

# Commonwealth of Australia

# **Gazette**

# Agricultural and veterinary chemicals

No. APVMA 21, 18 October 2022

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.

#### © Commonwealth of Australia 2022

This work is copyright. Apart from any use as permitted under the *Copyright Act 1968*, no part may be reproduced by any process without prior written permission from the Australian Pesticides and Veterinary Medicines Authority (APVMA). Requests and inquiries concerning reproduction and rights should be addressed to:

Assistant Director, Communications
Australian Pesticides and Veterinary Medicines Authority
GPO Box 3262
Sydney NSW 2001

Email: communications@apvma.gov.au

Website: apvma.gov.au

#### **General information**

The APVMA 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.

If you would like to subscribe to receive email notification when a new edition is published, please complete a subscription form.

#### **APVMA** contacts

For enquiries regarding the publishing and distribution of the APVMA Gazette: Telephone: +61 2 6770 2300.

For enquiries on APVMA Gazette content, please refer to the individual APVMA contacts listed under each notice.

#### **Privacy**

For information on how the APVMA manages personal information when you contact us, see our Privacy Policy.

# Contents

Agricultural chemical products and approved labels	1
Veterinary chemical products and approved labels	11
Approved active constituents	17
New active constituent: Dimpropyridaz	21
Efficon Insecticide containing 120 g/L dimpropyridaz	23
Licensing of veterinary chemical manufacturers	25
List of tables	
Table 1: Agricultural products based on existing active constituents	1
Table 2: Variations of registration – Agricultural chemical products and approved labels	4
Table 3: Label approval – Agricultural chemical products and approved labels	9
Table 4: Variation of label approval	9
Table 5: Veterinary products based on existing active constituents	11
Table 6: Variations of registration – Veterinary chemical products and approved labels	14
Table 7: Label approval – Veterinary chemical products and approved labels	16
Table 8: Active constituent	17
Table 9: Variations of active constituent	20
Table 10: Particulars of the active constituent dimpropyridaz	21
Table 11: Proposed active constituent standard for dimpropyridaz	22
Table 12: Particulars of the application – Efficon Insecticide containing 120 g/L dimpropyridaz	23
Table 13: New licences issued by the APVMA under subsection 123(1) of the Agvet Code	25
Table 14: Licences cancelled by the ADVMA under subsection 127(1) of the Agyet Code	25

# Agricultural chemical products and approved labels

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

Table 1: Agricultural products based on existing active constituents

Application no.	135622
Product name	Sharda Glyphosate 700 SG Herbicide
Active constituent	700 g/kg glyphosate present as the mono-ammonium salt
Applicant name	Sharda Cropchem Espana S.L.
Applicant ACN	N/A
Date of registration	29 September 2022
Product registration no.	92460
Label approval no.	92460/135622
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 700 g/kg glyphosate present as the monoammonium salt soluble granule formulation for the control of many annual and perennial weeds

Application no.	136078
Product name	NAADCO Glufosinate Ammonium 200 Herbicide
Active constituent	200 g/L glufosinate-ammonium
Applicant name	New Australia Agricultural Development Company Pty Ltd
Applicant ACN	138 055 553
Date of variation	30 September 2022
Product registration no.	92631
Label approval no.	92631/136078
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 200 g/L glufosinate-ammonium soluble concentrate product for the non-residual control of broadleaf and grass weeds in various situations

Application no.	130913
Product name	ClearoutPlus IGR Dust Insecticide
Active constituents	20 g/kg permethrin 25:75, 2 g/kg pyriproxyfen
Applicant name	Sherwood Chemicals Australasia Pty Ltd
Applicant ACN	136 993 630
Date of registration	4 October 2022
Product registration no.	91091
Label approval no.	91091/130913
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 20 g/kg permethrin plus 2 g/kg pyriproxyfen DP product for the control of cockroaches, ants, fleas, termites, bedbugs, European wasps, spiders and other insects in certain situations

Application no.	135970
Product name	Weed Force Dagger 250 Knockdown Herbicide
Active constituent	250 g/L paraquat present as paraquat dichloride
Applicant name	Weed Force Pty Ltd
Applicant ACN	602 207 152
Date of registration	4 October 2022
Product registration no.	92586
Label approval no.	92586/135970
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 250 g/L soluble concentrate of paraquat for the control of a wide range of grasses and broadleaf weeds as per the directions for use

Application no.	135972
Product name	Weed Force Dart 100SC Grub Spider Ant Insecticide
Active constituent	100 g/L bifenthrin
Applicant name	Weed Force Pty Ltd
Applicant ACN	602 207 152
Date of registration	5 October 2022
Product registration no.	92587
Label approval no.	92587/135972
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 100 g/L bifenthrin suspension concentrate product for the control of a range of urban interior and exterior pests, including spiders, mosquitoes, flies, and other pests, for protection of structures from subterranean termite damage and for control of various pests in turf, orchards and ornamentals

