Commonwealth of Australia

Gazette

No. APVMA 8, Tuesday, 19 April 2016

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

Director, Public Affairs and Communications
Australian Pesticides and Veterinary Medicines Authority
PO Box 6182
Kingston ACT 2604

Email: communications@apvma.gov.au
Website: www.apvma.gov.au.

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

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APVMA CONTACTS

For enquiries regarding the publishing and distribution of the *APVMA Gazette*: Telephone: +61 2 6210 4988

For enquiries on the *APVMA Gazette* content, please refer to the individual APVMA contacts listed under each notice.

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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.:	104765
Product name:	ACP Tribenuron 750 WG Herbicide
Active constituent/s:	750 g/kg tribenuron-methyl
Applicant name:	Australis Crop Protection Pty Ltd
Applicant ACN:	150 711 185
Summary of use	For the control of certain broadleaf weeds in fallows and pre-crop situations
Date of registration/approval:	29 March 2016
Product registration no.:	81989
Label approval no.:	81989/104765

Application no.:	103224
Product name:	Hovex Outdoor Control Bomb
Active constituent/s:	10 g/kg permethrin, 0.77 g/kg fenoxycarb
Applicant name:	Pascoe's Pty Ltd
Applicant ACN:	055 220 463
Summary of use	For use as an insecticide in outdoor home and garden use
Date of registration/approval:	30 March 2016
Product registration no.:	81505
Label approval no.:	81505/103224

Application no.:	105140
Product name:	Relyon Teboo 430SC Fungicide
Active constituent/s:	430 g/L tebuconazole
Applicant name:	Ruralco Holdings Limited
Applicant ACN:	009 660 879
Summary of use	For control of leaf spot and leaf speckle on bananas; rust, leaf spot and net blotch of peanuts; foliar diseases on cereal crops; and other diseases on beans, peas, onions, pawpaw, pyrethrum and ryegrass and fescue seed crops
Date of registration/approval:	31 March 2016
Product registration no.:	82181
Label approval no.:	82181/105140

Application no.:	105024
Product name:	Rumba 750 SG Herbicide
Active constituent/s:	750 g/kg clopyralid present as the potassium salt
Applicant name:	Rotam Agrochemical Co., Ltd
Applicant ACN:	N/A
Summary of use	For the control of a wide range of broadleaf weeds in wheat, barley, oats, triticale, canola, pastures and fallow land
Date of registration/approval:	4 April 2016
Product registration no.:	82105
Label approval no.:	82105/105024

Application no:	104891
Product name:	Relyon Ronlan 200GR Herbicide
Active constituent/s:	200 g/kg tebuthiuron
Applicant name:	Ruralco Holdings Limited
Applicant ACN:	009 660 879
Summary of use	For control of brigalow regrowth, tea tree regrowth, mimosa pigra and certain problem woody weeds on grazing lands as by hand, aerial and ground application
Date of registration/approval:	4 April 2016
Product registration no.:	82059
Label approval no.:	82059/104891

Application no.:	101198
Product name:	Tri-Form Drip 60 Soil Fumigant
Active constituent/s:	567 g/kg (801 g/L) chloropicrin, 371 g/kg (525 g/L) 1,3-dichloropropene
Applicant name:	Trical Australia Pty Ltd
Applicant ACN:	600 066 966
Summary of use	For use in the control of various soil borne pests and diseases in agricultural soils
Date of registration/approval:	4 April 2016
Product registration no.:	80597
Label approval no.:	80597/101198

Application no.:	105055
Product name:	Hexanil 750 SG Herbicide
Active constituent/s:	750 g/kg hexazinone
Applicant name:	Rotam Agrochemical Co., Ltd
Applicant ACN:	N/A
Summary of use	For the control of certain sedges, perennial grasses, broadleaf and woody weeds in pinus radiata forests and industrial weed control situations
Date of registration/approval:	4 April 2016
Product registration no.:	82123
Label approval no.:	82123/105055

Application no.:	102006
Product name:	Pyxal Insect Growth Regulator
Active constituent/s:	100 g/L pyriproxyfen
Applicant name:	FMC Australasia Pty Ltd
Applicant ACN:	095 326 891
Summary of use	For use in the control of pests including scale and whitefly in various crops and ornamentals in conjunction with the approval of pyriproxyfen
Date of registration/approval:	4 April 2016
Product registration no.:	80956
Label approval no.:	80956/102006

Application no:	105045
Product name:	Adama MCPA LVE 570 EC Herbicide
Active constituent/s:	570 g/L MCPA present as the 2-ethylhexyl ester
Applicant name:	Adama Australia Pty Limited
Applicant ACN:	050 328 973
Summary of use	For selective control of certain weeds in agricultural crops
Date of registration/approval:	5 April 2016
Product registration no.:	82115
Label approval no.:	82115/105045

Application no.:	101344
Product name:	Saniklenz Acid Detergent Sanitiser
Active constituent/s:	400 g/L phosphoric acid, 50 g/L sulphuric acid, 50 g/L glycolic acid
Applicant name:	Ruakura Pty Limited
Applicant ACN:	003 632 120
Summary of use	For use on stainless steel milking equipment
Date of registration/approval:	5 April 2016
Product registration no.:	80657
Label approval no.:	80657/101344

Application no.:	104016
Product name:	Wipe-Out 450 Herbicide
Active constituent/s:	450 g/L glyphosate (present as the isopropylamine salt)
Applicant name:	Adama Australia Pty Limited
Applicant ACN:	050 328 973
Summary of use	For the non-selective control of many annual and perennial weeds in conservation tillage situations
Date of registration/approval:	5 April 2016
Product registration no.:	81765
Label approval no.:	81765/104016

Application no.:	104771
Product name:	Relyon Glyphomate 540 Herbicide
Active constituent/s:	540 g/L glyphosate (present as the potassium salt)
Applicant name:	Ruralco Holdings Limited
Applicant ACN:	009 660 879
Summary of use	For non-selective control of many annual and perennial weeds
Date of registration/approval:	5 April 2016
Product registration no.:	81992
Label approval no.:	81992/104771

Application no.:	103037
Product name:	HANSA ADD 1055 Penetrant
Active constituent/s:	1020 g/L polyether modified polysiloxane
Applicant name:	CHT Australia Pty Ltd
Applicant ACN:	006 849 869
Summary of use	For use as a spray additive for improved coverage, penetration and uptake of agricultural chemical sprays
Date of registration/approval:	6 April 2016
Product registration no.:	81402
Label approval no.:	81402/103037

Application no.:	103194
Product name:	Farmalinx Brigadier Herbicide
Active constituent/s:	240 g/L triclopyr present as the butoxyethyl ester, 120 g/L picloram present as the isooctyl ester
Applicant name:	Farmalinx Pty Ltd
Applicant ACN:	134 353 245
Summary of use	For selective control of a wide range of woody and noxious weeds in commercial and industrial areas, public lands, fence lines and pastures by basal bark and cut stump applications
Date of registration/approval:	6 April 2016
Product registration no.:	81480
Label approval no.:	81480/103194

