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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/news-and-publications/publications/gazette

If you would like to receive email notification when a new edition is published, please subscribe on the APVMA website.

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Agricultural Chemical Products and Approved Labels

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

1. AGRICULTURAL PRODUCTS BASED ON EXISTING ACTIVE CONSTITUENTS

Application no.:	105778
Product name:	82448
Active constituent/s:	625 g/L 2,4-D present as the dimethylamine and diethanolamine salts
Applicant name:	Ruralco Holdings Limited
Applicant ACN:	009 660 879
Summary of use	For the control of broadleaf weeds in fallow before direct drilling or sowing of cereals and pastures; and in cereal crops, pastures, sugar cane, peanuts and non-agricultural areas
Date of registration/approval:	16 July 2016
Product registration no.:	82448
Label approval no.:	82448/105778
Application no.:	105139
Product name:	Allout 360 Herbicide
Active constituent/s:	360 g/L glyphosate present as the isopropylamine salt
Applicant name:	UPL Australia Limited
Applicant ACN:	066 391 384
Summary of use	For control of a wide range of annual and perennial weeds in a variety of situations
Date of registration/approval:	8 June 2016
Product registration no.:	82180
Label approval no.:	82180/105139
Application no.:	103921
Product name:	ACP Chlorpyrifos 500 Insecticide
Active constituent/s:	500 g/L Chlorpyrifos (an anti-cholinesterase compound)
Applicant name:	Australis Crop Protection Pty Ltd
Applicant ACN:	150 711 185
Summary of use	For the control of certain insect pests of cassava, cereals, forage crops, fruit, ginger, grapevines, hops, oilseeds, pasture, pineapples, sugarcane, turf and vegetable crops
Date of registration/approval:	8 June 2016
Product registration no.:	81735
Label approval no.:	81735/103921
Application no.:	105482
Product name:	Veritas Fungicide
Active constituent/s:	200 g/L tebuconazole 120 g/L azoxystrobin
Applicant name:	Adama Australia Pty Limited
Applicant ACN:	050 328 973
Summary of use	For the control or suppression of various foliar fungal diseases in barley, wheat and peanuts
Date of registration/approval:	8 June 2016
Product registration no.:	82348
Label approval no.:	82348/105482

Application no.:	105873
Product name:	Zeal Selective Miticide
Active constituent/s:	110 g/L etoxazole
Applicant name:	Sumitomo Chemical Australia Pty Limited
Applicant ACN:	081 096 255
Summary of use	For the control of mites in cotton
Date of registration/approval:	9 June 2016
Product registration no.:	82491
Label approval no.:	82491/105873
Application no.:	101291
Product name:	Tervigo Nematicide
Active constituent/s:	20 g/L abamectin
Applicant name:	Syngenta Australia Pty Ltd
Applicant ACN:	002 933 717
Summary of use	For the control of root-knot nematodes (<i>meloidogyne spp.</i>) in fruiting vegetables and cucurbits
Date of registration/approval:	10 June 2016
Product registration no.:	80620
Label approval no.:	80620/101291
Application no.:	105144
Product name:	Relyon Quizon 200EC Herbicide
Active constituent/s:	200 g/L quizalofop-p-ethyl
Applicant name:	Ruralco Holdings Limited
Applicant ACN:	009 660 879
Summary of use	For use in certain broadleaf crops to control certain grass weeds
Date of registration/approval:	10 June 2016
Product registration no.:	82183
Label approval no.:	82183/105144
Application no.:	105683
Product name:	3-D Herbicide
Active constituent/s:	192 g/L bentazone present as the sodium salt, 112 g/L MCPA present as the dimethylamine salt, 19 g/L dicamba present as the dimethylamine salt
Applicant name:	Adama Australia Pty Limited
Applicant ACN:	050 328 973
Summary of use	For the control of mullumbimby couch and broadleaf weeds in turf
Date of registration/approval:	10 June 2016
Product registration no.:	82412
Label approval no.:	82412/105683
Application no.:	103591
Product name:	Macspred Trimac GR Granular Herbicide
Active constituent/s:	44 g/kg terbacil 2 g/kg sulfometuron methyl
Applicant name:	Macspred Pty. Ltd
Applicant ACN:	011 029 495
Summary of use	For the control of certain annual and perennial weeds in commercial and industrial areas
Date of registration/approval:	16 June 2016
Product registration no.:	81670
Label approval no.:	81670/103591

Application no.:	103463
Product name:	Farmalinx Rinkals Fungicide
Active constituent/s:	500 g/kg boscalid
Applicant name:	Farmalinx Pty Ltd
Applicant ACN:	134 353 245
Summary of use	For the control of bunch rot (<i>botrytis cinerea</i>) in grapevines
Date of registration/approval:	17 June 2016
Product registration no.:	81615
Label approval no.:	81615/103463
Application no.:	106174
Product name:	Ozcrop Flumetsulam 800 WG Herbicide
Active constituent/s:	800 g/kg flumetsulam
Applicant name:	Ozcrop Pty. Ltd
Applicant ACN:	160 656 431
Summary of use	For the post emergence and salvage control of certain broadleaf weeds in winter cereals (including those undersown with clover, lucerne or medics) clover, fenugreek, lathyrus, lucerne, medic, serradella and vetch (popany only) seed crops and pastures, chickpeas, field peas, lentils, maize, peanuts and for the pre emergence control on certain broadleaf weeds in maize and soybeans
Date of registration/approval:	17 June 2016
Product registration no.:	82599
Label approval no.:	82599/106174
Application no.:	102947
Product name:	Ardeo Herbicide
Active constituent/s:	224 g/L acifluorfen present as the sodium salt
Applicant name:	Adama Australia Pty Limited
Applicant ACN:	050 328 973
Summary of use	For the control of broadleaf weeds and grasses as per the directions for use in mung beans, adzuki beans, peanuts, soybeans, green beans, and seed crops of siratro
Date of registration/approval:	17 June 2016
Product registration no.:	81376
Label approval no.:	81376/102947
Application no.:	106063
Product name:	ACP Imidacloprid 600 Seed Treatment Insecticide
Active constituent/s:	600 g/L imidacloprid
Applicant name:	Australis Crop Protection Pty Ltd
Applicant ACN:	150 711 185
Summary of use	For the control of various insect pests in a range of crops and the protection of spread of barley yellow dwarf virus in cereal crops
Date of registration/approval:	17 June 2016
Product registration no.:	82558
Label approval no.:	82558/106063

Application no.:	105880
Product name:	eChem Simazine 900 WG Herbicide
Active constituent/s:	900 g/kg simazine
Applicant name:	Echem (Aust) Pty Limited
Applicant ACN:	089 133 095
Summary of use	For the control of weeds in chickpeas, lupins, T-T canola, orchards, vineyards and certain other horticultural crops and non-crop situations
Date of registration/approval:	17 June 2016
Product registration no.:	82494
Label approval no.:	82494/105880

2. VARIATIONS OF REGISTRATION

Application no.:	104889
Product name:	Crop Care Intercept Herbicide
Active constituent/s:	33 g/L imazamox 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	To update label details
Date of registration/approval:	15 June 2016
Product registration no.:	69353
Label approval no.:	69353/104889

