Commonwealth of Australia

Gazette

Agricultural and Veterinary Chemicals

No. APVMA 10, Tuesday, 19 May 2020

Published by the Australian Pesticides and Veterinary Medicines Authority

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.

ISSN 1837-7629

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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.

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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.:	123818
Product name:	Smart Hasta La Vista Mouse Bait
Active constituent/s:	25 g/kg zinc phosphide
Applicant name:	Crop Smart Pty Ltd
Applicant ACN:	093 927 961
Summary of use:	For the control of heavy infestations of mice in agricultural situations
Date of registration:	28 April 2020
Product registration no.:	89165
Label approval no.:	89165/123818

Application no.:	118767
Product name:	Minecto Forte Insecticide
Active constituent/s:	400 g/L diafenthiuron, 80 g/L cyantraniliprole
Applicant name:	Syngenta Australia Pty Ltd
Applicant ACN:	002 933 717
Summary of use:	For control of certain mite and insect pests in fruiting vegetables and cucurbits
Date of registration:	29 April 2020
Product registration no.:	87610
Label approval no.:	87610/118767

Application no.:	119975
Product name:	EuroChem Sentura Fungicide
Active constituent/s:	230 g/L fludioxonil
Applicant name:	TGAC Australia Pty Ltd
Applicant ACN:	134 570 700
Summary of use:	For the control of certain post-harvest diseases in pome fruit
Date of registration:	1 May 2020
Product registration no.:	87989
Label approval no.:	87989/119975

Application no.:	124057
Product name:	NAADCO Clodinafop 240 Herbicide
Active constituent/s:	240 g/L clodinafop-proprargyl, 60 g/L cloquintocet-mexyl
Applicant name:	New Australia Agricultural Development Company Pty Ltd
Applicant ACN:	138 055 553
Summary of use:	For the control of wild oats, paradoxa grass (*annual phalaris*), canary grass and annual ryegrass in wheat
Date of registration:	1 May 2020
Product registration no.:	89228
Label approval no.:	89228/124057

Application no.:	123834
Product name:	Choice Teb Pro 420 Fungicide
Active constituent/s:	210 g/L prothioconazole, 210 g/L tebuconazole
Applicant name:	Grow Choice Pty Ltd
Applicant ACN:	161 264 884
Summary of use:	For the control of various diseases in wheat, barley, oats, triticale, canola and pyrethrum
Date of registration:	1 May 2020
Product registration no.:	89172
Label approval no.:	89172/123834

Application no.:	121210
Product name:	Fuhua Glufosinate Ammonium 200 SL Herbicide
Active constituent/s:	200 g/L glufosinate ammonium
Applicant name:	Sichuan Leshan Fuhua Tongda Agro-Chemical Tech Co Ltd
Applicant ACN:	N/A
Summary of use:	For the control of annual and perennial weeds in agricultural crops
Date of registration:	1 May 2020
Product registration no.:	88399
Label approval no.:	88399/121210

Application no.:	124043
Product name:	TILT 500 EC Fungicide
Active constituent/s:	500 g/L propiconazole
Applicant name:	Syngenta Australia Pty Ltd
Applicant ACN:	002 933 717
Summary of use:	For the control of certain fungal diseases of bananas, peanuts, pineapples, stone fruit, sugarcane, turf, wheat and other crops
Date of registration:	5 May 2020
Product registration no.:	89226
Label approval no.:	89226/124043

Application no.:	120987
Product name:	OsmoFume Wood Preservative
Active constituent/s:	911 g/kg dazomet
Applicant name:	Osmose Utilities Services INC
Applicant ACN:	N/A
Summary of use:	For the control of insects including termites and fungi inside wooden products such as utility poles, pilings, standing timbers, and other standing large solid or laminated wood products
Date of registration:	5 May 2020
Product registration no.:	88348
Label approval no.:	88348/120987

Application no.:	123964
Product name:	Double Nozzle Technology Raid Pro Series Multi Insect Killer
Active constituent/s:	0.5 g/kg imiprothrin, 0.5 g/kg prallethrin, 0.15 g/kg cyfluthrin
Applicant name:	S.C. Johnson & Son Pty Ltd
Applicant ACN:	000 021 009
Summary of use:	For the control of flying and crawling insects in household situations
Date of registration:	5 May 2020
Product registration no.:	89201
Label approval no.:	89201/123964

Application no.:	125124
Product name:	Coles Insect Control Bomb
Active constituent/s:	10.0 g/kg permethrin, 1.54 g/kg fenoxycarb
Applicant name:	Aaron Laboratories Pty Ltd
Applicant ACN:	004 856 848
Summary of use:	For the killing of insect infestations and prevention of reinfestations
Date of registration:	7 May 2020
Product registration no.:	89519
Label approval no.:	89519/125124

Application no.:	125121
Product name:	Virkon H The Broad Spectrum Virucidal Bactericidal Fungicidal Disinfectant
Active constituent/s:	494g/kg potassium peroxomonosulfate triple salt, 132g/kg sodium dodecyl benzene sulfonate, 15g/kg sodium chloride
Applicant name:	Alltech Lienert Australia Pty Ltd
Applicant ACN:	008 293 007
Summary of use:	For use for greenhouses and horticultural equipment
Date of registration:	7 May 2020
Product registration no.:	89517
Label approval no.:	89517/125121

Application no.:	125200
Product name:	Chemwet 1000 Wetting Agent
Active constituent/s:	1000g/L alcohol alkoxylate
Applicant name:	Victorian Chemical Company Pty Ltd
Applicant ACN:	004 188 863
Summary of use:	For the improvement of spray coverage when using agricultural chemicals
Date of registration:	7 May 2020
Product registration no.:	89535
Label approval no.:	89535/125200

Application no.:	123966
Product name:	Double Nozzle Technology Raid Pro Series Flying Insect Killer
Active constituent/s:	0.5 g/kg imiprothrin, 0.5 g/kg prallethrin, 0.15 g/kg cyfluthrin
Applicant name:	S.C. Johnson & Son Pty Ltd
Applicant ACN:	000 021 009
Summary of use:	For the control of flying and crawling insects in household situations
Date of registration:	7 May 2020
Product registration no.:	89202
Label approval no.:	89202/123966

Application no.:	123974
Product name:	Genfarm 2,4-D B Herbicide
Active constituent/s:	500 g/L 2,4-D B present as the dimethylamine salt
Applicant name:	Nutrien Ag Solutions Limited
Applicant ACN:	008 743 217
Summary of use:	For the control of broadleaf weeds in seedling and established lucerne, medic and clover pastures, peanuts and cereal crops undersown with lucerne, medic or clover
Date of registration:	7 May 2020
Product registration no.:	89205
Label approval no.:	89205/123974

Application no.:	124175
Product name:	Surefire Tempra 750 WG Herbicide
Active constituent/s:	750 g/kg halosulfuron-methyl
Applicant name:	PCT Holdings Pty Ltd
Applicant ACN:	099 023 962
Summary of use:	For selective control of nutgrass and Mullumbimby couch in various situations
Date of registration:	7 May 2020
Product registration no.:	89255
Label approval no.:	89255/124175

