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Gazette

**Agricultural and
Veterinary Chemicals**

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**Australian Pesticides and
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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 (Australian Pesticides and Veterinary Medicines Authority) 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](http://apvma.gov.au).

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APVMA CONTACTS

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For enquiries on the *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.

1. AGRICULTURAL PRODUCTS BASED ON NEW ACTIVE CONSTITUENTS

Application no.:	118313
Product name:	Good Riddance Tropical Insect Repellent
Active constituent/s:	12.2 g/L essential oil of <i>cymbopogon</i> spp, 9.4 g/L lemon tea tree oil
Applicant name:	Natural Wonders Australia Pty Ltd
Applicant ACN:	069 260 788
Summary of use:	For protection against mosquitoes and midges (sandflies) for at least 90 minutes when applied topically to human skin
Date of registration:	12 June 2020
Product registration no.:	87414
Label approval no.:	87414/118313

Application no.:	118255
Product name:	Good Riddance Sensitive Insect Repellent
Active constituent/s:	12.36 g/L lavender oil, 6.18 g/L essential oil of <i>cymbopogon</i> spp
Applicant name:	Natural Wonders Australia Pty Ltd
Applicant ACN:	069 260 788
Summary of use:	For protection against mosquitoes and midges (sandflies) for up to 90 minutes when applied topically to human skin
Date of registration:	12 June 2020
Product registration no.:	87393
Label approval no.:	87393/118255

2. AGRICULTURAL PRODUCTS BASED ON EXISTING ACTIVE CONSTITUENTS

Application no.:	119824
Product name:	Weedol Weedkiller Pathclear
Active constituent/s:	3.6 g/L glyphosate present as the isopropylamine salt, 0.576 g/L diflufenican
Applicant name:	Evergreen Garden Care Australia Pty Ltd
Applicant ACN:	003 123 162
Summary of use:	For control of common annual and perennial broadleaved weeds and grasses in the home garden on surfaces not intended to bear vegetation
Date of registration:	10 June 2020
Product registration no.:	87930
Label approval no.:	87930/119824

Application no.:	125398
Product name:	Cyren 500 EC Insecticide
Active constituent/s:	500 g/L chlorpyrifos
Applicant name:	FMC Australasia Pty Ltd
Applicant ACN:	095 326 891
Summary of use:	For control of a wide range of insect pests on cereals, cotton, fruit, oilseeds, pastures, vegetables and other situations
Date of registration:	10 June 2020
Product registration no.:	89597
Label approval no.:	89597/125398

Application no.:	118820
Product name:	Tough 600 EC Herbicide
Active constituent/s:	600 g/L pyridate
Applicant name:	Belchim Crop Protection NV
Applicant ACN:	N/A
Summary of use:	For the control of seedling broadleaf weeds in chickpeas
Date of registration:	12 June 2020
Product registration no.:	87622
Label approval no.:	87622/118820

Application no.:	124514
Product name:	Surefire Erazer Organic Herbicide
Active constituent/s:	525 g/L nonanoic acid
Applicant name:	PCT Holdings Pty Ltd
Applicant ACN:	099 023 962
Summary of use:	For non-selective control of seedling and young broadleaf and grass weeds, for suppression of established weeds and perennial species and for control of moss and algae
Date of registration:	17 June 2020
Product registration no.:	89368
Label approval no.:	89368/124514

Application no.:	123537
Product name:	Runer Cotton Growth Regulant
Active constituent/s:	38 g/L mepiquat present as the chloride salt
Applicant name:	Kincora Corporation
Applicant ACN:	N/A
Summary of use:	For the control of excessive vegetative growth in cotton
Date of registration:	17 June 2020
Product registration no.:	89068
Label approval no.:	89068/123537

Application no.:	119985
Product name:	Brunnings NA Weedkiller 525g/L
Active constituent/s:	525 g/L nonanoic acid
Applicant name:	Brunnings Garden Products Pty Ltd
Applicant ACN:	050 655 760
Summary of use:	For non-selective control of seedling and young broadleaf and grass weeds; for suppression of established weeds and perennial species; and for control of moss and algae
Date of registration:	18 June 2020
Product registration no.:	87994
Label approval no.:	87994/119985

Application no.:	124539
Product name:	Fosinate 200 SL Herbicide
Active constituent/s:	200 g/L glufosinate-ammonium
Applicant name:	KD Plant Care Pty Ltd
Applicant ACN:	134 592 804
Summary of use:	For the non-residual control of broadleaf and grass weeds in various situations
Date of registration:	18 June 2020
Product registration no.:	89376
Label approval no.:	89376/124539

