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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.

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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.	141566
Product name	Imtrade Tebuthiuron 200 GR Herbicide
Active constituent	200 g/kg tebuthiuron
Applicant name	Imtrade Australia Pty Ltd
Applicant ACN	090 151 134
Date of registration	2 January 2024
Product registration no.	94112
Label approval no.	94112/141566
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 200 g/kg tebuthiuron granular formulation product for control of brigalow regrowth, tea tree regrowth, <i>Mimosa pigra</i> and certain problem woody weeds on grazing lands by hand, aerial and ground application

Application no.	141841
Product name	F.S.A. Paraquat 360 Herbicide
Active constituent	360 g/L paraquat (present as paraquat dichloride)
Applicant name	Four Seasons Agribusiness Pty Ltd
Applicant ACN	115 133 189
Date of registration	5 January 2024
Product registration no.	94216
Label approval no.	94216/141841
Description of the application and its purpose, including the intended use of the chemical product	Registration of a soluble concentrate (SL) product containing 360 g/L paraquat (present as paraquat dichloride) for the control of a wide range of grasses and broadleaf weeds

Application no.	141812
Product name	Swan Pyroxasulfone 850 WG Herbicide
Active constituent	850 g/kg pyroxasulfone
Applicant name	Swan Chemical Holdings Pty Ltd
Applicant ACN	669 863 067
Date of registration	5 January 2024
Product registration no.	94202
Label approval no.	94202/141812
Description of the application and its purpose, including the intended use of the chemical product	Registration of a water dispersible granule (WG) product containing 850 g/kg pyroxasulfone for pre- emergence control of annual ryegrass, barley grass, annual phalaris, silver grass and toad rush and suppression of certain grass weeds in wheat (not durum wheat), triticale and certain winter legume crops

Application no.	141770
Product name	Sinchlora 350 WG Insecticide
Active constituent	350 g/kg chlorantraniliprole
Applicant name	Sinon Australia Pty Ltd
Applicant ACN	102 741 024
Date of registration	5 January 2024
Product registration no.	94180
Label approval no.	94180/141770
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 350 g/kg chlorantraniliprole water dispersible granule product for the control of Lepidopteran species of insect pests in pulse crops

Application no.	139025
Product name	Conquest Bromo 400 EC Selective Herbicide
Active constituent	400 g/L bromoxynil (present as the n-octanoyl ester)
Applicant name	Conquest Crop Protection Pty Ltd
Applicant ACN	098 814 932
Date of registration	9 January 2024
Product registration no.	93415
Label approval no.	93415/139025
Description of the application and its purpose, including the intended use of the chemical product	Registration of a bromoxynil 400 g/L emulsifiable concentrate for the control of broadleaf weeds in wheat, oats, barley, cereal rye and triticale, fallow, non-crop, roadsides, and rights-of-way

Application no.	141676
Product name	Smart Azure 500 Fungicide
Active constituent	500 g/L flutriafol
Applicant name	Crop Smart Pty Ltd
Applicant ACN	093 927 961
Date of registration	9 January 2024
Product registration no.	94139
Label approval no.	94139/141676
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 500 g/L suspension concentrate formulation of flutriafol for control of certain fungal diseases on wheat, barley, and canola when mixed with fertiliser

Application no.	141718
Product name	Benuron 750 WG Herbicide
Active constituent	750 g/kg tribenuron-methyl
Applicant name	Sinon Australia Pty Ltd
Applicant ACN	102 741 024
Date of registration	10 January 2024
Product registration no.	94160
Label approval no.	94160/141718
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 750 g/kg water dispersible granule formulation of tribenuron-methyl for the control of certain broadleaf weeds in fallows and pre-crop situations

Application no.	141817
Product name	Water TechniX Stabilised Chlorine Shock
Active constituent	560 g/kg available chlorine (CI) (present as sodium dichloroisocyanurate)
Applicant name	Mr Pool Man Pty Ltd
Applicant CAN	600 015 647
Date of registration	11 January 2024
Product registration no.	94206
Label approval no.	94206/141817
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 560 g/kg available chlorine (CI) (present as sodium dichloroisocyanurate) granular product for the control of bacteria, viruses, and algae in swimming pools

