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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	8
Approved active constituents	13
New active constituent – Famoxadone.....	15
Application for registration of a new product, Zorvec Encantia Fungicide containing famoxadone and oxathiapiprolin	18
New veterinary chemical products containing a new veterinary active constituent	20
Agvet chemical voluntary recall: Neptra Otic Solution for Dogs	27
Agvet chemical voluntary recall: NITROFURAZONE CREAM ANTI-BACTERIAL CREAM FOR HORSES.....	28
Notice of cancellation at the request of the holder.....	29

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.	144368
Product name	Sanitiser Bromine Tabs
Active constituents	650 g/kg bromine present as bromo chloro dimethylhydantoin, 280 g/kg chlorine present as bromo chloro dimethylhydantoin
Applicant name	PoolPlus Aquatics Pty Ltd
Applicant ACN	658 882 823
Date of registration	10 September 2024
Product registration no.	94977
Label approval no.	94977/144368
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 650 g/kg available bromine and 280 g/kg available chlorine in a tablet formulation use to disinfect water and eliminate bacteria in spa pools, swimming pools, and hot tubs

Application no.	144307
Product name	ACP Rats Tail 745 Herbicide
Active constituent	745 g/L flupropanate present as the sodium salt
Applicant name	Australis Crop Protection Pty Ltd
Applicant ACN	150 711 185
Date of registration	10 September 2024
Product registration no.	94960
Label approval no.	94960/144307
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 745 g/L flupropanate present as the sodium salt, soluble concentrate product for a component of integrated management of serrated tussock, giant parramatta grass, giant rat's tail grass, Chilean needle grass, African lovegrass and certain grasses

Application no.	144465
Product name	Ozcrop Lambda-Cyhalothrin 250 CS Insecticide
Active constituent	250 g/L lambda-cyhalothrin
Applicant name	Oz Crop Pty Ltd
Applicant ACN	160 656 431
Date of registration	12 September 2024
Product registration no.	95018
Label approval no.	95018/144465
Description of the application and its purpose, including the intended use of the chemical product	Registration of a capsule suspension (CS) product containing 250 g/L lambda-cyhalothrin for the control of certain insect pests in cotton, barley, wheat and various field crops

Application no.	144440
Product name	TITAN Mesosulfuron 30 OD Herbicide
Active constituents	90 g/L mefenpyr-diethyl, 30 g/L mesosulfuron-methyl
Applicant name	Titan Ag Pty Ltd
Applicant ACN	122 081 574
Date of registration	16 September 2024
Product registration no.	95006
Label approval no.	95006/144440
Description of the application and its purpose, including the intended use of the chemical product	Registration of a mesosulfuron-methyl 30 g/L + mefenpyr-diethyl 90 g/L oil-based suspension concentrate (OD) product for the post-emergent control of wild oats and annual <i>Phalaris</i> , and suppression of brome grass, barley grass and annual ryegrass in wheat

Application no.	144492
Product name	Electra 900 SP Veriphy Insecticide
Active constituent	900 g/kg methomyl (an anti-cholinesterase compound)
Applicant name	ADAMA Australia Pty Limited
Applicant ACN	050 328 973
Date of registration	16 September 2024
Product registration no.	95026
Label approval no.	95026/144492
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 900 g/kg methomyl water soluble powder product for the control of insect pests in various crops

Application no.	144540
Product name	Take Control Conquer Moth Balls
Active constituent	990 g/kg naphthalene
Applicant name	Yatsal Distributors Pty Ltd
Applicant ACN	000 620 557
Date of registration	18 September 2024
Product registration no.	95044
Label approval no.	95044/144540
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 990 g/kg naphthalene slow-release generator product for household control of moths and silverfish

Application no.	144493
Product name	F.S.A. Paraquat + Diquat 250 Herbicide
Active constituents	135 g/L paraquat present as paraquat dichloride, 115 g/L diquat present as diquat dibromide monohydrate
Applicant name	Four Seasons Agribusiness Pty Ltd
Applicant ACN	115 133 189
Date of registration	19 September 2024
Product registration no.	95027
Label approval no.	95027/144493
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 135 g/L paraquat present as paraquat dichloride and 115 g/L diquat present as diquat dibromide monohydrate soluble concentrate formulation for the control of a wide range of grasses and broadleaf weeds

Table 2: Variations of registration – agricultural chemical products

Application no.	145193
Product name	Density WG Herbicide
Active constituent	400 g/kg tralkoxydim
Applicant name	Sipcam Pacific Australia Pty. Limited
Applicant ACN	073 176 888
Date of variation	27 August 2024
Product registration no.	59334
Label approval no.	59334/145193
Description of the application and its purpose, including the intended use of the chemical product	Variation to the safety directions appearing on a label to reflect the current FAISD handbook

Application no.	145251
Product name	Bird Fend Bird Deterrent
Active constituents	720 g/kg polybutene, 5.3 g/kg peppermint oil
Applicant name	Bird Free Australia Pty Ltd
Applicant ACN	622 083 470
Date of variation	5 September 2024
Product registration no.	85617
Label approval no.	85617/145251
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 'Bird Free Bird Deterrent' to 'Bird Fend Bird Deterrent'

