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Gazette

Agricultural and veterinary chemicals

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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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Contents

Agricultural chemical products and approved labels	1
Veterinary chemical products and approved labels	9
Approved active constituents	15
New veterinary chemical products containing a new veterinary active constituent	19
Licensing of veterinary chemical manufacturers	28
Agvet chemical voluntary recall: THIMET 200G SYSTEMIC GRANULAR INSECTICIDE (20 kg)	30
Agyet chemical voluntary recall: COUNTER 150G GRANULAR SOIL INSECTICIDE/NEMATICIDE (20 kg)	31

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.	140159
Product name	Spruce Herbicide
Active constituents	250 g/L diflufenican, 200 g/L pyroxasulfone
Applicant name	UPL Australia Pty Ltd
Applicant ACN	066 391 384
Date of registration	7 October 2025
Product registration no.	93681
Label approval no.	93681/140159
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 250 g/L diflufenican and 200 g/L pyroxasulfone suspension concentrate product for control of various weeds in wheat

Application no.	148804
Product name	Inego Xtra Herbicide
Active constituents	50 g/L pinoxaden, 12.5 g/L cloquintocet-mexyl
Applicant name	ADAMA Australia Pty Limited
Applicant ACN	050 328 973
Date of registration	8 October 2025
Product registration no.	96284
Label approval no.	96284/148804
Description of the application and its purpose, including the intended use of the chemical product	Registration of a pinoxaden 50 g/L + cloquintocet-mexyl EC product for the control of key grass weeds and selective spray topping of wild oats in wheat and barley

Application no.	148979
Application no.	14007.0
Product name	Hunters Settling Day Fast Knockdown Insect Spray Household Insecticide
Active constituents	1.0 g/kg esbiothrin, 0.5 g/kg permethrin, 0.2 g/kg imiprothrin
Applicant name	Aaron Laboratories Proprietary Limited
Applicant ACN	004 856 848
Date of registration	9 October 2025
Product registration no.	96334
Label approval no.	96334/148979
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 0.5 g/kg Permethrin, 1.0 g/kg Esbiothrin and 0.2 g/kg Imiprothrin aerosol product for the control of flying and crawling insects

Application no.	148468
Product name	Banishpro
Active constituent	142.5 g/L quaternary ammonium compound
Applicant name	Ferrules and More Pty Ltd
Applicant ACN	641 126 829
Date of registration	10 October 2025
Product registration no.	96183
Label approval no.	96183/148468
Description of the application and its purpose, including the intended use of the chemical product	Registration of the product Banishpro containing 142.5 g/L quaternary ammonium compound (liquid) for the control of algae and black spot in swimming and therapeutic pools and air conditioning waters. The product will control algae and mould growth on surfaces such as tiles, bricks, concrete, fibro, artificial grasses and coatings

Application no.	147803
Product name	Yates Home Pest Ant & Cockroach Super Gel Kills Ants and Cockroaches for up to 6 months
Active constituent	0.56 g/kg indoxacarb (90:10) (equivalent to 0.5 g/kg active s-isomer)
Applicant name	Duluxgroup (Australia) Pty Ltd
Applicant ACN	000 049 427
Date of registration	15 October 2025
Product registration no.	95979
Label approval no.	95979/147803
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 0.56 g/kg INDOXACARB (90:10) (equivalent to 0.5 g/kg active s-isomer) gel product for the control of ants and cockroaches in indoor and outdoor situations

Application no.	143907
Product name	MS Megades Novo Liquid Disinfectant
Active constituents	151 g/L glutaraldehyde, 101 g/L benzalkonium chloride
Applicant name	Stockyard Industries Pty Ltd
Applicant ACN	010 371 141
Date of registration	16 October 2025
Product registration no.	94873
Label approval no.	94873/143907
Description of the application and its purpose, including the intended use of the chemical product	Registration of Registration of a 151 g/L glutaraldehyde and 101 g/L benzalkonium chloride soluble concentrate (SL) disinfectant product for use as a surface disinfectant in animal housing and associated areas

Application no.	147292
Product name	No Mice Difend Prefilled Bait Station
Active constituent	0.05 g/kg difenacoum
Applicant name	Pelgar International (Aus) Pty Ltd
Applicant ACN	159 699 779
Date of registration	17 October 2025
Product registration no.	95823
Label approval no.	95823/147292
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 0.05 g/kg difenacoum ready to use bait product for control of mice in household situations

Table 2: Variations of registration – agricultural chemical products

Application no.	150379
Product name	Repelling Rid Since 1956 Tropical Antiseptic Bite Protection Repels + Protects 8 hrs Insect Repellent
Active constituents	191 g/kg N,N-diethly-m-toluamide, 40 g/kg N-Octyl bicycloheptene dicarboximide, 1 g/kg triclosan
Applicant name	Cavalieri Investing Pty Ltd
Applicant ACN	162 722 625
Date of variation	25 September 2025
Product registration no.	53407
Label approval no.	53407/150379
Description of the application and its purpose, including the intended use of the chemical product	To update the storage and safety directions appearing on a label to reflect the current FAISD handbook

Application no.	150381
Product name	Quantum Bifenthrin 100 EC Insecticide
Active constituent	100 g/L bifenthrin
Applicant name	Quantum Agrosciences Holdings Pty Ltd
Applicant ACN	680 792 625
Date of variation	26 September 2025
Product registration no.	91712
Label approval no.	91712/150381
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 'AgMerch Bifenthrin 100 EC Insecticide' to 'Quantum Bifenthrin 100 EC Insecticide'

Application no.	150384
Product name	Quantum Fluazifop 212 EC Herbicide
Active constituent	212 g/L fluazifop-P present as the butyl ester
Applicant name	Quantum Agrosciences Holdings Pty Ltd
Applicant ACN	680 792 625
Date of variation	26 September 2025
Product registration no.	90331
Label approval no.	90331/150384
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 'AgMerch Fluazifop 212 Selective Herbicide' to 'Quantum Fluazifop 212 EC Herbicide'

