Commonwealth of Australia

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/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.

APVMA CONTACTS

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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.:	107026
Product name:	Apparent Sinister Lawn Insecticide
Active constituent/s:	15 g/L imidacloprid
Applicant name:	Apparent Pty Ltd
Applicant ACN:	143 724 136
Summary of use	For the systemic control of insect pests on flowers, shrubs, fruit trees, vegetables and lawns in the home garden
Date of registration/approval:	13 September 2016
Product registration no.:	82874
Label approval no.:	82874/107026

Application no.:	101405
Product name:	International Biolux New Technology Micron Extra 2 High Strength Self Polishing Antifouling
Active constituent/s:	Dover white label 60 g/L zineb, 594 g/L copper-sufficient cuprous oxide red label 60 g/L zineb, 611 g/L copper-sufficient cuprous oxide blue label 60 g/L zineb, 578 g/L copper-sufficient cuprous oxide navy label 58 g/L zineb, 599 g/L copper- sufficient cuprous oxide black label 60 g/L zineb, 598 g/L copper-sufficient cuprous oxide green label 60 g/L zineb, 591 g/L copper- sufficient cuprous oxide dark grey label 61 g/L zineb, 598 g/L copper-sufficient cuprous oxide
Applicant name:	Akzo Nobel Pty Limited
Applicant ACN:	000 119 424
Summary of use	For use as an antifouling paint to control marine growth below the waterline on pleasure craft
Date of registration/approval:	13 September 2016
Product registration no.:	80681
Label approval no.:	80681/101405

Application no.:	104922
Product name:	Trimmit Growth Regulator
Active constituent/s:	250 g/L paclobutrazol
Applicant name:	Syngenta Australia Pty Ltd
Applicant ACN:	002 933 717
Summary of use	To control the growth of hedging plants
Date of registration/approval:	20 September 2016
Product registration no.:	82071
Label approval no.:	82071/104922

Application no.:	103773
Product name:	Aquastar Max 200 SC Termiticide & Insecticide
Active constituent/s:	200 g/L bifenthrin
Applicant name:	PCT Holdings Pty Ltd
Applicant ACN:	099 023 962
Summary of use	For the control of a range of urban interior and exterior pests, the protection of structures from subterranean termite damage and the control of termites
Date of registration/approval:	21 September 2016
Product registration no.:	81703
Label approval no.:	81703/103773

Application no.:	103414
Product name:	EuroChem Precision GA Tablet Plant Growth Regulator
Active constituent/s:	200 g/kg gibberellic acid (1 gram gibberellic acid per tablet)
Applicant name:	TGAC Australia Pty. Ltd
Applicant ACN:	134 570 700
Summary of use	For foliar spray application to certain varieties of grapes, citrus and prunes to promote desirable harvest effects
Date of registration/approval:	22 September 2016
Product registration no.:	81587
Label approval no.:	81587/103414

2. VARIATIONS OF REGISTRATION

Application no:	107503
Product name:	Huilong Broadleaf Lawn Weeder
Active constituent/s:	25 g/L dicamba present as the dimethylamine salt, 150 g/L MCPA present as the dimethylamine salt
Applicant name:	Huilong Agrochemicals Australia Pty Ltd
Applicant ACN:	165 921 031
Summary of variation:	To change the distinguishing product name and the name that appears on the label from 'AGSPRAY BROADLEAF LAWN WEEDER' to 'HUILONG BROADLEAF LAWN WEEDER'
Date of variation:	3 August 2016
Product registration no.:	47664
Label approval no.:	47664/107503

Application no:	107519
Product name:	Huilong Oxalis Soursob Killer
Active constituent/s:	220 g/L ammonium thiocyanate, 250 g/L amitrole
Applicant name:	Huilong Agrochemicals Australia Pty Ltd
Applicant ACN:	165 921 031
Summary of variation:	To change the distinguishing product name and the name that appears on the label from 'AGSPRAY OXALIS SOUR SOB KILLER' to 'HUILONG OXALIS SOURSOB KILLER'
Date of variation:	4 August 2016
Product registration no.:	31220
Label approval no.:	31220/107519

Application no:	107570
Product name:	Bromakil Block Bait For Rats And Mice
Active constituent/s:	0.05 g/kg bromadiolone
Applicant name:	De Sangosse Australia Pty Ltd
Applicant ACN:	601 609 545
Summary of variation:	To change the distinguishing product name and the name that appears on the label from 'RENTOKIL BROMAKIL BLOCK BAIT FOR RATS AND MICE' to 'BROMAKIL BLOCK BAIT FOR RATS AND MICE'
Date of variation:	8 August 2016
Product registration no.:	33908
Label approval no.:	33908/107570

Application no:	107586
Product name:	Bromakil Kills Rats And Mice!
Active constituent/s:	0.05 g/kg bromadiolone
Applicant name:	De Sangosse Australia Pty Ltd
Applicant ACN:	601 609 545
Summary of variation:	To change the distinguishing product name and the name that appears on the label from 'RENTOKIL BROMAKIL KILLS RATS AND MICE!' to 'BROMAKIL KILLS RATS AND MICE!'
Date of variation:	10 August 2016
Product registration no.:	61668
Label approval no.:	61668/107586

Application no:	107621
Product name:	Rygel Bifenthrin 100EC Insecticide/Miticide
Active constituent/s:	100 g/L bifenthrin
Applicant name:	Profeng Australia Pty Ltd
Applicant ACN:	156 055 533
Summary of variation:	To change the distinguishing product name and the name that appears on the label from 'AC BEAST INSECTICIDE' to 'RYGEL BIFENTHRIN 100EC INSECTICIDE/MITICIDE'
Date of variation:	12 August 2016
Product registration no.:	66605
Label approval no.:	66605/107621

Application no:	106321
Product name:	Farmalinx Accelerate 200 SG Growth Regulant
Active constituent/s:	200 g/kg gibberellic acid
Applicant name:	Farmalinx Pty Ltd
Applicant ACN:	134 353 245
Summary of variation:	To extend the use to stimulate the production of winter-dormant, grass-dominant pastures for high intensity grazing such as sheep lambing paddocks and dairy pasture
Date of variation:	14 September 2016
Product registration no.:	69753
Label approval no.:	69753/106321

Application no:	106335
Product name:	Supercharge Elite Spray Tank Adjuvant
Active constituent/s:	471 g/L paraffin oil
Applicant name:	Crop Care Australasia Pty Ltd
Applicant ACN:	061 362 347
Summary of variation:	To amend registration to include additional companion products
Date of variation:	16 September 2016
Product registration no.:	69346
Label approval no.:	69346/106335

Application no:	105181
Product name:	Vapormate Fumigant
Active constituent/s:	166.7 g/kg ethyl formate
Applicant name:	BOC Limited
Applicant ACN:	000 029 729
Summary of variation:	To extend the use to include stored products and fresh food commodities
Date of variation:	19 September 2016
Product registration no.:	56186
Label approval no.:	56186/105181

Application no:	106799
Product name:	Alto Lab Bug Shield Ready For Use Insecticide
Active constituent/s:	1 mg/mL permethrin (25:75::CIS:TRANS), 4 mg/mL piperonyl butoxide
Applicant name:	Greg Grant Australia Pty Ltd
Applicant ACN:	000 764 492
Summary of variation:	To change the distinguishing product name and the name that appears on the label from 'BLUE RIBBON READY TO USE INSECTICIDE' to 'ALTO LAB BUG SHIELD READY FOR USE INSECTICIDE'
Date of variation:	21 September 2016
Product registration no.:	42018
Label approval no.:	42018/106799

Application no:	105076
Product name:	Accu-Tab SI Tablets
Active constituent/s:	650 g/kg chlorine present as calcium hypochlorite
Applicant name:	Axiall LLC
Applicant ACN:	N/A
Summary of variation:	To change the distinguishing product name and the name that appears on the label from 'ACCU-TAB BLUE TABLETS' to 'ACCU-TAB SI TABLETS' and minor label update
Date of variation:	21 September 2016
Product registration no.:	53321
Label approval no.:	53321/105076

Application no:	107100
Product name:	Genfarm Imazethapyr 700 WG Herbicide
Active constituent/s:	700 g/kg imazethapyr
Applicant name:	Landmark Operations Limited
Applicant ACN:	008 743 217
Summary of variation:	Variation of product label to extend use to include lentils
Date of variation:	22 September 2016
Product registration no.:	60255
Label approval no.:	60255/107100

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.:	57748
Product name:	Nobilis® Paramyxo P201
Active constituent/s:	300 HA units/dose pigeon paramyxo virus-1 (PPMV-1) antigen strain P201 inactivated, 552 mg/mL liquid paraffin
Applicant name:	Intervet Australia Pty Limited
Applicant ACN:	008 467 034
Summary of use	For use in the active immunisation of pigeons to reduce clinical signs caused by virulent PPMV-1 infection
Date of registration/approval:	19 September 2016
Product registration no.:	68193
Label approval no.:	68193/57748

2. VETERINARY PRODUCTS BASED ON EXISTING ACTIVE CONSTITUENTS

Application no.:	103342
Product name:	Vetmedin 3.5 mg/ml Oral Solution For Dogs
Active constituent/s:	3.5 mg/mL pimobendan
Applicant name:	Luoda Pharma Pty Ltd
Applicant ACN:	149 604 259
Summary of use	For the treatment of canine congestive heart failure (CHF) originating from dilated cardiomyopathy (DCM) or valvular insufficiency (mitral and/or tricuspid regurgitation) For the treatment of preclinical DCM in large breed dogs
Date of registration/approval:	15 September 2016
Product registration no.:	81552
Label approval no.:	81552/103342

