



**Commonwealth
of Australia**

Gazette

Agricultural and veterinary chemicals

No. APVMA 17, 20 August 2024

Published by the Australian Pesticides and Veterinary Medicines Authority



Australian Government

**Australian Pesticides and
Veterinary Medicines Authority**

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.

© Commonwealth of Australia 2024

This work is copyright. Apart from any use as permitted under the *Copyright Act 1968*, no part may be reproduced by any process without prior written permission from the Australian Pesticides and Veterinary Medicines Authority (APVMA). Requests and inquiries concerning reproduction and rights should be addressed to:

Assistant Director, Communications
Australian Pesticides and Veterinary Medicines Authority
GPO Box 3262
Sydney NSW 2001

Email: communications@apvma.gov.au

Website: apvma.gov.au

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](#).

If you would like to subscribe to receive email notification when a new edition is published, please complete a [subscription form](#).

APVMA contacts

For enquiries regarding the publishing and distribution of the APVMA Gazette: Telephone: +61 2 6770 2300.

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

Privacy

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

Contents

Agricultural chemical products and approved labels	1
Veterinary chemical products and approved labels	7
Approved active constituents	13
Application for the approval of a new active constituent, cyclobutrifluram	17
New product, TREFINTI Turf Nematicide containing a new active constituent, cyclobutrifluram	20
Licensing of veterinary chemical manufacturers	22
Notice of cancellation at the request of the holder.....	23

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.	142789
Product name	Titan Stoli SE Fungicide
Active constituents	322 g/L azoxystrobin, 124 g/L metalaxyl-M
Applicant name	Titan Ag Pty Ltd
Applicant ACN	122 081 574
Date of registration	5 August 2024
Product registration no.	94560
Label approval no.	94560/142789
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 322 g/L azoxystrobin and 124 g/L metalaxyl-M suspo-emulsion product for the control of rhizoctonia, pythium, leaf rust and net blotch in barley, control of rhizoctonia, pythium and stripe rust in wheat, and suppression of powdery mildew in barley and yellow spot in wheat

Application no.	143905
Product name	OzCrop Butroxydim 250 WG Herbicide
Active constituent	250 g/kg butroxydim
Applicant name	Oz Crop Pty Ltd
Applicant ACN	160 656 431
Date of registration	8 August 2024
Product registration no.	94871
Label approval no.	94871/143905
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 250 g/kg butroxydim g/kg water dispersible granules product 'Ozcrop Butroxydim 250 WG Herbicide' for the control of certain grasses in a range of broadacre crops as per the directions for use

Application no.	143885
Product name	Ozcrop Flubendiamide 480 SC Insecticide
Active constituent	480 g/L flubendiamide
Applicant name	Oz Crop Pty Ltd
Applicant ACN	160 656 431
Date of registration	9 August 2024
Product registration no.	94863
Label approval no.	94863/143885
Description of the application and its purpose, including the intended use of the chemical product	Registration of Ozcrop Flubendiamide 480 g/L Suspension Concentrate Insecticide product for the control of various <i>Lepidopteran</i> pests in vegetable crops and chia as per the direction for use

Application no.	143959
Product name	FlexAg 2,4-D Amine 625 Herbicide
Active constituent	625 g/L 2,4-D present as the dimethylamine and diethanolamine salts
Applicant name	FlexAg Pty Ltd
Applicant ACN	675 254 734
Date of registration	9 August 2024
Product registration no.	94894
Label approval no.	94894/143959
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 625 g/L 2,4-D present as the dimethylamine and diethanolamine salts soluble concentrate (SL) product for the control of broadleaf weeds in fallow before direct drilling or sowing of cereals and pastures; and in cereal crops, pastures, sugarcane, peanuts, and non-agricultural areas

Application no.	143966
Product name	Agrobeats Epoxiconazole 125 SC Fungicide
Active constituent	125 g/L epoxiconazole
Applicant name	Agrobeats Tech Co. Ltd.
Applicant ACN	N/A
Date of registration	9 August 2024
Product registration no.	94897
Label approval no.	94897/143966
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 125 g/L epoxiconazole suspension concentrate product, for the control of leaf rust, stripe rust and <i>Septoria nodorum</i> blotch of wheat, and leaf rust of barley

