Commonwealth of Australia Gazette

No. APVMA 8, Tuesday, 24 April 2018

Published by The Australian Pesticides and Veterinary Medicines Authority

AGRICULTURAL AND VETERINARY CHEMICALS

Australian Government

Australian Pesticides and Veterinary Medicines Authority

The *Agricultural and Veterinary Chemical Code Act 1994* (the Act) commenced on 15 March 1995. The Agricultural and Veterinary Chemicals Code (the Agvet Code) scheduled to the Act requires notices to be published in the *Gazette* containing details of the registration of agricultural and veterinary chemical products and other approvals granted by the Australian Pesticides and Veterinary Medicines Authority. The Agvet Code and related legislation also requires certain other notices to be published in the *Gazette*. A reference to Agvet Codes in this publication is a reference to the Agvet Code in each state and territory jurisdiction.

ISSN 1837 - 7629

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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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Agricultural Chemical Products and Approved Labels

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

1. AGRICULTURAL PRODUCTS BASED ON EXISTING ACTIVE CONSTITUENTS

Application no.:	114570
Product name:	Puraway Black Spot Remover for Pools
Active constituent/s:	900 g/kg available chlorine (Cl) present as trichloroisocyanuric acid
Applicant name:	Bundalo Pty Ltd
Applicant ACN:	010 347 314
Summary of use:	For killing blackspot in swimming pools
Date of registration:	3 April 2018
Product registration no.:	86056
Label approval no.:	86056/114570

Application no.:	111097
Product name:	Scotts Lawn Builder, Bindii, Clover & Broadleaf, Kills And Prevents
Active constituent/s:	8.7 g/L bromoxynil present as the potassium salt, 8.7 g/L MCPA present as the potassium salt
Applicant name:	Scotts Australia Pty Limited
Applicant ACN:	003 123 162
Summary of use:	For selective control of broadleaf weeds in domestic lawns
Date of registration:	3 April 2018
Product registration no.:	84676
Label approval no.:	84676/111097

Application no.:	114815
Product name:	EmuAg 2,4-D 625 Selective Herbicide
Active constituent/s:	625 g/L 2,4-D present as the dimethylamine and diethanolamine salts
Applicant name:	EmuAg Pty Ltd
Applicant ACN:	620 374 307
Summary of use:	For use as a selective herbicide 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
Date of registration:	3 April 2018
Product registration no.:	86157
Label approval no.:	86157/114815

Application no.:	109776
Product name:	Hovex Outback Mosquito Citronella Oil With Eucalyptus
Active constituent/s:	18 g/L citronella oil, 800 mg/L bifenthrin
Applicant name:	Pascoe's Pty Ltd
Applicant ACN:	055 220 463
Summary of use:	To kill and repel adult mosquitoes in and around the home and garden
Date of registration:	4 April 2018
Product registration no.:	84140
Label approval no.:	84140/109776

Application no.:	109775
Product name:	Hovex Outback Mosquito Citronella Oil With Sandalwood
Active constituent/s:	18 g/L citronella oil, 800 mg/L bifenthrin
Applicant name:	Pascoe's Pty Ltd
Applicant ACN:	055 220 463
Summary of use:	To kill and repel adult mosquitoes in and around the home and garden
Date of registration:	4 April 2018
Product registration no.:	84139
Label approval no.:	84139/109775

Application no.:	109606
Product name:	Imtrade Bolta Duo Herbicide
Active constituent/s:	250 g/L trifluralin, 670 g/L prosulfocarb
Applicant name:	Imtrade Australia Pty Ltd
Applicant ACN:	090 151 134
Summary of use:	For the pre-emergent control of annual ryegrass, silver grass and wireweed, and the suppression of barley grass in barley and wheat
Date of registration:	4 April 2018
Product registration no.:	84061
Label approval no.:	84061/109606

Application no.:	114614
Product name:	Amtrade Ammonium Sulphate Spray Adjuvant
Active constituent/s:	980 g/kg ammonium sulfate
Applicant name:	Amtrade International Pty Ltd
Applicant ACN:	006 409 936
Summary of use:	To be used with glyphosate-based herbicides to minimise antagonism when tank mixing with flowable herbicides and to improve performance under adverse environmental conditions
Date of registration:	4 April 2018
Product registration no.:	86082
Label approval no.:	86082/114614

Application no.:	109053
Product name:	Rainquat Full Herbicide
Active constituent/s:	360 g/L paraquat present as paraquat dichloride
Applicant name:	Shandong Rainbow International Co Ltd
Applicant ACN:	N/A
Summary of use:	For control of a wide range of grasses and broadleaf weeds
Date of registration:	9 April 2018
Product registration no.:	83835
Label approval no.:	83835/109053

Application no.:	114098
Product name:	Agrevo Trifluralin 480EC Herbicide
Active constituent/s:	480 g/L trifluralin
Applicant name:	Agrevo Australia Pty Ltd
Applicant ACN:	618 606 161
Summary of use:	For the control of annual grasses and certain broadleaf weeds in certain horticultural and agricultural crops
Date of registration:	9 April 2018
Product registration no.:	85810
Label approval no.:	85810/114098

Application no.:	114814
Product name:	EmuAg 2,4-D 680EC Herbicide
Active constituent/s:	680 g/L 2,4-D present as the 2-ethylhexyl ester
Applicant name:	EmuAg Pty Ltd
Applicant ACN:	620 374 307
Summary of use:	For selective control of various weeds in crops, pastures and non-agricultural areas
Date of registration:	9 April 2018
Product registration no.:	86156
Label approval no.:	86156/114814

Application no.:	114599
Product name:	AgProtect Propiconazole 250 EC Fungicide
Active constituent/s:	250 g/L propiconazole
Applicant name:	Agprotect Australasia Pty Ltd
Applicant ACN:	621 073 023
Summary of use:	For the control of certain fungal diseases in bananas, oats, peanuts, perennial ryegrass, pineapples, stone fruit, sugarcane, wheat and other crops
Date of registration:	9 April 2018
Product registration no.:	86076
Label approval no.:	86076/114599

Application no.:	107663
Product name:	Kingstar Fungicide
Active constituent/s:	600 g/kg azoxystrobin, 240 g/kg cyproconazole
Applicant name:	Shandong Rainbow International Co Ltd
Applicant ACN:	N/A
Summary of use:	For control of certain fungal diseases in barley and wheat
Date of registration:	9 April 2018
Product registration no.:	83161
Label approval no.:	83161/107663

Application no.:	111478
Product name:	Farmalinx Sucker Insecticide
Active constituent/s:	200 g/L clothianidin
Applicant name:	Farmalinx Pty Ltd
Applicant ACN:	134 353 245
Summary of use:	For the control of leaf eating insects in eucalypt seedlings and young trees
Date of registration:	10 April 2018
Product registration no.:	84811
Label approval no.:	84811/111478

Application no.:	114590
Product name:	Puraway AlgiProtect Pool Algaecide
Active constituent/s:	32 g/L copper present as copper triethanolamine complex
Applicant name:	Bundalo Pty Ltd
Applicant ACN:	010 347 314
Summary of use:	For killing and controlling black and green algae in swimming pools
Date of registration:	11 April 2018
Product registration no.:	86069
Label approval no.:	86069/114590

Application no.:	114591
Product name:	Puraway PolyClear Pool Algaecide
Active constituent/s:	285 g/L 1,2-ethanediamine polymer with (chloromethyl)-oxirane and n-methylmethanamine
Applicant name:	Bundalo Pty Ltd
Applicant ACN:	010 347 314
Summary of use:	For eradication of blue-green and black algae in swimming pools, fountains and ornamental ponds
Date of registration:	11 April 2018
Product registration no.:	86070
Label approval no.:	86070/114591

Application no.:	114569
Product name:	Puraway AlgiClear Pool Algaecide
Active constituent/s:	200 g/L benzalkonium chloride
Applicant name:	Bundalo Pty Ltd
Applicant ACN:	010 347 314
Summary of use:	For the control of algae in swimming pools
Date of registration:	11 April 2018
Product registration no.:	86055
Label approval no.:	86055/114569

Application no.:	114320
Product name:	Sharda Chlorothalonil 720 Fungicide
Active constituent/s:	720 g/L chlorothalonil
Applicant name:	Sharda Cropchem Espana SL
Applicant ACN:	N/A
Summary of use:	For the control of fungal diseases on almonds, bananas, cucurbits, grapes, ornamentals, peanuts, stone fruit, tobacco and vegetables
Date of registration:	12 April 2018
Product registration no.:	85978
Label approval no.:	85978/114320

Application no.:	108225
Product name:	International Biolux New Technology Ultra 2 High Strength Hard Antifouling
Active constituent/s:	Dover White 60 g/L zineb, 586 g/L copper present as cuprous oxide Red 60 g/L zineb, 551 g/L copper present as cuprous oxide Blue 60 g/L zineb, 558 g/L copper present as cuprous oxide Navy 58 g/L zineb, 542 g/L copper present as cuprous oxide Black 60 g/L zineb, 551 g/L copper present as cuprous oxide Green 60 g/L zineb, 557 g/L copper present as cuprous oxide Dark Grey 61 g/L zineb, 557 g/L copper present as cuprous oxide
Applicant name:	Akzo Nobel Pty Limited
Applicant ACN:	000 119 424
Summary of use:	For use below the waterline on vessels to prevent marine growth
Date of registration:	12 April 2018
Product registration no.:	83417
Label approval no.:	83417/108225

Application no.:	108501
Product name:	Genfarm Iodosulfuron 100 Selective Herbicide
Active constituent/s:	100 g/L iodosulfuron-methyl-sodium, 300 g/L mefenpyr-diethyl
Applicant name:	Landmark Operations Limited
Applicant ACN:	008 743 217
Summary of use:	For the control of annual ryegrass, wild oats and phalaris in wheat and barley, and certain broadleaf weeds in wheat
Date of registration:	12 April 2018
Product registration no.:	83502
Label approval no.:	83502/108501

Application no.:	114055
Product name:	Sharda Metsulfuron 600 Herbicide
Active constituent/s:	600 g/kg metsulfuron-methyl
Applicant name:	Sharda Cropchem Espana SL
Applicant ACN:	N/A
Summary of use:	For control of certain brush and broadleaf species in native pastures, rights of way and commercial and industrial areas, and for the control of certain broadleaf weeds in winter cereal crops, grass pastures and pasture renovation
Date of registration:	12 April 2018
Product registration no.:	85781
Label approval no.:	85781/114055

Application no.:	111884
Product name:	Accensi Cypermethrin 25 ULV Duo Insecticide
Active constituent/s:	25 g/L cypermethrin
Applicant name:	Accensi Pty Ltd
Applicant ACN:	079 875 184
Summary of use:	For the control of adult mosquitoes, biting midges, flies and cockroaches
Date of registration:	13 April 2018
Product registration no.:	84949
Label approval no.:	84949/111884

Application no.:	110251
Product name:	BioSmarte Clothes Moth Pheromone Glue Trap
Active constituent/s:	0.2 g/kg koiginal I and koiginal II
Applicant name:	Smartec Solutions Ltd
Applicant ACN:	N/A
Summary of use:	To protect clothes and furnishings from moth damage
Date of registration:	13 April 2018
Product registration no.:	84372
Label approval no.:	84372/110251

