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of Australia**

Gazette

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**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/news-and-publications/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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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 NEW ACTIVE CONSTITUENTS

Application no.:	60590
Product name:	Aviator Xpro Foliar Fungicide
Active constituent/s:	75 g/L bixafen, 150 g/L prothioconazole
Applicant name:	Bayer Cropsience Pty Ltd
Applicant ACN:	000 226 022
Summary of use	For the control of blackleg in canola
Date of registration/approval:	29 June 2016
Product registration no.:	69361
Label approval no.:	69361/60590

2. AGRICULTURAL PRODUCTS BASED ON EXISTING ACTIVE CONSTITUENTS

Application no.:	105772
Product name:	Brandt Adjust 700 Surfactant
Active constituent/s:	350 g/L soyal phospholipids 350 g/L propionic acid
Applicant name:	Brandt Consolidated Inc
Applicant ACN:	N/A
Summary of use	For acidifying and penetrating surfactant, reducing alkaline hydrolysis of dimethoate, assisting with uptake of foliar fertilisers and assisting in management of spray droplet size
Date of registration/approval:	16 June 2016
Product registration no.:	82443
Label approval no.:	82443/105772

Application no.:	104791
Product name:	CGS Prep 720 Growth Regulator
Active constituent/s:	720 g/L ethephon (an anticholinesterase compound)
Applicant name:	Cotton Growers Services Pty Ltd
Applicant ACN:	001 723 048
Summary of use	For accelerated boll opening and pre-conditioning before defoliation of cotton
Date of registration/approval:	20 June 2016
Product registration no.:	82011
Label approval no.:	82011/104791

Application no.:	105048
Product name:	Adama MCPA 750 SL Herbicide
Active constituent/s:	750 g/L MCPA present as the dimethylamine salt
Applicant name:	Adama Australia Pty Limited
Applicant ACN:	050 328 973
Summary of use	For the control of broadleaf weeds in cereals, linseed, pastures, rice, sugar cane and turf
Date of registration/approval:	20 June 2016
Product registration no.:	82118
Label approval no.:	82118/105048
Application no.:	105707

Product name:	Relyon Caboose 500SC Fungicide
Active constituent/s:	500 g/L carbendazim
Applicant name:	Ruralco Holdings Limited
Applicant ACN:	009 660 879
Summary of use	For the control of fungal diseases in various crops
Date of registration/approval:	21 June 2016
Product registration no.:	82417
Label approval no.:	82417/105707
Application no.:	106140
Product name:	Double Alpha Isoxaflutole 750 WG Herbicide
Active constituent/s:	750 g/kg isoxaflutole
Applicant name:	Alpha Crop Protection Pty Ltd
Applicant ACN:	165 653 047
Summary of use	For the control and suppression of various broadleaf weeds and grasses in sugarcane and chickpeas
Date of registration/approval:	21 June 2016
Product registration no.:	82590
Label approval no.:	82590/106140
Application no.:	105606
Product name:	Titan Imazapic 240 Herbicide
Active constituent/s:	240 g/L imazapic present as the ammonium salt
Applicant name:	Titan AG Pty Ltd
Applicant ACN:	122 081 574
Summary of use	For the pre-emergence control of certain annual grass and broadleaf weeds in fallow situations, sugarcane and peanuts and early post-emergence control of certain annual grass and broadleaf weed in peanuts and sugarcane
Date of registration/approval:	21 June 2016
Product registration no.:	82379
Label approval no.:	82379/105606
Application no.:	102875
Product name:	Biofilm Termite Barrier Systems
Active constituent/s:	1 g/kg bifenthrin
Applicant name:	The Trustee for Termicide Pest Control Trust
Applicant ACN:	N/A
Summary of use	For the protection of structures from concealed termite entry
Date of registration/approval:	22 June 2016
Product registration no.:	81353
Label approval no.:	81353/102875
Application no.:	102902
Product name:	Hy-Clor We Make Water Fun! Li'l Pools Mini Tablets For Small Pools
Active constituent/s:	900 g/kg available chlorine (Cl) present as trichloroisocyanuric acid
Applicant name:	Hy-Clor (Australia) Pty Ltd
Applicant ACN:	000 655 381
Summary of use	For control of bacteria, viruses and algae in swimming pools
Date of registration/approval:	22 June 2016
Product registration no.:	81362
Label approval no.:	81362/102902

Application no.:	58104
Product name:	Kendon Carbaryl Wettable Granule Insecticide
Active constituent/s:	800 g/kg carbaryl (an anti-cholinesterase compound)
Applicant name:	Kendon Plant Care Pty Ltd
Applicant ACN:	065 737 948
Summary of use	For the control of certain insects in fruit and vegetables crops and for certain other uses as specified
Date of registration/approval:	24 June 2016
Product registration no.:	68322
Label approval no.:	68322/58104

Application no.:	106142
Product name:	Double Alpha MCPA 500 Selective Herbicide
Active constituent/s:	500 g/L MCPA present as the dimethylamine salt
Applicant name:	Alpha Crop Protection Pty Ltd
Applicant ACN:	165 653 047
Summary of use	For selective control of broadleaf weeds in cereals, field peas, linseed, pastures, sugarcane and turf
Date of registration/approval:	24 June 2016
Product registration no.:	82592
Label approval no.:	82592/106142

Application no.:	106290
Product name:	Atlas Outdoor Fogger
Active constituent/s:	1.1 g/kg esbiothrin, 0.5 g/kg permethrin
Applicant name:	Pascoe's Pty Ltd
Applicant ACN:	055 220 463
Summary of use	For the control of certain insects around the home and garden
Date of registration/approval:	24 June 2016
Product registration no.:	82630
Label approval no.:	82630/106290

Application no.:	105281
Product name:	WeedPro 360 BIO Herbicide
Active constituent/s:	360 g/L glyphosate present as the isopropylamine salt
Applicant name:	PCT Holdings Pty Ltd
Applicant ACN:	099 023 962
Summary of use	For the control of a range of annual, perennial and aquatic weeds
Date of registration/approval:	24 June 2016
Product registration no.:	82251
Label approval no.:	82251/105281

Application no.:	104562
Product name:	AQ 200 Aquatic Herbicide
Active constituent/s:	200 g/L diquat present as diquat dibromide monohydrate
Applicant name:	Aquatic Site Maintenance Pty Ltd
Applicant ACN:	105 824 164
Summary of use	For the control of a range of broadleaf weeds in aquatic areas
Date of registration/approval:	27 June 2016
Product registration no.:	81984
Label approval no.:	81984/104562

