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Gazette

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AGRICULTURAL AND VETERINARY CHEMICALS

Australian Government

Australian Pesticides and Veterinary Medicines Authority

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

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GENERAL INFORMATION

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

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

DISTRIBUTION AND SUBSCRIPTION

The *APVMA Gazette* is published in electronic format only and is available from the APVMA website, www.apvma.gov.au/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.:	103163
Product name:	Conserve Plus Grain Protector
Active constituent/s:	100 g/L spinosad 100 g/L s-methoprene
Applicant name:	Dow Agrosciences Australia Limited
Applicant ACN:	003 771 659
Summary of use	For control of insect pests in stored cereal grain
Date of registration/approval:	22 June 2016
Product registration no.:	81465
Label approval no.:	81465/103163OF, 81465/103163BH

Application no.:	106141
Product name:	Double Alpha Azoxystrobin 250 SC Fungicide
Active constituent/s:	250 g/L azoxystrobin
Applicant name:	Alpha Crop Protection Pty Ltd
Applicant ACN:	165 653 047
Summary of use	For the control of various diseases of grapes, potatoes, tomatoes, cucurbits, avocados, mangoes, passionfruit and poppies
Date of registration/approval:	22 June 2016
Product registration no.:	82591
Label approval no.:	82591/106141

Application no.:	102592
Product name:	Sedge Control For Lawns
Active constituent/s:	48.75 g/kg halosulfuron-methyl
Applicant name:	Crop Culture Pty Ltd
Applicant ACN:	142 860 473
Summary of use	For the selective post-emergence control of nutgrass and mullumbimby couch in turf for home garden situation
Date of registration/approval:	24 June 2016
Product registration no.:	81221
Label approval no.:	81221/102592

Application no.:	106486
Product name:	Atlas Outdoor Fly & Mosquito Shield
Active constituent/s:	5 g/kg transfluthrin, 0.5 g/kg permethrin
Applicant name:	Pascoe's Pty Ltd
Applicant ACN:	055 220 463
Summary of use	For the control of flies and mosquitoes in the home
Date of registration/approval:	30 June 2016
Product registration no.:	82685
Label approval no.:	82685/106486

Application no.:	106130
Product name:	Kelpie A-Zine 900 DF Herbicide
Active constituent/s:	900 g/kg atrazine
Applicant name:	Sinochem International Australia Pty Ltd
Applicant ACN:	160 164 616
Summary of use	For the control of weeds and grasses on sorghum, maize, sugarcane, triazine tolerant canola, lucerne and fallow area maintenance and other situations
Date of registration/approval:	1 July 2016
Product registration no.:	82583
Label approval no.:	82583/106130

Application no.:	106166
Product name:	Kelpie S-Zine 900 Herbicide
Active constituent/s:	900 g/kg simazine
Applicant name:	Sinochem International Australia Pty Ltd
Applicant ACN:	160 164 616
Summary of use	For the control of weeds in chickpeas, lupins, TT canola, orchards, vineyards and certain other horticultural crops and non-crop situations
Date of registration/approval:	1 July 2016
Product registration no.:	82597
Label approval no.:	82597/106166

Application no.:	105117
Product name:	Spa Soft Spa Sanitiser
Active constituent/s:	20 g/L polihexanide hydrochloride
Applicant name:	M I International Pty Ltd
Applicant ACN:	002 869 089
Summary of use	For the control of bacteria in spa pools
Date of registration/approval:	1 July 2016
Product registration no.:	82162
Label approval no.:	82162/105117

Application no.:	106550
Product name:	Reylon Futura 250SC Fungicide
Active constituent/s:	250 g/L flutriafol
Applicant name:	Ruralco Holdings Limited
Applicant ACN:	009 660 879
Summary of use	For the control of certain fungal diseases on wheat, barley and canola when mixed with fertiliser or applied as a foliar spray
Date of registration/approval:	1 July 2016
Product registration no.:	82729
Label approval no.:	82729/106550

Application no.:	106270
Product name:	Bifen 100EC Termiticide & Insecticide
Active constituent/s:	100 g/L bifenthrin
Applicant name:	Premier Shukuroglou AU Pty Ltd
Applicant ACN:	603 303 939
Summary of use	For the protection of structures from subterranean termite damage and for the control of termites and a range of other urban pests
Date of registration/approval:	1 July 2016
Product registration no.:	82622
Label approval no.:	82622/106270

Application no.:	105774
Product name:	Hovex Germgard Bed Bug & Flea Killer
Active constituent/s:	0.7 g/kg imiprothrin, 2 g/kg cypermethrin
Applicant name:	Pascoe's Pty Ltd
Applicant ACN:	055 220 463
Summary of use	For use against bed bugs, fleas and crawling insects around the home garden
Date of registration/approval:	4 July 2016
Product registration no.:	82445
Label approval no.:	82445/105774

Application no.:	102957
Product name:	Enviromax Indoxocarb Cockroach Gel Bait
Active constituent/s:	6 g/kg indoxocarb (S:R 3:1)
Applicant name:	Enviromax Technologies Pty Ltd
Applicant ACN:	132 643 577
Summary of use	For the control of cockroaches in domestic, commercial and public service buildings
Date of registration/approval:	4 July 2016
Product registration no.:	81378
Label approval no.:	81378/102957

Application no.:	104159
Product name:	eChem S-Metol 960 Herbicide
Active constituent/s:	960 g/L s-metolachlor
Applicant name:	eChem (Aust) Pty Ltd
Applicant ACN:	089 133 095
Summary of use	For the control of certain annual grasses and broadleaf weeds in certain crops
Date of registration/approval:	4 July 2016
Product registration no.:	81853
Label approval no.:	81853/104159