Application no.:	103151
Product name:	MacPhersons Torpico 750 WG Herbicide
Active constituent/s:	750 g/kg picolinafen
Applicant name:	TGAC Australia Pty. Ltd
Applicant ACN:	134 570 700
Summary of use	For the control of wild radish in field peas and narrow leaf lupins
Date of registration/approval:	6 April 2016
Product registration no.:	81456
Label approval no.:	81456/103151

Application no.:	105278
Product name:	Weed Force Hexazinone 750 SG Herbicide
Active constituent/s:	750 g/kg hexazinone
Applicant name:	Weed Force Pty Ltd
Applicant ACN:	602 207 152
Summary of use	For the control of certain sedges, perennial grasses, broadleaf and woody weeds in pinus radiata forests and industrial weed control situations
Date of registration/approval:	7 April 2016
Product registration no.:	82249
Label approval no.:	82249/105278

Application no.:	105143
Product name:	Relyon Picaro 250EC Fungicide
Active constituent/s:	250 g/L propiconazole
Applicant name:	Ruralco Holdings Limited
Applicant ACN:	009 660 879
Summary of use	For the control of certain fungal diseases of bananas, oats, peanuts, perennial ryegrass, pineapples, stone fruit, sugarcane, wheat and other crops
Date of registration/approval:	7 April 2016
Product registration no.:	82182
Label approval no.:	82182/105143

Application no.:	104773
Product name:	AC Abseil 500 Herbicide
Active constituent/s:	500 g/L atrazine
Applicant name:	Axichem Pty Ltd
Applicant ACN:	131 628 594
Summary of use	For use in the crops and situations described in the directions for use table
Date of registration/approval:	7 April 2016
Product registration no.:	81994
Label approval no.:	81994/104773

Application no.:	105246
Product name:	The Big Cheese Ultra Power Disposable Mouse Kill Bait Station
Active constituent/s:	0.05 g/kg brodifacoum
Applicant name:	Pelgar International (Aus) Pty Ltd
Applicant ACN:	159 699 779
Summary of use	For the control of mice in various urban situations
Date of registration/approval:	7 April 2016
Product registration no.:	82234
Label approval no.:	82234/105246

Application no.:	105228
Product name:	Cherokee 900 Fungicide
Active constituent/s:	900 g/kg chlorothalonil
Applicant name:	Crop Culture Pty Ltd
Applicant ACN:	142 860 473
Summary of use	For the control of fungal diseases on almonds, apricots, bananas, carrots, celery, cherries, faba beans, grapes, onions, peaches, peanuts, peas, plums, potatoes, tomatoes and vegetables
Date of registration/approval:	8 April 2016
Product registration no.:	82224
Label approval no.:	82224/105228

Application no.:	101558
Product name:	Hovex Natural Mosquito Coils
Active constituent/s:	2.5 g/kg pyrethrin
Applicant name:	Pascoe's Pty Ltd
Applicant ACN:	055 220 463
Summary of use	For repelling and killing mosquitoes for up to 8 hours
Date of registration/approval:	8 April 2016
Product registration no.:	80755
Label approval no.:	80755/101558

Application no.:	103036
Product name:	EuroChem SHAPEX Plant Growth Regulator
Active constituent/s:	19 g/L gibberellins A4 and A7 19 g/L 6-benzyladenine
Applicant name:	Ronic International Pty Limited
Applicant ACN:	101 193 131
Summary of use	Can improve fruit shape/typiness in apples, for use in thinning in apples when used in combination with a 20 g/L 6-benzyladenine (6-BA) plant growth regulator, for thinning of red delicious and gala apples in combination with NAA and also for promotion of lateral growth in red delicious apples and cherries
Date of registration/approval:	8 April 2016
Product registration no.:	81401
Label approval no.:	81401/103036

Application no.:	60603
Product name:	Term-Seal Creo-Fen Ten Termite and Waterproof Barrier
Active constituent/s:	1 g/L bifenthrin
Applicant name:	Term-Seal (Aust) Pty Limited
Applicant ACN:	104 603 983
Summary of use	For the protection of softwood and non-durable hardwood timber posts, poles, fencing and landscape timbers from concealed entry by subterranean termites
Date of registration/approval:	11 April 2016
Product registration no.:	69368
Label approval no.:	69368/60603

2. VARIATIONS OF REGISTRATION

Application no.:	105726
Product name:	Relyon Performa M Herbicide
Active constituent/s:	340 g/L MCPA (present as the dimethylamine salt), 80 g/L dicamba (present as the dimethylamine salt)
Applicant name:	Ruralco Holdings Limited
Applicant ACN:	009 660 879
Summary of variation:	To change the distinguishing product name and the name that appears on the label from 'RELYON SAMBA M 500 HERBICIDE' to 'RELYON PERFORMA M HERBICIDE'
Date of variation:	22 February 2016
Product no.:	81885
Label approval no.:	81885/105726

Application no.:	105820
Product name:	Macro Protect LV Ester 680 Herbicide
Active constituent/s:	680 g/L 2, 4-D present as the 2-ethylhexyl ester
Applicant name:	Macrofertil Australia Pty Ltd
Applicant ACN:	166 370 976
Summary of variation:	To change the distinguishing product name and the name that appears on the label from 'D CLEAN ESTER 680 HERBICIDE' to 'MACRO PROTECT LV ESTER 680 HERBICIDE'
Date of variation:	2 March 2016
Product no.:	64539
Label approval no.:	64539/105820

Application no.:	105928
Product name:	Allgraze Grassland Herbicide
Active constituent/s:	200 g/kg tebuthiuron
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 'SCRUBMASTER HERBICIDE' to 'ALLGRAZE GRASSLAND HERBICIDE'
Date of variation:	7 March 2016
Product no.:	64267
Label approval no.:	64267/105928

Application no.:	105929
Product name:	Reserve Stressgard Turf Fungicide
Active constituent/s:	720 g/L chlorothalonil
Applicant name:	Bayer Cropscience Pty Ltd
Applicant ACN:	000 226 022
Summary of variation:	To change the distinguishing product name and the name that appears on the label from 'RESERVE FUNGICIDE' to 'RESERVE STRESSGARD TURF FUNGICIDE'
Date of variation:	8 March 2016
Product no.:	81269
Label approval no.:	81269/105929

Application no.:	105986
Product name:	Apparent Fireball 400 Herbicide
Active constituent/s:	400 g/L fluroxypyr present as the methyl heptyl ester
Applicant name:	Apparent Pty. Ltd
Applicant ACN:	143 724 136
Summary of variation:	To change the distinguishing product name and the name that appears on the label from 'APPARENT FLUROXYPYR 400 HERBICIDE' to 'APPARENT FIREBALL 400 HERBICIDE'
Date of variation:	16 March 2016
Product no.:	81917
Label approval no.:	81917/105986

