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Gazette

Agricultural and veterinary chemicals

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The Agricultural and Veterinary Chemical Code Act 1994 (the Act) commenced on 15 March 1995. The Agricultural and Veterinary Chemicals Code (the Agvet Code) scheduled to the Act requires notices to be published in the Gazette containing details of the registration of agricultural and veterinary chemical products and other approvals granted by the Australian Pesticides and Veterinary Medicines Authority. The Agvet Code and related legislation also requires certain other notices to be published in the Gazette. A reference to Agvet Codes in this publication is a reference to the Agvet Code in each state and territory jurisdiction.

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General information

The APVMA Gazette is published fortnightly and contains details of the registration of agricultural and veterinary chemicals products and other approvals granted by the APVMA, notices as required by the Agricultural and Veterinary Chemicals Code (the Agvet Code) and related legislation and a range of regulatory material issued by the APVMA.

Pursuant to section 8J(1) of the Agvet Code, the APVMA has decided that it is unnecessary to publish details of applications made for the purpose of notifying minor variations to registration details. The APVMA will however report notifications activity in quarterly statistical reports.

Distribution and subscription

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

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APVMA contacts

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For enquiries on APVMA Gazette content, please refer to the individual APVMA contacts listed under each notice.

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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 new active constituents

Application no.	126101
Product name	Soleto 500 SC Herbicide
Active constituent/s	500 g/L metobromuron
Applicant name	Belchim Crop Protection NV
Applicant ACN	N/A
Date of registration	20 June 2022
Product registration no.	89790
Label approval no.	89790/126101
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 500 g/L metobromuron suspension concentrate product for use as a pre-emergence herbicide for the control of annual broad-leaved weeds and annual grasses in potatoes

Table 2: Variations of registration

Application no.	135738
Product name	Vacsol BT100 Timber Insecticide
Active constituent/s	100 g/L bifenthrin
Applicant name	Arch Wood Protection (Australia) Pty Ltd
Applicant ACN	003 780 872
Date of variation	6 June 2022
Product registration no.	56896
Label approval no.	56896/135738
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 'Permatek BT 100 Timber Insecticide' to 'Vacsol BT100 Timber Insecticide'

Application no.	135739
Product name	Unirane 400 Herbicide
Active constituent/s	400 g/L fluroxypyr present as the methylheptyl ester
Applicant name	UPL Australia Pty Ltd
Applicant ACN	066 391 384
Date of variation	6 June 2022
Product registration no.	86422
Label approval no.	86422/135739
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 update the first aid instructions and safety directions appearing on a label to reflect the current FAISD Handbook

Application no.	135760
Product name	Zeemil 50G Systemic Granular Fungicide
Active constituent/s	50 g/kg metalaxyl
Applicant name	UPL Australia Pty Ltd
Applicant ACN	066 391 384
Date of variation	7 June 2022
Product registration no.	50433
Label approval no.	50433/135760
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 update the first aid instructions and safety directions appearing on a label to reflect the current FAISD Handbook

Application no.	135773
Product name	Agrisul 800 WG Fungicide and Miticide
Active constituent/s	800 g/kg sulphur (S) wettable powder
Applicant name	Agro Life Science Corporation
Applicant ACN	N/A
Date of variation	8 June 2022
Product registration no.	80817
Label approval no.	80817/135773
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 'NovaGuard Sulphur 800 WG Fungicide and Miticide' to 'Agrisul 800 WG Fungicide and Miticide'

Application no.	135774
Product name	Tubo 430 SC Fungicide
Active constituent/s	430 g/L tebuconazole
Applicant name	Agro Life Science Corporation
Applicant ACN	N/A
Date of variation	8 June 2022
Product registration no.	68217
Label approval no.	68217/135774
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 'Novaguard Tebuconazole 430 SC Fungicide' to 'Tubo 430 SC Fungicide'

Application no.	135806
Product name	Microthiol Disperss Wettable Sulphur Fungicide, Miticide And Insecticide
Active constituent	800 g/kg sulphur
Applicant name	UPL Australia Pty Ltd
Applicant ACN	066 391 384
Date of variation	10 June 2022
Product registration no.	51784
Label approval no.	51784/135806
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 update the first aid instructions appearing on a label to reflect the current FAISD Handbook