Application no.:	106022
Product name:	Alphaprem 100 Insecticide
Active constituent/s:	100 g/L alpha-cypermethrin
Applicant name:	Premier Shukuroglou AU Pty Ltd
Applicant ACN:	603 303 939
Summary of use	For the control of certain insect pests, including heliothis (*helicoverpa spp*,) on various crops and redlegged earth mite and blue oat mite on certain field crops and pastures and certain insect pests on fruit and vegetable crops
Date of registration/approval:	4 July 2016
Product registration no.:	82542
Label approval no.:	82542/106022

Application no.:	106324
Product name:	Atlas Enviroshield Insect Control Bomb
Active constituent/s:	10 g/kg permethrin, 0.77 g/kg fenoxycarb
Applicant name:	Pascoe's Pty Ltd
Applicant ACN:	055 220 463
Summary of use	For use in enclosed areas around the home
Date of registration/approval:	5 July 2016
Product registration no.:	82635
Label approval no.:	82635/106324

Application no.:	101645
Product name:	Manic WG Fungicide Plus
Active constituent/s:	625 g/kg mancozeb
Applicant name:	UPL Australia Limited
Applicant ACN:	066 391 384
Summary of use	For the control of certain fungus diseases of field crops, vegetables, fruit, tobacco, turf and ornamentals and for the correction of zinc deficiency in crops
Date of registration/approval:	6 July 2016
Product registration no.:	80787
Label approval no.:	80787/101645

Application no.:	106258
Product name:	Deltraforce Residual Insecticide
Active constituent/s:	10 g/L deltamethrin, 10 g/L d-tetramethrin 20:80, 80 g/L piperonyl butoxide
Applicant name:	Premier Shukuroglou AU Pty Ltd
Applicant ACN:	603 303 939
Summary of use	For the control of a range of insect pests in in urban and timber treatment situations
Date of registration/approval:	7 July 2016
Product registration no.:	82616
Label approval no.:	82616/106258

Application no.:	106259
Product name:	Fipro-Pro 200 SC Insecticide
Active constituent/s:	200 g/L fipronil
Applicant name:	Premier Shukuroglou AU Pty Ltd
Applicant ACN:	603 303 939
Summary of use	For the control of various insect pests in asparagus, bananas, brassicas, cotton, forestry, ginger, wine grapevines, mushrooms, pasture, potatoes, sorghum, sugarcane and swede
Date of registration/approval:	7 July 2016
Product registration no.:	82617
Label approval no.:	82617/106259

Application no.:	105703
Product name:	Genfarm Imidacloprid 600 Flowable Seed Treatment Insecticide
Active constituent/s:	600 g/L imidacloprid
Applicant name:	Landmark Operations Limited
Applicant ACN:	008 743 217
Summary of use	For the control of various insect pests in a range of crops and prevention of the spread of barley yellow dwarf virus in cereal crops
Date of registration/approval:	12 July 2016
Product registration no.:	82416
Label approval no.:	82416/105703

Application no.:	106522
Product name:	Glymount 540K Herbicide
Active constituent/s:	540 g/L glyphosate (present as the potassium salt)
Applicant name:	Grow Choice Pty Ltd
Applicant ACN:	069 839 961
Summary of use	For the non-selective control of many annual and perennial weeds
Date of registration/approval:	13 July 2016
Product registration no.:	82715
Label approval no.:	82715/106522

Application no.:	103621
Product name:	ACTIGARD Plant Activator
Active constituent/s:	500 g/kg acibenzolar-s-methyl
Applicant name:	Syngenta Australia Pty Ltd
Applicant ACN:	002 933 717
Summary of use	For protection against certain bacterial diseases and powdery mildew of tomatoes by activating the plants natural resistance mechanisms
Date of registration/approval:	14 July 2016
Product registration no.:	81677
Label approval no.:	81677/103621

Application no.:	102203
Product name:	Maxforce Activ Cockroach Gel
Active constituent/s:	10 g/kg clothianidin
Applicant name:	Bayer Cropscience Pty Ltd
Applicant ACN:	000 226 022
Summary of use	For the control of cockroaches in a range of urban and public transport situations
Date of registration/approval:	15 July 2016
Product registration no.:	81040
Label approval no.:	81040/102203

Application no.:	103781
Product name:	ARCADE Herbicide
Active constituent/s:	800 g/L prosulfocarb
Applicant name:	Syngenta Australia Pty Ltd
Applicant ACN:	002 933 717
Summary of use	For use in wheat and barley
Date of registration/approval:	15 July 2016
Product registration no.:	81708
Label approval no.:	81708/103781

2. VARIATIONS OF REGISTRATION

Application no:	106981
Product name:	Mozzigear Mosquito-Band Anti-Insect Band
Active constituent/s:	0.75 g per band citronella oil
Applicant name:	Franbar Glen Pty Ltd T/A Intelligent Health Systems
Applicant ACN:	109 292 284
Summary of variation:	To change the distinguishing product name and the name that appears on the label from 'MOSQUITO-BAND ANTI-INSECT BAND' to 'MOZZIGEAR MOSQUITO-BAND ANTI-INSECT BAND' and to remove a use
Date of variation:	9 June 2016
Product registration no.:	60836
Label approval no.:	60836/106981

Application no:	107068
Product name:	Mozzigear Mosquito-Patch Insect Repellent
Active constituent/s:	120 mg/patch citronella oil
Applicant name:	Franbar Glen Pty Ltd T/A Intelligent Health Systems
Applicant ACN:	109 292 284
Summary of variation:	To change the distinguishing product name and the name that appears on the label from 'MOSQUITO-PATCH INSECT REPELLENT' to 'MOZZIGEAR MOSQUITO-PATCH INSECT REPELLENT'
Date of variation:	9 June 2016
Product registration no.:	63148
Label approval no.:	63148/107068