Application no.:	114954
Product name:	EuroChem Feathertop 520 Herbicide
Active constituent/s:	520 g/L haloxyfop present as the haloxyfop-r methyl ester
Applicant name:	Ronic International Pty Limited
Applicant ACN:	101 193 131
Summary of use:	For the post-emergent control of a wide range of annual and perennial grass weeds in grain legume and oilseed crops, lucerne, medic, clover pasture and seed crops, forestry, bananas, citrus, grapes, pineapples, pome and stone fruit, pyrethrum, tropical fruit and nut crops
Date of registration:	13 April 2018
Product registration no.:	86193
Label approval no.:	86193/114954

Application no.:	109719
Product name:	Yates Weedkiller
Active constituent/s:	1.2 g/L glufosinate-ammonium
Applicant name:	Duluxgroup (Australia) Pty Ltd
Applicant ACN:	000 049 427
Summary of use:	For non-residual control of broadleaf and grass weeds in pathways, garden beds, rockeries, driveways and along fences
Date of registration	17 April 2018
Product registration no.:	84105
Label approval no.:	84105/109719

2. VARIATIONS OF REGISTRATION

Application no.:	114744
Product name:	Avatar Insecticide
Active constituent/s:	300 g/kg indoxacarb
Applicant name:	FMC Australasia Pty Ltd
Applicant ACN:	095 326 891
Summary of variation:	To change the distinguishing product name and the name that appears on the label from 'DUPONT AVATAR INSECTICIDE' to 'AVATAR INSECTICIDE'
Date of variation:	20 February 2018
Product registration no.:	52546
Label approval no.:	52546/114744

Application no.:	115005
Product name:	Dinon 700 WG Fungicide
Active constituent/s:	700 g/kg dithianon
Applicant name:	Grochem Australia Pty Ltd
Applicant ACN:	169 400 033
Summary of variation:	To change the distinguishing product name and the name that appears on the label from 'MELPAT DINON 700 WG FUNGICIDE' to 'DINON 700 WG FUNGICIDE'
Date of variation:	13 March 2018
Product registration no.:	80823
Label approval no.:	80823/115005

Application no.:	115009
Product name:	Accensi Diuron 900 WG Herbicide
Active constituent/s:	900 g/kg diuron
Applicant name:	Accensi Pty Ltd
Applicant ACN:	079 875 184
Summary of variation:	To change the distinguishing product name and the name that appears on the label from 'COUNTRY DIURON 900 WG HERBICIDE' to 'ACCENSI DIURON 900 WG HERBICIDE'
Date of variation:	13 March 2018
Product registration no.:	55094
Label approval no.:	55094/115009

Application no.:	115069
Product name:	Sinon S-Metol 960 EC Herbicide
Active constituent/s:	960 g/L s-metolachlor
Applicant name:	Sinon Australia Pty Limited
Applicant ACN:	102 741 024
Summary of variation:	To change the distinguishing product name and the name that appears on the label from 'SINON S-METO 960 EC HERBICIDE' to 'SINON S-METOL 960 EC HERBICIDE'
Date of variation:	19 March 2018
Product registration no.:	85088
Label approval no.:	85088/115069

Application no.:	115071
Product name:	Mortein Powergard Multi Insect Killer
Active constituent/s:	0.7 g/kg imiprothrin, 1 g/kg esbiothrin, 0.3 g/kg permethrin
Applicant name:	Reckitt Benckiser (Australia) Pty Limited
Applicant ACN:	003 274 655
Summary of variation:	To change the distinguishing product name and the name that appears on the label from 'MORTEIN HOME EXPERT MULTI INSECT KILLER' to 'MORTEIN POWERGARD MULTI INSECT KILLER'
Date of variation:	19 March 2018
Product registration no.:	83812
Label approval no.:	83812/115071

Application no.:	115078
Product name:	Pheroklip CM Pheromone Mating Disruption Agent
Active constituent/s:	39.6 g/400 dispensers (E,E) 8,10 dodecadien-1-ol, 21.4 g/400 dispensers dodecanol, 5.8 g/400 dispensers tetradecanol
Applicant name:	Smartgreen Bioscience Pty Ltd
Applicant ACN:	010 834 125
Summary of variation:	To change the distinguishing product name and the name that appears on the label from 'KLIPI CM PHEROMONE MATING DISRUPTION AGENT' to 'PHEROKLIP CM PHEROMONE MATING DISRUPTION AGENT'
Date of variation:	20 March 2018
Product registration no.:	83943
Label approval no.:	83943/115078

Application no.:	115079
Product name:	Pheroklip OFM Pheromone Mating Disruption Agent
Active constituent/s:	44.6 g/200 dispensers Z,8 dodecenyl acetate, 2.9 g/200 dispensers E,8 dodecenyl acetate, 0.5 g/200 dispensers Z,8 dodecenol
Applicant name:	Smartgreen Bioscience Pty Ltd
Applicant ACN:	010 834 125
Summary of variation:	To change the distinguishing product name and the name that appears on the label from 'KLIPI OFM PHEROMONE MATING DISRUPTION AGENT' to 'PHEROKLIP OFM PHEROMONE MATING DISRUPTION AGENT'
Date of variation:	20 March 2018
Product registration no.:	83890
Label approval no.:	83890/115079

Application no.:	115083
Product name:	Benevia Insecticide
Active constituent/s:	100 g/L cyantraniliprole
Applicant name:	FMC Australasia Pty Ltd
Applicant ACN:	095 326 891
Summary of variation:	To change the distinguishing product name and the name that appears on the label from 'DUPONT BENEVIA INSECTICIDE' to 'BENEVIA INSECTICIDE'
Date of variation:	21 March 2018
Product registration no.:	66684
Label approval no.:	66684/115083

Application no.:	115092
Product name:	Raid Max Crawling Insect Killer
Active constituent/s:	1.0 g/kg imiprothrin, 0.5 g/kg deltamethrin
Applicant name:	S.C. Johnson & Son Pty Ltd
Applicant ACN:	000 021 009
Summary of variation:	To change the distinguishing product name and the name that appears on the label from 'RAID MAX COCKROACH KILLER SURFACE SPRAY' to 'RAID MAX CRAWLING INSECT KILLER'
Date of variation:	21 March 2018
Product registration no.:	68425
Label approval no.:	68425/115092

Application no.:	115095
Product name:	Raid Max Cockroach Baits
Active constituent/s:	9.5 g/kg indoxacarb
Applicant name:	S.C. Johnson & Son Pty Ltd
Applicant ACN:	000 021 009
Summary of variation:	To change the distinguishing product name and the name that appears on the label from 'RAID COCKROACH BAITS' to 'RAID MAX COCKROACH BAITS'
Date of variation:	21 March 2018
Product registration no.:	61513
Label approval no.:	61513/115095

Application no.:	115099
Product name:	Raid Max Fly & Mosquito Protection Plug-In
Active constituent/s:	134 g/kg transfluthrin
Applicant name:	S.C. Johnson & Son Pty Ltd
Applicant ACN:	000 021 009
Summary of variation:	To change the distinguishing product name and the name that appears on the label from 'RAID NIGHT & DAY PLUG-IN FLY & MOSQUITO PROTECTION' to 'RAID MAX FLY & MOSQUITO PROTECTION PLUG-IN'
Date of variation:	22 March 2018
Product registration no.:	62356
Label approval no.:	62356/115099

Application no.:	115103
Product name:	Raid Max Outdoor Surface Spray
Active constituent/s:	0.5 g/L bifenthrin
Applicant name:	S.C. Johnson & Son Pty Ltd
Applicant ACN:	000 021 009
Summary of variation:	To change the distinguishing product name and the name that appears on the label from 'RAID TESTED BY EXPERTS OUTDOOR HOME SURFACE SPRAY' to 'RAID MAX OUTDOOR SURFACE SPRAY'
Date of variation:	22 March 2018
Product registration no.:	65105
Label approval no.:	65105/115103

Application no.:	115136
Product name:	Harrier 700 WG Herbicide
Active constituent/s:	700 g/kg imazamox
Applicant name:	FMC Australasia Pty Ltd
Applicant ACN:	095 326 891
Summary of variation:	To change the distinguishing product name and the name that appears on the label from 'FMC HARRIER 700 WG HERBICIDE' to 'HARRIER 700 WG HERBICIDE'
Date of variation:	26 March 2018
Product registration no.:	69719
Label approval no.:	69719/115136

Application no.:	115161
Product name:	Peregrine Insecticide
Active constituent/s:	240 g/L methoxyfenozide
Applicant name:	Grochem Australia Pty Ltd
Applicant ACN:	169 400 033
Summary of variation:	To change the distinguishing product name and the name that appears on the label from 'PEREGRINE AGRICULTURAL INSECTICIDE' to 'PEREGRINE INSECTICIDE'
Date of variation:	27 March 2018
Product registration no.:	84525
Label approval no.:	84525/115161

Application no.:	115202
Product name:	Mortein Powergard The Expert's Ant Baits
Active constituent/s:	1 g/kg indoxacarb
Applicant name:	Reckitt Benckiser (Australia) Pty Limited
Applicant ACN:	003 274 655
Summary of variation:	To change the distinguishing product name and the name that appears on the label from 'MORTEIN HOME EXPERT ANT BAITS' to 'MORTEIN POWERGARD THE EXPERT'S ANT BAITS'
Date of variation:	29 March 2018
Product registration no.:	69901
Label approval no.:	69901/115202

Application no.:	115211
Product name:	Conquest Preceed Herbicide
Active constituent/s:	800 g/L prosulfocarb
Applicant name:	Conquest Crop Protection Pty Ltd
Applicant ACN:	098 814 932
Summary of variation:	To change the distinguishing product name and the name that appears on the label from 'CONQUEST PRESEED HERBICIDE' to 'CONQUEST PRECEED HERBICIDE'
Date of variation:	3 April 2018
Product registration no.:	82413
Label approval no.:	82413/115211

Application no.:	112813
Product name:	Determite 100 Glue Line Insecticide
Active constituent/s:	100 g/L bifenthrin
Applicant name:	Koppers Performance Chemicals Australia Pty Ltd
Applicant ACN:	088 260 575
Summary of variation:	To extend use to include protection against termites (excluding *Mastotermes darwiniensis*) in the treatment of not thicker than 4.8 mm hardwood veneer in plywood and laminated veneer lumber (LVL) in hazard class H2 for all areas south of the Tropic of Capricorn
Date of variation:	3 April 2018
Product registration no.:	83996
Label approval no.:	83996/112813

Application no.:	114217
Product name:	Smackdown Herbicide
Active constituent/s:	240 g/L carfentrazone-ethyl
Applicant name:	Turf Culture Pty Ltd
Applicant ACN:	117 986 615
Summary of variation:	To update label information, storage and disposal, withholding periods and protection statements
Date of variation:	4 April 2018
Product registration no.:	64135
Label approval no.:	64135/114217

Application no.:	111689
Product name:	Intake Combi Sapphire In-Furrow And Foliar Fungicide
Active constituent/s:	500 g/L flutriafol
Applicant name:	Nufarm Australia Limited
Applicant ACN:	004 377 780
Summary of variation:	To increase the in-furrow application rate for control of black leg in canola from 200 mL/ha up to 400 mL/ha when mixed with a granulated fertiliser or injected into the soil at the time of planting
Date of variation:	4 April 2018
Product registration no.:	66358
Label approval no.:	66358/111689

Application no.:	111431
Product name:	Titan Diflufenican 25 + Bromoxynil 250 Selective Herbicide
Active constituent/s:	25 g/L diflufenican, 250 g/L bromoxynil present as the octanoate
Applicant name:	Titan Ag Pty Ltd
Applicant ACN:	122 081 574
Summary of variation:	To amend tank-mix partner instructions
Date of variation:	4 April 2018
Product registration no.:	69416
Label approval no.:	69416/111431

