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Gazette

Agricultural and veterinary chemicals

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

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Assistant Director, Communications
Australian Pesticides and Veterinary Medicines Authority
GPO Box 3262
Sydney NSW 2001

Email: communications@apvma.gov.au

Website: apvma.gov.au

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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APVMA contacts

For enquiries regarding the publishing and distribution of the APVMA Gazette: Telephone: +61 2 6770 2300.

For enquiries on APVMA Gazette content, please refer to the individual APVMA contacts listed under each notice.

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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 new active constituents

Application no.	131879
Product name	MIGIWA Fungicide
Active constituent	218 g/L ipflufenoquin
Applicant name	AgNova Technologies Pty Ltd
Applicant ACN	097 705 158
Date of registration	10 March 2023
Product registration no.	91333
Label approval no.	91333/131879
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 218 g/L ipflufenoquin suspension concentrate product for the control of grey mould in strawberries in conjunction with the approval of ipflufenoquin

Table 2: Agricultural products based on existing active constituents

Application no.	137910
Product name	AC Axis 500 SC Herbicide
Active constituent	500 g/L atrazine
Applicant name	Axichem Pty Ltd
Applicant ACN	131 628 594
Date of registration	27 February 2023
Product registration no.	93082
Label approval no.	93082/137910
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 500 g/L suspension concentrate formulation of atrazine – a pre-emergent and post-emergent herbicide for control of selected weeds in crops, Pinus radiata plantations and TT-Canola

Application no.	135516
Product name	ADAMA Indox Clear Ant and Cockroach Gel
Active constituents	0.67 g/kg indoxacarb (75:25) (equivalent to 0.5 g/kg active s-isomer) or 0.56 g/kg indoxacarb (90:10) (equivalent to 0.5 g/kg active s-isomer)
Applicant name	ADAMA Australia Pty Ltd
Applicant ACN	050 328 973
Date of registration	28 February 2023
Product registration no.	92439
Label approval no.	92439/135516
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 0.5 g/kg s-indoxacarb gel product for control of ants and cockroaches

Application no.	136009
Product name	Farmalinx Roxstar 250 WG Herbicide
Active constituent	250 g/kg butroxydim
Applicant name	Farmalinx Pty Ltd
Applicant ACN	134 353 245
Date of registration	28 February 2023
Product registration no.	92611
Label approval no.	92611/136009
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 250 g/kg water dispersible granule product for the control of certain grasses in a range of broadacre crops

Application no.	133517
Product name	FEND Insect Repellent
Active constituent	200 g/L ethyl butylacetylaminopropionate
Applicant name	Fend Australia Pty Ltd
Applicant ACN	648 209 018
Date of registration	3 March 2023
Product registration no.	91808
Label approval no.	91808/133517
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 200 g/L ethyl butylacetylaminopropionate lotion for use in repelling mosquitoes

Application no.	135712
Product name	Titan Glyphosate 550 Twin Salt SL Herbicide
Active constituent	550 g/L glyphosate (present as the potassium and monoethanolamine salts)
Applicant name	Titan Ag Pty Ltd
Applicant ACN	122 081 574
Date of registration	7 March 2023
Product registration no.	92493
Label approval no.	92493/135712
Description of the application and its purpose, including the intended use of the chemical product	Registration of a new soluble concentrate product containing 550 g/L glyphosate (present as the potassium/monoethanolamine salt) for use as a non-selective herbicide for the control of many annual and perennial weeds

Application no.	124956
Product name	EQUENTO Insecticide Seed Treatment
Active constituent	100 g/L isocycloseram
Applicant name	Syngenta Australia Pty Ltd
Applicant ACN	002 933 717
Date of registration	7 March 2023
Product registration no.	89461
Label approval no.	89461/124956
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 100 g/L isocycloseram flowable suspension concentrate for seed treatment product for treatment of canola seed for early plant protection against redlegged earth mite

Application no.	135931
Product name	Apoint Herbicide
Active constituents	100 g/L pinoxaden, 25 g/L cloquintocet-mexyl
Applicant name	Grow Choice Pty Ltd
Applicant ACN	161 264 884
Date of registration	8 March 2023
Product registration no.	92577
Label approval no.	92577/135931
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 100 g/L pinoxaden and 25 g/L cloquintocet-mexyl emulsifiable concentrate formulation for the control of key grass weeds and selective spray topping of wild oats in wheat and barley

Application no.	135989
Product name	Genfarm Pyraclostrobin 250 EC Fungicide
Active constituent	250 g/L pyraclostrobin
Applicant name	Nutrien Ag Solutions Limited
Applicant ACN	008 743 217
Date of registration	8 March 2023
Product registration no.	92600
Label approval no.	92600/135989
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 250 g/L emulsifiable concentrate pyraclostrobin formulation, for the control of leaf speckle and leaf spot in bananas and downy and powdery mildew in grapevines, husk spot in macadamia and rust in almond

