



**Commonwealth  
of Australia**

**Gazette**

No. APVMA 5, Tuesday, 10 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, [www.apvma.gov.au/publications/gazette/](http://www.apvma.gov.au/publications/gazette/).

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

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## CONTENTS

Agricultural Chemical Products and Approved Labels.....	4
Veterinary Chemical Products and approved labels.....	21
Approved Active Constituents .....	23
Amendments to the APVMA MRL Standard.....	24
Proposal to Amend Standard 1.4.2 of the Australia New Zealand Food Standards Code .....	25
Cefquinome sulphate in the product Cobactan IV .....	29
Final Pesticide and Veterinary Medicines Product Sales 2013–14 Financial Year.....	35

## 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

<b>Application no.:</b>	62601
<b>Product name:</b>	Farmalinx Bomber 750 SG Herbicide
<b>Active constituent/s:</b>	750 g/kg imazapyr
<b>Applicant name:</b>	Farmalinx Pty Ltd
<b>Applicant ACN:</b>	134 353 245
<b>Summary of use</b>	For the control of various annual and perennial weeds in non-crop situations
<b>Date of registration/approval:</b>	5 February 2015
<b>Product registration no.:</b>	70142
<b>Label approval no.:</b>	70142/62601
<b>Application no.:</b>	62634
<b>Product name:</b>	Genfarm Carfentrazone 240 EC Herbicide
<b>Active constituent/s:</b>	240 g/L carfentrazone-ethyl
<b>Applicant name:</b>	Landmark Operations Limited
<b>Applicant ACN:</b>	008 743 217
<b>Summary of use</b>	For improvement in the control of marshmallow and certain other broadleaf weeds prior to establishment of broadacre crops, fallows or forest plantations in commercial, industrial and public service areas, and around agricultural buildings and yards, in treefruits, nuts, grapevines in tank mixture with knockdown herbicides; for the control of marshmallow and annual nettles in grass pastures and rough grass/turf areas; and control of volunteer cotton seedlings
<b>Date of registration/approval:</b>	5 February 2015
<b>Product registration no.:</b>	70154
<b>Label approval no.:</b>	70154/62634
<b>Application no.:</b>	62625
<b>Product name:</b>	S-Maestro 960 Herbicide
<b>Active constituent/s:</b>	960 g/L s-metolachlor
<b>Applicant name:</b>	Shandong Rainbow International Co., Ltd
<b>Applicant ACN:</b>	N/A
<b>Summary of use</b>	For the control of certain annual grasses and broadleaf weeds in certain crops
<b>Date of registration/approval:</b>	5 February 2015
<b>Product registration no.:</b>	70150
<b>Label approval no.:</b>	70150/62625
<b>Application no.:</b>	62959
<b>Product name:</b>	Sabrecut 800 WG Herbicide
<b>Active constituent/s:</b>	800 g/kg flumetsulam
<b>Applicant name:</b>	Grow Choice Pty Limited
<b>Applicant ACN:</b>	069 839 961
<b>Summary of use</b>	For the post-emergence and salvage control of certain broadleaf weeds in winter cereals (including those undersown with clover, lucerne or medics) clover, fenugreek, lathyrus, lucerne, medic, serradella, and vetch (Popany only) seed crops and pastures; chickpeas, field peas, lentils, maize, peanuts and for the pre-emergent control of certain broadleaf weeds in maize and soybeans
<b>Date of registration/approval:</b>	9 February 2015
<b>Product registration no.:</b>	70303
<b>Label approval no.:</b>	70303/62959

<b>Application no.:</b>	100665
<b>Product name:</b>	Surefire Spectrum Public Health 200SC Insecticide
<b>Active constituent/s:</b>	200 g/L imidacloprid
<b>Applicant name:</b>	PCT Holdings Pty Ltd
<b>Applicant ACN:</b>	099 023 962
<b>Summary of use</b>	For the control of insect pests in various crops and ornamentals and for the management of subterranean termites as per the directions for use
<b>Date of registration/approval:</b>	10 February 2015
<b>Product registration no.:</b>	80348
<b>Label approval no.:</b>	80348/100665
<b>Application no.:</b>	61461
<b>Product name:</b>	Bobcat i-Maxx Herbicide
<b>Active constituent/s:</b>	25 g/L imazapic present as the ammonium and urea salt, 125 g/L hexazinone
<b>Applicant name:</b>	Adama Australia Pty Limited
<b>Applicant ACN:</b>	050 328 973
<b>Summary of use</b>	For the control of a wide range of annual and perennial grasses and broadleaf weeds in sugar cane
<b>Date of registration/approval:</b>	10 February 2015
<b>Product registration no.:</b>	69698
<b>Label approval no.:</b>	69698/61461
<b>Application no.:</b>	62239
<b>Product name:</b>	agVantage Paraquat 250 SL Herbicide
<b>Active constituent/s:</b>	250 g/L paraquat present as paraquat dichloride
<b>Applicant name:</b>	Landmark Operations Limited
<b>Applicant ACN:</b>	008 743 217
<b>Summary of use</b>	For the control of a wide range of grasses and broadleaf weeds in a range of situations
<b>Date of registration/approval:</b>	11 February 2015
<b>Product registration no.:</b>	69986
<b>Label approval no.:</b>	69986/62239
<b>Application no.:</b>	62485
<b>Product name:</b>	Resource Gardening Glypho 100 Weedkiller
<b>Active constituent/s:</b>	100 g/L glyphosate present as the isopropylamine salt
<b>Applicant name:</b>	Amgrow Pty Ltd
<b>Applicant ACN:</b>	100 684 786
<b>Summary of use</b>	For use to kill weeds and grasses in the home garden
<b>Date of registration/approval:</b>	12 February 2015
<b>Product registration no.:</b>	70091
<b>Label approval no.:</b>	70091/62485
<b>Application no.:</b>	61194
<b>Product name:</b>	Barmac Clear Up Bio 360 Herbicide
<b>Active constituent/s:</b>	360 g/L glyphosate present as the isopropylamine salt
<b>Applicant name:</b>	Amgrow Pty Ltd
<b>Applicant ACN:</b>	100 684 786
<b>Summary of use</b>	For the control of a range of annual, perennial and woody weeds
<b>Date of registration/approval:</b>	13 February 2015
<b>Product registration no.:</b>	69595
<b>Label approval no.:</b>	69595/61194

<b>Application no.:</b>	62846
<b>Product name:</b>	Wellfarm Imidacloprid 350 SC Insecticide
<b>Active constituent/s:</b>	350 g/L imidacloprid
<b>Applicant name:</b>	Wellfarm Pty Ltd
<b>Applicant ACN:</b>	158 518 551
<b>Summary of use</b>	For the control of greyback and childers canegrub in sugarcane and silverleaf whitefly in various vegetables as specified in the directions for use
<b>Date of registration/approval:</b>	13 February 2015
<b>Product registration no.:</b>	70263
<b>Label approval no.:</b>	70263/62846
<b>Application no.:</b>	62845
<b>Product name:</b>	Wellfarm Clopyralid 750 SG Herbicide
<b>Active constituent/s:</b>	750 g/kg clopyralid present as the potassium salt
<b>Applicant name:</b>	Wellfarm Pty Ltd
<b>Applicant ACN:</b>	158 518 551
<b>Summary of use</b>	For the control of a wide range of broadleaf weeds in wheat, barley, oats, triticale, canola, pastures and fallow land
<b>Date of registration/approval:</b>	16 February 2015
<b>Product registration no.:</b>	70262
<b>Label approval no.:</b>	70262/62845
<b>Application no.:</b>	60371
<b>Product name:</b>	Yates Nature's Way Citrus And Ornamental Spray
<b>Active constituent/s:</b>	0.3 g/L pyrethrins, 8 g/L canola oil
<b>Applicant name:</b>	Duluxgroup (Australia) Pty Ltd
<b>Applicant ACN:</b>	000 049 427
<b>Summary of variation:</b>	For the control of a range of insect pests on citrus, ornamentals and vegetables in the home and garden
<b>Date of variation:</b>	16 February 2015
<b>Product registration no.:</b>	69267
<b>Label approval no.:</b>	69267/60371
<b>Application no.:</b>	63328
<b>Product name:</b>	H2O Pool Chemicals Blackspot Remover
<b>Active constituent/s:</b>	50 g/L copper, present as copper sulphate pentahydrate, 100 g/L benzalkonium chloride
<b>Applicant name:</b>	Kleenco Australia Pty Limited
<b>Applicant ACN:</b>	003 131 539
<b>Summary of use</b>	For the control of blackspot algae and general algae in swimming pools
<b>Date of registration/approval:</b>	18 February 2015
<b>Product registration no.:</b>	70383
<b>Label approval no.:</b>	70383/63328
<b>Application no.:</b>	58671
<b>Product name:</b>	Farmalinx Trifluralin 580 Herbicide
<b>Active constituent/s:</b>	580 g/L trifluralin
<b>Applicant name:</b>	Farmalinx Pty Ltd
<b>Applicant ACN:</b>	134 353 245
<b>Summary of use</b>	For the control of annual grasses and certain broadleaf weeds in certain horticultural and agricultural crops
<b>Date of registration/approval:</b>	18 February 2015
<b>Product registration no.:</b>	68604
<b>Label approval no.:</b>	68604/58671