Application no.:	114394
Product name:	Rancona Dimension Seed Treatment
Active constituent/s:	20 g/L metalaxyl, 25 g/L ipconazole
Applicant name:	Arysta Lifescience Australia Pty Ltd
Applicant ACN:	005 225 507
Summary of variation:	To update compatibility advice on label
Date of variation:	5 April 2018
Product registration no.:	67985
Label approval no.:	67985/114394

Application no.:	113217
Product name:	Dacthal 900 WG Pre-Emergence Herbicide
Active constituent/s:	900 g/kg chlorthal dimethyl
Applicant name:	Nufarm Australia Limited
Applicant ACN:	004 377 780
Summary of variation:	To extend the label to include use in leeks and include pack size range
Date of variation:	6 April 2018
Product registration no.:	59137
Label approval no.:	59137/113217

Application no.:	113302
Product name:	Gro-Wet Low Volume Application Spreader
Active constituent/s:	300 g/L trisiloxane ethoxylate
Applicant name:	Agrinova New Zealand Limited
Applicant ACN:	N/A
Summary of variation:	To extend the use to include pink lady apples as per the directions for use
Date of variation:	6 April 2018
Product registration no.:	69943
Label approval no.:	69943/113302

Application no.:	114754
Product name:	Serenade Opti Biofungicide
Active constituent/s:	Not less than 1.3 x 10^{10} CFU/g *Bacillus amyloliquefaciens* strain QST 713
Applicant name:	Bayer Cropscience Pty Ltd
Applicant ACN:	000 226 022
Summary of variation:	To extend use to include control of botrytis in strawberries and suppression of blackspot in tomatoes, capsicums and chillies
Date of variation:	6 April 2018
Product registration no.:	82242
Label approval no.:	82242/114754

Application no.:	114668
Product name:	Grow Force Spray Grade Ammonium Sulphate Herbicide Adjuvant
Active constituent/s:	980 g/kg ammonium sulphate
Applicant name:	Ruralco Holdings Limited
Applicant ACN:	009 660 879
Summary of variation:	To approve a new label for the product 'GROW FORCE SPRAY GRADE AMMONIUM SULPHATE HERBICIDE ADJUVANT ' with the label name 'RELYON AMMONIUM SULPHATE —SPRAY GRADE'
Date of variation:	9 April 2018
Product registration no.:	64675
Label approval no.:	64675/114668

Application no.:	113934
Product name:	EuroChem 6-BA Plant growth Regulator
Active constituent/s:	20 g/L 6-benzyladenine
Applicant name:	Ronic International Pty Limited
Applicant ACN:	101 193 131
Summary of variation:	To extend the use to improve fruit shape and increase fruit size in apples and to stimulate lateral growth of non-bearing cherry trees when tank mixed with another plant growth regulator product
Date of variation:	10 April 2018
Product registration no.:	81342
Label approval no.:	81342/113934

Application no.:	113166
Product name:	Pirimor WG Aphicide
Active constituent/s:	500 g/kg pirimicarb
Applicant name:	Syngenta Australia Pty Ltd
Applicant ACN:	002 933 717
Summary of variation:	To include a control of Russian wheat aphid in winter cereals
Date of variation:	10 April 2018
Product registration no.:	49835
Label approval no.:	49835/113166

Application no.:	112600
Product name:	Fendona Plus 60 SC Insecticide
Active constituent/s:	60 g/L alpha-cypermethrin
Applicant name:	BASF Australia Ltd
Applicant ACN:	008 437 867
Summary of variation:	To include the control of litter beetles in poultry sheds
Date of variation:	13 April 2018
Product registration no.:	80739
Label approval no.:	80739/112600

Application no.:	113428
Product name:	Comet 400 Herbicide
Active constituent/s:	400 g/L fluroxypyr as the methyl heptyl ester
Applicant name:	Nufarm Australia Limited
Applicant ACN:	004 377 780
Summary of variation:	To add volunteer cotton and ratoon cotton in fallows and optical spray section and to add pack size range
Date of variation:	11 April 2018
Product registration no.:	61667
Label approval no.:	61667/113428

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.:	106347
Product name:	BioWorma
Active constituent/s:	Each gram contains: minimum of 500,000 chlamydospores of *Duddingtonia flagrans* strain IAH 1297
Applicant name:	International Animal Health Products Pty Ltd
Applicant ACN:	003 185 699
Summary of use:	For use as a natural biological control that captures and consumes infective worm larvae (including multi-resistant) within the manure of grazing animals (sheep, goats, cattle, horses, deer, alpaca, zoo animals)
Date of registration:	5 April 2018
Product registration no.:	82645
Label approval no.:	82645/106347

Application no.:	106348
Product name:	Livamol with BioWorma
Active constituent/s:	Each gram contains: minimum of 30,000 chlamydospores of *Duddingtonia flagrans* strain IAH 1297
Applicant name:	International Animal Health Products Pty Ltd
Applicant ACN:	003 185 699
Summary of use:	For use as a natural biological control that captures and consumes infective worm larvae (including multi-resistant) within the manure of grazing animals (sheep, goats, cattle, horses, deer, alpaca, zoo animals)
Date of registration:	5 April 2018
Product registration no.:	82646
Label approval no.:	82646/106348

2. VETERINARY PRODUCTS BASED ON EXISTING ACTIVE CONSTITUENTS

Application no.:	109860
Product name:	Milpro Film Coated Tablets For Small Dogs And Puppies
Active constituent/s:	25 mg praziquantel, 2.5 mg milbemycin oxime
Applicant name:	Virbac (Australia) Pty Ltd
Applicant ACN:	003 268 871
Summary of use:	For oral use in the treatment and control of roundworms, hookworms, whipworm, and tapeworms, and for prevention of heartworm in small dogs and puppies
Date of registration:	28 March 2018
Product registration no.:	84185
Label approval no.:	84185/109860

Application no.:	108734
Product name:	Moxiclear for Puppies and Small Dogs up to 4 kg
Active constituent/s:	100 g/L imidacloprid, 25 g/L moxidectin
Applicant name:	Norbrook Laboratories Australia Pty Limited
Applicant ACN:	080 972 596
Summary of use:	For the treatment and prevention of fleas, the prevention of heartworm, and the treatment and control of intestinal worms, sarcoptic mange, lice and ear mites in puppies and small dogs up to 4 kg
Date of registration:	12 April 2018
Product registration no.:	83619
Label approval no.:	83619/108734

Application no.:	108735
Product name:	Moxiclear for Dogs 4–10 kg
Active constituent/s:	100 g/L imidacloprid, 25 g/L moxidectin
Applicant name:	Norbrook Laboratories Australia Pty Limited
Applicant ACN:	080 972 596
Summary of use:	For the treatment and prevention of fleas, the prevention of heartworm, and the treatment and control of intestinal worms, sarcoptic mange, lice and ear mites in dogs weighing 4–10 kg
Date of registration:	12 April 2018
Product registration no.:	83620
Label approval no.:	83620/108735

Application no.:	109693
Product name:	Abastar Plus Selenium High Volume Oral Drench For Sheep
Active constituent/s:	0.8 g/L abamectin, 0.4 g/L selenium as sodium selenate
Applicant name:	The Hunter River Company Pty Limited
Applicant ACN:	133 798 615
Summary of use:	For the treatment and control of gastrointestinal parasites, nasal bot and itch mite of sheep, and selenium deficiency in sheep
Date of registration:	12 April 2018
Product registration no.:	84096
Label approval no.:	84096/109693

Application no.:	108736
Product name:	Moxiclear for Dogs 10–25 kg
Active constituent/s:	100 g/L imidacloprid, 25 g/L moxidectin
Applicant name:	Norbrook Laboratories Australia Pty Limited
Applicant ACN:	080 972 596
Summary of use:	For the treatment and prevention of fleas, the prevention of heartworm, the treatment and control of intestinal worms, sarcoptic mange, lice and ear mites in dogs weighing 10–25 kg
Date of registration:	12 April 2018
Product registration no.:	83621
Label approval no.:	83621/108736

Application no.:	108737
Product name:	Moxiclear for Dogs Over 25 kg
Active constituent/s:	100 g/L imidacloprid, 25 g/L moxidectin
Applicant name:	Norbrook Laboratories Australia Pty Limited
Applicant ACN:	080 972 596
Summary of use:	For the treatment and prevention of fleas, the prevention of heartworm, and the treatment and control of intestinal worms, sarcoptic mange, lice and ear mites in dogs weighing over 25 kg
Date of registration:	12 April 2018
Product registration no.:	83622
Label approval no.:	83622/108737

Application no.:	114669
Product name:	Di-Fly Spray-On Sheep Blowfly Treatment
Active constituent/s:	50 g/L dicyclanil
Applicant name:	Abbey Laboratories Pty Ltd
Applicant ACN:	156 000 430
Summary of use:	For the protection of sheep against fly strike
Date of registration:	12 April 2018
Product registration no.:	86092
Label approval no.:	86092/114669

Application no.:	113946
Product name:	Doramax Pour-On Endectocide
Active constituent/s:	5 mg/mL doramectin
Applicant name:	The Hunter River Company Pty Limited
Applicant ACN:	133 798 615
Summary of use:	For the treatment and control of doramectin sensitive internal and external parasites of cattle
Date of registration:	13 April 2018
Product registration no.:	85729
Label approval no.:	85729/113946

Application no.:	109863
Product name:	Tylophos Premix Concentrate For Pigs And Cattle
Active constituent/s:	903 g/kg tylosin as tylosin phosphate
Applicant name:	Abbey Laboratories Pty Ltd
Applicant ACN:	156 000 430
Summary of use:	For the control of liver abscess in feedlot cattle and the control of ileitis in pigs
Date of registration:	13 April 2018
Product registration no.:	84188
Label approval no.:	84188/109863

Application no.:	106271
Product name:	Sedator Injection
Active constituent/s:	10 mg/ml detomidine hydrochloride
Applicant name:	Randlab Australia Pty Ltd
Applicant ACN:	114 948 837
Summary of use:	For mild to heavy sedation and for analgesia in horses and for the control of pain in uncomplicated colic in horses
Date of registration:	17 April 2018
Product registration no.:	82623
Label approval no.:	82623/106271

3. VARIATIONS OF REGISTRATION

Application no.:	114926
Product name:	Silirum Vaccine
Active constituent/s:	2.5 mg/ml *Mycobacterium paratuberculosis*
Applicant name:	Zoetis Australia Pty Ltd
Applicant ACN:	156 476 425
Summary of variation:	To amend the method of identification of treated animals
Date of variation:	12 April 2018
Product registration no.:	59642
Label approval no.:	59642/114926

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.:	106349
Active constituent/s:	*Duddingtonia flagrans* (IAH 1297)
Applicant name:	International Animal Health Products Pty Ltd
Applicant ACN:	003 185 699
Summary of use:	For use in veterinary chemical products
Date of approval:	5 April 2018
Approval no.:	82647

Application no.:	110057
Active constituent/s:	Ceftiofur hydrochloride
Applicant name:	Abbey Laboratories Pty Ltd
Applicant ACN:	156 000 430
Summary of use:	For use in veterinary chemical products
Date of approval:	6 April 2018
Approval no.:	84288

Application no.:	111991
Active constituent/s:	Simazine
Applicant name:	Hebei Shanli Chemical Company Limited
Applicant ACN:	N/A
Summary of use:	For use in agricultural chemical products
Date of approval:	6 April 2018
Approval no.:	84996

Application no.:	112662
Active constituent/s:	Metribuzin
Applicant name:	Jiangsu Sword Agrochemicals Co Ltd
Applicant ACN:	N/A
Summary of use:	For use in agricultural chemical products
Date of approval:	12 April 2018
Approval no.:	85221

Application no.:	112705
Active constituent/s:	Prothioconazole
Applicant name:	Sipcam Pacific Australia Pty Ltd
Applicant ACN:	073 176 888
Summary of use:	For use in agricultural chemical products
Date of approval:	13 April 2018
Approval no.:	85235

Application no.:	112408
Active constituent/s:	Tribenuron-methyl
Applicant name:	Jiangsu Agrochem Laboratory Co Ltd
Applicant ACN:	N/A
Summary of use:	For use in agricultural chemical products
Date of approval:	13 April 2018
Approval no.:	85154

Licensing of Veterinary Chemical Manufacturers

Pursuant to Part 8 of the Agricultural and Veterinary Chemicals Code (Agvet Code), 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 Agvet Code:

FLORES NOMINEES PTY. LTD.

