

# Commonwealth of Australia

# **Gazette**

# Agricultural and veterinary chemicals

No. APVMA 15, 25 July 2023

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.

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#### **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**

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# Agricultural chemical products and approved labels

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

Table 1: Agricultural products based on existing active constituents

Application no.	139189
Product name	eChem Paraquat 360 Herbicide
Active constituent	360 g/L paraquat present as paraquat dichloride
Applicant name	eChem (AUST) Pty Ltd
Applicant ACN	089 133 095
Date of registration	3 July 2023
Product registration no.	93444
Label approval no.	93444/139189
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 360 g/L paraquat present as the paraquat dichloride soluble concentrate (SL) product for the control of a wide range of grasses and broadleaf weeds

Application no.	138095
Product name	Quali-Pro Evolution Advance Fungicide
Active constituents	370 g/L tebuconazole, 222 g/L azoxystrobin
Applicant name	ADAMA Australia Pty Ltd
Applicant ACN	050 328 973
Date of registration	3 July 2023
Product registration no.	93144
Label approval no.	93144/138095
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 370 g/L tebuconazole and 222 g/L azoxystrobin suspension concentrate product for control of diseases in turf including golf greens, tees and fairways, bowling clubs, sports fields, and racetracks

Application no.	139144
Product name	CHEM-ISAN Disinfectant
Active constituent	120 g/L didecyl dimethyl ammonium chloride
Applicant name	Chemology Pty Ltd
Applicant ACN	142 721 533
Date of registration	3 July 2023
Product registration no.	93437
Label approval no.	93437/139144
Description of the application and its purpose, including the intended use of the chemical product	Registration of 'CHEM-ISAN Disinfectant', a soluble concentrate (SL) product containing 120 g/L didecyl dimethyl ammonium chloride as a broad-spectrum sanitation and water treatment solution for use in agriculture and horticulture as specified in the directions for use table

Application no.	135586
Product name	Kenso Agcare Tal-Ken BA 200 EW Insecticide/Miticide
Active constituent	200 g/L bifenthrin
Applicant name	Kenso Corporation (M) Sdn. Bhd.
Applicant ACN	N/A
Date of registration	4 July 2023
Product registration no.	92451
Label approval no.	92451/135586
Description of the application and its purpose, including the intended use of the chemical product	Registration of a bifenthrin 200 g/L EW product for the control of certain insect pests of wheat, canola, cotton, sugarcane, citrus and various other crops as specified in the directions for use table

Application no.	139417
Product name	Relyon Prothioconazole 420 SC Fungicide
Active constituent	420 g/L prothioconazole
Applicant name	Nutrien Ag Solutions Limited
Applicant ACN	008 743 217
Date of registration	4 July 2023
Product registration no.	93519
Label approval no.	93519/139417
Description of the application and its purpose, including the intended use of the chemical product	Registration of a suspension concentrate (SC) fungicide product containing 420 g/L prothioconazole for the control of various diseases in wheat, barley, oats, triticale and pyrethrum

Application no.	135665
Product name	Musket 240 SC Insecticide
Active constituent	240 g/L spirotetramat
Applicant name	Yifan Biotechnology Group Co Ltd
Applicant ACN	N/A
Date of registration	4 July 2023
Product registration no.	92474
Label approval no.	92474/135665
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 240 g/L spirotetramat suspension concentrate product for the control of various insect pests in cotton and certain fruit and vegetable crops

Application no.	139289
Product name	OzCrop Flutriafol 500 Fungicide
Active constituent	500 g/L flutriafol
Applicant name	Oz Crop Pty Ltd
Applicant ACN	160 656 431
Date of registration	4 July 2023
Product registration no.	93476
Label approval no.	93476/139289
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 500 g/L flutriafol suspension concentrate as OzCrop Flutriafol 500 fungicide for the control of certain fungal diseases on wheat, barley and canola when mixed with fertiliser

Application no.	137613
Product name	Titan Triforto EC Herbicide
Active constituents	250 g/L MCPA present as the ethyl hexyl ester, 250 g/L bromoxynil present as the octanoate, 25 g/L diflufenican
Applicant name	Titan Ag Pty Ltd
Applicant ACN	122 081 574
Date of registration	5 July 2023
Product registration no.	93011
Label approval no.	93011/137613
Description of the application and its purpose, including the intended use of the chemical product	Registration and label approval of a 250 g/L MCPA present as the ethyl hexyl ester 250 g/L bromoxynil present as the octanoate 25 g/L diflufenican emulsifiable concentrate for the control of certain broadleaf weeds including wild radish with developing Group 4 and/or Group 12 herbicide resistance in winter cereals

Application no.	140036
Product name	Hy-Clor Stabilised Granular Pool Chlorine
Active constituent	560 g/kg available chlorine (CI) present as sodium dichloroisocyanurate dihydrate
Applicant name	Hy-Clor (Australia) Pty Ltd
Applicant ACN	000 655 381
Date of registration	5 July 2023
Product registration no.	93644
Label approval no.	93644/140036
Description of the application and its purpose, including the intended use of the chemical product	Registration of a granular formulation product containing 560 g/kg available chlorine present as sodium dichloroisocyanurate dihydrate, for killing and controlling algae and bacteria in swimming pools