Application no.:	103645
Product name:	Agrimin 24.7 Copper 30 g Sustained Release Boluses For Cattle
Active constituent/s:	732 g/kg copper (as copper oxide)
Applicant name:	Agrimin Ltd
Applicant ACN:	N/A
Summary of use	For use in prevention and treatment of copper deficiency in cattle over 300 kg bodyweight
Date of registration/approval:	19 September 2016
Product registration no.:	81682
Label approval no.:	81682/103645

Application no.:	103646
Product name:	Agrimin 24.7 Copper 36 g Sustained Release Boluses For Cattle
Active constituent/s:	732 g/kg copper (as copper oxide)
Applicant name:	Agrimin Ltd
Applicant ACN:	N/A
Summary of use	For use in prevention and treatment of copper deficiency in cattle over 360 kg bodyweight
Date of registration/approval:	19 September 2016
Product registration no.:	81683
Label approval no.:	81683/103646

Application no.:	103765
Product name:	Agrimin 24.7 Copper 20 g Sustained Release Boluses For Cattle
Active constituent/s:	732 g/kg copper (as copper oxide)
Applicant name:	Agrimin Ltd
Applicant ACN:	N/A
Summary of use	For use in prevention and treatment of copper deficiency in cattle over 200 kg bodyweight
Date of registration/approval:	19 September 2016
Product registration no.:	81699
Label approval no.:	81699/103765

3. VARIATIONS OF REGISTRATION

Application no.:	106075
Product name:	Tri-Solfen Topical Anaesthetic & Antiseptic Solution For Pain Relief In Lambs
Active constituent/s:	40.6 g/L lignocaine (as hydrochloride), 4.2 g/L bupivacaine (as hydrochloride), 24.8 mg/L adrenaline (as acid tartrate), 5 g/L cetrimide
Applicant name:	Bayer Australia Ltd (Animal Health)
Applicant ACN:	000 138 714
Summary of use	To change the distinguishing product name from 'TRI-SOLFEN TOPICAL ANAESTHETIC & ANTISEPTIC SOLUTION FOR PAIN RELIEF IN LAMBS FOLLOWING MULESING' to 'TRI-SOLFEN TOPICAL ANAESTHETIC & ANTISEPTIC SOLUTION FOR PAIN RELIEF IN LAMBS' and to extend the use to include pain relief following castration and tail docking in lambs
Date of registration/approval:	21 September 2016
Product registration no.:	60099
Label approval no.:	60099/106075

Approved Active Constituents—Agricultural

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.:	105449
Active constituent/s:	Thiamethoxam
Applicant name:	Colin Campbell (Chemicals) Pty Ltd
Applicant ACN:	000 045 59
Summary of use:	For use in agricultural chemical products
Date of approval:	15 September 2016
Approval no.:	82332

Application no.:	105058
Active constituent/s:	Pigeon paramyxovirus-1 Strain P201 (Inactivated)
Applicant name:	Intervet Australia Pty Limited
Applicant ACN:	008 467 034
Summary of use:	For use in veterinary chemical products
Date of approval:	19 September 2016
Approval no.:	82125

Application no.:	105372
Active constituent/s:	Metalaxyl-M
Applicant name:	Agchem Australia Pty Ltd
Applicant ACN:	158 701 332
Summary of use:	For use in agricultural chemical products
Date of approval:	16 September 2016
Approval no.:	82288

Application no.:	107389
Active constituent/s:	*Salmonella typhimurium*, AWC 591 (live)
Applicant name:	Zoetis Australia Pty Ltd
Applicant ACN:	156 476 425
Summary of use:	For use in veterinary chemical products
Date of approval:	23 September 2016
Approval no.:	83051

Approved Active Constituents—Veterinary

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 CONSITUTENT

Application no.:	106510
Active constituent/s:	Pentobarbital sodium
Applicant name:	Abbey Laboratories Pty Ltd
Applicant ACN:	156 000 430
Summary of use:	For use in veterinary chemical products
Date of approval:	29 August 2016
Approval no.:	82706

Application no.:	106812
Active constituent/s:	Apramycin sulphate
Applicant name:	Abbey Laboratories Pty Ltd
Applicant ACN:	156 000 430
Summary of use:	For use in veterinary chemical products
Date of approval:	29 August 2016
Approval no.:	82799

Application no.:	106802
Active constituent/s:	Pyrantel pamoate
Applicant name:	Abbey Laboratories Pty Ltd
Applicant ACN:	156 000 430
Summary of use:	For use in veterinary chemical products
Date of approval:	1 September 2016
Approval no.:	82793

Application no.:	106968
Active constituent/s:	Oxytetracycline Hydrochloride
Applicant name:	Abbey Laboratories Pty Ltd
Applicant ACN:	156 000 430
Summary of use:	For use in veterinary chemical products
Date of approval:	1 September 2016
Approval no.:	82852

Application no.:	106709
Active constituent/s:	Praziquantel
Applicant name:	Abbey Laboratories Pty Ltd
Applicant ACN:	156 000 430
Summary of use:	For use in veterinary chemical products
Date of approval:	1 September 2016
Approval no.:	82765

Application no.:	106702
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:	1 September 2016
Approval no.:	82759

Application no.:	105835
Active constituent/s:	Oclacitinib maleate
Applicant name:	Zoetis Australia Pty Ltd
Applicant ACN:	156 476 425
Summary of use:	For use in veterinary chemical products
Date of approval:	2 September 2016
Approval no.:	82477

Application no.:	105121
Active constituent/s:	Pyridoxine hydrochloride
Applicant name:	Virbac (Australia) Pty Ltd
Applicant ACN:	003 268 871
Summary of use:	For use in veterinary chemical products
Date of approval:	2 September 2016
Approval no.:	82165

Application no.:	106815
Active constituent/s:	Oxantel pamoate
Applicant name:	Abbey Laboratories Pty Ltd
Applicant ACN:	156 000 430
Summary of use:	For use in veterinary chemical products
Date of approval:	2 September 2016
Approval no.:	82802

Application no.:	106704
Active constituent/s:	Clorsulon
Applicant name:	Abbey Laboratories Pty Ltd
Applicant ACN:	156 000 430
Summary of use:	For use in veterinary chemical products
Date of approval:	2 September 2016
Approval no.:	82761

Application no.:	105356
Active constituent/s:	Riboflavin
Applicant name:	Virbac (Australia) Pty Ltd
Applicant ACN:	003 268 871
Summary of use:	For use in veterinary chemical products
Date of approval:	2 September 2016
Approval no.:	82280

Application no.:	105743
Active constituent/s:	Hydrocortisone
Applicant name:	Ceva Animal Health Pty Ltd
Applicant ACN:	002 692 426
Summary of use:	For use in veterinary chemical products
Date of approval:	2 September 2016
Approval no.:	82439

Application no.:	105338
Active constituent/s:	Dl-Alpha tocopheryl acetate
Applicant name:	Virbac (Australia) Pty Ltd
Applicant ACN:	003 268 871
Summary of use:	For use in veterinary chemical products
Date of approval:	6 September 2016
Approval no.:	82268

Application no.:	107791
Active constituent/s:	Pimobendan
Applicant name:	Luoda Pharma Pty Ltd
Applicant ACN:	149 604 259
Summary of use:	For use in veterinary chemical products
Date of approval:	7 September 2016
Approval no.:	83234

Application no.:	107769
Active constituent/s:	Progesterone
Applicant name:	Boehringer Ingelheim Pty Limited, Vetmedica Division
Applicant ACN:	000 452 308
Summary of use:	For use in veterinary chemical products
Date of approval:	7 September 2016
Approval no.:	83227

Application no.:	105406
Active constituent/s:	Ferronyl iron
Applicant name:	Virbac (Australia) Pty Ltd
Applicant ACN:	003 268 871
Summary of use:	For use in veterinary chemical products
Date of approval:	7 September 2016
Approval no.:	82308

Application no.:	105386
Active constituent/s:	Doramectin
Applicant name:	Merial Australia Pty Ltd
Applicant ACN:	071 187 285
Summary of use:	For use in veterinary chemical products
Date of approval:	7 September 2016
Approval no.:	82295

Application no.:	105344
Active constituent/s:	Sodium chloride
Applicant name:	Virbac (Australia) Pty Ltd
Applicant ACN:	003 268 871
Summary of use:	For use in veterinary chemical products
Date of approval:	7 September 2016
Approval no.:	82275

Application no.:	105380
Active constituent/s:	Tetracycline hydrochloride
Applicant name:	Aristopet Pty Ltd
Applicant ACN:	145 418 882
Summary of use:	For use in veterinary chemical products
Date of approval:	7 September 2016
Approval no.:	82292

Application no.:	106009
Active constituent/s:	Chorionic gonadotrophin
Applicant name:	Intervet Australia Pty Limited
Applicant ACN:	008 467 034
Summary of use:	For use in veterinary chemical products
Date of approval:	8 September 2016
Approval no.:	82533

Application no.:	105382
Active constituent/s:	Glycine
Applicant name:	Virbac (Australia) Pty Ltd
Applicant ACN:	003 268 871
Summary of use:	For use in veterinary chemical products
Date of approval:	9 September 2016
Approval no.:	82293