Application no.	137423
Product name	Valor Eze 480 SC Herbicide
Active constituent	480 g/L flumioxazin
Applicant name	Sumitomo Chemical Australia Pty Ltd
Applicant ACN	081 096 255
Date of registration	9 March 2023
Product registration no.	92955
Label approval no.	92955/137423
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 480 g/L flumioxaizn suspension concentrate product for knockdown and residual control of broadleaf weeds and grasses in broadacre crops, fallow and in non-crop situations

Application no.	137943
Product name	Yates Weed 'N' Feed Weed Killer and Lawn Fertiliser Hose On
Active constituents	15 g/L MCPA, as the dimethylamine salt, 2.3 g/L dicamba, as the dimethylamine salt
Applicant name	DuluxGroup (Australia) Pty Ltd
Applicant ACN	000 049 427
Date of registration	10 March 2023
Product registration no.	93094
Label approval no.	93094/137943
Description of the application and its purpose, including the intended use of the chemical product	Registration of a product containing 15 g/L MCPA present as the dimethylamine salt and 2.3 g/L dicamba present as the dimethylamine salt, for use in lawns for broadleaf weed control

Table 3: Variations of registration – agricultural chemical products

Application no.	137594
Product name	Runge Agrichems Manfil Mancozeb 750 WG Agricultural Fungicide
Active constituent	750 g/kg mancozeb
Applicant name	Runge Agrichems Pty Ltd
Applicant ACN	108 094 266
Date of variation	27 February 2023
Product registration no.	59516
Label approval no.	59516/137594
Description of the application and its purpose, including the intended use of the chemical product	Variation to registration particulars, particulars of label approval, conditions of registration, to amend the expiry date to 3 years after date of manufacture, to add pack sizes and to update the rate per hectare in bananas

Application no.	133987
Product name	Mirage Fungicide
Active constituent	450 g/L prochloraz
Applicant name	ADAMA Australia Pty Ltd
Applicant ACN	050 328 973
Date of variation	27 February 2023
Product registration no.	59676
Label approval no.	59676/133987
Description of the application and its purpose, including the intended use of the chemical product	Variation of product registration and label approval to vary the product name and various label updates in accordance with the current Agricultural Labelling Code

Application no.	138725
Product name	Titan Top Wettable Sulphur Fungicide and Miticide
Active constituent	800 g/kg sulphur (S)
Applicant name	Titan Ag Pty Ltd
Applicant ACN	122 081 574
Date of variation	1 March 2023
Product registration no.	48056
Label approval no.	48056/138725
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 'Top Wettable Sulphur Fungicide and Miticide' to 'Titan Top Wettable Sulphur Fungicide and Miticide'. Also update the first aid instructions to align with the current FAISD Handbook

Application no.	134832
Product name	Serifel Biofungicide
Active constituent	110 g/kg (>5.5 × 10 ¹⁰ cfu/g) bacillus amyloliquefaciens strain mbi600
Applicant name	BASF Australia Ltd
Applicant ACN	008 437 867
Date of variation	2 March 2023
Product registration no.	82600
Label approval no.	82600/134832
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 berries, and to extend the currently approved use in strawberry for both field and protected situations

Application no.	137913
Product name	Spray.Seed 250 Herbicide
Active constituents	135 g/L paraquat present as paraquat dichloride, 115 g/L diquat present as diquat dibromide monohydrate
Applicant name	Syngenta Australia Pty Ltd
Applicant ACN	002 933 717
Date of variation	2 March 2023
Product registration no.	46516
Label approval no.	46516/137913
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 hazelnuts, pistachios and walnuts

Application no.	134505
Product name	Titan Epoxiconazole 500 SC Fungicide
Active constituent	500 g/L epoxiconazole
Applicant name	Titan Ag Pty Ltd
Applicant ACN	122 081 574
Date of variation	3 March 2023
Product registration no.	90313
Label approval no.	90313/134505
Description of the application and its purpose, including the intended use of the chemical product	Variation of product registration and label approval to add claims for mixture with Titan Azoxystrobin 250 SC Fungicide to registration details

Application no.	136270
Product name	Surefire Chlorantraniliprole 350 WG Insecticide
Active constituent	350 g/kg chlorantraniliprole
Applicant name	PCT Holdings Pty Ltd
Applicant ACN	099 023 962
Date of variation	3 March 2023
Product registration no.	88598
Label approval no.	88598/136270
Description of the application and its purpose, including the intended use of the chemical product	Variation to registration particulars, particulars of label, to add uses for control of insect pests in turf

