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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.

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Agricultural chemical products and approved labels

Pursuant to the Agricultural and Veterinary Chemicals Code scheduled to the *Agricultural and Veterinary Chemicals Code Act 1994*, the APVMA hereby gives notice that it has registered or varied the relevant particulars or conditions of the registration in respect of the following products and has approved the label or varied the relevant particulars or conditions of the approval in respect of the containers for the chemical product, with effect from the dates shown.

Table 1: Agricultural products based on existing active constituents

| Application no. | 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 *Lepidopteran* 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 *Septoria nodorum* 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 florylpicoxamid |
| 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 | Cropnosys 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 1: Particulars of the active constituent

| Common name | Cyclobutrifluram |
| --- | --- |
| IUPAC name | Mixture comprised of 80–100% *N*-[(1*S*,2*S*)-2-(2,4-dichlorophenyl)cyclobutyl]-2-(trifluoromethyl)pyridine-3-carboxamide and 20–0% of the (1*R*,2*R*)-enantiomer |
| CAS name | *rel-N*-[(1*R*,2*R*)-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 | C17H13Cl2F3N2O |
| Molecular weight | 389.2 gmol-1 |
| Structure | Image of the chemical structure of cyclobutrifluram. Description below.1*S*, 2*S*-enantiomer 1*R*, 2*R*-enantiomer (SYN547386) (SYN548941) |
| Chemical family | Pyridine carboxamide |
| Mode of action | Cyclobutrifluram is a broad-spectrum of nematicide 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 *Fusarium* 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](https://apvma.gov.au/news-and-publications/public-consultations) 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](https://www.apvma.gov.au/news-and-publications/public-consultations/ooo-vet-vaccine-permit-applications), unless you have asked for the submission to remain confidential (see [public submission coversheet](https://apvma.gov.au/node/72856)).

Please lodge your submission with a [public submission coversheet](https://apvma.gov.au/node/72856), 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](https://apvma.gov.au/node/59876).

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:
2. 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.

1. 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.
2. 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.
3. 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:
4. 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.
5. 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:
6. 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](https://apvma.gov.au/news-and-publications/public-consultations) 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](https://www.apvma.gov.au/news-and-publications/public-consultations/ooo-vet-vaccine-permit-applications), unless you have asked for the submission to remain confidential (see [public submission coversheet](https://apvma.gov.au/node/72856)).

Please lodge your submission with a [public submission coversheet](https://apvma.gov.au/node/72856), 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](https://apvma.gov.au/node/59876).

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](https://apvma.gov.au/node/12326).

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 RoadAlexandria 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 DriveBoronia 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 1–436 Curtis RoadMulgrave NSW 2756 | Category 2: Creams, lotions, ointments, gels, pastes, powders, sprays, liquids and suspensionsCategory 3: Liquids, sprays and powdersCategory 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](https://apvma.gov.au/node/69446) on its website, and provides a [subscription option](https://apvma.us2.list-manage.com/subscribe?u=f09f7f9ed2a2867a19b99e2e4&id=a025640240) to be notified by email when the list is updated.