Application no.	144444
Product name	Sinon Propyz 500 SC Herbicide
Active constituent	500 g/L propyzamide
Applicant name	Sinon Australia Pty Limited
Applicant ACN	102 741 024
Date of variation	11 September 2024
Product registration no.	94396
Label approval no.	94396/144444
Description of the application and its purpose, including the intended use of the chemical product	Variation to the registration particulars and the particulars of label, to add uses in winter grain legumes and to add additional restraints and withholding periods

Application no.	141931
Product name	Affirm Insecticide
Active constituent	17 g/L emamectin present as emamectin benzoate
Applicant name	Syngenta Australia Pty Ltd
Applicant ACN	002 933 717
Date of variation	12 September 2024
Product registration no.	51321
Label approval no.	51321/141931
Description of the application and its purpose, including the intended use of the chemical product	Variation to registration and label particulars to extend the use of 'Affirm Insecticide' to maize

Application no.	143716
Product name	Colex-D Herbicide
Active constituent	456 g/L 2,4-D present as the choline salt
Applicant name	Corteva Agriscience Australia Pty Ltd
Applicant ACN	003 771 659
Date of variation	16 September 2024
Product registration no.	91625
Label approval no.	91625/143716
Description of the application and its purpose, including the intended use of the chemical product	Variation to registration particulars, particulars of label, to amend buffer zones for optical spot spraying technologies

Application no.	144403
Product name	Nufarm Amicide Advance 700 Herbicide
Active constituent	700 g/L 2,4-D present as the dimethylamine and monomethylamine salts
Applicant name	Nufarm Australia Limited
Applicant ACN	004 377 780
Date of variation	18 September 2024
Product registration no.	66167
Label approval no.	66167/144403
Description of the application and its purpose, including the intended use of the chemical product	Variation of product registration and label approval to amend the statement of claims

Application no.	142092
Product name	Mortein Powergard The Expert's Cockroach Baits
Active constituent	3.3 g/kg indoxacarb (3:1) (equivalent to 2.5 g/kg active S-isomer)
Applicant name	RB (Hygiene Home) Australia Pty Ltd
Applicant ACN	629 549 506
Date of variation	19 September 2024
Product registration no.	68731
Label approval no.	68731/142092
Description of the application and its purpose, including the intended use of the chemical product	Variation of product registration and label approval to extend the duration of protection claim to 12 months

Application no.	142091
Product name	Mortein Kill & Protect Cockroach Baits
Active constituent	3.3 g/kg indoxacarb (3:1) (equivalent to 2.5 g/kg active S-isomer)
Applicant name	RB (Hygiene Home) Australia Pty Ltd
Applicant ACN	629 549 506
Date of variation	19 September 2024
Product registration no.	61000
Label approval no.	61000/142091
Description of the application and its purpose, including the intended use of the chemical product	Variation of product registration and label approval to extend the duration of protection claim to 12 months

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.	144024
Product name	VP Canine Allwormer Tablets for Dogs and Puppies
Active constituents	542 mg/tablet oxantel embonate, 143 mg/tablet pyrantel embonate, 50 mg/tablet praziquantel
Applicant name	Zoo Pets Pty Ltd
Applicant ACN	612 180 908
Date of registration	11 September 2024
Product registration no.	94912
Label approval no.	94912/144024
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 542 mg oxantel embonate, 143 mg pyrantel embonate, 50 mg praziquantel tablet product for the control of roundworm, hookworm, whipworm, tapeworm (including hydatid tapeworm) in dogs and puppies

Application no.	142391
Product name	Kato Alfaxalone Injection for Dogs and Cats
Active constituent	10 mg/mL alphaxalone
Applicant name	Kato Laboratories Pty Ltd
Applicant ACN	000 397 240
Date of registration	13 September 2024
Product registration no.	94421
Label approval no.	94421/142391
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 10 mg/mL alphaxalone parenteral solution product for use as an anaesthetic induction agent prior to gaseous anaesthesia, or as a sole anaesthetic agent for the induction and maintenance of anaesthesia for the performance of examination or surgical procedures in dogs and cats

Application no.	142362
Product name	Prasequine Oral Tablets
Active constituent	1 mg/tablet pergolide mesylate
Applicant name	Abbey Laboratories Pty Ltd
Applicant ACN	156 000 430
Date of registration	16 September 2024
Product registration no.	94407
Label approval no.	94407/142362
Description of the application and its purpose, including the intended use of the chemical product	Registration of 1 mg/tab pergolide mesylate tablet product for the control of clinical signs associated with Pituitary Pars Intermedia Dysfunction (PPID) (Equine Cushing's Disease) in horses and ponies

Application no.	143285
Product name	Meloxiway 40 mg/mL Injection
Active constituent	40 mg/mL meloxicam
Applicant name	Headway Investments Pty Ltd
Applicant ACN	655 095 855
Date of registration	18 September 2024
Product registration no.	94715
Label approval no.	94715/143285
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 40 mg/mL meloxicam parenteral solution product for use as a non-steroidal anti-inflammatory, analgesic, antipyretic in cattle

Application no.	143171
Product name	Levabamax Combination Pour-on for Cattle
Active constituents	10 g/L abamectin, 200 g/L levamisole
Applicant name	Nutrien Ag Solutions Limited
Applicant ACN	008 743 217
Date of registration	20 September 2024
Product registration no.	94680
Label approval no.	94680/143171
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 10 g/L abamectin, 200 g/L levamisole pour-on solution product for the treatment and control of roundworms, including macrocyclic lactones or levamisole resistant strains, and external parasites in cattle

