

| **Gazette** | **Agricultural and**  **Veterinary Chemicals** |
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No. APVMA 7, Tuesday, 6 April 2021

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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://www.apvma.gov.au/news-and-publications/publications/gazette).

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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 EXSITING Active Constituents

| Application no.: | 121494 |
| --- | --- |
| Product name: | Eco-NemGuard G |
| Active constituent/s: | 450 g/kg garlic extract containing a minimum 9 g/kg total polysulfides |
| Applicant name: | DuluxGroup (Australia) Pty Ltd |
| Applicant ACN: | 003 149 719 |
| Summary of use: | For the reduction in free-living parasitic nematode populations and damage to vegetable crops and turf |
| Date of registration: | 16 March 2021 |
| Product registration no.: | 88493 |
| Label approval no.: | 88493/121494 |

|  |  |
| --- | --- |
| Application no.: | 125113 |
| Product name: | Sharda Linuron 500 WP Herbicide |
| Active constituent/s: | 500 g/kg linuron |
| Applicant name: | Sharda Cropchem Espana S L |
| Applicant ACN: | N/A |
| Summary of use: | For selective weed control in carrots, coriander, parsnips, cereals, onions, potatoes, soybeans, sweet corn and maize |
| Date of registration: | 16 March 2021 |
| Product registration no.: | 89513 |
| Label approval no.: | 89513/125113 |

| Application no.: | 129183 |
| --- | --- |
| Product name: | Inside & Outside Pest Barrier Spray |
| Active constituent/s: | 0.5 g/L bifenthrin |
| Applicant name: | Farmalinx Pty Ltd |
| Applicant ACN: | 134 353 245 |
| Summary of use: | For indoor and outdoor control of insects with residual control |
| Date of registration: | 16 March 2021 |
| Product registration no.: | 90512 |
| Label approval no.: | 90512/129183 |

| Application no.: | 129197 |
| --- | --- |
| Product name: | Spalding Battista 100 SC Termiticide And Insecticide |
| Active constituent/s: | 100 g/L bifenthrin |
| Applicant name: | Spalding Holdings Pty Ltd |
| Applicant ACN: | 010 155 852 |
| Summary of use: | For the control of a range of urban interior and exterior pests, subterranean termite damage and various pests in turf, orchards and ornamentals |
| Date of registration: | 17 March 2021 |
| Product registration no.: | 90518 |
| Label approval no.: | 90518/129197 |

| Application no.: | 129213 |
| --- | --- |
| Product name: | CropSure Region 200SC Insecticide |
| Active constituent/s: | 200 g/L fipronil |
| Applicant name: | CropSure Pty Ltd |
| Applicant ACN: | 643 829 190 |
| Summary of use: | For the control of various insect pests in asparagus, bananas, brassicas, cotton, forestry, ginger, wine grapevines, mushrooms, pasture, potatoes, sorghum, sugarcane and swede |
| Date of registration: | 18 March 2021 |
| Product registration no.: | 90525 |
| Label approval no.: | 90525/129213 |

| Application no.: | 129254 |
| --- | --- |
| Product name: | Relyon Saflufenacil 700 WG Herbicide |
| Active constituent/s: | 700 g/kg saflufenacil |
| Applicant name: | Nutrien Ag Solutions Limited |
| Applicant ACN: | 008 743 217 |
| Summary of use: | For the control of broadleaf weeds prior to establishment of crops and forestry plantations, fallows, established orchards, pulses, cereals, lucerne and various other situations |
| Date of registration: | 18 March 2021 |
| Product registration no.: | 90543 |
| Label approval no.: | 90543/129254 |

| Application no.: | 129255 |
| --- | --- |
| Product name: | Genfarm Saflufenacil 700 WG Herbicide |
| Active constituent/s: | 700 g/kg saflufenacil |
| Applicant name: | Nutrien Ag Solutions Limited |
| Applicant ACN: | 008 743 217 |
| Summary of use: | For the control of broadleaf weeds prior to establishment of crops and forestry plantations, fallows, established orchards, pulses, cereals, lucerne and various other situations |
| Date of registration: | 18 March 2021 |
| Product registration no.: | 90544 |
| Label approval no.: | 90544/129255 |

| Application no.: | 129196 |
| --- | --- |
| Product name: | CropSure Hexasure 250 Herbicide |
| Active constituent/s: | 250 g/L hexazinone |
| Applicant name: | CropSure Pty Ltd |
| Applicant ACN: | 643 829 190 |
| Summary of use: | For control of certain broadleaf weeds, perennial and annual grasses, woody weeds in *Pinus radiata* plantations, pasture situations and commercial and industrial areas and rights of way |
| Date of registration: | 18 March 2021 |
| Product registration no.: | 90517 |
| Label approval no.: | 90517/129196 |

