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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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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. RESTRICTED PRODUCT

Application no.:	63303
Product name:	Termspec Termite Management Collars
Active constituent/s:	1 g/kg bifenthrin
Applicant name:	Termspec Pty Ltd
Applicant ACN:	169 524 707
Summary of use	For the protection of service penetrations at pre-construction from concealed termite entry
Date of registration/approval:	10 December 2014
Product registration no.:	70370
Label approval no.:	70370/63303

Application no.:	63293
Product name:	Termspec Termite Management Sheeting
Active constituent/s:	1 g/kg bifenthrin
Applicant name:	Termspec Pty Ltd
Applicant ACN:	169 524 707
Summary of use	For the protection of buildings from concealed termite entry
Date of registration/approval:	5 December 2014
Product registration no.:	70368
Label approval no.:	70368/63293

2. AGRICULTURAL PRODUCTS BASED ON EXISTING ACTIVE CONSTITUENTS

Application no.:	62949
Product name:	Hy-Clor Green Blaster Pool Oxidiser
Active constituent/s:	630 g/kg available chlorine (Cl) present as trichloroisocyanuric acid, 300 g/kg sodium tetraborate pentahydrate
Applicant name:	Hy-Clor (Australia) Pty Ltd
Applicant ACN:	000 655 381
Summary of use	For controlling algae and bacteria in outdoor swimming pools
Date of registration/approval:	27 November 2014
Product registration no.:	70296
Label approval no.:	70296/62949

Application no.:	62271
Product name:	PestXpert DIY Pest Control Like the Professionals WASP JET Long Reach Wasp Spray
Active constituent/s:	1.5 g/kg cyphenothrin, 1.5 g/kg d-tetramethrin
Applicant name:	Sumitomo Chemical Australia Pty Limited
Applicant ACN:	081 096 255
Summary of use	For the control of wasps
Date of registration/approval:	27 November 2014
Product registration no.:	70002
Label approval no.:	70002/62271

Application no.:	62777
Product name:	Surewet 370 Wetting Agent
Active constituent/s:	370 g/L alcohol ethoxylate
Applicant name:	Victorian Chemical Company Proprietary Limited
Applicant ACN:	004 188 863
Summary of use	For use as a non-ionic wetter/spreader for agricultural sprays
Date of registration/approval:	28 November 2014
Product registration no.:	70224
Label approval no.:	70224/62777

Application no.:	62950
Product name:	Hy-Clor Green Blaster High Strength Algaecide
Active constituent/s:	250 g/L benzalkonium chloride
Applicant name:	Hy-Clor (Australia) Pty Ltd
Applicant ACN:	000 655 381
Summary of use	For the control of algae in swimming pools
Date of registration/approval:	28 November 2014
Product registration no.:	70297
Label approval no.:	70297/62950

Application no.:	61700
Product name:	Nail 600EC Herbicide
Active constituent/s:	600 g/L carfentrazone-ethyl
Applicant name:	Crop Care Australasia Pty Ltd
Applicant ACN:	061 362 347
Summary of use	For the control of various weeds in crop and non-crop situations
Date of registration/approval:	28 November 2014
Product registration no.:	69772
Label approval no.:	69772/61700

Application no.:	61808
Product name:	Yates Zero Rapid 1-HR Action Weedkiller
Active constituent/s:	16 g/L glyphosate present as the ammonium salt, 20.5 g/L nonanoic acid
Applicant name:	Duluxgroup (Australia) Pty Ltd
Applicant ACN:	000 049 427
Summary of use	For controlling a wide range of annual and perennial weeds and grasses found in home gardens
Date of registration/approval:	28 November 2014
Product registration no.:	69818
Label approval no.:	69818/61808

Application no.:	60598
Product name:	Imtrade Haloxyfop 900 EC Herbicide
Active constituent/s:	900 g/L haloxyfop-p present as haloxyfop-p methyl ester
Applicant name:	Imtrade Australia Pty Ltd
Applicant ACN:	090 151 134
Summary of use	For the post-emergent control of a wide range of annual and perennial grass weeds in a range of cropping situations
Date of registration/approval:	28 November 2014
Product registration no.:	69365
Label approval no.:	69365/60598

Application no.:	60573
Product name:	Nufarm Champ 500 WG Fungicide
Active constituent/s:	500 g/kg copper (Cu) present as cupric hydroxide
Applicant name:	Nufarm Australia Limited
Applicant ACN:	004 377 780
Summary of use	For the control of various diseases of fruits and vegetables
Date of registration/approval:	1 December 2014
Product registration no.:	69351
Label approval no.:	69351/60573

Application no.:	62039
Product name:	Imark 240 Herbicide
Active constituent/s:	240 g/L imazapic present as the ammonium salt
Applicant name:	Shandong Rainbow International Co., Ltd
Applicant ACN:	N/A
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 weed in peanuts and sugarcane
Date of registration/approval:	1 December 2014
Product registration no.:	69905
Label approval no.:	69905/62039

Application no.:	61372
Product name:	Ecomist Enhancing your Environment BugBullit Personal Insect Repellent 6 hour Protection
Active constituent/s:	191 g/kg diethyltoluamide, 40 g/kg n octyl bicycloheptene dicarboximide
Applicant name:	Damar Industries Pty Ltd
Applicant ACN:	097 723 610
Summary of use	For protection against mosquitoes. Also repels flies, sandflies, leeches, ticks and biting insects
Date of registration/approval:	1 December 2014
Product registration no.:	69659
Label approval no.:	69659/61372

Application no.:	59506
Product name:	Slimax Broadacre Slug and Snail Bait
Active constituent/s:	30 g/kg metaldehyde
Applicant name:	De Sangosse SA
Applicant ACN:	N/A
Summary of use	For the control of slugs and snails in agricultural crops
Date of registration/approval:	1 December 2014
Product registration no.:	68963
Label approval no.:	68963/59506

Application no.:	61140
Product name:	Accensi Fipronil 200 SC Insecticide
Active constituent/s:	200 g/L fipronil
Applicant name:	Accensi Pty Ltd
Applicant ACN:	079 875 184
Summary of use	For the control of various insect pests in asparagus, bananas, brassicas, cotton, forestry, ginger, wine grapevines, mushrooms, pasture, potatoes, sorghum, sugarcane and swede
Date of registration/approval:	2 December 2014
Product registration no.:	69567
Label approval no.:	69567/61140

Application no.:	100142
Product name:	Farmalinx RoDi Pellets
Active constituent/s:	0.05 g/kg brodifacoum
Applicant name:	Farmalinx Pty Ltd
Applicant ACN:	134 353 245
Summary of use:	For the control of rats and mice in and around industrial, agricultural and domestic buildings
Date of registration/approval:	2 December 2014
Product registration no.:	80059
Label approval no.:	80059/100142

Application no.:	100141
Product name:	Farmalinx ZincPhos Pellets
Active constituent/s:	25 g/kg zinc phosphide
Applicant name:	Farmalinx Pty Ltd
Applicant ACN:	134 353 245
Summary of use:	For control of heavy infestations of mice in agricultural situations
Date of registration/approval:	2 December 2014
Product registration no.:	80058
Label approval no.:	80058/100141

Application no.:	60575
Product name:	Crop Care Intercept Herbicide
Active constituent/s:	33 g/L imazamox present as the ammonium salt, 15 g/L imazapyr present as the ammonium salt
Applicant name:	Crop Care Australasia Pty Ltd
Applicant ACN:	061 362 347
Summary of use	For post-emergence control of certain annual grass and broadleaf weeds in imidazolinone tolerant canola
Date of registration/approval:	3 December 2014
Product registration no.:	69353
Label approval no.:	69353/60575

Application no.:	63137
Product name:	Maxunitech Carfentrazone-Ethyl 240 EC Herbicide
Active constituent/s:	240 g/L carfentrazone-ethyl
Applicant name:	Oriental (Luzhou) Agrochemicals Co., Ltd
Applicant ACN:	N/A
Summary of use	For the control of marshmallow and certain other broadleaf weeds prior to establishment of broad-care crops, fallow or forest plantations, in commercial, industrial, and public service areas, around agricultural buildings and yards and other situations
Date of registration/approval:	3 December 2014
Product registration no.:	70327
Label approval no.:	70327/63137

Application no.:	58886
Product name:	Amgrow Organix Weed Blitz Concentrate Herbicide
Active constituent/s:	680 g/L pine oil
Applicant name:	Amgrow Pty Ltd
Applicant ACN:	100 684 786
Summary of use	Non-selective weed control of seedlings, young annual weeds and grasses in commercial, industrial and public service areas, around agricultural buildings and other non-crop farm situations
Date of registration/approval:	4 December 2014
Product registration no.:	68676
Label approval no.:	68676/58886

Application no.:	62874
Product name:	Protege Insecticidal Seed Treatment
Active constituent/s:	500 g/L fipronil
Applicant name:	Crop Care Australasia Pty Ltd
Applicant ACN:	061 362 347
Summary of use	For the control of redlegged earth mite in canola and false wireworm in sorghum and sunflowers and for the protection of sorghum and sunflower seedlings from attack by black field earwig
Date of registration/approval:	5 December 2014
Product registration no.:	70278
Label approval no.:	70278/62874

Application no.:	62326
Product name:	HOVEX Vaporgard Bin Kill
Active constituent/s:	7.8 g/kg transfluthrin
Applicant name:	SmarTec Solutions Ltd
Applicant ACN:	N/A
Summary of use	For control of flies in household garbage bins
Date of registration/approval:	5 December 2014
Product registration no.:	70027
Label approval no.:	70027/62326

Application no.:	53527
Product name:	Mainman 500 WG Insecticide
Active constituent/s:	500 g/kg flonicamid
Applicant name:	Ishihara Sangyo Kaisha, Ltd
Applicant ACN:	N/A
Summary of use	For the control of aphids and mealybug in apples, aphids and mirids in cotton, aphids and silverleaf whitefly in curcurbits and aphids in potatoes
Date of registration/approval:	5 December 2014
Product registration no.:	66373
Label approval no.:	66373/53527

Application no.:	100031
Product name:	Conquest Bayonet FERT 500 Fungicide
Active constituent/s:	500 g/L flutriafol
Applicant name:	Conquest Crop Protection Pty Ltd
Applicant ACN:	098 814 932
Summary of use	For the control of certain fungal diseases on wheat, barley and canola when mixed with fertiliser
Date of registration/approval:	5 December 2014
Product registration no.:	80012
Label approval no.:	80012/100031