Application no.:	106644
Product name:	Family Protection Aerogard Odourless Protection Low Irritant* 4 Hours Protection Great For Kids 12 Months + Insect Repellent Roll On
Active constituent/s:	99.6 g/L picaridin
Applicant name:	Reckitt Benckiser (Australia) Pty Limited
Applicant ACN:	003 274 655
Summary of variation:	To change the distinguishing product name and the name that appears on the label from 'FAMILY PROTECTION AEROGARD ODOURLESS PROTECTION 4 HOURS PROTECTION LOW IRRITANT* GREAT FOR KIDS 12 MONTHS + INSECT REPELLENT ROLL ON' to 'FAMILY PROTECTION AEROGARD ODOURLESS PROTECTION LOW IRRITANT* 4 HOURS PROTECTION GREAT FOR KIDS 12 MONTHS + INSECT REPELLENT ROLL ON'
Date of variation:	16 May 2016
Product registration no.:	61363
Label approval no.:	61363/106644

Application no.:	106795
Product name:	Richgro Naturally Based Fruit Fly Spray Concentrate
Active constituent/s:	150 g/L garlic, 4 g/L pyrethrins, 16 g/L piperonyl butoxide
Applicant name:	A. Richards Pty Ltd T/A Richgro Garden Products
Applicant ACN:	008 734 852
Summary of variation:	To change the distinguishing product name and the name that appears on the label from 'RICHGRO NATURALLY BASED FRUIT FLY SPRAY' to 'RICHGRO NATURALLY BASED FRUIT FLY SPRAY CONCENTRATE'
Date of variation:	27 May 2016
Product registration no.:	81339
Label approval no.:	81339/106795

Application no:	106806
Product name:	Rumba 300 Herbicide
Active constituent/s:	300 g/L clopyralid present as the triisopropanolamine salt
Applicant name:	Rotam Agrochemical Co., Ltd
Applicant ACN:	N/A
Summary of variation:	To change the distinguishing product name and the name that appears on the label from 'ROTAM CLOPYRALID 300 HERBICIDE' to 'RUMBA 300 HERBICIDE'
Date of variation:	30 May 2016
Product registration no.:	81080
Label approval no.:	81080/106806
Application no:	106878
Product name:	Rophosate 700 Herbicide
Active constituent/s:	700 g/kg glyphosate present as the mono-ammonium salt
Applicant name:	Rotam Agrochemical Co., Ltd
Applicant ACN:	N/A
Summary of variation:	To change the distinguishing product name and the name that appears on the label from 'ROTAM GLYPHOSATE 700 HERBICIDE' to 'ROPHOSATE 700 HERBICIDE'
Date of variation:	3 June 2016
Product registration no.:	81320
Label approval no.:	81320/106878
Application no:	105677
Product name:	Yates Weed 'N' Feed Granular
Active constituent/s:	50 g/kg iron as ferrous sulfate
Applicant name:	Duluxgroup (Australia) Pty Ltd
Applicant ACN:	000 049 427
Summary of variation:	To change the product name from 'YATES DOUBLE ACTION WEED 'N' FEED GRANULAR' to 'YATES WEED 'N' FEED GRANULAR'
Date of variation:	8 June 2016
Product registration no.:	39868
Label approval no.:	39868/105677
Application no:	63371
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 extend the use on to cotton, almonds and pistachios, various vegetables, crops, and ornamental and nursery crops for control of aphids and silverleaf whitefly
Date of variation:	9 June 2016
Product registration no.:	53311
Label approval no.:	53311/63371
Application no.:	104029
Product name:	Generation Block Single-Feed Rodenticide
Active constituent/s:	0.025 g/kg difethialone
Applicant name:	Liphatech S.A.S
Applicant ACN:	N/A
Summary of use	To reduce the use rates against rats
Date of registration/approval:	15 June 2016
Product registration no.:	62694
Label approval no.:	62694/104029

Application no.:	104899
Product name:	Richgro Bug Killa Granular Garden Insecticide
Active constituent/s:	70 g/kg imidacloprid
Applicant name:	A. Richards Pty Ltd T/A Richgro Garden Products
Applicant ACN:	008 734 852
Summary of variation:	To extend the period of protection, to add two pests with all pests besides scarab beetle larvae characterised as 'sucking insects' and to provide appropriate rates of use for ornamentals in pots and ornamentals in the ground
Date of variation:	9 June 2016
Label approval no.:	67498/104899
Application no:	106243
Product name:	Fipforce Aqua Termiticide & Insecticide
Active constituent/s:	100 g/L fipronil
Applicant name:	Sherwood Chemicals Public Company Limited
Applicant ACN:	N/A
Summary of variation:	To add control of ants
Date of variation:	17 June 2016
Product registration no.:	63789
Label approval no.:	63789/106243
Application no:	105965
Product name:	Valor 500 WG Herbicide
Active constituent/s:	500 g/kg flumioxazin
Applicant name:	Sumitomo Chemical Australia Pty Limited
Applicant ACN:	081 096 255
Summary of variation:	To add additional claims for knockdown and residual control of various grass and broadleaf weeds in sugarcane
Date of variation:	17 June 2016
Product registration no.:	61622
Label approval no.:	61622/105965
Application no:	103559
Product name:	Melpat Bordeaux WG Bactericide/Fungicide
Active constituent/s:	200 g/kg copper (CU) present as tribasic copper sulphate
Applicant name:	Melpat International Pty Ltd
Applicant ACN:	066 067 507
Summary of variation:	To extend the uses to include hazelnuts, pistachios and macadamias
Date of variation:	17 June 2016
Product registration no.:	62430
Label approval no.:	62430/103559
Application no:	63110
Product name:	Umine 625 Selective Herbicide
Active constituent/s:	625 g/L 2,4-D present as the dimethylamine and diethanolamine salts
Applicant name:	UPL Australia Limited
Applicant ACN:	066 391 384
Summary of variation:	To extend the use to include maize and sweet corn, expand the use to winter cereals, sorghum and peanuts, add additional weeds and update disposal statements
Date of variation:	20 June 2016
Product registration no.:	68363
Label approval no.:	68363/63110

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. VARIATIONS OF REGISTRATION

Application no.:	102756
Product name:	Nexgard Chewables for Dogs 25.1–50 kg
Active constituent/s:	Each chew contains 136 mg afoxolaner
Applicant name:	Merial Australia Pty Ltd
Applicant ACN:	071 187 285
Summary of variation:	To extend the claims to control flea allergy dermatitis, speed of kill of fleas and kill newly acquired fleas
Date of variation:	10 June 2016
Product registration no.:	67939
Label approval no.:	67939/102756

Application no.:	102732
Product name:	Nexgard Chewables for Dogs 10.1–25 kg
Active constituent/s:	Each chew contains 68 mg afoxolaner
Applicant name:	Merial Australia Pty Ltd
Applicant ACN:	071 187 285
Summary of variation:	To extend the claims to control flea allergy dermatitis, speed of kill of fleas and kill newly acquired fleas
Date of variation:	10 June 2016
Product registration no.:	67940
Label approval no.:	67940/102732

Application no.:	102751
Product name:	Nexgard Chewables for Dogs 4.1–10 kg
Active constituent/s:	Each chew contains 28.3 mg afoxolaner
Applicant name:	Merial Australia Pty Ltd
Applicant ACN:	071 187 285
Summary of variation:	To extend the claims to control flea allergy dermatitis, speed of kill of fleas and kill newly acquired fleas
Date of variation:	10 June 2016
Product registration no.:	67941
Label approval no.:	67941/102751

Application no.:	102752
Product name:	Nexgard Chewables for Dogs 2–4 kg
Active constituent/s:	Each chew contains 11.3 mg afoxolaner
Applicant name:	Merial Australia Pty Ltd
Applicant ACN:	071 187 285
Summary of variation:	To extend the claims to control flea allergy dermatitis, speed of kill of fleas and kill newly acquired fleas
Date of variation:	10 June 2016
Product registration no.:	67942
Label approval no.:	67942/102752

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.

