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Agricultural and Veterinary Chemicals

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

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GENERAL INFORMATION

The *APVMA (Australian Pesticides and Veterinary Medicines Authority) Gazette* is published fortnightly and contains details of the registration of agricultural and veterinary chemicals products and other approvals granted by the APVMA, notices as required by the Agricultural and Veterinary Chemicals Code (the Agvet Code) and related legislation and a range of regulatory material issued by the APVMA.

Pursuant to section 8J(1) of the Agvet Code, the APVMA has decided that it is unnecessary to publish details of applications made for the purpose of notifying minor variations to registration details. The APVMA will however report notifications activity in quarterly statistical reports.

DISTRIBUTION AND SUBSCRIPTION

The *APVMA Gazette* is published in electronic format only and is available from the APVMA website.

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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:	122177
Product name:	Indogulf 2,4-D IPA 300 Herbicide
Active constituent/s:	300 g/L 2,4-D present as the isopropylamine salt
Applicant name:	Indogulf Cropsciences Australia Pty Ltd
Applicant ACN:	635 320 348
Summary of use:	For the control of emerged broadleaf weeds prior to sowing crops and pastures in conservation tillage situations and for selective weed control in crops and situations detailed in the Directions for Use
Date of registration:	6 January 2020
Product registration no.:	88751
Label approval no.:	88751/122177

Application no:	122065
Product name:	Indogulf 2,4-D Amine 625 Herbicide
Active constituent/s:	625 g/L 2,4-D present as the dimethylamine and diethanolamine salts
Applicant name:	Indogulf Cropsciences Australia Pty Ltd
Applicant ACN:	635 320 348
Summary of use:	For the control of broadleaf weeds in fallow before direct drilling or sowing of cereals and pastures; and in cereal crops, pastures, sugarcane, peanuts and non-agricultural areas
Date of registration:	6 January 2020
Product registration no.:	88710
Label approval no.:	88710/122065

Application no:	118604
Product name:	Foamstream Plus Marker
Active constituent/s:	50.4 g/L potassium salts of fatty acid derivatives
Applicant name:	Weeding Technologies Ltd
Applicant ACN:	N/A
Summary of use:	For use with steam weeding equipment as a foam marker
Date of registration:	7 January 2020
Product registration no.:	87528
Label approval no.:	87528/118604

Application no:	120103
Product name:	Promote 1000 Growth Regulator
Active constituent/s:	1000 g/L ethephon (an anticholinesterase compound)
Applicant name:	Adama Australia Pty Limited
Applicant ACN:	050 328 973
Summary of use:	For anti-lodging in barley or crop thinning, loosening or ripening in various crops, and for accelerating boll opening, defoliation and pre-conditioning before defoliation of cotton
Date of registration:	7 January 2020
Product registration no.:	88033
Label approval no.:	88033/120103

Application no:	119213
Product name:	Surefire Aztec Fungicide
Active constituent/s:	200 g/L tebuconazole, 120 g/L azoxystrobin
Applicant name:	PCT Holdings Pty Ltd
Applicant ACN:	099 023 962
Summary of use:	For the control of foliar diseases on grapevines
Date of registration:	9 January 2020
Product registration no.:	87767
Label approval no.:	87767/119213

Application no:	118499
Product name:	Foamstream V4 Marker
Active constituent/s:	203 g/L nonionic surfactant blend
Applicant name:	Weeding Technologies Ltd
Applicant ACN:	07575896
Summary of use:	For use with steam weeding equipment as a foam marker
Date of registration:	9 January 2020
Product registration no.:	87491
Label approval no.:	87491/118499

Application no:	122115
Product name:	Genfarm Bromoxynil 400 Herbicide
Active constituent/s:	400 g/L bromoxynil present as the N-octanoyl ester
Applicant name:	Landmark Operations Limited
Applicant ACN:	008 743 217
Summary of use:	For use on cereals, linseed, clover, lucerne, turf, fallow and non-crop situations and a range of broadleaf weeds
Date of registration:	9 January 2020
Product registration no.:	88731
Label approval no.:	88731/122115

Application no:	122760
Product name:	Farmalinx Sixgun 510 Herbicide
Active constituent/s:	510 g/L glyphosate present as the isopropylamine salt
Applicant name:	Farmalinx Pty Ltd
Applicant ACN:	134 353 245
Summary of variation:	To approve a new label for the product 'FARMALINX SIXGUN 510 HERBICIDE' with the label name 'PROFORCE RAPID FIRE 510 SL HERBICIDE'
Date of variation:	9 January 2020
Product registration no.:	64362
Label approval no.:	64362/122760

Application no:	120043
Product name:	Genfarm Acetamiprid 225 Insecticide
Active constituent/s:	225 g/L acetamiprid
Applicant name:	Landmark Operations Limited
Applicant ACN:	008 743 217
Summary of use:	For the control of cotton aphid and green mirids in cotton and green peach aphid in potatoes
Date of registration:	9 January 2020
Product registration no.:	88016
Label approval no.:	88016/120043

Application no:	122117
Product name:	IA Transcend Molluscicide & Insecticide
Active constituent/s:	50 g/kg metaldehyde, 1.5 g/kg fipronil
Applicant name:	Imtrade Australia Pty Ltd
Applicant ACN:	090 151 134
Summary of use:	For the control of snails and slugs in brassicas and ornamentals and other agricultural non-crop areas
Date of registration:	9 January 2020
Product registration no.:	88733
Label approval no.:	88733/122117

Application no:	122114
Product name:	Genfarm 2,4-D Duo Herbicide
Active constituent/s:	720 g/L 2,4-D present as the isopropylamine and the dimethylamine salts
Applicant name:	Landmark Operations Limited
Applicant ACN:	008 743 217
Summary of use:	For the control of broadleaf weeds in fallow, cereal crops, pastures, sugarcane and peanuts and in non-agricultural areas
Date of registration:	9 January 2020
Product registration no.:	88730
Label approval no.:	88730/122114

Application no:	122149
Product name:	FSA Clethodim 360 Herbicide
Active constituent/s:	360 g/L clethodim
Applicant name:	Four Seasons Agribusiness Pty Ltd
Applicant ACN:	115 133 189
Summary of use:	For the control of certain grass weeds in beetroot, cabbage, canola, celery, cotton, forestry, lettuce, non-bearing fruit trees, onions, ornamentals, peanuts, pulses (including adzuki beans, broad beans, chickpeas, faba beans, field peas, lentils, lupins and mung beans), potatoes, soybeans and pasture legume (lucerne, clover and medic) seed crops (and pastures)
Date of registration:	10 January 2020
Product registration no.:	88745
Label approval no.:	88745/122149

Application no:	122130
Product name:	Sanonda Herbicide Fluroxypyr 400EC
Active constituent/s:	400 g/L fluroxypyr present as the methyl heptyl ester
Applicant name:	Sanonda (Australia) Pty Ltd
Applicant ACN:	059 813 973
Summary of use:	For the control of a wide range of broadleaf weeds in fallow, lucerne, maize, millets, pastures, poppies, sorghum, sugar cane, sweetcorn and winter cereals. Also for the control of woody weeds in agricultural non-crop areas, commercial and industrial areas, forests, pastures and rights-of-way
Date of registration:	10 January 2020
Product registration no.:	88740
Label approval no.:	88740/122130

Application no:	122190
Product name:	Weed Force Amitrole 250 SL Herbicide
Active constituent/s:	250 g/L amitrole, 220 g/L ammonium thiocyanate
Applicant name:	Weed Force Pty Ltd
Applicant ACN:	602 207 152
Summary of use:	For the control of weeds in orchards, vineyards, irrigation ditches and drains, roadsides, wheat and barley, and for general industrial situations
Date of registration:	10 January 2020
Product registration no.:	88754
Label approval no.:	88754/122190

Application no:	122225
Product name:	AC Caddie 250 Fungicide
Active constituent/s:	250 g/L pyraclostrobin
Applicant name:	Axichem Pty Ltd
Applicant ACN:	131 628 594
Summary of use:	For the control of leaf speckle and leaf spot in bananas and downy and powdery mildew in grapevines, husk spot in macadamia and rust in almond
Date of registration:	10 January 2020
Product registration no.:	88768
Label approval no.:	88768/122225

Application no:	122116
Product name:	Genfarm Brom M Plus Herbicide
Active constituent/s:	280 g/L bromoxynil present as the N-octanoyl ester, 280 g/L MCPA present as the iso-octyl ester
Applicant name:	Landmark Operations Limited
Applicant ACN:	008 743 217
Summary of use:	For the control of broadleaf weeds in cereals, linseed, grass pastures and turf
Date of registration:	10 January 2020
Product registration no.:	88732
Label approval no.:	88732/122116

Application no:	122251
Product name:	Bang 750 WG Herbicide
Active constituent/s:	750 g/kg metribuzin
Applicant name:	Hemani Industries Limited
Applicant ACN:	N/A
Summary of use:	For selective weed control in potatoes, peas, soybeans, faba beans, tomatoes, barley, white lupins and sugarcane
Date of registration:	13 January 2020
Product registration no.:	88782
Label approval no.:	88782/122251

Application no:	121613
Product name:	Farmalinx Bifentin 2 G Insecticide
Active constituent/s:	2 g/kg bifenthrin
Applicant name:	Farmalinx Pty Ltd
Applicant ACN:	134 353 245
Summary of use:	For the control of certain pests in turf and the control of ants, fleas and ticks in the external surrounds of buildings and structures
Date of registration:	13 January 2020
Product registration no.:	88530
Label approval no.:	88530/121613

Application no:	122237
Product name:	Relyon 2,4-D Duo Herbicide
Active constituent/s:	720 g/L 2,4-D present as the isopropylamine and the dimethylamine salts
Applicant name:	RuralCo Holdings Limited
Applicant ACN:	009 660 879
Summary of use:	For use in fallow, cereal crops, pastures, sugarcane and peanuts and in non-agricultural areas for the control of broadleaf weeds
Date of registration:	13 January 2020
Product registration no.:	88774
Label approval no.:	88774/122237

Application no:	120231
Product name:	4Farmers Carfentrazone 240 EW Herbicide
Active constituent/s:	240 g/L carfentrazone
Applicant name:	4 Farmers Australia Pty Ltd
Applicant ACN:	160 092 428
Summary of use:	For the control of certain annual broadleaf weeds in winter cereals
Date of registration:	13 January 2020
Product registration no.:	88083
Label approval no.:	88083/120231

Application no:	120309
Product name:	Opal Propyzamide 500 SC Herbicide
Active constituent/s:	500 g/L propyzamide, 50 g/L ethylene glycol
Applicant name:	Opal Australasia Pty Ltd
Applicant ACN:	103 454 879
Summary of use:	For selective control of certain grasses and broadleaf weeds in lettuce, sports turf, home lawns and legume seed crops and pastures
Date of registration:	13 January 2020
Product registration no.:	88113
Label approval no.:	88113/120309

Application no:	122183
Product name:	Sharp 800 WG Fungicide and Miticide
Active constituent/s:	800 g/kg sulfur (S) present as elemental sulfur
Applicant name:	Hemani Industries Limited
Applicant ACN:	N/A
Summary of use:	For the control of powdery mildew, rust and mites in pome and stone fruit, citrus, grapevines, kiwifruit, strawberries and some vegetables
Date of registration:	13 January 2020
Product registration no.:	88753
Label approval no.:	88753/122183