| Application no.: | 129210 |
| --- | --- |
| Product name: | CropSure Confidant 350SC Insecticide |
| Active constituent/s: | 350 g/L imidacloprid |
| Applicant name: | CropSure Pty Ltd |
| Applicant ACN: | 643 829 190 |
| Summary of use: | For the control of greyback and Childers canegrub in sugarcane and silverleaf whitefly in various vegetable crops |
| Date of registration: | 18 March 2021 |
| Product registration no.: | 90522 |
| Label approval no.: | 90522/129210 |

| Application no.: | 123706 |
| --- | --- |
| Product name: | Contact Organics Farmsafe Weed Terminator Plus |
| Active constituent/s: | 868 g/L acetic acid |
| Applicant name: | Contact Organics Pty Ltd |
| Applicant ACN: | 607 848 091 |
| Summary of use: | For control of weeds in horticulture, orchards, vineyards, paddocks and around buildings and other non-crop areas |
| Date of registration: | 19 March 2021 |
| Product registration no.: | 89129 |
| Label approval no.: | 89129/123706 |

| Application no.: | 123708 |
| --- | --- |
| Product name: | Contact Organics Localsafe Weed Terminator Plus |
| Active constituent/s: | 868 g/L acetic acid |
| Applicant name: | Contact Organics Pty Ltd |
| Applicant ACN: | 607 848 091 |
| Summary of use: | For the control of weeds in public areas including parks, curbs, verges, playgrounds, gardens, schools, sporting grounds, nurseries, rail lines, vineyards, orchards and other situations as per the directions for use |
| Date of registration: | 19 March 2021 |
| Product registration no.: | 89131 |
| Label approval no.: | 89131/123708 |

| Application no.: | 125823 |
| --- | --- |
| Product name: | Veritas Opti Fungicide |
| Active constituent/s: | 370 g/L tebuconazole, 222 g/L azoxystrobin |
| Applicant name: | Adama Australia Pty Ltd |
| Applicant ACN: | 050 328 973 |
| Summary of use: | For control/suppression of various diseases in barley, canola, peanuts, pulses and wheat |
| Date of registration: | 19 March 2021 |
| Product registration no.: | 89698 |
| Label approval no.: | 89698/125823 |

| Application no.: | 129214 |
| --- | --- |
| Product name: | Titan AMS Combine 950 Adjuvant |
| Active constituent/s: | 800 g/kg ammonium sulphate, 150 g/kg carboxylic acid |
| Applicant name: | Titan Ag Pty Ltd |
| Applicant ACN: | 122 081 574 |
| Summary of use: | For use as an adjuvant with glyphosate products as a water softener, acidifier, penetrant, wetting agent |
| Date of registration: | 19 March 2021 |
| Product registration no.: | 90526 |
| Label approval no.: | 90526/129214 |

| Application no.: | 129272 |
| --- | --- |
| Product name: | Hollow Heart CB Wood Preservative |
| Active constituent/s: | 60 g/L copper present as copper ethanolamine complex, 31.5 g/L boron present as disodium octaborate tetrahydrate |
| Applicant name: | Osmose Utilities Services Inc |
| Applicant ACN: | N/A |
| Summary of use: | For remedial treatment of in-service poles, poles and poletops, bore holes, posts, beams, lumber, bridge and mine timbers and piling, to stop existing wood decay and protects against future decay |
| Date of registration: | 19 March 2021 |
| Product registration no.: | 90556 |
| Label approval no.: | 90556/129272 |

| Application no.: | 123550 |
| --- | --- |
| Product name: | Contact Organics HomeSafe Weed Terminator Plus Ready-to-Use Spray Mixture |
| Active constituent/s: | 47 g/L acetic acid |
| Applicant name: | Contact Organics Pty Ltd |
| Applicant ACN: | 607 848 091 |
| Summary of use: | For control of weeds, grasses, moss and algae in home gardens |
| Date of registration: | 23 March 2021 |
| Product registration no.: | 89079 |
| Label approval no.: | 89079/123550 |

| Application no.: | 123644 |
| --- | --- |
| Product name: | Seajet 039 Platinum Mono-Component Antifouling |
| Active constituent/s: | 480.0 g/L copper as cuprous oxide, 51.9 g/L copper pyrithione |
| Applicant name: | Chugoku Marine Paints Ltd |
| Applicant ACN: | N/A |
| Summary of use: | For the prevention of biofouling on vessel hulls |
| Date of registration: | 25 March 2021 |
| Product registration no.: | 89111 |
| Label approval no.: | 89111/123644 |

| Application no.: | 124753 |
| --- | --- |
| Product name: | Proviso Fungicide |
| Active constituent/s: | 250 g/L prothioconazole |
| Applicant name: | Adama Australia Pty Ltd |
| Applicant ACN: | 050 328 973 |
| Summary of use: | For control or suppression of various fungal diseases in wheat, barley, oats and canola |
| Date of registration: | 26 March 2021 |
| Product registration no.: | 89415 |
| Label approval no.: | 89415/124753 |