Note: The APVMA is currently assigning separate approval numbers for vet actives which means some vet actives listed in this gazette will have an approval date that occurred in the past. [For more information.](#)

1. ACTIVE CONSITUTENT

Application no.:	104034
Active constituent/s:	Amicarbazone
Applicant name:	Arysta Lifescience North America LLC
Applicant ACN:	N/A
Summary of use:	For use in agricultural chemical products
Date of approval:	8 June 2016
Approval no.:	81775

Application no.:	104101
Active constituent/s:	Prothioconazole
Applicant name:	UPL Australia Limited
Applicant ACN:	066 391 384
Summary of use:	For use in agricultural chemical products
Date of approval:	9 June 2016
Approval no.:	81815

Application no.:	104449
Active constituent/s:	Dicamba
Applicant Name:	Syngenta Australia Pty Ltd
Applicant ACN:	002 933 717
Summary of use:	For use in agricultural chemical products
Date of approval:	10 June 2016
Approval no.:	81933

Application no.:	103810
Active constituent/s:	Pinoxaden
Applicant name:	Grow Choice Pty Limited
Applicant ACN:	069 839 961
Summary of use:	For use in agricultural chemical products
Date of approval:	15 June 2016
Approval no.:	81716

Application no.:	62645
Active constituent/s:	Amisulbrom
Applicant name:	Nufarm Australia Limited
Applicant ACN:	004 377 780
Summary of use:	For use in agricultural chemical products
Date of approval:	16 June 2016
Approval no.:	70162

ACTIVE CONSTITUENT

Application no.:	105786
Active constituent/s:	Florfenicol
Applicant name:	Elanco Australasia Pty Ltd
Applicant ACN:	076 745 198
Summary of use:	For use in veterinary chemical products
Date of approval:	5 April 2016
Approval no.:	82453

Application no.:	105787
Active constituent/s:	Betamethasone Acetate
Applicant name:	Elanco Australasia Pty Ltd
Applicant ACN:	076 745 198
Summary of use:	For use in veterinary chemical products
Date of approval:	5 April 2016
Approval no.:	82454

Application no.:	106024
Active constituent/s:	Praziquantel
Applicant name:	Intervet Australia Pty Limited
Applicant ACN:	008 467 034
Summary of use:	For use in veterinary chemical products
Date of approval:	6 April 2016
Approval no.:	82544

Application no.:	103868
Active constituent/s:	Pimobendan
Applicant name:	Eurovet Animal Health BV
Applicant ACN:	N/A
Summary of use:	For use in veterinary chemical products
Date of approval:	29 April 2016
Approval no.:	81722

Application no.:	106417
Active constituent/s:	Ivermectin
Applicant name:	Abbey Laboratories Pty Ltd
Applicant ACN:	156 000 430
Summary of use:	For use in veterinary chemical products
Date of approval:	6 May 2016
Approval no.:	82676

Application no.:	106027
Active constituent/s:	Amoxicillin Trihydrate
Applicant name:	Neove Pharma Australia Pty Limited
Applicant ACN:	140 367 442
Summary of use:	For use in veterinary chemical products
Date of approval:	10 June 2016
Approval no.:	82547

Application no.:	104508
Active constituent/s:	Milbemycin Oxime
Applicant name:	Virbac (Australia) Pty Ltd
Applicant ACN:	003 268 871
Summary of use:	For use in veterinary chemical products
Date of approval:	20 June 2016
Approval no.:	81964

Application no.:	104357
Active constituent/s:	Praziquantel
Applicant name:	Virbac (Australia) Pty Ltd
Applicant ACN:	003 268 871
Summary of use:	For use in veterinary chemical products
Date of approval:	21 June 2016
Approval no.:	81894

Application no.:	107000
Active constituent/s:	Eprinomectin
Applicant name:	Bayer Australia Ltd (Animal Health)
Applicant ACN:	000 138 714
Summary of variation:	For use in veterinary chemical products
Date of variation:	22 June 2016
Approval no.:	828862

Application no.:	106517
Active constituent/s:	Florfenicol
Applicant name:	Abbey Laboratories Pty Ltd
Applicant ACN:	156 000 430
Summary of use:	For use in veterinary chemical products
Date of approval:	23 June 2016
Approval no.:	82713

Application no.:	106511
Active constituent/s:	Toltrazuril
Applicant name:	Abbey Laboratories Pty Ltd
Applicant ACN:	156 000 430
Summary of use:	For use in veterinary chemical products
Date of approval:	23 June 2016
Approval no.:	82707

Application no.:	104450
Active constituent/s:	Praziquantel
Applicant name:	Virbac (Australia) Pty Ltd
Applicant ACN:	003 268 871
Summary of use:	For use in veterinary chemical products
Date of approval:	23 June 2016
Approval no.:	81934

Application no.:	104768
Active constituent/s:	Moxidectin
Applicant name:	Virbac (Australia) Pty Ltd
Applicant ACN:	003 268 871
Summary of use:	For use in veterinary chemical product
Date of approval:	23 June 2016
Approval no.:	81990

Application no.:	105259
Active constituent/s:	Proprantheline Bromide
Applicant name:	Caledonian Holdings Distribution Pty Ltd
Applicant ACN:	122 162 190
Summary of use:	For use in veterinary chemical products
Date of approval:	24 June 2016
Approval no.:	82237

VARIATIONS OF ACTIVE CONSTITUENT

Application no.:	103563
Active constituent/s:	Afoxolaner
Applicant name:	Merial Australia Pty Ltd
Applicant ACN:	071 184 285
Summary of variation:	Variation of relevant particulars or conditions of an approved active constituent
Date of variation:	14 April 2016
Approval no.:	81625

Application no.:	103633
Active constituent/s:	Mepivacaine Hydrochloride
Applicant name:	Ceva Animal Health Pty Ltd
Applicant ACN:	002 692 426
Summary of variation:	Variation of relevant particulars or conditions of an approved active constituent
Date of variation:	15 April 2016
Approval no.:	55807

Application no.:	104031
Active constituent/s:	Clorsulon
Applicant name:	Merial Australia Pty Ltd
Applicant ACN:	071 184 285
Summary of variation:	Variation of relevant particulars or conditions of an approved active constituent
Date of variation:	4 May 2016
Approval no.:	54900

Application no.:	104267
Active constituent/s:	Ivermectin
Applicant name:	Merial Australia Pty Ltd
Applicant ACN:	071 184 285
Summary of variation:	Variation of relevant particulars or conditions of an approved active constituent
Date of variation:	6 May 2016
Approval no.:	81625

Application no.:	104980
Active constituent/s:	Mepivacaine Hydrochloride
Applicant name:	Ceva Animal Health Pty Ltd
Applicant ACN:	002 692 426
Summary of variation:	Variation of relevant particulars or conditions of an approved active constituent
Date of variation:	16 May 2016
Approval no.:	55807
Application no.:	106121
Active constituent/s:	Praziquantel
Applicant name:	Chanelle Pharmaceuticals Manufacturing Ltd
Applicant ACN:	N/A
Summary of variation:	Variation of relevant particulars or conditions of an approved active constituent
Date of variation:	1 June 2016
Approval no.:	82471
Application no.:	106392
Active constituent/s:	Fenbendazole
Applicant name:	Chanelle Pharmaceuticals Manufacturing Ltd
Applicant ACN:	N/A
Summary of variation:	Variation of relevant particulars or conditions of an approved active constituent
Date of variation:	1 June 2016
Approval no.:	82473
Application no.:	105991
Active constituent/s:	Clindamycin Hydrochloride
Applicant name:	Chanelle Pharmaceuticals Manufacturing Ltd
Applicant ACN:	N/A
Summary of variation:	Variation of relevant particulars or conditions of an approved active constituent
Date of variation:	8 June 2016
Approval no.:	82458
Application no.:	100254
Active constituent/s:	Propoxur
Applicant name:	Bayer Australia Ltd (Animal Health)
Applicant ACN:	000 138 714
Summary of variation:	Variation of relevant particulars or conditions of an approved active constituent
Date of variation:	20 June 2016
Approval no.:	44570
Application no.:	103666
Active constituent/s:	Carprofen
Applicant name:	Zoetis Australia Pty Ltd
Applicant ACN:	156 476 425
Summary of variation:	Variation of relevant particulars or conditions of an approved active constituent
Date of variation:	21 June 2016
Approval no.:	54831