Application no:	122234
Product name:	Relyon Bromoxynil 400 Herbicide
Active constituent/s:	400 g/L bromoxynil present as the N-octanoyl ester
Applicant name:	Ruralco Holdings Limited
Applicant ACN:	009 660 879
Summary of use:	For use in cereals, linseed, clover, lucerne, turf, fallow and non-crop situations to control a range of broadleaf weeds
Date of registration:	14 January 2020
Product registration no.:	88771
Label approval no.:	88771/122234

Application no:	122283
Product name:	Spalding Imazapic 240 SL Herbicide
Active constituent/s:	240 g/L imazapic present as the ammonium salt
Applicant name:	Spalding Holdings Pty Ltd
Applicant ACN:	010 155 852
Summary of use:	For the pre-emergence control of certain annual grass and broadleaf weeds in fallow situations, sugarcane and peanuts and early post-emergence control of certain annual grass and broadleaf weeds in peanuts and sugarcane
Date of registration:	14 January 2020
Product registration no.:	88789
Label approval no.:	88789/122283

Application no:	122345
Product name:	Foison Diquat 200SL Herbicide
Active constituent/s:	200 g/L diquat present as diquat dibromide monohydrate
Applicant name:	Foison Scitech Co Limited
Applicant ACN:	N/A
Summary of use:	For pre-harvest crop desiccation and the control of a wide range of broadleaf weeds in certain crops
Date of registration:	14 January 2020
Product registration no.:	88796
Label approval no.:	88796/122345

Application no:	122346
Product name:	WaMachine 250 Fungicide
Active constituent/s:	250 g/L azoxystrobin
Applicant name:	Sunrise Crop Science Co Ltd
Applicant ACN:	N/A
Summary of use:	For the control of various diseases of grapes, potatoes, tomatoes, cucurbits, avocados, mangoes, passionfruit and poppies
Date of registration:	15 January 2020
Product registration no.:	88797
Label approval no.:	88797/122346

Application no:	120527
Product name:	Genfarm Panzer 510K Herbicide
Active constituent/s:	510 g/L glyphosate (present as the potassium salt)
Applicant name:	Landmark Operations Limited
Applicant ACN:	008 743 217
Summary of use:	For the control of a wide range of annual and perennial weeds
Date of registration:	15 January 2020
Product registration no.:	88190
Label approval no.:	88190/120527

Application no:	118149
Product name:	Seajet 039 Platinum 2-Components Antifouling
Active constituent/s:	54-57 g/L zinc pyrithione, 960 g/kg cuprous oxide
Applicant name:	Chugoku Marine Paints Ltd
Applicant ACN:	N/A
Summary of use:	For the prevention of biofouling on vessel hulls
Date of registration:	15 January 2020
Product registration no.:	87337
Label approval no.:	87337/118149

Application no:	122285
Product name:	OzCrop Bromo/MCPA Herbicide
Active constituent/s:	200 g/L bromoxynil present as the N-octanoyl ester, 200 g/L MCPA present as the ethyl hexyl ester
Applicant name:	OzCrop Pty Ltd
Applicant ACN:	160 656 431
Summary of use:	For the control of certain broadleaf weeds in wheat, oats, barley, cereal rye, triticale, linseed, grass pastures and turf
Date of registration:	15 January 2020
Product registration no.:	88790
Label approval no.:	88790/122285

Application no:	122232
Product name:	Relyon Diuron 900 WG Herbicide
Active constituent/s:	900 g/kg diuron
Applicant name:	Ruralco Holdings Limited
Applicant ACN:	009 660 879
Summary of use:	For the control of weeds in asparagus, bananas, cereals, cotton, lucerne, lupins, pulse crops and sugar cane
Date of registration:	15 January 2020
Product registration no.:	88769
Label approval no.:	88769/122232

Application no:	122254
Product name:	FSA Terbuthylazine 875 WG Herbicide
Active constituent/s:	875 g/kg terbuthylazine
Applicant name:	Four Seasons Agribusiness Pty Ltd
Applicant ACN:	115 133 189
Summary of use:	For the control of weeds in sorghum and triazine tolerant canola as per the directions for use table
Date of registration:	15 January 2020
Product registration no.:	88785
Label approval no.:	88785/122254

Application no:	122725
Product name:	Apparent Territory 500 WG Herbicide
Active constituent/s:	500 g/kg flumioxazin
Applicant name:	Titan Ag Pty Ltd
Applicant ACN:	122 081 574
Summary of use:	For rapid knockdown and control of various grass and broadleaved weeds when mixed with certain glyphosate or paraquat/diquat herbicides, and for control of volunteer cotton when applied alone, prior to sowing cotton and its rotation crops, or for rapid knockdown and control of various broadleaved weeds when applied as a directed spray in cotton
Date of registration:	16 January 2020
Product registration no.:	88880
Label approval no.:	88880/122725

Application no:	120370
Product name:	AC Mightyzole 420 Fungicide
Active constituent/s:	210 g/L prothioconazole, 210 g/L tebuconazole
Applicant name:	Axichem Pty Ltd
Applicant ACN:	131 628 594
Summary of use:	For the control of various diseases in wheat, barley, oats, triticale, canola and pyrethrum
Date of registration:	16 January 2020
Product registration no.:	88134
Label approval no.:	88134/120370

Application no:	120401
Product name:	Sharda Pyriproxyfen 100 EC Insecticide
Active constituent/s:	100 g/L pyriproxyfen
Applicant name:	Sharda Cropchem Espana SL
Applicant ACN:	N/A
Summary of use:	For the control of silverleaf whitefly (*Bemisia tabaci* Biotype B) in cotton, rockmelon and capsicum, the control of silverleaf whitefly (*Bemisia tabaci* Biotype B) and greenhouse whitefly in tomatoes, and the control of various scale in citrus, mangoes and olives
Date of registration:	17 January 2020
Product registration no.:	88141
Label approval no.:	88141/120401

Application no:	116960
Product name:	Imtrade Roadster 250 EC Fungicide
Active constituent/s:	250 g/L pyraclostrobin
Applicant name:	Imtrade Australia Pty Ltd
Applicant ACN:	090 151 134
Summary of use:	For the control of husk spot in macadamia and rust in almond
Date of registration:	17 January 2020
Product registration no.:	86902
Label approval no.:	86902/116960

2. LISTED REGISTRATIONS

Application no:	122650
Product name:	Vitalyse Stabilised Slow Release Chlorine Tablets
Active constituent/s:	890 g/kg available chlorine (Cl) present as trichloroisocyanuric acid
Applicant name:	Focus Products Pty Ltd
Applicant ACN:	073 540 520
Summary of use:	For the control of bacteria, viruses and protozoa in swimming pools and spas
Date of registration:	7 January 2020
Product registration no.:	88842
Label approval no.:	88842/122650

3. VARIATIONS OF REGISTRATION

Application no:	121078
Product name:	Conquest Fighter Herbicide
Active constituent/s:	800 g/L prosulfocarb
Applicant name:	Conquest Crop Protection Pty Ltd
Applicant ACN:	098 814 932
Summary of variation:	To extend the uses to include suppression of annual ryegrass and improved in-furrow control
Date of variation:	6 January 2020
Product registration no.:	83851
Label approval no.:	83851/121078

Application no:	119610
Product name:	Campbell Magnate 750WG Fungicide
Active constituent/s:	750 g/kg imazalil present as the sulphate
Applicant name:	Colin Campbell (Chemicals) Pty Ltd
Applicant ACN:	000 045 590
Summary of variation:	To add a second application to seed potatoes not intended for direct human or animal use, for control of fungal diseases in storage
Date of variation:	6 January 2020
Product registration no.:	52223
Label approval no.:	52223/119610

Application no:	122045
Product name:	Chemag Dicamba - MCPA Herbicide
Active constituent/s:	340 g/L MCPA present as the dimethylamine salt, 80 g/L dicamba present as the dimethylamine salt
Applicant name:	Imtrade Australia Pty Ltd
Applicant ACN:	090 151 134
Summary of variation:	To add use to control pimelea in agricultural non-crop areas, commercial and industrial areas, grass pastures and rights-of-way as part of the Permit to Label project
Date of variation:	9 January 2020
Product registration no.:	54886
Label approval no.:	54886/122045

Application no:	122081
Product name:	4Farmers Metaldehyde Snail and Slug Bait
Active constituent/s:	15 g/kg metaldehyde
Applicant name:	4 Farmers Australia Pty Ltd
Applicant ACN:	160 092 428
Summary of variation:	To add uses in winter cereals, oil seeds, pulses and pasture establishment
Date of variation:	10 January 2020
Product registration no.:	69820
Label approval no.:	69820/122081

Application no:	122056
Product name:	Titan Propiconazole 625 EC Fungicide
Active constituent/s:	625 g/L propiconazole
Applicant name:	Titan Ag Pty Ltd
Applicant ACN:	122 081 574
Summary of variation:	To add use patterns based on a reference product
Date of variation:	13 January 2020
Product registration no.:	86411
Label approval no.:	86411/122056

Application no:	122288
Product name:	Hemani Dicamba 500 SL Herbicide
Active constituent/s:	500 g/L dicamba present as the dimethylamine salt
Applicant name:	Hemani Industries Limited
Applicant ACN:	N/A
Summary of variation:	To add use in pine plantations to encourage wood wasp attack and in rice to control dirty dora, sedges and starfruit
Date of variation:	13 January 2020
Product registration no.:	88003
Label approval no.:	88003/122288

Application no:	122125
Product name:	FSA Fluroxypyr 400 Herbicide
Active constituent/s:	400 g/L fluroxypyr, 316 g/L hydrocarbon liquid, 100 g/L N-methyl-2-pyrrolidone
Applicant name:	Four Seasons Agribusiness Pty Ltd
Applicant ACN:	115 133 189
Summary of variation:	To correct the rates for tank-mixes with glyphosate in summer fallow
Date of variation:	13 January 2020
Product registration no.:	87961
Label approval no.:	87961/122125

Application no:	122338
Product name:	Sipcam Pyranica Miticide
Active constituent/s:	200 g/kg tebufenpyrad
Applicant name:	Sipcam Pacific Australia Pty Ltd
Applicant ACN:	073 176 888
Summary of variation:	To add use for control of European Red Mite and Two-Spotted Mite in cucumbers
Date of variation:	13 January 2020
Product registration no.:	45182
Label approval no.:	45182/122338

Application no:	122238
Product name:	Titan MCPA 750 Selective Herbicide
Active constituent/s:	750 g/L MCPA present as the dimethylamine salt
Applicant name:	Titan Ag Pty Ltd
Applicant ACN:	122 081 574
Summary of variation:	To add uses in poppies and extend use in rice to all states as part of the Permit to Label project
Date of variation:	15 January 2020
Product registration no.:	64337
Label approval no.:	64337/122238