Application no.:	105054
Product name:	Enforcer 242 Herbicide
Active constituent/s:	420 g/L MCPA present as the potassium salt, 26 g/L picloram present as the potassium salt
Applicant name:	Adama Australia Pty Limited
Applicant ACN:	050 328 973
Summary of use	For the control of climbing buckwheat, common sowthistle, skeleton weed, capeweed, doublegee and other broadleaf weeds in winter cereals and linseed crops
Date of registration/approval:	27 June 2016
Product registration no.:	82122
Label approval no.:	82122/105054

Application no.:	104026
Product name:	Brunnings Trade Ready to Use Weed Kill
Active constituent/s:	7.2 g/L glyphosate present as the isopropylamine salt
Applicant name:	Brunnings Garden Products Pty Ltd
Applicant ACN:	050 655 760
Summary of use	For the control of weeds in the home garden
Date of registration/approval:	27 June 2016
Product registration no.:	81772
Label approval no.:	81772/104026

Application no.:	104036
Product name:	Conquest Amine 700 Dual Salt Selective Herbicide
Active constituent/s:	700 g/L 2,4-d present as dimethylamine and diethanolamine salts
Applicant name:	Conquest Crop Protection Pty Ltd
Applicant ACN:	098 814 932
Summary of use	For the control of broadleaf weeds in fallow before direct drilling or sowing of cereals and pastures; and in cereal crops, pastures, sugar cane, peanuts and non-agricultural areas as per the directions for use
Date of registration/approval:	27 June 2016
Product registration no.:	81776
Label approval no.:	81776/104036

Application no.:	103821
Product name:	Smart Maxx 540 Herbicide
Active constituent/s:	540 g/L glyphosate (present as the monoethanolamine salt)
Applicant name:	Crop Smart Pty Ltd
Applicant ACN:	093 927 961
Summary of use	For the control of most emerged weeds and plants in situations
Date of registration/approval:	28 June 2016
Product registration no.:	81719
Label approval no.:	81919/103821

Application no.:	106370
Product name:	Avobalance Plant Growth Regulator
Active constituent/s:	250 g/L paclobutrazol
Applicant name:	Rotam Agrochemical Co., Ltd
Applicant ACN:	N/A
Summary of use	For reduction of vegetative growth in mango, stone fruit and apple trees
Date of registration/approval:	29 June 2016
Product registration no.:	82649
Label approval no.:	82649/106370

Application no.:	105583
Product name:	Gardenline Extra Strength Weed & Feed For Lawns
Active constituent/s:	3.5 g/L dicamba present as dimethylamine salt, 23 g/L MCPA present as the dimethylamine salt
Applicant name:	Brunnings Garden Products Pty Ltd
Applicant ACN:	050 655 760
Summary of use	For the control of broadleaf weeds in wheat, oats, barley, cereal rye, triticale, linseed, grass pastures and turf
Date of registration/approval:	29 June 2016
Product registration no.:	82369
Label approval no.:	82369/105583
Application no.:	106378
Product name:	Atlas Rose Spray
Active constituent/s:	0.1 g/L tau-fluvalinate, 0.05 g/L muclobutanil
Applicant name:	Pascoe's Pty Ltd
Applicant ACN:	055 220 463
Summary of use	For the control of various insects and fungal diseases on roses and ornamentals. Systemic control of black spot, powdery mildew and rust. Kills aphids, thrips, caterpillars, budworm and mites on roses and ornamentals. Works via contact and stomach action
Date of registration/approval:	29 June 2016
Product registration no.:	82657
Label approval no.:	82657/106378
Application no.:	104370
Product name:	eChem Ethephon 900 Growth Regulator
Active constituent/s:	900 g/L ethephon (an anti-cholinesterase compound)
Applicant name:	eChem (Aust) Pty Limited
Applicant ACN:	089 133 095
Summary of use	For crop thinning, loosening or ripening in various crops and for accelerating boll opening, defoliation and pre-conditioning before defoliation of cotton
Date of registration/approval:	29 June 2016
Product registration no.:	81899
Label approval no.:	81899/104370
Application no.:	106128
Product name:	Genfarm Tebuthiuron 200 Herbicide
Active constituent/s:	200 g/kg tebuthiuron
Applicant name:	Landmark Operations Limited
Applicant ACN:	008 743 217
Summary of use	For control of brigalow regrowth, tea tree regrowth, mimoa pigra and certain problem wood weeds on grazing lands
Date of registration/approval:	29 June 2016
Product registration no.:	82582
Label approval no.:	82582/106128
Application no.:	106388
Product name:	Atlas Garden Insect Spray
Active constituent/s:	0.125 g/L imidacloprid
Applicant name:	Pascoe's Pty Ltd
Applicant ACN:	055 220 463
Summary of use	For the systemic control of various insect pests around the home garden
Date of registration/approval:	30 June 2016
Product registration no.:	82664
Label approval no.:	82664/106388

Application no.:	101730
Product name:	Melpat Dinon 700 WG Fungicide
Active constituent/s:	700 g/kg dithianon
Applicant name:	Melpat International Pty Ltd
Applicant ACN:	066 067 507
Summary of use	For the control a range of diseases in pome fruit, stone fruit and grapevines
Date of registration/approval:	30 June 2016
Product registration no.:	80823
Label approval no.:	80823/101730
Application no.:	106377
Product name:	Atlas White Spray Oil
Active constituent/s:	19.46 g/L paraffin oil
Applicant name:	Pascoe's Pty Ltd
Applicant ACN:	055 220 463
Summary of use	For control of various scales, mites, mealy bugs, leafminers, whiteflies and aphids
Date of registration/approval:	30 June 2016
Product registration no.:	82656
Label approval no.:	82656/106377
Application no.:	106512
Product name:	Sundew BattleaxePRO Roach Bait
Active constituent/s:	0.5 g/kg fipronil
Applicant name:	Sundew Solutions Pty Ltd
Applicant ACN:	135 400 261
Summary of use	For the control of cockroaches
Date of registration/approval:	30 June 2016
Product registration no.:	82708
Label approval no.:	82708/106512

