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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

The APVMA Gazette is published in electronic format only and is available from the APVMA website.

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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.	149860
Product name	One Dose Australia Liquid Chlorine
Active constituent	125 g/L available chlorine (Cl) present as sodium hypochlorite
Applicant name	One Dose Australia Pty Ltd
Applicant ACN	684 878 993
Date of registration	1 December 2025
Product registration no.	96559
Label approval no.	96559/149860
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 125 g/L sodium hypochlorite aqueous solution for the control of algae and bacteria in swimming pools

Application no.	148376
Product name	Etong TwinAzole WG Fungicide
Active constituents	300 g/kg prothioconazole, 300 g/kg tebuconazole
Applicant name	Shanghai E-Tong Chemical Co Ltd
Applicant ACN	N/A
Date of registration	2 December 2025
Product registration no.	96156
Label approval no.	96156/148376
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 300 g/kg prothioconazole and 300 g/kg tebuconazole product, formulated as a water dispersible granule (WG) for the control of various diseases in wheat, barley, oats, triticale, canola and pyrethrum

Application no.	149553
Product name	ACARION Miticide
Active constituent	500 g/kg bifenazate
Applicant name	Centris Solutions Pty Ltd
Applicant ACN	682 650 577
Date of registration	4 December 2025
Product registration no.	96501
Label approval no.	96501/149553
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 500 g/kg bifenazate product, formulated as a water dispersible granule (WG) for the control of two-spotted mite, european red mite and bryobia mite in pome fruits, stone fruits and almonds as indicated in the directions for use table

Application no.	147849
Product name	Imtrade Nonanoic Acid Herbicide
Active constituent	525 g/L nonanoic acid
Applicant name	Imtrade Australia Pty Ltd
Applicant ACN	090 151 134
Date of registration	11 December 2025
Product registration no.	95994
Label approval no.	95994/147849
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 525 g/L nonanoic acid emulsifiable concentrate product for non-selective control of seedling and young broadleaf and grass weeds, for suppression of established weeds and perennial species and for control of moss and algae

Application no.	149795
Product name	Genfarm Asulam 400 SL Selective Herbicide
Active constituent	400 g/L asulam present as the sodium salt
Applicant name	Nutrien Ag Solutions Limited
Applicant ACN	008 743 217
Date of registration	12 December 2025
Product registration no.	96542
Label approval no.	96542/149795
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 400 g/L asulam present as the sodium salt, formulated as a soluble concentrate (SL) product for control of bracken fern in pastures, grasses in sugar cane, and a range of weeds and grasses in crops and pastures

Application no.	148603
Product name	Novaguard Boscalid 500 WG Fungicide
Active constituent	500 g/kg boscalid
Applicant name	Novaguard Pty Ltd
Applicant ACN	153 121 156
Date of registration	12 December 2025
Product registration no.	96231
Label approval no.	96231/148603
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 500 g/kg boscalid product, formulated as a water dispersible granule (WG) for the control of bunch rot (botrytis cinerea) in grapevines

Application no.	149696
Product name	Genfarm Pinox 100 EC Herbicide
Active constituents	100 g/L pinoxaden, 25 g/L cloquintocet-mexyl
Applicant name	Nutrien Ag Solutions Limited
Applicant ACN	008 743 217
Date of registration	12 December 2025
Product registration no.	96532
Label approval no.	96532/149696
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 100 g/L pinoxaden product, formulated as an emulsifiable concentrate (EC) for control of key grass weeds and selective spray topping of wild oats in barley and wheat

Table 2: Variations of registration – agricultural chemical products

Application no.	151009
Product name	Quantum Poly Penetrant
Active constituent	1020 g/L polyether modified polysiloxane
Applicant name	Quantum Agrosciences Holdings Pty Ltd
Applicant ACN	680 792 625
Date of variation	18 November 2025
Product registration no.	91880
Label approval no.	91880/151009
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 ‘Quantum Organosilicone 1020 Penetrant’ to ‘Quantum Poly Penetrant’

Application no.	151145
Product name	Titan DFF 25 + Brom 250 Selective Herbicide
Active constituents	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 variation	26 November 2025
Product registration no.	69416
Label approval no.	69416/151145
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 'TITAN DIFLUFENICAN 25 + BROMOXYNIL 250 SELECTIVE HERBICIDE' to 'Titan DFF 25 + Brom 250 Selective Herbicide'

Application no.	N/A – variation under s29A
Product name	Farmalinx Dimetholinx Insecticide
Active constituent/s	400 g/L dimethoate
Applicant name	Farmalinx Pty Ltd
Applicant ACN	134 353 245
Date of variation	8 December 2025
Product registration no.	64309
Label approval no.	64309/RV2025
Description of the application and its purpose, including the intended use of the chemical product	Amendment of instructions to increase withholding periods after use of product from 1 to 14 days for blueberries and 7 to 14 days for blackberries and raspberries

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 3: Veterinary products based on existing active constituents

Application no.	144564
Product name	Vetmec Multi Plus B12 Vitamin and Mineral Injection for Beef Cattle
Active constituents	40 g/L zinc as disodium zinc EDTA, 15 g/L copper as disodium copper EDTA, 5.0 g/L selenium as sodium selenate, 2.0 g/L cyanocobalamin
Applicant name	Chemvet Australia Pty Ltd
Applicant ACN	138 711 289
Date of registration	8 December 2025
Product registration no.	95055
Label approval no.	95055/144564
Description of the application and its purpose, including the intended use of the chemical product	Registration of a multi active chelated trace element injection containing 15 g/L copper, 40 g/L zinc, 5 g/L selenium and 2.0 g/L vitamin B12 for beef cattle

Application no.	145049
Product name	Vetmec Pour-On Lousicide for Sheep
Active constituent	35 g/L imidacloprid
Applicant name	Chemvet Australia Pty Ltd
Applicant ACN	138 711 289
Date of registration	8 December 2025
Product registration no.	95235
Label approval no.	95235/145049
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 35 g/L imidacloprid pour-on solution product for prevention of blowfly strike (Lucilia cuprina) in sheep in long or short wool and control of neonicotinoid susceptible body lice (Bovicola ovis)

