



Commonwealth of Australia

Gazette

Agricultural and Veterinary Chemicals

No. APVMA 13, Tuesday, 2 July 2019

Published by the Australian Pesticides and Veterinary Medicines Authority



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](http://apvma.gov.au).

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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:	106178
Product name:	Serifel Biofungicide
Active constituent/s:	110 g/kg (>5.5 x 10 ¹⁰ CFU/g) <i>Bacillus amyloliquefaciens</i> strain MBI600
Applicant name:	BASF Australia Ltd
Applicant ACN:	008 437 867
Summary of use:	For the control of <i>Botrytis cinerea</i> in grapes and strawberries
Date of registration:	21 June 2019
Product registration no.:	82600
Label approval no.:	82600/106178

2. AGRICULTURAL PRODUCTS BASED ON EXISTING ACTIVE CONSTITUENTS

Application no:	115990
Product name:	Thijet Spray Fly Bait
Active constituent/s:	500 mg/kg (z)-9-tricosene, 100 g/kg thiamethoxam
Applicant name:	Sharda Cropchem Espana SL
Applicant ACN:	N/A
Summary of use:	For the control of house flies (<i>Musca domestica</i>) in animal housing including dairies, cattle feedlots, abattoirs, piggeries, poultry facilities, horse stables, and kennels. For use in commercial, industrial and domestic areas
Date of registration:	11 June 2019
Product registration no.:	86535
Label approval no.:	86535/115990

Application no:	116707
Product name:	Imtrade Effigy 900 WG Herbicide
Active constituent/s:	600 g/kg terbuthylazine, 300 g/kg propyzamide
Applicant name:	Imtrade Australia Pty Ltd
Applicant ACN:	090 151 134
Summary of use:	For the control and suppression of various annual grass and broadleaved weeds in triazine tolerant (TT) canola and various pulses
Date of registration:	12 June 2019
Product registration no.:	86841
Label approval no.:	86841/116707

Application no:	117967
Product name:	Conquest Explode 360 Herbicide
Active constituent/s:	360 g/L paraquat present as paraquat dichloride
Applicant name:	Conquest Crop Protection Pty Ltd
Applicant ACN:	098 814 932
Summary of use:	For the control of a wide range of grasses and broadleaf weeds
Date of registration:	12 June 2019
Product registration no.:	87259
Label approval no.:	87259/117967

Application no:	116536
Product name:	Signature Xtra Stressgard Systemic Turf Fungicide
Active constituent/s:	600 g/kg fosetyl-aluminium
Applicant name:	Bayer Cropscience Pty Ltd
Applicant ACN:	000 226 022
Summary of use:	For the control of pythium and anthracnose in turf
Date of registration:	12 June 2019
Product registration no.:	86770
Label approval no.:	86770/116536
Application no:	117699
Product name:	Accensi Prosulfocarb 800 EC Herbicide
Active constituent/s:	800 g/L prosulfocarb
Applicant name:	Accensi Pty Ltd
Applicant ACN:	079 875 184
Summary of use:	For control of annual ryegrass (<i>Lolium rigidum</i>) and other grass and broadleaf weeds in barley and wheat
Date of registration:	13 June 2019
Product registration no.:	87178
Label approval no.:	87178/117699
Application no:	119736
Product name:	Spalding MCPA Picolinafen Herbicide
Active constituent/s:	500 g/L MCPA present as the ethyl hexyl ester, 50 g/L picolinafen
Applicant name:	Spalding Holdings Pty Ltd
Applicant ACN:	010 155 852
Summary of use:	For the control of certain broadleaf weeds in winter cereals
Date of registration:	13 June 2019
Product registration no.:	87897
Label approval no.:	87897/119736
Application no:	119744
Product name:	Complete 950 Adjuvant
Active constituent/s:	800 g/kg ammonium sulphate, 150 g/kg carboxylic acid
Applicant name:	Four Seasons Agribusiness Pty Ltd
Applicant ACN:	115 133 189
Summary of use:	For use as an adjuvant with glyphosate products
Date of registration:	14 June 2019
Product registration no.:	87900
Label approval no.:	87900/119744
Application no:	115678
Product name:	Strippa 625 Herbicide
Active constituent/s:	625 g/L 2,4-D present as the dimethylamine and diethanolamine salts
Applicant name:	FDC Eco Solutions Pty Ltd
Applicant ACN:	608 235 187
Summary of use:	For the control of broadleaf weeds in commercial, industrial and aquatic areas
Date of registration:	14 June 2019
Product registration no.:	86397
Label approval no.:	86397/115678

