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# Gazette

## Agricultural and veterinary chemicals

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**Australian Pesticides and  
Veterinary Medicines Authority**

The *Agricultural and Veterinary Chemical Code Act 1994* (the Act) commenced on 15 March 1995. The Agricultural and Veterinary Chemicals Code (the Agvet Code) scheduled to the Act requires notices to be published in the *Gazette* containing details of the registration of agricultural and veterinary chemical products and other approvals granted by the Australian Pesticides and Veterinary Medicines Authority. The Agvet Code and related legislation also requires certain other notices to be published in the *Gazette*. A reference to Agvet Codes in this publication is a reference to the Agvet Code in each state and territory jurisdiction.

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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.

## **Distribution and subscription**

The APVMA Gazette is published in electronic format only and is available from the [APVMA website](#).

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## **Privacy**

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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**

<b>Application no.</b>	129037
<b>Product name</b>	Citroside Plus Processing Aid in the Post-Harvest Treatment of Fruit and Vegetables
<b>Active constituent/s</b>	257 g/L hydrogen peroxide, 168 g/L peroxyacetic acid
<b>Applicant name</b>	Productos Citrosol S.A.
<b>Applicant ACN</b>	N/A
<b>Date of registration</b>	14 March 2022
<b>Product registration no.</b>	90466
<b>Label approval no.</b>	90466/129037
<b>Description of the application and its purpose, including the intended use of the chemical product</b>	Registration of a 168 g/L peroxyacetic acid and 257 g/L hydrogen peroxide soluble liquid product for the control of bacterial growth in the process water for post-harvest processing of fruit and vegetables

<b>Application no.</b>	134057
<b>Product name</b>	ExiFlea Bomb
<b>Active constituent/s</b>	0.25 g/kg imidacloprid
<b>Applicant name</b>	Abbey Laboratories Pty Ltd
<b>Applicant ACN</b>	156 000 430
<b>Date of registration</b>	15 March 2022
<b>Product registration no.</b>	91967
<b>Label approval no.</b>	91967/134057
<b>Description of the application and its purpose, including the intended use of the chemical product</b>	Registration of ExiFlea Bomb containing 0.25 g/kg imidacloprid for the control of fleas in houses

<b>Application no.</b>	130158
<b>Product name</b>	Kenso Agcare Max Out 600 Duo Herbicide
<b>Active constituents</b>	600 g/L glyphosate present as potassium and monoethanolamine salts
<b>Applicant name</b>	Kenso Corporation (M) Sdn. Bhd.
<b>Applicant ACN</b>	N/A
<b>Date of registration</b>	16 March 2022
<b>Product registration no.</b>	90825
<b>Label approval no.</b>	90825/130158
<b>Description of the application and its purpose, including the intended use of the chemical product</b>	Registration of a 600 g/L glyphosate product, the active present as potassium and monoethanolamine salts for the control of a range of annual and perennial weeds

<b>Application no.</b>	134496
<b>Product name</b>	AgMerch Azoxystrobin 250 SC Fungicide
<b>Active constituent</b>	250 g/L azoxystrobin
<b>Applicant name</b>	AgMerch Pty Ltd
<b>Applicant ACN</b>	645 371 017
<b>Date of registration</b>	18 March 2022
<b>Product registration no.</b>	92097
<b>Label approval no.</b>	92097/134496
<b>Description of the application and its purpose, including the intended use of the chemical product</b>	Registration of a 250 g/L azoxystrobin suspension concentrate formulation for the control of various diseases of grapes, potatoes, tomatoes, cucurbits, avocados, mangoes, passionfruit and poppies

<b>Application no.</b>	134184
<b>Product name</b>	F.S.A. Clethodim 360EC Xtra Herbicide
<b>Active constituent</b>	360 g/L clethodim
<b>Applicant name</b>	Yifan Biotechnology Group Co., Ltd.
<b>Applicant ACN</b>	N/A
<b>Date of registration</b>	18 March 2022
<b>Product registration no.</b>	92020
<b>Label approval no.</b>	92020/134184
<b>Description of the application and its purpose, including the intended use of the chemical product</b>	Registration of a 360 g/L clethodim emulsifiable concentrate product for the control of certain grass weeds in beetroot, cabbage, canola, celery, cotton, forestry, lettuce, non-bearing fruit trees, onions, ornamentals, peanuts, pulses (including adzuki beans, broad beans, chickpeas, faba beans, field peas, lentils, lupins and mung beans), potatoes, soybeans and pasture legume (lucerne, clover and medic) seed crops and pastures (including pastures containing chicory and plantain) as per the directions for use table

<b>Application no.</b>	134104
<b>Product name</b>	Brandt Crop Oil
<b>Active constituent/s</b>	582 g/L paraffinic oil, 120 g/L alcohol ethoxylate oil, 120 g/L nonyl phenyl ethoxylate
<b>Applicant name</b>	Brandt International LLC
<b>Applicant ACN</b>	N/A
<b>Date of registration</b>	21 March 2022
<b>Product registration no.</b>	91991
<b>Label approval no.</b>	91991/134104
<b>Description of the application and its purpose, including the intended use of the chemical product</b>	Registration of a 582 g/L paraffinic oil, 120 g/L nonyl phenyl ethoxylate and 120 g/L alcohol ethoxylate oil miscible liquid formulation product for use as an adjuvated spraying oil to improve the spreading and wetting of herbicides, insecticides and defoliant on plant surfaces

<b>Application no.</b>	131023
<b>Product name</b>	Cupboard Moth Killer
<b>Active constituent/s</b>	7.8 g/kg transfluthrin
<b>Applicant name</b>	Lifeguard Sciences (Pty) Ltd
<b>Applicant ACN</b>	N/A
<b>Date of registration</b>	22 March 2022
<b>Product registration no.</b>	91137
<b>Label approval no.</b>	91137/131023
<b>Description of the application and its purpose, including the intended use of the chemical product</b>	Registration of a 7.8 g/kg transfluthrin matrix release formulation product for the control of adult clothing moths for up to 3 months