Application no.	135816
Product name	Zeemil Plus Systemic Fungicide
Active constituents	350 g/kg copper (Cu) present as copper oxychloride 150 g/kg metalaxyl
Applicant name	UPL Australia Pty Ltd
Applicant ACN	066 391 384
Date of variation	14 June 2022
Product registration no.	50429
Label approval no.	50429/135816
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 update the first aid instructions and safety directions appearing on a label to reflect the current FAISD Handbook

Application no.	135836
Product name	Fist HydroCap Herbicide
Active constituent	456 g/L pendimethalin
Applicant name	UPL Australia Pty Ltd
Applicant ACN	066 391 384
Date of variation	17 June 2022
Product registration no.	80856
Label approval no.	80856/135836
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 update the first aid instructions appearing on a label to reflect the current FAISD Handbook

Application no.	135000
Product name	Imtrade Tyranex 500 VeripHy SL Insecticide
Active constituent	500 g/L trichlorfon (an anticholinesterase compound)
Applicant name	Imtrade Australia Pty Ltd
Applicant ACN	090 151 134
Date of variation	20 June 2022
Product registration no.	87790
Label approval no.	87790/135000
Description of the application and its purpose, including the intended use of the chemical product	Variation to the particulars of product registration and label approval, to amend the registered product name, update the product formulation, update the pack size range, update the label storage and disposal instructions and first aid instructions

Application no.	132825
Product name	Specticle Herbicide
Active constituent	200 g/L indaziflam
Applicant name	Bayer CropScience Pty Ltd
Applicant ACN	000 226 022
Date of variation	20 June 2022
Product registration no.	64673
Label approval no.	64673/132825
Description of the application and its purpose, including the intended use of the chemical product	Variation to the particulars of registration and label approval to add a smaller minimum pack size

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.	134736
Product name	YP Tiamulin Soluble Liquid
Active constituent/s	101.2 g/L tiamulin (as tiamulin hydrogen fumarate)
Applicant name	South Yarra Pharma Pty Ltd
Applicant ACN	629 173 351
Date of registration	7 June 2022
Product registration no.	92169
Label approval no.	92169/134736
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 125 g/L tiamulin hydrogen fumarate liquid solution oral product for treatment of swine dysentery, swine enzootic pneumonia and chronic respiratory disease in non-laying chickens

Application no.	134835
Product name	Tylo-T 800 g/kg Soluble Antibiotic Powder
Active constituent/s	800 mg/g tylosin as tartrate
Applicant name	Probus Pharmaceuticals Pty Ltd
Applicant ACN	638 193 674
Date of registration	8 June 2022
Product registration no.	92203
Label approval no.	92203/134835
Description of the application and its purpose, including the intended use of the chemical product	Registration of an 800 mg/g tylosin as tartrate water soluble powder product to be used as an aid in the prevention and treatment of chronic respiratory disease in broilers and replacement chickens, infectious sinusitis in turkeys and swine dysentery in pigs

Application no.	134813
Product name	[Wagg & Purr] Pimobendan 5 mg Chewable Tablets For Dogs
Active constituent/s	5 mg/tablet pimobendan
Applicant name	Avet Health Pty Ltd
Applicant ACN	616 838 101
Date of registration	15 June 2022
Product registration no.	92196
Label approval no.	92196/134813
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 5 mg pimobendan chewable tablet product for the treatment of canine congestive heart failure (CHF) originating from dilated cardiomyopathy (DCM) or valvular insufficiency (mitral and/or tricuspid regurgitation), treatment of preclinical DCM in large breed dogs and treatment in dogs with evidence of increased heart size secondary to asymptomatic (preclinical) myxomatous mitral valve disease

Application no.	134575
Product name	ODB Injection
Active constituent/s	1 mg/mL oestradiol benzoate
Applicant name	Abbey Laboratories Pty Ltd
Applicant ACN	156 000 430
Date of registration	17 June 2022
Product registration no.	92123
Label approval no.	92123/134575
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 1 mg/mL oestradiol benzoate liquid solution injectable product for use to improve the precision of the onset of oestrus and maximise fertility in oestrous synchronisation programmes using an intravaginal insert containing progesterone in cycling cattle

Table 4: Variations of registration

Application no.	134446
Product name	Elanco AH0206 Tylan 200 Tylosin Injection 200 mg/mL
Active constituent/s	200 mg/mL tylosin
Applicant name	Elanco Australasia Pty Ltd
Applicant ACN	076 745 198
Date of variation	7 June 2022
Product registration no.	36796
Label approval no.	36796/134446
Description of the application and its purpose, including the intended use of the chemical product	Variation of the conditions of the label approval by aligning to the current Veterinary Labelling Code