Application no.:	124502
Product name:	TKO Out For The Count Flying Insect Killer Odourless
Active constituent/s:	1.26 g/kg esbiothrin, 0.5 g/kg permethrin
Applicant name:	Pascoe's Pty Ltd
Applicant ACN:	055 220 463
Summary of use:	To kill most flying insects but can also be used to kill most crawling insects
Date of registration:	18 June 2020
Product registration no.:	89363
Label approval no.:	89363/124502

Application no.:	124503
Product name:	TKO Out For The Count Multi Insect Killer Odourless
Active constituent/s:	1.0g/kg esbiothrin, 0.5g/kg permethrin, 0.2g/kg imiprothrin
Applicant name:	Pascoe's Pty Ltd
Applicant ACN:	055 220 463
Summary of use:	For control of various flying and crawling insect pests around the home and garden
Date of registration:	18 June 2020
Product registration no.:	89364
Label approval no.:	89364/124503

Application no.:	124538
Product name:	Fluazaway 212 Herbicide
Active constituent/s:	212 g/L fluazifop-p present as the butyl ester
Applicant name:	KD Plant Care Pty Ltd
Applicant ACN:	134 592 804
Summary of use:	For the control of certain grasses in crops
Date of registration:	19 June 2020
Product registration no.:	89375
Label approval no.:	89375/124538

Application no.:	120533
Product name:	Vitae Fungicide
Active constituent/s:	250 g/L quinoxifen
Applicant name:	AgriNova New Zealand Limited
Applicant ACN:	34 004 099 592
Summary of use:	For the protection of grapevines from powdery mildew infections
Date of registration:	19 June 2020
Product registration no.:	88196
Label approval no.:	88196/120533

Application no.:	121829
Product name:	Gharda Alphaguard 100 EC Insecticide
Active constituent/s:	100 g/L alpha-cypermethrin
Applicant name:	Gharda Australia Pty Ltd
Applicant ACN:	087 753 151
Summary of use:	For control of certain insect pests on various crops and redlegged earth mite and blue oat mite on certain field crops and pastures
Date of registration:	19 June 2020
Product registration no.:	88616
Label approval no.:	88616/121829

3. VARIATIONS OF REGISTRATION

Application no.:	125724
Product name:	Algae-Died 'B' For Killing Algae And Black Spot
Active constituent/s:	142.5 g/L quaternary ammonium compound
Applicant name:	Chemlux Pty Ltd
Applicant ACN:	626 183 060
Summary of variation:	To vary the distinguishing product name and the name that appears on the label from 'Chemron Algae-Died 'B' For Killing Algae And Black Spot' to 'Algae-Died 'B' For Killing Algae And Black Spot'
Date of variation:	1 June 2020
Product registration no.:	47349
Label approval no.:	47349/125724

Application no.:	125725
Product name:	Sentinel Automatically Dispensed Pyrethrum Insecticide Spray
Active constituent/s:	45 g/kg piperonyl butoxide, 9 g/kg pyrethrins
Applicant name:	Chemlux Pty Ltd
Applicant ACN:	626 183 060
Summary of variation:	To vary the distinguishing product name and the name that appears on the label from 'Chemron Sentinel Automatically Dispensed Pyrethrum Insecticide' to 'Sentinel Automatically Dispensed Pyrethrum Insecticide Spray'
Date of variation:	1 June 2020
Product registration no.:	54165
Label approval no.:	54165/125725

Application no.:	125726
Product name:	Kelpie Par-Q 250 Herbicide
Active constituent/s:	250 g/L paraquat present as paraquat dichloride
Applicant name:	Sinochem International Australia Pty Ltd
Applicant ACN:	160 164 616
Summary of variation:	To vary the distinguishing product name and the name that appears on the label from 'Accensi Paraquat Total 250 Herbicide' to 'Kelpie Par-Q 250 Herbicide'
Date of variation:	1 June 2020
Product registration no.:	83115
Label approval no.:	83115/125726

Application no.:	125807
Product name:	Rustler Selective Herbicide
Active constituent/s:	500 g/L propyzamide
Applicant name:	FMC Australasia Pty Ltd
Applicant ACN:	095 326 891
Summary of variation:	To remove the use of lettuce from the instructions
Date of variation:	5 June 2020
Product registration no.:	61360
Label approval no.:	61360/125807
Application no.:	123495
Product name:	Banole EC Agricultural & Horticultural All Purpose Spraying Oil
Active constituent/s:	800 g/L petroleum oil
Applicant name:	Total Fluides SAS
Applicant ACN:	N/A
Summary of variation:	Addition of uses in bananas based on a reference product
Date of variation:	16 June 2020
Product registration no.:	69132
Label approval no.:	69132/123495
Application no.:	122050
Product name:	Farmalinx Rebel Herbicide
Active constituent/s:	440 g/L 2,4-D acid
Applicant name:	Farmalinx Pty Ltd
Applicant ACN:	134 353 245
Summary of variation:	To include the control of weeds in turf and lawns
Date of variation:	16 June 2020
Product registration no.:	84093
Label approval no.:	84093/122050
Application no.:	124540
Product name:	Steri-Max Biocide
Active constituent/s:	120 g/L didecyl dimethyl ammonium chloride
Applicant name:	Sipcam Pacific Australia Pty Ltd
Applicant ACN:	073 176 888
Summary of variation:	To add uses for the post-harvest treatment of certain tropical and subtropical fruit, cut flowers in containers, and grapevine cuttings
Date of variation:	19 June 2020
Product registration no.:	59462
Label approval no.:	59462/124540

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.