Application no.	148834
Product name	Promin Plus B12 Injection for Cattle
Active constituent	40 g/L zinc (as disodium zinc EDTA), 15 g/L copper (as disodium copper EDTA), 10 g/L manganese (as disodium manganese EDTA), 5 g/L selenium (as sodium selenite), 1.4 g/L cyanocobalamin
Applicant name	Virbac (Australia) Pty Ltd
Applicant ACN	003 268 871
Date of registration	10 December 2025
Product registration no.	96294
Label approval no.	96294/148834
Description of the application and its purpose, including the intended use of the chemical product	Registration of an injectable solution product containing 40.0 g/L zinc (as disodium zinc EDTA), 15.0 g/L copper (as disodium copper EDTA), 10.0 g/L manganese (as disodium manganese EDTA), 5.0 g/ L selenium (as sodium selenite) and 1.4 g/L cyanocobalamin (Vitamin B12) indicated for administration to beef and dairy cattle deficient in and/or responsive to zinc, copper, manganese, selenium and/or Vitamin B12 supplementation

Application no.	148835
Product name	Promin Injection for Cattle
Active constituent	40 g/L zinc (as disodium zinc EDTA), 15 g/L copper (as disodium copper EDTA), 10 g/L manganese (as disodium manganese EDTA), 5 g/L selenium (as sodium selenite)
Applicant name	Virbac (Australia) Pty Ltd
Applicant ACN	003 268 871
Date of registration	10 December 2025
Product registration no.	96295
Label approval no.	96295/148835
Description of the application and its purpose, including the intended use of the chemical product	Registration of an injectable solution product containing 40.0 g/L zinc (as disodium zinc EDTA), 15.0 g/L copper (as disodium copper EDTA), 10.0 g/L manganese (as disodium manganese EDTA) and 5.0 g/ L selenium (as sodium selenite) indicated for administration to beef and dairy cattle deficient in and/or responsive to zinc, copper, manganese and/or selenium

Application no.	147694
Product name	Trioshield LV 3-way Combination Drench for Sheep and Cattle
Active constituents	80 g/L levamisole hydrochloride, 45.3 g/L oxfendazole, 5 g/L cobalt as disodium cobalt EDTA, 2 g/L abamectin, 1 g/L selenium as sodium selenate
Applicant name	Nutrien Ag Solutions Limited
Applicant ACN	008 743 217
Date of registration	11 December 2025
Product registration no.	95961
Label approval no.	95961/147694
Description of the application and its purpose, including the intended use of the chemical product	Registration of an oral suspension containing 80 g/L levamisole hydrochloride, 45.3 g/L oxfendazole, 5 g/L cobalt (as cobalt EDTA), 2 g/L abamectin and 1 g/L selenium (as sodium selenate) product for the treatment and control of internal parasites of sheep including those resistant to Macrocyclic Lactone (ML), Benzimidazole (BZ) or Levamisole (LEV) drench families

Table 4: Variations of registration – veterinary chemical products

Application no.	148853
Product name	Dermcare Malaseb Medicated Shampoo
Active constituents	20 g/L Chlorhexidine gluconate, 20 g/L Miconazole nitrate
Applicant name	Dermcare-Vet Pty Ltd
Applicant ACN	010 280 010
Date of variation	1 December 2025
Product registration no.	47682
Label approval no.	47682/148853
Description of the application and its purpose, including the intended use of the chemical product	Variation of the relevant particulars of the registered chemical product and label approval to update the directions for use

Application no.	148852
Product name	Dermcare Malaseb Medicated Shampoo
Active constituents	20 g/L chlorhexidine gluconate, 20 g/L miconazole nitrate
Applicant name	Dermcare-Vet Pty. Ltd.
Applicant ACN	010 280 010
Date of variation	2 December 2025
Product registration no.	47682
Label approval no.	47682/148852
Description of the application and its purpose, including the intended use of the chemical product	Variation of the relevant particulars of the registered chemical product and label approval to update the directions for use

Application no.	147795
Product name	Alfaxan Multidose Anaesthetic Injection
Active constituent	10 mg/mL alfaxalone
Applicant name	Zoetis Australia Pty Ltd
Applicant ACN	156 476 425
Date of variation	3 December 2025
Product registration no.	83248
Label approval no.	83248/147795
Description of the application and its purpose, including the intended use of the chemical product	Variation of relevant particulars of product registration and label approval to update in-use shelf-life of the product

Application no.	147736
Product name	Dermcare Pyohex Medicated Shampoo
Active constituent	30 g/L chlorhexidine gluconate
Applicant name	Dermcare-Vet Pty Ltd
Applicant ACN	010 280 010
Date of variation	12 December 2025
Product registration no.	47567
Label approval no.	47567/147736
Description of the application and its purpose, including the intended use of the chemical product	Variation to relevant particulars of product registration and label approval to the precautions and dosage and administration statements on the label

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 5: Approved active constituents

Application no.	148024
Active constituent	Meloxicam
Applicant name	Ashish Life Science Pvt Ltd
Applicant ACN	N/A
Date of approval	1 December 2025
Approval no.	96047
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent meloxicam for use in veterinary chemical products

Application no.	148040
Active constituent	Cyantraniliprole
Applicant name	Tagros Chemicals India Private Limited
Applicant ACN	N/A
Date of approval	1 December 2025
Approval no.	96057
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.	149560
Active constituent	Pentobarbital sodium
Applicant name	Troy Laboratories Pty Ltd
Applicant ACN	000 283 769
Date of approval	1 December 2025
Approval no.	96506
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent pentobarbital sodium for use in veterinary chemical products

Application no.	146946
Active constituent	Maropitant
Applicant name	Virbac (Australia) Pty Ltd
Applicant ACN	003 268 871
Date of approval	2 December 2025
Approval no.	95697
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent maropitant for use in veterinary chemical products

Application no.	149653
Active constituent	Deltamethrin
Applicant name	Intervet Australia Pty Limited
Applicant ACN	008 467 034
Date of approval	2 December 2025
Approval no.	96528
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent deltamethrin for use in veterinary chemical products

Application no.	148131
Active constituent	Bromoxynil octanoate
Applicant name	Gharda Australia Pty. Ltd.
Applicant ACN	087 753 151
Date of approval	3 December 2025
Approval no.	96084
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent bromoxynil octanoate for use in agricultural chemical products