Application no:	107018
Product name:	Sipcam Atrazine 500 SC Herbicide
Active constituent/s:	500 g/L atrazine
Applicant name:	Sipcam Pacific Australia Pty Ltd
Applicant ACN:	073 176 888
Summary of variation:	To change the distinguishing product name and the name that appears on the label from 'SIPCAM MAIZINA 500 FLOWABLE HERBICIDE' to 'SIPCAM ATRAZINE 500 SC HERBICIDE'
Date of variation:	15 June 2016
Product registration no.:	50164
Label approval no.:	50164/107018

Application no:	107113
Product name:	Swim Kleen
Active constituent/s:	60 g/L copper (Cu) present as copper sulphate pentahydrate
Applicant name:	Keith Stanley Wall
Applicant ACN:	N/A
Summary of variation:	To change the distinguishing product name and the name that appears on the label from 'CLEAR WATER ALGAECIDE' to 'SWIM KLEEN'
Date of variation:	24 June 2016
Product registration no.:	67391
Label approval no.:	67391/107113

Application no:	107143
Product name:	Axiom Plus Fungicide
Active constituent/s:	350 g/kg copper (Cu) present as copper oxychloride, 150 g/kg metalaxyl
Applicant name:	Adama Australia Pty Limited
Applicant ACN:	050 328 973
Summary of variation:	To change the distinguishing product name and the name that appears on the label from 'FARMOZ AXIOM PLUS SYSTEMIC FUNGICIDE' to 'AXIOM PLUS FUNGICIDE'
Date of variation:	28 June 2016
Product registration no.:	50833
Label approval no.:	50833/107143

Application no.:	105160
Product name:	Aqua K-Othrine Insecticide Space-Spray Concentrate
Active constituent/s:	20 g/L deltamethrin
Applicant name:	Bayer Cropscience Pty Ltd
Applicant ACN:	000 226 022
Summary of use	To include biting midges within the same general use pattern
Date of variation:	5 July 2016
Product registration no.:	63246
Label approval no.:	63246/105160

Application no.:	101720
Product name:	Legend Fungicide
Active constituent/s:	250 g/L quinoxyfen
Applicant name:	Dow Agrosciences Australia Limited
Applicant ACN:	003 771 659
Summary of use	To extend the uses into barley for the control of powdery mildew
Date of variation:	13 July 2016
Product registration no.:	53607
Label approval no.:	53607/101720

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.:	59647
Product name:	Prilactone 80 mg Tablets For Dogs
Active constituent/s:	Each tablet contains 80 mg spironolactone
Applicant name:	Ceva Animal Health Pty Ltd
Applicant ACN:	002 692 426
Summary of use	For use in combination with standard therapy for the treatment of congestive heart failure caused by mitral valvular regurgitation in dogs
Date of registration/approval:	6 July 2016
Product registration no.:	69014
Label approval no.:	69014/59647

Application no.:	59648
Product name:	Prilactone 40 mg Tablets For Dogs
Active constituent/s:	Each tablet contains 40 mg spironolactone
Applicant name:	Ceva Animal Health Pty Ltd
Applicant ACN:	002 692 426
Summary of use	For use in combination with standard therapy for the treatment of congestive heart failure caused by mitral valvular regurgitation in dogs
Date of registration/approval:	6 July 2016
Product registration no.:	69015
Label approval no.:	69015/59648

Application no.:	59649
Product name:	Prilactone 10 mg Tablets For Dogs
Active constituent/s:	Each tablet contains 10 mg spironolactone
Applicant name:	Ceva Animal Health Pty Ltd
Applicant ACN:	002 692 426
Summary of use	For use in combination with standard therapy for the treatment of congestive heart failure caused by mitral valvular regurgitation in dogs
Date of registration/approval:	7 July 2016
Product registration no.:	69016
Label approval no.:	69016/59649

2. VETERINARY PRODUCTS BASED ON EXISTING ACTIVE CONSTITUENTS

Application no.:	102394
Product name:	Abbeyflor Premix Concentrate for Pigs
Active constituent/s:	1000 g/kg florfenicol
Applicant name:	Abbey Laboratories Pty Ltd
Applicant ACN:	156 000 430
Summary of use	For the treatment of pig respiratory disease associated with *actinobacillus pleuropneumoniae*, *pasteurella multocida*, mycoplasma spp. and *streptococcus suis* type 2
Date of registration/approval:	4 July 2016
Product registration no.:	81128
Label approval no.:	81128/102394

Application no.:	102727
Product name:	Neove Amoxicillin Powder
Active constituent/s:	870 mg/g amoxicillin as the trihydrate
Applicant name:	Neove Pharma Australia Pty Ltd
Applicant ACN:	140 367 442
Summary of use	For the treatment of diseases caused by bacteria susceptible to amoxycillin in poultry
Date of registration/approval:	5 July 2016
Product registration no.:	81277
Label approval no.:	81277/102727

Application no.:	102029
Product name:	Coxi-Stop 25 Coccidiocide Solution For Poultry
Active constituent/s:	25 g/L toltrazuril
Applicant name:	Abbey Laboratories Pty Ltd
Applicant ACN:	156 000 430
Summary of use	For the treatment and control of coccidiosis in chickens caused by *eimeria* species
Date of registration/approval:	5 July 2016
Product registration no.:	80980
Label approval no.:	80980/102029

Application no.:	105402
Product name:	KelatoGEN Astringent and Antiseptic Concentrate
Active constituent/s:	Each 100 mL contains: 36 g of the condensation product of meta-cresol monosulphonic acids and formaldehyde
Applicant name:	Kelato Animal Health a div of Evolution Animal Health Pty Ltd
Applicant ACN:	110 139 145
Summary of use	For the topical treatment and healing of persistent bleeding conditions in dogs, cats and horses
Date of registration/approval:	7 July 2016
Product registration no.:	82306
Label approval no.:	82306/105402

