

# Commonwealth of Australia



No. APVMA 6, Tuesday, 24 March 2015

Published by The Australian Pesticides and Veterinary Medicines Authority

# AGRICULTURAL AND VETERINARY CHEMICALS



# Australian Government Australian Pesticides and Veterinary Medicines Authority

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* (*Australian Pesticides and Veterinary Medicines Authority*) *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

The *APVMA Gazette* is published in electronic format only and is available from the APVMA website, <u>www.apvma.gov.au/publications/gazette/</u>.

If you would like to receive email notification when a new edition is published, please subscribe on the APVMA website.

#### **APVMA CONTACTS**

For enquiries regarding the publishing and distribution of the *APVMA Gazette*: Telephone: +61 2 6210 4870 For enquiries on the *APVMA Gazette* content, please refer to the individual APVMA contacts listed under each notice.

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# **Erratum Notice**

The Australian Pesticides and Veterinary Medicines Authority advises that an error was published in the Commonwealth of Australia Gazette for Agricultural and Veterinary Chemicals, No. APVMA 3, Tuesday, 10 February 2015

In the Notice, Bioquell HPV-AQ Disinfectant the summary of use statement has been amended.

The correct entry for the summary of use statement in the Notice of Registration for Bioquell HPV-AQ Disinfectant appears on page 4 of this Gazette.

# **Agricultural Chemical Products and Approved Labels**

Pursuant to the Agricultural and Veterinary Chemicals Code scheduled to the *Agricultural and Veterinary Chemicals Code Act 1994*, the APVMA hereby gives notice that it has registered or varied the relevant particulars or conditions of the registration in respect of the following products and has approved the label or varied the relevant particulars or conditions of the approval in respect of the containers for the chemical product, with effect from the dates shown.

### 1. AGRICULTURAL PRODUCTS BASED ON EXISTING ACTIVE CONSTITUENTS

Application no.:	58257
Product name:	Bioquell HPV-AQ Disinfectant
Active constituent/s:	350 g/L hydrogen peroxide
Applicant name:	Bioquell UK
Applicant ACN:	N/A
Summary of use	For use as a sporicidal disinfectant on environmental surfaces or enclosure and other inanimate objects in conjunction with Bioquell hydrogen peroxide vapour (HPV) generating equipment as instructed in the Bioquell use manual
Date of registration/approval:	30 January 2015
Product registration no.:	68380
Label approval no.:	68380/58257
Annellandland	
Application no.:	63480
Product name:	FMC Vulcan 250WG Herbicide
Active constituent/s:	250 g/kg butroxydim
Applicant name:	FMC Australasia Pty Ltd 095 326 891
Applicant ACN:	
Summary of use	For the control of certain grasses in a range of broadacre crops 4 March 2015
Date of registration/approval: Product registration no.:	70456
Label approval no.:	70456/63480
	10430/03400
Application no.:	62787
Product name:	Surefire Fipronil Granular Ant Killer
Active constituent/s:	0.25 g/kg fipronil
Applicant name:	PCT Holdings Pty Ltd
, appriount manior	
Applicant ACN:	099 023 962
	099 023 962 For the treatment of ant infestations in turf and around domestic, commercial and public service buildings
Applicant ACN:	For the treatment of ant infestations in turf and around domestic, commercial and public service
Applicant ACN: Summary of use Date of registration/approval: Product registration no.:	For the treatment of ant infestations in turf and around domestic, commercial and public service buildings
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Applicant ACN: Summary of use Date of registration/approval: Product registration no.: Label approval no.: Application no.:	For the treatment of ant infestations in turf and around domestic, commercial and public service buildings 6 March 2015 70230 70230/62787 59979
Applicant ACN: Summary of use Date of registration/approval: Product registration no.: Label approval no.:	For the treatment of ant infestations in turf and around domestic, commercial and public service buildings 6 March 2015 70230 70230/62787 59979 Conquest Soar Selective Herbicide
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Applicant ACN: Summary of use Date of registration/approval: Product registration no.: Label approval no.: Application no.: Product name: Active constituent/s:	For the treatment of ant infestations in turf and around domestic, commercial and public service buildings 6 March 2015 70230 70230/62787 59979 Conquest Soar Selective Herbicide 25 g/L diflufenican, 250 g/L MCPA (present as the ethyl hexyl ester), 150 g/L bromoxynil present as the n-octanoyl ester
Applicant ACN: Summary of use Date of registration/approval: Product registration no.: Label approval no.: Application no.: Product name: Active constituent/s: Applicant name: Applicant ACN: Summary of use	For the treatment of ant infestations in turf and around domestic, commercial and public service buildings 6 March 2015 70230 70230/62787 59979 Conquest Soar Selective Herbicide 25 g/L diflufenican, 250 g/L MCPA (present as the ethyl hexyl ester), 150 g/L bromoxynil present as the n-octanoyl ester Conquest Crop Protection Pty Ltd
Applicant ACN: Summary of use Date of registration/approval: Product registration no.: Label approval no.: Application no.: Product name: Active constituent/s: Applicant name: Applicant ACN:	For the treatment of ant infestations in turf and around domestic, commercial and public service buildings 6 March 2015 70230 70230/62787 59979 Conquest Soar Selective Herbicide 25 g/L diflufenican, 250 g/L MCPA (present as the ethyl hexyl ester), 150 g/L bromoxynil present as the n-octanoyl ester Conquest Crop Protection Pty Ltd 098 814 932
Applicant ACN: Summary of use Date of registration/approval: Product registration no.: Label approval no.: Application no.: Product name: Active constituent/s: Applicant name: Applicant ACN: Summary of use	For the treatment of ant infestations in turf and around domestic, commercial and public service buildings 6 March 2015 70230 70230/62787 59979 Conquest Soar Selective Herbicide 25 g/L diflufenican, 250 g/L MCPA (present as the ethyl hexyl ester), 150 g/L bromoxynil present as the n-octanoyl ester Conquest Crop Protection Pty Ltd 098 814 932 For the control of certain broadleaf weeds in winter cereals