Application no:	122287
Product name:	Termigold Termite Bait
Active constituent/s:	1 g/kg chlorfluazuron
Applicant name:	Termigold Pty Ltd
Applicant ACN:	631 651 888
Summary of variation:	To change the product name and update the First Aid Information section
Date of variation:	16 January 2020
Product registration no.:	87771
Label approval no.:	87771/122287

4. LABEL APPROVAL

Application no:	122998
Product name:	Raid Max Outdoor Surface Spray
Active constituent/s:	0.5 g/L bifenthrin
Applicant name:	SC Johnson & Son Pty Ltd
Applicant ACN:	000 021 009
Summary of variation:	To approve a new label for the product 'RAID MAX OUTDOOR SURFACE SPRAY' with the label name 'RAID PRO SERIES OUTDOOR SURFACE SPRAY'
Date of variation:	10 January 2020
Product registration no.:	65105
Label approval no.:	65105/122998

Application no:	121955
Product name:	Nobites Personal Insect Repellent Pump Spray
Active constituent/s:	360 g/L oil of lemon eucalyptus (hydrated, cyclized)
Applicant name:	Australian Outdoor Lifestyle Pty Ltd
Applicant ACN:	618 205 977
Summary of variation:	To approve a new label for the product 'NOBITES PERSONAL INSECT REPELLENT PUMP SPRAY' with the label name 'NOBITES JUNIOR PERSONAL INSECT REPELLENT PUMP SPRAY'
Date of variation:	13 January 2020
Product registration no.:	86299
Label approval no.:	86299/121955

Application no:	123000
Product name:	Muskil Soft Bait With Two Actives For Faster Kill Of Rats & Mice
Active constituent/s:	0.025 g/kg bromadiolone, 0.025 g/kg difenacoum
Applicant name:	Zapi SPA
Applicant ACN:	N/A
Summary of variation:	To approve a new label for the product 'MUSKIL SOFT BAIT WITH TWO ACTIVES FOR FASTER KILL OF RATS & MICE' with the label name 'PROTECT-US VERMAX DUAL STRIKE SOFT BAIT RODENTICIDE WITH FLUO-NP TECHNOLOGY'
Date of variation:	13 January 2020
Product registration no.:	82450
Label approval no.:	82450/123000

Application no:	123005
Product name:	Muskil Dual Active Rodenticide Blocks With Fluo-NP Technology
Active constituent/s:	0.025 g/kg bromadiolone, 0.025 g/kg difenacoum
Applicant name:	Zapi SPA
Applicant ACN:	N/A
Summary of variation:	To approve a new label for the product 'MUSKIL DUAL ACTIVE RODENTICIDE BLOCKS WITH FLUO-NP TECHNOLOGY' with the label name 'PROTECT-US VERMAX DUAL STRIKE BLOCK BAIT RODENTICIDE WITH FLUO-NP'
Date of variation:	13 January 2020
Product registration no.:	69994
Label approval no.:	69994/123005

5. VARIATION OF LABEL APPROVAL

Application no:	122022
Product name:	Titan Thiram 600 SC Fungicide
Active constituent/s:	600 g/L thiram
Applicant name:	Titan Ag Pty Ltd
Applicant ACN:	122 081 574
Summary of variation:	To amend first aid instructions, safety directions and storage and disposal statement on labels
Date of variation:	6 January 2020
Product registration no.:	84206
Label approval no.:	84206/122022

Application no:	122123
Product name:	Baysol Snail & Slug Bait
Active constituent/s:	20 g/kg methiocarb (an anticholinesterase compound)
Applicant name:	Bayer Cropscience Pty Ltd
Applicant ACN:	000 226 022
Summary of variation:	To update the label in accordance with the APVMA final regulatory decision on methiocarb
Date of variation:	10 January 2020
Product registration no.:	51851
Label approval no.:	51851/122123

Application no:	122310
Product name:	Expedite Full Insecticide
Active constituent/s:	500 g/kg sulfoxaflor
Applicant name:	Dow Agrosciences Australia Limited
Applicant ACN:	003 771 659
Summary of variation:	To update the product name on the secondary label and to add uses from the primary label to the secondary label
Date of variation:	13 January 2020
Product registration no.:	65464
Label approval no.:	65464/122310

Application no:	120436
Product name:	Advocate For Kittens And Small Cats Up To 4kg
Active constituent/s:	100 g/L imidacloprid, 10 g/L moxidectin
Applicant name:	Bayer Australia Ltd (Animal Health)
Applicant ACN:	000 138 714
Summary of variation:	To extend a label claim to include the treatment and control of *Ancylostoma ceylanicum* in cats
Date of variation:	13 January 2020
Product registration no.:	55325
Label approval no.:	55325/120436

Application no:	123006
Product name:	Scotts Lawn Builder Buffalo Weed, Feed & Green-Up
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:	Evergreen Garden Care Australia Pty Ltd
Applicant ACN:	003 123 162
Summary of variation:	To approve a new label for the product 'SCOTTS LAWN BUILDER BUFFALO WEED, FEED & GREEN-UP' with the label name 'SCOTTS LAWN BUILDER WEED, FEED & GREEN-UP 3 in 1'
Date of variation:	13 January 2020
Product registration no.:	82584
Label approval no.:	82584/123006

Application no:	122110
Product name:	Smart 2,4-D Amine 625 Herbicide
Active constituent/s:	625 g/L 2,4-D present as the dimethylamine and diethanolamine salts
Applicant name:	Crop Smart Pty Ltd
Applicant ACN:	093 927 961
Summary of variation:	To update the label to include the spray drift restraints which were part of the 2,4-D permit dated 1/10/2019
Date of variation:	15 January 2020
Product registration no.:	61327
Label approval no.:	61327/122110

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:	119607
Product name:	Pneumaxxin
Active constituent/s:	100 mg/mL tulathromycin
Applicant name:	South Yarra Pharma Pty Ltd
Applicant ACN:	629 173 351
Summary of use:	For the treatment of respiratory infections in cattle and pigs
Date of registration:	7 January 2020
Product registration no.:	87868
Label approval no.:	87868/119607

Application no:	122639
Product name:	Pastoral Ag Moxidectin Long Acting Injection For Sheep
Active constituent/s:	20 g/L moxidectin
Applicant name:	The Hunter River Company Pty Limited
Applicant ACN:	133 798 615
Summary of use:	For the treatment and control of roundworms, nasal bots and itch mite in sheep. For protection against severe challenge by *Haemonchus contortus* (Barber's Pole Worm) for up to 4 months
Date of registration:	7 January 2020
Product registration no.:	88838
Label approval no.:	88838/122639

Application no:	122383
Product name:	Pastoral Ag Deltamethrin Quick-dose Pour-on Cattle Lice And Fly Treatment
Active constituent/s:	15 g/L deltamethrin
Applicant name:	The Hunter River Company Pty Limited
Applicant ACN:	133 798 615
Summary of use:	For the control of stable fly, house fly, lice, buffalo fly and biting midge in beef and dairy cattle, and the control of buffalo fly, stable fly and biting midge in horses
Date of registration:	7 January 2020
Product registration no.:	88816
Label approval no.:	88816/122383

Application no:	122631
Product name:	Pastoral Ag Levamisole LV Oral Drench
Active constituent/s:	80 g/L levamisole hydrochloride equivalent to 68 g/L levamisole
Applicant name:	The Hunter River Company Pty Limited
Applicant ACN:	133 798 615
Summary of use:	For the control of round worms, gastrointestinal roundworms and lungworms in sheep and cattle
Date of registration:	7 January 2020
Product registration no.:	88834
Label approval no.:	88834/122631

Application no:	122575
Product name:	Pastoral Ag Eprinomectin Pour-on For Beef And Dairy Cattle
Active constituent/s:	5 mg/mL eprinomectin
Applicant name:	The Hunter River Company Pty Limited
Applicant ACN:	133 798 615
Summary of use:	For the treatment and control of internal and external parasites in beef and dairy cattle and internal parasites in deer
Date of registration:	8 January 2020
Product registration no.:	88823
Label approval no.:	88823/122575

Application no:	122576
Product name:	Pastoral Ag Fluazuron + Ivermectin Pour-on Tick Development Inhibitor
Active constituent/s:	15 g/L fluazuron, 5 g/L ivermectin
Applicant name:	The Hunter River Company Pty Limited
Applicant ACN:	133 798 615
Summary of use:	For treatment and control of internal and external parasites in beef cattle
Date of registration:	14 January 2020
Product registration no.:	88824
Label approval no.:	88824/122576

Application no:	122637
Product name:	Pastoral Ag Levamisole Oral Drench
Active constituent/s:	32 g/L levamisole hydrochloride equivalent to 27 g/L levamisole
Applicant name:	The Hunter River Company Pty Limited
Applicant ACN:	133 798 615
Summary of use:	For the registration of an oral drench product for the control of roundworms in sheep and cattle
Date of registration:	15 January 2020
Product registration no.:	88836
Label approval no.:	88836/122637

2. VARIATIONS OF REGISTRATION

Application no:	122061
Product name:	Cydectin Oral Drench For Sheep
Active constituent/s:	1 g/L moxidectin
Applicant name:	Virbac (Australia) Pty Ltd
Applicant ACN:	77 003 268 871
Summary of variation:	Addition of the Export Slaughter Interval
Date of variation:	7 January 2020
Product registration no.:	45738
Label approval no.:	45738/122061

Application no:	122562
Product name:	Cal-plus With Biotin Calcium, Vitamin A & D Supplement With Biotin For Horses
Active constituent/s:	Each 1kg contains: 258 g Calcium (Ca) (from 658 g Calcium carbonate as microfined limestone), 250 mg Biotin, 46 g Calcium (Ca) (from 200 g Dicalcium phosphate dihydrate), 90 mg (300,000 IU) Retinol (Vitamin A) (as Retinyl acetate), 5 mg (200,000 IU) Cholecalciferol (Vitamin D3), 4.65 g Calcium (Ca) (from 50 g Calcium gluconate). Also contains: 5 g Ammonium chloride, 5 g Ferric pyrophosphate, 25 g Magnesium sulfate—dried, 2 g Manganese sulfate monohydrate, 2 g Zinc oxide
Applicant name:	Virbac (Australia) Pty Ltd
Applicant ACN:	77 003 268 871
Summary of variation:	Variation of formulation and label approval to comply with APVMA records
Date of variation:	15 January 2020
Product registration no.:	38755
Label approval no.:	38755/122562

3. VARIATION OF LABEL APPROVAL

Application no:	122674
Product name:	Doxy 100 Antibiotic Tablets
Active constituent/s:	100 mg doxycycline (as monohydrate)
Applicant name:	Dechra Veterinary Products (Australia) Pty Ltd
Applicant ACN:	614 716 700
Summary of variation:	To amend the dosage and administration section
Date of variation:	7 January 2020
Product registration no.:	56206
Label approval no.:	56206/122674

Application no:	122671
Product name:	Doxy 50 Antibiotic Tablets
Active constituent/s:	50 mg doxycycline (as monohydrate)
Applicant name:	Dechra Veterinary Products (Australia) Pty Ltd
Applicant ACN:	614 716 700
Summary of variation:	To amend the dosage and administration section
Date of variation:	7 January 2020
Product registration no.:	58341
Label approval no.:	58341/122671