Application no.:	106631
Product name:	ULCERGOLD Paste for Horses
Active constituent/s:	370 mg/g omeprazole
Applicant name:	Ferrari Animal Health Pty Ltd
Applicant ACN:	162 206 671
Summary of use	For the treatment and prevention of gastric ulcers in horses and foals
Date of registration/approval:	8 July 2016
Product registration no.:	82742
Label approval no.:	82742/106631

Application no.:	102923
Product name:	Coopers Eryguard Vaccine for Sheep, Lambs and Pigs
Active constituent/s:	Inactivated adjuvanted vaccine containing: 1x10^9 orgs/mL erysipelothrix rhusiopathiae 3050, 5x10^8 orgs/mL erysipelothrix rhusiopathiae x299
Applicant name:	Intervet Australia Pty Ltd
Applicant ACN:	008 467 034
Summary of use	For use in the prevention of signs of erysipelas arthritis in lambs, and for protection against erysipelas infection in pigs
Date of registration/approval:	8 July 2016
Product registration no.:	81368
Label approval no.:	81368/102923

Application no.:	102597
Product name:	Neove Tylosin Tartrate Soluble
Active constituent/s:	Not less than 800 mg/g tylosin as the tartrate
Applicant name:	Neove Pharma Australia Pty Ltd
Applicant ACN:	140 367 442
Summary of use	An aid in the prevention and treatment of chronic respiratory disease in broilers and replacement chickens
Date of registration/approval:	18 July 2016
Product registration no.:	81223
Label approval no.:	81223/102597

3. VARIATIONS OF REGISTRATION

Application no.:	107042
Product name:	Elanco AF0250 Tylan 250 Tylosin Phosphate Premix
Active constituent/s:	250 g/kg tylosin as the phosphate
Applicant name:	Elanco Animal Health A Div Of Eli Lilly Aust Pty Ltd
Applicant ACN:	000 233 992
Summary of variation:	To remove use as a growth stimulant in pigs
Date of variation:	17 June 2016
Product registration no.:	36806
Label approval no.:	36806/107042

4. LABEL APPROVAL

Application no.:	106518
Product name:	Bob Martin Since 1892 Flea Rid For Dogs, Cats, Puppies And Kittens Powder
Active constituent/s:	10 g/kg piperonyl butoxide, 1.5 g/kg pyrethrins
Applicant name:	Bob Martin (Australia) Pty Ltd
Applicant ACN:	062 627 883
Summary of use:	To add an additional label name to the product under 'FURRY FACE VETERINARY FLEA RID POWDER FOR DOGS, CATS, PUPPIES & KITTENS'
Date of approval:	11 July 2016
Label approval no.:	80967/106518

Application no.:	106520
Product name:	Bob Martin Since 1892 Flea Rid For Dogs, Cats, Puppies And Kittens Powder
Active constituent/s:	10 g/kg piperonyl butoxide, 1.5 g/kg pyrethrins
Applicant name:	Bob Martin (Australia) Pty Ltd
Applicant ACN:	062 627 883
Summary of use:	To add an additional label name to the product under 'PET LOVERS OWN FLEA RID POWDER FOR DOGS, CATS, PUPPIES & KITTENS'
Date of approval:	11 July 2016
Label approval no.:	80967/106520

Revocation of Cancelled Products

Pursuant to the Agricultural and Veterinary Chemicals Code scheduled to the *Agricultural and Veterinary Chemicals Code Act 1994 (Agvet Code)*, the APVMA hereby gives notice that it has revoked the cancellation of the registrations of the following products with effect from the dates shown on grounds that the applicants now have nominated agents in Australia and therefore meet the requirements of section 8N of the Agvet Code.

1. AGRICULTURAL PRODUCTS

Product name:	Astec Propiconzonale 250EC Fungicide
Applicant name:	Astec Lifescience Ltd
Date of revocation:	14 April 2016
Product registration no.:	65761

Product name:	Citrole Agricultural & Horticultrual All Purpose Spraying Oil
Applicant name:	Total Raffinage Marketing
Date of revocation:	4 May 2016
Product registration no.:	50152

Product name:	Fuhua Glyphosate 450 Herbicide
Applicant name:	Sichuan Leshan Fuhua Tongda Agro-Chemical Technology Co., Ltd
Date of revocation:	5 July 2016
Product registration no.:	68614

Product name:	Fuhua Glyphosate 360 Herbicide
Applicant name:	Sichuan Leshan Fuhua Tongda Agro-Chemical Technology Co., Ltd
Date of revocation:	5 July 2016
Product registration no.:	68846

Revocation of Cancelled Actives

Pursuant to the Agricultural and Veterinary Chemicals Code scheduled to the *Agricultural and Veterinary Chemicals Code Act 1994 (Agvet Code)*, the APVMA hereby gives notice that it has revoked the cancellation of the approvals of the following actives with effect from the dates shown on grounds that the applicants now have nominated agents in Australia and therefore meet the requirements of section 8N of the Agvet Code.

