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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.

APVMA CONTACTS

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Erratum Notice

The Australian Pesticides and Veterinary Medicines Authority advises that an error was published in the Commonwealth of Australia Gazette for Agricultural and Veterinary Chemicals, APVMA 7, Tuesday, 5 April 2016.

In the Notice, the product name ‘FRENTA 750 WG FUNGICIDE’ was incorrect.

The correct entry for the Notice of Registration for ‘FRENTA 750 WG INSECTICIDE’ is on page 4 of this gazette.

Agricultural Chemical Products and Approved Labels

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

1. AGRICULTURAL PRODUCTS BASED ON NEW ACTIVE CONSTITUENTS

Application no.:	57838
Product name:	Prolectus Fungicide
Active constituent/s:	400 g/L fenpyrazamine
Applicant name:	Sumitomo Chemical Australia Pty Limited
Applicant ACN:	081 096 255
Summary of use	For the control of grey mould in grapes
Date of registration/approval:	5 May 2016
Product registration no.:	68251
Label approval no.:	68251/57838

2. AGRICULTURAL PRODUCTS BASED ON EXISTING ACTIVE CONSTITUENTS

Application no.:	104988
Product name:	Frenta 750 WG Fungicide
Active constituent/s:	750 g/kg mancozeb
Applicant name:	Rotam Agrochemical Co., Ltd
Applicant ACN:	N/A
Summary of use	For the control of certain fungus diseases of fruit, field crops, tobacco, turf, vegetables and ornamentals
Date of registration/approval:	21 March 2016
Product registration no.:	82094
Label approval no.:	82094/104988

Application no.:	102747
Product Name:	Vortex Herbicide
Active constituent/s:	300 g/L 2,4-D present as the 2-ethylhexyl ester, 6.25 g/L florasulam
Applicant name:	Adama Australia Pty Limited
Applicant ACN:	050 328 973
Summary of use	For the control of broadleaf weeds in wheat, barley and triticale
Date of registration/approval:	27 April 2016
Product registration no.:	81288
Label approval no.:	81288/102747

Application no.:	105334
Product name:	Stadium Turf Selective Herbicide
Active constituent/s:	20 g/L clopyralid present as the potassium salt 15 g/L diflufenican 300 g/L MCPA present as the potassium salt
Applicant name:	Adama Australia Pty Limited
Applicant ACN:	050 328 973
Summary of use	For the control of certain broadleaf weeds in turf
Date of registration/approval:	27 April 2016
Product registration no.:	82266
Label approval no.:	82266/105334

Application no.:	104779
Product name:	Don't Bug Me Organic Insect Repellent
Active constituent/s:	6.5 g/kg citronella oil
Applicant name:	Naturally Australian Products Pty Ltd
Applicant ACN:	606 930 714
Summary of use	For use as a personal insect repellent
Date of registration/approval:	27 April 2016
Product registration no.:	81999
Label approval no.:	81999/104779

Application no.:	105911
Product name:	Novaguard Glyphosate 540 K Herbicide
Active constituent/s:	540 g/L glyphosate present as the potassium salt
Applicant name:	Novaguard Pty Ltd
Applicant ACN:	153 121 156
Summary of use	For the non-selective control of many annual and perennial weeds
Date of registration/approval:	28 April 2016
Product registration no.:	82501
Label approval no.:	82501/105911

Application no.:	105157
Product name:	Aprisco 900 WG Fungicide
Active constituent/s:	900 g/kg chlorothalonil
Applicant name:	Rotam Agrochemical Co., Ltd
Applicant ACN:	N/A
Summary of use	For the control of fungal diseases on almonds, apricots, bananas, carrots, celery, cherries, faba beans, grapes, onions, peaches, peanuts, peas, plums, potatoes, tomatoes and vegetables
Date of registration/approval:	29 April 2016
Product registration no.:	82194
Label approval no.:	82194/105157

Application no.:	105067
Product name:	Tebix 200 G Granular Herbicide
Active constituent/s:	200 g/kg tebuthiuron
Applicant name:	Rotam Agrochemical Co., Ltd
Applicant ACN:	N/A
Summary of use	For control of brigalow regrowth, tea tree regrowth, mimosa pigra and certain problem woody weeds on grazing lands by hand, aerial and ground application
Date of registration/approval:	29 April 2016
Product registration no.:	82133
Label approval no.:	82133/105067

Application no.:	105877
Product name:	eChem Atrazine 900 WG Herbicide
Active constituent/s:	900 g/kg atrazine
Applicant name:	eChem (Aust) Pty Limited
Applicant ACN:	089 133 095
Summary of use	For the control of weeds and grasses in sorghum, maize, sugarcane, TT-canola, lucerne and for fallow area maintenance and other situations
Date of registration/approval:	2 May 2016
Product registration no.:	82492
Label approval no.:	82492/105877

Application no.:	105300
Product name:	Relyon Drill 240EC Herbicide
Active constituent/s:	240 g/L carfentrazone-ethyl
Applicant name:	Ruralco Holdings Limited
Applicant ACN:	009 660 879
Summary of use	For improvement in the control of marshmallow and certain other broadleaf weeds prior to establishment of broadacre crops, fallows, in commercial, industrial and public service areas, and around agricultural buildings and yards, in tank mixtures with knockdown herbicides: for the control of marshmallow and annual nettles in grass pastures and rough/turf areas, control of volunteer cotton seedlings including roundup ready cotton and desiccation of cotton re-growth
Date of registration/approval:	2 May 2016
Product registration no.:	82259
Label approval no.:	82259/105300