Application no.	139086
Product name	The Great Aussie Pool Chlorine
Active constituent	130 g/L available chlorine (CI) present as sodium hypochlorite
Applicant name	S&J Mineral Group Pty Ltd
Applicant ACN	646 729 768
Date of registration	6 July 2023
Product registration no.	93419
Label approval no.	93419/139086
Description of the application and its purpose, including the intended use of the chemical product	Registration of 'The Great Aussie Pool Chlorine', a liquid product containing 130 g/L available chlorine present as sodium hypochlorite, for the control of bacteria and algae in swimming pools and spas

Application no.	139260
Product name	MainMan Broadacre 500 WG Insecticide
Active constituent	500 g/kg flonicamid
Applicant name	Ishihara Sangyo Kaisha, Ltd
Applicant ACN	N/A
Date of registration	6 July 2023
Product registration no.	93469
Label approval no.	93469/139260
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 500 g/kg flonicamid WG product for the control of insect pests in various agricultural crops

Application no.	135517
Product name	GLIFORTE 480 SP Herbicide
Active constituent	480 g/kg glyphosate
Applicant name	Beta Chemicals Ltd
Applicant ACN	N/A
Date of registration	7 July 2023
Product registration no.	92440
Label approval no.	92440/135517
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 480 g/kg glyphosate soluble power product, a non-selective herbicide for the control of a wide range of annual and perennial weeds

Application no.	136276
Product name	Titan Fluroxypyr 140 + Aminopyralid 10 EC Herbicide
Active constituents	140 g/L fluroxypyr present as the methylheptyl ester, 10 g/L aminopyralid present as the triisopropanolamine salt
Applicant name	Titan Ag Pty Ltd
Applicant ACN	122 081 574
Date of registration	10 July 2023
Product registration no.	92666
Label approval no.	92666/136276
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 10 g/L aminopyralid present as the triisopropanolamine salt and 140 g/L fluroxypyr present as the methylheptyl ester emulsifiable concentrate product for the control of lantana in agricultural non-crop areas, commercial and industrial areas, forests, pastures and rights-of-way

Application no.	139261
Product name	Aria 500 WG Insecticide
Active constituent	500 g/kg flonicamid
Applicant name	Ishihara Sangyo Kaisha, Ltd
Applicant ACN	N/A
Date of registration	10 July 2023
Product registration no.	93470
Label approval no.	93470/139261
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 500 g/kg flonicamid WG product for the control of insect pests in various agricultural crops

Application no.	139375
Product name	Rainlic Xtra Growth Regulator
Active constituent	200 g/kg gibberellic acid
Applicant name	Shandong Rainbow International Co Ltd
Applicant ACN	N/A
Date of registration	12 July 2023
Product registration no.	93495
Label approval no.	93495/139375
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 200 g/kg gibberellic acid soluble granule (SG) product for foliar spray application to certain varieties of grapes, citrus and prunes to promote desirable harvest effects

Application no.	139392
Product name	Relyon Alpha Cypermethrin 500 SC Insecticide
Active constituent	500 g/L alpha-cypermethrin
Applicant name	Nutrien Ag Solutions Limited
Applicant ACN	008 743 217
Date of registration	12 July 2023
Product registration no.	93501
Label approval no.	93501/139392
Description of the application and its purpose, including the intended use of the chemical product	Registration of an insecticide product in the formulation of suspension concentrate and containing 500 g/L alpha-cypermethrin for the control of certain insect pests including redlegged earth mite on certain field crops and pastures, and certain insect pests on fruit and vegetable crops

Application no.	139425
Product name	TKO Vapour Active Shield
Active constituents	5.0 g/kg transfluthrin, 0.5 g/kg permethrin
Applicant name	Pascoe's Pty Ltd
Applicant ACN	055 220 463
Date of registration	12 July 2023
Product registration no.	93521
Label approval no.	93521/139425
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 0.5 g/kg permethrin, 5 g/kg transfluthrin aerosol product to repel flying insects for up to 6 hours

Application no.	139407
Product name	Pyripax Insecticide
Active constituent	100 g/L pyriproxyfen
Applicant name	Agrocura Limited
Applicant ACN	N/A
Date of registration	12 July 2023
Product registration no.	93511
Label approval no.	93511/139407
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 100 g/L pyriproxyfen emulsifiable concentrate (EC) product for the control of silverleaf whitefly ( <i>Bemisia tabaci</i> biotype B) in cotton, the control of silverleaf whitefly ( <i>Bemisia tabaci</i> biotype B) and greenhouse whitefly in tomatoes, rockmelon and capsicum, and the control of various scale in citrus, mangoes and olives

