



**Commonwealth
of Australia**

Gazette

Agricultural and veterinary chemicals

No. APVMA 12, 13 June 2023

Published by the Australian Pesticides and Veterinary Medicines Authority



Australian Government
**Australian Pesticides and
Veterinary Medicines Authority**

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

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General information

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

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

Distribution and subscription

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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.	130464
Product name	Excalia Fungicide
Active constituent	400 g/L inpyrfluxam
Applicant name	Sumitomo Chemical Australia Pty Ltd
Applicant ACN	081 096 255
Date of registration	26 May 2023
Product registration no.	90901
Label approval no.	90901/130464
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 400 g/L suspension concentrate product for the control of <i>Rhizoctonia solani</i> in potatoes and yellow sigatoka in bananas in conjunction with the approval of inpyrfluxam

Table 2: Agricultural products based on existing active constituents

Application no.	139556
Product name	Momiji 850 WG Herbicide
Active constituent	850 g/kg pyroxasulfone
Applicant name	Bayer CropScience Pty Ltd
Applicant ACN	000 226 022
Date of registration	22 May 2023
Product registration no.	93567
Label approval no.	93567/139556
Description of the application and its purpose, including the intended use of the chemical product	Registration of an 850 g/kg pyroxasulfone water-dispersible granule for the control of certain weeds in certain cereal and legume crops

Application no.	139200
Product name	Conquest CropCover Insecticide
Active constituent	815 g/L paraffinic oil
Applicant name	Conquest Crop Protection Pty Ltd
Applicant ACN	098 814 932
Date of registration	24 May 2023
Product registration no.	93445
Label approval no.	93445/139200
Description of the application and its purpose, including the intended use of the chemical product	Registration of an 815 g/L paraffinic oil as emulsifiable concentrate for the management of pests

Application no.	139560
Product name	Momiji 480 SC Herbicide
Active constituent	480 g/L pyroxasulfone
Applicant name	Bayer CropScience Pty Ltd
Applicant ACN	000 226 022
Date of registration	24 May 2023
Product registration no.	93569
Label approval no.	93569/139560
Description of the application and its purpose, including the intended use of the chemical product	Registration of 'Momiji 480 SC Herbicide', an SC (suspension concentrate) product containing 480 g/L pyroxasulfone for the control of certain weeds in certain cereal and legume crops

Application no.	139377
Product name	Franat Herbicide
Active constituent	745 g/L flupropanate present as the sodium salt
Applicant name	Shandong Rainbow International Co Ltd
Applicant ACN	N/A
Date of registration	24 May 2023
Product registration no.	93497
Label approval no.	93497/139377
Description of the application and its purpose, including the intended use of the chemical product	Registration of 'Franat Herbicide', an SL (soluble concentrate) herbicide product containing 745 g/L flupropanate present as the sodium salt as a component of integrated management of serrated tussock, giant parramatta grass, giant rat's tail grass, Chilean needle grass, African lovegrass and certain grasses as per the directions for use table

Application no.	136242
Product name	Shenzi Insecticide
Active constituent	400 g/L chlorantraniliprole
Applicant name	UPL Australia Pty Ltd
Applicant ACN	066 391 384
Date of registration	25 May 2023
Product registration no.	92656
Label approval no.	92656/136242
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 400 g/L chlorantraniliprole suspension concentrate product for the control of <i>Lepidopteran</i> species of insect pests in certain vegetable, fruit, cotton, and pulse crops

Application no.	134081
Product name	Infinity Ultra Herbicide
Active constituents	250 g/L pyrasulfotole, 125 g/L diflufenican
Applicant name	Bayer CropScience Pty Ltd
Applicant ACN	000 226 022
Date of registration	31 May 2023
Product registration no.	91984
Label approval no.	91984/134081
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 250 g/L pyrasulfotole, 125 g/L diflufenican and 62.5 g/L mefenpyr-diethyl suspension concentrate product for the post-emergent control of various broadleaf weeds in wheat (including durum wheat), barley, triticale, oats and fallow situations

