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Gazette

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**AGRICULTURAL AND
VETERINARY CHEMICALS**



Australian Government
**Australian Pesticides and
Veterinary Medicines Authority**

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

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GENERAL INFORMATION

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

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

DISTRIBUTION AND SUBSCRIPTION

The *APVMA Gazette* is published in electronic format only and is available from the APVMA website, www.apvma.gov.au/publications/gazette/.

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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. RESTRICTED PRODUCT

Application no.:	101947
Product name:	ACTA 1080 Dried Meat Wild Dog Bait
Active constituent/s:	150 mg/kg sodium fluoroacetate
Applicant name:	Animal Control Technologies (Australia) Pty Ltd
Applicant ACN:	137 868 449
Summary of use	For the control of wild dogs
Date of registration/approval:	25 November 2015
Product registration no.:	80919
Label approval no.:	80919/101947

Application no.:	101951
Product name:	ACTA 1080 Dried Meat Fox Bait
Active constituent/s:	80 mg/kg sodium fluoroacetate (1080)
Applicant name:	Animal Control Technologies (Australia) Pty Ltd
Applicant ACN:	137 868 449
Summary of use	For the control of foxes
Date of registration/approval:	26 November 2015
Product registration no.:	80924
Label approval no.:	80924/101951

Application no.:	103340
Product name:	EUREKA! Bifenthrin 100 EC Insecticide and Miticide
Active constituent/s:	100 g/L bifenthrin
Applicant name:	Eureka! Agresearch Pty Ltd
Applicant ACN:	086 194 738
Summary of use	For installing chemical soil barriers, post-construction management of subterranean termites and the control of a large range of other urban pests
Date of registration/approval:	1 December 2015
Product registration no.:	81549
Label approval no.:	81549/103340

2. AGRICULTURAL PRODUCTS BASED ON EXISTING ACTIVE CONSTITUENTS

Application no.:	56223
Product name:	Conserve On-Farm Grain Protector
Active constituent/s:	500 g/L chlorpyrifos-methyl, 30 g/L s-methoprene, 120 g/L spinosad
Applicant name:	Dow Agrosciences Australia Limited
Applicant ACN:	003 771 659
Summary of use	For the control of a broad range of stored product insects in stored cereal grains (excluding rice and malting barley)
Date of registration/approval:	19 November 2015
Product registration no.:	67508
Label approval no.:	67508/56223
Application no.:	103053
Product name:	AC Attack Dog 540SL Herbicide
Active constituent/s:	540 g/L glyphosate present as the potassium salt
Applicant name:	Axichem Pty Ltd
Applicant ACN:	131 628 594
Summary of use	For the control of many annual and perennial weeds
Date of registration/approval:	24 November 2015
Product registration no.:	81410
Label approval no.:	81410/103053
Application no.:	102321
Product name:	Fascinate 200 Herbicide
Active constituent/s:	200 g/L glufosinate-ammonium
Applicant name:	UPL Australia Limited
Applicant ACN:	066 391 384
Summary of use	For the control of non-residual broadleaf and grass weeds in various situations
Date of registration/approval:	25 November 2015
Product registration no.:	81099
Label approval no.:	81099/102321
Application no.:	103016
Product name:	Santalum Estate Mosquito Repellent Incense Sandalwood Sticks
Active constituent/s:	15 g/kg eucalyptus oil 15g/kg citronella oil
Applicant name:	Mayo Hardware Pty Ltd
Applicant ACN:	071517176
Summary of use	For the use of repelling mosquitoes
Date of registration/approval:	25 November 2015
Product registration no.:	81388
Label approval no.:	81388/103016

Application no.:	101341
Product name:	AC Invoke 750 WG Herbicide
Active constituent/s:	750 g/kg isoxaflutole
Applicant name:	Axichem Pty Ltd
Applicant ACN:	131 628 594
Summary of use	For the control and suppression of various broadleaf weeds and grasses in sugarcane and chickpeas
Date of registration/approval:	25 November 2015
Product registration no.:	80655
Label approval no.:	80655/101341
Application no.:	103229
Product name:	ATLAS Fly & Mosquito Coils
Active constituent/s:	0.5 g/kg citronella oil, 4 g/kg d-allethrin.
Applicant name:	Pascoe's Pty Ltd
Applicant ACN:	055 220 463
Summary of use	For the control of flies and mosquitoes in the home and garden
Date of registration/approval:	25 November 2015
Product registration no.:	81506
Label approval no.:	81506/103229
Application no.:	102307
Product name:	Hexanil 250 SL Herbicide
Active constituent/s:	250 g/L hexazinone
Applicant name:	Rotam Agrochemical Co., Ltd
Applicant ACN:	N/A
Summary of use	For the control of certain broadleaf weeds, perennial and annual grasses, woody weeds in Pinus radiata plantations, pasture situations and commercial and industrial areas and rights of way
Date of registration/approval:	25 November 2015
Product registration no.:	81083
Label approval no.:	81083/102307
Application no.:	103557
Product name:	Eureka! Glufosinate 200 SL Herbicide
Active constituent/s:	200 g/L glufosinate-ammonium
Applicant name:	Eureka! Agresearch PTY LTD
Applicant ACN:	086 194 738
Summary of use	For the control of broadleaf and grass weeds in various situations
Date of registration/approval:	25 November 2015
Product registration no.:	81653
Label approval no.:	81653/103557
Application no.:	103238
Product name:	Hovex Crawling Insect Killer Odourless
Active constituent/s:	0.15 g/kg imiprothrin, 2.79 g/kg permethrin
Applicant name:	Pascoe's Pty Ltd
Applicant ACN:	055 220 463
Summary of use	For the control of cockroaches and other crawling insects
Date of registration/approval:	26 November 2015
Product registration no.:	81509
Label approval no.:	81509/103238

Application no.:	102816
Product name:	Zipper 200 Herbicide
Active constituent/s:	200 g/L glufosinate-ammonium
Applicant name:	Rotam Agrochemical Co., Ltd
Applicant ACN:	N/A
Summary of use	For the control of broadleaf and grass weeds in various situations
Date of registration/approval:	26 November 2015
Product registration no.:	81319
Label approval no.:	81319/102816
Application no.:	102817
Product name:	Rotam Glyphosate 700 Herbicide
Active constituent/s:	700 g/kg glyphosate
Applicant name:	Rotam Agrochemical Co., Ltd
Applicant ACN:	N/A
Summary of use	For the control of many annual and perennial weeds in certain situations
Date of registration/approval:	26 November 2015
Product registration no.:	81320
Label approval no.:	81320/102817
Application no.:	101770
Product name:	JH Termite Barrier
Active constituent/s:	2.0 g/kg deltamethrin
Applicant name:	Jinhong Australia Pty Ltd
Applicant ACN:	163 906 241
Summary of use	For the protection of buildings and structures from subterranean termites
Date of registration/approval:	26 November 2015
Product registration no.:	80846
Label approval no.:	80846/101770
Application no.:	100217
Product name:	Osku Hellas Grape Guards
Active constituent/s:	735 g/kg sodium metabisulphite
Applicant name:	Biopac Pty Ltd
Applicant ACN:	158 624 705
Summary of use	For the control of botrytis in packaged grapes
Date of registration/approval:	26 November 2015
Product registration no.:	80103
Label approval no.:	80103/100217
Application no.:	101901
Product name:	Icasso 240 Herbicide
Active constituent/s:	240 g/L clethodim
Applicant name:	Rotam Agrochemical Co., Ltd
Applicant ACN:	N/A
Summary of use	For the control of certain grass weeds in beetroot, cabbage, canola, celery, chickpeas, cotton, faba beans, field peas, forestry, lentils, lettuce, lupins, mung beans, non-bearing fruit trees, onions, ornamentals, peanuts, potatoes and soy beans
Date of registration/approval:	26 November 2015
Product registration no.:	80906
Label approval no.:	80906/101901

Application no.:	102212
Product name:	Tuken Extra Herbicide
Active constituent/s:	25 g/L diflufenican, 250 g/L MCPA present as the ethyl hexyl ester
Applicant name:	Rotam Agrochemical Co., Ltd
Applicant ACN:	N/A
Summary of use	For the control of certain broadleaf weeds in winter cereals and clover
Date of registration/approval:	26 November 2015
Product registration no.:	81044
Label approval no.:	81044/102212
Application no.:	100429
Product name:	eChem Glyphosate 540 K Herbicide
Active constituent/s:	540 g/L glyphosate present as the potassium salt
Applicant name:	Echem (Aust) Pty Limited
Applicant ACN:	089 133 095
Summary of use	For the control of many annual and perennial weeds
Date of registration/approval:	27 November 2015
Product registration no.:	80222
Label approval no.:	80222/100429
Application no.:	102314
Product name:	Haluron Herbicide
Active constituent/s:	750 g/kg halosulfuron-methyl
Applicant name:	Rotam Agrochemical Co., Ltd
Applicant ACN:	N/A
Summary of use	For selective post-emergence control of nutgrass in sugarcane and corn/maize and sorghum and for selective post-emergence control of nutgrass and Mullumbimby couch in turf. Also for the control of nutgrass in cotton using shielded sprayers
Date of registration/approval:	27 November 2015
Product registration no.:	81091
Label approval no.:	81091/102314
Application no.:	102903
Product name:	Pest Controller's Own Cockroach Gel
Active constituent/s:	20 g/kg hydramethylnon
Applicant name:	Amgrow Pty Ltd
Applicant ACN:	100 684 786
Summary of use	For the control of cockroaches, by professional pest control operators, in residential and commercial situations
Date of registration/approval:	30 November 2015
Product registration no.:	81363
Label approval no.:	81363/102903