Application no.: Product name:	61915 K.O.Dyne Acid Detergent Sanitiser
Active constituent/s:	680 g/L ortho phosphoric acid, 5 g/L iodine, present as iodophor
Applicant name:	GEA Farm Technologies Australia Pty Ltd
Applicant ACN:	078 926 477
Summary of use	For use as a low foam, acid based detergent sanitiser for milk lines and vats 10 March 2015
Date of registration/approval:	69864
Product registration no.:	69864/61915
Label approval no.:	
Application no.:	62512
Product name:	Loveland Products MSO With Leci-Tech Spray Adjuvant
Active constituent/s:	630 g/L methyl esters of vegetable oil
Applicant name:	Loveland Products, Inc.
Applicant ACN:	N/A
Summary of use	For use as an adjuvant with certain herbicides
Date of registration/approval:	10 March 2015
Product registration no.:	70101
Label approval no.:	70101/62512
Application no.:	61938
Product name:	Kenso Agcare Epoxy 750 WG Fungicide
Active constituent/s:	750 g/kg epoxiconazole
Applicant name:	Kenso Corporation (M) Sdn. Bhd
Applicant ACN:	N/A
Summary of use	For the control of certain fungal diseases of wheat and barley
Date of registration/approval:	11 March 2015
Product registration no.:	69874
Label approval no.:	69874/61938
Application no.:	
Product name:	Turf Culture Steer 750 Herbicide
Active constituent/s:	750 g/kg quinclorac
Applicant name:	Turf Culture Pty Ltd
Applicant ACN:	117 986 615
Summary of use	For the post-emergence control of summer grass and white clover and the suppression of kikuyu in turf
Date of registration/approval:	13 March 2015
Product registration no.:	70424
Label approval no.:	70424/63431
Application no.:	101030
Product name:	Mission Epoxiconazole 800 WG Fungicide
Active constituent/s:	800 g/kg epoxiconazole
Applicant name:	Mission Bell Holdings Pty Ltd
Applicant ACN:	149 573 651
Summary of use	For the control of leaf rust, stripe rust and septoria nodorum blotch of wheat and leaf rust of
-	barley
Date of registration/approval:	18 March 2015
Product registration no.:	80518
Label approval no.:	80518/101030

Application no.:	62349
Product name:	Oracle Insecticide
Active constituent/s:	17 g/L emamectin present as emamectin benzoate
Applicant name:	Adama Australia Pty Limited
Applicant ACN:	050 328 973
Summary of use	For the control of heliothis and suppression of green mirids in cotton
Date of registration/approval:	18 March 2015
Product registration no.:	70039
Label approval no.:	70039/62349
Application no.:	100680
Product name:	Mission Chlorothalinil 720 SC Fungicide
Active constituent/s:	720 g/L chlorothalonil
Applicant name:	Mission Bell Holdings Pty Ltd
Applicant ACN:	149 573 651
Summary of use	For the control of fungal diseases on various fruit, vegetables and turf
Date of registration/approval:	18 March 2015
Product registration no.:	80358

80358/100680

### 2. VARIATIONS OF REGISTRATION

Label approval no.:

Product name:Farm Fluid S Concentrated DisinfectantActive constituent/s:419.2 g/L tar acid high boiling, 324.9 g/L acetic acid, 52.4 g/L cresylic acidApplicant name:Lienert Australia Pty. LtdApplicant ACN:008 293 007Summary of variation:To change the distinguishing product name from 'ANTEC FARM FLUIDS CONCENTRATEDDiSINFECTANT' to 'FARM FLUID S CONCENTRATED DISINFECTANT'Date of variation:17 February 2015Product registration no:47386Label approval no:101717Product name:Rodemise Super Bromadiolone Rodent BlockActive constituent/s:0.05 g/kg bromadioloneApplicant ACN:137 868 449Summary of variation:10 February 2015Product registration no:137 868 449Summary of variation:10 February 2015Product registration no:19 February 2015Product registration no:101760Product registration no:67578Label approval no:67578/101717Application no:101760Product registration no:101760Product rame:Conan Sticks 720 SC FungicideActive constituent/s:720 g/L chlorothalonilApplicant ACN:066 391 384Summary of variation:06 63 91 384Summary of variation:50 February 2015Product registration no:63 19 384Summary of variation:72 c herothalonilApplicant ACN:26 February 2015Product registration no:25 February 2015Product registration no:25 Feb	Application no:	101688
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Date of variation:     25 February 2015	Applicant ACN:	066 391 384
	Summary of variation:	
Product registration no.: 68458	Date of variation:	25 February 2015
	Product registration no.:	68458

Label approval no.:	68458/101760
Application no:	63165
Product name:	Duomax HC520 Plant Growth Regulator
Active constituent/s:	520 g/L cyanamide
Applicant name:	Duomax Agro-Development Pty Limited
Applicant ACN:	080 162 929
Summary of variation:	To approve the addition of regulation of bud dormancy in apples
Date of variation:	4 March 2015
Product registration no.:	58843
Label approval no.:	58843/63165
Application no:	101376
Product name:	Divap 500EC Insecticide
Active constituent/s:	500 g/L dichlorvos (an anticholinesterase compound)
Applicant name:	UPL Australia Limited
Applicant ACN:	066 391 384
Summary of variation:	To remove the grain protection use as per APVMA request
Date of variation:	4 March 2015
Product registration no.:	49362
Label approval no.:	49362/101376
Luber approval no	+5502/1015/0
Application no:	100971
Product name:	David Grays D.D.V.P. 500 Insecticide
Active constituent/s:	500 g/L dichlorvos (an anticholinesterase compound)
Applicant name:	David Gray & Co. Pty Limited
Applicant ACN:	008 671 127
Summary of variation:	To remove the grain protection use as per APVMA request
Date of variation:	4 March 2015
Product registration no.:	48975
Label approval no.:	48975/100971
Application no:	100022
Product name:	Protect-Us Mineral Snail And Slug Killer With Elemental Iron
Active constituent/s:	10 g/kg iron powder
Applicant name:	Ensystex Australasia Pty Ltd
Applicant ACN:	102 221 965
Summary of variation:	To include statements relating to safety to non-target animals
Date of variation:	4 March 2015
Product registration no.:	68516
Label approval no.:	68516/100022
	I
Application no:	100970
Product name:	Imtrade Dichlorvos 500 Insecticide
Active constituent/s:	500 g/L dichlorvos (an anticholinesterase compound)
Applicant name:	Imtrade Australia Pty Ltd
Applicant ACN:	090 151 134
Summary of variation:	To remove the grain protection use as per APVMA request
Date of variation:	4 March 2015
Product registration no.:	53320
Label approval no.:	53320/100970

Application no:	100973
Product name:	Cropro Stalk Insecticide
Active constituent/s:	400 g/L dimethoate (an anticholinesterase compound)
Applicant name:	PCT Holdings Pty Ltd
Applicant ACN:	099 023 962
Summary of variation:	To amend label claims as per APVMA request
Date of variation:	6 March 2015
Product registration no.:	58374
Label approval no.:	58374/100973
Application no:	100753
Product name:	Mortein Kill & Protect Crawling Insect Control Bomb
Active constituent/s:	0.77 g/kg fenoxycarb, 10 g/kg permethrin
Applicant name:	Reckitt Benckiser (Australia) Pty Limited
Applicant ACN:	003 274 655
Summary of variation:	To change the product name from 'MORTEIN CONTROL BOMB' to 'MORTEIN KILL & PROTECT CRAWLING INSECT CONTROL BOMB', make minor changes to claims and to add a new pack size
Date of variation:	10 March 2015
Product registration no.:	55630
Label approval no.:	55630/100753
	1
Application no:	100053
Product name:	Roundup Ready Herbicide With Plantshield By Monsanto
Active constituent/s:	690 g/kg glyphosate present as the mono-ammonium salt
Applicant name:	Monsanto Australia Ltd
Applicant ACN:	006 725 560
Summary of variation:	To extend the use to TruFlex Roundup Ready canola
Date of variation:	16 March 2015
Product registration no.:	63268
Label approval no.:	63268/100053