1. VETERINARY PRODUCTS BASED ON NEW ACTIVE CONSTITUENTS

Application no.:	124431
Product name:	Adrestan 10mg Capsules
Active constituent/s:	10 mg/capsule trilostane
Applicant name:	Dechra Ltd
Applicant ACN:	N/A
Summary of use:	For the treatment of pituitary-dependent and adrenal-dependent hyperadrenocorticism (Cushing's syndrome) in dogs
Date of registration:	11 June 2020
Product registration no.:	89332
Label approval no.:	89332/124431

Application no.:	124432
Product name:	Adrestan 30mg Capsules
Active constituent/s:	30 mg/capsule trilostane
Applicant name:	Dechra Ltd
Applicant ACN:	N/A
Summary of use:	For the treatment of pituitary-dependent and adrenal-dependent hyperadrenocorticism (Cushing's syndrome) in dogs
Date of registration:	11 June 2020
Product registration no.:	89333
Label approval no.:	89333/124432

Application no.:	124433
Product name:	Adrestan 60mg Capsules
Active constituent/s:	60 mg/capsule trilostane
Applicant name:	Dechra Ltd
Applicant ACN:	N/A
Summary of use:	For the treatment of pituitary-dependent and adrenal-dependent hyperadrenocorticism (Cushing's syndrome) in dogs
Date of registration:	11 June 2020
Product registration no.:	89334
Label approval no.:	89334/124433

Application no.:	120471
Product name:	Clavaseptin 50 MG Palatable Tablets For Dogs And Cats
Active constituent/s:	40 mg/tablet amoxicillin (as amoxicillin trihydrate), 10 mg/tablet clavulanic acid (as potassium clavulanate)
Applicant name:	Vetoquinol Australia Pty Ltd
Applicant ACN:	006 949 480
Summary of use:	For the treatment of infections in dogs and cats caused by bacteria sensitive to amoxicillin in combination with clavulanic acid
Date of registration:	15 June 2020
Product registration no.:	88165
Label approval no.:	88165/120471

Application no.:	120469
Product name:	Clavaseptin 62.5 MG Palatable Tablets For Dogs And Cats
Active constituent/s:	50 mg/tablet amoxicillin (as amoxicillin trihydrate), 12.5 mg/tablet clavulanic acid (as potassium clavulanate)
Applicant name:	Vetoquinol Australia Pty Ltd
Applicant ACN:	006 949 480
Summary of use:	For the treatment of infections in dogs and cats caused by bacteria sensitive to amoxicillin in combination with clavulanic acid
Date of registration:	15 June 2020
Product registration no.:	88163
Label approval no.:	88163/120469

Application no.:	120467
Product name:	Clavaseptin 250 MG Palatable Tablets For Dogs
Active constituent/s:	200 mg/tablet amoxicillin (as amoxicillin trihydrate), 50 mg/tablet clavulanic acid (as potassium clavulanate)
Applicant name:	Vetoquinol Australia Pty Ltd
Applicant ACN:	006 949 480
Summary of use:	For the treatment of infections in dogs caused by bacteria sensitive to amoxicillin in combination with clavulanic acid
Date of registration:	15 June 2020
Product registration no.:	88162
Label approval no.:	88162/120467

Application no.:	120465
Product name:	Clavaseptin 500 MG Palatable Tablets For Dogs
Active constituent/s:	400 mg/tablet amoxicillin (as amoxicillin trihydrate), 100 mg/tablet clavulanic acid (as potassium clavulanate)
Applicant name:	Vetoquinol Australia Pty Ltd
Applicant ACN:	006 949 480
Summary of use:	For the treatment of infections in dogs caused by bacteria sensitive to amoxicillin in combination with clavulanic acid
Date of registration:	15 June 2020
Product registration no.:	88161
Label approval no.:	88161/120465

Application no.:	123632
Product name:	Dalgety Duomax Tick Development Inhibitor And Broad Spectrum Pour-On
Active constituent/s:	15 g/L fluazuron, 5 g/L ivermectin
Applicant name:	Nutrien Ag Solutions Limited
Applicant ACN:	008 743 217
Summary of use:	For the registration of a topical solution product for use in beef cattle for the treatment and control of internal and external parasites
Date of registration:	16 June 2020
Product registration no.:	89106
Label approval no.:	89106/123632