Application no.:	105784
Product name:	Alpha 2,4-D 625 Herbicide
Active constituent/s:	625 g/L 2,4-D present as the dimethylamine and diethanolamine salts
Applicant name:	Alpha Crop Protection Pty Ltd
Applicant ACN:	165 653 047
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, sugarcane, peanuts and non-agricultural areas
Date of registration/approval:	2 May 2016
Product registration no.:	82451
Label approval no.:	82451/105784

Application no.:	104389
Product name:	Relyon Sledge 240EC Herbicide
Active constituent/s:	240 g/L carfentrazone-ethyl
Applicant name:	Ruralco Holdings Limited
Applicant ACN:	009 660 879
Summary of use	For improvement in the control of marshmallow broadleaf weeds prior to establishment of broadacre crops
Date of registration/approval:	2 May 2016
Product registration no.:	81904
Label approval no.:	81904/104389

Application no.:	105771
Product name:	Brandt Umbrella 905 Non-Ionic Sticker Spreader
Active constituent/s:	905 g/L di-1-p-menthene
Applicant name:	Brandt Consolidated Inc
Applicant ACN:	N/A
Summary of use	To control the life of pesticides
Date of registration/approval:	3 May 2016
Product registration no.:	82442
Label approval no.:	82442/105771

Application no.:	100953
Product name:	Imtrade Cracker Jack 750 EC Fungicide
Active constituent/s:	750 g/L propiconazole
Applicant name:	Imtrade Australia Pty Ltd
Applicant ACN:	090 151 134
Summary of use	For the control of certain fungal diseases of oats, perennial ryegrass, wheat and other crops in certain states and the control of dollar spot in bent and Queensland blue couch, and spring dead spot in couch
Date of registration/approval:	3 May 2016
Product registration no.:	80490
Label approval no.:	80490/100953

Application no.:	103284
Product name:	Campbell Cobra 480SC Insecticide
Active constituent/s:	480 g/L thiacloprid
Applicant name:	Colin Campbell (Chemicals) Pty Ltd
Applicant ACN:	000 045 590
Summary of use	For the control of codling moth in pome fruit, oriental fruit moth in pome fruit and stone fruit, and apple dimpling bug in apples
Date of registration/approval:	4 May 2016
Product registration no.:	81523
Label approval no.:	81523/103284

Application no.:	105969
Product name:	Ozcrop Imazamox 700 WG Herbicide
Active constituent/s:	700 g/kg imazamox
Applicant name:	Ozcrop Pty Ltd
Applicant ACN:	160 656 431
Summary of use	For the post-emergence control of certain annual grass and broadleaf weeds in field peas, legume-based pastures, lucerne, peanuts and soybeans
Date of registration/approval:	4 May 2016
Product registration no.:	82512
Label approval no.:	82512/105969

Application no.:	105085
Product name:	Mentor Herbicide
Active constituent/s:	750 g/kg metribuzin
Applicant name:	Adama Australia Pty Limited
Applicant ACN:	050 328 973
Summary of use	For selective weed control in cereals, pastures and other crops, including vegetables
Date of registration/approval:	4 May 2016
Product registration no.:	82144
Label approval no.:	82144/105085

Application no.:	105655
Product name:	Rygel Glufosinate 200 Herbicide
Active constituent/s:	200 g/L glufosinate-ammonium
Applicant name:	Profeng Australia Pty Ltd
Applicant ACN:	156 055 533
Summary of use	For the non-residual control of broadleaf and grass weeds in various situations
Date of registration/approval:	5 May 2016
Product registration no.:	82400
Label approval no.:	82400/105655

Application no.:	105773
Product name:	Brandt Organosilicone Surfactant
Active constituent/s:	1020 g/L polyether modified polysiloxane
Applicant name:	Brandt Consolidated Inc
Applicant ACN:	N/A
Summary of use	For use as a non-ionic wetter-spreader-penetrant used as a spray additive for improved coverage, penetration and uptake of herbicides, fungicides, insecticides, miticides and foliar micro-nutrients
Date of registration/approval:	5 May 2016
Product registration no.:	82444
Label approval no.:	82444/105773

Application no.:	103315
Product name:	Shaolin Fungicide
Active constituent/s:	375 g/kg cyprodinil, 250 g/kg fludioxonil
Applicant name:	Shandong Rainbow International Co., Ltd
Applicant ACN:	N/A
Summary of use	For control of grey mould in grapes
Date of registration/approval:	6 May 2016
Product registration no.:	81537
Label approval no.:	81537/103315

Application no.:	105027
Product name:	Orcal 750 WG Herbicide
Active constituent/s:	750 g/kg sulfometuron methyl
Applicant name:	Rotam Agrochemical Co., Ltd
Applicant ACN:	N/A
Summary of use	For the control of certain annual and perennial grasses and broadleaf weeds in commercial and industrial areas around agricultural buildings and rights of way
Date of registration/approval:	6 May 2016
Product registration no.:	82106
Label approval no.:	82106/105027