Application no.	139410
Product name	Lainco Metham Sodium 510 Soil Fumigant
Active constituent	423 g/L metham present as sodium salt
Applicant name	Lainco S.A.
Applicant ACN	N/A
Date of registration	13 July 2023
Product registration no.	93513
Label approval no.	93513/139410
Description of the application and its purpose, including the intended use of the chemical product	Registration of a soil fumigant product in the formulation of soluble concentrate (SL) containing 423 g/L metham present as the sodium salt for pre-planting treatment for control of soil born pests as per the directions for use table

Application no.	139751
Product name	Sim-Force 500SC Industrial Herbicide
Active constituent	500 g/L simazine
Applicant name	Indigo Specialty Products Pty Ltd
Applicant ACN	631 459 660
Date of registration	13 July 2023
Product registration no.	93577
Label approval no.	93577/139751
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 500 g/L simazine suspension concentrate product for the control of annual grasses and broadleaf weeds in orchards, vineyards, chickpeas, faba beans, lupins, non-crop areas and other crops and for use in triazine tolerant canola

Application no.	139767
Product name	Trustchem Captan 900 WG Fungicide
Active constituent	900 g/kg captan
Applicant name	Sunrise Crop Science Co Ltd
Applicant ACN	N/A
Date of registration	13 July 2023
Product registration no.	93578
Label approval no.	93578/139767
Description of the application and its purpose, including the intended use of the chemical product	Registration of 'Trustchem Captan 900 WG Fungicide', a water dispersible granule (WG) product containing 900 g/kg captan for the control of certain diseases in almonds, a range of fruit crops, turf and ornamentals

Application no.	137771
Product name	Sabakem Sabatage 850 WG Herbicide
Active constituent	850 g/kg pyroxasulfone
Applicant name	Sabakem Pty Ltd
Applicant ACN	151 682 138
Date of registration	13 July 2023
Product registration no.	93045
Label approval no.	93045/137771
Description of the application and its purpose, including the intended use of the chemical product	Registration of an 850 g/kg pyroxasulfone water dispersible granule (WG) product for the pre- emergence control of annual ryegrass, barley grass, annual phalaris, silver grass and toad rush and suppression of certain grass weeds in wheat (not durum wheat), triticale and certain winter legume crops

Application no.	139461
Product name	Sinon Emamectin 44 SG Insecticide
Active constituent	44 g/kg emamectin present as emamectin benzoate
Applicant name	Sinon Australia Pty Ltd
Applicant ACN	102 741 024
Date of registration	13 July 2023
Product registration no.	93541
Label approval no.	93541/139461
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 44 g/kg water soluble granule formulation of emamectin present as emamectin benzoate for the control of diamondback moth (cabbage moth) and cabbage white butterfly in brassica vegetables, light brown apple moth and grapevine moth in grapes and heliothis in capsicum, lettuce, sweet corn and tomatoes

Application no.	139204
Product name	Siqura VetX Veterinary Disinfectant Concentrate
Active constituents	54.0 g/L benzalkonium chloride, 4.0 g/L poly(hexamethylene biguanide) hydrochloride
Applicant name	Fresche Bioscience Pty Ltd
Applicant ACN	152 225 351
Date of registration	13 July 2023
Product registration no.	93447
Label approval no.	93447/139204
Description of the application and its purpose, including the intended use of the chemical product	Registration of a benzalkonium chloride, 4 g/L poly (hexamethylene biguanide hydrochloride) hydrochloride soluble concentrates veterinary disinfectant product for the disinfection of hard surfaces, equipment, surgical and veterinary equipment and airspaces

Application no.	139946
Product name	Relyon Spirotetramat 240 SC Insecticide
Active constituent	240 g/L spirotetramat
Applicant name	Nutrien Ag Solutions Limited
Applicant ACN	008 743 217
Date of registration	14 July 2023
Product registration no.	93615
Label approval no.	93615/139946
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 240 g/L suspension concentrate spirotetramat insecticide formulation for the control of various insect pests in cotton and certain fruit and vegetable crops

Application no.	135075
Product name	ADAMA Di-Bak AM Herbicide
Active constituents	93.7 g/kg aminopyralid, 75 g/kg metsulfuron-methyl
Applicant name	ADAMA Australia Pty Ltd
Applicant ACN	050 328 973
Date of registration	14 July 2023
Product registration no.	92290
Label approval no.	92290/135075
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 93.7 g/kg aminopyralid and 75 g/kg metsulfuron-methyl in a tablet formulation for the control of tree weeds and unwanted tree plants in forestry, pasture, commercial, industrial and public service areas

Application no.	135198
Product name	Genfarm Butafenacil 100 EC Herbicide
Active constituent	100 g/L butafenacil
Applicant name	Nutrien Ag Solutions Limited
Applicant ACN	008 743 217
Date of registration	14 July 2023
Product registration no.	92333
Label approval no.	92333/135198
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 100 g/L butafenacil emulsifiable concentrate product for knockdown, pre-emergent and residual control of various weeds prior to the planting of wheat when mixed with triasulfuron and glyphosate and for the improvement of the control of various broadleaf weeds in fallows when mixed with glyphosate