Application no.:	103217
Product name:	Hovex Germgard Crawling Insect Killer High Performance
Active constituent/s:	0.7 g/kg imiprothrin, 2.0 g/kg cypermethrin
Applicant name:	Pascoe's Pty Ltd
Applicant ACN:	055 220 463
Summary of use	For the control of crawling insects in the home and garden
Date of registration/approval:	30 November 2015
Product registration no.:	81500
Label approval no.:	81500/103217
Application no.:	103282
Product name:	Powerforce Algaecide
Active constituent/s:	150 g/L benzalkonium chloride
Applicant name:	N & F Pty Ltd
Applicant ACN:	103 942 427
Summary of use	For the control of algae in swimming pools
Date of registration/approval:	30 November 2015
Product registration no.:	81522
Label approval no.:	81522/103282
Application no.:	104059
Product name:	Relyon Glyphix 450 Herbicide
Active constituent/s:	450 g/L glyphosate present as the isopropylamine salt
Applicant name:	Ruralco Holdings Limited
Applicant ACN:	009 660 879
Summary of use	For the control of a broad range of annual and perennial weeds
Date of registration/approval:	30 November 2015
Product registration no.:	81791
Label approval no.:	81791/104059
Application no.:	103409
Product name:	Pest Defence Professional Cockroach Gel Bait
Active constituent/s:	0.5 g/kg abamectin
Applicant name:	Ensystem Australasia Pty Ltd
Applicant ACN:	102 221 965
Summary of use	For the control of cockroaches in commercial, industrial and residential buildings
Date of registration/approval:	30 November 2015
Product registration no.:	81583
Label approval no.:	81583/103409

Application no.:	100482
Product name:	Yates Zero Rapid Gel 1-Hr Action Weedkiller
Active constituent/s:	20.5 g/L nonanoic acid, 40 g/L glyphosate present as the ammonium salt
Applicant name:	Duluxgroup (Australia) Pty Ltd
Applicant ACN:	000 049 427
Summary of use	For the control of a wide range of annual and perennial weeds and grasses found in home gardens
Date of registration/approval:	1 December 2015
Product registration no.:	80255
Label approval no.:	80255/100482

Application no.:	102325
Product name:	Rotam Haloxyfop 520 EC Herbicide
Active constituent/s:	520 g/L haloxyfop-p present as the haloxyfop-p-methyl ester
Applicant name:	Rotam Agrochemical Co., Ltd
Applicant ACN:	N/A
Summary of use	For the control of a wide range of annual and perennial grass weeds in a wide range of crops
Date of registration/approval:	1 December 2015
Product registration no.:	81102
Label approval no.:	81102/102325

Application no.:	103474
Product name:	Pest Defence Professional Termiticide & Insecticide
Active constituent/s:	100 g/L bifenthrin
Applicant name:	Ensystem Australasia Pty Ltd
Applicant ACN:	102 221 965
Summary of use	For the protection of structures from subterranean termite damage, the control of various urban insect pests and the control of a range of pests in ornamental plants and turf
Date of registration/approval:	2 December 2015
Product registration no.:	81621
Label approval no.:	81621/103474

Application no.:	101878
Product name:	EUREKA! Imazethapyr 700 WG Herbicide
Active constituent/s:	700 g/kg imazethapyr
Applicant name:	EUREKA! Agresearch Pty Ltd
Applicant ACN:	086 194 738
Summary of use	For the pre-emergence or post-emergence control of certain weeds in Centrosema (Cavalcade), chickpeas, faba beans, field peas, lucerne, mung beans, peanuts, serradella, soybeans and subterranean clover
Date of registration/approval:	2 December 2015
Product registration no.:	80889
Label approval no.:	80889/101878

Application no.:	62990
Product name:	Tybalt 275 EC Herbicide
Active constituent/s:	25 g/L diflufenican, 250 g/L bromoxynil present as the octanoate.
Applicant name:	UPL Australia Limited
Applicant ACN:	066 391 384
Summary of use	For control of certain broadleaf weeds in winter cereals and pastures
Date of registration/approval:	2 December 2015
Product registration no.:	70310
Label approval no.:	70310/62990
Application no.:	101957
Product name:	AC Brushlia 80 Insecticide/Miticide
Active constituent/s:	80 g/L bifenthrin
Applicant name:	Axichem Pty Ltd
Applicant ACN:	131 628 594
Summary of use	For the control of apple dimpling bug and plague thrips in apples, scab moth and flower thrips in bananas, two spotted mites in pears and several pests in ornamentals
Date of registration/approval:	2 December 2015
Product registration no.:	80930
Label approval no.:	80930/101957
Application no.:	55846
Product name:	Preventol TM-Termiticide for Expanded Polystyrene Foam
Active constituent/s:	970 g/kg imidacloprid
Applicant name:	Lanxess Pty Ltd
Applicant ACN:	071 919 116
Summary of use	For the control of termites infesting construction grade expanded polystyrene foam
Date of registration/approval:	2 December 2015
Product registration no.:	67342
Label approval no.:	67342/55846
Application no.:	103434
Product name:	Kenso Agcare Castor 720 SC Fungicide
Active constituent/s:	720 g/L chlorothalonil
Applicant name:	Kenso Corporation (M) SDN. BHD
Applicant ACN:	N/A
Summary of use	For the control of fungal diseases on almonds, apricots, bananas, carrots, celery, cherries, faba beans, grapes, onions, peaches, peanuts, peas, plums, potatoes, tomatoes, turf and vegetables
Date of registration/approval:	2 December 2015
Product registration no.:	81600
Label approval no.:	81600/103434

Application no.:	103550
Product Name:	Genfarm Fluroxypyr 400 Herbicide
Active constituent/s:	400 g/L fluroxypyr present as the methylheptyl ester
Applicant name:	Landmark Operations Limited
Applicant ACN:	008 743 217
Summary of use	For the control of a wide range of broadleaf weeds in fallow, lucerne, maize, millets, pastures, poppies, sorghum, sugar cane, sweet corn, 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/approval:	3 December 2015
Product registration no.:	81650
Label approval no.:	81650/103550
Application no.:	103564
Product name:	Smart Cargo Snail Bait
Active constituent/s:	15 g/kg metaldehyde
Applicant name:	Crop Smart Pty Ltd
Applicant ACN:	093 927 961
Summary of use	For the control of snails and slugs in many agricultural and horticultural situations
Date of registration/approval:	3 December 2015
Product registration no.:	81654
Label approval no.:	81654/103564
Application no.:	104134
Product name:	Relyon Basher 200 Herbicide
Active constituent/s:	200 g/L glufosinate-ammonium
Applicant name:	Ruralco Holdings Limited
Applicant ACN:	009 660 879
Summary of use	For the non-residual control of broadleaf and grass weeds in various situations
Date of registration/approval:	3 December 2015
Product registration no.:	81832
Label approval no.:	81832/104134
Application no.:	101744
Product name:	Conan 500 Fungicide
Active constituent/s:	500 g/L chlorothalonil
Applicant name:	UPL Australia Limited
Applicant ACN:	066 391 384
Summary of use	For the control of fungal diseases on fruits, vegetables, turf and other areas
Date of registration/approval:	3 December 2015
Product registration no.:	80829
Label approval no.:	80829/101744

Application no.:	103784
Product name:	Atlas 3 In 1 Garden Indoor & Outdoor Surface Spray
Active constituent/s:	1 g/L esfenvalerate
Applicant name:	Pascoe's Pty Ltd
Applicant ACN:	055 220 463
Summary of use	For protection against flying and crawling insects around the home and garden
Date of registration/approval:	7 December 2015
Product registration no.:	81709
Label approval no.:	81709/103784
Application no.:	63364
Product name:	eChem Triasulfuron 750 WG Herbicide
Active constituent/s:	750 g/kg triasulfuron
Applicant name:	eChem (Aust) Pty Limited
Applicant ACN:	089 133 095
Summary of use	For pre-plant control of annual ryegrass, paradoxa grass and certain broadleaf weeds in wheat and for post-emergent control of wild radish in wheat, oats and barley
Date of registration/approval:	8 December 2015
Product registration no.:	70396
Label approval no.:	70396/63364
Application no.:	103470
Product name:	Interspeed 376 Hard Antifouling For Aluminium
Active constituent/s:	125 g/L copper present as cuprous thiocyanate, 50 g/L zinc pyrithione
Applicant name:	Akzo Nobel Pty Limited
Applicant ACN:	000 119 424
Summary of use	For use on the aluminium hull of vessels for the control of marine growth
Date of registration/approval:	8 December 2015
Product registration no.:	81619
Label approval no.:	81619/103470
Application no.:	100170
Product name:	Farmalinx Axy-M Fungicide Seed Treatment
Active constituent/s:	350 g/L metalaxyl-M
Applicant name:	Farmalinx Pty Ltd
Applicant ACN:	134 353 245
Summary of use	For the control of seedling disease in cotton, peas, lucerne, subterranean clover, carrots, beetroot, maize, sweetcorn and radish
Date of registration/approval:	8 December 2015
Product registration no.:	80082
Label approval no.:	80082/100170
Application no.:	101647
Product name:	Brunnings Weed Kill For Buffalo
Active constituent/s:	6.7 g/L bromoxynil present as the potassium salt, 6.7 g/L MCPA present as the potassium salt
Applicant name:	Brunnings Garden Products Pty Ltd
Applicant ACN:	050 655 760
Summary of use	For the control of bindii, clover, oxalis and other broadleaf weeds in lawns
Date of registration/approval:	8 December 2015
Product registration no.:	80788
Label approval no.:	80788/101647

