved labels listed in Table 1 in Attachment A of this notice to include the following amended and additional environmental protections statements, as set out in the *Diazinon Review Technical Report* and reflected in the proposed labels in Attachment D of this notice:
 - *Very toxic to aquatic life. DO NOT contaminate wetlands or watercourses with this product or used containers.*
- III. In relation to the concerns identified in paragraph 39)b)V regarding the instructions for the withholding period after the use of the product (s5D(1)(e)), the APVMA proposes to remove all uses of diazinon on food producing crops or animals intended for human consumption, as reflected in the proposed labels in Attachment D of this notice, which removes the need for withholding periods for diazinon products.
- IV. In relation to the concern identified in paragraph 38)f) regarding the re-entry period after use of the product (s5D(1)(f)), the APVMA proposes to vary the instructions on the labels listed in Table 1 of Attachment A to include the following general re-entry period instructions as recommended in the *Diazinon Review Technical Report* and reflected in the proposed labels in Attachment D of this notice.

- *If re-entering treated areas before the spray has dried wear cotton overalls buttoned to the neck and wrist (or equivalent clothing) and chemical resistant gloves. Clothing must be laundered after each day's use.*

V. In relation to the concerns identified in paragraph 39)b)VII and 39)b)VIII regarding the disposal of the product when it is no longer required (s5D(1)(g) and disposal of containers for the product (s5D(1)(h), respectively, the APVMA proposes to vary the relevant label approvals listed in Table 1 of Attachment A to include the following disposal instructions:

- Emulsifiable concentrate products, based on the type of container(s) used:
- Veterinary 200 g/L EC chemical products
 - 500 mL: *"Dispose of container by wrapping with paper and putting in garbage."*
 - 5 L: *"Triple or (preferably) pressure rinse containers into spray. 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 in compliance with relevant local, state or territory government regulations. DO NOT burn empty containers or product."*
- Agricultural 800 g/L EC chemical products
 - Refillable containers: *"Empty contents fully into application equipment. Close all valves and return to point of supply for refill or storage."*
 - Non-refillable metal or plastic containers: *"Triple-rinse containers before disposal. Add rinsings to spray tank. DO NOT dispose of undiluted chemicals on site. If recycling, replace cap and return clean containers to recycler or designated collection point. If not recycling, break, crush, or puncture and deliver empty packaging or unused product 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."*
 - DrumMUSTER containers: *"This container can be recycled if it is clean, dry, free of visible residues and has the drumMUSTER logo visible. Triple-rinse container for disposal. Add rinsings to spray tank. DO NOT dispose of undiluted chemical on site. Wash outside of the container and the cap. Store cleaned container in a sheltered place with cap removed. It will then be acceptable for recycling at any drumMUSTER collection or similar container management program site. The cap should not be replaced, but may be taken separately."*

VI. In relation to the concerns identified in paragraph 39)b)IX regarding 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 proposes to vary the relevant label approvals listed in Table 1 of Attachment A to include the following safety directions instructions, as set out in the *Diazinon Review Technical Report* and reflected in the proposed labels in Attachment D of this notice:

- EC 215 g/L or less in liquid hydrocarbons (other than xylene) 750 g/L or less, with surfactants
 - *Poisonous if swallowed. Repeated minor exposure may have a cumulative poisoning effect. Will irritate the eyes and skin. Avoid contact with eyes and skin. Do not inhale vapour or spray mist. When opening the container and preparing spray, wear cotton overalls buttoned to the neck and wrist or equivalent clothing and a washable hat, and elbow-length chemical resistant gloves. When using the prepared spray, wear protective waterproof clothing, cotton overalls buttoned to the neck and wrist or equivalent clothing and a washable hat, elbow-length chemical resistant gloves and a half-face piece respirator. If clothing becomes contaminated with product, remove clothing immediately. If product on skin, immediately wash area with soap and water. After use and before eating, drinking or smoking, wash hands, arms and face thoroughly with soap and water. After each day's use, wash gloves, respirator and if rubber wash with detergent and warm water, and contaminated clothing.*
- EC ULV 200 – 800 g/L
 - *Product is poisonous if absorbed by skin contact or swallowed. Repeated minor exposure may have a cumulative poisoning effect. Will irritate the eyes and skin. Avoid contact with eyes and skin. DO NOT inhale spray mist. When preparing the spray and using the prepared spray, wear cotton overalls buttoned to the neck and wrist and a washable hat, elbow length chemical resistant gloves and face shield or goggles. If product on skin, immediately wash area with soap and water. After use and before eating drinking or smoking, wash hands, arms and face thoroughly with soap and water. After each day's use, wash gloves, face shield or goggles and contaminated clothing.*

VII. In relation to concerns identified in paragraph 39)b)X regarding the storage of containers of the product, the APVMA proposes to vary the approved labels listed in Table 1 in Attachment A to include the instructions “Store below 30° C (room temperature), in the closed, original container in a cool, well ventilated area. Do not use after {insert expiry date}”.