Application no.:	120152
Product name:	AceSedate 10 Mg/MI Injection
Active constituent/s:	13.55 mg/mL acepromazine maleate (equivalent to acepromazine 10.0 mg/mL)
Applicant name:	Jurox Pty Ltd
Applicant ACN:	000 932 230
Summary of use:	For anaesthetic premedication and as a tranquiliser and travel sickness medication in horses, cattle, pigs and sheep
Date of registration:	18 June 2020
Product registration no.:	88055
Label approval no.:	88055/120152

2. VARIATIONS OF REGISTRATION

Application no.:	124490
Product name:	Onsior 5 Mg Tablets For Dogs
Active constituent/s:	5 mg/tablet robenacoxib
Applicant name:	Elanco Australasia Pty Ltd
Applicant ACN:	076 745 198
Summary of variation:	To vary the particulars of the registered chemical product and the label by changing the net contents
Date of variation:	12 June 2020
Product registration no.:	63104
Label approval no.:	63104/124490

Application no.:	124493
Product name:	Onsior 10 Mg Tablets For Dogs
Active constituent/s:	10 mg/tablet robenacoxib
Applicant name:	Elanco Australasia Pty Ltd
Applicant ACN:	076 745 198
Summary of variation:	To vary the particulars of the registered chemical product and the label by changing the net contents
Date of variation:	12 June 2020
Product registration no.:	63105
Label approval no.:	63105/124493

Application no.:	124491
Product name:	Onsior 20 Mg Tablets For Dogs
Active constituent/s:	20 mg/tablet robenacoxib
Applicant name:	Elanco Australasia Pty Ltd
Applicant ACN:	076 745 198
Summary of variation:	To vary the particulars of the registered chemical product and the label by changing the net contents
Date of variation:	12 June 2020
Product registration no.:	63107
Label approval no.:	63107/124491

Application no.:	124492
Product name:	Onsior 40 Mg Tablets For Dogs
Active constituent/s:	40 mg/tablet robenacoxib
Applicant name:	Elanco Australasia Pty Ltd
Applicant ACN:	076 745 198
Summary of variation:	To vary the particulars of the registered chemical product and the label by changing the net contents
Date of variation:	12 June 2020
Product registration no.:	63109
Label approval no.:	63109/124492

Application no.:	124543
Product name:	Larvadex 10% Feed Premix
Active constituent/s:	100 g/kg cyromazine
Applicant name:	Elanco Australasia Pty Ltd
Applicant ACN:	076 745 198
Summary of variation:	To update label to align with the Veterinary Labelling Code
Date of variation:	12 June 2020
Product registration no.:	52308
Label approval no.:	52308/124543

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.

1. ACTIVE CONSTITUENT

Application no.:	123032
Active constituent/s:	Carprofen
Applicant name:	South Yarra Pharma Pty Ltd
Applicant ACN:	629 173 351
Summary of use:	For use in veterinary chemical products
Date of approval:	12 June 2020
Approval no.:	88962
Application no.:	123113
Active constituent/s:	Clomipramine hydrochloride
Applicant name:	Mavlab Pty Ltd
Applicant ACN:	009 708 187
Summary of use:	For use in veterinary chemical products
Date of approval:	12 June 2020
Approval no.:	88992
Application no.:	120055
Active constituent/s:	Flumioxazin
Applicant name:	Imtrade Australia Pty Ltd
Applicant ACN:	090 151 134
Summary of use:	For use in agricultural chemical products
Date of approval:	16 June 2020
Approval no.:	88025
Application no.:	124119
Active constituent/s:	Hydroxocobalamin acetate
Applicant name:	Zoetis Australia Pty Ltd
Applicant ACN:	156 476 425
Summary of use:	For use in veterinary chemical products
Date of approval:	18 June 2020
Approval no.:	89244
Application no.:	122122
Active constituent:	Tiamulin fumarate
Applicant name:	South Yarra Pharma Pty Ltd
Applicant ACN:	629 173 351
Summary of use:	For use in veterinary chemical products
Date of approval:	19 June 2020
Approval no.:	88736