Application no.:	104434
Active constituent/s:	Melarsomine Dihydrochloride
Applicant name:	Merial Australia Pty Ltd
Applicant ACN:	071 184 285
Summary of variation:	Variation of relevant particulars or conditions of an approved active constituent
Date of variation:	21 June 2016
Approval no.:	55803
Application no.:	103426
Active constituent/s:	Albendazole
Applicant name:	Merial Australia Pty Ltd
Applicant ACN:	071 184 285
Summary of variation:	Variation of relevant particulars or conditions of an approved active constituent
Date of variation:	21 June 2016
Approval no.:	81918
Application no.:	104478
Active constituent/s:	Levamisole Base
Applicant name:	Merial Australia Pty Ltd
Applicant ACN:	071 184 285
Summary of variation:	Variation of relevant particulars or conditions of an approved active constituent
Date of variation:	22 June 2016
Approval no.:	81860
Application no.:	104497
Active constituent/s:	Oxfendazole
Applicant name:	Merial Australia Pty Ltd
Applicant ACN:	071 184 285
Summary of variation:	Variation of relevant particulars or conditions of an approved active constituent
Date of variation:	22 June 2016
Approval no.:	81916
Application no.:	104769
Active constituent/s:	Praziquantel
Applicant name:	Merial Australia Pty Ltd
Applicant ACN:	071 184 285
Summary of variation:	Variation of relevant particulars or conditions of an approved active constituent
Date of variation:	22 June 2016
Approval no.:	81873
Application no.:	105277
Active constituent/s:	Carprofen
Applicant name:	Apex Laboratories Pty Ltd
Applicant ACN:	000 397 240
Summary of variation:	Variation of relevant particulars or conditions of an approved active constituent
Date of variation:	23 June 2016
Approval no.:	82092

Application no.:	105354
Active constituent/s:	Frusemide
Applicant name:	Apex Laboratories Pty Ltd
Applicant ACN:	000 397 240
Summary of variation:	Variation of relevant particulars or conditions of an approved active constituent
Date of variation:	23 June 2016
Approval no.:	82061

Pursuant to the Agricultural and Veterinary Chemicals Code scheduled to the *Agricultural and Veterinary Chemicals Code Act 1994*, s14A, 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 CONSTITUTENT

Application no.:	106553
Active constituent/s:	Copper Oxide
Applicant name:	Australian Pesticides and Veterinary Medicines Authority
Applicant ACN:	N/A
Summary of use:	For use in veterinary chemical products
Date of approval:	4 August 1995
Approval no.:	82730

Application no.:	30885
Active constituent/s:	Sodium Glycerophosphate
Applicant name:	Australian Pesticides and Veterinary Medicines Authority
Applicant ACN:	N/A
Summary of use:	For use in veterinary chemical products
Date of approval:	20 December 1999
Approval no.:	57591

Application no.:	30681
Active constituent/s:	Manganese (II) Sulphate
Applicant name:	Australian Pesticides and Veterinary Medicines Authority
Applicant ACN:	N/A
Summary of use:	For use in veterinary chemical products
Date of approval:	3 March 2000
Approval no.:	57399

Application no.:	30578
Active constituent/s:	Iron and its Salts as Ammonium Ferric Citrate
Applicant name:	Australian Pesticides and Veterinary Medicines Authority
Applicant ACN:	N/A
Summary of use:	For use in veterinary chemical products
Date of approval:	1 August 2001
Approval no.:	57312

Application no.:	25189
Active constituent/s:	Choline Bitartrate
Applicant name:	Australian Pesticides and Veterinary Medicines Authority
Applicant ACN:	N/A
Summary of use:	For use in veterinary chemical products
Date of approval:	19 October 2001
Approval no.:	54862

Application no.:	30358
Active constituent/s:	Bismuth Subnitrate
Applicant name:	Australian Pesticides and Veterinary Medicines Authority
Applicant ACN:	N/A
Summary of use:	For use in veterinary chemical products
Date of approval:	19 December 2001
Approval no.:	57108

Application no.:	26136
Active constituent/s:	Biotin-D
Applicant name:	Australian Pesticides and Veterinary Medicines Authority
Applicant ACN:	N/A
Summary of use:	For use in veterinary chemical products
Date of approval:	30 January 2002
Approval no.:	55386

Application no.:	30390
Active constituent/s:	Choline Chloride
Applicant name:	Australian Pesticides and Veterinary Medicines Authority
Applicant ACN:	N/A
Summary of use:	For use in veterinary chemical products
Date of approval:	19 March 2003
Approval no.:	57140

Application no.:	30855
Active constituent/s:	Shark Cartilage
Applicant name:	Australian Pesticides and Veterinary Medicines Authority
Applicant ACN:	N/A
Summary of use:	For use in veterinary chemical products
Date of approval:	27 March 2003
Approval no.:	57562

Application no.:	30900
Active constituent/s:	Sodium Selenate
Applicant name:	Australian Pesticides and Veterinary Medicines Authority
Applicant ACN:	N/A
Summary of use:	For use in veterinary chemical products
Date of approval:	27 March 2003
Approval no.:	57604

Application no.:	27100
Active constituent/s:	Choline Bitartrate
Applicant name:	Australian Pesticides and Veterinary Medicines Authority
Applicant ACN:	N/A
Summary of use:	For use in veterinary chemical products
Date of approval:	19 May 2003
Approval no.:	55874

Application no.:	30809
Active constituent/s:	Potassium Citrate
Applicant name:	Australian Pesticides and Veterinary Medicines Authority
Applicant ACN:	N/A
Summary of use:	For use in veterinary chemical products
Date of approval:	20 May 2003
Approval no.:	57516

Application no.:	30671
Active constituent/s:	Magnesium Sulfate Dried
Applicant name:	Australian Pesticides and Veterinary Medicines Authority
Applicant ACN:	N/A
Summary of use:	For use in veterinary chemical products
Date of approval:	29 May 2003
Approval no.:	57393

Application no.:	58273
Active constituent/s:	Ethanol
Applicant name:	Australian Pesticides and Veterinary Medicines Authority
Applicant ACN:	N/A
Summary of use:	For use in veterinary chemical products
Date of approval:	9 November 2012
Approval no.:	68385

Application no.:	58271
Active constituent/s:	Ethyl Acetate
Applicant name:	Australian Pesticides and Veterinary Medicines Authority
Applicant ACN:	N/A
Summary of use:	For use in veterinary chemical products
Date of approval:	9 November 2012
Approval no.:	68386

Application no.:	58272
Active constituent/s:	2-Methyl-1-Butanol
Applicant name:	Australian Pesticides and Veterinary Medicines Authority
Applicant ACN:	N/A
Summary of use:	For use in veterinary chemical products
Date of approval:	9 November 2012
Approval no.:	68387