<b>Application no.</b>	134030
<b>Product name</b>	Strychnine Alkaloid Crystals For Wild Dog Control
<b>Active constituent</b>	999 g/kg strychnine alkaloid
<b>Applicant name</b>	Goldfields Nullarbor Rangelands Biosecurity Ass Inc.
<b>Applicant ACN</b>	16 281 950 022
<b>Date of registration</b>	22 March 2022
<b>Product registration no.</b>	91952
<b>Label approval no.</b>	91952/134030
<b>Description of the application and its purpose, including the intended use of the chemical product</b>	Registration of a 999 g/kg strychnine bait product for use in wild dog control

<b>Application no.</b>	130288
<b>Product name</b>	Titan Besuto 850 WG Herbicide
<b>Active constituent</b>	850 g/kg pyroxasulfone
<b>Applicant name</b>	Titan Ag Pty Ltd
<b>Applicant ACN</b>	122 081 574
<b>Date of registration</b>	22 March 2022
<b>Product registration no.</b>	90874
<b>Label approval no.</b>	90874/130288
<b>Description of the application and its purpose, including the intended use of the chemical product</b>	Registration of an 850 g/kg pyroxasulfone water dispersible granule product for the pre-emergence control of annual ryegrass, barley grass, annual phalaris, silver grass and toad rush and suppression of certain grass weeds in wheat (not durum wheat) and triticale

<b>Application no.</b>	134152
<b>Product name</b>	Presticor Insecticide
<b>Active constituent/s</b>	600 g/L chlorantraniliprole
<b>Applicant name</b>	FMC Australasia Pty Ltd
<b>Applicant ACN</b>	095 326 891
<b>Date of registration</b>	22 March 2022
<b>Product registration no.</b>	92008
<b>Label approval no.</b>	92008/134152
<b>Description of the application and its purpose, including the intended use of the chemical product</b>	Registration of a 600 g/L chlorantraniliprole SC for the control of lepidopteran species of insect pests in cotton and pulse crops

<b>Application no.</b>	134741
<b>Product name</b>	AgMerch Clethodim 360 Herbicide
<b>Active constituent/s</b>	360 g/L clethodim
<b>Applicant name</b>	AgMerch Pty Ltd
<b>Applicant ACN</b>	645 371 017
<b>Date of registration</b>	24 March 2022
<b>Product registration no.</b>	92172
<b>Label approval no.</b>	92172/134741
<b>Description of the application and its purpose, including the intended use of the chemical product</b>	Registration of a 360 g/L clethodim product formulated as emulsifiable concentrate for the control of certain grass weeds in beetroot, cabbage, canola, celery, cotton, forestry lettuce, non-bearing fruit trees, onions, ornamentals, peanuts, pulses (including adzuki beans, broad beans, chickpeas, faba beans, field peas, lentils, lupins and mung beans), potatoes, soybeans and pasture legume (lucerne, clover and medic) seed crops and pastures

Table 2: Variations of registration

Application no.	134653
Product name	Nufarm Avadex Xtra Herbicide
Active constituent/s	500 g/L triallate
Applicant name	Nufarm Australia Limited
Applicant ACN	004 377 780
Date of variation	2 March 2022
Product registration no.	56598
Label approval no.	56598/134653
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 'Nufarm Avadex Xtra Selective Herbicide' to 'Nufarm Avadex Xtra Herbicide'

Application no.	133961
Product name	Farmalinx Accelerate LX Growth Regulant
Active constituent/s	100 g/L gibberellic acid
Applicant name	Farmalinx Pty Ltd
Applicant ACN	134 353 245
Date of variation	15 March 2022
Product registration no.	68766
Label approval no.	68766/133961
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 add use in pastures and change the product name

Application no.	134257
Product name	Trio Simazine 900 WG Herbicide
Active constituent/s	900 g/kg simazine
Applicant name	CTS Chemicals Pty Ltd
Applicant ACN	605 759 644
Date of variation	16 March 2022
Product registration no.	64242
Label approval no.	64242/134257
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 add a pack size, and to include additional uses for the control of weeds in walnuts, hazelnuts, pyrethrum, leeks, oil tea tree, nursery stock (non-food), foliage, cut flowers, wildflowers, ginger, vineyards, TT-canola and berries



<b>Application no.</b>	133974
<b>Product name</b>	Precept Selective Herbicide
<b>Active constituents</b>	125 g/L MCPA as the 2-ethylhexyl ester, 25 g/L pyrasulfotole, 6.25 g/L mefenpyr-diethyl
<b>Applicant name</b>	Bayer CropScience Pty Ltd
<b>Applicant ACN</b>	000 226 022
<b>Date of variation</b>	18 March 2022
<b>Product registration no.</b>	60897
<b>Label approval no.</b>	60897/133974
<b>Description of the application and its purpose, including the intended use of the chemical product</b>	Variation to the particulars of product registration and label approval to update the formulation, manufacturers and label constituent statements

<b>Application no.</b>	134841
<b>Product name</b>	Brunnings Fast Action Organic Weed Kill
<b>Active constituent/s</b>	36.8 g/L nonanoic acid
<b>Applicant name</b>	Brunnings Garden Products Pty Ltd
<b>Applicant ACN</b>	050 655 760
<b>Date of variation</b>	18 March 2022
<b>Product registration no.</b>	88791
<b>Label approval no.</b>	88791/134841
<b>Description of the application and its purpose, including the intended use of the chemical product</b>	Variation to the particulars of registration and label approval to change the distinguishing product name and the name that appears on the label from 'Brunnings NA Weed Kill Ready to Use' to 'Brunnings Fast Action Organic Weed Kill'

<b>Application no.</b>	133061
<b>Product name</b>	Imtrade Guerrilla Herbicide
<b>Active constituent/s</b>	300 g/L paraquat present as paraquat dichloride, 12 g/L amitrole
<b>Applicant name</b>	Imtrade Australia Pty Ltd
<b>Applicant ACN</b>	090 151 134
<b>Date of variation</b>	18 March 2022
<b>Product registration no.</b>	89484
<b>Label approval no.</b>	89484/133061
<b>Description of the application and its purpose, including the intended use of the chemical product</b>	Variation to the particulars of registration and label approval to add a use for optical spot spraying technologies in fallow