Application no.	136081
Product name	NAADCO Propiconazole 500 Fungicide
Active constituent	500 g/L propiconazole
Applicant name	New Australia Agricultural Development Company Pty Ltd
Applicant ACN	138 055 553
Date of registration	5 October 2022
Product registration no.	92634
Label approval no.	92634/136081
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 500 g/L propiconazole emulsifiable concentrate product for the control of certain fungal diseases of bananas, oats, peanuts, perennial ryegrass, pineapples, stone fruit, sugar cane, wheat and other crops in certain states as specified in the directions for use table and for the control of dollar spot in bent and Queensland blue couch, and spring dead spot in couch as specified in the directions for use table for turfs

Application no.	135981
Product name	IA Outperform 630 Veriphy EC Insecticide/Miticide
Active constituents	600 g/L chlorpyrifos (an anticholinesterase compound), 30 g/L bifenthrin
Applicant name	Imtrade Australia Pty Ltd
Applicant ACN	090 151 134
Date of registration	5 October 2022
Product registration no.	92594
Label approval no.	92594/135981
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 600 g/L chlorpyriphos plus 30 g/L bifenthrin emulsifiable concentrate product for the control of certain insect pests of broadacre crops, cotton, sugarcane and tomatoes

Application no.	136079
Product name	NAADCO Atrazine 900 Herbicide
Active constituent	900 g/kg atrazine
Applicant name	New Australia Agricultural Development Company Pty Ltd
Applicant ACN	138 055 553
Date of registration	6 October 2022
Product registration no.	92632
Label approval no.	92632/136079
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 900 g/kg atrazine water dispersible granule product for the control of annual grasses and broadleaf weeds in sorghum, maize, sugar cane, TT-canola, lucerne and for fallow area maintenance and other situations as per the directions for use

Table 2: Variations of registration – Agricultural chemical products and approved labels

Application no.	137025
Product name	Conan 500 Fungicide
Active constituent	500 g/L chlorothalonil
Applicant name	UPL Australia Pty Ltd
Applicant ACN	066 391 384
Date of variation	16 September 2022
Product registration no.	80829
Label approval no.	80829/137025
Description of the application and its purpose, including the intended use of the chemical product	Variation to the particulars of registration and label approval to update the first aid instructions appearing on a label to reflect the current FAISD Handbook.

Application no.	137064
Product name	Nufarm Collide 700 Adjuvant
Active constituents	350 g/L soyal phospholipids, 350 g/L propionic acid
Applicant name	Nufarm Australia Limited
Applicant ACN	004 377 780
Date of variation	20 September 2022
Product registration no.	70329
Label approval no.	70329/137064
Description of the application and its purpose, including the intended use of the chemical product	Variation to the particulars of registration and label approval to change the distinguishing product name and the name that appears on the label from 'Collide 700 Adjuvant' to 'Nufarm Collide 700 Adjuvant' and to update the storage and disposal and first aid statements

Application no.	136019
Product name	Amgrow Phospot 400 pH7.2 Systemic Fungicide
Active constituent	400 g/L phosphorous (phosphonic) acid present as mono and di potassium phosphite
Applicant name	Amgrow Pty Ltd
Applicant ACN	100 684 786
Date of variation	26 September 2022
Product registration no.	83179
Label approval no.	83179/136019
Description of the application and its purpose, including the intended use of the chemical product	Variation of label approval to add a timing restriction for use in grapes 'DO NOT apply after E-L 33'

Application no.	132497
Product name	AC Tressel 250 SL Herbicide
Active constituent	250 g/L hexazinone
Applicant name	Axichem Pty Ltd
Applicant ACN	131 628 594
Date of variation	26 September 2022
Product registration no.	64858
Label approval no.	64858/132497
Description of the application and its purpose, including the intended use of the chemical product	Variation to the particulars of registration and label approval to extend the use to add sugarcane and amend the pack sizes

Application no.	135333
Product name	Unishield Fungicide, Miticide and Insecticide
Active constituent	800 g/kg sulfur
Applicant name	UPL Australia Pty Ltd
Applicant ACN	066 391 384
Date of variation	27 September 2022
Product registration no.	62282
Label approval no.	62282/135333
Description of the application and its purpose, including the intended use of the chemical product	Variation to registration particulars, particulars of label, product conditions and label conditions, to add uses against lichens and moss in citrus, mites and powdery mildew in table grapes and other label amendments

Application no.	135947
Product name	Farmalinx Forge Herbicide
Active constituent	750 g/kg hexazinone
Applicant name	Farmalinx Pty Ltd
Applicant ACN	134 353 245
Date of variation	28 September 2022
Product registration no.	86835
Label approval no.	86835/135947
Description of the application and its purpose, including the intended use of the chemical product	Variation to particulars of registration and label approval, to replace instructions for use of the product on slopes with no vegetation or slash or on uncultivated areas or non-mounded or bare ground