Application no.	150380
Product name	Quantum Sulfometuron 750 WG Herbicide
Active constituent	750 g/kg sulfometuron-methyl
Applicant name	Quantum Agrosciences Holdings Pty Ltd
Applicant ACN	680 792 625
Date of variation	26 September 2025
Product registration no.	91875
Label approval no.	91875/150380
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 'AgMerch Sulfometuron 750 WG Herbicide' to 'Quantum Sulfometuron 750 WG Herbicide'

Application no.	150383
Product name	Quantum Imazapyr 750 WG Herbicide
Active constituent	750 g/kg imazapyr
Applicant name	Quantum AgroSciences Holdings Pty Ltd
Applicant ACN	680 792 625
Date of variation	26 September 2025
Product registration no.	84453
Label approval no.	84453/150383
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 'AgMerch Imazapyr 750 WG Herbicide' to 'Quantum Imazapyr 750 WG Herbicide'

Application no.	150382
Product name	Quantum Imazamox 700 WG Herbicide
Active constituent	700 g/kg imazamox
Applicant name	Quantum Agrosciences Holdings Pty Ltd
Applicant ACN	680 792 625
Date of variation	26 September 2025
Product registration no.	91613
Label approval no.	91613/150382
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 'AgMerch Imazamox 700 WG Herbicide' to 'Quantum Imazamox 700 WG Herbicide'

Application no.	150463
Product name	Teburon 200 Herbicide
Active constituent	200 g/kg tebuthiuron
Applicant name	Shandong Rainbow International Co Ltd
Applicant ACN	N/A
Date of variation	2 October 2025
Product registration no.	68456
Label approval no.	68456/150463
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 'OZCROP TEBUTHIURON 200 HERBICIDE' to 'TEBURON 200 HERBICIDE'

Application no.	148849
Product name	Duomax HC520 Plant Growth Regulator
Active constituent	520 g/L cyanamide
Applicant name	Eurochem Pty. Ltd.
Applicant ACN	622 603 507
Date of variation	7 October 2025
Product registration no.	58843
Label approval no.	58843/148849
Description of the application and its purpose, including the intended use of the chemical product	Variation to registration and label particulars to add additional crops and use situations for almonds, plums and prunes, and walnuts

Application no.	140427
Product name	MIRAVIS PRIME Adepidyn Technology Fungicide
Active constituents	250 g/L fludioxonil, 150 g/L pydiflumetofen
Applicant name	Syngenta Australia Pty Ltd
Applicant ACN	002 933 717
Date of variation	7 October 2025
Product registration no.	88887
Label approval no.	88887/140427
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 uses in grey mould in cherries

Application no.	148878
Product name	Oxydul WG Fungicid
Active constituent	500 g/kg copper (Cu) present as copper oxychloride
Applicant name	Grochem Australia Pty Ltd
Applicant ACN	169 400 033
Date of variation	8 October 2025
Product registration no.	51820
Label approval no.	51820/148878
Description of the application and its purpose, including the intended use of the chemical product	Variation of registration and label particulars to change the product name and update minor aspects of the label in line with the current Agriculture Labelling Code

Application no.	148816
Product name	Bollgard 3
Active constituent	Bacillus thuringiensis subsp. kurstaki delta endotoxins as produced by the Cry1Ac and Cry2Ab genes and their controlling sequences. Bacillus thuringiensis strain AB88 exotoxin as produced by the vip3A(a) gene and its controlling sequence.
Applicant name	Monsanto Australia Pty Ltd
Applicant ACN	006 725 560
Date of variation	8 October 2025
Product registration no.	69656
Label approval no.	69656/14881
Description of the application and its purpose, including the intended use of the chemical product	Variation to product registration to amend the Bollgard 3 Southern Resistance Management Plan (Southern RMP) associated with the Conditions of Registration

Application no.	140770
Product name	Infinity Ultra Herbicide
Active constituents	250 g/L pyrasulfotole, 125 g/L diflufenican
Applicant name	Bayer Cropscience Pty Ltd
Applicant ACN	000 226 022
Date of variation	10 October 2025
Product registration no.	91984
Label approval no.	91984/140770
Description of the application and its purpose, including the intended use of the chemical product	Variation of product registration and label particulars to add a higher rate, tank mixes and weeds controlled

Application no.	140770
Product name	Infinity Ultra Herbicide
Active constituents	250 g/L pyrasulfotole, 125 g/L diflufenican
Applicant name	Bayer CropScience
Applicant ACN	000 226 022
Date of variation	13 October 2025
Product registration no.	91984
Label approval no.	91984/140770
Description of the application and its purpose, including the intended use of the chemical product	Variation of Registration and label particulars to correct buffer zones for tank mixes with glyphosate

Application no.	148076
Product name	Titan Flumioxazin 500 WG Herbicide
Active constituent	500 g/kg flumioxazin
Applicant name	Titan Ag Pty Ltd
Applicant ACN	122 081 574
Date of variation	17 October 2025
Product registration no.	87182
Label approval no.	87182/148076
Description of the application and its purpose, including the intended use of the chemical product	Variation to registration particulars, and particulars of label, to include the residual control of weeds in various orchard crops and vineyards

Table 3: Label approval – agricultural chemical products

Application no.	149233
Product name	Enviromax Indoxaguard 200SC Insecticide
Active constituent	222 g/L indoxacarb (S:R 9:1)
Applicant name	Enviromax Technologies Pty Ltd
Applicant ACN	132 643 577
Date of variation	8 October 2025
Product registration no.	94130
Label approval no.	94130/149233
Description of the application and its purpose, including the intended use of the chemical product	Registration of a new label for the existing product 'Enviromax IndoxaGuard 200SC Insecticide' with the label name 'Strikezone 200SC Insecticide'

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 new active constituents

Application no.	141506
Product name	Zenrelia 15 mg Tablets for Dogs
Active constituent	Each tablet contains 15 mg ilunocitinib
Applicant name	Elanco Australasia Pty Ltd
Applicant ACN	076 745 198
Date of registration	13 October 2025
Product registration no.	94087
Label approval no.	94087/141506
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 15 mg ilunocitinib oral tablet product for the reduction of pruritus associated with allergic dermatitis and reduction of clinical signs of atopic dermatitis in dogs, in conjunction with the approval of a new active ilunocitinib