VIII. In relation to concerns identified in paragraph 39)b)X regarding the prevention of undue prejudice to trade or commerce between Australia and places outside of Australia, the APVMA proposes to vary the approved labels listed in Table 1 in Attachment A of this notice as follows and reflected in the proposed labels in Attachment D of this notice.

- The APVMA proposes to remove all instructions for use on crops for human consumption or for feed for animals intended for human consumption, or for use directly on animals intended for human consumption from labels for containers for diazinon products.
- For diazinon products with instructions for use on horses not intended for human consumption the APVMA proposes to remove the current withholding period and add the restraint “DO NOT use on horses that may be used for human consumption”.

b) In relation to the concerns identified when considering the criteria in section 5D(2)(d) of the Agvet Code related to compliance with the Veterinary Labelling Code or Agricultural Labelling Code, the APVMA is satisfied that label approvals listed in Table 1 in Attachment A will meet the relevant Veterinary Labelling

Code or Agricultural Labelling Code if they are varied in the ways set out above, and in the additional ways set out below, as reflected in the proposed labels in Attachment D of this notice.

- I. The instructions for small spill management for veterinary chemical products can be varied to *“For small spill management, refer to instructions listed in the Safety Data Sheet”*.
- 44) 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 will consult with each co-ordinator designated for a jurisdiction and take into account any recommendations made by the co-ordinators prior to making any variations that would affect instructions for use on a label, noting the proposals set out in this statement of reasons may be amended after consideration of all consultation submissions.
- 45) The APVMA is satisfied that the relevant particulars of the label approvals listed in Table 1 of Attachment A can be varied in the ways set out in paragraph 43), so that the labels contain adequate instructions so as to meet the labelling criteria and comply with any requirement prescribed by the regulations.
- 46) The APVMA is **not satisfied** that the relevant particulars or conditions of the label approvals in Table 2 of Attachment A can be varied so that labels contain adequate instructions so as to meet the labelling criteria because the instructions for use of the products cannot be varied to allow the APVMA to be satisfied that the products meet the safety or trade criteria.

Conclusions

- 47) For the purposes of sections 34(1), 34A(1) and 34AA(1) of the Agvet Code, and having regard to the matters set out above, the APVMA has determined as follows:
- a) Regarding diazinon active constituent approvals, the APVMA:
 - I. is satisfied that the conditions of the diazinon active constituent approvals listed in Table 1 in Attachment A of this notice can be varied as described in paragraph 6) of this statement of reasons to meet the safety criteria and allow the approvals to be affirmed
 - II. is **not satisfied** that the relevant particulars or conditions of approval for the diazinon active constituent listed in Table 2 of Attachment A of this notice, can be varied to meet the safety criteria to allow the approval to be affirmed
 - III. is satisfied that the active constituents listed in Table 1 comply with any requirement prescribed by the regulations.
 - b) Regarding diazinon chemical product registrations, the APVMA is:
 - I. **not satisfied** that the diazinon chemical product registrations meet the safety criteria, trade criteria and any requirement prescribed by the regulations
 - II. satisfied that the diazinon chemical product registrations meet the efficacy criteria

- III. satisfied that the relevant particulars and conditions of diazinon chemical product registrations listed in Table 1 can be varied in such a way (as set out in paragraphs 20) and 30), of the statement of reasons) to allow the chemical product registrations to be affirmed
- IV. **not satisfied** that the particulars of diazinon chemical product registrations listed in Table 2 can be varied in such a way to allow the chemical product registrations to be affirmed.

c) Regarding diazinon label approvals, the APVMA is:

- I. **not satisfied** that the labels approvals for containers for diazinon chemical products meet the labelling criteria and comply with any requirement prescribed by the regulations
- II. satisfied that the particulars of diazinon label approvals listed Table 1 of Attachment A of this notice can be varied, as set out in paragraph 43) of the statement of reasons and as reflected in the proposed labels in Attachment D of this notice, to allow the APVMA to be satisfied that the labels meet the labelling criteria in 5D of the Agvet Code and to allow the label approvals to be affirmed
- III. **not satisfied** that the particulars or conditions of diazinon label approvals listed in Table 2 of Attachment A can be varied in such a way to allow the label approvals to be affirmed for the reasons set out in paragraph 43) of the statement of reasons.