ACN: 005 593 091

Unit 2A, 77–83 Bayfield Road

EAST BAYSWATER VIC 3153

Licence number: 2242

Product types:*

- *Category 2*: Powders, liquids
- *Category 4:* Powders, liquids

Steps of manufacture: Quality assurance (QA) of raw materials, formulation including blending, filling, packaging, labelling, analysis and testing (physical), storage and release for supply.

Licence issued: 7 March 2018

2. CHANGES TO EXISTING LICENCES

The APVMA has issued the following licences under subsection 123(1) of the Agvet Code:

Nil

3. LICENCE CANCELLATIONS

The APVMA has cancelled the following licences under subsection 127(1) of the Agvet Code:

Nil

4. LICENCE SUSPENSIONS

The APVMA has suspended the following licences under subsection 127(1) of 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 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: *Single-step manufacturer*

6. REVOCATION OF LICENCE SUSPENSION

The APVMA has revoked the suspension of the following licences under subsection 127(7) of the Agvet Code:

Nil

APVMA CONTACT

Manufacturing Quality and Licensing
Australian Pesticides and Veterinary Medicines Authority
PO Box 6182
KINGSTON ACT 2604

Phone: +61 2 6210 4899
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: *Single-step manufacturer*

Variations to Schedule 20 of the Australia New Zealand Food Standards Code

The APVMA has previously gazetted particular amendments which it had made to the APVMA *MRL Standard* and which have been proposed as variations to maximum residue limits (MRLs) for substances contained in agricultural and veterinary chemical products as set out as in Schedule 20–Maximum Residue Limits of the Australia New Zealand Food Standards Code. This notice pertains to certain MRLs specified in proposals (No. 1) gazetted on 16 January 2018 (No. APVMA 1), (No. 2) gazetted on 13 February 2018 (No. APVMA 3) and (No. 3) gazetted on 13 March 2018 (No. APVMA 5).

Submissions have been sought on these proposals and the APVMA has written separately to each person or organisation that made a submission. All matters raised in the submissions have been resolved.

Under subsection 82(1) of the *Food Standards Australia New Zealand Act 1991*, the APVMA has, by legislative instrument, incorporated these variations to MRLs into Schedule 20. A copy of the Amendment Instrument (No. APVMA 8, 2018) accompanies this notice. For a complete and up-to-date version of Schedule 20, including these amendments together with their Explanatory Statement, please refer to the Federal Register of Legislation available on the Legislation website at www.legislation.gov.au

Based on dietary exposure assessments and current health standards, the APVMA and Food Standards Australia and New Zealand (FSANZ) are satisfied that these MRLs are not harmful to public health. MRLs contained in Schedule 20 provide the limits for residues of agricultural and veterinary chemicals that may legitimately occur in foods. By this means, Schedule 20 permits the sale of treated foods and protects public health by minimising residues in foods consistent with the effective control of pests and diseases.

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

A copy of these variations have been given to FSANZ.

The variations take effect as from the date of this notice.

This notice is published in accordance with subsection 82(7) of the *Food Standards Australia New Zealand Act 1991*.

For further information please contact:

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

Phone: +61 2 6210 4897
Fax: +61 2 6210 4840
Email: enquiries@apvma.gov.au

Australian Government

Australian Pesticides and Veterinary Medicines Authority

Australia New Zealand Food Standards Code—Schedule 20—Maximum residue limits Variation Instrument No. APVMA 3, 2018

I, Phil Reeves, Chief Scientist, Office of the Chief Scientist and delegate of the Australian Pesticides and Veterinary Medicines Authority, acting in accordance with my powers under subsection 11(1) of the *Agricultural and Veterinary Chemicals (Administration) Act 1992*, make this instrument for the purposes of subsection 82(1) of the *Food Standards Australia New Zealand Act 1991*.

Phil Reeves
Delegate of the Chief Executive Officer of the Australian Pesticides and Veterinary Medicines Authority

Dated this Eighteenth day of April 2018

Part 1 Preliminary

1 Name of instrument

This instrument is the *Australia New Zealand Food Standards Code— Schedule 20–Maximum residue limits Variation Instrument No. APVMA 3, 2018*.

2 Commencement

In accordance with subsection 82(8) of the *Food Standards Australia New Zealand Act 1991*, this instrument commences on the day it is published in the *Gazette*.

Note: A copy of the variations made by the Amendment Instrument was published in the Commonwealth of Australia Agricultural and Veterinary Chemicals Gazette No. APVMA 8 of 24 April 2018.

3 Object

The object of this instrument is for the APVMA to make variations to Schedule 20–Maximum residue limits in the *Australia New Zealand Food Standards Code* to include or change maximum residue limits pertaining to agricultural and veterinary chemical products.

4 Interpretation

In this instrument: —

APVMA means the Australian Pesticides and Veterinary Medicines Authority established by section 6 of the *Agricultural and Veterinary Chemicals (Administration) Act 1992*; and

Principal Instrument means Schedule 20–Maximum residue limits in the Australia New Zealand Food Standard Code as defined in Section 4 of the *Food Standards Australia New Zealand Act 1991* being the Code published in *Gazette* No. P 27 on 27 August 1987 together with any amendments of the standards in that Code. Schedule 20 was published in the *Food Standards Gazette* FSC 96 on Thursday 10 April 2015 and was registered as a legislative instrument on 1 April 2015 (F2015L00468).

Part 2 Variations to Schedule 20–Maximum Residue Limits

5 Variations to Schedule 20

The Schedule to this instrument sets out the variations made to the Principal Instrument by this instrument.

Schedule

Variations to Schedule 20–Maximum residue limits

[1] The table to section S20–3 in Schedule 20 is varied by

[1.1] inserting in alphabetical order

Agvet chemical: Afidopyropen	
Permitted residue: commodities of plant origin: Afidopyropen	
Permitted residue: commodities of animal origin: Afidopyropen and the carnitine conjugate of cyclopropanecarboxylic acid (M440I060), expressed as afidopyropen	
Brassica (cole or cabbage) vegetables, head cabbages, flowerhead brassicas	0.5
Celery	3
Cotton seed	0.1
Edible offal (mammalian)	*0.1
Eggs	*0.1
Fruiting vegetables, cucurbits	0.7
Fruiting vegetables, other than cucurbits	0.2
Ginger, root	*0.01
Leafy vegetables	5
Meat (mammalian)	*0.1
Milks	*0.01
Parsley	5
Potato	*0.01
Poultry, edible offal of	*0.1
Poultry meat	*0.1
Sweet potato	*0.01

Permitted residue: Isopyrazam	
Permitted residue: Isopyrazam	
Edible offal (mammalian)	*0.005
Eggs	*0.005
Meat (mammalian) (in the fat)	*0.005
Milks	*0.005
Pome fruit	0.7
Poultry, edible offal of	*0.005
Poultry meat (in the fat)	*0.005

Agvet chemical: Pydiflumetofen	
Permitted residue: Pydiflumetofen	
All other foods except animal food commodities	T0.05
Brassica (cole or cabbage) vegetables, head cabbages, flowerhead brassicas	T0.5
Brassica leafy vegetables	T10
Celery	T15
Cereal grains [except maize and popcorn]	T3
Dried grapes (currants, raisins and sultanas)	T5
Edible offal (mammalian)	*0.01
Eggs	*0.01
Fruiting vegetables, cucurbits	T0.5
Fruiting vegetables, other than cucurbits [except mushrooms; sweet corn (corn-on-the-cob)]	T0.7
Grapes	T2
Leafy vegetables (except brassica leafy vegetables)	T30
Legume vegetables	T0.5
Maize	T0.02
Meat (mammalian)	*0.01
Milks	*0.01
Peanut	T0.03
Pome fruits	T0.2
Popcorn	T0.02
Poultry, edible offal of	*0.01
Poultry meat	*0.01
Pulses	T0.5
Rape seed (canola)	T0.07
Root and tuber vegetables	T0.05
Sweet corn (corn-on-the-cob)	T*0.01

[1.2] inserting for each of the following chemicals the foods and associated MRLs in alphabetical order

Agvet chemical: Abamectin	
Permitted residue: Avermectin B1a	
Fig	T0.05

Agvet chemical: Azoxystrobin	
Permitted residue: Azoxystrobin	
Basil	T70

Agvet chemical: Bifenthrin	
Permitted residue: Bifenthrin	
Currants, black, red, white	T3

Agvet chemical: Buprofezin	
Permitted residue: Buprofezin	
All other foods except animal food commodities	0.05

Agvet chemical: Cyantraniliprole	
Permitted residue: Cyantraniliprole	
Strawberry	0.7

Agvet chemical: Cyazofamid	
Permitted residue: Cyazofamid	
All other foods except animal food commodities	0.02
Basil	T30
Basil, dry	T90
Chard (silver beet)	T10
Spinach	T10

Agvet chemical: Cyhalothrin	
Permitted residue: Cyhalothrin, sum of isomers	
Hazelnuts	T*0.01

Agvet chemical: Endothal	
Permitted residue: Endothal	
Edible offal (mammalian)	T*0.05
Eggs	T*0.05
Meat (mammalian)	T*0.05
Milks	T*0.01
Poultry, edible offal of	T*0.05
Poultry meat	T*0.05

Agvet chemical: Fluopicolide	
Permitted residue: Fluopicolide	
Brassica (cole or cabbage) vegetables, head cabbages, flowerhead brassicas	T5
Leafy vegetables [except lettuce, head and lettuce, leaf]	T30

Agvet chemical: Fluroxypyr	
Permitted residue: Fluroxypyr	
All other foods except animal food commodities	0.02
Onion, bulb	0.2

Agvet chemical: Imazalil	
Permitted residue: Imazalil	
All other foods except animal food commodities	0.05
Tomato	0.5

Agvet chemical: Metribuzin	
Permitted residue: Metribuzin	
All other foods except animal food commodities	0.05
Ginger root	T*0.05

Agvet chemical: Myclobutanil	
Permitted residue: Myclobutanil	
Edible offal (mammalian)	*0.01
Meat (mammalian)	*0.01
Milks	*0.01

Agvet chemical: Oxathiapiprolin	
Permitted residue: Oxathiapiprolin	
Basil	T10
Basil, dry	T90

Agvet chemical: Prosulfocarb	
Permitted residue: Prosulfocarb	
Carrot	T*0.01

[1.3] omitting for each of the following chemicals, the maximum residue limit for the food and substituting

Agvet chemical: Buprofezin	
Permitted residue: Buprofezin	
Tomato	1

Agvet chemical: Dithiocarbamates	
Permitted residue: Total dithiocarbamates, determined as carbon disulphide evolved during acid digestion and expressed as milligrams of carbon disulphide per kilogram of food	
Berries and other small fruits [except strawberry]	T15

Agvet chemical: Endothal	
Permitted residue: Endothal	
Cotton seed	T2

Agvet chemical: Florpyrauxifen-benzyl	
Permitted residue: Sum of florpyrauxifen-benzyl and the XDE-848 acid metabolite [4-amino-3-chloro-6-(4-chloro-2-fluoro-3-methoxyphenyl)-5-fluoropyridine-2-carboxylic acid] expressed as florpyrauxifen-benzyl	
Edible offal (mammalian)	*0.02
Eggs	*0.02
Meat (mammalian) (in the fat)	*0.02
Milks	*0.02
Poultry, edible offal of	*0.02
Poultry meat (in the fat)	*0.02
Rice	*0.02

Agvet chemical: Fludioxonil	
Permitted residue—commodities of animal origin: Sum of fludioxonil and oxidisable metabolites, expressed as Fludioxonil	
Permitted residue—commodities of plant origin: Fludioxonil	
Blueberries	T3

Agvet chemical: Propamocarb	
Permitted residue: Propamocarb (base)	
Brassica (cole or cabbage) vegetables, head cabbages, flowerhead brassicas	T30
Leafy vegetables [except lettuce, head and lettuce, leaf]	T70

Toad Blitz Cane Toad Killer Containing 112 g/l Eugenol

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application for registration of a new product containing an approved active where this application presents the first product containing this active constituent. The product is Toad Blitz Cane Toad Killer.