Application no.	148318
Active constituent	Imazamox
Applicant name	Kingtai Chemicals Co., Limited
Applicant ACN	N/A
Date of approval	3 December 2025
Approval no.	96140
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent imazamox for use in agricultural chemical products

Application no.	146380
Active constituent	Flupropanate-sodium
Applicant name	Granular Products Assets Pty Ltd
Applicant ACN	614 694 405
Date of approval	4 December 2025
Approval no.	95566
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent flupropanate-sodium for use in agricultural chemical products

Application no.	148427
Active constituent	Pyriproxyfen
Applicant name	Hemani Australia Pty Ltd
Applicant ACN	634 346 357
Date of approval	10 December 2025
Approval no.	96171
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent pyriproxyfen for use in agricultural and veterinary chemical products

Table 6: Variations of active constituent

Application no.	149506
Active constituent	Basic Cobalt (II) Carbonate
Applicant name	Agrimin Limited
Applicant ACN	N/A
Date of variation	3 December 2025
Approval no.	82677
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.	149433
Active constituent	Lincomycin hydrochloride
Applicant name	South Yarra Pharma Pty Ltd
Applicant ACN	629 173 351
Date of variation	8 December 2025
Approval no.	87556
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

Revocation of suspension of registration

Pursuant to section 46(2)(b) of the Agricultural and Veterinary Chemicals Code scheduled to the *Agricultural and Veterinary Chemicals Code Act 1994*, the APVMA hereby gives notice that it has revoked the suspensions of the registrations listed below with effect from the dates shown.

Table 7. Product registrations that are no longer suspended

Product name	Farmalinx Dimetholinx Insecticide
Active constituent/s	400 g/L dimethoate
Holder name	Farmalinx Pty Ltd
Holder ACN	134 353 245
Date suspension revoked	8 December 2025
Product registration no.	64309
Label approval no.	64309/RV2025
Brief reasons	The APVMA suspended the registration of Farmalinx Dimetholinx Insecticide on 11 November 2025 on the basis that it appeared to the APVMA that the product may not meet the safety criteria when used on blueberries, blackberries and raspberries, according to the instructions for use on the approved label. On 8 December 2025, the APVMA varied the product registration and label approval to increase withholding periods after use of the product from 1 to 14 days for blueberries and 7 to 14 days for blackberries and raspberries, with the holder's consent under section 29A of the Agvet Code. Therefore, the reason for the APVMA's decision to suspend the product registration has been removed.

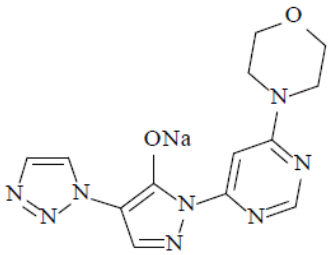
New veterinary chemical products containing a new veterinary active constituent

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application for the approval of a new active constituent, **molidustat sodium**, from Bayer Cropscience Pty Ltd, and from Elanco Australasia Pty Ltd, an application for the registration of a new product containing this new active constituent, **Varenzin Oral Suspension for Cats**, as an aid in the control of nonregenerative anaemia associated with chronic kidney disease (CKD) in cats.

Active constituent particulars

The APVMA has evaluated the safety of the new active constituent molidustat sodium.

Table 8: Particulars of the active constituent molidustat sodium

Common name	Molidustat sodium
Applicant company	Bayer Cropscience Pty Ltd
IUPAC name	Sodium 1-[6-(morpholin-4-yl)pyrimidin-4-yl]-4-(1*H*-1,2,3-triazol-1-yl)-1*H*-pyrazol-5-olate
CAS name	1*H*-Pyrazol-5-ol, 1-[6-(4-morpholinyl)-4-pyrimidinyl]-4-(1*H*-1,2,3-triazol-1-yl)-, sodium salt (1:1)
CAS registry number	1375799-59-9
Specific purity	98.0-102.0% (dried substance)
Molecular formula	$C_{13}H_{13}N_8NaO_2$
Molecular weight	336.28 g/mol
Structure	
Chemical family	Chemical families of pyrazolones, pyrazoles, and triazoles
Mode of action	Molidustat acts as a hypoxia-inducible factor prolyl-hydroxylase inhibitor (HIF-PHI).

Summary of the APVMA's evaluation of molidustat sodium active constituent

A summary of the APVMA's evaluation of **molidustat sodium** in accordance with the requirements of section 14(1)(b) 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:

    a. The APVMA is satisfied that the chemistry aspects of molidustat sodium (physico-chemical properties, stability, identification, manufacturing process, quality control procedures, specifications, batch analysis results and analytical methods) and found them to be acceptable.

    b. The APVMA is satisfied that the toxicological and human health aspects of molidustat sodium active constituent are acceptable and concluded that there are no toxicological concerns regarding the approval of this active constituent.

        i. No Acceptable Daily Intake (ADI) or Acute Reference Dose (ARfD) is required because the active constituent is not proposed for use in food-producing animals. No impurities of toxicological concern were identified in the health assessment.

        ii. As a proposed prescription veterinary medicine, molidustat sodium has been included in Schedule 4 and clause 5 of Appendix D of the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP).

2. The APVMA proposes to be satisfied under sections 5A(1) of the Agvet Code that molidustat sodium would not be an undue hazard to the safety of people exposed to it during its handling or people using anything containing its residues; would not be likely to have an effect that is harmful to human beings; and would not be likely to have an unintended effect that is harmful to animals, plants or things, or to the environment.

Varenzin Oral Suspension for Cats containing molidustat sodium

The APVMA has under consideration an application to register a new product, **Varenzin Oral Suspension for Cats,** containing the new active, **molidustat sodium**.