Application no.:	105447
Active constituent/s:	Gleptoferron
Applicant name:	Ceva Animal Health Pty Ltd
Applicant ACN:	002 692 426
Summary of use:	For use in veterinary chemical products
Date of approval:	19 September 2016
Approval no.:	82312

Application no.:	106513
Active constituent/s:	Tiamulin hydrogen fumarate
Applicant name:	Abbey Laboratories Pty Ltd
Applicant ACN:	156 000 430
Summary of use:	For use in veterinary chemical products
Date of approval:	20 September 2016
Approval no.:	82709

Application no.:	106405
Active constituent/s:	Clavulanic acid (as potassium clavulanate)
Applicant name:	Vetoquinol Australia Pty Ltd
Applicant ACN:	006 949 480
Summary of use:	For use in veterinary chemical products
Date of approval:	20 September 2016
Approval no.:	82670

Application no.:	106406
Active constituent/s:	Amoxicillin trihydrate
Applicant name:	Vetoquinol Australia Pty Ltd
Applicant ACN:	006 949 480
Summary of use:	For use in veterinary chemical products
Date of approval:	20 September 2016
Approval no.:	82671

Application no.:	107219
Active constituent/s:	Eprinomectin
Applicant name:	Neove Pharma Australia Pty Limited
Applicant ACN:	140 367 442
Summary of use:	For use in veterinary chemical products
Date of approval:	20 September 2016
Approval no.:	82962

Application no.:	106514
Active constituent/s:	Tylosln tartrate
Applicant name:	Abbey Laboratories Pty Ltd
Applicant ACN:	156 000 430
Summary of use:	For use in veterinary chemical products
Date of approval:	20 September 2016
Approval no.:	82710

Application no.:	106516
Active constituent/s:	Lincomycin hydrochloride
Applicant name:	Abbey Laboratories Pty Ltd
Applicant ACN:	156 000 430
Summary of use:	For use in veterinary chemical products
Date of approval:	20 September 2016
Approval no.:	82712

Application no.:	107223
Active constituent/s:	Selamectin
Applicant name:	Neove Pharma Australia Pty Limited
Applicant ACN:	140 367 442
Summary of use:	For use in veterinary chemical products
Date of approval:	20 September 2016
Approval no.:	82965

Application no.:	107541
Active constituent/s:	Oestradiol
Applicant name:	Elanco Animal Health A Div Of Eli Lilly Aust Pty Ltd
Applicant ACN:	000 233 992
Summary of use:	For use in veterinary chemical products
Date of approval:	21 September 2016
Approval no.:	83107

Application no.:	107529
Active constituent/s:	Praziquantel
Applicant name:	Ranvet Pty. Limited
Applicant ACN:	001 606 033
Summary of use:	For use in veterinary chemical products
Date of approval:	21 September 2016
Approval no.:	83101

Application no.:	107525
Active constituent/s:	Methandriol dipropionate
Applicant name:	Ranvet Pty. Limited
Applicant ACN:	001 606 033
Summary of use:	For use in veterinary chemical products
Date of approval:	21 September 2016
Approval no.:	83098

Application no.:	107556
Active constituent/s:	Progesterone
Applicant name:	Elanco Animal Health A Div Of Eli Lilly Aust Pty Ltd
Applicant ACN:	000 233 992
Summary of use:	For use in veterinary chemical products
Date of approval:	21 September 2016
Approval no.:	83113

Application no.:	107612
Active constituent/s:	Calcium chloride dihydrate
Applicant name:	Virbac (Australia) Pty Ltd
Applicant ACN:	003 268 871
Summary of use:	For use in veterinary chemical products
Date of approval:	21 September 2016
Approval no.:	83137

Application no.:	107605
Active constituent/s:	Deltamethrin
Applicant name:	Landmark Operations Limited
Applicant ACN:	008 743 217
Summary of use:	For use in veterinary chemical products
Date of approval:	21 September 2016
Approval no.:	83134

Application no.:	107602
Active constituent/s:	Spinosad
Applicant name:	Landmark Operations Limited
Applicant ACN:	008 743 217
Summary of use:	For use in veterinary chemical products
Date of approval:	21 September 2016
Approval no.:	83131

Application no.:	105424
Active constituent/s:	Hydrocortisone aceponate
Applicant name:	Virbac (Australia) Pty Ltd
Applicant ACN:	003 268 871
Summary of use:	For use in veterinary chemical products
Date of approval:	22 September 2016
Approval no.:	82322

Application no.:	105421
Active constituent/s:	Gentamycin sulphate
Applicant name:	Virbac (Australia) Pty Ltd
Applicant ACN:	003 268 871
Summary of use:	For use in veterinary chemical products
Date of approval:	22 September 2016
Approval no.:	82321

Application no.:	105429
Active constituent/s:	Ivermectin
Applicant name:	Virbac (Australia) Pty Ltd
Applicant ACN:	003 268 871
Summary of use:	For use in veterinary chemical products
Date of approval:	22 September 2016
Approval no.:	82323

Application no.:	105443
Active constituent/s:	Cetrimide
Applicant name:	Virbac (Australia) Pty Ltd
Applicant ACN:	003 268 871
Summary of use:	For use in veterinary chemical products
Date of approval:	22 September 2016
Approval no.:	82330

Application no.:	105987
Active constituent/s:	Econazole nitrate
Applicant name:	Virbac (Australia) Pty Ltd
Applicant ACN:	003 268 871
Summary of use:	For use in veterinary chemical products
Date of approval:	22 September 2016
Approval no.:	82521

Application no.:	106002
Active constituent/s:	Propylene glycol
Applicant name:	Virbac (Australia) Pty Ltd
Applicant ACN:	003 268 871
Summary of use:	For use in veterinary chemical products
Date of approval:	27 September 2016
Approval no.:	82530

Application no.:	105362
Active constituent/s:	Proflavine hemisulfate
Applicant name:	Virbac (Australia) Pty Ltd
Applicant ACN:	003 268 871
Summary of use:	For use in veterinary chemical products
Date of approval:	27 September 2016
Approval no.:	82283

Application no.:	106491
Active constituent/s:	Chlortetracycline hydrochloride
Applicant name:	International Animal Health Products Pty Ltd
Applicant ACN:	003 185 699
Summary of use:	For use in veterinary chemical products
Date of approval:	27 September 2016
Approval no.:	82688

Application no.:	106017
Active constituent/s:	Moxidectin
Applicant name:	Neove Pharma Australia Pty Limited
Applicant ACN:	140 367 442
Summary of use:	For use in veterinary chemical products
Date of approval:	27 September 2016
Approval no.:	82540

Application no.:	106490
Active constituent/s:	Roxarsone
Applicant name:	International Animal Health Products Pty Ltd
Applicant ACN:	003 185 699
Summary of use:	For use in veterinary chemical products
Date of approval:	28 September 2016
Approval no.:	82687

2. VARIATIONS OF ACTIVE CONSTITUENT

Application no.:	103466
Active constituent/s:	Cyanocobalamin
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:	22 September 2016
Approval no.:	82009

Application no.:	105082
Active constituent/s:	Cyanocobalamin
Applicant name:	Ceva Animal Health Pty Ltd
Applicant ACN:	002 692 426
Summary of use:	Variation of relevant particulars or conditions of an approved active constituent
Date of approval:	22 September 2016
Approval no.:	82009

Approved Active Constituents—Veterinary

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.:	104949
Active constituent/s:	Imidacloprid
Applicant name:	Merial Australia Pty Ltd
Applicant ACN:	071 187 285
Summary of use:	For use in veterinary chemical products
Date of approval:	22 July 2016
Approval no.:	82084

Application no.:	107204
Active constituent/s:	Metoclopramide hydrochloride
Applicant name:	Ceva Animal Health Pty Ltd
Applicant ACN:	002 692 426
Summary of use:	For use in veterinary chemical products
Date of approval:	9 August 2016
Approval no.:	82954

Application no.:	107157
Active constituent/s:	Oxytetracycline hydrochloride
Applicant name:	Norbrook Laboratories Australia Pty Limited
Applicant ACN:	080 972 596
Summary of use:	For use in veterinary chemical products
Date of approval:	9 August 2016
Approval no.:	82936

Application no.:	107132
Active constituent/s:	Oxytetracycline dihydrate
Applicant name:	Norbrook Laboratories Australia Pty Limited
Applicant ACN:	080 972 596
Summary of use:	For use in veterinary chemical products
Date of approval:	9 August 2016
Approval no.:	82923

Application no.:	105414
Active constituent/s:	Aglepristone
Applicant name:	Virbac (Australia) Pty Ltd
Applicant ACN:	003 268 871
Summary of use:	For use in veterinary chemical products
Date of approval:	11 August 2016
Approval no.:	82311

Application no.:	105613
Active constituent/s:	Imidacloprid
Applicant name:	Neove Pharma Australia Pty Limited
Applicant ACN:	140 367 442
Summary of use:	For use in veterinary chemical products
Date of approval:	11 August 2016
Approval no.:	82384

Application no.:	107020
Active constituent/s:	Monensin sodium
Applicant name:	Dox-Al Italia S.P.A
Applicant ACN:	N/A
Summary of use:	For use in veterinary chemical products
Date of approval:	11 August 2016
Approval no.:	82870