# Table 2: Listed registrations – agricultural chemical products

Application no.	140288
Product name	PoolPlus 700 Pool Chlorine
Active constituent	700 g/kg available chlorine (CL) present as calcium hypochlorite
Applicant name	PoolPlus Aquatics Pty Ltd
Applicant ACN	658 882 823
Date of registration	13 July 2023
Product registration no.	93733
Label approval no.	93733/140288
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 700 g/kg chlorine present as calcium hypochlorite granule product for control of bacteria, viruses and protozoa in swimming pools

Table 3: Variations of registration – agricultural chemical products

Application no.	140421
Product name	Sphinx Fungicide
Active constituent	500 g/L dimethomorph
Applicant name	ADAMA Australia Pty Ltd
Applicant ACN	050 328 973
Date of variation	27 June 2023
Product registration no.	63373
Label approval no.	63373/140421
Description of the application and its purpose, including the intended use of the chemical product	Variation to update the sites of manufacture, register a pack size range and update the relevant label particulars in accordance with the current Agricultural Labelling Code

Application no.	140534
Product name	Nufarm Cobber Herbicide
Active constituent	475 g/L 2,4-D present as the dimethylamine and diethanolamine salt
Applicant name	Nufarm Australia Limited
Applicant ACN	004 377 780
Date of variation	5 July 2023
Product registration no.	61565
Label approval no.	61565/140534
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 'Cobber 475 Herbicide' to 'Nufarm Cobber Herbicide'

Application no.	139390
Product name	Titan Paraquat 250 Herbicide
Active constituent	250 g/L paraquat present as paraquat dichloride
Applicant name	Titan Ag Pty Ltd
Applicant ACN	122 081 574
Date of variation	12 July 2023
Product registration no.	61869
Label approval no.	61869/139390
Description of the application and its purpose, including the intended use of the chemical product	Variation to registration particulars and particulars of label to add uses for optical spray technology and to update the label to meet current Agricultural Labelling Code requirements

Application no.	135834
Product name	Glean Herbicide
Active constituent	750 g/kg chlorsulfuron
Applicant name	FMC Australasia Pty Ltd
Applicant ACN	095 326 891
Date of variation	12 July 2023
Product registration no.	90141
Label approval no.	90141/135834
Description of the application and its purpose, including the intended use of the chemical product	Variation to registration particulars, particulars of label, to extend the uses to include the control of label weeds in cleancrop forage brassicas

Application no.	139355
Product name	Nufarm Bromoxynil 200 Herbicide
Active constituent	200 g/L bromoxynil present as bromoxynil octanoate
Applicant name	Nufarm Australia Limited
Applicant ACN	004 377 780
Date of variation	12 July 2023
Product registration no.	31614
Label approval no.	31614/139355
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 product and label name, add a tank mix with 'Nufarm Galaxy Herbicide' and to change the recommended adjuvant

Application no.	139439
Product name	Genfarm Panzer 540 Herbicide
Active constituent	540 g/L glyphosate (present as the potassium salt)
Applicant name	Nutrien Ag Solutions Limited
Applicant ACN	008 743 217
Date of variation	12 July 2023
Product registration no.	89795
Label approval no.	89795/139439
Description of the application and its purpose, including the intended use of the chemical product	Variation to the particulars of registration and the label approval to amend the restraints section of the label

Application no.	139299
Product name	Imtrade Activist 225 Veriphy SL Insecticide
Active constituent	225 g/L methomyl (an anti-cholinesterase compound)
Applicant name	Imtrade Australia Pty Ltd
Applicant ACN	090 151 134
Date of variation	13 July 2023
Product registration no.	92346
Label approval no.	92346/139299
Description of the application and its purpose, including the intended use of the chemical product	Variation to the particulars of the label approval to amend the first aid instructions section of the label

Application no.	137911
Product name	Termidor HE Residual Termiticide
Active constituent	96 g/L fipronil
Applicant name	BASF Australia Ltd
Applicant ACN	008 437 867
Date of variation	13 July 2023
Product registration no.	80820
Label approval no.	80820/137911
Description of the application and its purpose, including the intended use of the chemical product	Variation of the product label to amend critical comments to bottom 150 mm of trench can remain unexcavated for protection of poles and fence posts

# **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 4: Veterinary products based on existing active constituents

Application no.	138277
Product name	Itchderm
Active constituent	100 mg/mL cyclosporin
Applicant name	Invetro Pty Ltd
Applicant ACN	654 837 733
Date of registration	3 July 2023
Product registration no.	93206
Label approval no.	93206/138277
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 100 mg/mL cyclosporin liquid for the treatment of allergic dermatitis in cats

Application no.	135938
Product name	Nutrinicarb 250 Granular Anticoccidial Feed Premix
Active constituent	250 g/kg nicarbazin
Applicant name	Nutriment Health Pty Ltd
Applicant ACN	138 061 266
Date of registration	5 July 2023
Product registration no.	92580
Label approval no.	92580/135938
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 250 g/kg Nicarbazin granular feed premix product for prevention and control of coccidiosis caused by Eimeria spp in broiler chickens