<b>Application no.:</b>	62692
<b>Product name:</b>	Wellfarm Diflufenican 25 + MCPA Iso-Octyl Ester 250 EC Herbicide
<b>Active constituent/s:</b>	25 g/L diflufenican, 250 g/L MCPA present as the ethyl hexyl ester
<b>Applicant name:</b>	Wellfarm Pty Ltd
<b>Applicant ACN:</b>	158 518 551
<b>Summary of use</b>	For the control of certain broadleaf weeds in winter cereals and clover
<b>Date of registration/approval:</b>	19 February 2015
<b>Product registration no.:</b>	70185
<b>Label approval no.:</b>	70185/62692
<b>Application no.:</b>	62791
<b>Product name:</b>	Wellfarm Imazethapyr 700 WG Herbicide
<b>Active constituent/s:</b>	700 g/kg imazethapyr
<b>Applicant name:</b>	Wellfarm Pty Ltd
<b>Applicant ACN:</b>	158 518 551
<b>Summary of use</b>	For the pre- or post-emergence control of certain weeds in centrosema (cavalcade), chickpeas, faba beans, field peas, Lucerne, mung beans, peanuts, serradella and soybeans
<b>Date of registration/approval:</b>	19 February 2015
<b>Product registration no.:</b>	70234
<b>Label approval no.:</b>	70234/62791
<b>Application no.:</b>	100674
<b>Product name:</b>	AgVantage 700 Surfactant
<b>Active constituent/s:</b>	350 g/L soyal phospholipids, 350 g/L propionic acid
<b>Applicant name:</b>	Landmark Operations Limited
<b>Applicant ACN:</b>	008 743 217
<b>Summary of use:</b>	For use as a surfactant, reduction of alkaline hydrolysis of dimethoate, assistance in uptake of foliar fertilisers and management of droplet size
<b>Date of registration/approval:</b>	19 February 2015
<b>Product registration no.:</b>	80354
<b>Label approval no.:</b>	80354/100674
<b>Application no.:</b>	55636
<b>Product name:</b>	Micronised Copper Azole Wood Preservative
<b>Active constituent/s:</b>	582 g/L copper (Cu) present as copper carbonate, 23.80 g/L tebuconazole
<b>Applicant name:</b>	Koppers Performance Chemicals Australia Pty Ltd
<b>Applicant ACN:</b>	088 260 575
<b>Summary of use</b>	For the protection of timber against fungal decay, wood borers and timbers
<b>Date of registration/approval:</b>	20 February 2015
<b>Product registration no.:</b>	67259
<b>Label approval no.:</b>	67259/55636
<b>Application no.:</b>	62615
<b>Product name:</b>	FMC Patron 500 WG Fungicide
<b>Active constituent/s:</b>	500 g/kg boscalid
<b>Applicant name:</b>	FMC Australasia Pty Ltd
<b>Applicant ACN:</b>	095 326 891
<b>Summary of use</b>	For the control of bunch rot in grapevines
<b>Date of registration/approval:</b>	20 February 2015
<b>Product registration no.:</b>	70146
<b>Label approval no.:</b>	70146/62615

<b>Application no.:</b>	62191
<b>Product name:</b>	Conquest Gunner 750 WG Herbicide
<b>Active constituent/s:</b>	750 g/kg imazapyr
<b>Applicant name:</b>	Conquest Crop Protection Pty Ltd
<b>Applicant ACN:</b>	098 814 932
<b>Summary of use</b>	For the control of various annual and perennial weeds in non-crop situations
<b>Date of registration/approval:</b>	23 February 2015
<b>Product registration no.:</b>	69968
<b>Label approval no.:</b>	69968/62191
<b>Application no.:</b>	62379
<b>Product name:</b>	Clearchem Liquid Pool Chlorine
<b>Active constituent/s:</b>	125 g/L available chlorine (Cl) present as sodium hypochlorite
<b>Applicant name:</b>	Clearchem Pty Ltd
<b>Applicant ACN:</b>	125 203 803
<b>Summary of use</b>	For the control of bacteria and algae in swimming pools and spas
<b>Date of registration/approval:</b>	23 February 2015
<b>Product registration no.:</b>	70053
<b>Label approval no.:</b>	70053/62379
<b>Application no.:</b>	62353
<b>Product name:</b>	Job's Done Garden Weed & Feed
<b>Active constituent/s:</b>	15 g/L MCPA present as the dimethylamine salt, 2.3 g/L dicamba present as the dimethylamine salt
<b>Applicant name:</b>	Agcare Pty Ltd
<b>Applicant ACN:</b>	159 778 757
<b>Summary of use</b>	For the control of weeds in lawn
<b>Date of registration/approval:</b>	23 February 2015
<b>Product registration no.:</b>	70042
<b>Label approval no.:</b>	70042/62353
<b>Application no.:</b>	100659
<b>Product name:</b>	Brunnings Triple Action Bug Kill
<b>Active constituent/s:</b>	0.167 g/L difenoconazole, 0.100 g/L thiamethoxam, 0.015 g/L abamectin
<b>Applicant name:</b>	Syngenta Australia Pty Ltd
<b>Applicant ACN:</b>	002 933 717
<b>Summary of use</b>	For the control of insects, fungus and mites
<b>Date of registration/approval:</b>	23 February 2015
<b>Product registration no.:</b>	80345
<b>Label approval no.:</b>	80345/100659
<b>Application no.:</b>	100069
<b>Product name:</b>	Ratshot One Shot Rodenticide Pellets
<b>Active constituent/s:</b>	0.05 g/kg brodifacoum contains denatonium benzoate (bittering agent)
<b>Applicant name:</b>	Freezone Public Health Pty Ltd
<b>Applicant ACN:</b>	132 080 098
<b>Summary of use</b>	For the control of rats and mice
<b>Date of registration/approval:</b>	23 February 2015
<b>Product registration no.:</b>	80029
<b>Label approval no.:</b>	80029/100069



<b>Application no.:</b>	100677
<b>Product name:</b>	agVantage Di-Par 250 Herbicide
<b>Active constituent/s:</b>	135 g/L paraquat present as paraquat dichloride 115 g/L diquat present as diquat dibromide
<b>Applicant name:</b>	Landmark Operations Limited
<b>Applicant ACN:</b>	008 743 217
<b>Summary of use</b>	For the control of a wide range of grasses and broadleaf weeds
<b>Date of registration/approval:</b>	24 February 2015
<b>Product registration no.:</b>	80357
<b>Label approval no.:</b>	80357/100677
<b>Application no.:</b>	62727
<b>Product name:</b>	Farmalinx Bromoxapac Herbicide
<b>Active constituent/s:</b>	200 g/L bromoxynil present as the n-octanoyl ester, 200 g/L MCPA present as the ethyl hexyl ester
<b>Applicant name:</b>	Farmalinx Pty Ltd
<b>Applicant ACN:</b>	134 353 245
<b>Summary of use</b>	For the control of weeds in wheat, oats, barley, cereal rye, triticale, linseed, grass pastures and turf
<b>Date of registration/approval:</b>	24 February 2015
<b>Product registration no.:</b>	70206
<b>Label approval no.:</b>	70206/62727
<b>Application no.:</b>	100675
<b>Product name:</b>	agVantage Triclopyr 600EC Herbicide
<b>Active constituent/s:</b>	600 g/L triclopyr present as the butoxyethyl ester
<b>Applicant name:</b>	Landmark Operations Limited
<b>Applicant ACN:</b>	008 743 217
<b>Summary of use</b>	For the control of a range of woody weeds and melons
<b>Date of registration/approval:</b>	24 February 2015
<b>Product registration no.:</b>	80355
<b>Label approval no.:</b>	80355/100675
<b>Application no.:</b>	100776
<b>Product name:</b>	Apparent Savage Weed And Gentle Feed RTU
<b>Active constituent/s:</b>	15 g/L MCPA present as dimethylamine salt, 2.3 g/L dicamba present as dimethylamine salt
<b>Applicant name:</b>	Apparent Pty. Ltd
<b>Applicant ACN:</b>	143 724 136
<b>Summary of use</b>	For killing broadleaf weeds and feeding the lawn
<b>Date of registration/approval:</b>	24 February 2015
<b>Product registration no.:</b>	80399
<b>Label approval no.:</b>	80399/100776
<b>Application no.:</b>	100773
<b>Product name:</b>	Apparent Knock-Out RTU Herbicide
<b>Active constituent/s:</b>	7.2 g/L glyphosate present as the isopropylamine salt
<b>Applicant name:</b>	Apparent Pty. Ltd
<b>Applicant ACN:</b>	143 724 136
<b>Summary of use</b>	For killing annual and perennial weeds and grasses
<b>Date of registration/approval:</b>	25 February 2015
<b>Product registration no.:</b>	80396
<b>Label approval no.:</b>	80396/100773

<b>Application no.:</b>	100777
<b>Product name:</b>	Brunnings Triple Action Rose Spray Insect, Mite And Disease Control
<b>Active constituent/s:</b>	0.167 g/L difenoconazole, 0.100 g/L thiamethoxam, 0.015 g/L abamectin
<b>Applicant name:</b>	Syngenta Australia Pty Ltd
<b>Applicant ACN:</b>	002 933 717
<b>Summary of use</b>	To kill and control Black Spot, Aphids, Mealy Bugs, Powdery Mildew, Mites and more
<b>Date of registration/approval:</b>	25 February 2015
<b>Product registration no.:</b>	80400
<b>Label approval no.:</b>	80400/100777
<b>Application no.:</b>	100805
<b>Product name:</b>	Apparent Clethodim 360 Herbicide
<b>Active constituent/s:</b>	360 g/L clethodim
<b>Applicant name:</b>	Apparent Pty. Ltd
<b>Applicant ACN:</b>	143 724 136
<b>Summary of use</b>	For the control of certain grass weeds in beetroot, cabbage, canola, celery, chickpeas, cotton, faba beans, field peas, forestry, lentils, lettuce, lupins, mung beans, non-bearing fruit trees, onions, ornamentals, peanuts, potatoes and soybeans
<b>Date of registration/approval:</b>	25 February 2015
<b>Product registration no.:</b>	80404
<b>Label approval no.:</b>	80404/100805
<b>Application no.:</b>	56654
<b>Product name:</b>	Moddus Evo Yield & Quality Enhancer
<b>Active constituent/s:</b>	250 g/L trinexapac-ethyl
<b>Applicant name:</b>	Syngenta Australia Pty Ltd
<b>Applicant ACN:</b>	002 933 717
<b>Summary of use</b>	To reduce lodging and enhance yields in wheat, barley and oats
<b>Date of registration/approval:</b>	25 February 2015
<b>Product registration no.:</b>	67695
<b>Label approval no.:</b>	67695/56654
<b>Application no.:</b>	62648
<b>Product name:</b>	Wellfarm Simazine 900 WG Herbicide
<b>Active constituent/s:</b>	900 g/kg simazine
<b>Applicant name:</b>	Wellfarm Pty Ltd
<b>Applicant ACN:</b>	158 518 551
<b>Summary of use</b>	For the control of weeds in chickpeas, lupins, t-t canola, orchards, vineyards and certain other horticultural crops and non-crop situations
<b>Date of registration/approval:</b>	25 February 2015
<b>Product registration no.:</b>	70163
<b>Label approval no.:</b>	70163/62648
<b>Application no.:</b>	62666
<b>Product name:</b>	Wellfarm Propyzamide 500 SC Herbicide
<b>Active constituent/s:</b>	500 g/L propyzamide
<b>Applicant name:</b>	Wellfarm Pty Ltd
<b>Applicant ACN:</b>	158 518 551
<b>Summary of use</b>	For the selective control of certain grasses and broad leaf weeds in lettuce, sports turf, home lawns and legumes seed crops and pastures
<b>Date of registration/approval:</b>	25 February 2015
<b>Product registration no.:</b>	70168
<b>Label approval no.:</b>	70168/62666