Application no.:	124209
Product name:	Farmalinx Imi 200 SC Insecticide
Active constituent/s:	200 g/L imidacloprid
Applicant name:	Farmalinx Pty Ltd
Applicant ACN:	134 353 245
Summary of use:	For the control of various pests of certain vegetables and turf
Date of registration:	7 May 2020
Product registration no.:	89271
Label approval no.:	89271/124209

Application no.:	124205
Product name:	Farmalinx Bifentin 80 SC Insecticide
Active constituent/s:	80 g/L bifenthrin
Applicant name:	Farmalinx Pty Ltd
Applicant ACN:	134 353 245
Summary of use:	For the control of pests of turf and the control of a range of urban pests; spiders, ants, cockroaches, mosquitoes, fleas, flies and ticks; and for the management of subterranean termites
Date of registration:	8 May 2020
Product registration no.:	89269
Label approval no.:	89269/124205

Application no.:	123878
Product name:	Combat Moth-Rid Pantry Moth Trap
Active constituent/s:	4.9 g/kg (z,e)-9,12-tetradecadien-1-yl acetate
Applicant name:	Henkel Australia Pty Ltd
Applicant ACN:	001 302 996
Summary of use:	For control of pantry moths
Date of registration:	8 May 2020
Product registration no.:	89180
Label approval no.:	89180/123878

Application no.:	123977
Product name:	Relyon Imaza Duo Herbicide
Active constituent/s:	33 g/L imazamox present as the ammonium salt, 15 g/L imazapyr present as the ammonium salt
Applicant name:	Ruralco Holdings Limited
Applicant ACN:	009 660 879
Summary of use:	For the early post-emergence control of certain annual grass and broadleaf weeds as part of the Clearfield Production System for Clearfield Plus wheat, Clearfield barley, and Clearfield canola
Date of registration:	8 May 2020
Product registration no.:	89207
Label approval no.:	89207/123977

2. LISTED REGISTRATIONS

Application no.:	124553
Product name:	Evopure Liquid Pool Chlorine
Active constituent/s:	130 g/L available chlorine (Cl) present as sodium hypochlorite
Applicant name:	Evolution Water And Lighting Solutions Pty Ltd
Applicant ACN:	606 601 147
Summary of use:	For use in the control of bacteria, viruses and protozoa in swimming pools and spas
Date of registration:	5 May 2020
Product registration no.:	89381
Label approval no.:	89381/124553

3. VARIATIONS OF REGISTRATION

Application no.:	125001
Product name:	Relyon Imazamox 700 WG Herbicide
Active constituent/s:	700 g/kg imazamox
Applicant name:	Ruralco Holdings Limited
Applicant ACN:	009 660 879
Summary of variation:	To vary the distinguishing product name and the name that appears on the label from ‘Draymox 700WG Herbicide’ to ‘Relyon Imazamox 700 WG Herbicide’
Date of variation:	17 April 2020
Product registration no.:	85439
Label approval no.:	85439/125001

Application no.:	125016
Product name:	Vydate L Insecticide/Nematicide
Active constituent/s:	240 g/L oxamyl (an anticholinesterase compound)
Applicant name:	Production Agriscience (Australia) Pty Ltd
Applicant ACN:	616 181 769
Summary of variation:	To vary the distinguishing product name and the name that appears on the label from ‘Dupont Vydate L Insecticide/Nematicide’ to ‘Vydate L Insecticide/Nematicide’
Date of variation:	20 April 2020
Product registration no.:	33297
Label approval no.:	33297/125016

Application no.:	125075
Product name:	Gardenline Weed Terminator
Active constituent/s:	90 g/L acetic acid
Applicant name:	Amgrow Pty Ltd
Applicant ACN:	100 684 786
Summary of variation:	To vary the distinguishing product name and the name that appears on the label from ‘Amgrow Naturals Weed Terminator RTU’ to ‘Gardenline Weed Terminator’
Date of variation:	21 April 2020
Product registration no.:	88254
Label approval no.:	88254/125075

Application no.:	125085
Product name:	Conquest Sultan 225 Insecticide
Active constituent/s:	225 g/L acetamiprid
Applicant name:	Conquest Crop Protection Pty Ltd
Applicant ACN:	098 814 932
Summary of variation:	To vary the distinguishing product name and the name that appears on the label from 'Conquest Acetamiprid 225 Insecticide' to 'Conquest Sultan 225 Insecticide'
Date of variation:	22 April 2020
Product registration no.:	88229
Label approval no.:	8822 /125085

Application no.:	125082
Product name:	Tripicrin Soil Fumigant
Active constituent/s:	985 g/kg chloropicrin
Applicant name:	Trical Australia Pty Ltd
Applicant ACN:	600 066 966
Summary of variation:	To remove the use with reference to club root from the instructions
Date of variation:	22 April 2020
Product registration no.:	62231
Label approval no.:	62231/125082

Application no.:	125078
Product name:	Corteva Agriscience Rizacon S IGR Grain Protector
Active constituent/s:	300 g/L (s)-methoprene
Applicant name:	Dow Agrosciences Australia Limited
Applicant ACN:	003 771 659
Summary of variation:	To vary the distinguishing product name and the name that appears on the label from 'DOW Agrosciences Rizacon S IGR Grain Protector' to 'Corteva Agriscience Rizacon S IGR Grain Protector'
Date of variation:	22 April 2020
Product registration no.:	55854
Label approval no.:	55854/125078

Application no.:	121640
Product name:	Potus Yield & Quality Enhancer
Active constituent/s:	250 g/L trinexapac-ethyl
Applicant name:	Crop Culture Pty Ltd
Applicant ACN:	142 860 473
Summary of variation:	To register an additional formulation
Date of variation:	28 April 2020
Product registration no.:	67883
Label approval no.:	67883/121640

Application no.:	123879
Product name:	Alpha Atrazine 900WG Herbicide
Active constituent/s:	900 g/kg atrazine
Applicant name:	Alpha Crop Protection Pty Ltd
Applicant ACN:	165 653 047
Summary of variation:	To add use to control purple top verbena in tea tree plantations and to update the safety directions
Date of variation:	30 April 2020
Product registration no.:	81826
Label approval no.:	81826/123879

Application no.:	120124
Product name:	EChem Acetam 225 Insecticide
Active constituent/s:	515 g/L dimethyl sulfoxide, 334 g/L n-methylpyrrolidone, 225 g/L acetamiprid
Applicant name:	eChem (Aust) Pty Ltd
Applicant ACN:	089 133 095
Summary of variation:	To add control of silverleaf whitefly in cotton and vary the pack size
Date of variation:	30 April 2020
Product registration no.:	67783
Label approval no.:	67783/120124

Application no.:	122821
Product name:	Delegate Insecticide
Active constituent/s:	250 g/kg spinetoram
Applicant name:	Dow Agrosciences Australia Limited
Applicant ACN:	003 771 659
Summary of variation:	To add control of carob moth in almonds
Date of variation:	30 April 2020
Product registration no.:	61717
Label approval no.:	61717/122821