1. Variations of registration

| Application no.: | 130094 |
| --- | --- |
| Product name: | e-Tron Cotton Defoliant Oil |
| Active constituent/s: | 794 g/L paraffinic oil |
| Applicant name: | Echem (Aust) Pty Ltd |
| Applicant ACN: | 089 133 095 |
| Summary of variation: | To vary the distinguishing product name and the name that appears on the label  from ‘e-Oil Cotton Defoliant Oil’ to ‘e-Tron Cotton Defoliant Oil’ |
| Date of variation: | 8 March 2021 |
| Product registration no.: | 85198 |
| Label approval no.: | 85198/130094 |

| Application no.: | 130093 |
| --- | --- |
| Product name: | Parasol Insecticide and Defoliant Oil |
| Active constituent/s: | 794 g/L paraffinic oil |
| Applicant name: | eChem (Aust) Pty Ltd |
| Applicant ACN: | 089 133 095 |
| Summary of variation: | To vary the distinguishing product name and the name that appears on the label from ‘eChem e-Oil Insecticide and Defoliant Oil’ to ‘Parasol Insecticide and Defoliant Oil’ |
| Date of variation: | 8 March 2021 |
| Product registration no.: | 84730 |
| Label approval no.: | 84730/130093 |

| Application no.: | 130114 |
| --- | --- |
| Product name: | Tanalith Q Wood Preservative |
| Active constituent/s: | 90.24 g/L copper (Cu) present as basic copper carbonate, 56.4 g/L didecyl dimethyl ammonium chloride (quaternary ammonium compound) |
| Applicant name: | Arch Wood Protection (Aust) Pty Ltd |
| Applicant ACN: | 003 780 872 |
| Summary of variation: | To vary the distinguishing product name and the name that appears on the label from ‘Taratek Alkaline Copper Quaternary Timber Treatment’ to ‘Tanalith Q Wood Preservative’ |
| Date of variation: | 9 March 2021 |
| Product registration no.: | 58242 |
| Label approval no.: | 58242/130114 |

| Application no.: | 130120 |
| --- | --- |
| Product name: | Titan Top Wettable Sulphur 800WG Fungicide/Miticide |
| Active constituent/s: | 800 g/kg sulfur (S) as wettable sulfur |
| Applicant name: | Titan Ag |
| Applicant ACN: | 122 081 574 |
| Summary of variation: | To vary the distinguishing product name and the name that appears on the label from ‘Titan Sulpher 800 WG Fungicide/Miticide’ to ‘Titan Top Wettable Sulphur 800WG Fungicide/Miticide’ |
| Date of variation: | 10 March 2021 |
| Product registration no.: | 63727 |
| Label approval no.: | 63727/130120 |

| Application no.: | 130163 |
| --- | --- |
| Product name: | Dedicate Forte Stressgard Turf Fungicide |
| Active constituent/s: | 240 g/L tebuconazole |
| Applicant name: | Bayer Crop Science Pty Ltd |
| Applicant ACN: | 000 226 022 |
| Summary of variation: | To vary the distinguishing product name and the name that appears on the label from ‘Bayer Stressgard 240 SC Fungicide’ to ‘Dedicate Forte Stressgard Turf Fungicide’ |
| Date of variation: | 11 March 2021 |
| Product registration no.: | 89422 |
| Label approval no.: | 89422/130163 |

| Application no.: | 129142 |
| --- | --- |
| Product name: | Banjo Spray Adjuvant |
| Active constituent/s: | 725 g/L methyl esters of canola oil fatty acids |
| Applicant name: | Nufarm Australia Limited |
| Applicant ACN: | 004 377 780 |
| Summary of variation: | To include additional herbicides and fungicides that ‘Banjo Spray Adjuvant’ can be used with |
| Date of variation: | 15 March 2021 |
| Product registration no.: | 68451 |
| Label approval no.: | 68451/129142 |