Application no.	141510
Product name	Zenrelia 8.5 mg Tablets for Dogs
Active constituent	Each tablet contains 8.5 mg ilunocitinib
Applicant name	Elanco Australasia Pty Ltd
Applicant ACN	076 745 198
Date of registration	13 October 2025
Product registration no.	94088
Label approval no.	94088/141510
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 8.5 mg ilunocitinib oral tablet product for the reduction of pruritus associated with allergic dermatitis and reduction of clinical signs of atopic dermatitis in dogs, in conjunction with the approval of a new active ilunocitinib

Application no.	141511
Product name	Zenrelia 6.4 mg Tablets for Dogs
Active constituent	Each tablet contains 6.4 mg ilunocitinib
Applicant name	Elanco Australasia Pty Ltd
Applicant ACN	076 745 198
Date of registration	13 October 2025
Product registration no.	94089
Label approval no.	94089/141511
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 6.4 mg ilunocitinib oral tablet product for the reduction of pruritus associated with allergic dermatitis and reduction of clinical signs of atopic dermatitis in dogs, in conjunction with the approval of a new active ilunocitinib

Application no.	141512
Product name	Zenrelia 4.8 mg Tablets for Dogs
Active constituent	Each tablet contains 4.8 mg ilunocitinib
Applicant name	Elanco Australasia Pty Ltd
Applicant ACN	076 745 198
Date of registration	13 October 2025
Product registration no.	94090
Label approval no.	94090/141512
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 4.8 mg ilunocitinib oral tablet product for the reduction of pruritus associated with allergic dermatitis and reduction of clinical signs of atopic dermatitis in dogs, in conjunction with the approval of a new active ilunocitinib

Table 5: Veterinary products based on existing active constituents

Application no.	147110
Product name	Abbey Flunixx Paste
Active constituent	50 mg/g flunixin (equivalent to 83 mg/g flunixin meglumine)
Applicant name	Abbey Laboratories Pty Ltd
Applicant ACN	156 000 430
Date of registration	13 October 2025
Product registration no.	95770
Label approval no.	95770/147110
Description of the application and its purpose, including the intended use of the chemical product	Registration of Abbey Flunixx Paste containing Flunixin 50 mg/g for the alleviation of inflammation and pain associated with musculoskeletal disorders in horses

Application no.	146784
Product name	Farmers' Own Moxidectin Long Acting Injection for Sheep
Active constituent	20 g/L moxidectin
Applicant name	Arrovet Pty Ltd
Applicant ACN	674 072 532
Date of registration	15 October 2025
Product registration no.	95673
Label approval no.	95673/146784
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 20 g/L moxidectin injectable product for the treatment and control of roundworms, nasal bot and itch mite in sheep and for the protection against severe challenge by barber's pole worm for up to 4 months

Application no.	145911
Product name	Owtbac Moxidone Long Acting Injection for Sheep
Active constituent	20 g/L moxidectin
Applicant name	Owtbac Australia Pty Ltd
Applicant ACN	679 042 098
Date of registration	20 October 2025
Product registration no.	95510
Label approval no.	95510/145911
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 20g/L Moxidectin solution for Injection for the treatment and control of roundworms, nasal bot and itch mite in sheep and for protection against severe challenge by Haemonchus contortus (Barber's Pole Worm) for up to 4 months

Application no.	148109
Product name	Doravet Pour-On Endectocide
Active constituent	5 mg/mL doramectin
Applicant name	Vetpharm Pty Limited
Applicant ACN	626 894 086
Date of registration	20 October 2025
Product registration no.	96080
Label approval no.	96080/148109
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 5 mg/mL doramectin injectable product for the treatment and control of doramectin sensitive internal and external parasites of cattle

Table 6: Variations of registration – veterinary chemical products

Application no.	150399
Product name	ExiFlea Plus 3-in-1 Defence for Cats over 4 kg
Active constituents	100 g/L imidacloprid, 10 g/L moxidectin
Applicant name	Abbey Laboratories Pty Ltd
Applicant ACN	156 000 430
Date of variation	29 September 2025
Product registration no.	86381
Label approval no.	86381/150399
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 'ExiFlea Plus 3-in-1 Defence Against Fleas, Worms & Heartworm for Cats over 4 kg' to 'ExiFlea Plus 3-in-1 Defence for Cats over 4 kg'

Application no.	150405
Product name	ExiFlea Plus 3-in-1 Defence for Dogs 4-10 kg
Active constituents	100 g/L imidacloprid, 25 g/L moxidectin
Applicant name	Abbey Laboratories Pty Ltd
Applicant ACN	156 000 430
Date of variation	29 September 2025
Product registration no.	86383
Label approval no.	86383/150405
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 'ExiFlea Plus 3-in-1 Defence Against Fleas, Worms & Heartworm for Dogs 4-10 kg' to 'ExiFlea Plus 3-in-1 Defence for Dogs 4-10 kg'

Application no.	150406
Product name	ExiFlea Plus 3-in-1 Defence for Kittens and Small Cats up to 4 kg
Active constituents	100 g/L imidacloprid, 10 g/L moxidectin
Applicant name	Abbey Laboratories Pty Ltd
Applicant ACN	156 000 430
Date of variation	29 September 2025
Product registration no.	86378
Label approval no.	86378/150406
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 'ExiFlea Plus 3-in-1 Defence Against Fleas, Worms & Heartworm for Kittens and Small Cats up to 4 kg' to 'ExiFlea Plus 3-in-1 Defence for Kittens and Small Cats up to 4 kg'

Application no.	150407
7 Application from	100.107
Product name	ExiFlea Plus 3-in-1 Defence for Dogs over 25 kg
Active constituents	100 g/L imidacloprid, 25 g/L moxidectin
Applicant name	Abbey Laboratories Pty Ltd
Applicant ACN	156 000 430
Date of variation	29 September 2025
Product registration no.	86385
Label approval no.	86385/150407
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 'ExiFlea Plus 3-in-1 Defence Against Fleas, Worms & Heartworm for Dogs over 25 kg' to 'ExiFlea Plus 3-in-1 Defence for Dogs over 25 kg'