Application no.:	123843
Product name:	Imtrade Abachem 18 Miticide/Insecticide
Active constituent/s:	18 g/L abamectin
Applicant name:	Imtrade Australia Pty Ltd
Applicant ACN:	090 151 134
Summary of variation:	To add use in lettuce, snow peas, sugar snap peas, cultivated mushrooms, citrus trees, rhubarb, duboisia, raspberry, blackberry, blackcurrant, papaya (pawpaw), blueberries, sweet corn, chillies, paprika, spring onions and shallots, avocadoes, passionfruit, capsicum, cucumber, eggplant, zucchini, tomato, citrus, mung bean, adzuki bean, navy bean, tea tree oil, custard apples, nursery stock, cut flowers and lychee as part of the APVMA permit to label project
Date of variation:	30 April 2020
Product registration no.:	53325
Label approval no.:	53325/123843

Application no.:	123928
Product name:	Titan Abamectin 18 Insecticide/Miticide
Active constituent/s:	18 g/L abamectin
Applicant name:	Titan Ag Pty Ltd
Applicant ACN:	122 081 574
Summary of variation:	To add use in lettuce, snow peas, sugar snap peas, cultivated mushrooms, citrus trees, rhubarb, duboisia, raspberry, blackberry, blackcurrant, papaya (pawapaw), blueberries, sweet corn, chillies, paprika, spring onions and shallots, avocadoes, passionfruit, capsicum, cucumber, eggplant, zucchini, tomato, citrus, mung bean, adzuki bean, navy bean, tea tree oil, custard apples, nursery stock, cut flowers and lychee as per the APVMA permit to label project
Date of variation:	30 April 2020
Product registration no.:	65889
Label approval no.:	65889/123928

Application no.:	123885
Product name:	Nufarm Champ Dry Prill WG Fungicide
Active constituent/s:	375 g/kg copper (CU) present as cupric hydroxide
Applicant name:	Nufarm Australia Limited
Applicant ACN:	004 377 780
Summary of variation:	To increase the pack size range
Date of variation:	30 April 2020
Product registration no.:	53935
Label approval no.:	53935/123885

Application no.:	123929
Product name:	Titan Metsulfuron 600 WG Herbicide
Active constituent/s:	600 g/kg metsulfuron-methyl
Applicant name:	Titan Ag Pty Ltd
Applicant ACN:	122 081 574
Summary of variation:	To update the safety directions
Date of variation:	30 April 2020
Product registration no.:	61522
Label approval no.:	61522/123929

Application no.:	123869
Product name:	Atrizon 900WG Herbicide
Active constituent/s:	900 g/kg atrazine
Applicant name:	Ruralco Holdings Limited
Applicant ACN:	009 660 879
Summary of variation:	To add use to control purple top verbena in tea tree plantations under the permit to label program
Date of variation:	30 April 2020
Product registration no.:	81793
Label approval no.:	81793/123869

Application no.:	123833
Product name:	Chemag Amitraz 200 EC / ULV Insecticide / Miticide
Active constituent/s:	200 g/L amitraz
Applicant name:	Imtrade Australia Pty Ltd
Applicant ACN:	090 151 134
Summary of variation:	To add the use for control of citrus red mites in nursery citrus trees
Date of variation:	1 May 2020
Product registration no.:	53362
Label approval no.:	53362/123833

Application no.:	123859
Product name:	Genfarm Atrazine 900 WG Herbicide
Active constituent/s:	900 g/kg atrazine
Applicant name:	Nutrien Ag Solutions Limited
Applicant ACN:	008 743 217
Summary of variation:	To add use to control purple top verbena in tea tree plantations. Also to update the statement of claims, safety direction and first aid instructions as per FAISD handbook
Date of variation:	1 May 2020
Product registration no.:	68292
Label approval no.:	68292/123859

Application no.:	124382
Product name:	Nudrin 225 Insecticide
Active constituent/s:	225 g/L methomyl (an anticholinesterase compound)
Applicant name:	Nufarm Australia Limited
Applicant ACN:	004 377 780
Summary of variation:	To add uses in lettuce and *Centrosema pascuorum* seed crops, remove uses in tobacco, and make other minor changes to the label
Date of variation:	1 May 2020
Product registration no.:	47470
Label approval no.:	47470/124382

Application no.:	123944
Product name:	Campbell Apollo SC Miticide
Active constituent/s:	500 g/L clofentezine
Applicant name:	Colin Campbell (Chemicals) Pty Ltd
Applicant ACN:	000 045 590
Summary of variation:	To add the following uses: control of citrus red mites in citrus trees, control of two-spotted mite and brown almond mite in almonds and control of two-spotted mites in tomatoes (protected)
Date of variation:	4 May 2020
Product registration no.:	54059
Label approval no.:	54059/123944

Application no.:	123832
Product name:	Cropro Stealth Miticide and Insecticide
Active constituent/s:	18 g/L abamectin
Applicant name:	PCT Holdings Pty Ltd
Applicant ACN:	099 023 962
Summary of variation:	To add use in lettuce, snow peas, sugar snap peas, cultivated mushrooms, citrus trees, rhubarb, duboisia, raspberry, blackberry, blackcurrant, papaya (pawpaw), blueberries, sweet corn, chillies, paprika, spring onions and shallots, avocadoes, passionfruit, capsicum, cucumber, eggplant, zucchini, tomato, citrus, mung bean, adzuki bean, navy bean, tea tree oil, custard apples, nursery stock, cut flowers and lychee as per the APVMA permit to label project
Date of variation:	4 May 2020
Product registration no.:	53511
Label approval no.:	53511/123832

Application no.:	122646
Product name:	Biffo Non-Selective Herbicide
Active constituent/s:	200 g/L glufosinate-ammonium
Applicant name:	Nufarm Australia Limited
Applicant ACN:	004 377 780
Summary of variation:	To add certain uses as per the APVMA permit to label project; add optical spot spray technology as a new application method; and make minor amendments to the label
Date of variation:	5 May 2020
Product registration no.:	62489
Label approval no.:	62489/122646

Application no.:	119735
Product name:	Paraquick Plus 360 Herbicide
Active constituent/s:	360 g/L paraquat present as paraquat dichloride
Applicant name:	Ruralco Holdings Limited
Applicant ACN:	009 660 879
Summary of variation:	To update direction for use and general instructions on the label
Date of variation:	6 May 2020
Product registration no.:	87228
Label approval no.:	87228/119735

Application no.:	120542
Product name:	Liberty Herbicide
Active constituent/s:	200g/L glufosinate-ammonium
Applicant name:	BASF Australia Ltd
Applicant ACN:	008 437 867
Summary of variation:	To update product application rates in canola for control of annual ryegrass and suppression of wild radish
Date of variation:	7 May 2020
Product registration no.:	53595
Label approval no.:	53595/120542

Application no.:	124006
Product name:	Ambush EC Insecticide
Active constituent/s:	50 g/L permethrin (40:60:cis:trans)
Applicant name:	Agnova Technologies Pty Ltd
Applicant ACN:	097 705 158
Summary of variation:	To add the control of heliothis and looper in celery
Date of variation:	8 May 2020
Product registration no.:	63975
Label approval no.:	63975/124006