Application no:	117870
Product name:	Cyzmic Insecticide
Active constituent/s:	100 g/L lambda-cyhalothrin
Applicant name:	Adama Australia Pty Limited
Applicant ACN:	050 328 973
Summary of use:	For control of cockroaches, spiders, fleas, ants, flies, silverfish and mosquitoes in domestic, commercial, public and industrial situations
Date of registration:	18 June 2018
Product registration no.:	87248
Label approval no.:	87248/117870
Application no:	119938
Product name:	Alginox High Performance Pool Algaecide
Active constituent/s:	150 g/kg benzalkonium chloride
Applicant name:	Zodiac Group Australia Pty Ltd
Applicant ACN:	002 641 965
Summary of use:	To approve a new label for the product 'Alginox High Performance Pool Algaecide' with the label name 'Powerforce Pool Algaecide'
Date of registration:	18 June 2019
Product registration no.:	48805
Label approval no.:	48805/119938
Application no:	115160
Product name:	Frequency Herbicide
Active constituent/s:	60 g/L topramezone, 60 g/L cloquintocet-mexyl
Applicant name:	BASF Australia Ltd
Applicant ACN:	008 437 867
Summary of use:	For the control of various weeds in cereals
Date of registration:	18 June 2019
Product registration no.:	86267
Label approval no.:	86267/115160
Application no:	119904
Product name:	Maxunitech Ethephon 900 Growth Regulator
Active constituent/s:	900 g/L ethephon (an anticholinesterase compound)
Applicant name:	Max (Rudong) Chemicals Co Ltd
Applicant ACN:	N/A
Summary of use:	For anti-lodging in barley or crop thinning, loosening or ripening in various crops and for accelerating boll opening, defoliation and pre-conditioning before defoliation of cotton
Date of registration:	19 June 2019
Product registration no.:	87958
Label approval no.:	87958/119904
Application no:	117868
Product name:	Imtrade Bromacil 800 WG Herbicide
Active constituent/s:	800 g/kg bromacil
Applicant name:	Imtrade Australia Pty Ltd
Applicant ACN:	090 151 134
Summary of use:	For the control of certain annual broadleaf weeds and grasses in commercial and industrial areas, rights of way and around agricultural buildings
Date of registration:	19 June 2019
Product registration no.:	87247
Label approval no.:	87247/117868

Application no:	119836
Product name:	Coles Personal Insect Repellent Tropical Strength Roll-on 6 Hours Protection
Active constituent/s:	191 g/L n,n-diethyl-m-toluamide, 40 g/L n-octyl bicycloheptene dicarboximide, 20 g/L di-n-propyl isocinchomeronate,
Applicant name:	Cavalieri Investing Pty Ltd
Applicant ACN:	162 722 625
Summary of use:	For 6 hour protection against mosquitoes
Date of registration:	19 June 2019
Product registration no.:	87934
Label approval no.:	87934/119836
Application no:	119981
Product name:	Sanonda Herbicide 2,4-D Ester 680EC
Active constituent/s:	680 g/L 2,4-D present as the 2-ethylhexyl ester
Applicant name:	Sanonda (Australia) Pty Ltd
Applicant ACN:	059 813 973
Summary of use:	For selective control of various weeds in crops, pastures and non-agricultural areas
Date of registration:	20 June 2019
Product registration no.:	87991
Label approval no.:	87991/119981
Application no:	119847
Product name:	Proterra Hi-gly 540-K Herbicide
Active constituent/s:	540 g/L glyphosate present as the potassium salt
Applicant name:	Proterra Pty Ltd
Applicant ACN:	120 507 182
Summary of use:	For non-selective control of many annual and perennial weeds
Date of registration:	20 June 2019
Product registration no.:	87941
Label approval no.:	87941/119847
Application no:	119548
Product name:	Chemforce Epoxiconazole 125 SC Fungicide
Active constituent/s:	125 g/L epoxiconazole
Applicant name:	Chemforce 2010 Pty Ltd
Applicant ACN:	146 807 356
Summary of use:	For the control of leaf rust, stripe rust and <i>Septoria nodorum</i> blotch of wheat and leaf rust of barley
Date of registration:	20 June 2019
Product registration no.:	87847
Label approval no.:	87847/119548
Application no:	120135
Product name:	AC Tipster 500 SL Insecticide
Active constituent/s:	500 g/L trichlorfon (an anti-cholinesterase compound)
Applicant name:	Axichem Pty Ltd
Applicant ACN:	131 628 594
Summary of use:	For the control of a wide range of insects in various situations
Date of registration:	20 June 2019
Product registration no.:	88049
Label approval no.:	88049/120135