3. VARIATIONS OF REGISTRATION

Application no.:	104764
Product name:	Virkon S The Broad Spectrum Virucidal Bactericidal Fungicidal Disinfectant
Active constituent/s:	132 g/kg sodium dodecyl benzene sulphonate, 494 g/kg potassium peroxomonosulphate triple salt, 15 g/kg sodium chloride
Applicant name:	Lienert Australia Pty. Ltd
Applicant ACN:	008 293 007
Summary of variation:	To change the distinguishing product name and the name that appears on the label from 'ANTEC VIRKON S THE BROAD SPECTRUM VIRUCIDAL BACTERICIDAL FUNGICIDAL DISINFECTANT' to 'VIRKON S THE BROAD SPECTRUM VIRUCIDAL BACTERICIDAL FUNGICIDAL DISINFECTANT'
Date of variation:	3 November 2015
Product registration no.:	48185
Label approval no.:	48185/104764
Application no.:	104764
Product name:	Virkon S The Broad Spectrum Virucidal Bactericidal Fungicidal Disinfectant
Active constituent/s:	132 g/kg sodium dodecyl benzene sulphonate, 494 g/kg potassium peroxomonosulfate triple salt, 15 g/kg sodium chloride
Applicant name:	Lienert Australia Pty. Ltd
Applicant ACN:	008 293 007
Summary of variation:	To change the distinguishing product name and the name that appears on the label from 'ANTEC VIRKON S THE BROAD SPECTRUM VIRUCIDAL BACTERICIDAL FUNGICIDAL DISINFECTANT' to 'VIRKON S THE BROAD SPECTRUM VIRUCIDAL BACTERICIDAL FUNGICIDAL DISINFECTANT'
Date of variation:	3 November 2015
Product no.:	48185
Label approval no.:	48185/104764
Application no.:	104837
Product name:	Hortico Insect Killer Ready To Spray Tomatoes & Vegetables
Active constituent/s:	1.2 g/L piperonyl butoxide, 0.3 g/L pyrethrins
Applicant name:	Duluxgroup (Australia) Pty Ltd
Applicant ACN:	000 049 427
Summary of variation:	To change the distinguishing product name and the name that appears on the label from 'HORTICO INSECT KILLER READY TO USE NATURAL PYRETHRUM' to 'HORTICO INSECT KILLER READY TO SPRAY TOMATOES & VEGETABLES'
Date of variation:	11 November 2015
Product registration no.:	60782
Label approval no.:	60782/104837
Application no.:	104893
Product name:	Hortico Insect Killer Ready To Spray Fruit & Citrus
Active constituent/s:	20 g/L petroleum oil
Applicant name:	Duluxgroup (Australia) Pty Ltd
Applicant ACN:	000 049 427
Summary of variation:	To change the distinguishing product name and the name that appears on the label from 'HORTICO WHITE OIL READY TO USE INSECTICIDE' to 'HORTICO INSECT KILLER READY TO SPRAY FRUIT & CITRUS'
Date of variation:	17 November 2015
Product registration no.:	67060
Label approval no.:	67060/104893

Application no.:	104894
Product name:	Hortico Insect Killer Concentrate Fruit & Citrus
Active constituent/s:	825 g/L petroleum oil
Applicant name:	Duluxgroup (Australia) Pty Ltd
Applicant ACN:	000 049 427
Summary of variation:	To change the distinguishing product name and the name that appears on the label from 'HORTICO WHITE OIL CONCENTRATE INSECTICIDE' to 'HORTICO INSECT KILLER CONCENTRATE FRUIT & CITRUS'
Date of variation:	18 November 2015
Product registration no.:	67059
Label approval no.:	67059/104894
Application no.:	104908
Product name:	Hortico Bindii Killer Concentrate Lawns
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:	Duluxgroup (Australia) Pty Ltd
Applicant ACN:	000 049 427
Summary of variation:	To change the distinguishing product name and the name that appears on the label from 'HORTICO WEED KILLER FOR BUFFALO LAWNS' to 'HORTICO BINDII KILLER CONCENTRATE LAWNS'
Date of variation:	18 November 2015
Product registration no.:	67027
Label approval no.:	67027/104908
Application no.:	104907
Product name:	Hortico Bindii Killer Hose On Lawns
Active constituent/s:	6 g/L bromoxynil present as the potassium salt, 6 g/L MCPA present as the potassium salt
Applicant name:	Duluxgroup (Australia) Pty Ltd
Applicant ACN:	000 049 427
Summary of variation:	To change the distinguishing product name and the name that appears on the label from 'HORTICO WEED KILLER FOR BUFFALO LAWNS HOSE-ON' to 'HORTICO BINDII KILLER HOSE ON LAWNS'
Date of variation:	18 November 2015
Product registration no.:	67086
Label approval no.:	67086/104907
Application no.:	104916
Product name:	Protect-Us Verminate Soft Bait Rodenticide
Active constituent/s:	0.05 g/kg brodifacoum
Applicant name:	Zapi S.P.A
Applicant ACN:	N/A
Summary of variation:	To change the distinguishing product name and the name that appears on the label from 'PROTECT-US PROFESSIONAL SOFT BAIT RODENTICIDE' to 'PROTECT-US VERMINATE SOFT BAIT RODENTICIDE'
Date of variation:	18 November 2015
Product no.:	68664
Label approval no.:	68664/104916

Application no.:	104943
Product name:	Zoliar 800 DF Herbicide
Active constituent/s:	800 g/kg norflurazon
Applicant name:	Agnova Technologies Pty Ltd
Applicant ACN:	097 705 158
Summary of variation:	To remove use on cotton and cotton fallow
Date of variation:	20 November 2015
Product registration no.:	63329
Label approval no.:	63329/104943
Application no:	102565
Product name:	Macro Protect 900 WG Herbicide
Active constituent/s:	900 g/kg atrazine
Applicant name:	Macrofertil Australia Pty Ltd
Applicant ACN:	166 370 976
Summary of variation:	To change the product name from 'RAVENSDOWN ATRAZINE 900 WG HERBICIDE' to 'MACRO PROTECT 900 WG HERBICIDE'
Date of variation:	25 November 2015
Product registration no.:	58456
Label approval no.:	58456/102565
Application no:	100764
Product name:	Basta Non-Selective Herbicide
Active constituent/s:	200 g/L glufosinate-ammonium
Applicant name:	Bayer Cropscience Pty Ltd
Applicant ACN:	000 226 022
Summary of variation:	To extend the use in sugarcane and along fence lines in agricultural areas as well as the inclusion of two additional Ipomea weed spp
Date of variation:	25 November 2015
Product registration no.:	39118
Label approval no.:	39118/100764
Application no:	103546
Product name:	Ultraforce Cockroach Powder
Active constituent/s:	5 g/kg fipronil
Applicant name:	Sherwood Chemicals Public Company Limited
Applicant ACN:	N/A
Summary of variation:	To include an additional pack size
Date of variation:	26 November 2015
Product registration no.:	80043
Label approval no.:	80043/103546
Application no:	103296
Product name:	Saboteur Systemic Insecticide
Active constituent/s:	400 g/L dimethoate (an anti-cholinesterase compound)
Applicant name:	Crop Care Australasia Pty Ltd
Applicant ACN:	061 362 347
Summary of variation:	To update the label in accordance with the review of dimethoate, and add additional 500 mL and 10 L pack sizes
Date of variation:	27 November 2015
Product registration no.:	49600
Label approval no.:	49600/103296

Application no:	102802
Product name:	Nufarm Avadex Xtend Selective Herbicide
Active constituent/s:	600 g/L triallate
Applicant name:	Nufarm Australia Limited
Applicant ACN:	004 377 780
Summary of variation:	To add uses to control certain weeds in wheat, barley, triticale and canola
Date of variation:	30 November 2015
Product registration no.:	67827
Label approval no.:	67827/102802

Application no:	102685
Product name:	Mortein Outdoor Mosquito Coils
Active constituent/s:	2 g/kg d-allethrin
Applicant name:	Reckitt Benckiser (Australia) Pty Limited
Applicant ACN:	003 274 655
Summary of variation:	To include a new label claim
Date of variation:	3 December 2015
Product registration no.:	48228
Label approval no.:	48228/102685

Application no.:	101846
Product name:	Bioguard Spa Chlorinated Concentrate Sanitiser & Oxidiser
Active constituent/s:	350 g/kg chlorine present as lithium hypochlorite
Applicant name:	Biolab Australia Pty Ltd
Applicant ACN:	005 878 017
Summary of variation:	For the control of algae and bacteria in spas
Date of variation:	3 December 2015
Product registration no:	62108
Label approval no.:	62108/101846

Application no:	103957
Product name:	Nufarm Pulse Penetrant
Active constituent/s:	1000 g/L modified polydimethylsiloxane
Applicant name:	Nufarm Australia Limited
Applicant ACN:	004 377 780
Summary of variation:	To correct active constituent statement and include a pack size range
Date of variation:	8 December 2015
Product registration no.:	57279
Label approval no.:	57279/103957

4. LABEL APPROVAL

Application no.:	104115
Product name:	Trithor Termite Protection
Active constituent/s:	2 g/kg deltamethrin (equivalent to 1 g/m ² deltamethrin)
Applicant name:	Ensystem Australia Pty Ltd
Applicant ACN:	096 839 815
Summary of use:	To add an additional label name to the product under 'FLICKGUARD TERMITE PROTECTION SHEET'
Date of approval:	30 November 2015
Label approval no.:	59139/104115