# **Veterinary Chemical Products and Approved Labels**

Pursuant to the Agricultural and Veterinary Chemicals Code scheduled to the *Agricultural and Veterinary Chemicals Code Act 1994*, the APVMA hereby gives notice that it has registered or varied the relevant particulars or conditions of the registration in respect of the following products and has approved the label or varied the relevant particulars or conditions of the approval in respect of the containers for the chemical product, with effect from the dates shown.

#### 1. VETERINARY PRODUCTS BASED ON NEW ACTIVE CONSTITUENTS

Application no.:	45156	
Product name:	Mycofix Plus BBSH	
Active constituent/s:	460 g/kg bentonite, 2.5 x 10 <sup>10</sup> cfu/kg <i>Eubacterium</i> strain Biomin BBSH 797	
Applicant name:	Biomin (Australia) Pty Ltd	
Applicant ACN:	102 287 570	
Summary of use	For use in the management of trichothecenes, aflatoxins and fumosins in feed for pigs and poultry	
Date of Registration/approval:	5 March 2015	
Product registration no.:	59620	
Label approval no.:	59620/45156	

#### 2. VETERINARY PRODUCTS BASED ON EXISTING ACTIVE CONSTITUENTS

Application no.:	100371
Product name:	Metaject 4 In 1 Metabolic Treatment For Cattle And Sheep
Active constituent/s:	24.5 g/L calcium (as calcium borogluconate) 4.7 g/L magnesium (as magnesium hypophosphite) 12.1 g/L phosphorus (as hypophosphite)
Applicant name:	The Hunter River Company Pty Limited
Applicant ACN:	133 798 615
Summary of use	For the use in the treatment of milk fever and grass tetany in cattle and sheep
Date of registration/approval:	12 March 2015
Product registration no.:	80187
Label approval no.:	80187/100371
	1
Application no.:	59545
Product name:	Ilium Buccalgesic OTM
Active constituent/s:	10 mg/mL meloxicam
Applicant name:	Troy Laboratories Pty Ltd
Applicant ACN:	000 283 769
Summary of use	For alleviation of pain associated with the routine surgical husbandry procedure of castration in calves, in conjunction with the administration of local anaesthetic at the surgical site
Date of registration/approval:	12 March 2015
Product registration no.:	68974
Label approval no.:	68974/59545

#### 3. VARIATIONS OF REGISTRATION

Application no.:	101752
Product name:	Aristopet Animal Health Flea Powder For Dogs And Puppies
Active constituent/s:	10 g/kg piperonyl butoxide, 1.5 g/kg pyrethrins
Applicant name:	Aristopet Pty Ltd
Applicant ACN:	145 418 882
Summary of variation:	To change the product name from 'ARISTOPET ANIMAL HEALTH FLEA POWDER FOR DOGS, CATS, PUPPIES & KITTENS' to 'ARISTOPET ANIMAL HEALTH FLEA POWDER FOR DOGS AND PUPPIES' and to remove use on cats
Date of variation:	24 February 2015
Product registration no.:	47514
Label approval no.:	47514/101752
	1
Application no.:	60684
Product name:	Sulprim Oral Powder
Active constituent/s:	430 mg/g sulfadimidine, 86 mg/g trimethoprim
Applicant name:	Troy Laboratories Pty Ltd
Applicant ACN:	000 283 769
Summary of variation:	To include replacement layer pullets prior to the onset of lay
Date of variation:	3 March 2015
Product registration no.:	51718
Label approval no.:	51718/60684
Application no :	101663
Application no.: Product name:	Mastalone Intramammary Suspension For Lactating Cows
Active constituent/s:	
Active constituent/s:	Each 10 mL contains: 185 mg oxytetracycline as hydrochloride, 100 mg oleandomycin as phosphate, 100 mg neomycin as sulphate
Applicant name:	Zoetis Australia Pty Ltd
Applicant ACN:	156 476 425
Summary of variation:	To add new sites of manufacture
Date of variation:	13 March 2015
Product registration no.:	49851
Label approval no.:	49851/101663

## **Approved Active Constituents**

Pursuant to the Agricultural and Veterinary Chemicals Code scheduled to the *Agricultural and Veterinary Chemicals Code Act 1994*, the APVMA hereby gives notice that it has approved or varied the relevant particulars or conditions of the approval of the following active constituents, with effect from the dates shown.