Application no.	135701
Product name	Genfarm Simazine 500 Flowable Herbicide
Active constituent	500 g/L simazine
Applicant name	Nutrien Ag Solutions Limited
Applicant ACN	008 743 217
Date of variation	3 March 2023
Product registration no.	91675
Label approval no.	91675/135701
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 update safety directions and restraints

Application no.	136526
Product name	Nufarm Thistrol Gold Herbicide
Active constituents	300 g/L MCPB (present as the dimethylamine salt), 20 g/L MCPA (present as the dimethylamine salt), 10 g/L flumetsulam
Applicant name	Nufarm Australia Limited
Applicant ACN	004 377 780
Date of variation	3 March 2023
Product registration no.	87300
Label approval no.	87300/136526
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 an additional weed, fireweed

Application no.	137965
Product name	Raid MAX Outdoor Home Barrier & Spider Killer Surface Spray
Active constituents	1 g/kg imiprothrin, 0.5 g/kg deltamethrin
Applicant name	S.C. Johnson & Son Pty Ltd
Applicant ACN	000 021 009
Date of variation	3 March 2023
Product registration no.	68421
Label approval no.	68421/137965
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 'RAID OUTDOOR & SPIDER SURFACE SPRAY' to 'Raid MAX Outdoor Home Barrier & Spider Killer Surface Spray'

Application no.	138207
Product name	Nufarm Amishield Fungicide
Active constituent	500 g/kg amisulbrom
Applicant name	Nufarm Australia Limited
Applicant ACN	004 377 780
Date of variation	7 March 2023
Product registration no.	88958
Label approval no.	88958/138207
Description of the application and its purpose, including the intended use of the chemical product	Variation of product registration and label approval to add additional uses in brassica vegetables (excluding brassica leafy vegetables)

Application no.	138015
Product name	Hydrocop WG Fungicide/Bactericide
Active constituent	500 g/kg copper (Cu) present as cupric hydroxide
Applicant name	Grochem Australia Pty Ltd
Applicant ACN	169 400 033
Date of variation	8 March 2023
Product registration no.	62910
Label approval no.	62910/138015
Description of the application and its purpose, including the intended use of the chemical product	Variation to registration and label particulars to add use in olives

Application no.	137338
Product name	Macspred Trimac GR Granular Herbicide
Active constituents	44 g/kg terbacil, 2 g/kg sulfometuron-methyl
Applicant name	Macspred Pty. Ltd
Applicant ACN	011 029 495
Date of variation	9 March 2023
Product registration no.	81670
Label approval no.	81670/137338
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 new uses in eucalypts

Application no.	138799
Product name	Nufarm Axe Insecticide
Active constituent	500 g/L permethrin (40:60::cis:trans)
Applicant name	Nufarm Australia Limited
Applicant ACN	004 377 780
Date of variation	9 March 2023
Product registration no.	54245
Label approval no.	54245/138799
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 Permethrin 500 Insecticide' to 'Nufarm Axe Insecticide'

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 4: Veterinary products based on existing active constituents

Application no.	137775
Product name	Vetmec LA Long Acting Antiparasitic Injection for Cattle
Active constituent	100 mg/mL moxidectin
Applicant name	Chemvet Australia Pty Ltd
Applicant ACN	138 711 289
Date of registration	28 February 2023
Product registration no.	93047
Label approval no.	93047/137775
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 100 mg/mL moxidectin sterile injectable product for the treatment of internal and external parasites in cattle

Application no.	134364
Product name	Mate Oral Progestagen for Horses
Active constituent	2.2 mg/mL altrenogest
Applicant name	Aurora Pharmaceutical, Inc
Applicant ACN	N/A
Date of registration	8 March 2023
Product registration no.	92068
Label approval no.	92068/134364
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 2.2 mg/mL altrenogest oral solution product for the regulation and control of the breeding cycle of mares and the maintenance of pregnancy in habitually aborting mares or mares at risk of early abortion

Application no.	135906
Product name	Faxone Anaesthetic Injection for Dogs and Cats
Active constituent	10 mg/mL alfaxalone
Applicant name	Vetpharm Laboratories IP Pty Ltd
Applicant ACN	654 406 756
Date of registration	8 March 2023
Product registration no.	92563
Label approval no.	92563/135906
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 10 mg/mL alfaxalone injectable steroid anaesthetic product for injectable steroid anaesthetic for use as an induction agent prior to gaseous anaesthesia for the performance of examination or surgical procedures in dogs and cats