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.:	118251
Product name:	Neptra Otic Solution For Dogs
Active constituent/s:	16.7 mg/mL florfenicol, 14.8 mg/mL terbinafine (as terbinafine hydrochloride), 2.2 mg/mL mometasone furoate
Applicant name:	Bayer Australia Ltd (Animal Health)
Applicant ACN:	000 138 714
Summary of use:	For the treatment of *Otitis externa* in dogs
Date of Registration:	4 May 2020
Product registration no.:	87389
Label approval no.:	87389/118251

Application no.:	115249
Product name:	Eryvac E-Oral (Live) Vaccine For Pigs
Active constituent/s:	Erysipelothrix rhusiopathiae strain 31 (≥ 1.0 x $10^{8.08}$ CFU/dose)
Applicant name:	Zoetis Australia Pty Ltd
Applicant ACN:	156 476 425
Summary of use:	For in-water administration to healthy pigs 11 weeks of age or older as an aid in the prevention of disease caused by Erysipelothrix rhusiopathiae
Date of Registration:	6 May 2020
Product registration no.:	86289
Label approval no.:	86289/115249

2. VETERINARY PRODUCTS BASED ON EXISTING ACTIVE CONSTITUENTS

Application no.:	120053
Product name:	Kesium Chewable Tablets For Dogs 500mg
Active constituent/s:	400 mg/tablet amoxicillin as amoxicillin trihydrate, 100 mg/tablet clavulanic acid as potassium clavulanate
Applicant name:	Ceva Animal Health Pty Ltd
Applicant ACN:	002 692 426
Summary of use:	For the registration of an antibiotic tablet for use in dogs for the treatment of bacterial infections caused by ß-lactamase producing strains of bacteria
Date of registration:	28 April 2020
Product registration no.:	88023
Label approval no.:	88023/120053

Application no.:	120052
Product name:	Kesium Chewable Tablets For Dogs 250mg
Active constituent/s:	200 mg/tablet amoxicillin as amoxicillin trihydrate, 50 mg/tablet clavulanic acid as potassium clavulanate
Applicant name:	Ceva Animal Health Pty Ltd
Applicant ACN:	002 692 426
Summary of use:	For the registration of an antibiotic tablet product for use in dogs for the treatment of bacterial infections caused by ß-lactamase producing strains of bacteria
Date of registration:	28 April 2020
Product registration no.:	88022
Label approval no.:	88022/120052

Application no.:	120051
Product name:	Kesium Chewable Tablets For Cats And Dogs 50mg
Active constituent/s:	40 mg/ tablet amoxicillin as amoxicillin trihydrate, 10mg/tablet clavulanic acid as potassium clavulanate
Applicant name:	Ceva Animal Health Pty Ltd
Applicant ACN:	002 692 426
Summary of use:	For the registration of an antibiotic tablet product for use in cats and dogs for the treatment of bacterial infections caused by ß-lactamase producing strains of bacteria
Date of registration:	28 April 2020
Product registration no.:	88021
Label approval no.:	88021/120051

Application no.:	122894
Product name:	Tetramax LA 300 Injection
Active constituent/s:	300 mg/mL oxytetracycline (as the dihydrate)
Applicant name:	Abbey Laboratories Pty Ltd
Applicant ACN:	156 000 430
Summary of use:	For use in cattle, sheep and pigs as a broad spectrum antibiotic injection
Date of registration:	30 April 2020
Product registration no.:	88917
Label approval no.:	88917/122894

Application no.:	123947
Product name:	Enro 50 mg/mL Injection
Active constituent/s:	50 mg/mL enrofloxacin
Applicant name:	Ferrari Animal Health Pty Ltd
Applicant ACN:	162 206 671
Summary of use:	For use in diseases caused by susceptible bacterial pathogens in dogs and cats
Date of registration:	30 April 2020
Product registration no.:	89196
Label approval no.:	89196/123947

Application no.:	120582
Product name:	Simparica Trio Chews For Dogs 40.1–60 Kg
Active constituent/s:	300 mg pyrantel (as embonate), 72 mg sarolaner, 1.44 mg moxidectin
Applicant name:	Zoetis Australia Pty Ltd
Applicant ACN:	156 476 425
Summary of use:	For the treatment, prevention and control of endo- and ecto-parasites in dogs
Date of registration:	1 May 2020
Product registration no.:	88214
Label approval no.:	88214/120582

Application no.:	120584
Product name:	Simparica Trio Chews For Dogs 20.1–40 Kg
Active constituent/s:	200 mg pyrantel (as embonate), 48 mg sarolaner, 0.96 mg moxidectin
Applicant name:	Zoetis Australia Pty Ltd
Applicant ACN:	156 476 425
Summary of use:	For the treatment, prevention and control of endo- and ecto-parasites in dogs
Date of registration:	1 May 2020
Product registration no.:	88216
Label approval no.:	88216/120584

Application no.:	120585
Product name:	Simparica Trio Chews For Dogs 10.1–20 Kg
Active constituent/s:	100 mg pyrantel (as embonate), 24 mg sarolaner, 0.48 mg moxidectin
Applicant name:	Zoetis Australia Pty Ltd
Applicant ACN:	156 476 425
Summary of use:	For the treatment, prevention and control of endo- and ecto-parasites in dogs
Date of registration:	1 May 2020
Product registration no.:	88217
Label approval no.:	88217/120585

Application no.:	120586
Product name:	Simparica Trio Chews For Dogs 5.1–10 Kg
Active constituent/s:	50 mg pyrantel (as embonate), 12 mg sarolaner, 0.24 mg moxidectin
Applicant name:	Zoetis Australia Pty Ltd
Applicant ACN:	156 476 425
Summary of use:	For the treatment, prevention and control of endo- and ecto-parasites in dogs
Date of registration:	1 May 2020
Product registration no.:	88218
Label approval no.:	88218/120586

Application no.:	120587
Product name:	Simparica Trio Chews For Dogs 2.6–5 Kg
Active constituent/s:	25 mg pyrantel (as embonate), 6 mg sarolaner, 0.12 mg moxidectin
Applicant name:	Zoetis Australia Pty Ltd
Applicant ACN:	156 476 425
Summary of use:	For the treatment, prevention and control of endo- and ecto-parasites in dogs
Date of registration:	1 May 2020
Product registration no.:	88219
Label approval no.:	88219/120587

Application no.:	120588
Product name:	Simparica Trio Chews For Dogs 1.25–2.5 Kg
Active constituent/s:	12.5 mg pyrantel (as embonate), 3 mg sarolaner, 0.06 mg moxidectin
Applicant name:	Zoetis Australia Pty Ltd
Applicant ACN:	156 476 425
Summary of use:	For the treatment, prevention and control of endo- and ecto-parasites in dogs
Date of registration:	1 May 2020
Product registration no.:	88220
Label approval no.:	88220/120588

Application no.:	123930
Product name:	Hexiguard Broad-Spectrum Disinfectant
Active constituent/s:	8 g/L chlorhexidine gluconate equivalent to 4.5 g/L chlorhexidine
Applicant name:	WSD Agribusiness Pty Ltd
Applicant ACN:	600 111 135
Summary of use:	To register a topical solution for general disinfection
Date of registration:	4 May 2020
Product registration no.:	89189
Label approval no.:	89189/123930