3. VARIATIONS OF REGISTRATION

Application no.:	106104
Product name:	Macro Protect Spike 240 EC Herbicide
Active constituent/s:	240 g/L oxyfluorfen
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 OXYFLUORFEN 240 EC HERBICIDE' to 'MACRO PROTECT SPIKE 240 EC HERBICIDE'
Date of variation:	30 March 2016
Product no.:	60464
Label approval no.:	60464/106104

Application no.:	106105
Product name:	Macro Protect Bifenthrin 100 Insecticide/Miticide
Active constituent/s:	100 g/L bifenthrin
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 BIFENTHRIN 100 INSECTICIDE/MITICIDE' to 'MACRO PROTECT BIFENTHRIN 100 INSECTICIDE/MITICIDE'
Date of variation:	30 March 2016
Product no.:	59461
Label approval no.:	59461/106105

Application no.:	1061117
Product name:	Macro Protect Triclopyr 600 Herbicide
Active constituent/s:	600 g/L triclopyr present as the butoxyethyl ester
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 TRICLOPYR 600 HERBICIDE; to 'MACRO PROTECT TRICLOPYR 600 HERBICIDE'
Date of variation:	30 March 2016
Product no.:	59351
Label approval no.:	59351/106117

Application no.:	106159
Product name:	Isacop Fungicide
Active constituent/s:	500 g/kg copper (cu) present as copper oxychloride
Applicant name:	Isagro Australia Pty Limited
Applicant ACN:	066 736 114
Summary of variation:	To change the distinguishing product name and the name that appears on the label from 'BRYCOP COPPER OXYCHLORIDE AGRICULTURAL FUNGICIDE' to 'ISACOP FUNGICIDE'
Date of variation:	1 April 2016
Product no.:	53597
Label approval no.:	53597/106159

Application no.:	106284
Product name:	Apparent Left Hook 960 Herbicide
Active constituent/s:	960 g/L s-metolachlor
Applicant name:	Apparent Pty. Ltd
Applicant ACN:	143 724 136
Summary of variation:	To change the distinguishing product name and the name that appears on the label from 'APPARENT S-METOLACHLOR 960 HERBICIDE' to 'APPARENT LEFT HOOK 960 HERBICIDE'
Date of variation:	12 April 2016
Product no.:	66008
Label approval no.:	66008/106284

Application no:	103675
Product name:	Pyramin WG Selective Herbicide
Active constituent/s:	650 g/kg chloridazon
Applicant name:	BASF Australia Ltd
Applicant ACN:	008 437 867
Summary of variation:	To extend the use to the control of annual broadleaf weeds and various grasses in baby leaf spinach, and baby leaf beet/chard
Date of variation:	26 April 2016
Product registration no.:	65284
Label approval no.:	65284/103675

Application no:	105077
Product name:	Grazon Extra Herbicide
Active constituent/s:	8 g/L aminopyralid present as hexyloxypropylamine salt, 100 g/L picloram present as the hexyloxypropylamine salt, 300 g/L triclopyr present as the butoxyethyl ester
Applicant name:	Dow Agrosciences Australia Limited
Applicant ACN:	003 771 659
Summary of variation:	To extend the use for control of two additional weeds, flax-leaf fleabane and tropical soda apple in agricultural non-crop areas, commercial and industrial areas, forests and rights-of-way
Date of variation:	27 April 2016
Product registration no.:	60830
Label approval no.:	60830/105077

Application no:	105255
Product name:	Agro-Essence Propyzamide 500 SC Herbicide
Active constituent/s:	500 g/L propyzamide
Applicant name:	Agro-Alliance (Australia) Pty Ltd
Applicant ACN:	130 864 603
Summary of variation:	To add a new pack size range of 110 L to 1000 L
Date of variation:	2 May 2016
Product registration no.:	66646
Label approval no.:	66646/105255

Application no:	103674
Product name:	Farmalinx Snail Trail Snail and Slug Pellets
Active constituent/s:	15 g/kg metaldehyde
Applicant name:	Farmalinx Pty Ltd
Applicant ACN:	134 353 245
Summary of variation:	To extend crop uses
Date of variation:	6 May 2016
Product registration no.:	65053
Label approval no.:	65053/103674

Application no:	105471
Product name:	Monarch Insecticide
Active constituent/s:	125 g/L fipronil
Applicant name:	Turf Culture Pty Ltd
Applicant ACN:	117 986 615
Summary of variation:	To change the name of the product from 'TURF CULTURE MONARCH INSECTICIDE' to 'MONARCH INSECTICIDE' and to amend the re-entry period
Date of variation:	6 May 2016
Product registration no.:	66187
Label approval no.:	66187/105471

4. LABEL APPROVAL

Application no.:	105675
Product name:	Hy-Clor High Performance Pool Tablets
Active constituent/s:	610 g/kg available chlorine (Cl) present as trichloroisocyanuric acid 320 g/kg sodium tetraborate pentahydrate
Applicant name:	Hy-Clor (Australia) Pty Ltd
Applicant ACN:	000 655 381
Summary of use:	To add an additional label name to the product under 'HOMEBRAND CONCENTRATE POOL TABLETS'
Date of approval:	2 May 2016
Label approval no.:	80624/105675

Application no.:	105865
Product name:	Custodia Fungicide
Active constituent/s:	120 g/L azoxystrobin, 200 g/L tebuconazole
Applicant name:	Adama Australia Pty Limited
Applicant ACN:	050 328 973
Summary of use:	To add an additional label name to the product under 'CUSTODIA 320 SC FUNGICIDE'
Date of approval:	6 May 2016
Label approval no.:	66541/105865