Application no.:	106863
Active constituent/s:	Dicyclanil
Applicant name:	The Hunter River Company Pty Limited
Applicant ACN:	133 798 615
Summary of use:	For use in veterinary chemical products
Date of approval:	12 August 2016
Approval no.:	82825

Application no.:	105708
Active constituent/s:	Clenbuterol hydrochloride
Applicant name:	Virbac (Australia) Pty Ltd
Applicant ACN:	003 268 871
Summary of use:	For use in veterinary chemical products
Date of approval:	12 August 2016
Approval no.:	82418

2. VARIATIONS OF ACTIVE CONSTITUENT

Application no.:	103975
Active constituent/s:	Oil of lemon eucalyptus (hydrated, cyclized)
Applicant name:	Citrefine International Ltd
Applicant ACN:	N/A
Summary of variation:	Variation of relevant particulars or conditions of an approved active constituent
Date of variation:	8 August 2016
Approval no.:	54942

Application no.:	105706
Active constituent/s:	Pentosan polysulfate sodium
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:	10 August 2016
Approval no.:	82016

Application no.:	105553
Active constituent/s:	Enilconazole
Applicant name:	Elanco Animal Health A Div Of Eli Lilly Aust Pty Ltd
Applicant ACN:	000 233 992
Summary of variation:	Variation of relevant particulars or conditions of an approved active constituent
Date of variation:	11 August 2016
Approval no.:	55104

Application no.:	105641
Active constituent/s:	Tilmicosin
Applicant name:	Huvepharma EOOD
Applicant ACN:	N/A
Summary of variation:	Variation of relevant particulars or conditions of an approved active constituent
Date of variation:	11 August 2016
Approval no.:	82339

Application no.:	55103
Active constituent/s:	Enalapril maleate
Applicant name:	Merial Australia Pty Ltd
Applicant ACN:	071 187 285
Summary of variation:	Variation of relevant particulars or conditions of an approved active constituent
Date of variation:	11 August 2016
Approval no.:	104123

Application no.:	105704
Active constituent/s:	Diazepam
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:	12 August 2016
Approval no.:	55040

Application no.:	105447
Active constituent/s:	Gleptoferron
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:	19 September 2016
Approval no.:	82312

Application no.:	105396
Active constituent/s:	Apramycin sulfate
Applicant name:	Elanco Animal Health A Div Of Eli Lilly Aust Pty Ltd
Applicant ACN:	000 233 992
Summary of variation:	Variation of relevant particulars or conditions of an approved active constituent
Date of variation:	20 September 2016
Approval no.:	81928

Application no.:	106390
Active constituent/s:	Thyroxine sodium
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:	21 September 2016
Approval no.:	56385

Application no.:	105465
Active constituent/s:	Dimethyl azelate
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:	21 September 2016
Approval no.:	59169

Application no.:	103936
Active constituent/s:	Nicotinamide
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:	22 September 2016
Approval no.:	82021

New Veterinary Active Constituent and Chemical Product Osurnia Ear Gel for Dogs Containing Terbinafine

(Florfenicol and Betamethasone Acetate are Existing Active Constituents)

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application from Elanco Australasia Pty Ltd for the approval of a new active constituent, terbinafine, for use as an anti-fungal active constituent in veterinary products. The APVMA also has before it an application for the registration of a new product containing the new active constituent in combination with two existing active constituents—florfenicol and betamethasone acetate. The product is Osurnia Ear Gel for Dogs.

PARTICULARS OF THE ACTIVE CONSTITUENT

Common name: Terbinafine

IUPAC name: (E)-N-(6, 6-Dimethylhept-2-en-4-yn-1-yl)-N-methylnaphthalen-1-ylmethanamine

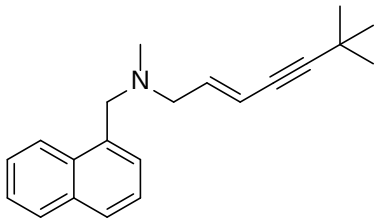
Chemical abstracts name: 1-Naphthalenemethanamine, N-[(2E)-6,6-dimethyl-2-hepten-4-yn-1-yl]-N-methyl-

CAS number: 91161-71-6

Molecular formula: $C_{21}H_{25}N$

Molar weight: 291.44

Structure:



Chemical family: Allylamine

Mode of action: Antifungal

SUMMARY OF THE APVMA'S EVALUATION OF TERBINAFINE ACTIVE CONSTITUENT

The APVMA has evaluated the chemistry aspects of terbinafine 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 terbinafine active constituent:

Constituent	Specification	Level
Terbinafine	Assay	980 g/kg minimum on a dry weight basis

Impurities of toxicological significance are not expected to occur in terbinafine as a result of the raw materials and the synthetic route used.

The APVMA has considered the toxicological aspects of terbinafine, and concluded that there are no toxicological concerns to the approval of this active constituent. Neither an Acceptable Daily Intake (ADI) nor an Acute Reference Dose (ARD) have been established in this assessment.

Terbinafine is approved for therapeutic use in humans and is listed in Schedule 4 (S4) of the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP). The APVMA has considered that an S4 Poisons Schedule status is appropriate for terbinafine for use in veterinary products.

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

PARTICULARS OF THE PRODUCT APPLICATION

Proposed product name:	**OSURNIA EAR GEL FOR DOGS**
Applicant company:	Elanco Australasia Pty Ltd
Name of new active constituent:	Terbinafine 10 mg/tube
Existing active constituents:	Florfenicol 10 mg/tube and betamethasone acetate 1 mg/tube
Signal heading:	Schedule 4
Summary of proposed use:	Treatment of otitis externa in dogs
Formulation type	Gel
Pack sizes:	2, 12, 20 and 40 packs of 1 mL tubes
Withholding period:	Not applicable

SUMMARY OF THE APVMA'S EVALUATION OF OSURNIA EAR GEL FOR DOGS IN ACCORDANCE WITH THE REQUIREMENTS OF SECTION 14(1)(C) OF THE AGRICULTURAL AND VETERINARY CHEMICALS CODE (THE 'AGVET CODE'), SCHEDULED TO THE *AGRICULTURAL AND VETERINARY CHEMICALS CODE ACT 1994*

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

(i) The APVMA is satisfied that the proposed use of Osurnia Ear Gel for Dogs would not be an undue hazard to the safety of people exposed to it during its handling and use.

An external toxicology reviewer has conducted a risk assessment on the product and has concluded that it can be used safely.

Based on acute toxicity studies conducted with Osurnia Ear Gel for Dogs, the product has very low acute oral toxicity and is a moderate eye irritant. The product is not a skin irritant or a skin sensitiser. Dermal treatment of rats with very high doses (>2020 mg/kg) of the product does not cause mortality or signs of systemic toxicity, although some animals display reversible desquamation and alopecia. Inhalation toxicity studies have not been submitted and are not required since the product is unlikely to form respiratory aerosols or be inhaled during use.

The external toxicology reviewer has conducted an assessment of exposure and risk. The reviewer has identified veterinarians or pet owners are most likely to become exposed to the product via the dermal route, with the possibility of oral or ocular exposure via hand-to-mouth or hand-to-eye transfer. Based on estimations of exposure to terbinafine, florfenicol and betamethasone, the reviewer has concluded that it is unlikely that the presence of the

three active constituents will create any significant toxicological hazard or risk to persons using the product in an occupational setting or to members of the public. Additionally for florfenicol, the reviewer has considered the lower margin of exposure estimate could be offset against the low likelihood of exposure to the active when handling and administering the product, and the potential to quickly remove any dermal contamination by hand-washing. In considering accidental poisoning in children, the reviewer has concluded accidental oral or dermal exposure to the product would unlikely to create any significant acute toxicological hazard to a child. It is anticipated the child could experience eye irritation in the event of hand-to-eye transfer of the gel, given that Osurnia Ear Gel for Dogs is a moderate eye irritant.

In order to mitigate the acute and repeat-dose risk associated with Osurnia Ear Gel for Dogs, the reviewer has recommended first aid statement (a)—*If poison occurs, contact a doctor or Poisons Information Centre. Phone Australia 13 11 26.* The reviewer has also recommended the following safety directions: *Will irritate the eyes. Avoid contact with eyes. Do not allow children to play with (dosing units). If product in eyes, wash it out immediately with water. Wash hands after use*. The first aid instruction and safety directions will be included on the product label.

The APVMA has considered and has accepted the findings and recommendations of the external toxicology reviewer.

An external reviewer has assessed a qualitative risk assessment of antimicrobial resistance the applicant had prepared and provided for the product. The main hazard is identified as florfenicol resistant bacteria or genetic elements selected by the use of Osurnia Ear Gel for Dogs. Direct exposure in people is through close contact with treated dogs. The risk from the use of Osurnia Ear Gel for Dogs is considered to be infection and treatment failure in humans due to exposure to florfenicol resistant bacteria. Hygiene and infection control practices such as wearing gloves and washing hands should reduce exposure.

Although the applicant has characterised the risk as being low, the characterisation did not consider the possibility of the presence of florfenicol resistant methicillin resistant *Staphylococcus aureus* (MRSA) or *Staphylococcus pseudintermedius* strains or florfenicol resistance in *Enterococcus* spp. and the Gram-negative aural organisms, *Escherichia coli* and *Proteus* spp. The risk of *cfr*-mediated resistant strains of bacteria is a public health concern since the *cfr* gene encodes for florfenicol and linezolid resistance. Linezolid is a last line treatment of methicillin resistant staphylococcal infections in humans. MRSA is a public health risk due to its inherent multi-resistance and the widespread distribution of *cfr* and other florfenicol resistance genes.