Application no.	143742
Product name	Gro-Sure Canola Oil Concentrate
Active constituent	840 g/L canola oil
Applicant name	Agritrading Pty Limited
Applicant ACN	134 291 295
Date of registration	9 August 2024
Product registration no.	94813
Label approval no.	94813/143742
Description of the application and its purpose, including the intended use of the chemical product	Registration of an 840 g/L canola oil aqueous concentrate to improve chemical uptake, rain-fastness and drift control of horticultural and agricultural pesticide or foliar sprays

Table 2: Variations of registration – agricultural chemical products

Application no.	144813
Product name	Outdoor Mosquito Coils Repels for up to 8 Hours
Active constituent	2 g/kg d-allethrin
Applicant name	Cavalieri Investing Pty Ltd
Applicant ACN	162 722 625
Date of variation	24 July 2024
Product registration no.	88009
Label approval no.	88009/144813
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 from 'Coles Outdoor Mosquito Coils Repels for up to 8 Hours' to 'Outdoor Mosquito Coils Repels for up to 8 Hours'

Application no.	144814
Product name	Repelling Rid since 1956 Bite Relief Repellent Antiseptic Bite Protection 6 Repels Mosquitos for 6 Hours Soothes Existing Bites Chamomile and Vitamin E Insect Repellent Spray
Active constituents	160 g/L diethyltoluamide, 20 g/L n-octyl bicycloheptene dicarboximide, 1 g/L triclosan
Applicant name	Cavalieri Investing Pty Ltd
Applicant ACN	162 722 625
Date of variation	24 July 2024
Product registration no.	53403
Label approval no.	53403/144814
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 'Repelling Rid Since 1956 Insect Repellent Spray' to 'Repelling Rid since 1956 Bite Relief Repellent Antiseptic Bite Protection 6 Repels Mosquitos for 6 Hours Soothes Existing Bites Chamomile and Vitamin E Insect Repellent Spray'

Application no.	140732
Product name	Genfarm Diflu-MCPA Selective Herbicide
Active constituents	250 g/L MCPA present as the ethyl hexyl ester, 25 g/L diflufenican
Applicant name	Nutrien Ag Solutions Limited
Applicant ACN	008 743 217
Date of variation	30 July 2024
Product registration no.	64997
Label approval no.	64997/140732
Description of the application and its purpose, including the intended use of the chemical product	Variation to the registration particulars and the particulars of label to update constituent statements, restraints, directions for use, general instructions, and safety directions

Application no.	142820
Product name	Monarch G Insecticide
Active constituent	0.5 g/kg fipronil
Applicant name	Turf Culture Pty Ltd
Applicant ACN	117 986 615
Date of variation	30 July 2024
Product registration no.	86567
Label approval no.	86567/142820
Description of the application and its purpose, including the intended use of the chemical product	Variation to registration particulars, particulars of label, to add use for targeted spot control of ants and nests

Application no.	142885
Product name	Nufarm MCPA LVE 570 Herbicide
Active constituent	570 g/L MCPA present as the 2-ethyl hexyl ester
Applicant name	Nufarm Australia Limited
Applicant ACN	004 377 780
Date of variation	31 July 2024
Product registration no.	63597
Label approval no.	63597/142885
Description of the application and its purpose, including the intended use of the chemical product	Variation to particulars of label, to update the directions for use and other minor changes

Application no.	143838
Product name	Titan Wetter 1000 Wetting Agent
Active constituents	800 g/L nonyl phenol ethoxylates, 200 g/L diethylene glycol monobutyl ether
Applicant name	Titan Ag Pty Ltd
Applicant ACN	122 081 574
Date of variation	31 July 2024
Product registration no.	50389
Label approval no.	50389/143838
Description of the application and its purpose, including the intended use of the chemical product	Variation to the registration particulars and the particulars of label to update signal headings, constituent statements, and safety directions

Application no.	142508
Product name	Verpixo Adavelt active Fungicide
Active constituent	100 g/L florypicoxamid
Applicant name	Corteva Agriscience Australia Pty Ltd
Applicant ACN	003 771 659
Date of variation	31 July 2024
Product registration no.	91871
Label approval no.	91871/142508
Description of the application and its purpose, including the intended use of the chemical product	Variation to registration and label particulars to include new diseases