Application no:	120200
Product name:	Selapro For Cats
Active constituent/s:	60 mg/mL selamectin
Applicant name:	Norbrook Laboratories Australia Pty Limited
Applicant ACN:	080 972 596
Summary of variation:	To update the product label
Date of variation:	7 January 2020
Product registration no.:	86131
Label approval no.:	86131/120200

Application no:	120438
Product name:	Advocate For Cats Over 4kg
Active constituent/s:	100 g/L imidacloprid, 10 g/L moxidectin
Applicant name:	Bayer Australia Ltd (Animal Health)
Applicant ACN:	000 138 714
Summary of variation:	To add an additional claim to the label against the hookworm *Ancylostoma ceylanicum* for Australian cats
Date of variation:	13 January 2020
Product registration no.:	55326
Label approval no.:	55326/120438

Application no:	120461
Product name:	Drontal Large Cat Allwormer
Active constituent/s:	120 mg/Tb pyrantel as pyrantel embonate, 30 mg/Tb praziquantel
Applicant name:	Bayer Australia Ltd (Animal Health)
Applicant ACN:	000 138 714
Summary of variation:	To extend a label claim to include for the treatment against the hookworm *Ancylostoma ceylanicum* for Australian cats
Date of variation:	15 January 2020
Product registration no.:	53751
Label approval no.:	53751/120461

Application no:	120462
Product name:	Drontal Cat Allwormer
Active constituent/s:	80 mg/Tb pyrantel as pyrantel embonate, 20 mg/Tb praziquantel
Applicant name:	Bayer Australia Ltd (Animal Health)
Applicant ACN:	000 138 714
Summary of variation:	To extend a label claim to include for the treatment against the hookworm *Ancylostoma ceylanicum* for Australian cats
Date of variation:	15 January 2020
Product registration no.:	46718
Label approval no.:	46718/120462

Application no:	120458
Product name:	Profender Allwormer For Large Cats 5 To 8 Kg
Active constituent/s:	85.8 g/L praziquantel, 21.4 g/L emodepside
Applicant name:	Bayer Australia Ltd (Animal Health)
Applicant ACN:	000 138 714
Summary of variation:	To extend a label claim to include for the treatment against the hookworm *Ancylostoma ceylanicum* for Australian cats
Date of variation:	15 January 2020
Product registration no.:	59155
Label approval no.:	59155/120458

Application no:	120460
Product name:	Profender Allwormer For Cats 2.5 To 5 Kg
Active constituent/s:	85.8 g/L praziquantel, 21.4 g/L emodepside
Applicant name:	Bayer Australia Ltd (Animal Health)
Applicant ACN:	000 138 714
Summary of variation:	To extend a label claim to include for the treatment against the hookworm *Ancylostoma ceylanicum* for Australian cats
Date of variation:	15 January 2020
Product registration no.:	59154
Label approval no.:	59154/120460

Application no:	120460
Product name:	Profender Allwormer For Cats 2.5 To 5 Kg
Active constituent/s:	85.8 g/L praziquantel, 21.4 g/L emodepside
Applicant name:	Bayer Australia Ltd (Animal Health)
Applicant ACN:	000 138 714
Summary of variation:	To extend a label claim to include for the treatment against the hookworm *Ancylostoma ceylanicum* for Australian cats
Date of variation:	15 January 2020
Product registration no.:	59154
Label approval no.:	59154/120460

Application no:	120199
Product name:	Selapro For Dogs (20.1 - 40 kg)
Active constituent/s:	120 mg/mL selamectin
Applicant name:	Norbrook Laboratories Australia Pty Limited
Applicant ACN:	080 972 596
Summary of variation:	To update the product label
Date of variation:	15 January 2020
Product registration no.:	86128
Label approval no.:	86128/120199

Application no:	120180
Product name:	Selapro For Dogs (2.6 - 5 kg)
Active constituent/s:	120 mg/mL selamectin
Applicant name:	Norbrook Laboratories Australia Pty Limited
Applicant ACN:	080 972 596
Summary of variation:	To update the product label
Date of variation:	15 January 2020
Product registration no.:	86125
Label approval no.:	86125/120180

Application no:	120203
Product name:	Selapro For Puppies And Kittens
Active constituent/s:	60 mg/mL selamectin
Applicant name:	Norbrook Laboratories Australia Pty Limited
Applicant ACN:	080 972 596
Summary of variation:	To update the product label
Date of variation:	15 January 2020
Product registration no.:	86133
Label approval no.:	86133/120203

Application no:	118553
Product name:	Bovatec 20cc Lasalocid Sodium Premix
Active constituent/s:	200 g/kg lasalocid sodium
Applicant name:	Zoetis Australia Pty Ltd
Applicant ACN:	156 476 425
Summary of use:	To vary the MRL for lasalocid sodium, and to reduce the meat withholding periods for chickens from 3 days to 1 day
Date of registration:	16 January 2020
Product registration no.:	60761
Label approval no.:	60761/118553

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.:	119264
Active constituent/s:	tulathromycin
Applicant name:	Norbrook Laboratories Australia Pty Ltd
Applicant ACN:	080 972 596
Summary of use:	For use in veterinary chemical products
Date of approval:	7 January 2020
Approval no.:	87793

Application no.:	120325
Active constituent/s:	pinoxaden
Applicant name:	Agroshine Australia Pty Ltd
Applicant ACN:	105 873 023
Summary of use:	For use in agricultural chemical products
Date of approval:	8 January 2020
Approval no.:	88117

Application no.:	121222
Active constituent/s:	albendazole
Applicant name:	Abbey Laboratories Pty Ltd
Applicant ACN:	156 000 430
Summary of use:	For use in veterinary chemical products
Date of approval:	8 January 2020
Approval no.:	88403

Application no.:	120622
Active constituent/s:	dicyclanil
Applicant name:	Shanghai Pharmtech Co Ltd
Applicant ACN:	N/A
Summary of use:	For use in agricultural and veterinary chemical products
Date of approval:	9 January 2020
Approval no.:	88236

Application no.:	120026
Active constituent/s:	acetamiprid
Applicant name:	Shandong United Pesticide Industry Co Ltd
Applicant ACN:	N/A
Summary of use:	For use in agricultural chemical products
Date of approval:	9 January 2020
Approval no.:	88006

Application no.:	121311
Active constituent/s:	chlorantraniliprole
Applicant name:	Yongnong Biosciences Co Ltd
Applicant ACN:	N/A
Summary of use:	For use in agricultural chemical products
Date of approval:	10 January 2020
Approval no.:	88437

Application no.:	121330
Active constituent/s:	progesterone
Applicant name:	Zoetis Australia Pty Ltd
Applicant ACN:	156 476 425
Summary of use:	For use in veterinary chemical products
Date of approval:	10 January 2020
Approval no.:	88439

Application no.:	120841
Active constituent/s:	prometryn
Applicant name:	Shandong Binnong Technology Co Ltd
Applicant ACN:	N/A
Summary of use:	For use in agricultural chemical products
Date of approval:	10 January 2020
Approval no.:	88312

Application no.:	120948
Active constituent/s:	toltrazuril
Applicant name:	Chanelle Pharmaceuticals Manufacturing Ltd
Applicant ACN:	N/A
Summary of use:	For use in veterinary chemical products
Date of approval:	10 January 2020
Approval no.:	88339

Application no.:	121225
Active constituent/s:	trifluralin
Applicant name:	Fufarm Co Pty Ltd
Applicant ACN:	614 090 336
Summary of use:	For use in agricultural chemical products
Date of approval:	10 January 2020
Approval no.:	88406

Application no.:	120949
Active constituent/s:	boscalid
Applicant name:	Sabero Australia Pty Limited
Applicant ACN:	087 313 059
Summary of use:	For use in agricultural chemical products
Date of approval:	10 January 2020
Approval no.:	88340

Application no.:	119043
Active constituent/s:	maldison
Applicant name:	Tagros Chemicals India Private Limited
Applicant ACN:	N/A
Summary of use:	For use in agricultural chemical products
Date of approval:	10 January 2020
Approval no.:	87713

Application no.:	115695
Active constituent/s:	grapiprant
Applicant name:	Elanco Australasia Pty Ltd
Applicant ACN:	076 745 198
Summary of use:	For use in veterinary chemical products
Date of approval:	14 January 2020
Approval no.:	86404

Application no.:	121064
Active constituent/s:	aminopyralid
Applicant name:	Yongnong Biosciences Co Ltd
Applicant ACN:	N/A
Summary of use:	For use in agricultural chemical products
Date of approval:	15 January 2020
Approval no.:	88366

Application no.:	120307
Active constituent/s:	ipconazole
Applicant name:	Arysta Lifescience Australia Pty Ltd
Applicant ACN:	005 225 507
Summary of use:	For use in agricultural chemical products
Date of approval:	15 January 2020
Approval no.:	88111

Application no.:	120827
Active constituent/s:	oxadiazon
Applicant name:	Bayer Cropscience Pty Ltd
Applicant ACN:	000 226 022
Summary of use:	For use in agricultural chemical products
Date of approval:	15 January 2020
Approval no.:	88303

Application no.:	120836
Active constituent/s:	thiamethoxam
Applicant name:	Syngenta Australia Pty Ltd
Applicant ACN:	002 933 717
Summary of use:	For use in agricultural chemical products
Date of approval:	16 January 2020
Approval no.:	88308

2. VARIATIONS OF ACTIVE CONSTITUENT

Application no.:	120247
Active constituent/s:	betamethasone acetate
Applicant name:	Elanco Australasia Pty Ltd
Applicant ACN:	076 745 198
Summary of variation:	Variation of relevant particulars or conditions of an approved active constituent
Date of variation:	6 January 2020
Approval no.:	82454

Application no.:	121015
Active constituent/s:	oxfendazole
Applicant name:	Jurox Pty Limited
Applicant ACN:	000 932 230
Summary of variation:	Variation of relevant particulars or conditions of an approved active constituent
Date of variation:	6 January 2020
Approval no.:	55905

Application no.:	121212
Active constituent/s:	phenylbutazone
Applicant name:	Troy Laboratories Pty Ltd
Applicant ACN:	000 283 769
Summary of variation:	Variation of relevant particulars or conditions of an approved active constituent
Date of variation:	6 January 2020
Approval no.:	85658

Application no.:	121574
Active constituent/s:	miconazole nitrate
Applicant name:	Troy Laboratories Pty Ltd
Applicant ACN:	000 283 769
Summary of variation:	Variation of relevant particulars or conditions of an approved active constituent
Date of variation:	10 January 2020
Approval no.:	85660

Application no.:	121839
Active constituent/s:	hydroxocobalamin acetate
Applicant name:	Troy Laboratories Pty Ltd
Applicant ACN:	000 283 769
Summary of variation:	Variation of relevant particulars or conditions of an approved active constituent
Date of variation:	13 January 2020
Approval no.:	85937

Application no.:	122131
Active constituent/s:	bordetella bronchiseptica
Applicant name:	Boehringer Ingelheim Animal Health Australia Pty Ltd
Applicant ACN:	071 187 285
Summary of variation:	Variation of relevant particulars or conditions of an approved active constituent
Date of variation:	14 January 2020
Approval no.:	83715

Application no.:	120626
Active constituent/s:	amoxycillin trihydrate
Applicant name:	Norbrook Laboratories Australia Pty Limited
Applicant ACN:	080 972 596
Summary of variation:	Variation of relevant particulars or conditions of an approved active constituent
Date of variation:	16 January 2020
Approval no.:	86080

Application no.:	121029
Active constituent/s:	L-isoleucine
Applicant name:	Ceva Animal Health Pty Ltd
Applicant ACN:	002 692 426
Summary of variation:	Variation of relevant particulars or conditions of an approved active constituent
Date of variation:	17 January 2020
Approval no.:	84646

Application no.:	121834
Active constituent/s:	tranexamic acid
Applicant name:	Troy Laboratories Pty Ltd
Applicant ACN:	000 283 769
Summary of variation:	Variation of relevant particulars or conditions of an approved active constituent
Date of variation:	10 January 2020
Approval no.:	56434

Eryvac E-Oral (Live) Vaccine for Pigs containing *Erysipelothrix rhusiopathiae* strain 31

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, ***Erysipelothrix rhusiopathiae* strain 31**, and application for registration of a new product containing the new active constituent. The product is **Eryvac E-Oral (Live) Vaccine for Pigs,** a live bacterial vaccine for in-water administration to healthy pigs 11 weeks of age or older as an aid in the prevention of disease caused by *Erysipelothrix rhusiopathiae*.