#### 1. ACTIVE CONSITUTENT

Date of approval: Approval no.:

Application no.:	40115
Active constituent/s:	Eubacterium sp strain BBSH 797
Applicant name:	Biomin (Australia) Pty Ltd
Applicant ACN:	102 287 570
Summary of use:	For use in veterinary chemical products
Date of approval:	5 March 2015
Approval no.:	61243/40115
Application no.:	50779
Active constituent/s:	Cyazofamid
Applicant name:	Ishihara Sangyo Kaisha, Ltd
Applicant ACN:	N/A
Summary of use:	For use in agricultural chemical products

12 March 2015

65376/50779

# Reconsideration of Approvals and Registrations Related to Azinphos-methyl

The APVMA, in accordance with Part 2, Division 4, of the Agricultural and Veterinary Chemicals Code scheduled to the *Agricultural and Veterinary Chemicals Code Act 1994* (Agvet Code), has reconsidered the approval of the active constituent azinphos-methyl, registrations of all products containing azinphos-methyl, and the approvals of all associated product labels. This notice is published in accordance with paragraphs 34(1)(f) of the Agvet Code.

Azinphos-methyl is a broad-spectrum, non-systemic insecticide that has been registered for use in Australia for over 40 years. It is used on fruit and nut crops primarily for the control of codling moth and light brown apple moth.

Currently there is one approved active constituent of azinphos-methyl (Table 1) and two registered products containing azinphos-methyl (Table 2).

#### Table 1: Active constituent approvals for azinphos-methyl

Approval No.	Approval Holder
44188	Adama Australia Pty Limited

#### Table 2: Registered products containing azinphos-methyl

(A) Product No.	(B) Product Name	(C) Registrant	(D) Label Approval No. before variation	(E) Label approval No. after variation
53215	Campbell Benthion 200 Flowable Insecticide	Colin Campbell (Chemicals) Pty Ltd	53215/0511	53215/0315
62221	Farmoz Gusathion 200 SC Insecticide	Adama Australia Pty Linited	62221/0511	62221/0315

The active constituent azinphos-methyl, product registrations containing azinphos-methyl and associated label approvals were placed under review in 1995 because of public health, occupational health and safety, environmental and trade concerns.

After assessing all the available information and data, the APVMA prepared the Preliminary Review Findings report (PRF) and released it for public consultation in October 2006. After considering submissions, the APVMA published the Azinphos-methyl Review Findings Report, *The reconsideration of the approvals of the active constituent azinphos-methyl, registration of products containing azinphos-methyl and their associated labels* in July 2011.

The key review findings were:

- a) approvals of the active constituent can be affirmed; and
- b) labels did not contain adequate instructions for the products to be used safely;
- c) however, the labels can be varied in such a way that the products can be used safely, and therefore the product registrations can be affirmed after varying the labels.

Although the APVMA published the Review Findings Report in 2011, it did not finalise the review pending an examination of regulatory decisions in other countries to remove azinphos-methyl from the market.

The risks to human health, OHS, the environment and trade identified in the APVMA's review findings, were mitigated, pending any such revisions, through registrants voluntarily applying for amendment of their product labels to bring them in line with the review findings. While the APVMA approved amendments to the labels in 2011, these amendments did not constitute completion of the review.

The APVMA in collaboration with the Office of Chemical Safety (OCS) and the Department of the Environment has now reviewed the basis of these decisions and has concluded that there is no new information that would warrant a revision of the APVMA's 2011 Review Findings Report.

On this basis the APVMA has made the following decisions, and put into affect regulatory actions, under s.34 of the Agvet Codes, regarding the continuation of approvals and registrations relating to azinphos-methyl.