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

- a) vary the conditions of diazinon active constituent approvals listed in Table 1 in Attachment A of this notice, in a manner set out in paragraph 8) of the statement of reasons, to allow affirmation under section 34(1) of the Agvet Code; and
- b) vary the relevant particulars and conditions of the chemical product registrations listed in Table 1 of Attachment A, in a manner set out in paragraphs 20), and 30) of the statement of reasons, to allow affirmation under section 34(1) of the Agvet Code; and
- c) vary the relevant particulars of the label approvals listed in Table 1 of Attachment A in the manner set out in paragraph 43) of the statement of reasons, and as reflected in the proposed labels in Attachment D of this notice, to allow affirmation under section 34(1) of the Agvet Code.

49) Further, pursuant to section 34AA(1) of the Agvet Code, the APVMA proposes to:

- a) cancel the diazinon active constituent approval listed in Table 2 of Attachment A, as the APVMA is not satisfied that the relevant particulars or conditions of the approvals can be varied in such a way as to allow the approvals to be affirmed; and
- b) cancel the chemical product registrations listed in Table 2 of Attachment A, as the APVMA is not satisfied that the relevant particulars or conditions of the registrations can be varied in such a way as to allow the registrations to be affirmed; and
- c) cancel the label approvals listed in Table 2 of Attachment A, as the APVMA is not satisfied that the relevant particulars or conditions of the approvals can be varied in such a way as to allow the approvals to be affirmed.

Preliminary consideration of a phase-out period

- 50) The APVMA has considered whether a phase-out period could be applied to existing diazinon approvals and registrations in the event of any final decision to suspend, cancel or vary any diazinon approvals or registrations.
- 51) If, having considered all submissions received in response to this section 34AB notice, the APVMA proceeds to suspend or cancel any diazinon active constituent approvals, chemical product registrations or label approvals, this will be done in accordance with the Agvet Code and in particular Division 5 of Part 2 of that Code. Division 5 of Part 2 includes requirements regarding the giving of notice of suspensions and cancellations and the inclusion of instructions relating to possession, custody or use of the constituent or product (section 45A). This Division also includes provision in relation to the deeming of a permit to possess, have custody of or use the constituent or product, or product as labelled (section 45B).
- 52) If, having considered all submissions received in response to this section 34AB notice, the APVMA proceeds to vary any diazinon label approvals, a determination can be made under section 81(3) of the Agvet Code to permit the supply of registered chemical products with labels that were approved at an earlier time for a period allowed by the APVMA.
- 53) While the APVMA has not yet made any final decision to suspend, cancel or vary any diazinon approvals or registrations, the preliminary view of the APVMA is that, in the event that a decision to cancel, suspend or vary is made, any section 45B permit could have the maximum duration of 12 months and any determination under section 81(3) of the Agvet Code could allow supply of relevant chemical products with the earlier approved label also for a 12 month period.

Attachment C: Information on which the reasons are based

The information on which the reasons in the Draft Statement of Reasons is based is set out below:

- 1) Information provided to the APVMA in response to notices
 - a. Issued to Holders under section 33 of the Agvet Code on 5 April 2022, 20 June 2022, 26 September 2022, 16 December 2022, 21 April, 2 June 2023 and 12 July 2023
 - b. Issued to Holders under section 32 of the Agvet Code on 5 July 1996, and additional s32 notices issued on 1 July 2015, 11 April 2019, 20 June 2022 and 1 December 2022
 - c. Published in the APVMA Gazette under section 32 of the Agvet Code on 3 December 1996
- 2) Data submitted in response to the publication of the Diazinon Review Findings Report Part 1 in 2003
- 3) Other information assessed by the APVMA and summarised in the following published reports:
 - a. *Diazinon Review Technical Report* (APVMA, 2023)
 - b. *Diazinon human health risk assessment part 2: toxicological hazard assessment* (APVMA, 2011)
 - c. *Diazinon preliminary review findings, part 2, volume 2* (APVMA, 2006b)
 - d. *Diazinon preliminary review findings, part 2, volume 1* (APVMA, 2006b)
 - e. *Diazinon review findings report, part 1* (APVMA, 2003)
 - f. *Diazinon revised draft report: summary* (APVMA, 2002a)
 - g. *Diazinon environmental assessment* (APVMA, 2002b)
 - h. *Diazinon occupational health and safety assessment* (APVMA, 2002c)
 - i. *Diazinon toxicology assessment* (APVMA, 2002d)
 - j. *Diazinon agriculture assessment* (APVMA, 2002e)
 - k. *Diazinon chemistry assessment – draft* (APVMA, 2002f)
 - l. *Diazinon residues assessment* (APVMA, 2002g)
 - m. *Call for public comment on the NRA draft review report of Diazinon* (APVMA, 2000)
- 4) The relevant provisions of the Agvet Code and instruments under that Code, in particular those set out below:

Table C1: Agricultural and Veterinary Chemicals Code Act 1994

Section	Section heading
3	Definitions
5A	Definition of <i>meets the safety criteria</i>
5B	Definition of <i>meets the efficacy criteria</i>
5C	Definition of <i>meets the trade criteria</i>
5D	Definition of <i>meets the labelling criteria</i>
6E	The APVMA may make standards

Section	Section heading
19	How approval of active constituent takes place
20	How registration of chemical product takes place
21	How approval of label takes place
23	Conditions of approval or registration
31	APVMA may reconsider an approval or registration
33	APVMA may require information, reports, results or samples
34	Reconsideration by APVMA
34A	Varying relevant particulars or conditions to allow affirmation
34AA	Suspension or cancellation
34AB	Notice of proposed decision

Table C2: Agricultural and Veterinary Chemicals Code Regulations 1995

Section	Section heading
8AA	Safety Criteria – active constituents
8AB	Safety Criteria – chemical products
8AD	Trade Criteria
8AE	Labelling Criteria
15	Particulars of approved active constituents to be recorded
16	Particulars of registered chemical products to be recorded
17	Particulars for label
17C	Conditions of approval or registration – active constituents and chemical products
18	Conditions of registration of chemical products – containers
18E	Labelling standards and requirements

Table C3: Other legislative instruments under the *Agricultural and Veterinary Chemicals Code Act 1994*

Legislative instruments
<u>Agricultural and Veterinary Chemical Code (Efficacy Criteria) Determination 2014</u>
<u>Agricultural and Veterinary Chemicals Code (Conditions of Approval or Registration) Order 2021</u>
<u>Agricultural and Veterinary Chemicals Code (Agricultural Active Constituents) Standards 2022</u>

Legislative instruments

Agricultural and Veterinary Chemicals Code (Allowable Variation in Concentrations of Constituents in Agricultural Chemical Products) Standard 2022

- 5) Therapeutic Goods (Poisons Standard – October 2023) Instrument 2023 (i.e. the Standard for the Uniform Scheduling of Medicines and Poisons)
- 6) The Agricultural Labelling Code as published on the APVMA website
- 7) The Veterinary Labelling Code as published on the APVMA website

Attachment D: Proposed sample labels for diazinon chemical products

49876 NUCIDOL 200 EC INSECTICIDE AND ACARICIDE

Signal Headings:	POISON KEEP OUT OF REACH OF CHILDREN READ SAFETY DIRECTIONS BEFORE OPENING OR USING FOR ANIMAL TREATMENT ONLY
Product Name:	Nucidol 200 EC Insecticide and Acaricide
Constituent Statements:	200 g/L DIAZINON (anticholinesterase compound) Also contains: 552 g/L HYDROCARBON-LIQUID (solvent)
Claims:	THIS PRODUCT IS TOO HAZARDOUS FOR USE BY HOUSEHOLDERS Controls: Horses: <i>Flies (Musca vetustissima)</i> <i>Lice on horses (Damalinia equi; Haematopinus asini)</i> Animal sheds: <i>Flies (Musca domestica; Stomoxys calcitrans)</i> Resistance may develop to any chemical.
Net Contents:	500 mL, 5 L
Directions for Use:	
Restrains:	DO NOT use in areas accessible to children DO NOT use on horses that may be used for human consumption DO NOT treat farm buildings and animal sheds by spray in the presence of animals. Wait until chemical clears after treatment, then thoroughly ventilate treated area, before allowing re-entry of animals DO NOT spray water or feed troughs DO NOT allow water to enter this container DO NOT rinse lid with water
Contraindications:	
Precautions:	Re-entry Period If re-entering treated areas before the spray has dried wear cotton overalls buttoned to the neck and wrist (or equivalent clothing) and chemical resistant gloves. Clothing must be laundered after each day's use
Side Effects:	
Dosage and Administration:	This section contains file attachment.
General Directions:	NUCIDOL mixes readily with hard or soft water.