Application no.:	58273
Active constituent/s:	2-Methyl-1-Propanol
Applicant name:	Australian Pesticides and Veterinary Medicines Authority
Applicant ACN:	N/A
Summary of use:	For use in veterinary chemical products
Date of approval:	9 November 2012
Approval no.:	68388

Application no.:	58275
Active constituent/s:	3-Methyl-1-Butanol
Applicant name:	Australian Pesticides and Veterinary Medicines Authority
Applicant ACN:	N/A
Summary of use:	For use in veterinary chemical products
Date of approval:	9 November 2012
Approval no.:	68389

Application no.:	58276
Active constituent/s:	Acetaldehyde
Applicant name:	Australian Pesticides and Veterinary Medicines Authority
Applicant ACN:	N/A
Summary of use:	For use in veterinary chemical products
Date of approval:	9 November 2012
Approval no.:	68390

Application no.:	58277
Active constituent/s:	Carpophilus Aggregation Pheromone
Applicant name:	Australian Pesticides and Veterinary Medicines Authority
Applicant ACN:	N/A
Summary of use:	For use in veterinary chemical products
Date of approval:	9 November 2012
Approval no.:	68391

Application no.:	61831
Active constituent/s:	Polygalactomannan Hydroxy Propyl Ether (Guar Gum)
Applicant name:	Australian Pesticides and Veterinary Medicines Authority
Applicant ACN:	N/A
Summary of use:	For use in veterinary chemical products
Date of approval:	24 December 2013
Approval no.:	69824

Application no.:	30430
Active constituent/s:	Cyanocobalamin
Applicant name:	Australian Pesticides and Veterinary Medicines Authority
Applicant ACN:	N/A
Summary of use:	For use in veterinary chemical products
Date of approval:	29 March 2016
Approval no.:	57179

Application no.:	106078
Active constituent/s:	L-Carnitine
Applicant name:	Australian Pesticides and Veterinary Medicines Authority
Applicant ACN:	N/A
Summary of use:	For use in veterinary chemical products
Date of approval:	29 March 2016
Approval no.:	82567

Application no.:	30710
Active constituent/s:	Methionine (D and L)
Applicant name:	Australian Pesticides and Veterinary Medicines Authority
Applicant ACN:	N/A
Summary of use:	For use in veterinary chemical products
Date of approval:	29 March 2016
Approval no.:	57423

Application no.:	30952
Active constituent/s:	Tocopherol
Applicant name:	Australian Pesticides and Veterinary Medicines Authority
Applicant ACN:	N/A
Summary of use:	For use in veterinary chemical products
Date of approval:	29 March 2016
Approval no.:	57651

Application no.:	106135
Active constituent/s:	Ammonium Ferric Citrate
Applicant name:	Australian Pesticides and Veterinary Medicines Authority
Applicant ACN:	N/A
Summary of use:	For use in veterinary chemical products
Date of approval:	1 April 2016
Approval no.:	82586

Application no.:	25083
Active constituent/s:	Calcium Carbonate
Applicant name:	Australian Pesticides and Veterinary Medicines Authority
Applicant ACN:	N/A
Summary of use:	For use in veterinary chemical products
Date of approval:	1 April 2016
Approval no.:	54803

Application no.:	25091
Active constituent/s:	Calcium Gluconate
Applicant name:	Australian Pesticides and Veterinary Medicines Authority
Applicant ACN:	N/A
Summary of use:	For use in veterinary chemical products
Date of approval:	1 April 2016
Approval no.:	54807

Application no.:	25075
Active constituent/s:	Calcium Phosphate
Applicant name:	Australian Pesticides and Veterinary Medicines Authority
Applicant ACN:	N/A
Summary of use:	For use in veterinary chemical products
Date of approval:	1 April 2016
Approval no.:	54798

Application no.:	30774
Active constituent/s:	Dicalcium Phosphate
Applicant name:	Australian Pesticides and Veterinary Medicines Authority
Applicant ACN:	N/A
Summary of use:	For use in veterinary chemical products
Date of approval:	1 April 2016
Approval no.:	57485

Application no.:	25485
Active constituent/s:	Dicalcium Phosphate Dihydrate
Applicant name:	Australian Pesticides and Veterinary Medicines Authority
Applicant ACN:	N/A
Summary of use:	For use in veterinary chemical products
Date of approval:	1 April 2016
Approval no.:	55041

Application no.:	31022
Active constituent/s:	EDTA and its Salts
Applicant name:	Australian Pesticides and Veterinary Medicines Authority
Applicant ACN:	N/A
Summary of use:	For use in veterinary chemical products
Date of approval:	1 April 2016
Approval no.:	57718

Application no.:	30508
Active constituent/s:	Glucosamine Hydrochloride
Applicant name:	Australian Pesticides and Veterinary Medicines Authority
Applicant ACN:	N/A
Summary of use:	For use in veterinary chemical products
Date of approval:	1 April 2016
Approval no.:	57253

Application no.:	106138
Active constituent/s:	Glucosamine Sulphate
Applicant name:	Australian Pesticides and Veterinary Medicines Authority
Applicant ACN:	N/A
Summary of use:	For use in veterinary chemical products
Date of approval:	1 April 2016
Approval no.:	82589

Application no.:	30559
Active constituent/s:	Inositol
Applicant name:	Australian Pesticides and Veterinary Medicines Authority
Applicant ACN:	N/A
Summary of use:	For use in veterinary chemical products
Date of approval:	1 April 2016
Approval no.:	57293

Application no.:	30705
Active constituent/s:	Melaleuca Alternifolia Oil
Applicant name:	Australian Pesticides and Veterinary Medicines Authority
Applicant ACN:	N/A
Summary of use:	For use in veterinary chemical products
Date of approval:	1 April 2016
Approval no.:	57418

Application no.:	30667
Active constituent/s:	Magnesium Oxide
Applicant name:	Australian Pesticides and Veterinary Medicines Authority
Applicant ACN:	N/A
Summary of use:	For use in veterinary chemical products
Date of approval:	1 April 2016
Approval no.:	57389

Application no.:	30741
Active constituent/s:	Nicotinic Acid
Applicant name:	Australian Pesticides and Veterinary Medicines Authority
Applicant ACN:	N/A
Summary of use:	For use in veterinary chemical products
Date of approval:	1 April 2016
Approval no.:	57452

Application no.:	106136
Active constituent/s:	Pantothenol
Applicant name:	Australian Pesticides and Veterinary Medicines Authority
Applicant ACN:	N/A
Summary of use:	For use in veterinary chemical products
Date of approval:	1 April 2016
Approval no.:	82587

Application no.:	106137
Active constituent/s:	Chondroitin Sulphate
Applicant name:	Australian Pesticides and Veterinary Medicines Authority
Applicant ACN:	N/A
Summary of use:	For use in veterinary chemical products
Date of approval:	1 April 2016
Approval no.:	82588

Application no.:	30812
Active constituent/s:	Potassium Iodide
Applicant name:	Australian Pesticides and Veterinary Medicines Authority
Applicant ACN:	N/A
Summary of use:	For use in veterinary chemical products
Date of approval:	1 April 2016
Approval no.:	57519

Application no.:	30854
Active constituent/s:	Semduramicin Sodium
Applicant name:	Australian Pesticides and Veterinary Medicines Authority
Applicant ACN:	N/A
Summary of use:	For use in veterinary chemical products
Date of approval:	1 April 2016
Approval no.:	57561