- a) in accordance with s.34(1)(a) of the *Agricultural and Veterinary Chemicals Code Act 1994* (Agvet Code) the APVMA was **SATISFIED** that the continued use of, or any dealing with, the active constituent shown in Table 1 in accordance with the instructions for its use or for such a dealing that the APVMA has approved:
  - i) 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
  - ii) would not be likely to have an effect that is harmful to human beings; and
  - iii) would not be likely to have an unintended effect that is harmful to animals, plants or things or to the environment; and
  - iv) would not unduly prejudice trade or commerce between Australia and places outside Australia
- b) in accordance with s.34(1)(c) of the Agvet Codes, the APVMA was NOT SATISFIED that labels (Column D of Table 2) contain adequate instructions in relation to the criteria set out in s.14(3)(d) and s.14(3)(g) of the Agvet Codes as well as those referred to in regulations 11 and 12 of the Agvet Code Regulations.
- c) in accordance with s.34(5) of the Agvet Codes that the APVMA was SATISFIED the relevant particulars of label approval (column D of Table 2) can be VARIED in such a way that the requirements prescribed by the regulations for continued approval or registration will be complied with;
- d) in accordance with s.34(5)(a)(ii), the APVMA varied the relevant particulars of the approvals of the labels in Column D of Table 2 as described below;
  - Replaced the label Safety Directions with the following: Poisonous if absorbed by skin contact or inhaled or swallowed. Will irritate the eyes and skin. May irritate the nose and throat. Repeated exposure may cause allergic disorders. Repeated minor exposure may have a cumulative poisoning effect. 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 protective waterproof clothing and elbow-length PVC gloves and water resistant footwear and face shield or goggles. When using the prepared spray by open cab wear cotton overalls buttoned to the neck and wrist (or equivalent clothing) and protective waterproof clothing including a hood or waterproof hat and elbow length PVC gloves and water resistant footwear and half face piece respirator with -combined dust and gas cartridge. When using the prepared spray by closed cab fitted with charcoal filters wear cotton overalls buttoned to the neck and wrist (or equivalent clothing). If clothing becomes contaminated with product or wet with spray remove clothing immediately. If product on skin, immediately wash area with soap and water. If product in eyes, wash it out immediately with 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 respirator and if rubber wash with detergent and warm water and face shield or goggles and contaminated clothing.

- ii) Added the following restraint to the labels: DO NOT apply using hand-held spraying equipment.
- e) Following the label variations, the APVMA was **SATISFIED**, under s.34(1)(a) of the Agvet Codes, that the continued use of, or any dealing with, the products shown in Table 2 in accordance with the instructions for its use or for such a dealing that the APVMA has approved:
  - i) 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
  - ii) would not be likely to have an effect that is harmful to human beings; and
  - iii) would not be likely to have an unintended effect that is harmful to animals, plants or things or to the environment; and
  - iv) would not unduly prejudice trade or commerce between Australia and places outside Australia
- f) The APVMA **AFFIRMED** the approval of the active constituent (listed in Table 1) and the registration of the products( listed in Table 2) with varied label approvals in accordance with s.34(1)(a) of the Agvet Codes.

Further details can be found in the APVMA report entitled *Azinphos-methyl Review: Regulatory Decisions Report*. Copies of the report or further information can be obtained from the APVMA website <u>www.apvma.gov.au</u> or by request to the Chemical Review Liaison Officer on +61 2 6210 4700 or <u>chemicalreview@apvma.gov.au</u>.

#### APVMA CONTACT

Chemical Review Australian Pesticides and Veterinary Medicines Authority PO Box 6182 KINGSTON ACT 2604

 Phone:
 +61 2 6210 4700

 Fax:
 +61 2 6210 4776

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 chemicalreview@apvma.gov.au

# Revocation of Suspension of a Product Containing Dimethoate to allow approval of new label

On 6 March 2015 the APVMA revoked the suspension of the following dimethoate product registration to allow approval of a new product label that has instructions consistent with the previous suspension instructions as published on 7 October 2014.

	Product No	Product Name	Registrant	Label Approvals that remain suspended	New approved Label Number that is not suspended
:	58374	Cropro Stalk Insecticide	PCT Holdings Pty Ltd	58374/0504	58374/100973

The suspension of the above product registration listed in Table 1 has been revoked to allow the approval of a new label with instructions consistent with those issued by the APVMA.

Please note that the label approval listed in Column 4 remains suspended. Product bearing this suspended label must continue to be used only in accordance with the instructions issued by the APVMA to allow continued use of suspended dimethoate products. See permit PER 13155 for the current instructions for the use of suspended dimethoate products and products bearing suspended labels. The new approved label listed in Column 5 of Table 1 may be used according to its label instructions.

# CERTAIN OTHER DIMETHOATE PRODUCTS AND LABEL APPROVALS ARE NOT INCLUDED IN THIS REVOCATION

Certain other dimethoate products and labels (as listed in Table 2 below) as well as previous label for the above product (as listed in column 4 of Table 1) remain suspended and must only continue to be used in accordance with the instructions issued by the APVMA in permit PER 13155. See *Gazette Notice No. APVMA 20, Tuesday, 11 October 2011 Suspension of Products Containing Dimethoate and Associated Label Approvals* for the original suspension notice.