1. ACTIVE CONSITUTENTS

Active constituent/s:	Propiconzonale
Applicant name:	Astec Lifescience Ltd
Date of revocation:	14 April 2016
Approval no.:	62402

Active constituent/s:	Tebuconazole
Applicant name:	Astec Lifescience Ltd
Date of revocation:	14 April 2016
Approval no.:	62217

Active constituent/s:	Glyphosate
Applicant name:	Sichuan Leshan Fuhua Tongda Agro-Chemical Technology Co., Ltd
Date of revocation:	5 July 2016
Approval no.:	68365

Active constituent/s:	Azoxystrobin
Applicant name:	Sichuan Leshan Fuhua Tongda Agro-Chemical Technology Co., Ltd
Date of revocation:	5 July 2016
Approval no.:	69812

Approved Active Constituents

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

1. ACTIVE CONSITUTENT

Application no.:	105883
Active constituent/s:	Acifluorfen
Applicant name:	Grow Choice Pty. Ltd
Applicant ACN:	069 839 961
Summary of use:	For use in agricultural chemical products
Date of approval:	5 July 2016
Approval no.:	82496

Application no.:	105604
Active constituent/s:	Spironolactone
Applicant name:	Ceva Animal Health Pty Ltd
Applicant ACN:	002 692 426
Summary of use:	For use in veterinary chemical products
Date of approval:	6 July 2016
Approval no.:	82343

Application no.:	106817
Active constituent/s:	Equine herpes virus 4 (EHV-4) 405/76strain
Applicant name:	Zoetis Australia Pty Ltd
Applicant ACN:	156 476 425
Summary of use:	For use in veterinary chemical products
Date of approval:	5 July 2016
Approval no.:	82803

Application no.:	106684
Active constituent/s:	Equine herpes virus 1 (EHV-1) 438/77strain
Applicant name:	Zoetis Australia Pty Ltd
Applicant ACN:	156 476 425
Summary of use:	For use in veterinary chemical products
Date of approval:	5 July 2016
Approval no.:	82888

Application no.:	104464
Active constituent/s:	Prohexadione calcium
Applicant name:	TGAC Australia Pty. Ltd
Applicant ACN:	134 570 700
Summary of use:	For use in agricultural products
Date of approval:	12 July 2016
Approval no.:	81943

Application no.:	107077
Active constituent/s:	Altrenogest
Applicant name:	Ceva Animal Health Pty Ltd
Applicant ACN:	002 692 426
Summary of use:	For use in veterinary chemical products
Date of approval:	23 June 2016
Approval no.:	82896

Application no.:	106018
Active constituent/s:	Tylosin tartrate
Applicant name:	Neove Pharma Australia Pty Limited
Applicant ACN:	140 367 442
Summary of use:	For use in veterinary chemical products
Date of approval:	1 July 2016
Approval no.:	82541

Application no.:	104787
Active constituent/s:	Ketoprofen
Applicant name:	Virbac (Australia) Pty Ltd
Applicant ACN:	003 268 871
Summary of use:	For use in veterinary chemical products
Date of approval:	5 July 2016
Approval no.:	82007

Application no.:	106686
Active constituent/s:	Oxytetracycline hydrochloride
Applicant name:	Intervet Australia Pty Limited
Applicant ACN:	008 467 034
Summary of use:	For use in veterinary chemical products
Date of approval:	6 July 2016
Approval no.:	82755

Application no.:	104563
Active constituent/s:	Praziquantel
Applicant name:	Virbac (Australia) Pty Ltd
Applicant ACN:	003 268 871
Summary of use:	For use in veterinary chemical products
Date of approval:	7 July 2016
Approval no.:	81985

Application no.:	104755
Active constituent/s:	Praziquantel
Applicant name:	Virbac (Australia) Pty Ltd
Applicant ACN:	003 268 871
Summary of use:	For use in veterinary chemical products
Date of approval:	7 July 2016
Approval no.:	81986

Application no.:	107228
Active constituent/s:	Benazepril hydrochloride
Applicant name:	Apex Laboratories Pty Ltd
Applicant ACN:	000 397 240
Summary of use:	For use in veterinary chemical products
Date of approval:	15 July 2016
Approval no.:	82966

Application no.:	107251
Active constituent/s:	Deoxycortone pivalate
Applicant name:	Dechra Ltd
Applicant ACN:	N/A
Summary of use:	For use in veterinary chemical products
Date of approval:	15 July 2016
Approval no.:	82978

Application no.:	107036
Active constituent/s:	Benazepril 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:	15 July 2016
Approval no.:	82884

Application no.:	105609
Active constituent/s:	Moxidectin Technical Concentrate (MTC)
Applicant name:	Virbac (Australia) Pty Ltd
Applicant ACN:	003 268 871
Summary of use:	For use in veterinary chemical products
Date of approval:	21 July 2016
Approval no.:	82382

Application no.:	105419
Active constituent/s:	Amitraz
Applicant name:	Virbac (Australia) Pty Ltd
Applicant ACN:	003 268 871
Summary of use:	For use in veterinary chemical products
Date of approval:	21 July 2016
Approval no.:	82320

Application no.:	107137
Active constituent/s:	Meloxicam
Applicant name:	Apex Laboratories Pty Ltd
Applicant ACN:	000 397 240
Summary of use:	For use in veterinary chemical products
Date of approval:	21 July 2016
Approval no.:	82924

Application no.:	105187
Active constituent/s:	Milbemycin oxime
Applicant name:	Merial Australia Pty Ltd
Applicant ACN:	071 187 285
Summary of use:	For use in veterinary chemical products
Date of approval:	21 July 2016
Approval no.:	82206

Application no.:	106568
Active constituent/s:	Ivermectin
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:	22 July 2016
Approval no.:	82733

2. VARIATIONS OF ACTIVE CONSTITUENT

Application no.:	104928
Active constituent/s:	Metronidazole
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:	16 May 2016
Approval no.:	55839

Application no.:	104536
Active constituent/s:	Triclabendazole
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:	21 June 2016
Approval no.:	81937

Application no.:	107016
Active constituent/s:	Carprofen
Applicant name:	Zoetis Australia Pty Ltd
Applicant ACN:	156 476 425
Summary of variation:	Variation of relevant particulars or conditions of an approved active constituent
Date of variation:	4 July 2016
Approval no.:	54831