<b>Application no.:</b>	62826
<b>Product name:</b>	Smart MCPA Amine 750 Selective Herbicide
<b>Active constituent/s:</b>	750 g/L MCPA present as the dimethylamine salt
<b>Applicant name:</b>	Crop Smart Pty Ltd
<b>Applicant ACN:</b>	093 927 961
<b>Summary of use</b>	For the selective control of broadleaf weeds in cereals, linseed, oilseed poppies, pastures, rice, sugar cane and turf
<b>Date of registration/approval:</b>	25 February 2015
<b>Product registration no.:</b>	70249
<b>Label approval no.:</b>	70249/62826
<b>Application no.:</b>	62955
<b>Product name:</b>	Wellfarm Triadimefon 125 EC Fungicide
<b>Active constituent/s:</b>	125 g/L triadimefon
<b>Applicant name:</b>	Wellfarm Pty Ltd
<b>Applicant ACN:</b>	158 518 551
<b>Summary of use</b>	For the control of fungal diseases of wheat, barley, peas, grapevines, cucurbits and sugar cane
<b>Date of registration/approval:</b>	25 February 2015
<b>Product registration no.:</b>	70301
<b>Label approval no.:</b>	70301/62955
<b>Application no.:</b>	100672
<b>Product name:</b>	agVantage Wetter 1000
<b>Active constituent/s:</b>	1000 g/L alkoxyated alcohol
<b>Applicant name:</b>	Landmark Operations Limited
<b>Applicant ACN:</b>	008 743 217
<b>Summary of use</b>	For use with knockdown and residual herbicides
<b>Date of registration/approval:</b>	26 February 2015
<b>Product registration no.:</b>	80352
<b>Label approval no.:</b>	80352/100672
<b>Application no.:</b>	100201
<b>Product name:</b>	Oztec Ethephon Growth Regulator
<b>Active constituent/s:</b>	720 g/L ethephon (an anticholinesterase compound)
<b>Applicant name:</b>	Oztec Rural Pty Ltd
<b>Applicant ACN:</b>	056 693 095
<b>Summary of use</b>	For crop thinning, loosening or ripening in various crops and for accelerating boll opening, defoliation and pre-conditioning before defoliation of cotton
<b>Date of registration/approval:</b>	26 February 2015
<b>Product registration no.:</b>	80097
<b>Label approval no.:</b>	80097/100201
<b>Application no.:</b>	100683
<b>Product name:</b>	agVantage Trifluralin 480 Selective Herbicide
<b>Active constituent/s:</b>	480 g/L trifluralin
<b>Applicant name:</b>	Landmark Operations Limited
<b>Applicant ACN:</b>	008 743 217
<b>Summary of use</b>	For the pre-emergence control of annual grasses and certain broadleaf weeds in certain horticultural and agricultural crops
<b>Date of registration/approval:</b>	26 February 2015
<b>Product registration no.:</b>	80361
<b>Label approval no.:</b>	80361/100683

<b>Application no.:</b>	62677
<b>Product name:</b>	Wellfarm Tebuconazole 430 SC Fungicide
<b>Active constituent/s:</b>	430 g/L tebuconazole
<b>Applicant name:</b>	Wellfarm Pty Ltd
<b>Applicant ACN:</b>	158 518 551
<b>Summary of use</b>	For the control of various diseases on bananas, peanuts, cereal crops, beans, peas, onions, pawpaw, pyrethrum and ryegrass and fescue seed crops
<b>Date of registration/approval:</b>	26 February 2015
<b>Product registration no.:</b>	70177
<b>Label approval no.:</b>	70177/62677
<b>Application no.:</b>	62680
<b>Product name:</b>	Wellfarm Propiconazole 250 EC Fungicide
<b>Active constituent/s:</b>	250 g/L propiconazole
<b>Applicant name:</b>	Wellfarm Pty Ltd
<b>Applicant ACN:</b>	158 518 551
<b>Summary of use</b>	For the control of certain fungal diseases in bananas, oats, peanuts, perennial ryegrass, pineapples, stone fruit, sugarcane, wheat and other crops
<b>Date of registration/approval:</b>	26 February 2015
<b>Product registration no.:</b>	70179
<b>Label approval no.:</b>	70179/62680
<b>Application no.:</b>	62815
<b>Product name:</b>	Lawn Solutions Grub Guard Insecticide Concentrate
<b>Active constituent/s:</b>	50 g/L esfenvalerate
<b>Applicant name:</b>	Amgrow Pty Ltd
<b>Applicant ACN:</b>	100 684 786
<b>Summary of use</b>	For use in the home and garden on outdoor and ornamental plants, trees, shrubs, non-bearing fruit trees and lawn and for use in domestic areas for the control of nuisance insects
<b>Date of registration/approval:</b>	27 February 2015
<b>Product registration no.:</b>	70248
<b>Label approval no.:</b>	70248/62815
<b>Application no.:</b>	60600
<b>Product name:</b>	Raid Max Multi Insect Killer
<b>Active constituent/s:</b>	0.5 g/kg imiprothrin, 0.5 g/kg prallethrin, 0.15 g/kg cyfluthrin
<b>Applicant name:</b>	S.C. Johnson & Son Pty Ltd
<b>Applicant ACN:</b>	000 021 009
<b>Summary of use</b>	For the control of flying and crawling insects in household situations
<b>Date of registration/approval:</b>	27 February 2015
<b>Product registration no.:</b>	69366
<b>Label approval no.:</b>	69366/60600
<b>Application no.:</b>	62806
<b>Product name:</b>	Wellfarm Tri-Allate 500 EC Herbicide
<b>Active constituent/s:</b>	500 g/L tri-allate
<b>Applicant name:</b>	Wellfarm Pty Ltd
<b>Applicant ACN:</b>	158 518 551
<b>Summary of use</b>	For the control of wild oats in wheat, triticale, chickpeas, barley, peas, linseed, lupins, canola (rape seed), faba beans and safflower
<b>Date of registration/approval:</b>	2 March 2015
<b>Product registration no.:</b>	70241
<b>Label approval no.:</b>	70241/62806

<b>Application no.:</b>	62805
<b>Product name:</b>	Wellfarm Oxyfluorfen 240 EC Herbicide
<b>Active constituent/s:</b>	240 g/L oxyfluorfen
<b>Applicant name:</b>	Wellfarm Pty Ltd
<b>Applicant ACN:</b>	158 518 551
<b>Summary of use</b>	For the selective control of certain broadleaf and grass weeds
<b>Date of registration/approval:</b>	2 March 2015
<b>Product registration no.:</b>	70240
<b>Label approval no.:</b>	70240/62805
<b>Application no.:</b>	62804
<b>Product name:</b>	Wellfarm Bromoxynil 200 EC Herbicide
<b>Active constituent/s:</b>	200 g/L bromoxynil present as the n-octanoyl ester
<b>Applicant name:</b>	Wellfarm Pty Ltd
<b>Applicant ACN:</b>	158 518 551
<b>Summary of use</b>	For the control of weeds in wheat, oats, barley, cereal rye and triticale (alone or undersown), linseed, clover and Lucerne pastures, turf, fallow, non-crop, roadsides and rights-of-way
<b>Date of registration/approval:</b>	2 March 2015
<b>Product registration no.:</b>	70239
<b>Label approval no.:</b>	70239/62804
<b>Application no.:</b>	100852
<b>Product name:</b>	agVantage Tebuconazole 430 Fungicide
<b>Active constituent/s:</b>	430 g/L tebuconazole
<b>Applicant name:</b>	Landmark Operations Limited
<b>Applicant ACN:</b>	008 743 217
<b>Summary of use</b>	For the control of leaf spot and leaf speckle on bananas; rust, leaf spot and net blotch of peanuts; foliar diseases on cereal crops; and other diseases on beans, lettuce, peas, onions, papaw, pyrethrum and ryegrass and fescue seed crops
<b>Date of registration/approval:</b>	2 March 2015
<b>Product registration no.:</b>	80430
<b>Label approval no.:</b>	80430/100852
<b>Application no.:</b>	100100
<b>Product name:</b>	Imtrade CC-77 Plant Growth Regulator
<b>Active constituent/s:</b>	77 g/l chlormequat present as chlormequat chloride
<b>Applicant name:</b>	Imtrade Australia Pty Ltd
<b>Applicant ACN:</b>	090 151 134
<b>Summary of use</b>	To increase the berry set and yield of wine grapes and increases setting of currants
<b>Date of registration/approval:</b>	3 March 2015
<b>Product registration no.:</b>	80036
<b>Label approval no.:</b>	80036/100100
<b>Application no.:</b>	100450
<b>Product name:</b>	Sanonda Herbicide MCPA 750SL
<b>Active constituent/s:</b>	750 g/L MCPA present as the dimethylamine salt
<b>Applicant name:</b>	Sanonda (Australia) Pty Ltd
<b>Applicant ACN:</b>	059 813 973
<b>Summary of use</b>	For the selective control of broadleaf weeds in cereals, linseed, pastures, rice, sugar cane and turf
<b>Date of registration/approval:</b>	3 March 2015
<b>Product registration no.:</b>	80235
<b>Label approval no.:</b>	80235/100450

## 2. VARIATIONS OF REGISTRATION

<b>Application no:</b>	101505
<b>Product name:</b>	Legion Insecticidal Seed Treatment
<b>Active constituent/s:</b>	500 g/L fipronil
<b>Applicant name:</b>	Crop Care Australasia Pty Ltd
<b>Applicant ACN:</b>	061 362 347
<b>Summary of variation:</b>	To change the product name from 'PROTEGE INSECTICIDAL SEED TREATMENT' to 'LEGION INSECTICIDAL SEED TREATMENT'
<b>Date of variation:</b>	29 January 2015
<b>Product registration no.:</b>	70278
<b>Label approval no.:</b>	70278/101505
<b>Application no:</b>	101538
<b>Product name:</b>	Muligan Insect Growth Regulator
<b>Active constituent/s:</b>	100 g/L pyriproxyfen
<b>Applicant name:</b>	Proplan Plant Protection Company S.L
<b>Applicant ACN:</b>	N/A
<b>Summary of variation:</b>	To change the approved label name from 'MULIGAN INSECT GROWTH REGULATOR' to 'EICHEM PYRIPROXYFEN 100EC INSECT GROWTH REGULATOR' and to remove use on rockmelon, capsicum, tomatoes, citrus and olives
<b>Date of variation:</b>	4 February 2015
<b>Product registration no.:</b>	69692
<b>Label approval no.:</b>	69692/101538
<b>Application no:</b>	63231
<b>Product name:</b>	Sharpen WG Herbicide
<b>Active constituent/s:</b>	700 g/kg saflufenacil
<b>Applicant name:</b>	BASF Australia Ltd
<b>Applicant ACN:</b>	008 437 867
<b>Summary of variation:</b>	To amend canola plant back timing
<b>Date of variation:</b>	5 February 2015
<b>Product registration no.:</b>	62853
<b>Label approval no.:</b>	62853/63231
<b>Application no:</b>	100457
<b>Product name:</b>	Aquablockaid Termiticide Sealant
<b>Active constituent/s:</b>	2 g/kg bifenthrin
<b>Applicant name:</b>	Granitgard Marketing Pty Ltd
<b>Applicant ACN:</b>	003 630 153
<b>Summary of variation:</b>	To change the product name from 'AQUABLOCK TERMITICIDE SEALANT' to 'AQUABLOCKAID TERMITICIDE SEALANT'
<b>Date of variation:</b>	6 February 2015
<b>Product registration no.:</b>	69789
<b>Label approval no.:</b>	69789/100457