Application no.	134573
Product name	Feliway Diffuser Analogue of Feline Facial Pheromone
Active constituent/s	16.5 mg/mL synthetic analogue of F3 fraction feline facial pheromone
Applicant name	Ceva Animal Health Pty Ltd
Applicant ACN	002 692 426
Date of variation	7 June 2022
Product registration no.	59157
Label approval no.	59157/134573
Description of the application and its purpose, including the intended use of the chemical product	Variation to the relevant particulars of the product and the label by amending the claims, and the relevant sections on the instructions of use of the product

Application no.	134768
Product name	Pharmachemical Maldison 50 Insecticide
Active constituent/s	500 g/L maldison
Applicant name	Bocko P/I & Flexsky P/I In Partnership
Applicant ACN	147 389 678
Date of variation	8 June 2022
Product registration no.	33021
Label approval no.	33021/134768
Description of the application and its purpose, including the intended use of the chemical product	Variation to the relevant particulars of the product and the label by removing the directions for control of flies and mosquitoes

Application no.	133088
Product name	Nobivac KC Continuum Vaccine
Active constituent/s	each single dose contains at least: 10 ^{8.0} CFU bordetella bronchiseptica (living, B-C2 strain) and 10 ^{4.0} TCID50 canine parainfluenza virus (living, cornell strain)
Applicant name	Intervet Australia Pty Ltd
Applicant ACN	008 467 034
Date of variation	9 June 2022
Product registration no.	59010
Label approval no.	59010/133088
Description of the application and its purpose, including the intended use of the chemical product	Variation of particulars of registration and label, for the addition of onset of immunity and concurrent use claims

Application no.	134492
Product name	Apex Carprofen 50 mg Tablets with Beef Flavouring
Active constituent/s	50 mg/tablet carprofen
Applicant name	Dechra Veterinary Products (Australia) Pty Ltd
Applicant ACN	614 716 700
Date of variation	14 June 2022
Product registration no.	63922
Label approval no.	63922/134492
Description of the application and its purpose, including the intended use of the chemical product	Variation to the relevant particulars of the product and the label by amending the precautions section of the label

Application no.	134515
Product name	Apex Carprofen 20 mg Tablets with Beef Flavouring
Active constituent/s	20 mg/tablet carprofen
Applicant name	Dechra Veterinary Products (Australia) Pty Ltd
Applicant ACN	614 716 700
Date of variation	15 June 2022
Product registration no.	63924
Label approval no.	63924/134515
Description of the application and its purpose, including the intended use of the chemical product	Variation to the relevant particulars of the product and the label by amending the precautions section of the label

Application no.	134517
Product name	Apex Carprofen 100 mg Tablets with Beef Flavouring
Active constituent/s	100 mg/tablet carprofen
Applicant name	Dechra Veterinary Products (Australia) Pty Ltd
Applicant ACN	614 716 700
Date of variation	15 June 2022
Product registration no.	63923
Label approval no.	63923/134517
Description of the application and its purpose, including the intended use of the chemical product	Variation to the relevant particulars of the product and the label by amending the precautions section of the label

Application no.	127482
Product name	Numocaine Injectable Pain Relief
Active constituent/s	17.2 mg/mL lignocaine (present as 20 mg/mL lignocaine hydrochloride)
Applicant name	Mavlab Pty Ltd
Applicant ACN	009 708 187
Date of variation	16 June 2022
Product registration no.	87460
Label approval no.	87460/127482
Description of the application and its purpose, including the intended use of the chemical product	Variation to the relevant particulars of a registered chemical product and label approval to change the scheduling of the lignocaine (lidocaine) from Schedule 4 to Schedule 5 when packaged in a container with a tamper resistant cartridge which can only be dispensed through a rubber ring applicator for tail docking and castration of lambs

Application no.	132333			
Product name	NV V.A.M. Injection			
Active constituent/s	0 mg/mL lysine-I hydrochloride, 15 mg/mL ammonium ferric citrate, 10 mg/mL vitamin b2= riboflavin, 0 µg/mL copper sulfate			
Applicant name	Ceva Animal Health Pty Ltd			
Applicant ACN	002 692 426			
Date of variation	16 June 2022			
Product registration no.	50147			
Label approval no.	50147/132333			
Description of the application and its purpose, including the intended use of the chemical product	Variation of chemical product registration and label approval particulars to include the intravenous (IV) injection administration in horses			