PARTICULARS OF THE ACTIVE CONSTITUENT

Common name:	*Erysipelothrix rhusiopathiae* strain 31
Purity:	As per US 9CFR 113.27
Identification:	As per US 9CFR 113.64
Gene technology:	Not applicable
Mode of action:	Induction of active immunological response

SUMMARY OF THE APVMA'S EVALUATION OF THE ACTIVE CONSTITUENT *ERYSIPELOTHRIX RHUSIOPATHIAE* STRAIN 31 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 ***Erysipelothrix rhusiopathiae* strain 31** under sections 5A(1)(a),(b) and (c) of the Agvet Code and proposes to be satisfied that the active constituent is not, or would not: be an undue hazard to the safety of people exposed to it during its handling or people using anything containing its residues; be likely to have an effect that is harmful to human beings; or be likely to have an unintended effect that is harmful to animals, plants or things or to the environment.

The APVMA has evaluated the chemistry and manufacturing aspects of ***Erysipelothrix rhusiopathiae* strain 31** 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.

***Erysipelothrix rhusiopathiae* strain 31** master seed details were provided. The original isolate was from Canada after which the applicant established the master seed by growing colonies on Erysipelas medium. This seed was assessed and approved by the Department of Agriculture for import into Australia. The master seed stock was tested as free of bacterial and fungal contamination in accordance with US 9CFR requirements. The relevance of the isolate to Australian field conditions has been demonstrated by the conduct of specific field studies, conducted in Australian pig herds with **Eryvac E-Oral (Live) Vaccine for Pigs**.

***Erysipelothrix rhusiopathiae* strain** 31 is an avirulent Serotype 1a isolate. Pigs are susceptible to up to 15 of the 28 described serotypes of the genus *Erysipelothrix*, however, strains of serotype's 1a, 1b and 2 from the species *E. rhusiopathiae* are the main cause of disease in pigs.

The APVMA has considered the health aspect of the active constituent. ***Erysipelothrix rhusiopathiae* strain 31** is avirulent (attenuated), thus even if non-target species are exposed to the vaccine organism it is unlikely to infect and cause harm. The vaccine has been registered or approved for use in the US (2001), Canada (2002), New Zealand (2003) and the United Kingdom (2015) with more than 62 million doses distributed since 2010. There has been only 16 reports of adverse events in the field and therefore the incidence rate is considered extremely low.

The risks posed by the proposed strain in relation to skin irritation and skin sensitisation are expected to be extremely low, but care should be exercised and skin washed immediately with plenty of water if contact occurs and medical advice sought. Low toxicity of the active constituent, and lack of human infectivity and pathogenicity, are expected.

PARTICULARS OF THE PRODUCT

Proposed name:	Eryvac E-Oral (Live) Vaccine for Pigs
Applicant company:	ZOETIS AUSTRALIA PTY LTD
Name of active constituent:	*Erysipelothrix rhusiopathiae* strain 31
Adjuvant:	Not applicable
Scheduling:	Not applicable
Pharmaceutical form:	Lyophilized cake supplied with flavoured diluent
Pack sizes:	250 or 500 dose glass vials supplied with 50 mL or 100 mL flavoured diluent in a plastic bottle
Summary of proposed use:	A live bacterial vaccine for in-water administration to healthy pigs 11 weeks of age or older as an aid in the prevention of disease caused by *Erysipelothrix rhusiopathiae*
Dose and route of administration:	Dose: For oral use only **Caution: Chlorine or other antimicrobial agents (antibiotics, disinfectants or sanitisers), if present in the vaccine water, may inactivate this live vaccine. Avoid the use of untreated bore water or non-potable water in the preparation of this vaccine. Do not use other vaccines or immunobiological products in the water at the same time as this product**. Please follow administration instructions carefully to ensure the efficacy of this live vaccine. Re-suspend the Iyophilised vaccine cake with the supplied diluent (Eryvac E-Oral Flavoured Diluent). After reconstitution of the Iyophilised vaccine cake with diluent, shake well before further dilution and administration. Use entire contents when first opened. Dilute the reconstituted vaccine in an appropriate volume of UHT skim milk stock solution and then administer in non-chlorinated drinking water using an in-line proportioner as indicated below. The reconstituted vaccine in UHT skim milk stock solution should be mixed into drinking water within 30 minutes of first opening and reconstitution. Dosage is based on the number of pigs to be treated, not the weight of pigs. Use at least one dose of vaccine per pig being vaccinated. Vaccinate pigs at 11 weeks of age or older with two doses given two weeks apart. Onset of immunity has been shown to occur at three weeks following the primary course of two oral doses. Duration of immunity has not been firmly established but data exists to support protection up to 90 days if pigs are successfully primed. **PREPARATION AND VACCINATION** 72 hours prior to vaccination

1. For pigs to be vaccinated, ensure that no antibiotics or antimicrobials are used in the feed or in the water lines, 72 hours prior to vaccination.

Day prior to vaccination

2. Measure the amount of water consumed by the group of pigs to be vaccinated during a 4 to 6-hour period—at the same time of day as vaccination will occur.

3. Count the number of pigs to be vaccinated and record the number. Use the table below to determine the number of Eryvac E-oral (Live) Vaccine packs required to ensure adequate supplies are on hand.

[*Note: only one of the tables below will appear on the product label of the relevant pack size*]

Number of pigs to be vaccinated	Number of 250 dose packs required
1–250	1
251–500	2
501–750	3
751–1 000	4

Number of pigs to be vaccinated	Number of 500 dose packs required
1–500	1
501–1 000	2
1 001–1 500	3
1 501–2 000	4

Day of vaccination

4. Rinse the stock solution bucket or tank, stirring stick and dosing tubes thoroughly with non-chlorinated drinking water to remove all disinfectants and potential contaminants.

5. Prior to mixing of the vaccine, flush the water line, stock solution container and dose tubing with 1–2 litres of UHT skim milk stock solution.

6. With the Eryvac E-oral Flavoured Diluent bottle on a solid horizontal surface, use the supplied transfer spike to pierce the bottle stopper.

7. Take the Eryvac E-oral vaccine vial (containing the freeze-dried cake) and attach it to the protruding end of the transfer spike, then invert the vaccine vial to allow delivery of the diluent solution into the Eryvac E-oral vaccine vial. Once the diluent solution is fully transferred, remove the transfer spike and shake the vaccine vial well to ensure all the freeze-dried vaccine cake is completely dissolved.

NOTE: Eryvac E-oral (Live) Vaccine must be used within 30 minutes after reconstitution.

8. Follow the instructions of the automated water proportioner device to calculate the volume of the UHT skim milk stock solution required and the dose flow rate to achieve a minimum 4 hours and a maximum of 6 hours administration period.

	9. Add the entire contents of the reconstituted Eryvac E-oral vaccine vial to the UHT skim milk stock solution. Rinse the vaccine vial with stock solution to ensure all vaccine is transferred. Stir the stock solution to ensure even distribution of the vaccine solution. 10. Following manufacturer's instructions, turn on the automated water proportioner device. Do not supply any other drinking water to the pigs during vaccination. 11. Hourly, during the administration period, walk through the pigs to ensure the pigs are awake and drinking. Check the nipples that are at the furthest point from the automated water proportioner device for the presence of a faint milky colouration in the drinking water. Routinely check that the automated water proportioner device is working and stir the vaccine-stock solution approximately every 30 minutes. Monitor the consumption of the stock solution volume during the 4 to 6-hour administration period. 12. When the vaccine-stock solution is consumed, add 1–2 litres of UHT skim milk to the stock solution container to flush any remaining vaccine through the system. 13. Once all the added UHT skim milk has passed through the system, stop the automated water proportioner device and recommence normal water supply to the pigs. 14. Clean and rinse the stock solution container, stirring stick and dosing tubing with clean water. 15. Maintain a record of the vaccination date. **<u>Caution</u>: Do not use any in-feed or in-water antibiotic/antimicrobial medications for 72 hours following vaccination**
Onset of immunity:	21 days after the primary course of two doses.
Duration of immunity:	Duration of immunity has not been firmly established but data exists to support protection up to 90 days if pigs are successfully primed.
Side effects:	None reported in the pivotal safety trials.
Precautions:	The product has not been tested for safety in pregnant pigs. The vaccine strain may be excreted by vaccinated pigs following vaccination and spread to other pigs in contact with vaccinated pigs.
Withholding period:	Zero (0) days.

SUMMARY OF THE APVMA'S EVALUATION OF ERYVAC E-ORAL (LIVE) VACCINE FOR PIGS 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 **ERYVAC E-ORAL (LIVE) VACCINE FOR PIGS** 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 **ERYVAC E-ORAL (LIVE) VACCINE FOR PIGS** containing ***Erysipelothrix rhusiopathiae* strain 31**.

The excipients in **ERYVAC E-ORAL (LIVE) VACCINE FOR PIGS** 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 user safety directions of:

"The vaccine solution may cause irritation if splashed into the eyes. If in eyes, immediately hold eyes open and rinse with plenty of water and seek medical advice. No known effects from contact of the vaccine solution with skin, but care should be exercised and if contact occurs, wash skin immediately with plenty of water and seek medical advice. Wear protective clothing including latex gloves and safety glasses when reconstituting the vaccine and when mixing vaccine with stock solution".

(ii) The APVMA is satisfied that the proposed use of **ERYVAC E-ORAL (LIVE) VACCINE FOR PIGS** 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 **ERYVAC E-ORAL (LIVE) VACCINE FOR PIGS,** 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 **ERYVAC E-ORAL (LIVE) VACCINE FOR PIGS** containing the live attenuated active constituent, ***Erysipelothrix rhusiopathiae* strain 31**, 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 **ERYVAC E-ORAL (LIVE) VACCINE FOR PIGS** containing the active constituent strain ***Erysipelothrix rhusiopathiae* strain 31**, would not be likely to have an unintended effect that is harmful to animals, plants or things or the environment.