Methicillin resistant *S. pseudintermedius* (MRSP) is a lesser public health risk presently. The *cfr* gene has not yet been identified in *S. pseudintermedius*. The impact of *S. pseudintermedius* on public health would be the bacterium carrying the *cfr* gene and encoding resistance to florfenicol and linezolid.

Terbinafine resistant *malassezia pachydermatis* is also considered a hazard. Exposure to terbinafine resistant organisms is expected to be low. The hazard and exposure of terbinafine resistant *malassezia* are reported as negligible and the impact as low. The risk is classified as being low.

The reviewer has advised that the probability of the spread of resistant organisms to susceptible humans is considered negligible for *malassezia*, low for *S. pseudintermedius* and medium for MRSA. The probability of the establishment of colonisation by MRSA in exposed humans is also regarded as medium.

In accepting the findings of the reviewer, the APVMA has considered concerns that exposure to florfenicol could drive the emergence of staphylococci resistant to linezolid. These concerns are based on the two-way transmission of MRSA between humans and dogs; florfenicol is not used in humans and has not been registered for use in dogs; resistance to florfenicol emerges very quickly when it is used; and terbinafine is widely used in human medicine, but has not been registered for use in dogs.

The APVMA proposes to be satisfied of the public health risks by adopting the following regulatory approach for the registration of Osurnia Ear Gel for Dogs:

- mandate treatment should be based on culture/sensitivity testing
- mandate that veterinarians or their staff administer the first treatment of Osurnia Ear Gel for Dogs
- mandate the use of gloves when administering the product
- rely on EU and USA surveillance information, supported by APVMA's existing powers to initiate a targeted review of the registration of the product should the overseas surveillance information shows the product may not meet the safety and efficacy criteria.

(ii) The APVMA is satisfied that the proposed use of Osurnia Ear Gel for Dogs will not be an undue hazard to the safety of people using anything containing its residues.

The product is for use on companion animals (dogs) only. Terbinafine is unlikely to enter the food chain and therefore the determination of an Acceptable Daily Intake, an Acute Reference Dose and Maximum Residue Limits are not considered necessary.

(iii) The APVMA is satisfied that the proposed use of Osurnia Ear Gel for Dogs is not likely to be harmful to human beings if used according to the product label directions.

Terbinafine, florfenicol and betamethasone are currently included in Schedule 4 of the SUSMP. The currently listing for the three active constituents is determined to be appropriate for this product. The Schedule 4 signal heading PRESCRIPTION ANIMAL REMEDY, the recommended first aid instruction and safety directions will be included on the product label.

(iv) The APVMA is satisfied that the proposed use of Osurnia Ear Gel for Dogs is not likely to have an unintended effect that is harmful to animals, plants or the environment if used according to the product label directions.

The Department of the Environment has conducted a VICH Phase I Preliminary assessment. Based on estimates from modelling, the Department of Environment has classified terbinafine as being persistent in water and sediment, but not in soil. The active constituent is considered to be highly toxic to aquatic organisms. As treatment with the product is limited to individual dogs, environmental exposure to terbinafine is likely to occur via waste products in/on soils which may also find its way into aquatic habitats as a result of run-off from areas such as backyards, parks and kennels. The Department of Environment has concluded the concentration of terbinafine calculated in soil is unlikely to result in a significant environmental risk under the proposed use pattern, as it would only occurs in a small percentage of backyards. On this basis, it is not required that the environmental risk assessment proceeds to VICH Phase II.

The Department of Environment has recommended that the APVMA be satisfied that the proposed use of Osurnia Ear Gel for Dogs would not be likely to have an unintended effect that is harmful to animals, plants or things, or to the environment. The APVMA has considered these findings and accepts the recommendation. The product label will contain a disposal statement as follows: *Dispose of empty container by wrapping with paper and putting in garbage*.

An external reviewer has assessed the safety of Osurnia Ear Gel for Dogs in a single dose study, margin of safety studies at 1X, 3X and 5X the recommended dose rate and a meta-analysis of data from clinical studies.

Treatment with the product has resulted in systemic absorption of betamethasone which exerts dose-related systemic corticosteroid effects that were transient. Results from these studies support the precaution of applying the product to dogs with suspected or confirmed endocrine disorders.

Adverse laboratory or clinical effects of florfenicol or terbinafine have not been observed in the safety studies. The data support a safety margin of 3X dose volume, 1X dose frequency and 1X dose duration for laboratory adverse effects and a safety margin of >3X dose volume, 1X dose frequency and 1.5X dose duration for clinical adverse effects.

The APVMA is satisfied that Osurnia Ear Gel for Dogs would not have an unintended effect that is harmful to the target animals (dogs). Appropriate contraindications and precautionary statements will be included on the label, including a statement warning users not to use the product in ears with perforated tympanic membranes.

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

(i) In relation to its assessment of efficacy under section 14(3)(f), the APVMA is satisfied that data from trials supporting the efficacy of the product adequately demonstrate that if used according to the product label directions, the product is effective for its proposed uses.

Osurnia Ear Gel for Dogs is intended for the treatment of canine otitis externa. One tube of the product is administered to each infected ear of dogs. A second treatment is repeated after 7 days. Each tube provides 10 mg terbinafine, 10 mg florfenicol and 1 mg betamethasone acetate.

The efficacy data package is comprised of development studies, laboratory model studies, pharmacokinetic studies, dose determination studies, a dose confirmation study, confirmatory field/clinical studies, plus supporting published information. The studies have been conducted in Europe, Canada and the USA in accordance with Good Laboratory Practice or Good Clinical Practice. Data from these studies support the intended claim and treatment schedule. Data from MIC studies indirectly support the efficacy of Osurnia Ear Gel for Dogs in canine otitis externa under Australian conditions, as most *malassezia pachydermatis* isolates are susceptible to terbinafine. Most strains of *Proteus* spp., *Escherichia coli* and all strains of *Staphylococcus pseudintermedius* and beta haemolytic streptococci are susceptible to florfenicol, while most strains of other enterobacteriaceae/G- organisms show intermediate susceptibility. Most strains of *Pseudomonas aeruginosa* are resistant to florfenicol.

The APVMA has concluded that the data generated from the efficacy studies support the product would be effective in treating dogs affected with otitis externa caused by *malassezia pachydermatis*, *proteus* spp., *escherichia coli*, *staphylococcus pseudintermedius* and beta haemolytic streptococci. The label will include an instruction for infected ears to be cleaned with saline prior to treatment.

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:

(ii) The APVMA is satisfied that the proposed use of Osurnia Ear Gel for Dogs would not adversely affect trade between Australia and places outside Australia. The product is for use on dogs, which are not food-producing animals and which do not produce any major Australian export commodities.

MAKING A SUBMISSION

In accordance with sections 12 and13 of the Agvet Code, the APVMA invites any person to submit a relevant written submission as to whether terbinafine should be approved and whether Osurnia Ear Gel for Dogs should be registered. Submissions regarding the active constituent should relate only to matters that are considered in determining whether the safety criteria set out in section 5A of the Agvet Code have been met. Submissions regarding the product 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 for the active constituent should be addressed in writing to:

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

Phone: +61 2 6210 4701
Fax: +61 2 6210 4721
Email: enquiries@apvma.gov.au

Written submissions for the product should be addressed in writing to:

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

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

Continued Suspension of Certain Products Containing Dimethoate and their Associated Label Approvals

The APVMA has continued the suspension of the registrations and label approvals for eight products containing dimethoate, as identified in the table below. The decisions to extend the suspensions of the registrations and label approvals were made under subsections 41(1) and 41(2) of the *Agricultural and Veterinary Chemicals Code Act 1994* (Agvet Code).

The suspension of product registrations and label approvals are now in effect until 5 April 2017.

Active constituent approvals are not affected by the APVMA's decision to continue this suspension.

REASONS FOR CONTINUING THE SUSPENSION

The APVMA suspended all products containing dimethoate and their associated labels on 6 October 2011 due to unacceptable health risks to humans exposed to residues of dimethoate in food. These risks that formed the basis of this original suspension of label approvals and product registrations have not altered for the products listed in Table 1. Therefore continued suspension is necessary to ensure that the use of products containing dimethoate does not result in any undue hazard to the safety of people or have an effect that is harmful to human beings.

The APVMA has decided to continue the suspension of product registrations under subsection 41(1)(b) of the Agvet Code, because the continued use of, or other dealings with the products containing dimethoate as listed below, in accordance with their instructions for use may be an undue hazard to the safety of people using (ie consuming) anything containing dimethoate residues.

In addition, the APVMA has decided that the instructions on the previously approved labels associated with those products may no longer be adequate as they do not have appropriate instructions for the circumstances under which the product should be used, the frequency of use of the product and the withholding period after the use of the product for specific use patterns and crop types. The APVMA has decide to continue the suspension of these labels under Subsection 41(2) and to issue modified instructions for the use of these products during the suspension period.