Application no.	134480
Product name	Dermcare Malaseb Lite Medicated Shampoo
Active constituents	20 g/L chlorhexidine gluconate, 20 g/L miconazole nitrate
Applicant name	Dermcare-Vet Pty Ltd
Applicant CAN	010 280 010
Date of registration	9 March 2023
Product registration no.	92090
Label approval no.	92090/134480
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 20 g/L chlorhexidine gluconate, 20 g/L miconazole nitrate topical solution/suspension medicated shampoo product for treatment and control of seborrheic dermatitis in dogs and cats; and aiding in the treatment of dermatophyte (ringworm) infections in dogs and cats

Table 5: Variations of registration – veterinary chemical products

Application no.	138657
Product name	Benakor Oral Solution
Active constituent	5 mg/mL benazepril hydrochloride
Applicant name	Dechra Veterinary Products (Australia) Pty Ltd
Applicant ACN	614 716 700
Date of variation	21 February 2023
Product registration no.	80867
Label approval no.	80867/138657
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 'Apex Benazepril Oral Solution' to 'Benakor Oral Solution'

Application no.	138658
Product name	Troy Doramate Injectable Endectocide
Active constituent	10 mg/mL doramectin
Applicant name	Troy Laboratories Pty Ltd
Applicant ACN	000 283 769
Date of variation	22 February 2023
Product registration no.	86367
Label approval no.	86367/138658
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 'Doramate Injectable Endectocide' to 'Troy Doramate Injectable Endectocide'

Application no.	138660
Product name	Metacoxx Oral Solution for Cats
Active constituent	5 mg/mL meloxicam
Applicant name	Dechra Veterinary Products (Australia) Pty Ltd
Applicant ACN	614 716 700
Date of variation	22 February 2023
Product registration no.	83287
Label approval no.	83287/138660
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 'Apex Meloxicam Oral Suspension for Cats' to 'Metacoxx Oral Solution for Cats'

Application no.	138661
Product name	Abastar Plus Selenium LV Oral Drench for Sheep
Active constituents	2.0 g/L abamectin, 1.0 g/L selenium as sodium selenate
Applicant name	The Hunter River Company Pty Ltd
Applicant ACN	133 798 615
Date of variation	23 February 2023
Product registration no.	87028
Label approval no.	87028/138661
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 'Independents Own Abastar plus Selenium LV Oral Drench for Sheep' to 'Abastar Plus Selenium LV Oral Drench for Sheep', and a variation to safety directions and first aid instructions appearing on a label to reflect the current FAISD Handbook

Application no.	138663
Product name	Abastar Plus Selenium HV Oral Drench for Sheep
Active constituents	0.8 g/L abamectin, 0.4 g/L selenium as sodium selenate
Applicant name	The Hunter River Company Pty Ltd
Applicant ACN	133 798 615
Date of variation	23 February 2023
Product registration no.	84096
Label approval no.	84096/138663
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 'Independents Own Abastar plus Selenium High Volume Oral Drench for Sheep' to 'Abastar Plus Selenium HV Oral Drench for Sheep', and a variation to safety directions and first aid instructions appearing on a label to reflect the current FAISD Handbook

Application no.	134447
Product name	Exzolt Fluralaner Oral Solution for Chickens
Active constituent	10 g/L fluralaner
Applicant name	Intervet Australia Pty Ltd
Applicant ACN	008 467 034
Date of variation	27 February 2023
Product registration no.	85688
Label approval no.	85688/134447
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 a new pack size (50 mL) and an animal welfare claim

Application no.	137822
Product name	Tracerite Selenium Pellets for Cattle
Active constituent	100 g/kg elemental selenium (each 30 g pellet contains 3 g selenium)
Applicant name	Barten Investments Trust & The Voltar Trust
Applicant CAN	23 085 887 123
Date of variation	27 February 2023
Product registration no.	89438
Label approval no.	89438/137822
Description of the application and its purpose, including the intended use of the chemical product	Variation of relevant particulars of the registered chemical product and label approval by adding new pack sizes (26 pellets, 50 pellets)

Application no.	137059
Product name	Ilium Meloxicam 20 Anti-Inflammatory Injection for Cattle, Sheep, Pigs and Horses
Active constituent	20 mg/mL meloxicam
Applicant name	Troy Laboratories Pty Ltd
Applicant CAN	000 283 769
Date of variation	28 February 2023
Product registration no.	62535
Label approval no.	62535/137059
Description of the application and its purpose, including the intended use of the chemical product	Variation of the relevant particulars of the product registration and label approval to add a new pack size and to align the label with the Veterinary Labelling Code

Application no.	137823
Product name	Tracerite Cobalt Pellets for Cattle
Active constituent	300 g/kg cobalt oxide (each 30 g pellet contains 9 g cobalt oxide)
Applicant name	Barten Investments Trust & The Voltar Trust
Applicant ACN	23 085 887 123
Date of variation	28 February 2023
Product registration no.	89302
Label approval no.	89302/137823
Description of the application and its purpose, including the intended use of the chemical product	Variation of relevant particulars of the registered chemical product and label approval by adding new pack sizes (25 pellets, 50 pellets)