Application no.:	104269
Active constituent/s:	Cephalexin
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:	4 July 2016
Approval no.:	54841

Application no.:	104524
Active constituent/s:	Abamectin
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:	5 July 2016
Approval no.:	81872

Application no.:	106463
Active constituent/s:	Cyromazine
Applicant name:	Agrocare Pty. Ltd
Applicant ACN:	162 650 955
Summary of variation:	Variation of relevant particulars or conditions of an approved active constituent
Date of variation:	21 July 2016
Approval no.:	44338

Application no.:	105355
Active constituent/s:	Enrofloxacin
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 July 2016
Approval no.:	82082

Application no.:	105084
Active constituent/s:	Detomidine hydrochloride
Applicant name:	Ceva Animal Health Pty Ltd
Applicant ACN:	002 692 426
Summary of variation:	Variation of relevant particulars or conditions of an approved active constituent
Date of variation:	21 July 2016
Approval no.:	81977

Application no.:	103367
Active constituent/s:	Prednisolone
Applicant name:	Dermcare-Vet Pty. Ltd
Applicant ACN:	010 280 010
Summary of variation:	Variation of relevant particulars or conditions of an approved active constituent
Date of variation:	22 July 2016
Approval no.:	82014

Application no.:	105201
Active constituent/s:	Moxidectin
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:	22 July 2016
Approval no.:	82193

Application no.:	105202
Active constituent/s:	Dimethylglycine hydrochloride
Applicant name:	Ceva Animal Health Pty Ltd
Applicant ACN:	002 692 426
Summary of variation:	Variation of relevant particulars or conditions of an approved active constituent
Date of variation:	22 July 2016
Approval no.:	82187

Application no.:	105353
Active constituent/s:	Framycetin sulfate
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:	22 July 2016
Approval no.:	82091

Application no.:	105227
Active constituent/s:	Levamisole hydrochloride
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:	22 July 2016
Approval no.:	82196

New Agricultural Active Constituent Flupyradifurone

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

Flupyradifurone is white powder with an uncharacteristic weak odour and a melting point of 69ºC.

Common name: Flupyradifurone

IUPAC name: 4-[[(6-chloropyridin-3-yl)methyl](2,2-difluoroethyl)amino]furan-2(5H)-one.

CAS name: 2(5H)-furanone, 4-[[(6-chloro-3-pyridinyl)methyl](2,2-difluoroethyl) amino]-

CAS registry number: 951659-40-8

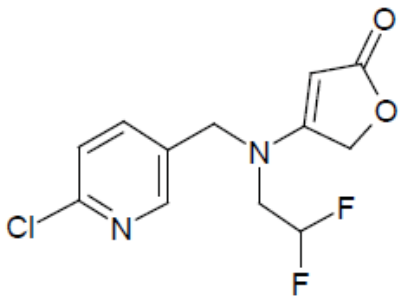
Manufacturer's codes: BYI 02960

Minimum purity: 960 g/kg

Molecular formula: $C_{12}H_{11}ClF_2N_2O_2$

Molecular weight: 288.68

Structure:



Chemical family: Butenolide insecticides

Mode of action: Flupyradifurone is a butenolide systemic insecticide. Flupyradifurone interacts with insect nicotinic acetylcholine receptors, a class of neurotransmitter-gated cation channels which are involved in excitatory neurotransmission.
The compound acts as an agonist, ie, the binding of flupyradifurone to the receptor protein induces a depolarising ion current and subsequent excitation of the nerve cell. Flupyradifurone cannot be inactivated by acetylcholinesterase resulting in a disorder of the nervous system of the insect and subsequent death of the treated insects.

SUMMARY OF THE APVMA'S EVALUATION OF FLUPYRADIFURONE ACTIVE CONSTITUENT

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

Constituent	Specification
Flupyradifurone	Flupyradifurone: 960 g/kg minimum

Other compounds of toxicological significance are not expected to occur in flupyradifurone TGAC.

The Office of Chemical Safety (OCS) has completed a toxicological evaluation of flupyradifurone.

The acceptable daily intake (ADI) for flupyradifurone is established at 0.08 mg/kg bw/d using the No Observable Adverse Effect Level (NOAEL) of 7.8 mg/kg bw/d from a 52 week dietary study in beagle dogs, based on skeletal muscle myofiber degeneration at higher doses and applying a 100 fold safety factor (consisting of a 10–fold safety actor for both intra and inter-species variation). This ADI is supported by the parental female NOAEL of 7.7 mg/kg bw/d from the two-generation reproduction study, where decreased bodyweight and body weight gain were observed pre-mating, with carry over effects into other phases of the study at higher doses.

The acute reference dose (ARfD) for flupyradifurone is established at 0.35 mg/kg bw using a NOAEL of 35 mg/kg bw in an acute neurotoxicity study based on increased incidences of piloerection in both sexes and increased incidences of pupil dilation in females at the next highest dose (50 mg/kg bw) and using a default 100–fold safety factor.

On 23 July 2015 the Delegate to the Secretary of the Department of Health published a final scheduling decision to create a new schedule 6 listing for flupyradifurone without schedule exemptions and confirmed an implementation date of 1 October 2015.

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

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

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

MAKING A SUBMISSION

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

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

When making a submission please include:

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

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

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

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

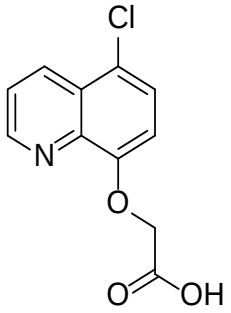
Phone: +61 2 6210 4936
Fax: +61 2 6210 4840
Email: chemistry@apvma.gov.au

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

New Agricultural Active Constituent Cloquintocet Acid

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

Cloquintocet acid is a tan powder with a mild odour and a melting point of 223.7ºC. Its solubility in water is 3.12 g/L at pH 5; >50 g/L at pH 7; >50 g/L at pH 9; 451 mg/L in purified water at 20 °C.