Table 1: Suspended and cancelled products and suspended label approvals

Product no.	Product name	Registrant	Label approval numbers
55272	Superway Dimethoate 300 Systemic Insecticide	Superway Garden Ag & Pest Products Pty Ltd	55272/0202
57860	Halley Dimethoate 400 Systemic Insecticide	Halley International Enterprise (Australia) Pty Ltd	57860/0603
58375	Surefire Orchard and Garden Insecticide	PCT Holdings Pty Ltd	58375/0104
59469	AW Dimethoate 400 Systemic Insecticide	Agri West Pty Limited	59469/0105, 59469/0609
61916	Richgro Fruit Fly & Garden Insecticide	A Richards Pty Ltd T/A Richgro Garden Products	61916/1007, 61916/53035
63470	Country Dimethoate 400 Systemic Insecticide	Accensi Pty Ltd	63470/1208
64309	Farmalinx Dimetholinx Insecticide	Farmalinx Pty Ltd	64309/0809
65260	Rogor Upgrade Insecticide	Cheminova Australia Pty Ltd	65260/50541

All other products containing dimethoate are not suspended because their approved labels contain instructions that are consistent with the instructions for use of suspended products. Those products may be used according to the instructions on their approved labels.

INSTRUCTIONS

In accordance with subsection 45C(2) of the Agvet Code, a person may only possess, have custody of or deal with a suspended product (as identified in Table 1) in accordance with the instructions contained in this notice of suspension. During the period of suspension, a person may not possess, have custody of, use or deal with any of the suspended products or products bearing suspended labels other than in accordance with:

- the instructions set out at the end of this notice; or
- a permit issued by the APVMA.

In October 2011, a permit specifying modified instructions for use for agricultural products, was issued under section 114 of the Agvet Code (PER 13155 for agricultural products). The duration of this permit has been extended to 5 April 2017. The instructions for use in that permit are consistent with those at the end of this notice.

WARNING

The registration and label approvals of the products listed above are not in force during the period of suspension. In accordance with subsection 45C(2) of the Agvet Code, a person may only possess, have custody of, use or otherwise deal with the products identified above in accordance with a permit issued by the APVMA and the instructions set out at the end of this notice.

The APVMA may cancel permit PER13155 and issue replacement permits at any time during the suspension period. Before using, supplying or otherwise dealing with suspended products containing dimethoate, suppliers and users need

to be satisfied that the instructions set out at the end of this Notice continue to apply, and that their activities are authorised by a permit. Current permits are available at www.apvma.gov.au/node/611

According to subsection 45B(5) of the Agvet Code this notice does not authorise the holder or person to manufacture or import the suspended product.

From 6 October 2016 failure to comply with the instructions set out at the end of this Notice is an offence which attracts a penalty of 300 units under section 45C(2) of the Agvet Code.

Further, from 6 October 2011 to 6 October 2016 failure to comply with the instructions set out in the Gazette Notices of 11 October 2011, 25 September 2012, 24 September 2013, 7 October 2014 and 6 October 2015 is an offence which attracts a penalty of 300 units under section 45C(2) of the Agvet Code.

APVMA CONTACT

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

Contact Officer
Chemical Review
Scientific Assessment and Chemical Review
Australian Pesticides and Veterinary Medicines Authority
PO Box 6182
KINGSTON ACT 2604

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

INSTRUCTIONS FOR POSSESSING, HAVING CUSTODY OF, USING OR DEALING WITH SUSPENDED PRODUCTS CONTAINING DIMETHOATE

1. Possession and custody

A person may possess, have custody of, use or otherwise deal with the suspended or cancelled dimethoate products only in accordance with these instructions or permit PER 13155 for agricultural products issued by the APVMA.

2. Supply

All suppliers must at the time of the supply of a product covered by these instructions provide to the person taking responsibility for the supplied product:

- a copy of the relevant permit (currently PER 13155 for agricultural products,) in full setting out the conditions and instructions for use, and
- supply product with a copy of the instructions contained in that permit securely affixed to each container of product.

3. Use

4. PERSONS who wish to use suspended products containing dimethoate (as listed above) must read, or have read to them, the instructions included in the relevant APVMA permit. Users who have had the instructions read to them must confirm to the reader that they understand the instructions.

Read these instructions before using or otherwise handling the product.

When using or otherwise handling the product, follow the instructions of the current label except as follows:

PROHIBITED CROP USES: HOME GARDEN PRODUCTS

The current (suspended) label may include instructions for use on fruit trees and vegetables. The use of dimethoate on these crops is no longer approved and the following restraint applies.

DO NOT apply to food producing plants in the Home Garden

PROHIBITED CROP USES: AGRICULTURAL PRODUCTS

The existing (suspended) label may include instructions for use on the crops listed below. The use of dimethoate on these crops is no longer approved and the following restraints apply.

DO NOT USE as a post-harvest treatment for capsicums or tomatoes**.**

DO NOT USE as a post-harvest quarantine treatment for capsicums or tomatoes**.**
DO NOT USE on tomatoes grown in covered or protected situations such as glasshouses, green houses or plastic tunnels.

DO NOT USE on cherry, grape or mini tomatoes

DO NOT USE as a foliar, post harvest or quarantine treatment on:

- Tropical or subtropical edible peel fruit [babacos, carambolas (five corner), figs and edible peel varieties of guavas, kiwifruit and persimmons].
- Pome fruit [apples, loquats, pears, quinces],
- Stone fruit after petal fall [apricots, cherries, nectarines, peaches, plums, apricot],
- Grapes after commencement of flowering,
- Berry fruit, (other than blackberries, raspberries, bilberries, blueberries and other vaccinium berries)
- Strawberries (except strawberry runners—vegetative planting material only)
- Vegetables, other than those listed below
    - o Dimethoate may be used on artichoke (globe), asparagus, beans, beetroot, broccoli, cabbage (drumhead varieties only),capsicums, carrot, cauliflower, celery, chilli, peppers, peas, potatoes and sweet potatoes, onion, parsnips, radish, rhubarb, sweetcorn, tomatoes for processing, tomatoes (large field grown for fresh consumption) prior to fruit set, turnip and zucchini,
- Cucurbits (other than melons, watermelons and zucchini)

Directions for Use:

These directions for use must be used in conjunction with existing label directions and the restraint statements. Where the instructions in this notice are inconsistent with the label instructions, the instructions in this notice must be followed.

Table 1 Crops where existing label directions may continue to be followed.

Fruit crops	Vegetable crops	Non-food crops
Abius Avocado Banana Blackberries Cactus fruit Casimiroas (white sapote) Chinese gooseberries (kiwifruit) (inedible peel varieties ONLY) Citrus fruit Custard apple and cherimoya Feijoa Granadillas Guavas (inedible peel varieties only) Litchis (lychee) Mangoes Passionfruit and banana passionfruit Pawpaw (papaya) Persimmons (American—inedible peel varieties ONLY) Pomegranates Raspberries	*Existing labels include preharvest uses only* Asparagus Melons and watermelons Onions Rhubarb Watermelons Zucchini Seed dressings (vetches, lupins, peas, lucerne, clover, linseed, canola)	Duboisia, Farm and forest trees Eucalyptus Kurrajongs Oil tea-tree Ornamentals, protea Shrubs Umbrella trees Wildflowers

Fruit crops	Vegetable crops	Non-food crops
Santols Sapodillas (chikus) Tamarillos Wax jambus		

Table 2: Crops that are subject to additional restrictions/variations to their existing approved use patterns.

Crop	Additional use restrictions
Blueberries, bilberries and other vaccinium berries	**DO NOT** exceed a maximum number of 7 applications per crop per season with a minimum retreatment interval of 21 days between consecutive applications. **DO NOT** harvest for 1 day after final application.
Grapes	**DO NOT** use after flowering commences
Stone fruit	**DO NOT** use after petal fall
Artichoke, globe	**DO NOT** harvest for 14 days after final application
Beetroot	
Beans	**DO NOT** harvest for 7 days after application **DO NOT** graze or cut for stockfood for 7 days after application
Broccoli	**DO NOT** harvest for 21 days after final application
Cabbage specified drumhead varieties only when grown to maturity to be harvested as head cabbages (see attachment 3)	**DO NOT** harvest for 21 days after final application
Capsicum	**DO NOT USE** as a post-harvest treatment for capsicums. **DO NOT USE** as a post-harvest quarantine treatment for capsicums**.**.
Chilli	**Preharvest uses** **DO NOT** harvest for 3 days after application
Carrots	**DO NOT** harvest for 14 days after final application
Cauliflower	**DO NOT** harvest for 21 days after final application
Celery	
Peas	**DO NOT** harvest for 7 days after application **DO NOT** graze or cut for stockfood for 7 days after application
Parsnips	**DO NOT** harvest for 14 days after final application
Potatoes	**DO NOT** harvest for 14 days after final application
Sweet potatoes	
Radishes	**DO NOT** harvest for 14 days after application
Strawberry (runner production—vegetative planting material only)	**DO NOT** use on fruiting strawberries
Sweet corn	**DO NOT** graze or cut for stockfood for 7 days after application
Tomatoes for processing only	**DO NOT** harvest for 21 days after final application **DO NOT USE** as a post-harvest treatment for tomatoes. **DO NOT USE** as a post-harvest quarantine treatment for tomatoes. **DO NOT USE** on tomatoes grown in covered or protected situations such as glasshouses, green houses or plastic tunnels **DO NOT USE** on cherry, grape or mini tomatoes
Tomatoes, large, field grown for fresh consumption	**DO NOT** apply after commencement of flowering **DO NOT USE** on tomatoes grown in covered or protected situations such as glasshouses, green houses or plastic tunnels. **DO NOT USE** as a post-harvest treatment for tomatoes. **DO NOT USE** as a post-harvest quarantine treatment for tomatoes. **DO NOT USE** on cherry, grape or mini tomatoes
Turnips	**DO NOT** harvest for 14 days after final application