Application no.:	124168
Product name:	Dycectin Long Lasting Injection For Sheep
Active constituent/s:	20 g/L moxidectin
Applicant name:	Four Seasons Agribusiness Pty Ltd
Applicant ACN:	115 133 189
Summary of use:	For treatment and control of roundworms, nasal bot and itch mite in sheep and for protection against severe challenge by *Haemonchus contortus* (barber's pole worm) for up to 4 months
Date of registration:	5 May 2020
Product registration no.:	89250
Label approval no.:	89250/124168

Application no.:	123951
Product name:	Multitrace Copper Free Injection For Sheep And Cattle
Active constituent/s:	40 g/L zinc as disodium zinc EDTA, 10 g/L manganese as disodium manganese EDTA, 5 g/L selenium as sodium selenite
Applicant name:	Intervet Australia Pty Ltd
Applicant ACN:	008 467 034
Summary of use:	For sheep and beef and dairy cattle deficient in and/or responsive to manganese, zinc, and/or selenium supplementation containing active constituents: 40 g/L ZINC as disodium zinc EDTA 10 g/L manganese as disodium manganese EDTA 5 g/L selenium as sodium selenite
Date of registration:	6 May 2020
Product registration no.:	89197
Label approval no.:	89197/123951

3. VARIATIONS OF REGISTRATION

Application no.:	125205
Product name:	Pastoral Ag Cyrolab Liquid Blowfly Treatment For Sheep
Active constituent/s:	500 g/L cyromazine
Applicant name:	The Hunter River Company Pty Ltd
Applicant ACN:	133 798 615
Summary of variation:	To vary the distinguishing product name and the name that appears on the label from ‘Pastoral Ag Cyromazine Liquid Sheep Blowfly Treatment’ to ‘Pastoral Ag Cyrolab Liquid Blowfly Treatment For Sheep’
Date of variation:	29 April 2020
Product registration no.:	66589
Label approval no.:	66589/125205

Application no.:	125207
Product name:	Pastoral Ag Cyrolab Spray-On Blowfly Treatment For Sheep
Active constituent/s:	60 g/L cyromazine
Applicant name:	The Hunter River Company Pty Ltd
Applicant ACN:	133 798 615
Summary of variation:	To vary the distinguishing product name and the name that appears on the label from 'Pastoral Ag Cyromazine Spray-on Sheep Blowfly Treatment' to 'Pastoral Ag Cyrolab Spray-on Blowfly Treatment For Sheep'
Date of variation:	29 April 2020
Product registration no.:	65089
Label approval no.:	65089/125207

Application no.:	119853
Product name:	Websters 6 In 1 SE Vaccine
Active constituent/s:	5.0 U/mL *Clostridium perfringens* type D, 1.0 U/mL aluminium adjuvanted toxoid and cellular antigen from *corynebacterium pseudotuberculosis (ovis)*, 3.5 U/mL Cl. *novyi* type B, 2.5 U/mL Cl. *tetani*, 2.5 IU/mL Cl. *septicum*, ≥ 0.3% pcv/mL Cl. *chauvoei* , 1 mg/mL selenium (as sodium selenate)
Applicant name:	Virbac (Australia) Pty Ltd
Applicant ACN:	003 268 871
Summary of variation:	To vary the product registration and label approval to update relevant particulars
Date of variation:	4 May 2020
Product registration no.:	51337
Label approval no.:	51337/119853

Application no.:	119857
Product name:	Websters 5 In 1 Vaccine
Active constituent/s:	5.0 U/mL toxoid and cell concentrates prepared from formalin killed *clostridium perfringens* type D, 3.5 U/mL Cl. *novyi* type B, 2.5 IU/mL Cl. *septicum*, 2.5 U/mL Cl. *tetani*, ≥ 0.3% pcv/mL Cl. *chauvoei*
Applicant name:	Virbac (Australia) Pty Ltd
Applicant ACN:	003 268 871
Summary of variation:	To vary the product registration and label approval to update relevant particulars
Date of variation:	11 May 2020
Product registration no.:	51333
Label approval no.:	51333/119857

Application no.:	119861
Product name:	Websters 6 In 1 Vaccine
Active constituent/s:	5.0 U/mL *Clostridium perfringens* type D, 3.5 U/mL Cl. *novyi* type B, 2.5 U/mL Cl. *septicum*, 2.5 U/mL Cl. *tetani*, 1.0 U/mL toxoid and cell concentrates prepared from formalin killed *corynebacterium pseudotuberculosis (ovis)*, ≥0.3% pcv/mL Cl. *chauvoei*
Applicant name:	Virbac (Australia) Pty Ltd
Applicant ACN:	003 268 871
Summary of variation:	To vary the product registration and label approval to update relevant particulars
Date of variation:	11 May 2020
Product registration no.:	51336
Label approval no.:	51336/119861

Application no.:	119863
Product name:	Websters 7 In 1 Vaccine
Active constituent/s:	5.0 U/mL aluminium adjuvanted toxoid and cellular antigen from clostridium perfringens type D, 3.5 U/mL Cl. novyi type B, 2.5 IU/mL Cl. septicum, 2.5 U/mL Cl. tetani, ≥ 0.15% pcv/mL Cl. chauvoei, 0.5 x 109 org/mL Leptospira interrogans serovar hardjo, 0.5 x 109 org/mL Leptospira interrogans serovar pomona Contains 0.13 mg/mL thiomersal.
Applicant name:	Virbac (Australia) Pty Ltd
Applicant ACN:	003 268 871
Summary of variation:	To vary the product registration and label approval to update relevant particulars
Date of variation:	11 May 2020
Product registration no.:	47947
Label approval no.:	47947/119863

Application no.:	119858
Product name:	Websters 5 In 1 B12 Vaccine
Active constituent/s:	5.0 U/mL toxoid and cell concentrates prepared from formalin killed *clostridium perfringens* type D, 3.5 U/mL Cl*. novyi* type B, 2.5 U/mL Cl. *septicum*, 2.5 U/mL Cl. *tetani*, ≥ 0.15% pcv/mL Cl. *chauvoei*, 1mg/mL Vitamin B12 (hydroxocobalamin acetate) 0.13 g/L thiomersal added as a preservative.
Applicant name:	Virbac (Australia) Pty Ltd
Applicant ACN:	003 268 871
Summary of variation:	To vary the product registration and label approval to update relevant particulars
Date of variation:	11 May 2020
Product registration no.:	50632
Label approval no.:	50632/119858

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 CONSTITUENT

Application no.:	120582
Active constituent/s:	Pyrantel Embonate
Applicant name:	Zoetis Australia Pty Ltd
Applicant ACN:	156 476 425
Summary of use:	For use in veterinary chemical products
Date of approval:	29 April 2020
Approval no.:	88688

Application no.:	124388
Active constituent/s:	Lemongrass cochin oil
Applicant name:	Natural Wonders Australia Pty Ltd
Applicant ACN:	069 260 788
Summary of use:	For use in agricultural chemical products
Date of approval:	29 April 2020
Approval no.:	89313

Application no.:	124398
Active constituent/s:	Palmarosa oil
Applicant name:	Natural Wonders Australia Pty Ltd
Applicant ACN:	069 260 788
Summary of use:	For use in agricultural chemical products
Date of approval:	29 April 2020
Approval no.:	89321