Veterinary Chemical Products and Approved Labels

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

1. VETERINARY PRODUCTS BASED ON NEW ACTIVE CONSTITUENTS

Application no.:	62953
Product name:	Loxicom 1 mg Chewable Tablets for Dogs
Active constituent/s:	1 mg meloxicam
Applicant name:	Norbrook Laboratories Australia Pty Limited
Applicant ACN:	080 972 596
Summary of use	For the use in dogs for the alleviation of inflammation and pain in acute and chronic musculoskeletal disorders
Date of registration/approval:	9 May 2016
Product registration no.:	70299
Label approval no.:	70299/62953

2. VETERINARY PRODUCTS BASED ON EXISTING ACTIVE CONSTITUENTS

Application no.:	105006
Product name:	Purina Total Care Flea And Tick Control For Medium Dogs
Active constituent/s:	100 g/L fipronil
Applicant name:	Nestle Purina Petcare A Div Of Nestle Australia Ltd
Applicant ACN:	000 011 316
Summary of use	For use in the treatment and prevention of flea infestations, control of flea allergy dermatitis, control of ticks and biting lice on medium dogs
Date of registration/approval:	22 April 2016
Product registration no.:	82099
Label approval no.:	82099/105006

Application no.:	105008
Product name:	Purina Total Care Flea And Tick Control For Small Dogs
Active constituent/s:	100 g/L fipronil
Applicant name:	Nestle Purina Petcare A Div Of Nestle Australia Ltd
Applicant ACN:	000 011 316
Summary of use	For use in the treatment and prevention of flea infestations, control of flea allergy dermatitis, control of ticks and biting lice on small dogs
Date of registration/approval:	22 April 2016
Product registration no.:	82100
Label approval no.:	82100/105008

Application no.:	62952
Product name:	Loxicam 2.5 mg Chewable Tablets for Dogs
Active constituent/s:	Each tablet contains 2.5 mg meloxicam
Applicant name:	Norbrook Laboratories Australia Pty Ltd
Applicant ACN:	080 972 596
Summary of use	For use in dogs for the alleviation of inflammation and pain acute and chronic musculoskeletal disorders
Date of registration/approval:	6 May 2016
Product registration no.:	70298
Label approval no.:	70298/62952

3. VARIATIONS OF REGISTRATION

Application no:	102355
Product name:	Metacam 20 mg/mL Solution For Injection
Active constituent/s:	20 mg/mL meloxicam
Applicant name:	Boehringer Ingelheim Pty Limited, Vetmedica Division
Applicant ACN:	000 452 308
Summary of variation:	To extend the use to sheep and lambs for the alleviation of pain and inflammation
Date of variation:	28 April 2016
Product registration no.:	54061
Label approval no.:	54061/102355

Application no.:	106173
Product name:	Fido's All Wormer Tablets For Dogs, Cats, Puppies And Kittens
Active constituent/s:	50 mg/tablet praziquantel, 500 mg/tablet fenbendazole
Applicant name:	Chanelle Pharmaceuticals Manufacturing Ltd.
Applicant ACN:	N/A
Summary of variation:	To change the distinguishing product name and the name that appears on the label from 'ZANTEL INTESTINAL WORMER FOR DOGS AND CATS, PUPPIES AND KITTENS' to 'FIDO'S ALL WORMER TABLETS FOR DOGS, CATS, PUPPIES AND KITTENS'
Date of variation:	4 April 2016
Product no.:	59650
Label approval no.:	59650/106173

Application no.:	106194
Product name:	Equimune Mycobacterial Cell Wall Fraction Immunostimulant
Active constituent/s:	1 mg/mL mycobacterium cell wall fraction, contains 30 µg/mL gentamicin as a preservative
Applicant name:	Novavive Australasia Pty Ltd
Applicant ACN:	607 502 198
Summary of variation:	To change the distinguishing product name and the name that appears on the label from 'EQUIMUNE I.V. MYCOBACTERIAL CELL WALL FRACTION IMMUNOSTIMULANT FOR HORSES' to 'EQUIMUNE MYCOBACTERIAL CELL WALL FRACTION IMMUNOSTIMULANT'
Date of variation:	6 April 2016
Product no.:	51105
Label approval no.:	51105/106194

Application no.:	103218
Product name:	Randlab Meloxicam Injection Anti-Inflammatory Injection
Active constituent/s:	20 mg/mL meloxicam
Applicant name:	Randlab Australia Pty Ltd
Applicant ACN:	114 948 837
Summary of variation:	To extend the use to cattle and pigs
Date of variation:	4 May 2016
Product registration no.:	68070
Label approval no.:	68070/103218

4. LABEL APPROVAL

Application no.:	105854
Product name:	RWR Mor-N-Mectin Oral Horse Worming Paste
Active constituent/s:	167 mg morantel tartrate, 4 mg abamectin
Applicant name:	RWR Veterinary Products Pty Ltd
Applicant ACN:	088 423 018
Summary of use:	To add an additional label name to the product under 'IO EQUI-DOSE COMPLETE ORAL HORSE WORMING PASTE'
Date of approval:	6 May 2016
Label approval no.:	69678/105854