Application no.:	106080
Product name:	Harlem 520 EC Herbicide
Active constituent/s:	520 g/L haloxyfop-p present as the haloxyfop-p-methyl ester
Applicant name:	Rotam Agrochemical Co., Ltd
Applicant ACN:	N/A
Summary of variation:	To change the distinguishing product name and the name that appears on the label from 'ROTAM HALOXYFOP 520 EC HERBICIDE' to 'HARLEM 520 EC HERBICIDE'
Date of variation:	28 March 2016
Product no.:	81102
Label approval no.:	81102/106080

Application no:	104998
Product name:	Rotam Acaramik Insecticide/Miticide EC
Active constituent/s:	18 g/L abamectin
Applicant name:	Rotam Agrochemical Co., Ltd
Applicant ACN:	N/A
Summary of variation:	To add new 10 L and 20 L pack sizes
Date of variation:	29 March 2016
Product registration no.:	56346
Label approval no.:	56346/104998

Application no:	105113
Product name:	Rotam Rometri 480 SC Selective Herbicide
Active constituent/s:	480 g/L metribuzin
Applicant name:	Rotam Agrochemical Co., Ltd
Applicant ACN:	N/A
Summary of variation:	To add new 10 L, 20 L, 50 L and 200 L pack sizes
Date of variation:	30 March 2016
Product registration no.:	69264
Label approval no.:	69264/105113

Application no:	105112
Product name:	Rotam Escudo 250 SC Fungicide
Active constituent/s:	250 g/L azoxystrobin
Applicant name:	Rotam Agrochemical Co., Ltd
Applicant ACN:	N/A
Summary of variation:	To add new 10 L and 50 L pack sizes
Date of variation:	30 March 2016
Product registration no.:	69551
Label approval no.:	69551/105112

Application no:	103982
Product name:	Slugger Slug and Snail Pellets
Active constituent/s:	15 g/kg metaldehyde
Applicant name:	Adama Australia Pty Limited
Applicant ACN:	050 328 973
Summary of variation:	To extend use to snails and slugs including: common white snail, white Italian snail, conical small snail and grey field slug in winter cereals, oilseeds pulses and pasture establishment
Date of variation:	30 March 2016
Product registration no.:	46023
Label approval no.:	46023/103982

Application no:	102406
Product name:	Crop Care Sentry Herbicide
Active constituent/s:	525 g/kg imazapic, 175 g/kg imazapyr
Applicant name:	Crop Care Australasia Pty Ltd
Applicant ACN:	061 362 347
Summary of variation:	To extend the use to add pre-emergent weed control in barley and wheat (single gene)
Date of variation:	31 March 2016
Product registration no.:	67951
Label approval no.:	67951/102406

Application no:	102566
Product name:	Delaval Antistone Acid Milking Machine Detergent
Active constituent/s:	204 g/L nitric acid, 56 g/L sulfamic acid
Applicant name:	Delaval Pty Ltd
Applicant ACN:	004 210 459
Summary of variation:	To vary dose range
Date of variation:	31 March 2016
Product registration no.:	54468
Label approval no.:	54468/102566

Application no.:	103527
Product name:	Terbyne Xtreme 875 WG Herbicide
Active constituent/s:	875 g/kg terbuthylazine
Applicant name:	Sipcam Pacific Australia Pty Ltd
Applicant ACN:	073 176 888
Summary of variation:	To extend use to control weeds in vetch in a pre-sowing and incorporate by sowing (IBS) situation
Date of variation:	1 April 2016
Product registration no.:	68613
Label approval no.:	68613/103527

Application no.:	103900
Product name:	Foragemax Herbicide
Active constituent/s:	50 g/L aminopyralid present as triisopropanolamine salt, 100 g/L halauxifen-methyl
Applicant name:	Dow Agrosciences Australia Limited
Applicant ACN:	003 771 659
Summary of variation:	To extend use to additional weeds and refine the plant back periods
Date of variation:	5 April 2016
Product registration no.:	68249
Label approval no.:	68249/103900

Application no:	105102
Product name:	Rotam Milor 720 WP Fungicide
Active constituent/s:	640 g/kg mancozeb, 80 g/kg metalaxyl
Applicant name:	Rotam Agrochemical Co., Ltd
Applicant ACN:	N/A
Summary of variation:	To add a new 10 kg pack size
Date of variation:	5 April 2016
Product registration no.:	69437
Label approval no.:	69437/105102

Application no:	103018
Product name:	Apparent S-Metolachlor 960 Herbicide
Active constituent/s:	960 g/L s-metolachlor
Applicant name:	Apparent Pty. Ltd
Applicant ACN:	143 724 136
Summary of variation:	To change the name of the product from ‘APPARENT METOLACHLOR 960 HERBICIDE’ to ‘APPARENT S-METOLACHLOR 960 HERBICIDE’
Date of variation:	6 April 2016
Product registration no.:	66008
Label approval no.:	66008/103018

Application no:	105104
Product name:	Rotam Allez 350 SC Insecticide
Active constituent/s:	350 g/L imidacloprid
Applicant name:	Rotam Agrochemical Co., Ltd
Applicant ACN:	N/A
Summary of variation:	To add new 20 L, 50 L, 100 L and 200 L pack sizes
Date of variation:	6 April 2016
Product registration no.:	69506
Label approval no.:	69506/105104

Application no:	105035
Product name:	Weed and Grass Roundup Ready to Use Weedkiller
Active constituent/s:	7.4 g/L glyphosate present as the isopropylamine salt, 0.72 g/L triclopyr as the triethylamine salt
Applicant name:	Monsanto Australia Ltd
Applicant ACN:	006 725 560
Summary of variation:	To include use on hard surfaces and include a range of pack sizes
Date of variation:	6 April 2016
Product registration no.:	69979
Label approval no.:	69979/105035

Application no:	105165
Product name:	Disect 100 EC Insecticide/Miticide
Active constituent/s:	100 g/L bifenthrin
Applicant name:	UPL Australia Limited
Applicant ACN:	066 391 384
Summary of variation:	To add a 110 L pack size
Date of variation:	7 April 2016
Product registration no.:	56684
Label approval no.:	56684/105165

Application no.:	101733
Product name:	Senator 700WG Insecticide
Active constituent/s:	700 g/kg imidacloprid
Applicant name:	Crop Care Australasia Pty Ltd
Applicant ACN:	061 362 347
Summary of variation:	To extend the use to include the control of silverleaf whitefly and aphids in brassicas and lettuce when applied as a seedling drench and as a furrow spray into potatoes, and additional canegrub species in sugarcane
Date of variation:	8 April 2016
Label approval no.:	68192/101733

Application no:	105659
Product name:	Sharp Shooter Rose Black Spot & Insect Spray Concentrate
Active constituent/s:	4.8 g/L tau-fluvalinate, 2.2 g/L myclobutanil
Applicant name:	Ausgro Technologies Pty Ltd
Applicant ACN:	062 891 123
Summary of variation:	To change the name of the product from 'SHARP SHOOTER ROSE BLACK SPOT & PYRETHRUM CONCENTRATE' to 'SHARP SHOOTER ROSE BLACK SPOT & INSECT SPRAY CONCENTRATE'
Date of variation:	11 April 2016
Product registration no.:	63482
Label approval no.:	63482/105659

