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# Gazette

## Agricultural and veterinary chemicals

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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**

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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>	133163
<b>Product name</b>	Imtrade Tyranex 900 Veriphy SG Insecticide
<b>Active constituent</b>	900 g/kg trichlorfon (an anticholinesterase compound)
<b>Applicant name</b>	Imtrade Australia Pty Ltd
<b>Applicant ACN</b>	090 151 134
<b>Date of registration</b>	5 January 2023
<b>Product registration no.</b>	91697
<b>Label approval no.</b>	91697/133163
<b>Description of the application and its purpose, including the intended use of the chemical product</b>	Registration of a 900 g/kg trichlorfon water soluble granule for control of a wide variety of insects in field and pasture crops, tree and vine crops, berries, dried fruit, vegetables, turfs and lawns and animal housing

<b>Application no.</b>	137393
<b>Product name</b>	Genfarm Mesosulfuron-Methyl OD Herbicide
<b>Active constituents</b>	90 g/L mefenpyr-diethyl, 30 g/L mesosulfuron-methyl
<b>Applicant name</b>	Nutrien Ag Solutions Limited
<b>Applicant ACN</b>	008 743 217
<b>Date of registration</b>	5 January 2023
<b>Product registration no.</b>	92939
<b>Label approval no.</b>	92939/137393
<b>Description of the application and its purpose, including the intended use of the chemical product</b>	Registration of a 30 g/L mesosulfuron-methyl and 90 g/L mefenpyr-diethyl oil-based suspension product for the post-emergent control of wild oats and annual phalaris, and suppression of brome grass, barley grass and annual ryegrass in wheat

<b>Application no.</b>	137420
<b>Product name</b>	Relyon Fipronil 500 SC Insecticidal Seed Treatment
<b>Active constituent</b>	500 g/L fipronil
<b>Applicant name</b>	Nutrien Ag Solutions Limited
<b>Applicant ACN</b>	008 743 217
<b>Date of registration</b>	5 January 2023
<b>Product registration no.</b>	92953
<b>Label approval no.</b>	92953/137420
<b>Description of the application and its purpose, including the intended use of the chemical product</b>	Registration of a 500 g/L suspension concentrate fipronil formulation for the control of various pests in canola, rice, sorghum and sunflowers, and to protect seedlings from attack from black field earwig in sorghum and sunflowers

<b>Application no.</b>	137451
<b>Product name</b>	eChem Pyroxa 850 WG Herbicide
<b>Active constituent</b>	850 g/kg pyroxasulfone
<b>Applicant name</b>	eChem (Aust) Pty Ltd
<b>Applicant ACN</b>	089 133 095
<b>Date of registration</b>	5 January 2023
<b>Product registration no.</b>	92967
<b>Label approval no.</b>	92967/137451
<b>Description of the application and its purpose, including the intended use of the chemical product</b>	Registration and label approval of an 850 g/kg pyroxasulfone water dispersible concentrate 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), triticale and certain winter legume crops

<b>Application no.</b>	137361
<b>Product name</b>	Ezycrop Mepiquat 38 Cotton Growth Regulator
<b>Active constituent</b>	38 g/L mepiquat, present as the chloride
<b>Applicant name</b>	Ezycrop Pty Ltd
<b>Applicant ACN</b>	156 476 827
<b>Date of registration</b>	6 January 2023
<b>Product registration no.</b>	92929
<b>Label approval no.</b>	92929/137361
<b>Description of the application and its purpose, including the intended use of the chemical product</b>	Registration of a 38 g/L mepiquat, present as the chloride, soluble concentrate (SL) product for the management of fruiting and excessive vegetative growth in cotton

<b>Application no.</b>	136556
<b>Product name</b>	Eurochem Chlorothalonil 900 WG Fungicide
<b>Active constituent</b>	900 g/kg chlorothalonil
<b>Applicant name</b>	EuroChem Pty Ltd
<b>Applicant ACN</b>	622 603 507
<b>Date of registration</b>	10 January 2023
<b>Product registration no.</b>	92759
<b>Label approval no.</b>	92759/136556
<b>Description of the application and its purpose, including the intended use of the chemical product</b>	Registration of a 900 g/kg water dispersible granule of chlorothalonil for the control of fungal diseases on almonds, apricots, bananas, carrots, celery, cherries, chickpeas, faba beans, grapes, lentils, onions, peaches, nectarines, peanuts, peas, plums, potatoes, tomatoes, vegetables and ornamentals as per the directions for use table

<b>Application no.</b>	135354
<b>Product name</b>	Brunnings Weed Kill Concentrate
<b>Active constituent</b>	50 g/L glyphosate (present as the isopropylamine salt)
<b>Applicant name</b>	Brunnings Garden Products Pty Ltd
<b>Applicant ACN</b>	050 655 760
<b>Date of registration</b>	10 January 2023
<b>Product registration no.</b>	92388
<b>Label approval no.</b>	92388/135354
<b>Description of the application and its purpose, including the intended use of the chemical product</b>	Registration of a 50 g/L soluble concentrate of glyphosate to kill weeds and grasses in the home garden

<b>Application no.</b>	137382
<b>Product name</b>	Relyon Boscalid 500 WG Fungicide
<b>Active constituent</b>	500 g/kg boscalid
<b>Applicant name</b>	Nutrien Ag Solutions Limited
<b>Applicant ACN</b>	008 743 217
<b>Date of registration</b>	10 January 2023
<b>Product registration no.</b>	92933
<b>Label approval no.</b>	92933/137382
<b>Description of the application and its purpose, including the intended use of the chemical product</b>	Registration of a 500 g/kg boscalid WG fungicide product for the control of botrytis bunch rot and powdery mildew in grapevines; and early blight in potatoes, tomatoes, eggplant, capsicums and peppers; sclerotinia rot in a range of vegetable crops; and neck rot in onions

<b>Application no.</b>	137381
<b>Product name</b>	Genfarm Boscalid 500 WG Fungicide
<b>Active constituent</b>	500 g/kg boscalid
<b>Applicant name</b>	Nutrien Ag Solutions Limited
<b>Applicant ACN</b>	008 743 217
<b>Date of registration</b>	11 January 2023
<b>Product registration no.</b>	92932
<b>Label approval no.</b>	92932/137381
<b>Description of the application and its purpose, including the intended use of the chemical product</b>	Registration of a 500 g/kg boscalid WG fungicide product for the control of botrytis bunch rot and powdery mildew in grapevines; and early blight in potatoes, tomatoes, eggplant, capsicums and peppers; sclerotinia rot in a range of vegetable crops; and neck rot in onions

<b>Application no.</b>	137331
<b>Product name</b>	Campbell Potato Tycoon 500EC Fungicide
<b>Active constituent</b>	500 g/L imazalil
<b>Applicant name</b>	Colin Campbell (Chemicals) Pty Ltd
<b>Applicant ACN</b>	000 045 590
<b>Date of registration</b>	11 January 2023
<b>Product registration no.</b>	92921
<b>Label approval no.</b>	92921/137331
<b>Description of the application and its purpose, including the intended use of the chemical product</b>	Registration of a 500 g/L imazalil emulsifiable concentrate product for control of storage diseases of potatoes