Application no.	137845
Product name	Interseal Teat Sealant for Dry Cows
Active constituent	650 mg/g bismuth subnitrate
Applicant name	Elanco Australasia Pty Ltd
Applicant ACN	076 745 198
Date of variation	28 February 2023
Product registration no.	90789
Label approval no.	90789/137845
Description of the application and its purpose, including the intended use of the chemical product	Variation of relevant particulars of product registration and label approval by adding a new pack size, amending the product name, and aligning the label to the Veterinary Labelling Code

Application no.	137926
Product name	Equimax Oral Paste for Horses
Active constituents	50 mg/mL praziquantel, 4 mg/mL abamectin
Applicant name	Virbac (Australia) Pty Ltd
Applicant ACN	003 268 871
Date of variation	28 February 2023
Product registration no.	47955
Label approval no.	47955/137926
Description of the application and its purpose, including the intended use of the chemical product	Variation of relevant particulars of product registration and label approval by changing the instructions of use on the label

Application no.	137929
Product name	Equimax Elevation Oral Broad Spectrum Wormer and Boticide Paste for Horses
Active constituents	Each 23.1 mL syringe contains: 9.0 g pyrantel embonate, 1.0 g praziquantel, 0.14 g ivermectin
Applicant name	Virbac (Australia) Pty Ltd
Applicant ACN	003 268 871
Date of variation	28 February 2023
Product registration no.	63478
Label approval no.	63478/137929
Description of the application and its purpose, including the intended use of the chemical product	Variation of relevant particulars of product registration and label approval by changing the instructions of use on the label

Application no.	137933
Product name	Strategy-T Oral Broad Spectrum Worm Paste for Horses
Active constituents	Each 35 mL syringe contains: 9.1 g pyrantel embonate, 7.0 g oxfendazole
Applicant name	Virbac (Australia) Pty Ltd
Applicant CAN	003 268 871
Date of variation	28 February 2023
Product registration no.	61370
Label approval no.	61370/137933
Description of the application and its purpose, including the intended use of the chemical product	Variation of relevant particulars of product registration and label approval by changing the instructions of use on the label

Application no.	136621
Product name	NexGard Spectra Chewables for Dogs 30.1 – 60 kg
Active constituents	150 mg/chew afoxolaner, 30 mg/chew milbemycin oxime
Applicant name	Boehringer Ingelheim Animal Health Australia Pty Ltd
Applicant ACN	071 187 285
Date of variation	8 March 2023
Product registration no.	81055
Label approval no.	81055/136621
Description of the application and its purpose, including the intended use of the chemical product	Variation to the particulars of a registered chemical product and label approval by updating label instructions

Application no.	136624
Product name	NexGard Spectra Chewables for Dogs 15.1 – 30 kg
Active constituents	75 mg/chew afoxolaner, 15 mg/chew milbemycin oxime
Applicant name	Boehringer Ingelheim Animal Health Australia Pty Ltd
Applicant ACN	071 187 285
Date of variation	8 March 2023
Product registration no.	81012
Label approval no.	81012/136624
Description of the application and its purpose, including the intended use of the chemical product	Variation to the particulars of a registered chemical product and label approval by updating label instructions

Application no.	136625
Product name	NexGard Spectra Chewables for Dogs 7.6 – 15 kg
Active constituents	37.5 mg/chew afoxolaner, 7.5 mg/chew milbemycin oxime
Applicant name	Boehringer Ingelheim Animal Health Australia Pty Ltd
Applicant ACN	071 187 285
Date of variation	8 March 2023
Product registration no.	81011
Label approval no.	81011/136625
Description of the application and its purpose, including the intended use of the chemical product	Variation to the particulars of a registered chemical product and label approval by updating label instructions

Application no.	136626
Product name	NexGard Spectra Chewables for Dogs 3.6 – 7.5 kg
Active constituents	18.8 mg/chew afoxolaner, 3.8 mg/chew milbemycin oxime
Applicant name	Boehringer Ingelheim Animal Health Australia Pty Ltd
Applicant CAN	071 187 285
Date of variation	8 March 2023
Product registration no.	81010
Label approval no.	81010/136626
Description of the application and its purpose, including the intended use of the chemical product	Variation to the particulars of a registered chemical product and label approval by updating label instructions

Application no.	136627
Product name	NexGard Spectra Chewables for Dogs 2 – 3.5 kg
Active constituents	9.4 mg/chew afoxolaner, 1.9 mg/chew milbemycin oxime
Applicant name	Boehringer Ingelheim Animal Health Australia Pty Ltd
Applicant ACN	071 187 285
Date of variation	8 March 2023
Product registration no.	81008
Label approval no.	81008/136627
Description of the application and its purpose, including the intended use of the chemical product	Variation to the particulars of a registered chemical product and label approval by updating label instructions