<b>Application no:</b>	100666
<b>Product name:</b>	Surefire Vista 200SC Insecticide
<b>Active constituent/s:</b>	200 g/L fipronil
<b>Applicant name:</b>	PCT Holdings Pty Ltd
<b>Applicant ACN:</b>	099 023 962
<b>Summary of variation:</b>	To extend use to include mushrooms
<b>Date of variation:</b>	9 February 2015
<b>Product registration no.:</b>	63581
<b>Label approval no.:</b>	63581/100666
<b>Application no:</b>	100747
<b>Product name:</b>	Mortein Kill & Protect Do-It-Yourself Professional Outdoor & Indoor Surface Spray Same Technology Used By Professionals
<b>Active constituent/s:</b>	0.6 g/L deltamethrin
<b>Applicant name:</b>	Reckitt Benckiser (Australia) Pty Limited
<b>Applicant ACN:</b>	003 274 655
<b>Summary of variation:</b>	To change the product name from 'MORTEIN PROGARD PROTECTION DO-IT-YOURSELF PROFESSIONAL OUTDOOR & INDOOR SURFACE SPRAY SAME TECHNOLOGY USED BY PROFESSIONALS' to 'MORTEIN KILL & PROTECT DO-IT-YOURSELF PROFESSIONAL OUTDOOR & INDOOR SURFACE SPRAY SAME TECHNOLOGY USED BY PROFESSIONALS' and make minor changes to the claims
<b>Date of variation:</b>	10 February 2015
<b>Product registration no.:</b>	62224
<b>Label approval no.:</b>	62224/100747
<b>Application no:</b>	100748
<b>Product name:</b>	Mortein Kill & Protect Spider Control Outdoor Surface Spray
<b>Active constituent/s:</b>	0.3 g/kg imiprothrin, 0.6 g/kg deltamethrin
<b>Applicant name:</b>	Reckitt Benckiser (Australia) Pty Limited
<b>Applicant ACN:</b>	003 274 655
<b>Summary of variation:</b>	To change the product name from 'MORTEIN PROGARD PROTECTION OUTDOOR SURFACE SPRAY SPIDER CONTROL' to 'MORTEIN KILL & PROTECT SPIDER CONTROL OUTDOOR SURFACE SPRAY' and make minor changes to claims
<b>Date of variation:</b>	10 February 2015
<b>Product registration no.:</b>	62675
<b>Label approval no.:</b>	62675/100748
<b>Application no:</b>	100456
<b>Product name:</b>	Termiblockaid Termiticide Sealant
<b>Active constituent/s:</b>	2 g/kg bifenthrin
<b>Applicant name:</b>	Granitgard Marketing Pty Ltd
<b>Applicant ACN:</b>	003 630 153
<b>Summary of variation:</b>	To change the product name from 'TERMIBLOCK TERMITICIDE SEALANT' to 'TERMIBLOCKAID TERMITICIDE SEALANT'
<b>Date of variation:</b>	12 February 2015
<b>Product registration no.:</b>	67161
<b>Label approval no.:</b>	67161/100456

<b>Application no:</b>	62681
<b>Product name:</b>	Termcoat Sealant Termite Surface Barrier
<b>Active constituent/s:</b>	10 g/L bifenthrin
<b>Applicant name:</b>	Magisurf Pty Ltd
<b>Applicant ACN:</b>	121 670 997
<b>Summary of variation:</b>	To extend use to include internal surface treatment of wall cavity below damp proof course
<b>Date of variation:</b>	16 February 2015
<b>Product registration no.:</b>	64218
<b>Label approval no.:</b>	64218/62681
<b>Application no:</b>	101431
<b>Product name:</b>	Nuturf OxaMAX Herbicide Plus Fertiliser 18-10-9
<b>Active constituent/s:</b>	10 g/kg oxadiazon
<b>Applicant name:</b>	Amgrow Pty Ltd
<b>Applicant ACN:</b>	100 684 786
<b>Summary of variation:</b>	To change the product name from 'OX HERBICIDE PLUS FERTILIZER 18-10-9' to 'NUTURF OXAMAX HERBICIDE PLUS FERTILISER 18-10-9' and amend the Directions for Use table
<b>Date of variation:</b>	16 February 2015
<b>Product registration no.:</b>	69594
<b>Label approval no.:</b>	69594/101431
<b>Application no:</b>	101432
<b>Product name:</b>	Nuturf OxaMAX Herbicide Plus Fertiliser 15-2-8
<b>Active constituent/s:</b>	10 g/kg oxadiazon
<b>Applicant name:</b>	Amgrow Pty Ltd
<b>Applicant ACN:</b>	100 684 786
<b>Summary of variation:</b>	To change the product name from 'OX HERBICIDE PLUS FERTILIZER 15-2-8' to 'NUTURF OXAMAX HERBICIDE PLUS FERTILISER 15-2-8' and amend the Directions for Use table
<b>Date of variation:</b>	16 February 2015
<b>Product registration no.:</b>	69262
<b>Label approval no.:</b>	69262/101432
<b>Application no:</b>	100655
<b>Product name:</b>	Virkon S Tablets Broad Spectrum Virucidal Bactericidal Fungicidal Disinfectant
<b>Active constituent/s:</b>	494 g/kg potassium peroxymonosulfate triple salt
<b>Applicant name:</b>	Lienert Australia Pty. Ltd.
<b>Applicant ACN:</b>	008 293 007
<b>Summary of variation:</b>	To change the product name from 'DDUPONT VIRKON S TABLETS BROAD SPECTRUM VIRUCIDAL BACTERICIDAL FUNGICIDAL DISINFECTANT' to 'VIRKON S TABLETS BROAD SPECTRUM VIRUCIDAL BACTERICIDAL FUNGICIDAL DISINFECTANT'
<b>Date of variation:</b>	8 December 2014
<b>Product registration no.:</b>	68502
<b>Label approval no.:</b>	68502/100655



<b>Application no:</b>	101560
<b>Product name:</b>	DIB-V
<b>Active constituent/s:</b>	1g/Dv progesterone
<b>Applicant name:</b>	Syntex S.A
<b>Applicant ACN:</b>	N/A
<b>Summary of variation:</b>	To change the product name from 'SYNTEX INTRAVAGINAL DEVICE (DIB)' to 'DIB-V'
<b>Date of variation:</b>	5 February 2015
<b>Product registration no.:</b>	62744
<b>Label approval no.:</b>	62744/101560
<b>Application no:</b>	101636
<b>Product name:</b>	Macro Protect Triflur 480 Herbicide
<b>Active constituent/s:</b>	480 g/L trifluralin
<b>Applicant name:</b>	Macrofertil Australia Pty Ltd
<b>Applicant ACN:</b>	166 370 976
<b>Summary of variation:</b>	To change the product name from 'RAVENSDOWN TRIFLURALIN 480 HERBICIDE' to 'MACRO PROTECT TRIFLUR 480 HERBICIDE'
<b>Date of variation:</b>	11 February 2015
<b>Product registration no.:</b>	56869
<b>Label approval no.:</b>	56869/101636
<b>Application no:</b>	101654
<b>Product name:</b>	Unishield Fungicide, Miticide and Insecticide
<b>Active constituent/s:</b>	800 g/kg sulfur
<b>Applicant name:</b>	UPL Australia Limited
<b>Applicant ACN:</b>	066 391 384
<b>Summary of variation:</b>	To change the product name from 'UNI-SHIELD FUNGICIDE, MITICIDE AND INSECTICIDE' to 'UNISHIELD FUNGICIDE, MITICIDE AND INSECTICIDE'
<b>Date of variation:</b>	12 February 2015
<b>Product registration no.:</b>	62282
<b>Label approval no.:</b>	62282/101654
<b>Application no:</b>	100743
<b>Product name:</b>	Mortein Kill & Protect Flea Bomb
<b>Active constituent/s:</b>	10 g/kg permethrin, 1.07 g/kg fenoxycarb
<b>Applicant name:</b>	Reckitt Benckiser (Australia) Pty Limited
<b>Applicant ACN:</b>	003 274 655
<b>Summary of variation:</b>	To change the product name from: 'MORTEIN FLEA BOMB' to 'MORTEIN KILL & PROTECT FLEA BOMB', to add pack sizes and make minor changes to statement of claim
<b>Date of variation:</b>	23 February 2015
<b>Product registration no.:</b>	55629
<b>Label approval no.:</b>	55629/100743
<b>Application no:</b>	100693
<b>Product name:</b>	Agador Turf Nematicide
<b>Active constituent/s:</b>	20 g/L abamectin
<b>Applicant name:</b>	Syngenta Australia Pty Ltd
<b>Applicant ACN:</b>	002 933 717
<b>Summary of variation:</b>	To change the product name from 'AGADOR TURF NEMATOCIDE AND MITICIDE' to 'AGADOR TURF NEMATOCIDE' and to remove use on couch mite
<b>Date of variation:</b>	24 February 2015
<b>Product registration no.:</b>	66380
<b>Label approval no.:</b>	66380/100693