2. VARIATIONS OF ACTIVE CONSTITUENT

Application no.:	122635
Active constituent/s:	Cyanocobalamin
Applicant name:	Troy Laboratories Pty Ltd
Applicant ACN:	000 283 769
Summary of variation:	Variation of relevant particulars or conditions of an approved active constituent
Date of variation:	10 June 2020
Approval no.:	84243
Application no.:	123153
Active constituent/s:	Dexamethasone sodium phosphate
Applicant name:	Troy Laboratories Pty Ltd
Applicant ACN:	000 283 769
Summary of variation:	Variation of relevant particulars or conditions of an approved active constituent
Date of variation:	10 June 2020
Approval no.:	86259
Application no.:	123110
Active constituent/s:	Niclosamide
Applicant name:	Aristopet Pty Ltd
Applicant ACN:	145 418 882
Summary of variation:	Variation of relevant particulars or conditions of an approved active constituent
Date of variation:	10 June 2020
Approval no.:	83405
Application no.:	122721
Active constituent/s:	Pimobendan
Applicant name:	Jurox Pty Ltd
Applicant ACN:	000 932 230
Summary of variation:	Variation of relevant particulars or conditions of an approved active constituent
Date of variation:	10 June 2020
Approval no.:	83503
Application no.:	125443
Active constituent/s:	Altrenogest
Applicant name:	Ceva Animal Health Pty Ltd
Applicant ACN:	002 692 426
Summary of variation:	Variation of relevant particulars or conditions of an approved active constituent
Date of variation:	12 June 2020
Approval no.:	82896
Application no.:	122620
Active constituent/s:	Procaine benzylpenicillin
Applicant name:	Troy Laboratories Pty Ltd
Applicant ACN:	000 283 769
Summary of variation:	Variation of relevant particulars or conditions of an approved active constituent
Date of variation:	12 June 2020
Approval no.:	84166

Application no.:	122667
Active constituent/s:	Xylazine hydrochloride
Applicant name:	Troy Laboratories Pty Ltd
Applicant ACN:	000 283 769
Summary of variation:	Variation of relevant particulars or conditions of an approved active constituent
Date of variation:	18 June 2020
Approval no.:	85655

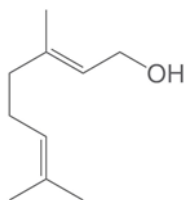
Application no.:	125461
Active constituent/s:	Gentamicin sulfate
Applicant name:	Ceva Animal Health Pty Ltd
Applicant ACN:	002 692 426
Summary of variation:	Variation of relevant particulars or conditions of an approved active constituent
Date of variation:	19 June 2020
Approval no.:	82507

New agricultural active constituent: geraniol

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application for the approval of a new active constituent, geraniol, for use in agricultural chemical products as a fungicide.

Common name:	Geraniol
IUPAC name:	(2E)-3,7-dimethyl-2,6-octadien-1-ol
CAS name:	(2E)-3,7-dimethyl-2,6-octadien-1-ol
CAS registry number:	106-24-1
Minimum purity:	980 g/kg
Molecular formula:	C ₁₀ H ₁₈ O
Molecular weight:	154.25 g/mol

Structure:



Chemical family: Monoterpenoid

SUMMARY OF THE APVMA'S EVALUATION OF GERANIOL ACTIVE CONSTITUENT

The APVMA has evaluated the chemistry aspects of geraniol active constituent (physico-chemical properties, identification, stability, 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 geraniol.

The Acceptable Daily Intake (ADI) for geraniol is 0.5 mg/kg bw/d.

An Acute Reference Dose (ARfD) for geraniol is not considered necessary for the general population on the basis of absence any acute neurotoxicity or any other toxicologically relevant effect that might be attributable to a single dose.

Geraniol is currently listed in Schedule 6 of the Poisons Standard (covered by the entry for 3,7-dimethyl-2,6-octadien-1-ol), with preparations containing geraniol exempt from scheduling if they contain five per cent geraniol or less.

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

Specification	Level
Geraniol content	Minimum 980 g/kg

Other compounds of toxicological significance are not expected to occur in geraniol technical active constituent.

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

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 the application for approval of geraniol should be granted. Submissions should relate only to matters are considered in determining whether the safety criteria set out in section 5A of the Agvet Code are 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 (if available)
- the date you made the submission.

All personal and confidential commercial information (CCI)¹ material contained in submissions will be treated confidentially.

Submissions should be addressed in writing to:

Director Chemistry and Manufacture
Risk Assessment Capability
Australian Pesticides and Veterinary Medicines Authority
GPO Box 3262
Sydney NSW 2001

Phone: +61 2 6770 2300

Email: enquiries@apvma.gov.au

¹ A full definition of 'confidential commercial information' is contained in the Agvet Code.

Novellus Fungicide containing geraniol, eugenol and thymol

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application for registration of a new product containing a new active constituent. The product is 87197/117745—Novellus Fungicide.