Application no:	119725
Product name:	Tebuthiuron 200 GR Herbicide
Active constituent/s:	200 g/kg tebuthiuron
Applicant name:	Cirrus Ag Pty Ltd
Applicant ACN:	623 780 852
Summary of use:	For control of brigalow regrowth, prickly acacia, Mimosa pigra and certain problem woody weeds on grazing lands by hand, aerial and ground application
Date of registration:	20 June 2019
Product registration no.:	87894
Label approval no.:	87894/119725

Application no:	119908
Product name:	Kenso Agcare Ken-Fos 600 Systemic Fungicide
Active constituent/s:	600 g/L phosphorous (phosphonic) acid present as mono (and) di potassium phosphite
Applicant name:	Kenso Corporation (M) SDN BHD
Applicant ACN:	N/A
Summary of use:	For effective control of root rot in avocado, root and collar rot in citrus, root and crown rot in ornamentals and root and heart rot in pineapples caused by phytophthora fungi, and for the control of downy mildew in grapes, poppies and cucurbits
Date of registration:	20 June 2019
Product registration no.:	87962
Label approval no.:	87962/119908

Application no:	120029
Product name:	Coles Outdoor Mosquito Coils Repels For Up To 8 Hours
Active constituent/s:	2 g/kg D-allethrin
Applicant name:	Cavalleri Investing Pty Ltd
Applicant ACN:	162 722 625
Summary of use:	For repelling mosquitoes for up to 8 hours outdoors
Date of registration:	21 June 2019
Product registration no.:	88009
Label approval no.:	88009/120029

3. VARIATIONS OF REGISTRATION

Application no:	120540
Product name:	Nufarm CRUCIAL Advanced Technology Herbicide
Active constituent/s:	600 g/L glyphosate present as potassium, monomethylamine & ammonium salt
Applicant name:	Nufarm Australia Limited
Applicant ACN:	004 377 780
Summary of variation:	To change the distinguishing product name and the name that appears on the label from 'Nufarm CRUCIAL Advanced Glyphosate Technology Herbicide' to 'Nufarm CRUCIAL Advanced Technology Herbicide'
Date of variation:	6 June 2019
Product registration no.:	86761
Label approval no.:	86761/120540

Application no:	119902
Product name:	Mortein Kills Rats & Mice And The Fleas They Carry Dual Action Throwpack
Active constituent/s:	0.05 g/kg brodifacoum, 0.04 g/kg fipronil
Applicant name:	RB (Hygiene Home) Australia Pty Ltd
Applicant ACN:	629 549 506
Summary of variation:	To amend the product name and vary the statement of claims to include ticks
Date of variation:	13 June 2019
Product registration no.:	63885
Label approval no.:	63885/119902
Application no:	119901
Product name:	Mortein Kills Rats & Mice And The Fleas They Carry Dual Action Bait
Active constituent/s:	0.05 g/kg brodifacoum, 0.04 g/kg fipronil
Applicant name:	RB (Hygiene Home) Australia Pty Ltd
Applicant ACN:	629 549 506
Summary of variation:	To amend the product name from 'Mortein Rat Kill With Flea Eliminator' to 'Mortein Kills Rats & Mice And The Fleas They Carry Dual Action Bait' and vary the statement of claims to include ticks
Date of variation:	13 June 2019
Product registration no.:	58661
Label approval no.:	58661/119901
Application no:	120003
Product name:	Titan Azoxystrobin 250SC Fungicide
Active constituent/s:	250 g/L azoxystrobin
Applicant name:	Titan Ag Pty Ltd
Applicant ACN:	122 081 574
Summary of variation:	To add a number of additional claims to the label
Date of variation:	17 June 2019
Product registration no.:	67421
Label approval no.:	67421/120003
Application no:	120123
Product name:	eChem e-Oil Insecticide and Defoliant Oil
Active constituent/s:	794 g/L paraffinic oil
Applicant name:	eChem (Aust) Pty Limited
Applicant ACN:	089 133 095
Summary of variation:	To add insecticidal and other uses and change the name of the product from 'eChem e-Oil Cotton Defoliant Oil' to 'eChem e-Oil Insecticide And Defoliant Oil'
Date of variation:	17 June 2019
Product registration no.:	84730
Label approval no.:	84730/120123
Application no:	120012
Product name:	F.S.A. Carfentrazone 400 Herbicide
Active constituent/s:	400 g/L carfentrazone-ethyl
Applicant name:	Four Seasons Agribusiness Pty Ltd
Applicant ACN:	115 133 189
Summary of variation:	Variation of label and product registration to correct label errors and update instructions including withholding period
Date of variation:	18 June 2019
Product registration no.:	87056
Label approval no.:	87056/120012