Application no.	150408
Product name	ExiFlea Plus 3-in-1 Defence for Dogs 10-25 kg
Active constituents	100 g/L imidacloprid, 25 g/L moxidectin
Applicant name	Abbey Laboratories Pty Ltd
Applicant ACN	156 000 430
Date of variation	29 September 2025
Product registration no.	86384
Label approval no.	86384/150408
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 'ExiFlea Plus 3-in-1 Defence Against Fleas, Worms & Heartworm for Dogs 10-25 kg' to 'ExiFlea Plus 3-in-1 Defence for Dogs 10-25 kg'

Application no.	150409
Product name	ExiFlea Plus 3-in-1 Defence for Puppies and Small Dogs up to 4 kg
Active constituents	100 g/L imidacloprid, 25 g/L moxidectin
Applicant name	Abbey Laboratories Pty Ltd
Applicant ACN	156 000 430
Date of variation	29 September 2025
Product registration no.	86382
Label approval no.	86382/150409
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 'ExiFlea Plus 3-in-1 Defence Against Fleas, Worms & Heartworm for Puppies and Small Dogs up to 4 kg' to 'ExiFlea Plus 3-in-1 Defence for Puppies and Small Dogs up to 4 kg'

Application no.	149063
Product name	Abantel Broad Spectrum Wormer for Dogs
Active constituents	Each tablet contains 545 mg oxantel embonate, 140 mg pyrantel embonate, 50 mg praziquantel
Applicant name	Abbey Laboratories Pty Ltd
Applicant ACN	156 000 430
Date of variation	7 October 2025
Product registration no.	69893
Label approval no.	69893/149063
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 label according to the current Veterinary Labelling Code and adding Signal Heading 'Caution'

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 7: Approved active constituents

Application no.	148902
Active constituent	Clindamycin hydrochloride
Applicant name	Jiyu Biopharm Co., Ltd.
Applicant ACN	N/A
Date of approval	7 October 2025
Approval no.	96312
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent clindamycin hydrochloride for use in veterinary chemical products

Application no.	145682
Active constituent	Metoclopramide hydrochloride
Applicant name	Invetro Pty Ltd
Applicant ACN	654 837 733
Date of approval	8 October 2025
Approval no.	95436
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent metoclopramide hydrochloride for use in veterinary chemical products

Application no.	147316
Active constituent	Ipconazole
Applicant name	UPL Australia Pty Ltd
Applicant ACN	066 391 384
Date of approval	8 October 2025
Approval no.	95833
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent ipconazole for use in agricultural chemical products

Application no.	149280
Active constituent	Eprinomectin
Applicant name	Bimeda (Australia) Pty. Limited
Applicant ACN	058 196 508
Date of approval	8 October 2025
Approval no.	96434
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent eprinomectin for use in veterinary chemical products

Application no.	147134
Active constituent	Pinoxaden
Applicant name	Jiangsu Flag Chemical Industry Co Ltd
Applicant ACN	N/A
Date of approval	9 October 2025
Approval no.	95774
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent pinoxaden for use in agricultural chemical products

Application no.	147390
Active constituent	Cyantraniliprole
Applicant name	UPL Australia Pty Ltd
Applicant ACN	066 391 384
Date of approval	9 October 2025
Approval no.	95860
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent cyantraniliprole for use in agricultural chemical products

Application no.	147673
Active constituent	Florasulam
Applicant name	Kingtai Chemicals Co., Limited
Applicant ACN	N/A
Date of approval	9 October 2025
Approval no.	95949
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent florasulam for use in agricultural chemical products

Application no.	146528
Active constituent	Fluralaner
Applicant name	Agro-Alliance (Australia) Pty Ltd
Applicant ACN	130 864 603
Date of approval	10 October 2025
Approval no.	95618
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent fluralaner for use in veterinary chemical products

Application no.	147369
Active constituent	Maropitant citrate
Applicant name	Ashish Life Science Pvt. Ltd.
Applicant ACN	N/A
Date of approval	10 October 2025
Approval no.	95855
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent maropitant citrate for use in veterinary chemical products

Application no.	147625
Active constituent	Coumatetralyl
Applicant name	Helidon Tech. Pty. Ltd.
Applicant ACN	002 643 816
Date of approval	10 October 2025
Approval no.	95919
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent coumatetralyl for use in agricultural chemical products

Application no.	141505
Active constituent	Ilunocitinib
Applicant name	Elanco Australasia Pty Ltd
Applicant ACN	076 745 198
Date of approval	13 October 2025
Approval no.	94086
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent ilunocitinib for use in veterinary chemical products

Application no.	147583			
Active constituent	МСРВ			
Applicant name	Shanghai Hanfu Biotechnology Co., Ltd			
Applicant ACN	N/A			
Date of approval	20 October 2025			
Approval no.	95911			
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent MCPB for use in agricultural chemical products			

Table 8: Variations of active constituent

Application no.	148923				
Active constituent	Praziquantel				
Applicant name	Boehringer Ingelheim Animal Health Australia Pty. Ltd.				
Applicant ACN	071 187 285				
Date of variation	8 October 2025				
Approval no.	81873				
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.	149064
Active constituent	Methocarbamol
Applicant name	Troy Laboratories Pty Ltd
Applicant ACN	000 283 769
Date of variation	20 October 2025
Approval no.	88337
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 veterinary chemical products containing a new veterinary active constituent

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application for the approval of a new active constituent, **capromorelin tartrate**, and an application for the registration of a new product containing the new active constituent, **Eluracat Flavoured Oral Solution for Cats**, for body weight gain in cats experiencing poor appetite or unintended weight loss resulting from chronic medical conditions including kidney disease.

Active constituent particulars

As part of the application to register **Eluracat Flavoured Oral Solution for Cats**, containing **capromorelin tartrate**, the APVMA has evaluated the safety of the new active constituent, capromorelin tartrate.