Common name:	Cloquintocet acid
IUPAC name:	(5-chloroquinolin-8-yloxy)acetic acid
CAS name:	2-[(5-chloro-8-quinolinyl)oxy]acetic acid.
CAS registry number:	88349-88-6
Manufacturer's codes:	XDE-558, CQC-A
Minimum purity:	956 g/kg
Molecular formula:	$C_{11}H_8ClNO_3$
Molecular weight:	237.6
Structure:	
Chemical family:	Herbicide safener
Mode of action:	Used as a herbicide safener in combination with grass-active herbicides (pinoxaden, clodinafop-propargyl) for selective control of annual grasses. It accelerates the detoxification process of clodinafop-propargyl in cereals.

SUMMARY OF THE APVMA'S EVALUATION OF CLOQUINTOCET ACID ACTIVE CONSTITUENT

The APVMA has evaluated the chemistry aspects of cloquintocet acid 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 cloquintocet acid active constituent:

Constituent	Specification
Cloquintocet acid	Cloquintocet acid: 956 g/kg minimum

Other compounds of toxicological significance are not expected to occur in cloquintocet acid TGAC.

The Office of Chemical Safety (OCS) has completed a toxicological evaluation of cloquintocet acid.

An ADI was established for the sum of cloquintocet, its acid and esters, expressed as cloquintocet-mexyl. The ADI of 0.04 mg/kg bw/day was established on the basis of the NOEL of 4.3 mg/kg bw/day for thyroid follicular epithelium hyperplasia in females at 41.3 mg/kg bw/day and above in a 2–year dietary rat study and using a 100–fold safety factor. Since there was no toxicity observed following acute exposure an ARfD was not considered to be necessary. The Advisory Committee on Chemicals Scheduling (ACCS) considered cloquintocet acid to be appropriate for inclusion in schedule 5 (five) of the Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP).

The OCS has indicated that there are no objections on toxicological grounds to the approval of the active constituent cloquintocet acid.

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

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

MAKING A SUBMISSION

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

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

When making a submission please include:

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

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

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

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

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

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

New Veterinary Chemical Product Containing a New Veterinary Active Constituent—Green Lipped Mussel Oil in 50 mg/capsule Antinol PCSO-524 Joint Support Formula

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application from PHARMALINK MARKETING AUSTRALIA PTY LTD for the approval of a new active constituent green lipped mussel oil. The APVMA also has before it a related application from the same applicant for the registration of the new product ANTINOL PCSO-524 JOINT SUPPORT FORMULA, containing the new active constituent (herein referred to as the product). The product is proposed to be registered for use to assist in the reduction of arthritic signs in dogs.

PARTICULARS OF THE ACTIVE CONSTITUENT

Common Name:	Green Lipped Mussel Oil
TGA Approved Name:	Green Lipped Mussel Oil
Species Name:	*Perna canaliculus*
Chemical Abstracts Name:	Lyprinol (A lipid-rich extract prepared from the New Zealand green-lipped mussel)
CAS Number:	200818-72-0

SUMMARY OF THE APVMA'S EVALUATION OF THE ACTIVE CONSTITUENT GREEN LIPPED MUSSEL OIL IN ACCORDANCE WITH SECTION 5A OF THE AGRICULTURAL AND VETERINARY CHEMICALS CODE (THE 'AGVET CODE'), SCHEDULED TO THE *AGRICULTURAL AND VETERINARY CHEMICALS CODE ACT 1994*

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

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

PARTICULARS OF THE PRODUCT ANTINOL PCSO-524 JOINT SUPPORT FORMULA

Proposed Product Name(s):	ANTINOL PCSO-524 JOINT SUPPORT FORMULA
Applicant Company:	Pharmalink Marketing Australia Pty Ltd
Name of Active Constituent:	Green lipped mussel oil
Summary of Proposed Use:	For use in dogs, may assist in the relief of arthritic signs
Pack Sizes:	Bottle with 30 capsules

SUMMARY OF THE APVMA'S EVALUATION OF THE PRODUCTS IN ACCORDANCE WITH SECTION 5A, 5B AND 5C OF THE AGRICULTURAL AND VETERINARY CHEMICALS CODE (THE 'AGVET CODE'), SCHEDULED TO THE *AGRICULTURAL AND VETERINARY CHEMICALS CODE ACT 1994*

1. The APVMA has evaluated the applications 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 the product would not be an undue hazard to the safety of people exposed to it during its handling.

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

The product is proposed to be registered for use in companion animals (dogs) only. Green lipped mussel oil is unlikely to enter the food chain and therefore the determination of an acceptable daily intake, acute reference dose and maximum residue limits is not considered necessary.

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

(iv) The APVMA is satisfied that the proposed use of the product 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.

2. The APVMA has evaluated the product and in its assessment in relation to target animal safety under section 5A(1)(c) of the Agvet Code, it proposes to determine that:

(i) The APVMA is satisfied that ANTINOL PCSO-524 JOINT SUPPORT FORMULA if used according to label directions, is not, or would not be, likely to have an unintended effect that is harmful to animals.

An external reviewer evaluated the data provided and found that the submitted data supports the safety of the proposed product when used for the relief of arthritic signs on dogs.

The laboratory safety study used beagle dogs of both genders, 1–3yo, 1yo representing a relevant minimum age for the applicant formulation. The dogs received 0, 1x, 3x or 5x the proposed dose of the applicant formulation PO sid for 8 weeks.