| Application no.: | 129207 |
| --- | --- |
| Product name: | Arysta LifeScience Lantern 625 Herbicide |
| Active constituent/s: | 625 g/L 2,4-D present as the dimethylamine and diethanolamine salts |
| Applicant name: | Arysta LifeScience Australia Pty Ltd |
| Applicant ACN: | 005 225 507 |
| Summary of variation: | To amend the product label in line with the 2,4-D reconsideration final regulatory decision and add uses in fallow, hardwood and softwood plantations, cavendish bananas, agricultural non-crop areas, commercial and industrial areas, pastures, rights of way, and oil tea tree under the Permit to Label project |
| Date of variation: | 15 March 2021 |
| Product registration no.: | 66749 |
| Label approval no.: | 66749/129207 |

| Application no.: | 129199 |
| --- | --- |
| Product name: | Titan Glufosinate 200 Herbicide |
| Active constituent/s: | 200 g/L glufosinate-ammonium |
| Applicant name: | Titan Ag Pty Ltd |
| Applicant ACN: | 122 081 574 |
| Summary of variation: | To add uses in sugarcane |
| Date of variation: | 16 March 2021 |
| Product registration no.: | 66364 |
| Label approval no.: | 66364/129199 |

| Application no.: | 125057 |
| --- | --- |
| Product name: | Sledge Herbicide |
| Active constituent/s: | 102 g/L n-methyl-2-pyrrolidone, 25 g/L pyraflufen-ethyl |
| Applicant name: | Sipcam Pacific Australia Pty Ltd |
| Applicant ACN: | 073 176 888 |
| Summary of variation: | To add a pre-harvest use in nominated pulse crops |
| Date of variation: | 19 March 2021 |
| Product registration no.: | 83053 |
| Label approval no.: | 83053/125057 |

| Application no.: | 129217 |
| --- | --- |
| Product name: | Mortein Naturgard Fly & Mosquito Killer Eucalyptus Scent |
| Active constituent/s: | 16.1 g/kg piperonyl butoxide, 3.5 g/kg pyrethrins |
| Applicant name: | RB (Hygiene Home) Australia Pty Ltd |
| Applicant ACN: | 629 549 506 |
| Summary of variation: | To change the distinguishing product name and the name that appears on the label from ‘Mortein Naturgard Fly Control Spray’ to ‘Mortein Naturgard Fly & Mosquito Killer Eucalyptus Scent’ and to vary label particulars |
| Date of variation: | 19 March 2021 |
| Product registration no.: | 61747 |
| Label approval no.: | 61747/129217 |

| Application no.: | 129409 |
| --- | --- |
| Product name: | Genfarm Panzer 450 Herbicide |
| Active constituent/s: | 450 g/L glyphosate present as the isopropylamine salt |
| Applicant name: | Nutrien Ag Solutions Limited |
| Applicant ACN: | 008 743 217 |
| Summary of variation: | To amend the constituent statement, withholding periods, protections and storage and disposal statements, add uses in onions, peanuts and soybeans, and include additional weeds for existing uses |
| Date of variation: | 24 March 2021 |
| Product registration no.: | 58830 |
| Label approval no.: | 58830/129409 |

| Application no.: | 128572 |
| --- | --- |
| Product name: | Imtrade Dalbie 800 WG Fungicide |
| Active constituent/s: | 800 g/kg prothioconazole |
| Applicant name: | Imtrade Australia Pty Ltd |
| Applicant ACN: | 090 151 134 |
| Summary of variation: | To extend label uses to include control of fungal diseases in cereals and canola when used in combination with Imtrade Turbulence 800 WG Fungicide |
| Date of variation: | 25 March 2021 |
| Product registration no.: | 87492 |
| Label approval no.: | 87492/128572 |

| Application no.: | 129335 |
| --- | --- |
| Product name: | Relyon 2,4-D LV Ester 680 Herbicide |
| Active constituent/s: | 680 g/L 2,4-D present as the 2-ethylhexyl ester |
| Applicant name: | Nutrien Ag Solutions Limited |
| Applicant ACN: | 008 743 217 |
| Summary of variation: | To change the product name from Optane LV 680 Herbicide to Relyon 2,4-D LV Ester 680 Herbicide and amend the product label in line with the 2,4-D reconsideration final regulatory decision |
| Date of variation: | 25 March 2021 |
| Product registration no.: | 81788 |
| Label approval no.: | 81788/129335 |

| Application no.: | 129648 |
| --- | --- |
| Product name: | Nufarm Amicide Advance 700 Selective Herbicide |
| Active constituent/s: | 700 g/L 2,4-D present as the dimethylamine and monomethylamine salts |
| Applicant name: | Nufarm Australia Limited |
| Applicant ACN: | 004 377 780 |
| Summary of variation: | To update the label in line with the APVMA 2,4-D reconsideration, increase weed densities for optical spot spraying and to make amendments to the safety directions and sugarcane spray window |
| Date of variation: | 26 March 2021 |
| Product registration no.: | 66167 |
| Label approval no.: | 66167/129648 |