Table 9: Particulars of the active constituent capromorelin tartrate

Common name	Capromorelin tartrate				
IUPAC name	N-[(2 R)-1-[(3 aR)-3 a -benzyl-2-methyl-3-oxo-6,7-dihydro-4 H -pyrazolo[4,3-c]pyridin-5-yl]-1-oxo-3-phenylmethoxypropan-2-yl]-2-amino-2-methylpropanamide; (2 R ,3 R)-2,3-dihydroxybutanedioic acid				
CAS name	N-{(1R)-2-[(3aR)-2-methyl-3-oxo-3a-benzyl(2H- 4,5,6,7,3a-Pentahydro-5-azaindazol-5-yl)]-2-oxo-1-[(phenylmethoxy)methyl]ethyl}-2-amino-2-methylpropanamide, L-tartaric acid salt.				
CAS registry number	193273-66-4 (capromorelin free base) 193273-69-7 (capromorelin tartrate salt)				
Manufacturer's codes	2049500; AT-002; ATA002-11; FP-197; CP-424; 391-0018; RQ-5				
Minimum purity	97-103% (as is)				
Molecular formula	$C_{28}H_{35}N_5O_4$ $C_4H_6O_6$				
Molecular weight	655.70 gmol ⁻¹				
Structure	OH OH OH OH				
Chemical family	Capromorelin is a selective ghrelin receptor agonist.				
Mode of action	Capromorelin tartrate belongs to the growth hormone (GH)-releasing peptide class of GH-releasing agents and acts as a selective ghrelin receptor agonist (GRA) in the hypothalamic neurons in the arcuate nucleus. Capromorelin also binds to the growth hormone secretagogue receptor in the pituitary gland to increase growth hormone secretion. Capromorelin tartrate stimulates food-seeking behaviours in cats.				

Summary of the APVMA's evaluation of capromorelin tartrate active constituent

- 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:
 - a. The APVMA has evaluated the chemistry aspects of capromorelin tartrate (identification, physicochemical properties, stability, manufacturing process, quality control procedures, batch analysis results and analytical methods) and found them to be acceptable. Capromorelin tartrate is manufactured to the standard of the manufacturer's specifications.
 - b. The APVMA is satisfied that the toxicological and human health aspects of capromorelin tartrate active constituent are acceptable:
 - i. No ADI or ARfD was established, as capromorelin tartrate is not currently proposed for use in food producing animals.
 - ii. Impurities of toxicological significance are not expected to occur in capromorelin tartrate because of the raw materials and the synthetic route used.
 - iii. Based on its toxicity profile and intended use pattern, capromorelin tartrate is listed in Schedule 4 in the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP).
 - iv. The health and toxicology assessment has indicated that there are no objections on toxicological grounds to the approval of the active constituent, capromorelin tartrate.
 - c. The APVMA is satisfied that the proposed importation and use of capromorelin tartrate would not be an undue toxicological hazard to the safety of people exposed to it during its handling and use, nor would it be likely to have an unintended effect that is harmful to human beings, animals, plants or things or to the environment.

Eluracat Flavoured Oral Solution for Cats containing capromorelin tartrate

In addition to the application to approve the new active constituent capromorelin tartrate, the APVMA has under consideration an application to register a new product containing capromorelin tartrate, Eluracat Flavoured Oral Solution for Cats.

Table 10: Particulars of the product

Proposed product name	Eluracat Flavoured Oral Solution for Cats	
Applicant company	ELANCO AUSTRALASIA PTY LTD	
Name of active constituent	Capromorelin tartrate	
Signal heading	Schedule 4	
Summary of proposed use	Eluracat Flavoured Oral Solution for Cats contains capromorelin tartrate, a selective ghrelin receptor agonist. Capromorelin binds to ghrelin receptors in the hypothalamus to stimulate appetite and in the pituitary to stimulate secretion of growth hormone (GH). Increased GH stimulates release of insulin like growth factor 1 (IGF-1) from the liver, which in turn stimulates weight gain. Eluracat Flavoured Oral Solution for Cats is for body weight gain in cats experiencing poor appetite or unintended weight loss resulting from chronic medical conditions including kidney disease.	
Dose rate	The recommended dose is 2 mg/kg which is equivalent to 0.1 mL/kg body weight and the product is to be administered once daily directly into the mouth.	
Pack sizes	10 mL, 15 mL	
Withholding period	N/A	

A summary of the APVMA's evaluation of **Eluracat Flavoured Oral Solution for Cats**, 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 Eluracat Flavoured Oral Solution for Cats, would not be an undue hazard to the safety of people exposed to it during its handling and use.
 - a. Eluracat is intended for professional (veterinary prescription only) use.
 - b. The applicant submitted an adequate data package in support of the approval of capromorelin tartrate.
 - c. The applicant did not submit an acute toxicity data package for the formulation; therefore, the acute toxicity of the formulated product was estimated based on the hazard profile of each constituent to establish appropriate safety directions for Eluracat. The product is expected to have low acute oral, dermal and inhalation toxicity, it is likely to be neither a skin irritant nor sensitiser but is likely to be a slight eye irritant.
 - d. Capromorelin tartrate is currently included in Schedule 4 of the Poisons Standard (Health, 2025). This is considered appropriate for the proposed use of this veterinary medicine. None of the excipients in the product are listed or require listing in the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP). As *Eluracat Flavoured Oral Solution for Cats* contain a Schedule 4 substance, it will require the signal heading 'PRESCRIPTION ANIMAL REMEDY'. The applicant should consider the use of child-resistant packaging if this product will be prescribed for home use due to the risks associated with accidental ingestion by small children.
 - e. To mitigate potential risks to human health, the following signal headings, first aid instructions, safety directions, and restraint statements are to appear on the product label:

Signal Heading

PRESCRIPTION ANIMAL REMEDY

KEEP OUT OF REACH OF CHILDREN

FOR ANIMAL TREATMENT ONLY

READ SAFETY DIRECTIONS BEFORE OPENING OR USING

First aid instructions

If poisoning occurs, contact a doctor or Poisons Information Centre. Phone Australia 13 11 26.

Safety directions

May irritate the eyes. Avoid contact with eyes. If product in eyes, wash it out immediately with water. Wash hands after use.

Additional User Safety

In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.