<b>Application no.</b>	131978
<b>Product name</b>	Mirador 625 Fungicide
<b>Active constituent/s</b>	625 g/L azoxystrobin
<b>Applicant name</b>	ADAMA Australia Pty Ltd
<b>Applicant ACN</b>	050 328 973
<b>Date of variation</b>	21 March 2022
<b>Product registration no.</b>	87530
<b>Label approval no.</b>	87530/131978
<b>Description of the application and its purpose, including the intended use of the chemical product</b>	Variation of product registration and label approval to increase the pack size range and add additional uses in almonds, adzuki beans, citrus, mangoes, olives, passionfruit, pistachio, ribberries, barley, beans, brassica leafy vegetables, carrots, canola, chickpeas, broad beans and faba beans, field peas, lupins, lentils, mung beans, navy beans, vetch, garlic, oats, shallots, spring onions, horseradish, leeks, lettuce, nursery stock, peanuts, poppies, pyrethrum, radish, <i>rubus</i> , snow peas and wheat

<b>Application no.</b>	129280
<b>Product name</b>	Nufarm CRUCIAL Herbicide
<b>Active constituent/s</b>	600 g/L glyphosate as potassium, monomethylamine & ammonium salt
<b>Applicant name</b>	Nufarm Australia Limited
<b>Applicant ACN</b>	004 377 780
<b>Date of variation</b>	21 March 2022
<b>Product registration no.</b>	86761
<b>Label approval no.</b>	86761/129280
<b>Description of the application and its purpose, including the intended use of the chemical product</b>	Variation of registration and label approval to add uses in lupins, mustard, sesame, poppies and safflower and cross label with Terrad'or 700WG Herbicide

<b>Application no.</b>	134207
<b>Product name</b>	Duomax HC520 Plant Growth Regulator
<b>Active constituent/s</b>	520 g/L cyanamide
<b>Applicant name</b>	Eurochem Pty Ltd
<b>Applicant ACN</b>	622 603 507
<b>Date of variation</b>	21 March 2022
<b>Product registration no.</b>	58843
<b>Label approval no.</b>	58843/134207
<b>Description of the application and its purpose, including the intended use of the chemical product</b>	Variation of product registration and label approval to amend and update first aid instructions as per the latest FAISD Handbook

<b>Application no.</b>	134159
<b>Product name</b>	Monarch G Insecticide
<b>Active constituent/s</b>	0.5 g/kg fipronil
<b>Applicant name</b>	Turf Culture Pty Ltd
<b>Applicant ACN</b>	117 986 615
<b>Date of variation</b>	22 March 2022
<b>Product registration no.</b>	86567
<b>Label approval no.</b>	86567/134159
<b>Description of the application and its purpose, including the intended use of the chemical product</b>	Variation of particulars of label approval to amend the label text to include a precaution statement

<b>Application no.</b>	131932
<b>Product name</b>	Warden 100SC Insecticide
<b>Active constituent</b>	100 g/L fipronil
<b>Applicant name</b>	ADAMA Australia Pty Ltd
<b>Applicant ACN</b>	050 328 973
<b>Date of variation</b>	23 March 2022
<b>Product registration no.</b>	67463
<b>Label approval no.</b>	67463/131932
<b>Description of the application and its purpose, including the intended use of the chemical product</b>	Variation to the particulars of registration and label approval to add various pests in external areas and surrounds of domestic, commercial, public and industrial buildings and structures and control of subterranean termites using reticulation systems

<b>Application no.</b>	133847
<b>Product name</b>	Surefire Kult Plant Growth Regulator
<b>Active constituent</b>	250 g/L paclobutrazol
<b>Applicant name</b>	PCT Holdings Pty Ltd
<b>Applicant ACN</b>	099 023 962
<b>Date of variation</b>	25 March 2022
<b>Product registration no.</b>	80149
<b>Label approval no.</b>	80149/133847
<b>Description of the application and its purpose, including the intended use of the chemical product</b>	Variation to the particulars of registration and label approval to add uses in ornamental hedges

## 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 new active constituents**

<b>Application no.</b>	124578
<b>Product name</b>	SOLENSIA Solution for Injection for Cats
<b>Active constituent/s</b>	7 mg/mL frunevetmab per vial
<b>Applicant name</b>	Zoetis Australia Pty Ltd
<b>Applicant ACN</b>	156 476 425
<b>Date of registration</b>	14 March 2022
<b>Product registration no.</b>	89387
<b>Label approval no.</b>	89387/124578
<b>Description of the application and its purpose, including the intended use of the chemical product</b>	Registration of a 7 mg/mL frunevetmab liquid product for the alleviation of pain associated with osteoarthritis in cats

**Table 4: Veterinary products based on existing active constituents**

<b>Application no.</b>	133938
<b>Product name</b>	Purina TotalCare Flea and Tick Control 1-Month Chew for Large Dogs
<b>Active constituent/s</b>	54.6 g/kg fluralaner
<b>Applicant name</b>	Intervet Australia Pty Ltd
<b>Applicant ACN</b>	008 467 034
<b>Date of registration</b>	16 March 2022
<b>Product registration no.</b>	91911
<b>Label approval no.</b>	91911/133938
<b>Description of the application and its purpose, including the intended use of the chemical product</b>	Registration of a 54.6 g/kg fluralaner chew product for the treatment and prevention of fleas and ticks in dogs

<b>Application no.</b>	133943
<b>Product name</b>	Purina TotalCare Flea and Tick Control 1-Month Chew for Medium Dogs
<b>Active constituent/s</b>	54.6 g/kg fluralaner
<b>Applicant name</b>	Intervet Australia Pty Ltd
<b>Applicant ACN</b>	008 467 034
<b>Date of registration</b>	16 March 2022
<b>Product registration no.</b>	91913
<b>Label approval no.</b>	91913/133943
<b>Description of the application and its purpose, including the intended use of the chemical product</b>	Registration of a 54.6 g/kg fluralaner chew product for the treatment and prevention of fleas and ticks in dogs

<b>Application no.</b>	133945
<b>Product name</b>	Purina TotalCare Flea and Tick Control 1-month Chew for Small Dogs
<b>Active constituent/s</b>	54.6 g/kg fluralaner
<b>Applicant name</b>	Intervet Australia Pty Ltd
<b>Applicant ACN</b>	008 467 034
<b>Date of registration</b>	16 March 2022
<b>Product registration no.</b>	91914
<b>Label approval no.</b>	91914/133945
<b>Description of the application and its purpose, including the intended use of the chemical product</b>	Registration of a 54.6 g/kg fluralaner chew product for the treatment and prevention of fleas and ticks in dogs