Application no.	142276
Product name	Nufarm Kamba 750 Herbicide
Active constituent	750 g/L dicamba as the dimethylamine and monomethylamine salts
Applicant name	Nufarm Australia Limited
Applicant ACN	004 377 780
Date of variation	1 August 2024
Product registration no.	69302
Label approval no.	69302/142276
Description of the application and its purpose, including the intended use of the chemical product	Variation to registration and label particulars to add herbicide spray drift restraints, extend use states and generally update the label

Application no.	140697
Product name	ProFume Fumigant
Active constituent	998 g/kg sulfuryl fluoride
Applicant name	Douglas Products & Packaging Company
Applicant ACN	N/A
Date of variation	1 August 2024
Product registration no.	59952
Label approval no.	59952/140697
Description of the application and its purpose, including the intended use of the chemical product	Variation to product registration and particulars of label approval to add use on rodents to an additional use situation, add use in phosphine resistant pests, add a quarantine use for brown marmorated stink bug, and change the product name to 'ProFume Fumigant'

Application no.	143839
Product name	Apparent Wetter 1000
Active constituents	800 g/L nonyl phenol ethoxylates, 200 g/L diethylene glycol monobutyl ether
Applicant name	Titan Ag Pty Ltd
Applicant ACN	122 081 574
Date of variation	7 August 2024
Product registration no.	67008
Label approval no.	67008/143839
Description of the application and its purpose, including the intended use of the chemical product	Variation of product registration and label approval to amend label signal headings, constituent statements, and safety directions

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.	142873
Product name	TIKDIP EC Cattle & Pig Spray
Active constituent	125 g/L amitraz
Applicant name	Nutrien Ag Solutions Limited
Applicant ACN	008 743 217
Date of registration	29 July 2024
Product registration no.	94591
Label approval no.	94591/142873
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 125 g/L amitraz liquid formulation product for the control of organophosphate and synthetic pyrethroid-resistant cattle tick, paralysis tick and bush tick on cattle, cattle tick on sheep, goats, and deer, and mange on pigs

Application no.	141939
Product name	Macrosyn Tulathromycin 100 mg/mL Injection for Cattle and Pigs
Active constituent	100 mg/mL tulathromycin
Applicant name	Bimeda (Australia) Pty Limited
Applicant ACN	058 196 508
Date of registration	2 August 2024
Product registration no.	94261
Label approval no.	94261/141939
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 100 mg/mL tulathromycin parenteral solution product for the treatment of respiratory infections in cattle and pigs

Table 4: Variations of registration – veterinary chemical products

Application no.	144735
Product name	KB CLAV FORTE 62.5 mg Tablets for Dogs and Cats
Active constituents	50 mg/tablet amoxicillin (as amoxicillin trihydrate), 12.5 mg/tablet clavulanic acid (as potassium clavulanate)
Applicant name	Knight Benedikt Australia Pty Ltd
Applicant ACN	647 150 874
Date of variation	15 July 2024
Product registration no.	93450
Label approval no.	93450/144735
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 'KB Clav Forte 50/12.5 Tablets for Dogs and Cats' to 'KB CLAV FORTE 62.5 mg Tablets for Dogs and Cats'

Application no.	143856
Product name	Apivar 500 mg Bee Hive Strips for Honey Bees
Active constituent	500 mg/strip amitraz
Applicant name	Veto-Pharma SAS
Applicant ACN	N/A
Date of variation	29 July 2024
Product registration no.	88615
Label approval no.	88615/143856
Description of the application and its purpose, including the intended use of the chemical product	Variation of the relevant particulars of the product registration and label approval to add a new pack size and updating the label to align with the current Veterinary Labelling Code

Application no.	143846
Product name	Moxistar Long Acting Injection for Cattle
Active constituent	100 mg/mL moxidectin
Applicant name	The Hunter River Company Pty Limited
Applicant ACN	133 798 615
Date of variation	30 July 2024
Product registration no.	84849
Label approval no.	84849/143846
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 extending the use to 1000 kg cattle and updating the label according to current Veterinary Labelling Code