Application no.	134199			
Product name	Bravecto 500 mg Fluralaner Spot-on Solution for Large Cats			
Active constituent/s	80 mg/mL fluralaner			
Applicant name	Intervet Australia Pty Ltd			
Applicant ACN	008 467 034			
Date of variation	16 June 2022			
Product registration no.	82804			
Label approval no.	82804/134199			
Description of the application and its purpose, including the intended use of the chemical product	Variation to the relevant particulars of label by adding a side effects statement			

Application no.	134204				
Product name	Bravecto Plus Flea, Tick and Worm 500 mg Fluralaner and 25 mg Moxidectin Spot-on Solution for Large Cats				
Active constituent/s	80 mg/mL fluralaner, 14 mg/mL moxidectin				
Applicant name	Intervet Australia Pty Ltd				
Applicant ACN	008 467 034				
Date of variation	16 June 2022				
Product registration no.	85413				
Label approval no.	85413/134204				
Description of the application and its purpose, including the intended use of the chemical product	Variation to the relevant particulars of label to add a side effect statement				

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: Variations of active constituent

Application no.	133647
Active constituent/s	Sulfoxaflor
Applicant name	Corteva Agriscience Australia Pty Ltd
Applicant ACN	003 771 659
Date of variation	27 June 2022
Approval no.	89571
Description of the application and its purpose, including the intended use of the active constituent	Variation of relevant particulars or conditions of an approved active constituent

New active constituent: Calcined kaolin

The APVMA has before it an application for the approval of a new active constituent, calcined kaolin.

Table 6: Particulars of the active constituent

Common name	Calcined kaolin			
IUPAC name	Dialuminium(3+) [(trioxidosilyl)oxy]silanetris(olate)			
CAS name	N/A			
CAS registry number	92704-41-1			
Manufacturer's codes	M99SP1			
	Satintone® 5HB			
Minimum purity	995 g/kg			
Empirical formula	Al ₂ Si ₂ O ₇			
Molecular weight	N/A due to its 2-dimensional structure and covalent bonding			
Chemical family	N/A			
Mode of action	Physical barrier			

Summary of the APVMA's evaluation of calcined kaolin active constituent

The APVMA has evaluated the chemistry aspects of active constituent calcined kaolin (physico-chemical properties, stability, identification, spectra, 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 calcined kaolin and concluded that there are no toxicological concerns regarding the approval of this active constituent. An acceptable daily intake (ADI) and an acute reference dose (ARfD) was not considered necessary. Respirable crystalline silica has been identified as a toxicologically significant impurity in calcined kaolin technical active constituent. Therefore a maximum limit of 1 g/kg is included for this impurity in the APVMA standard.

Calcined kaolin is a derivative of kaolin and is therefore considered to be in Appendix B of the SUSMP.

On the basis of the data provided, and the toxicological assessment, it is proposed that the following active constituent standard be established for calcined kaolin:

Table 7: Proposed active constituent standard for calcined kaolin

Constituent	Specification	Level
Calcined kaolin	Calcined kaolin Respirable crystalline silica	995 g/kg minimum 1 g/kg maximum

Other compounds of toxicological significance are not expected to occur in calcined kaolin as a result of the raw materials and the synthetic route used.

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

Further information

A Public Release Summary (PRS) of the evaluation of this product is available from the <u>APVMA website</u> or from the contact listed below.

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 calcined kaolin 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

Privacy

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

Surround WP Crop Protectant containing calcined kaolin

The APVMA has before it an application for registration of a new product, Surround WP Crop Protectant, containing a new active constituent, calcined kaolin.

Table 8: Particulars of the application

Proposed product name	Surround WP Crop Protectant
Applicant company	Tessenderlo Kerley, Inc.
Name of active constituent	Calcined kaolin
Signal heading	Schedule 0 (Appendix B)
Summary of proposed use	For repellency of citrus gall wasp in citrus.
Pack sizes	12.5 kg
Withholding period	Not required when used as directed

A summary of the APVMA's evaluation of Surround WP Crop Protectant 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 Agyet Code, proposes to determine that:
 - i. The APVMA is satisfied that proposed use of Surround WP Crop Protectant 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 Surround WP Crop Protectant will not be an undue hazard to the safety of people using anything containing its residues.
 - iii. The APVMA is satisfied that the proposed use of the new product Surround WP Crop Protectant containing the active constituent calcined kaolin, 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:
 - 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:
 - i. The APVMA is satisfied that the proposed use of Surround WP Crop Protectant 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 <u>APVMA website</u> 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 Surround WP Crop Protectant should be registered. Submissions should relate only to matters that are required by the APVMA to be taken into consideration in determining whether the safety, efficacy or trade criteria have been met. Submissions should state the grounds on which they are based.