Application no.	135306
Product name	Sabakem Propyzamide 500 SC Herbicide
Active constituent	500 g/L propyzamide
Applicant name	Sabakem Pty Ltd
Applicant ACN	151 682 138
Date of variation	29 September 2022
Product registration no.	86707
Label approval no.	86707/135306
Description of the application and its purpose, including the intended use of the chemical product	Variation to the particulars of registration and label approval to add use on canola

Application no.	135294
Product name	CropSure Confidant 200SC Insecticide
Active constituent	200 g/L imidacloprid
Applicant name	CropSure Pty Ltd
Applicant ACN	643 829 190
Date of variation	29 September 2022
Product registration no.	91129
Label approval no.	91129/135294
Description of the application and its purpose, including the intended use of the chemical product	Variation to registration particulars, particulars of label, to include uses as a seedling drench in brassicas, lettuce and other leafy crops

Application no.	135961
Product name	Quarterback Insecticide
Active constituent	200 g/L chlorantraniliprole
Applicant name	Turf Culture Pty Ltd
Applicant ACN	117 986 615
Date of variation	29 September 2022
Product registration no.	89878
Label approval no.	89878/135961
Description of the application and its purpose, including the intended use of the chemical product	Variation of registered chemical product and label approval to add new restraints and update the aquatic protection statements in accordance with the APVMA risk assessment manual and the Agricultural Labelling Code

Application no.	136051
Product name	Nipro Throw Down Systemic Fungicide
Active constituent	400 g/L phosphorous (phosphonic) acid present as mono (and) di potassium phosphite
Applicant name	Yara Nipro Pty Ltd
Applicant ACN	066 700 276
Date of variation	30 September 2022
Product registration no.	52577
Label approval no.	52577/136051
Description of the application and its purpose, including the intended use of the chemical product	Variation to the particulars of registration and label approval to add a timing restriction for use in grapes 'DO NOT apply after E-L 33'

Application no.	135959
Product name	Accensi Phospot 600 Systemic Fungicide
Active constituent	600 g/L phosphorous (phosphonic) acid present as mono and di potassium phosphite
Applicant name	Accensi Pty Ltd
Applicant ACN	079 875 184
Date of variation	5 October 2022
Product registration no.	69801
Label approval no.	69801/135959
Description of the application and its purpose, including the intended use of the chemical product	Variation to the particulars of registration and label approval to add a timing restriction for use in grapes 'DO NOT apply after E-L 33'

Application no.	135109
Product name	Dedicate Forte Stressgard Turf Fungicide
Active constituent	240 g/L tebuconazole
Applicant name	2022 Environmental Science AU Pty Ltd
Applicant ACN	656 513 923
Date of variation	6 October 2022
Product registration no.	89422
Label approval no.	89422/135109
Description of the application and its purpose, including the intended use of the chemical product	Variation to the particulars of registration and label approval to add control of take-all patch (Gaeumannomyces spp.) in turf

Application no.	136161
Product name	Receptor Insecticide
Active constituent	500 g/L diafenthiuron
Applicant name	ADAMA Australia Pty Ltd
Applicant ACN	050 328 973
Date of variation	6 October 2022
Product registration no.	91583
Label approval no.	91583/136161
Description of the application and its purpose, including the intended use of the chemical product	Variation to the conditions of label approval to add the spray drift restraints and to update the safety directions

Application no.	134363
Product name	Dairy Power Inline Heavy Duty Alkali Cleaner-Low Foam
Active constituents	800 g/kg sodium hydroxide, 9 g/kg non-ionic detergents
Applicant name	Ecolab Pty Ltd
Applicant ACN	000 449 990
Date of variation	6 October 2022
Product registration no.	49191
Label approval no.	49191/134363
Description of the application and its purpose, including the intended use of the chemical product	Variation to the particulars of registration and label approval to update the label according to the current FAISD Handbook and Agricultural Labelling Code

Application no.	134331
Product name	Dairy Power Clenex General Purpose Powdered Low Foam Detergent
Active constituent	690 g/kg alkaline salts, 18 g/kg non-ionic detergents
Applicant name	Ecolab Pty Ltd
Applicant ACN	000 449 990
Date of variation	7 October 2022
Product registration no.	49185
Label approval no.	49185/134331
Description of the application and its purpose, including the intended use of the chemical product	Variation to the particulars of registration and label approval to update the label according to the current FAISD Handbook and Agricultural Labelling Code

Table 3: Label approval – Agricultural chemical products and approved labels

Application no.	136290
Product name	Brunnings Imidacloprid Bug Kill Systemic Insect Control
Active constituent	0.125 g/L imidacloprid
Applicant name	Brunnings Garden Products Pty Ltd
Applicant ACN	050 655 760
Date of variation	7 October 2022
Product registration no.	62924
Label approval no.	62924/136290
Description of the application and its purpose, including the intended use of the chemical product	Registration of a new label for the existing product 'Brunnings Imidacloprid Bug Kill Systemic Insect Control' with the label name 'Contendor Insecticide'