Table 4: Variations of registration – veterinary chemical products

Application no.	143299
Product name	DIPA TIK Cattle Dip and Spray
Active constituent	500 g/kg amitraz
Applicant name	Nutrien Ag Solutions Limited
Applicant ACN	008 743 217
Date of variation	9 September 2024
Product registration no.	69649
Label approval no.	69649/143299
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 to remove reference under the claims of 'NSW only' and align the label with the current Veterinary Labelling Code

Application no.	143876
Product name	Romazine 20 Sedative, Analgesic and Muscle Relaxant for Cattle, Horses, Deer, Dogs and Cats
Active constituent	20 mg/mL xylazine (as the hydrochloride)
Applicant name	Ausrichter Pty Ltd
Applicant ACN	000 908 529
Date of variation	9 September 2024
Product registration no.	47524
Label approval no.	47524/143876
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 by updating the distinguishing name of the product, instructions of use on the label and aligning the label to the current Veterinary Labelling Code

Application no.	144397
Product name	Coxidin 400 Monensin Feed Additive
Active constituent	400 g/kg monensin (as monensin sodium)
Applicant name	Huvepharma EOOD
Applicant ACN	N/A
Date of variation	13 September 2024
Product registration no.	62232
Label approval no.	62232/144397
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 by updating and aligning the label to the current Veterinary Labelling Code

Application no.	144392
Product name	Profender Allwormer for Large Cats 5 to 8 kg
Active constituents	85.8 g/L praziquantel, 21.4 g/L emodepside
Applicant name	Vetoquinol Australia Pty Ltd
Applicant ACN	006 949 480
Date of variation	13 September 2024
Product registration no.	59155
Label approval no.	59155/144392
Description of the application and its purpose, including the intended use of the chemical product	Variation of the relevant particulars of product registration and label approved to align the label with the current Veterinary Labelling Code

Application no.	144393
Product name	Profender Allwormer for Medium Cats 2.5 to 5 kg
Active constituents	85.8 g/L praziquantel, 21.4 g/L emodepside
Applicant name	Vetoquinol Australia Pty Ltd
Applicant ACN	006 949 480
Date of variation	13 September 2024
Product registration no.	59154
Label approval no.	59154/144393
Description of the application and its purpose, including the intended use of the chemical product	Variation of the relevant particulars of the product registration and label approval to amend the product name and aligning the label with the current Veterinary Labelling Code

Application no.	144394
Product name	Profender Allwormer for Small Cats and Kittens 0.5 to 2.5 kg
Active constituents	85.8 g/L praziquantel, 21.4 g/L emodepside
Applicant name	Vetoquinol Australia Pty Ltd
Applicant ACN	006 949 480
Date of variation	13 September 2024
Product registration no.	59153
Label approval no.	59153/144394
Description of the application and its purpose, including the intended use of the chemical product	Variation of the relevant particulars of product registration and label approved to align the label with the current Veterinary Labelling Code

Application no.	144418
Product name	Sacox 120 Microgranulate
Active constituent	116.4 g/kg salinomycin (equivalent to 120 g/kg salinomycin sodium)
Applicant name	Huvepharma EOOD
Applicant ACN	N/A
Date of variation	17 September 2024
Product registration no.	47451
Label approval no.	47451/144418
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 by updating and aligning the label to the current Veterinary Labelling Code

Application no.	144464
Product name	Wagg & Purr Praziquantel Tablets
Active constituent	50 mg/tablet praziquantel
Applicant name	Avet Health Limited
Applicant ACN	616 838 101
Date of variation	17 September 2024
Product registration no.	93245
Label approval no.	93245/144464
Description of the application and its purpose, including the intended use of the chemical product	Variation to the relevant particulars of both the chemical product and label by including an additional 100 tablet pack size

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.	139842
Active constituent	Bacitracin zinc 15%
Applicant name	Phibro Animal Health Pty Limited
Applicant ACN	093 869 991
Date of approval	10 September 2024
Approval no.	93608
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent bacitracin zinc 15% for use in veterinary medicines

Application no.	141578
Active constituent	Fluxapyroxad
Applicant name	Hailir Pesticides and Chemicals Group Co., Ltd
Applicant ACN	N/A
Date of approval	11 September 2024
Approval no.	94117
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent fluxapyroxad for use in agricultural chemical products

Application no.	142743
Active constituent	Paclobutrazol
Applicant name	Jiangsu Sword Agrochemicals Co., Ltd
Applicant ACN	N/A
Date of approval	12 September 2024
Approval no.	94548
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent paclobutrazol for use in agricultural chemical products

Application no.	142867
Active constituent	Thiamethoxam
Applicant name	Syngenta Australia Pty Ltd
Applicant ACN	002 933 717
Date of approval	16 September 2024
Approval no.	94588
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent thiamethoxam for use in agricultural chemical products