Application no.:	105857
Product name:	Equiwormer Plus Tape Oral Paste for Horses
Active constituent/s:	3.7 mg/g abamectin, 46.2 mg/g praziquantel
Applicant name:	RWR Veterinary Products Pty Ltd
Applicant ACN:	088 423 018
Summary of use:	To add an additional label name to the product under 'IO EQUI-DOSE PLUS WORMER PLUS TAPE ORAL PASTE FOR HORSES'
Date of approval:	6 May 2016
Label approval no.:	58236/105857

Application no.:	105856
Product name:	Equiwormer Oral Broad Spectrum Parasite Control for Horses
Active constituent/s:	3.7 mg/g abamectin
Applicant name:	RWR Veterinary Products Pty Ltd
Applicant ACN:	088 423 018
Summary of use:	To add an additional label name to the product under 'IO EQUI-DOSE WORMER ORAL BROAD SPECTRUM PARASITE CONTROL PASTE FOR HORSES'
Date of approval:	9 May 2016
Label approval no.:	58246/105856

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.:	102900
Active constituent/s:	Acifluorfen
Applicant name:	Adama Australia Pty Limited
Applicant ACN:	050 328 973
Summary of use:	For use in agricultural chemical products
Date of approval:	27 April 2016
Approval no.:	81360

Application no.:	102269
Active constituent/s:	Indoxacarb
Applicant name:	Du Pont (Australia) Pty Ltd
Applicant ACN:	000 716 469
Summary of use:	For use in agricultural and veterinary chemical products
Date of approval:	28 April 2016
Approval no.:	81072

Application no.:	102605
Active constituent/s:	Dicamba
Applicant name:	UPL Australia Limited
Applicant ACN:	066 391 384
Summary of use:	For use in agricultural chemical products
Date of approval:	3 May 2016
Approval no.:	81229

Application no.:	103997
Active constituent/s:	Trifloxysulfuron sodium
Applicant name:	Syngenta Australia Pty Ltd
Applicant ACN:	002 933 717
Summary of use:	For use in agricultural chemical products
Date of approval:	4 May 2016
Approval no.:	81762

Application no.:	57842
Active constituent/s:	Fenpyrazamine
Applicant name:	Sumitomo Chemical Australia Pty Limited
Applicant ACN:	081 096 255
Summary of use:	For use in agricultural chemical products
Date of approval:	4 May 2016
Approval no.:	68252

Application no.:	103871
Active constituent/s:	Phenmedipham
Applicant name:	Adama Australia Pty Limited
Applicant ACN:	050 328 973
Summary of use:	For use in agricultural chemical products
Date of approval:	9 May 2016
Approval no.:	81723

2. VARIATIONS OF ACTIVE CONSTITUENT

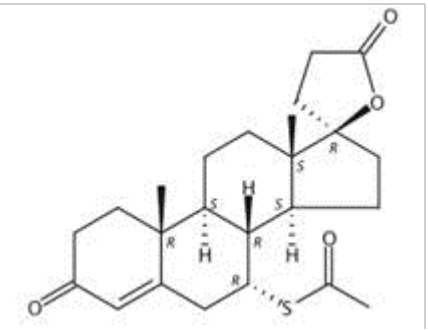
Application no.:	102077
Active constituent/s:	Alpha Cypermethrin
Applicant name:	Gharda Australia Pty Ltd
Applicant ACN:	087 753 151
Summary of variation:	Variation of active approval
Date of variation:	3 May 2016
Approval no.:	45759

New Veterinary Chemical Product Containing a New Veterinary Active Constituent

Spironolactone in Prilactone 80 mg Tablets for Dogs, Prilactone 40 mg Tablets for Dogs and Prilactone 10 mg Tablets for Dogs

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application from CEVA ANIMAL HEALTH PTY LTD for the approval of a new active constituent spironolactone. The APVMA also has before it three related applications from the same applicant for the registration of the new products, Prilactone 80 mg Tablets for Dogs, Prilactone 40 mg Tablets for Dogs and Prilactone 10 mg Tablets for Dogs (herein referred to as THE PRODUCTS), containing the new active constituent. THE PRODUCTS are proposed to be registered for use in conjunction with standard therapy (including diuretic support, where necessary) for the treatment of congestive heart failure caused by mitral valvular regurgitation in dogs.

PARTICULARS OF THE ACTIVE CONSTITUENT

Common Name:	Spironolactone
IUPAC Name:	7α-(acetylthio)-17α-hydroxy-3-oxo-pregn-4-ene-21-carboxylic acid-γ-lactone
CAS Name:	Pregn-4-ene-21-carboxylic acid, 7-(acetylthio)-17-hydroxy-3-oxo-, γ-lactone, (7α,17α)-
CAS Registry Number:	52-01-7
Manufacturer's Codes:	SPI
Assay (dried basis):	97.5-102.0%
Molecular Formula:	$C_{24}H_{32}O_4S$
Molar Mass:	416.6
Structure:	
Chemical Family:	Synthetic 17-spironolactone corticosteroids
Mode of Action:	Diuretic

SUMMARY OF THE APVMA'S EVALUATION OF THE ACTIVE CONSTITUENT SPIRONOLACTONE IN ACCORDANCE WITH SECTION 5A OF THE AGRICULTURAL AND VETERINARY CHEMICALS CODE (THE 'AGVET CODE'), SCHEDULED TO THE *AGRICULTURAL AND VETERINARY CHEMICALS CODE ACT 1994*

The APVMA has evaluated the new active constituent spironolactone under sections 5A(1)(a),(b) and (c) of the Agvet Code and proposes to be satisfied that the active constituent is not, or would not: be an undue hazard to the safety of people exposed to it during its handling or people using anything containing its residues; be likely to have an effect that is harmful to human beings; or be likely to have an unintended effect that is harmful to animals, plants or things or to the environment.