Application no:	120039
Product name:	Hovex Shatterproof Mosquito Coils
Active constituent/s:	2.5 g/kg pyrethrin
Applicant name:	Pascoe's Pty Ltd
Applicant ACN:	055 220 463
Summary of variation:	To change the name of the product from 'Hovex Natural Mosquito Coils' to 'Hovex Shatterproof Mosquito Coils' and amend the statement of claims
Date of variation:	18 June 2019
Product registration no.:	80755
Label approval no.:	80755/120039

Application no:	119218
Product name:	Etee Defoliant
Active constituent/s:	25 g/L pyraflufen-ethyl
Applicant name:	Sipcam Pacific Australia Pty Ltd
Applicant ACN:	073 176 888
Summary of variation:	To extend the claim for defoliation and acceleration of boll opening in cotton
Date of variation:	19 June 2019
Product registration no.:	60329
Label approval no.:	60329/119218

Application no:	115538
Product name:	Rainbow Chlorothalonil 900 WG Fungicide
Active constituent/s:	900 g/kg chlorothalonil
Applicant name:	Shandong Rainbow International Co Ltd
Applicant ACN:	N/A
Summary of variation:	To include control of various fungal diseases in peas, chickpeas, lentils, nectarines and plums
Date of variation:	20 June 2019
Product registration no.:	67756
Label approval no.:	67756/115538

Application no:	119556
Product name:	Polo 570 LVE Herbicide
Active constituent/s:	570 g/L MCPA present as the 2-ethyl hexyl ester
Applicant name:	Nufarm Australia Limited
Applicant ACN:	004 377 780
Summary of variation:	To vary the label to include tank-mix instructions with Frequency Herbicide
Date of variation:	20 June 2019
Product registration no.:	63597
Label approval no.:	63597/119556

Application no:	118503
Product name:	Attrathor Targeted Insecticide
Active constituent/s:	26 g/L fipronil
Applicant name:	Ensystex Australasia Pty Ltd
Applicant ACN:	102 221 965
Summary of variation:	To extend the use to include additional urban pest species
Date of variation:	17 June 2019
Product registration no.:	68053
Label approval no.:	68053/118503

4. VARIATION OF LABEL APPROVAL

Application no:	120608
Product name:	Slasher Organic Weedkiller Ready To Use
Active constituent/s:	36.8 g/L nonanoic acid
Applicant name:	Duluxgroup (Australia) Pty Ltd
Applicant ACN:	000 049 427
Summary of variation:	To change the name that appears on the label from 'Yates Zero Rapid Action Weedkiller' to 'Yates Weeds Gone Rapid Action Weedkiller'
Date of variation:	12 June 2019
Product registration no.:	68128
Label approval no.:	68128/120608

Application no:	120615
Product name:	Slasher Organic Weedkiller
Active constituent/s:	525 g/L nonanoic acid
Applicant name:	Duluxgroup (Australia) Pty Ltd
Applicant ACN:	000 049 427
Summary of variation:	To change the name that appears on the label from 'Yates Zero Rapid Action Weedkiller Concentrate' to 'Yates Weeds Gone Rapid Action Weedkiller Concentrate'
Date of variation:	12 June 2019
Product registration no.:	68118
Label approval no.:	68118/120615

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:	115761
Product name:	Pentamox Mineralised Oral Drench for Sheep
Active constituent/s:	2.1 g/L copper (as disodium copper EDTA), 1.0 g/L moxidectin, 1.0 g/L iodine (as ethylenediamine dihydroiodide), 0.6 g/L zinc (as disodium zinc EDTA), 0.5 g/L selenium (as sodium selenate), 0.2 g/L cobalt (as disodium cobalt EDTA)
Applicant name:	Jurox Pty Limited
Applicant ACN:	000 932 230
Summary of use:	For the treatment and control of moxidectin sensitive gastrointestinal parasites (including benzimidazole and/or levamisole resistant strains), lungworms and itch mites. As an aid in the control of selenium responsive conditions and to supplement diets that may be deficient in selenium, cobalt, copper, zinc and iodine
Date of registration:	12 June 2019
Product registration no.:	86433
Label approval no.:	86433/115761
Application no:	116033
Product name:	U-Seal
Active constituent/s:	650 mg/g bismuth subnitrate
Applicant name:	Jurox Pty Limited
Applicant ACN:	000 932 230
Summary of use:	For use in cows during the non-lactating (dry) period and early post-calving to prevent clinical and subclinical mastitis
Date of registration:	13 June 2019
Product registration no.:	86556
Label approval no.:	86556/116033
Application no:	117715
Product name:	Acesedate 2 mg/mL Injection
Active constituent/s:	2.7 mg/mL acepromazine maleate (equivalent to 2.0 mg/mL acepromazine)
Applicant name:	Jurox Pty Limited
Applicant ACN:	000 932 230
Summary of use:	For anaesthetic premedication, tranquilliser and travel sickness for use in dogs and cats
Date of registration:	21 June 2019
Product registration no.:	87183
Label approval no.:	87183/117715