The APVMA be satisfied under s14 of the *Agricultural and Veterinary Chemicals Code Act 1994* that the proposed use of the product **ERYVAC E-ORAL (LIVE) VACCINE** and the active constituent ***Erysipelothrix rhusiopathiae* Strain 31** meets the safety criteria with respect to s5A(1)(c), and the proposed label meets the labelling criteria under s5D(1), with respect to environmental considerations.

The potential risk to the environment and non-target species that may be exposed to the live bacterial vaccine strain have been considered and assessed. It is concluded that the use of this product under the proposed label conditions is unlikely to have any adverse effects on non-target species in the Australian environment as the vaccine strain is avirulent and unlikely to persist in the environment even if it replicates in vaccinated pigs and subsequently shed. A study in American piggeries supports the transient nature of the shedding as the vaccine strain was not detected in the manure of pigs who had previously been administered this vaccine through drinking water. A further study in pigs that were vaccinated by intranasal inoculation demonstrated that the vaccine strain could not be detected or reisolated from vaccinated animals at any time point. Furthermore*, Erysipelothrix rhusiopathiae* is ubiquitous in the environment and, therefore, even if the vaccine strain is shed into the environment will make a negligible contribution to the environmental load.

Safety aspect of this proposed product is further supported by reversion-to-virulence studies and antigen overdose studies. The reversion virulent study demonstrated that the vaccine strain, ***Erysipelothrix rhusiopathiae* strain 31**, did not become persistently established in pigs post vaccination, did not cause any local or systemic signs consistent with swine erysipelas, and was unlikely to revert to a virulent state when used in a field setting.

Field and pen studies were performed to demonstrate the safety under Australian conditions for typical pig farm practices. The trial and vaccine batch data supported safety of batch release limits for the vaccine formulation when the product is used as directed.

Overall, the conclusion drawn from these studies is that the vaccine is safe when administered to pigs from 11 weeks of age 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:

In relation to its assessment of efficacy, 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.

ERYVAC E-ORAL (LIVE) VACCINE FOR PIGS is a live bacterial vaccine for in-water administration to healthy pigs 11 weeks of age or older as an aid in the prevention of disease caused by *Erysipelothrix rhusiopathiae*. A similar product containing the same active is currently registered in the US and Canada as SUVAXYN E-ORAL.

The applicant has supplied efficacy studies conducted in Australia and the US to demonstrate the overall efficacy of the product which included dose determination, antigen efficacy, dose confirmatory and onset and duration of immunity studies. Evaluations demonstrated that **ERYVAC E-ORAL (LIVE) VACCINE FOR PIGS** was an aid in the prevention of disease caused by *Erysipelothrix rhusiopathiae*.

The data supports a minimum efficacious dose of ***Erysipelothrix rhusiopathiae* strain 31** ≥ $1.0 \times 10^{8.08}$ CFU/dose to protect against clinical disease caused by virulent *Erysipelothrix rhusiopathiae*. Clinical efficacy studies demonstrated protection against mortality, lameness, skin lesions and pyrexia in vaccinated pigs challenged with virulent isolates of *Erysipelothrix rhusiopathiae*.

Onset of immunity has been established at 21 days after completion of the two-dose vaccination schedule. Specific duration of immunity studies have not been conducted in Australia but data from US studies demonstrates a duration of immunity of up to 90 days in vaccinated pigs.

To ensure this live vaccine is efficacious it is critical to avoid the use of chlorine or other antimicrobial agents (antibiotics, disinfectants or sanitisers), in the water system at least 72 hours prior to administration of the vaccine as these agents may inactivate the vaccine organism. Furthermore, avoid the use of untreated bore water or non-potable water in the preparation of this vaccine as the effect on the vaccine organism is unknown and do not use other vaccines or immunobiological products in the water at the same time as specific interaction and compatibility studies with other products have not bene performed.

In summary, the APVMA has concluded that the data generated from the studies are consistent with the claim: For in-water administration to healthy pigs 11 weeks of age or older as an aid in the prevention of disease caused by *Erysipelothrix rhusiopathiae.*

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 **ERYVAC E-ORAL (LIVE) VACCINE FOR PIGS** is negligible. 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 **ERYVAC E-ORAL (LIVE) VACCINE FOR PIGS** is supported from a Residues and Trade perspective. A withholding period and an Export Slaughter Interval (ESI) 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 ***Erysipelothrix rhusiopathiae*** **strain 31** should be approved and whether the application for registration of **ERYVAC E-ORAL (LIVE) VACCINE FOR PIGS** 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 **ERYVAC E-ORAL (LIVE) VACCINE FOR PIGS**. These grounds include: for approval of the active constituent, the safety criteria; for the registration application for **ERYVAC E-ORAL (LIVE) VACCINE FOR PIGS** 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) material contained in submissions will be treated confidentially.

Written submissions should be addressed in writing to:

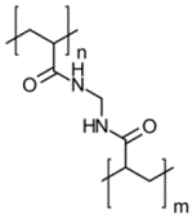
Enquiries
Registration Management and Evaluation
Australian Pesticides and Veterinary Medicines Authority
GPO Box 3262
Sydney NSW 2001

Phone: +61 2 6770 2300
Email: enquiries@apvma.gov.au

Arthramid Vet containing the active cross-linked polyacrylamide hydrogel

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application for the approval of a new active constituent, cross-linked **polyacrylamide hydrogel**, and an application for registration of the new product **Arthramid Vet**. The product is proposed for use in horses as an intra-articular sterile injection for lameness.

PARTICULARS OF THE ACTIVE CONSTITUENT

Common name:	Cross-linked polyacrylamide hydrogel (Australian approved name)
IUPAC name:	Not available, but for polyacrylamide: Poly(2-propenamide)
Chemical abstracts name:	Not available, but for polyacrylamide: Poly(2-propenamide)
CAS number:	Not available, but for polyacrylamide: 9003-05-8
Molecular formula:	Not available, but for polyacrylamide: (C3 H5 N O)x
Molecular weight:	Not available
Structure:	

SUMMARY OF THE APVMA'S EVALUATION OF THE ACTIVE CONSTITUENT CROSS-LINKED POLYACRYLAMIDE HYDROGEL 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 chemistry aspects of cross-linked **polyacrylamide hydrogel** active constituent (identification, manufacturing process, specifications, quality control procedures, batch analysis results and analytical methods) and found them to be acceptable.

The active constituent cross-linked **polyacrylamide hydrogel** is manufactured to the manufacturer's specifications.

Impurities of toxicological significance are not expected to occur in cross-linked **polyacrylamide hydrogel** as a result of the raw materials and the synthetic route used.

The APVMA has considered the toxicological aspects of cross-linked **polyacrylamide hydrogel**, and concluded that there are no toxicological concerns to the approval of this active constituent. Since the product is for use in companion animals only, and is not intended for use in food-producing animals, neither an ADI nor an ARfD has been established.

Polyacrylamide is currently listed in Schedule 4 of the Poisons Standard (*Standard for the Uniform Scheduling of Medicines and Poisons*—SUSMP) and is considered to be appropriate for the proposed active/product. The proposed labelling of the product is consistent with a Schedule 4 entry (Prescription animal remedy; Keep out of reach of children; For animal treatment only).

The APVMA is satisfied that the proposed use of cross-linked **polyacrylamide hydrogel** would not be an undue toxicological hazard to the safety of people exposed to it during its handling and use.

PARTICULARS OF THE PRODUCT

Proposed product name:	ARTHRAMID VET
Applicant company:	IMS VET PTY LIMITED
Name of active constituent:	Cross-linked polyacrylamide hydrogel
Signal heading:	Schedule 4
Summary of proposed use:	For use in horses as an intra-articular sterile injection for lameness.
Pack sizes:	1 mL syringe

SUMMARY OF THE APVMA'S EVALUATION OF ARTHRAMID VET 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 **ARTHRAMID VET** would not be an undue hazard to the safety of people exposed to the product during its handling or use.

As discussed above, the APVMA has considered the toxicological aspects of cross-linked **polyacrylamide hydrogel** and there are no objections on public or occupational health grounds to the approval of **polyacrylamide,** as a new active constituent for veterinary use. The current S4 Poisons Schedule is considered appropriate for **polyacrylamide** when present in **ARTHRAMID VET** and during the assessment of this application, the Scheduling Delegate has amended the Schedule 4 entry to include "veterinary use". This change will be included in the SUSMP, on 1 February 2020.

When assessing the acute and repeat-dose risks associated with **ARTHRAMID VET**, to mitigate the risk, the following "First Aid" statement on the product label is recommended:

If poisoning occurs, contact a doctor or Poisons Information Centre. Phone Australia 131 126.

Taking into consideration the potential toxicological hazard, use pattern and likelihood of handler exposure the following "Safety Directions" statement on the product label are recommended:

Wash hands after use.

Additionally, a precautionary statement under "Additional User Safety" has been recommended on the label:

In the case of accidental self-injection, consult a doctor.

The recommended first aid instruction, safety direction and additional user safety statement, will be included on the product label.

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

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

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

Polyacrylamide 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), with no exceptions. An amended entry to include "veterinary use" has been approved for SUSMP. **ARTHRAMID VET** contains 25 mg/mL polyacrylamide (as Cross-linked **polyacrylamide hydroge**l). Based on the concentration of polyacrylamide, and the toxicological profile of the product, this scheduling is considered appropriate.

(iv) The APVMA is satisfied that the proposed use of the new product, **ARTHRAMID VET** containing the active constituent, 25 mg/mL polyacrylamide 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.

This veterinary medicinal product will only be used as an individual treatment in non-food animals (horses). 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 container by wrapping with paper and putting in garbage. Discarded needles/sharps should immediately be placed in a designated and appropriately labelled 'sharps' container.*

An external reviewer has assessed the target animal safety of **ARTHRAMID VET** in horses. The study investigated the safety of the product at one x, two x, and five x the normal recommended dose against controls. At baseline (Day 0), all horses were injected intra-articularly with either two, four or 10ml of the product, using aseptic technique. Controls were injected with *two ml* sterile saline.

It was a double-blind, randomised design using eight horses per treatment group in accordance with VICH GL43. Additionally, to investigate multiple dosing regimen requirements (five x) and the potential systemic effects of an overdose, the use of multiple joints in a single animal was utilised at, up to five x the recommended dose; which APVMA deems as acceptable.

Clinical examinations, including joint health and mobility, as well as blood samples for haematology and blood serum biochemistry were taken before treatments and at day one, three, seven and 14 days' post treatment. Study animals were healthy animals without signs of joint disease as determined at the pre-examination.

Iatrogenic joint sepsis is known to be a significant risk with any intra-articular treatment resulting in acute clinical signs. However, the product label warns that transient oedema and tenderness may develop and take up to 'a couple of weeks to resolve'. Therefore, monitoring the horses to 14 days' post treatment was appropriate to assess either of these possible responses to treatment.

Results of the safety study showed no adverse clinical responses or serum haematology or biochemistry results outside normal reference ranges to administration of the product in any of the treatment groups. No animals were reported to show any signs of any adverse reaction with musculoskeletal health, joint range of movement or joint effusion following the treatments.