PARTICULARS OF THE APPLICATION

Proposed product name(s):	87197/117745—Novellus Fungicide
Applicant company:	Eden Research PLC
Name of active constituents:	Geraniol, eugenol and thymol
Signal heading:	POISON
Summary of proposed use:	For the control of grey mould/bunch rot (<i>Botrytis cinerea</i>) in grapes
Pack sizes:	1–1000 L
Withholding period:	Harvest (H) Grapes (table or wine for domestic consumption) DO NOT HARVEST FOR 7 DAYS AFTER APPLICATION Grapes (table or wine intended for export) CONSULT YOUR WINEMAKER, INDUSTRY SPRAY DIARY OR PEAK INDUSTRY BODY FOR THE RECOMMENDED WITHHOLDING PERIOD Grazing (G) DO NOT GRAZE TREATED VINEYARDS OR CUT FOR STOCKFOOD FOR 7 DAYS AFTER APPLICATION

SUMMARY OF THE APVMA'S EVALUATION OF NOVELLUS 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, and proposes to determine that:
 - (i) The APVMA is satisfied that the proposed use of Novellus Fungicide would not be an undue hazard to the safety of people exposed to it during its handling and use.
 - (ii) The APVMA is satisfied that the proposed use of Novellus Fungicide 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 Novellus Fungicide is not likely to be harmful to human beings if used according to the product label directions.
 - (iv) The APVMA is satisfied that the proposed use of Novellus Fungicide is not likely to have an unintended effect that is harmful to animals, plants, or things or the environment if used according to the product label directions.

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 under section 14(3)(f), the APVMA is satisfied that data from trials supporting the efficacy of the product Novellus Fungicide 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, and proposes to determine that:
 - (ii) The APVMA is satisfied that the proposed use of Novellus Fungicide would not adversely affect trade between Australia and places outside Australia.

FURTHER INFORMATION

A Public Release Summary (PRS) of the evaluation of the product Novellus Fungicide is available from the APVMA website's '[Public Consultation](#)' page, 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 Novellus 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 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.

When making a submission please include:

- 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)² 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
GPO Box 3262
Sydney NSW 2001

Phone: +61 2 6770 2300

Email: enquiries@apvma.gov.au

² A full definition of 'confidential commercial information' is contained in the Agvet Code.

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](#).

1. NEW LICENCES

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

Multipack LJM Pty Ltd ACN: 100 109 019 47 Heathcote Road Moorebank NSW 2170	Licence number: 6231 Product types:* <ul style="list-style-type: none">• <i>Category 6:</i> All dosage forms Steps of manufacture: Secondary packaging, secondary labelling, storage and release for supply. Licence issued: 9 April 2020
Multipack LJM Pty Ltd ACN: 100 109 019 22B Hanson Place Eastern Creek NSW 2766	Licence number: 6229 Product types:* <ul style="list-style-type: none">• <i>Category 6:</i> All dosage forms Steps of manufacture: Secondary packaging, secondary labelling, storage and release for supply. Licence issued: 11 May 2020
Complementary Medicines Group Pty Ltd ACN: 146 924 343 Unit 1, 9 Apollo Street Warriewood NSW 2102	Licence number: 6232 Product types:* <ul style="list-style-type: none">• <i>Category 6:</i> Non-sterile all dosage forms Steps of manufacture: Packaging, secondary packaging, labelling, secondary labelling, repackaging and relabelling. Licence issued: 26 May 2020
Phibro Animal Health Pty Ltd ACN: 093 869 991 6 Distribution Drive Orchard Hills NSW 2748	Licence number: 6228 Product types:* <ul style="list-style-type: none">• <i>Category 6:</i> All dosage forms Steps of manufacture: Quality assurance (QA) of raw materials, labelling, relabelling, storage and release for supply. Licence issued: 10 June 2020

Elanco Australasia Pty Ltd

Licence number: 6227

ACN: 076 745 198

Product types:*

7 Eden Park Drive

- Category 6: All dosage forms

Macquarie Park NSW 2113

Steps of manufacture: Release for supply.

Licence issued: 10 June 2020

**Victorian Chemical Company
Pty Ltd**

Licence number: 2264

ACN: 004 188 863

Product types:*

83 Maffra St

- Category 2: Liquids (oral) and sprays

Coolaroo VIC 3048

Steps of manufacture: Quality assurance (QA) of raw materials, formulation including blending, analysis and testing (physical and chemical), filling, packaging, labelling, storage and release for supply.

Licence issued: 10 June 2020

Jalco Cosmetics Pty Ltd

Licence number: 2262

ACN: 084 809 450

Product types:*

45 King Road

- Category 2: Creams/lotions, ointments, gels, pastes, sprays and liquids (oral and topical)

Hornsby NSW 2077

Steps of manufacture: Quality assurance (QA) of raw materials, formulation including blending, filling, analysis and testing (chemical and microbiological) packaging, labelling, storage and release for supply.