Application no.:	30870
Active constituent/s:	Sodium Bicarbonate
Applicant name:	Australian Pesticides and Veterinary Medicines Authority
Applicant ACN:	N/A
Summary of use:	For use in veterinary chemical products
Date of approval:	1 April 2016
Approval no.:	57576

Application no.:	30873
Active constituent/s:	Sodium Chloride
Applicant name:	Australian Pesticides and Veterinary Medicines Authority
Applicant ACN:	N/A
Summary of use:	For use in veterinary chemical products
Date of approval:	1 April 2016
Approval no.:	57579

Application no.:	30875
Active constituent/s:	Sodium Chondroitin Sulfate
Applicant name:	Australian Pesticides and Veterinary Medicines Authority
Applicant ACN:	N/A
Summary of use:	For use in veterinary chemical products
Date of approval:	1 April 2016
Approval no.:	57581

Application no.:	30876
Active constituent/s:	Sodium Citrate
Applicant name:	Australian Pesticides and Veterinary Medicines Authority
Applicant ACN:	N/A
Summary of use:	For use in veterinary chemical products
Date of approval:	1 April 2016
Approval no.:	57582

Application no.:	30883
Active constituent/s:	Sodium Gluconate
Applicant name:	Australian Pesticides and Veterinary Medicines Authority
Applicant ACN:	N/A
Summary of use:	For use in veterinary chemical products
Date of approval:	1 April 2016
Approval no.:	575789

Application no.:	30865
Active constituent/s:	Sodium Sulphate
Applicant name:	Australian Pesticides and Veterinary Medicines Authority
Applicant ACN:	N/A
Summary of use:	For use in veterinary chemical products
Date of approval:	1 April 2016
Approval no.:	57572

Application no.:	30786
Active constituent/s:	Tri-Calcium Phosphate
Applicant name:	Australian Pesticides and Veterinary Medicines Authority
Applicant ACN:	N/A
Summary of use:	For use in veterinary chemical products
Date of approval:	1 April 2016
Approval no.:	57494

Application no.:	30955
Active constituent/s:	Trisodium Citrate
Applicant name:	Australian Pesticides and Veterinary Medicines Authority
Applicant ACN:	N/A
Summary of use:	For use in veterinary chemical products
Date of approval:	1 April 2016
Approval no.:	57654

Application no.:	30968
Active constituent/s:	Vitamin A
Applicant name:	Australian Pesticides and Veterinary Medicines Authority
Applicant ACN:	N/A
Summary of use:	For use in veterinary chemical products
Date of approval:	1 April 2016
Approval no.:	57665

Application no.:	30970
Active constituent/s:	Vitamin B1
Applicant name:	Australian Pesticides and Veterinary Medicines Authority
Applicant ACN:	N/A
Summary of use:	For use in veterinary chemical products
Date of approval:	1 April 2016
Approval no.:	57667

Application no.:	30168
Active constituent/s:	Vitamin D3
Applicant name:	Australian Pesticides and Veterinary Medicines Authority
Applicant ACN:	N/A
Summary of use:	For use in veterinary chemical products
Date of approval:	1 April 2016
Approval no.:	57010

Application no.:	31014
Active constituent/s:	Zinc and its Salts
Applicant name:	Australian Pesticides and Veterinary Medicines Authority
Applicant ACN:	N/A
Summary of use:	For use in veterinary chemical products
Date of approval:	1 April 2016
Approval no.:	57710

Application no.:	106333
Active constituent/s:	Biota Orientalis Seed Oil
Applicant name:	Interpath Pty Ltd
Applicant ACN:	082 881 187
Summary of use:	For use in veterinary chemical products
Date of approval:	8 June 2016
Approval no.:	82640

Application no.:	107050
Active constituent/s:	Ferric Hydroxide Sucrose Complex
Applicant name:	Ausrichter Pty Ltd
Applicant ACN:	000 908 529
Summary of use:	For use in veterinary chemical products
Date of approval:	20 June 2016
Approval no.:	82890

2. VARIATIONS OF ACTIVE CONSTITUENT

N/A

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 2016 (No. 8)*.

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:

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

Phone: +61 2 6210 4897

Fax: +61 2 6210 4840

Email: enquiries@apvma.gov.au

Proposal to amend Schedule 20 in the 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 2016 (No. 8)*) to MRLs into Schedule 20—Maximum residue limits in the *Australia New Zealand Food Standards 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.

PROPOSED AMENDMENT (AGRICULTURAL AND VETERINARY CHEMICALS CODE INSTRUMENT NO. 4 (MRL STANDARD) AMENDMENT INSTRUMENT 2016 (NO. 8))

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

Agvet chemical: Carbendazim

Permitted residue: Sum of carbendazim and 2-aminobenzimidazole, expressed as carbendazim

Onion, bulb	T*0.2
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Agvet chemical: Clothianidin

Permitted residue: Clothianidin

Cherries	T5
Stone fruits [except cherries]	T3

Agvet chemical: Pirimicarb

Permitted residue: Sum of pirimicarb, demethyl-pirimicarb and the N-formyl-(methylamino) analogue (demethylformamido-pirimicarb), expressed as pirimicarb

Adzuki bean (dry)	T0.5
Mung bean (dry)	T0.5
Pulses [except adzuki bean (dry), mung bean (dry); soya bean (dry)]	T*0.01
Soya bean (dry)	T0.5
Vegetables [except adzuki bean (dry); celeriac; celery; leafy vegetables; lupin (dry); mung bean (dry); onion, Welsh; shallot; soya bean (dry); spring onion; sweet corn (corn-on-the-cob)]	1

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

Agvet chemical: Clothianidin

Permitted residue: Clothianidin

Citrus fruits	T0.2
Stone fruits	3

Agvet chemical: Linuron

Permitted residue: Sum of linuron plus 3,4-dichloroaniline, expressed as linuron

Chia	T*0.05
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Agvet chemical: Pirimicarb
Permitted residue: Sum of pirimicarb, demethyl-pirimicarb and the N-formyl-(methylamino) analogue (demethylformamido-pirimicarb), expressed as pirimicarb

Pulses	T*0.02
Vegetables [except celeriac; celery; leafy vegetables; onion, Welsh; shallot; spring onion; sweet corn (corn-on-the-cob)]	1

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

Agvet chemical: Bromoxynil
Permitted residue: Bromoxynil

Garlic	T*0.05
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Agvet chemical: Carbendazim
Permitted residue: Sum of carbendazim and 2-aminobenzimidazole, expressed as carbendazim

Garlic	T*0.01
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Agvet chemical: Clothianidin
Permitted residue: Clothianidin

Fruiting vegetables, cucurbits	0.5
Fruiting vegetables, other than cucurbits [except mushrooms; sweet corn (corn-on-the-cob)]	0.7
Persimmon, American	2
Persimmon, Japanese	2
Pome fruits	2

Agvet chemical: Ethephon
Permitted residue: Ethephon

Olives	T20
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Agvet chemical: Iprodione
Permitted residue: Iprodione

Garlic	T0.3
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Agvet chemical: Methabenzthiazuron
Permitted residue: Methabenzthiazuron

Garlic	T*0.01
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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 in 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 (AEST) 26 July 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:

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

Phone: +61 2 6210 4897

Fax: +61 2 6210 4840

Email: enquiries@apvma.gov.au

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

The APVMA has previously gazetted particular amendments which it had made to the APVMA *MRL Standard* and which have been proposed as variations to maximum residue limits (MRLs) for substances contained in agricultural and veterinary chemical products as set out as in Schedule 20–Maximum Residue Limits of the *Australia New Zealand Food Standards Code*. This notice pertains to proposals (No. 4) gazetted on 5 April 2016 (No. APVMA 7).