3. VARIATIONS OF REGISTRATION

Application no:	106245
Product name:	Ptsan 5 Sanitiser
Active constituent/s:	250 g/L hydrogen peroxide, 50 g/L peroxyacetic acid
Applicant name:	AJL8 Enterprises Pty Ltd
Applicant ACN:	150 377 683
Summary of variation:	To change the distinguishing product name and the name that appears on the label from 'PERATEC 5 SANITISER' to 'PTSAN 5 SANITISER'
Date of variation:	8 April 2016
Product registration no.:	48906
Label approval no.:	48906/106245

Application no:	105860
Product name:	Macro Protect Cleth 240 Herbicide
Active constituent/s:	240 g/L clethodim
Applicant name:	Macrofertil Australia Pty Ltd
Applicant ACN:	166 370 976
Summary of variation:	To change the distinguishing product name and the name that appears on the label from 'RAVENSDOWN BLADE 240EC HERBICIDE' to 'MACRO PROTECT CLETH 240 HERBICIDE'
Date of variation:	3 March 2016
Product registration no.:	60717
Label approval no.:	60717/105860
Application no.:	101326
Product name:	Fyfanon 440 EW Insecticide
Active constituent/s:	440 g/L maldison (an anticholinesterase compound)
Applicant name:	Cheminova Australia Pty Limited
Applicant ACN:	110 199 169
Summary of variation:	To modify uses for fruit fly
Date of variation:	21 June 2016
Label approval no.:	51150/101326
Application no:	103561
Product name:	Melpat Tribasic Liquid Flowable Copper Fungicide
Active constituent/s:	190 g/L copper (CU) present as tribasic copper sulphate
Applicant name:	Melpat International Pty Ltd
Applicant ACN:	066 067 507
Summary of variation:	To extend the uses into hazelnuts, pistachios and macadamias
Date of variation:	22 June 2016
Product registration no.:	67618
Label approval no.:	67618/103561
Application no.:	103780
Product name:	Campbell Stanza WP Fungicide
Active constituent/s:	462 g/kg prochloraz present as the manganese chloride complex
Applicant name:	Colin Campbell (Chemicals) Pty Ltd
Applicant ACN:	000 045 590
Summary of variation:	To extend the use to control colletotrichum crown rot, stolon rot in non-fruited strawberry runners
Date of variation:	22 June 2016
Label approval no.:	69707/103780
Application no:	106020
Product name:	Crop Care Barrack 720 Fungicide
Active constituent/s:	720 g/L chlorothalonil
Applicant name:	Crop Care Australasia Pty Ltd
Applicant ACN:	061 362 347
Summary of variation:	To add additional pack sizes
Date of variation:	29 June 2016
Product registration no.:	53884
Label approval no.:	53884/106020

Application no.:	106072
Product name:	Bollgard 3
Active constituent/s:	<i>Bacillus thuringiensis subsp. kurstaki delta</i> endotoxins as produced by the Cry1Ac and Cry2Ab genes and their controlling sequences. <i>Bacillus thuringiensis</i> strain AB88 exotoxin as produced by the Vip3A(a) gene and its controlling sequence
Applicant name:	Monsanto Australia Ltd
Applicant ACN:	006 725 560
Summary of use	To change the name of the product from 'BOLLGARD III' to 'BOLLGARD 3', to extend use to Victoria, and to amend the planting window
Date of registration/approval:	29 June 2016
Product registration no.:	69656
Label approval no.:	69656/106072
Application no:	105301
Product name:	Triclops Herbicide
Active constituent/s:	600 g/L triclopyr present as the butoxyethyl ester
Applicant name:	Crop Culture Pty Ltd
Applicant ACN:	142 860 473
Summary of variation:	To change the product name from 'CROP CULTURE TRICLOPS HERBICIDE' to 'TRICLOPS HERBICIDE', add an additional 10 L pack size and add uses
Date of variation:	1 July 2016
Product registration no.:	67456
Label approval no.:	67456/105301

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

Application no.:	51312
Product name:	Apiguard Gel for Beehives
Active constituent/s:	250 g/kg thymol
Applicant name:	Vita (Europe) Limited
Applicant ACN:	N/A
Summary of use	For use in beehives to control the parasitic mite, <i>Varroa destructor</i> , on honey bees. This product must only be supplied in the event the Chief Plant Protection Officer of the Commonwealth declares an outbreak of varroa mite (<i>Varroa destructor</i>) in accordance with the Emergency Plant Pest Response Deed. This product must only be used by persons authorised by the Chief Plant Protection Officer of the Commonwealth in accordance with the Emergency Plant Pest Response Deed in the event of a declared outbreak of varroa mite (<i>Varroa destructor</i>)
Date of registration/approval:	29 June 2016
Product registration no.:	65570
Label approval no.:	65570/51312

Application no.:	61891
Product name:	READYSERVE Altrenogest Injection for Horses
Active constituent/s:	50 mg/mL altrenogest
Applicant name:	Ceva Animal Health Pty Ltd
Applicant ACN:	002 692 426
Summary of use	For the suppression of oestrus in normally cycling mares
Date of registration/approval:	30 June 2016
Product registration no.:	69854
Label approval no.:	69854/61891

2. VARIATIONS OF REGISTRATION

Application no:	106959
Product name:	Bexepiril Flavoured 20 mg Tablets For Dogs
Active constituent/s:	Each tablet contains 20 mg benazepril hydrochloride
Applicant name:	Zoetis Australia Pty Ltd
Applicant ACN:	156 476 425
Summary of variation:	To change the distinguishing product name and the name that appears on the label from 'FORTERIL FLAVOURED 20MG TABLETS FOR DOGS' to 'BEXEPRIL FLAVOURED 20MG TABLETS FOR DOGS'
Date of variation:	8 June 2016
Product registration no.:	69454
Label approval no.:	69454/106959