## Table 4: Variation of label approval

Application no.	136075
Product name	Ezycrop Phosphorous Systemic Fungicide
Active constituent	600 g/L phosphorous (phosphonic) acid present as the mono (and) di potassium phosphite
Applicant name	Ezycrop Pty Ltd
Applicant ACN	156 476 827
Date of variation	4 October 2022
Product registration no.	81494
Label approval no.	81494/136075
Description of the application and its purpose, including the intended use of the chemical product	Variation of label approval to add a timing restriction for use in grapes 'DO NOT apply after E-L 33'

Application no.	135960
Product name	Accensi Phospot 400 PH7.2 Systemic Fungicide
Active constituent	400 g/L phosphorous (phosphonic) acid present as mono and di potassium phosphite
Applicant name	Accensi Pty Ltd
Applicant ACN	079 875 184
Date of variation	5 October 2022
Product registration no.	69800
Label approval no.	69800/135960
Description of the application and its purpose, including the intended use of the chemical product	Variation to the conditions of label approval to add a timing restriction for use in grapes 'DO NOT apply after E-L 33'

Application no.	136055
Product name	Crop Doc 600 Fungicide
Active constituent	600 g/L phosphorous (phosphonic) acid as mono-di k phosphonate
Applicant name	AgriNova New Zealand Limited
Applicant ACN	N/A
Date of variation	5 October 2022
Product registration no.	81930
Label approval no.	81930/136055
Description of the application and its purpose, including the intended use of the chemical product	Variation of label approval to add a timing restriction for use in grapes 'DO NOT apply after E-L 33'

Application no.	136105
Product name	Stoller's Fungacid 600 Systemic Fungicide
Active constituent	600 g/L phosphorous (phosphonic) acid present as mono (and) di potassium phosphite
Applicant name	Stoller Australia Pty Ltd
Applicant ACN	065 320 747
Date of variation	6 October 2022
Product registration no.	68325
Label approval no.	68325/136105
Description of the application and its purpose, including the intended use of the chemical product	Variation of label approval to add a timing restriction for use in grapes

Application no.	136199
Product name	NovaGuard Phosphorous Systemic Fungicide
Active constituent	600 g/L phosphorous (phosphonic) acid present as mono and di potassium phosphite
Applicant name	Novaguard Pty Ltd
Applicant ACN	153 121 156
Date of variation	7 October 2022
Product registration no.	80816
Label approval no.	80816/136199
Description of the application and its purpose, including the intended use of the chemical product	Variation of label approval to add a timing restriction for use in grapes

# 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.

Table 5: Veterinary products based on existing active constituents

Application no.	135849
Product name	Elevet+ Moxidectin Praziquantel Long Acting Horse Wormer and Boticide Gel
Active constituents	125 mg/mL praziquantel, 20 mg/mL moxidectin
Applicant name	Avet Health Pty Ltd
Applicant ACN	616 838 101
Date of registration	30 September 2022
Product registration no.	92534
Label approval no.	92534/135849
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 20 mg/mL moxidectin, 125 mg/mL praziquantel oral gel product for the treatment and control of internal parasites in horses

Application no.	135847
Product name	Elevet+ Meloxicam 40 mg/mL Solution for Injection
Active constituent	40 mg/mL meloxicam
Applicant name	Avet Health Pty Ltd
Applicant ACN	616 838 101
Date of registration	30 September 2022
Product registration no.	92533
Label approval no.	92533/135847
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 40 mg/mL meloxicam parental solution product for use as a non-steroidal anti-inflammatory, analgesic and antipyretic in cattle

Application no.	135095
Product name	Vitaject ADE Injection
Active constituent/s	294.0 mg/mL (500,000 IU/mL) retinol palmitate (vitamin A) 1.25 mg/mL (50,000 IU/mL) cholecalciferol (vitamin D3) 50.0 mg/mL (50 IU/mL) alpha tocopherol acetate (vitamin E)
Applicant name	Abbey Laboratories Pty Ltd
Applicant ACN	156 000 430
Date of registration	30 September 2022
Product registration no.	92294
Label approval no.	92294/135095
Description of the application and its purpose, including the intended use of the chemical product	Registration of 294 mg/mL (500,000 IU/mL) vitamin A, 1.25 mg/mL (50,000 IU/mL) vitamin D3, 50 mg/mL (50 IU/mL) vitamin E injectable solution product for the treatment and prevention of vitamin A, D and E deficiencies in cattle, sheep and pigs