Table 9: Particulars of the product

Proposed product name/s	Varenzin Oral Suspension for Cats
Applicant company	Elanco Australasia Pty Ltd
Name of active constituent	Molidustat sodium
Signal heading	Schedule 4
Formulation type	Oral suspension
Summary of proposed use	As an aid in the control of nonregenerative anaemia associated with chronic kidney disease (CKD) in cats.
Dose rate	The effective dose is 5.0 mg/kg body weight (bw). The product is administered orally once daily for 28 days. The dosing table below shows the dose volume of the product required for different body weight classes, measured and administered by using the syringe provided with the product. Weight Range in kilograms (kg) — Volume (mL) 2.0 — 0.4 2.1 to 2.5 — 0.5 2.6 to 3.0 — 0.6 3.1 to 3.5 — 0.7 3.6 to 4.0 — 0.8 4.1 to 4.5 — 0.9 4.6 to 5.0 — 1.0 5.1 to 5.5 — 1.1 5.6 to 6.0 — 1.2 Cats greater than 6.0 kg should be treated with a dose of 0.2 mL/kg bodyweight.
Pack sizes	27 mL
Withholding period	N/A

A summary of the APVMA's evaluation of **Varenzin Oral Suspension 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 Varenzin Oral Suspension for Cats would not be an undue hazard to the safety of people exposed to it during its handling and use. Assessment included, acute oral toxicology studies in a range of animals including Wistar rats, mice, Beagle dogs in 3 short term, 5 sub chronic and 2 chronic studies. Reproductive studies in rats, developmental studies in rats and Himalayan rabbits and carcinogenicity in rats and genotoxicity studies were also evaluated. While there were no acute dermal or inhalation studies, skin irritation and corrosivity of product were evaluated in *in vitro* reconstructed human epidermis model (RhE), skin sensitisation was tested using mouse Local lymph node assay (LLNA). *In vitro* studies for eye irritation were evaluated in *In vitro r*econstructed human cornea-like epithelium (RhCE) and *In vitro* Bovine Corneal Opacity and Permeability (BCOP) Test. The pharmacokinetics of molidustat were evaluated in studies in rat, dog, cat and monkeys. Based on the results of these studies the APVMA determined that:

a. The product is unlikely to be a skin or eye irritant; the main risk is potential dermal absorption from spillage.

b. Molidustat was not a carcinogen in mice or rats. Genotoxicity assays (Ames test, *in vivo* UDS and cytotoxic bone barrow tests in rats) were negative.

c. No effect was shown on reproduction parameters in rats, including male or female fertility.

d. In a developmental toxicity study in rats, administration of molidustat led to an increased number of ocular malformations in foetuses at 30 mg/kg bw/d. No maternal toxicity was observed in rabbits and no influence on foetal development up to the highest test dose of 20 mg/kg bw. The no observed adverse effect level (NOAEL) for maternal and foetal toxicity was established at 10 mg/kg bw/d. APVMA considered that an acute NOAEL of 5 mg/kg bw would be sufficiently protective of incidental and/or accidental exposure during the use of the product.

e. No evidence of neurotoxicity was seen in repeat-dose studies or acute studies specifically designed to identify such effects.

f. Regarding potential repeated exposure, there is evidence for little potential for bioaccumulation.

g. It was concluded that accidental dermal exposure to veterinarians or pet owners, does not present an unacceptable risk, either as a single or repeated event. However, it would be prudent to wear disposable gloves during product application, particularly as molidustat has been associated with developmental effects in rats, albeit at doses greater than 10 mg/kg bw/d.

h. Molidustat was added in the Schedule 4 and clause 5 of Appendix D substance of the Poisons Standard (Standard for the Uniform Scheduling of Medicines and Poisons (SUMP), Health, 2024). 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 SUSMP. Based on the active constituent inclusion in the SUSMP Varenzin Oral Suspension for Cats will have an entry in the Handbook of First Aid Instructions, Safety Directions, Warning Statements, and General Safety Precautions for Agricultural and Veterinary Chemicals (FAISD) and requires the signal heading ‘PRESCRIPTION ANIMAL REMEDY’ and ‘FOR ANIMAL TREATMENT ONLY’.

i. To mitigate potential risks, 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*

Claims

- *For use by or under direction of a veterinarian*

Directions for use:

- *Use as directed by prescribing veterinarian*

First aid instructions

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

Safety directions

- ***WARNING –*** *contains molidustat which causes birth defects in laboratory animals. Women of childbearing age should avoid contact with molidustat.*
- *Wash hands after use.*

Additional user safety

- *Not for human use.*
- *Keep this drug, including used syringes, out of reach of children.*
- *Wash hands immediately after spillage.*
- *In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.*
- *Symptoms of exposure to molidustat may include:*
  - *gastrointestinal effects (nausea, vomiting, diarrhea), blood and clotting effects (increases in reticulocytes, erythropoietin, and haemoglobin), dizziness, fainting, hypertension (increased blood pressure) and tachycardia (increased heart rate).*
- *Symptoms may not occur immediately; therefore, the exposed individual should be monitored.*
- *People with known hypersensitivity to molidustat should avoid direct contact with this product and should administer the product to cats with caution.*
- *If there is a risk for spillage and skin exposure during product administration, wearing disposable gloves is advisable to pregnant women and people with hypersensitivity to molidustat sodium.*

j. After consideration of the toxicological profile and likely human exposure associated with the use Varenzin Oral Suspension 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 (DFU).

ii. The APVMA is satisfied that the proposed use of Varenzin Oral Suspension 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. Varenzin Oral Suspension for Cats is therefore, unlikely to enter the food chain.

iii. The APVMA is satisfied that the proposed use of Varenzin Oral Suspension for Cats containing the active constituent Molidustat sodium is not likely to have an unintended effect that is harmful to plants or the **environment** if used according to the product label directions.

a. Environmental risks of Varenzin Oral Suspension for Cats (containing 25 mg/mL molidustat sodium) were assessed according to the VICH [1]Phase I decision tree. The assessment determined that the amount of molidustat sodium 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:

[1] Veterinary International Cooperation on Harmonisation (VICH)

Disposal

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

iv. The APVMA is satisfied that the proposed use of Varenzin Oral Suspension for Cats is not likely to have an unintended effect that is harmful to **target animals (cats)** if used according to the product label directions.

a. Target Animal Safety (TAS) was investigated in a pivotal TAS study, with 0.5X and 1X of 5 mg/kg dose conducted with 16 healthy male cats (approximately 10 to 11 months) for 4 weeks, supported by 2 field studies in cats with diagnosed CKD and 2 efficacy trials in healthy cats. A 2X safety was observed 15 days in a dose determination study conducted with 10 mg/kg bw dose rate in healthy cats and discontinued due to development of polycythaemia. Two target animal efficacy field studies conducted with cats having diagnosed CKD also provided evidence for safety of the intended use of the product in cats with CKD.