Licence issued: 10 June 2020

2. CHANGES TO EXISTING LICENCES

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

Troy Laboratories Pty Ltd ACN: 000 283 769 37 Glendenning Road Glendenning NSW 2761	Licence number: 1092 Product types: * <ul style="list-style-type: none">• Category 1: Sterile products and terminally sterilised ointment• Category 2: Tablets, creams / lotions, ointments, gels, pastes, powders, sprays, granules, suspensions and liquids• Category 3: Liquids and sprays• Category 4: Supplements Steps of manufacture: Quality assurance (QA) of raw materials, formulation including blending, granulation, dry milling, aseptic filling, filling, packaging (including strip, blister and sachet) labelling, tableting, sterilisation (heat and filtration), microbiological reduction treatment (heat, filtration and chemical), analysis and testing (physical, chemical and endotoxin), storage and release for supply. Amended licence issued: 30 March 2020
Nutrien Ag Solutions Limited ACN: 008 743 217 71 Colebard Street West Acacia Ridge QLD 4110	Licence number: 6202 Product types: * <ul style="list-style-type: none">• Category 6: all dosage forms Steps of manufacture: Secondary packaging, secondary labelling, storage and release for supply. Amended licence issued: 30 March 2020
Nutrien Ag Solutions Limited ACN: 008 743 217 Suite 3, Level 1, Building B 11 Talavera Road Macquarie Park NSW 2113	Licence number: 6201 Product types: * <ul style="list-style-type: none">• Category 6: all dosage forms Steps of manufacture: Release for supply. Amended licence issued: 30 March 2020
Nutrien Ag Solutions Limited ACN: 008 743 217 24-26 Hydrive Close Dandenong VIC 3175	Licence number: 2249 Product types: * <ul style="list-style-type: none">• Category 2: Liquids• Category 3: Liquids, Suspensions Steps of manufacture: Quality assurance (QA) of raw materials, formulation including blending, filling, packaging, labelling, secondary packaging, secondary labelling, repackaging, relabelling, analysis and testing (physical and chemical), storage and release for supply. Amended licence issued: 30 March 2020

C M Laboratories Pty Ltd

ACN: 098 897 637

Units 1–4, 36 Curtis Road
Mulgrave NSW 2756

Licence number: 2150

Product types: *

- Category 2: Creams, lotions, ointments, gels, pastes, powders, sprays, liquids and suspensions.
- Category 3: Liquids, sprays and powders
- Category 4: Premixes and supplements

Steps of manufacture: Quality assurance (QA) of raw materials, formulation including blending, wet milling, filling, packaging, labelling, analysis and testing (physical), storage and release for supply.

Amended licence issued: 20 March 2020

Plasvacc Pty Ltd

ACN: 009 547 841

“Rigby”
6066 Cunningham Highway
Kalbar QLD 43309

Licence number: 1072

Product types: *

- Category 1: Immunobiologicals (plasma products and canine red blood cells (RBC))

Steps of manufacture: Quality assurance (QA) of raw materials, plasma collection via plasmapheresis machine, blood collection, management and immunisation of donor animals, aseptic filling, packaging, labelling, microbiological reduction treatment (filtration), analysis and testing (physical, sterility, serological, immunobiological, and haematological), storage and release for supply.

Amended licence issued: 20 April 2020

Arthroparm Pty Ltd

ACN: 003 261 907

105–113 Bronte Road
Bondi Junction NSW 2022

Licence number: 1107

Product types: *

- Category 1: sterile products for injection

Steps of manufacture: Quality Assurance (QA) of raw materials, formulation including blending, aseptic filling, packaging, secondary packaging, labelling, sterilisation (heat, filtration), analysis and testing (physical, chemical, endotoxin, microbiological and sterility), storage and release for supply.

Amended licence issued: 8 May 2020

Mavlab Animal Health Pty Ltd

Licence number: 1104

ACN: 164 339 637

29–33 Rowland Street
Slacks Creek QLD 4127

Product types: *

- Category 1: sterile products
- Category 2: Tablets, powders, granules, sprays, liquids and gels
- Category 3: Liquids, sprays and powders
- Category 4: Premixes and supplements

Steps of manufacture: Quality assurance (QA) of raw materials, formulation including blending, dry milling, filling, packaging, labelling, tableting, aseptic filling, granulation, sterilisation (heat and filtration), wet milling of powders, microbiological reduction treatment (filtration, heat and chemical), analysis and testing (physical and chemical), storage and release for supply.

Amended licence issued: 11 May 2020

Arthroparm Pty Ltd

Licence number: 1107

ACN: 003 261 907

105–113 Bronte Road
Bondi Junction NSW 2022

Product types: *

- Category 1: Sterile products for injection

Steps of manufacture: Quality Assurance (QA) of raw materials, formulation including blending, aseptic filling, packaging, secondary packaging, labelling, sterilisation (heat, filtration), analysis and testing (physical, chemical, endotoxin, microbiological and sterility), storage and release for supply.