Withholding Periods:	
Trade Advice:	
Safety Directions:	Poisonous if swallowed. Repeated minor exposure may have a cumulative poisoning effect. Will irritate the eyes and skin. Avoid contact with eyes and skin. Do not inhale vapour or spray mist. When opening the container and preparing spray, wear cotton overalls buttoned to the neck and wrist or equivalent clothing and a washable hat, and elbow-length chemical resistant gloves. When using the prepared spray, wear protective waterproof clothing, cotton overalls buttoned to the neck and wrist or equivalent clothing and a washable hat, elbow-length chemical resistant gloves and a half-face piece respirator. If clothing becomes contaminated with product, remove clothing immediately. If product on skin, immediately wash area with soap and water. After use and before eating, drinking or smoking, wash hands, arms and face thoroughly with soap and water. After each day's use, wash gloves, respirator and if rubber wash with detergent and warm water, 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, 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.
Additional User Safety:	If additional hazard information is required, refer to Material Safety Data Sheet, which is available from http://www.pacificbiologics.com.au .
Environmental Protection:	Very toxic to aquatic life. DO NOT contaminate wetlands or watercourses with this product or used containers. Highly toxic to bees. However, the use of this product as directed is not expected to have adverse effects on bees.
Disposal:	500 mL: Dispose of container by wrapping with paper and putting in garbage. 5 L: Triple or (preferably) pressure rinse containers into spray. 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 in compliance with relevant local, state or territory government regulations. Do not burn empty containers or product.
Storage:	Store in original container tightly closed in a dry cool place. DO NOT store in direct sunlight. Store below 30 °C (Room Temperature). DO NOT use after {insert expiry date}.

Dosage and Administration

Animal/ Situation	Pest	High Volume Spray	Critical Comments
Horses	Flies (<i>Musca vetustissima</i>) and Lice (<i>Damalinia equi</i> ; <i>Haematopinus asini</i>)	25 mL per 10 litres of water	Apply by mechanically pressurised hand wand only. Spray liberally as required.
Animal Sheds	Flies (<i>Musca domestica</i> ; <i>Stomoxys calcitrans</i>)	250 mL per 10 litres of water	Spray the inner walls and any other places where flies settle thoroughly. Respray as necessary.

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

800 g/L Diazinon EC products (50007, 59707, 68534, 88946)

Signal Heading:	POISON KEEP OUT OF REACH OF CHILDREN READ SAFETY DIRECTIONS BEFORE OPENING OR USING		
Product Name:	(product name)		
Constituent Statement:	800 g/L DIAZINON (AN ANTICHOLINESTERASE COMPOUND)		
Mode of Action:	GROUP	1B	INSECTICIDE
Statement of Claims:	THIS PRODUCT IS TOO HAZARDOUS FOR USE BY HOUSEHOLDERS For the control of insect pests in various commercial and industrial areas as per the Directions for Use table.		
Net Contents:	(product specific statement)		
Restraints:	DO NOT use in areas accessible to children DO NOT spray water or feed troughs DO NOT treat farm buildings and animal sheds by fog or spray in the presence of animals. Wait until chemical clears after treatment, then thoroughly ventilate treated area, before allowing re-entry of animals. DO NOT treat outdoor areas if rain is expected within 24 hours DO NOT plant treated material if heavy rains or storms are forecast within 3 days		
Directions For Use:			
Other Limitations:			
Withholding Period:			
Trade Advice:			
General Instructions:	GENERAL INSTRUCTIONS Before opening, carefully read directions for use, precautionary statements, safety directions, first aid instructions and attached leaflet. Thorough coverage is essential. COMPATIBILITY This product is compatible with Winter and Summer Oils and White Oil. This product should not be mixed with dodine, lime sulphur, oxythioquinox or 2,4-DB. MIXING Measure out the required amount of [product] and slowly add to water in the spray tank under agitation.		
Resistance Warning:	Insecticide Resistance Warning GROUP 1B INSECTICIDE For insecticide resistance management, [product] is a Group 1B insecticide. Some naturally occurring insect biotypes resistant to [product] 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 [product] or other Group 1B insecticides are used repeatedly. The effectiveness of [product] on resistant individuals could be significantly reduced. Since the occurrence of resistant individuals is difficult to detect prior to use, [holder] accepts no liability for any losses that may result from the failure of [product] to control resistant insects. [product] may be subject to specific resistance management strategies. For further information contact your local supplier, [holder] representative or local agricultural department agronomist.		