Application no.	136669
Product name	NexGard Chewables for Dogs 25.1 – 50 kg
Active constituent	136 mg/chew afoxolaner
Applicant name	Boehringer Ingelheim Animal Health Australia Pty Ltd
Applicant ACN	071 187 285
Date of variation	9 March 2023
Product registration no.	67939
Label approval no.	67939/136669
Description of the application and its purpose, including the intended use of the chemical product	Variation to the particulars of a registered chemical product and label approval by updating label instructions

Application no.	136674
Product name	NexGard Chewables for Dogs 10.1 – 25 kg
Active constituent	68 mg/chew afoxolaner
Applicant name	Boehringer Ingelheim Animal Health Australia Pty Ltd
Applicant ACN	071 187 285
Date of variation	9 March 2023
Product registration no.	67940
Label approval no.	67940/136674
Description of the application and its purpose, including the intended use of the chemical product	Variation to the particulars of a registered chemical product and label approval by updating label instructions

Application no.	136675
Product name	NexGard Chewables for Dogs 4.1 – 10 kg
Active constituent	28.3 mg/chew afoxolaner
Applicant name	Boehringer Ingelheim Animal Health Australia Pty Ltd
Applicant ACN	071 187 285
Date of variation	9 March 2023
Product registration no.	67941
Label approval no.	67941/136675
Description of the application and its purpose, including the intended use of the chemical product	Variation to the particulars of a registered chemical product and label approval by updating label instructions

Application no.	136677
Product name	NexGard Chewables for Dogs 2 – 4 kg
Active constituent	11.3 mg/chew afoxolaner
Applicant name	Boehringer Ingelheim Animal Health Australia Pty Ltd
Applicant ACN	071 187 285
Date of variation	9 March 2023
Product registration no.	67942
Label approval no.	67942/136677
Description of the application and its purpose, including the intended use of the chemical product	Variation to the particulars of a registered chemical product and label approval by updating label instructions

Approved active constituents

Pursuant to the Agricultural and Veterinary Chemicals Code scheduled to the *Agricultural and Veterinary Chemicals Code Act 1994*, the APVMA hereby gives notice that it has approved or varied the relevant particulars or conditions of the approval of the following active constituents, with effect from the dates shown.

Table 6: Active constituent

Application no.	135809
Active constituent	Diazinon
Applicant name	Sanonda (Australia) Pty Ltd
Applicant ACN	059 813 973
Date of approval	27 February 2023
Approval no.	92520
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent diazinon for use in agricultural chemical products

Application no.	135977
Active constituent	Pyroxasulfone
Applicant name	Anhui Jiuyi Agriculture Co Ltd
Applicant ACN	N/A
Date of approval	28 February 2023
Approval no.	92591
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent pyroxasulfone for use in agricultural chemical products

Application no.	136602
Active constituent	Oxyfluorfen
Applicant name	Yifan Biotechnology Group Co Ltd
Applicant ACN	N/A
Date of approval	28 February 2023
Approval no.	92769
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent oxyfluorfen for use in agricultural chemical products

Application no.	136667
Active constituent	Triclabendazole
Applicant name	Virbac (Australia) Pty Ltd
Applicant ACN	003 268 871
Date of approval	3 March 2023
Approval no.	92790
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent triclabendazole for use in veterinary chemical products

Application no.	136328
Active constituent	Alfaxalone
Applicant name	Vetpharm Laboratories IP Pty Ltd
Applicant ACN	654 406 756
Date of approval	8 March 2023
Approval no.	92685
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent alfaxalone for use in veterinary chemical products

Application no.	136385
Active constituent	Esomeprazole magnesium enteric coated pellets
Applicant name	Abbey Laboratories Pty Ltd
Applicant ACN	156 000 430
Date of approval	8 March 2023
Approval no.	92709
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent esomeprazole magnesium enteric coated pellets for use in veterinary chemical products

Table 7: Variations of active constituent

Application no.	136284
Active constituent	Carprofen
Applicant name	Avet Health Limited
Applicant ACN	616 838 101
Date of variation	27 February 2023
Approval no.	91643
Description of the application and its purpose, including the intended use of the active constituent	Variation of relevant particulars or conditions of an approved active constituent

Application no.	136354
Active constituent	L-lysine hydrochloride
Applicant name	Jurox Pty Ltd
Applicant ACN	000 932 230
Date of variation	2 March 2023
Approval no.	85239
Description of the application and its purpose, including the intended use of the active constituent	Variation of relevant particulars or conditions of an approved active constituent