Application no.:	122175
Active constituent/s:	Tebufenozide
Applicant name:	Imtrade Australia Pty Ltd
Applicant ACN:	090 151 134
Summary of use:	For use in agricultural chemical products
Date of approval:	30 April 2020
Approval no.:	88750

Application no.:	118250
Active constituent/s:	Terbinafine hydrochloride
Applicant name:	Bayer Australia Ltd (Animal Health)
Applicant ACN:	000 138 714
Summary of use:	For use in veterinary chemical products
Date of approval:	4 May 2020
Approval no.:	87388

Application no.:	120403
Active constituent/s:	Sulfuryl fluoride
Applicant name:	Ensystex Australasia Pty Ltd
Applicant ACN:	102 221 965
Summary of use:	For use in agricultural chemical products
Date of approval:	5 May 2020
Approval no.:	88143

Application no.:	121144
Active constituent/s:	Bifenthrin
Applicant name:	Agrogill Chemicals Pty Ltd
Applicant ACN:	094 672 107
Summary of use:	For use in agricultural chemical products
Date of approval:	5 May 2020
Approval no.:	88375

Application no.:	121938
Active constituent/s:	Chlorthal-dimethyl
Applicant name:	Amvac Netherlands B.V.
Applicant ACN:	N/A
Summary of use:	For use in agricultural chemical products
Date of approval:	5 May 2020
Approval no.:	88666

Application no.:	115248
Active constituent/s:	Erysipelothrix rhusiopathiae, Strain 31
Applicant name:	Zoetis Australia Pty Ltd
Applicant ACN:	156 476 425
Summary of use:	For use in veterinary chemical products
Date of approval:	6 May 2020
Approval no.:	86288

Application no.:	122253
Active constituent/s:	Fludioxonil
Applicant name:	Jiangsu Agrochem Laboratory Co Ltd
Applicant ACN:	N/A
Summary of use:	For use in agricultural chemical products
Date of approval:	7 May 2020
Approval no.:	88784

Application no.:	122661
Active constituent/s:	Bifenthrin
Applicant name:	Adama Australia Pty Ltd
Applicant ACN:	050 328 973
Summary of use:	For use in agricultural chemical products
Date of approval:	7 May 2020
Approval no.:	88843

Application no.:	120854
Active constituent/s:	Glufosinate-ammonium (manufacturing concentrate)
Applicant name:	Foison Scitech Co. Ltd
Applicant ACN:	N/A
Summary of use:	For use in agricultural chemical products
Date of approval:	8 May 2020
Approval no.:	88319

Application no.:	121946
Active constituent/s:	Trinexapac-ethyl
Applicant name:	FMC Australasia Pty Ltd
Applicant ACN:	095 326 891
Summary of use:	For use in agricultural chemical products
Date of approval:	8 May 2020
Approval no.:	88669

2. VARIATIONS OF ACTIVE CONSTITUENT

Application no.:	122622
Active constituent/s:	Prednisolone acetate
Applicant name:	Troy Laboratories Pty Ltd
Applicant ACN:	000 283 769
Summary of variation:	Variation of relevant particulars or conditions of an approved active constituent
Date of variation:	8 May 2020
Approval no.:	85914

New chemical product SCAL 5169 CIK containing momfluorothrin and d-phenothrin

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application for registration of a new product, SCAL 5169 CIK, containing the approved active constituents momfluorothrin and d-phenothrin. This will be the first product registration for the approved active constituent, momfluorothrin.

PARTICULARS OF THE APPLICATION

Proposed product name:	SCAL 5169 CIK
Applicant company:	Sumitomo Chemical Australia Pty Ltd
Name of active constituents:	Momfluorothrin, d-phenothrin
Signal heading:	Unscheduled (interim decision, proposed date of effect 1 June 2020)
Summary of proposed use:	For the control of crawling insects in a home and garden situation
Pack sizes:	200–500 g
Withholding period:	Not applicable

SUMMARY OF THE APVMA'S EVALUATION OF SCAL 5169 CIK 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 SCAL 5169 CIK containing the active constituents momfluorothrin and d-phenothrin would not be an undue hazard to the safety of people exposed to it during its handling and use.

d-phenothrin is listed in Appendix B of the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) so does not require scheduling.

Momfluorothrin is currently listed in Schedule 6 of the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP), with no exceptions. An application was made to the Delegate of the Advisory Committee on Chemicals Scheduling for a scheduling cut-off consideration for momfluorothrin. The Delegate made a final decision to amend the current Poisons Standard entry in relation to momfluorothrin effective 1 June 2020 as follows:

Schedule 6

Momfluorothrin except in preparations containing 0.2 per cent or less of momfluorothrin.

Given SCAL 5169 CIK has a momfluorothrin concentration less than 0.2 per cent it is unscheduled.

(ii) The APVMA is satisfied that the proposed use of SCAL 5169 CIK containing the active constituents momfluorothrin and d-phenothrin will not be an undue hazard to the safety of people using anything containing its residues.

(iii) The APVMA is satisfied that the proposed use of SCAL 5169 CIK containing the active constituents momfluorothrin and d-phenothrin is not likely to be harmful to human beings if used according to the product label directions.

(iv) The APVMA is satisfied that the proposed use of SCAL 5169 CIK containing the active constituents momfluorothrin and d-phenothrin 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.

Exposure of non-target species to momfluorothrin is expected to be negligible since the product is not intended to be applied directly to outdoor plants or soil. Therefore, risks to all non-target species are considered to be acceptable under the proposed conditions of use.

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.

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

(i) The APVMA is satisfied that the proposed use of SCAL 5169 CIK 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 section13 of the Agvet Code, the APVMA invites any person to submit a relevant written submission as to whether SCAL 5169 CIK should be registered. Submissions should relate only to matters that are required by the APVMA to be taken into consideration in determining whether the safety, efficacy or trade criteria have been met. Submissions should state the grounds on which they are based.

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

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

When making a submission please include:

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

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

Written submissions should be addressed in writing to:

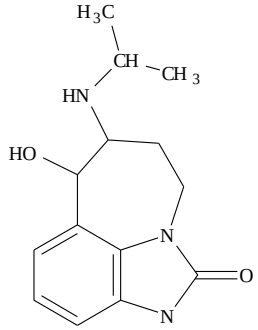
Case Management and Administration Unit
Australian Pesticides and Veterinary Medicines Authority
GPO Box 3262
Sydney NSW 2001

Phone: +61 2 6770 2300
Email: enquiries@apvma.gov.au

Zilmax Medicated Premix containing the new active constituent zilpaterol hydrochloride

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application from Intervet Australia Pty Ltd for the approval of a new active constituent, zilpaterol hydrochloride, and an application for the registration of a new product Zilmax Medicated Premix. The product is a medicated premix administered to cattle fed in confinement for slaughter during the last 20 days on feed to increase carcass leanness, increase dressing percent, improve rate of body weight gain and improve feed efficiency.