<b>Application no:</b>	62854
<b>Product name:</b>	Barometer Herbicide
<b>Active constituent/s:</b>	200 g/L bromoxynil present as the n-octanoyl ester, 200 g/L MCPA present as the ethyl hexyl ester
<b>Applicant name:</b>	Cheminova Australia Pty Limited
<b>Applicant ACN:</b>	110 199 169
<b>Summary of variation:</b>	To add a pack size range and update the Registered Label Particulars
<b>Date of variation:</b>	24 February 2015
<b>Product registration no.:</b>	63239
<b>Label approval no.:</b>	63239/62854
<b>Application no:</b>	100750
<b>Product name:</b>	Mortein Kill & Protect Cockroach Baits
<b>Active constituent/s:</b>	2.5 g/kg indoxacarb
<b>Applicant name:</b>	Reckitt Benckiser (Australia) Pty Limited
<b>Applicant ACN:</b>	003 274 655
<b>Summary of variation:</b>	To change the product name from 'MORTEIN PROGARD PROTECTION COCKROACH BAITS' to 'MORTEIN KILL & PROTECT COCKROACH BAITS' and make minor changes to the claims
<b>Date of variation:</b>	26 February 2015
<b>Product registration no.:</b>	61000
<b>Label approval no.:</b>	61000/100750
<b>Application no:</b>	100746
<b>Product name:</b>	Mortein Kill & Protect Crawling Insect Surface Spray Odourless
<b>Active constituent/s:</b>	2.79 g/kg permethrin, 0.15 g/kg imiprothrin
<b>Applicant name:</b>	Reckitt Benckiser (Australia) Pty Limited
<b>Applicant ACN:</b>	003 274 655
<b>Summary of variation:</b>	To change the product name from 'MORTEIN CRAWLING INSECT SURFACE SPRAY KILL & PROTECT ODOURLESS' to 'MORTEIN KILL & PROTECT CRAWLING INSECT SURFACE SPRAY ODOURLESS' and make minor amendments to the statement of claims
<b>Date of variation:</b>	26 February 2015
<b>Product registration no.:</b>	54626
<b>Label approval no.:</b>	54626/100746
<b>Application no:</b>	100778
<b>Product name:</b>	Meta Slug And Snail Pellets
<b>Active constituent/s:</b>	15 g/kg metaldehyde
<b>Applicant name:</b>	Crop Care Australasia Pty Ltd
<b>Applicant ACN:</b>	061 362 347
<b>Summary of variation:</b>	To add additional pack size
<b>Date of variation:</b>	26 February 2015
<b>Product registration no.:</b>	49568
<b>Label approval no.:</b>	49568/100778
<b>Application no:</b>	100752
<b>Product name:</b>	Mortein Kill & Protect Ant Baits
<b>Active constituent/s:</b>	1 g/kg indoxacarb
<b>Applicant name:</b>	Reckitt Benckiser (Australia) Pty Limited
<b>Applicant ACN:</b>	003 274 655
<b>Summary of variation:</b>	To change the product name from 'MORTEIN PROGARD PROTECTION ANT BAITS' to 'MORTEIN KILL & PROTECT ANT BAITS' and make minor changes to the claims
<b>Date of variation:</b>	26 February 2015
<b>Product registration no.:</b>	62416
<b>Label approval no.:</b>	62416/100752

<b>Application no:</b>	100745
<b>Product name:</b>	Mortein Kill & Protect Crawling Insect Surface Spray High Performance
<b>Active constituent/s:</b>	0.7 g/kg imiprothrin, 2 g/kg cypermethrin
<b>Applicant name:</b>	Reckitt Benckiser (Australia) Pty Limited
<b>Applicant ACN:</b>	003 274 655
<b>Summary of variation:</b>	To change the product name from 'MORTEIN CRAWLING INSECT SURFACE SPRAY KILL & PROTECT HIGH PERFORMANCE FAST DIRECT KILL EASY REACH' to 'MORTEIN KILL & PROTECT CRAWLING INSECT SURFACE SPRAY HIGH PERFORMANCE', add a manufacturer and make minor amendments to the claims
<b>Date of variation:</b>	26 February 2015
<b>Product registration no.:</b>	70109
<b>Label approval no.:</b>	70109/100745
<b>Application no:</b>	63456
<b>Product name:</b>	Vantal Upgrade Miticide/Insecticide
<b>Active constituent/s:</b>	36 g/L abamectin
<b>Applicant name:</b>	Cheminova Australia Pty Limited
<b>Applicant ACN:</b>	110 199 169
<b>Summary of variation:</b>	To extend the use to include almonds and add an additional pack size range
<b>Date of variation:</b>	27 February 2015
<b>Product registration no.:</b>	67524
<b>Label approval no.:</b>	67524/63456
<b>Application no:</b>	59105
<b>Product name:</b>	Vibrance Fungicide Seed Treatment
<b>Active constituent/s:</b>	66.2 g/L difenoconazole, 16.5 g/L metalaxyl-m, 13.8 g/L sedaxane
<b>Applicant name:</b>	Syngenta Australia Pty Ltd
<b>Applicant ACN:</b>	002 933 717
<b>Summary of variation:</b>	To include suppression of fusarium head blight and white grain in wheat and triticale, and lower the application rates for control of smuts and suppression of Rhizoctonia in barley
<b>Date of variation:</b>	27 February 2015
<b>Product registration no.:</b>	64098
<b>Label approval no.:</b>	64098/59105
<b>Application no:</b>	62301
<b>Product name:</b>	Vapormate Fumigant
<b>Active constituent/s:</b>	166.7 g/kg ethyl formate
<b>Applicant name:</b>	BOC Limited
<b>Applicant ACN:</b>	000 029 729
<b>Summary of variation:</b>	To extend the use to include the control of a range of pests in post-harvest citrus, blueberries, persimmons, dried fruits and dates
<b>Date of variation:</b>	2 March 2015
<b>Product registration no.:</b>	56186
<b>Label approval no.:</b>	56186/62301
<b>Application no:</b>	100653
<b>Product name:</b>	Ultraforce Aqua Termiticide & Insecticide
<b>Active constituent/s:</b>	100 g/L fipronil
<b>Applicant name:</b>	Sherwood Chemicals Australasia Pty Ltd
<b>Applicant ACN:</b>	136 993 630
<b>Summary of variation:</b>	Removal of use for ants.
<b>Date of variation:</b>	2 March 2015
<b>Product registration no.:</b>	69524
<b>Label approval no.:</b>	69524/100653

<b>Application no:</b>	63288
<b>Product name:</b>	Olympus Fungicide
<b>Active constituent/s:</b>	125 g/L epoxiconazole
<b>Applicant name:</b>	Cheminova Australia Pty Limited
<b>Applicant ACN:</b>	110 199 169
<b>Summary of variation:</b>	To change the product name from 'OSPRAY OLYMPUS FUNGICIDE' to 'OLYMPUS FUNGICIDE' and to update registration particulars
<b>Date of variation:</b>	3 March 2015
<b>Product registration no.:</b>	62840
<b>Label approval no.:</b>	62840/63288

### 3. VARIATION OF LABEL APPROVAL

<b>Application no:</b>	101539
<b>Product name:</b>	Rodemise Bromadiolone Rodent Block
<b>Active constituent/s:</b>	0.05 g/kg bromadiolone
<b>Applicant name:</b>	Animal Control Technologies (Australia) Pty Ltd
<b>Applicant ACN:</b>	137 868 449
<b>Summary of variation:</b>	To change the approved label name from 'RODEMISE BROMADIOLONE RODENT BLOCK' to 'MOUSEOFF BROMADIOLONE RODENT BLOCK'
<b>Date of variation:</b>	04 February 2015
<b>Label approval no.:</b>	64931/101539

<b>Application no:</b>	100045
<b>Product name:</b>	Regular Roundup Ready To Use Weedkiller
<b>Active constituent/s:</b>	21 g/L nonanoic acid, 7.2 g/L glyphosate present as the isopropylamine salt
<b>Applicant name:</b>	Monsanto Australia Ltd
<b>Applicant ACN:</b>	006 725 560
<b>Summary of variation:</b>	To add the statement 'starts to work on most broadleaf weeds and grasses within 24 hours'
<b>Date of variation:</b>	17 February 2015
<b>Label approval no.:</b>	67857/100045

## 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 EXISTING ACTIVE CONSTITUENTS

<b>Application no.:</b>	100376
<b>Product name:</b>	Vets Choice For Cats 2.5 kg To 5 kg Allwormer Spot-On
<b>Active constituent/s:</b>	21.4 g/L emodepside, 85.8 g/L praziquantel
<b>Applicant name:</b>	Bayer Australia Ltd (Animal Health)
<b>Applicant ACN:</b>	000 138 714
<b>Summary of use</b>	For use in the treatment and control of intestinal parasites and lungworm in cats
<b>Date of registration/approval:</b>	23 February 2015
<b>Product registration no.:</b>	80191
<b>Label approval no.:</b>	80191/100376

<b>Application no.:</b>	100378
<b>Product name:</b>	Vets Choice For Cats 5 kg To 8 kg Allwormer Spot-On
<b>Active constituent/s:</b>	21.4 g/L emodepside, 85.8 g/L praziquantel
<b>Applicant name:</b>	Bayer Australia Ltd (Animal Health)
<b>Applicant ACN:</b>	000 138 714
<b>Summary of use</b>	For use in the treatment and control of intestinal parasites and lungworm in cats
<b>Date of registration/approval:</b>	25 February 2015
<b>Product registration no.:</b>	80193
<b>Label approval no.:</b>	80193/100378

<b>Application no.:</b>	100845
<b>Product name:</b>	Projet Jetting Fluid
<b>Active constituent/s:</b>	75 mg/mL ivermectin
<b>Applicant name:</b>	Merial Australia Pty Ltd
<b>Applicant ACN:</b>	071 187 285
<b>Summary of use</b>	For the control of lice, the treatment of blowfly strike and for protection against blowfly strike when applied by jetting to sheep with long wool
<b>Date of registration/approval:</b>	26 February 2015
<b>Product registration no.:</b>	80428
<b>Label approval no.:</b>	80428/100845

### 2. VARIATIONS OF REGISTRATION

<b>Application no:</b>	101531
<b>Product name:</b>	Flusapex Tablets Diuretic
<b>Active constituent/s:</b>	each tablet contains 40 mg frusemide
<b>Applicant name:</b>	Apex Laboratories Pty Ltd
<b>Applicant ACN:</b>	000 397 240
<b>Summary of variation:</b>	To remove use on cattle
<b>Date of variation:</b>	3 February 2015
<b>Product registration no.:</b>	35638
<b>Label approval no.:</b>	35638/101531

<b>Application no.:</b>	100508
<b>Product name:</b>	Metricure Benzathine Cephapirin Intra-Uterine Suspension
<b>Active constituent/s:</b>	500 mg cephapirin (as benzathine) per 19 gram syringe
<b>Applicant name:</b>	Intervet Australia Pty Limited
<b>Applicant ACN:</b>	008 467 034
<b>Summary of variation:</b>	To include additional pack sizes
<b>Date of variation:</b>	11 February 2015
<b>Product registration no.:</b>	47091
<b>Label approval no.:</b>	47091/100508

## 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 CONSTITUENT

<b>Application no.:</b>	62941
<b>Active constituent/s:</b>	Alpha-cypermethrin
<b>Applicant name:</b>	Hemani Industries Limited
<b>Applicant ACN:</b>	N/A
<b>Summary of use:</b>	For use in agricultural chemical products
<b>Date of approval:</b>	5 February 2015
<b>Approval no.:</b>	70290/62941

## Amendments to the APVMA MRL Standard

The Australian Pesticides and Veterinary Medicines Authority (APVMA) approves maximum residue limits (MRLs) of agricultural and veterinary chemicals in agricultural produce, particularly produce entering the food chain. The MRLs approved by the APVMA are associated with a regulatory decision to register a product, grant a permit approval, or as an outcome from a review decision and are set out in the *Agricultural and Veterinary Chemicals Code Instrument No. 4 (MRL Standard) 2012*. The *MRL Standard* lists MRLs of substances that may arise from the approved use of agricultural and veterinary chemical products containing those substances on commodities used for human consumption as well as livestock feeds. The *MRL Standard* also provides the relevant residue definitions to which these MRLs apply. There may be situations where the residue definition for monitoring and enforcement is different to the definition used for dietary risk assessment purposes.