<b>Application no.</b>	129964
<b>Product name</b>	AnaSed Injection
<b>Active constituent/s</b>	100 mg/mL xylazine as xylazine hydrochloride
<b>Applicant name</b>	Akorn Animal Health Inc
<b>Applicant ACN</b>	N/A
<b>Date of registration</b>	16 March 2022
<b>Product registration no.</b>	90756
<b>Label approval no.</b>	90756/129964
<b>Description of the application and its purpose, including the intended use of the chemical product</b>	Registration of a 100 mg/mL xylazine injection product for use as a sedative, analgesic and muscle relaxant in horses and cattle

<b>Application no.</b>	132756
<b>Product name</b>	YP Tylosin Tartrate Soluble
<b>Active constituent/s</b>	800 mg/g tylosin as tartrate
<b>Applicant name</b>	South Yarra Pharma Pty Ltd
<b>Applicant ACN</b>	629 173 351
<b>Date of registration</b>	17 March 2022
<b>Product registration no.</b>	91589
<b>Label approval no.</b>	91589/132756
<b>Description of the application and its purpose, including the intended use of the chemical product</b>	Registration of an 800 mg/g tylosin (as tartrate) soluble powder product for the prevention and treatment of chronic respiratory disease in broilers and replacement chickens, infectious sinusitis in turkeys and swine dysentery in pigs

<b>Application no.</b>	133335
<b>Product name</b>	Covine Toromec LV Pour-On Endectocide for Cattle
<b>Active constituent/s</b>	10 mg/mL ivermectin
<b>Applicant name</b>	Nutrien Ag Solutions Limited
<b>Applicant ACN</b>	008 743 217
<b>Date of registration</b>	22 March 2022
<b>Product registration no.</b>	91743
<b>Label approval no.</b>	91743/133335
<b>Description of the application and its purpose, including the intended use of the chemical product</b>	Registration of a 10 mg/mL ivermectin topical solution product for the treatment and control of ivermectin sensitive internal and external parasites of beef and dairy cattle

<b>Application no.</b>	134155
<b>Product name</b>	Ecovet Soluble Heartworm Monthly for Large Dogs 23 to 45kg
<b>Active constituent/s</b>	272 µg/tablet ivermectin
<b>Applicant name</b>	Vet Med IP Pty Ltd
<b>Applicant ACN</b>	623 869 723
<b>Date of registration</b>	24 March 2022
<b>Product registration no.</b>	92010
<b>Label approval no.</b>	92010/134155
<b>Description of the application and its purpose, including the intended use of the chemical product</b>	Registration of a 272 µg ivermectin oral tablet product for prevention of heartworm disease in canines

<b>Application no.</b>	134156
<b>Product name</b>	Ecovet Soluble Heartworm Monthly for Medium Dogs 11 to 23kg
<b>Active constituent/s</b>	136 µg/tablet ivermectin
<b>Applicant name</b>	Vet Med IP Pty Ltd
<b>Applicant ACN</b>	623 869 723
<b>Date of registration</b>	24 March 2022
<b>Product registration no.</b>	92011
<b>Label approval no.</b>	92011/134156
<b>Description of the application and its purpose, including the intended use of the chemical product</b>	Registration of a 136 µg ivermectin oral tablet product for prevention of heartworm disease in canines

<b>Application no.</b>	134062
<b>Product name</b>	Ecovet Soluble Heartworm Monthly for Small Dogs Up to 11kg
<b>Active constituent/s</b>	68 µg/tablet ivermectin
<b>Applicant name</b>	Vet Med IP Pty Ltd
<b>Applicant ACN</b>	623 869 723
<b>Date of registration</b>	24 March 2022
<b>Product registration no.</b>	91970
<b>Label approval no.</b>	91970/134062
<b>Description of the application and its purpose, including the intended use of the chemical product</b>	Registration of a 68 µg ivermectin oral tablet product for prevention of heartworm disease in canines

<b>Application no.</b>	131885
<b>Product name</b>	Feliway Friends Diffuser
<b>Active constituent/s</b>	16.2 mg/mL Synthetic Analogue Naturally Occurring Cat Appeasing Pheromone
<b>Applicant name</b>	Ceva Animal Health Pty Ltd
<b>Applicant ACN</b>	002 692 426
<b>Date of registration</b>	24 March 2022
<b>Product registration no.</b>	91337
<b>Label approval no.</b>	91337/131885
<b>Description of the application and its purpose, including the intended use of the chemical product</b>	Registration of the product 'FELIWAY FRIENDS DIFFUSER' which contains the active, synthetic analogue of feline facial pheromone, at a concentration of 16.2 mg/mL to aid in alleviating signs associated with tension and conflict between cats in the home

Table 5: Variations of registration

Application no.	133615
Product name	Imax CD Pour-On for Cattle
Active constituent/s	10 mg/mL ivermectin
Applicant name	Elanco Australasia Pty Ltd
Applicant ACN	076 745 198
Date of variation	14 March 2022
Product registration no.	59344
Label approval no.	59344/133615
Description of the application and its purpose, including the intended use of the chemical product	Variation to the particulars and conditions of registration, and variation of the labelling particulars including updating the name of the Australian cattle tick

Application no.	133834
Product name	Osumia Ear Gel for Dogs
Active constituent/s	10 mg flufenicol, 10 mg terbinafine, 1 mg betamethasone acetate per 1.2 g tube
Applicant name	Dechra Ltd
Applicant ACN	N/A
Date of variation	17 March 2022
Product registration no.	69931
Label approval no.	69931/133834
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 precautions and dosage and administration statements

Application no.	131950
Product name	Pron8ure Paste
Active constituent/s	Each gram contains 180 million CFU as: <i>Lactobacillus acidophilus</i> ; <i>Lactobacillus delbrueckii</i> subsp. <i>bulgaricus</i> ; <i>Lactobacillus plantarum</i> ; <i>Lactobacillus rhamnosus</i> ; <i>Bifidobacterium bifidum</i> ; <i>Enterococcus faecium</i> ; <i>Streptococcus salivarius</i> subsp. <i>thermophilus</i>
Applicant name	International Animal Health Products Pty Ltd
Applicant ACN	003 185 699
Date of variation	25 March 2022
Product registration no.	58902
Label approval no.	58902/131950
Description of the application and its purpose, including the intended use of the chemical product	Variation to the relevant particulars of a registered chemical product and label approval by adding new 1 and 4 kg pack sizes and updating dosage and administration instructions



