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

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

DISTRIBUTION AND SUBSCRIPTION

The *APVMA Gazette* is published in electronic format only and is available from the [APVMA website](http://apvma.gov.au).

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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 <i>Pinus radiata</i> 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:	Osmoste 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

2. 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 Sulphur 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

3. 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

2. 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) $\geq 10^{5.0}$ 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

3. 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-AI 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

2. 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

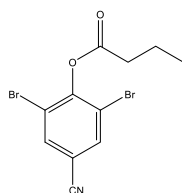
Application no.:	125878
Active constituent/s:	Oxibendazole
Applicant name:	Boehringer Ingelheim Animal Health Australia Pty Ltd
Applicant ACN:	071 187 285
Summary of variation:	Variation of relevant particulars or conditions of an approved active constituent
Date of variation:	22 March 2021
Approval 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:	C ₁₁ H ₉ Br ₂ NO ₂
Molecular weight:	347.0 g.mol ⁻¹

Structure:



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](#).

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](#)).

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 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:
 - (i) 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.
 - (ii) 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.
 - (iii) 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.
 - (iv) 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.
2. The APVMA has evaluated the application and in its assessment in relation to whether the efficacy criteria have been met in accordance with the definition set out in section 5B of the Agvet Code, and proposes to determine that:
 - (i) In relation to its assessment of efficacy under section 14(3)(f), the APVMA is satisfied that data from trials supporting the efficacy of the product adequately demonstrate that, if used according to the product label directions, the product is effective for its proposed uses.
3. The APVMA has evaluated the application and in its assessment in relation to whether the trade criteria have been met in accordance with the definition set out in section 5C of the Agvet Code, and proposes to determine that:

- (ii) The 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, 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](#)).

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:

Case Management and Administration Unit
Australian Pesticides and Veterinary Medicines Authority
GPO Box 3262
Sydney NSW 2001