Application no.	143034
Product name	Beransa 30 mg Solution for Injection for Dogs
Active constituent/s	30 mg/mL bedinvetmab
Applicant name	Zoetis Australia Pty Ltd
Applicant ACN	156 476 425
Date of variation	1 August 2024
Product registration no.	89695
Label approval no.	89695/143034
Description of the application and its purpose, including the intended use of the chemical product	Variation of relevant particulars of product registration and label approval by updating the side effects and general directions sections on the label and aligning the label to the current Veterinary Labelling Code

Application no.	143818
Product name	Q-Drench Multi-Combination Drench for Sheep
Active constituents	37.5 g/L closantel, 34 g/L levamisole (as levamisole hydrochloride), 25 g/L albendazole, 1 g/L abamectin
Applicant name	Zoetis Australia Pty Ltd
Applicant ACN	156 476 425
Date of variation	2 August 2024
Product registration no.	56573
Label approval no.	56573/143818
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 updating the first aid instructions, safety directions and additional user safety sections of the label

Application no.	143069
Product name	Beransa 20 mg Solution for Injection for Dogs
Active constituent	20 mg/mL bedinvetmab
Applicant name	Zoetis Australia Pty Ltd
Applicant ACN	156 476 425
Date of variation	5 August 2024
Product registration no.	89655
Label approval no.	89655/143069
Description of the application and its purpose, including the intended use of the chemical product	Variation of relevant particulars of product registration and label approval by updating the side effects and general directions sections on the label and aligning the label to the current Veterinary Labelling Code

Application no.	143074
Product name	Beransa 15 mg Solution for Injection for Dogs
Active constituent	15 mg/mL bedinvetmab
Applicant name	Zoetis Australia Pty Ltd
Applicant ACN	156 476 425
Date of variation	5 August 2024
Product registration no.	89656
Label approval no.	89656/143074
Description of the application and its purpose, including the intended use of the chemical product	Variation of relevant particulars of product registration and label approval by updating the side effects and general directions sections on the label and aligning the label to the current Veterinary Labelling Code

Application no.	143076
Product name	Beransa 10 mg Solution for Injection for Dogs
Active constituent	10 mg/mL bedinvetmab
Applicant name	Zoetis Australia Pty Ltd
Applicant ACN	156 476 425
Date of variation	6 August 2024
Product registration no.	89657
Label approval no.	89657/143076
Description of the application and its purpose, including the intended use of the chemical product	Variation of relevant particulars of product registration and label approval by updating the side effects and general directions sections on the label and aligning the label to the current Veterinary Labelling Code

Application no.	143077
Product name	Beransa 5 mg Solution for Injection for Dogs
Active constituent	5 mg/mL bedinvetmab
Applicant name	Zoetis Australia Pty Ltd
Applicant ACN	156 476 425
Date of variation	6 August 2024
Product registration no.	89658
Label approval no.	89658/143077
Description of the application and its purpose, including the intended use of the chemical product	Variation of relevant particulars of product registration and label approval by updating the side effects and general directions sections on the label and aligning the label to the current Veterinary Labelling Code

Application no.	143855
Product name	Closamax Closantel Sustained Action Oral Anthelmintic and Flukicide for Sheep and Lambs
Active constituent	37.5 g/L closantel
Applicant name	Elanco Australasia Pty Ltd
Applicant ACN	076 745 198
Date of variation	6 August 2024
Product registration no.	60582
Label approval no.	60582/143855
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 updating the first aid instructions, safety directions and additional user safety sections of the label

Application no.	143864
Product name	Sustain + Se Sustained Action Oral Anthelmintic and Flukicide for Sheep with Selenium
Active constituents	37.5 g/L closantel, 0.5 g/L selenium (as 1.2 g/L sodium selenate)
Applicant name	Zoetis Australia Pty Ltd
Applicant ACN	156 476 425
Date of variation	6 August 2024
Product registration no.	48471
Label approval no.	48471/143864
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 updating the first aid instructions, safety directions and additional user safety sections of the label