PARTICULARS OF THE ACTIVE CONSTITUENT

Common name:	Zilpaterol hydrochloride
IUPAC name:	(±)-Trans-4,5,6,7-Tetrahydro-7-hydroxy-6-isopropylamino) imidazo[4,5,1-jk]-[1]benzazepin -2(1H)- one, monohydrochloride
Chemical abstracts name:	Trans-(±)-4,5,6,7-tetrahydro-7-hydroxy-6-[(1-methylethyl)amino]-imidazo[4,5,1-jk][1]benzazepin-2(1H)-one, monohydrochloride
CAS number:	119520-06-8
Molecular formula:	$C_{14}H_{19}N_3O_2.HCl$
Molecular weight:	297.78 g/mol
Structure:	
Mode of action:	beta II- adrenergic agonist

SUMMARY OF THE APVMA'S EVALUATION OF THE ACTIVE CONSTITUENT ZILPATEROL HYDROCHLORIDE CONSTITUENT 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 new active constituent, zilpaterol hydrochloride, under sections 5A(1)(a),(b) and (c) of the Agvet Code and is satisfied that the active constituent is not, or would not: be an undue hazard to the safety of people exposed to it during its handling or people using anything containing its residues; be likely to have an effect that is harmful to human beings; or be likely to have an unintended effect that is harmful to animals, plants or things or to the environment.

The APVMA has evaluated the chemistry aspects of zilpaterol hydrochloride (manufacturing process, quality control procedures, batch analysis results and analytical methods) and found them to be acceptable. Based on a review of the data, the APVMA is satisfied that the chemistry and manufacturing details of zilpaterol hydrochloride are acceptable for use in veterinary chemical products.

Impurities of known toxicological concern are unlikely to be formed during the manufacture of zilpaterol hydrochloride, or be present in the end product.

The APVMA has considered the toxicological aspects of zilpaterol hydrochloride and concluded that there are no toxicological concerns to the approval of this active constituent. An Acceptable Daily Intake (ADI) of 0.04 µg/kg bw, and an Acute Reference Dose (ARfD) of 0.04 µg/kg bw have been established in this assessment.

In 1999, zilpaterol was listed in Schedule 4 of the Poisons Standard without a cut-off. The APVMA considered that the current S4 Poisons Schedule is appropriate for zilpaterol hydrochloride for use in veterinary products.

The APVMA is satisfied that the use of zilpaterol hydrochloride in a veterinary chemical product would not be an undue toxicological hazard to the safety of people exposed to it during its handling and use, nor would it be likely to have an unintended effect that is harmful to human beings, animals, plants or things or to the environment.

PARTICULARS OF THE PRODUCT

Proposed product name:	Zilmax Medicated Premix
Applicant:	Intervet Australia Pty Ltd
Name of active constituent:	Zilpaterol hydrochloride
Signal heading:	Schedule 4
Summary of purpose:	For increased carcass leanness, increased dressing percent, improved rate of body weight gain and improved feed efficiency in cattle fed in confinement for slaughter during the last 20 days on feed.
Pack size:	10 kg
Withholding period:	Meat: REMOVE ALL MEDICATED FEED 4 days before slaughter for human consumption Milk**:** DO NOT USE in cows which are producing or may in the future produce milk that may be used or processed for human consumption DO NOT USE in calves to be processed for veal.
Trade advice:	Exporters need to comply with the regulations/standards of importing countries with regard to the use of animal health products in livestock. Producers are advised to contact their export slaughter facility or Intervet Australia Pty Ltd for information before giving cattle feed to which this product has been added. EXPORT SLAUGHTER INTERVAL (ESI): DO NOT USE less than 4 days before slaughter for export to markets for which zilpaterol MRLs are established. Before using this product confirm the current export status for certain markets with Intervet Australia Pty Ltd on 1 800 033 461.

SUMMARY OF THE APVMA'S EVALUATION OF ZILMAX MEDICATED PREMIX 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.*

The APVMA has evaluated the proposed product Zilmax Medicated Premix and is satisfied that the proposed chemical product meets the safety (s 5A) and efficacy (s 5B) criteria if used according to label instructions. For the APVMA to be satisfied that the registration of Zilmax Medicated Premix meets the trade (s 5C) criteria, feedback is requested from industry stakeholders on the potential risk to trade associated with the use of the proposed product.

1. The APVMA has evaluated the application and in its assessment in relation to whether the safety criteria has 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 Zilmax Medicated Premix would not be an undue hazard to the safety of people exposed to the product during its handling and use.

The APVMA has conducted a risk assessment for the product, and in conjunction with the estimated hazard profile, determined whether the proposed use of the product would not be an undue health hazard to humans.

Based on the information provided by the applicant, zilpaterol hydrochloride presents moderate acute oral toxicity, low acute dermal toxicity and low inhalational toxicity, and is a slight eye irritant. Zilmax Medicated Premix was shown to be of low acute oral toxicity. To mitigate the acute risks associated with zilpaterol hydrochloride, the following first aid instructions and safety directions are proposed to be included on the product label:

First Aid: *If poisoning occurs, contact a doctor or Poisons Information Centre. Phone Australia 131 126*.

Safety Directions: *Harmful if swallowed. Harmful if inhaled especially the dust. May irritate the eyes. Do not touch or rub eyes, nose or mouth with hand when handling granules. When using the product wear goggles and a disposable dust mask. Wash hands after use*.

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

Following a review of available data the following zilpaterol Maximum Residue Limits (MRLs) are proposed at 3.5 µg/kg for cattle liver, 0.5 µg/kg for cattle muscle and 3.3 µg/kg for cattle kidney. These limits are considered by the APVMA to be appropriate for the proposed use in conjunction with a four day meat withholding period, and are consistent with the MRLs recommended as part of the Joint FAO/WHO Expert Committee on Food Additives (JECFA) evaluation in 2015. To mitigate the risks associated with zilpaterol hydrochloride, the APVMA recommends that the following withholding period, trade advice, and restraint statements be included on the label:

Withholding Period:

Meat: REMOVE ALL MEDICATED FEED 4 days before slaughter for human consumption.

Milk: DO NOT USE in cows which are producing or may in the future produce milk that may be used or processed for human consumption.

Restraints:

DO NOT USE in cows which are producing or may in the future produce milk or milk products for human consumption.

DO NOT USE in calves to be processed for veal.

(iii) The APVMA is satisfied that the proposed use of Zilmax Medicated Premix containing the active constituent zilpaterol hydrochloride is not likely to be harmful to human beings if used according to label directions.

The APVMA has conducted a risk assessment to consider the human safety of Zilmax Medicated Premix. '*Zilpaterol*' is listed in Schedule 4 of the Poisons Standard without any cut-offs. Zilmax Medicated Premix contains 48 g/kg zilpaterol hydrochloride and is classified as a Schedule 4 prescription veterinary remedy. Based on the toxicological profile of this active constituent, the APVMA considered the scheduling appropriate.

(iv) The APVMA is satisfied that the proposed use of Zilmax Medicated Premix 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.

For veterinary chemical products, the APVMA has adopted VICH guidelines (VICH 2000) on data requirements for environmental safety (amongst other things). It is assumed that veterinary chemical products that satisfy the criteria of VICH Phase I will have limited use and environmental exposure, and consequently, have limited environmental effects.

The APVMA has conducted an environmental assessment and applied the standard VICH GL6 guidance for a Phase 1 assessment. It was demonstrated that, based on conservative methodology (95 per cent excretion, 1 cm soil incorporation, 15,000 kg/ha manure application), soil predicted concentrations were below the VICH Phase 1 trigger value of 100 µg/kg soils, therefore, environmental risk of the use of Zilmax Medicated Premix were considered to be acceptable.