- f. After consideration of the toxicological profile and likely human exposure associated with the use of Eluracat Flavoured Oral Solution for Cats, the APVMA concludes that the human health risks are acceptable and the safety criteria of section 5A of the Agvet Code are met when used in accordance with the directions for use and adhering to the recommended safety directions.
- ii. The APVMA is satisfied that the proposed use of Eluracat Flavoured Oral Solution for Cats will not be an undue hazard to the safety of people using anything containing its residues.
 - a. The product is for use in companion animals (cats) only. Eluracat Flavoured Oral Solution for Cats is, therefore, unlikely to enter the food chain.
- iii. The APVMA is satisfied that the proposed use of Eluracat Flavoured Oral Solution for Cats containing the active constituent capromorelin tartrate is not likely to have an unintended effect that is harmful to animals (cats), plants or the environment if used according to the product label directions.
 - a. Environmental risks of Eluracat Flavoured Oral Solution for Cats (containing capromorelin tartrate) were assessed according to the VICH Phase I decision tree. The assessment determined that the amount of capromorelin tartrate introduced to the environment is expected to be negligible based on its uses in non-food animals (cats). Therefore, the assessment stopped in VICH phase I and no further assessment was required.
 - b. The following mitigation/labelling statement is recommended, based on the outcome of the risk assessment and current label standards:

Disposal

Dispose of container by wrapping with paper and putting in garbage.

iv. The APVMA is satisfied that the proposed use of Eluracat Flavoured Oral Solution for Cats containing the active constituent capromorelin tartrate would not be likely to have an unintended effect that is harmful to animals (cats) if used according to the product label directions.

There was substantial support for the safety of capromorelin in the cat, as in other species, with a pivotal **Target Animal Safety** study at dose rates of 1X, 3X and 5X the recommended dose rate (2 mg/kg) showing that the active was well tolerated by cats over 180 days. There were several additional studies with dose rates up to 30X the recommended dose rate for 14 days or 3X the recommended dose rate for 91 days that supported the safety of capromorelin in cats over prolonged exposure. Capromorelin was also shown to be safe to administer to animals suffering from cancer, despite high expression of ghrelin in neoplastic tissue.

The APVMA has therefore, concluded that the administration of *Eluracat Flavoured Oral Solution for Cats* is generally well tolerated and appropriate statements have been included on the label to mitigate the risks identified:

Contraindications

- This product should not be used in cats with known hypersensitivity to capromorelin.
- Do not use in patients with severe haemodynamic instability such as hypovolaemic shock.

Precautions

- Use with caution in cats younger than 5 months of age, pregnant, lactating or intended for breeding as the safety of Eluracat has not been established in these groups.
- Use with caution in cats that may have cardiac disease, hypotension, or severe dehydration, as the
 product caused transient decreases in heart rate and blood pressure up to 4 hours following dose
 administration to healthy cats. In a safety study, these cardiovascular effects were reversed when cats
 were handled by study personnel.
- The product may cause a transient increase in serum glucose for several hours after dosing. Use in cats with current or historical diabetes mellitus has not been evaluated.
- Use with caution in cats with hypersomatotropism (acromegaly). Capromorelin increased serum growth
 hormone concentrations in healthy cats at a dosage of 6 mg/kg. The effect was highest after the first
 dose and was attenuated on subsequent days.
- Use with caution in cats with hepatic dysfunction as capromorelin is metabolised in the liver.
- Use with caution in cats less than 6 years old or with less than 2 kg body weight as the efficacy has not been evaluated in these animals.
- Use with caution if used for more than 90 days as the efficacy of the veterinary medicinal product has not been established beyond this period. Therefore, the product should only be used for a period of greater than 90 days following a benefit-risk assessment by the responsible veterinary surgeon.

Side Effects

In field studies of cats with weight loss associated with chronic kidney disease and other medical
conditions, adverse events were reported commonly in both capromorelin and placebo-treated cats. In
capromorelin-treated cats hypersalivation is common but is generally transient at the time of dosing,
resolves within a few minutes of dosing and has no adverse systemic effects.

- Vomiting, anaemia, lethargy, dehydration and diarrhoea were reported in cats in both treated and
 placebo groups. Mild skin lesions on the mouth and chin were reported commonly and were attributed
 to the formulation sticking to fur. These skin lesions resolved uneventfully.
- 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.

The summary of the efficacy studies/assessment results have been provided below:

a. Pharmacology

Capromorelin is a selective ghrelin receptor agonist. Capromorelin binds to ghrelin receptors in the hypothalamus to stimulate appetite and in the pituitary to stimulate secretion of growth hormone (GH). Increased GH stimulates release of insulin like growth factor 1 (IGF-1) from the liver, which in turn stimulates weight gain.

The clinical effects of capromorelin in cats are a combination of increased food intake and metabolic changes resulting in weight gain.

b. Pharmacokinetics

Binding of capromorelin to cat plasma proteins was moderate (61%) over the assessed concentration range of 1 ng/ml to 100 ng/ml.

After oral administration, capromorelin was rapidly absorbed in cats with a T_{max} of 0.35 hours (without food). The mean half-life of capromorelin in serum following intravenous and oral administration is 0.9 and 1.1 hours. Mean systemic clearance is 31.1 ml/min/kg body weight and mean apparent volume of distribution is 1.6 L/kg body weight. The short half-life can be attributed to the medium systemic clearance coupled with a medium volume of distribution.

Administration of capromorelin with the entire daily ration compared to fasted cats led to increases in T_{max} (1.25 versus 0.35 hours) and decreases in C_{max} (28 versus 59 ng/ml) and $AUC_{(0-last)}$ (51 versus 83 ng. hour/ml). However, serum IGF-1 concentrations were increased by a similar amount when capromorelin was administered with or without food.