Application no.:	104223
Product name:	IQ Shock & Swim For Spas & Pools
Active constituent/s:	372 g/kg chlorine present as sodium dichloroisocyanurate, 100 g/kg sodium tetraborate pentahydrate
Applicant name:	International Quadratics Pty Ltd
Applicant ACN:	091 533 167
Summary of use:	To add an additional label name to the product under 'AQUAHEALTH SHOCK & SWIM FOR SPAS AND POOLS'
Date of approval:	30 November 2015
Label approval no.:	59801/104223
Application no.:	100103
Product name:	Shogun Herbicide
Active constituent/s:	100 g/L propaquizafop
Applicant name:	Adama Australia Pty Limited
Applicant ACN:	050 328 973
Summary of use:	To extend the use to include the control of feathertop rhodes grass (chloris virgata)
Date of approval:	1 December 2015
Label approval no.:	60764/100103
Application no.:	103950
Product name:	Enviro Alkali Wash
Active constituent/s:	686 g/L sodium hydroxide
Applicant name:	Envirochem Industries Pty Ltd
Applicant ACN:	119 218 549
Summary of use:	To add an additional label name to the product under 'TURBOWASH ALKALINE DETERGENT'
Date of approval:	1 December 2015
Label approval no.:	64579/103950
Application no.:	104068
Product name:	Counts Down Dairy Acid Cleaner
Active constituent/s:	1306 g/L phosphoric acid
Applicant name:	Envirochem Industries Pty Ltd
Applicant ACN:	119 218 549
Summary of use:	To add an additional label name to the product under 'TERMINATOR DAIRY ACID CLEANER'
Date of approval:	3 December 2015
Label approval no.:	64626/104068

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.:	102016
Product name:	Bob Martin Since 1892 Flea Rid For Dogs, Cats, Puppies And Kittens Powder
Active constituent/s:	1.5 g/kg pyrethrins, 10 g/kg piperonyl butoxide
Applicant name:	Bob Martin (Australia) Pty Ltd
Applicant ACN:	062 627 883
Summary of use	For the control of fleas (<i>ctennocephalides spp.</i>), lice (<i>trichodectes canis</i> , <i>heterodoxus spiniger</i> and <i>felicola subrostratus</i>)
Date of registration/approval:	23 November 2015
Product registration no.:	80967
Label approval no.:	80967/102016
Application no.:	61478
Product name:	DeLaval Teatsan Plus Extra Concentrated Post Milking Teat Sanitiser With Emollient
Active constituent/s:	220 g/L propylene glycol, 40 g/L available iodine, 215 g/L glycerine
Applicant name:	DeLaval Pty Ltd
Applicant ACN:	004 210 459
Summary of use	For use as an aid in reducing the spread of mastitis-causing organisms in lactating dairy cows
Date of registration/approval:	25 November 2015
Product registration no.:	69709
Label approval no.:	69709/61478
Application no.:	100774
Product name:	CloxaSeal 600
Active constituent/s:	600 mg cloxacillin (as benzathine salt), 2.6 g bismuth subnitrate
Applicant name:	Norbrook Laboratories Australia Pty Limited
Applicant ACN:	080 972 596
Summary of use	For the treatment of subclinical mastitis caused by organisms sensitive to cloxacillin in dairy cows at drying off
Date of registration/approval:	3 December 2015
Product registration no.:	80397
Label approval no.:	80397/100774

2. LISTED REGISTRATIONS

Application no.:	103074
Product name:	Glucosaguard
Active constituent/s:	37.4 g/kg glucosamine hydrochloride
Applicant name:	Holidayz Pty Ltd
Applicant ACN:	114 201 759
Summary of use	May improve joint health and function in dogs
Date of registration/approval:	23 November 2015
Product registration no.:	81427
Label approval no.:	81427/103074

3. LABEL APPROVAL

Application no.:	103661
Product name:	Bob Martin Since 1892 Flea Rid for Small Dogs and Puppies Spot On
Active constituent/s:	744 g/L permethrin (25:75::CIS:TRANS)
Applicant name:	Bob Martin (Australia) Pty Ltd
Applicant ACN:	062 627 883
Summary of use:	To add additional label names to the product under 'FURRY FACE VETERINARY FLEA & TICK SPOT ON FOR SMALL DOGS & PUPPIES', 'PET LOVERS OWN FLEA & TICK SPOT ON FOR SMALL DOGS & PUPPIES', 'BOB MARTIN CLEAR FLEA & TICK SPOT ON FOR PUPPIES & SMALL DOGS FROM 12 WEEKS', 'BOB MARTIN VETCARE FLEA & TICK SPOT ON FOR PUPPIES & SMALL DOGS FROM 12 WEEKS', 'VETZYME FLEA & TICK SPOT ON FOR PUPPIES & SMALL DOGS FROM 12 WEEKS', 'PESTROY FLEA & TICK SPOT ON FOR PUPPIES & SMALL DOGS FROM 12 WEEKS'
Date of approval:	2 December 2015
Label approval no.:	53952/103661
Application no.:	103672
Product name:	Bob Martin Since 1892 Flea Rid for Dogs, Cats, Puppies and Kittens Shampoo
Active constituent/s:	10 g/L piperonyl butoxide, 1 g/L pyrethrins
Applicant name:	Bob Martin (Australia) Pty Ltd
Applicant ACN:	062 627 883
Summary of use:	To add an additional label name to the product under 'FURRY FACE VETERINARY FLEA RID SHAMPOO FOR DOGS, CATS, PUPPIES & KITTENS', 'PET LOVERS OWN FLEA RID SHAMPOO FOR DOGS, CATS, PUPPIES & KITTENS', 'BOB MARTIN CLEAR FLEA & TICK SHAMPOO', 'BOB MARTIN VETCARE FLEA & TICK SHAMPOO', 'VETZYME FLEA & TICK SHAMPOO', 'PESTROY FLEA & TICK SHAMPOO'
Date of approval:	2 December 2015
Label approval no.:	65521/103672

Approved Active Constituents

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

1. ACTIVE CONSITUTENT

Application no.:	101768
Active constituent/s:	Diflufenican
Applicant name:	Alpha Crop Protection Pty Ltd
Applicant ACN:	165 653 047
Summary of use:	For use in agricultural chemical products
Date of approval:	2 December 2015
Approval no.:	80845
Application no.:	102274
Active constituent/s:	Tebuconazole
Applicant name:	Adama Australia Pty Limited
Applicant ACN:	050 328 973
Summary of use:	For use in agricultural chemical products
Date of approval:	2 December 2015
Approval no.:	81074
Application no.:	62718
Active constituent/s:	Imazamox
Applicant name:	Sinochem Agro Co., Ltd
Applicant ACN:	N/A
Summary of use:	For use in agricultural chemical products
Date of approval:	3 December 2015
Approval no.:	70203
Application no.:	102327
Active constituent/s:	Pyriproxyfen
Applicant name:	Tagros Chemicals India Limited
Applicant ACN:	N/A
Summary of use:	For use in agricultural chemical products
Date of approval:	8 December 2015
Approval no.:	81104

Licensing of Veterinary Chemical Manufacturers

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

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

1. NEW LICENCES

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

ARTHROPHARM PTY LTD **LICENCE NO:** 1107

ACN: 003 261 907

111 Bronte Road

BONDI JUNCTION NSW 2022

Product Types:*

- *Category 1:* Sterile products for injection
- *Category 2:* *Capsules*

Step(s) of Manufacture: Quality Assurance (QA) of raw materials, formulation including blending, aseptic filling, filling, packaging, secondary packaging, labelling, sterilisation (heat, filtration), microbiological reduction treatment (heat, filtration), analysis and testing (physical, chemical, endotoxin, microbiological), storage and release for supply.

Licence Issued: 23 October 2015

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

2. CHANGES TO EXISTING LICENCES

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

**THE COMMONWEALTH OF
AUSTRALIA ACTING
THROUGH THE
COMMONWEALTH SCIENTIFIC
AND INDUSTRIAL RESEARCH
ORGANISATION**

ABN: 41 687 119 230

CSIRO Manufacturing Flagship
CSIRO Tissue Culture Facility
Building 205B
Bayview Avenue
CLAYTON VIC 3168

LICENCE NO: 1110

Product Types: *

- *Category 1:* Immunobiologicals (snake antivenom and tetanus antitoxin)

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

Amended Licence Issued: 15 October 2015

**AUSTRALIAN LABORATORY
SERVICES PTY. LTD.**

ACN: 009 936 029

Unit 10
2–8 South Street
RYDALMERE NSW 2116

LICENCE NO: 6179

Product Types: *

- *Category 6:* Single step manufacture

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

Amended Licence Issued: 20 October 2015

PFIZER AUSTRALIA PTY LTD

ACN: 008 422 348

38–42 Wharf Road
WEST RYDE NSW 2114

LICENCE NO: 2063

Product Types: *

- *Category 2:* Tablets, capsules, creams/lotions, ointments, pastes, powders and suspensions (semi-solid).

Step(s) of Manufacture: Quality assurance (QA) of raw materials, formulation including blending, filling, packaging, labelling, strip, blister or sachet packaging, tableting, tablet coating, analysis and testing (physical, chemical, antibiotic assay, microbiological), storage and release for supply.

Amended Licence Issued: 21 October 2015

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

VETAFARM PTY. LTD.

ACN: 059 895 153

3 Bye Street

WAGGA WAGGA NSW 2650

LICENCE NO: 2010

Product Types: *

- *Category 2:* Tablets, powders, liquids and gels
- *Category 3:* Liquids

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

Amended Licence Issued: 21 October 2015

PHARMASYNTH PTY LTD

ACN: 074 656 509

2806 Ipswich Road

DARRA QLD 4076

LICENCE NO: 1086

Product Types: *

- *Category 1:* vaccines

Step(s) of Manufacture: Quality assurance (QA) of raw materials, cell propagation, virus cultivation, filling, packaging, labelling, sterilisation (heat and filtration), microbiological reduction treatment (heat, filtration and chemical), analysis and testing (physical), release for supply, storage.