The APVMA has evaluated the chemistry and manufacturing aspects of spironolactone in THE PRODUCTS through data provided by the applicant (including the physico-chemical properties, spectral identification, manufacturing and quality control aspects, impurity formation, active constituent specification, stability, batch analysis data, analytical methods and packaging information) and is satisfied that the safety criteria relevant to the approval of the active constituent and registration of THE PRODUCTS have been met.

An external reviewer has evaluated the toxicological profile of spironolactone through data provided by the applicant. Based on available data, the acute oral toxicity of spironolactone in mice, rats and rabbits was found to be low. Spironolactone was not a skin irritant and showed slight eye irritation in rabbits. It was a skin sensitiser in the guinea pig maximisation test but not in the Buehler test.

A number of studies using high parenteral doses investigated specific aspects which were relevant to reproductive performance. In female rats, plasma oestradiol levels were decreased and were associated with retarded follicular development, prolonged dioestrus and delayed or arrested development of ovaries and uteri. Ovulation was prevented in mice and the menstrual cycle was disrupted in monkeys. Because of its anti-androgenic activity and the pathological findings in reproductive organs of rats, dogs and monkeys, it was concluded that spironolactone could be expected to have a deleterious impact on reproduction and fertility.

Conventional developmental toxicity studies were not available and there were no studies in animals treated during the period of organogenesis. In studies where rats were dosed during the latter part of gestation, parturition was delayed, foetal death was increased, reproductive organ weights in male and female offspring were altered and there was evidence for feminisation of male external genitalia. These findings were likely related to the anti-androgenic properties of spironolactone.

Spironolactone is unlikely to enter the food chain and therefore the determination of an Acceptable Daily Intake, Acute Reference Dose and Maximum Residue Limits is not considered necessary.

Spironolactone has been registered for human therapeutic use by the Therapeutic Goods Administration (TGA) and is listed in Schedule 4 of the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) without exemptions or cut-offs. The current listing for spironolactone is determined to be appropriate .The appropriate Schedule 4 signal heading, first aid instructions and safety directions will appear on the product label.

The APVMA has considered and accepted the findings and recommendations of the advice providers.

PARTICULARS OF THE PRODUCTS

Proposed Product Name(s):	PRILACTONE 80 MG TABLETS FOR DOGS PRILACTONE 40 MG TABLETS FOR DOGS PRILACTONE 10 MG TABLETS FOR DOGS
Applicant Company:	CEVA ANIMAL HEALTH PTY LTD
Name of Active Constituent:	Spironolactone
Signal Heading:	PRESCRIPTION ANIMAL REMEDY—Schedule 4
Summary of Proposed Use:	For use in conjunction with standard therapy (including diuretic support, where necessary) for the treatment of congestive heart failure caused by mitral valvular regurgitation in dogs.
Pack Sizes:	30 tablets, 180 tablets
Withholding Period:	N/A

SUMMARY OF THE APVMA'S EVALUATION OF THE PRODUCTS IN ACCORDANCE WITH 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 applications and in its assessment in relation to whether the safety criteria have been met in accordance with the definition set out in section 5A of the Agvet Code, and proposes to determine that:

(i) The APVMA is satisfied that the proposed use of THE PRODUCTS would not be an undue hazard to the safety of people exposed to it during its handling.

An external reviewer has conducted a risk assessment and found that the submitted data support the safe use of the products from a toxicological perspective. The potential toxicity of THE PRODUCTS was estimated based on information on the individual components. The products were found to have low acute oral toxicity, moderate eye and slight skin irritation potential and to be a possible skin sensitiser.

Contact with the hands is likely during normal use of THE PRODUCTS. Skin contact will occur when the tablets are removed from the packaging and eye contact may occur as a transfer from hands. Acute toxicity following dermal doses and the extent of dermal absorption are not known. However, the small amounts on skin are not expected to lead to significant absorption and therefore are unlikely to pose a meaningful systemic risk. Delayed contact hypersensitivity with spironolactone was observed in guinea pigs and contact dermatitis has been noted in humans. Slight to moderate eye irritation is also possible. Label statements identifying these hazards and advice to avoid contact with eyes and skin and to wash hands after using the product were therefore recommended by the external reviewer.

The label statements required for a Schedule 4 substance will indicate the need to keep the products out of the reach of children. Further, THE PRODUCTS will be packaged into blister packaging which will minimise the risk of accidental ingestion.

The APVMA has considered and accepted the findings and recommendations of the external reviewer.

(ii) The APVMA is satisfied that the proposed use of THE PRODUCTS will not be an undue hazard to the safety of people using anything containing their residues.

THE PRODUCTS are proposed to be registered for use in companion animals (dogs) only. Spironolactone is unlikely to enter the food chain and therefore the determination of an Acceptable Daily Intake, Acute Reference Dose and Maximum Residue Limits is not considered necessary.