Application no.	138684
Product name	Flunax Flunixin Injection
Active constituent	50 mg/mL flunixin (as meglumine)
Applicant name	Ashish Life Science Pvt Ltd
Applicant ACN	N/A
Date of registration	5 July 2023
Product registration no.	93304
Label approval no.	93304/138684
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 50 mg/mL flunixin (as meglumine) parenteral solution product for use as a non- steroidal anti-inflammatory, non-narcotic analgesic and antipyretic agent for horses, cattle, pigs and dogs

Application no.	139279
Product name	AVET Trimethoprim Sulfadoxine 240 mg/mL Injection
Active constituents	200 mg/mL sulfadoxine, 40 mg/mL trimethoprim
Applicant name	AVet Health Limited
Applicant ACN	616 838 101
Date of registration	12 July 2023
Product registration no.	93473
Label approval no.	93473/139279
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 200 mg/mL sulfadoxine and 40 mg/mL trimethoprim parenteral product for the treatment and control of bacterial infections susceptible to sulfadoxine/trimethoprim combination in cattle, sheep, goats, pigs, dogs and horses

Application no.	138492
Product name	Moxidectin and Imidacloprid Spot On for Cats Over 4 kg
Active constituents	100 g/L imidacloprid, 10 g/L moxidectin
Applicant name	Redcap Solutions Pty Ltd
Applicant ACN	095 863 899
Date of registration	13 July 2023
Product registration no.	93252
Label approval no.	93252/138492
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 10 g/L moxidectin, 100 g/L imidacloprid topical solution spot-on product for the treatment of fleas, heartworm and worms in cats

Application no.	139280
Product name	AVET Prilocaine Hydrochloride Injection
Active constituent	20 mg/mL prilocaine hydrochloride
Applicant name	AVet Health Limited
Applicant ACN	616 838 101
Date of registration	13 July 2023
Product registration no.	93474
Label approval no.	93474/139280
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 20 mg/mL prilocaine hydrochloride parenteral solution product for tissue non-irritating local anaesthesia, for use in cat, dog, cattle and horses

# Table 5: Variations of registration – veterinary chemical products

Application no.	137606
Product name	Canaural Compositum Suspension for Treatment of Otitis Externa & Dermatosis
Active constituents	5 mg/g diethanolamine fusidate, 5 mg/g framycetin sulfate, 2.5 mg/g prednisolone, 100,000 IU/g nystatin
Applicant name	Dechra Regulatory B V
Applicant ACN	N/A
Date of variation	3 July 2023
Product registration no.	35926
Label approval no.	35926/137606
Description of the application and its purpose, including the intended use of the chemical product	Variation to the relevant particulars of a registered chemical product and label approval by the addition of a manufacturing site, extension of in-use shelf life and to harmonise the label between Australia and New Zealand

Application no.	139413
Product name	Abbeylinc Antibiotic Soluble Powder
Active constituent	1000 g/kg lincomycin hydrochloride equivalent to not less than 790 g/kg lincomycin base
Applicant name	Abbey Laboratories Pty Ltd
Applicant ACN	156 000 430
Date of variation	4 July 2023
Product registration no.	67803
Label approval no.	67803/139413
Description of the application and its purpose, including the intended use of the chemical product	Variation of relevant particulars of the product registration and label by updating the label to align with the Veterinary Labelling Code

Application no.	138415
Product name	Bomerol 1 mg/mL Oestradiol Benzoate Injection
Active constituent	1 mg/mL oestradiol benzoate
Applicant name	Elanco Australasia Pty Ltd
Applicant ACN	076 745 198
Date of variation	5 July 2023
Product registration no.	57865
Label approval no.	57865/138415
Description of the application and its purpose, including the intended use of the chemical product	Variation of the relevant particulars of product registration and label by updating instructions for use to align with the current Veterinary Labelling Code

Application no.	139310
Product name	Buprelieve Injection
Active constituent	0.3 mg/mL buprenorphine (as hydrochloride)
Applicant name	Jurox Pty Ltd
Applicant ACN	000 932 230
Date of variation	7 July 2023
Product registration no.	69057
Label approval no.	69057/139310
Description of the application and its purpose, including the intended use of the chemical product	Variation of product registration and label approval to include updated dosage directions for cats and dogs

Application no.	139284
Product name	Tilmodil 300 Tilmicosin Injection
Active constituent	300 mg/mL tilmicosin
Applicant name	Emdoka bvba
Applicant ACN	N/A
Date of variation	10 July 2023
Product registration no.	86584
Label approval no.	86584/139284
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 changing the instructions of use to align the label with the current Veterinary Labelling Code