Application no.:	63358
Product name:	eChem Pendimethalin 330 Herbicide
Active constituent/s:	330 g/L pendimethalin
Applicant name:	eChem (Aust) Pty Limited
Applicant ACN:	089 133 095
Summary of use	For the control of annual ryegrass and wireweed in wheat, barley, peas, annual grasses and certain broadleaved weeds in various crops
Date of registration/approval:	8 December 2014
Product registration no.:	70394
Label approval no.:	70394/63358

Application no.:	62602
Product name:	Farmalinx Powerquat 300 SL Herbicide
Active constituent/s:	300 g/L paraquat present as paraquat dichloride
Applicant name:	Farmalinx Pty Ltd
Applicant ACN:	134 353 245
Summary of use	For the control of a wide range of grass and broadleaf weeds
Date of registration/approval:	8 December 2014
Product registration no.:	70143
Label approval no.:	70143/62602

Application no.:	62812
Product name:	Titan Carfentrazone 240EC Herbicide
Active constituent/s:	240 g/L carfentrazone-ethyl
Applicant name:	Titan Ag Pty Ltd
Applicant ACN:	122 081 574
Summary of use	For the control of a range of broadleaf weeds in various situations in combination with other knockdown herbicides
Date of registration/approval:	8 December 2014
Product registration no.:	70246
Label approval no.:	70246/62812

Application no.:	62323
Product name:	Combat Ant-Rid Ant Killing Bait Strips
Active constituent/s:	0.01 g/kg fipronil
Applicant name:	Henkel Australia Pty Ltd
Applicant ACN:	001 302 996
Summary of use	For the control of ants in and around the home and garden
Date of registration/approval:	8 December 2014
Product registration no.:	70024
Label approval no.:	70024/62323

Application no.:	62044
Product name:	Amgrow Patrol Fixant Advanced Ant Sand Insecticide
Active constituent/s:	0.25 g/kg fipronil
Applicant name:	Sundew Solutions Pty Ltd
Applicant ACN:	135 400 261
Summary of use	For control of ants in external surrounds of buildings and structures in the home garden
Date of registration/approval:	9 December 2014
Product registration no.:	69907
Label approval no.:	69907/62044

Application no.:	60594
Product name:	Rainbow Imazapyr 750 SG Herbicide
Active constituent/s:	750 g/kg imazapyr
Applicant name:	Shandong Rainbow International Co., Ltd
Applicant ACN:	N/A
Summary of use	For the control of various annual and perennial weeds in non-crop situations
Date of registration/approval:	9 December 2014
Product registration no.:	69364
Label approval no.:	69364/60594

Application no.:	61954
Product name:	D-Pester Ant, Spider & Roach Killer Ready to Use
Active constituent/s:	3 g/L permethrin 25:75
Applicant name:	Biotis Life Science Pty Ltd
Applicant ACN:	103 118 887
Summary of use	For control of insect pests in the home garden
Date of registration/approval:	9 December 2014
Product registration no.:	69884
Label approval no.:	69884/61954

Application no.:	63325
Product name:	H2O Pool Chemicals Saltwater Booster
Active constituent/s:	504 g/kg available chlorine (Cl) present as Sodium dichloroisocyanurate also contains 100 g/kg sodium tetraborate pentahydrate
Applicant name:	Kleenco Australia Pty Limited
Applicant ACN:	003 131 539
Summary of use	For the control of algae & bacteria in outdoor swimming pools
Date of registration/approval:	10 December 2014
Product registration no.:	70380
Label approval no.:	70380/63325

3. VARIATION OF LABEL APPROVAL

Application no.:	53026
Product name:	DuPont ManKocide DF fungicide
Active constituent/s:	300 g/kg copper (Cu) present as cupric hydroxide, 150 g/kg mancozeb
Applicant name:	Du Pont (Australia) Pty Ltd
Applicant ACN:	000 716 469
Summary of variation:	To copy uses from reference products
Date of variation:	27 November 2014
Label approval no.:	60482/53026

Application no:	61293
Product name:	Dormex Plant Growth Regulator
Active constituent/s:	520 g/L cyanamide
Applicant name:	Crop Care Australasia Pty Ltd
Applicant ACN:	061 362 347
Summary of variation:	To include regulation of bud burst in plums and prunes
Date of variation:	27 November 2014
Product registration no.:	49200
Label approval no.:	49200/61293

Application no.:	63441
Product name:	Flexi Collars Termite Protection Barrier
Active constituent/s:	1 g/kg bifenthrin
Applicant name:	FMC Australasia Pty Ltd
Applicant ACN:	095 326 891
Summary of variation:	To change the product name from 'Eco Collars Termite Protection Barrier' to 'Flexi Collars Termite Protection Barrier' and variation of registration details
Date of variation:	1 December 2014
Product registration no.:	64393
Label approval no.:	64393/63441

Application no:	100092
Product name:	ADAMA 2,4-D Amine 625 Herbicide
Active constituent/s:	625 g/L 2,4-D present as the dimethylamine and diethanolamine salts
Applicant name:	Adama Australia Pty Limited
Applicant ACN:	050 328 973
Summary of variation:	To change the product name from 'Farmoz 2,4-D Amine 625 Selective Herbicide' to 'Adama 2,4-D Amine 625 Herbicide'
Date of variation:	2 December 2014
Product registration no.:	55046
Label approval no.:	55046/100092

Application no.:	100208
Product name:	Agral Spray Adjuvant
Active constituent/s:	600 g/L nonyl phenol ethylene oxide condensate non-ionic organic surfactant
Applicant name:	Syngenta Australia Pty Ltd
Applicant ACN:	002 933 717
Summary of variation:	To include Gramoxone 360 Pro Herbicide as a tank mix
Date of variation:	4 December 2014
Label approval no.:	54116/100208

Application no:	100651
Product name:	Virkon Aquatic Broad Spectrum Virucidal Bactericidal Fungicidal Disinfectant
Active constituent/s:	497 g/kg potassium peroxymonosulfate triple salt
Applicant name:	Lienert Australia Pty. Ltd
Applicant ACN:	008 293 007
Summary of variation:	To change the product name from 'DUPONT VIRKON AQUATIC BROAD SPECTRUM VIRUCIDAL BACTERICIDAL FUNGICIDAL DISINFECTANT' to 'VIRKON AQUATIC BROAD SPECTRUM VIRUCIDAL BACTERICIDAL FUNGICIDAL DISINFECTANT'
Date of variation:	5 December 2014
Product registration no.:	68503
Label approval no.:	68503/100651

Application no:	63125
Product name:	Chess Insecticide
Active constituent/s:	500 g/kg pymetrozine
Applicant name:	Syngenta Australia Pty Ltd
Applicant ACN:	002 933 717
Summary of variation:	To add 20 kg pack size and new packaging material (HDPE)
Date of variation:	5 December 2014
Product registration no.:	53311
Label approval no.:	53311/63125

Application no:	61669
Product name:	Thimet 100G Systemic Granular Insecticide
Active constituent/s:	100 g/kg phorate (an anti-cholinesterase compound)
Applicant name:	Amgrow Pty Ltd
Applicant ACN:	100 684 786
Summary of variation:	To include control of aphids, thrips, jassids, two spotted mite and wireworms in sweet potato
Date of variation:	5 December 2014
Product registration no.:	33071
Label approval no.:	33071/61669

Application no.:	100226
Product name:	Adama 2,4-D LV Ester 680 Herbicide
Active constituent/s:	680 g/L 2,4-D present as the 2–ethylhexyl ester
Applicant name:	Adama Australia Pty Limited
Applicant ACN:	050 328 973
Summary of variation:	To change the name of the product from 'FARMOZ 2,4-D LV ESTER 680 HERBICIDE' to 'ADAMA 2,4-D LV ESTER 680 HERBICIDE'
Date of variation:	9 December 2014
Label approval no.:	61895/100226

Application no:	59637
Product name:	Ridomil Gold 480 SL Systemic Fungicide
Active constituent/s:	480 g/L metalaxyl-m
Applicant name:	Syngenta Australia Pty Ltd
Applicant ACN:	002 933 717
Summary of variation:	To extend label claims to include control of phytopthora crown and spear Rot in asparagus
Date of variation:	9 December 2014
Product registration no.:	64812
Label approval no.:	64812/59637

Application no.:	100098
Product name:	Tupersan WP Turf Herbicide
Active constituent/s:	500 g/kg siduron
Applicant name:	Amgrow Pty Ltd
Applicant ACN:	100 684 786
Summary of variation:	To change the name of the product from 'NUTURF TUPERSAN WP TURF HERBICIDE' to 'TUPERSAN WP TURF HERBICIDE'
Date of variation:	9 December 2014
Label approval no.:	53714/100098

Application no.:	50404
Product name:	Sporekill Agricultural Disinfectant
Active constituent/s:	120 g/L didecyldimethyl-ammonium chloride
Applicant name:	Nufarm Australia Limited
Applicant ACN:	004 377 780
Summary of variation:	To extend the use to post-harvest sanitising as per the Directions for Use, to aid in the control of plant pathogens and storage decay diseases and for disinfection in non-food crop situations and to include a pack size range
Date of variation:	9 December 2014
Label approval no.:	51141/50404

Application no.:	100757
Product name:	Nuturf PendiMax Pre-Emerge Herbicide Plus Fertiliser 22–0–5
Active constituent/s:	7.5 g/kg pendimethalin
Applicant name:	Amgrow Pty Ltd
Applicant ACN:	100 684 786
Summary of variation:	To change the product name from 'NUTURF PRE-EMERGE HERBICIDE PLUS FERTILISER 22–0–5' to 'NUTURF PENDIMAX PRE-EMERGE HERBICIDE PLUS FERTILISER 22–0–5'
Date of variation:	10 December 2014
Label approval no.:	69261/100757

Application no.:	62743
Product name:	Schiltron High Performance Surface Spray
Active constituent/s:	0.7 g/kg imiprothrin, 2 g/kg cypermethrin
Applicant name:	Barr Glebe Group Pty Ltd
Applicant ACN:	119 998 435
Summary of variation:	To change the product name from 'BARD HIGH PERFORMANCE SURFACE SPRAY' to 'SCHILTRON HIGH PERFORMANCE SURFACE SPRAY'
Date of variation:	10 December 2014
Label approval no.:	69482/62743