Application no.	136527
Product name	Hose-on No Mosquitoes Professional Mosquito Control Biting Midge & Mosquito Barrier
Active constituent	25 g/L bifenthrin
Applicant name	Australian Outdoor Lifestyle Pty Ltd
Applicant ACN	618 205 977
Date of registration	1 June 2023
Product registration no.	92750
Label approval no.	92750/136527
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 25 g/L bifenthrin suspension concentrate product for the control of adult mosquitoes and midges around external areas and surrounds of domestic buildings and structures

Application no.	130815
Product name	Relzar Arylex Active Herbicide
Active constituents	200 g/kg halauxifen as the methyl ester, 200 g/kg florasulam
Applicant name	Corteva Agriscience Australia Pty Ltd
Applicant ACN	003 771 659
Date of registration	1 June 2023
Product registration no.	91049
Label approval no.	91049/130815
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 200 g/kg halauxifen-methyl and 200 g/kg florasulam wettable granule product for post-emergent control of broadleaf weeds in turf, playing fields, golf fairways, racecourses and amenity areas

Table 3: Variations of registration – agricultural chemical products

Application no.	139809
Product name	Kendon Mancozeb WG Agricultural Fungicide
Active constituent	750 g/kg mancozeb
Applicant name	Kendon Plant Care Pty Ltd
Applicant ACN	065 737 948
Date of variation	15 May 2023
Product registration no.	53223
Label approval no.	53223/139809
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 'Kendon Mancozeb DF Agricultural Fungicide' to 'Kendon Mancozeb WG Agricultural Fungicide'

Application no.	139822
Product name	Condor Herbicide
Active constituents	375 g/L MCPA present as the potassium salt, 10 g/L pyraflufen-ethyl
Applicant name	Sipcam Pacific Australia Pty Ltd
Applicant ACN	073 176 888
Date of variation	16 May 2023
Product registration no.	86923
Label approval no.	86923/139822
Description of the application and its purpose, including the intended use of the chemical product	Variation to update the first aid instructions and safety directions appearing on a label to reflect the current FAISD Handbook

Application no.	139935
Product name	Genfarm Flupropanate 745 SL Herbicide
Active constituent	745 g/L flupropanate present as the sodium salt
Applicant name	Nutrien Ag Solutions Limited
Applicant ACN	008 743 217
Date of variation	23 May 2023
Product registration no.	81889
Label approval no.	81889/139935
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 'Flupron 745 Herbicide' to 'Genfarm Flupropanate 745 SL Herbicide'

Application no.	134868
Product name	ADAMA MCPA 750 Herbicide
Active constituent	750 g/L MCPA present as the dimethylamine salt
Applicant name	ADAMA Australia Pty Ltd
Applicant ACN	050 328 973
Date of variation	24 May 2023
Product registration no.	53893
Label approval no.	53893/134868
Description of the application and its purpose, including the intended use of the chemical product	Variation to the particulars registration and label approval to amend the sugarcane use pattern

Application no.	139966
Product name	Intrepid Edge Jemvelva active Insecticide
Active constituent	300 g/L methoxyfenozide, 60 g/L spinetoram
Applicant name	Corteva Agriscience Australia Pty Ltd
Applicant ACN	003 771 659
Date of variation	25 May 2023
Product registration no.	92062
Label approval no.	92062/139966
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 'Intrepid Edge Insecticide' to 'Intrepid Edge Jemvelva active Insecticide'

Application no.	135645
Product name	Applaud Insecticide
Active constituent	440 g/L buprofezin
Applicant name	Corteva Agriscience Australia Pty Ltd
Applicant ACN	003 771 659
Date of variation	29 May 2023
Product registration no.	51547
Label approval no.	51547/135645
Description of the application and its purpose, including the intended use of the chemical product	Variation to registration particulars, particulars of label, to add use in protected cropping basil, chives, mint, oregano and thyme