1. label approval

| Application no.: | 129641 |
| --- | --- |
| Product name: | Aquapro Spa Brom Tabs |
| Active constituent/s: | 650 g/kg available bromine (Br), 280 g/kg available chlorine (Cl) present as bromochlorodimethylhydantoin |
| Applicant name: | M I International Pty Ltd |
| Applicant ACN: | 002 869 089 |
| Summary of variation: | To approve a new label for the product 'Aquapro Spa Brom Tabs' with the label name 'Spa Care Bromine Tabs' |
| Date of variation: | 23 March 2021 |
| Product registration no.: | 62087 |
| Label approval no.: | 62087/129641 |

| Application no.: | 129670 |
| --- | --- |
| Product name: | Sportak Fungicide |
| Active constituent/s: | 450 g/L prochloraz |
| Applicant name: | FMC Australasia Pty Ltd |
| Applicant ACN: | 095 326 891 |
| Summary of variation: | To approve a new label for the product 'Sportak Fungicide' with the label name 'Sportak xLo Fungicide' |
| Date of variation: | 26 March 2021 |
| Product registration no.: | 30484 |
| Label approval no.: | 30484/129670 |

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 Existing Active Constituents

| Application no.: | 124309 |
| --- | --- |
| Product name: | Pharmachem Kefvet 600 Mg Tablets For Dogs And Cats |
| Active constituent/s: | 600 mg/tablet cephalexin as monohydrate |
| Applicant name: | Bocko P/L & Flexsky P/L In Partnership |
| Applicant ACN: | 147 389 678 |
| Summary of use: | For the treatment of susceptible infections of the respiratory tract, urogenital tract, the skin, localised infections in soft tissues, treatment and prophylaxis of osteomyelitis in dogs and cats, and for the treatment of susceptible infections of the gastrointestinal tract in dogs |
| Date of registration: | 15 March 2021 |
| Product registration no.: | 89287 |
| Label approval no.: | 89287/124309 |

| Application no.: | 129163 |
| --- | --- |
| Product name: | Copgane Copper 20g Capsules For Cattle |
| Active constituent/s: | 16.8 g/capsule of copper as copper oxide |
| Applicant name: | Rural Chemical Industries (Aust) Pty Ltd |
| Applicant ACN: | 003 842 402 |
| Summary of use: | For the treatment and prevention of copper deficiency in cattle over 200 kg bodyweight |
| Date of registration: | 19 March 2021 |
| Product registration no.: | 90507 |
| Label approval no.: | 90507/129163 |

| Application no.: | 124904 |
| --- | --- |
| Product name: | Dechra TMPS Powder |
| Active constituent/s: | 450 mg/g sulfadimidine, 90 mg/g trimethoprim |
| Applicant name: | Dechra Veterinary Products (Australia) Pty Ltd |
| Applicant ACN: | 614 716 700 |
| Summary of use: | For the treatment of infections in horses caused by organisms susceptible to the combination of sulfadimidine and trimethoprim |
| Date of registration: | 25 March 2021 |
| Product registration no.: | 89448 |
| Label approval no.: | 89448/124904 |

| Application no.: | 128818 |
| --- | --- |
| Product name: | Independents Own Starmec Plus (Ivermectin Plus Clorsulon) Broad-Spectrum Antiparasitic Injection For Cattle |
| Active constituent/s: | 100 mg/mL clorsulon, 10 mg/mL ivermectin |
| Applicant name: | Vetpharm Pty Ltd |
| Applicant ACN: | 626 894 086 |
| Summary of use: | For the treatment and control of ivermectin and clorsulon sensitive strains of internal and external parasites of cattle, including adult liver flukes |
| Date of registration: | 25 March 2021 |
| Product registration no.: | 90419 |
| Label approval no.: | 90419/128818 |

| Application no.: | 128809 |
| --- | --- |
| Product name: | Dalgety Cattlemax LV Pour-On Endectocide for Cattle |
| Active constituent/s: | 10 mg/mL ivermectin |
| Applicant name: | Nutrien Ag Solutions Limited |
| Applicant ACN: | 008 743 217 |
| Summary of use: | For the treatment and control of ivermectin sensitive internal and external parasites of beef and dairy cattle |
| Date of registration: | 25 March 2021 |
| Product registration no.: | 90415 |
| Label approval no.: | 90415/128809 |