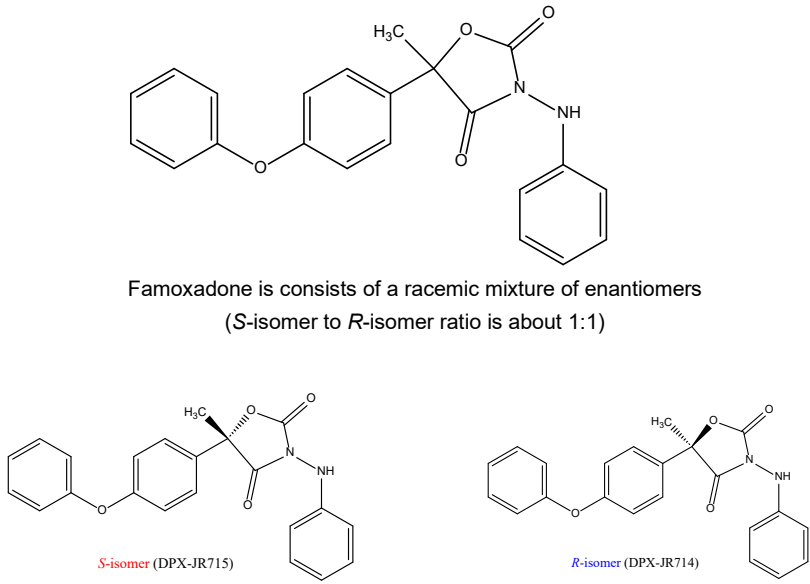
Application no.	143042
Active constituent	Fluopyram
Applicant name	Sinon Australia Pty Limited
Applicant ACN	102 741 024
Date of approval	18 September 2024
Approval no.	94632
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent fluopyram for use in agricultural chemical products

Table 6: Variations of active constituent

Application no.	144030
Active constituent	Clorsulon
Applicant name	Troy Laboratories Pty Ltd
Applicant ACN	000 283 769
Date of approval	13 September 2024
Approval no.	94916
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent clorsulon for use in veterinary chemical products

New active constituent – Famoxadone

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application for the approval of a new active constituent, famoxadone. Famoxadone is a fungicidal active constituent for the control of certain fungal diseases in leafy vegetables, including chard, chervil, chicory, corn salad, edible chrysanthemum, cosmos, endive, lettuce, orach, perilla leaves, spinach and rocket.

Common name:	Famoxadone
IUPAC name:	(<i>RS</i>)-3-Anilino-5-methyl-5-(4-phenoxyphenyl)-1,3-oxazolidine-2,4-dione
CAS name:	5-Methyl-5-(4-phenoxyphenyl)-3-(phenylamino)-2,4-oxazolidinedione
CAS registry numbers:	131807-57-3
Manufacturer's codes:	DPX-JE874
Minimum purity:	960 g/kg
Molecular formula:	C ₂₂ H ₁₈ N ₂ O ₄
Molecular weight:	374.4 g mol ⁻¹
Structure:	 <p>Famoxadone is consists of a racemic mixture of enantiomers (<i>S</i>-isomer to <i>R</i>-isomer ratio is about 1:1)</p> <p><i>S</i>-isomer (DPX-JR715)</p> <p><i>R</i>-isomer (DPX-JR714)</p>
Chemical family:	Oxazolidinedione fungicide
Mode of action:	Famoxadone is an oxazolidinedione fungicide belonging to the quinol inhibitor family, which inhibits mitochondrial respiration of fungi.

Summary of the APVMA's evaluation of famoxadone active constituent

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

The APVMA has completed a toxicological evaluation of famoxadone.

An Acceptable Daily Intake (ADI) of 0.006 mg/kg bw/d has been set, based on a No-Observed Effect Level (NOEL) of 1.2 mg/kg bw/d in both 90-day and 1-year dog studies, after applying a safety factor of 200. An Acute Reference Dose (ARfD) is not required based on the low acute toxicity, lack of evidence for any acute neurotoxicity and the absence of any other toxicologically relevant effect attributable to a single dose.

Famoxadone is included in **Schedule 6** of the Poisons Standard, with no exceptions or cut-offs.

The APVMA Health Assessment Team (HAT) considered the impurities in technical famoxadone and has determined that none of the impurities are of toxicological concern at the levels present. However, 4 impurities, benzene, phenylhydrazine, 1,5-diphenylcarbazine (2,2'-diphenylcarbonyl dihydrazide) and 1-acetyl-2-phenylhydrazine (acetic acid 2-phenylhydrazide) are of toxicological significance at levels higher than the maximum limits in the Declaration of Composition (DoC). In the absence of toxicologically determined maximum acceptable levels, it is proposed to include these impurities in the standard at the maximum levels specified in the DoC, to ensure visibility for future approvals of famoxadone.

The HAT has indicated that there are no objections on toxicological grounds to the approval of the active constituent famoxadone

The APVMA is satisfied that the proposed importation and use of famoxadone would not be an undue toxicological hazard to the safety of people exposed to it during its handling and use.

On the basis of the data provided, and the toxicological assessment, it is proposed that the following APVMA Active Constituent Standard be established for famoxadone:

Constituent	Specification	Level
Famoxadone	Famoxadone	960 g/kg minimum
	Benzene (CAS no. 71-43-2)	Maximum 50 mg/kg
	Phenylhydrazine (CAS no. 100-63-0)	Maximum 10 mg/kg
	1,5-Diphenylcarbazine (CAS no. 140-22-7)	Maximum 55 mg/kg
	1-Acetyl-2-phenylhydrazine (CAS no. 114-83-0)	Maximum 300 mg/kg

Further information

A Public Release Summary (PRS) of the evaluations of the active and the associated product is available from the APVMA website's 'Public Consultation' page, <https://apvma.gov.au/news-and-publications/public-consultations>.