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

Relevant comments will be taken into account by the APVMA in deciding whether the product should be registered and in determining appropriate conditions of registration and product labelling.

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

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

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

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

Email: casemanagement@apvma.gov.au

Post:

Case Management Team – Pesticides
Australian Pesticides and Veterinary Medicines Authority
GPO Box 3262
Sydney NSW 2001

Privacy

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Licensing of veterinary chemical manufacturers

Pursuant to Part 8 of the Agricultural and Veterinary Chemicals Code (Agvet Code), scheduled to the *Agricultural and Veterinary Chemicals Code Act 1994*, the APVMA hereby gives notice that it has taken action with respect to the licensing of the following veterinary chemical manufacturers with effect from the dates shown.

For a comprehensive listing of all licensed manufacturers please see the APVMA website.

New licences

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

Table 9: New licences issued by the APVMA under subsection 123(1) of the Agvet Code

Company name	Licence number	Company ACN	Address	Product types	Steps of manufacture	Date issued
Australian Rickettsial Laboratory Foundation Limited	1121	103 665 621	CSIRO Australian Centre for Disease Preparedness 5 Portarlington Road Geelong VIC 3219	Category 1 (Immunobiologicals and sterile veterinary preparations) – Immunobiologicals	Quality assurance (QA) of raw materials, sterilisation (chemical), microbiological reduction treatment (chemical), analysis and testing (chemical, physical, microbiological, sterility testing, immunobiological, polymerase chain reaction (PCR)), propagation in eggs (egg inoculation, incubation and ultracentrifugation), antigen harvest, purification and inactivation, storage and release from manufacture	26 May 2022
Eimeria Pty Ltd	6157	075 153 472	University of Melbourne School of Veterinary Sciences Building 450–451 250 Princes Highway Werribee VIC 3030	Category 6 (Single-step manufacture) – Immunobiologicals	Analysis and testing (immunobiological)	26 May 2022

APVMA contact

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

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

^{*}Category 1: Immunobiologicals and sterile veterinary preparations

Category 2: Non-sterile veterinary preparations other than ectoparasiticides, premixes and supplements

Category 3: Ectoparasiticides

Category 4: Premixes and supplements

Category 5: Exempt

Category 6: Single-step manufacturer

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 s 45A(3))	Date of cancellation
59268/0305	Genfarm Proflex 500 Fungicide	Label approval	Nutrien Ag Solutions Limited	N/A	24 May 2022
82474	1-Methylcyclopropene	Active constituent approval	Decco Worldwide Post-Harvest Holdings, BV	N/A	26 May 2022
84620	1-Methylcyclopropene	Active constituent approval	Decco Worldwide Post-Harvest Holdings, BV	N/A	26 May 2022
56302	Sulfatroxazole	Active constituent approval	Boehringer Ingelheim Animal Health Australia Pty Ltd	N/A	27 May 2022
69208/60248	Apparent Procymidone 500 Fungicide	Label approval	Titan Ag Pty Ltd	N/A	30 May 2022
50883/605 50883/905	Sumitomo Sumisclex 500 Fungicide	Label approval	Sumitomo Chemical Australia Pty Ltd	N/A	1 June 2022
53963/605	Sumitomo Sumisclex Broadacre Fungicide	Label approval	Sumitomo Chemical Australia Pty Ltd	N/A	1 June 2022
54455/1004 54455/112804	Spiral Aquaflo Fungicide	Label approval	ADAMA Australia Pty Ltd	N/A	2 June 2022

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 12 months 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 12 months 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 12 months after the date of cancellation.

Contraventions

After the day that is 12 months 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 GPO Box 3262 Sydney NSW 2001

Phone: +61 2 6770 2400

Email: chemicalreview@apvma.gov.au

More information

The APVMA publishes a list of <u>voluntary cancellations at the request of the holder</u> on its website, and provides a subscription option to be notified by email when the list is updated.