Application no.:	62744
Product name:	Schiltron Fly and Insect Spray
Active constituent/s:	2.16 g/kg tetramethrin 20:80, 0.5 g/kg phenothrin 20:80, 4.34 g/kg piperonyl butoxide, 6.36 g/kg n-octyl bicycloheptene dicarboximide
Applicant name:	Barr Glebe Group Pty Ltd
Applicant ACN:	119 998 435
Summary of variation:	To change the product name from 'BARD FLY AND INSECT SPRAY' to 'SCHILTRON FLY AND INSECT SPRAY'
Date of variation:	10 December 2014
Label approval no.:	69481/62744

Application no.:	62745
Product name:	Schiltron Fast Knockdown Insect Spray
Active constituent/s:	3.82 g/kg tetramethrin 20:80, 1.19 g/kg bioallethrin, 0.75 g/kg bioresmethrin
Applicant name:	Barr Glebe Group Pty Ltd
Applicant ACN:	119 998 435
Summary of variation:	To change the product name from 'BARD FAST KNOCKDOWN INSECT SPRAY' to 'SCHILTRON FAST KNOCKDOWN INSECT SPRAY'
Date of variation:	10 December 2014
Label approval no.:	69480/62745

Application no.:	62198
Product name:	30 Seconds Outdoor Cleaner Improved Cleaning Concentrate
Active constituent/s:	50 g/L sodium hypochlorite
Applicant name:	30 Seconds Limited (NZ)
Applicant ACN:	N/A
Summary of variation:	To change the product name from '30 SECONDS OUTDOOR CLEANER CONCENTRATE' to '30 SECONDS OUTDOOR CLEANER IMPROVED CLEANING CONCENTRATE'
Date of variation:	10 December 2014
Label approval no.:	52914/62198

Veterinary Chemical Products and Approved Labels

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

1. VETERINARY PRODUCTS BASED ON NEW ACTIVE CONSTITUENTS

Application no.:	57142
Product name:	NeXGard Chewables for Dogs 25.1–50 kg
Active constituent/s:	Each chewable contains 136 mg afoxolaner
Applicant name:	Merial Australia Pty Ltd
Applicant ACN:	071 187 285
Summary of use	For the treatment and prevention of flea infestations and control of ticks (*Ixodes holocyclus, Rhipicephalus sanguineus, Haemaphysalis longicornis*) on dogs and puppies
Date of Registration/approval:	2 December 2014
Product registration no.:	67939
Label approval no.:	67939/57142

Application no.:	57144
Product name:	NeXGard Chewables for Dogs 10.1–25 kg
Active constituent/s:	Each chewable contains 68 mg afoxolaner
Applicant name:	Merial Australia Pty Ltd
Applicant ACN:	071 187 285
Summary of use	For the treatment and prevention of flea infestations and control of ticks (*Ixodes holocyclus, Rhipicephalus sanguineus, Haemaphysalis longicornis*) on dogs and puppies
Date of Registration/approval:	2 December 2014
Product registration no.:	67940
Label approval no.:	67940/57144

Application no.:	57146
Product name:	NeXGard Chewables for Dogs 2–4 kg
Active constituent/s:	Each chewable contains 11.3 mg afoxolaner
Applicant name:	Merial Australia Pty Ltd
Applicant ACN:	071 187 285
Summary of use	For the treatment and prevention of flea infestations and control of ticks *(Ixodes holocyclus, Rhipicephalus sanguineus, Haemaphysalis longicornis*) on dogs and puppies
Date of Registration/approval:	2 December 2014
Product registration no.:	67942
Label approval no.:	67942/57146

Application no.:	57145
Product name:	NexGard Chewables for Dogs 4.1–10 kg
Active constituent/s:	Each chewable contains 28.3 mg afoxolaner
Applicant name:	Merial Australia Pty Ltd
Applicant ACN:	071 187 285
Summary of use	For the treatment and prevention of flea infestations and control of ticks (*Ixodes holocyclus, Rhipicephalus sanguineus, Haemaphysalis longicornis*) on dogs and puppies
Date of Registration/approval:	2 December 2014
Product registration no.:	67941
Label approval no.:	67941/57145

2. VETERINARY PRODUCTS BASED ON EXISTING ACTIVE CONSTITUENTS

Application no.:	59957
Product name:	Neove Salinomycin 120–Feed Additive Premix
Active constituent/s:	120 g/kg salinomycin sodium (equivalent to 116.6 g/kg salinomycin)
Applicant name:	Neove Pharma Australia Pty Limited
Applicant ACN:	140 367 442
Summary of use	For use in the prevention of coccidiosis caused by *Eimeria acervulina, E. brunetti, E. maxima, E. mivati, E. necatrix* and *E. tenella* in broiler chickens and in replacement pullets intended for use as caged layers
Date of registration/approval:	3 December 2014
Product registration no.:	59957
Label approval no.:	69091/59957

Application no.:	62332
Product name:	Austrazole Topical fungicide for dogs and horses
Active constituent/s:	100 mg/mL enilconazole
Applicant name:	Ausrichter Pty Ltd
Applicant ACN:	000 908 529
Summary of use	For the control of fungal infections of the skin of dogs and horses
Date of registration/approval:	3 December 2014
Product registration no.:	70030
Label approval no.:	70030/62332

3. VARIATION OF LABEL APPROVAL

Application no.:	61027
Product name:	Ultravac Scourshield Vaccine
Active constituent/s:	Bovine rotavirus G6≥1.3RP/2 mL, Bovine rotavirus G10≥1RP/2 mL, Bovine coronavirus ≥1RP/2 mL, E. coli K99≥1RP/2 mL
Applicant name:	Zoetis Australia Pty Ltd
Applicant ACN:	156 476 425
Summary of variation:	To update the in-use shelf life
Date of variation:	28 November 2014
Product registration no.:	65032
Label approval no.:	65032/61027

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.:	37445
Active constituent/s:	Carbonyl sulfide
Applicant name:	BOC Limited
Applicant ACN:	000 029 729
Summary of use:	For use in agricultural chemical products
Date of approval:	27 November 2014
Approval no.:	60111

Application no.:	63197
Active constituent/s:	Thiacloprid
Applicant name:	Bayer Cropscience Pty Ltd
Applicant ACN:	000 226 022
Summary of use:	For use in agricultural chemical products
Date of approval:	3 December 2014
Approval no.:	70332

Application no.:	62368
Active constituent/s:	Glyphosate-isopropylammonium
Applicant name:	Jiangsu Good Harvest-Weien Agrochemical Co Ltd
Applicant ACN:	N/A
Summary of use:	For use in agricultural chemical products
Date of approval:	3 December 2014
Approval no.:	70047

Application no.:	62427
Active constituent/s:	Tebuconazole
Applicant name:	Jiangsu Good Harvest-Weien Agrochemical Co Ltd
Applicant ACN:	N/A
Summary of use:	For use in agricultural chemical products
Date of approval:	3 December 2014
Approval no.:	70070

Application no.:	62575
Active constituent/s:	Metalaxyl
Applicant name:	Shandong Rainbow International Co., Ltd
Applicant ACN:	N/A
Summary of use:	For use in agricultural chemical products
Date of approval:	3 December 2014
Approval no.:	70130

Application no.:	62454
Active constituent/s:	Methomyl
Applicant name:	Joy Harvest Holding Pty Ltd
Applicant ACN:	130 503 829
Summary of use:	For use in agricultural chemical products
Date of approval:	3 December 2014
Approval no.:	70079

Application no.:	62451
Active constituent/s:	Atrazine
Applicant name:	Alpha Crop Protection Pty Ltd
Applicant ACN:	165 653 047
Summary of use:	For use in agricultural chemical products
Date of approval:	9 December 2014
Approval no.:	70078

Application no.:	62616
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:	9 December 2014
Approval no.:	70147

New Agricultural Active Constituent—Halauxifen-methyl

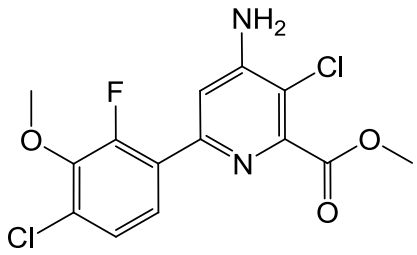
The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application for approval of a new active constituent, Halauxifen-methyl.

Halauxifen-methyl is a novel picolinic acid herbicide belonging to a member of the pyridine carboxylic acid family and possesses auxin-like properties, where the herbicide binds to protein receptor sites that normally regulate plant processes.

It will be used in products to control broadleaf weed in cereal crops such as wheat, barley, triticale and oats.

Common Name:	Halauxifen-methyl
IUPAC Name:	methyl 4-amino-3-chloro-6-(4-chloro-2-fluoro-3-methoxyphenyl)pyridine-2-carboxylate
CAS Name:	methyl 4-amino-3-chloro-6-(4-chloro-2-fluoro-3-methoxyphenyl)-2-pyridinecarboxylate
CAS Registry Number:	943831-98-9
Manufacturer's Codes:	XDE-729 methyl
Minimum Purity:	930 g/kg
Molecular Formula:	$C_{14}H_{11}Cl_2FN_2O_3$
Molecular Weight:	347.17 g/mol

Structures:



Chemical Family:	Pyridine carboxylic acid
Mode of Action:	Synthetic auxin

SUMMARY OF THE APVMA'S EVALUATION OF HALAUXIFEN-METHYL ACTIVE CONSTITUENT

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

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

Constituent	Specification
Halauxifen-methyl	Not less than 930 g/kg

Other compounds of toxicological significance are not expected to occur in the halauxifen-methyl TGAC.

The Office of Chemical Safety (OCS) has completed a toxicological evaluation of halauxifen-methyl.

An Acceptable Daily Intake (ADI) of 0.1 mg/kg bw/d has been set, based on a No-Observed Effect Level (NOEL) of 10 mg/kg and applying a 100–fold safety factor. Increased Cyp1a1 gene expression and associated increased liver weights and cholesterol (females) and increased hepatocellular vacuolation (males) observed at 53.4/52.3 mg/kg bw/d (males/females) from a 90 day dietary study in rats was the basis of the NOEL.

An acute reference dose (ARfD) for halauxifen-methyl is not proposed, as it is considered unlikely to present an acute hazard to humans after single dose administration based on the use patterns proposed.

Halauxifen-methyl is not currently in the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP). The delegate to the Secretary of the Department of Health has made a delegate only decision, that halauxifen methyl it does not require scheduling and therefore should be included in Appendix B of the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP), along with an implementation date of 1 October 2014.