Crop	Additional use restrictions
Cereals, (including maize, sorghum)	**DO NOT** harvest for 4 weeks after application **DO NOT** graze or cut for stockfood for 14 days after application
Cotton	**DO NOT** harvest for 14 days after application **DO NOT** feed cotton fodder, stubble or trash to livestock
Oilseeds, pulses (grain legumes)	**DO NOT** harvest for 14 days after application **DO NOT** graze or cut for stockfood for 14 days after application
Pastures, forage crops and leucaena	**DO NOT** graze or cut for stockfood for 14 days after application

WITHHOLDING PERIODS (see additional use restrictions above)

Citrus
DO NOT harvest for 7 days after application

Blueberries (and other vaccinium berries including bilberries)
DO NOT harvest for 1 day after application

Blackberries, raspberries
DO NOT harvest for 7 days after application

Grapes, stone fruit
Harvest withholding period: not required when used as directed

Assorted sub-tropical and tropical fruit—inedible peel (other than mango and pineapple), including abui, avocado, banana, banana passionfruit, casimiroas (white sapote), cherimoya, custard apple, granadillas, litchi/lychee, passionfruit, paw paw, santols, sapodillas (chikus), wax jambus
DO NOT harvest for 7 days after application

Mango
DO NOT harvest for 3 days after application

Post harvest dipping (avocados, bananas, cactus fruit, chilli, custard apples, feijoas, guavas, kiwifruit (chinese gooseberries inedible peel varieties), litchis (lychees), mangoes, melons, passionfruit, banana passionfruit, pawpaws, persimmons (inedible peel varieties), pomegranates, tamarillos, watermelons)
NOT REQUIRED WHEN USED AS DIRECTED (dip uses only)

Litchis (lychees) (pre-planting dip)
Harvest withholding period: not required when used as directed

Asparagus, onions, rhubarb, sweet corn
DO NOT harvest for 7 days after application

Sweetcorn:
DO NOT graze or cut for stockfood for 7 days after application

Beans, peas (green vegetables)
DO NOT harvest for 7 days after application
DO NOT graze or cut for stockfood for 7 days after application

Beetroot, carrot, globe artichoke, parsnips potatoes, radish, sweet potatoes, turnip
DO NOT harvest for 14 days after application.

Broccoli, cauliflower, celery
DO NOT harvest for 21 days after application

Strawberry plants (runner production—vegetative planting material only)
NOT REQUIRED WHEN USED AS DIRECTED

Tomatoes (for processing)
DO NOT harvest for 21 days after application

Tomatoes, large, field grown for fresh consumption
Harvest withholding period: **NOT REQUIRED WHEN USED AS DIRECTED**

Drumhead cabbage (specified varieties only)
DO NOT harvest for 21 days after application

Capsicums, chilli peppers
DO NOT harvest for 3 days after application

Melons (including watermelons), zucchini
DO NOT harvest for 1 day after application

Cereals, (including maize, sorghum)
DO NOT harvest for 4 weeks after application
DO NOT graze or cut for stockfood for 14 days after application
Cotton
DO NOT harvest for 14 days after application
DO NOT feed cotton fodder, stubble or trash to livestock

Oilseeds, pulses (grain legumes)
DO NOT harvest for 14 days after application
DO NOT graze or cut for stockfood for 14 days after application

Pastures, forage crops and leucaena
DO NOT graze or cut for stockfood for 14 days after application

Seed dressings (vetches, lupins, peas, lucerne, clover, linseed canola),
NOT REQUIRED WHEN USED AS DIRECTED

Table 3: Specified varieties of drumhead cabbage. Dimethoate may be used on these varieties to be grown to maturity to be harvested as head cabbages

Seed company	Drumhead Cabbage varieties
Fairbanks seed	Avachat F_1, grandslam F_1, superba
Terranova	Neptune, winterhead, red queen, green coronet, eureka
Lefroy valley seeds	Conquistador, burton, landini
Rijk zwaan	Racoma RZ F_1
Ace	Major F_1, red gem
S&G seeds	Maxfield
SPS	Arixos, asia, kameron, red jewel
Bejo seeds	Ducat F_1, gazelle F_1, megaton F_1, benelli F_1, gonzales F_1, mandy F_1, field glory F_1, score F_1
Eden seeds	Golden acre, mammoth red rock
King seeds	Campra F1, sunta
Yates	Racer drumhead, red dutch
Australian seed	Mammoth red rock, all seasons

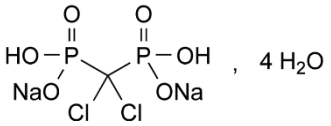
New Active Constituent and New Chemical Products Osphos 51 mg/ml Solution for Injection for Horses Containing Clodronicacid

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application for the approval of a new active constituent, clodronate disodium tetrahydrate, and an application for registration of a new product containing the new active constituent. The product is Osphos 51 mg/ml Solution for Injection for Horses.

PARTICULARS OF THE ACTIVE CONSTITUENT

Clodronate disodium tetrahydrate

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application for the approval of a new active constituent, clodronate disodium tetrahydrate for use as an anti-osteoporotic active constituent in veterinary products.

Ph. Eur. Name:	Clodronate disodium tetrahydrate
BP Name:	Sodium clodronate tetrahydrate
BP/Ph. Eur. Definition:	Disodium (dichloromethylene)bis(hydrogenphosphonate) tetrahydrate
IUPAC Name:	Disodium [dichloro-[hydroxy(oxido)phosphoryl]methyl]-hydroxyphosphinate tetrahydrate Phosphonic acid, *P*,*P*'-(dichloromethylene)bis-, sodium salt (1:2:4)
Chemical Abstracts Name:	
CAS Number:	88416-50-6
Molecular Formula:	$CH_2Cl_2Na_2O_6P_2.4H_2O$
Molecular Mass	360.92 g/mol
Structure:	 , 4 H_2O
Chemical Family:	Bisphosphate
Mode of Action:	Anti-osteoporotic activity

SUMMARY OF THE APVMA'S EVALUATION OF CLODRONATE DISODIUM TETRAHYDRATE ACTIVE CONSTITUENT

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

Impurities of toxicological significance are not expected to occur in clodronate disodium tetrahydrate as a result of the raw materials and the synthetic route used.

The APVMA has considered the toxicological aspects of clodronate disodium tetrahydrate, and concluded that there are no toxicological concerns to the approval of this active constituent. No ADI or ARfD has been established in this assessment.

Clodronate disodium tetrahydrate is included in Schedule 4 of the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) as clodronic acid. The APVMA considered that an S4 Poisons Schedule status is appropriate for clodronate disodium tetrahydrate for use in veterinary products.

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

PARTICULARS OF THE PRODUCT

Proposed product name(s):	Osphos 51 mg/ml Solution for Injection for Horses
Applicant company:	Dechra Ltd
Name of active constituent:	Clodronate disodium tetrahydrate
Signal heading:	Schedule 4
Summary of proposed use:	For the improvement of lameness associated with navicular syndrome in horses.
Pack sizes:	15 mL
Withholding period:	DO NOT USE in horses that may be used for human consumption.

SUMMARY OF THE APVMA'S EVALUATION OF OSPHOS 51 MG/ML SOLUTION FOR INJECTION FOR HORSES IN ACCORDANCE WITH THE REQUIREMENTS OF SECTION 14(1)(C) OF THE AGRICULTURAL AND VETERINARY CHEMICALS CODE (THE 'AGVET CODE'), SCHEDULED TO THE *AGRICULTURAL AND VETERINARY CHEMICALS CODE ACT 1994*

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

(i) The APVMA is satisfied that the proposed use of osphos 51 mg/ml solution for injection for horses would not be an undue hazard to the safety of people exposed to it during its handling and use.

An external toxicology reviewer has conducted a risk assessment on the product and concluded that it can be used safely.

The external reviewer has estimated the acute toxicity of Osphos 51 mg/ml Solution for Injection for Horses based on information provided by the applicant. The product is not a skin or eye irritant, and is expected to have low toxicity via all routes of exposure.

An operator qualitative risk assessment concluded that exposure to the product may occur during its use via skin exposure or needle-stick injury, but that these routes of exposure would result in very low to negligible exposure. Exposure via other routes was considered unlikely.

To mitigate the acute and repeat-dose risks associated with Osphos 51 mg/ml Solution for Injection for Horses, the reviewer has recommended first aid statement (a)—*If poison occurs, contact a doctor or Poisons Information Centre. Phone Australia 13 11 26*. This first aid instruction will be included on the product label.

The active constituent was not a teratogen in laboratory animal studies but maternal toxicity and consequent delayed foetal development were observed. The reviewer has recommended Safety Directions for the label–*Wash hands after use.*

The applicant has proposed additional user safety instructions for the label–*Care should be taken when handling the product to avoid self-injection especially by pregnant women. In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.* The reviewer agrees with the inclusion of the additional user safety instructions.

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

(ii) The APVMA is satisfied that the proposed use of Osphos 51 mg/ml Solution for Injection for Horses will not be an undue hazard to the safety of people using anything containing its residues.

The product is for use in horses only and so products from treated animals are unlikely to enter the food-chain. The label will contain the default restraint statement for horses—*DO NOT USE in horses that may be used for human consumption.*

(iii) The APVMA is satisfied that the proposed use of Osphos 51 mg/ml Solution for Injection for Horses containing the active constituent clodronate disodium tetrahydrate is not likely to be harmful to human beings if used according to the product label directions.