1. Variations of registration

| Application no.: | 127805 |
| --- | --- |
| Product name: | Randlab Medicaine Injection |
| Active constituent/s: | 20 mg/mL prilocaine hydrochloride |
| Applicant name: | Randlab Australia Pty Ltd |
| Applicant ACN: | 114 948 837 |
| Summary of variation: | To add an additional pack size |
| Date of variation: | 17 March 2021 |
| Product registration no.: | 88500 |
| Label approval no.: | 88500/127805 |

| Application no.: | 126458 |
| --- | --- |
| Product name: | Pamlin Injection |
| Active constituent/s: | 5 mg/mL diazepam |
| Applicant name: | Ceva Animal Health Pty Ltd |
| Applicant ACN: | 002 692 426 |
| Summary of variation: | To update the in-use shelf life |
| Date of variation: | 18 March 2021 |
| Product registration no.: | 37735 |
| Label approval no.: | 37735/126458 |

| Application no.: | 126405 |
| --- | --- |
| Product name: | Excede Sterile Suspension |
| Active constituent/s: | 200 mg/mL ceftiofur as ceftiofur crystalline free acid |
| Applicant name: | Zoetis Australia Pty Ltd |
| Applicant ACN: | 156 476 425 |
| Summary of variation: | To add an additional pack size |
| Date of variation: | 19 March 2021 |
| Product registration no.: | 65092 |
| Label approval no.: | 65092/126405 |

| Application no.: | 129907 |
| --- | --- |
| Product name: | Parvac Vaccine |
| Active constituent/s: | canine parvovirus (inactivated) ≥ 10^5.0 TCID 50/mL |
| Applicant name: | Zoetis Australia Pty Ltd |
| Applicant ACN: | 156 476 425 |
| Summary of variation: | To add an additional pack size |
| Date of variation: | 25 March 2021 |
| Product registration no.: | 51777 |
| Label approval no.: | 51777/129907 |

1. label approval

| Application no.: | 130095 |
| --- | --- |
| Product name: | [Wagg & Purr] Cephalexin 500mg |
| Active constituent/s: | 500 mg/tablet cephalexin as monohydrate |
| Applicant name: | AVet Health Pty Ltd |
| Applicant ACN: | 616 838 101 |
| Summary of variation: | To vary the distinguishing product name and the name that appears on the label from ‘[Wagg & Purr] Dogs & Cats Cephalexin 500mg Tablets’ to ‘[Wagg & Purr] Cephalexin 500mg’ |
| Date of variation: | 8 March 2021 |
| Product registration no.: | 89852 |
| Label approval no.: | 89852/130095 |

| Application no.: | 130096 |
| --- | --- |
| Product name: | [Wagg & Purr] Cephalexin 1000mg |
| Active constituent/s: | 1,000 mg/tablet cephalexin as monohydrate |
| Applicant name: | AVet Health Pty Ltd |
| Applicant ACN: | 616 838 101 |
| Summary of variation: | To vary the distinguishing product name and the name that appears on the label from ‘[Wagg & Purr] Dogs & Cats Cephalexin 1000mg Tablets’ to ‘[Wagg & Purr] Cephalexin 1000mg’ |
| Date of variation: | 8 March 2021 |
| Product registration no.: | 89860 |
| Label approval no.: | 89860/130096 |

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.: | 128827 |
| --- | --- |
| Active constituent/s: | Potassium bromide |
| Applicant name: | Mavlab Pty Ltd |
| Applicant ACN: | 009 708 187 |
| Summary of use: | For use in veterinary chemical products |
| Date of approval: | 17 March 2021 |
| Approval no.: | 90422 |

| Application no.: | 126586 |
| --- | --- |
| Active constituent/s: | Chlortetracycline hydrochloric acid |
| Applicant name: | Dox-Al Australia Pty Ltd |
| Applicant ACN: | 079 454 265 |
| Summary of use: | For use in veterinary chemical products |
| Date of approval: | 18 March 2021 |
| Approval no.: | 89971 |

| Application no.: | 127059 |
| --- | --- |
| Active constituent/s: | Carprofen |
| Applicant name: | Norbrook Laboratories Australia Pty Ltd |
| Applicant ACN: | 080 972 596 |
| Summary of use: | For use in veterinary chemical products |
| Date of approval: | 18 March 2021 |
| Approval no.: | 90015 |

| Application no.: | 129140 |
| --- | --- |
| Active constituent/s: | Pentobarbital sodium |
| Applicant name: | AVet Health Pty Ltd |
| Applicant ACN: | 616 838 101 |
| Summary of use: | For use in veterinary chemical products |
| Date of approval: | 18 March 2021 |
| Approval no.: | 90501 |

| Application no.: | 129138 |
| --- | --- |
| Active constituent/s: | Pimobendan |
| Applicant name: | AVet Health Pty Ltd |
| Applicant ACN: | 616 838 101 |
| Summary of use: | For use in veterinary chemical products |
| Date of approval: | 19 March 2021 |
| Approval no.: | 90500 |