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

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

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

MAKING A SUBMISSION

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

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

When making a submission please include a:

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

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

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

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

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

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

New Agricultural Chemical Product—Halauxifen-methyl in the product GF 2685 herbicide

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application from Dow AgroSciences Australia Limited for registration of a new product containing the active constituent HALAUXIFEN-METHYL. The product is GF-2685 HERBICIDE. The product is for control of aphids and a range of other insect pests in canola, cereals, cotton, soybeans and various fruit and vegetable crops.

PARTICULARS OF THE APPLICATION

Proposed Product Name(s):	GF-2685 HERBICIDE
Applicant Company:	DOW AGROSCIENCES AUSTRALIA LIMITED
Name of Active Constituent:	HALAUXIFEN - METHYL CLOQUINTOCET - MEXYL
Signal Heading:	Nil (Appendix B)
Summary of Proposed Use:	For the control of annual broadleaf weeds in wheat and barley.
Pack Sizes:	500 g, 1 kg , 5 kg, 10 kg
Withholding Periods:	
	HARVEST WITHHOLDING PERIODS (WHP)
	Cereals:
	NOT REQUIRED WHEN USED AS DIRECTED.
	GRAZING WITHHOLDING PERIODS (WHP):
	Cereals:
	DO NOT GRAZE OR CUT FOR STOCKFEED FOR 14 DAYS AFTER APPLICATION.

SUMMARY OF THE APVMA'S EVALUATION OF GF-2685 HERBICIDE IN ACCORDANCE WITH SECTION 14(3)(E) AND (F) 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 application and in its assessment in relation to human and environmental safety under section 14(3)(e) of the Agvet Code, it proposes to determine that:

(i) The APVMA is satisfied that the proposed use of GF-2685 HERBICIDE 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 and Ageing has conducted a risk assessment on the product and concluded that it can be used safely.

Commercial providers and farmers with their employees will be the main users of GF-2685 HERBICIDE. The product is not intended for use in the domestic market. Workers may be exposed to the product when opening

containers, mixing/loading, application, and cleaning up spills and equipment. The main route of exposure to the product will be dermal with inhalation, although ocular exposure is also possible. Dermal exposure may also occur during re-entry activities in treated crops. Based on the proposed use pattern the duration of exposure is expected to be short-term.

Comparison of the toxicological data and endpoints for halauxifen-methyl and cloquintocet mexyl revealed cloquintocet mexyl to be the driver of systemic toxicity. The risk assessment for GF-2685 Herbicide is therefore based on systemic exposure to cloquintocet mexyl.

In the absence of exposure data for the proposed mode of application, the Pesticide Handler Exposure Database (PHED) Surrogate Exposure Guide was used to estimate exposure. Exposure to the product during mixing and loading and application by ground boom and aerial application were at an acceptable level for workers without the use of personal protective equipment (PPE).

There is no re-entry risk associated with use of the product.

Slight skin and eye irritation and skin sensitisation are acute hazards of concern for the use of the product. Based on these acute hazards first aid instructions and safety directions have been recommended for the product label.

Based on an assessment of the toxicology and occupational health and safety, it was considered that there should be no adverse effects on human health from the use of GF-2685 Herbicide when used in accordance with the label directions.

(ii) The APVMA is satisfied that the proposed use of GF-2685 HERBICIDE will not be an undue hazard to the safety of people using anything containing its residues.

The chronic dietary intake risk for halauxifen-methyl has been assessed. The ADI for halauxifen-methyl is 0.1 mg/kg bw/day, based upon a NOEL of 10 mg/kg bw/day and a 100–fold safety factor. The NEDI calculation is made in accordance with WHO Guidelines[1] and is a conservative estimate of dietary exposure to chemical residues in food. The NEDI for halauxifen-methyl, is equivalent to <1% of the ADI DIAMOND Modelling[2] of chronic dietary exposure is also performed on new chemicals. The DIAMOND model estimated the chronic dietary exposure of halauxifen-methyl as <1% of the ADI for the general population.

An acute reference dose (ARfD) for halauxifen-methyl is not proposed, as it is considered unlikely to present an acute hazard to humans after single dose administration based on the use patterns proposed.

No changes are required for existing MRLs for cloquintocet-mexyl, and no changes to the dietary risk is expected for this active.

It is concluded that the dietary exposure to halauxifen-methyl is low and the risk from residues in food is acceptable when GF-2685 Herbicide is used according to label directions.

(iii) The APVMA is satisfied that the proposed use of GF-2685 HERBICIDE containing the active constituent halauxifen-methyl is not likely to be harmful to human beings if used according to the product label directions.

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[1] Guidelines for predicting dietary intake of pesticide residues, WHO, 1997.

[2]. DIAMOND: The Diamond Modelling of Nutritional Data is a computer dietary modelling program based upon statistical software that is used by FSANZ.

halauxifen-methyl is the first member of a class of new synthetic auxin herbicides, the arylpicolinates. Cloquintocet-mexyl acts as a safener, to prevent the phytotoxic action of the accompanying herbicide with which it is mixed. It is not classified in a chemical class.

The product GF-2685 Herbicide containing 100 g/L halauxifen (as methyl ester) and 100 g/L cloquintocet-mexyl as a WG formulation and is intended for post-emergent control of hard to kill broad leaf weeds in wheat and barley to control various weeds.

Acute hazards of concern for the product GF-2685 Herbicide were slight skin and eye irritation and positive skin sensitisation potential.

Toxicokinetic data from guideline studies in mice and rats and toxicokinetic data included in repeat dose studies in mice, rats and dogs demonstrated rapid hydrolysis of halauxifen-methyl to halauxifen acid, and that systemic exposure was to halauxifen acid with absorption from the GI tract considered to be essentially complete. Additionally, based on an in vivo dermal absorption study in rats on a product containing halauxifen-methyl it is considered that systemic exposure following application of halauxifen-methyl via the dermal route would be to halauxifen acid. Therefore, the toxicological database submitted was for halauxifen-acid with bridging studies provided for halauxifen-methyl. Although very similar structurally, the primary target organ of halauxifen acid is the kidney, while halauxifen methyl causes direct pre-systemic toxicity to the liver following repeat oral exposure, with liver toxicity appearing to be the more sensitive effect.

In vivo and in vitro mechanistic studies were also conducted to provide information on the mode of action of liver toxicity. Based on the available liver toxicity data, including liver enzyme induction data from guideline short-term and subchronic toxicity studies in rats and in vivo and in vitro mediated mode of action (MOA) studies, it was considered that XDE-729 methyl induces rodent liver effects via a proposed aryl hydrocarbon receptor-MOA through the following key events: (1) pre-systemic liver exposure to halauxifen methyl; (2) aryl hydrocarbon receptor (AhR) activation with associated liver weight increase and hepatocyte hypertrophy, leading to (3) hepatocellular proliferation. The rodent MOA data and in vitro mechanistic studies including PBPK modelling provide evidence that humans would be significantly less sensitive than rat to halauxifen methyl. Overall, these data strongly support the presence of a threshold to the key events of AhR-mediated liver toxicity in rats that would be protective of human health following chronic exposure.

Halauxifen-methyl and halauxifen acid are not developmental toxicants and halauxifen acid did not cause reproductive toxicity. Carcinogenicity studies conducted on halauxifen acid showed no evidence of carcinogenicity, and genotoxicity studies on halauxifen acid and halauxifen-methyl did not reveal any evidence of genotoxic potential. halauxifen acid was not neurotoxic in rats following acute and repeat dosing and halauxifen acid was not immunotoxic in rats.

Genotoxicity studies on the metabolite X11449757 did not reveal any evidence of genotoxic potential.

Cloquintocet-mexyl is a currently registered active constituent and the toxicological profile of this active has been previously established by OCS.

Toxicokinetic data indicates cloquintocet-mexyl absorption from the GI tract after oral administration may not be complete. Based on the available excretion data from urine, bile, tissues and cage wash it is considered that up to 61% of an administered oral dose was absorbed from the GI tract in rats.

The primary target organs of cloquintocet-mexyl following systemic exposure are the liver and kidney with rats being the most sensitive species and additionally demonstrating thyroid toxicity. The lowest reported NOEL was 4.3 mg bw/d for thyroid follicular epithelium hyperplasia in females observed at 41.3 mg/kg bw/d in a 2-year dietary study in rats.

Cloquintocet methyl is not carcinogenic with no evidence of carcinogenicity in repeat dose studies and negative findings in a battery of genotoxicity tests. Cloquintocet-mexyl is not considered to be reproductive or developmental toxicant with findings of delayed development only observed at and above maternotoxic doses.

(iv) The APVMA is satisfied that the proposed use of the new product GF-2685 HERBICIDE containing the active constituent halauxifen-methyl, would not be likely to have an unintended effect that is harmful to animals, plants or things or the environment.

The APVMA is satisfied that the proposed use of the new product, GF-2685 Herbicide, containing the new active constituent, halauxifen–methyl, for the control of annual broad leaf weeds in wheat and barley crops would not be likely to have an unintended effect that is harmful to animals, plants or things or to the environment.

Halauxifen-methyl is to be applied at application rates of 5 g ac/ha or 10 g ac/ha, with a single applications per crop. The risk assessment, which was performed using standard methodology, showed an acceptable risk to all environmental organisms considered.

The spray drift risk assessment was undertaken as per the APVMA spray drift policy and demonstrated risk to aquatic organisms and terrestrial plants is acceptable, provided the inclusion of appropriate downwind aquatic and terrestrial spray drift buffer zones are applied. The runoff risk assessment to aquatic organisms was undertaken as per the Department of the Environment screening model and demonstrated that risk to aquatic organisms from runoff of both active constituents, and halauxifen-methyl acid, was acceptable.

(v) The APVMA is considering whether the proposed use of GF-2685 HERBICIDE would not adversely affect trade between Australia and places outside Australia.

The risk to trade in cereal grains and animal commodities is expected to be low, as finite residues of halauxifen-methyl are not expected to be found in cereals, mammalian or poultry meat or offal, eggs, or milk. Finite residues of halauxifen-methyl may be found in oaten hay, however it is noted that Japan does not have a maximum residue level for halauxifen-methyl in animal feeds, and the risk to exports of oaten hay to Japan is expected to be low[3].