Amended licence issued: 8 May 2020

Dairy Technical Services Pty Ltd

Licence number: 6197

ACN: 004 319 171

52–58 Mark Street
North Melbourne VIC 3051

Product types: *

- Category 6: All dosage forms

Steps of manufacture: Analysis and testing (chemical and physical).

Amended licence issued: 18 June 2020

3. LICENCE CANCELLATIONS

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

The State of Victoria acting through the Department of Economic Development, Jobs, Transport, and Resources **Licence number:** 1071

ACN: 69 981 208 728 **Date cancelled:** 18 March 2020

Pig Services Centre

Corner of Taylor Street and
Midland Highway

Epsom VIC 3551

4. LICENCE SUSPENSIONS

Nil

5. REVOCATION OF LICENCE CANCELLATION

Nil

6. REVOCATION OF LICENCE SUSPENSION

Nil

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

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 Australian Pesticides and Veterinary Medicines Authority (APVMA) has cancelled the approvals and/or registrations set out in the table below on the date of cancellation nominated by the holder.

Approval or registration number	Name	Type of approval or registration	Holder	Date of cancellation
50082	Purina Totalcare Allwormer Worming Paste For Cats & Kittens	Product registration	Nestle Purina Petcare A Div Of Nestle Australia Ltd	22 June 2020
50082/120318 50082/50617 50082/0607 50082/0898 50082/0198	Purina Totalcare Allwormer Worming Paste For Cats & Kittens	Label approvals	Nestle Purina Petcare A Div Of Nestle Australia Ltd	22 June 2020
87627	Purina Totalcare Heartwormer, Allwormer & Flea Control For Cats	Product registration	Nestle Purina Petcare A Div Of Nestle Australia Ltd	22 June 2020
87627/118828	Purina Totalcare Heartwormer, Allwormer & Flea Control For Cats	Label approval	Nestle Purina Petcare A Div Of Nestle Australia Ltd	22 June 2020
59527/0105	Genfarm Diclofop-Methyl 375 Selective Herbicide	Label approval	Nutrien Ag Solutions Limited	22 May 2020
61975	Mortein Naturgard Fly Control Window Stickers	Product registration	Rb (Hygiene Home) Australia Pty Ltd	30 April 2020
61975/0809 61975/1007	Mortein Naturgard Fly Control Window Stickers	Label approvals	Rb (Hygiene Home) Australia Pty Ltd	30 April 2020
67883/112602	Potus Yield & Quality Enhancer	Label approval	Crop Culture Pty Ltd	28 April 2020
65237/50490	Evershield Seed Treatment	Label approval	Arysta Lifescience Australia Pty Ltd	27 April 2020
65830/52131	Ozcrop Mcpa 750 SI Selective Herbicide	Label approval	Ozcrop Pty Ltd	19 March 2020
65603/52082	Ozcrop Dicamba 500 SI Herbicide	Label approval	Ozcrop Pty Ltd	17 March 2020

Approval or registration number	Name	Type of approval or registration	Holder	Date of cancellation
67055/55091	Apparent Dicamba 500 Herbicide	Label approval	Titan Ag Pty Ltd	11 March 2020
69275/60390	Kenso Agcare Ken-Mide 900 Wg Herbicide	Label approvals	Kenso Corporation (M) Sdn. Bhd.	21 February 2020
63053/44605	Revus Mz Fungicide	Label approval	Syngenta Australia Pty Ltd	19 February 2020
66128/59902 66128/52779	Accensi Triadimenol 250 Fungicide	Label approvals	Accensi Pty Ltd	12 February 2020
59587/111935 59587/0708 59587/0506	Kenso Agcare Ken-Up Dry 680 Wg Herbicide	Label approvals	Kenso Corporation (M) Sdn. Bhd.	28 January 2020
84206/109884	Titan Thiram 600 Sc Fungicide	Label approval	Titan Ag Pty Ltd	6 January 2020
60092/0406	Amparo Seed Treatment Insecticide	Label approval	Bayer Cropscience Pty Ltd	29 November 2019
85948/114282	Kenso Agcare Taekwando 250 Cs Insecticide	Label approval	Kenso Corporation (M) Sdn. Bhd.	26 September 2019
87121/117599	F.S.A. Sulfosulfuron 750wg Herbicide	Label approval	Four Seasons Agribusiness Pty Ltd	26 September 2019

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 the above table.

REASONS

Pursuant to section 42(1)(b) of the Agvet Code, the APVMA was satisfied that there were no valid reasons why the APVMA should not agree to the request of the holder to cancel the approvals and/or registrations set out in the above table.

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 the above table 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 the above table 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 the above table 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 the above table, 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 the table above 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