PARTICULARS OF THE APPLICATION

Proposed product name(s):	Toad Blitz Cane Toad Killer
Applicant company:	Amgrow Pty Ltd
Name of active constituent:	Eugenol
Signal heading:	Not applicable (Appendix B)
Summary of proposed use:	For the humane control of cane toads in the home garden.
Pack sizes:	375 mL – 4 L
Withholding period:	Not applicable

SUMMARY OF THE APVMA'S EVALUATION OF TOAD BLITZ CANE TOAD KILLER 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 Toad Blitz Cane Toad Killer would not be an undue hazard to the safety of people exposed to it during its handling and use.

   (ii) The APVMA is satisfied that the proposed use of Toad Blitz Cane Toad Killer will not be an undue hazard to the safety of people.

   (iii) The APVMA is satisfied that the proposed use of Toad Blitz Cane Toad Killer containing the active constituent eugenol is not likely to be harmful to human beings if used according to the product label directions.

   The APVMA has conducted a risk assessment on the product and concluded that it can be used safely.

   The toxicological aspects of the active constituent have been considered and as eugenol is not currently or intended to be used in products which are used in food producing crops or animals an Acceptable Daily Intake (ADI) and an Acute Reference Dose (ARfD) are not necessary. The active eugenol is in Schedule 6 of the Standard of the Uniform Scheduling of Medicines and Poisons (SUSMP) except when in preparations containing 25% or less where it is exempt from the requirements of scheduling. The proposed product formulation at 112 g/L eugenol is therefore exempt from the requirements of scheduling.

The toxicological profile of the product was considered by reference to international reports on eugenol toxicity and these were considered to be adequate for the assessment. The APMVA estimated the hazard of the product based on the active and excipients contained in the formulation, and has determined that the acute toxicity of the product is expected to be low by oral, dermal and inhalational and it is not expected to be an irritant or sensitiser to the skin based on patch testing in 11,632 volunteers. The product is expected to be a slight eye irritant.

After consideration of the hazards associated with the proposed product, along with the exposure and risks expected with use of the product, it was considered that Toad Blitz Cane Toad Killer Agent will not be an undue health hazard to the safety of people.

(iv) The APVMA is satisfied that the proposed use of Toad Blitz Cane Toad Killer 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.

Since the active constituent is naturally derived from plants, it is expected to degrade in the environment through normal biological, physical and chemical processes. Based on the specific use pattern, the nature of the active constituent and the likelihood for rapid transformation under environmental conditions, the product is not expected to have an unintended effect that is harmful to animals, plants 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) 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.

Three laboratory trials were conducted to evaluate the efficacy of eugenol for the control of Cane toads (*Bufo marinas*). The concentrations of eugenol tested included the proposed label rate, half the label rate and twice the label rate applied at 2.5 mL/toad. The trials assessed efficacy and the effect on toads (time to reach each of 4 stages: Stage 1–light sedation, Stage 2–deep sedation, Stage 3–anesthetised and Stage 4–euthanasia. The efficacy of different application methods was also examined. Toad size also had an impact on the time and pattern of progression to euthanasia. Small toads progressed to euthanasia faster than medium and large sized toads. Stress had little effect on the time to euthanasia. Time to death decreased with increase in concentration of eugenol. The toads did not react to the spray and were not irritated by eugenol. The trial results demonstrated that Toad Blitz Cane Toad Killer is effective.

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:

(i) The APVMA is satisfied that the proposed use of Toad Blitz Cane Toad Killer would not adversely affect trade between Australia and places outside Australia. As noted above the product is not intended for use in food producing crops or animals and residues are not expected to occur and is therefore not expected to impact trade.

FURTHER INFORMATION

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 Toad Blitz Cane Toad Killer should be 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 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)[1] material contained in submissions will be treated confidentially.

Written submissions should be addressed in writing to:

Case Management and Administration Unit
Australian Pesticides and Veterinary Medicines Authority
PO Box 6182
KINGSTON ACT 2604

Phone: +61 2 6210 4701
Fax: +61 2 6210 4721
Email: enquiries@apvma.gov.au

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

Cancellation of Product Label Approvals at the Request of the Holder

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

Product no.	Product name	Registrant	Product label approval number	Date of effect
84882	Eurochem Indox 150EC Insecticide	TGAC Australia Pty Ltd	84882/111683	10 April 2018

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

SUPPLY

A person may supply or cause to be supplied the above product bearing the cancelled label manufactured prior to 10 April 2018 at wholesale and retail level, until the 10 April 2019.

After 10 April 2019 it will be an offence against the Agvet Codes to have possession or custody of the product bearing the cancelled label with the intention to supply, or to supply the product.

USE

A person may continue to use the product bearing the cancelled label according to its label instructions until 10 April 2019.

Any person who possesses, has custody of, uses, or otherwise deals with the listed product bearing the 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 the cancelled label until 10 April 2019.

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

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

APVMA CONTACT

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

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

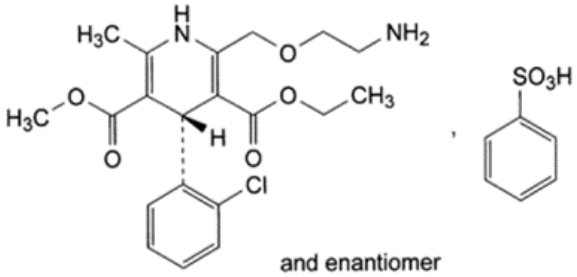
Phone: +61 2 6210 4779
Fax: +61 2 6210 4776
Email: chemicalreview@apvma.gov.au

Amodip Flavoured Tablets for Cats Containing Amlodipine Besilate

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application for the approval of a new active constituent, amlodipine besilate, and an application for registration of a new product containing the new active constituent. The product is Amodip Flavoured Tablets for Cats for use in the treatment of arterial hypertension**.**

PARTICULARS OF THE ACTIVE CONSTITUENT

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application for the approval of a new active constituent, amlodipine besilate. Amlodipine besilate is described in a European Pharmacopoeia monograph (No 1491) and also in the British Pharmacopoeia.

Common name:	Amlodipine besilate
IUPAC name:	3-Ethyl 5-methyl (4*RS*)-2-[(2-aminoethoxy)methyl)-4-(2-chlorophenyl)-6-methyl-1,4-dihydropyridine-3,5-dicarboxylate benzenesulfonate
Chemical abstracts name:	3-Ethyl 5-methyl (4*RS*)-2-[(2-aminoethoxy) methyl)-4-(2-chlorophenyl)-6-methyl-1,4-dihydropyridine-3,5-dicarboxylate benzenesulfonate
CAS number:	111470-99-6
Molecular formula:	$C_{20}H_{25}ClN_2O_5S$. $C_6H_6O_3S$
Molecular weight:	567.1 (free base 408.9)
Structure:	 and enantiomer
Chemical family:	1,4-dihydropyridine-3,5-dicarboxylate derivatives
Mode of action:	Dihydropyridine (L-type) calcium channel blocker

SUMMARY OF THE APVMA'S EVALUATION OF THE ACTIVE CONSTITUENT AMLODIPINE BESILATE 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 amlodipine besilate 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 aspects of amlodipine besilate (manufacturing process, quality control procedures, specifications, batch analysis results and analytical methods) and found them to be acceptable. Amlodipine besilate will be manufactured to comply with the European Pharmacopeia monograph for amlodipine besilate.

The APVMA has considered the toxicological aspects of amlodipine besilate, and concluded that there are no toxicological concerns to the approval of this active constituent. Neither an ADI nor an ARfD has been established since the active constituent is used in companion animals only, and is not intended for use in food-producing animals.

Amlodipine besilate has a history of use in human medicine and has been on the market in Australia for over 20 years. As a result, amlodipine is listed in Schedule 4 of the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP). This listing is appropriate for the proposed use in cats, with the product only to be available from a veterinarian on prescription.

The APVMA proposes to be satisfied that the use of amlodipine besilate in a veterinary chemical product would not be an undue toxicological hazard to the safety of people exposed to it during its handling and use, nor would it be likely to have an unintended effect that is harmful to human beings, animals, plants or things or to the environment.

PARTICULARS OF THE PRODUCT

Proposed product name(s):	Amodip Flavoured Tablets for Cats
Applicant company:	Ceva Animal Health Pty Ltd
Name of active constituent:	Amlodipine besilate
Signal heading:	Schedule 4
Summary of proposed use:	For use in the treatment of arterial hypertension in cats
Pack sizes:	30, 100 and 200 tablets
Withholding period:	NA

SUMMARY OF THE APVMA'S EVALUATION OF THE PRODUCT 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 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 Amodip Flavoured Tablets for Cats would not be an undue hazard to the safety of people exposed to it during its handling and use.

    An external toxicology reviewer has conducted a risk assessment on the product and concluded that it can be used safely.

    There are no objections on public or occupational health grounds to the approval of amlodipine besilate as a new active constituent.

    An S4 Poisons Schedule status is considered appropriate for amlodipine besilate when present in Amodip Flavoured Tablets for Cats.

    The following first aid instruction and safety direction will be included on the product label.

    First Aid: *If poisoning occurs, contact a doctor or Poisons Information Centre. Phone Australia 13 11 26.*

    Safety Directions: *Wash hands after use.*

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

(ii) The APVMA is satisfied that the proposed use of Amodip Flavoured Tablets for Cats will not be an undue hazard to the safety of people using anything containing its residues.

The product is for use in cats only and so products from treated animals are unlikely to enter the food-chain.

(iii) The APVMA is satisfied that the proposed use of Amodip Flavoured Tablets for Cats containing the active constituent amlodipine besilate is not likely to be harmful to human beings if used according to the product label directions.

Amlodipine besilate is approved for therapeutic use in humans, and is listed in Schedule 4 of the Australian Standard for Uniform Scheduling of Medicines and Poisons (SUSMP). Amodip Flavoured Tablets for Cats contains 1.25 mg amlodipine (as amlodipine besilate). Based on the concentration of amlodipine besilate and the toxicological profile of the product, this scheduling is considered appropriate.

(iv) The APVMA is satisfied that the proposed use of the new products Amodip Flavoured Tablets for Cats containing the active constituent amlodipine besilate, would not be likely to have an unintended effect that is harmful to animals, plants or things or the environment.