No changes are proposed to MRLs for cloquintocet-mexyl. In any case, MRLs for cloquintocet-mexyl in cereal grains, forage, and fodder (use of GF-2685 Herbicide in rye is not proposed), and animal commodities are established at the LOQ. Therefore, residues of cloquintocet-mexyl resulting from the proposed use of GF-2685 Herbicide will not change the already low risk to trade.

(vi) 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 GF-2685 HERBICIDE adequately demonstrate that if used according to the product label directions, the product GF-2685 HERBICIDE is effective for its proposed uses.

FURTHER INFORMATION

A Public Release Summary (PRS) of the evaluation of this product is available from the APVMA website's 'Public Consultation' page, www.apvma.gov.au/consultation/public or by contacting us as listed below.

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 registration of GF-2685 HERBICIDE should be granted. Submissions should

[3] Regulatory Frameworks to Ensure Feeds Safety in Japan, Food and Agricultural Materials Inspection Center, http://www.famic.go.jp/ffis/feed/r_safety/r_feeds_safety.html

relate only to matters that the APVMA is required by legislation to take into account in deciding whether to grant the application. These grounds include occupational health and safety, chemistry and manufacture, residues, safety and first aid, environmental fate and toxicity, trade and efficacy. Submissions should state the grounds on which they are based. Comments received outside these grounds cannot be considered by the APVMA.

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

Relevant comments will be taken into account by the APVMA in deciding whether the product should be registered and in determining appropriate conditions of registration and product labelling.

When making a submission please include:

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

All personal and confidential commercial information (CCI)[4] 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:

Enquiries
Registration Management and Evaluation Program
Australian Pesticides and Veterinary Medicines Authority
PO Box 6182
KINGSTON ACT 2604

Phone: +61 2 6210 4700
Fax: +61 2 6210 4776
Email: enquiries@apvma.gov.au

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

New Veterinary Chemical Product—Biomin BBSH 797 (active) in the Product Mycofix Plus BBSH

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application from Biomin (Australia) Pty Ltd for the approval of a new active constituent Biomin BBSH 797. The APVMA also has before it an application from the same applicant for the registration of a new product MYCOFIX PLUS BBSH containing the new active constituent and Bentonite, a previously approved active. The product is for use as a feed additive powder for the management of mycotoxins, specifically trichothecenes, aflatoxins and fumonisins in feed for pigs and poultry.

PARTICULARS OF THE ACTIVE CONSTITUENT

Applicant company:	Biomin (Australia) Pty Ltd
Name of active constituent:	*Eubacterium* sp. strain DSM 11798
Common name:	Biomin BBSH 797
Appearance and Identity:	An anaerobic bacterium originally isolated from a bovine rumen.
Poisons Schedule:	Appendix B—Substance considered not to require control by scheduling
Gene technology:	Not applicable
Mode of action:	Biomin BBSH 797 biotransforms the epoxide ring in trichothecenes.

SUMMARY OF THE APVMA'S EVALUATION OF BIOMIN BBSH 797 ACTIVE CONSTITUENT

Biomin BBSH 797 is a new active constituent and there is no compendial specification available. Biomin BBSH 797 is compliant with European Union directives regarding culture purity, consistency, passage stability, antibiotic production and genetic capacity to develop resistance.

The APVMA has evaluated the chemistry and manufacturing aspects of Biomin BBSH 797 and is satisfied that the method by which the constituent is to be manufactured would not yield impurities of human or environmental concern.

The APVMA has evaluated the application in relation to human and environmental safety and trade under section 14(3)(e) of the Agvet Code in combination with the end use product and its proposed label. The APVMA is satisfied that the new active constituent BIOMIN BBSH 797 when formulated into the proposed end use product would not be an undue hazard to the safety of people exposed to it during its handling or a prejudice to trade. For a full summary see sections (i) and (v) in the 'Summary of the product evaluation' section below.

The Office of Chemical Safety (OCS) in the Department of Health has conducted a risk assessment on the new active constituent and found that the submitted data supports the safety of the constituent from a toxicological perspective.

Biomin BBSH 797 is of low oral toxicity, moderate acute inhalation toxicity and is unlikely to be genotoxic. Pathogenicity via inhalation and other aerobic routes is not expected to present any concern as *Eubacterium* sp. strain DSM 11798 is an obligate anaerobe and unlikely to survive via these routes of administration. There was no evidence of pathogenicity or infectivity for this microorganism in any of the submitted studies in the usual test species. The OCS identified no concerns regarding the infectivity and pathogenicity of *Eubacterium* sp. strain DSM 11798 in humans.

The Secretary of the Department of Health and Aging has considered the new active constituent Biomin BBSH 797 and has included it in Appendix B of the Standard for the Uniform Scheduling of Medicines and Poisons—a substance not requiring control by scheduling.

The APVMA has considered and accepted these findings and recommendations. The APVMA is satisfied that the proposed use of Biomin BBSH 797 in the product would not be an undue hazard to the safety of people exposed to it during its handling or use.

PARTICULARS OF THE PRODUCT APPLICATION

Proposed Product Name(s):	MYCOFIX PLUS BBSH
Applicant Company:	Biomin (Australia) Pty Ltd
Name of Active Constituents:	Biomin BBSH 797 Bentonite
Signal Heading:	None
Summary of Proposed Use:	A feed additive powder for the management of trichothecenes, aflatoxins and fumonisins in feed for pigs and poultry.
Pack Sizes:	25 kg
Withholding Period:	**Withholding Periods:** **MEAT:** Zero (0) days **EGGS:** Zero (0) days

SUMMARY OF THE APVMA'S EVALUATION OF THE PRODUCT, MYCOFIX PLUS BBSH

The APVMA has evaluated the application in relation to human and environmental safety and trade under section 14(3)(e) and efficacy under section 14(3)(f) of the Agvet Code. It proposes to determine that:

(i) The APVMA is satisfied that the proposed use of MYCOFIX PLUS BBSH containing the new active constituent BIOMIN BBSH 797 and the existing active Bentonite, would not be an undue hazard to the safety of people exposed to it during its handling (section 14(3)(e)(i)).

The Office of Chemical Safety (OCS) in the Department of Health has conducted a risk assessment on the product and found that the submitted data supports the safe use of the products from a toxicological perspective.

Product toxicity was estimated based on data provided for the active constituent. Biomin BBSH 797 is of low oral toxicity, moderate acute inhalation toxicity and is unlikely to be genotoxic. Pathogenicity via inhalation and other aerobic routes is not expected to present any concern as *Eubacterium* sp. strain DSM 11798 is an obligate anaerobe and unlikely to survive via these routes of administration. There was no evidence of pathogenicity or infectivity for this microorganism in any of the submitted studies in the usual test species. The OCS recommends that there are no concerns regarding the infectivity and pathogenicity of *Eubacterium* sp. strain DSM 11798 in humans.

Based on available data, the use of the product, MYCOFIX PLUS BBSH, will present minimal hazards in the preparation and dispensation of treated feed. The OCS recommended the following safety Directions in relation to handling the product to minimise exposure to workers using the product.

May irritate the eyes, nose and throat. Avoid contact with eyes. If product in eyes, wash it our immediately with water. Do not inhale dust. When opening the container and preparing the feed mix, wear goggles and disposable dust mask covering mouth and nose. Wash hands after use. After each days use, wash goggles.

Appropriate First aid instructions are included on the label.

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

(ii) The APVMA is satisfied that the proposed use of MYCOFIX PLUS BBSH containing the new active constituent BIOMIN BBSH 797 and the existing active Bentonite, will not be an undue hazard to the safety of people using anything containing its residues (section 14(3)(e)(i)).

Biomin BBSH 797 is a naturally occurring organism found in animals. The particular strain under consideration demonstrates enhanced mycotoxin degradation compared to wild stains commonly found in gut flora. Direct-fed microbial products are used at low dosage levels in animal feeds to influence gut microflora populations. Any potential residues occurring from the proposed use are not expected to occur above naturally occurring background levels. There is no evidence that residues will arise from the use of this Bacterial strain. The Strain is not genetically modified, has no genetic capacity to produce antibiotics or to develop resistance.

The product has been assigned a zero (0) day withholding period.

(iii) The APVMA is satisfied that the proposed use of MYCOFIX PLUS BBSH containing the new active constituent BIOMIN BBSH 797 and the existing active Bentonite, is not likely to be harmful to human beings (section 14(3)(e)(ii).

The delegate to the Secretary of the Department of Health and Aging has included the active in Appendix B of the Standard for the Uniform Scheduling of Medicines and Poisons—a substance not requiring control by scheduling. Consequently, the product Mycofix plus BBSH requires no signal headings on label. Appropriate first aid instructions and safety directions will be included on the product label.

(iv) The APVMA is satisfied that the proposed use of MYCOFIX PLUS BBSH containing the new active constituent BIOMIN BBSH 797 and the existing active Bentonite, would not be likely to have an unintended effect that is harmful to animals, plants or things or to the environment (section 14(3)(e)(iii)) if used according to the product label instructions.

Eubacterium are common, naturally occurring, non-pathogenic, obligate anaerobes found in animal digestive systems. The strain under consideration is a non-genetically modified isolate from Bovine rumen. Trial data demonstrate that feeding of this microbe to pigs and poultry does not affect microbial population dynamics. The pathogenicity or persistence of the organism in the environment is not relevant to this consideration due to the organism being an obligate anaerobe. In considering the product use pattern and the new active constituent's characteristics, the APVMA is satisfied that Mycofix plus BBSH is safe for use when used in accordance with the proposed label directions.

The APVMA is satisfied that the proposed product would not have an unintended effect that is harmful to treated animals as testing at 100x overdose demonstrated no adverse effects in the pigs and poultry.

(v) The APVMA is satisfied that the proposed use of MYCOFIX PLUS BBSH containing the new active constituent BIOMIN BBSH 797 and the existing active bentonite, would not adversely affect trade between Australia and places outside Australia. (section 14(3)(e)(iv)).

Biomin BBSH 797 is compliant with European Union directives regarding antimicrobial substances, is not genetically modified, has no genetic capacity to produce antibiotics or to develop resistance. The feeding of Mycofix plus BBSH to pigs and poultry is not expected to result in detectable residues above normal background levels. There is no potential for prejudice to trade from use of the product in accordance with the label directions.

(vi) The APVMA is satisfied that the proposed use of MYCOFIX PLUS BBSH containing the new active constituent BIOMIN BBSH 797 and the existing active Bentonite, in accordance with its proposed label instructions would be effective according to criteria determined by the APVMA for the product (section 14(3)(f)).