Serum concentrations of capromorelin increased proportionally with increasing dose over the range 1 - 4 mg/kg body weight as evidenced by an increase in mean C_{max} and AUC and did not accumulate with repeated dosing over 10 days.

c. Dose finding

To determine the appropriate dose, 32 healthy cats (not suffering from inappetence) were randomly assigned as 4 males and 4 females to one of 4 groups. Group 1 was the control (placebo) and groups 2-4 were administered capromorelin at 1, 2 and 3 mg/kg daily PO, respectively, for 21 days. The cats were monitored for food consumption (daily), Body Weight (BW) changes and serum levels of IGF-1 (the latter on days 1, 14 and 21, at 0 and 8 hr post-treatment). The mean increase in BW for combined males and females was -1.00% for placebo, 4.48% for 1 mg/kg, 5.69% for 2 mg/kg and 2.56% for 3 mg/kg. This was predominantly due to increases in female cat's weight (and was significantly high than placebo for all treatment groups), with no change in male's BW in the 3 mg/kg group. Food consumption was also increased with treatment, the % increase in the placebo group (9.37%) was significantly less than 1 mg/kg (21.58%), 2 mg/kg (41.13%; P= 0.0019) and 3 mg/kg (28.03%). IGF-1 was unchanged in the placebo group but increased (0 hr compared to 8 hr) in all 3 treatment groups and for each collection point. This increase was sustained increased, compared to

pre-treatment. This was therefore, the first study to demonstrate that **2 mg/kg was the appropriate dose** for capromorelin in terms of BW gain and food consumption with the effects being most prominent in female cats.

d. Field Study

A pivotal clinical field study was done to evaluate the safety and effectiveness of capromorelin on weight management in cats with chronic kidney disease. This multicentre (n=23), placebo-controlled, randomized and masked field study screened 254 cases and enrolled 176 cats, which were randomly assigned to a treatment (n=118) or control (n=58) group. The treatment (2 mg/kg capromorelin) or placebo was administered daily PO for 56 days. There were no restrictions on age, gender, breed or weight. The exclusions were cats who were pregnant, lactating, participating in other clinical trials, crisis or moribund state; food intake contraindicated, dental disease severe enough to impair food intake documented and uncontrolled hyperthyroidism; documented and uncontrolled inflammatory bowel disease; documented congestive heart failure; documented cancer; documented diabetes. In healthy cats, capromorelin increased food consumption, body weight and serum IGF-1 concentrations. In cats with chronic kidney disease and ≥5% unintended body weight loss, capromorelin increased body weight in the per protocol population by 6.8% compared to an untreated control group after 56 days of treatment (body weight loss of 1.7% in the control group and body weight gain of 5.1% in the capromorelin group). The results of this study confirmed that capromorelin administered at a dose of 2 mg/kg once orally for 56 days was safe and effective in cats with CKD, improving weight loss.

ii. The APVMA has therefore, concluded that Eluracat Flavoured Oral Solution for Cats, would be effective for body weight gain in cats experiencing poor appetite or unintended weight loss resulting from chronic medical conditions including kidney disease. Relevant statements to mitigate the risks identified will be included on the product label:

Claims

- For body weight gain in cats experiencing poor appetite or unintended weight loss resulting from chronic medical conditions including kidney disease.
- This veterinary medicinal product does not treat the underlying chronic medical conditions but is intended to provide supportive therapy.

Dosage and Administration

- · Oral use only.
- Once broached use within 3 months of opening.
- The recommended dose is 2 mg/kg which is equivalent to 0.1 mL/kg body weight.
- The product is to be administered once daily directly into the mouth.
- The solution should be given using the measuring syringe provided in the package. The syringe has a kg-body weight scale.
- To administer ELURACAT:
 - Remove the cap, insert the dosing syringe, invert the bottle, withdraw the appropriate amount of solution.
 - Return the bottle to the upright position, remove syringe, replace the cap.
 - Administer the solution into the cat's mouth.
 - Rinse the syringe and plunger with water and leave apart to dry.

- Eluracat can be given with or without food and there is no need to alter the cat's normal feeding routine. If the cat vomits within 15 minutes or only receives a partial dose, then the dose may be re-administered.
- Duration of treatment will depend on the response observed to treatment. Chronic administration of the
 veterinary medicinal product is likely needed as chronic medical conditions tend to be progressive in nature
 and weight loss is expected to continue if not treated.

General Directions

DESCRIPTION: ELURACAT (capromorelin flavoured oral solution) is a vanilla flavoured colourless to yellow or orange, clear liquid.

Interactions with other medicinal products and other forms of interaction: None known.

Incompatibilities: None known.

INFORMATION FOR CAT OWNERS: Eluracat mimics the action of the naturally occurring hormone ghrelin which affects many systems in the body. Eluracat may affect these systems. Owners should monitor for changes in: thirst or water intake; lethargy or weakness; digestive issues (vomiting, diarrhoea, drooling, decreased appetite); and behaviour. If any of these or other symptoms are seen, please discuss with your veterinarian.

CLINICAL PHARMACOLOGY: Capromorelin is a selective ghrelin receptor agonist. Capromorelin binds to ghrelin receptors in the hypothalamus to stimulate appetite and in the pituitary to stimulate secretion of growth hormone (GH). Increased GH stimulates release of insulin like growth factor 1 (IGF-1) from the liver, which in turn stimulates weight gain. The clinical effects of capromorelin in cats are a combination of increased food intake and metabolic changes resulting in weight gain.

In healthy cats, capromorelin increased food consumption, body weight and serum IGF-1 concentrations. In cats with chronic kidney disease and unintended body weight loss, capromorelin increased bodyweight by 6.8% compared to an untreated control group after 55 days of treatment.

Capromorelin was rapidly absorbed following oral administration of Eluracat to cats fasted for 8 hours. The C_{max} (maximum serum concentration) and AUC_{last} (area under the curve from the time of dosing to the last quantifiable serum concentration) for capromorelin were 55% and 43% lower, respectively, when administered to cats in the fed state, as compared to the fasted state.

- 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 satisfied that the proposed use of Eluracat Flavoured Oral Solution for Cats, would not adversely affect trade between Australia and places outside Australia. The product is for use in cats, which are not food producing animals, and which do not produce any major Australian export commodities.
 - ii. Therefore, there are no concerns from a trade perspective relating to the registration of this product.

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 **capromorelin tartrate** should be approved. Submissions should relate only to matters that are considered in determining whether the safety criteria set out in section 5A of the Agvet Code have been met. Submissions should state the grounds on which they are based.