Application no:	105632
Product name:	Talon Rat & Mouse Killer All Weather Wax Blocks
Active constituent/s:	0.05 g/kg brodifacoum
Applicant name:	Syngenta Australia Pty Ltd
Applicant ACN:	002 933 717
Summary of variation:	To change the name of the product from 'TALON RODENTICIDE WAX BLOCKS' to 'TALON RAT & MOUSE KILLER ALL WEATHER WAX BLOCKS' and make minor label amendments
Date of variation:	11 April 2016
Product registration no.:	52675
Label approval no.:	52675/105632

Application no:	105629
Product name:	Talon Rat & Mouse Killer Wax Blocks
Active constituent/s:	0.05 g/kg brodifacoum
Applicant name:	Syngenta Australia Pty Ltd
Applicant ACN:	002 933 717
Summary of variation:	To change the name of the product from 'TALON RAT & MOUSE KILLER DAMP OR DRY AREAS' to 'TALON RAT & MOUSE KILLER WAX BLOCKS' and to make minor label amendments
Date of variation:	11 April 2016
Product registration no.:	58339
Label approval no.:	58339/105629

Application no:	104911
Product name:	Nufarm Terbazine 875WG Herbicide
Active constituent/s:	875 g/kg terbuthylazine
Applicant name:	Nufarm Australia Limited
Applicant ACN:	004 377 780
Summary of variation:	To include additional use pattern of 'fallows'
Date of variation:	11 April 2016
Product registration no.:	69790
Label approval no.:	69790/104911

Application no:	104222
Product name:	Rotam Aprisco Fungicide
Active constituent/s:	720 g/L chlorothalonil
Applicant name:	Rotam Agrochemical Co., Ltd
Applicant ACN:	N/A
Summary of variation:	To extend use into chickpeas and lentils
Date of variation:	11 April 2016
Product registration no.:	61705
Label approval no.:	61705/104222

3. LABEL APPROVAL

Application no.:	105071
Product name:	Concentrate Advance Roundup Weedkiller
Active constituent/s:	360 g/L glyphosate present as the isopropylamine salt
Applicant name:	Monsanto Australia Ltd
Applicant ACN:	006 725 560
Summary of use:	To approve a new label for the product with the label name 'CONCENTRATE ROUNDUP PATH & DRIVE WEEDKILLER'
Date of approval:	30 March 2016
Label approval no.:	52816/105071

Application no.:	104100
Product name:	IQ International Quadratics Pool Solutions Algae Eliminator
Active constituent/s:	400 g/L benzalkonium chloride
Applicant name:	International Quadratics Pty Ltd
Applicant ACN:	091 533 167
Summary of use:	To approve a new label for the product with the label name 'POOL WISE POOL ALGAECIDE'
Date of approval:	8 April 2016
Label approval no.:	63092/104100

Application no.:	105622
Product name:	Le-Mat 290 SL Insecticide
Active constituent/s:	290 g/L omethoate (an anticholinesterase compound)
Applicant name:	Arysta Lifescience North America LLC
Applicant ACN:	N/A
Summary of use:	To approve a new label for the product with the label name 'ARYSTA O-MAT 290 SL INSECTICIDE'
Date of approval:	11 April 2016
Label approval no.:	45672/105622

4. VARIATION OF LABEL APPROVAL

Application no:	104941
Product name:	Transform Insecticide
Active constituent/s:	240 g/L sulfoxaflor
Applicant name:	Dow Agrosciences Australia Limited
Applicant ACN:	003 771 659
Summary of variation:	To update restraints, directions for use statements and add critical comment statements
Date of variation:	1 April 2016
Product registration no.:	64101
Label approval no.:	64101/104941

Veterinary Chemical Products and Approved Labels

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

1. VETERINARY PRODUCTS BASED ON EXISTING ACTIVE CONSTITUENTS

Application no.:	104073
Product name:	Ulcershield Paste for Horses
Active constituent/s:	370 mg/g omeprazole
Applicant name:	Randlab Australia Pty Ltd
Applicant ACN:	114 948 837
Summary of use	For the treatment and prevention of gastric ulcers in horses and foals
Date of registration/approval:	27 January 2016
Product registration no.:	81799
Label approval no.:	81799/104073

Application no.:	105273
Product name:	Exelpet Intestinal All-Wormer Tablets for Dogs
Active constituent/s:	Each tablet contains 542 mg oxantel embonate, 143 mg pyrantel embonate and 50 mg praziquantel
Applicant name:	Exelpet Products A Division Of Mars Australia Pty Ltd
Applicant ACN:	008 454 313
Summary of use	For the control of roundworm, hookworm, whipworm and tapeworm in dogs. Also controls hydatid tapeworm
Date of registration/approval:	30 March 2016
Product registration no.:	82245
Label approval no.:	82245/105273

2. VARIATIONS OF REGISTRATION

Application no.:	105836
Product name:	Baymec Pour-On For Cattle
Active constituent/s:	5.0 g/L ivermectin
Applicant name:	Bayer Australia Ltd (Animal Health)
Applicant ACN:	000 138 714
Summary of variation:	To change the distinguishing product name and the name that appears on the label from 'IVERMECTIN BAYMEC POUR-ON FOR CATTLE' to 'BAYMEC POUR-ON FOR CATTLE'
Date of variation:	2 March 2016
Product no.:	51138
Label approval no.:	51138/105836

Application no:	102190
Product name:	Cephalexin 200 Tablets
Active constituent/s:	200 mg cephalexin (as cephalexin monohydrate)
Applicant name:	Apex Laboratories Pty Ltd
Applicant ACN:	000 397 240
Summary of variation:	To change the distinguishing product name from 'CEPHALEXIN 200 ANTIBIOTIC TABLETS' to 'CEPHALEXIN 200 TABLETS' and to add new pack sizes
Date of variation:	1 April 2016
Product registration no.:	41053
Label approval no.:	41053/102190

Approved Active Constituents

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

1. ACTIVE CONSITUTENT

Application no.:	103122
Active constituent/s:	Metalaxyl-M
Applicant name:	Nufarm Australia Limited
Applicant ACN:	004 377 780
Summary of use:	For use in agricultural chemical products
Date of approval:	29 March 2016
Approval no.:	81437

Application no.:	103532
Active constituent/s:	Fluquinconazole
Applicant name:	Landmark Operations Ltd
Applicant ACN:	008 743 217
Summary of use:	For use in agricultural chemical products
Date of approval:	4 April 2016
Approval no.:	81643

Application no.:	103347
Active constituent/s:	Fludioxonil
Applicant name:	Shandong Rainbow International Co., Ltd
Applicant ACN:	N/A
Summary of use:	For use in agricultural chemical products
Date of approval:	6 April 2016
Approval no.:	81553