The applicant provided *in vitro* evidence of the ability of Biomin BBSH 797 to detoxify DON to less toxic metabolites. Further experimental evidence of the ability of bentonite to bind aflatoxins was also provided. The APVMA accessed a European Food Safety Authority (EFSA) report which indicated that the product has the capacity to biotransform trichothecenes in feed. The efficacy data reviewed by the APVMA is sufficient to support the label claims proposed by the applicant.

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 MYCOFIX PLUS BBSH should be granted. Submissions should relate only to matters that the APVMA is required by legislation to consider in deciding whether to grant the application. These grounds include occupational health and safety, chemistry and manufacture, residues, safety and first aid, environmental fate and toxicity, trade and efficacy. Submissions should state the grounds on which they are based. Comments received outside these grounds cannot be considered by the APVMA.

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

When making a submission please include a:

- contact name
- company or group name (if relevant)
- postal address
- email address (if available).

The date you made the submission.

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

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

Enquiries
Veterinary Medicines Program
Australian Pesticides and Veterinary Medicines Authority
PO Box 6182
KINGSTON ACT 2604

Phone: +61 2 6210 4700
Fax: +61 2 6210 4741
Email: enquiries@apvma.gov.au

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

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]

DAIRY TECHNICAL SERVICES LIMITED
ACN: 004 319 171
52–58 Mark Street
NORTH MELBOURNE VIC 3051

LICENCE NO: 6197

Product Types:*

- *Category 6*: Single step manufacture

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

Licence Issued: 1 October 2014

DAIRY TECHNICAL SERVICES LIMITED
ACN: 004 319 171
Units 3–5/352 Macauley Road
KENSINGTON VIC 3031

LICENCE NO: 6196

Product Types:*

- *Category 6*: Single step manufacture

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

Licence Issued: 1 October 2014

* 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

BIOTEST LABORATORIES PTY LTD

ACN: 010 924 571

Unit 1–4, 2 Darnick Street

UNDERWOOD QLD 4119

LICENCE NO: 6036

Product Types: *

- *Category 6*: Single step manufacture

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

Amended Licence Issued: 8 October 2014

A C E PACKWELL PTY LTD

ACN: 002 416 640

6D Narabang Way

Austlink Corporate Park

BELROSE NSW 2085

LICENCE NO: 6058

Product Types: *

- *Category 6: Single step manufacture*

Step(s) of Manufacture: Packaging and labelling

Amended Licence Issued: 9 October 2014

SILLIKER AUSTRALIA PTY. LTD.

ACN: 006 462 335

Unit C2 Regents Park Estate

391 Park Road

REGENTS PARK NSW 2143

LICENCE NO: 6077

Product Types: *

- *Category 6: Single step manufacture*

Step(s) of Manufacture: Analysis and testing: Microbiological

Amended Licence Issued: 10 October 2014

* 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*

INTERVET AUSTRALIA PTY LIMITED

ACN: 008 467 034

91–105 Harpin Street

BENDIGO EAST VIC 3550

LICENCE NO: 1008

Product Types: *

- *Category 1*: Immunobiologicals and sterile products

Step(s) of Manufacture: Quality assurance (QA) of raw materials, bacterial fermentation, fungal fermentation, virus cultivation, formulation including blending, aseptic filling, filling, packaging, labelling, sterilisation (heat, chemical and filtration), microbiological reduction treatment (heat, chemical and filtration), freeze-drying, analysis and testing (physical, chemical, sterility test, safety test, serological and microbiological), storage and release for supply.

Amended Licence Issued: 20 October 2014

RURAL CHEMICAL INDUSTRIES (AUST.) PTY. LTD.

ACN: 003 842 402

Unit 5, 7–9 Kent Road

MASCOT NSW 2020

LICENCE NO: 6094

Product Types: *

- *Category 6*: Single step manufacture

Step(s) of Manufacture: Quality assurance (QA) of raw materials, labelling, storage and release for supply

Amended Licence Issued: 21 October 2014

NATURE'S GIFT AUSTRALIA PTY LTD

LICENCE NO: 4087

* 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*

ACN: 065 998 414
6–10 Blaxland Avenue
THOMASTOWN VIC 3074

Product Types: *

- *Category 4*: Therapeutic pet foods

Step(s) of Manufacture: Quality assurance (QA) of raw materials, formulation including blending, filling, packaging, labelling, sachet packaging, pellet extrusion, analysis and testing (physical) and storage

Amended Licence Issued: 21 October 2014

PLASVACC PTY LTD

LICENCE NO: 1072

ACN: 099 547 841
Rigby
6066 Cunningham Highway
KALBAR QLD 4309

Product Types: *

- *Category 1*: Immunobiologicals (plasma products and canine red blood cells [RBC])

Step(s) of Manufacture: Quality assurance (QA) of raw materials, plasma collection via plasmapheresis machine, blood collection, management and immunisation of donor animals, formulation including blending, aseptic filling, packaging, labelling, sterilisation (filtration), microbiological reduction treatment (filtration), analysis and testing (physical, chemical, sterility , serological, immunobiological and haematological), storage and release for supply.

Amended Licence Issued: 22 October 2014

CHARLES I.F.E PROPRIETARY LIMITED

LICENCE NO: 6155

ACN: 004 994 629
'Berrybank Farm'
34 Hendersons Road
WINDERMERE VIC 3352

Product Types: *

- *Category 6*: Single step manufacture

Step(s) of Manufacture: Analysis and testing (Immunobiological)

Amended Licence Issued: 24 October 2014

* 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*

CONTRACT PHARMACEUTICAL SERVICES OF AUSTRALIA PTY LIMITED

ACN: 003 131 548

5 Eden Park Drive

NORTH RYDE NSW 2113

LICENCE NO: 6113

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: 27 October 2014

INTERVET AUSTRALIA PTY LIMITED

ACN: 008 467 034

Unit B, 18 Lucca Road

WYONG NSW 2259

LICENCE NO: 6154

Product Types: *

- *Category 6*: Single step manufacture

Step(s) of Manufacture: Storage

Amended Licence Issued: 27 October 2014

DURABLEND PTY LTD

ACN: 094 764 315

6 Garling Road

KINGS PARK NSW 2148

LICENCE NO: 3035

Product Types:*

- *Category 3*: Powders
- *Category 4*: Powders

Step(s) of Manufacture: Formulation including blending, filling, packaging, labelling, strip, blister or sachet packaging, analysis and testing (physical) and storage.

Amended Licence Issued: 27 October 2014

* 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*

3. LICENCE CANCELLATIONS

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

CONTROLLED MEDICATIONS PTY LTD TRADING AS ALLFARM ANIMAL HEALTH
ACN: 005 977 739
2 Glendale Avenue
HASTINGS VIC 3915

LICENCE NO: 2134
Date Cancelled: 9 October 2014

FLYCAM PTY LTD
ACN: 059 194 491
Unit 7, 36 Achievement Crescent
ACACIA RIDGE QLD 4110

LICENCE NO: 6110
Date Cancelled: 9 October 2014

ALLFIREAH PTY LTD
ACN: 097 970 280
24–26 Hydrive Close
DANDENONG VIC 3175

LICENCE NO: 1084
Date Cancelled: 20 October 2014

THE PHARMACEUTICAL PLANT COMPANY PTY. LTD.
ACN: 058 801 335
2/24 London Drive
BAYSWATER NORTH VIC 3163

LICENCE NO: 2157
Date Cancelled: 24 October 2014

* 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*

4. LICENCE SUSPENSIONS

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

AUSTRALIAN ANIMAL BLOOD BANK PTY LTD

ACN: 140 128 990

50 Wills Road

LONG POINT NSW 2564

LICENCE NO: 1101

Date Suspended: 9 October 2014 to 9 April 2015

APVMA CONTACT

GMP Officer
Manufacturing, Quality and Licensing
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*

Cancellation of Registration and Approval at the Request of the Holder

At the request of the holder, the APVMA has cancelled the registration and the associated label approvals of the following product:

Product no.	Product/active name	Approval holder	Date of effect
59067	PACIFIC FENAMIPHOS 400 NEMATICIDE AND INSECTICIDE	PACIFIC AGRISCIENCE PTY LTD	1 December 2014

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

SUPPLY

A person may supply or cause to be supplied product manufactured prior to 1 December 2014 at wholesale and retail level, until the 1 December 2015.

After 1 December 2015 it will be an offence against the Agvet Codes to have possession or custody of the product with the intention to supply, or to supply the product.

USE

A person may continue to use the product according to its label instructions until 1 December 2015.

Any person who possesses, has custody of, uses, or otherwise deals with the listed product in accordance with the above instructions is taken to have been issued with a permit under the Agvet Codes to so possess, have custody of, use or otherwise deal with the product after the registration has been cancelled until 1 December 2015.

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

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

APVMA CONTACT

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

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

Phone: +61 2 6210 4749
Fax: +61 2 6210 4776
Email: chemicalreview@apvma.gov.au

Variations to Standard 1.4.2 of the Australia New Zealand Food Standards Code

The APVMA has previously gazetted particular amendments which it had made to the APVMA *MRL Standard* and which have been proposed as variations to maximum residue limits (MRLs) for substances contained in agricultural and veterinary chemical products as set out as in Standard 1.4.2 – Maximum Residue Limits of the *Australia New Zealand Food Standards Code*. This notice pertains to proposals (No. 8) gazetted on 23 September 2014 (No. APVMA 19).

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

Under subsection 82(1) of the *Food Standards Australia New Zealand Act 1991*, the APVMA has, by legislative instrument, incorporated these variations to MRLs into Standard 1.4.2. A copy of the Amendment Instrument (No. APVMA 9, 2014) accompanies this notice. For a complete and up-to-date version of Standard 1.4.2, including these amendments together with their Explanatory Statement, please refer to the Federal Register of Legislative Instrument available on the Comlaw website at www.comlaw.gov.au.

Based on dietary exposure assessments and current health standards, the APVMA and FSANZ are satisfied that these MRLs are not harmful to public health. MRLs contained in Standard 1.4.2 provide the limits for residues of agricultural and veterinary chemicals that may legitimately occur in foods. By this means, Standard 1.4.2 permits the sale of treated foods and protects public health by minimising residues in foods consistent with the effective control of pests and diseases.

The Agreement between the 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) made Sanitary and Phytosanitary (SPS) notification to the World Trade Organization (WTO) in relation to these variations and no comment was received in response to that notice.

A copy of these variations have been given to FSANZ.