<b>Application no.</b>	134773
<b>Product name</b>	Imtrade Tutor 900 WG Fungicide
<b>Active constituent</b>	900 g/kg triadimenol
<b>Applicant name</b>	Imtrade Australia Pty Ltd
<b>Applicant ACN</b>	090 151 134
<b>Date of registration</b>	12 January 2023
<b>Product registration no.</b>	92182
<b>Label approval no.</b>	92182/134773
<b>Description of the application and its purpose, including the intended use of the chemical product</b>	Registration of a 900 g/kg triadimenol water dispersible granule product for the systemic control of white rot in onions

<b>Application no.</b>	137481
<b>Product name</b>	Aries 95 Fungicide
<b>Active constituent</b>	95 g/L azoxystrobin
<b>Applicant name</b>	Turf Culture Pty Ltd
<b>Applicant ACN</b>	117 986 615
<b>Date of registration</b>	12 January 2023
<b>Product registration no.</b>	92975
<b>Label approval no.</b>	92975/137481
<b>Description of the application and its purpose, including the intended use of the chemical product</b>	Registration of a 95 g/L azoxystrobin dispersible concentrate product for the control of various diseases in turf

<b>Application no.</b>	133164
<b>Product name</b>	Imtrade Activist 900 Veriphy SG Insecticide
<b>Active constituent</b>	900 g/kg methomyl (an anti-cholinesterase compound)
<b>Applicant name</b>	Imtrade Australia Pty Ltd
<b>Applicant ACN</b>	090 151 134
<b>Date of registration</b>	13 January 2023
<b>Product registration no.</b>	91698
<b>Label approval no.</b>	91698/133164
<b>Description of the application and its purpose, including the intended use of the chemical product</b>	Registration of a 900 g/kg methomyl water soluble granule product for the control of insect pests in various crops

<b>Application no.</b>	134727
<b>Product name</b>	Farmalinx Colossal Trio Insecticide
<b>Active constituents</b>	116 g/L clothianidin, 83 g/L clofentezine, 13 g/L abamectin
<b>Applicant name</b>	Farmalinx Pty Ltd
<b>Applicant ACN</b>	134 353 245
<b>Date of registration</b>	13 January 2023
<b>Product registration no.</b>	92166
<b>Label approval no.</b>	92166/134727
<b>Description of the application and its purpose, including the intended use of the chemical product</b>	Registration of a 116 g/L clothianidin, 83 g/L clofentezine and 13 g/L abamectin suspension concentrate product for control of various pests in turf



<b>Application no.</b>	137394
<b>Product name</b>	Relyon Mesosulfuron-Methyl OD Herbicide
<b>Active constituents</b>	90 g/L mefenpyr-diethyl, 30 g/L mesosulfuron-methyl
<b>Applicant name</b>	Nutrien Ag Solutions Limited
<b>Applicant ACN</b>	008 743 217
<b>Date of registration</b>	13 January 2023
<b>Product registration no.</b>	92940
<b>Label approval no.</b>	92940/137394
<b>Description of the application and its purpose, including the intended use of the chemical product</b>	Registration of a 30 g/L mesosulfuron-methyl and 90 g/L mefenpyr-diethyl oil-based suspension product for the post-emergent control of wild oats and annual phalaris, and suppression of brome grass, barley grass and annual ryegrass in wheat

<b>Application no.</b>	137417
<b>Product name</b>	Relyon Brom-Di MCPA Herbicide
<b>Active constituents</b>	280 g/L MCPA present as the ethyl hexyl ester, 140 g/L bromoxynil present as the octanoate ester, 40 g/L dicamba present as the acid
<b>Applicant name</b>	Nutrien Ag Solutions Limited
<b>Applicant ACN</b>	008 743 217
<b>Date of registration</b>	13 January 2023
<b>Product registration no.</b>	92951
<b>Label approval no.</b>	92951/137417
<b>Description of the application and its purpose, including the intended use of the chemical product</b>	Registration and label approval of a 280 g/L MCPA plus 140 g/L bromoxynil plus 40 g/L dicamba emulsifiable concentrate herbicide product for the control of certain broadleaf weeds in wheat, barley, cereal rye, oats, triticale and turf

<b>Application no.</b>	137565
<b>Product name</b>	Conquest Nitro 360 Herbicide
<b>Active constituent</b>	360 g/L clethodim
<b>Applicant name</b>	Conquest Crop Protection Pty Ltd
<b>Applicant ACN</b>	098 814 932
<b>Date of registration</b>	13 January 2023
<b>Product registration no.</b>	92994
<b>Label approval no.</b>	92994/137565
<b>Description of the application and its purpose, including the intended use of the chemical product</b>	Registration and label approval 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) according to the directions for use table

**Table 2: Listed registrations – agricultural chemical products**

<b>Application no.</b>	137513
<b>Product name</b>	CCI Pool Chlorine
<b>Active constituent</b>	100 g/L available chlorine (Cl) present as sodium hypochlorite
<b>Applicant name</b>	Custom Chemicals International Pty Ltd
<b>Applicant ACN</b>	050 573 674
<b>Date of registration</b>	4 January 2023
<b>Product registration no.</b>	92982
<b>Label approval no.</b>	92982/137513
<b>Description of the application and its purpose, including the intended use of the chemical product</b>	Registration of a 100 g/L liquid chlorine for use as a sanitiser in pools and spas

**Table 3: Variations of registration – agricultural chemical products**

<b>Application no.</b>	138148
<b>Product name</b>	Nufarm Barrack Betterstick Fungicide
<b>Active constituent</b>	720 g/L chlorothalonil
<b>Applicant name</b>	Nufarm Australia Limited
<b>Applicant ACN</b>	004 377 780
<b>Date of variation</b>	30 December 2022
<b>Product registration no.</b>	61016
<b>Label approval no.</b>	61016/138148
<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 'Barrack Betterstick Fungicide' to 'Nufarm Barrack Betterstick Fungicide'. To update the safety directions appearing on a label to reflect the current FAISD Handbook

<b>Application no.</b>	133657
<b>Product name</b>	Affirm Insecticide
<b>Active constituent</b>	17 g/L emamectin present as emamectin benzoate
<b>Applicant name</b>	Syngenta Australia Pty Ltd
<b>Applicant ACN</b>	002 933 717
<b>Date of variation</b>	4 January 2023
<b>Product registration no.</b>	51321
<b>Label approval no.</b>	51321/133657
<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 include use in sorghum for control of fall army worm and add control of <i>Heliothis</i> in canola

<b>Application no.</b>	134299
<b>Product name</b>	Greenseal Pruning Wound Dressing
<b>Active constituent</b>	10 g/L tebuconazole
<b>Applicant name</b>	Omnia Specialities (Australia) Pty Ltd
<b>Applicant ACN</b>	102 717 019
<b>Date of variation</b>	4 January 2023
<b>Product registration no.</b>	61873
<b>Label approval no.</b>	61873/134299
<b>Description of the application and its purpose, including the intended use of the chemical product</b>	Variation of the particulars of registration and label approval to add a claim for control of <i>Botryosphaeria</i> (caused by <i>Diplodia seriata</i> ) and <i>Eutypa</i> dieback of almonds

<b>Application no.</b>	137323
<b>Product name</b>	Nufarm Paveden 100EC Selective Herbicide
<b>Active constituents</b>	100 g/L pinoxaden, 25 g/L cloquintocet-mexyl
<b>Applicant name</b>	Nufarm Australia Limited
<b>Applicant ACN</b>	004 377 780
<b>Date of variation</b>	9 January 2023
<b>Product registration no.</b>	87407
<b>Label approval no.</b>	87407/137323
<b>Description of the application and its purpose, including the intended use of the chemical product</b>	Variation of registered chemical product and label approval to update signal heading, constituent statement, first aid instructions and safety directions