MRLs are set at levels which are not likely to be exceeded if the agricultural or veterinary chemicals are used in accordance with approved label instructions. In considering MRLs and variation to MRLs, the APVMA takes into account studies on chemistry, metabolism, analytical methodology, residues, toxicology, good agricultural practice and dietary exposure. In approving MRLs, the APVMA is satisfied, from dietary exposure assessment, that the levels set are not an undue hazard to human health.

The APVMA has amended the *MRL Standard* and the changes will have affect the day after the instrument is registered.

Details of the amendment can be found in the *Agricultural and Veterinary Chemicals Code Instrument No. 4 (MRL Standard) Amendment Instrument 2015 (No. 2)*.

The amendments will be incorporated into the compilation of the [Agricultural and Veterinary Chemicals Code Instrument No. 4 \(MRL Standard\) 2012](#).

The *MRL Standard* is accessible via the ComLaw website [www.comlaw.gov.au](http://www.comlaw.gov.au) or the links above.

For further information please contact:

MRL Contact Officer  
Australian Pesticides and Veterinary Medicines Authority  
PO Box 6182  
KINGSTON ACT 2604

**Phone:** +61 2 6210 4897

**Fax:** +61 2 6210 4840

**Email:** [enquiries@apvma.gov.au](mailto:enquiries@apvma.gov.au)



## **Proposal to Amend Standard 1.4.2 of the Australia New Zealand Food Standards Code**

In the previous notice, the APVMA gazetted that amendments which it has approved varying maximum residue limits (MRLs) for substances contained in agricultural and veterinary chemical products as set out as in the APVMA's *MRL Standard*, have been made.

Under Section 82 of the *Food Standards Australia New Zealand Act 1991* the APVMA is proposing to incorporate those variations (*Agricultural and Veterinary Chemicals Code Instrument No. 4 (MRL Standard) Amendment Instrument 2015 (No. 2)*) to MRLs into Standard 1.4.2. Maximum Residue Limits of the Australia New Zealand Food Standards Code.

MRLs contained in Standard 1.4.2 provide the limits for residues of agricultural and veterinary chemicals that may legitimately occur in foods. By this means, Standard 1.4.2 permits the sale of treated foods and protects public health and safety by minimising residues in foods consistent with the effective control of pests and diseases.

The APVMA and FSANZ are satisfied, based on dietary exposure assessments and current health standards, that the proposed limits are not harmful to public health.

The Agreement between the Government of Australia and the Government of New Zealand concerning a Joint Food Standards System, excludes MRLs for agricultural and veterinary chemicals in food from the system setting joint food standards. Australia and New Zealand independently and separately develop MRLs for agricultural and veterinary chemicals in food.

Food Standards Australia New Zealand (FSANZ) will make a Sanitary and Phytosanitary (SPS) notification to the World Trade Organization (WTO).

The APVMA invites comment on these proposals. Details on how to make a submission appear near the end of this notice, below the details of the proposed amendment.

The APVMA will consider any public comments made in response to this proposal. If the APVMA decides to proceed with the proposal, it will further notify any variations it makes to Standard 1.4.2 in the APVMA *Gazette*. The variations will take effect as from the date of that subsequent notice.

## DRAFT VARIATIONS TO THE AUSTRALIA NEW ZEALAND FOOD STANDARDS CODE

Note: The following amendments are in a format that accords with the proposed amending Legislative Instrument which, in turn, has to be consistent with the existing format of Standard 1.4.2 (Maximum Residue Limits) of the *Australia New Zealand Food Standards Code*.

### PROPOSED AMENDMENT (AGRICULTURAL AND VETERINARY CHEMICALS CODE INSTRUMENT NO. 4 (MRL STANDARD) AMENDMENT INSTRUMENT 2015 (NO. 2))

Note: Subsection 82(2) of the *Food Standards Australia New Zealand Act 1991* provides that variations to standards are legislative instruments, but are not subject to disallowance or sunseting.

To commence: on gazettal of variation

**Standard 1.4.2** of the *Australia New Zealand Food Standards Code* is varied by –

1. inserting in alphabetical order in Schedule 1, the foods and associated MRLs for each of the following chemicals

<b>Azoxystrobin</b> Azoxystrobin	
Rucola (rocket) (i)	T50
<b>Buprofezin</b> Buprofezin	
Litchi (ii)	T0.5
<b>Clothianidin</b> Clothianidin	
Fruiting vegetables, cucurbits	T1
Fruiting vegetables, other than cucurbits [except sweet (corn-on-the-cob) and mushroom] (iii)	T0.7
<b>Dimethenamid-P</b> Sum of dimethenamid-P and its ( <i>R</i> )-isomer	
Onion, bulb (iv)	T*0.01
<b>Flonicamid</b> Flonicamid [ <i>N</i> -(cyanomethyl)-4-(trifluoromethyl)-3-pyridinecarboxamide] and its metabolites TFNA [4-trifluoromethylnicotinic acid], TFNA-AM [4-trifluoromethylnicotinamide] TFNG [ <i>N</i> -(4-trifluoromethylnicotinoyl)glycine]	
Apple (v)	0.7

2. omitting from Schedule 1 the foods and associated MRLs for each of the following chemicals –

<b>Clothianidin</b> Clothianidin	
Apricot <b>(vi)</b>	T2
<b>Flonicamid</b> Flonicamid [ <i>N</i> -(cyanomethyl)-4-(trifluoromethyl)-3-pyridinecarboxamide] and its metabolites TFNA [4-trifluoromethylnicotinic acid], TFNA-AM [4-trifluoromethylnicotinamide] TFNG [ <i>N</i> -(4-trifluoromethylnicotinoyl)glycine]	
Pome fruits <b>(vii)</b>	0.7
<b>Haloxypop</b> Sum of haloxypop, its esters and conjugates, expressed as haloxypop	
Green Elk <b>(viii)</b>	T0.5

3. omitting from Schedule 1, under the entries for the following chemicals, the maximum residue limit for the food, substituting –

<b>Clothianidin</b> Clothianidin	
Sweet corn (corn-on-the-cob) <b>(ix)</b>	0.02
<b>Prochloraz</b> Sum of prochloraz and its metabolites containing the 2,4,6-trichlorophenol moiety, expressed as prochloraz	
Litchi <b>(x)</b>	T1
<b>Thiodicarb</b> Sum of thiodicarb and methomyl, expressed as thiodicarb	
Chia <b>(xi)</b>	T1

## INVITATION FOR SUBMISSIONS

Written submissions are invited from interested individuals and organisations to assist the APVMA in considering the proposal to vary Standard 1.4.2 Maximum Residue Limits of the *Australia New Zealand Food Standards Code*. Submissions should be strictly confined to relevant matters that the APVMA must consider (such as public health and safety) which are associated with the occurrence of the proposed residues in foods. Comments received outside these grounds will not be considered by the APVMA. Claims made in submissions should be supported wherever possible by referencing or including relevant studies, research findings, trials, surveys etc. Technical information should be in sufficient detail to allow independent scientific assessment.

Please note that FSANZ will make a SPS notification to the WTO and submissions related to impacts on international trade should be made to FSANZ in response to that notification.

Submissions must be made in writing and should be clearly marked as a 'submission on the proposed amendment to Standard 1.4.2' and quote the correct amendment number.

**DEADLINE FOR PUBLIC SUBMISSIONS: 6 pm (AEST) 7 April 2015**

**SUBMISSIONS RECEIVED AFTER THIS DEADLINE WILL ONLY BE CONSIDERED BY PRIOR ARRANGEMENT**

Submissions received after this date will only be considered if agreement for an extension has been given prior to this closing date. Agreement to an extension of time will only be given if extraordinary circumstances warrant an extension to the submission period.

For further information please contact:

MRL Contact Officer  
Australian Pesticides and Veterinary Medicines Authority  
PO Box 6182  
KINGSTON ACT 2604

**Phone:** +61 2 6210 4897

**Fax:** +61 2 6210 4840

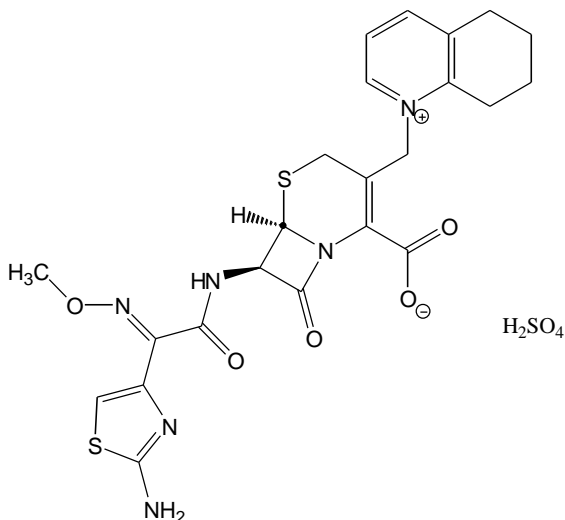
**Email:** [enquiries@apvma.gov.au](mailto:enquiries@apvma.gov.au)

## Cefquinome sulphate in the product Cobactan IV

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application from Intervet Australia Pty Limited for the approval of a new active constituent, cefquinome sulphate. The APVMA also has before it an application from the same applicant for the registration of a new product containing the new active constituent. The product is: Cobactan IV.