Product No.	Suspended Product Name	Registrant
49600	Saboteur Systemic Insecticide	Crop Care Australasia Pty Ltd
55272	Superway Dimethoate 300 Systemic Insecticide	Superway Garden Ag & Pest Products Pty Ltd
55441	4 Farmers Dimethoate 400 Systemic Insecticide	4 Farmers Pty Ltd
57860	Halley Dimethoate 400 Systemic Insecticide	Halley International Enterprise (Australia) Pty Ltd
58375	Surefire Orchard and Garden Insecticide	PCT Holdings Pty Ltd
59001	Amgrow Insect & Mite Systemic Insecticide	Amgrow Pty Ltd
59469	AW Dimethoate 400 Systemic Insecticide	Agri West Pty Limited
61916	Richgro Fruit Fly & Garden Insecticide	A Richards Pty Ltd T/A Richgro Garden Products
62511	Titan Dimethoate 400 Systemic Insecticide	Titan Ag Pty Ltd
63470	Country Dimethoate 400 Systemic Insecticide	Accensi Pty Ltd
64309	Farmalinx Dimetholinx Insecticide	Farmalinx Pty Ltd

Table 2:	Suspended	products	containing	dimethoate
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Product No.	Suspended Product Name	Registrant
65260	Rogor Upgrade Insecticide	Ospray Pty Ltd

The status of dimethoate products may be confirmed by searching for the product on the APVMA <u>PubCRIS</u> database search.

#### FURTHER CHANGES TO INSTRUCTIONS FOR USE MAY BE REQUIRED

Please note that the review of all dimethoate products is still ongoing and further changes to the status of registrations and the instructions for use of dimethoate products may be required prior to finalisation of the review. In particular, there are findings arising from the Human Health Risk Assessment of Dimethoate—<u>Exposure and Risk Assessment of</u> <u>Dimethoate (OHS component) Aug 2013 (PDF, 1.7MB)</u> that recommend changes to label use instructions. The APVMA will publish Preliminary Review Findings for dimethoate and then seek comments and information that may be used to refine the toxicology, OHS and residues assessments prior to finalising the review. The APVMA will also consider any proposals to amend label directions to address any identified concerns.

#### **APVMA CONTACT**

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

Chemical Review Scientific assessment and Chemical Review Australian Pesticides and Veterinary Medicines Authority PO Box 6182 KINGSTON ACT 2604

 Phone:
 +61 2 6210 4749

 Fax:
 +61 2 6210 4776

 Email:
 chemicalreview@apvma.gov.au

## Cancellation of Label Approval at the Request of the Holder

At the request of the holder, the APVMA has cancelled label approval for the following product:

Product no.	Product name	Approval holder	Cancelled label approval	Date of effect
62221	FARMOZ GUSATHION 200 SC INSECTICIDE	ADAMA AUSTRALIA PTY LIMITED	62221/0609 62221/0808	23 February 2015

The following instructions set out how a person can deal with the product bearing the cancelled labels.

#### SUPPLY

A person may supply or cause to be supplied product bearing the cancelled label manufactured prior to 23 February 2015 at wholesale and retail level, until 23 February 2016.

After 23 February 2016 it will be an offence against the Agvet Codes to have possession or custody of the product bearing the cancelled label with the intention to supply, or to supply the product bearing the cancelled label.

#### USE

A person may continue to use the product bearing the cancelled label according to its label instructions until 23 February 2016.

Any person who possesses, has custody of, uses, or otherwise deals with the listed product in accordance with the above instructions is taken to have been issued with a permit under the Agvet Codes to so possess, have custody of, use or otherwise deal with the product bearing the cancelled label after the approval has been cancelled until 23 February 2016.

The supply and use of the product bearing the cancelled label must be in accordance with the conditions of registration or approval, including any conditions relating to the shelf life or expiry date.

It is an offence to possess, have custody of, use, or deal with the product bearing the cancelled label listed in the table in a manner that contravenes the above instructions.

#### **APVMA CONTACT**

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

Chemical Review Australian Pesticides and Veterinary Medicines Authority PO Box 6182 SYMONSTON ACT 2609

 Phone:
 +61 2 6210 4749

 Fax:
 +61 2 6210 4776

 Email:
 chemicalreview@apvma.gov.au

## Cancellation of Label Approvals at the Request of the Holder

At the request of the holder, the APVMA has cancelled the following label approvals:

Product no.	Product name	Approval holder	Cancelled label approval	Date of effect
67161	TERMIBLOCKAID TERMITICIDE SEALANT	GRANITGARD MARKETING PTY LTD	67161/55365	12 March 2015
70278	LEGION INSECTICIDAL SEED TREATMENT	CROP CARE AUSTRALASIA PTY LTD	70278/62874	12 March 2015

The following instructions set out how a person can deal with the product bearing the cancelled labels.