<b>Application no.</b>	137280
<b>Product name</b>	Apparent Paraquat 250 Herbicide
<b>Active constituent</b>	250 g/L paraquat present as paraquat dichloride
<b>Applicant name</b>	Titan Ag Pty Ltd
<b>Applicant ACN</b>	122 081 574
<b>Date of variation</b>	9 January 2023
<b>Product registration no.</b>	66103
<b>Label approval no.</b>	66103/137280
<b>Description of the application and its purpose, including the intended use of the chemical product</b>	Variation to registration and label particulars to add withholding periods for uses in vetch

<b>Application no.</b>	138208
<b>Product name</b>	Nufarm MCPA LVE 570 Herbicide
<b>Active constituent</b>	570 g/L MCPA present as the 2-ethyl hexyl ester
<b>Applicant name</b>	Nufarm Australia Limited
<b>Applicant ACN</b>	004 377 780
<b>Date of variation</b>	9 January 2023
<b>Product registration no.</b>	63597
<b>Label approval no.</b>	63597/138208
<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 'Polo 570 LVE Herbicide' to 'Nufarm MCPA LVE 570 Herbicide'

<b>Application no.</b>	137367
<b>Product name</b>	Smart Clopyralid 300 Herbicide
<b>Active constituent</b>	300 g/L clopyralid present as the triisopropanolamine salt
<b>Applicant name</b>	Crop Smart Pty Ltd
<b>Applicant ACN</b>	093 927 961
<b>Date of variation</b>	10 January 2023
<b>Product registration no.</b>	68377
<b>Label approval no.</b>	68377/137367
<b>Description of the application and its purpose, including the intended use of the chemical product</b>	Variation to registration particulars and particulars of label approval, to update the label

<b>Application no.</b>	137346
<b>Product name</b>	Macspred Glymac 450 Herbicide
<b>Active constituent</b>	450 g/L glyphosate present as the isopropylamine salt
<b>Applicant name</b>	Macspred Pty Ltd
<b>Applicant ACN</b>	011 029 495
<b>Date of variation</b>	10 January 2023
<b>Product registration no.</b>	52780
<b>Label approval no.</b>	52780/137346
<b>Description of the application and its purpose, including the intended use of the chemical product</b>	Variation to registration particulars, particulars of label, to include uses in forestry plantations and label update

<b>Application no.</b>	137453
<b>Product name</b>	Axial 100 EC Selective Herbicide
<b>Active constituents</b>	100 g/L pinoxaden, 25 g/L cloquintocet-mexyl
<b>Applicant name</b>	Syngenta Australia Pty Ltd
<b>Applicant ACN</b>	002 933 717
<b>Date of variation</b>	10 January 2023
<b>Product registration no.</b>	59024
<b>Label approval no.</b>	59024/137453
<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 align with current scheduling, Agricultural Labelling Code and FAISD Handbook requirements

<b>Application no.</b>	134691
<b>Product name</b>	Genfarm Prosulfocarb 800 Herbicide
<b>Active constituent</b>	800 g/L prosulfocarb
<b>Applicant name</b>	Nutrien Ag Solutions Limited
<b>Applicant ACN</b>	008 743 217
<b>Date of variation</b>	13 January 2023
<b>Product registration no.</b>	82867
<b>Label approval no.</b>	82867/134691
<b>Description of the application and its purpose, including the intended use of the chemical product</b>	Variation to add a post-emergent application for barley ( <i>Hordeum vulgare</i> ) and wheat ( <i>Lolium rigidum</i> ) for the suppression of annual ryegrass

<b>Application no.</b>	137519
<b>Product name</b>	Tecto Flowable SC Fungicide
<b>Active constituent</b>	500 g/L thiabendazole
<b>Applicant name</b>	Syngenta Australia Pty Ltd
<b>Applicant ACN</b>	002 933 717
<b>Date of variation</b>	13 January 2023
<b>Product registration no.</b>	49910
<b>Label approval no.</b>	49910/137519
<b>Description of the application and its purpose, including the intended use of the chemical product</b>	Variation to registration particulars and particulars of label, to vary the product registration and label approval to add a statement in the critical comments for sweet potato (seed roots)

<b>Application no.</b>	136517
<b>Product name</b>	Lorox Linuron DF Herbicide
<b>Active constituent</b>	500 g/kg linuron
<b>Applicant name</b>	Tessenderlo Kerley, Inc
<b>Applicant ACN</b>	N/A
<b>Date of variation</b>	13 January 2023
<b>Product registration no.</b>	60222
<b>Label approval no.</b>	60222/136517
<b>Description of the application and its purpose, including the intended use of the chemical product</b>	Variation to the particulars or registration and label approval to add uses in leeks, shallots, spring onions, celery, pyrethrum and celeriac as a part of the permit to label project. In addition to revise the restraints, label format, weeds, withholding periods, mode of action, general instructions, and first aid instructions

Table 4: Label approval – agricultural chemical products

<b>Application no.</b>	137964
<b>Product name</b>	Off! Tropical Strength Insect Repellent Spray
<b>Active constituent</b>	191 g/L picaridin
<b>Applicant name</b>	S.C. Johnson & Son Pty Ltd
<b>Applicant ACN</b>	000 021 009
<b>Date of variation</b>	5 January 2023
<b>Product registration no.</b>	65744
<b>Label approval no.</b>	65744/137964
<b>Description of the application and its purpose, including the intended use of the chemical product</b>	Registration of a new label for the existing product 'OFF! TROPICAL STRENGTH INSECT REPELLENT SPRAY' with the label name 'OFF! CAMPING AND FISHING UP TO 8 HOURS LONG LASTING PROTECTION AGAINST MOSQUITOES INSECT REPELLENT SPRAY NON GREASY & LIGHTLY FRAGRANCED DERMATOLOGICALLY TESTED REPELS MOSQUITOES, FLIES, SANDFLIES, TICKS AND OTHER BITING INSECTS'

<b>Application no.</b>	137918
<b>Product name</b>	Agricrop Spraybuff 700 Surfactant
<b>Active constituents</b>	350 g/L propionic acid, 350 g/L soyal phospholipids
<b>Applicant name</b>	Sipcam Pacific Australia Pty Ltd
<b>Applicant ACN</b>	073 176 888
<b>Date of variation</b>	9 January 2023
<b>Product registration no.</b>	63019
<b>Label approval no.</b>	63019/137918
<b>Description of the application and its purpose, including the intended use of the chemical product</b>	Registration of a new label for the existing product 'AGRICROP SPRAYBUFF 700 SURFACTANT' with the label name 'SPRAYBUFF 700 SURFACTANT' and statements updated in line with the current FAISD Handbook