b. Standard requirements for safety trials to demonstrate 3X and 5X safety of 5 mg/kg dose was not conducted due to observation of increase of haematocrit (HCT) to abnormal levels with 1X and 2X studies in healthy cats and animal welfare issues arising due to very high haematocrit if higher doses are used. This abnormal elevation of haematocrit was not observed in trials conducted in CKD cats with the proposed 5 mg/kg bw dose rate.

c. The typical haematological parameters and signs observed at the dose levels studied are very similar in above studies and relate to the pharmacological action of molidustat. These include polycythaemia associated elevated haematocrit, haemoglobin and erythrocyte values. Correlating to these effects, related changes were noted in Mean Corpuscular Haemoglobin (MCH), Mean Corpuscular Haemoglobin Concentration (MCHC) and Mean Corpuscular Volume (MCV). Increases in serum potassium, creatinine, serum phosphorus, and systolic blood pressure were also seen.

d. Margin of safety study

- pivotal safety study showed increased haematocrit, haemoglobin and erythrocyte values although this increase was not dose dependent.
- An increased cellular density of the bone marrow, reduced thymus weight and histopathological findings of congestion of the vasculature in the brain, thrombosis/haemostasis in the heart, prominent myocardial vessels, minimal oedematous change of valves in the heart, and acute thrombosis of large pulmonary arteries in the lung were also observed in a safety study conducted in healthy cats.
- Findings related to stress were noticed in the thymus (increased atrophy/involution), the adrenal glands (increased severity score of cortical vacuolation) and the spleen (mild lymphoid depletion in the white pulp).

e. Target Animal Efficacy Field studies

- Vomiting was the most frequently reported adverse event in the field studies.
- The adverse effects reported in field studies conducted with cats with CKD and clinicopathologic parameters can be attributed to underlying CKD or conditions that are not unexpected in a large group of predominantly senior to geriatric cats. Vomiting, lethargy, inappetence, halitosis, polyuria, polydipsia, renal abnormality related serum chemistry, haematology and urine values were as expected in cats with CKD. Hypoalbuminemia, elevated globulin, mildly low chloride concentrations, occasional hypernatremia and hyperchloremia associated with dehydration, and hyper- or hypocalcaemia were also found.

- Two out of 55 cats (3.6%) had seizures in the phase II (unmasked safety phase) of the pivotal field study conducted with Varenzin. These cats had severe uraemia, severe anaemia, dehydration, hypertension and prior history of seizures.
- In the interim safety report, monocytosis, lymphopenia, neutrophilia, low platelets, low MCV, low reticulocyte-haemoglobin concentration and high reticulocyte counts were found. No evidence of abnormal coagulation was noticed except in one cat with prolonged coagulation.

f. The use of Varenzin Oral Suspension for Cats has neither been studied during pregnancy, lactation or intended for breeding. As indicated above, increase incidence of ocular malformations such as flat eye rudiments and microphthalmia were observed at doses of 30 mg/kg bw molidustat per day in rats. Therefore, precautions were imposed in the label for use of the product in pregnant, lactating cats or cats intended for breeding.

g. Studies in cats indicated that principal route of elimination of molidustat in cats appears to be faecal. Most of the molidustat found in faeces was actively excreted. Main metabolite in cat was glucuronic acid conjugate of molidustat. Considering the inefficient glucuronyl transferase enzyme activity in cats, the precaution statement was imposed to use with caution in cats with hepatic impairment.

h. The APVMA has therefore, concluded that the administration of Varenzin Oral Suspension for Cats is generally well tolerated at 5 mg/kg bw dose rate for 28 days treatment cycle and appropriate statements have been included on the label to mitigate the risks identified:

Contraindications:

- *Contraindicated for cats with known hypersensitivity to molidustat.*

Precautions:

- *The safe use of Varenzin has not been evaluated in cats less than 1 year of age and cats ≤ 2 kg.*
- *Use with caution in cats with hepatic impairment. Molidustat is metabolised by the liver. The safety of the product has not been studied in cats with hepatic impairment.*
- *The safe use of Varenzin has not been evaluated in cats that are pregnant, lactating, or intended for breeding. Therefore, use of Varenzin is not recommended in these classes of animals.*
- *Use with caution in cats with a history of seizures and cats that may be predisposed to thromboembolic disease.*
- *The use of Varenzin administered concurrently with other erythropoiesis-stimulating agents, Including recombinant erythropoietin drugs, has not been studied.*
- *Phosphate binders or other products containing multivalent cations such as calcium, iron, magnesium or aluminium have been shown to chelate with other HIF-PH inhibitors. Based on information in humans, staggered administration of Varenzin and phosphate binders (at least 1 hour apart), if possible, should be considered to prevent potentially decreasing absorption of molidustat.*

Side effects:

- *Vomiting was the most frequently reported adverse event in the pivotal field study, either alone or with other events, and was reported at least once in 28/55 (50.9%) of the cats treated with Varenzin in the pivotal field study. Vomiting was more frequent on treatment days than during treatment pause.*
- *Two out of 55 cats (3.6%) had seizures in the phase II (unmasked safety phase) of the pivotal field study conducted with Varenzin. One cat had a seizure associated with severe uraemia, severe anaemia, and*

dehydration. Other cat had a history of a seizure about 1 year prior, had severe hypertension and a seizure during the study. It was assessed that the seizures were not related to the administration of Varenzin.