Table 6: Label approval

<b>Application no.</b>	134016
<b>Product name</b>	Bob Martin Dewormer Tablet for Dogs
<b>Active constituent/s</b>	250 mg/tablet febantel, 50 mg/tablet praziquantel, 49.8 mg/tablet pyrantel as pyrantel embonate
<b>Applicant name</b>	Bob Martin (Australia) Pty Ltd
<b>Applicant ACN</b>	062 627 883
<b>Date of variation</b>	15 March 2022
<b>Product registration no.</b>	91629
<b>Label approval no.</b>	91629/134016
<b>Description of the application and its purpose, including the intended use of the chemical product</b>	Approval of a new label for the registered product 'Bob Martin Dewormer Tablet for Dogs' with the label name 'Bob Martin Dewormer Tablet for Large Dogs'

## 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 7: Active constituent**

<b>Application no.</b>	124577
<b>Active constituent/s</b>	Frunevetmab
<b>Applicant name</b>	Zoetis Australia Pty Ltd
<b>Applicant ACN</b>	156 476 425
<b>Date of approval</b>	14 March 2022
<b>Approval no.</b>	89386
<b>Description of the application and its purpose, including the intended use of the active constituent</b>	Approval of the active constituent frunevetmab for use in veterinary chemical products

<b>Application no.</b>	132533
<b>Active constituent</b>	Amisulbrom
<b>Applicant name</b>	Nissan Chemical Corporation
<b>Applicant ACN</b>	N/A
<b>Date of approval</b>	16 March 2022
<b>Approval no.</b>	91533
<b>Description of the application and its purpose, including the intended use of the active constituent</b>	Approval of the active constituent amisulbrom for use in agricultural chemical products

<b>Application no.</b>	130683
<b>Active constituent/s</b>	Xylazine hydrochloride
<b>Applicant name</b>	Akorn Animal Health Inc
<b>Applicant ACN</b>	N/A
<b>Date of approval</b>	16 March 2022
<b>Approval no.</b>	90995
<b>Description of the application and its purpose, including the intended use of the active constituent</b>	Approval of the active constituent xylazine hydrochloride for use in veterinary chemical products

<b>Application no.</b>	133583
<b>Active constituent/s</b>	Fluazinam
<b>Applicant name</b>	Zhejiang Corechem Co Ltd
<b>Applicant ACN</b>	N/A
<b>Date of approval</b>	16 March 2022
<b>Approval no.</b>	91822
<b>Description of the application and its purpose, including the intended use of the active constituent</b>	Approval of the active constituent fluazinam for use in agricultural chemical products

<b>Application no.</b>	130369
<b>Active constituent</b>	Chlorantraniliprole
<b>Applicant name</b>	ADAMA Australia Pty Ltd
<b>Applicant ACN</b>	050 328 973
<b>Date of approval</b>	17 March 2022
<b>Approval no.</b>	90896
<b>Description of the application and its purpose, including the intended use of the active constituent</b>	Approval of the active constituent chlorantraniliprole for use in agricultural chemical products

<b>Application no.</b>	132860
<b>Active constituent</b>	Trifloxystrobin
<b>Applicant name</b>	Thai Harvest Limited
<b>Applicant ACN</b>	N/A
<b>Date of approval</b>	25 March 2022
<b>Approval no.</b>	91621
<b>Description of the application and its purpose, including the intended use of the active constituent</b>	Approval of the active constituent trifloxystrobin for use in agricultural chemical products

**Table 8: Variations of active constituent**

<b>Application no.</b>	133846
<b>Active constituent/s</b>	Clindamycin hydrochloride
<b>Applicant name</b>	Chanelle Pharmaceuticals Manufacturing Ltd
<b>Applicant ACN</b>	N/A
<b>Date of variation</b>	16 March 2022
<b>Approval no.</b>	82458
<b>Description of the application and its purpose, including the intended use of the active constituent</b>	Variation of relevant particulars or conditions of an approved active constituent

<b>Application no.</b>	132367
<b>Active constituent/s</b>	Tigilanol tiglate
<b>Applicant name</b>	QBiotics Group Limited
<b>Applicant ACN</b>	617 596 139
<b>Date of variation</b>	17 March 2022
<b>Approval no.</b>	88411
<b>Description of the application and its purpose, including the intended use of the active constituent</b>	Variation of relevant particulars or conditions of an approved active constituent

## Licensing of veterinary chemical manufacturers

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

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

### New licences

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

**Table 9: New licences 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
Intervet Australia Pty Ltd	1008	008 467 034	91–105 Harpin Street Bendigo East VIC 3550	Category 1 (Immunobiologicals and sterile veterinary preparations) – Immunobiologicals and sterile products	Quality assurance (QA) of raw materials, bacterial fermentation, virus cultivation, formulation including blending, aseptic filling, filling, packaging, labelling, sterilisation (heat, and filtration), microbiological reduction treatment (filtration), freeze drying, analysis and testing (physical, chemical, sterility test, serological, immunobiological and microbiological), storage and release for supply.	4 March 2022
Dechra Veterinary Products (Australia) Pty Ltd	2245	614 716 700	2 Cal Close Somersby NSW 2250	Category 2 (Non-sterile veterinary preparations other than ectoparasiticides, premixes and supplements) – Tablets, creams/lotion, ointments, gels, granules, pastes, powders, liquids and suspensions	Quality assurance (QA) of raw materials, formulation including blending, filling, packaging, labelling, relabelling, strip, blister or sachet packaging, dry milling, wet milling, granulation, tableting, analysis and testing (physical), storage, and release for supply.	4 March 2022
Catalent Australia Pty Ltd	2271	007 219 990	217–221 Governor Road Braeside VIC 3195	Category 2 (Non-sterile veterinary preparations other than ectoparasiticides, premixes and supplements) – Tablets and capsules	Quality assurance (QA) of raw materials, formulation including blending, premixing in powder or granular form, filling, packaging, labelling, blister packaging, soft gelatine capsule manufacture, hard shell capsule manufacture, tableting, tablet coating, analysis and testing (physical and chemical), storage and release for supply.	4 March 2022