Application no:	120234
Product name:	Aristopet Animal Health Fleas, Heartworm And Worms For Dogs 10-25Kg
Active constituent/s:	100 g/L imidacloprid, 25 g/L moxidectin
Applicant name:	Shanghai Neway Animal Health Co Ltd
Applicant ACN:	N/A
Summary of use:	For the treatment and prevention of fleas, prevention of heartworm infection and the treatment and control of roundworms, hookworms, whipworm, sarcoptic mange, ear mites and lice for puppies and dogs
Date of registration:	21 June 2019
Product registration no.:	88085
Label approval no.:	88085/120234
Application no:	120218
Product name:	Aristopet Animal Health Fleas, Heartworm And Worms For Dogs Over 25Kg
Active constituent/s:	100 g/L imidacloprid, 25 g/L moxidectin
Applicant name:	Shanghai Neway Animal Health Co Ltd
Applicant ACN:	N/A
Summary of use:	For the treatment and prevention of fleas, prevention of heartworm infection and the treatment and control of roundworms, hookworms, whipworm, sarcoptic mange, ear mites and lice for puppies and dogs
Date of registration:	21 June 2019
Product registration no.:	88078
Label approval no.:	88078/120218
Application no:	120236
Product name:	Aristopet Animal Health Fleas, Heartworm And Worms For Puppies And Small Dogs Up To 4Kg
Active constituent/s:	100g/L imidacloprid, 25g/L moxidectin
Applicant name:	Shanghai Neway Animal Health Co Ltd
Applicant ACN:	N/A
Summary of use:	For the treatment and prevention of fleas, prevention of heartworm infection and the treatment and control of roundworms, hookworms, whipworm, sarcoptic mange, ear mites and lice for puppies and dogs
Date of registration:	21 June 2019
Product registration no.:	88087
Label approval no.:	88087/120236
Application no:	120235
Product name:	Aristopet Animal Health Fleas, Heartworm And Worms For Dogs 4-10Kg
Active constituent/s:	100 g/L imidacloprid, 25 g/L moxidectin
Applicant name:	Shanghai Neway Animal Health Co Ltd
Applicant ACN:	N/A
Summary of use:	For the treatment and prevention of fleas, prevention of heartworm infection and the treatment and control of roundworms, hookworms, whipworm, sarcoptic mange, ear mites and lice for puppies and dogs
Date of registration:	21 June 2019
Product registration no.:	88086
Label approval no.:	88086/120235

Application no:	119142
Product name:	Independents Own Abastar Ultra Pour-on Roundworm, Liver Fluke & External Parasiticide For Cattle
Active constituent/s:	300 mg/mL triclabendazole, 5 mg/mL abamectin
Applicant name:	Vetpharm Pty Limited
Applicant ACN:	629 894 086
Summary of use:	For the treatment and control of roundworms, liver fluke and external parasites of beef cattle
Date of registration:	21 June 2019
Product registration no.:	87742
Label approval no.:	87742/119142

2. VARIATIONS OF REGISTRATION

Application no:	119940
Product name:	Closicare Plus Selenium Sustained Action Oral Anthelmintic And Flukicide For Sheep
Active constituent/s:	37.5 g/L closantel, 1.2 g/L sodium selenate (equivalent to 0.5 g/L selenium)
Applicant name:	Virbac (Australia) Pty Ltd
Applicant ACN:	003 268 871
Summary of variation:	To vary the product registration and label approval to add Export Slaughter Interval (ESI) and update the relevant label particulars in accordance with the current Veterinary Labelling Code
Date of variation:	13 June 2019
Product registration no.:	50323
Label approval no.:	50323/119940