Application no.:	103570
Active constituent/s:	Bifenazate
Applicant name:	UPL Australia Limited
Applicant ACN:	066 391 384
Summary of use:	For use in agricultural chemical products
Date of approval:	7 April 2016
Approval no.:	81657

Application no.:	103411
Active constituent/s:	Gibberellic acid
Applicant name:	TGAC Australia Pty. Ltd
Applicant ACN:	134 570 700
Summary of use:	For use in agricultural chemical products
Date of approval:	7 April 2016
Approval no.:	81584

2. VARIATIONS OF ACTIVE CONSTITUENT

Application no.:	103219
Active constituent/s:	Copper Pyrithione
Applicant name:	Lonza Cologne GBMH
Applicant ACN:	N/A
Summary of variation:	Variation to particulars of the manufacturer
Date of variation:	7 April 2016
Approval no.:	58181

Licensing of Veterinary Chemical Manufacturers

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

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

1. NEW LICENCES

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

Nil

2. CHANGES TO EXISTING LICENCES

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

SEQUIRUS PTY LTD

ACN: 160 735 035

39–79 Poplar Road

PARKVILLE VIC 3052

LICENCE NO: 1106

Product Types:*

Category 1: Immunobiological and Sterile products

Step(s) of Manufacture: Quality assurance (QA) of raw materials, formulation including blending, aseptic filling, packaging, labelling, freeze-drying, sterilisation (filtration), microbiological reduction treatment (filtration), analysis and testing (physical, chemical, endotoxin, microbiological, sterility testing, serological, immunobiological) and storage.

Amended Licence Issued: 2 March 2016

NOWRA CHEMICAL MANUFACTURES PTY LTD

ACN: 001 505 988

112A Albatross Road

NOWRA NSW 2541

LICENCE NO: 2164

Product Types: *

Category 2: Creams, lotions, ointments, pastes and liquids

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

Amended Licence Issued: 4 March 2016

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

SUMMERLAND SERUMS PTY LTD

ACN: 122 400 908

192 Dalwood Road

ALSTONVILLE NSW 2477

LICENCE NO: 1083

Product Types:*

- *Category 1*: Immunobiologicals (tick antiserums), Immunobiologicals (snake antivenoms)

Step(s) of Manufacture: Quality assurance (QA) of raw materials, management and immunisation of donor animals, serum collection, formulation including blending, aseptic filling, packaging, labelling, sterilisation (heat, filtration), microbiological reduction treatment (heat, filtration), analysis and testing (physical), storage and release for supply.

Amended Licence Issued: 11 March 2016

SOUTHERN CROSS UNIVERSITY

ABN: 41 995 651 524

Southern Cross Plant Science Analytical Services

Level 3, T-Block and N-Block

Southern Cross University

Military Road

LISMORE NSW 2480

LICENCE NO: 6129

Product Types: *

- *Category 6*: Single step manufacture

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

Amended Licence Issued: 24 March 2016

DASCO PROPRIETARY LIMITED

ACN: 004 581 113

24–26 Helen Street

HEIDELBERG HEIGHTS VIC 3081

LICENCE NO: 2066

Product Types: *

- *Category 2*: Creams/lotions, ointments, pastes, powders and liquids

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

Amended Licence Issued: 24 March 2016

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

CHEMICAL ANALYSIS PTY LTD

ACN: 114 804 572

110 Merrindale Drive

CROYDON VIC 3136

LICENCE NO: 6177

Product Types: *

- *Category 6:* Single step manufacture

Step(s) of Manufacture: Analysis and testing (physical, chemical, microbiological, sterility and Limulus Amoebocyte Lysate [LAL] test)

Amended Licence Issued: 24 March 2016

THE UNIVERSITY OF MELBOURNE APCAH ASIA PACIFIC CENTRE FOR ANIMAL HEALTH

ABN: 84 002 705 224

250 Princes Highway

WERRIBEE VIC 3030

LICENCE NO: 6049

Product Types: *

- *Category 6*: Single step manufacture

Step(s) of Manufacture: Analysis and testing (microbiological and immunobiological)

Amended Licence Issued: 29 March 2016

3. LICENCE CANCELLATIONS

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

TSI PHARMACEUTICALS PTY LTD

ACN: 052 101 176

262 Evans Road

SALISBURY QLD 4107

LICENCE NO: 2226

Date Cancelled: 21 March 2016

4. LICENCE SUSPENSIONS

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

Nil

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

5. REVOCATION OF LICENCE CANCELLATION

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

Nil

6. REVOCATION OF LICENCE SUSPENSION

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

Nil

APVMA CONTACT

Manufacturing Quality and Licensing Section
Legal and Compliance Program
Australian Pesticides and Veterinary Medicines Authority
PO Box 6182
KINGSTON ACT 2604
Phone: +61 2 6210 4899
Fax: +61 2 6210 4813
Email: mls@apvma.gov.au

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

New Agricultural Active Constituent Fosthiazate

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

Common Name: Fosthiazate (ISO approved)

IUPAC Name: *(RS)-S-sec-butyl O-ethyl 2-oxo-1,3-thiazolidin-3-ylphosphonothioate*

CAS Name: *O-ethyl S-(1-methylpropyl) (2-oxo-3-thiazolidinyl)phosphonothioate*

CAS Registry Number: 98886-44-3

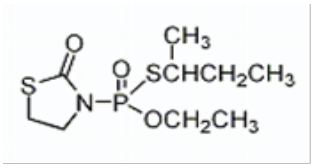
Manufacturer's Code: IKI-1145

Minimum Purity: 930 g/kg

Molecular Formula: $C_9H_{18}NO_3PS_2$

Molecular Weight: 283.3

Structure:



Chemical Family: Organothiophosphate

Mode of Action: Nematicide

SUMMARY OF THE APVMA'S EVALUATION OF FOSTHIAZATE ACTIVE CONSTITUENT

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

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

Constituent	Specification	Level
Fosthiazate	Fosthiazate	Not less than 930 g/kg

Other compounds of toxicological significance are not expected to occur in Fosthiazate TGAC as a result of the raw materials and the synthetic route used.

The Office of Chemical Safety (OCS) has considered the toxicological aspects of Fosthiazate TGAC, and advised that there are no toxicological objections to the approval of this chemical.

No Acceptable Daily Intake (ADI) and no Acute Reference Dose (ARfD) have been set as no product has been proposed for registration at this time.

Based on the toxicity profile of the active constituent, the OCS recommended to the Delegate of the Secretary of the Department of Health that fosthiazate be added to Schedule 7 of the SUSMP with no exemptions or cut-offs.

The National Drugs and Poisons Schedule Committee (NDPSC) considered Fosthiazate to be appropriate for inclusion in Schedule 7 of the SUSMP with no exemptions or cut-offs at its July 2014 meeting. The delegate's final decision was published on the TGA website on 17 December 2014. The implementation date was 1 February 2015.