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

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

When making a submission please include a:

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

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

Written submissions should be addressed in writing to:

Case Management and Administration Unit
Australian Pesticides and Veterinary Medicines Authority
PO Box 574
Canberra ACT 2601

Phone: +61 2 6770 2300

Email: enquiries@apvma.gov.au

Application for registration of a new product, Zorvec Encantia Fungicide containing famoxadone and oxathiapiprolin

The APVMA has before it an application for registration of a new product, Zorvec Encantia Fungicide, containing a new active constituent, Famoxadone.

Table 7: Particulars of the application

Proposed product name	Zorvec Encantia Fungicide
Applicant company	CORTEVA AGRISCIENCE AUSTRALIA PTY LTD
Name of active constituent	Famoxadone and oxathiapiprolin
Signal heading	Schedule 6
Summary of proposed use	For the control of downy mildew caused by <i>Peronospora spp.</i> in spinach and rocket
Pack sizes	1 to 20 L
Withholding period	Harvest (H): DO NOT harvest for 3 days after application Grazing (G): DO NOT graze or cut for stock food

A summary of the APVMA's evaluation of Zorvec Encantia Fungicide 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 Zorvec Encantia Fungicide would not be an undue hazard to the safety of people exposed to it during its handling and use.

The APVMA has conducted a risk assessment on the product and concluded that it can be used safely.
 - ii. The APVMA is satisfied that the proposed use of Zorvec Encantia Fungicide will not be an undue hazard to the safety of people using anything containing its residues.

The APVMA is satisfied that the proposed use of the new product Zorvec Encantia Fungicide containing the active constituents famoxadone and oxathiapiprolin, would not be likely to have an unintended effect that is harmful to animals, plants, or the environment.
- 2) The APVMA has evaluated the application and in its assessment in relation to whether the efficacy criteria have been met in accordance with the definition set out in section 5B of the Agvet Code, and proposes to determine that:
 - 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.
- 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:
 - ii. The APVMA is considering whether the proposed use of Zorvec Encantia Fungicide would not adversely affect trade between Australia and places outside Australia.

Further information

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

Making a submission

In accordance with section 13 of the Agvet Code, the APVMA invites any person to submit a relevant written submission as to whether Zorvec Encantia Fungicide 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.

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:

Case Management Team – Pesticides
Australian Pesticides and Veterinary Medicines Authority
PO Box 574
Canberra ACT 2601

Email: casemanagement@apvma.gov.au

Privacy

For information on how the APVMA manages personal information when you make a submission, see our [Privacy Policy](#)

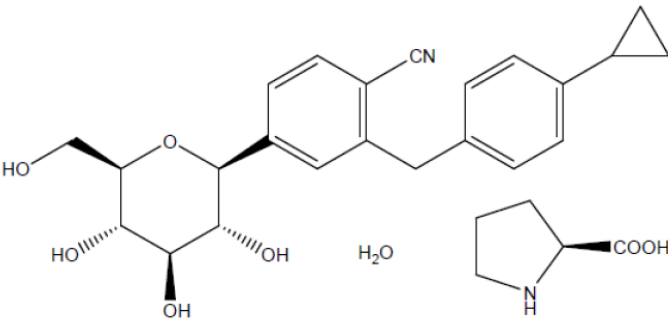
New veterinary chemical products containing a new veterinary active constituent

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application for the approval of a new active constituent, velagliflozin L-proline monohydrate, in conjunction with the registration of a new product, Senvelgo 15 mg/mL Oral Solution for Cats. Senvelgo 15 mg/mL Oral Solution for Cats is indicated for the reduction of hyperglycaemia and improvement in associated clinical signs in otherwise healthy cats with non-insulin-dependent diabetes mellitus.

Velagliflozin L-proline monohydrate

As part of the application to register Senvelgo 15 mg/mL Oral Solution for Cats, the APVMA has evaluated the safety of the new active constituent, velagliflozin L-proline monohydrate. Velagliflozin belongs to the sodium-glucose co-transporter 2 (SGLT2) inhibitor class of drugs that reduce renal glucose reabsorption, promote glucosuria, and consequently, decrease blood glucose.

Table 8: Particulars of the active constituent velagliflozin L-proline monohydrate

Common name	Velagliflozin L-proline monohydrate
IUPAC name	2-(4-(4-cyclopropylbenzyl)-4-((2S,3R,4R,5S,6R)-3,4,5-trihydroxy-6-hydroxymethyl-tetrahydropyran-2-yl)-benzonnitrile (S)-pyrrolidine-2-carboxylic acid monohydrate (velagliflozin L-proline monohydrate) 2-(4-(4-cyclopropylbenzyl)-4-((2S,3R,4R,5S,6R)-3,4,5-trihydroxy-6-hydroxymethyl-tetrahydropyran-2-yl)-benzonnitrile (velagliflozin)
CAS name	L-proline compound with 2-[(4-cyclopropylphenyl)methyl]-4-β-D-glucopyranosylbenzonnitrile hydrate (1:1:1)
CAS registry number	1661838-94-3 (velagliflozin L-proline monohydrate) 946525-65-1 (velagliflozin)
Purity	97.0-103.0% (as is) (velagliflozin L-proline monohydrate) 72.8-76.8% (velagliflozin)
Molecular formula	C ₂₈ H ₃₆ N ₂ O ₈ (C ₂₃ H ₂₅ NO ₅ · C ₅ H ₉ NO ₂ · H ₂ O)
Molecular weight	528.59 g/mol (velagliflozin L-proline monohydrate) 395.46 g/mol (velagliflozin)
Structure	
Mode of action	A sodium-glucose co-transporter 2 (SGLT2) inhibitor

Summary of the APVMA's evaluation of velagliflozin L-proline monohydrate active constituent

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

The APVMA has considered the toxicological aspects of velagliflozin, including the L-proline monohydrate, and concluded that there are no toxicological concerns regarding the approval of this active constituent. 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.