Application no.	135876
Product name	[Wagg & Purr] Pimobendan 10 mg Chewable Tablets for Dogs
Active constituent	10 mg/tablet pimobendan
Applicant name	Avet Health Pty Ltd
Applicant ACN	616 838 101
Date of registration	5 October 2022
Product registration no.	92545
Label approval no.	92545/135876
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 10 mg pimobendan chewable tablet product for the treatment of canine congestive heart failure (CHF) originating from dilated cardiomyopathy (DCM) or valvular insufficiency (mitral and/or tricuspid regurgitation), treatment of preclinical DCM in large breed dogs and treatment in dogs with evidence of increased heart size secondary to asymptomatic (preclinical) myxomatous mitral valve disease to delay the onset of clinical symptoms of heart failure, to reduce heart size and to increase survival time

Application no.	135882
Product name	[Wagg & Purr] Pimobendan 2.5 mg Chewable Tablets for Dogs
Active constituent/s	2.5 mg/tablet pimobendan
Applicant name	Avet Health Pty Ltd
Applicant ACN	616 838 101
Date of registration	5 October 2022
Product registration no.	92551
Label approval no.	92551/135882
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 2.5 mg pimobendan chewable tablet product for the treatment of canine congestive heart failure (CHF) originating from dilated cardiomyopathy (DCM) or valvular insufficiency (mitral and/or tricuspid regurgitation), treatment of preclinical DCM in large breed dogs and treatment in dogs with evidence of increased heart size secondary to asymptomatic (preclinical) myxomatous mitral valve disease to delay the onset of clinical symptoms of heart failure, to reduce heart size and to increase survival time

Application no.	135086
Product name	[Wagg & Purr] Cyclosporin Ophthalmic Ointment
Active constituent	2 mg/g cyclosporin
Applicant name	Avet Health Pty Ltd
Applicant ACN	616 838 101
Date of registration	5 October 2022
Product registration no.	92293
Label approval no.	92293/135086
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 2 mg/g cyclosporin ophthalmic ointment product for the treatment of idiopathic chronic keratoconjunctivitis sicca and chronic superficial keratitis in dogs

Application no.	134208
Product name	Carprofelican Injection
Active constituent/s	50 mg/mL carprofen
Applicant name	Dechra Regulatory B.V.
Applicant ACN	N/A
Date of registration	5 October 2022
Product registration no.	92024
Label approval no.	92024/134208
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 50 mg/mL carprofen parenteral solution product as an aid in the alleviation of pain and inflammation associated with musculoskeletal disorders and for anti-inflammatory treatment after surgery in the horses. In dogs and cats, it is indicated for the control of post-operative pain and inflammation following orthopaedic and soft tissue (including intra-ocular) surgery

Application no.	135915
Product name	4Farmers Dicyclanil 50 g/L Spray-On Fly Treatment
Active constituent/s	50 g/L dicyclanil
Applicant name	4 Farmers Australia Pty Ltd
Applicant ACN	160 092 428
Date of registration	6 October 2022
Product registration no.	92570
Label approval no.	92570/135915
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 50 g/L dycyclanil topical solution/suspension for the protection against fly strike

Application no.	136231
Product name	Oxytetracycline LA 200 mg/mL Injectable Solution
Active constituent/s	200 mg/mL oxytetracycline as the dihydrate
Applicant name	Redcap Solutions Pty Ltd
Applicant ACN	095 863 899
Date of registration	6 October 2022
Product registration no.	92653
Label approval no.	92653/136231
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 200 mg/mL oxytetracycline (as the dihydrate) injectable solution product for the treatment of conditions caused by, or associated with oxytetracycline-sensitive organisms and infections in cattle, sheep and pigs

Application no.	136246
Product name	Elevet+ Oestradiol Benzoate Injection
Active constituent/s	1 mg/mL oestradiol benzoate
Applicant name	Avet Health Pty Ltd
Applicant ACN	616 838 101
Date of registration	7 October 2022
Product registration no.	92658
Label approval no.	92658/136246
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 1 mg/mL oestradiol benzoate injectable product for use to improve the precision of the onset of oestrus and maximise fertility in oestrous synchronisation programmes using an intravaginal insert containing progesterone in cycling cattle and induce oestrus and ovulation after progesterone priming with an intravaginal insert containing progesterone in the treatment of anoestrus in cattle

Table 6: Variations of registration – Veterinary chemical products and approved labels

Application no.	137029
Product name	CLiK Ultra Spray-On Sheep Blowfly Treatment
Active constituent	65 g/L dicyclanil
Applicant name	Elanco Australasia Pty Ltd
Applicant ACN	076 745 198
Date of variation	15 September 2022
Product registration no.	81863
Label approval no.	81863/137029
Description of the application and its purpose, including the intended use of the chemical product	Variation to the particulars of registration and label approval to change the distinguishing product name and the name that appears on the label from 'CLiK Extra Spray-On Sheep Blowfly Treatment' to 'CLiK Ultra Spray-On Sheep Blowfly Treatment'