Application no:	118445
Product name:	Calefur Sterile Powder For Injection
Active constituent/s:	50 mg/mL ceftiofur (as ceftiofur sodium), when reconstituted as directed
Applicant name:	Dechra Veterinary Products (Australia) Pty Ltd
Applicant ACN:	614 716 700
Summary of variation:	To vary the storage conditions and align the label with the Veterinary labelling Code
Date of variation:	14 June 2019
Product registration no.:	62682
Label approval no.:	62682/118445

Application no:	120596
Product name:	HRC Uranus Sheep Blowfly Treatment
Active constituent/s:	500 g/L cyromazine
Applicant name:	The Hunter River Company Pty Limited
Applicant ACN:	133 798 615
Summary of variation:	To change the distinguishing product name and the name that appears on the label from 'Independents Own Venus Sheep Blowfly Treatment' to 'HRC Uranus Sheep Blowfly Treatment'
Date of variation:	12 June 2019
Product registration no.:	66589
Label approval no.:	66589/120596

Application no:	120594
Product name:	HRC Uranus Spray-On Sheep Blowfly Treatment
Active constituent/s:	60 g/L cyromazine
Applicant name:	The Hunter River Company Pty Limited
Applicant ACN:	133 798 615
Summary of variation:	To change the distinguishing product name and the name that appears on the label from 'Independents Own Venus Spray-On Sheep Blowfly Treatment' to 'HRC Uranus Spray-On Sheep Blowfly Treatment'
Date of variation:	12 June 2019
Product registration no.:	65089
Label approval no.:	65089/120594
Application no:	120145
Product name:	Cydectin Pour-On For Cattle And Red Deer
Active constituent/s:	5 g/L moxidectin
Applicant name:	Virbac (Australia) Pty Ltd
Applicant ACN:	003 268 871
Summary of variation:	To vary the product registration and label approval to add Export Slaughter Interval (ESI) and update the relevant label particulars in accordance with the current Veterinary Labelling Code
Date of variation:	18 June 2019
Product registration no.:	45970
Label approval no.:	45970/120145

Approved Active Constituents

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

1. ACTIVE CONSTITUENT

Application no.:	110153
Active constituent/s:	mefentrifluconazole
Applicant name:	BASF Australia Ltd
Applicant ACN:	008 437 867
Summary of use:	For use in agricultural chemical products
Date of approval:	11 June 2019
Approval no.:	84342

Application no.:	118113
Active constituent/s:	spirotramat
Applicant name:	Imtrade Australia Pty Ltd
Applicant ACN:	090 151 134
Summary of use:	For use in agricultural chemical products
Date of approval:	12 June 2019
Approval no.:	87328

Application no.:	116526
Active constituent/s:	mefenpyr-diethyl
Applicant name:	Jiangsu Agrochem Laboratory Co Ltd
Applicant ACN:	N/A
Summary of use:	For use in agricultural chemical products
Date of approval:	12 June 2019
Approval no.:	86766

Application no.:	107911
Active constituent/s:	Bacillus Amyloliquefaciens MBI 600
Applicant name:	BASF Australia Ltd
Applicant ACN:	008 437 867
Summary of use:	For use in agricultural chemical products
Date of approval:	12 June 2019
Approval no.:	83292

Application no.:	118380
Active constituent/s:	hexythiazox
Applicant name:	Shandong Binnong Technology Co Ltd
Applicant ACN:	N/A
Summary of use:	For use in agricultural chemical products
Date of approval:	12 June 2019
Approval no.:	87449

Application no.:	118340
Active constituent/s:	prothioconazole
Applicant name:	Zhejiang Zhongshan Chemical Industry Group Co Ltd
Applicant ACN:	N/A
Summary of use:	For use in agricultural chemical products
Date of approval:	12 June 2019
Approval no.:	87429

Application no.:	115159
Active constituent/s:	topramezone
Applicant name:	BASF Australia Ltd
Applicant ACN:	008 437 867
Summary of use:	For use in agricultural chemical products
Date of approval:	18 June 2019
Approval no.:	86266

Application no.:	117252
Active constituent/s:	trinexapac-ethyl
Applicant name:	Max (Rudong) Chemicals Co Ltd
Applicant ACN:	N/A
Summary of use:	For use in agricultural chemical products
Date of approval:	20 June 2019
Approval no.:	86993

Application no.:	117016
Active constituent/s:	imazamox
Applicant name:	Adama Australia Pty Limited
Applicant ACN:	050 328 973
Summary of use:	For use in agricultural chemical products
Date of approval:	21 June 2019
Approval no.:	86912