Clodronic acid is approved for therapeutic use in humans, and is listed in Schedule 4 of the Australian Standard for Uniform Scheduling of Medicines and Poisons (SUSMP), with no exceptions. Osphos 51 mg/ml Solution for Injection for Horses contains 51 mg/mL of of clodronic acid equivalent to 75mg/ml clodronate disodium tetrahydrate). Based on the concentration of clodronic acid and the toxicological profile of the product, this scheduling is considered appropriate.

(iv) The APVMA is satisfied that the proposed use of the new product Osphos 51 mg/ml Solution for Injection for Horses containing the active constituent clodronate disodium tetrahydrate, would not be likely to have an unintended effect that is harmful to animals, plants or things or the environment.

The APVMA has conducted a risk assessment to consider the environmental safety of Osphos 51 mg/ml Solution for Injection for Horses. The standard environmental release scenario for treatment of horses was considered in a Phase 1 assessment according to EMA Guideline on Environmental Impact Assessment for Veterinary Medicinal Products in support of the VICH Guidelines GL6 and GL38 (2008).

The risk assessment has concluded that the proposed use of the product on horses is unlikely to result in a significant environmental risk under the proposed use pattern. The label will contain a disposal statement as follows: *Dispose of empty container by wrapping with paper and putting in garbage*.

An external reviewer has assessed the target animal safety of Osphos 51 mg/ml Solution for Injection for Horses in a margin of safety study and a two-phase pilot safety study conducted in horses. The studies demonstrated that the product is well tolerated in the target species. Notable toxicity including elevated blood urea nitrogen and creatinine, as well as clinical signs associated with colic and the central nervous system were observed at dose levels considerably above the recommended dose range. These effects are included on the label.

A study evaluated the concurrent use of oral phenylbutazone and found that this was well-tolerated at the recommended label dose rate.

Appropriate contraindication statements relating to the use in horses with impaired renal function and horses less than four years of age will be included on the label. Appropriate precaution statements including use during pregnancy and lactation, concurrent use of aminoglycosides or tetracyclines, and potential impact on microfracture healing will be included on the label.

The APVMA is satisfied that osphos 51 mg/ml solution for injection for horses would not have an unintended effect that is harmful to the target animals (horses).

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

(v) In relation to its assessment of efficacy, the APVMA is satisfied that data from trials supporting the efficacy of the product adequately demonstrate that if used according to the product label directions, the product is effective for its proposed use.

Osphos 51 mg/ml Solution for Injection for Horses is intended for use in horses for improvement of lameness associated with navicular syndrome. The product is a solution for injection which is to be administered by intramuscular injection at a dose rate of 3 mL per 100 kg bodyweight (1.8 mg disodium clodronate per kg bodyweight (equivalent to 1.53 mg/kg clodronic acid per kg bodyweight)).

The efficacy studies include a dose determination study, a dose confirmation study and a field efficacy study. The applicant also provided publicly available background information.

The dose determination study demonstrated that 900 mg of disodium clodronate (equivalent to 765 mg clodronic acid) given intramuscularly was the lowest effective dose that resulted in clinical improvement in horses with clinical signs of navicular syndrome after 28 days. The dose confirmation study demonstrated that 900 mg of disodium clodronate (equivalent to 765 mg clodronic acid) given intramuscularly resulted in improved clinical signs in horses with clinical signs of navicular syndrome after 28 days compared to placebo, and that the drug appeared to be well tolerated.

The clinical field study showed that treatment with 1.4 mg disodium clodronate per/kg bodyweight (equivalent to 1.19 mg clodronic acid per/kg bodyweight) (up to a maximum of 900 mg disodium clodronate per horse) (equivalent to 765 mg clodronic acid) administered via three equal volume intramuscular injections significantly improved clinical signs of lameness compared with placebo at day 56. Some mild adverse events were reported which are detailed on the product label. Ten horses showed clinical signs of mild colic after administration, and one horse developed urticaria. These horses recovered with minimal intervention. These effects are included on the label.

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:

(vi) The APVMA is satisfied that the proposed use of osphos 51 mg/ml solution for injection for horses would not adversely affect trade between Australia and places outside Australia as the product is not for use in animals producing any major Australian export commodities.

MAKING A SUBMISSION

In accordance with section 12 of the Agvet Code, the APVMA invites any person to submit a relevant written submission as to whether the active constituent clodronate disodium tetrahydrate should be approved. Submissions should relate only to matters that are considered in determining whether the safety criteria set out in section 5A of the Agvet Code have been met. Submissions should state the grounds on which they are based.

In accordance with section13 of the Agvet Code, the APVMA invites any person to submit a relevant written submission as to whether the product osphos 51 mg/ml solution for injection for horses 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 set out in sections 5A, 5B and 5C of the Agvet Code have been met. Submissions should state the grounds on which they are based.

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

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:

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

Phone: +61 2 6210 4701
Fax: +61 2 6210 4721
Email: enquiries@apvma.gov.au

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.13)

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. 13)) 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. 13))

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 sunsetting.

To commence: on gazettal of variation

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

[1.1] inserting in alphabetical order

Agvet chemical: Niclosamide	
Permitted residue: Niclosamide	
Edible offal (mammalian)	T*0.01
Eggs	T*0.01
Meat (mammalian)	T*0.01
Milks	T*0.01
Poultry, edible offal of	T*0.01
Poultry meat	T*0.01
Rice	T*0.01

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

Agvet chemical: Cyproconazole	
Permitted residue: Cyproconazole, sum of isomers	
Chick-pea (dry)	T*0.01
Lentil (dry)	T*0.01

Agvet chemical: Prothioconazole	
Permitted residue—commodities of plant origin: Sum of prothioconazole and prothioconazole desthio (2-(1-chlorocyclopropyl)-1-(2-chlorophenyl)-3-(1H-1,2,4-triazol-1-yl)-propan-2-ol), expressed as prothioconazole	
Permitted residue—commodities of animal origin: Sum of prothioconazole, prothioconazole desthio (2-(1-chlorocyclopropyl)-1-(2-chlorophenyl)-3-(1H-1,2,4-triazol-1-yl)-propan-2-ol), prothioconazole-3-hydroxy-desthio (2-(1-chlorocyclopropyl)-1-(2-chloro-3-hydroxyphenyl)-3-(1H-1,2,4-triazol-1-yl)-propan-2-ol) and prothioconazole-4-hydroxy-desthio (2-(1-chlorocyclopropyl)-1-(2-chloro-4-hydroxyphenyl)-3-(1H-1,2,4-triazol-1-yl)-propan-2-ol), expressed as prothioconazole	
Chick-pea (dry)	T0.7
Lentil (dry)	T0.7
Pulses [except chick-pea (dry); lentil (dry)]	T0.1

Agvet chemical: Tebuconazole	
Permitted residue: Tebuconazole	
Broad bean (dry)	T0.5
Chick-pea (dry)	T0.2
Lentil (dry)	T0.2

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

Agvet chemical: Azoxystrobin	
Permitted residue: Azoxystrobin	
Broad bean (dry) (fava bean)	T0.05
Field pea (dry)	T0.05

Agvet chemical: Cyproconazole	
Permitted residue: Cyproconazole, sum of isomers	
Pulses	T0.07

Agvet chemical: Emamectin	
Permitted residue: Sum of emamectin B1a and emamectin B1b	
Podded pea (young pods) (snow and sugar snap)	T0.02

Agvet chemical: Prothioconazole	
Permitted residue—commodities of plant origin: Sum of prothioconazole and prothioconazole desthio (2-(1-chlorocyclopropyl)-1-(2-chlorophenyl)-3-(1H-1,2,4-triazol-1-yl)-propan-2-ol), expressed as prothioconazole	
Permitted residue—commodities of animal origin: Sum of prothioconazole, prothioconazole desthio (2-(1-chlorocyclopropyl)-1-(2-chlorophenyl)-3-(1H-1,2,4-triazol-1-yl)-propan-2-ol), prothioconazole-3-hydroxy-desthio (2-(1-chlorocyclopropyl)-1-(2-chloro-3-hydroxyphenyl)-3-(1H-1,2,4-triazol-1-yl)-propan-2-ol) and prothioconazole-4-hydroxy-desthio (2-(1-chlorocyclopropyl)-1-(2-chloro-4-hydroxyphenyl)-3-(1H-1,2,4-triazol-1-yl)-propan-2-ol), expressed as prothioconazole	
Pulses	T0.7

Agvet chemical: Tebuconazole	
Permitted residue: Tebuconazole	
Pulses [except mung bean (dry); soya bean (dry)]	T1

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 (ADST) 1 November 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. 8) gazetted on 28 June 2016 (No. APVMA 13).

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 9, 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 Legislation available on the Legislation website at www.legislation.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 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:

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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 9, 2016

I, Angela O'Sullivan, Acting Ag Executive Director, Registration Management and Evaluation 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*.

Angela O'Sullivan

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

Dated this Twenty Seventh day of September 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 9, 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 20 of 4 October 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] 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

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

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

Agvet chemical: Carbendazim *Permitted residue: Sum of carbendazim and 2-aminobenzimidazole, expressed as carbendazim*	
Garlic	T*0.01

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

Agvet chemical: Iprodione *Permitted residue: Iprodione*	
Garlic	T0.3

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