Application no.	135690
Product name	Moxylan LA Long Acting Injection Broad Spectrum Antibiotic
Active constituent	150 mg/mL amoxycillin as the trihydrate
Applicant name	Jurox Pty Limited
Applicant ACN	000 932 230
Date of variation	26 September 2022
Product registration no.	50609
Label approval no.	50609/135690
Description of the application and its purpose, including the intended use of the chemical product	Variation to the relevant particulars of the product and label by updating the instructions for use to align with the Veterinary Labelling Code

Application no.	137195
Product name	Easymec with Tape Oral Broad Spectrum Wormer and Boticide for Horses
Active constituents	15.5 mg/g ivermectin, 77.5 mg/g praziquantel
Applicant name	Abbey Laboratories Pty Ltd
Applicant ACN	156 000 430
Date of variation	29 September 2022
Product registration no.	92178
Label approval no.	92178/137195
Description of the application and its purpose, including the intended use of the chemical product	Variation to the particulars of registration and label approval to change the distinguishing product name and the name that appears on the label from 'Prazimax Duo Broad Spectrum Antiparasitic Paste for Horses' To 'Easymec with Tape Oral Broad Spectrum Wormer and Boticide for Horses'

Application no.	134374
Product name	Improvac for Pigs
Active constituent/s	≥300 µg/2mL dose GnRF-protein conjugate
Applicant name	Zoetis Australia Pty Ltd
Applicant ACN	156 476 425
Date of variation	30 September 2022
Product registration no.	70058
Label approval no.	70058/134374
Description of the application and its purpose, including the intended use of the chemical product	Variation to the relevant particulars of the product and label by extending the use to female pigs

Table 7: Label approval – Veterinary chemical products and approved labels

Application no.	136558
Product name	EquaCare Joint Health Powder for Horses
Active constituent/s	500 g/kg glucosamine hydrochloride
Applicant name	Equacare Pty Ltd
Applicant ACN	650 408 861
Date of variation	5 October 2022
Product registration no.	92430
Label approval no.	92430/136558
Description of the application and its purpose, including the intended use of the chemical product	Approve a new label for the registered product 'EquaCare Joint Health Powder for Horses' with the label name 'Horseland Joint Health Powder for Horses'

# **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.

**Table 8: Active constituent** 

Application no.	133453
Active constituent	Flumioxazin
Applicant name	ADAMA Australia Pty td
Applicant ACN	050 328 973
Date of approval	26 September 2022
Approval no.	91780
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent flumioxazin for use in agricultural chemical products

Application no.	134734
Active constituent/s	Difenoconazole
Applicant name	Hailir Pesticides and Chemicals Group Co. Ltd
Applicant ACN	N/A
Date of approval	29 September 2022
Approval no.	92168
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent difenoconazole for use in agricultural chemical products

Application no.	132857
Active constituent	Difenoconazole
Applicant name	Nufarm Australia Limited
Applicant ACN	004 377 780
Date of approval	29 September 2022
Approval no.	91619
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent difenoconazole for use in agricultural chemical products

Application no.	134809
Active constituent/s	Tebuconazole
Applicant name	Bharat Rasayan Limited
Applicant ACN	N/A
Date of approval	5 October 2022
Approval no.	92194
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent tebuconazole for use in agricultural chemical products

Application no.	134771
Active constituent	Imazalil
Applicant name	ADAMA Australia Pty Limited
Applicant ACN	050 328 973
Date of approval	5 October 2022
Approval no.	92181
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent imazalil for use in agricultural chemical products

Application no.	134236
Active constituent/s	Carprofen
Applicant name	Dechra Regulatory B.V.
Applicant ACN	N/A
Date of approval	5 October 2022
Approval no.	92031
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent carprofen for use in veterinary chemical products

Application no.	134881
Active constituent/s	Clorsulon
Applicant name	Avet Health Pty Ltd
Applicant ACN	616 838 101
Date of approval	6 October 2022
Approval no.	92226
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent clorsulon for use in veterinary chemical products

Application no.	134917
Active constituent/s	Deslorelin acetate
Applicant name	Avet Health Pty Ltd
Applicant ACN	616 838 101
Date of approval	7 October 2022
Approval no.	92247
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent deslorelin acetate for use in veterinary chemical products

Application no.	133617
Active constituent/s	Hydrocortisone aceponate
Applicant name	Avet Health Pty Ltd
Applicant ACN	616 838 101
Date of approval	7 October 2022
Approval no.	91835
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent hydrocortisone aceponate for use in veterinary chemical products

Application no.	134883
Active constituent/s	Sodium salicylate
Applicant name	Avet Health Pty Ltd
Applicant ACN	616 838 101
Date of approval	7 October 2022
Approval no.	92227
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent sodium salicylate for use in veterinary chemical products