## 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 5: Veterinary products based on existing active constituents**

<b>Application no.</b>	137187
<b>Product name</b>	Elevet+ Tilmicosin 300 mg/mL Injection for Cattle
<b>Active constituent</b>	300 mg/mL tilmicosin as tilmicosin phosphate
<b>Applicant name</b>	AVet Health Limited
<b>Applicant ACN</b>	616 838 101
<b>Date of registration</b>	4 January 2023
<b>Product registration no.</b>	92904
<b>Label approval no.</b>	92904/137187
<b>Description of the application and its purpose, including the intended use of the chemical product</b>	Registration of a 300 mg/mL tilmicosin (as tilmicosin phosphate) parental solution for use in lot-fed cattle for the treatment of Bovine Respiratory Disease (BRD) associated with <i>Mannheimia (Pasteurella) haemolytica</i> , <i>Pasteurella multocida</i> , and other organisms susceptible to tilmicosin

<b>Application no.</b>	137139
<b>Product name</b>	Elevet+ Xylazine 100 mg/mL Analgesic, Sedative and Muscle Relaxant Injection for Horses
<b>Active constituent</b>	100 mg/mL xylazine as hydrochloride
<b>Applicant name</b>	AVet Health Limited
<b>Applicant ACN</b>	616 838 101
<b>Date of registration</b>	10 January 2023
<b>Product registration no.</b>	92898
<b>Label approval no.</b>	92898/137139
<b>Description of the application and its purpose, including the intended use of the chemical product</b>	Registration of a 100 mg/mL xylazine (as hydrochloride) parenteral solution product for use as an analgesic, sedative and muscle relaxant in horses

Application no.	136981
Product name	YP Meloxicam 40 mg/mL Injectable for Use in Cattle
Active constituent	40 mg/mL meloxicam
Applicant name	South Yarra Pharma Pty Ltd
Applicant ACN	629 173 351
Date of registration	12 January 2023
Product registration no.	92861
Label approval no.	92861/136981
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 40 mg/mL meloxicam parenteral solution product for use as a non-steroidal anti-inflammatory, analgesic, antipyretic in cattle

Table 6: Variations of registration – veterinary chemical products

Application no.	138179
Product name	CLiK Extra Spray-On Sheep Blowfly Treatment
Active constituent/s	65 g/L dicyclanil
Applicant name	Elanco Australasia Pty Ltd
Applicant ACN	076 745 198
Date of variation	4 January 2023
Product registration no.	91837
Label approval no.	91837/138179
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 'Dicyclanil 65 g/L Spray-On Sheep Blowfly Treatment' to 'CLiK Extra Spray-On Sheep Blowfly Treatment'

Application no.	134041
Product name	Websters 6 in 1 SE Vaccine
Active constituents	Contains aluminium adjuvanted toxoid and cellular antigen from <i>Corynebacterium pseudotuberculosis (ovis)</i> 1.0 IU/mL, <i>Clostridium perfringens</i> type D 5.0 IU/mL, <i>Cl. novyi</i> type B 3.5 IU/mL, <i>Cl. tetani</i> 2.5 IU/mL, <i>Cl. septicum</i> 2.5 IU/mL, <i>Cl. chauvoei</i> ≥0.3% PCV/mL and selenium (as sodium selenate) 1 mg/mL
Applicant name	Virbac (Australia) Pty Ltd
Applicant ACN	003 268 871
Date of variation	12 January 2023
Product registration no.	51337
Label approval no.	51337/134041
Description of the application and its purpose, including the intended use of the chemical product	Variation of conditions of registration and labelling particulars including extension of in-use shelf life



<b>Application no.</b>	134042
<b>Product name</b>	Websters 6 in 1 Vaccine
<b>Active constituents</b>	Contains toxoid and cell concentrates prepared from formalin killed <i>Corynebacterium pseudotuberculosis (ovis)</i> (1.0 IU/mL), <i>Clostridium perfringens type D</i> (5.0 IU/mL), <i>Cl. novyi type B</i> (3.5 IU/mL), <i>Cl. septicum</i> (2.5 IU/mL), <i>Cl. tetani</i> (2.5 IU/mL) and <i>Cl. chauvoei</i> ( $\geq 0.3\%$ PCV/mL)
<b>Applicant name</b>	Virbac (Australia) Pty Ltd
<b>Applicant ACN</b>	003 268 871
<b>Date of variation</b>	12 January 2023
<b>Product registration no.</b>	51336
<b>Label approval no.</b>	51336/134042
<b>Description of the application and its purpose, including the intended use of the chemical product</b>	Variation of conditions of registration and labelling particulars including extension of in-use shelf life

<b>Application no.</b>	134043
<b>Product name</b>	Websters 5 in 1 Vaccine
<b>Active constituents</b>	Contains toxoid and cell concentrates prepared from formalin killed <i>Clostridium perfringens type D</i> (5.0 IU/mL), <i>Cl. novyi type B</i> (3.5 IU/mL), <i>Cl. septicum</i> (2.5 IU/mL), <i>Cl. tetani</i> (2.5 IU/mL) and <i>Cl. chauvoei</i> ( $\geq 0.3\%$ PCV/mL)
<b>Applicant name</b>	Virbac (Australia) Pty Ltd
<b>Applicant ACN</b>	003 268 871
<b>Date of variation</b>	12 January 2023
<b>Product registration no.</b>	51333
<b>Label approval no.</b>	51333/134043
<b>Description of the application and its purpose, including the intended use of the chemical product</b>	Variation of conditions of registration and labelling particulars including extension of in-use shelf life

## 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>	134482
<b>Active constituent</b>	Glufosinate-ammonium
<b>Applicant name</b>	Jiangsu ChunJiangRunTian Agrochemical Co Ltd
<b>Applicant ACN</b>	N/A
<b>Date of approval</b>	4 January 2023
<b>Approval no.</b>	92091
<b>Description of the application and its purpose, including the intended use of the active constituent</b>	Approval of the active constituent glufosinate-ammonium for use in agricultural chemical products

<b>Application no.</b>	135805
<b>Active constituent</b>	Atrazine
<b>Applicant name</b>	Syngenta Australia Pty Ltd
<b>Applicant ACN</b>	002 933 717
<b>Date of approval</b>	5 January 2023
<b>Approval no.</b>	92518
<b>Description of the application and its purpose, including the intended use of the active constituent</b>	Approval of the active constituent atrazine for use in agricultural chemical products

<b>Application no.</b>	135771
<b>Active constituent</b>	Lambda-cyhalothrin
<b>Applicant name</b>	Hextar Chemicals Pty Ltd
<b>Applicant ACN</b>	114 525 709
<b>Date of approval</b>	5 January 2023
<b>Approval no.</b>	92511
<b>Description of the application and its purpose, including the intended use of the active constituent</b>	Approval of the active constituent lambda-cyhalothrin for use in agricultural chemical products

<b>Application no.</b>	134907
<b>Active constituent</b>	Chlorfenapyr
<b>Applicant name</b>	Shandong United Pesticide Industry Co Ltd
<b>Applicant ACN</b>	N/A
<b>Date of approval</b>	5 January 2023
<b>Approval no.</b>	92241
<b>Description of the application and its purpose, including the intended use of the active constituent</b>	Approval of the active constituent chlorfenapyr for use in agricultural chemical products

<b>Application no.</b>	135811
<b>Active constituent</b>	Glufosinate-ammonium
<b>Applicant name</b>	Weifang Sino-Agri Union Chemical Co Ltd
<b>Applicant ACN</b>	N/A
<b>Date of approval</b>	5 January 2023
<b>Approval no.</b>	92521
<b>Description of the application and its purpose, including the intended use of the active constituent</b>	Approval of the active constituent glufosinate-ammonium for use in agricultural chemical products