Application no.	143894
Product name	Exelpet Ezy-Dose Monthly Heartworm & Intestinal All Wormer for Dogs
Active constituents	543 mg/chew oxantel embonate, 143 mg/chew pyrantel embonate, 50 mg/chew praziquantel, 60 µg/chew ivermectin
Applicant name	Exelpet Products a Div of Mars Australia Pty Ltd
Applicant ACN	008 454 313
Date of variation	9 August 2024
Product registration no.	61997
Label approval no.	61997/143894
Description of the application and its purpose, including the intended use of the chemical product	Variation to the relevant particulars of both the product registration and label by updating the product name and by aligning label statements with the current Veterinary Labelling Code

Application no.	143895
Product name	Sedaquin Gel Oral Doser for Horses
Active constituent	35 mg/mL acepromazine (as acepromazine the maleate)
Applicant name	Floris Veterinaire Produkten B.V.
Applicant ACN	N/A
Date of variation	9 August 2024
Product registration no.	60254
Label approval no.	60254/143895
Description of the application and its purpose, including the intended use of the chemical product	Variation of the relevant particulars of product registration and label approval by changing the product name and aligning the label statements with the current Veterinary Labelling Code

Table 5: Label approval – veterinary chemical products

Application no.	144274
Product name	Gastratone Paste
Active constituent	50 mg/mL omeprazole
Applicant name	Endeavour Animal Health Pty Ltd
Applicant ACN	632 235 646
Date of registration	30 July 2024
Product registration no.	92238
Label approval no.	92238/144274
Description of the application and its purpose, including the intended use of the chemical product	Approval of a new label for the registered product Gastratone Paste with the label name EquaCare CuraVet Omeprazole 50 mg/mL MicroCap Paste for Horses

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.	140343
Active constituent	Dimethenamid-P
Applicant name	Croponosys India Private Limited
Applicant ACN	N/A
Date of approval	29 April 2024
Approval no.	93750
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent dimethenamid-P for use in agricultural chemical products

Application no.	142994
Active constituent	Cyromazine
Applicant name	Vetsense Pty Ltd
Applicant ACN	150 968 871
Date of approval	30 July 2024
Approval no.	94625
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent cyromazine for use in veterinary chemical products

Application no.	143161
Active constituent	Cefalexin monohydrate
Applicant name	Abbey Laboratories Pty Ltd
Applicant ACN	156 000 430
Date of approval	30 July 2024
Approval no.	94678
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent cefalexin monohydrate for use in veterinary chemical products

Application no.	143272
Active constituent	Fenbendazole
Applicant name	Vetsense Pty Ltd
Applicant ACN	150 968 871
Date of approval	31 July 2024
Approval no.	94711
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent fenbendazole for use in veterinary chemical products

Application no.	142441
Active constituent	Imazethapyr
Applicant name	Jiangsu Yangnong Chemical Co Ltd
Applicant ACN	N/A
Date of approval	31 July 2024
Approval no.	94443
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent imazethapyr for use in agricultural chemical products

Application no.	142442
Active constituent	Diflufenican
Applicant name	Jiangsu Yangnong Chemical Co Ltd
Applicant ACN	N/A
Date of approval	6 August 2024
Approval no.	94444
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent diflufenican for use in agricultural chemical products

Application no.	142493
Active constituent	Clopyralid
Applicant name	Foison Scitech Co Limited
Applicant ACN	N/A
Date of approval	6 August 2024
Approval no.	94469
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent clopyralid for use in agricultural chemical products

Application no.	142570
Active constituent	Pyrasulfotole
Applicant name	Yifan Biotechnology Group Co Ltd
Applicant ACN	N/A
Date of approval	15 August 2024
Approval no.	94486
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent pyrasulfotole for use in agricultural chemical products

Application no.	144362
Active constituent	Albendazole
Applicant name	Virbac (Australia) Pty Ltd
Applicant ACN	003 268 871
Date of approval	9 August 2024
Approval no.	94976
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent albendazole for use in veterinary chemical products

Application no.	141692
Active constituent	2,4-D 2-ethylhexyl ester
Applicant name	Agro-Alliance (Australia) Pty Ltd
Applicant ACN	130 864 603
Date of approval	9 August 2024
Approval no.	94146
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent 2,4-D 2-ethylhexyl ester for use in agricultural chemical products