The APVMA recommends the following disposal statements which are consistent with the Vet Labelling Code for the appropriate package size:

Shake container into medicated feed. Do not dispose of undiluted chemicals on-site. Puncture bag and deliver to an approved waste management facility. If an approved waste management facility is not available, bury the container 500 mm below the surface in a disposal pit specifically marked and set up for this purpose clear of waterways, vegetation and tree roots, in compliance with relevant local, state or territory government regulations. Do not burn empty containers or product.

The results of the target animal safety studies submitted demonstrated that the product was safe up to 20 days if used according to the product label directions. A transient increase in heart rate was observed, but this is an expected effect for a beta II- adrenergic agonist. Observed increased respiratory rates and elevated levels of creatinine phosphokinase (CPK) and creatinine statement will be included on the label.

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) Zilmax Medicated Premix is a medicated premix to be administered to cattle fed in confinement for slaughter during the last 20 days on feed to increase carcass leanness, increase dressing percent, improve the rate of weight gain and improve feed efficiency. The product is to be fed to cattle at a concentration of 8.3 g zilpaterol hydrochloride per tonne based on 100 per cent dry matter basis for 20 consecutive days.

The efficacy data package comprised of results from dose determination studies, dose confirmation studies and field studies. The APVMA has concluded that the data generated from these studies support the claims that the product would be effective in increasing the rate of weight gain, improving feed efficiency and increasing carcass leanness and dressing percent if used according to the product label directions.

3. The APVMA 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 has noted the following as part of its risk assessment:

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

(ii) There is a risk to the international trade for cattle meat and offal associated with the proposed use for the markets that have not established zilpaterol MRLs including the European Union (EU), China, Taiwan, and countries that adopt Codex MRLs.

(iii) The applicant has proposed a Zilpaterol Management Plan to assist in the mitigation of trade risk. The proposed plan includes restriction of the supply of Zilmax Medicated Premix. The applicant states that the National Feedlot Accreditation Scheme has agreed to develop a β-agonist management plan and individual NFAS Accredited Feedlots will be required to develop feedlot specific QA policies and procedures to ensure the correct use of zilpaterol. Individual feedlot QA policies and procedures will be audited by NFAS prior to them gaining access to zilpaterol through accredited veterinarians. Feedlots will then continue to be audited by NFAS to maintain zilpaterol approved use status. A full copy of the applicants Management Plan is available in the Public Release Summary (PRS) for this product (refer below)

(iv) A restraint label statement "*USE ONLY by authorised NFAS accredited feedlots."* has been proposed by the applicant.

(v) In addition, the following trade related label statements are proposed by the applicant:

TRADE ADVICE: *Exporters need to comply with the regulations/standards of importing countries with regard to the use of animal health products in livestock. Producers are advised to contact their export slaughter facility or Intervet Australia Pty Ltd for information before giving cattle feed to which this product has been added.*

EXPORT SLAUGHTER INTERVAL (ESI): *DO NOT USE less than 4 days before slaughter for export to markets for which zilpaterol MRLs are established. Before using this product confirm the current export status for certain markets with Intervet Australia Pty Ltd on 1 800 033 461.*

The APVMA is seeking feedback from industry stakeholders on the potential risk to trade from the proposed use of the product. In particular industry feedback is being sought on aspects relating to industry practices, proposed label statements and the proposed Zilpaterol Management Plan to prevent tissues from beef cattle exposed to zilpaterol being exported to countries that do not currently have zilpaterol MRLs established such as China, the EU, Taiwan and countries that adopt codex MRLs.

FURTHER INFORMATION

A Public Release Summary (PRS) of the evaluation of this product is available from the APVMA website's Public Consultation page, or by contacting the APVMA below.

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 zilpaterol hydrochloride 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 section 13 of the Agvet Code, the APVMA invites any person to submit a relevant written submission as to whether Zilmax Medicated Premix should be registered. Submissions should relate only to matters that are required by the APVMA to be taken into consideration in determining whether the safety, efficacy or trade criteria have been met. Submissions should state the grounds on which they are based.

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

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

When making a submission please include:

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

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

Written submissions should be addressed in writing to:

Case Management and Administration Unit

Australian Pesticides and Veterinary Medicines Authority

GPO Box 3262

Sydney NSW 2001

Phone: +61 2 6770 2300

Email: enquiries@apvma.gov.au.

Notice of Cancellation at the Request of the Holder

At the request of the holder, in accordance with section 42(1) of the *Agricultural and Veterinary Chemicals Code Act 1994* (Agvet Code), the Australian Pesticides and Veterinary Medicines Authority (APVMA) has cancelled the approvals and/or registrations set out in the table below.

Approval or registration number	Name	Type of approval or registration	Holder	Date of cancellation
63564/0909	Tilmix injection	Product Registration	Jurox Pty Ltd	20 February 2020

In accordance with section 45A(1)(b) of the Agvet Code, the APVMA publishes this notice of the cancellation, including the following instructions which set out how a person can deal with the cancelled active constituent, cancelled product or product bearing a cancelled label referred to in the above table.

INSTRUCTIONS FOR PERSONS WHO POSSESS, HAVE CUSTODY OF OR USE THE CANCELLED ACTIVE CONSTITUENT, CANCELLED PRODUCT, OR THE PRODUCT BEARING A CANCELLED LABEL UNDER SECTION 45B(3) OF THE AGVET CODE

A person who possesses, has custody of or uses the cancelled active constituent, cancelled product or product bearing a cancelled label referred to in the above table in accordance with the instructions contained in this notice, is taken to have been issued with a permit under section 45B(3) of the Agvet Code to possess, have custody of or use the cancelled active constituent, cancelled product or product bearing a cancelled label, in accordance with those instructions.

POSSESSION OR CUSTODY

A person may possess the cancelled active constituent, cancelled product or product bearing a cancelled label referred to in the above table in accordance with its label instructions for 12 months from the date of cancellation.

USE, SUPPLY OR OTHERWISE DEAL WITH

A person may use the cancelled active constituent, cancelled product or products bearing a cancelled label referred to in the above table according to its label instructions, including any conditions relating to shelf life or expiry date, for 12 months after the date of cancellation.

A person may supply or cause to be supplied at wholesale or retail level the cancelled active constituent, cancelled product, or product bearing a cancelled label referred to in the above table, for 12 months after the date of cancellation.

CONTRAVENTIONS

After the day that is 12 months from the date of cancellation it will be an offence against the Agvet Code to have possession or custody of the cancelled active constituents, cancelled products or products bearing a cancelled label with the intention to supply, or to supply the cancelled active constituent, cancelled product, or product bearing a cancelled label.

It is an offence to possess, have custody of, use, or otherwise deal with the cancelled active constituents, cancelled products or products bearing the cancelled label listed in the table above in a manner that contravenes the above instructions.

APVMA CONTACT

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

Chemical Review
Australian Pesticides and Veterinary Medicines Authority
GPO Box 3262
Sydney NSW 2001

Phone: +61 2 6770 2400

Email: chemicalreview@apvma.gov.au.