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

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

For further information please contact:

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

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

Australia New Zealand Food Standards Code — Standard 1.4.2 — Maximum Residue Limits Amendment Instrument No. APVMA 10, 2014

I, Rajumati Bhula, Executive Director, Scientific Assessment and Chemical Review and delegate of the Australian Pesticides and Veterinary Medicines Authority, acting in accordance with my powers under subsection 11(1) of the *Agricultural and Veterinary Chemicals (Administration) Act 1992*, make this instrument for the purposes of subsection 82(1) of the *Food Standards Australia New Zealand Act 1991*.

Rajumati Bhula
Delegate of the Chief Executive Officer of the Australian Pesticides and Veterinary Medicines Authority

Dated this Twelfth day of December 2014

Part 1 Preliminary

1 Name of Instrument

This Instrument is the *Australia New Zealand Food Standards Code — Standard 1.4.2— Maximum Residue Limits Amendment Instrument No. APVMA 10, 2014*.

2 Commencement

Pursuant to subsection 82(8) of the *Food Standards Australia New Zealand Act 1991*, this Amendment Instrument commences on the day a copy of it is published in the *Gazette*.

Note: A copy of the variations made by the Amendment Instrument was published in the Commonwealth of Australia *Agricultural and Veterinary Chemicals Gazette* No. APVMA 25 of 16 December 2014.

3 Object

The object of this Instrument is for the APVMA to make variations to Standard 1.4.2 — Maximum Residue Limits of the *Australia New Zealand Food Standards Code* to include or change maximum residue limits pertaining to agricultural and veterinary chemical products.

4 Interpretation

In this Instrument: —

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

Principal Instrument means Standard 1.4.2 — Maximum Residue Limits of *the Australia New Zealand Food Standard Code* as defined in Section 4 of the *Food Standards Australia New Zealand Act 1991* being the code published in *Gazette* No. P 27 on 27 August 1987 together with any amendments of the standards in that code. The whole of the *Australia New Zealand Food Standard Code* (including Standard 1.4.2) was further published in *Gazette* P 30 of 20 December 2000.

Part 2 Variations to Standard 1.4.2 — Maximum Residue Limits

5 Variations to Standard 1.4.2

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

Schedule

Variations to Standard 1.4.2 — Maximum Residue Limits

1 Variations

(1) The Principal Instrument is varied by:

(a) *inserting in* Schedule 1 –

Derquantel Derquantel	
Sheep fat	0.0002
Sheep kidney	0.0002
Sheep liver	0.0002
Sheep muscle	0.0002
Didecyldimethylammonium chloride Didecyldimethylammonium chloride	
Assorted tropical and sub-tropical fruits—inedible peel	20

(b) *inserting in alphabetical order in* Schedule 1, *the foods and associated MRLs for each of the following chemicals*

Abamectin Sum of avermectin B1a, avermectin B1b and (Z)-8,9 avermectin B1a, and (Z)-8,9 avermectin B1b	
Avocado	T0.05
Passionfruit	T0.2
Potato	T0.01
Bifenazate Sum of bifenazate and bifenazate diazene (diazenecarboxylic acid, 2-(4-methoxy-[1,1′-biphenyl-3-yl] 1-methylethyl ester), expressed as bifenazate	
Melons, except watermelon	T0.3
Watermelon	T0.3
Bifenthrin Bifenthrin	
Chia	T0.2
Boscalid *Commodities of plant origin*: Boscalid *Commodities of animal origin*: Sum of boscalid, 2-chloro-N-(4′-chloro-5-hydroxybiphenyl-2-yl) nicotinamide and the glucuronide conjugate of 2-chloro-N-(4′-chloro-5-hydroxybiphenyl-2-yl) nicotinamide, expressed as boscalid equivalents	
Celery	T15
Chervil	T30
Coriander (leaves, stem, roots)	T30
Herbs	T30

Chlorantraniliprole *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)-1*H*-pyrazole-5-carboxamide, and 3-bromo-*N*-[4-chloro-2-(hydroxymethyl)-6-[[((hydroxymethyl)amino)carbonyl]phenyl]-1-(3-chloro-2-pyridinyl)-1*H*-pyrazole-5-carboxamide, expressed as chlorantraniliprole	
Chick-pea (dry)	0.07
Chlorothalonil *Commodities of plant origin*: Chlorothalonil *Commodities of animal origin*: 4-hydroxy-2,5,6-trichloroisophthalonitrile metabolite, expressed as chlorothalonil	
Onion, Welsh	T10
Persimmon, American	T5
Shallot	T10
Chlorpyrifos Chlorpyrifos	
Persimmon, American	T1
Clopyralid Clopyralid	
Poppy seed	T0.5
Clothianidin Clothianidin	
Popcorn	*0.01
Cyanamide Cyanamide	
Plums (including prunes)	*0.02
Cyantraniliprole *Commodities of plant origin:* Cyantraniliprole *Commodities of animal origin for enforcement:* Cyantraniliprole *Commodities of animal origin for dietary exposure assessment:* Sum of cyantraniliprole and 2-[3-bromo-1-(3-chloropyridin-2-yl)-1H-pyrazol-5-yl]-3,8-dimethyl-4-oxo-3,4-dihydroquinazoline-6-carbonitrile (IN-J9Z38), 2-[3-bromo-1-(3-chloropyridin-2-yl)-1H-pyrazol-5-yl]-8-methyl-4-oxo-3,4-dihydroquinazoline-6-carbonitrile (IN-MLA84), 3-bromo-1-(3-chloropyridin-2-yl)-N-{4-cyano-2-[(hydroxymethyl)carbamoyl]-6-methylphenyl}-1H-pyrazole-5-carboxamide (IN-MYX98) and 3-bromo-1-(3-chloropyridin-2-yl)-N-[4-cyano-2-(hydroxymethyl)-6-(methylcarbamoyl)phenyl]-1H-pyrazole-5-carboxamide (IN-N7B69), expressed as cyantraniliprole	
Bulb vegetables [except onion, bulb]	7
Fruiting vegetables, cucurbits	0.5
Fruiting vegetables, other than cucurbits	2
Onion, bulb	0.05
Potato	0.05

Cypermethrin Cypermethrin, sum of isomers	
Persimmon, American	T2
Persimmon, Japanese	T2
Cyromazine Cyromazine	
Mushrooms	10
Difenoconazole Difenoconazole	
Chard (silverbeet)	T3
Chicory leaves (green and red cultivars)	T3
Endive	T3
Spinach	T3
Flonicamid Flonicamid [*N* -(cyanomethyl)-4-(trifluoromethyl)-3-pyridinecarboxamide] and its metabolites TFNA [4-trifluoromethylnicotinic acid], TFNA-AM [4-trifluoromethylnicotinamide] TFNG [*N* -(4-trifluoromethylnicotinoyl)glycine]	
Fruiting vegetables, cucurbits	0.7
Pome fruits	0.7
Potato	0.2
Glufosinate and Glufosinate ammonium Sum of glufosinate-ammonium, N-acetyl glufosinate and 3-[hydroxy(methyl)-phosphinoyl] propionic acid, expressed as glufosinate (free acid)	
Peppers, Sweet (capsicum)	*0.05
Podded pea (young pods) (snow and sugar snap)	T1
Sugar cane	T*0.2
Hexythiazox Hexythiazox	
Cucumber	T1
Peas	T*0.05
Peppers, Sweet	T1
Tomato	T1
Imidacloprid Sum of imidacloprid and metabolites containing the 6-chloropyridinylmethylene moiety, expressed as imidacloprid	
Cereal grains [except maize; popcorn; sorghum]	*0.05
Popcorn	0.05
Indoxacarb Sum of indoxacarb and its *R*-isomer	
Chia	T*0.05
Metalaxyl Metalaxyl	
Asparagus	0.05
Vegetables [except asparagus; bulb vegetables (alliums); fruiting vegetables, cucurbits; leafy vegetables; peppers, Sweet; podded pea (young pods) (snow and sugar snap peas)]	T0.1

Methomyl Methomyl	
Persimmon, American	T0.2
Persimmon, Japanese	T0.2
Metolachlor Metolachlor	
Adzuki bean (dry)	T*0.05
Mung bean (dry)	T*0.05
Pulses [except soya beans (dry); adzuki bean (dry); mung bean (dry)]	*0.01
Milbemectin Sum of milbemycin MA_3 and milbemycin MA_4 and their photoisomers, milbemycin (Z) 8,9-MA_3 and (Z) 8,9-MA_4	
Fruiting vegetables, other than cucurbits	0.02
Oxamyl Sum of oxamyl and 2-hydroxyimino-N,N-dimethyl-2-(methylthio)-acetamide, expressed as oxamyl	
Onion, Welsh	T0.5
Shallot	T0.5
Spring onion	T0.5
Paclobutrazol Paclobutrazol	
Potato	T*0.01
Pirimicarb Sum of pirimicarb, demethyl-pirimicarb and the *N*-formyl-(methylamino) analogue (demethylformamido-pirimicarb), expressed as pirimicarb	
Pulses [except adzuki bean (dry); mung bean (dry); soya bean (dry)]	T*0.01
Pyriproxyfen Pyriproxyfen	
Brassica (cole or cabbage) vegetables, Head cabbages, Flowerhead brassicas	T0.7
Yard-long bean (pods)	T0.5
Trichlorfon Trichlorfon	
Thai egg plant	T0.5
Vegetables [except beetroot; Brussels sprouts; cape gooseberry; cauliflower; celery; egg plant; kale; pepino; peppers; pulses (dry); sugar beet; sweet corn (corn-on-the-cob); Thai egg plant]	0.1

(c) *omitting from* Schedule 1 *the foods and associated MRLs for each of the following chemicals –*

Cyanamide Cyanamide	
Stone fruits	T*0.05
Imidacloprid Sum of imidacloprid and metabolites containing the 6-chloropyridinylmethylene moiety, expressed as imidacloprid	
Cereal grains [except maize and sorghum]	*0.05
Metalaxyl Metalaxyl	
Vegetables [except bulb vegetables; fruiting vegetables, cucurbits; leafy vegetables; peppers; podded pea (young pods) (snow and sugar snap)]	T0.1
Metolachlor Metolachlor	
Beans [except broad bean and soya bean]	*0.02
Pulses [except soya bean (dry)]	T*0.05
Milbemectin Sum of milbemycin MA_3 and milbemycin MA_4 and their photoisomers, milbemycin (Z) 8,9-MA_3 and (Z) 8,9-MA_4	
Peppers, Sweet	0.02
Pirimicarb Sum of pirimicarb, demethyl-pirimicarb and the *N*-formyl-(methylamino) analogue (demethylformamido-pirimicarb), expressed as pirimicarb	
Lupin (dry)	*0.02
Trichlorfon Trichlorfon	
Vegetables [except beetroot; Brussels sprouts; cape gooseberry; cauliflower; celery; egg plant; kale; pepino; peppers; pulses; sugar beet; sweet corn (corn-on-the-cob)]	0.1