As a proposed prescription veterinary medicine, velagliflozin has been included in Schedule 4 of the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP). This entry covers the L-proline monohydrate form of velagliflozin.

The APVMA proposes to be satisfied under sections 5A(1)(a),(b) and (c) of the Agvet Code that velagliflozin L-proline monohydrate 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, or things, or to the environment.

Senvelgo 15 mg/mL Oral Solution for Cats containing velagliflozin L-proline monohydrate

In addition to the application to approve the new active constituent velagliflozin L-proline monohydrate, the APVMA has under consideration an application to register Senvelgo 15 mg/mL Oral Solution for Cats, containing 15 mg/mL velagliflozin present as velagliflozin L-proline monohydrate.

Table 9: Particulars of the product/s

Proposed product name/s	Senvelgo 15 mg/mL Oral Solution for Cats
Applicant company	Boehringer Ingelheim Animal Health Australia Pty. Ltd.
Name of active constituent	Velagliflozin present as velagliflozin L-proline monohydrate
Signal heading	Schedule 4
Summary of proposed use	For the reduction of hyperglycaemia and improvement in associated clinical signs in otherwise healthy cats with non-insulin dependent diabetes mellitus
Pack sizes	30 mL
Withholding period	n/a

A summary of the APVMA's evaluation of Senvelgo 15 mg/mL 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*:

- 4) 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 the proposed use of Senvelgo 15 mg/mL Oral Solution for Cats would not be an undue hazard to the safety of people exposed to it during its handling and use.
 - a. The product is intended to be used in a veterinary hospital/clinic or dispensed by veterinarians and used by cat owners at home. It will be administered orally to cats.
 - b. The data package comprised of acute oral toxicology studies on the active constituent and *in vivo* skin irritation and *in vitro* eye irritation studies on the formulated end-use product. The active constituent has low acute oral toxicity. The formulated end-use product is not a skin irritant but is a mild eye irritant.
 - c. The data package also included a series of safety pharmacology studies (single dose studies covering the major organ systems i.e., central nervous system (CNS), cardiovascular, respiratory, gastrointestinal, liver, and kidney); short-term oral toxicity studies in mice, rats and dogs; genotoxicity studies; and a reproductive toxicity/developmental toxicity study in rats. There was no indication of neurotoxicity. Results of the genotoxicity studies were negative.
 - d. Although velagliflozin is not registered for human use in Australia or internationally, there are extensive data in humans for other drugs of the same drug class. In a client-owned cat field trial, dermal user exposures were not associated with clinical signs, but 2 of 3 ocular exposures were associated with irritation. As a product to be used by owners at home, adult user exposure is expected to occur largely by the dermal route, with ocular and hand-to-mouth oral also possible. Access by children is unlikely because of the child-proof packaging; however worst-case scenarios exposure through unattended filled syringes was considered and determined to be acceptable.
 - e. To mitigate potential risks involving human exposure, the following signal headings, first aid instructions, and safety directions statements are to appear on the product label.

Poisons Standard and Signal Heading

Velagliflozin is a prescription medicine and is therefore covered by **Schedule 4** of the SUSMP. None of the other constituents in the formulation is captured by Scheduling. Senvelgo 15 mg/mL Oral Solution for Cats, will contain a Schedule 4 poison and thereby require '**PRESCRIPTION ANIMAL REMEDY**' and '**KEEP OUT OF REACH OF CHILDREN**' signal headers on the label.

First aid instructions (FAI)

'If poisoning occurs, contact a doctor or Poisons Information Centre. Phone Australia 131126; New Zealand 0800 764 766.'

Safety directions

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

The safety directions will be listed in the FAISD handbook - APVMA 2024 (Handbook of first aid instructions, safety directions, warning statements and general safety precautions for agricultural and veterinary chemicals) and will be required on the product label.

Additional user safety

The applicant proposed the following statement, which is acceptable:

'In case of experiencing any side effect, e.g., after accidental ingestion, or if skin or eye irritation occurs after accidental exposure, seek medical advice immediately and show this product information to the physician.'

Warning Statements

Not required.

Restraints/Restrictions

Not required.

Re-entry or Re-handling Statement

Not required.

- f. After consideration of the toxicological profile and likely human exposure associated with the use of *Senvelgo 15 mg/mL Oral Solution for Cats*, the APVMA concludes that the human health risks are acceptable according to the criteria stipulated in *Section 5A of the Agricultural and Veterinary Chemicals Code Act (1994 as amended)*, for the proposed administration methods, provided the recommendations are noted and where relevant, incorporated on the product label, as above.
- ii. The APVMA is satisfied that the proposed use of *Senvelgo 15 mg/mL Oral Solution for Cats*, containing the active constituent velagliflozin would not be likely to have an unintended effect that is harmful to **the environment**, if used according to the product label directions.
 - a. Environmental risks of *Senvelgo 15 mg/mL Oral Solution for Cats* were assessed according to the VICH Phase I decision tree. The assessment determined that the amount of velagliflozin 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.