Application no.	134811
Active constituent	Diafenthiuron
Applicant name	Bharat Rasayan Limited
Applicant ACN	N/A
Date of approval	7 October 2022
Approval no.	92195
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent diafenthiuron for use in agricultural chemical products

Application no.	134668
Active constituent/s	Gentamicin sulfate
Applicant name	Avet Health Pty Ltd
Applicant ACN	616 838 101
Date of approval	7 October 2022
Approval no.	92144
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent gentamicin sulfate for use in veterinary chemical products

#### **Table 9: Variations of active constituent**

Application no.	134753
Active constituent	Flumioxazin
Applicant name	PCT Holdings Pty Ltd
Applicant ACN	099 023 962
Date of variation	6 October 2022
Approval no.	84668
Description of the application and its purpose, including the intended use of the active constituent	Variation of relevant particulars or conditions of an approved active constituent

## New active constituent: Dimpropyridaz

The APVMA has before it an application for the approval of a new active constituent, dimpropyridaz.

Table 10: Particulars of the active constituent dimpropyridaz

Common name	Dimpropyridaz	
IUPAC name	N-ethyl-5-methyl-1-[(2RS)-3-methylbutan-2-yl]-N-(pyridazin-4-yl)-1H-pyrazole-4-carboxamide	
CAS name	1H-Pyrazole-4-carboxamide, 1-(1,2-dimethylpropyl)-N-ethyl-5-methyl-N-4-pyridazinyl-	
CAS registry number	1403615-77-9	
Manufacturer's codes	BAS 550 I Reg. no. 5845955	
Minimum purity	950 g/kg minimum	
Molecular formula	$C_{16}H_{23}N_5O$	
Molecular weight	301.39 g/mol	
Structure		
Chemical family	Pyrazole carboxamide	
Mode of action	The active constituent works by inhibiting firing of chordotonal organ neurons by blocking signalling upstream of the TRPV channel. As a result, signal transduction by the chordotonal organ is disrupted, the insects are uncoordinated, unable to feed and eventually die.	

#### Summary of the APVMA's evaluation of dimpropyridaz active constituent

The APVMA has evaluated the chemistry aspects of dimpropyridaz (physico-chemical properties, stability, identification, manufacturing process, quality control procedures, batch analysis results and analytical methods) and found them to be acceptable.

The APVMA has considered the toxicological aspects of dimpropyridaz and concluded that there are no toxicological concerns regarding the approval of this active constituent. An acceptable daily intake (ADI) of 0.2 mg/kg bw/d has been set, based on a no-observed adverse effect level (NOAEL) of 350 ppm (equivalent to 21 mg/kg bw/d). This was from a near life-time dietary exposure study in rats, based on a 10% reduction in body weight, reduced body weight gain and hepatic lipofuscinosis in females at the next highest dose (1400 ppm equivalent to 101 mg/kg bw/d).

No acute reference dose (ARfD) has been established for dimpropyridaz. An ARfD was considered unnecessary due to its level acute oral toxicity, lack of acute neurotoxicity, lack of effects on reproduction and development and lack of any effect that would likely occur following a single exposure event.

The Scheduling Delegate has made a final decision to include dimpropyridaz in Schedule 5 for preparations containing 13 per cent or less of dimpropyridaz and schedule 6 except when included in schedule 5 of the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP), with effect from 1 June 2022.

On the basis of the data provided, and the toxicological assessment, it is proposed that the following active constituent standard be established for dimpropyridaz:

Table 11: Proposed active constituent standard for dimpropyridaz

Constituent	Level
Dimpropyridaz	950 g/kg minimum

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

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

#### **Further information**

A Public Release Summary (PRS) of the evaluation of this product is available from the <u>APVMA website</u> or from the contact listed 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 dimpropyridaz 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.

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.

Please note: Submissions will be published on the APVMA's website unless you have asked for the submission to remain confidential (see <u>public submission coversheet</u>).

Please lodge your submission with a <u>public submission coversheet</u>, which provides options for how your submission will be published.

Note that all APVMA documents are subject to the access provisions of the *Freedom of Information Act 1982* and may be required to be released under that Act should a request for access be made.

Please send your written submission and coversheet by email or post to:

Email: enquiries@apvma.gov.au

Post:

Director Chemistry and Manufacture Australian Pesticides and Veterinary Medicines Authority GPO Box 3262 Sydney NSW 2001

#### **Privacy**

For information on how the APVMA manages personal information when you make a submission, see our <u>Privacy Policy</u>.

## Efficon Insecticide containing 120 g/L dimpropyridaz

The APVMA has before it an application for registration of a new product, Efficon Insecticide, containing the new active constituent, dimpropyridaz.