#### SUPPLY

A person may supply or cause to be supplied product bearing the cancelled label manufactured prior to 12 March 2015 at wholesale and retail level, until 12 March 2016.

After 12 March 2016 it will be an offence against the Agvet Codes to have possession or custody of the product bearing the cancelled label with the intention to supply, or to supply the product bearing the cancelled label.

#### USE

A person may continue to use the product bearing the cancelled label according to its label instructions until 12 March 2016.

Any person who possesses, has custody of, uses, or otherwise deals with the listed products in accordance with the above instructions is taken to have been issued with a permit under the Agvet Codes to so possess, have custody of, use or otherwise deal with the product bearing the cancelled label after the approval has been cancelled until 12 March 2016.

The supply and use of the product bearing the cancelled label must be in accordance with the conditions of registration or approval, including any conditions relating to the shelf life or expiry date.

It is an offence to possess, have custody of, use, or deal with the product bearing the cancelled label listed in the table in a manner that contravenes the above instructions.

#### **APVMA CONTACT**

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

Chemical Review Australian Pesticides and Veterinary Medicines Authority PO Box 6182 SYMONSTON ACT 2609

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 +61 2 6210 4749

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 +61 2 6210 4776

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 chemicalreview@apvma.gov.au

## New Agricultural Active Constituent approved under Section 14a—Clove oil

The Australian Pesticides and Veterinary Medicines Authority (APVMA) is proposing to add Clove oil to the list of Active Constituents Not Requiring Evaluation. Clove oil has been evaluated and has met the criteria under Section 14A of the Agvet Code.

Clove oil is extracted from the leaves, stems and buds of the clove plant, *Syzygium aromaticum*. The essential oil includes a complex mixture of numerous compounds; many of which are present in trace amounts. The main chemical constituents includes eugenol which accounts for 72–97%, eugenol acetate (0.07–21.32%) and  $\beta$ -caryophyllene (1.66–19.53%).

Clove oil CAS numbers:

Oil type	CAS No
clove bud oil	8000-34-8
clove leaf oil	8015-97-2
clove stem oil	8015-98-3
eugenol	97-53-0

In Australia, there are 52 entries for human medicinal products containing Clove oil listed in Australian Register of Therapeutic Goods (ARTG) of TGA. Products are used for the temporary relief of toothache and for their antioxidant, antifungal, antibacterial, anti-inflammatory and analgesic activity.

Clove oil and some of its components are generally recognized as safe (GRAS) in the USA where it is used in dental cement or as a food additive. The US EPA has placed clove oil in the Section 25(b) list of Minimum Risk Pesticides. Pesticides on this list are exempt from most pesticide registration requirements, including extensive toxicity testing.

The APVMA is satisfied under Section 14A(1)(b) of the Agvet Code, 'having regard to information that is readily available, the APVMA is satisfied that the constituent would meet the safety criteria.'

Common name: Clove oil

Scientific information: Clove oil is extracted from the leaves, stems and buds of the clove plant, *Syzygium* aromaticum.

#### MAKING A SUBMISSION

In accordance with sections 12 of the Agvet Code, the APVMA invites any person to submit a relevant written submission to the proposal to include Clove oil on the list of Active Constituents Not Requiring Evaluation. . Submissions should relate only to matters that the APVMA is required by legislation to consider in deciding whether to grant the approval via the section 14A route. These grounds include chemistry and manufacture, and toxicity. Submissions should state the grounds on which they are based. Comments received outside these grounds cannot be considered by the APVMA.

Submissions must be received by the APVMA within 28 days of the date of this notice and be directed to the contact below. All submissions to the APVMA will be acknowledged in writing via email or by post. A summary of relevant comments and the APVMA's response will be published on the APVMA website.

When making a submission please include a:

- contact name
- company or group name (if relevant)
- postal address
- email address (if available)
- the date you made the submission.

All personal and *confidential commercial information (CCI)*<sup>7</sup> material contained in submissions will be treated confidentially.

Written submissions on the APVMA's proposal to grant approval for clove oil that relate to the grounds for approval should be marked attention to the Director, Chemistry and Manufacture Section, Scientific Assessment and Chemical Review Program in writing to:

The Director Chemistry and Manufacture Section Australian Pesticides and Veterinary Medicines Authority PO Box 6182 KINGSTON ACT 2604

 Phone:
 +61 2 6210 4936

 Fax:
 +61 2 6210 4840

 Email:
 chemistry@apvma.gov.au

<sup>&</sup>lt;sup>1</sup> A full definition of 'confidential commercial information' is contained in the <u>Agvet Code</u>.