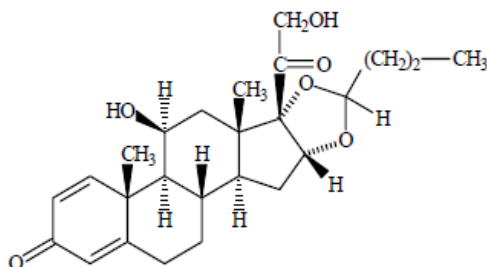
New Active Constituent and New Chemical Products **DERMCARE BARAZONE 0.25 g/L BUDESONIDE LEAVE-ON CONDITIONER** and **DERMCARE BARAZONE 0.125 G/L BUDESONIDE LEAVE-ON CONDITIONER** containing **BUDESONIDE**

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application for the approval of a new active constituent, BUDESONIDE, and applications for registration of two new products containing the new active constituent. The products are **DERMCARE BARAZONE 0.25 G/L BUDESONIDE LEAVE-ON CONDITIONER** and **DERMCARE BARAZONE 0.125 G/L BUDESONIDE LEAVE-ON CONDITIONER** for use in topically applied symptomatic treatments of canine atopic dermatitis, contact allergy and other pruritic conditions in dogs.

PARTICULARS OF THE ACTIVE CONSTITUENT

Common name:	Budesonide
IUPAC Name:	(1S,2S,4R,8S,9S,11S,12S,13R)-11-hydroxy-8-(2-hydroxyacetyl)-9,13-dimethyl-6-propyl-5,7-dioxapentacyclo[10.8.0.0.2,9.0.4,8.0.13,18]icosa-14,17-dien-16-one
Chemical Abstracts Name:	16, 17-(butylidenebis(oxy))-11,21-dihydroxy-(11 β , 16 α)-pregna-1,4-diene-3,20-dione
CAS Number:	51333-22-3
Molecular Formula:	C ₂₅ H ₃₄ O ₆
Molecular Weight:	430.53

Structure:



Chemical family: Synthetic, non-halogenated corticosteroid

Mode of Action: Anti-inflammatory corticosteroid that exhibits potent glucocorticoid activity

SUMMARY OF THE APVMA'S EVALUATION

The APVMA has evaluated the chemistry aspects of budesonide (manufacturing process, quality control procedures, batch analysis results and analytical methods) and found them to be acceptable. The active budesonide is manufactured to the standard of the European Pharmacopoeia (Ph.Eur.) monograph.

Impurities of toxicological significance are not expected to occur in budesonide as a result of the raw materials and the synthetic route used.

The APVMA has considered the toxicological aspects of budesonide and concluded that there are no toxicological concerns regarding the approval of this active constituent. Since budesonide is not being proposed for use in food producing animals but for use in companion animals only, neither an Acceptable Daily Intake (ADI) nor an Acute Reference Dose (ARfD) has been established.

Budesonide is currently scheduled as a prescription only medicine (Schedule 4) of the Australian Standard for Uniform Scheduling of Medicines and Poisons (SUSMP) as a result of its use in prescription medicines for human use.

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

PARTICULARS OF THE PRODUCTS

Proposed product name(s):	DERMCARE BARAZONE 0.25 G/L BUDESONIDE LEAVE-ON CONDITIONER DERMCARE BARAZONE 0.125 G/L BUDESONIDE LEAVE-ON CONDITIONER
Applicant company:	DERMCARE-VET PTY. LTD
Name of active constituent:	BUDESONIDE
Signal heading:	Schedule 4
Summary of proposed use:	For the symptomatic treatment of Canine Atopic Dermatitis, contact allergy and other pruritic conditions of the dog.
Pack sizes:	100 mL
Withholding period:	n/a

SUMMARY OF THE APVMA'S EVALUATION OF DERM CARE BARAZONE 0.25 G/L BUDESONIDE LEAVE-ON CONDITIONER AND DERM CARE BARAZONE 0.125 G/L BUDESONIDE LEAVE-ON CONDITIONER IN ACCORDANCE WITH THE REQUIREMENTS OF SECTION 14(1)(C) 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 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 and use.

As noted above budesonide is currently listed in Schedule 4 of the SUSMP. The APVMA has conducted a risk assessment on the products and concluded that they can be used safely.

The APVMA assessment estimated the acute toxicity of the products based on the results of toxicology studies. The toxicological effects of budesonide are typical for a corticosteroid. Further, clinical safety data for both orally- and inhalationally-administered budesonide reveal that rates of reported corticosteroid-related side effects for budesonide were not significantly different from those reported for placebo. Thus, exposure to the products, would not be expected to result in any serious adverse effects.