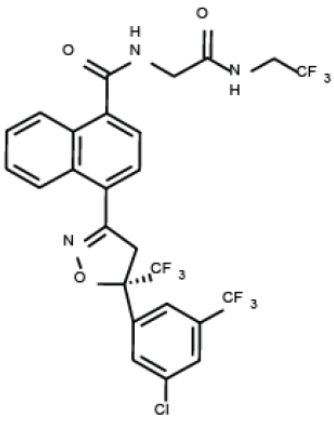
<b>Application no.</b>	135819
<b>Active constituent</b>	Pinoxaden
<b>Applicant name</b>	Hailir Pesticides and Chemicals Group Co Ltd
<b>Applicant ACN</b>	N/A
<b>Date of approval</b>	5 January 2023
<b>Approval no.</b>	92525
<b>Description of the application and its purpose, including the intended use of the active constituent</b>	Approval of the active constituent pinoxaden for use in agricultural chemical products

<b>Application no.</b>	135857
<b>Active constituent</b>	Propyzamide
<b>Applicant name</b>	Imtrade Australia Pty Ltd
<b>Applicant ACN</b>	090 151 134
<b>Date of approval</b>	13 January 2023
<b>Approval no.</b>	92537
<b>Description of the application and its purpose, including the intended use of the active constituent</b>	Approval of the active constituent propyzamide for use in agricultural chemical products

## New veterinary chemical products containing a new veterinary active constituent – Nexgard Spectra Spot-On for Cats 0.8 – 2.4 kg and Nexgard Spectra Spot-On for Cats 2.5 – 7.5 kg containing esafoxolaner

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application for the approval of a new active constituent, esafoxolaner, and applications for the registration of 2 new products containing the new active constituent. The products are Nexgard Spectra Spot-On for Cats 0.8 – 2.4 kg and Nexgard Spectra Spot-On for Cats 2.5 – 7.5 kg, for the treatment and prevention of flea infestations, control of ticks and mites, prevention of heartworm disease, and treatment and control of intestinal worms in cats and kittens from 8 weeks of age. The suite of products will be referred to in this summary collectively as Nexgard Spectra Spot-On for Cats.

**Table 8: Particulars of the active constituent esafoxolaner**

<b>Common name</b>	Esafoxolaner
<b>IUPAC name</b>	4-[(5S)-5-[3-chloro-5-(trifluoromethyl)phenyl]-5-(trifluoromethyl)-4,5-dihydro-1,2-oxazol-3-yl]-N-[2-oxo-2-[(2,2,2-trifluoroethyl)amino]ethyl]-1-naphthamide
<b>CAS name</b>	1-Naphthalenecarboxamide, 4-[(5S)-5-[3-chloro-5-(trifluoromethyl)phenyl]-4,5-dihydro-5-(trifluoromethyl)-3-isoxazoly]-N-[2-oxo-2-[(2,2,2-trifluoroethyl)amino]ethyl]-
<b>CAS registry number</b>	1096103-99-9
<b>Manufacturer's codes</b>	ML-163 or ML-3,314,163
<b>Specified purity</b>	95.0-102.0%
<b>Molecular formula</b>	C <sub>26</sub> H <sub>17</sub> ClF <sub>9</sub> N <sub>3</sub> O <sub>3</sub>
<b>Molecular weight</b>	625.87 g/mol
<b>Structure</b>	
<b>Chemical family</b>	Isoxazoline chemical compound group
<b>Mode of action</b>	Esafoxolaner acts as an antagonist at ligand-gated chloride channels, in particular those gated by the neurotransmitter gamma-aminobutyric acid.

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

The APVMA has evaluated the new active constituent esafoxolaner under sections 5A(1)(a),(b) and (c) of the Agvet Code and proposes to be satisfied that the active constituent is not, or would not: be an undue hazard to the safety of people exposed to it during its handling or people using anything containing its residues; be likely to have an effect that is harmful to human beings; or be likely to have an unintended effect that is harmful to animals, plants or things or to the environment.

The APVMA has evaluated the chemistry aspects of esafoxolaner (identification, physicochemical properties, stability, manufacturing process, quality control procedures, batch analysis results and analytical methods) and found them to be

acceptable. Esafoxolaner is manufactured to the standard of the manufacturer's internal specifications. Impurities of toxicological significance are not expected to occur in esafoxolaner as a result of the raw materials and the synthetic route used.

The APVMA has considered the toxicological aspects of esafoxolaner and concluded that there are no toxicological concerns regarding the approval of this active constituent.

Esafoxolaner is only for use in non-food-producing animals (cats), and hence establishment of health-based guidance values such as an acceptable daily intake (ADI) or acute reference dose (ARfD) are not required.

Based on its toxicity profile and intended use pattern, esafoxolaner is covered by the existing entry for afoxolaner (the racemic mixture of esafoxolaner and the R isomer) in schedule 5 in the standard for the Uniform Scheduling of Medicines and Poisons.

The APVMA proposes to be satisfied that the proposed use of esafoxolaner in a veterinary chemical product would not be an undue toxicological hazard to the safety of people exposed to it during its handling and use, nor would it be likely to have an unintended effect that is harmful to human beings, animals, plants or things or to the environment.

**Table 9: Particulars of the products Nexgard Spectra Spot-On for Cats 0.8 – 2.4 kg and Nexgard Spectra Spot-On for Cats 2.5 – 7.5 kg**

<b>Proposed product names</b>	Nexgard Spectra Spot-On for Cats 0.8 – 2.4 kg and Nexgard Spectra Spot-On for Cats 2.5 – 7.5 kg
<b>Applicant company</b>	Boehringer Ingelheim Animal Health Australia Pty Ltd
<b>Name of active constituent</b>	Esafoxolaner
<b>Signal heading</b>	Schedule 5
<b>Formulation type:</b>	Topical spot-on solution
<b>Summary of proposed use</b>	For the treatment and prevention of flea infestations, control of ticks and mites, prevention of heartworm disease, and treatment and control of intestinal worms in cats and kittens from 8 weeks of age.
<b>Pack sizes</b>	For Nexgard Spectra Spot-On for Cats 0.8 – 2.4 kg: 1 × 0.3 mL, 2 × 0.3 mL, 3 × 0.3 mL, 4 × 0.3 mL, 6 × 0.3 mL, 9 × 0.3 mL, 12 × 0.3 mL and 15 × 0.3 mL  For Nexgard Spectra Spot-On for Cats 2.5 - 7.5 kg: 1 × 0.9 mL, 2 × 0.9 mL, 3 × 0.9 mL, 4 × 0.9 mL, 6 × 0.9 mL, 9 × 0.9 mL, 12 × 0.9 mL and 15 × 0.9 mL
<b>Withholding period</b>	Not applicable

## Summary of proposed products use

NexGard Spectra Spot-on for Cats (2 sizes: 0.8 to 2.4 kg, and 2.5 to 7.5 kg), is a topical spot-on solution containing 12 g/L esafoxolaner (1.2% w/v), 83 g/L praziquantel (8.3% w/v) and 4 g/L eprinomectin (0.4% w/v), for the treatment and prevention of flea infestations, control of ticks and mites, prevention of heartworm disease, and treatment and control of intestinal worms in cats and kittens from 8 weeks of age.