| Application no.: | 127185 |
| --- | --- |
| Active constituent/s: | Imazalil |
| Applicant name: | Decco US Post-Harvest Inc |
| Applicant ACN: | N/A |
| Summary of use: | For use in agricultural chemical products |
| Date of approval: | 23 March 2021 |
| Approval no.: | 90045 |

| Application no.: | 128651 |
| --- | --- |
| Active constituent/s: | Menthol |
| Applicant name: | AVet Health Pty Ltd |
| Applicant ACN: | 616 838 101 |
| Summary of use: | For use in veterinary chemical products |
| Date of approval: | 23 March 2021 |
| Approval no.: | 90365 |

| Application no.: | 127863 |
| --- | --- |
| Active constituent/s: | Oxytetracycline dihydrate |
| Applicant name: | Randlab Australia Pty Ltd |
| Applicant ACN: | 114 948 837 |
| Summary of use: | For use in veterinary chemical products |
| Date of approval: | 24 March 2021 |
| Approval no.: | 90175 |

| Application no.: | 128601 |
| --- | --- |
| Active constituent/s: | Eprinomectin |
| Applicant name: | Virbac (Australia) Pty Ltd |
| Applicant ACN: | 003 268 871 |
| Summary of use: | For use in veterinary chemical products |
| Date of approval: | 25 March 2021 |
| Approval no.: | 90343 |

| Application no.: | 127321 |
| --- | --- |
| Active constituent/s: | Fipronil |
| Applicant name: | Tagros Chemicals India Private Limited |
| Applicant ACN: | N/A |
| Summary of use: | For use in agricultural and veterinary chemical products |
| Date of approval: | 25 March 2021 |
| Approval no.: | 90084 |

| Application no.: | 126112 |
| --- | --- |
| Active constituent/s: | Pyraclostrobin |
| Applicant name: | Shandong Binnong Technology Co Ltd |
| Applicant ACN: | N/A |
| Summary of use: | For use in agricultural chemical products |
| Date of approval: | 25 March 2021 |
| Approval no.: | 89793 |

| Application no.: | 128491 |
| --- | --- |
| Active constituent/s: | Metronidazole |
| Applicant name: | Dechra Veterinary Products (Australia) Pty Ltd |
| Applicant ACN: | 614 716 700 |
| Summary of use: | For use in veterinary chemical products |
| Date of approval: | 25 March 2021 |
| Approval no.: | 90308 |

| Application no.: | 129123 |
| --- | --- |
| Active constituent/s: | Bacitracin zinc |
| Applicant name: | AVet Health Pty Ltd |
| Applicant ACN: | 616 838 101 |
| Summary of use: | For use in veterinary chemical products |
| Date of approval: | 26 March 2021 |
| Approval no.: | 90497 |

| Application no.: | 126020 |
| --- | --- |
| Active constituent/s: | Tulathromycin |
| Applicant name: | Jurox Pty Ltd |
| Applicant ACN: | 000 932 230 |
| Summary of use: | For use in veterinary chemical products |
| Date of approval: | 26 March 2021 |
| Approval no.: | 89762 |

| Application no.: | 127663 |
| --- | --- |
| Active constituent/s: | Triclopyr butoxyethyl ester |
| Applicant name: | Foison Scitech Co Ltd |
| Applicant ACN: | N/A |
| Summary of use: | For use in agricultural chemical products |
| Date of approval: | 26 March 2021 |
| Approval no.: | 90126 |

1. Variations of actIve constituent

| Application no.: | 128602 |
| --- | --- |
| Active constituent/s: | Meloxicam |
| Applicant name: | Dechra Veterinary Products (Australia) Pty Ltd |
| Applicant ACN: | 614 716 700 |
| Summary of variation: | Variation of relevant particulars or conditions of an approved active constituent |
| Date of variation: | 9 March 2021 |
| Approval no.: | 82924 |

| Application no.: | 125878 |
| --- | --- |
| Active constituent/s: | Oxibendazole |
| Applicant name: | Boehringer Ingelheim Animal Health Australia Pty Ltd |
| Applicant ACN: | 071 187 285 |
| Summary of variation: | Variation of relevant particulars or conditions of an approved active constituent |
| Date of variation: | 22 March 2021 |
| Approval no.: | 81883 |

New agricultural active constituent: bromoxynil butyrate

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application for the approval of a new active constituent, bromoxynil butyrate. Bromoxynil butyrate is an herbicide proposed for use in control of broadleaf weeds in bulb onions. It is a new ester form of bromoxynil. Currently, there are approvals for the phenol form (bromoxynil), and the heptanoate and octanoate esters.