Dermal toxicity in studies employing topical administration were consistent with dermal absorption. To mitigate the acute and repeat-dose risks associated with the products the following First Aid instruction will be included on the product label—*If poisoning occurs, contact a doctor or Poisons Information Centre. Phone Australia 13 11 26.*

In view of the risk of oral and dermal exposure and given that budesonide is dermally absorbed and has characteristic glucocorticoid effects the following Safety Directions will appear on the label—*'May irritate eyes. Avoid contact with eyes. Repeated exposure may cause allergic disorder. When using the product wear disposable gloves. Wash hands after use.'*

- (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 its residues.

The products are for topical use in dogs only. As dogs are not considered to be food producing animals, and do not produce any commodity that is traded outside of Australia, no assessment of the residues aspects of the safety criteria or the trade criteria is required.

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

As discussed above budesonide is currently listed in Schedule 4 of the SUSMP and the APVMA has reviewed toxicological studies and clinical safety data for the products. The APVMA has concluded that the product can be safely used and has required product labelling in relation to First Aid and Safety Directions for persons handling and using the products.

- (iv) The APVMA is satisfied that the proposed use of the products containing the active constituent BUDESONIDE, would not be likely to have an unintended effect that is harmful to animals, plants or things or the environment.

The APVMA has conducted a risk assessment to consider the environmental safety of the products. The standard environmental release scenario for treatment of dogs was considered through a VICH Phase 1 assessment. These products will only be used in non-food producing animals. Hence, it satisfies the requirements of VICH phase 1. The APVMA is therefore satisfied that the proposed products meet the environmental safety criteria.

The label will contain the following disposal statement: *'Dispose of empty container by wrapping with paper and putting in garbage'*.

The assessment of target animal safety of the products was considered in (i) two randomised parallel design multicentre clinical trials, (ii) a peer reviewed manuscript describing a randomised cross-over multicentre clinical trial, (iii) one pilot safety study, (iv) one final target animal safety study and (v) a report comprising of a case series (evaluated retrospectively).

In the efficacy and target animal safety report provided by the applicant it is reported that systemic side effects are minimal and not clinically detectable at up to three times the maximum clinical use dose rate.

The assessment demonstrated that the products are well tolerated in the target species. From the results of animal toxicology studies it would appear that all the toxicological effects of budesonide are typical for a corticosteroid. There are sufficient instructions and warning signs on the label in this regard.

Appropriate contraindication statements relating to the use in dogs in whom the use of corticosteroids may be contraindicated will be included on the label. Appropriate precaution statements will be added to the label regarding their use when there are complicating factors such as secondary infections, which should to be treated with appropriate antimicrobials. Also, the precaution will be included on the label that the data for use of these products in stud dogs and pregnant or lactating bitches is limited and that the use in these animals should be based on a risk benefit analysis by the prescribing veterinarian.

The APVMA is satisfied that the products would not have an unintended effect that is harmful to the target animals (dogs) when used according to the label instructions.

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, the APVMA is satisfied that data from trials provided adequately demonstrate that if used according to the product label directions, the product is effective for its proposed use.

The products are intended for use in dogs for the symptomatic treatment of Canine Atopic Dermatitis, contact allergy and other pruritic conditions. The products are formulated as a cream to be applied topically up to a maximum dose rate of 0.25mg ai/kg bw once weekly.

The efficacy studies included (i) two randomised parallel design multicentre clinical trials, (ii) a peer reviewed manuscript describing a randomised cross-over multicentre clinical trial, (iii) a report comprising of a case series, and (iv) reviewed literature.

A double blinded placebo controlled multicentre clinical field study assessing dose response of 0.0125% budesonide vs 0.025% budesonide in a topical leave-in conditioner. This was a multicentre (3 sites) prospective randomized blinded, placebo controlled, clinical efficacy and tolerance study of six weeks duration. The other multicentre randomized controlled blinded trial compared oral cyclosporine to the product for the control of atopy in dogs. This was a multi-site prospective randomized blinded, clinical efficacy and tolerance study, stated to be a positive controlled trial spread over nineteen months duration. The APVMA's assessment concluded that the recommended weekly maximum application rate of 0.25 mg ai/kg bw/week for up to 6 weeks is supportive of efficacy.

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.

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 the active constituent BUDESONIDE should be approved and the products registered. Submissions should relate only to matters that are required by the APVMA to be taken into consideration in determining whether the safety, efficacy or trade criteria set out in sections 5A, 5B and 5C of the Agvet Code have been met. Submissions should state the grounds on which they are based.

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

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) material contained in submissions will be treated confidentially.

Written submissions 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 6770 2300

Email: enquiries@apvma.gov.au.