The target animal safety study showed that **ARTHRAMID VET** is safe with no adverse reactions or adverse clinical, blood haematology or biochemistry effects in any of the treated animals, even at up to five x the recommended dose.

Appropriate "Precaution" statements are included on the label:

The injection site should be prepared with an antiseptic agent for aseptic injection. Anamnesis data of ongoing infections, contaminant medication, surgery, etc. must be reviewed prior to injection in order to prevent possible infections. The use of Arthramid Vet has not been investigated in pregnant or lactating animals. The use of the product during pregnancy or lactation in mares is not recommended, unless considered essential by the veterinary surgeon.

Appropriate "Restraints" statements are included on the label:

DO NOT USE in actively infected areas.
DO NOT USE in animals with acute/chronic diseases receiving treatment with systemic corticosteroids or antibiotics.
DO NOT USE Arthramid Vet if package is open or damaged.
DO NOT resterilise Arthramid Vet.
DO NOT inject Arthramid Vet intravascularly.

Based on the provided data, the APVMA is therefore satisfied, that **ARTHRAMID VET** would not have an unintended effect that is harmful to horses.

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.

The supporting information included a number of scientific publications, clinical efficacy studies (including pharmacokinetics and pharmacodynamics studies. The recommended dose is one–four mL/joint (two mL for horse fetlock joint), with the dose determination being under the responsibility of the veterinary surgeon.

The product is not pharmacologically active, and acts locally in the joint by providing a three-dimensional structure allowing passive invasion of synoviocytes, macrophages and giant cells that are gradually replaced by a thin, vessel-bearing network. **ARTHRAMID VET** acts primarily through the thickening of the synovial membrane. Due to the size of the molecule, it does not migrate from the injection site nor is it degraded or absorbed. The product remains soft to the touch and in place. Capsule formation around the gel, hardness, calcification, and degradation without infection have never been reported for the product.

The scientific evidence provided in support, demonstrated that the hydrogel is integrated into the synovial tissue of joints in as little as 10 days in rabbits and two weeks in horses; wherein, histological appearance persisted up to *two years* post-injection in horse joints.

A controlled pilot study was conducted to investigate the efficacy of the product, in surgically created osteoarthritis affected stifle joints in goats. At seven months, three of the four treated goats were free from lameness, while both of the control groups were still lame.

Additionally, five published studies conducted on horses, have consistently demonstrated the number of horses responding to treatment, from being graded as lame to non-lame is consistently around 70 per cent at six months, with most horses responding to the treatment by one month, meaning their lameness scores improved.

Furthermore, there were three efficacy studies carried out by the applicant: a clinical case study using 49 horses; synoviocentesis from 10 horses; a blinded, randomised positive control efficacy study using 31 horses (10 horses administered with the product). It was found that the percentage of horses free of lameness at four weeks and six months post-injection was 43 per cent and 62 per cent respectively, following a single intraarticular injection of *two mL* of the product. Synoviocentesis samples show overall, that there were no significant differences between treated and control joints and all values were within normal laboratory reference limits in all horses up to 90 days' post treatment. This indicates no issues with irritation, inflammation or an immune response within the joint capsule due to administration of the product, and provides further support to the safety of the product in the target animal.

For the blinded, randomised, a positive control study was conducted. **ARTHRAMID VET** successfully treated 8/12 joints in 10 horses, a success rate of 66.67 per cent. This was compared to two positive controls, wherein, control one successfully treated only 1/11 joints from 11 horses, and control two, had a zero success rate after six weeks post-treatment. It is therefore, evident that the full effect of the product in these horses, was not realised until six weeks after treatment.

From the provided results, it appears that **ARTHRAMID VET** was superior to the positive control treatments, in the resolution of lameness in horses presenting with clinical lameness localized to the inter-carpal joint.

It is recommended to include the addition of the following statement under "Dosage and Administration" on the product label.

Allow up to 6 weeks for the full effect of treatment to be realised before considering further treatment.

1. 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 **ARTHRAMID VET** would not adversely affect trade between Australia and places outside of Australia. The product is for use in horses, 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 the application for approval of the active cross-linked **polyacrylamide hydrogel** and whether the application for registration of the product **ARTHRAMID VET** 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 product. These grounds include: for approval of the active constituent, the safety criteria; for the registration application for the product; 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
- company or group name (if relevant)
- email or postal address (if available)
- 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:

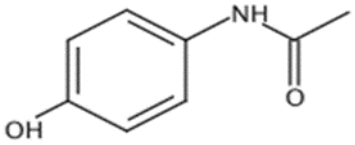
Enquiries
Registration Management and Evaluation
Australian Pesticides and Veterinary Medicines Authority
GPO Box 3262
Sydney NSW 2001

Phone: +61 2 6770 2300
Email: enquiries@apvma.gov.au

PRACETAM 400 mg/mL ORAL SOLUTION FOR PIGS containing the active constituent Paracetamol

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application from CEVA ANIMAL HEALTH PTY LTD for the approval of a new active constituent, **Paracetamol,** and an application for the registration of a new product containing the new active constituent. The product is **PRACETAM 400 mg/mL ORAL SOLUTION FOR PIGS,** a liquid formulation added to drinking water for the symptomatic treatment of fever in pigs.

PARTICULARS OF THE ACTIVE CONSTITUENT

Common name:	Paracetamol
IUPAC name:	*N*-(4-hydroxyphenyl)acetamide
CAS number:	103-90-2
Molecular formula:	$C_8H_9NO_2$
Molecular weight:	151.2 g/mol
Structure:	
Chemical family:	Acetyl derivative of para amino phenol
Mode of action:	Paracetamol is believed to exert its effect by inhibiting the nitric oxide pathway mediated by a variety of neurotransmitter receptors including N-methyl-D-aspartate and substance P, resulting in elevation of the pain threshold. The antipyretic activity may result from inhibition of prostaglandin synthesis and release in the central nervous system and prostaglandin-mediated effects on the heat-regulating centre in the anterior hypothalamus.

SUMMARY OF THE APVMA'S EVALUATION OF THE ACTIVE CONSTITUENT PARACETAMOL 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, **Paracetamol**, under sections 5A(1)(a),(b) and (c) of the Agvet Code and proposes to be satisfied that the active constituent is not, or would not: be an undue hazard to the safety of people exposed to it during its handling or people using anything containing its residues; be likely to have an effect that is harmful to human beings; or be likely to have an unintended effect that is harmful to animals, plants or things or to the environment.

The APVMA has evaluated the chemistry and manufacturing aspects of **Paracetamol** active constituent and has determined that the active constituent is manufactured to an acceptable standard. The assessment included starting materials, identification, manufacturing process, specifications, quality control procedures, batch analysis results and analytical methods. Based on a review of the data, the APVMA is satisfied that the chemistry and manufacturing details of **Paracetamol** are acceptable for use in veterinary chemical products. Impurities of known toxicological concern are unlikely to be formed during the manufacture of **Paracetamol**, or be present in the end product.

The APVMA has considered the health aspects of the active constituent. The toxicological evaluation of **Paracetamol** concluded that there are no toxicological concerns to the approval of this active constituent. An ADI of 0.05 mg/kg bw/d and an ARfD of 0.05 mg/kg bw have been established.

Paracetamol is listed in Schedule 4 of the Poisons Standard without a cut-off. An amendment has been made to include **Paracetamol** for the treatment of animals. The APVMA considered that the current S4 Poisons Schedule is appropriate for **Paracetamol** for use in veterinary products.

The APVMA is satisfied that the use of the active constituent, **Paracetamol** 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:	PRACETAM 400 mg/mL ORAL SOLUTION FOR PIGS
Applicant company:	CEVA ANIMAL HEALTH PTY LTD
Name of active constituent:	Paracetamol
Also contains:	Dimethyl sulfoxide
Signal heading:	Schedule 4
Summary of proposed use:	For the symptomatic treatment of fever in pigs
Pack sizes:	500 mL, 1 L, 2.5 L, 5 L
Withholding period:	MEAT: REMOVE ALL MEDICATED WATER (3) days before slaughter for human consumption
Trade advice:	EXPORT SLAUGHTER INTERVAL (ESI): DO NOT USE less than 3 days before slaughter for export

SUMMARY OF THE APVMA'S EVALUATION OF PRACETAM 400 mg/mL ORAL SOLUTION FOR PIGS 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*

The APVMA has evaluated the proposed product **PRACETAM 400 mg/mL ORAL SOLUTION FOR PIGS** and proposes to be satisfied that the proposed chemical product meets the safety (s 5A), efficacy (s 5B) and the trade (s 5D) criteria if used according to label instructions.

1. The APVMA has evaluated the application and in its assessment in relation to whether the safety criteria has 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 **PRACETAM 400 mg/mL ORAL SOLUTION FOR PIGS** would not be an undue hazard to the safety of people exposed to the product during its handling and use.

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

Acute toxicity was estimated based on a consideration of its individual constituents. **PRACETAM 400 mg/mL ORAL SOLUTION FOR PIGS** was considered of moderate oral toxicity and low dermal toxicity and a slight skin

and eye irritant. Based on the acute and repeat dose risks associated with **PRACETAM 400 mg/mL ORAL SOLUTION FOR PIGS**, the APVMA included the following First Aid Instructions, Safety Directions and Warning Statements on the label of the product:

FIRST AID INSTRUCTIONS

If poisoning occurs, contact a doctor or Poisons Information Centre. Phone Australia 131 126; New Zealand; New Zealand 0800 764 766. If swallowed, do NOT induce vomiting.

SAFETY DIRECTIONS

Poisonous if swallowed. Avoid contact with eyes and skin. When preparing product for use wear disposable gloves. Wash hands after use.

PRECAUTIONARY (WARNING) STATEMENTS

Do not mix with other medication except on veterinarian's advice.

(ii) The APVMA is satisfied that the proposed use of **PRACETAM 400 mg/mL ORAL SOLUTION FOR PIGS** will not be an undue hazard to the safety of people using anything containing its residues.

The **Paracetamol** MRLs set at 0.1 mg/kg for pig fat/skin, pig kidney, pig liver and pig muscle are considered by the APVMA to be appropriate for the proposed use in conjunction with a three day meat withholding period. To mitigate the risks associated with **Paracetamol**, the APVMA recommends that the following withholding period statements be included on the label:

WITHHOLDING PERIOD: MEAT: REMOVE ALL MEDICATED WATER three (3) days before slaughter for human consumption.

The APVMA is satisfied that the proposed use of **PRACETAM 400 mg/mL ORAL SOLUTION FOR PIGS** containing the active constituent **Paracetamol** is not likely to have an effect that is harmful to human beings if used according to label directions.

The APVMA has conducted a risk assessment to consider the human safety of **PRACETAM 400 mg/mL ORAL SOLUTION FOR PIGS**. After consideration of the toxicological profile and likely exposure associated with the use of **PRACETAM 400 mg/mL ORAL SOLUTION FOR PIGS**, the APVMA has concluded that the human health risk posed by the product is acceptable.