Table 12: Particulars of the application - Efficon Insecticide containing 120 g/L dimpropyridaz

Proposed product name	Efficon Insecticide					
Applicant company	BASF Australia Pty Ltd					
Name of active constituent	Dimpropyridaz					
Signal heading	Schedule 5					
Summary of proposed use	For the control of whiteflies and aphids in certain vegetables crops and cotton					
Pack sizes	1 to 10 L					
Withholding period	Brassica vegetables, leafy vegetables and brassica leafy vegetables, fruiting vegetables, cucurbits:					
	Harvest - DO NOT HARVEST FOR 1 DAY AFTER APPLICATION					
	Cotton:					
	Harvest - DO NOT HARVEST FOR 28 DAYS AFTER APPLICATION					

A summary of the APVMA's evaluation of Efficon Insecticide 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, proposes to determine that:
  - i. The APVMA is satisfied that proposed use of Efficon Insecticide would not be an undue hazard to the safety of people exposed to it during its handling and use.
    - The APVMA has conducted a risk assessment on the product and concluded that it can be used safely.
  - ii. The APVMA is satisfied that the proposed use of Efficon Insecticide 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 the new product Efficon Insecticide containing the active constituent dimpropyridaz, would not be likely to have an unintended effect that is harmful to animals, plants, or the environment.
- 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:
  - In relation to its assessment of efficacy the APVMA is satisfied that data from trials supporting the efficacy of the
    product adequately demonstrate that if used according to the product label directions, the product is effective for its
    proposed 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, proposes to determine that:
  - i. The APVMA is considering whether the proposed use of Efficon Insecticide would not adversely affect trade between Australia and places outside Australia.

#### **Further information**

A Public Release Summary (PRS) of the evaluation of this product is available from the APVMA website or by contacting the APVMA as listed below.

#### Making a submission

In accordance with section 13 of the Agvet Code, the APVMA invites any person to submit a relevant written submission as to whether Simodis Plinazolin Technology Insecticide 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.

Please note: Submissions will be published on the APVMA's website unless you have asked for the submission to remain confidential (see <u>public submission coversheet</u>).

Please lodge your submission with a <u>public submission coversheet</u>, which provides options for how your submission will be published.

Note that all APVMA documents are subject to the access provisions of the *Freedom of Information Act 1982* and may be required to be released under that Act should a request for access be made.

Please send your written submission and coversheet by email or post to:

Email: casemanagement@apvma.gov.au

Post:

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

#### **Privacy**

For information on how the APVMA manages personal information when you make a submission, see our Privacy Policy.

## Licensing of veterinary chemical manufacturers

Pursuant to Part 8 of the Agricultural and Veterinary Chemicals Code (Agvet Code), scheduled to the *Agricultural and Veterinary Chemicals Code Act 1994*, the APVMA hereby gives notice that it has taken action with respect to the licensing of the following veterinary chemical manufacturers with effect from the dates shown.

For a comprehensive listing of all licensed manufacturers please see the APVMA website.

#### **New licences**

Table 13: New licences issued by the APVMA under subsection 123(1) of the Agvet Code

Company name	Licence number	Company ACN	Address	Product types	Steps of manufacture	Date issued
Acura Bio Pty Ltd	1086	074 656 509	2806 Ipswich Road Darra, QLD 4076	Category 1 (Immunobiologicals and sterile veterinary preparations) - Vaccine (Low bioburden processing)	Quality assurance (QA) of raw materials, cell propagation, virus cultivation, bacterial fermentation, low bioburden filling, packaging, labelling, microbiological reduction treatment (heat, filtration, chemical), freeze drying, analysis and testing (physical, chemical), release for supply, storage.	22 September 2022

#### Licence cancellations

The APVMA has cancelled the following licences under subsection 127(1) of the Agvet Code:

Table 14: Licences cancelled by the APVMA under subsection 127(1) of the Agvet Code

Company name	Licence number	Company ACN	Address	Date cancelled
Pia Pharma Pty Ltd	2232	150 999 974	Unit 3, 46 Buffalo Rd Gladesville NSW 2111	23 September 2022
Eurofins AMS Laboratories Pty Ltd	6139	075 467 757	8 Rachael CI Silverwater NSW 2128	23 September 2022

<sup>\*</sup>Category 1: Immunobiologicals and sterile veterinary preparations

Category 2: Non-sterile veterinary preparations other than ectoparasiticides, premixes and supplements

Category 3: Ectoparasiticides

Category 4: Premixes and supplements

Category 6: Single-step manufacturer

#### **APVMA** contact

Manufacturing Quality and Licensing Australian Pesticides and Veterinary Medicines Authority GPO Box 3262 Sydney NSW 2001

**Phone:** +61 2 6770 2301 **Email:** <u>mls@apvma.gov.au</u>

<sup>\*</sup>Category 1: Immunobiologicals and sterile veterinary preparations

Category 2: Non-sterile veterinary preparations other than ectoparasiticides, premixes and supplements

Category 3: Ectoparasiticides

Category 4: Premixes and supplements

Category 6: Single-step manufacturer