Application no.	141716
Product name	Agro-Essence Brom-DFF Herbicide
Active constituents	250 g/L bromoxynil (present as the octanoate, 25 g/L diflufenican)
Applicant name	Agro-Alliance (Australia) Pty Ltd
Applicant ACN	130 864 603
Date of registration	11 January 2024
Product registration no.	94158
Label approval no.	94158/141716
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 250 g/L bromoxynil, (present as the octanoate and 25 g/L diflufenican) emulsifiable concentrate (EC) formulation for the control of certain broadleaf weeds in winter cereals and pasture

Application no.	140210
Product name	McGregor's Weed Out Protect
Active constituents	10 g/kg pendimethalin and 7.5 g/kg dimethenamid-P
Applicant name	BASF Australia Ltd.
Applicant ACN	008 437 867
Date of registration	12 January 2024
Product registration no.	93696
Label approval no.	93696/140210
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 10 g/kg pendimethalin and 7.5 g/kg dimethenamid-P granule (GR) product for use in the home garden for the control of pre-emergent weeds in ornamentals and turf

Table 2: Variations of registration – agricultural chemical products

Application no.	140963
Product name	Titan Azoxystrobin 250SC Fungicide
Active constituent	250 g/L azoxystrobin
Applicant name	Titan Ag Pty Ltd
Applicant ACN	122 081 574
Date of variation	9 January 2024
Product registration no.	67421
Label approval no.	67421/140963
Description of the application and its purpose, including the intended use of the chemical product	Variation to the particulars of registrations and label approval to add uses in wheat, barley, and oats

Application no.	Not applicable – variation by the APVMA under s 29A of the Agvet Code
Product name	Accensi Diazinon 800 Insecticide
Active constituent	800 g/L diazinon
Applicant name	Accensi Pty Ltd
Applicant ACN	079 875 184
Date of variation	10 January 2024
Product registration no.	68534
Description of the application and its purpose, including the intended use of the chemical product	Variation of formulation type from liquid concentrate (LC) to emulsifiable concentrate (EC)

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.	141084
Product name	Elevet+ Deslorelin Injection
Active constituent	1.25 mg/mL deslorelin (as deslorelin acetate)
Applicant name	Avet Health Limited
Applicant ACN	616 838 101
Date of registration	2 January 2024
Product registration no.	93963
Label approval no.	93963/141084
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 1.25 mg/mL deslorelin (as deslorelin acetate) parenteral solution product for the induction of ovulation in mares

Application no.	141969
Product name	Troy Oxytet-200 mg/mL Long-acting Broad-spectrum Antibiotic Injection
Active constituent	200 mg/mL oxytetracycline (as the dihydrate)
Applicant name	Troy Laboratories Pty Ltd
Applicant ACN	000 283 769
Date of registration	4 January 2024
Product registration no.	94277
Label approval no.	94277/141969
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 200 mg/mL oxytetracycline injection to treat conditions caused by, or associated with, oxytetracycline-sensitive organisms and infections in cattle, sheep and pigs

Application no.	138019
Product name	Coxi-Stat Feed Additive for Poultry
Active constituents	250 g/kg amprolium hydrochloride and 16 g/kg ethopabate
Applicant name	Abbey Laboratories Pty Ltd
Applicant ACN	156 000 430
Date of registration	8 January 2024
Product registration no.	93118
Label approval no.	93118/138019
Description of the application and its purpose, including the intended use of the chemical product	Registration of 250 g/kg amprolium hydrochloride and 16 g/kg ethopabate powder product for oral administration for the treatment and aid in prevention of coccidiosis in poultry. A combination preparation designed for the control of important Eimeria species, namely E. tenella, E. acervulina, E. maxima and E. brunetti

Table 4: Variations of registration – veterinary chemical products

Application no.	142471
Product name	Troy Oxytet-200 L.A. Long-acting Broad-spectrum Antibiotic Injection
Active constituent	200 mg/mL oxytetracycline (as the base)
Applicant name	Troy Laboratories Pty Ltd
Applicant ACN	000 283 769
Date of variation	9 January 2024
Product registration no.	40057
Label approval no.	40057/142471
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 'Ilium Oxytet-200 L.A. Long-Acting Broad-Spectrum Antibiotic Injection' to 'Troy Oxytet-200 L.A. Long-Acting Broad-Spectrum Antibiotic Injection'