## Dose and route of administration

The products are for use on kittens from 8 weeks of age and are for topical application onto the skin (spot-on) only, with the recommended minimum dose being 1.44 mg/kg esafoxolaner, 0.5 mg/kg eprinomectin, and 10 mg/kg praziquantel.

The products are intended for home use and will be applied manually by the cat owner. The entire contents of the applicator should be applied to dry skin in an area where the cat cannot lick it off: e.g. on the back of the neck. In long-haired breeds, special attention should be paid to apply the products onto the skin, and not on the hair, to ensure optimal efficacy.

The users are advised to select the appropriate applicator size for the weight of the cat as follows:

Cat weight	Treatment volume (mL)
0.8 to 2.4 kg	0.3 mL applicator
2.5 to 7.5 kg*	0.9 mL applicator

\*For cats over 7.5 kg, the applicant advises to use the appropriate combination of applicators.

Monthly application is recommended. For optimal performance, it is advised to treat the cat on or about the same day each month.

Side effects: If licking occurs shortly after application, a brief period of hypersalivation may occur. Hypersalivation, diarrhoea, transient skin reactions at the application site (alopecia, pruritus), anorexia, lethargy, and emesis were uncommonly observed in clinical trials shortly after administration. These were mostly mild reactions of short duration and self-limiting.

Precautions: Avoid contact with the cat's eyes. If accidental eye contact occurs, flush the eyes immediately with water. If eye irritation persists, seek veterinary advice.

### **Summary of the APVMA's evaluation of Nexgard Spectra Spot-On for Cats 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 applications 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 Nexgard Spectra Spot-On for Cats would not be an undue hazard to the safety of people exposed to it during its handling and use.

The APVMA conducted a risk assessment for the products and in conjunction with the estimated hazard profile, determined whether the proposed use of the products would be an undue health hazard to humans.

The products are intended for home use and will be applied manually by the cat owner to the skin on the neck of the cat between the shoulders. Pet owners are the main group at risk of exposure via the dermal route (and secondarily by the ocular routes).

The submitted data package comprised of bridging toxicological studies in laboratory animals - acute oral and dermal toxicity studies, dermal and ocular irritation studies, and a local lymph node assay for skin sensitisation studies. An acute inhalational toxicity study was not conducted as no substantial exposure via this route is expected. It was found that NexGard Spectra Spot-on for Cats has low acute oral and acute dermal toxicity. It is neither an irritant nor a sensitiser to skin but is a moderate to severe eye irritant. Given the eye irritation found for the products, further investigation of eye irritation (various formulations/excipients) was conducted. The data suggested that an excipient in the final formulation is likely to be responsible, at least in part, for the ocular irritancy of the products. The proposed safety directions and additional user safety statements on the products label are expected to effectively manage the ocular risk associated with products use.

Considering that these products have 3 actives, it was determined that out of the 3 active constituents, praziquantel was assessed to be the constituent driving the toxicological risk assessment of the products (or eprinomectin for chronic dermal exposure). It should, however, be noted that there was no evidence suggesting a toxicological interaction between the active constituents of NexGard Spectra Spot-on for Cats.

After consideration of the toxicological profile and likely human exposure associated with the use of NexGard Spectra Spot-on for Cats, the APVMA concludes that the human health risks are acceptable according to the criteria stipulated in Section 5A of the *Agricultural and Veterinary Chemicals Code Act* (1994 as amended), for the proposed topical application for cats, when used in accordance with the Directions for Use and in adherence to the recommended Safety Directions.

To mitigate the risks, the following signal headings, first aid instructions, safety directions, and additional user safety statements are to appear on the products labels:

Signal headings:

CAUTION

KEEP OUT OF REACH OF CHILDREN

FOR ANIMAL TREATMENT ONLY

READ SAFETY DIRECTIONS

First aid instructions:

If poisoning occurs, contact a doctor or Poisons Information Centre. Phone Australia 131 126.

Safety directions:

Will irritate the eyes. Avoid contact with eyes and skin. If product in eyes, wash it out immediately with water. If skin contact occurs, wash the affected area immediately with clean water. Wash hands after use.

Additional User Safety:

Do not contact or allow children to contact the application site until it is dry. Handling of treated animals should be limited during this period. On the day of treatment, treated animals should not be permitted to sleep with their owner, especially children. Additional information is listed in the Safety Data Sheet.

- ii. The APVMA is satisfied that the proposed use of Nexgard Spectra Spot-On for Cats, will not be an undue hazard to the safety of people using anything containing their residues.

The products are for use in companion animals (cats) only. Nexgard Spectra Spot-On for Cats is unlikely to enter the food chain.

- iii. The APVMA is satisfied that the proposed use of Nexgard Spectra Spot-On for Cats containing the active constituents: 12 g/L esafoxolaner (1.2% w/v), 83 g/L praziquantel (8.3% w/v) and 4 g/L eprinomectin (0.4% w/v), is not likely to be harmful to human beings if used according to the products label directions.

Praziquantel is listed in Schedule 4 of the Standard for the Uniform Scheduling of Medicines and Poisons, for human therapeutic use. Other uses of praziquantel are not Scheduled.

Eprinomectin is present in the proposed products at 0.4% and is captured under Schedule 5.

Esafoxolaner is covered by the existing entry for afoxolaner (the racemic mixture of esafoxolaner and the R isomer) in schedule 5 in the Standard for the Uniform Scheduling of Medicines and Poisons.

All other constituents in the formulation are not captured by Scheduling.

As Schedule 5 products, Nexgard Spectra Spot-On for Cats, will have CAUTION as a signal header on the labels.

- iv. The APVMA is satisfied that the proposed use of Nexgard Spectra Spot-On for Cats is not likely to have an unintended effect that is harmful to animals, plants or the environment if used according to the products label directions.

For veterinary medicinal products (VMPs), the APVMA has adopted VICH guidelines (VICH 2000) on data requirements for environmental safety (amongst other things). It is assumed that VMPs that satisfy the criteria of VICH phase 1 will have limited use and limited environmental exposure and consequently have limited environmental effects.

These Veterinary Medicinal Products will only be used in non-food animals. Hence, it satisfies the requirements of VICH phase 1. The APVMA is therefore satisfied that the 2 proposed products meet the environmental safety criteria.

The label will have the minimum required disposal statement in alignment with the Veterinary Labelling Code: Dispose of container by wrapping with paper and putting in garbage.

- v. Target Animal Safety (treated cats) was demonstrated in a series of controlled studies with single and repeated treatments with the new products, at the recommended dose and at the required  $3\times$  and  $5\times$  dose rates. Two studies at multiple dose rates, for 4 and 6 treatments, included a wide range of clinical and physical observations, plus haematology, clinical chemistry, urinalysis and gross- and histopathology assessments.

Additional studies included a similar range of observations (without necropsy and pathology) at the recommended dose (maximum for a weight range). The studies involved young cats on the edge of the recommended treatment age and weight (i.e., a minimum of 8 weeks and 0.8 kg) and lower, and therefore tested the effects in susceptible animals.

As well as the specific safety studies, health observations on a large number of cats in efficacy studies were not associated with significant side-effects or treatment reactions.

In addition, the safety of very high doses of the new active, esafoxolaner, was investigated in one study (as well as in toxicological assessment reports), with no adverse effects shown from a  $23\times$  overdose.

A single but detailed reproductive study with breeding female cats found no indication of significant differences between control animals and those treated monthly from mating to kitten weaning (at both the recommended and a  $3\times$  times dose rate). Observations included a range of reproductive indices and detail pathological and clinical examinations of the kittens. However, no reproductive studies with male cats were submitted.