### PARTICULARS OF THE ACTIVE CONSTITUENT

<b>Common name:</b>	Cefquinome sulphate
<b>IUPAC name:</b>	1-[[[(6R,7R)-7-[[[(2Z)-(2-Amino-4-thiazolyl)-(methoxyimino)acetyl]amino]-2-carboxy-8-oxo-5-thia-1-azabicyclo[4.2.0-oct-2-en-3-yl]methyl]-5,6,7,8-tetrahydroquinolinium inner salt sulfate
<b>CAS name:</b>	[6R-[6 $\alpha$ ,7 $\beta$ (Z)]]-7-[[[(2-Amino-4-thiazolyl)-(methoxyimino)acetyl]amino]-3-[(5,7-tetrahydroquinoline)-N-methyl]-8-oxo-5-thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylic acid inner salt monosulphate
<b>CAS registry number:</b>	118443-89-3 84957-30-2 (inner salt)
<b>Manufacturer's code:</b>	Cefquinome sulfate
<b>Minimum purity:</b>	80.0% (anhydrous)
<b>Molecular formula:</b>	C <sub>23</sub> H <sub>24</sub> N <sub>6</sub> O <sub>5</sub> S <sub>2</sub> .H <sub>2</sub> SO <sub>4</sub>
<b>Molar weight:</b>	626.7
<b>Structure:</b>	



<b>Chemical family:</b>	Cephalosporin
<b>Mode of action:</b>	An antibiotic that inhibits cell wall synthesis
<b>Stereochemistry:</b>	Two stereogenic centres are present at C6 (R) and C7 (R) and the methoxyamino group is indicated to be in the Z configuration

## SUMMARY OF THE APVMA'S EVALUATION OF CEFQUINOME SULPHATE

Cefquinome sulphate is a new active constituent and there is no compendial specification available.

The APVMA has evaluated the chemistry aspects of cefquinome sulphate and is satisfied that criteria (including the physio-chemical properties, spectral identity, manufacturing process and quality control aspects, impurity formation, stability, active constituent specifications, batch analysis, analytical methods and packaging information) necessary for the approval of this new active constituent have been met.

The Office of Chemical Safety in the Department of Health has conducted a toxicology evaluation of cefquinome sulphate and advised that there are no objections on human health grounds to the approval of the active constituent. Based on the data provided, cefquinome sulphate has low acute oral, intravenous and subcutaneous toxicity. It is not a skin sensitiser. Cefquinome sulphate is not mutagenic or genotoxic *in vitro*, or genotoxic *in vivo*. The active is not a developmental toxicant and has no effects on reproductive parameters.

An Acceptable Daily Intake (ADI) and Acute Reference Dose (ARfD) have not been established as the product is intended for use in non-food-producing animals.

The Delegate to the Secretary of the Department of Health for scheduling has included cefquinome sulphate in Schedule 4 of the Standard for the Uniform Scheduling of Medicines and Poisons.

The APVMA has accepted the findings and recommendations of its advisers. The APVMA is satisfied that the proposed use of cefquinome sulphate would not be an undue toxicology hazard to the safety of people exposed to it during its handling and use.

## PARTICULARS OF THE PRODUCT APPLICATION

<b>Proposed product name:</b>	COBACTAN IV
<b>Applicant company:</b>	Intervet Australia Pty Limited
<b>Name of active constituent:</b>	Cefquinome sulphate
<b>Signal heading:</b>	Prescription Animal Remedy - Schedule 4
<b>Summary of proposed use:</b>	For the treatment of respiratory infections caused by <i>Streptococcus equi</i> subsp. <i>zooepidemicus</i> in adult horses.
<b>Pack sizes:</b>	1x30 mL vial with 30 mL diluent
<b>Withholding period:</b>	Not Applicable

**SUMMARY OF THE APVMA'S EVALUATION OF COBACTAN IV IN ACCORDANCE WITH THE REQUIREMENTS OF SECTION 14(3)(e) AND (f) OF THE AGRICULTURAL AND VETERINARY CHEMICALS CODE (THE 'AGVET CODE'), SCHEDULED TO THE AGRICULTURAL AND VETERINARY CHEMICALS CODE ACT 1994**

1. The APVMA has evaluated the application and in its assessment in relation to human and environmental safety under section 14(3)(e)(i) and 14(3)(e)(ii) of the Agvet Code, it proposes to determine that:

- (i) The APVMA is satisfied that the proposed use of COBACTAN IV would not be an undue hazard to the safety of people exposed to them during their handling and use (section 14(3)(e)(i)).

The Office of Chemical safety has conducted a risk assessment and found that the submitted data support the safe use of COBACTAN IV from a toxicological perspective.

The acute toxicity of COBACTAN IV was estimated, based on information provided for cefquinome sulphate and information available on components of the diluent ingredients and their concentration in the formulations. It was concluded that COBACTAN IV has low acute oral, intravenous and subcutaneous toxicity.

Human exposure to COBACTAN IV is expected to be minimal, as the product is presented in single use vials and, once reconstituted, will be administered by injection by veterinarians and trained workers in the equine industry. For this reason, the Office of Chemical Safety did not establish safety directions and personal protective equipment for Cobactan IV. End users are expected to observe normal precautions to avoid self-injection. When the potential toxicological hazards, use pattern and likelihood of handler exposure have been considered, the Office of Chemical Safety recommended the following first aid instruction: *If poisoning occurs, contact a doctor or Poisons Information Centre. Phone Australia 131126.*

The APVMA has considered these findings and has accepted the recommendations of the Office of Chemical Safety.

The APVMA has assessed a qualitative risk assessment and arguments the Applicant had provided. The hazard was characterised as cefquinome resistant bacteria (or their mobile genetic elements) in horses or their environment arising from the use of cefquinome in horses, and having the potential to transfer to humans. The potential for harm is associated with either the direct transfer of bacteria resistant to cefquinome to humans who are in close association with horses or the transfer of highly mobile, plasmid-borne genes to commensal bacteria in horse. These genes confer resistance to cephalosporins.

Although at the time of that assessment, the risk was rated low based on the low level of exposure, concerns have been raised about cefquinome's potential to cause extended-spectrum  $\beta$ -lactamase (ESBL)-mediated resistance in equine pathogens and commensal organisms and for this resistance or the resistance genes to transfer to bacteria that can infect humans and cause treatment failure. The risk of transfer of ESBL-mediated resistance from horse to handlers and then the wider human population as a result of Cobactan IV treatments in horses has been considered further. Once Cobactan IV is introduced to the Australian market, there is likelihood of the dissemination of ESBL-encoding genes in Enterobacteriaceae, due to the selection pressure from cefquinome treatments.

The National Health and Medical Research Council (NHMRC) has expressed strong concerns about the potential of introducing or amplifying antimicrobial resistance in humans. The NHMRC has advised the APVMA that our assessment need to carefully balance the proposed exposure patterns against risk, including procedures to minimise the development of antimicrobial resistance.

The APVMA has considered the advice from its advisers. The APVMA proposes to be satisfied that the risk to human health as a result of cefquinome treatments in adult horses could be mitigated when COBACTAN IV is prescribed only for the indication in the target animal specified on the label and based on sensitivity testing, and COBACTAN IV is prescribed when the response to other treatments is poor and there are no suitable alternatives.

- (ii) The APVMA is satisfied that the proposed use of COBACTAN IV will not be an undue hazard to the safety of people using anything containing their residues (section 14(3)(e)(i)).

COBACTAN IV is intended for use in non-food-producing animals only. Cefquinome sulphate is unlikely to enter the food chain and therefore the determinations of an Acceptable Daily Intake, an Acute Reference Dose and Maximum Residue Limits are not considered necessary.

- (iii) The APVMA is satisfied that the proposed use of COBACTAN IV containing the active constituent cefquinome sulphate is not likely to be harmful to human beings if used according to the product label directions (section 14(3)(e)(i)).

The Delegate to the Secretary of the Department of Health for scheduling has decided cefquinome sulphate is appropriate for inclusion in Schedule 4 of the Standard for the Uniform Scheduling of Medicines and Poisons with no cut-offs. The signal heading appropriate to Schedule 4 and the first aid instructions the Office of Chemical Safety has recommended will appear on the product label.

2. The APVMA has evaluated the application and in its assessment in relation to environmental safety under section 14(3)(e)(iii) of the Agvet Code, it proposes to determine that:

- (i) The APVMA is satisfied that the proposed use of the new product COBACTAN IV containing the active constituent cefquinome sulphate would not be likely to have an unintended effect that is harmful to animals, plants or things or the environment.

The Department of the Environment has conducted a VICH Phase 1 assessment and has concluded that the proposed use of Cobactan IV in horses under Australian conditions is unlikely to exceed the VICH trigger value of 100 µg/kg soil. The APVMA has accepted this conclusion. The product label will contain a suitable disposal statement.

The APVMA has assessed the safety of Cobactan IV to the target animal species based on the data the Applicant had provided. A safety study with the product demonstrated that adult horses tolerated twice daily intramuscular doses of 1 mg/kg BW for 14 days, followed by a single intravenous dose of 3 mg cefquinome /kg BW on the day after the last intramuscular injection. Mares showed transient oedematous subcutaneous swellings below the site of injection. These swellings resolved within 15 days of the last intramuscular injection and were attributed possibly to the greater injection volume given to them. Plasma creatine kinase concentrations increased substantially throughout treatment but returned to pre-treatment levels 48 hours after the last intramuscular injection. Abnormalities in respiratory or heart rate, on auscultation of the lungs and heart, in the visible mucosal membranes, in feed consumption, defecation, faecal consistency, body temperature or general behaviour were not observed.

The product is contraindicated for use in horses that are known to be hypersensitive to cephalosporin antibiotics and other β-lactams.

The APVMA is satisfied that Cobactan IV would not have an unintended effect that is harmful to animals. The contraindications and side effects will be included on the product label.

3. The APVMA has evaluated the application and in its assessment in relation to whether the trade criterion has been met in accordance with section 14(3)(e)(iv) of the Agvet Code, it proposes to determine that:

- (i) The APVMA is satisfied that the proposed use of COBACTAN IV would not unduly prejudice trade and commerce between Australia and places outside Australia as the product is not for use in animals producing any major Australian export commodities.



COBACTAN IV is intended for use in non-food-producing animals only. The label restricts the product from being used in horses that are intended for human consumption. Therefore, it is unlikely that humans would be exposed to residues of cefquinome sulphate in their diet.

4. The APVMA has evaluated the application and in its assessment in relation to whether the efficacy criterion has been met in accordance with section 14(3)(f) of the Agvet Code, it proposes to determine that:

- (i) The APVMA is satisfied that data from trials supporting the efficacy of COBACTAN IV adequately demonstrate that COBACTAN IV will be effective for its proposed use if used according to the product label directions.