Application no.	138414			
Product name	Ovurelin Injection			
Active constituent	100 μg/mL gonadorelin as acetate			
Applicant name	Elanco Australasia Pty Ltd			
Applicant ACN	076 745 198			
Date of variation	10 July 2023			
Product registration no.	63035			
Label approval no.	63035/138414			
Description of the application and its purpose, including the intended use of the chemical product	Variation of the relevant particulars of product registration and label by updating instructions for use to align with the current Veterinary Labelling Code			

Application no.	139418			
Product name	aw Pure Animal Wellbeing by Blackmores Osteosupport Joint Relief for Cats			
Active constituent	500 mg/capsule green lipped mussel powder (Pema canaliculus)			
Applicant name	Blackmores Limited			
Applicant ACN	009 713 437			
Date of variation	11 July 2023			
Product registration no.	65473			
Label approval no.	65473/139418			
Description of the application and its purpose, including the intended use of the chemical product	Variation of the product and label name			

Application no.	137307			
Product name	HY-50 (Sodium Hyaluronate Sterile Injection 17mg/mL)			
Active constituent	17 mg/mL sodium hyaluronate			
Applicant name	Dechra Ltd			
Applicant ACN	N/A			
Date of variation	12 July 2023			
Product registration no.	53840			
Label approval no.	53840/137307			
Description of the application and its purpose, including the intended use of the chemical product	Variation of particulars and conditions of product and label to update the chemistry details, include a new indication and update the withholding period			

Application no.	138410
Product name	Ovuprost Injection
Active constituent	250 μg/mL cloprostenol (as the sodium salt)
Applicant name	Elanco Australasia Pty Ltd
Applicant ACN	076 745 198
Date of variation	12 July 2023
Product registration no.	63034
Label approval no.	63034/138410
Description of the application and its purpose, including the intended use of the chemical product	Variation of the relevant particulars of product registration and label by updating instructions for use to align with the current Veterinary Labelling Code and to add an additional safety direction

# **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 6: Approved active constituents** 

Application no.	136570
Active constituent	Cyproconazole
Applicant name	ASTEC LifeSciences Ltd
Applicant ACN	N/A
Date of approval	4 July 2023
Approval no.	92761
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent cyproconazole for use in agricultural chemical products

Application no.	137623
Active constituent	Newcastle Disease Virus Vaccine strain V4
Applicant name	Bioproperties Pty Ltd
Applicant ACN	007 303 728
Date of approval	4 July 2023
Approval no.	93016
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent Newcastle Disease Virus Vaccine strain V4 for use in veterinary chemical products

Application no.	138059			
Active constituent	Picloram			
Applicant name	Zhejiang Hengdian Imp & Exp Co Ltd			
Applicant ACN	N/A			
Date of approval	12 July 2023			
Approval no.	93133			
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent picloram for use in agricultural chemical products			

Application no.	137939
Active constituent	Bifenthrin
Applicant name	Hextar Chemicals Pty Ltd
Applicant ACN	114 525 709
Date of approval	13 July 2023
Approval no.	93093
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent bifenthrin for use in agricultural chemical products

# **Table 7: Variations of active constituent**

Application no.	138000
Active constituent	Fluazaindolizine
Applicant name	Production Agriscience (Australia) Pty Ltd
Applicant ACN	616 181 769
Date of variation	11 July 2023
Approval no.	89012
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

Application no.	137974
Active constituent	Florfenicol
Applicant name	Intervet Australia Pty Ltd
Applicant ACN	008 467 034
Date of variation	12 July 2023
Approval no.	85735
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

# 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**

The APVMA has issued the following licences under subsection 123(1) of the Agvet Code:

Table 8: 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
Probus Pharmaceuticals Pty Ltd	6249	638 193 674	Unit 10, 222 Wisemans Ferry Road Somersby NSW 2250	Category 6: Powders	Secondary packaging, secondary labelling, relabelling, storage and release for supply	29 June 2023
International Animal Health Products Pty Ltd	2015	003 185 699	18 Healey Circuit Huntingwood NSW 2148	Category 2: Creams/lotions, ointments, pastes, powders, pellets, sprays, tablets, bolus, and liquids Category 3: Liquids, sprays, and powders Category 4: Premixes, supplements, and probiotics	Quality assurance (QA) of raw materials, formulation including blending, dry milling, granulation, filling, packaging, labelling, pellet extrusion, tableting, analysis and testing (physical), secondary packaging, secondary labelling, repackaging, relabelling, storage and release for supply	11 July 2023
Scientest Analytical Services Pty Ltd	6250	116 585 936	64 Blanck St Ormeau QLD 4208	Category 6: All dosage forms	Analysis and testing (physical and chemical)	11 July 2023

# **APVMA** contact

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

**Phone:** +61 2 6770 2301 **Email:** mls@apvma.gov.au

\*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 5: Exempt

Category 6: Single-step manufacturer

# Variations to Schedule 20 of the Australian New Zealand Food Standards Code

The APVMA has previously gazetted particular amendments which it had made to the APVMA MRL Standard and which have been proposed as variations to maximum residue limits (MRLs) for substances contained in agricultural and veterinary chemical products as set out as in Schedule 20 – Maximum residue limits of the Australia New Zealand Food Standards Code. This notice pertains to proposal No. 2 gazetted on 21 March 2023 (No. APVMA 6).