- *Polycythaemia may result from use of Varenzin. When starting treatment with Varenzin, cats should have their haematocrit (HCT) or packed cell volume (PCV) levels monitored fortnightly during the treatment cycle to ensure HCT or PCV does not exceed the upper limit of the reference range. Discontinue Varenzin if HCT or PCV exceeds the upper limit of the reference range.*
- *Polycythaemia was observed with the use of Varenzin in studies conducted with healthy cats. This was associated with changes in mucous membrane colour, slightly prolonged capillary refill time, heart pounding, and tachycardia. Polycythaemia is expected when Varenzin is administered to non-anaemic cats.*
- *Overdose: A safety study was conducted in healthy cats administered 10 mg/kg (2x) recommended dose. The most common adverse effect noted was polycythaemia. In case of an overdose, seek advice from a veterinarian and treat symptomatically.*

General directions:

- *Monitoring and follow up recommendations:*
  - *Cats should have their haematocrit (HCT) or packed cell volume (PCV) levels monitored fortnightly during the treatment cycle to ensure HCT or PCV does not exceed the upper limit of the reference range.*
  - *Polycythaemia after administration of Varenzin was also associated with generally mild increases in serum potassium, creatinine, serum phosphorus, and systolic blood pressure in studies in healthy cats.*
- *Observations from Safety study*
  - *The administration of molidustat to healthy cats in the pivotal safety study (0.5X (2.5 mg/kg) and 1X (5 mg/kg) was associated with postmortem findings: reduced thymus weight, histopathological findings of congestion of the vasculature in the brain, thrombosis/ haemostasis in the heart, prominent myocardial vessels, minimal oedematous change of valves in the heart, and acute thrombosis of large pulmonary arteries in the lung. These findings were attributed to the pharmacologic mode of action (erythropoiesis via HIF-PH inhibition) of molidustat oral suspension.*
  - *An increased cellular density of the bone marrow mainly due to an increased erythropoietic activity and increased extra-medullary haematopoiesis was observed in several cats at 5 mg/kg bw dose rate.*
  - *Polycythaemia after administration of Varenzin was also associated with generally mild increases in serum potassium, creatinine, serum phosphorus, and systolic blood pressure in studies in healthy cats.*
- *A nontarget animal safety study in rats has shown increase incidence of ocular malformations such as flat eye rudiments and microphthalmia at doses of 30 mg/kg bw per day. There was evidence for excretion of molidustat in milk in studies conducted with rats. It may be advisable to bottle feed kittens with milk replacers if a lactating queen is treated with Varenzin in unavoidable circumstances.*

2) The APVMA has evaluated the application and in its assessment in relation to whether the **efficacy criteria** have been met in accordance with the definition set out in section 5B of the Agvet Code, and proposes to determine that:

i. In relation to its assessment of efficacy 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 studies included 6 pharmacological studies in the target species, 3 dose determination, 2 dose confirmation, one pilot scale multi-site filed efficacy study, a pivotal field efficacy/ safety study and 2 palatability studies have been provided to support this submission in relation to cats. The summary of the efficacy studies/assessment results have been provided below:

a. Pharmacodynamics:

Varenzin (molidustat oral suspension) is a competitive and reversible inhibitor of hypoxia-inducible factor prolyl hydroxylase (HIF-PH). The inhibition of HIF-PH induces a dose-dependent increase of endogenous erythropoietin (EPO) by stabilizing HIF, resulting in increased erythropoiesis (red blood cell production). Dose dependent EPO release was demonstrated and a pivotal study showed that multiple daily doses did not cause accumulatio. Molidustat associated production of EPO was indistinguishable from endogenous production but with few other pharmacological targets. Due to this selectivity, molidustat had negligible effects on most physiological systems or ion channel function. increased production of endogenous erythropoietin (EPO) in turn, stimulates red blood cell production.

b. Interactions:

Field study indicated that wide range of concomitant medications relevant to CKD do not interact with molidustat adversely. Due to the dependencies of metabolism in the liver, interactions are likely only with potent inhibitors of individual and/or dual UDP transferase inhibitors.

c. Pharmacokinetics:

Absorption

In a study in cats, Varenzin showed a high oral bioavailability (mean 81%; 58-110% range) at the proposed dose rate (5 mg/kg bw) in cats after oral administration. A slightly different formulation used in another study resulted in 65% bioavailability in cats. The exposure of molidustat demonstrated dose-proportionality up to 10 mg/kg bw with Varenzin oral suspension in cats. The accumulation index in cats was 1.1. Some relatively small differences were seen between sexes and it is likely that the lower exposure of females can be related to greater clearance and elimination of both parent and metabolite.

Distribution

The binding of molidustat to plasma proteins was low in all species (mouse, rat, rabbit, cat, dog, including humans) investigated in laboratory studies using blood samples obtained from these species. In rats, highest levels were found in liver, kidneys, and adrenals. Most organs and tissues showed moderate to low concentrations, including blood, skeletal muscles, lungs, thymus, bone marrow, heart, adipose tissue, pancreas, testes and epididymides. There was virtually no penetration across the blood/brain barrier.

Metabolism and Elimination

Molidustat is biotransformed to one major metabolite (N-glucuronide) in most species including cat. Hepatocyte studies confirmed similar mechanisms in cats. The metabolites M-1 (the glucuronic acid conjugate of molidustat) was formed to 29.4% after 4 hours and M2 (a combination of oxidative activation and subsequent hydrolysis of the pyrazolone moiety and an elimination of the triazole moiety) to 17.6%, respectively in the hepatocyte study in cats.

The excretion pattern of molidustat is different between species. Enterohepatic circulation (EHC) is likely. The principal route of elimination appears to be faecal. The systemic clearance of Molidustat was in the same order of magnitude as the faecal clearance and more than 100 times higher compared to renal clearance in cats.

Some molidustat found in faeces may be unabsorbed compound after oral administration). However, the total elimination in faeces after oral administration was similar to that after intravenous (IV administration, suggesting that most of the molidustat found in faeces was actively excreted in cats.

d. Dose finding:

Three dose determination studies were conducted, investigating 0.1, 0.5, 2.5, 3, 5, 6, 10 mg/kg bw dose rates. The effective dose was identified as 5 mg/kg per os (PO) in an oily vehicle and the possibility of toxic effects (polycythaemia) with higher dose rates was highlighted.

Efficacy of 5 mg/kg dose rate was confirmed in an exploratory laboratory study involving healthy cats.

In treated groups, the concentration of EPO in plasma peaked 6 hours post-treatment on day 0 and day 2. The mean concentration of EPO paralleled that of molidustat. Levels were 1.4 times and almost 1.5 higher in fasted cats than in fed cats 6 hours post-treatment on day 0, and day 2 respectively.

The concentration of EPO markedly decreased by 24h after treatment on day 0, day 1 and day 2 and returned to near pre-treatment values by 48 hours after the last treatment. Mean values at 24, 30 and/or 48h after each treatment were higher in fed compared to fasted cats throughout the study. Peak levels of EPO are elevated in fasting cats; the duration of EPO elevation is longer in fed cats. Given the requirement to maintain cats below the upper reference limit for haematocrit, feeding prior to treatment may be advisable to achieve the effect while reducing the EPO maxima. In addition to EPO, the beneficial increased erythrocytes, haemoglobin and HCT as well as increased RBC distribution width was strong evidence of the desired effect of molidustat.