Application no:	106958
Product name:	Bexepiril Flavoured 5 mg Tablets For Dogs
Active constituent/s:	Each tablet contains 5 mg benazepril hydrochloride
Applicant name:	Zoetis Australia Pty Ltd
Applicant ACN:	156 476 425
Summary of variation:	To change the distinguishing product name and the name that appears on the label from 'FORTERIL FLAVOURED 5MG TABLETS FOR DOGS AND CATS' to 'BEXEPRIL FLAVOURED 5MG TABLETS FOR DOGS'
Date of variation:	8 June 2016
Product registration no.:	69456
Label approval no.:	69456/106958
Application no:	106960
Product name:	Bexepiril Flavoured 2.5 mg Tablets For Dogs
Active constituent/s:	Each tablet contains 2.5 mg benazepril hydrochloride
Applicant name:	Zoetis Australia Pty Ltd
Applicant ACN:	156 476 425
Summary of variation:	To change the distinguishing product name and the name that appears on the label from 'FORTERIL FLAVOURED 2.5MG TABLETS FOR DOGS' to 'BEXEPRIL FLAVOURED 2.5MG TABLETS FOR DOGS'
Date of variation:	8 June 2016
Product registration no.:	69455
Label approval no.:	69455/106960
Application no:	106963
Product name:	Rheumocam 20 mg/mL Injection for Horses
Active constituent/s:	meloxicam 20 mg/mL
Applicant name:	Zoetis Australia Pty Ltd
Applicant ACN:	156 476 425
Summary of variation:	To change the distinguishing product name and the name that appears on the label from 'M-ELOXYN 20 MG/ML INJECTION FOR HORSES' to 'RHEUMOCAM 20 MG/ML INJECTION FOR HORSES'
Date of variation:	8 June 2016
Product registration no.:	69089
Label approval no.:	69089/106963
Application no:	106964
Product name:	Rheumocam 20 mg/mL Solution for Injection
Active constituent/s:	meloxicam 20 mg/mL
Applicant name:	Zoetis Australia Pty Ltd
Applicant ACN:	156 476 425
Summary of variation:	To change the distinguishing product name and the name that appears on the label from 'M-ELOXYN 20 MG/ML SOLUTION FOR INJECTION' to 'RHEUMOCAM 20 MG/ML SOLUTION FOR INJECTION'
Date of variation:	8 June 2016
Product registration no.:	67935
Label approval no.:	67935/106964

Application no:	106965
Product name:	Rumifert Mineral Bolus For Cattle
Active constituent/s:	Each bolus contains 13,400 mg copper, 500 mg cobalt, 300 mg selenium
Applicant name:	Bimeda (Australia) Pty Limited
Applicant ACN:	058 196 508
Summary of variation:	To change the distinguishing product name and the name that appears on the label from 'COSECURE NUTRITIONAL SUPPLEMENT FOR CATTLE' to 'RUMIFERT MINERAL BOLUS FOR CATTLE'
Date of variation:	8 June 2016
Product registration no.:	48197
Label approval no.:	48197/106965
Application no.:	100910
Product name:	Avenge Pour-On Lousicide for Sheep
Active constituent/s:	35 g/L imidacloprid
Applicant name:	Bayer Australia Ltd (Animal Health)
Applicant ACN:	000 138 714
Summary of variation:	To add use in prevention of blow fly (<i>Lucilia cuprina</i>) strike up to 10 weeks
Date of variation:	24 June 2016
Product registration no.:	62598
Label approval no.:	62598/100910
Application no.:	101478
Product name:	Improvest for Male Pigs
Active constituent/s:	Each 2 mL dose provides minimum 300 µg/2 mL GnRF-protein conjugate
Applicant name:	Zoetis Australia Pty Ltd
Applicant ACN:	156 476 425
Summary of variation:	To reduce the in-use shelf life from 30 to 28 days and reduce the shelf life to 24 months
Date of variation:	30 June 2016
Product registration no.:	70058
Label approval no.:	70058/101478

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

Application no.:	104475
Active constituent/s:	Fluquinconazole
Applicant name:	4 Farmers Australia Pty Ltd
Applicant ACN:	160 092 428
Summary of use:	For use in agricultural chemical products
Date of approval:	24 June 2016
Approval no.:	81952

Application no.:	60592
Active constituent/s:	Bixafen
Applicant name:	Bayer Cropscience Pty Ltd
Applicant ACN:	000 226 022
Summary of use:	For use in agricultural chemical products
Date of approval:	28 June 2016
Approval no.:	69362

Application no.:	104151
Active constituent/s:	Metalaxyl
Applicant name:	Industrias Quimicas Del Valles, S.A
Applicant ACN:	N/A
Summary of use:	For use in agricultural chemical products
Date of approval:	29 June 2016
Approval no.:	81846

Application no.:	103199
Active constituent/s:	Dodine
Applicant name:	AgriNova New Zealand Limited T/A Gro-Chem
Applicant ACN:	N/A
Summary of use:	For use in agricultural chemical products
Date of approval:	30 June 2016
Approval no.:	81484

Application no.:	104448
Active constituent/s:	Dicamba
Applicant name:	Syngenta Australia Pty Ltd
Applicant ACN:	002 933 717
Summary of use:	For use in agricultural chemical products
Date of approval:	1 July 2016
Approval no.:	81932

Cancellation of Registration and Approval at the Request of the Holder

At the request of the holder, the APVMA has cancelled the registration and the associated label approvals of the following products:

Product no.	Product name	Approval holder	Date of effect
59355	RUMI-BUFF NATURAL RUMINANT BUFFER BASED ON CALCIFIED SEAWEED	RABAR PTY LTD	27 June 2016
59362	TYLOPHARM SOLUBLE TYLOSIN TARTRATE SOLUBLE POWDER	ABBEY LABORATORIES PTY LTD	27 June 2016
69741	ABATAK LV LOW VOLUME ABAMECTIN BROAD SPECTRUM ANTIPARASITIC FOR SHEEP AND LAMBS	ABBEY LABORATORIES PTY LTD	27 June 2016
68716	FLOW SURE ELECTROLYTE HARTMANN'S SOLUTION	ABBEY LABORATORIES PTY LTD	27 June 2016
68717	FLOW SURE CAL MILK FEVER INJECTION	ABBEY LABORATORIES PTY LTD	27 June 2016
68718	FLOW SURE 0.9% SODIUM CHLORIDE INTRAVENOUS INFUSION BP	ABBEY LABORATORIES PTY LTD	27 June 2016
68719	FLOW SURE 4 IN 1 BALANCED MINERAL INJECTION	ABBEY LABORATORIES PTY LTD	27 June 2016
55262	TIAMUPHARM SOLUBLE POWDER	ABBEY LABORATORIES PTY LTD	27 June 2016
66147	ICS BUFFERING ADJUVANT	INNOVATIVE CHEMICAL SERVICES PTY LTD	27 June 2016
66148	ICS HYBRID SPRAY ADJUVANT	INNOVATIVE CHEMICAL SERVICES PTY LTD	27 June 2016
66149	ICS ESTERIFIED SEED OIL SPRAY ADJUVANT	INNOVATIVE CHEMICAL SERVICES PTY LTD	27 June 2016
66150	ICS-GA GROWTH REGULATOR	INNOVATIVE CHEMICAL SERVICES PTY LTD	27 June 2016
48838	COXISTAC BROAD SPECTRUM COCCIDIOCIDAL FEED ADDITIVE PREMIX	PHIBRO ANIMAL HEALTH PTY LIMITED	27 June 2016
50996	POSISTAC 450 GROWTH PROMOTANT AND ANTICOCCIDIAL FEED PREMIX	PHIBRO ANIMAL HEALTH PTY LIMITED	27 June 2016
50235	POSISTAC 60 GROWTH PROMOTANT AND ANTICOCCIDIAL FEED PREMIX	PHIBRO ANIMAL HEALTH PTY LIMITED	27 June 2016

The following instructions set out how a person can deal with the cancelled products.