For veterinary medicinal products (VMPs), the APVMA has adopted VICH guidelines (VICH 2000) on data requirements for environmental safety (amongst other things). It is assumed that VMPs that satisfy the criteria of VICH phase 1 will have limited use and limited environmental exposure and consequently have limited environmental effects.

This Veterinary Medicinal Product will only be used in non-food animals. Hence, it satisfies the requirements of VICH phase 1. The APVMA is therefore satisfied that the proposed product meets the environmental safety criteria.

The label will contain a disposal statement as follows: *Dispose of empty container by wrapping with paper and putting in garbage*.

An external reviewer has assessed the target animal safety of AMODIP FLAVOURED TABLETS FOR CATS in a target animal safety which administered Amodip to a single cat at either 7X, 8X (2 cats) and 10X the recommended dose rate (0.25 mg/kg daily) for 2 weeks. The study suggested that the 7X dose rate was well tolerated, but this is at odds with an increased incidence of adverse effects in the two cats receiving an 8X dose rate, while the cat receiving the 10X dose rate died. A second target animal safety study assigned 32 cats to one of four groups: placebo (0X, control) or Amodip at 0.25 (1X), 0.75 (3X) and 1.25 (5X) mg amlodipine /kg body weight/day for a total of 6 months. The study demonstrated that Amodip was reasonably well tolerated in cats when dosed at 1X, but increasing the dose rate induced a marked increase in the severity of gingival hyperplasia and adverse effects on the kidney and reproductive organs. A reduction in plasma potassium was also a potential concern and may require oral supplementation of cats with potassium. It was noted that the Amodip is directed on the label to be administered initially at the lower dose rate (0.125 mg/kg) and only increased to the higher dose rate (0.25 mg/kg) if insufficient reductions in blood pressure are observed (and it is also noted that 0.25 mg/kg was considered the 1X dose rate in the safety studies).

Appropriate precaution statements relating to concomitant use of diuretics, drugs inhibiting the renin angiotensin aldosterone system including renin inhibitors, angiotensin II receptor blockers, ACEI, and aldosterone antagonists (such as spironolactone), beta blockers, other vasodilators; reduction in plasma

concentrations; and the possibility of renal dysfunction and gingival hyperplasia, will be included on the label.

Appropriate contraindication statements relating to severe hepatic failure, use in cardiogenic shock and severe aortic stenosis, and cases of hypersensitivity to the active substance are included on the label.

The APVMA is satisfied that Amodip Flavoured Tablets for Cats would not have an unintended effect that is harmful to the target animals (cats).

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 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.

Amodip Flavoured Tablets for Cats is intended for use in the treatment of arterial hypertension in cats. The product is a tablet to be administered orally with or without a small quantity of food at the recommended starting dose of 0.125–0.250 mg/kg amlodipine.

The supporting information included a field efficacy study, expert reports and publicly available background information.

The efficacy study was a randomised, multicentre, double-blinded, placebo controlled, parallel group study design across 20 European veterinary hospitals to determine efficacy. The dose rate in the treated group commenced at 0.125 mg/kg daily and was increased to 0.25 mg/kg after 14 days if the treatment response cut off (BP < 150 mmHg or had decreased ≥ 15% from baseline) was not attained, which was necessary in 54% of cats. After a further 14 days, the treated cats continued on the dose rate they were currently on for 2 months, while the placebo cats were treated (i.e. either 0.125 mg/kg or increased to 0.25 mg/kg if insufficient response) for 3 months. It was found that Amodip significantly reduced BP with minimal adverse effects. A palatability study during this trial also reported that 78.8% of cats spontaneously consumed Amodip tablets when offered.

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:

(i) The APVMA is satisfied that the proposed use of Amodip Flavoured Tablets for Cats would not adversely affect trade between Australia and places outside Australia as the product is 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 amlodipine besilate should be approved and whether the application for registration of Amodip Flavoured Tablets for Cats 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 Amodip Flavoured Tablets for Cats. These grounds include: for approval of the active constituent, the safety criteria; for the registration application for Amodip Flavoured Tablets for Cats 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 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)[1] 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 6210 4701
Fax: +61 2 6210 4721
Email: enquiries@apvma.gov.au

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

Cytopoint Solution for Injection for Dogs Containing Lokivetmab

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application for the approval of a new active constituent, Lokivetmab, and applications for registration of new products containing the new active constituent. The products are Cytopoint Solution for Injection for Dogs 40 mg, Cytopoint Solution for Injection for Dogs 30 mg, Cytopoint Solution for Injection for Dogs 20 mg and Cytopoint Solution for Injection for Dogs 10 mg for the treatment of the clinical manifestations of atopic dermatitis in dogs.

PARTICULARS OF THE ACTIVE CONSTITUENT

The APVMA has before it an application for the approval of a new active constituent, Lokivetmab.

Common name: Lokivetmab

CAS Registry number: 1533403-95-0

Chemical family: Monoclonal antibody

Mode of action: Specifically targeting and inactivating the pruritogenic and pro-inflammatory cytokine canine interleukin-31 (cIL-31).

SUMMARY OF THE APVMA'S EVALUATION OF LOKIVETMAB ACTIVE CONSTITUENT

SUMMARY OF THE APVMA'S EVALUATION OF THE ACTIVE CONSTITUENT AMLODIPINE BESILATE 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 lokivetmab 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 aspects of lokivetmab active constituent (identification and physico-chemical properties, manufacturing process and quality control procedures, specifications, batch analysis and stability results and analytical methods) and found them to be acceptable.

Impurities of toxicological significance are not expected to occur with lokivetmab as a result of the raw materials and the manufacturing process.

Lokivetmab is only for use in non-food-producing animals (dogs), hence establishment of health based guidance values such as Acceptable Daily Intake (ADI) or Acute Reference Dose (ARfD) are not required. The APVMA has considered the toxicological aspects of lokivetmab, and concluded that there are no toxicological concerns to the approval of this active constituent.

Lokivetmab is a 'monoclonal antibody', which are included in a Schedule 4 generic entry for monoclonal antibodies of the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP).

The APVMA proposes to be satisfied that the proposed importation and use of Lokivetmab in a veterinary chemical product would not be an undue toxicological hazard to the safety of people exposed to it during its handling and use, nor would it be likely to have an unintended effect that is harmful to human beings, animals, plants or things or to the environment.

PARTICULARS OF THE PRODUCT APPLICATIONS

Proposed product name(s):	Cytopoint Solution for Injection for Dogs 40 mg Cytopoint Solution for Injection for Dogs 30 mg Cytopoint Solution for Injection for Dogs 20 mg Cytopoint Solution for Injection for Dogs 10 mg
Applicant company:	Zoetis Australia Pty Ltd
Name of active constituent:	Lokivetmab
Signal heading:	Schedule 4
Summary of proposed use:	For the treatment of the clinical manifestations of atopic dermatitis in dogs.
Pack sizes:	1 mL vials of 40 mg/mL, 30 mg/mL 20 mg/mL 10 mg/mL
Withholding period:	Not applicable

The suite of products will be referred to in this summary collectively as Cytopoint Solution for Injection for Dogs**.**

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 Cytopoint Solution for Injection for Dogs would not be an undue hazard to the safety of people exposed to them during their handling and use.

   The APVMA conducted a risk assessment for the products and in conjunction with the estimated hazard profile, determined whether the proposed use of the products would be an undue health hazard to humans.

   The APVMA has recommended first aid statement (a)—*If poison occurs, contact a doctor or Poisons Information Centre. Phone Australia 13 11 26.* The APVMA also recommends the following label statements:

   - *Hypersensitivity reactions, including anaphylaxis, could potentially occur in the case of accidental self-injection.*
   - *In case of accidental self-injection, seek medical advice immediately and show the package leaflet of the label to the physician*.

   (ii) The APVMA is satisfied that the proposed use of Cytopoint Solution for Injection for Dogs will not be an undue hazard to the safety of people using anything containing their residues.

   The product is for use in companion animals (dogs) only. Cytopoint Solution for Injection for Dogs is unlikely to enter the food chain.

(iii) The APVMA is satisfied that the proposed use of Cytopoint Solution for Injection for Dogs containing the active constituent lokivetmab is not likely to be harmful to human beings if used according to the product label directions.

Lokivetmab is a 'monoclonal antibody', which are included in a Schedule 4 generic entry for monoclonal antibodies of the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP).

(iv) The APVMA is satisfied that the proposed use of Cytopoint Solution for Injection for Dogs 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.

For veterinary medicinal products (VMPs), the APVMA has adopted VICH guidelines (VICH 2000) on data requirements for environmental safety (amongst other things). It is assumed that VMPs that satisfy the criteria of VICH phase 1 will have limited use and limited environmental exposure and consequently have limited environmental effects.

This Veterinary Medicinal Product will only be used in non-food animals. Hence, it satisfies the requirements of VICH phase 1. The APVMA is therefore satisfied that the proposed product meets the environmental safety criteria.

Lokivetmab is an immunological product and disposal instructions consistent with the Vet Labelling Code will be included on the label.

The results of the target animal safety studies indicated that, at the proposed label dose rate of 1.0-3.3 mg/kg bodyweight (see table above), CYTOPOINT Solution for Injection for Dogs is unlikely to cause serious adverse reactions in dogs and appropriate, precautions, side effects and contraindicated statements are 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:

(i) 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 products adequately demonstrate that if used according to the product label directions, the products are effective for the proposed uses.

The suite of products, Cytopoint Solution for Injection for Dogs is intended for the treatment of the clinical manifestations of atopic dermatitis in dogs.

The recommended minimum dose of Cytopoint Solution for Injection for Dogs is 1 mg/kg bodyweight, administered subcutaneously once a month. Dogs will be treated according to the table below.

	Cytopoint strength (mg) to be administered monthly			
Bodyweight (kg)	**10**	**20**	**30**	**40**
3.0 – 10.0	1 vial			
10.1 – 20.0		1 vial		
20.1 – 30.0			1 vial	
30.1 – 40.0				1 vial
Dogs over 40.1 kg require 2 vials as below				
40.1 – 50.0	1 vial			1 vial
50.1 – 60.0			2 vials	
60.1 – 70.0			1 vial	1 vial
70.1 – 80.0				2 vials

The efficacy data package comprised of published literatures, dose determination studies, dose confirmation studies for onset of effectiveness, field efficacy studies and target animal safety studies. The APVMA has concluded that the data generated from the efficacy studies support the claims that the product would be effective for the treatment of the clinical manifestations of atopic dermatitis in dogs.

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:

   (i) The APVMA is satisfied that the proposed use of Cytopoint Solution for Injection for Dogs would not adversely affect trade between Australia and places outside Australia. The product is for use on dogs, which are not food-producing animals and which do not produce 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 lokivetmab should be approved and whether the application for registration of the products Cytopoint Solution for Injection for Dogs 40 mg, Cytopoint Solution for Injection for Dogs 30 mg, Cytopoint Solution for Injection for Dogs 20 mg and Cytopoint Solution for Injection for Dogs 10 mg 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 of 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 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)[1] material contained in submissions will be treated confidentially.

Written submissions should be addressed in writing to:

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

Phone: +61 2 6210 4701
Fax: +61 2 6210 4721
Email: enquiries@apvma.gov.au

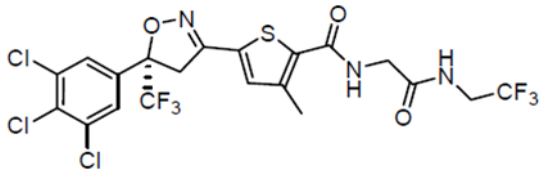
[1] A full definition of 'confidential commercial information' is contained in the Agvet Code.