Amended Licence Issued: 2 November 2015

**MEGA LIFESCIENCES
(AUSTRALIA) PTY LTD**

ACN: 076 713 392

60 National Avenue

PAKENHAM, VIC 3810

LICENCE NO: 4095

Product Types: *

- *Category 4:* Premixes and supplements

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

Amended Licence Issued: 3 November 2015

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

**ZOETIS AUSTRALIA
RESEARCH AND
MANUFACTURING PTY LTD**

ACN: 158 433 053

45 Poplar Road

PARKVILLE VIC 3052

LICENCE NO: 1098

Product Types: *

- *Category 1:* Immunobiologicals and sterile products

Step(s) of Manufacture: Quality assurance (QA) of raw materials, bacterial fermentation, virus cultivation, peptide conjugation, propagation of genetically modified mammalian cells, extraction and purification of viral protein, formulation including blending, aseptic filling, filling, packaging, labelling, sterilisation (heat, filtration), microbiological reduction treatment (heat, filtration), freeze-drying, storage and release for supply.

Amended Licence Issued: 3 November 2015

**PHARMAPAK
TECHNOLOGIES PTY LTD**

ACN: 093 794 104

7 Inman Road

DEE WHY NSW 2099

LICENCE NO: 6107

Product Types: *

- *Category 6:* Single step manufacture

Step(s) of Manufacture: Quality assurance (QA) of raw materials, filling, packaging, labelling, strip, blister and sachet packaging, storage and release for supply.

Amended Licence Issued: 4 November 2015

**WESTERN AUSTRALIAN
AGRICULTURE AUTHORITY**

ABN: 86 611 226 341

Animal Health Laboratories

Department of Agriculture &
Food

444 Albany Highway

ALBANY WA 6330

LICENCE NO: 1091

Product Types: *

- *Category 1:* Immunobiologicals

Step(s) of Manufacture: Quality assurance (QA) of raw materials, collection and preparation of mature nematodes, antigen extraction, formulation including blending, sterilisation (heat, filtration), microbiological reduction treatment (filtration), aseptic filling, packaging, labelling, analysis and testing (physical, chemical, immunobiological), storage and release for supply.

Amended Licence Issued: 5 November 2015

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

BLACKMORES LIMITED
ACN: 009 713 437
20 Jubilee Avenue
WARRIEWOOD NSW 2102

LICENCE NO: 6186
Product Types:*

- *Category 6:* Single step manufacture

Step(s) of Manufacture: Packaging, labelling and release for supply.
Amended Licence Issued: 10 November 2015

**PROPHARMA AUSTRALIA
PTY. LTD.**
ACN: 004 983 984
6 Elliot Road
DANDENONG VIC 3175

LICENCE NO: 4025
Product Types: *

- *Category 4:* Premixes and supplements

Step(s) of Manufacture: Quality assurance (QA) raw materials, formulation including blending, dry milling, filling, packaging, labelling, analysis and testing (physical), storage and release for supply
Amended Licence Issued: 25 November 2015

3. LICENCE CANCELLATIONS

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

AUSRICHTER PTY LTD
ACN: 000 908 529
Camperdown Mews
2/21 Chester Street
CAMPERDOWN NSW 2050

LICENCE NO: 6012
Date Cancelled: 23 October 2015

**DEPARTMENT OF
AGRICULTURE (WA)**
ABN: 18 951 343 745
3 Baron-Hay Court
SOUTH PERTH WA 6151

LICENCE NO: 6079
Date Cancelled: 2 November 2015

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

**AZPA PHARMACEUTICALS
PTY LTD** **LICENCE NO:** 2224
ACN: 156 127 230 **Date Cancelled:** 19 November 2015
48 Translink Road
KEILOR PARK VIC 3042

**INTEGRIA HEALTHCARE
(BALLINA) PTY LTD** **LICENCE NO:** 3009
ACN: 002 833 141 **Date Cancelled:** 19 November 2015
Pacific Highway
BALLINA NSW 2478

DERMCARE-VET PTY LTD **LICENCE NO:** 1052
ACN: 010 280 010 **Date Cancelled:** 19 November 2015
22 Aranda Street
SPRINGWOOD QLD 4127

CSL LIMITED **LICENCE NO:** 1030
ACN: 051 588 348 **Date Cancelled:** 23 November 2015
45 Poplar Road
PARKVILLE VIC 3052

**REBOP HOLDINGS PTY LTD,
TRADING AS WESTERN
STOCK DISTRIBUTORS** **LICENCE NO:** 2033
ACN: 009 372 525 **Date Cancelled:** 23 November 2015
Koojan Avenue
SOUTH GUILDFORD WA 6055

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

**THE UNIVERSITY OF
MELBOURNE VETERINARY
HOSPITAL**

ABN: 75 360 513 347
250 Princess Highway
WERRIBEE VIC 3030

LICENCE NO: 1078

Date Cancelled: 23 November 2015

SUNNYFIELD

ACN: 000 415 127
5 Kurrajong Road
ST MARYS NSW 2760

LICENCE NO: 6170

Date Cancelled: 25 November 2015

ANNEX HOLDINGS PTY LTD

ACN: 080 349 828
114 Fairbank Road
CLAYTON SOUTH VIC 3169

LICENCE NO: 6141

Date Cancelled: 25 November 2015

**AGRISEARCH ANALYTICAL
PTY LIMITED**

ACN: 094 752 959
Level 1, 48 Victoria Road
ROZELLE NSW 2039

LICENCE NO: 6106

Date Cancelled: 25 November 2015

4. LICENCE SUSPENSIONS

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

MODERN ARK PTY LTD

ACN: 104 514 801
10 Activity Street
WARWICK QLD 4370

LICENCE NO: 2215

Date Suspended: 1 October 2015 (to 31 December 2015)

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

AUSTRALIAN ANIMAL BLOOD LICENCE NO: 1101

BANK PTY LTD

ACN: 140 128 990

Date Suspended: 15 November 2015 (to 15 February 2016)

50 Wills Road

LONG POINT NSW 2564

5. REVOCATION OF LICENCE CANCELLATION

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

Nil

6. REVOCATION OF LICENCE SUSPENSION

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

Nil

APVMA CONTACT

Manufacturing Quality and Licensing Section
Legal and Compliance Program
Australian Pesticides and Veterinary Medicines Authority
PO Box 6182
KINGSTON ACT 2604

Phone: +61 2 6210 4899

Fax: +61 2 6210 4813

Email: mls@apvma.gov.au

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

New Active Constituent Rabbit Haemorrhagic Disease Virus, 08Q712 Strain

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application for approval of a new active constituent, Rabbit haemorrhagic disease virus, 08Q712 strain.

Common name:	Rabbit haemorrhagic disease virus, 08Q712 strain
IUPAC name:	Not applicable
CAS name:	Not applicable
CAS registry number:	Not applicable
Manufacturer's code:	Rabbit haemorrhagic disease virus, K5 variant
Minimum purity:	Not applicable
Molecular formula:	Not applicable
Molecular weight:	Not applicable
Structure:	RHDV is an RNA virus which has been measured in the range of 28–42 nm in diameter
Chemical family:	RHDV is a naturally occurring RNA based Lagovirus (Family Caliciviridae)
Mode of action:	Not applicable

SUMMARY OF THE APVMA'S EVALUATION OF RABBIT HAEMORRHAGIC DISEASE VIRUS, 08Q712 STRAIN ACTIVE CONSTITUENT

The APVMA has evaluated the chemistry aspects (manufacturing process, quality control procedures, batch analysis results, stability, analytical methods, physico-chemical properties, formulation process, and packaging) of both active, Rabbit haemorrhagic disease virus, 08Q712 strain, and product, RHDV K5, concurrently and found them to be acceptable.

Other compounds of toxicological significance are not expected to occur in Rabbit haemorrhagic disease virus, 08Q712 strain active constituent.

The Office of Chemical Safety (OCS) has completed a toxicological evaluation of Rabbit haemorrhagic disease virus, 08Q712 strain.

No Acceptable Daily Intake (ADI) or Acute Reference Dose (ARfD) for Rabbit haemorrhagic disease virus, 08Q712 strain is required since the proposed product RHDV K5 containing Rabbit haemorrhagic disease virus, 08Q712 strain is proposed for use as a biological control for wild rabbits and has no apparent toxicological concerns for humans.

Rabbit haemorrhagic disease virus, 08Q712 strain, an antigenic variant of the already registered Rabbit Calicivirus active constituent (Rabbit haemorrhagic disease virus, v351 strain), has no apparent toxicological concerns. Therefore, placement in a poisons schedule is not recommended.

The OCS has indicated that there are no objections on toxicological grounds to the approval of the active constituent Rabbit haemorrhagic disease virus, 08Q712 strain.

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

The APVMA is satisfied that the proposed manufacture and use of Rabbit haemorrhagic disease virus, 08Q712 strain would not be an undue toxicological hazard to the safety of people exposed to it during its handling and use.

MAKING A SUBMISSION

In accordance with section 12 of the Agvet Code, the APVMA invites any person to submit a relevant written submission as to whether Rabbit haemorrhagic disease virus, 08Q712 strain 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.

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

When making a submission please include:

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

All personal and *confidential commercial information (CCI)*¹ material contained in submissions will be treated confidentially.

Written submissions should be addressed in writing to:

Director of Chemistry
Scientific Assessment and Chemical Review Program
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¹ A full definition of 'confidential commercial information' is contained in the [Agvet Code](#).

New Chemical Product RHDV K5 Containing Rabbit Haemorrhagic Disease Virus, 08Q712 Strain

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application for registration of a new product containing a new active constituent, Rabbit haemorrhagic disease virus, 08Q712 strain. The product is RHDV K5.