Application no.	136509
Active constituent	Cloxacillin benzathine
Applicant name	Zoetis Australia Pty Ltd
Applicant ACN	156 476 425
Date of variation	2 March 2023
Approval no.	84146
Description of the application and its purpose, including the intended use of the active constituent	Variation of relevant particulars or conditions of an approved active constituent

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. 2) 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

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

In the previous notice on page 22 of APVMA Gazette No. 6, 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. 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

21 March 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 sunsetting.

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

Agvet chemical: Indaziflam

Permitted residue – commodities of plant origin: Sum of indaziflam and 6-[(1R)-1-fluoroethyl]-1,3,5-triazine-2,4-diamine, expressed as indaziflam

Permitted residue – commodities of animal origin: Indaziflam

Almonds	*0.01
Citrus fruits	*0.01
Edible offal (mammalian)	0.1
Grapes	*0.01
Meat (mammalian) [in the fat]	0.03
Milks	*0.005

Agvet chemical: Inpyrfluxam

Permitted residue – commodities of plant origin: Inpyrfluxam

Permitted residue – commodities of animal origin: Sum of inpyrfluxam and 1'-CH2OH-S-2840 (free or conjugated), expressed as inpyrfluxam.

Banana	0.7
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	0.05

Agvet chemical: Ipflufenoquin	
Permitted residue: Ipflufenoquin	
Edible offal (mammalian)	*0.01
Eggs	*0.01
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: Ipflufenoquin	
Strawberry	0.3

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

Agvet chemical: Fipronil

Permitted residue: Sum of fipronil, the sulphenyl metabolite (5-amino-1-[2,6-dichloro-4- (trifluoromethyl)phenyl]-4-[(trifluoromethyl) sulphenyl]-1H-pyrazole-3-carbonitrile), the sulphonyl metabolite (5-amino-1-[2,6-dichloro-4- (trifluoromethyl)phenyl]-4-[(trifluoromethyl)sulphonyl]-1H-pyrazole-3-carbonitrile), and the trifluoromethyl metabolite (5-amino-4-trifluoromethyl-1-[2,6-dichloro-4-(trifluoromethyl)phenyl]-1H-pyrazole-3-carbonitrile)

Citrus fruits [except kumquats]	T*0.01
Stone fruits [except jujube, Chinese]	0.01

Agvet chemical: Fluopicolide	
Permitted residue: Fluopicolide	
Brassica vegetables (except Brassica leafy vegetables) [except Chinese cabbage (Pe-tsai)]	5
Broccoli, Chinese (Gai lan)	5
Chinese cabbage (Pe-tsai)	30
Leafy vegetables [except broccoli, Chinese (Gai lan); witloof chicory]	30

Agvet chemical: Mandestrobin	
Permitted residue: Mandestrobin	
Stone fruit [except jujube, Chinese]	3

Agvet chemical: Propamocarb	
Permitted residue: Propamocarb (base)	
Brassica vegetables (except Brassica leafy vegetables) [except Chinese cabbage (Pe-tsai)]	30
Broccoli, Chinese (Gai lan)	30
Chinese cabbage (Pe-tsai)	70
Leafy vegetables [except broccoli, Chinese (Gai lan); witloof chicory]	70

Agvet chemical: Proquinazid

Permitted residue – commodities of plant

origin: Proquinazid

Permitted residue – commodities of animal origin: Sum of proquinazid and 3-(6-iodo-4-oxo-3-propyl-3H-quinazolin-2-yloxy)propionic acid, expressed as proquinazid

Agvet chemical: Proquinazid	
Pome fruit [except Persimmon, Japanese]	0.3

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

expressed as semoxydim	
Basil	T1
Basil, dry	T5
Coriander (leaves, roots, stems)	*0.1
Coriander, seed	*0.1
Leafy vegetables [except broccoli, Chinese (Gai lan); lettuce, head; lettuce, leaf; witloof chicory]	T0.5
Turmeric, root	1

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

Agvet chemical: Dodine	
Permitted residue: Dodine	
All other foods except animal food commodities	0.1
Walnuts	T0.3

Agvet chemical: Fipronil

Permitted residue: Sum of fipronil, the sulphenyl metabolite (5-amino-1-[2,6-dichloro-4-(trifluoromethyl)phenyl]-4-[(trifluoromethyl) sulphenyl]-1H-pyrazole-3-carbonitrile), the sulphonyl metabolite (5-amino-1-[2,6-dichloro-4-(trifluoromethyl)phenyl]-4-[(trifluoromethyl)sulphonyl]-1H-pyrazole-3-carbonitrile), and the trifluoromethyl metabolite (5-amino-4-trifluoromethyl-1-[2,6-dichloro-4-(trifluoromethyl)phenyl]-1H-pyrazole-3-carbonitrile)