Paracetamol is listed in Schedule 4 of the Poisons Standard without a cut-off. An amendment has been made to include **Paracetamol** for the treatment of animals. The APVMA considered that the current S4 Poisons Schedule is appropriate for **Paracetamol** for use in veterinary products. In addition, a new listing has been created in Part 2 of the Poisons Standard to include the requirement for child resistant closures for **Paracetamol** included in Schedule 4, when packed and labelled for the treatment of animals.

(iii) The APVMA is satisfied that the proposed use of **PRACETAM 400 mg/mL ORAL SOLUTION FOR PIGS** is not likely to have an unintended effect that is harmful to animals, plants or things or the environment if used according to the product label directions.

For veterinary chemical products, the APVMA has adopted VICH guidelines (VICH 2000) on data requirements for environmental safety. A VICH phase II assessment was performed for use of **Paracetamol** for treatment of fever in pigs has followed conservative exposure modelling based on VICH guidelines and methodology. Test data on

persistence and mobility of **Paracetamol** in the environment based on the proposed use pattern were provided along with a range of acute and chronic toxicity tests to standard aquatic and terrestrial species. Applying Australian-based assessment factors to the available toxicity data for **Paracetamol** to terrestrial and aquatic organisms, acceptable risks could be concluded for both the terrestrial and aquatic environments.

The results of the target animal safety studies submitted demonstrated that the product was safe to use in pigs if used according to the product label directions. The product was also deemed to be safe for use in pregnant sows with no effects reported in reproductive studies conducted. In rare cases, transient soft faeces can occur and can persist up to eight days after the withdrawal of administration and resolves without any specific treatment. Based on the evidence and literature evaluated, the contraindications, precautions, side effects and other label statements made relating to target animal safety are considered appropriate.

2. The APVMA has evaluated the application and in its assessment in relation to whether the efficacy criteria has been met in accordance with the definition set out in section 5B of the Agvet Code, and proposes to determine that:

PRACETAM 400 mg/mL ORAL SOLUTION FOR PIGS is a liquid product containing 400 g/L **Paracetamol** for the symptomatic treatment of fever in pigs. The product will be added to drinking water at a dose of 30 mg of **Paracetamol** per kg body weight per day, equivalent to 0.75 ml of Pracetam Solution per 10 kg body weight per day for five days.

The efficacy data package compromised of results from pharmacokinetic studies, dose determination studies, a dose confirmation study and field studies. The APVMA has concluded that the data generated from these studies support the claims that the product would be effective in the treatment of signs associated with fever due to infectious diseases, such as respiratory disease, or as a result of vaccination in pigs.

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 proposed use involves treatment of a pigs which are a major export species however, based on the available data, **Paracetamol** residues above the validated LOQ of 0.1 mg/kg are not expected to arise in pig meat or offal after observing a three day withdrawal period. It is therefore concluded that an **Export Slaughter Interval (ESI) of three days** (equal to the recommended meat withholding period) should prevent an undue risk to international trade.

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 active constituent **Paracetamol** 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 section 13 of the Agvet Code, the APVMA invites any person to submit a relevant written submission as to whether **PRACETAM 400 mg/mL SOLUTION FOR PIGS** 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) 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
GPO Box 3262
Sydney NSW 2001

Phone: +61 2 6770 2300
Email: enquiries@apvma.gov.au

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.

1. NEW LICENCES

Nil

2. CHANGES TO EXISTING LICENCES

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

BIOPROPERTIES PTY LTD

ACN: 007 303 728

11–15 Moores Road

GLENORIE NSW 2157

Licence number: 1061

Product types: *

- *Category 1*: (Immunobiologicals and sterile products) - Immunobiologicals, sterile diluents

Steps of manufacture: Quality assurance (QA) of raw materials, management of donor animals, virus cultivation, mycoplasma cultivation, bacterial fermentation, oocyst antigen production, oocyst processing, formulation including blending, aseptic filling, filling, packaging, labelling, microbiological reduction treatment (heat, chemical, filtration), sterilisation (heat, chemical, filtration), freeze-drying, analysis and testing (physical, immunobiological, microbiological, oocyst counts), storage and release for supply.

Amended licence issued: 20 December 2019

INTERNATIONAL ANIMAL HEALTH PRODUCTS PTY LTD

ACN: 003 185 699

18 Healey Circuit

HUNTINGWOOD NSW 2148

Licence number: 2015

Product types: *

- *Category 2:* (*Non-sterile veterinary chemical products other than ectoparasiticides, premixes and supplements*)—creams/lotions, ointments, pastes, powders, pellets, sprays, tablets, bolus and liquids
- *Category 3:* (*Ectoparasiticides*)—liquids, sprays and powders
- *Category 4*: (*Premixes and supplements*)—premixes, supplements and probiotics

Steps of manufacture: Quality assurance (QA) of raw materials, formulation including blending, dry milling, granulation, filling, packaging, labelling, pellet extrusion, tableting, analysis and testing (physical), secondary packaging, secondary labelling, relabelling, storage and release for supply.

Amended licence issued: 14 January 2020

LIPA PHARMACEUTICALS LTD

ACN: 070 106 526

21 Reaghs Farm Road

MINTO NSW 2566

Licence number: 2140

Product types: *

- *Category 2:* (Non-sterile veterinary chemical preparations other than ectoparasiticides, premixes and supplements)—tablets, capsules, creams, lotions and liquids.
- *Category 3:* (*Ectoparasiticides*)—liquids and powders
- *Category 4*: (*Premixes and supplements*)—premixes

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

Amended licence issued: 20 January 2020

ECOLAB PTY LTD

ACN: 000 449 990

350 Reserve Road

CHELTENHAM VIC 3192

Licence number: 2128

Product types: *

- *Category 2:* (Non-sterile veterinary preparations except ectoparasiticides, premixes and supplements)—liquids

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

Amended licence issued: 21 January 2020

3. LICENCE CANCELLATIONS

Nil

4. LICENCE SUSPENSIONS

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

TREND LABORATORIES PTY LTD

ACN: 001 627 103

1 Corella Close

BERKELEY VALE NSW 2261

Licence number: 2169

Period of suspension: From 20 November 2019 to 19 November 2020

5. REVOCATION OF LICENCE CANCELLATION

Nil

6. REVOCATION OF LICENCE SUSPENSION

Nil

APVMA CONTACT

Manufacturing Quality and Licensing

Australian Pesticides and Veterinary Medicines Authority

GPO Box 3262

Sydney NSW 2001

Phone: +61 2 6770 2301

Email: mls@apvma.gov.au

Cancellation of Product Registration and Label Approvals at the Request of the Holder

At the request of the holder, in accordance with s42(1) of the Agvet Code, the APVMA has cancelled the product registration and associated label approvals of the following products:

Product no	Product name	Label approvals	Registrant	Date of effect
33284	FURADAN 360 FLOWABLE INSECTICIDE NEMATICIDE	33284/0309	FMC AUSTRALASIA PTY LTD	10 December 2019
33286	FURADAN 10G INSECTICIDE/NEMATICIDE	33286/0905 33286/1199 33286/0999	FMC AUSTRALASIA PTY LTD	10 December 2019
48827	MARSHAL 250 EC INSECTICIDE	48827/0905 48827/0798 48827/1097	FMC AUSTRALASIA PTY LTD	10 December 2019

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

SUPPLY

A person may supply or cause to be supplied the cancelled products manufactured prior to 10 December 2019 at wholesale and retail level, until the 10 December 2020.

After 10 December 2020 it will be an offence against the Agvet Codes to have possession or custody of the cancelled products with the intention to supply, or to supply the product.

USE

A person may continue to use the cancelled products according to its label instructions until 10 December 2020.

Any person who possesses, has custody of, uses, or otherwise deals with the cancelled products in accordance with the above instructions is taken to have been issued with a permit under the Agvet Codes to so possess, have custody of, use or otherwise deal with the cancelled products after the registration has been cancelled until 10 December 2020.

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

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

APVMA CONTACT

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

Chemical Review
Australian Pesticides and Veterinary Medicines Authority
GPO Box 3262
Sydney NSW 2001

Phone: +61 2 6770 2400
Email: chemicalreview@apvma.gov.au

Cancellation of Active Constituent Approval at the Request of the Holder

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

Active no.	Active name	Approval holder	Date of effect
44594	CARBOFURAN	FMC AUSTRALASIA PTY LTD	10 December 2019
48828	CARBOSULFAN MANUFACTURING CONCENTRATE	FMC AUSTRALASIA PTY LTD	10 December 2019

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

SUPPLY

A person may supply or cause to be supplied the cancelled active constituents manufactured prior to 10 December 2019 at wholesale and retail level, until 10 December 2020.

After 10 December 2020 it will be an offence against the Agvet Codes to have possession or custody of the cancelled active constituents with the intention to supply.

USE

A person may continue to use the cancelled active constituents until 10 December 2020.

Any person who possesses, has custody of, uses, or otherwise deals with the cancelled active constituents 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 cancelled active constituent after the approval has been cancelled until 10 December 2020.

The supply and use of the cancelled active constituents must be in accordance with the conditions of approval.

It is an offence to possess, have custody of, use, or deal with the cancelled active constituents 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
GPO Box 3262
Sydney NSW 2001

Phone: +61 2 6770 2400
Email: chemicalreview@apvma.gov.au

Cancellation of Product Label Approvals at the Request of the Holder

At the request of the holder, in accordance with s42(1) of the Agvet Code, the APVMA has cancelled the product label approvals of the following products:

Product no	Product name	Label approvals	Registrant	Date of effect
39065	WSD SPURT OFF-SHEARS, POUR-ON SHEEP LICE CONTROL	39065/0614	WSD AGRIBUSINESS PTY LTD	10 December 2019
48239	FARMOZ APHIDEX 500 WETTABLE POWDER APHICIDE	48239/01 48239/1097 48239/1001 48239/0504	ADAMA AUSTRALIA PTY LIMITED	10 December 2019
61086	CHEMFORCE METRIBUZIN 750 WG HERBICIDE	61086/0606	CHEMFORCE 2010 PTY LTD	10 December 2019
61595	APHIDEX WG APHICIDE	61595/63161 61595/0609 61595/0607	ADAMA AUSTRALIA PTY LTD	10 December 2019
69361	AVIATOR XPRO FOLIAR FUNGICIDE	69361/107709 69361/110880 69361/60590	BAYER CROPSCIENCE PTY LTD	10 December 2019
69772	NAIL 600 EC HERBICIDE	69772/106741 69772/102279 69772/61700	NUFARM AUSTRALIA LIMITED	10 December 2019

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

SUPPLY

A person may supply or cause to be supplied the above products bearing the cancelled label manufactured prior to 10 December 2019 at wholesale and retail level, until 10 December 2020.

After 10 December 2020 it will be an offence against the Agvet Codes to have possession or custody of products bearing the cancelled label with the intention to supply, or to supply the product.

USE

A person may continue to use the products bearing the cancelled label according to its label instructions until 10 December 2020.

Any person who possesses, has custody of, uses, or otherwise deals with the products 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 products bearing the cancelled label after the registration has been cancelled until 10 December 2020.

The supply and use of the products 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 products 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
GPO Box 3262
Sydney NSW 2001

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Email: chemicalreview@apvma.gov.au