Application no.	142470
Product name	Ilium Oxytet-200 mg/mL Long-Acting Broad-Spectrum Antibiotic Injection
Active constituent	200 mg/mL oxytetracycline (as the dihydrate)
Applicant name	Troy Laboratories Pty Ltd
Applicant ACN	000 283 769
Date of variation	9 January 2024
Product registration no.	94277
Label approval no.	94277/142470
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 'Troy Oxytet-200 mg/mL Long-Acting Broad-Spectrum Antibiotic Injection' to 'Ilium Oxytet-200 mg/mL Long-Acting Broad-Spectrum Antibiotic Injection'

Application no.	141201
Product name	Tylomix 100 Tylosin Tartrate Premix
Active constituent	100 g/kg tylosin (as the tartrate)
Applicant name	Abbey Laboratories Pty Ltd
Applicant ACN	156 000 430
Date of variation	11 January 2024
Product registration no.	53703
Label approval no.	53703/141201
Description of the application and its purpose, including the intended use of the chemical product	Variation to the relevant particulars of the product and label by changing the instructions of use to align the label with the current Veterinary Labelling Code

Application no.	141758
Product name	Felpreva Spot-on Solution for Small Cats 1.0 to 2.5 kg
Active constituents	36.22 mg/pipette tigolaner, 30.12 mg/pipette praziquantel and 7.53 mg/pipette emodepside
Applicant name	Vetoquinol Australia Pty Ltd
Applicant ACN	006 949 480
Date of variation	12 January 2024
Product registration no.	91768
Label approval no.	91768/141758
Description of the application and its purpose, including the intended use of the chemical product	Variation of the relevant particulars of the registration and of the label to amend the label short claim

Application no.	141769
Product name	Felpreva Spot-On Solution for Medium Cats 2.5 to 5 kg
Active constituents	72.4 mg/pipette tigolaner, 60.24 mg/pipette praziquantel and 15.06 mg/pipette emodepside
Applicant name	Vetoquinol Australia Pty Ltd
Applicant ACN	006 949 480
Date of variation	12 January 2024
Product registration no.	91769
Label approval no.	91769/141769
Description of the application and its purpose, including the intended use of the chemical product	Variation of the relevant particulars of the registration and of the label to amend the label short claim

Application no.	141772
Product name	Felpreva Spot-On Solution for Large Cats 5 to 8 kg
Active constituents	115.52 mg/pipette tigolaner, 96.05 mg/pipette praziquantel and 24.01 mg/pipette emodepside
Applicant name	Vetoquinol Australia Pty Ltd
Applicant ACN	006 949 480
Date of variation	12 January 2024
Product registration no.	91770
Label approval no.	91770/141772
Description of the application and its purpose, including the intended use of the chemical product	Variation of the relevant particulars of the registration and of the label to amend the label short claim

Application no.	142056
Product name	Tilmicabs AC (Tilmicosin Phosphate) Aqueous Concentrate
Active constituent	250 mg/mL tilmicosin (as tilmicosin phosphate)
Applicant name	Abbey Laboratories Pty Ltd
Applicant ACN	156 000 430
Date of variation	12 January 2024
Product registration no.	69566
Label approval no.	69566/142056
Description of the application and its purpose, including the intended use of the chemical product	Variation to the relevant particulars of the product and label by changing the instructions of use to align the label with the current Veterinary Labelling Code

Table 5: Label approval – veterinary chemical products

Application no.	141935
Product name	Equacare Ice-cool Gel For Horses And Dogs
Active constituent/s	350 mg/g isopropyl alcohol, 20 mg/g menthol and 6.25 mg/g camphor
Applicant name	Equacare Pty Ltd
Applicant ACN	650 408 861
Date of registration	12 January 2024
Product registration no.	92831
Label approval no.	92831/141935
Description of the application and its purpose, including the intended use of the chemical product	Approve a new label for the registered product 'EquaCare Ice-Cool Gel for Horses and Dogs' with the label name 'Horseland Muscle Gel for Horses and Dogs'

Approved active constituents

Pursuant to the Agricultural and Veterinary Chemicals Code scheduled to the Agricultural and Veterinary Chemicals Code Act 1994, the APVMA hereby gives notice that it has approved or varied the relevant particulars or conditions of the approval of the following active constituents, with effect from the dates shown.