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

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

MAKING A SUBMISSION

In accordance with section 12 of the Agvet Code, the APVMA invites any person to submit a relevant written submission as to whether the application for approval of Fosthiazate should be granted.

Submissions should relate only to matters that are considered in determining whether the safety criteria set out in section 5A of the Agvet Code have been met. Submissions should state the grounds on which they are based.

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

When making a submission please include:

- 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:

Chemistry and Manufacture Director
Scientific Assessment and Chemical Review Program
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.

New Agricultural Active Constituent Amisulbrom

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

Amisulbrom is a white odourless, pale yellow crystalline solid (99.8%) or pale brown fine powder (98.9%) with no odour, a melting range of 128–130ºC. Its solubility in water is 0.11 mg/l at 20 °C.

Common Name: Amisulbrom

IUPAC Name: 3-(3-bromo-6-fluoro-2-methylindol-1-ylsulfonyl)-N,N-dimethyl-1H-1,2,4-triazole-1-sulfonamide.

CAS Name: 3-[(3-bromo-6-fluoro-2-methyl-1H-indol-1-yl)sulfonyl]-N,N-dimethyl-1H-1,2,4-triazole-1-sulfonamide.

CAS Registry Number: 348635-87-0

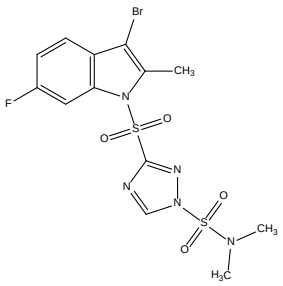
Manufacturer's Codes: NC-224

Minimum Purity: 965 g/kg

Molecular Formula: C13H13BrFN5O4S2

Molecular Weight: 466.3

Structure:



Chemical Family: Sulfonamide fungicides; triazole fungicides

Mode of Action: Amisulbrom is a quinone inside inhibitor. It Inhibits fungal respiration with binding to the Qi centre site on cytochrome bc1 (ubiquinone reductase) in complex iii.

SUMMARY OF THE APVMA'S EVALUATION OF AMISULBROM ACTIVE CONSTITUENT

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

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

Constituent	Specification	Level
Amisulbrom	Amisulbrom	965 g/kg minimum

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

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

An Acceptable Daily Intake (ADI) of 0.1 mg/kg bw/d has been set, based on a No-Observed Effect Level (NOEL) of 11 mg/kg bw/d in a 2–year combined carcinogenicity/chronic toxicity study in rats and a 78–week carcinogenicity study in mice. A safety factor of 100 accounts for both intra- and inter-species variation and effects seen on the liver and kidney at higher doses.

The Advisory Committee on Chemicals Scheduling (ACCS) considered amisulbrom to be appropriate for inclusion in Schedule 5 of the Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP).

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

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

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

MAKING A SUBMISSION

In accordance with sections 12 of the Agvet Code, the APVMA invites any person to submit a relevant written submission as to whether the application for approval of amisulbrom should be granted. Submissions should relate only to matters that the APVMA is required by legislation to consider in deciding whether to grant the approval. These grounds include chemistry and manufacture, and toxicity. Submissions should state the grounds on which they are based. Comments received outside these grounds cannot be considered by the APVMA.

Submissions must be received by the APVMA within 28 days of the date of this notice and be directed to the contact listed below. All submissions to the APVMA will be acknowledged in writing via email or by post. A summary of relevant comments and the APVMA's response will be published on the APVMA website.

When making a submission please include:

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

All personal and *confidential commercial information (CCI)*[2] material contained in submissions will be treated confidentially.

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

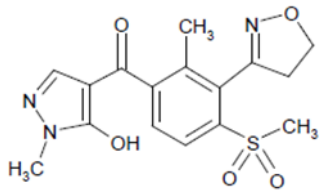
Director Chemistry and Manufacture
Scientific Assessments and Chemical Review Program
Australian Pesticides and Veterinary Medicines Authority
PO Box 6182
KINGSTON ACT 2604

Phone: +61 2 6210 4936
Fax: +61 2 6210 4840
Email: chemistry@apvma.gov.au

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

New Agricultural Active Constituent Topramezone

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application for approval of a new active constituent, topramezone for use as a herbicide in agricultural end-use products.

Common Name	Topramezone
IUPAC Name:	[3-(4,5-dihydro-isoxazol-3-yl)-4-methylsulfonyl-2-methylphenyl](5-hydroxy-1-methyl-1*H*-pyrazol-4-yl)methanone
Chemical Abstracts Name:	[3-(4,5-dihydro-3-isoxazolyl)-2-methyl-4-(methylsulfonyl)phenyl](5-hydroxy-1-methyl-1*H*-pyrazol-4-yl)-Methanone
Manufacturer's Code/s	BAS 670 H
CAS Number:	210631-68-8
Molecular Formula:	C16H17N3O5S
Molecular Weight:	363.39
Structure:	
Chemical Family:	Benzoylpyrazoles or oxazoles
Mode of Action:	Herbicide

SUMMARY OF THE APVMA'S EVALUATION OF TOPRAMEZONE ACTIVE CONSTITUENT

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

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

Constituent	Specification	Level
topramezone	topramezone	970 g/kg minimum

Other compounds of toxicological significance are not expected to occur in topramezone TGAC as a result of the raw materials and the synthetic route used.

The Office of Chemical Safety (OCS) has considered the toxicological aspects of topramezone TGAC, and has advised that there should be no concerns on human health grounds to the approval of the active constituent topramezone.

The ADI and ARfD for topramezone were established at 0.001 mg/kg bw/d, based on a NOEL of 0.5 mg/kg bw/d in developmental studies in rabbits, and applying a 500–fold safety factor; 10 each for intraspecies and interspecies effects, and an additional 5–fold factor for the severity of toxicity (teratogenicity), which may occur as a result of acute exposure.

Embryofoetal effects observed at the higher dose of 5 mg/kg bw/d included an increased incidence of skeletal variations (delayed ossification and supernumerary vertebrae and/or ribs) and visceral malformations (missing kidney/ureter).

The Advisory Committee on Chemicals Scheduling (ACCS) recommended at its meeting of November 2015 that it is appropriate to include topramezone in Schedule 5 of the Poisons Standard. In the Reasons for the scheduling in the Delegate's final decision (published on 17 March 201, the Delegate confirmed that listing of topramezone in Schedule 5 is appropriate with no exemptions. This decision is based on the overall toxicological profile of topramezone, which is consistent with the Scheduling Policy Framework (SPF) criteria for listing in Schedule 5. The equivocal nature of the foetal developmental effects, including the apparently flat dose-response relationship and their possible relationship to the elevated tyrosine levels associated with treatment with this 4–hydroxyphenylpyruvate dioxygenase (4–HPPD) inhibitor, were considered insufficient to require listing in Schedule 6. The implementation date of topramezone is 1 June 2016.