| Common name: | Bromoxynil butyrate (Bromoxynil butanoate) |
| --- | --- |
| IUPAC name: | 2,6-Dibromo-4-cyanophenyl butyrate |
| CAS name: | 2,6-Dibromo-4-cyanophenyl ester butanoic acid |
| CAS registry number: | 3861-41-4 |
| Manufacturer’s codes: | M&B-10666, AE F087710, BCS-BB43031 |
| Minimum purity: | 967 g/kg |
| Molecular formula: | C11H9Br2NO2 |
| Molecular weight: | 347.0 g.mol-1 |
| Structure: | Structure of bromoxynil butyrate |
| Chemical family: | Benzonitrile |
| Mode of action: | Bromoxynil butyrate is a nitrile group herbicide, which acts as an inhibitor of photosynthesis (PSII inhibitor) and mitochondrial oxidative phosphorylation in plants. |

Summary of the APVMA’s Evaluation of Bromoxynil butyrate Active Constituent

The APVMA has evaluated the chemistry aspects of the active constituent bromoxynil butyrate (physico-chemical properties, identification, spectra, stability, 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 bromoxynil butyrate, and concluded that there are no toxicological concerns regarding the approval of this active constituent. The current acceptable daily intake (ADI) for bromoxynil (0.003 mg/kg bw/day) is appropriate to cover bromoxynil butyrate. An acute reference dose (ARfD) has not previously been established. It is proposed to establish an ARfD of 0.04 mg/kg bw for bromoxynil, to cover all forms of bromoxynil. No toxicologically significant impurities have been identified in bromoxynil butyrate technical active constituent.

Bromoxynil butyrate is not listed *per se* in the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP), however bromoxynil is listed in Schedule 6 (with no exceptions or cut-offs), which includes its salts and derivatives. Bromoxynil butyrate is rapidly metabolised to bromoxynil in mammals and is therefore a Schedule 6 poison.

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

| Specification | Level |
| --- | --- |
| **Bromoxynil butyrate** | Minimum 967 g/kg |

Other compounds of toxicological significance are not expected to occur in bromoxynil butyrate technical active constituent as a result of the raw materials and the synthetic route used.

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

FuRther Information

A Public Release Summary (PRS) of the evaluations of the active and the associated product is available from the APVMA website’s [‘Public Consultation’ page](https://apvma.gov.au/news-and-publications/public-consultations).

Making a Submission

In accordance with sections 12 of the Agvet Code, the APVMA invites any person to submit a relevant written submission as to whether bromoxynil butyrate 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](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](mailto:enquiries@apvma.gov.au)

Post:

Director of Chemistry and Manufacture

Risk Assessment Capability

Australian Pesticides and Veterinary Medicines Authority

GPO Box 3262

Sydney NSW 2001

New chemical products: Maya Herbicide containing bromoxynil butyrate

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 Maya Herbicide.

Particulars of The Application

| Proposed product name(s): | Maya Herbicide |
| --- | --- |
| Applicant company: | Nufarm Australia Ltd |
| Name of active constituent: | Bromoxynil butyrate |
| Signal heading: | Schedule 6 |
| Summary of proposed use: | For post-emergent spray or as a post-sowing pre-emergence (PSPE) spray for the control of broadleaf weeds in bulb onions |
| Pack sizes: | 5, 10 and 20 L |
| Withholding period: | Harvest: not required when used as directed  Grazing/stock food: do not graze or cut for stock food |

Summary of the APVMA’s evaluation of MAYA HERBICIDE 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:
2. The APVMA is satisfied that the proposed use of Maya Herbicide would not be an undue hazard to the safety of people exposed to it during its handling and use.
3. The APVMA is satisfied that the proposed use of Maya Herbicide will not be an undue hazard to the safety of people using anything containing its residues.
4. The APVMA is satisfied that the proposed use of Maya Herbicide is not likely to be harmful to human beings if used according to the product label directions.
5. The APVMA is satisfied that the proposed use of Maya Herbicide is not likely to have an unintended effect that is harmful to animals, plants or the environment when used according to the product label directions.
6. 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:
7. 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 adequately demonstrate that, if used according to the product label directions, the product is effective for its proposed uses.
8. 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:
9. The proposed use of Maya Herbicide would not adversely affect trade between Australia and places outside Australia.

FuRther Information

A Public Release Summary (PRS) of the evaluation of this product is available from the APVMA website’s ‘[Public Consultation’ page](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 Maya Herbicide 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](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.

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

Email: [enquiries@apvma.gov.au](mailto:enquiries@apvma.gov.au)

Post:

Case Management and Administration Unit

Australian Pesticides and Veterinary Medicines Authority

GPO Box 3262

Sydney NSW 2001