Precautions:	<p>PRECAUTIONS</p> <p>DO NOT spray directly on to humans.</p> <p>Avoid contact with food, food utensils, places where food is prepared or stored and food processing machinery. Ventilate treated rooms or buildings before reoccupying. DO NOT expose wild or domestic birds to the product.</p> <p>Re-entry Period</p> <p>If re-entering treated areas before the spray has dried wear cotton overalls buttoned to the neck and wrist (or equivalent clothing) and chemical resistant gloves. Clothing must be laundered after each day's use.</p>
Protection Statements:	<p>PROTECTION OF LIVESTOCK</p> <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>Highly 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), in the closed, original container in a cool, well ventilated area. Do not use after {insert expiry date}. 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. 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 in compliance with relevant local, state or territory government regulations. Do not burn empty containers or product.</p> <p>(If applicable for product)</p> <p>This container can be recycled if it is clean, dry, free of visible residues and has the drumMUSTER logo visible. Triple-rinse container for disposal. Dispose of rinsate or any undiluted chemical according to state legislative requirements. Wash outside of the container and the cap. Store cleaned container in a sheltered place with cap removed. It will then be acceptable for recycling at any drumMUSTER collection or similar container management program site. The cap should not be replaced but may be taken separately.</p> <p>Spent Dip</p> <p>Dispose of dip in an authorised dip disposal facility. If an authorised dip disposal facility is not available, dispose of dip in compliance with the relevant local, state or territory government regulations.</p>
Safety Directions:	<p>Product is poisonous if absorbed by skin contact or swallowed. Repeated minor exposure may have a cumulative poisoning effect. Will irritate the eyes and skin. Avoid contact with eyes and skin. DO NOT inhale spray mist.</p> <p>When preparing or using the prepared spray, wear cotton overalls buttoned to the neck and wrist, washable hat, elbow length chemical resistant gloves and face shield or goggles. If product on skin, immediately wash area with soap and water. After use and before eating, drinking or smoking, wash hands, arms and face thoroughly with soap and water. After each day's use, wash gloves and face shield or goggles 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

Nursery plants

Crop	Pest	State	Rate per hectare diluted in water. Boom spray, Aircraft, Mister	Critical comments
Nursery Plants	Aphids, Thrips, Mealy Bugs, Scale Insects, Plant Bugs, Beetles	NSW, ACT, Vic, WA only	Dipping mixture: 60 mL per 100 litres	Thoroughly drench plant material with the dipping mixture. Treatment can be used from plants being transported from NSW into Victoria.

PEST CONTROL

Crop	Pest	Rate		Critical comments
		Sprayer	Mister	
Commercial and Industrial Buildings, Ships, Farm Buildings including Kennels, Stables and Piggeries, Refuse Areas, Garbage Containers	Cockroaches, Silverfish	6 mL per litre of water	15 mL per litre of water	Apply to crevices, cracks and hiding places, eg beneath cupboards, behind sinks and stoves.
	Carpet Beetles			Apply to floors and under carpets.
	Fleas			Areas generally infested with fleas should be sprayed
	Flies			Apply to surfaces on which insects congregate, eg ceilings, under eaves, walls
	Spiders		-	Remove existing webbing and saturate area with the mixture.
	Ants		-	Apply to ant trails. Attempt to locate nests and thoroughly saturate surface. Use at least 1 litre of mixture per 10 square meters.
Refuse Areas, Garbage Containers	Maggots	60 mL per 100 litres of water	15 mL per litre of water	Apply to thoroughly penetrate the refuse.
Temporary water pools (puddles)	Mosquito Larvae	125 mL per 100 litres of water	-	Apply to breeding areas.
Skins & hides	Skin and Hide Beetles	5 mL per litre of water	-	Apply 60 mL of mixture per hide individually, and spray area with 5 litres of mixture per 100 square meters.

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