Data from the laboratory safety study suggests that the NOEL and NOAEL for the applicant formulation is 20 capsules PO sid x8wk in 1–3yo healthy Beagle dogs (10–15kg BW). The data therefore supports a 5x safety margin for the applicant formulation in dogs.

The APVMA is satisfied that ANTINOL PCSO-524 JOINT SUPPORT FORMULA would not have an unintended effect that is harmful to dogs. A precaution warning users that the safety of this product has not been tested in pregnant or lactating animals has been included on the product label.

3. The APVMA has evaluated the product and in its assessment in relation to efficacy under section 5B(1) of the Agvet Code, it proposes to determine that:

The APVMA is satisfied that ANTINOL PCSO-524 JOINT SUPPORT FORMULA, if used according to label directions would be effective for use in dogs and may assist in the relief of arthritic signs.

(i) An external reviewer evaluated the data provided and found that the submitted data supports the efficacy of the proposed product.

From an efficacy perspective, the data provided support the label claim:

‘May assist in the relief of arthritic signs in dogs’

The pilot field efficacy study use a total of 84 dogs (31 with osteoarthritis of the hips and shoulder, 33 with osteoarthriti of the stifle and 20 with cauda equina syndrome).

In dogs with osteoarthritis of the hip and shoulder, clinical improvement was noted by the clinician in 90.3% of dogs, and by the owner in 87% of dogs, despite limited improvement in radiographic findings (16.12% of dogs). An improvement in lameneses score of at least 2 (out of 5) was noted in 54.83% of dogs.

In dogs with osteoarthritis of the stifle, clinical improvement was noted by the clinician in 87.87% of dogs, and by the owner in 90.90% of dogs, despite limited improvement in radiographic findigs (6.6% of dogs). An improvement in lameneses score of at least 2 was noted in 15.69% of dogs. The magnitude of observed clinical improvement appeared less than for OA of the hip and shoulder.

In dogs with cauda equina syndrome, clinical improvement was noted by the clinician and owner in 85% of dogs. The two dogs with ventral spinal compression on MRI improved from paraplegia to ataxia by 2 weeks. By week 4, 75% of the dogs were able to at least walk short distances (some could run).

The APVMA is satisfied that the product would be effective when used according to label directions.

4. 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, proposes to determine that:

    (i) The APVMA is satisfied that the proposed use of the product would not adversely affect trade between Australia and places outside Australia as the product is not for use in animals producing any major Australian export commodities.

FURTHER INFORMATION

MAKING A SUBMISSION

In accordance with sections 12 and 13 of the Agvet Code, the APVMA invites any person to submit a relevant written submission as to whether the active constituent should be approved and whether the application for registration of the product should be granted. Submissions should relate only to matters that the APVMA is required by legislation to take into account in deciding whether to approve the active constituent or grant the registration application for the product. These grounds include: for approval of the active constituent, the safety criteria; for the registration application for the product**:** the safety, efficacy and trade criteria. Submissions should state the grounds on which they are based. Comments received outside these grounds cannot be considered by the APVMA.

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

Relevant comments will be taken into account by the APVMA in deciding whether the active constituent should be approved and 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)*[1] material contained in submissions will be treated confidentially.

Written submissions on the APVMA's proposal to approve the active constituent and grant the application for registration that relate to the grounds for active approval and/or product registration 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

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

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. 5) gazetted on 3 May 2016 (No. APVMA 9).

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 7, 2016) accompanies this notice. For a complete and up-to-date version of Schedule 20, including these amendments together with their Explanatory Statement, please refer to the Federal Register of Legislative Instrument available on the Comlaw website at www.comlaw.gov.au.

Based on dietary exposure assessments and current health standards, the APVMA and FSANZ are satisfied that these MRLs are not harmful to public health. MRLs contained in Schedule 20 provide the limits for residues of agricultural and veterinary chemicals that may legitimately occur in foods. By this means, Schedule 20 permits the sale of treated foods and protects public health by minimising residues in foods consistent with the effective control of pests and diseases.

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

Food Standards Australia New Zealand (FSANZ) made Sanitary and Phytosanitary (SPS) notification to the World Trade Organization (WTO) in relation to these variations and no comment was received in response to that notice.

A copy of these variations have been given to FSANZ.

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

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

For further information please contact:

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

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

Australian Government

Australian Pesticides and Veterinary Medicines Authority

Australia New Zealand Food Standards Code—Schedule 20– Maximum residue limits Variation Instrument No. APVMA 7, 2016

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

Matthew O'Mullane

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

Dated this Twentieth day of July 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 7, 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 15 of 26 July 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: Flamprop-methyl *Permitted residue: Flamprop-methyl*	
Lupin (dry)	0.05

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

Agvet chemical: Azoxystrobin *Permitted residue: Azoxystrobin*	
Egg plant	T2
Okra	T2
Sweet corn (kernels)	T0.05

Agvet chemical: Chloridazon *Permitted residue: Chloridazon*	
Beetroot leaves	1
Chard (silver beet)	1
Spinach	1

Agvet chemical: Fluensulfone *Permitted residue: Sum of fluensulfone, 3,4,4-trifluorobut-3-ene-1-sulfonic acid (M-3627) and 5-chloro-thiazole-2-sulfonic acid (M-3625)*	
Sweet potato	T1

Agvet chemical: Mandipropamid *Permitted residue: Mandipropamid*	
Mizuna	30

Agvet chemical: Meloxicam *Permitted residue: Meloxicam*	
Sheep fat	0.01
Sheep kidney	0.01
Sheep liver	0.01
Sheep meat	0.01

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

Agvet chemical: Mandipropamid *Permitted residue: Mandipropamid*	
Leafy vegetables	30