Company name	Licence number	Company ACN	Address	Product types	Steps of manufacture	Date issued
Austasia Animal Products Pty Ltd	4090	083 458 566	29 Wongajong Road Forbes NSW 2871	Category 4 (Premixes and supplements) – Premixes and supplements	Quality assurance (QA) of raw materials, formulation including blending, filling, packaging, labelling, pellet extrusion, storage and release for supply.	10 March 2022

## Licence cancellations

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

**Table 10: Licences cancelled by the APVMA under subsection 127(1) of the Agvet Code**

Company name	Licence number	Company ACN	Address	Date cancelled
Endeavour Foundation	6161	009 670 704	12–16 Leabons Lane Seven Hills NSW 2147	28 February 2022
Charles I.F.E. Proprietary Limited	6155	004 994 629	Berrybank Farm 34 Hendersons Road Windermere VIC 3352	7 March 2022
Alltech Lienert Australia Pty Ltd	4085	008 293 007	28 Durham Street Forbes NSW 2871	10 March 2022

## Licence suspensions

The APVMA has suspended the following licences under subsection 127(1) of the Agvet code:

**Table 11: Licences suspended by the APVMA under subsection 127(1) of the Agvet Code**

Company name	Licence number	Company ACN	Address	Period of suspension
Australian Animal Blood Bank	1101	98 140 128 990	50 Wills Point Road Long Point NSW 2564	From 30 June 2021 to 29 June 2022

## 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](mailto:mls@apvma.gov.au)

## Amendments to the APVMA MRL Standard

The APVMA approves maximum residue limits (MRLs) of agricultural and veterinary chemicals in agricultural produce, particularly produce entering the food chain. The MRLs approved by the APVMA are associated with a regulatory decision to register a product, grant a permit approval, or as an outcome from a review decision and are set out in the Agricultural and Veterinary Chemicals Code (MRL Standard) Instrument 2019. The MRL Standard lists MRLs of substances that may arise from the approved use of agricultural and veterinary chemical products containing those substances on commodities used for human consumption as well as livestock feeds. The *MRL Standard* also provides the relevant residue definitions to which these MRLs apply. There may be situations where the residue definition for monitoring and enforcement is different to the definition used for dietary risk assessment purposes.

MRLs are set at levels which are not likely to be exceeded if the agricultural or veterinary chemicals are used in accordance with approved label instructions. In considering MRLs and variation to MRLs, the APVMA takes into account studies on chemistry, metabolism, analytical methodology, residues, toxicology, good agricultural practice and dietary exposure. In approving MRLs, the APVMA is satisfied, from dietary exposure assessment, that the levels set are not an undue hazard to human health.

The APVMA has amended the *MRL Standard* and the changes will have affect the day after the instrument is registered.

Details of the amendment can be found in the Agricultural and Veterinary Chemicals Code (MRL Standard) Amendment Instrument (No. 2) 2022.

The amendments will be incorporated into the compilation of the Agricultural and Veterinary Chemicals Code (MRL Standard) Instrument 2019.

The MRL Standard is accessible via the [Federal Register of Legislation website](#).

For further information please contact:

MRL Contact Officer  
Australian Pesticides and Veterinary Medicines Authority  
GPO Box 3262  
Sydney NSW 2001

**Phone:** +61 2 6770 2300

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

## Proposal to amend Schedule 20 in the Australian New Zealand Food Standards Code

In the previous notice on page 20 of APVMA Gazette No. 7, the APVMA gazetted amendments which it has approved to vary maximum residue limits (MRLs) for substances contained in agricultural and veterinary chemical products as set out in the APVMA's MRL Standard.

Under section 82 of the *Food Standards Australia New Zealand Act 1991*, the APVMA is proposing to incorporate those variations (Agricultural and Veterinary Chemicals Code (MRL Standard) Amendment Instrument 2022 (No. 2)) to MRLs into Schedule 20 – Maximum residue limits in the Australia New Zealand Food Standards Code.

MRLs contained in Schedule 20 provide the limits for residues of agricultural and veterinary chemicals that may legitimately occur in foods. By this means Schedule 20 permits the sale of treated foods and protects public health and safety by minimising residues in foods consistent with the effective control of pests and diseases.

The APVMA and Food Standards Australia New Zealand (FSANZ) are satisfied, based on dietary exposure assessments and current health standards, that the proposed limits are not harmful to public health.

The agreement between the Australian Government and the New Zealand Government concerning a Joint Food Standards System excludes MRLs for agricultural and veterinary chemicals in food from the system setting joint food standards. Australia and New Zealand independently and separately develop MRLs for agricultural and veterinary chemicals in food.

A Sanitary and Phytosanitary (SPS) notification to the World Trade Organization (WTO) will be made.

The APVMA invites comment on these proposals. Details on how to make a submission appear near the end of this notice, below the details of the proposed amendment.

The APVMA will consider any public comments made in response to this proposal. If the APVMA decides to proceed with the proposal, it will further notify any variations it makes to Schedule 20 in the APVMA Gazette. The variations will take effect as from the date of that subsequent notice.



## Proposed variation to Schedule 20 in the Australia New Zealand Food Standards Code

5 April 2022

Note: Subsection 82(2) of the *Food Standards Australia New Zealand Act 1991* provides that variations to standards are legislative instruments but are not subject to disallowance or sunseting.