- iii. The APVMA is satisfied that the proposed use of *Senvelgo 15 mg/mL Oral Solution for Cats*, containing the active constituent velagliflozin would not be likely to have an unintended effect that is harmful to animals if used according to the product label directions

Target Animal Safety was demonstrated using laboratory and field trials and supportive data:

- a. The submission provided a range of pharmacological studies, target animal safety (TAS) studies, dose confirmation studies, pilot and pivotal field studies.
 - b. The recommended dosage regimen is 1 mg/kg bodyweight administered orally once daily. Velagliflozin administered at 1 mg/kg, irrespective of formulation, generally appeared safe when assessed in a TAS study (at 1X, 3X and 5X recommended dose rates) or in a 90-day tolerance study. In the 90-day tolerance study in healthy cats evaluating repeated dose of 1, 3 and 5 mg/kg velagliflozin, a dose dependent softening of stool was observed.
 - c. In healthy 9-month-old adult cats exposed to repeated overdose of up to 5 times the highest recommended dose of 1 mg velagliflozin per kg bodyweight for 180 days, a reduced weight gain was noted. Water uptake was increased under treatment with velagliflozin. A transient increase of mean triglyceride and mean cholesterol values were noted in all treatment groups. Both remained within the respective reference range of historical controls in healthy animals and are of no clinical relevance.
 - d. In field studies, the following side effects were observed: diarrhoea, polydipsia or polyuria, weight loss, dehydration, vomiting, diabetic ketoacidosis and diabetic ketonuria. Most of these side effects are transient and resolved without specific therapy. The side effects statements will be included on the label.
 - e. However, velagliflozin has been determined to be not suitable for cats with evidence of diabetic ketoacidosis, diabetic ketonuria or severe dehydration requiring IV fluid supplementation. Therefore, the label will include contraindications statements for use in cats with diabetic ketoacidosis, diabetic ketonuria or severe dehydration, cats with confirmed insulin-dependent diabetes mellitus as well as in cases of hypersensitivity to velagliflozin.
 - f. The safety of the product has not been established during breeding, pregnancy and lactation. The safety of combined treatment or concurrent use with insulin or other blood glucose lowering treatments (excluding diet) and velagliflozin in cats has not been investigated. Due to the mode of action of insulin there is an increased risk for symptomatic hypoglycaemia, therefore combined treatment with insulin or other antidiabetics is not recommended. These statements will be placed on the label.
 - g. The APVMA has determined that *Senvelgo 15 mg/mL Oral Solution for Cats* is safe to use for the reduction in hyperglycaemia and improvement in associated clinical signs in otherwise healthy cats with non-insulin dependent diabetes mellitus, when used in accordance with the label directions.
- 2) The APVMA has evaluated the application, 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:
- iv. In relation to its assessment of efficacy the APVMA is satisfied that data from trials supporting the efficacy of the product adequately demonstrated that if used according to the product label directions, the product is effective for its proposed uses.
 - v. Efficacy of the product is supported by both product specific studies and published literature. The submission consisted of 7 pharmacological studies, 2 dose confirmation studies, 3 pilot and 3 pivotal field studies.
 - a. Velagliflozin is rapidly absorbed following oral administration.

- b. Based on the mode of action of SGLT-2 inhibitors (such as velagliflozin), adequate endogenous insulin production is a requirement for successful management of diabetes mellitus with this veterinary medicinal product. Therefore, it is determined that specific label instructions will be included to identify cats suitable for treatment start and treatment continuation, aiming to ensure that the treated cats benefit from monotherapy.
- vi. Dose confirmation studies investigated a range of dose rates (0.01, 0.1 and 1.0 mg/kg given orally daily) and showed a dose-dependent increase in maximum plasma concentration (C_{max}) and overall drug exposure (AUC), which corresponded to a dose-dependent increase in glucose concentrations in the urine. Field trial studies reported a higher percentage of cats treated with the proposed dose showed rapid and increased frequency of improvement in at least one clinical sign. Comparative studies with other diabetes treatment groups showed that there was improved overall control of diabetes and quality of life in the Senvelgo treated groups. All the studies submitted concluded that the recommended dose of 1 mg/kg body weight once daily was efficacious in reducing hyperglycaemia and hyperglycaemia-associated clinical signs in cats.
 - a. The efficacy of concurrent use with insulin or other blood glucose lowering treatments (excluding diet) and velagliflozin in cats has not been investigated. Due to the mode of action of insulin there is an increased risk for symptomatic hypoglycaemia, therefore combined treatment with insulin or other antidiabetics is not recommended.
 - b. The efficacy of the product has not been established in cats younger than one year of age.
 - c. The APVMA has determined that Senvelgo 15 mg/mL Oral Solution for Cats is efficacious to use for the reduction in hyperglycaemia and improvement in associated clinical signs in otherwise healthy cats with non-insulin dependent diabetes mellitus, when used in accordance with the label directions.
- 3) The APVMA has considered the application, 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:
 - vii. The intended use is in companion animals only (cats); therefore, no assessment of residues or trade is required. The APVMA is satisfied that the proposed use of Senvelgo 15 mg/mL Oral Solution for Cats would not adversely affect trade between Australia and places outside Australia as the product is not for use in animals producing 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 velagliflozin L-proline monohydrate 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 Senvelgo 15 mg/mL 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 [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:

Case Management
Australian Pesticides and Veterinary Medicines Authority
PO Box 574
Canberra ACT 2601

Email: casemanagement@apvma.gov.au

Privacy

For information on how the APVMA manages personal information when you make a submission, see our [Privacy Policy](#).