In a pivotal field study involving cats with diagnosed CKD confirmed safety and efficacy of the use of proposed 5 mg/kg dose rate.

e. Field studies:

In field studies conducted with Varenzin, the treatment success was based on an absolute increase of ≥4 percentage points in HCT observed on study day 28 compared to study day 0, or a relative increase of 25% in HCT on study day 28 compared to study day 0.

- Pilot multi-site field study:

Some positive effects were confirmed in a pilot multi-site field study, which, while not using the final formulation, also demonstrated relative safety over a 28-day period. However, the study did not demonstrate significant effective increases in trial ‘success’. The study did not observe parallel EPO release and safety and confirmed the need to monitor haematocrit (HCT) or packed cell volume (PCV) during treatment. When beneficial effects reach their maximum, the proposed product can become toxic as HCT rises.

- Pivotal multi-site field study:

A ‘pivotal’ multi-site field study demonstrated statistical success on HCT/PCV at both 21 and 28 days after treatment but with no improvement in ‘quality of life’. Only 40 cats with CKD were exposed to molidustat in the final formulation in this trial. The field study also provided evidence that a wide range of concomitant medications relevant to CKD do not interact with molidustat adversely. Treatment success was evaluated on day 28 (± 2) relative to day 0.

‘Success’ was defined as an increase of >4% HCT observed on day 28 and/or an overall increase of 25% in HCT relative to day 0.

  - The proportion of cats showing treatment successes in the pivotal field study on day 28 in the IVP group was clear and significantly greater than the placebo group. After 28 days of treatment, ~68% of IVP group cats compared with 17% of placebo cats had achieved treatment success. Similarly, the proportion of cats showing treatment successes on day 21 in the IVP group was also significantly greater than the placebo group. After 21 days of treatment, 69% of IVP group

cats compared with ~24% of placebo cats had achieved treatment success. There was no evidence for a gender-based difference in response.

- The adverse effects (AE) reported and changes in clinicopathologic parameters were attributed to underlying CKD or conditions that are not unexpected in a large group of predominantly senior to geriatric cats. In AEs or abnormalities in clinicopathologic data, no obvious pattern was apparent in relation to concomitant medication. No patterns were detected linking reported AEs to the IVP as opposed to spontaneously arising from concurrent diseases and or conditions. There were 8 serious adverse events which could all be attributed to late stages of CKD.
- The product was compatible with wide range of additional medications used in the community-based cats diagnosed with CKD already receiving in the field study. These included supportive therapies and symptomatic treatments with combinations of electrolytes, antibiotics, vitamin and mineral supplements, probiotics, treatments for hypertension, antacids, antiemetics and antidepressants etc. No compatibility issues were identified with these medications.

f. Palatability

Two exploratory palatability studies have been conducted using different formulations and acceptable palatability of molidustat in an oily vehicle was demonstrated. However, the studies did not include the final formulation. Overseas pharmacovigilance data show 1.8% of product complaints and indicate a low level of resistance by patients to the product in terms of palatability. Appropriate label statements were added to consult veterinarian if cat shows resistance to dosing.

ii. The APVMA has therefore, concluded that of Varenzin Oral Suspension for Cats is, would be effective as an aid in control of nonregenerative anaemia associated with chronic kidney disease (CKD) in cats, and relevant statements have been placed on the label to mitigate any risks identified:

Claims:

- *Aids in the control of nonregenerative anaemia associated with chronic kidney disease (CKD) in cats.*

Dosage and administration:

- *Shake well before use.*
- *Use content within 28 days after first broaching the vial. Discard unused portion.*
- *The dosage of Varenzin is 5.0 mg/kg body weight (bw). The product is administered once daily for 28 days. Varenzin should be administered using the dosing syringe provided in the package. The dosing syringe is marked in increments of 0.1 mL. The dose should be rounded up to the nearest 0.1 mL.*
- *If the cat demonstrates resistance to dosing, please consult your veterinarian.*

Administration

- *Remove screw cap. Use the enclosed syringe for each treatment. Place the syringe nozzle firmly into the opening of the bottle. Turn the bottle upside down and withdraw the necessary volume. Ensure the bottle is returned to an upright position before removing the syringe. The product should be administered with the syringe into the cat's mouth.*
- *After administration, close bottle tightly with cap and store syringe in the carton together with the product. Do not disassemble or wash the syringe. The product should be given once daily for 28 consecutive days.*

General directions:

Monitoring and follow up recommendations:

- *After treatment cessation the haematocrit level should be periodically checked, beginning 7 days after cessation, with the frequency depending on the clinical status of the patient (e.g. weekly, 2 weekly or monthly).*
- *When the HCT or PCV level declines below the lower limit of the reference range, a new treatment cycle should be started. The ideal interval between treatment cycles will vary between cats and may change over time for an individual cat.*
- *If a cat does not respond to treatment after 3 weeks, it is recommended to re-examine the animal for any other underlying condition that may contribute to anaemia, such as iron deficiency, inflammatory disease, or blood loss. It is advised to treat the underlying condition before re-starting treatment with Varenzin.*
- *Efficacy studies have shown reduced clinical response when vomiting occurs immediately after dosing, related to under dosing. Consult your veterinarian if vomiting after dosing continues in subsequent administrations.*

Demonstrated efficacy in field studies:

- *In field studies conducted with Varenzin, the applicant's determination of treatment success was based on an absolute increase of ≥4 percentage points in HCT observed on study day 28 compared to study day 0, or a relative increase of 25% in HCT on study day 28 compared to study day 0.*
- *In the efficacy study population of the pivotal field study involving CKD cats showed 68% and 17% success rates respectively for molidustat treatment group [n=40] and placebo group [n=35], at day 28. At day 21 the success rate was 69% for molidustat treatment group [n=39] and 24% for control group [n=34]. At both time points the success rates in treatment groups were statistically significant over the placebo group. It was noted however, only 17 of 39 and 16 of 40 cats were back within the normal reference range of HCT at days 21 and 28 respectively.*
- *In a pilot field study, 15 cats with chronic kidney disease (CKD) were assigned to the molidustat treatment group, and 6 cats with (CKD) were assigned to the control group. Treatment success rate in the molidustat treated group was numerically superior to the vehicle control group on study day 28 (50% [7/14] vs. 20% [1/5]). Eight cats from the effectiveness phase were enrolled in a continuation phase, which lasted an additional 56 days, and received, depending on their PCV, either 2.5 mg/kg or 5 mg/kg bw of the same molidustat oral suspension formulation. The continuation phase was a multi-center, unmasked, non-randomized, uncontrolled field safety and effectiveness study. During the continuation phase of the study, PCV was evaluated weekly, and HCT was evaluated on study days 56 and 84 (± 2 days). Treatment success for each cat during the continuation phase was defined the same as during the 28-day study. On study day 56, 75% (6/8) of the cats were considered successes and on study day 84, 62.5% (5/8) of the cats were considered successes.*

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:

iii. The APVMA is satisfied that the proposed use of Varenzin Oral Suspension for Cats would not adversely affect **trade** between Australia and places outside Australia as the product is for use in cats, which are not food-producing animals, and which do not produce any major Australian export commodities.

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 **molidustat sodium** 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 **Varenzin Oral Suspension 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 public submission coversheet).

Please lodge your submission with a public submission coversheet, 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 10: 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
Treidlia Biovet Pty Ltd	1096	150 496 138	Unit 76 Power Business Park, 45 Powers Road Seven Hills NSW 2147	Category 1: Immunobiologicals	Quality assurance (QA) of raw materials, bacterial fermentation, fungal fermentation, wart tissue extraction, pilot scale affinity chromatography, formulation including blending, aseptic filling, packaging, labelling, sterilisation (chemical, filtration, and heat), microbiological reduction treatment (chemical, filtration, and heat), analysis and testing (chemical, microbiological, physical, protein biochemistry, serological, sterility testing, vaccine safety testing), storage, and release for supply.	31 July 2025
Vetafarm Manufacturing Pty Ltd	2239	152 427 453	50 Webb Street Bomen NSW 2650	Category 2: Tablets, bolus, gels, powders, liquids Category 3: liquids and sprays	Quality assurance (QA) of raw materials, formulation including blending, filling, granulation, dry milling, tableting, packaging, secondary packaging, repackaging, labelling, secondary labelling, relabelling, analysis and testing (chemical, physical and antibiotic assay), storage, and release for supply.	4 November 2025
Australian Laboratory Services Pty Ltd	6181	009 936 029	22 Dalmore Drive Scoresby VIC 3179	Category 6: All dosage forms	Analysis and testing (physical, chemical, microbiological, and endotoxin).	11 November 2025

Company name	Licence number	Company ACN	Address	Product types	Steps of manufacture	Date issued
Zoetis Australia Research & Manufacturing Pty Ltd	1098	158 433 053	45 Poplar Road Parkville VIC 3052	Category 1: Immunobiologicals, sterile products, subcutaneous implants, and dermal scratch	Quality assurance (QA) of raw materials, bacterial fermentation, virus cultivation, propagation of genetically modified mammalian cells, extraction and purification of viral protein, peptide conjugation, formulation including blending, aseptic filling, filling, packaging, labelling, sterilisation (heat, and filtration), microbiological reduction treatment (chemical, heat, and filtration), freeze drying, analysis and testing (physical, chemical, immunological, microbiological), secondary packaging, secondary labelling, repackaging, relabelling, storage, and release for supply.	3 December 2025
CBE Pure Solutions Pty Ltd	1126	651 336 640	5 William Street Ferntree Gully VIC 3156	Category 1: Sterile products for Injection (sterilsation by filtration and aseptic filling) Category 2: Gels, sprays, liquids (oral, topical), and suspensions	Quality assurance (QA) of raw materials, Formulation including blending, Sterilisation by filtration, Aseptic Filling, filling, analysis and testing (physical, microbiological, endotoxin testing, and sterility testing), packaging, labelling, repackaging, relabelling, storage, and release for supply.	5 December 2025
Troy Laboratories Pty Ltd	1092	000 283 769	37 Glendenning Road Glendenning NSW 2761	Category 1: Sterile products and terminally sterilised ointment Category 2: Tablets, creams / lotions, ointments, gels, pastes, sprays, suspensions and liquids Category 3: Liquids and sprays	Quality assurance (QA) of raw materials, formulation including blending, granulation, dry milling, wet milling, aseptic filling, filling, packaging, secondary packaging, labelling, secondary labelling, tableting, sterilisation (heat and filtration), microbiological reduction treatment (filtration and chemical), analysis and testing (physical, chemical, microbiological, and endotoxin), storage, and release for supply.	15 December 2025

Licence cancellations

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

Table 11: Licenses cancelled by the APVMA under subsection 127(1) of the Agvet Code

Company name	Licence number	Company ACN	Address	Date cancelled
Probiotec Multipack Pty Ltd	6229	100 109 019	22B Hanson Place Eastern Creek NSW 2766	26 November 2025
ABS (Aus) Pty Ltd	6226	633 680 065	18 Distribution Place Seven Hills NSW 2147	26 November 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: Bloat-Drench Oral Bloat Control

Product name: Bloat-Drench Oral Bloat Control

APVMA registration number: 38823

APVMA approved label number: 60429

Batch number: 25100140

Sold by: Victorian Chemical Company Pty Ltd in VIC, NSW, SA and TAS between 29 October 2025 to 18 December 2025.

On 18 December 2025, Victorian Chemical Company Pty Ltd (ACN 004 188 863) 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

Due to reports of bulging packaging observed in certain units.

Hazard

Bulging packaging may indicate microbial contamination or fermentation within the container, which can compromise the potency and safety of the product. Using a product with compromised integrity may result in:

- Reduced effectiveness of the treatment.
- Pose a safety hazard to handlers and to the animals.

What to do if in possession of this chemical product

- DO NOT use any containers of the above-mentioned batch.
- Please return the product to the place of purchase for a full refund.

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 agvet chemical recall notices on its website and provides a subscription option to be notified by email when a new recall notice is published.

Contact

Questions about this voluntary recall should be directed to:

Victorian Chemical Company Pty Ltd
Phone: 03 9301 7000
Email: agsales@vicchem.com