Carob	T*0.01
Citrus fruit	T*0.01
Stone fruits	0.01

Agvet chemical: Fluopicolide	
Permitted residue: Fluopicolide	
Brassica vegetables (except Brassica leafy vegetables)	5
Cane berries	T1.5
Leafy vegetables	30

Agvet chemical: Mandestrob	oin
Permitted residue: Mandestrok	oin
Fruiting vegetables, cucurbits	0.6
Stone fruit	3
Agvet chemical: Mesotrione	
Permitted residue: Mesotrione	
Oats	*0.01
Triticale	*0.01
Agvet chemical: Metrafenon	е
Permitted residue: Metrafenon	е
Wheat bran, processed	T0.3
Agvet chemical: Propamocal	rb
Permitted residue: Propamoca	rb (base)
Brassica vegetables (except Brassica leafy vegetables)	30
Cane berries	T15
Leafy vegetables	70
Agvet chemical: Proquinazio	1
Permitted residue – commoditi origin: Proquinazid	ies of plant
Permitted residue – commoditi origin: Sum of proquinazid and propyl-3H-quinazolin-2-yloxy)p expressed as proquinazid	l 3-(6-iodo-4-oxo-3-
Pome fruit	0.3
Wheat	T*0.02
_	
Agvet chemical: Prosulfocar	b
Permitted residue: Prosulfocar	b
Oats	*0.01
Triticale	*0.01
Agvet chemical: Sethoxydim	1
Permitted residue: Sum of seth metabolites containing the 5-(2 ethylthiopropyl)cyclohexene-3-ethylthiopropyl)-5-hydroxycyclo	one and 5-(2-

etnyitniopropyi)-5-nydroxycycionexene-3-o moieties and their sulfoxides and sulfones, expressed as sethoxydim

Chives, Chinese	T1
Dried herbs {except Hops, dry}	T5

Agvet chemical: Sethoxydim	
Fennel, bulb	T1
Garlic chives	T1
Herbs	T1
Leafy vegetables {except Lettuce, head; Lettuce, leaf}	T1
Spices	T5
Agvet chemical: Tetraniliprole	
Permitted residue: Tetraniliprole	
Pineapple	T*0.01

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

Agvet chemical: Fluralaner	
Permitted residue: Fluralaner	
Sheep fat	0.35
Sheep kidney	0.15
Sheep liver	0.4
Sheep muscle	0.1

Agvet chemical: Pyraclostrobin

Permitted residue - commodities of plant

origin: Pyraclostrobin

Permitted residue - commodities of animal origin: Sum of pyraclostrobin and metabolites hydrolysed to 1-(4-chloro-phenyl)-1H-pyrazol-3-ol, expressed as pyraclostrobin

Celery	Т8	

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 18 April 2023 (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 <u>public consultation coversheet</u>).

Please lodge your submission using the <u>public consultation coversheet</u>, 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

Privacy

For information on how the APVMA manages personal information when you make a submission, see our Privacy Policy.

Agvet chemical voluntary safety recall: Barricade 'S' Cattle Dip and Spray

Product name: Barricade 'S' Cattle Dip and Spray

APVMA registration number: 45211

APVMA approved label number: 0509

Batch numbers: E221251 and E211712 (expired)

Sold by: Zoetis Australia Pty Ltd nationwide between 15 December 2021 and 16 January 2023

On 6 March 2023, Zoetis Australia Pty Ltd (ACN 156 476 425) initiated a voluntary recall under section 106 of the Agricultural and Veterinary Chemicals Code scheduled to the Agricultural and Veterinary Chemicals Code Act 1994 (Cth) in relation to the chemical product described above.

Reason for voluntary safety recall

The 800 mL pack size of this product is normally fitted with a child-resistant cap. Batches E22125 and E21171 have been fitted with a standard cap.

Hazard

Units from the affected batch will be easier for children to open while product is being handled or in storage.

What to do if in possession of this chemical product

Please inspect your stock and immediately isolate and store all units from batches E22125 and E21171 in a child-safe place. Please return affected units to your place of purchase for credit (E22125) or destruction (E21171) if the absence of a child-resistant cap is a risk in your workplace.

More information

Visit the APVMA website to view the notice of voluntary recall for the chemical product described above.

The APVMA publishes a list of <u>agvet chemical recall notices</u> on its website and provides a <u>subscription option</u> to be notified by email when a new recall notice is published.

Contact

Questions about this voluntary recall should be directed to:

Zoetis Customer Service

Phone: 1800 022 442

¹ Batch E22125 - shipped from 15 July 2022 to 16 January 2023.

² Batch E21171 – shipped from 15 December 2021 to 2 August 2022. Expired January 2023.