Safety for use in heartworm-positive cats was demonstrated, at both the recommended and a  $3\times$  times dose rate. No adverse reactions were observed, consistent with the usual experience of avermectins (here, eprinomectin) in heartworm-positive felines.

The results of the target animal safety studies therefore, indicated that, at the proposed label dose rate of 1.44 mg/kg esafoxolaner, 0.5 mg/kg eprinomectin, and 10 mg/kg praziquantel, Nexgard Spectra Spot-On for Cats is unlikely to cause any serious adverse reactions in cats. Appropriate statements on contraindications, precautions and side effects have been included on the label.

- 2) The APVMA has evaluated the 2 applications 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 5B(2)(a), the APVMA is satisfied that data from trials supporting the efficacy of the products adequately demonstrate that if used according to the products label directions, the products Nexgard Spectra Spot-On for Cats, are effective for the proposed uses.

The Applicant based their submission on the contention that each of the 3 actives has activity against a specific parasite grouping, with no overlap in activity (i.e., esafoxolaner, ecto-parasites; eprinomectin, nematodes; praziquantel, cestodes), as confirmed by non-interference studies that were submitted. Several studies were submitted to support the efficacy of the products, including:



- A full set of studies for esafoxolaner (dose-determination, dose confirmation and field efficacy observations).
  - Dose confirmation and field efficacy observations only for eprinomectin and praziquantel, including data for the registration of the similar formulation “Broadline” (overseas-registered multi-active), with bridging studies to confirm the non-interference by the addition of esafoxolaner.
  - Data from dose-limiting species in lieu of new studies for minor species and species more susceptible to the actives.
  - Data from overseas studies covering a wide variety of countries and parasite strains of relevance to the Australian context.
  - Local studies for species specific to Australia or subject to environmental effects like the paralysis tick (*Ixodes holocyclus*) and cat flea (*Ctenocephalides felis*).
- ii. From an extensive series of dose confirmation studies, and field confirmatory studies in typical household situations, the APVMA has concluded that with monthly treatments, the data generated from the efficacy studies support the label claims. Efficacy against major parasite species – including the paralysis tick (*Ixodes holocyclus*); ear mite (*Otodectes cynotis*); roundworm (*Toxocara cati*); tapeworm (*Dipylidium caninum*), cat flea (*Ctenocephalides felis*); the hookworm (*Ancylostoma tubaeforme*); and heartworm (*Dirofilaria immitis*) – was supported. A smaller number of studies support the label claims for lesser species like the bush tick, (*Haemaphysalis longicornis*); the nematodes (*Toxascaris leonina*, *A.braziliense*, *A.ceylonicum*); the lesser tapeworm, (*Taenia taeniaformis*); and the cat lungworm, (*Aelurostrongyls abstrusus*). The studies also support the claims for larval stages where specified (*T.cati* and *A.tubaeforme*). Additional label statements will be added regarding the control of flea allergy dermatitis and the control of newly acquired paralysis ticks with additional vigilance in daily searching and removal of ticks being recommended.
- iii. The recommended minimum dose is 1.44 mg/kg esafoxolaner, 0.5 mg/kg eprinomectin, and 10 mg/kg praziquantel. The users are advised to select the appropriate applicator size for the weight of the cat as follows:

Cat weight	Treatment volume (mL)
0.8 to 2.4 kg	0.3 mL applicator
2.5 to 7.5 kg*	0.9 mL applicator

\*For cats over 7.5 kg, the applicant advises to use the appropriate combination of applicators.

Monthly application is recommended. For optimal performance, it is advised to treat the cat on or about the same day each month.

- 3) The APVMA has evaluated the 2 applications 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:
- i. The APVMA is satisfied that the proposed use of Nexgard Spectra Spot-On for Cats, would not adversely affect trade between Australia and places outside Australia as the products are intended for use in companion animals (cats) only which do not produce any major Australian export commodities.

Therefore, there are no concerns from a trade perspective relating to the registration of these products.

## 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 esafoxolaner 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.

In accordance with section 13 of the Agvet Code, the APVMA invites any person to submit a relevant written submission as to whether Nexgard Spectra Spot-On for Cats 0.8 – 2.4 kg and Nexgard Spectra Spot-On for Cats 2.5 – 7.5 kg 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.

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:

Post:

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

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

## **Privacy**

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

## Licensing of veterinary chemical manufacturers

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

For a comprehensive listing of all licensed manufacturers please see the APVMA website.

### New licences

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

**Table 10: 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
DHL Supply Chain (Australia) Pty	6071	071 798 617	16 Picrite Close Greystanes NSW 2145	Category 6 (single step manufacture) – all product dosage forms	Secondary packaging, secondary/supplementary labelling, storage, and release for supply.	7 December 2022
Global Medical Solutions Australia Pty Limited t/a Radpharm Scientific	1073	072 147 561	53–57 Oatley Court Belconnen ACT 2617	Category 1 (Immunobiologicals and sterile products) – Terminally sterilised products for injection (powder, solution and diluent).	Formulation including blending, filling, packaging, labelling, sterilisation (heat), microbiological reduction treatment (heat, and filtration), analysis and testing (physical, and chemical), storage and release for supply.	13 December 2022
Australian Life Sciences Pharma Pty Ltd	2250	604 520 532	Unit 2–3, 4 Endeavour Road Caringbah NSW 2229	Category 2 (Non-sterile veterinary preparations other than ectoparasiticides, premixes and supplements) – Pastes, powders, creams/lotions and ointments Category 4 (Premixes and supplements) – premixes – powders, supplements – powders	Quality assurance (QA) of raw materials, formulation including blending, filling, packaging, labelling, analysis and testing (chemical, physical), storage, and release for supply.	4 January 2023
Complementary Medicines Group Pty Limited	6246	146 924 343	5A/5B Jubilee Avenue Warriewood NSW 2102	Category 6 (Single-step manufacture) – non-sterile all dosage forms	Packaging, secondary packaging, labelling, secondary/supplementary labelling, repackaging and relabelling, storage and release for supply.	12 January 2023

## Licence cancellations

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

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

Company name	Licence number	Company ACN	Address	Date cancelled
Pia Pharma Pty Ltd	6242	150 999 974	Unit 3, 46 Buffalo Rd Gladesville NSW 2111	10 January 2023

## 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 Australian Pesticides and Veterinary Medicines Authority (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. 1) 2023.