Credelio Chewable Tablets for Dogs Containing the Active Lotilaner

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application for the approval of a new active constituent, lotilaner, and an application for registration of a suite of new products containing the new active constituent. The products are Credelio 900 mg Chewable Tablets for Dogs, Credelio 450 mg Chewable Tablets for Dogs, Credelio 225 mg Chewable Tablets for Dogs, Credelio 112.5 mg Chewable Tablets for Dogs and Credelio 56.25 mg Chewable Tablets for Dogs for use as an oral ectoparasticide for dogs.

PARTICULARS OF THE ACTIVE CONSTITUENT

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

Common name	Lotilaner
IUPAC name:	3-Methyl-*N*-[2-oxo-2-(2,2,2-trifluoroethylamino)ethyl]-5-[(5*S*)-5-(3,4,5-trichlorophenyl)-5-(trifluoromethyl)-4*H*-1,2-oxazol-3-yl]thiophene-2-carboxamide
Chemical abstracts name:	2-Thiophenecarboxamide, 5-[(5*S*)-4,5-dihydro-5-(3,4,5-trichlorophenyl)-5-(trifluoromethyl)-3-isoxazolyl]-3-methyl-*N*-[2-oxo-2-[(2,2,2-trifluoroethyl)amino]ethyl]-
CAS number:	1369852-71-0
Molecular formula:	$C_{20}H_{14}Cl_3F_6N_3O_3S$
Molecular weight:	596.76
Structure:	
Chemical family:	Isoxazoline
Mode of action:	Inhibition of GABA- and glutamate-gated chloride channels

SUMMARY OF THE APVMA'S EVALUATION OF THE ACTIVE CONSTITUENT LOTILANER 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 lotilaner 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 aspects of lotilaner (manufacturing process, quality control procedures, batch analysis results and analytical methods) and found them to be acceptable. There is currently no pharmacopeia monograph for lotilaner.

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

The APVMA has considered the toxicological aspects of lotilaner, and concluded that there are no toxicological concerns regarding the approval of this active constituent. No ADI or ARfD was established, as lotilaner will not be used in food-producing situations at this time.

The Scheduling Delegate for the Poisons Standard (commonly referred to as the *Standard for the Uniform Scheduling of Medicines and Poisons* – SUSMP) has made a final decision regarding lotilaner to list it in Schedule 5 of the SUSMP.

The APVMA proposes to be satisfied that the use of lotilaner in a veterinary chemical product would not be an undue toxicological hazard to the safety of people exposed to it during its handling and use, nor would it be likely to have an unintended effect that is harmful to human beings, animals, plants or things or to the environment.

PARTICULARS OF THE PRODUCT APPLICATIONS

Proposed product name(s):	Credelio 900 mg Chewable Tablets for Dogs Credelio 450 mg Chewable Tablets for Dogs Credelio 225 mg Chewable Tablets for Dogs Credelio 112.5 mg Chewable Tablets for Dogs Credelio 56.25 mg Chewable Tablets for Dogs
Applicant company:	Elanco Australasia Pty Ltd
Name of active constituent:	Lotilaner
Signal heading:	Schedule 5
Summary of proposed use:	For the treatment and prevention of fleas and the treatment and control of tick species on dogs.
Pack sizes:	1, 3, 6 tablets
Withholding period:	Not applicable

The suite of products will be referred to in this summary collectively as Credelio Chewable Tablets for Dogs

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 Credelio Chewable Tablets for Dogs would not be an undue hazard to the safety of people exposed to them during their handling or use, from handling the excreta of treated dogs, or from the accidental ingestion of the tablets.

   The APVMA has conducted a risk assessment for the products and in conjunction with the estimated hazard profile, determined whether the proposed use of the products would not be an undue health hazard to humans.

   The APVMA estimated the acute toxicity of Credelio Chewable Tablets for Dogs based on information provided by the applicant. The acute toxicity of the proposed products was ascertained from toxicological

studies in laboratory animals using the active constituent and the product formulation. Based on the findings of the acute toxicological studies, the active constituent, lotilaner, and the products present a low acute oral and dermal toxicity, are not irritating to the skin, are slight irritating to the eyes but do not demonstrate the potential for skin sensitisation. The product is intended to be used by adults and a tablet is not usually removed from the packaging until just prior to pet treatment. The risk of accidental ingestion by a child is limited by child-resistant packaging.

The APVMA recommends first aid statement (a)–*If poison occurs, contact a doctor or Poisons Information Centre. Phone Australia 13 11 26.* The APVMA also recommends the following safety directions: *May irritate the eyes. Avoid contact with eyes. Wash hands after use.* The first aid instruction and safety directions will be included on the product label.

(ii) The APVMA is satisfied that the proposed use of Credelio Chewable Tablets for Dogs will not be an undue hazard to the safety of people using anything containing their residues.

The product is for use in companion animals (dogs) only and so products from treated animals are unlikely to enter the food-chain.

(iii) The APVMA is satisfied that the proposed use of Credelio Chewable Tablets for Dogs containing the active constituent lotilaner is not likely to be harmful to human beings if used according to the product label directions.

Lotilaner is listed in Schedule 5 of the Australian Standard for Uniform Scheduling of Medicines and Poisons (SUSMP). The Schedule 5 signal heading is CAUTION.

(iv) The APVMA is satisfied that the proposed use of Credelio Chewable Tablets for Dogs 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.

For veterinary medicinal products (VMPs), the APVMA has adopted VICH guidelines (VICH 2000) on data requirements for environmental safety (amongst other things). It is assumed that VMPs that satisfy the criteria of VICH phase 1 will have limited use and limited environmental exposure and consequently have limited environmental effects.

The APVMA has conducted a VICH Phase I Preliminary assessment to determine the potential for entry of lotilaner into the environment. Lotilaner will only be used in dogs, which are non-food producing animals. As dogs are not intensively reared and treatments are on an individual basis, environmental exposure is expected to be negligible. The VICH phase I assessment concluded that the proposed use of lotilaner will not present a significant risk to the environment.

Disposal instructions consistent with the Vet Labelling Code for the appropriate package size(s) and material will also be included on the label–*Disposal of container by wrapping with paper and putting in garbage.*

The results of the target animal safety studies indicated that, at the proposed label dose rate of 20 mg/kg bodyweight, Credelio Chewable Tablets for Dogs is unlikely to cause serious adverse reactions in dogs, including puppies from eight weeks of age.

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:

(i) 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 products adequately demonstrate that if used according to the product label directions, the products are effective for the proposed uses.

The suite of products, Credelio Chewable Tablets for Dogs is intended for the treatment and prevention of flea infestations and treatment and control of ticks (Paralysis Ticks, Brown Dog Ticks and Bush Ticks) on dogs and puppies for up to one month. Five chewable tablet strengths are the basis for the products in the range. The minimum lotilaner dose rate is 20 mg/kg bodyweight and the maximum dose rate 43 mg/kg bodyweight.

This efficacy data package comprised of results from determination studies, dose confirmation studies, flea speed-of-kill studies, efficacy in a simulated home environment, field efficacy studies and target animal safety studies. The APVMA has concluded that the data generated from the efficacy studies support the claims that the product would be effective for the treatment and prevention of flea infestations and the treatment and control of ticks on dogs and puppies. The products have persistent tick killing activity for up to one month, including Paralysis ticks (*Ixodes holocyclus*), Brown Dog ticks (*Rhipicephalus sanguineus*) and Bush ticks (*Haemaphysalis longicornis*). Credelio Chewable Tablets for Dogs was found to be effective in the treatment and prevention of flea (*Ctenocephalides felis*) infestations and demonstrated killing activity within four to six hours of treatment.

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:

(i) The APVMA is satisfied that the proposed use of Credelio Chewable Tablets for Dogs would not adversely affect trade between Australia and places outside Australia. The product is for use in dogs, which are not food-producing animals and which do not produce 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 lotilaner should be approved and whether the application for registration of the products Credelio 900 Mg Chewable Tablets for Dogs, Credelio 450 Mg Chewable Tablets for Dogs, Credelio 225 Mg Chewable Tablets for Dogs, Credelio 112.5 Mg Chewable Tablets for Dogs And Credelio 56.25 Mg Chewable Tablets for Dogs 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 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)[1] material contained in submissions will be treated confidentially.

Written submissions should be addressed in writing to:

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

Phone: +61 2 6210 4701
Fax: +61 2 6210 4721
Email: enquiries@apvma.gov.au

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

Eimeriavax Plus Vaccine Containing Eimeria Brunetti Strain Roybru3+28

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application from Eimeria Pty Limited for the approval of the new active constituent, Eimeria Brunetti Strain Roybru$_{3+28}$, and for the registration of a new product containing this new active constituent. The proposed product is Eimeriavax Plus Vaccine as an aid in the control of coccidiosis caused by Eimeria necatrix and Eimeria brunetti in breeder, broiler and layer chickens.

PARTICULARS OF THE ACTIVE CONSTITUENT

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application for the approval of a new active constituent, Eimeria Brunetti Strain Roybru$_{3+28.}$

Name of active constituent:	Eimeria Brunetti Strain Roybru$_{3+28}$
Appearance:	Suspension
Sterility:	As per the European Pharmacopoeia
Extraneous agents:	As per the European Pharmacopoeia
Mycoplasma:	As per the European Pharmacopoeia
Gene technology:	Not Applicable
Mode of action:	Induction of immunological response

SUMMARY OF THE APVMA'S EVALUATION OF THE ACTIVE CONSTITUENT EIMERIA BRUNETTI STRAIN ROYBRU$_{3+28}$ 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 Eimeria Brunetti Strain Roybru$_{3+28}$ 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 assessed the chemistry and manufacturing aspects of the live attenuated Eimeria Brunetti Strain Roybru$_{3+28}$ and has determined that the active constituent is manufactured to an acceptable standard. The assessment included starting materials, master seeds (source, identity and purity), culture media, vaccine production, quality control, shelf life and batch release analysis.

The APVMA has considered the health aspect of the active constituent. The formulation does not contain an adjuvant, and different strains of E. brunetti are already approved for use in other registered products. The risks posed by the proposed strain in relation to skin irritation and skin sensitisation are expected to be highly similar, if not the same, as other registered products containing different strains. Low toxicity of the active constituent, and lack of human infectivity and pathogenicity, are expected.

The APVMA proposes to be satisfied that the use of live attenuated Eimeria Brunetti Strain Roybru$_{3+28}$ in a veterinary chemical product would not be an undue hazard to the safety of people exposed to it during its handling and use; and would not be likely to have an effect that is harmful to human beings; and would not be likely to have an unintended effect that is harmful to animals, plants or things or to the environment.