### To commence: on gazettal of variation

[1] The table to section S20–3 in Schedule 20 is varied by

[1.1] inserting in alphabetical order

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**Agvet chemical: Fluoxapiprolin**

*Permitted residue: Fluoxapiprolin*

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Dried grapes (=currants, raisins and sultanas)	0.5
Edible offal (mammalian)	*0.01
Eggs	*0.01
Grapes	0.15
Meat (mammalian) [in the fat]	*0.01
Milks	*0.01
Poultry meat [in the fat]	*0.01
Poultry, edible offal of	*0.01

---

**Agvet chemical: Isotianil**

*Permitted residue: Commodities of plant origin: Isotianil*

*Permitted residue: Commodities of animal origin: sum of isotianil and 3,4-dichloro-5-thiazole-5-carboxylic acid, expressed as isotianil*

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Banana	0.03
Edible offal (mammalian)	*0.02
Eggs	*0.02
Meat (mammalian)	*0.02
Milks	*0.02
Poultry meat	*0.02
Poultry, edible offal of	*0.02

---

**Agvet chemical: Metobromuron**

*Permitted residue: Commodities of plant origin: Sum of metobromuron and 4-bromophenylurea (CGA18237), expressed as metobromuron*

*Permitted residue: Commodities of animal origin: Sum of 4-bromo-2-hydroxyphenylurea (CGA 72905) and 4-bromophenyl urea (CGA18237), expressed as metobromuron*

Edible offal (mammalian)	*0.02
Eggs	*0.02
Meat (mammalian)	*0.02
Milks	*0.02
Poultry, edible offal of	*0.02
Poultry meat	*0.02
Potato	*0.02

[1.2] omitting from each of the following chemicals, the foods and associated MRLs

**Agvet chemical: Glyphosate**

*Permitted residue: Sum of glyphosate, N-acetyl-glyphosate and aminomethylphosphonic acid (AMPA) metabolite, expressed as glyphosate*

Cereal grains [except barley; maize; popcorn, sorghum; wheat]	T*0.1
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**Agvet chemical: Maldison**

*Permitted residue: Maldison*

Currant, black	T2
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**Agvet chemical: Mandestrobin**

*Permitted residue: Mandestrobin*

Lettuce, leaf	7
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[1.3] inserting for each of the following chemicals the foods and associated MRLs in alphabetical order

**Agvet chemical: Fluroxypyr**

*Permitted residue: Fluroxypyr*

Rice bran, unprocessed	T0.3
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**Agvet chemical: Glyphosate**

*Permitted residue: Sum of glyphosate, N-acetyl-glyphosate and aminomethylphosphonic acid (AMPA) metabolite, expressed as glyphosate*

Cereal grains {except Barley; Maize; Millet; Popcorn; Sorghum; Wheat}}	T*0.1
Millet	T15

**Agvet chemical: Imidacloprid**

*Permitted residue: Sum of imidacloprid and metabolites containing the 6-chloropyridinylmethylene moiety, expressed as imidacloprid*

Poppy seed	T*0.05
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**Agvet chemical: Isofetamid**

*Permitted residue: commodities of plant origin: Isofetamid*

*Permitted residue: commodities of animal origin: Sum of isofetamid and 2-[3-methyl-4-[2-methyl-2-(3-methylthiophene-2-carboxamido)propanoyl]phenoxy]propanoic acid (PPA), expressed as isofetamid*

Lettuce, head	30
Lettuce, leaf	30

**Agvet chemical: Mandestrobin**

*Permitted residue: Mandestrobin*

Brassica (cole or cabbage) vegetables, head cabbages, flowerhead brassicas	2
Leafy vegetables [except lettuce, head]	20
Onion, bulb	*0.01

**Agvet chemical: Permethrin**

*Permitted residue: Permethrin, sum of isomers*

Chervil	T30
Chives	T30
Coriander (leaves, roots, stems)	T30
Herbs	T30

**Agvet chemical: Sethoxydim**

*Permitted residue: Sum of sethoxydim and metabolites containing the 5-(2-ethylthiopropyl)cyclohexene-3-one and 5-(2-ethylthiopropyl)-5-hydroxycyclohexene-3-one moieties and their sulfoxides and sulfones, expressed as sethoxydim*

Basil	T1
Basil, dry	T5
Hazelnut	T*0.03

[1.4] omitting for each of the following chemicals, the maximum residue limit for the food and substituting

**Agvet chemical: Florpyrauxifen-benzyl**

*Permitted residue: Sum of florpyrauxifen-benzyl and the XDE-848 acid metabolite [4-amino-3-chloro-6-(4-chloro-2-fluoro-3-methoxyphenyl)-5-fluoropyridine-2-carboxylic acid] expressed as florpyrauxifen-benzyl*

Sorghum	*0.02
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**Agvet chemical: Glyphosate**

*Permitted residue: Sum of glyphosate, N-acetyl-glyphosate and aminomethylphosphonic acid (AMPA) metabolite, expressed as glyphosate*

Linseed	15
Poppy seed	20
Safflower seed	7
Sesame seed	20
Sunflower seed	20

**Agvet chemical: Haloxyfop**

*Permitted residue: Sum of haloxyfop, its esters and conjugates, expressed as haloxyfop*

Poppy seed	T0.5
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**Agvet chemical: Mandestrobin**

*Permitted residue: Mandestrobin*

Lettuce, head	5
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## Invitation for submissions

Written submissions are invited from interested individuals and organisations to assist the APVMA in considering the proposal to vary Schedule 20 – Maximum residue limits in the Australia New Zealand Food Standards Code.

Submissions should be strictly confined to relevant matters that the APVMA must consider (such as public health and safety) which are associated with the occurrence of the proposed residues in foods. Comments received outside these grounds will not be considered by the APVMA.

Claims made in submissions should be supported wherever possible by referencing or including relevant studies, research findings, trials and surveys. Technical information should be in sufficient detail to allow independent scientific assessment.

Submissions must be made in writing and should be clearly marked as a 'submission on the proposed amendment to Schedule 20' and quote the correct amendment number.

## Deadline for public submissions

Submissions must be received by 3 May 2022 (28 days from date Gazette published). Submissions received after this deadline will only be considered by prior arrangement or if agreement for an extension has been given prior to this closing date. Agreement to an extension of time will only be given if extraordinary circumstances warrant an extension to the submission period.

Please note: submissions will be published on the APVMA's website, unless you have asked for the submission to remain confidential, or if the APVMA chooses at its discretion not to publish any submissions received (refer to the [public consultation coversheet](#)).

Please lodge your submission using the [public consultation 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.