SUPPLY

A person may supply or cause to be supplied products manufactured prior to 27 June 2016 at wholesale and retail level, until the 27 June 2017.

After 27 June 2017 it will be an offence against the Agvet Codes to have possession or custody of the products with the intention to supply, or to supply the products.

USE

A person may continue to use the products according to its label instructions until 27 June 2017.

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 products after the registration has been cancelled until 27 June 2017.

The supply and use of the products 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 products 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 Approval at the Request of the Holder

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

Product no.	Product name	Holder	Cancelled Label Approvals	Date of effect
46534	REGLONE NON-RESIDUAL HERBICIDE	SYNGENTA AUSTRALIA PTY LTD	46534/103283	27 June 2016

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

SUPPLY

A person may supply or cause to be supplied product bearing a cancelled label manufactured prior to 27 June 2016 at wholesale and retail level, until 27 June 2017.

After 27 June 2017 it will be an offence against the Agvet Codes to have possession or custody of the product bearing a cancelled label with the intention to supply, or to supply the product bearing a cancelled label.

USE

A person may continue to use the product bearing a cancelled label according to its label instructions until 27 June 2017.

Any person who possesses, has custody of, uses, or otherwise deals with the listed product bearing a cancelled label 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 a cancelled label after the approval has been cancelled until 27 June 2017.

The supply and use of the product bearing a 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 a 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

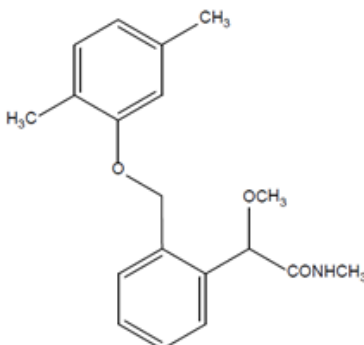
New Agricultural Active Constituent Mandestrobin

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application for the approval of a new active constituent, mandestrobin.

Mandestrobin is a white, crystalline powdery solid (98.8%) with no odour, a melting point of 102°C and a boiling point of 296°C. Its solubility in water is 15.8 mg/L at 20°C.

Common Name:	Mandestrobin
IUPAC Name:	(RS)-2-Methoxy-N-methyl-2-[α -(2,5-xilyloxy)-o-tolyl] acetamide.
CAS Name:	2-[(2,5-dimethylphenoxy)methyl]- α -methoxy-N-methylbenzene acetamide.
CAS Registry Number:	173662-97-0
Manufacturer's Codes:	S-2200
Minimum Purity:	940 g/kg
Molecular Formula:	C ₁₉ H ₂₃ NO ₃
Molecular Weight:	313.39

Structure:



Chemical Family: Strobilurin fungicides

Mode of Action: Mandestrobin inhibits mitochondrial fungal respiration by binding to the Qo1-centre site on cytochrome b. This inhibits electron transfer between cytochrome b1 and cytochrome c1. The inhibition then disrupts the energy cycle within the fungus by halting the production of ATP. As S-2200 is a racemic mixture of two stereoisomers (S-isomer and R-isomer) it is demonstrated that only the R-isomer has fungicidal activity.

SUMMARY OF THE APVMA'S EVALUATION OF MANDESTROBIN ACTIVE CONSTITUENT

The APVMA has evaluated the chemistry aspects of mandestrobin active constituent (manufacturing process, quality control procedures, batch analysis results and analytical methods) and found them to be acceptable.

On the basis of the data provided, and the toxicological assessment, it is proposed that the following APVMA Active Constituent Standard be established for mandestrobin active constituent:

Constituent	Specification	Level
Mandestrobin	Mandestrobin	940 g/kg minimum

Other compounds of toxicological significance are not expected to occur in mandestrobin TGAC.

The Office of Chemical Safety (OCS) has completed a toxicological evaluation of mandestrobin.

The Acceptable Daily Intake for mandestrobin was established at 0.19 mg/kg bw/d using the NOEL of 19.2 mg/kg bw/d from a 52 week dietary study in dogs and applying a 100-fold safety factor, based on dark liver, centrilobular hepatocyte hypertrophy and pigmented hepatocytes in both sexes at doses of 92.0 mg/kg/d.

An acute reference dose was not established for mandestrobin, as it was not considered likely to present an acute hazard to humans.

Based on the toxicity profile of the active constituent and the product, the Delegate of the Secretary of the Department of Health made a Delegate-only decision, listing mandestrobin in Schedule 5 of the SUSMP with an exemption cut-off for preparations containing 25 per cent or less of mandestrobin.

The OCS has indicated that there are no objections on toxicological grounds to the approval of the active constituent mandestrobin.

The APVMA accepts the findings and recommendations of its advisers on these criteria.

The APVMA is satisfied that the proposed importation and use of mandestrobin would not be an undue toxicological hazard to the safety of people exposed to it during its handling and use.

MAKING A SUBMISSION

In accordance with sections 12 of the Agvet Code, the APVMA invites any person to submit a relevant written submission as to whether the application for approval of Mandestrobin should be granted. Submissions should relate only to matters that the APVMA is required by legislation to consider in deciding whether to grant the approval. 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 listed 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:

- 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)*¹ material contained in submissions will be treated confidentially.

Written submissions on the APVMA's proposal to grant approval for mandestrobin that relate to the grounds for approval should be addressed in writing to:

Director Chemistry and Manufacture
Scientific Assessments and Chemical Review Program
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

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

New Agricultural Chemical Product Containing a New Agricultural Active Constituent mandestrobin in Intuity Fungicide

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application from Sumitomo Chemical Australia Pty Limited for registration of a new product Intuity Fungicide containing the new active constituent mandestrobin. The product is proposed to be registered for use on stone fruit.