(iii) The APVMA is satisfied that the proposed use of THE PRODUCTS containing the active constituent spironolactone is not likely to be harmful to human beings if used according to label directions.

Spironolactone has been registered for human therapeutic use by the Therapeutic Goods Administration (TGA) and is listed in Schedule 4 of the SUSMP without exemptions or cut-offs. The existing Schedule 4 entry for spironolactone is appropriate for THE PRODUCTS. The appropriate Schedule 4 signal headings and the following first aid instructions and safety directions will appear on the product label, in accordance with the recommendations of the external reviewer.

FIRST AID: If poisoning occurs, contact a doctor or Poisons Information Centre. Phone Australia 13 11 26.

SAFETY DIRECTIONS: Harmful if swallowed. Will irritate the eyes and skin. Repeated exposure may cause allergic disorders. Avoid contact with eyes and skin. Wash hands after use.

(iv) The APVMA is satisfied that the proposed use of THE PRODUCTS is not likely to have an unintended effect that is harmful to animals, plants or the environment if used according to the product label directions.

The Department of the Environment has evaluated the environmental aspects of THE PRODUCTS and has advised that THE PRODUCTS meet the criteria for the environmental risk assessment to stop at VICH Phase I (where the potential for environmental exposure is assessed based on the intended use of the product—in this case for companion animals only). The Department of the Environment has recommended to the APVMA that the use of THE PRODUCTS in dogs under the proposed use pattern is unlikely to have an unintended effect that is harmful to animals, plants or the environment. The APVMA has considered these findings and accepts the recommendations of the Department of the Environment. The product labels will contain a suitable disposal statement.

An external reviewer evaluated the data provided and found that the submitted data support the safety of the proposed products for use in conjunction with standard therapy (including diuretic support, where necessary) for the treatment of congestive heart failure caused by mitral valvular regurgitation in dogs.

To support the safety of the proposed product to target animals, the applicant provided published literature on the use of spironolactone in the target species, pharmacokinetic studies and two margin of safety studies.

The laboratory margin and duration of safety study was conducted using healthy male and female Beagle dogs. Dogs were allocated to 4 treatment groups. Control animals received placebo tablets. The required number of tablets were administered to provide 1x (2 mg/kg bodyweight orally once a day), 5x (10 mg/kg bodyweight orally once a day) and 10x (20 mg/kg bodyweight orally once a day) for 91 days in the remaining treatment groups. Four animals in the 0 and 20 mg/kg groups received no treatment for the subsequent 21 days (reversibility phase).

There were no differences in clinical findings between groups during the study. Sporadic vomiting and diarrhoea were observed in all groups. No notable differences were observed between groups for clinical observations, status of hydration, heart rate and heart rhythm, mucous membrane colour, rectal temperature and examination of mammary glands during the course of the study.

Mean bodyweight of the males in the 20 mg/kg group was 9% lower than that of the 2 mg/kg group males at 91 days. It remained 14% lower by the end of the reversibility study (112 days). An increase in mean liver weight was observed in the 2, 10 and 20 mg/kg groups relative to the 0 mg/kg group. Although this effect persisted to the end of the reversibility phase, no histological abnormalities were observed.

A dose-dependent decrease in weight of the prostate was observed in the males of the 2, 10 and 20 mg/kg groups compared to the 0 mg/kg group. This difference had almost disappeared by the end of the reversibility phase. The changes correlated with a dose-dependent atrophy of the specific glandular epithelium of the prostate observed on histopathology. There were adrenal cortical changes in some animals in the 10 and 20 mg/kg groups and the effect appeared to be dose-dependent. No adrenal anomalies were detected at the end of the reversibility phase.

The data support a no observed effect level of <2 mg/kg orally once a day for 91 days in healthy dogs, as reversible, dose-dependent oestrogenic effects were observed at all dose levels examined. The data support a no observable adverse effect level of 20 mg/kg orally once a day for 91 days in healthy dogs. This supports a 10x safety margin for the proposed products when used as directed in dogs.

The APVMA is satisfied that the product would not be likely to have an unintended effect that is harmful to dogs. Contraindications, precautions and side effects statements will be included on the label.

2. The APVMA has evaluated the applications 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:

    In relation to its assessment of efficacy under section 14(3)(f), 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 uses.

    An external reviewer evaluated the data provided and found that the submitted data support the efficacy of the proposed product when used in conjunction with standard therapy (including diuretic support, where necessary) for the treatment of congestive heart failure caused by mitral valvular regurgitation in dogs. Dogs are to be given 2 mg of spironolactone per kg body weight once daily. The product is to be administered with food; either mixed with a small amount of food offered prior to the main meal, or administered directly into the mouth after feeding.

    To support the effectiveness of the proposed product, the applicant provided published literature on the use of spironolactone in the target species, pharmacokinetic studies, a dose-determination study and five confirmatory clinical studies.

    The dose determination study results supported the proposed dose of 2 mg/kg orally once a day in dogs, which was used as the prescribed dose in the clinical studies. The applicant provided a pooled data analysis of 4 double-blind, randomised, placebo-controlled studies conducted to Good Clinical Practice (GCP) standards. The studies included dogs with naturally occurring Chronic Heart Failure (CHF) due to canine Chronic Degenerative Valvular Disease (CDVD) or Dilated Cardiomyopathy (DCM) with Buchanan Vertebral Heart Size (BVHS) >10.5 and at least 3 of the following clinical signs; cough, dyspnoea, syncope, reduced activity, reduced mobility, altered demeanour. The most widely used angiotensin converting enzyme inhibitor (ACEI) was benazepril (BZ), in use in 52% of cases at inclusion.