Table 6: Approved active constituents

Application no.	140258
Active constituent	Trifluralin
Applicant name	Shandong Exceris Chemical Co., Ltd
Applicant ACN	N/A
Date of approval	9 January 2024
Approval no.	93721
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent trifluralin for use in agricultural chemical products

Application no.	139769
Active constituent	Maropitant
Applicant name	Virbac (Australia) Pty Ltd
Applicant ACN	003 268 871
Date of approval	10 January 2024
Approval no.	93579
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.	140592
Active constituent	Propofol
Applicant name	Headway Investments Pty Ltd
Applicant ACN	655 095 855
Date of approval	11 January 2024
Approval no.	93825
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent propofol for use in veterinary chemical products

Application no.	140743
Active constituent	Grapiprant
Applicant name	Elanco Australasia Pty Ltd
Applicant ACN	076 745 198
Date of approval	11 January 2024
Approval no.	93870
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent grapiprant for use in veterinary chemical products

Application no.	141598
Active constituent	Apramycin sulphate
Applicant name	Abbey Laboratories Pty Ltd
Applicant ACN	156 000 430
Date of approval	12 January 2024
Approval no.	94125
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent apramycin sulphate for use in veterinary chemical products

Table 7: Variations of active constituent

Application no.	141724
Active constituent	Pyrantel embonate
Applicant name	Vetoquinol Australia Pty Ltd
Applicant ACN	006 949 480
Date of variation	5 January 2024
Approval no.	84280
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.	141573
Active constituent	Febantel
Applicant name	Vetoquinol Australia Pty Ltd
Applicant ACN	006 949 480
Date of variation	11 January 2024
Approval no.	55169
Description of the application and its purpose, including the intended use of the active constituent	Variation to add manufacturing sites for the existing approval

New active constituent – glufosinate-P-ammonium

The APVMA has before it an application for the approval of a new active constituent, glufosinate-P-ammonium.

Table 8: Particulars of the active constituent, glufosinate-P-ammonium

Common name	Glufosinate-P-ammonium		
IUPAC name	Ammonium [(3S)-3-amino-3-carboxypropyl] methylphosphinate		
CAS name	(2S)-2-amino-4-(hydroxymethylphosphinyl) butanoic acid ammonium salt (1:1)		
CAS registry number	73777-50-1		
Manufacturer's codes	BAS 1010 H, 6104428		
Minimum purity	880 g/kg		
Molecular formula	$C_5H_{15}N_2O_4P$		
Molecular weight	198.1 g/mol		
Structure	HO S O O NH ₂ NH ₄		
Chemical family	Phosphonic acid		
Mode of action	Non-selective, contact herbicide with some systemic activity, translocated only within leaves, primarily from the leaf base to the leaf tip.		

Summary of the APVMA's evaluation of glufosinate-P-ammonium active constituent

The APVMA has evaluated the chemistry aspects of glufosinate-P-ammonium active constituent (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 completed a toxicological evaluation of glufosinate-P-ammonium. An acceptable daily intake (ADI) for glufosinate-ammonium as the racemate or S-enantiomer (i.e., glufosinate-P-ammonium) of 0.01 mg/kg bw/d has been set. This is based on a No-Observed Effect Level (NOAEL) of 1 mg/kg bw/d in a capsule study in dogs, after applying a safety factor of 100. An Acute Reference Dose (ARfD) for glufosinate-ammonium as the racemate or S-enantiomer (i.e., glufosinate-P-ammonium) of 0.01 mg/kg bw has been set based on a NOAEL of 1 mg/kg bw/d in a capsule study in dogs.

Based on the information available, there is potential for trace quantities of cyanide to be present in technical glufosinate-P-ammonium. It is proposed therefore to include a maximum limit of 10 mg/kg for cyanide in the standard for glufosinate-P-ammonium.

Glufosinate-P-ammonium is the L isomer of glufosinate-ammonium which is included in Schedule 5 of the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP). No amendments are required for the SUSMP.

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

Table 9: Proposed APVMA Active Constituent Standard for glufosinate-P-ammonium

Constituent	Parameter	Specification
Glufosinate-P-ammonium	Purity	880 g/kg minimum
Cyanide	Toxicologically significant impurity	10 mg/kg maximum

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

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

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

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

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

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

Email: enquiries@apvma.gov.au

Post:

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

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