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

Under subsection 82(1) of the *Food Standards Australia New Zealand Act 1991*, the APVMA has, by legislative instrument, incorporated these variations to MRLs into Schedule 20. A copy of the Amendment Instrument (No. APVMA 6, 2016) accompanies this notice. For a complete and up-to-date version of Schedule 20, including these amendments together with their Explanatory Statement, please refer to the Federal Register of 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 Schedule 20 provide the limits for residues of agricultural and veterinary chemicals that may legitimately occur in foods. By this means, Schedule 20 permits the sale of treated foods and protects public health by minimising residues in foods consistent with the effective control of pests and diseases.

The Agreement between the 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:

MRL Contact Officer
Australian Pesticides and Veterinary Medicines Authority
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Australian Government

**Australian Pesticides and
Veterinary Medicines Authority**

***Australia New Zealand Food Standards
Code—Schedule 20—Maximum residue limits
Variation Instrument No. APVMA 6, 2016***

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 Twenty First day of June 2016

Part 1 Preliminary

1 Name of instrument

This instrument is the *Australia New Zealand Food Standards Code—Schedule 20—Maximum residue limits Variation Instrument No. APVMA 6, 2016*.

2 Commencement

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

Note: A copy of the variations made by the Amendment Instrument was published in the Commonwealth of Australia Agricultural and Veterinary Chemicals Gazette No. APVMA 13 of 28 June 2016.

3 Object

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

4 Interpretation

In this instrument: —

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

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

Part 2 Variations to Schedule 20—Maximum Residue Limits

5 Variations to Schedule 20

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

Schedule

Variations to Schedule 20—Maximum residue limits

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

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

Agvet chemical: Fenvalerate
Permitted residue: Fenvalerate, sum of isomers

Olives	T1
Olive oil, refined	T7

Agvet chemical: Imazapic
Permitted residue: Sum of imazapic and its hydroxymethyl derivative

Barley	0.02
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Agvet chemical: Imazapyr
Permitted residue: Imazapyr

Eggs	*0.01
Poultry, edible offal of	*0.01
Poultry meat (in the fat)	*0.01

Agvet chemical: Quinoxifen
Permitted residue: Quinoxifen

Barley	*0.01
Eggs	*0.01
Milk fats	0.2
Poultry, edible offal of	*0.01
Poultry meat (in the fat)	*0.01

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

Agvet chemical: Bixafen
*Permitted residue—commodities of plant origin:
Bixafen*
*Permitted residue—commodities of animal origin:
Sum of bixafen and N-(3',4'-dichloro-5-fluorobiphenyl-2-yl)-3-(difluoromethyl)-1H-pyrazole-4-carboxamide (bixafen-desmethyl), expressed as bixafen*

Eggs	*0.02
Milks	*0.02
Poultry, edible offal of	*0.02
Poultry meat (in the fat)	*0.02
Rape seed	*0.01

Agvet chemical: Difenoconazole

Permitted residue: *Difenoconazole*

Beetroot	0.5
Celery	3

Agvet chemical: Milbemectin

Permitted residue: *Sum of milbemycin MA₃ and milbemycin MA₄ and their photoisomers, milbemycin (Z) 8,9-MA₃ and (Z) 8,9Z-MA₄*

Pome fruits	0.03
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Amicus Blue Fungicide containing Amisulbrom

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application for registration of a new product containing a new active constituent. The product is Amicus Blue Fungicide.

PARTICULARS OF THE APPLICATION

Proposed product name(s):	Amicus Blue Fungicide
Applicant company:	Nufarm Australia Limited
Name of active constituent:	Amisulbrom
Signal heading:	Poison
Summary of proposed use:	For the control of downy mildew in grapes and white blister and downy mildew in brassica vegetables.
Pack sizes:	5 L – 1000 L
Withholding periods:	Brassicac: Not required when used as directed Grapevines: Do not harvest for 28 days after application

SUMMARY OF THE APVMA'S EVALUATION OF AMICUS BLUE 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 in its assessment in relation to whether the safety criteria have been met in accordance with the definition set out in section 5A of the Agvet Code, and proposes to determine that:
 - (i) The proposed use of AMICUS BLUE FUNGICIDE 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.

The product AMICUS BLUE FUNGICIDE will be used by farmers and their employees, as well as contract sprayers. Users may be exposed to the product when opening containers, mixing/loading/application, cleaning up spills, maintaining equipment and entering treated crops. The main routes of exposure to the product/spray will be dermal and inhalation, although ocular exposure is also possible.

Based on the risk assessment, first aid instructions, safety directions and re-entry statements have been recommended for the product label.

Based on an assessment of the toxicology, it was considered that there should be no adverse effects on human health from the use of the product AMICUS BLUE FUNGICIDE when used in accordance with the label directions.

- (ii) The proposed use of AMICUS BLUE FUNGICIDE will not be an undue hazard to the safety of people using anything containing its residues.

The chronic dietary exposure to amisulbrom is estimated by the National Estimated Daily Intake (NEDI) calculation encompassing all registered and/or temporary uses of the chemical and the mean daily dietary consumption data derived primarily from the 1995 National Nutrition Survey of Australia. The NEDI calculation is made in accordance with World Health Organisation (WHO) Guidelines and is a conservative estimate of dietary exposure to chemical residues in food. The NEDI for amisulbrom is equivalent to <2% of the ADI. It is concluded that the chronic dietary exposure to amisulbrom is acceptable.

Maximum Residue Limits (MRLs) for brassicas vegetables, grapes, dried grapes and animal commodities have been recommended.

- (iii) The proposed use of AMICUS BLUE FUNGICIDE containing the active constituent amisulbrom is not likely to be harmful to human beings if used according to the product label directions.

In toxicokinetic studies in rats, amisulbrom oral absorption was approximately 50% at low doses (10 mg/kg bw) but much lower with high doses (5% at 1000 mg/kg bw). Amisulbrom does not accumulate in the body. It is readily excreted after single or repeat administrations to rats, with >90% eliminated primarily in faeces within 72 hours. Patterns of excretion are similar between sexes. Only small proportions (<0.5%) of administered doses are retained in the body 120 hours after single or repeat administration, with most of the residual administered dose found in the liver, kidney, whole blood and blood cells.

Based on the findings of the acute toxicological studies evaluated, amisulbrom is of low acute oral, dermal, and inhalational toxicity in rats, and is non-irritating to the skin of rabbits and non-sensitising in guinea pigs by the Guinea Pig Maximisation Test method. Amisulbrom was considered to be a slight but persistent eye irritant in rabbits, noting the extended observation of low-level conjunctival effects in a single animal up to 22 days after treatment.

Repeat dose studies conducted with amisulbrom in rats, mice and dogs revealed treatment-related effects generally limited to non-specific toxicity (i.e. decreases in body weight, body weight gain, food consumption, or food conversion efficiency) and effects on the liver (e.g. serum liver enzyme changes, increased liver weights, or hepatocyte hypertrophy).

Amisulbrom was not genotoxic in several *in vitro* and *in vivo* studies. In long-term toxicity/carcinogenicity studies with rats, mice and dogs, the target organs of toxicity were the liver and kidney. Effects observed included non-specific toxicity (i.e. decreased body weight gains and reduced food consumption at higher concentrations) as well as changes in the liver and kidneys, such as increased γ -glutamyl transpeptidase activity in male rats (also in females at higher doses), increased relative kidney and liver weights, increased adrenal weights in dogs, as well as histopathological changes in the liver (midzonal and centrilobular hepatocyte vacuolation) and kidney (cortical tubular pigmentation). The effects were more marked at higher doses.