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

Under subsection 82(1) of the *Food Standards Australia New Zealand Act 1991*, the APVMA has, by legislative instrument, incorporated these variations to MRLs into Schedule 20. A copy of the Amendment Instrument (No. APVMA 3, 2023) accompanies this notice. For a complete and up-to-date version of Schedule 20, including these amendments together with their Explanatory Statement, please refer to the Federal Register of Legislation.

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

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

A Sanitary and Phytosanitary notification to the World Trade Organization (WTO) was also made in relation to the variations to MRLs in Schedule 20 and no comment was received in response to that notice.

A copy of these variations have been given to FSANZ.

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

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

For further information please contact:

MRL Contact Officer Australian Pesticides and Veterinary Medicines Authority GPO Box 3262 Sydney NSW 2001

Phone: +61 2 6770 2300

Email: enquiries@apvma.gov.au

#### **Privacy**

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



# **Australian Government**

# Australian Pesticides and Veterinary Medicines Authority

# Australia New Zealand Food Standards Code — Schedule 20 — Maximum residue limits Variation Instrument No. APVMA 3, 2023

I, Sheila Logan, delegate of the Australian Pesticides and Veterinary Medicines Authority, acting in accordance with my powers under subsection 11(1) of the *Agricultural and Veterinary Chemicals* (*Administration*) *Act 1992*, make this instrument for the purposes of subsection 82(1) of the *Food Standards Australia New Zealand Act 1991*.

Sheila Logan

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

Dated this seventeenth day of July 2023

# Part 1 Preliminary

#### 1 Name of instrument

This instrument is the *Australia New Zealand Food Standards Code* — *Schedule 20 – Maximum residue limits Variation Instrument No. APVMA 3, 2023* (Amendment Instrument).

#### 2 Commencement

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

Note: A copy of the variations made by the Amendment Instrument was published in the Commonwealth of Australia Agricultural and Veterinary Chemicals Gazette.

# 3 Object

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

# 4 Interpretation

In this instrument: —

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

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

# Part 2 Variations to Schedule 20– Maximum Residue Limits

#### 5 Variations to Schedule 20

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

# **Schedule**

# Variations to Schedule 20 - Maximum residue limits

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

[1.1] inserting in alphabetical order

# Agvet chemical: Indaziflam

Permitted residue – commodities of plant origin: Sum of indaziflam and 6-[(1R)-1-fluoroethyl]-1,3,5-triazine-2,4-diamine, expressed as indaziflam

Permitted residue – commodities of animal origin: Indaziflam

Almonds	*0.01
Citrus fruits	*0.01
Edible offal (mammalian)	0.1
Grapes	*0.01
Meat (mammalian) [in the fat]	0.03
Milks	*0.005

#### Agvet chemical: Inpyrfluxam

Permitted residue – commodities of plant origin: Inpyrfluxam

Permitted residue – commodities of animal origin: Sum of inpyrfluxam and 1'-CH2OH-S-2840 (free or conjugated), expressed as inpyrfluxam.

Banana	0.7
Edible offal (mammalian)	*0.02
Eggs	*0.02
Meat (mammalian)	*0.02
Milks	*0.02
Poultry, edible offal of	*0.02
Poultry meat	*0.02
Potato	0.05

Agvet chemical: Ipflufenoquin	
Permitted residue: Ipflufenoquin	
Edible offal (mammalian)	*0.01
Eggs	*0.01
Meat (mammalian) [in the fat]	*0.01
Milks	*0.01
Poultry meat [in the fat]	*0.01
Poultry, edible offal of	*0.01
Strawberry	0.3

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

# Agvet chemical: Fipronil

Permitted residue: Sum of fipronil, the sulphenyl metabolite (5-amino-1-[2,6-dichloro-4-(trifluoromethyl)phenyl]-4-[(trifluoromethyl) sulphenyl]-1H-pyrazole-3-carbonitrile), the sulphonyl metabolite (5-amino-1-[2,6-dichloro-4-(trifluoromethyl)phenyl]-4-[(trifluoromethyl)sulphonyl]-1H-pyrazole-3-carbonitrile), and the trifluoromethyl metabolite (5-amino-4-trifluoromethyl-1-[2,6-dichloro-4-(trifluoromethyl)phenyl]-1H-pyrazole-3-carbonitrile)

Citrus fruits [except kumquats]	T*0.01
Stone fruits [except jujube, Chinese]	0.01

Agvet chemical: Fluopicolide	
Permitted residue: Fluopicolide	
Brassica vegetables (except Brassica leafy vegetables) [except Chinese cabbage (Pe-tsai)]	5
Broccoli, Chinese (Gai lan)	5
Chinese cabbage (Pe-tsai)	30
Leafy vegetables [except broccoli, Chinese (Gai lan); witloof chicory]	30