PARTICULARS OF THE APPLICATION

Proposed product name(s):	INTUITY FUNGICIDE
Applicant company:	Sumitomo Chemical Australia Pty Limited
Name of active constituent:	Mandestrobin
Signal heading:	Not required (unscheduled as the product contains 25% or less mandestrobin)
Summary of proposed use:	For the control of blossom blight and brown rot in stone fruit
Pack sizes:	1 L, 5 L, 10 L and 20 L
Withholding period:	Harvest: Do not harvest fruit for 7 days after application Grazing: Do not allow grazing of inter-rows in stone fruit orchards

SUMMARY OF THE APVMA'S EVALUATION OF INTUITY FUNGICIDE IN ACCORDANCE WITH THE REQUIREMENTS OF SECTION 5A, 5B AND 5C 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 whether the safety criteria have been met in accordance with the definition set out in sections 5A of the Agvet Code, and proposes to determine that:
 - (i) The APVMA is satisfied that the proposed use of INTUITY FUNGICIDE would not be an undue hazard to the safety of people exposed to it during its handling and use.

The absorption, distribution, metabolism and elimination of mandestrobin were investigated in rats. Mandestrobin is rapidly absorbed and then distributed to organs. There was no evidence of accumulation into the tissues. Mandestrobin was extensively metabolised and rapidly excreted, mainly in the faeces via the bile.

Based on the findings of the acute toxicological studies evaluated, mandestrobin is of low acute oral toxicity, low acute dermal toxicity, and low acute inhalational toxicity in rats. Mandestrobin was a moderate eye irritant in rabbits, but was not a skin irritant in rabbits and was non-sensitising in guinea pigs by the guinea pig maximisation test method.

Repeat dose studies with mandestrobin have been conducted in rats, mice and dogs. The common toxicological effects in all species include reductions in body weight/body weight gain, liver enlargement and an increased incidence and severity of histopathological changes in the liver.

Mandestrobin was not genotoxic in several in vitro and in vivo studies. There was no evidence of treatment related carcinogenicity in mice or rats. Reproductive and developmental studies indicated that mandestrobin was not a reproductive or developmental toxicant. There was no evidence of immunotoxicity following 28 days of dietary exposure and overall the weight of evidence indicated that mandestrobin was not neurotoxic.

Based on the findings of the acute toxicological studies evaluated, the product Intuity Fungicide has low acute oral, dermal and inhalational toxicity in rats, is not a skin or eye irritant in rabbits, and is not a skin sensitiser in guinea pig (Buehler method).

Intuity Fungicide will be professionally used for commercial situations, and farmers and their employees will be the main users of the product. Workers may be exposed to the product when opening containers, mixing/loading/application, cleaning up spills, maintaining equipment and entering treated areas. The main routes of exposure to the product will be dermal, inhalational and ocular exposure.

In the absence of exposure data for the proposed mode of application, the Pesticide Handler Exposure Database (PHED) Surrogate Exposure Guide was used to estimate exposure.

Exposure to the product when preparing and using the spray for airblast application was at an acceptable level when a single layer of personal protective equipment (PPE) and gloves are used by workers during mixing/loading and application of the product. Based on the risk assessment, First Aid Instructions and Safety Directions have been recommended for the product label.

Based on an assessment of the toxicology, it was considered that there should be no adverse effects on human health from the use of Intuity Fungicide when used in accordance with the label directions.

The APVMA is satisfied that the proposed use of INTUITY FUNGICIDE containing the active constituent mandestrobin is not likely to be harmful to human beings if used according to the product label directions.

- (ii) The APVMA is satisfied that the proposed use of INTUITY FUNGICIDE will not be an undue hazard to the safety of people using anything containing its residues.

The product will be used as a foliar spray on stone fruit. The APVMA Residues and Trade Section has evaluated the residues aspects of the proposed product and has recommended amendments to the APVMA MRL Standard for mandestrobin. Dietary intake modelling has shown the expected chronic dietary exposures to mandestrobin are below the Acceptable Daily Intake (ADI) level. Recommendations in regard to the withholding period and protection statements for livestock have been included on the label.

The APVMA is satisfied that the proposed use of Intuity Fungicide containing the active constituent mandestrobin is not likely to be harmful to safety of people using anything containing its residues if used according to the product label.

- (iii) The APVMA is satisfied that the proposed use of the new product INTUITY FUNGICIDE containing the active constituent mandestrobin, would not be likely to have an unintended effect that is harmful to animals, plants or things or the environment.

Data provided in support of the proposed use have been assessed and it is concluded that the risks to the environment from this use are acceptable provided that the draft label is updated to meet current spray drift requirements.

Photolysis on soils is unlikely to be a major degradation route. In aerobic soils, the R-isomer degraded more slowly than the S-isomer with geometric mean half-lives (n = 6) of 105 days and 73.4 days respectively. The major soil metabolites identified were not persistent with half-lives in aerobic soil of 41 days or less. Despite individual laboratory soil half-lives up to 322 days, in field dissipation trials mandestrobin dissipated rapidly with half-lives of 8.3 days or less. Residues were primarily restricted to the top 10 cm of soil and no major metabolites (>10%) were identified. In anaerobic soil mandestrobin showed only limited degradation.

Mandestrobin has low to medium mobility in soils. There was no evidence of any pH or percentage of organic carbon dependence. Two metabolites were shown to be more mobile than mandestrobin. In water, mandestrobin is hydrolytically stable in the environmental pH range, however, it may be expected to photodegrade (DT₅₀ <1 week).

When released to water, mandestrobin may be expected to partition to the sediments where degradation is likely to be slow.

Mandestrobin is not expected to bioconcentrate in organisms. Mandestrobin is practically non-toxic to birds through acute oral and short term dietary testing. Mandestrobin is highly toxic to fish, highly toxic to aquatic invertebrates based on testing to the mysid shrimp, and moderately toxic to algae. The major metabolites were all less toxic to aquatic organisms than the parent compound.

Mandestrobin was shown to not be of concern to bees, non-target arthropods, earthworms, soil micro-organisms, and non-target terrestrial plants (subject to appropriate downwind buffer zones).