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 26 of APVMA Gazette No. 2, 24 January 2023, 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 2023 (No. 1)) 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

24 January 2023

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

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#### **Agvet chemical: Acetamiprid**

*Permitted residue – commodities of plant origin: Acetamiprid*

*Permitted residue – commodities of animal origin: Sum of acetamiprid and N-demethyl acetamiprid ((E)-N<sup>1</sup>-[(6-chloro-3-pyridyl)methyl]-N<sup>2</sup>-cyanoacetamidine), expressed as acetamiprid*

Cherries	2
Citrus fruits [except kumquats]	1
Plums (including prunes)	0.5
Stone fruits [except cherries; jujube, Chinese; plums]	1

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#### **Agvet chemical: Bifenthrin**

*Permitted residue: Bifenthrin*

Citrus fruits [except kumquats]	*0.05
Field pea (dry)	T*0.01
Lupin (dry)	T*0.02
Pulses [except field pea (dry); lupin (dry)]	*0.02

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#### **Agvet chemical: Fluopyram**

*Permitted residue – commodities of plant origin: Fluopyram*

*Permitted residue – commodities of animal origin: Sum of fluopyram and 2-(trifluoromethyl)-benzamide, expressed as fluopyram*

Citrus fruits [except kumquats]	1
Stone fruits [except cherries; jujube, Chinese]	2
Tomato	0.9

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#### **Agvet chemical: Methoxyfenozide**

*Permitted residue: Methoxyfenozide*

Citrus fruits [except kumquats]	3
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**Agvet chemical: Procymidone***Permitted residue: Procymidone*

Stone fruits [except jujube, Chinese]	T10
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**Agvet chemical: Spinetoram***Permitted residue: Sum of Ethyl-spinosyn-J and Ethyl-spinosyn-L*

Pome fruits [except Persimmon, Japanese]	0.1
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**Agvet chemical: Sulfoxaflor***Permitted residue: Sulfoxaflor*

Avocado	0.3
Citrus fruits [except kumquats]	0.7
Cherimoya	T0.5
Cereal grains [except rice; rice husked; rice, polished, sorghum]	*0.01
Custard apple	T0.5
Ilama	T0.5
Litchi	T3
Longans	T3
Mango	T0.7
Papaya	T0.7
Passionfruit	T1
Persimmon, Japanese	T1
Pome fruits [except Persimmon, Japanese]	0.5
Soursop	T0.5
Stone fruits [except cherries; jujube, Chinese]	1
Sugar apple	T0.5

**Agvet chemical: Trifloxystrobin***Permitted residue: Sum of trifloxystrobin and its acid metabolite ((E,E)-methoxyimino-[2-[1-(3-trifluoromethylphenyl)-ethylideneaminoxymethyl]phenyl] acetic acid), expressed as trifloxystrobin equivalents*

Stone fruits [except jujube, Chinese]	5
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[1.2] inserting for each of the following chemicals the foods and associated MRLs in alphabetical order

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**Agvet chemical: Acetamiprid**

*Permitted residue – commodities of plant origin: Acetamiprid*

*Permitted residue – commodities of animal origin: Sum of acetamiprid and N-demethyl acetamiprid (€-N<sup>1</sup>-[(6-chloro-3-pyridyl)methyl]-N<sup>2</sup>-cyanoacetamide), expressed as acetamiprid*

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Cherries (subgroup)	2
Citrus fruits	1
Peaches (subgroup)	1
Plums (subgroup)	0.5

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**Agvet chemical: Bifenthrin**

*Permitted residue: Bifenthrin*

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Citrus fruits	*0.05
Common bean (dry) (navy bean)	0.2
Mung bean (dry)	T0.2
Pulses [except common bean (dry); mung bean (dry)]	*0.02

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**Agvet chemical: Cyfluthrin**

*Permitted residue: Cyfluthrin, sum of isomers*

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Pomegranate	T0.1
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**Agvet chemical: Dithiocarbamates**

*Permitted residue: Total dithiocarbamates, determined as carbon disulphide evolved during acid digestion and expressed as milligrams of carbon disulphide per kilogram of food*

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Pomegranate	T5
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**Agvet chemical: Flazasulfuron**

*Permitted residue: Flazasulfuron*

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Citrus fruits	*0.01
Edible offal (mammalian)	*0.01
Eggs	*0.01
Grapes	*0.01
Meat (mammalian)	*0.01
Milks	*0.01
Olives for oil production	*0.01
Poultry meat	*0.01
Poultry, edible offal of	*0.01
Table olives	*0.01

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**Agvet chemical: Fluopyram***Permitted residue – commodities of plant origin: Fluopyram**Permitted residue – commodities of animal origin: Sum of fluopyram and 2-(trifluoromethyl)-benzamide, expressed as fluopyram*

Citrus fruits	1
Stone fruits [except cherries]	2
Persimmon, Japanese	1.5
Root and tuber vegetables	T0.2
Tomatoes (subgroup)	T1.5

**Agvet chemical: Methoxyfenozide***Permitted residue: Methoxyfenozide*

Chick-pea (dry)	2
Citrus fruits	3
Eggs	*0.01
Maize	*0.02
Mung bean (dry)	0.5
Poultry, edible offal of	*0.01
Poultry meat (in the fat)	*0.01
Soya bean (dry)	0.9

**Agvet chemical: Procymidone***Permitted residue: Procymidone*

Cherries	7
Stone fruits [except cherries]	2

**Agvet chemical: Spinetoram***Permitted residue: Sum of Ethyl-spinosyn-J and Ethyl-spinosyn-L*

Pome fruits	0.1
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**Agvet chemical: Sulfoxaflor***Permitted residue: Sulfoxaflor*

Assorted tropical and sub-tropical fruits – inedible peel [except banana and pineapple]	0.5
Barley, similar grains, and pseudocereals with husks [except oats]	0.2
Carob	5
Citrus fruits	0.7
Herbs	20
Mustard seeds	T0.15

**Agvet chemical: Sulfoxaflor**

Oats	*0.01
Pome fruits	0.5
Sorghum grain and millet	0.15
Stone fruits [except cherries]	1
Wheat, similar grains, and pseudocereals without husks	0.05

**Agvet chemical: Trifloxystrobin**

*Permitted residue: Sum of trifloxystrobin and its acid metabolite ((E,E)-methoxyimino-[2-[1-(3-trifluoromethylphenyl)-ethylideneaminoxyethyl]phenyl] acetic acid), expressed as trifloxystrobin equivalents*

Persimmon, Japanese	1.5
Stone fruits	5

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

**Agvet chemical: Acetamiprid**

*Permitted residue – commodities of plant origin: Acetamiprid*

*Permitted residue – commodities of animal origin: Sum of acetamiprid and N-demethyl acetamiprid ((E)-N1-[(6-chloro-3-pyridyl)methyl]-N2-cyanoacetamide), expressed as acetamiprid*

Cotton seed	0.2
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**Agvet chemical: Methoxyfenozide**

*Permitted residue: Methoxyfenozide*

Cotton seed	2
Edible offal (mammalian)	0.05
Meat (mammalian) (in the fat)	0.1

**Agvet chemical: Procymidone**

*Permitted residue: Procymidone*

Edible offal (mammalian)	0.05
Eggs	*0.01
Garlic	5
Lupin (dry)	*0.01
Meat (mammalian) (in the fat)	0.2
Milks	0.02
Onion, bulb	0.2
Potato	0.2
Poultry meat (in the fat)	*0.01
Poultry, edible offal of	*0.01

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**Agvet chemical: Procymidone**

Rape seed (canola)	0.5
Rape seed (canola) oil, crude	2
Wine grapes	5

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**Agvet chemical: Spinetoram**

*Permitted residue: Sum of Ethyl-spinosyn-J and Ethyl-spinosyn-L*

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Maize cereals	*0.01
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**Agvet chemical: Sulfoxaflor**

*Permitted residue: Sulfoxaflor*

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Cane berries	1.5
Edible offal (mammalian)	2
Meat (mammalian)	0.7
Pineapple	0.2
Poultry, edible offal of	0.02
Rape seed (canola)	0.15
Strawberry	0.7

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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 21 February 2023. 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:

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GPO Box 3262  
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