PARTICULARS OF THE APPLICATION

Proposed product name:	RHDV K5
Applicant company:	NSW Department of Primary Industries
Name of active constituent:	Rabbit haemorrhagic disease virus, 08Q712 strain
Signal heading:	Not applicable
Summary of proposed use:	For the infection of wild European rabbits (<i>Oryctolagus cuniculus</i>) in accordance with directions of the appropriate State or Territory government authority
Pack sizes:	10 mL
Withholding period:	Not applicable

SUMMARY OF THE APVMA'S EVALUATION OF RHDV K5 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 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 RHDV K5 containing the active constituent Rabbit haemorrhagic disease virus, 08Q712 strain would not be an undue hazard to the safety of people exposed to it during its handling and use.

The Office of Chemical Safety (OCS) in the Department of Health has conducted a risk assessment on the product and concluded it can be used safely.

The product is a lyophilised (freeze-dried) formulation of at least 30,000 ID₅₀ units Rabbit haemorrhagic disease virus, 08Q712 strain contained in a 10 mL multi use glass vial. This lyophilised formulation must be reconstituted in distilled water prior to use. Once reconstituted, it will be used to either inject live rabbits, or prepare a carrot or oat bait and fed to live rabbits, in order to infect them with Rabbit haemorrhagic disease virus, 08Q712 strain. Infected rabbits will then spread Rabbit haemorrhagic disease virus, 08Q712 strain to other rabbits by direct contact or indirectly through faeces and other vectors such as insects. This should lead to a local epizootic of rabbit haemorrhagic disease (RHD) which causes mortality and is claimed to reduce overall rabbit numbers across Australia.

Workers may be exposed to the product when opening the vials, mixing and diluting the virus to prepare the end use product, product application via injection or mixed feed and cleaning up spills and equipment. The main route of exposure to the product will be dermal, although accidental self-injection or ocular exposure may also occur.

Based on the outcomes of the risk assessment, First Aid Instructions and Safety Directions have been recommended for inclusion on the product labels.

Based on an assessment of worker health and safety, it was considered that there should be no adverse effects on human health from the use of RHDV K5 when used in accordance with the label directions.

- (ii) The APVMA is satisfied that the proposed use of RHDV K5 will not be an undue hazard to the safety of people using anything containing its residues as the product is proposed for use as a biological control for wild rabbits and has no apparent toxicological concerns for humans.
- (iii) The APVMA is satisfied that the proposed use of RHDV K5 containing the active constituent Rabbit haemorrhagic disease virus, 08Q712 strain is not likely to be harmful to human beings if used according to the product label directions.

The product is a lyophilised (freeze-dried) formulation of at least 30,000 ID₅₀ units Rabbit haemorrhagic disease virus, 08Q712 strain contained in a 10 mL multi use glass vial. This lyophilised formulation must be reconstituted in distilled water prior to use. Once reconstituted, it will be used to either inject live rabbits, or prepare a carrot or oat bait and fed to live rabbits, in order to infect them with Rabbit haemorrhagic disease virus, 08Q712 strain. Infected rabbits will then spread Rabbit haemorrhagic disease virus, 08Q712 strain to other rabbits by direct contact or indirectly through faeces and other vectors such as insects. This should lead to a local epizootic of rabbit haemorrhagic disease (RHD) which causes mortality and is claimed to reduce overall rabbit numbers across Australia.

The product RHDV K5 is not intended for home use and therefore exposure to members of the public via normal use of the product is not expected to occur. RHDV K5 is proposed for use as a biological control for wild rabbits and has no apparent toxicological concerns for humans.

The APVMA has considered the findings of the Department of Health and accepts these conclusions. Based on an assessment of the toxicology, it was considered that there should be no adverse effects on human health from the use of RHDV K5 when used in accordance with their label directions.

- (iv) The APVMA is satisfied that the proposed use of the new product RHDV K5 containing the active constituent Rabbit haemorrhagic disease virus, 08Q712 strain, would not be likely to have an unintended effect that is harmful to animals, plants or things or the environment.

Data provided in support of the proposed use have been assessed and it is concluded that the risks to the environment from this use are acceptable.

The Rabbit haemorrhagic disease virus, 08Q712 strain, is a G6 strain belonging to Clade 1/D, also known as a Rabbit haemorrhagic disease virus antigenic variant (RHDVa) strain. It is considered to be closely enough related with maximum nucleotide and amino acid differences of 10% and 6%, respectively to the currently registered Rabbit haemorrhagic disease virus, Czech v351 (RHDV-Czech v351) strain, that it can be expected to have an equivalent environment risk profile to that existing strain. Despite genetic and antigenic variability, the variants are the same lagovirus type (RHDV) but belong to differing subtypes ('classical' RHDV and RHDVa). Importantly, Rabbit haemorrhagic disease virus, 08Q712 strain is not an RHDV2 strain which have been shown to overcome RHDV antibodies and cause mortality in both rabbits and hares.

As such, the registered product containing RHDV-Czech v351 is a suitable reference product to assist in the characterisation of environmental fate, ecotoxicity and risk of proposed product. However, consideration of Rabbit haemorrhagic disease virus, 08Q712 strain with respect to its fate in the environment in relation to host resistance

and potential for direct and indirect effects on non-target plants and animals has been undertaken by APVMA's advisor.

Environmental effects of RHDV can be divided into direct and non-direct effects. Direct effects include pathogenicity, infectivity, and exposure. Indirect effects include prey switching/shifting, prey loss and effects on native predators, and risk of increase in woody weeds. It is considered that the risk of RHDV to non-target organisms is low because:

- there are no substantiated reports of epidemiologically relevant infectivity of RHDV in animal species other than rabbits
- there is limited increased predation on populations of native animals by rabbit predators following decline in rabbit numbers (prey switching)
- there is no evidence of adverse impacts on vegetation, e.g. due to loss of rabbit herbivory on woody weeds
- the release of RHDV-Czech v351 strain has resulted in no apparent environmental risk.

The RHDV-Czech v351 and the Rabbit haemorrhagic disease virus, 08Q712 strain are likely to contact each other due to co-infection in rabbit populations as such viral recombination may pose a risk to the environment; however, due to the low likelihood of this recombination causing a potential increase in host range the environmental risk remains low.

An RHDV vaccine, with an existing APVMA registration, is available for the protection of valuable (non-pest) rabbits that are farmed or kept as domestic pets. This vaccine is protective, when used in accordance with its directions for use, against the RHDV-Czech v351 strain and the Rabbit haemorrhagic disease virus, 08Q712 strain.

The risk assessment determined that RHDV K5 is unlikely to pose an environmental risk under the proposed use pattern. The APVMA has considered the findings of their advisor and accepts these conclusions.

2. The APVMA has evaluated the applications and in its assessment in relation to whether the efficacy criteria have been met in accordance with the definition set out in section 5B of the Agvet Code, and proposes to determine that:
 - (i) In relation to its assessment of efficacy under section 14(3)(f), the APVMA is satisfied that data from trials supporting the efficacy of RHDV K5 adequately demonstrates that if used according to the product label directions, the product is effective for its proposed use.
3. The APVMA has evaluated the applications and in its assessment in relation to whether the trade criteria have been met in accordance with the definition set out in section 5C of the Agvet Code, and proposes to determine that:
 - (i) The APVMA is satisfied that the proposed use of RHDV K5 would not adversely affect trade between Australia and places outside Australia as the product is not for use in animals producing any major Australian export commodities.

FURTHER INFORMATION

A Public Release Summary (PRS) of the evaluation of this product is available from the APVMA website's 'Public Consultation' page, apvma.gov.au/news-and-publications/public-consultations or by contacting the evaluator listed below.

MAKING A SUBMISSION

In accordance with section 13 of the Agvet Code, the APVMA invites any person to submit a relevant written submission as to whether RHDV K5 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)*² material contained in submissions will be treated confidentially.

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

Case Management and Administration Unit
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² A full definition of 'confidential commercial information' is contained in the [Agvet Code](#).

New Chemical Product Dupont Zorvec Enicade Fungicide Containing Oxathiapiprolin

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application for registration of a new product containing a new active constituent, oxathiapiprolin. The product is DUPONT ZORVEC ENICADE FUNGICIDE.

PARTICULARS OF THE APPLICATION

Proposed product name:	DUPONT ZORVEC ENICADE FUNGICIDE
Applicant company:	DU PONT (AUSTRALIA) PTY LTD
Name of active constituent:	Oxathiapiprolin (100 g/L)
Signal heading:	Not applicable (proposed)
Summary of proposed use:	For the control of certain fungal disease species in oilseed poppies and vegetable crops as per the Directions for Use
Pack sizes:	1 L and 5 L
Withholding period:	BRASSICA VEGETABLES: NOT REQUIRED WHEN USED AS DIRECTED CUCURBIT VEGETABLES: DO NOT HARVEST FOR 1 DAY AFTER APPLICATION BRASSICA LEAFY VEGETABLES, LEAFY VEGETABLES: DO NOT HARVEST FOR 3 DAYS AFTER APPLICATION BULB VEGETABLES: DO NOT HARVEST FOR 10 DAYS AFTER APPLICATION POPPIES: DO NOT HARVEST FOR 6 WEEKS AFTER APPLICATION

SUMMARY OF THE APVMA'S EVALUATION OF DUPONT ZORVEC ENICADE FUNGICIDE 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 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 DUPONT ZORVEC ENICADE FUNGICIDE containing the active constituent oxathiapiprolin would not be an undue hazard to the safety of people exposed to it during its handling and use.

The Office of Chemical Safety (OCS) in the Department of Health has conducted a risk assessment on the product and concluded it can be used safely.

DUPONT ZORVEC ENICADE FUNGICIDE is proposed for use in bulb, brassica, cucurbit and leafy vegetables and poppies as a foliar fungicide for control of downy mildew at use rates up to 350 mL product/ha by ground boom equipment.