Pharmacokinetics, pharmacodynamics and clinical field studies have been provided to support the efficacy and safety of Cobactan IV.

Pharmacokinetic studies have established the recommended label dose of 1 mg/kg BW once daily for 5-10 days. In these studies, groups of adult mares were administered 1 mg cefquinome/kg BW intramuscularly and intravenously. Peak serum concentrations of about 2.47 µg/mL ( $C_{max}$ ) were reached in adult horses within 1 hour after intramuscular administration. The period of time plasma concentrations of cefquinome were above the minimum inhibition concentration ( $T > MIC$ ) were 55.4% of the treatment interval (24 hours) for the intramuscular route and 49.6% for the intravenous route.  $MIC_{90}$  for the target pathogen, *Streptococcus equi* subpecies *zooepidemicus* was 32 ng/mL. The  $T > MIC$  result indicated that cefquinome is expected to be above MIC for about 50% of the dosing interval – an acceptable indicator for cephalosporins, which possess time-dependent killing action. The bioavailability of cefquinome in adult horses was high (98%). Cefquinome is eliminated unchanged from serum with a half-life of approximately 2 hours.

Clinical trials in horses have demonstrated that cefquinome at a dose rate of 1 mg/kg BW/day was efficacious in achieving clinical cure of acute respiratory tract infections caused by *Streptococcus equi* subpecies *zooepidemicus*. Treatment was administered for 5-10 days, depending on the response to therapy.

The label bears adequate instructions for the use of the product.

## MAKING A SUBMISSION

In accordance with sections 12 and 13 of the Agvet Code, the APVMA invites any person to submit a relevant written submission as to whether cefquinome sulphate should be approved and whether COBACTAN IV should be registered. Submissions regarding the active constituent should relate only to matters that are considered in determining whether the legislative criteria set out in section 14(4) of the Agvet Code have been met. Submissions regarding COBACTAN IV should relate only to matters that are required by the APVMA to be taken into consideration in determining whether the legislative criteria set out in section 14(3)(e) of the Agvet Code have been met. Submissions should state the grounds on which they are based.

Submissions must be received by the APVMA within 28 days of the date of this notice and be directed to the contact listed below. All submissions to the APVMA will be acknowledged in writing via email or by post.

When making a submission please include a:

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

All personal and confidential commercial information (CCI)<sup>1</sup> material contained in submissions will be treated confidentially.

Written submissions should be addressed in writing to:

Enquiries

Registration Management and Evaluation Program

Australian Pesticides and Veterinary Medicines Authority

PO Box 6182

KINGSTON ACT 2604

**Phone:** +61 2 6210 4701

**Fax:** +61 2 6210 4741

**Email:** [enquiries@apvma.gov.au](mailto:enquiries@apvma.gov.au)

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<sup>1</sup> A full definition of 'confidential commercial information' is contained in the [Agvet Code](#).

## Final Pesticide and Veterinary Medicines Product Sales 2013–14 Financial Year

This notice provides the collated final product sales information provided to the APVMA for the 2013–14 financial year.

### AGRICULTURAL (PESTICIDES) PRODUCT SALES FOR THE 13–14 FINANCIAL YEAR

AGRICULTURAL PRODUCT TYPES	NO OF PRODUCTS	TOTAL \$
ADJUVANTS/SURFACTANTS	412	79,287,464.00
ANTIFOULING—BOAT	46	17,286,771.00
DAIRY CLEANSER	138	12,109,122.00
DISINFECTANT/SANITISER	98	9,886,966.00
FUNGICIDE	874	179,959,190.00
GROWTH PROMOTERS/REGULATORS	242	35,056,102.00
HERBICIDE	3083	1,481,453,070.00
HOUSEHOLD INSECTICIDE	615	137,710,684.00
INSECTICIDE	1365	356,580,593.00
MISC(E.G: SEED SAFENERS, MARKERS ETC)	71	4,046,575.00
MITICIDE	122	14,092,315.00
MIXED FUNCTION PESTICIDE	148	26,400,084.00
MOLLUSCICIDE	53	16,587,594.00
NEMATICIDE	20	3,793,442.00
POOL PRODUCTS/ALGICIDE	755	46,784,772.00
REPELLENT—DOGS/BIRDS ETC	24	1,372,179.00
SEED TREATMENTS	172	38,954,418.00
VERTEBRATE POISON	206	19,041,783.00
WOOD PRESERVATIVE	120	53,186,664.00
<b>Grand Total</b>	<b>8564</b>	<b>2,533,589,788.00</b>

**VETERINARY MEDICINES PRODUCT SALES FOR THE 13-14 FINANCIAL YEAR**

<b>VETERINARY PRODUCT TYPES</b>		<b>NO OF PRODUCTS</b>	<b>TOTAL \$</b>
ALIMENTARY SYSTEM	ANTI BLOAT	16	1,294,072.00
ALIMENTARY SYSTEM	ANTIDIARRHOEALS AND SCOUR TREATMENTS	17	975,211.00
ALIMENTARY SYSTEM	LAXATIVES, PURGATIVES & LUBRICANTS, ANTISPASMODICS	14	2,036,032.00
ANAESTHETICS/ANALGESICS	ANAESTHETICS—LOCAL AND GENERAL	56	10,895,329.00
ANAESTHETICS/ANALGESICS	ANALGESICS	20	5,444,651.00
ANTIBIOTIC & RELATED	ANTIBIOTIC—INTRAMAMMARY	27	10,846,550.00
ANTIBIOTIC & RELATED	ANTIBIOTIC—ORAL	188	24,601,812.00
ANTIBIOTIC & RELATED	ANTIBIOTIC—PARENTERAL	80	22,305,846.00
ANTIBIOTIC & RELATED	OTHER ANTI-INFECTION AGENTS	46	1,599,585.00
ANTIBIOTIC & RELATED	SULFONAMIDES	41	2,892,699.00
ANTIDOTES	ANTIDOTES	16	1,332,001.00
CARDIOVASCULAR SYSTEM	CARDIAC REACTANTS, CLOTTING AGENTS	40	7,794,048.00
CENTRAL NERVOUS SYSTEM	HYPNOTICS, TRANQUILIZERS, EMETICS, ANTIEMETICS	42	4,075,308.00
DERMATOLOGICAL PREPS.	ANTIBIOTICS, ANTIFUNGALS, CORTICOSTEROID COMBINATIONS	30	2,354,032.00
DERMATOLOGICAL PREPS.	ANTISEPTICS (DERMATOLOGICAL AND GENERAL)	145	23,514,362.00
DERMATOLOGICAL PREPS.	NONSTEROIDAL ANTIPRURITICS, KERATOLYICS	35	5,314,490.00
EAR,NOSE,THROAT PREPS.	AURAL	27	5,792,259.00
ENDOCRINE SYSTEM	ANABOLIC STEROIDS	21	355,491.00
ENDOCRINE SYSTEM	CORTICOSTEROIDS AND ADRENAL COMPOUNDS	33	2,987,491.00
ENDOCRINE SYSTEM	SEX HORMONES	55	8,243,596.00
ENDOCRINE SYSTEM	TROPIC HORMONES (PITUITARY) & INSULIN PREPARATIONS	35	6,091,283.00
GENITOURINARY SYSTEM	DIURETICS, ACIDIFIERS, ALKALISERS	26	1,674,454.00

VETERINARY PRODUCT TYPES		NO OF PRODUCTS	TOTAL \$
GENITOURINARY SYSTEM	UTERINE OR VAGINAL ACTING AGENTS	7	1,028,650.00
IMMUNOTHERAPY	ANTISERA, ANTIVENIM	11	3,272,303.00
IMMUNOTHERAPY	IMMUNOMODIFYING AGENTS	12	3,665,290.00
IMMUNOTHERAPY	INJECTABLE VACCINES	175	133,591,033.00
IMMUNOTHERAPY	NASAL, ORAL, OPHTHALMIC VACCINES	33	27,820,596.00
MISC	MISC	85	21,098,715.00
MUSCULOSKELETAL SYSTEM	ANTI-INFLAMMATORY AGENTS	229	32,842,590.00
MUSCULOSKELETAL SYSTEM	COUNTER-IRRITANTS, RUBEFACIENTS, POULTICES	16	2,429,271.00
NUTRITION & METABOLISM	ANTIBIOTIC AND ANTI-INFECTIVE SUPPLEMENTS	48	3,899,091.00
NUTRITION & METABOLISM	DIETARY/THERAPEUTIC PET FOODS	148	58,060,774.00
NUTRITION & METABOLISM	DIGESTIVE ENZYME SUPPLEMENTS	80	17,674,222.00
NUTRITION & METABOLISM	ELECTROLYTES	70	4,319,291.00
NUTRITION & METABOLISM	GROWTH PROMOTANTS	69	25,516,782.00
NUTRITION & METABOLISM	IRON AND HAEMOPOIETIC AGENTS	21	1,665,227.00
NUTRITION & METABOLISM	PROBIOTIC AND PREBIOTIC	22	1,305,669.00
NUTRITION & METABOLISM	TONICS, STIMULANTS	13	618,985.00
NUTRITION & METABOLISM	VITAMIN, MINERAL, & NUTRITIONAL SUPPLEMENTS	228	26,889,524.00
OPHTHALMIC PREPARATIONS	OPHTHALMIC PREPARATIONS	22	4,960,016.00
PARASITICIDES	BIRDS—EXTERNAL	12	321,463.00
PARASITICIDES	BIRDS—INTERNAL	31	2,627,200.00
PARASITICIDES	LARGE & SMALL ANIMALS— EXTERNAL	18	1,840,150.00
PARASITICIDES	LARGE ANIMALS—EXTERNAL	187	70,093,759.00
PARASITICIDES	LARGE ANIMALS—INTERNAL	294	51,917,861.00
PARASITICIDES	LARGE ANIMALS—INTERNAL & EXTERNAL	86	55,503,289.00
PARASITICIDES	SMALL ANIMALS—EXTERNAL	203	92,836,797.00
PARASITICIDES	SMALL ANIMALS—INTERNAL	250	79,898,001.00

<b>VETERINARY PRODUCT TYPES</b>		<b>NO OF PRODUCTS</b>	<b>TOTAL \$</b>
PARASITICIDES	SMALL ANIMALS INTERNAL AND EXTERNAL	28	54,766,076.00
RESPIRATORY SYSTEM	EXPECTORANTS, MUCOLYTICS, DECONGESTANTS, BRONCHODILATORS, RESP STIMULANTS	22	1,216,145.00
<b>GRAND TOTAL</b>		<b>3430</b>	<b>934,099,372.00</b>

#### **APVMA CONTACT**

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