PARTICULARS OF THE PRODUCT

Proposed name:	Eimeriavax Plus Vaccine
Applicant Company:	Eimeria Pty Limited
Active constituent:	Eimeria Brunetti Strain Roybru$_{3+28}$
	Eimeria Necatrix Strain Mednec$_{3+8}$ (currently APVMA approved)
Adjuvant:	Not applicable
Scheduling:	Not applicable
Pharmaceutical form:	Suspension
Pack sizes:	1000 or 5000 dose of 25 ml suspension in 30 ml bottle
Summary of proposed use:	For vaccination of birds from 14 days of age as an aid in the control of coccidiosis caused by Eimeria necatrix and Eimeria brunetti in breeder, broiler and layer chickens in Australia**.**
Dose and route of administration:	Reconstitute the vaccine with clean water and administer allowing a single drop to fall freely into the open eye, or administration via drinking water. With individual bird administration, it is essential for each bird to receive a full dose. A second dose should be administered if the first is not fully absorbed by the eye. For the administration of the vaccine via drinking, an adequate number of drinkers or drinking space should be provided, so that all chicks have access to the vaccinal water and thus can receive the correct dose. It is recommended that all birds be vaccinated prior to 18 weeks of age.
Onset of immunity:	21 days
Duration of immunity:	A duration of immunity of 18 weeks post single vaccination in 14 day old birds.
Side effects:	If depression associated with vaccination is noted, light intensity should be increased and/or extended and extra feed provided. Monitor birds carefully for 4 weeks post-vaccination. Some lesions can be expected. Lesions can be associated with an immune response. Investigate all suspect coccidiosis lesions as this vaccine does not protect against Eimeria species that are not represented in the vaccine. Monitor gross lesions scores for 4 weeks post-vaccination.
Withholding period:	Zero (0) days

SUMMARY OF THE APVMA'S EVALUATION OF THE PRODUCT 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 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 Eimeriavax Plus Vaccine would not be an undue hazard to the safety of people exposed to it during its handling and use.

The live active is attenuated through passaging and the APVMA has concluded that there are negligible risks to the health and safety of people from the proposed commercial release of Eimeriavax Plus Vaccine containing Eimeria Brunetti Strain Roybru$_{3+28}$.

The excipients in Eimeriavax Plus Vaccine are already present in several vaccines registered for use in Australia or overseas, and would be expected to be of low oral, dermal and inhalational toxicity. There are no adjuvants, novel or otherwise.

The APVMA has determined that work health and safety for this live vaccine is acceptable and that labelling includes the following first aid instructions and safety directions of '*Accidental contact of Eimeriavax® Plus with eyes or mouth may cause irritation. Eyes should be rinsed immediately and medical advice sought. The mouth should be rinsed two or three times with a mouth gargle.*' are to be labelled to mitigate the risk. The product label will contain first aid statement '*if poisoning occurs, contact a doctor or Poisons Information Centre. Phone Australia 13 11 26.*'

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

The APVMA has conducted a review of the formulation of the proposed product Eimeriavax Plus Vaccine**,** which include excipients that are not novel and currently present in other registered vaccines. Therefore, there are no concerns from a residues and trade perspective.

(iii) The APVMA is satisfied that the proposed use of Eimeriavax Plus Vaccine containing the live attenuated active constituent, Eimeria Brunetti Strain Roybru$_{3+28}$, is not likely to be harmful to human beings if used according to the product label directions.

Given the low toxicity of the strain, and lack of human infectivity and pathogenicity, scheduling in the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) is not considered to be necessary.

(iv) The APVMA is satisfied that the proposed use of the product Eimeriavax Plus Vaccine containing the active constituent strain Eimeria Brunetti Strain Roybru$_{3+28}$, would not be likely to have an unintended effect that is harmful to animals, plants or things or the environment.

For veterinary medicinal products (VMPs), the APVMA has adopted VICH guidelines (VICH 2000) on data requirements for environmental safety (amongst other things). It is assumed that VMPs that satisfy the criteria of VICH phase 1 will have limited use and limited environmental exposure and consequently have limited environmental effects. A VICH Phase I environmental assessment was undertaken to identify environmental hazards and associated risks related to the new product Eimeriavax Plus Vaccine containing the active constituent Eimeria Brunetti Strain Roybru$_{3+28}$. The VICH Phase I assessment concluded that the risks that the product poses to the environment were considered to be acceptable, and are unlikely to be significantly different to those of similarly approved products containing E. brunetti. The live active constituent is attenuated through passaging. It is not a genetically-modified organism.

Eimeria Brunetti Strain Roybru$_{3+28}$ master seed lots were provided. The original isolate was from a non-commercial flock in Australia. The parent strain was prepared by the selection of 96 single oocysts from the small intestine of birds, with size of oocysts being the main selection criterion. The parent strain was purified by three successive single-oocyst passages, then attenuated by passaging in chicks 28 times for precocious development. An aliquot ARI # B61 of 31st passage E. brunetti RM$_{3+28}$, identified as Eimeria Brunetti Strain Roybru$_{3+28}$, was passed once through SPF chickens. The harvested oocysts were sporulated and stored as seed stock. The seed stock was passaged once in SPF chickens. Oocysts from the 33rd passage level were harvested, sporulated and stored as the master seed bulk oocyst suspension. The master seed bulk oocyst suspension was processed to release sporocysts and stored in cryo-preservative Eagles medium. A complete history tracing the first isolate through to the culture of the Eimeria Brunetti Strain Roybru3+28 Eimeria brunetti (Strain Roybru$_{3+28}$) master seed lots was provided with the application.

Confirmation of the identity of the master seed as Eimeria brunetti was effected by PCR. Potency testing was by Sporulated Oocyst Counts of master seed bulk stock prior to dispensing into the Master Seed Lots.

The master seed stock was tested as free of bacterial and fungal contamination in accordance with the monograph the European Pharmacopoeia (Ph. Eur.) 2.6.1., free of mycoplasma contamination in accordance with Ph. Eur. 2.6.7, and free from extraneous agents in accordance with Ph. Eur. 2.6.24.The master seed stocks were formulated in a cryo-preservation buffer composed of Eagles medium supplemented with foetal calf serum, streptomycin, penicillin and amphotericin.

There are no working seeds described for the application. It was confirmed that each batch of the production culture is grown from the master seed stock at passages three or four. There is no designated working seed, but harvested oocysts from the intervening passages are frozen and stored and resuscitated for passaging to make production cultures. The seed lineage is maintained, production cultures may be produced from activation of stored stock from intermediate passages one, two, three or four in a random manner.

Safety aspect of this proposed product is further supported by reversion-to-virulence studies. Two reversion-to-virulence studies that comply with the Ph. Eur. validity criteria were provided. No birds died from any cause during the study. The results also comply with the Ph. Eur. pass criteria for residual pathogenicity, and support a lack of reversion to virulence of the antigen organisms.

Data from an overdose study supports the safety of a 10x overdose of the applicant formulation, formulated at the proposed maximum release titre, in 14–day-old White Leghorn chicks of both gender. The results of a second 10x and third (28x) overdose study complied with the Ph. Eur. validity criteria. No more than 10% of birds dying from causes not attributable to vaccine oocysts. The results also complied with the Ph. Eur. pass criteria for residual pathogenicity. Data from a fourth and fifth overdose studies support the safety of the applicant formulation, in chickens less than the proposed minimum age (1 day old vs 14 days old) or at the proposed minimum age (14 day old) when administered by eye drop at 10x the proposed maximum titre of 460 oocysts/mL. The data therefore supports the proposed maximum release titre of 465 occysts/mL (310 oocysts/mL E. necatrix and 155 occysts/mL E. brunetti).

Field studies submitted were conducted in breeding birds and there were no reports of adverse reproductive outcomes after these birds were transitioned to reproduction farms. Thus, the trial data provided adequately supports the safety of the applicant formulation, when used as directed. No adverse interactions between the applicant formulation and other vaccines and medications used in routine husbandry were reported in the field studies.

Potential environmental exposure may occur from shedding of live organisms. The presence of live organisms in excrement is part of the preferred approach to lifting the immune response in the flock. The environmental risk of attenuated Eimeria necatrix in the proposed product is considered similar to the currently registered product, Eimeriavax 3M (APVMA No. 63631). Attenuated Eimeria brunetti species have not previously been administered to chickens for vaccination against coccidiosis. This may result in its release to the environment. However, for most chicken-rearing practices, there would be no release of viable organisms to the environment. There is the potential for some release from free-range chickens. However, Eimeria brunetti is no more pathogenic than other species of Eimeria spp. for which approval has already been granted. As these are attenuated species, they are likely to be even less pathogenic. Further, spread of the attenuated Eimeria brunetti to other species is considered unlikely as Eimeria spp. infect only specific species and tissues. The risks are therefore considered acceptable and unlikely to be significantly different to already approved products. To mitigate the risk, controls provided on the labels for the two existing registered vaccines (APVMA No. 54495 and 63631) will be included on the label for this new product including washing containers and spills with dilute bleach solution.

The safety of the product was extensively tested under both pen and field conditions. Studies demonstrated that the vaccine administered at a dose greater than 10 times the maximum release titre did not produce clinical signs of coccidiosis, and that the antigens did not display signs of residual pathogenicity. Further studies were performed to determine whether the live antigens might increase in virulence following repeated bird to bird passage. These studies demonstrated no signs of any increase in virulence following repeated passage of the antigens. Field studies were conducted in breeding birds and there were no reports of adverse reproductive outcomes after these birds were transitioned to reproduction farms. Thus, the trial data provided adequately support the safety of the formulation when used as directed. Overall, the conclusion drawn from these studies is that the vaccine is safe when administered to 14 day old birds by eye drop or drinking water under field conditions.

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 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.

Eimeriavax Plus Vaccine is intended for vaccination of birds from 14 days of age as an aid in the control of coccidiosis caused by Eimeria necatrix and Eimeria brunetti in breeder, broiler and layer chickens in Australia. The applicant has supplied studies conducted in Australia or Europe to demonstrate the overall efficacy of the product. Evaluations demonstrated that Eimeriavax Plus Vaccine was an aid in the control of coccidiosis caused by Eimeria necatrix and Eimeria brunetti in chickens.

The dose confirmation study has used the Eimeria Brunetti Strain Roybru$_{3+28}$ antigen, which is the new active constituent in the applicant formulation. The data supports a dose selection of 50 oocysts/dose for the E brunetti antigen.

For the laboratory efficacy study, the Ph. Eur. criteria for adequate efficacy are that at least 80% of the vaccinated birds must have intestinal lesion score (ILS) <1. At 7 days PC, 80% of the eye drop group and 90% of the drinking water group had ILS<1. Thus the vaccine efficacy criteria were met for both groups. The data supports the efficacy of the applicant formulation at 100 oocysts/dose E necatrix Mednec 3+8. Further six field studies were conducted to support comparable clinical efficacy, against E brunetti and E necatrix, at 1day old (by eye drop or spray on the birds) followed by a single dose of the applicant formulation at 7–14 day old, in layer or broiler breeder chickens.

Data from the duration of protection study supports the comparable efficacy of the vaccination at 9 months in birds vaccinated at 7 days old. The data supports duration of immunity of at least 9 months in chickens vaccinated with the applicant formulation via drinking water at 7 days old.

In summary, the APVMA has concluded that the data generated from the studies are consistent with the claim: *For vaccination of birds from 14 days of age as an aid in the control of coccidiosis caused by Eimeria necatrix and Eimeria brunetti in breeder, broiler and layer chickens in Australia.*

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:

The trade risk associated with the proposed use of Eimeriavax Plus Vaccine is low. Assessment of the formulation indicates that the excipients are not novel for use in vaccines, therefore, there are no concerns from a residues and trade perspective to the registration of this product. The proposed use of Eimeriavax Plus Vaccine on chickens (broiler, layer and breeder) is supported from a Residues and Trade Perspective. A withholding period of 'Zero (0) days' will be associated with the proposed use.

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 Eimeria Brunetti Strain Roybru$_{3+28}$ should be approved and whether the application for registration of Eimeriavax Plus Vaccine 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 Eimeriavax Plus Vaccine. These grounds include: for approval of the active constituent, the safety criteria; for the registration application for Eimeriavax Plus Vaccine 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.

When making a submission please include:

- a contact name
- a company or group name (if relevant)
- an 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 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 4701
Fax: +61 2 6210 4721
Email: enquiries@apvma.gov.au

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