In the 2-year combined chronic and carcinogenic study in rats, neoplastic changes, including higher incidences of liver hepatocellular adenoma and carcinoma, were seen at ≥ 10000 ppm (496/697 mg/kg bw/d M/F), which was considered above the maximum tolerated dose (MTD). The increased incidence of forestomach tumours in female rats were caused by local irritation of the stomach mucosa and not considered relevant to humans. In mice, a dose-related increased

incidence in hepatocellular adenoma was observed in males. These neoplastic changes were noted at levels below the MTD of 8000 ppm (1035 mg/kg bw/d). Mechanistic studies submitted suggesting a carcinogenicity mode of action for amisulbrom similar to phenobarbital, a mechanism which is generally not considered relevant to humans, did not provide comprehensive evidence to eliminate the possibility of other modes of action. However, noting that the hepatocellular carcinoma findings only occurred at doses above the MTD, hepatocellular adenomas were only observed below the MTD in male mice, and there was a lack of pre-neoplastic lesions and negative genotoxicity results, it is not considered that amisulbrom poses a carcinogenic risk.

No effect on fertility was observed in the F₀ generation in a 2-generation reproductive study in rats. However, prolonged or irregular oestrous cycles, impaired fertility and ovarian atrophy were evident in F₁ females. Fertility in F₁ males was unaffected by treatment. Mechanistic data (including an anti-oestrogenic uterotrophic assay, an anti-aromatase assay and reproductive hormone level analysis) submitted by the applicant provided evidence that impaired fertility in F₁ females was likely secondary to reduced food intake and impaired body weight gain associated with poor palatability of amisulbrom, rather than a direct amisulbrom-related effect. Therefore amisulbrom is not considered to be a reproductive toxicant.

There was no evidence of embryofoetal toxicity in developmental studies in rats and rabbits. Amisulbrom is not considered to be a developmental toxicant. Acute and repeat-dose neurotoxicity studies conducted with amisulbrom were unremarkable.

Based on the findings of the acute toxicological studies evaluated, the product AMICUS BLUE FUNGICIDE has low acute oral, dermal and inhalational toxicity. It was not a skin irritant in rabbits or a skin sensitiser in guinea pigs (Maximisation method), but slight eye irritation was seen in rabbits.

Based on an assessment of the toxicology, it was considered that there should be no adverse effects on human health from the use of AMICUS BLUE FUNGICIDE when used in accordance with the label directions.

Based on the toxicity profile of amisulbrom, the Delegate to the Secretary of the Department of Health published a final decision that amisulbrom be included in Schedule 5 of the Poisons Standard, with an implementation date of 1 June 2016.

- (iv) The proposed use of AMICUS BLUE FUNGICIDE containing the active constituent amisulbrom would not be likely to have an unintended effect that is harmful to animals, plants or things or to the environment when used in accordance with the label directions.

Environmental data were assessed in support of the proposed use and it was concluded that the risks to the environment from this use are acceptable.

Amisulbrom is considered to be fairly hydrolysing at pH 9 but slightly hydrolysing at pH 4 and 7. The major metabolite identified was IT-4 and is formed through cleavage of the sulphonylamino side chain on the triazole ring. Photolysis could be a major removal mechanism for amisulbrom from surface water. In soil, photolysis is not an important route of degradation of amisulbrom.

Under laboratory aerobic conditions, amisulbrom was relatively persistent in soil and the rate of degradation was dependent on soil pH. IT-4 was a major soil metabolite that was moderately persistent in aerobic soil. In anaerobic soils and aquatic systems, amisulbrom and metabolites were slightly to readily degradable with rapid dissipation from the water phase. In field dissipation

trials, amisulbrom was readily degradable in soil whereas IT-4 was slightly more persistent. Amisulbrom and IT-4 were classified as immobile and low to immobile in various soils, respectively. Amisulbrom is not expected to bioaccumulate.

Amisulbrom is considered to be practically non-toxic to birds and mammals. It was acutely very highly toxic to aquatic and sediment dwelling organisms. It was chronically moderately toxic to aquatic organisms and slightly toxic to sediment dwelling organisms. Metabolites were less toxic than the parent compound to aquatic and sediment dwelling organisms. AMICUS BLUE FUNGICIDE was no more toxic than the active constituent amisulbrom.

Amisulbrom is not considered to be toxic to honey bees or earthworms. Several non-target arthropod species were insensitive to amisulbrom. No harmful effects were observed in soil microorganisms and terrestrial plants at the proposed application rate.

At the proposed rate, the risk to birds, mammals, honey bees, earthworms and other non-target terrestrial invertebrates and non-target terrestrial plants, was found acceptable, and no harmful impact on soil nitrogen and carbon metabolism is expected from the proposed uses. Based on the acute and chronic aquatic toxicity studies provided, with the proposed uses the risk to aquatic and sediment dwelling organisms from spray drift and run-off or groundwater were found acceptable, provided the spray drift restraints required on the label are observed.

2. The APVMA has evaluated the application and in its assessment in relation to whether the efficacy criteria have been met in accordance with the definition set out in section 5B of the Agvet Code, and proposes to determine that:
 - (i) data from trials supporting the efficacy of the product adequately demonstrate that if used according to the product label directions, the product is effective for its proposed uses.
3. The APVMA has evaluated the application and in its assessment in relation to whether the trade criteria have been met in accordance with the definition set out in section 5C of the Agvet Code, and proposes to determine that:
 - (i) the proposed use of AMICUS BLUE FUNGICIDE containing the active constituent amisulbrom would not adversely affect trade between Australia and places outside Australia.

Grapes (including dried grapes) and wine are considered to be major export commodities, as are commodities of animal origin, such as meat, offal and dairy products, which may be derived from livestock fed feeds produced from commodities treated with amisulbrom.

Residues in these commodities resulting from the use of AMICUS BLUE FUNGICIDE may have the potential to unduly prejudice trade.

Export of treated produce containing finite (measurable) residues of amisulbrom may pose a risk to Australian trade in situations where (i) no residue tolerance (import tolerance) is established in the importing country or (ii) where residues in Australian produce are likely to exceed a residue tolerance (import tolerance) established in the importing country.

For grapes and dried grapes (raisins), Maximum Residue Limits (MRLs) of 0.5 mg/kg and 1 mg/kg respectively are proposed.

While Codex has not established MRLs for amisulbrom, the EU and Japan have established MRLs of 0.5 mg/kg and 5 mg/kg respectively for grapes. The US has established grape and raisin MRLs at 0.4 mg/kg and 1.0 mg/kg respectively. The proposed MRL of 0.5 mg/kg for grapes is in line with the EU MRL of 0.5 mg/kg, only slightly higher than the US MRL of 0.4 mg/kg and significantly lower than that established by Japan.

Based on a processing study, residues of amisulbrom in wine are not expected to be above the LOQ (0.01 mg/kg) following the proposed use, thus potential risk to trade in wine is considered to be low.

Residues of amisulbrom or its metabolites above the limit of quantification (0.01 mg/kg) are not expected in edible animal commodities following the proposed use. MRLs of *0.01 mg/kg for cattle (edible offal, meat and milks) and poultry (edible offal, meat and eggs) commodities are recommended. Potential risk to trade in animal commodities is considered to be low.

Comment is invited on the potential for the proposed use of Amicus Blue Fungicide to unduly prejudice Australian export trade.

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/news-and-publications/public-consultations or by contacting the section 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 AMICUS BLUE 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) material contained in submissions will be treated confidentially.

Written submissions should be addressed in writing to:

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