Agvet chemical: Mandestrobin	
Permitted residue: Mandestrobin	
Stone fruit [except jujube, Chinese]	3

Agvet chemical: Propamocarb	
Permitted residue: Propamocarb (base)	
Brassica vegetables (except Brassica leafy vegetables) [except Chinese cabbage (Pe-tsai)]	30
Broccoli, Chinese (Gai lan)	30
Chinese cabbage (Pe-tsai)	70
Leafy vegetables [except broccoli, Chinese (Gai lan); witloof chicory]	70

# Agvet chemical: Proquinazid

Permitted residue – commodities of plant origin: Proquinazid

Permitted residue – commodities of animal origin: Sum of proquinazid and 3-(6-iodo-4-oxo-3-propyl-3Hquinazolin-2-yloxy)propionic acid, expressed as proquinazid

Pome fruit [except Persimmon,	0.3
Japanese]	

#### Agvet chemical: Sethoxydim

Permitted residue: Sum of sethoxydim and metabolites containing the 5-(2-ethylthiopropyl)cyclohexene-3-one and 5-(2-ethylthiopropyl)-5-hydroxycyclohexene-3-one moieties and their sulfoxides and sulfones, expressed as sethoxydim

expressed as sethoxydim	
Basil	T1
Basil, dry	T5
Coriander (leaves, roots, stems)	*0.1
Coriander, seed	*0.1
Leafy vegetables [except broccoli, Chinese (Gai lan); lettuce, head; lettuce, leaf; witloof chicory]	T0.5
Turmeric, root	1

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

Agvet chemical: Dodine	
Permitted residue: Dodine	
All other foods except animal food commodities	0.1
Walnuts	T0.3

# Agvet chemical: Fipronil

Permitted residue: Sum of fipronil, the sulphenyl metabolite (5-amino-1-[2,6-dichloro-4-(trifluoromethyl)phenyl]-4-[(trifluoromethyl) sulphenyl]-1H-pyrazole-3-carbonitrile), the sulphonyl metabolite (5-amino-1-[2,6-dichloro-4-(trifluoromethyl)phenyl]-4-[(trifluoromethyl)sulphonyl]-1H-pyrazole-3-carbonitrile), and the trifluoromethyl metabolite (5-amino-4-trifluoromethyl-1-[2,6-dichloro-4-(trifluoromethyl)phenyl]-1H-pyrazole-3-carbonitrile)

Carob	T*0.01
Citrus fruit	T*0.01
Stone fruits	0.01

Agvet chemical: Fluopicolide	
Permitted residue: Fluopicolide	
Brassica vegetables (except Brassica leafy vegetables)	5
Cane berries	T1.5
Leafy vegetables	30

Triticale

Agvet chemical: Mandestrobin	
Permitted residue: Mandestrobin	
Fruiting vegetables, cucurbits	0.6
Stone fruit	3
Agvet chemical: Mesotrione	
Permitted residue: Mesotrione	
Oats	*0.01
Triticale	*0.01
Agvet chemical: Metrafenone	
Permitted residue: Metrafenone	
Wheat bran, processed	T0.3
Agvet chemical: Propamocarb	
Permitted residue: Propamocarb (base)	
Brassica vegetables (except Brassica leafy vegetables)	30
Cane berries	T15
Leafy vegetables	70
Agvet chemical: Proquinazid	
Permitted residue – commodities of plant origin: Proquinazid	
Permitted residue – commodities of animal origin: Sum of proquinazid and 3-(6-iodo-4-ox propyl-3H-quinazolin-2-yloxy)propionic acid, expressed as proquinazid	co-3-
Pome fruit	0.3
Wheat	T*0.02
Agvet chemical: Prosulfocarb	
Permitted residue: Prosulfocarb	

\*0.01

# Agvet chemical: Sethoxydim

Permitted residue: Sum of sethoxydim and metabolites containing the 5-(2-ethylthiopropyl)cyclohexene-3-one and 5-(2-ethylthiopropyl)-5-hydroxycyclohexene-3-one moieties and their sulfoxides and sulfones, expressed as sethoxydim

Chives, Chinese	T1
Dried herbs {except Hops, dry}	T5
Fennel, bulb	T1
Garlic chives	T1
Herbs	T1
Leafy vegetables {except Lettuce, head; Lettuce, leaf}	T1
Spices	T5

# Agvet chemical: Tetraniliprole Permitted residue: Tetraniliprole Pineapple T\*0.01

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

T8

Agvet chemical: Fluralaner	
Permitted residue: Fluralaner	
Sheep fat	0.35
Sheep kidney	0.15
Sheep liver	0.4
Sheep muscle	0.1

# Agvet chemical: Pyraclostrobin

Permitted residue - commodities of plant

origin: Pyraclostrobin

Permitted residue – commodities of animal origin: Sum of pyraclostrobin and metabolites hydrolysed to 1-(4-chloro-phenyl)-1H-pyrazol-3-ol, expressed as pyraclostrobin

Celery