Based on the proposed use patterns the likely exposure for users is expected to be short to long term. The main routes of exposure are likely to be dermal and inhalational with possible accidental ocular exposure. Workers may re-enter treated crops to scout for disease control, weeding, irrigation and harvesting.

In the absence of exposure data for the proposed mode of application, the Pesticide Handler Exposure Database (PHED) Surrogate Exposure Guide (1998) was used to estimate exposure. Dislodgeable Foliar Residue (DFR) data provided was used to refine the post-application exposure estimates.

The risk assessment concluded that exposure to the product during mixing, loading ground boom application were determined to be at acceptable levels without the use of personal protective equipment (PPE). However based on the hazard profile of the product, PPE is required during use (mixing/loading) of the product. Based on the outcomes of the risk assessment, First Aid Instructions and Safety Directions have been recommended for inclusion on the product label.

Based on an assessment of worker health and safety, it was considered that there should be no adverse effects on human health from the use of DUPONT ZORVEC ENICADE FUNGICIDE when used in accordance with the label directions.

- (ii) The APVMA is satisfied that the proposed use of DUPONT ZORVEC ENICADE FUNGICIDE will not be an undue hazard to the safety of people using anything containing its residues.

The chronic dietary intake risk for oxathiapiprolin has been assessed. The Acceptable Daily Intake (ADI) for oxathiapiprolin is 4.1 mg/kg bw/day, based upon a No Observable Adverse Effect Level (NOAEL) of 411 mg/kg bw/day and a 100-fold safety factor. The National Estimated Daily Intake (NEDI) calculation is a conservative estimate of dietary exposure to chemical residues in food. The NEDI for oxathiapiprolin, is equivalent to <0.1% of the ADI. HARVEST Modelling (software used by Food Standards Australia and New Zealand) of chronic dietary exposure is also performed on new chemicals. The HARVEST model estimated the chronic dietary exposure of oxathiapiprolin as <0.1% of the ADI for the general population.

An acute reference dose (ARfD) has not been established for oxathiapiprolin due to the lack of an identified acute toxicological hazard.

It is concluded that the dietary exposure to oxathiapiprolin is low and the risk from residues in food is acceptable when DUPONT ZORVEC ENICADE FUNGICIDE is used according to label directions.

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

DUPONT ZORVEC ENICADE FUNGICIDE is intended for use in bulb, brassica, cucurbit and leafy vegetables and poppies as a protectant fungicide against downy mildew.

The data package provided in the present submission was evaluated as part of a Global Joint Review. It included studies on toxicokinetics/metabolism, dermal absorption, acute (both active constituent and product), short-term, subchronic, chronic and carcinogenicity, reproduction and developmental studies, as well as studies on neurotoxicity, immunotoxicity and genotoxicity. Genotoxicity studies were also conducted on a number of metabolites and impurities of oxathiapiprolin. The studies were conducted to Good Laboratory Practice (GLP), Quality Assurance (QA) and Organisation for Economic Co-operation and Development (OECD)-equivalent guidelines. These studies were considered reliable to establish the toxicity profile of oxathiapiprolin and DUPONT ZORVEC ENICADE FUNGICIDE.

The Advisory Committee on Chemicals Scheduling (ACCS) have considered the OCS recommendations to the Chemicals Scheduling Delegate of the Department of Health that consideration be given to a listing in Appendix B of the Poisons Standard for Oxathiapiprolin. The Delegate's interim decision is expected to be published in February 2016 at the TGA website.

In toxicokinetics studies, oxathiapiprolin was moderately (up to 50%) and rapidly absorbed at low doses, widely distributed throughout the body and moderately metabolised. Oxathiapiprolin was rapidly excreted via the faecal pathway. There were no marked sex differences in the absorption, distribution, metabolism, and excretion (ADME) of oxathiapiprolin regardless of the different positions of radio-label. Excretion was relatively rapid and extensive, with the majority of the administered dose excreted, predominantly as unchanged parent compound, within 24 hours and virtually complete by 48 hours, indicating a low probability of bioaccumulation of the parent compound or metabolites.

In acute toxicity studies in rats, oxathiapiprolin was of low acute oral, dermal and inhalational toxicity in rats. Oxathiapiprolin was a non-irritant to the skin and eye in rabbits, and was not a skin sensitiser in guinea pigs (Maximization method).

Repeat dose studies were unremarkable with no toxicologically relevant effects seen at the highest administered doses, with the exception of the two generation reproduction study in rat. In the reproduction study there was a slight but significant delay in preputial separation in male pups of both generations at the highest dose.

Based on the findings of the toxicological studies evaluated, the product DUPONT ZORVEC ENICADE FUNGICIDE was of low acute oral, dermal and inhalational toxicity in rats, was a slight skin irritant but not an eye irritant in rabbits, and was a skin sensitiser in guinea pigs (Maximization method).

The acute toxicology data evaluated in this assessment, along with evaluated information on the repeat-dose toxicology of the active constituent were relied on by the OCS to establish a hazard profile for the proposed product.

After consideration of the hazards associated with the active constituent and the proposed product, along with the exposure and risks expected with use of the proposed product, it was considered that the approval of the active constituent oxathiapiprolin, and the proposed use of DUPONT ZORVEC ENICADE FUNGICIDE will not be an undue health hazard to humans.

The APVMA has considered the findings of the Department of Health and accepts these conclusions. Based on an assessment of the toxicology, it was considered that there should be no adverse effects on human health from the use of DUPONT ZORVEC ENICADE FUNGICIDE when used in accordance with its label directions.

- (iv) The APVMA is satisfied that the proposed use of the new product DUPONT ZORVEC ENICADE FUNGICIDE containing the active constituent oxathiapiprolin, would not be likely to have an unintended effect that is harmful to animals, plants or things or the environment.

The Department of the Environment (DotE) has assessed fate and effects data in support of the proposed use and has concluded that the risks to the environment from this use are acceptable.

Oxathiapiprolin is slightly soluble in water and stable to hydrolysis. It is moderately degradable by photolysis in water. Under aerobic and anaerobic conditions, oxathiapiprolin partitions from water to sediment, where it is slightly/very slightly degradable. Oxathiapiprolin is readily to slightly/very slightly degradable by biotic processes in soil under aerobic, anaerobic and field conditions. The main metabolites are slightly/fairly degradable in aerobic soils but readily degradable in aquatic sediment systems. The mobility of oxathiapiprolin ranges from slight to

immobile in soil while its metabolites range from being very highly mobile to immobile. Oxathiapiprolin does not bioaccumulate in fish.

Oxathiapiprolin is practically non-toxic to mammals acutely and at worst is moderately toxic to birds with dietary exposure but some reproduction parameters were affected in chronic studies. It is highly acutely toxic and moderately chronically toxic to aquatic organisms and moderately toxic to sediment dwelling organisms chronically. The main metabolites range from practically non-toxic to moderately toxic to aquatic organisms. Oxathiapiprolin and its main metabolites are at worst slightly/very slightly toxic to honey bees. No effects on reproduction on earthworms was observed. Terrestrial arthropods, both soil dwelling and above ground, were insensitive to oxathiapiprolin and its major metabolites at the tested rates. No significant adverse effects were observed on soil micro-organisms and terrestrial plants.

In considering the submitted fate and effects data, DotE has given particular attention to environmental exposure arising from the proposed use of oxathiapiprolin. The risk assessment to aquatic systems from spray drift and run-off with multiple applications concluded that the acute and chronic risks can be considered acceptable for the protection of the aquatic and sediment systems for the proposed use on vegetables and poppies.

Risks from the exposure of the product to terrestrial organisms, including birds, small mammals, honey bees, earthworms, soil macro- and micro-organisms, beneficial non-target arthropods and non-target plants were assessed based on the available endpoints and proposed application rate of the product. The environmental risk assessment has concluded that the risks from the proposed use of the product will be acceptable to terrestrial organisms.

The risk assessment determined that DUPONT ZORVEC ENICADE FUNGICIDE is unlikely to pose an environmental risk under the proposed use pattern. The APVMA has considered the findings of DotE and accepts these conclusions.

2. The APVMA has evaluated the applications and in its assessment in relation to whether the efficacy criteria have been met in accordance with the definition set out in section 5B of the Agvet Code, and proposes to determine that:
 - (i) In relation to its assessment of efficacy under section 14(3)(f), the APVMA is satisfied that data from trials supporting the efficacy of DUPONT ZORVEC ENICADE FUNGICIDE adequately demonstrates that if used according to the product label directions, the product is effective for its proposed use.
3. The APVMA has evaluated the applications and in its assessment in relation to whether the trade criteria have been met in accordance with the definition set out in section 5C of the Agvet Code, and proposes to determine that:
 - (i) The APVMA is satisfied that the proposed use of DUPONT ZORVEC ENICADE FUNGICIDE would not adversely affect trade between Australia and places outside Australia.

The risk to trade is considered to be low, as none of the proposed use patterns in crops involve major export commodities, and finite residues of oxathiapiprolin are not expected to be found in mammalian or poultry meat or offal, eggs, or milk.

FURTHER INFORMATION

A Public Release Summary (PRS) of the evaluation of this product is available from the APVMA website's 'Public Consultation' page, apvma.gov.au/news-and-publications/public-consultations or by contacting the evaluator listed below.

MAKING A SUBMISSION

In accordance with section 13 of the Agvet Code, the APVMA invites any person to submit a relevant written submission as to whether DUPONT ZORVEC ENICADE FUNGICIDE 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)*³ material contained in submissions will be treated confidentially.