Based on the tested environmental effects of the active constituents and the end-use product, and its proposed use pattern, the environmental risk was determined to be acceptable. Risk mitigation measures (downwind buffer zones) have been recommended to protect the aquatic environment.

The APVMA is satisfied that the use of Intuity Fungicide would not be likely to have an unintended effect that is harmful to animals, plants or things or the environment

2. The APVMA has evaluated the application and in its assessment in relation to whether the efficacy criteria have been met in accordance with the definition set out in section 5B of the Agvet Code, and proposes to determine that:
 - (i) In relation to its assessment of efficacy under section 5B, the APVMA is satisfied that data from trials supporting the efficacy of the product adequately demonstrate that, if used according to the product label directions, the product is effective for its proposed use in stone fruit for the control of blossom blight and brown rot.
3. The APVMA has evaluated the application and in its assessment in relation to whether the trade criteria have been met in accordance with the definition set out in section 5C of the Agvet Code, and proposes to determine that:
 - (ii) The APVMA is satisfied that the proposed use of INTUITY FUNGICIDE would not adversely affect trade between Australia and places outside Australia as identified risks can be mitigated with sufficient label instructions given stone fruit are the only crop to be approved for use.

Export of treated produce containing finite (measurable) residues of mandestrobin may pose a risk to Australian trade in situations where (i) no residue tolerance (import tolerance) is established in the importing country or (ii) where residues in Australian produce are likely to exceed a residue tolerance (import tolerance) established in the importing country.

Mandestrobin MRLs have not been established by Codex or any other international authority, other than Japan and Canada. Stone fruit is a major export commodity. The proposed use of mandestrobin on stone fruit is expected to result in finite residues. The proposed use of Intuity Fungicide on stone fruit therefore may potentially cause an undue risk to international trade if no mitigation measures are implemented.

The following label advice relating to trade has been proposed:

Treated crops for export to particular destinations outside Australia may require a longer interval before harvest to comply with residues standards of importing countries. Please contact your industry body, exporter or Sumitomo Chemical Australia before using INTUITY FUNGICIDE.

The relevant industry groups should provide comment on the perceived level of risk and whether any industry-initiated strategies are required to manage the risk prior to a recommendation being made on the trade criteria.

FURTHER INFORMATION

A Public Release Summary (PRS) of the evaluation of this product is available from the APVMA website's 'Public Consultation' page or by contacting the APVMA via the details listed below.

MAKING A SUBMISSION

In accordance with section 13 of the Agvet Code, the APVMA invites any person to submit a relevant written submission as to whether INTUITY FUNGICIDE should be registered. Submissions should relate only to matters that the APVMA is required by legislation to take into account in deciding whether to grant the application. These grounds include occupational health and safety, chemistry and manufacture, residues, safety and first aid, environmental fate and toxicity, efficacy or trade. 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 listed below. All submissions to the APVMA will be acknowledged in writing via email or by post.

Relevant comments will be taken into account by the APVMA in deciding whether the product should be registered and in determining appropriate conditions of registration and product labelling.

When making a submission please include:

- 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)² material contained in submissions will be treated confidentially.

Written submissions on the APVMA's proposal to grant the application for registration that relate to the grounds for registration should be addressed in writing to:

Case Management and Evaluation
Registration Management and Evaluation
Australian Pesticides and Veterinary Medicines Authority
PO Box 6182
KINGSTON ACT 2604

Phone: +61 2 6210 4700

Fax: +61 2 6210 4776

Email: enquiries@apvma.gov.au

² A full definition of 'confidential commercial information' is contained in the [Agvet Code](#).

Licensing of Veterinary Chemical Manufacturers

Pursuant to Part 8 of the Agricultural and Veterinary Chemical Codes scheduled to the *Agricultural and Veterinary Chemicals Code Act 1994*, the APVMA hereby gives notice that it has taken action, with respect to the licensing of the following veterinary chemical manufacturers, with effect from the dates shown.

For a comprehensive listing of all licensed manufacturers please see the APVMA's website www.apvma.gov.au.

1. NEW LICENCES

The APVMA has issued the following licences under subsection 123(1) of the Agricultural and Veterinary Chemicals Code [the Agvet Code]

ALPHA CHEMICALS PTY LTD **LICENCE NO:** 2237

ACN: 001 174 741

18 Inman Road

CROMER NSW 2099

Product Types:*

- *Category 2:* Liquids (topical)

Step(s) of Manufacture: Quality assurance (QA) of raw materials, chemical synthesis, formulation including blending, filling, packaging, labelling, analysis and testing (physical and chemical), storage and release for supply

Licence Issued: 6 June 2016

2. CHANGES TO EXISTING LICENCES

The APVMA has issued the following licences under subsection 123(1) of the Agricultural and Veterinary Chemicals Code [the Agvet Code]

LIPA PHARMACEUTICALS **LICENCE NO:** 2140

LTD

ACN: 070 106 526

21 Reaghs Farm Road

MINTO NSW 2566

Product Types: *

- *Category 2:* tablets, capsules, creams and lotions, liquids
- *Category 3:* liquids and powders
- *Category 4:* premixes

Step(s) of Manufacture: Quality assurance (QA) of raw materials, formulation including blending, filling, packaging, labelling, tableting, tablet coating, capsule filling from bulk, analysis and testing (physical, chemical and antibiotic assay), storage and release for supply

Amended Licence Issued: 15 June 2016

* Category 1: *Immunobiologicals and sterile veterinary preparations*
Category 2: *Non-sterile veterinary preparations other than ectoparasiticides, premixes and supplements*
Category 3: *Ectoparasiticides*
Category 4: *Premixes and supplements*
Category 5: *Exempt*
Category 6: *One-step manufacturer*

**THE STATE OF
QUEENSLAND, ACTING
THROUGH THE DEPARTMENT
OF AGRICULTURE AND
FISHERIES**

ABN: 66 934 348 189

Biosecurity Sciences Laboratory
Health and Food Sciences
Precinct
39 Kessels Road
COOPERS PLAINS QLD 4108

LICENCE NO: 6175

Product Types: *

- *Category 6:* Single step manufacture

Step(s) of Manufacture: Analysis and testing (serological, immunological, virological (vaccine potency and purity testing))