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

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

MAKING A SUBMISSION

In accordance with sections 12 of the Agvet Code, the APVMA invites any person to submit a relevant written submission as to whether the application for approval of topramezone should be granted. Submissions should relate only to matters that the APVMA is required by legislation to consider in deciding whether to grant the approval. These grounds include chemistry and manufacture, and toxicity. Submissions should state the grounds on which they are based. Comments received outside these grounds cannot be considered by the APVMA.

Submissions must be received by the APVMA within 28 days of the date of this notice and be directed to the contact listed below. All submissions to the APVMA will be acknowledged in writing via email or by post. A summary of relevant comments and the APVMA's response will be published on the APVMA website.

When making a submission please include:

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

All personal and *confidential commercial information (CCI)*[3] material contained in submissions will be treated confidentially.

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

Director of Chemistry and Manufacture
Scientific Assessment and Chemical Review Program
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

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

New Active Constituent and Veterinary Chemical Product

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application from Zoetis Australia Pty Ltd for the approval of a new active constituent, Live aroA-gene deleted Escherichia coli, type O78, strain EC34195, and for registration of a new product containing this new active constituent. The product is Poulvac E.coli.

PARTICULARS OF THE ACTIVE CONSTITUENT

Name of active constituent:	Live aroA-gene deleted Escherichia coli, type O78, strain EC34195
Identity:	Escherichia coli EC34195
Appearance:	Freeze-dried pellet
Sterility:	As per European Pharmacopoeia
Extraneous agents:	As per European Pharmacopoeia
Mycoplasma:	As per European Pharmacopoeia
Gene technology:	Deletion of biosynthetic gene aroA
Mode of Action:	Induction of immunological response

SUMMARY OF THE APVMA'S EVALUATION OF LIVE AROA-GENE DELETED ESCHERICHIA COLI, TYPE O78, STRAIN EC34195 ACTIVE CONSTITUENT

Live aroA-gene deleted Escherichia coli, type O78, strain EC34195 is a new active constituent for which there is no compendial specification available.

The APVMA has assessed the chemistry and manufacturing aspects of live attenuated aroA-gene deleted *Escherichia coli*, type O78, strain *EC34195* (active constituent) 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 conducted a health assessment. Given the low toxicity, and lack of human infectivity and pathogenicity, of *E. coli* serotype O78 (strain EC34195) *aroA*, an Acute Reference Dose (ARfD) for this active has not been considered necessary, and scheduling in the SUSMP is not required.

An external reviewer has conducted a Phase I environmental risk assessment according to VICH GL6. The assessment includes a hazard identification and assessment of the exposure to the hazard as well as the likelihood that the hazard may occur. The VICH Phase 1 assessment outlines qualitatively that the potential exposure of the environment to the product and the level of risk associated with it is low. Matters relating to the genetically modified organism, genetic stability, clearance, and shedding, spreading, and environmental persistence have been assessed. The conclusion is that the active strain is highly unlikely to spread in the environment. The APVMA considered the likelihood of the vaccine strain being transmitted to non-target avian species to be limited as the deletion of the aroA-gene from the vaccine strain prevents the vaccine strain from replicating and reverting to virulence.

The Office of the Gene Technology Regulator (OGTR) has conducted a risk assessment and concluded that there are negligible risks to the health and safety of people, or the environment, from the proposed commercial release of the active *Escherichia coli* serotype O78, strain EC34195, either in the short or long term. No controls are required to manage these negligible risks. The OGTR has granted a licence (DIR 125) to Zoetis Australia Research & Manufacturing Pty Ltd (Zoetis) for commercial release of the genetically modified vaccine to protect chickens against pathogenic *Escherichia coli.*

The APVMA accepts the findings and recommendations of its advisors on the safety of the active constituent. The APVMA is satisfied that the proposed use of live aroA-gene deleted Escherichia coli, type O78, strain EC34195 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:	POULVAC E.COLI
Applicant Company:	ZOETIS Australia Pty Ltd
Active constituent:	Live aroA-gene deleted Escherichia coli, type O78, strain EC34195
Adjuvant:	Not applicable
Scheduling:	Not scheduled
Pharmaceutical form:	Freeze-dried pellet
Pack sizes:	10 x 2,500 doses**;** 10 x 5,000 doses; 10 x 10,000 doses
Summary of proposed use:	For the active immunisation of healthy chickens as an aid in the prevention of disease caused by *Escherichia coli.*
Dose and route of administration:	Vaccinate by coarse spray at 1 day of age. A second vaccination is recommended for long lived birds at 12–14 weeks of age via drinking water.
Onset of immunity:	14 days
Duration of immunity:	6 weeks duration of immunity for birds receiving a second vaccination at 14 weeks; 8 week duration of immunity by coarse spray at 1 day old.
Side effects:	No significant adverse reactions attributable to the vaccine were observed
Withholding period:	Zero (0) days

SUMMARY OF THE APVMA'S EVALUATION OF POULVAC E.COLI 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 POULVAC E.COLI would not be an undue hazard to the safety of people exposed to it during its handling and use.

The OGTR concluded in their assessment that there are negligible risks to the health and safety of people from the proposed commercial release of *Escherichia coli* serotype O78, strain EC34195, either in the short or long term.

The APVMA has conducted a health risk assessment on the product and concluded that it can be used safely. The APVMA has estimated the acute toxicity profile of POULVAC E.COLI based on information that was provided for strain *EC34195* and information available on the excipients in the formulation. The APVMA has concluded that POULVAC E.COLI is expected to have low acute oral, dermal and inhalational toxicity. POULVAC E.COLI is expected to be neither a skin irritant nor a skin sensitiser. The product is also not expected to be an eye irritant. The excipients are already present in several vaccines registered for use in Australia, and would be expected to be of low oral, dermal and inhalational toxicity.

Human exposure on broiler farms to POULVAC E.COLI is expected to be minimal since farm biosecurity measures are practised on Australian chicken farms. Farmers, farm workers and veterinarians will be the main occupations directly exposed to POULVAC E.COLI. General interactions such as checking and moving flocks, feeding, cleaning, attendance to sick animals and maintenance could all likely result in *E. coli aroA*$^-$ contact. However, no risks to human health and safety have been identified that warrant precautionary statements, safety directions or personal protective equipment (PPE).

The product label will contain first aid statement *if poisoning occurs, contact a doctor or Poisons Information Centre. Phone Australia 13 11 26*. Taking into consideration the potential toxicological and pathogenic risks, use pattern and likelihood of occupational and bystander/handler exposure, no label statements relating to human health risks are considered necessary. Precautionary re-entry or re-handling statements are also not considered necessary as the active constituent is not an identified human pathogen and does not readily survive in the environment.

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

The APVMA has conducted a residues assessment of POULVAC E.COLI. A review of the formulation indicates that the excipients are not novel. Therefore, there are no concerns from a residues and trade perspective to the registration of this product. The proposed zero (0) day withholding period is acceptable, and an Export Slaughter Interval of zero (0) days is also acceptable.