    The survival rate for the spironolactone group was 68% and for the placebo group 53%. The mean morbidity-mortality risk was reduced by 46% in the spironolactone group compared to the placebo group. In the placebo group, most of the withdrawal reasons were linked to heart failure, spontaneous death or euthanasia. More acute pulmonary oedema events were observed in the placebo group (11.5%) compared to the spironolactone group (1.9%). This reduction of severe effusion observed in the spironolactone group is an expected effect due to the diuretic potency of spironolactone.

    After one-year treatment with the applicant formulation, the difference in survival rates between the spironolactone and placebo groups was 12% (84% vs 72%) and after 2 years of treatment the difference was 11% (72% vs 61%). The data support the efficacy of the applicant formulation administered under field conditions at 2 mg/kg orally once a day for up to 3 years in dogs with CHF due to CDVD or DCM when given in addition to a standard treatment regimen including an ACEI with or without furosemide, digoxin and carnitine.

    The APVMA is satisfied that THE PRODUCTS would be effective when used according to label directions.

3. The APVMA has evaluated the applications 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:

    (i) The APVMA is satisfied that the proposed use of THE PRODUCTS would not adversely affect trade between Australia and places outside Australia as THE PRODUCTS are not for use in animals producing any major Australian export commodities.

FURTHER INFORMATION

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 spironolactone should be approved and whether the application for registration of THE PRODUCTS should be granted. Submissions should relate only to matters that the APVMA is required by legislation to take into account in deciding whether to approve the active or grant the registration application for THE PRODUCTS. These grounds include: for approval of the active constituent, the safety criteria; for the registration application for THE PRODUCTS: the safety, efficacy and trade criteria. 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 active constituent should be approved and whether THE PRODUCTS 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)*[1] material contained in submissions will be treated confidentially.

Written submissions on the APVMA's proposal to approve the active constituent and grant the application for registration that relate to the grounds for active approval and/or product registration should be addressed in writing to:

Enquiries
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 4741
Email: enquiries@apvma.gov.au

[1] 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]

Nil

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]

AUSTRALIAN PET BRANDS PTY LTD

ACN: 138 614 150

12 Williamson Road

INGLEBURN NSW 2565

LICENCE NO: 4089

Product Types: *

- *Category 4*: Therapeutic Pet Foods

Step(s) of Manufacture: Quality assurance (QA) of raw materials, formulation including blending, wet milling, filling, packaging, labelling, pellet extrusion, microbiological reduction treatment (heat), analysis and testing (physical, chemical and microbiological), storage and release for supply.

Amended Licence Issued: 1 April 2016

PRIMARY INDUSTRIES MANAGEMENT SERVICES PTY LTD TRADING AS CONMAC LABORATORY SERVICES

ACN: 001 933 142

6 Glasson Drive

BETHANIA QLD 4205

LICENCE NO: 6013

Product Types: *

- *Category 6*: Single step manufacture

Step(s) of Manufacture: Analysis and testing (physical, chemical, antibiotic assay and microbiological)

Amended Licence Issued: 5 April 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*

LIENERT AUSTRALIA PTY. LTD.

ACN: 008 293 007

8 Roseworthy Road

ROSEWORTHY SA 5371

LICENCE NO: 4091

Product Types:*

- *Category 4:* Premixes, supplements and custom mixes

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

Amended Licence Issued : 8 April 2016

SUNNYFIELD

ACN: 000 415 127

185 Allambie Road

ALLAMBIE HEIGHTS NSW 2100

LICENCE NO: 6158

Product Types:*

- *Category 6:* Single step manufacture

Step(s) of Manufacture: secondary packaging, secondary/supplementary labelling, storage and release for supply.

Amended Licence Issued : 15 April 2016

EUROFINS AMS LABORATORIES PTY LIMITED

ACN: 075 467 757

8 Rachael Close

SILVERWATER NSW 2128

LICENCE NO: 6139

Product Types: *

- *Category 6*: Single step manufacture

Step(s) of Manufacture: Analysis and testing (Endotoxin testing, antibiotic assay, sterility and microbiological)

Amended Licence Issued: 20 April 2016

EUROFINS AMS LABORATORIES PTY LIMITED

ACN: 075 467 757

2/120 Bluestone Circuit

SEVENTEEN MILE ROCKS

QLD 4073

LICENCE NO: 6191

Product Types: *

- *Category 6*: Single step manufacture

Step(s) of Manufacture: Analysis and testing (Microbiological and endotoxin testing)

Amended Licence Issued: 20 April 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*

JOHN KOHNKE PRODUCTS PTY LTD

ACN: 095 561 505

8 Speedwell Place

SOUTH WINDSOR NSW 2756

LICENCE NO: 2216

Product Types:*

- *Category 2:* Powders, tablets
- *Category 4:* Supplements—powders

Step(s) of Manufacture: Quality assurance (QA) of raw materials, formulation including blending, dry milling, filling, packaging, labelling, storage and release for supply.

Amended Licence Issued : 26 April 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].

Nil

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

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*
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