Amended Licence Issued: 15 June 2016

**MAVLAB ANIMAL HEALTH
PTY LTD**

ACN: 164 339 637

29–33 Rowland Street
SLACKS CREEK QLD 4127

LICENCE NO: 1104

Product Types: *

- *Category 1:* sterile products
- *Category 2:* tablets, powders, granules, sprays, liquids and gels
- *Category 3:* liquids, sprays and powders
- *Category 4:* premixes and supplements

Step(s) of Manufacture: Quality assurance (QA) of raw materials, formulation including blending, dry milling, filling, packaging, labelling, tableting, aseptic filling, granulation, sterilisation (heat and filtration), wet milling of powders, microbiological reduction treatment (filtration, heat and chemical), analysis and testing (physical), storage and release for supply

Amended Licence Issued: 16 June 2016

**APEX LABORATORIES PTY
LTD**

ACN: 000 397 240

61 Chivers Road
SOMERSBY NSW 2250

LICENCE NO: 2119

Product Types: *

- *Category 2:* Tablets, creams/lotion, ointments, pastes, powders and liquids

Step(s) of Manufacture: Quality assurance (QA) of raw materials, formulation including blending, filling, packaging, labelling, strip, blister or sachet packaging, dry milling, microencapsulation, granulation, tableting, tablet coating, analysis and testing (physical), storage and release for supply

Amended Licence Issued: 17 June 2016

* Category 1: *Immunobiologicals and sterile veterinary preparations*
Category 2: *Non-sterile veterinary preparations other than ectoparasiticides, premixes and supplements*
Category 3: *Ectoparasiticides*
Category 4: *Premixes and supplements*
Category 5: *Exempt*
Category 6: *One-step manufacturer*

**ENSIGN LABORATORIES
PROPRIETARY LIMITED**

ACN: 004 395 242

490–500 Wellington Road

MULGRAVE VIC 3170

LICENCE NO: 2040

Product Types: *

- *Category 2:* sprays, suspensions and liquids
- *Category 3:* liquids and sprays
- *Category 4:* premixes and supplements

Step(s) of Manufacture: Quality assurance (QA) of raw materials, formulation including blending, wet milling, filling, packaging, sachet packaging, labelling, aerosol filling from bulk, analysis and testing (physical, chemical, microbiological and antibiotic assay), storage and release for supply

Amended Licence Issued: 21 June 2016

**TROY LABORATORIES PTY
LTD**

ACN: 000 283 769

31–35 Glendenning Road

GLENDENNING NSW 2761

LICENCE NO: 1092

Product Types: *

- *Category 1:* Sterile products and terminally sterilised ointments
- *Category 2:* Tablets, creams/lotions, ointments, gels, pastes, powders, sprays, granules, suspensions and liquids
- *Category 3:* Liquids and sprays
- *Category 4:* Supplements

Step(s) of Manufacture: Quality assurance (QA) of raw materials, formulation including blending, granulation, dry milling, aseptic filling, filling, packaging, labelling, strip, blister or sachet packaging, tableting, sterilisation (heat and filtration), microbiological reduction treatment (filtration and chemical), analysis and testing (physical and chemical), storage and release for supply

Amended Licence Issued: 23 June 2016

**CURTIN UNIVERSITY OF
TECHNOLOGY**

ABN: 99 143 842 569

School of Pharmacy

Building 306

Curtin University

Kent Street

BENTLEY WA 6102

LICENCE NO: 6144

Product Types: *

- *Category 6:* Single step manufacture

Step(s) of Manufacture: Analysis and testing (physical and chemical)

Amended Licence Issued: 23 June 2016

* Category 1: *Immunobiologicals and sterile veterinary preparations*
Category 2: *Non-sterile veterinary preparations other than ectoparasiticides, premixes and supplements*
Category 3: *Ectoparasiticides*
Category 4: *Premixes and supplements*
Category 5: *Exempt*
Category 6: *One-step manufacturer*

**FELTON GRIMWADE &
BOSISTO'S PTY LTD**

ACN: 004 809 161

61–81 Clarinda Road

OAKLEIGH SOUTH VIC 3167

LICENCE NO: 2053

Product Types: *

- *Category 2: Liquids*

Step(s) of Manufacture: Formulation including blending, filling, packaging, labelling, analysis and testing (physical and chemical), storage and release for supply

Amended Licence Issued: 27 June 2016

3. LICENCE CANCELLATIONS

The APVMA has cancelled the following licences under subsection 127(1) of the Agricultural and Veterinary Chemicals Code [the Agvet Code].

Nil

4. LICENCE SUSPENSIONS

The APVMA has suspended the following licences under subsection 127(1) of the Agricultural and Veterinary Chemicals Code [the Agvet Code].

MARKITFORCE PTY. LTD.

ACN: 23 095 684 834

1/13 Childs Road

CHIPPING NORTON NSW 2170

LICENCE NO: 6194

Date Suspended: 6 June 2016 to 1 November 2016

CHARLES I. F. E.

PROPRIETARY LIMITED

ACN: 004 994 629

'Berrybank Farm'

34 Hendersons Road

WINDERMERE VIC 3352

LICENCE NO: 6155

Date Suspended: 23 June 2016 to 21 June 2017

5. REVOCATION OF LICENCE CANCELLATION

The APVMA has revoked the cancellation of the following licences under subsection 127(7) of the Agricultural and Veterinary Chemicals Code [the Agvet Code].

Nil

* Category 1: *Immunobiologicals and sterile veterinary preparations*
Category 2: *Non-sterile veterinary preparations other than ectoparasiticides, premixes and supplements*
Category 3: *Ectoparasiticides*
Category 4: *Premixes and supplements*
Category 5: *Exempt*
Category 6: *One-step manufacturer*

6. REVOCATION OF LICENCE SUSPENSION

The APVMA has revoked the suspension of the following licences under subsection 127(7) of the Agricultural and Veterinary Chemicals Code [the Agvet Code].

Nil

APVMA CONTACT

Manufacturing Quality and Licensing Section
Legal and Compliance Program
Australian Pesticides and Veterinary Medicines Authority
PO Box 6182
KINGSTON ACT 2604

Phone: +61 2 6210 4899

Fax: +61 2 6210 4813

Email: mls@apvma.gov.au

* Category 1: *Immunobiologicals and sterile veterinary preparations*
Category 2: *Non-sterile veterinary preparations other than ectoparasiticides, premixes and supplements*
Category 3: *Ectoparasiticides*
Category 4: *Premixes and supplements*
Category 5: *Exempt*
Category 6: *One-step manufacturer*