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

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

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Fax: +61 2 6210 4721

Email: enquiries@apvma.gov.au

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

Amendments to the APVMA MRL Standard

The Australian Pesticides and Veterinary Medicines Authority (APVMA) approves maximum residue limits (MRLs) of agricultural and veterinary chemicals in agricultural produce, particularly produce entering the food chain. The MRLs approved by the APVMA are associated with a regulatory decision to register a product, grant a permit approval, or as an outcome from a review decision and are set out in the *Agricultural and Veterinary Chemicals Code Instrument No. 4 (MRL Standard) 2012*. The *MRL Standard* lists MRLs of substances that may arise from the approved use of agricultural and veterinary chemical products containing those substances on commodities used for human consumption as well as livestock feeds. The *MRL Standard* also provides the relevant residue definitions to which these MRLs apply. There may be situations where the residue definition for monitoring and enforcement is different to the definition used for dietary risk assessment purposes.

MRLs are set at levels which are not likely to be exceeded if the agricultural or veterinary chemicals are used in accordance with approved label instructions. In considering MRLs and variation to MRLs, the APVMA takes into account studies on chemistry, metabolism, analytical methodology, residues, toxicology, good agricultural practice and dietary exposure. In approving MRLs, the APVMA is satisfied, from dietary exposure assessment, that the levels set are not an undue hazard to human health.

The APVMA has amended the *MRL Standard* and the changes will have affect the day after the instrument is registered.

Details of the amendment can be found in the *Agricultural and Veterinary Chemicals Code Instrument No. 4 (MRL Standard) Amendment Instrument 2015 (No. 11)*.

The amendments will be incorporated into the compilation of the [Agricultural and Veterinary Chemicals Code Instrument No. 4 \(MRL Standard\) 2012](#).

The *MRL Standard* is accessible via the ComLaw website www.comlaw.gov.au/or the links above.

For further information please contact:

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KINGSTON ACT 2604

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Proposal to amend Schedule 20 of the revised Australia New Zealand Food Standards Code

In the previous notice, the APVMA gazetted amendments which it has approved varying maximum residue limits (MRLs) for substances contained in agricultural and veterinary chemical products as set out as in the APVMA's *MRL Standard*, have been made.

Under section 82 of the *Food Standards Australia New Zealand Act 1991*, the APVMA is proposing to incorporate those variations (*Agricultural and Veterinary Chemicals Code Instrument No. 4 (MRL Standard) Amendment Instrument 2015 (No. 11)*) in Schedule 20 of the revised *Australia New Zealand Food Standards Code* which commences on 1 March 2016 (revised Code), with the repeal of Chapters 1 and 2 of the current Code.

MRLs contained in Schedule 20 provide the limits for residues of agricultural and veterinary chemicals that may legitimately occur in foods. By this means, Schedule 20 permits the sale of treated foods and protects public health and safety by minimising residues in foods consistent with the effective control of pests and diseases.

The APVMA and FSANZ are satisfied, based on dietary exposure assessments and current health standards, that the proposed limits are not harmful to public health.

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

Food Standards Australia New Zealand (FSANZ) will make a Sanitary and Phytosanitary (SPS) notification to the World Trade Organization (WTO).

The APVMA invites comment on these proposals. Details on how to make a submission appear near the end of this notice, below the details of the proposed amendment.

The APVMA will consider any public comments made in response to this proposal. If the APVMA decides to proceed with the proposal, it will further notify any variations it makes to Schedule 20 in the *APVMA Gazette*. The variations will take effect as from the date of that subsequent notice.

DRAFT VARIATIONS TO THE AUSTRALIA NEW ZEALAND FOOD STANDARDS CODE

Note: The following proposed amendments are in a format that accords with the proposed amending Legislative Instrument which, in turn, has to be consistent with the existing format of Schedule 20 in the revised Code

PROPOSED AMENDMENT (AGRICULTURAL AND VETERINARY CHEMICALS CODE INSTRUMENT NO. 4 (MRL STANDARD) AMENDMENT INSTRUMENT 2015 (NO. 11))

Note: Subsection 82(2) of the *Food Standards Australia New Zealand Act 1991* provides that variations to standards are legislative instruments, but are not subject to disallowance or sunset.

To commence: on gazettal of variation

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

[1.1] inserting in alphabetical order

Agvet chemical: Oxathiapiprolin

Permitted residue: Oxathiapiprolin

Brassica (cole or cabbage) vegetables, Head cabbages, Flowerhead brassicas	2
Bulb vegetables [except onion, bulb]	1
Cardoon	15
Edible offal (mammalian)	*0.01
Eggs	*0.01
Fruiting vegetables, cucurbits	0.2
Leafy vegetables [except lettuce, head]	15
Lettuce, head	2
Meat (mammalian) (in the fat)	*0.01
Milks	*0.01
Onion, bulb	0.02
Poppy seed	*0.01
Poultry, edible offal of	*0.01
Poultry meat (in the fat)	*0.01

[1.2] omitting from each of the following chemicals, the foods and associated MRLs

Agvet chemical: Chlorantraniliprole

Permitted residue: Plant commodities and animal commodities other than milk: Chlorantraniliprole

Milk: Sum of chlorantraniliprole, 3-bromo-N-[4-chloro-2-(hydroxymethyl)-6-[(methylamino)carbonyl]phenyl]-1-(3-chloro-2-pyridinyl)-1H-pyrazole-5-carboxamide, and 3-bromo-N-[4-chloro-2-(hydroxymethyl)-6-[[[(hydroxymethyl)amino]carbonyl]phenyl]-1-(3-chloro-2-pyridinyl)-1H-pyrazole-5-carboxamide, expressed as chlorantraniliprole

Tree nuts [except almonds; pistachio nut]	0.02
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Agvet chemical: Glyphosate

Permitted residue: Sum of glyphosate and Aminomethylphosphonic acid (AMPA) metabolite, expressed as glyphosate

Lemon myrtle	T20
Native foods [except lemon myrtle]	T2

Agvet chemical: Propiconazole

Permitted residue: Propiconazole

Herbs	T10
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[1.3] inserting for each of the following chemicals the foods and associated MRLs in alphabetical order

Agvet chemical: Aminoethoxyvinyl-glycine

Permitted residue: Aminoethoxyvinylglycine

Cherries	*0.05
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Agvet chemical: Chlorantraniliprole

Permitted residue: Plant commodities and animal commodities other than milk: Chlorantraniliprole

Milk: Sum of chlorantraniliprole, 3-bromo-N-[4-chloro-2-(hydroxymethyl)-6-[(methylamino)carbonyl]phenyl]-1-(3-chloro-2-pyridinyl)-1H-pyrazole-5-carboxamide, and 3-bromo-N-[4-chloro-2-(hydroxymethyl)-6-[[[(hydroxymethyl)amino]carbonyl]phenyl]-1-(3-chloro-2-pyridinyl)-1H-pyrazole-5-carboxamide, expressed as chlorantraniliprole

Tree nuts [except almonds; pistachio nut; walnuts]	0.02
Walnuts	T0.05

Agvet chemical: Etoxazole

Permitted residue: Etoxazole

Maize	T*0.01
Popcorn	T*0.01

Agvet chemical: Flumioxazin

Permitted residue: Flumioxazin

Grapes	*0.01
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Agvet chemical: Glyphosate

Permitted residue: Sum of glyphosate and Aminomethylphosphonic acid (AMPA) metabolite, expressed as glyphosate

Native foods	T2
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Agvet chemical: Prochloraz

Permitted residue: Sum of prochloraz and its metabolites containing the 2,4,6-trichlorophenol moiety, expressed as prochloraz

Lettuce, leaf	T3
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Agvet chemical: Propiconazole

Permitted residue: Propiconazole

Herbs [except parsley]	T10
Parsley	T30

Agvet chemical: Sethoxydim

Permitted residue: Sum of sethoxydim and metabolites containing the 5-(2-ethylthiopropyl)cyclohexene-3-one and 5-(2-ethylthiopropyl)-5-hydroxycyclohexene-3-one moieties and their sulfoxides and sulfones, expressed as sethoxydim

Chia	T0.7
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Agvet chemical: Spirotetramat

Permitted residue: Sum of spirotetramat, and cis-3-(2,5-dimethylphenyl)-4-hydroxy-8-methoxy-1-azaspiro[4.5]dec-3-en-2-one, expressed as spirotetramat

Fig	T1
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Agvet chemical: Triclabendazole

Permitted residue: Sum of triclabendazole and metabolites oxidisable to keto-triclabendazole and expressed as keto-triclabendazole equivalents

Milks	0.01
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[1.4] omitting for each of the following chemicals, the maximum residue limit for the food and substituting

Agvet chemical: Difenoconazole

Permitted residue: Difenoconazole

Celeriac	T1
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INVITATION FOR SUBMISSIONS

Written submissions are invited from interested individuals and organisations to assist the APVMA in considering the proposal to vary Schedule 20 Maximum Residue Limits of the *Australia New Zealand Food Standards Code*.

Submissions should be strictly confined to relevant matters that the APVMA must consider (such as public health and safety) which are associated with the occurrence of the proposed residues in foods. Comments received outside these grounds will not be considered by the APVMA. Claims made in submissions should be supported wherever possible by referencing or including relevant studies, research findings, trials, surveys etc. Technical information should be in sufficient detail to allow independent scientific assessment.

Please note that FSANZ will make a SPS notification to the WTO and submissions related to impacts on international trade should be made to FSANZ in response to that notification.

Submissions must be made in writing and should be clearly marked as a 'submission on the proposed amendment to Schedule 20 and quote the correct amendment number.

DEADLINE FOR PUBLIC SUBMISSIONS: 6 pm (AEDT) 26 January 2016

SUBMISSIONS RECEIVED AFTER THIS DEADLINE WILL ONLY BE CONSIDERED BY PRIOR ARRANGEMENT

Submissions received after this date will only be considered if agreement for an extension has been given prior to this closing date. Agreement to an extension of time will only be given if extraordinary circumstances warrant an extension to the submission period.

For further information please contact:

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