(iii) The APVMA is satisfied that the proposed use of POULVAC E.COLI containing the active constituent live attenuated aroA-gene deleted *Escherichia coli*, type O78, strain *EC34195* is not likely to be harmful to human beings if used according to the product label directions. Given the low toxicity, and lack of human infectivity and pathogenicity, of the strain, scheduling in the SUSMP is not considered necessary.

(iv) The APVMA is satisfied that the proposed use of the product POULVAC E.COLI containing the active constituent strain aroA-gene deleted *Escherichia coli*, type O78, strain *EC34195*, would not be likely to have an unintended effect that is harmful to animals, plants or things or the environment.

The OGTR concluded that there are negligible risks to the environment from commercial release, either in the short or long term.

An external reviewer has conducted a VICH Phase I environmental assessment which the Department of Environment has peer-reviewed. The external reviewer recommended a VICH Phase II assessment was not necessary since the potential exposure of the environment to the vaccine and the level of risk associated with it is low. This recommendation was based on *E. coli* being ubiquitous in nature; *aroA-E. coli* rapidly departs the animal, with no traces of the vaccine 14 days after application; the persistence of *E.coli* in inoculated litter ranged from 24 h– 42 days; and the vaccine cannot replicate due to the removal of the *aroA* gene. Entry to the terrestrial environment is potentially prevented through disposal of the terrestrial waste matrix. It is expected that the *E. coli aroA*- vaccine in waste litter would decline below detection limits after the composing process. The product label will contain the following disposal statement: '*Dispose of vial/container in a designated and appropriately labelled biologicals containe'*. The APVMA accepts the findings and recommendation of the external reviewer.

The APVMA has assessed the safety aspects of POULVAC E.COLI. The target animal safety studies under field condition by coarse spray or oral gavage with two single dosing (1.7×10^9 and 6.0×10^8 cfu/bird), and over dosing (9.1×10^9 and 1.0×10^{10} cfu/bird) have been conducted, respectively. No significant adverse events attributable to the vaccine have been observed during the studies. The mean percent mortality for the period 1–13 day old was

1.48% for treatment and control groups, while the 95% Confidence Interval (CI) was 1.13–1.88% for controls and 1.14–1.88% for vaccinates. These observations support the safety aspects of the product.

Safety is supported further by reversion to virulence studies intended to recover GMOs from inoculated birds for subsequent back passage, and environmental persistence studies in chickens. No GMOs have been recovered from any birds at any time points. These birds did not show any symptoms associated with *Colibacillosis*.

An environmental persistence study of *aroA- E.coli* has shown that the persistence on litter was short lived. On day 1, more than 2 log10 reduction was observed. On day 4 almost no viable bacteria were recorded. No bacteria were isolated from 7 days samples. A decrease in persistence has been observed in A*roA- E.coli* sampled from desiccated litter.

Favourable percent mortality with daily weight gains obtained in the field efficacy and safety studies support POULVAC E.COLI is safe for use when administered to 1day old broiler chicks by coarse spray at $1.3x10^8$ cfu/dose.

The APVMA is satisfied that POULVAC E.COLI would not have an unintended effect that is harmful to chickens, plants or things or the environment. The antibacterial substances present at the time of vaccination may interfere with vaccine efficacy, eg chlorination of drinking water, or antibiotics administered in drinking water or feed. This can be mitigated through label statement that disinfectants or antibiotics should not be used for the 3 day period prior to/at vaccination. The coarse spray should use distilled water (i.e. non-chlorinated), and skim milk powder should be added in the drinking water—to facilitate inactivation of chlorine and persistence of the vaccine organism.

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:

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.

POULVAC E.COLI is intended for use in chickens for preventing and controlling *Colibacillosis* infection. The data to support the efficacy aspects consisted of supporting information (published data) and efficacy studies (duration of protection, laboratory and field studies).

The published literature describes a candidate live vaccine for avian pathogenic *E coli* (APEC), which was constructed from a virulent field APEC O78 strain by mutation of the aroA gene (i.e. the applicant vaccine antigen). The mutant is similar to the parent wild-type strain in respect of colony morphology, motility and the elaboration of surface antigens. The mutant has proven to be avirulent when inoculated in 1day old chicks by spray application at 1.6 or $0.82x10^6$ cfu/dose, and when presented again in the drinking water at 7 day old at $3.2x10^6$ cfu/dose. Chickens and turkeys vaccinated with an O78 aroA- mutant have been protected against a challenge at 6 week old by virulent APEC strains—APEC 078 and APEC X at approximately $1x10^9$ cfu/dose. Following challenge with APEC O78, the incidence of mortality was 28.1% in the control chickens and 0% in vaccinated chickens.

Dose determination studies support the adequacy of the proposed vaccination regimen of one dose at 1d old followed by an optional second dose at 12 week old in laying birds. Doses corresponding to 0.1X, 0.2X, 4.68X and 5.49X the label dose administered by coarse spray, and doses of 0.08X and 1.03X the label dose via drinking water have been tested in chickens. Vaccinated chickens showed a significant ($p<0.05$) reduction in mortality and lesions caused by *E.coli*, compared to unvaccinated chickens.

The duration of protection study supports an 8–week duration of immunity for female SPF White Leghorn chicks vaccinated with the proposed formulation at $1.373x10^6$ cfu/dose. This lower dose supports the end of shelf life titre of $8.2x10^6$ cfu/dose claimed in the label.

The laboratory studies support the effectiveness of the vaccine when it is administered at $3.11x10^6$ cfu/bird at 1 day old by coarse spray. In this study, a reduction of lesions of *Colibacillosis* has been observed in vaccinate chickens challenged with *E. coli* field strains.

Results from the field studies in broiler chickens vaccinated with an unspecified dose by coarse spray at 1day old have shown a reduction in carcass condemnations at slaughter for lesions primarily associated with *Colibacillosis*. The results from these studies support that POULVAC E.COLI is efficacious when administered through coarse spray at 1 day of age, and at 12–14 weeks of age via drinking water at $8.2x10^6$ cfu/dose.

The APVMA has concluded that the data generated from the studies are consistent with the claim: *This vaccine is recommended for mass administration to healthy chickens as an aid in the prevention of disease caused by E. coli.*

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 APVMA has concluded that the trade risk associated with the proposed use of POULVAC E.COLI is low. Review of the formulation indicates that the excipients are not novel. Therefore, there are no concerns from a residues and trade perspective to the registration of this product.

MAKING A SUBMISSION

In accordance with section 12 of the Agvet Code, the APVMA invites any person to submit a relevant written submission as to whether live aroA-gene deleted Escherichia coli, type O78, strain EC34195 should be approved. Submissions should relate only to matters that are considered in determining whether the safety criteria set out in section 5A of the Agvet Code have been met. Submissions should state the grounds on which they are based.

In accordance with section13 of the Agvet Code, the APVMA invites any person to submit a relevant written submission as to whether POULVAC E.COLI 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.

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) 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