(d) *omitting from* Schedule 1, *under the entries for the following chemicals, the maximum residue limit for the food, substituting –*

Amoxycillin Inhibitory substance, identified as amoxycillin	
Eggs	*0.01
Boscalid *Commodities of plant origin*: Boscalid *Commodities of animal origin*: Sum of boscalid, 2-chloro-N-(4′-chloro-5-hydroxybiphenyl-2-yl) nicotinamide and the glucuronide conjugate of 2-chloro-N-(4′-chloro-5-hydroxybiphenyl-2-yl) nicotinamide, expressed as boscalid equivalents	
Bulb vegetables [except onion, bulb]	T5
Chlorantraniliprole *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)-1*H*-pyrazole-5-carboxamide, and 3-bromo-*N*-[4-chloro-2-(hydroxymethyl)-6-[[((hydroxymethyl)amino)carbonyl]phenyl]-1-(3-chloro-2-pyridinyl)-1*H*-pyrazole-5-carboxamide, expressed as chlorantraniliprole	
Mung bean (dry) Soya bean (dry)	0.7 0.07
Chlorpyrifos Chlorpyrifos	
Persimmon, Japanese	T1
Clothianidin Clothianidin	
Maize Rape seed (canola) Sorghum Sunflower seed Sweet corn (corn-on-the cob)	*0.01 *0.01 *0.01 *0.01 0.2
Etoxazole Etoxazole	
Citrus fruits	0.5
Flonicamid Flonicamid [*N* -(cyanomethyl)-4-(trifluoromethyl)-3-pyridinecarboxamide] and its metabolites TFNA [4-trifluoromethylnicotinic acid], TFNA-AM [4-trifluoromethylnicotinamide] TFNG [*N* -(4-trifluoromethylnicotinoyl)glycine]	
Cotton seed Edible offal (mammalian) Eggs Meat (mammalian) Milks Poultry, edible offal of Poultry meat	1 *0.02 *0.02 *0.02 *0.02 *0.02 *0.02

Iprodione Iprodione	
Beans [except broad bean and soya bean]	T2
Chard (silver beet)	T15
Prosulfocarb Prosulfocarb	
Pulses	*0.01
Pyriproxyfen Pyriproxyfen	
Beans [except broad bean and soya bean]	T0.5
Spirotetramat 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	
Pome fruits	0.5

Interim Pesticide and Veterinary Medicines Product Sales 13–14 Financial Year

This notice provides the collated interim product sales information provided to the APVMA for the 2013–14 financial year. The information includes product sales declarations received up until 12 December 2014. The interim information comprises 95.5% of all veterinary products and 92.5% of all agricultural products. In total the APVMA has received 94.00% of product sales/disposals declarations. A further and final notice of product sales data for the 2013–14 financial year will be gazetted in March 2015.

AGRICULTURAL (PESTICIDES) PRODUCT SALES FOR THE 13–14 FINANCIAL YEAR

AGRICULTURAL PRODUCT TYPES	NO OF PRODUCTS	TOTAL $
ADJUVANT/SURFACTANTS	412	79,246,892
ANTIFOULING—BOAT	46	17,286,771
DAIRY CLEANSER	138	12,109,122
DISINFECTANT/SANITISER	98	9,596,238
FUNGICIDE	874	174,088,287
GROWTH PROMOTERS/REGULATORS	242	33,894,411
HERBICIDE	3083	1,474,620,548
HOUSEHOLD INSECTICIDE	614	137,551,462
INSECTICIDE	1365	355,283,567
MISCELLANEOUS	72	8,276,782
MITICIDE	122	13,588,544
MIXED FUNCTION PESTICIDE	148	26,190,984
MOLLUSCICIDE	53	16,587,594
NEMATICIDE	20	3,758,562
POOL PRODUCTS/ALGICIDE	755	42,489,351
REPELLENT—DOGS/BIRDS ETC	24	1,372,179
SEED TREATMENTS	172	38,232,508
VERTEBRATE POISON	206	19,041,783
WOOD PRESERVATIVE	120	53,186,664
GRAND TOTAL	**8564**	**2,516,402,249**

VETERINARY MEDICINES PRODUCT SALES FOR THE 13–14 FINANCIAL YEAR

VETERINARY PRODUCT TYPES		NO OF PRODUCTS	TOTAL $
ALIMENTARY SYSTEM	ANTI BLOAT	16	1,294,072
ALIMENTARY SYSTEM	ANTIDIARRHOEALS AND SCOUR TREATMENTS	17	975,211
ALIMENTARY SYSTEM	LAXATIVES, PURGATIVES & LUBICANTS, ANTISPASMODICS	14	2,036,032
ANAESTHETICS/ANALGESICS	ANAESTHETICS—LOCAL AND GENERAL	56	10,364,149
ANAESTHETICS/ANALGESICS	ANALGESICS	20	5,444,651
ANTIBIOTIC & RELATED	ANTIBIOTIC—INTRAMAMMARY	27	10,846,550
ANTIBIOTIC & RELATED	ANTIBIOTIC—ORAL	188	24,500,384
ANTIBIOTIC & RELATED	ANTIBIOTIC—PARENTERAL	80	22,305,846
ANTIBIOTIC & RELATED	OTHER ANTI-INFECTIVE AGENTS	46	1,599,585
ANTIBIOTIC & RELATED	SULFONAMIDES	41	2,892,699
ANTIDOTES	ANTIDOTES	16	1,332,001
CARDIOVASCULAR SYSTEM	CARDIAC REACTANTS, CLOTTING AGENTS	40	7,794,048
CENTRAL NERVOUS SYSTEM	HYPNOTICS, TRANQUILIZERS, EMETICS, ANTIEMETICS	42	4,075,308
DERMATOLOGICAL PREPS	ANTIBIOTICS, ANTIFUNGALS, CORTICOSTEROID COMBINATIONS	30	2,354,032
DERMATOLOGICAL PREPS	ANTISEPTICS (DERMATOLOGICAL AND GENERAL)	145	23,514,362
DERMATOLOGICAL PREPS	NONSTEROIDAL ANTIPRURITICS, KERATOLYICS	35	5,314,490
EAR,NOSE,THROAT PREPS	AURAL	27	5,792,259
ENDOCRINE SYSTEM	ANABOLIC STEROIDS	21	355,491
ENDOCRINE SYSTEM	CORTICOSTEROIDS AND ADRENAL COMPOUNDS	33	2,987,491

VETERINARY PRODUCT TYPES		NO OF PRODUCTS	TOTAL $
ENDOCRINE SYSTEM	SEX HORMONES	55	8,243,596
ENDOCRINE SYSTEM	TROPIC HORMONES (PITUITARY) & INSULIN PREPARATIONS	35	6,091,283
GENITOURINARY SYSTEM	DIURETICS, ACIDIFIERS, ALKANISERS	26	1,674,454
GENITOURINARY SYSTEM	UTERINE OR VAGINAL ACTING AGENTS	7	1,028,650
IMMUNOTHERAPY	ANTISERA, ANTIVENIM	11	3,272,303
IMMUNOTHERAPY	IMMUNOMODIFYING AGENTS	12	3,535,383
IMMUNOTHERAPY	INJECTABLE VACCINES	175	133,591,033
IMMUNOTHERAPY	NASAL, ORAL, OPTHALMIC VACCINES	33	27,820,596
MISC	MISC	80	20,094,992
MUSCULOSKELETAL SYSTEM	ANTI-INFLAMMATORY AGENTS	229	32,873,765
MUSCULOSKELETAL SYSTEM	COUNTER-IRRITANTS, RUBEFACIENTS, POULTICES	16	2,429,271
NUTRITION & METABOLISM	ANTIBIOTIC AND ANTI-INFECTIVE SUPPLEMENTS	48	3,899,091
NUTRITION & METABOLISM	DIETARY/THERAPEUTIC PET FOODS	148	58,060,774
NUTRITION & METABOLISM	DIGESTIVE ENZYME SUPPLEMENTS	80	17,674,222
NUTRITION & METABOLISM	ELECTROLYTES	70	4,292,423
NUTRITION & METABOLISM	GROWTH PROMOTANTS	69	25,516,782
NUTRITION & METABOLISM	IRON AND HAEMOPOIETIC AGENTS	21	1,665,227
NUTRITION & METABOLISM	PROBIOTIC AND PREBIOTIC	22	1,305,669
NUTRITION & METABOLISM	TONICS, STIMULANTS	13	618,985
NUTRITION & METABOLISM	VITAMIN, MINERAL, & NUTRITIONAL SUPPLEMENTS	228	26,889,524
OPHTHALMIC PREPARATIONS	OPHTHALMIC PREPARATIONS	22	4,960,016
PARASITICIDES	BIRDS—EXTERNAL	12	321,463

VETERINARY PRODUCT TYPES		NO OF PRODUCTS	TOTAL $
PARASITICIDES	BIRDS—INTERNAL	31	2,627,200
PARASITICIDES	LARGE & SMALL ANIMALS—EXTERNAL	18	1,840,150
PARASITICIDES	LARGE ANIMALS—EXTERNAL	187	70,093,759
PARASITICIDES	LARGE ANIMALS—INTERNAL	294	51,917,861
PARASITICIDES	LARGE ANIMALS—INTERNAL & EXTERNAL	86	55,503,289
PARASITICIDES	SMALL ANIMALS—EXTERNAL	203	92,836,797
PARASITICIDES	SMALL ANIMALS—INTERNAL	250	79,898,001
PARASITICIDES	SMALL ANIMALS & BIRDS—EXTERNAL	5	1,003,723
PARASITICIDES	SMALL ANIMALS INTERNAL AND EXTERNAL	28	54,766,076
RESPIRATORY SYSTEM	EXPECTORANTS, MUCOLYTICS, DECONGESTANTS, BRONCHODILATORS, RESP STIMULANTS	22	1,216,145
	GRAND TOTAL	**3430**	**933,341,164**

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