In accordance with section 13 of the Agvet Code, the APVMA invites any person to submit a relevant written submission as to whether **Eluracat Flavoured Oral Solution for Cats** 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
Australian Pesticides and Veterinary Medicines Authority
GPO Box 574
Canberra ACT 2601

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 licenses

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

Table 11: New licenses 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
Comvita Australia Pty Ltd	4118	088 909 648	767 Bischoffs Road Coominya QLD 4311	Category 4: Supplements (liquid)	Quality assurance (QA) of raw materials, formulation including blending, microbiological reduction treatment (heat), filling, packaging, labelling, storage, and release for supply.	29 September 2025
C M Laboratories Pty Ltd	2150	098 897 637	Units 1-4, 36 Curtis Road Mulgrave NSW 2756	Category 2: Creams, lotions, ointments, gels, pastes, powders, sprays, liquids and suspensions Category 3: Liquids, sprays and powders Category 4: Premixes and supplements	Quality assurance (QA) of raw materials, formulation including blending, wet milling, filling, packaging, labelling, relabelling, analysis and testing (physical), storage and release for supply.	13 October 2025
Australian Pharmavet Contract Manufacturing Pty Ltd	2240	607 905 733	92 Antimony Street Carole Park QLD 4300	Category 2: Creams / lotions, ointment, pastes, powders, granular, sprays, liquids, suspensions, gels Category 3: Liquids, sprays, powders Category 4: Premix (powders) and supplements (powders)	Quality Assurance (QA) of raw materials, formulation including blending, dry milling, wet milling, granulation, filling, microbiological reduction treatment (heat), secondary packaging, secondary labelling, analysis and testing (physical), storage, release for supply.	14 October 2025

Licence cancellations

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

Table 12: Licenses cancelled by the APVMA under subsection 127(1) of the Agvet Code

Company name	Licence number	Company ACN	Address	Date cancelled
Teradoran Pty Ltd	2236	081 432 411	2 Blackmore Road Smeaton Grange NSW 2567	1 October 2025
Blackmores Limited	6186	009 713 437	20 Jubilee Avenue Warriewood NSW 2102	14 October 2025

APVMA contact

Manufacturing Quality and Licensing Australian Pesticides and Veterinary Medicines Authority GPO Box 574 Canberra ACT 2601

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

Agvet chemical voluntary recall: THIMET 200G SYSTEMIC GRANULAR INSECTICIDE (20 kg)

Product name: THIMET 200G SYSTEMIC GRANULAR INSECTICIDE

APVMA registration number: 41439

APVMA approved label number: 115427

Batch numbers: AAC2I42043, AAC1I40157, AAC3D43038, AAC3G43284, AAC1G39926, AAC3I43500, AAC2E41296, AAC2I42066, AAC4G44299, AAC2E41295, AAC3H43400, AFTLL2602251, AFTLL2602252, AFTLL2702253, AMTLL2103251, AMTLL2503252, AMTLL2503253, AMTLL2503254, AATLL1504251, AMTLL1905251, AMTLL2005252, AJLTLL2107251, AJLTLL2207252, 304920AX0286, AUGSBX140825, SEPTLNL0909253, SEPTLNL2409255

Sold by: AgNova Technologies Pty Ltd in New South Wales and Queensland between 1 June 2025 to 14 October 2025.

On 15 October 2025, AgNova Technologies Pty Ltd (ACN 097 705 158) initiated a voluntary recall under section 106 of the Agricultural and Veterinary Chemicals Code scheduled to the Agricultural and Veterinary Chemicals Code Act 1994 (Cth) in relation to the chemical product described above.

Reason for voluntary recall

Some Lock'N Load 20 kg containers have been found to have loose closure (connection) valves, which may dislodge during handling of the product.

Hazard

The closure (connection) valves on the affected Lock'N Load 20 kg containers may dislodge with handling, especially when inverting the container to attach to application machinery. Therefore, there is a risk of spillage and may present an exposure hazard to persons handling the product.

What to do if in possession of this chemical product

DO NOT use any Lock'N Load 20 kg containers of THIMET 200G SYSTEMIC GRANULAR INSECTICIDE from the above-mentioned batches.

Wearing PPE as stated on the label, quarantine any containers in a locked pesticide storage area and contact AgNova Technologies for instructions for collection and refund or replacement of product.

More information

Visit the APVMA website to view the notice of voluntary recall for the chemical product described above.

The APVMA publishes a list of <u>agvet chemical recall notices</u> on its website and provides a <u>subscription option</u> to be notified by email when a new recall notice is published.

Contact

Questions about this voluntary recall should be directed to AgNova Technologies

Phone: (03) 9899 8100 Email: info@agnova.com.au

Agvet chemical voluntary recall: COUNTER 150G GRANULAR SOIL INSECTICIDE/NEMATICIDE (20 kg)

Product name: COUNTER 150G GRANULAR SOIL INSECTICIDE/NEMATICIDE

APVMA registration number: 33300

APVMA approved label number: 106323

Batch numbers: 401830AX0003, 401830AX0002, AMCLL0303251, AMCII0303251, AMCSB0503252,

AMCLNL2605254, AJLCLL2407251, AUGLNL260825

Sold by: AgNova Technologies Pty Ltd in New South Wales and Queensland between 1 June 2025 to 14 October 2025.

On 15 October 2025, AgNova Technologies Pty Ltd (ACN 097 705 158) initiated a voluntary recall under section 106 of the Agricultural and Veterinary Chemicals Code scheduled to the Agricultural and Veterinary Chemicals Code Act 1994 (Cth) in relation to the chemical product described above.

Reason for voluntary recall

Some Lock'N Load 20 kg containers have been found to have loose closure (connection) valves, which may dislodge during handling of the product.

Hazard

The closure (connection) valves on the affected Lock'N Load 20 kg containers may dislodge with handling, especially when inverting the container to attach to application machinery. Therefore, there is a risk of spillage and may present an exposure hazard to persons handling the product.

What to do if in possession of this chemical product

DO NOT use any Lock'N Load 20 kg containers of COUNTER 150G GRANULAR SOIL INSECTICIDE/NEMATICIDE from the above-mentioned batches.

Wearing PPE as stated on the label, quarantine any containers in a locked pesticide storage area and contact AgNova Technologies for instructions for collection and refund or replacement of product.

More information

Visit the APVMA website to view the notice of voluntary recall for the chemical product described above.

The APVMA publishes a list of <u>agvet chemical recall notices</u> on its website and provides a <u>subscription option</u> to be notified by email when a new recall notice is published.

Contact

Questions about this voluntary recall should be directed to AgNova Technologies:

Phone: (03) 9899 8100 **Email**: <u>info@agnova.com.au</u>