Agvet chemical voluntary recall: Neptra Otic Solution for Dogs

Product name: Neptra Otic Solution for Dogs

APVMA registration number: 87389

APVMA approved label number: 142806

Batch numbers: KV0529G and E124391A

Sold by: veterinary wholesalers nationally between 25 July 2023 to 19 September 2024.

On 24 September 2024, Elanco Australasia Pty Ltd (ABN 64 076 745 198) 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

There have been overseas reports of leaking product tubes, and the batches listed above have shown an out-of-specification result for unknown impurity or impurities related to the active constituent florfenicol. This defect appears to be occurring during the manufacture of the tube and resulting in the finished product, Neptra, coming in contact with the aluminium layer of the product tube.

Hazard

This is a low safety risk to users or animals to which the product is administered.

What to do if in possession of this chemical product

Do not use Neptra from the batches listed above. Contact your veterinary wholesaler to arrange return and credit for the product from affected batches. Wholesalers should immediately quarantine all the stock on hand of the recalled product and contact Elanco Australasia to arrange return and credit for the affected units. Neptra from batches other than those stated above can be used normally.

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:

Elanco Australasia

Phone: 1800 995 709

Agvet chemical voluntary recall: NITROFURAZONE CREAM ANTI-BACTERIAL CREAM FOR HORSES

Product name: NITROFURAZONE CREAM ANTI-BACTERIAL CREAM FOR HORSES

APVMA registration number: 56306

APVMA approved label number: 0304

Batch number: 019093

Sold by: veterinary wholesalers and retailers in NSW, QLD and Victoria between 18 September 2024 to 27 September 2024.

On 27 September 2024, RANVET PTY. LIMITED (ABN 001 606 033) 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

A low out of specification result was observed for Nitrofurazone.

Hazard

There is a low hazard with this recall. Product efficacy may be impacted.

What to do if in possession of this chemical product

Do not use Nitrofurazone cream from the batch 019093. Contact your veterinary wholesaler to arrange return and credit for the product from affected batch. Wholesalers should immediately quarantine all the stock on hand of the recalled product and contact Ranvet to arrange return and credit for the affected units.

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:

Ranvet Customer Service Team

Phone: 02 9549 6008

Email: Sheridan.Butler@ranvet.com.au

Notice of cancellation at the request of the holder

At the request of the holder, in accordance with section 42(1) of the *Agricultural and Veterinary Chemicals Code Act 1994* (Agvet Code), the APVMA has cancelled the approvals and/or registrations set out in Table 10:

Table 10: Active constituent approval/product registration/label approval cancelled at the request of the holder

Approval or registration number	Name	Type of approval or registration	Holder	Reason for cancellation (if relevant pursuant to s45A(3))	Date of cancellation
60099	Tri-Solfen Topical Anaesthetic & Antiseptic Solution For Pain Relief In Lambs And Calves	Product	Dechra Veterinary Products (Australia) Pty. Ltd.	Business reasons	19 September 2024
64104	Imbrex Fungicide	Product	BASF Australia Ltd.	Business reasons	19 September 2024
81799/106129	Goldguard Paste for Horses	Label	Randlab Australia Pty Ltd	Business reasons	19 September 2024
82742	Ulcergold Paste for Horses	Product	Ferrari Animal Health Pty Ltd	Business reasons	19 September 2024

In accordance with section 45A(1)(b) of the Agvet Code, the APVMA publishes this notice of the cancellation, including the following instructions which set out how a person can deal with the cancelled active constituent, cancelled product or product bearing a cancelled label referred to in Table 10.

Instructions

Instructions for persons who possess, have custody of or use the cancelled active constituent, cancelled product, or the product bearing a cancelled label under section 45B(3) of the Agvet Code.

A person who possesses, has custody of or uses the cancelled active constituent, cancelled product or product bearing a cancelled label referred to in Table 10 in accordance with the instructions contained in this notice, is taken to have been issued with a permit under section 45B(3) of the Agvet Code to possess, have custody of or use the cancelled active constituent, cancelled product or product bearing a cancelled label, in accordance with those instructions.

Possession or custody

A person may possess the cancelled active constituent, cancelled product or product bearing a cancelled label referred to in Table 10 in accordance with its label instructions for one year from the date of cancellation.

Use, supply or otherwise deal with

A person may use the cancelled active constituent, cancelled product or products bearing a cancelled label referred to in Table 10 according to its label instructions, including any conditions relating to shelf life or expiry date, for one year after the date of cancellation.

A person may supply or cause to be supplied at wholesale or retail level the cancelled active constituent, cancelled product, or product bearing a cancelled label referred to in Table 10, for one year after the date of cancellation.

Contraventions

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

It is an offence to possess, have custody of, use, or otherwise deal with the cancelled active constituents, cancelled products or products bearing the cancelled label listed in Table 10 in a manner that contravenes the above instructions.

APVMA contact

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

Chemical Review
Australian Pesticides and Veterinary Medicines Authority
PO Box 574
Canberra ACT 2601

Phone: +61 2 6770 2400

Email: chemicalreview@apvma.gov.au

More information

The APVMA publishes a list of [voluntary cancellations at the request of the holder](#) on its website, and provides a [subscription option](#) to be notified by email when the list is updated.