Application for the approval of a new active constituent, cyclobutrifluram

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

Table 7: Particulars of the active constituent

Common name	Cyclobutrifluram
IUPAC name	Mixture comprised of 80–100% <i>N</i> -[(1 <i>S</i> ,2 <i>S</i>)-2-(2,4-dichlorophenyl)cyclobutyl]-2-(trifluoromethyl)pyridine-3-carboxamide and 20–0% of the (1 <i>R</i> ,2 <i>R</i>)-enantiomer
CAS name	<i>rel-N</i> -[(1 <i>R</i> ,2 <i>R</i>)-2-(2,4-dichlorophenyl)cyclobutyl]-2-(trifluoromethyl)-3-pyridinecarboxamide
CAS registry number	1460292-16-3
Manufacturer's codes	SYN549522
Minimum purity	950 g/kg (dry weight basis)
Molecular formula	C ₁₇ H ₁₃ Cl ₂ F ₃ N ₂ O
Molecular weight	389.2 gmol ⁻¹
Structure	<p>1<i>S</i>, 2<i>S</i>-enantiomer (SYN547386)</p> <p>1<i>R</i>, 2<i>R</i>-enantiomer (SYN548941)</p> <p>ABSOLUTE</p>
Chemical family	Pyridine carboxamide
Mode of action	Cyclobutrifluram is a broad-spectrum of nematocide and fungicide. It acts by inhibition of the succinate dehydrogenase enzyme of the mitochondrial electron transport chain complex II, thereby blocking the availability of ATP and cell growth. It is used for the control of nematodes and soil-borne diseases such as <i>Fusarium</i> species as a seed treatment or soil applications. By protecting the root mass, it plays a critical part in enabling no-tillage and conservation-tillage practices.

Summary of the APVMA's evaluation of cyclobutrifluram active constituent

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

The APVMA has considered the toxicological aspects of cyclobutrifluram and concluded that there are no toxicological concerns to the approval of this active constituent. The ADI for cyclobutrifluram was established at 0.14 mg/kg bw/day based on a NOAEL of 14 mg/kg bw/d in an 80-week dietary toxicity and carcinogenicity study in mice on increased organ weights, liver masses and increased incidence of hepatocellular carcinoma. An ARfD was considered unnecessary for cyclobutrifluram in the general population due to its low oral toxicity and the absence of any neurological effects or developmental toxicity after a single dose.

The Scheduling Delegate made a final decision to include cyclobutrifluram in Appendix B of the Poison Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP).

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

Constituent	Level
Cyclobutrifluram	Minimum purity 950 g/kg (dried basis)
1S,2S enantiomer	Minimum 850 g/kg (dried basis)
1R,2R enantiomer	Maximum 100 g/kg (dried basis)

Impurities of toxicological significance are not expected to occur in cyclobutrifluram as a result of the raw materials and the synthetic route used.

The APVMA accepts the findings and recommendations of its advisors on these criteria.

Further information

A Public Release Summary (PRS) of the evaluation of this product is available from the APVMA website 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 cyclobutrifluram 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 [public submission coversheet](#)).

Please lodge your submission with a [public submission coversheet](#), which provides options for how your submission will be published.

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

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

Email: 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](#).

New product, TREFINTI Turf Nematicide containing a new active constituent, cyclobutrifluram

The APVMA has before it an application for registration of a new product, TREFINTI Turf Nematicide containing a new active constituent, cyclobutrifluram.

Table 8: Particulars of the application

Proposed product name	TREFINTI Turf Nematicide
Applicant company	Syngenta Australia Pty Ltd
Name of active constituent	Cyclobutrifluram
Signal heading	0 – Unscheduled
Summary of proposed use	For the control of Nematodes in Turf
Pack sizes	500 mL – 20 L
Withholding period	Not required

A summary of the APVMA's evaluation of TREFINTI Turf Nematicide in accordance with the requirements of section 14(1)(C) of the Agricultural and Veterinary Chemicals Code (the 'Agvet Code'), scheduled to the *Agricultural and Veterinary Chemicals Code Act 1994*:

- 1) The APVMA has evaluated the application and in its assessment in relation to whether the safety criteria have been met in accordance with the definition set out in section 5A of the Agvet Code, proposes to determine that:
 - i. The APVMA is satisfied that proposed use of TREFINTI Turf Nematicide would not be an undue hazard to the safety of people exposed to its 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 TREFINTI Turf Nematicide 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 TREFINTI Turf Nematicide containing the active constituent cyclobutrifluram, would not be likely to have an unintended effect that is harmful to animals, plants or the environment.
- 2) The APVMA has evaluated the application and in its assessment in relation to whether the efficacy criteria have been met in accordance with the definition set out in section 5B of the Agvet Code, and proposes to determine that:
 - i. In relation to its assessment of efficacy the APVMA is satisfied that data from trials supporting the efficacy of the product adequately demonstrate that if used according to the product label directions, the product is effective for its proposed uses.
- 3) The APVMA has evaluated the application and in its assessment in relation to whether the trade criteria have been met in accordance with the definition set out in section 5C of the Agvet Code, proposes to determine that:
 - i. The APVMA is satisfied that the proposed use of TREFINTI Turf Nematicide would not adversely affect trade between Australia and places outside Australia as the product is not for use in animals producing any major Australian export commodities.

Further information

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

Making a submission

In accordance with section 13 of the Agvet Code, the APVMA invites any person to submit a relevant written submission as to whether TREFINTI Turf Nematicide should be registered. Submissions should relate only to matters that are required by the APVMA to be taken into consideration in determining whether the safety, efficacy or trade criteria have been met. Submissions should state the grounds on which they are based.

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

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

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

Please lodge your submission with a [public submission coversheet](#), which provides options for how your submission will be published.

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

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

Email: casemanagement@apvma.gov.au

Post:

Case Management and Administration Unit
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](#).

Licensing of veterinary chemical manufacturers

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

For a comprehensive listing of all licensed manufacturers please see the [APVMA website](#).

New licenses

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

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

Company name	Licence number	Company ACN	Address	Product types	Steps of manufacture	Date issued
Parnell Manufacturing Pty Ltd	1088	138 251 582	Unit 4, Century Estate, 476 Gardeners Road Alexandria NSW 2015	Category 1: Sterile products	Quality assurance (QA) of raw materials, formulation including blending, filling, aseptic filling, packaging, labelling, sterilisation (heat, and filtration), microbiological reduction treatment (heat, chemical, and filtration), analysis and testing (physical, chemical, and endotoxin testing), storage, and release for supply.	1 August 2024
IDT AUSTRALIA LIMITED	1124	006 522 970	39-57 Wadhurst Drive Boronia VIC 3155	Category 1: Sterile products for injection	Quality assurance (QA) of raw materials, Formulation including blending, Aseptic filling, Packaging, Labelling, Repackaging, Relabelling, Sterilisation (filtration), Analysis and testing (physical, chemical, endotoxin, microbiological) and Storage.	19 July 2024
C M Laboratories Pty Ltd	2150	098 897 637	Units 1-4 36 Curtis Road Mulgrave NSW 2756	Category 2: Creams, lotions, ointments, gels, pastes, powders, sprays, liquids and suspensions Category 3: Liquids, sprays and powders Category 4: Premixes and supplements	Quality assurance (QA) of raw materials, formulation including blending, wet milling, filling, packaging, labelling, analysis and testing (physical), storage and release for supply.	29 July 2024

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 APVMA has cancelled the approvals and/or registrations set out in Table 10:

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

Approval or registration number	Name	Type of approval or registration	Holder	Reason for cancellation (if relevant pursuant to s45A(3))	Date of cancellation
46177	Ivomec (Ivermectin) Premix For Pigs	Product	Boehringer Ingelheim Animal Health Australia Pty. Ltd.	Business reasons	14 August 2024
51188	Ilium Ketamil Injection	Product	Troy Laboratories Pty Ltd	Business reasons	14 August 2024

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

Instructions

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

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

Possession or custody

A person may possess the cancelled active constituent, cancelled product or product bearing a cancelled label referred to in Table 10 in accordance with its label instructions for 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 [voluntary cancellations at the request of the holder](#) on its website, and provides a [subscription option](#) to be notified by email when the list is updated.