For further information please contact:

MRL Contact Officer  
Australian Pesticides and Veterinary Medicines Authority  
GPO Box 3262  
Sydney NSW 2001

**Phone:** +61 2 6770 2300

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

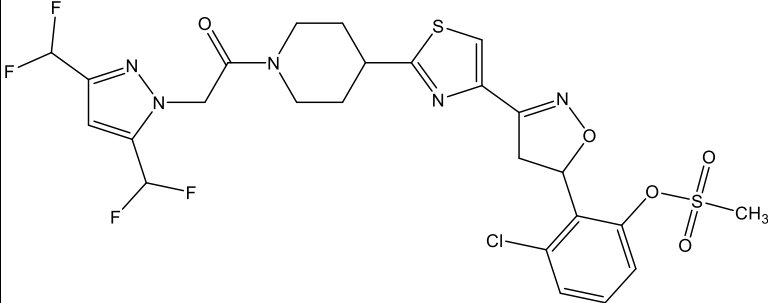
## Privacy

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

## New active constituent: Fluoxapiprolin

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

**Table 12: Particulars of the active constituent**

<b>Common name</b>	Fluoxapiprolin
<b>IUPAC name</b>	2-((5 <i>RS</i> )-3-[2-(1-[[3,5-bis(difluoromethyl)-1 <i>H</i> -pyrazol-1-yl]acetyl]piperidin-4-yl)-1,3-thiazol-4-yl]-4,5-dihydro-1,2-oxazol-5-yl)-3-chlorophenyl methanesulfonate
<b>CAS name</b>	2-[3,5-bis(difluoromethyl)-1 <i>H</i> -pyrazol-1-yl]-1-[4-[4-[5-[2-chloro-6-[(methylsulfonyl)oxy]phenyl]-4,5-dihydro-3-isoxazolyl]-2-thiazolyl]-1-piperidinyl]ethanone
<b>CAS registry number</b>	1360819-11-9
<b>Manufacturer's codes</b>	FXN, BCS-CS55621, BCS-CS55621-a.s., 621
<b>Minimum purity</b>	950 g/kg
<b>Molecular formula</b>	C <sub>25</sub> H <sub>24</sub> ClF <sub>4</sub> N <sub>5</sub> O <sub>5</sub> S <sub>2</sub>
<b>Molecular weight</b>	650.1 g/mol
<b>Structure</b>	 <p>The chemical structure of Fluoxapiprolin is a complex molecule. It features a central piperidine ring connected via an amide linkage to a thiazole ring. This thiazole ring is further connected to an oxazole ring, which is substituted with a 2-chloro-6-[(methylsulfonyl)oxy]phenyl group. The oxazole ring is also connected to a pyrazole ring, which is substituted with two difluoromethyl groups.</p>
<b>Chemical family</b>	Oxazole, pyrazole, thiazole
<b>Mode of action</b>	Oxysterol-binding protein homologue inhibition (OSBPI)

### Summary of the APVMA's evaluation of fluoxapiprolin active constituent

The APVMA has evaluated the chemistry aspects of active constituent fluoxapiprolin (physico-chemical properties, stability, identification, spectra, 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 fluoxapiprolin and concluded that there are no toxicological concerns regarding the approval of this active constituent. An acceptable daily intake (ADI) for fluoxapiprolin was established at 3 mg/kg bw/day, while an acute reference dose (ARfD) was not considered necessary. No toxicologically significant impurities have been identified in fluoxapiprolin technical active constituent.

The Scheduling Delegate made a final decision to include fluoxapiprolin in Appendix B of the SUSMP.

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

**Table 13: Active constituent standard for fluoxapiprolin**

Constituent	Level
Fluoxapiprolin	950 g/kg minimum

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

The APVMA is satisfied that the proposed importation and use of fluoxapiprolin 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 evaluation of this product is available from the [APVMA website](#) or from the contact listed below.

### Making a submission

In accordance with section 12 of the Agvet Code, the APVMA invites any person to submit a relevant written submission as to whether fluoxapiprolin 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](mailto: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](#).



## Xivana Prime 20 SC Fungicide containing fluoxapiprolin

The APVMA has before it an application for registration of a new product, Xivana Prime 20 SC Fungicide containing a new active constituent, fluoxapiprolin.

**Table 14: Particulars of the application**

<b>Proposed product name</b>	Xivana Prime 20 SC Fungicide
<b>Applicant company</b>	Bayer CropScience Pty Ltd
<b>Name of active constituent</b>	Fluoxapiprolin
<b>Signal heading</b>	Unscheduled
<b>Summary of proposed use</b>	Registration of a 20 g/L fluoxapiprolin suspension concentrate agricultural chemical product for the control of Downy mildew ( <i>Plasmopara viticola</i> ) in grapevine
<b>Pack sizes</b>	1 L to 110 L
<b>Withholding period</b>	Grapes: Harvest: not required when used as directed Grazing: do not graze livestock in treated vineyards

A summary of the APVMA's evaluation of Xivana Prime 20 SC Fungicide in accordance with the requirements of section 14(1)(C) of the Agricultural and Veterinary Chemicals Code (the 'Agvet Code'), scheduled to the *Agricultural and Veterinary Chemicals Code Act 1994*:

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:

The APVMA is satisfied that proposed use of Xivana Prime 20 SC Fungicide would not be an undue hazard to the safety of people exposed to it during its handling and use.

The APVMA has conducted a risk assessment on the product and concluded that it can be used safely.

The APVMA is satisfied that the proposed use of Xivana Prime 20 SC Fungicide will not be an undue hazard to the safety of people using anything containing its residues.

The APVMA is satisfied that the proposed use of Xivana Prime 20 SC Fungicide is not likely to have an unintended effect that is harmful to animals, plants or the environment if used according to the product label directions.

The APVMA has evaluated the application and in its assessment in relation to whether the efficacy criteria have been met in accordance with the definition set out in section 5B of the Agvet Code, and proposes to determine that:

- i. In relation to its assessment of efficacy, the APVMA is satisfied that data from trials supporting the efficacy of the product adequately demonstrate that when used according to the product label directions, the product is effective for its proposed uses.

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:

- i. The APVMA is considering whether the proposed use of Xivana Prime 20 SC Fungicide 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](#) 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 Xivana Prime 20 SC Fungicide should be registered. Submissions should relate only to matters that are required by the APVMA to be taken into consideration in determining whether the safety, efficacy or trade criteria have been met. Submissions should state the grounds on which they are based.

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

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

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

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

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

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

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