Application no.	N/A – variation under s29A of Agvet Code
Product name	Agrobest Buffer 700 Surfactant
Active constituent	350 g/L propionic acid, 350 g/L soya phospholipids
Applicant name	AgroBest IP Pty Ltd
Applicant ACN	128 029 701
Date of variation	1 June 2023
Product registration no.	67791
Label approval no.	67791/56883
Description of the application and its purpose, including the intended use of the chemical product	Variation of registration to amend formulation type

Table 4: Label approval – agricultural chemical products

Application no.	139214
Product name	Legend Fungicide
Active constituent	250 g/L quinoxifen
Applicant name	Gowan Crop Protection Australia Pty Ltd
Applicant ACN	637 927 765
Date of variation	22 May 2023
Product registration no.	53607
Label approval no.	53607/139214
Description of the application and its purpose, including the intended use of the chemical product	Registration of a new label for the existing product 'Legend Fungicide' with the label name 'Legend Cereal Fungicide'

Application no.	139022
Product name	Sumitomo Sumisclex 500 Fungicide
Active constituent	500 g/L procymidone
Applicant name	Sumitomo Chemical Australia Pty Ltd
Applicant ACN	081 096 255
Date of variation	25 May 2023
Product registration no.	50883
Label approval no.	50883/139022
Description of the application and its purpose, including the intended use of the chemical product	Registration of a new label for the existing product 'Sumitomo Sumisclex 500 Fungicide' with the label name 'Sumisclex 500 Fungicide'

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

Application no.	135532
Product name	Jurox Progesterone Intravaginal Delivery System [IVD]
Active constituent	1.38 g/device progesterone
Applicant name	Jurox Pty Ltd
Applicant ACN	000 932 230
Date of registration	26 May 2023
Product registration no.	92444
Label approval no.	92444/135532
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 1.38 g/device progesterone intravaginal delivery system for controlled breeding in cattle

Application no.	138468
Product name	Elevet + Tylosin Injection
Active constituent	200 mg/mL tylosin
Applicant name	AVet Health Limited
Applicant ACN	616 838 101
Date of registration	29 May 2023
Product registration no.	93244
Label approval no.	93244/138468
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 200 mg/mL tylosin injection product for the treatment of tylosin-susceptible bacterial and mycoplasma infections in cattle and pigs

Application no.	138731
Product name	[Wagg & Purr] Acepromazine 2 mg/mL Injection
Active constituent	2.7 mg/mL acepromazine maleate
Applicant name	AVet Health Limited
Applicant ACN	616 838 101
Date of registration	30 May 2023
Product registration no.	93319
Label approval no.	93319/138731
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 2 mg/mL acepromazine parenteral injectable solution product for use as an anaesthetic premedication, tranquiliser and travel sickness suppressant in cats and dogs

Application no.	138271
Product name	Oticare
Active constituents	1505 IU/mL gentamicin as the sulfate, 15.1 mg/mL miconazole as the nitrate, 1.11 mg/mL hydrocortisone aceponate
Applicant name	Invetro Pty Ltd
Applicant ACN	654 837 733
Date of registration	30 May 2023
Product registration no.	93204
Label approval no.	93204/138271
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 15.1 mg/mL miconazole (as the nitrate), 1505 IU/mL gentamicin (as the sulphate) and 1.11 mg/mL hydrocortisone aceponate suspension product for the treatment of otitis externa of bacterial, fungal or inflammatory origin in dogs

Application no.	138288
Product name	Selamectin Spot On for Dogs 2.6–5 kg Fleas & Heartworm
Active constituent	120 mg/mL selamectin
Applicant name	Redcap Solutions Pty Ltd
Applicant ACN	095 863 899
Date of registration	30 May 2023
Product registration no.	93211
Label approval no.	93211/138288
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 120 mg/mL selamectin topical solution/suspension product for the control of fleas, heartworms, ear mites, sarcoptic mange and lice in dogs

Application no.	138378
Product name	Abbey TMPS Injection
Active constituents	200 mg/mL sulfadoxine, 40 mg/mL trimethoprim
Applicant name	Abbey Laboratories Pty Ltd
Applicant ACN	156 000 430
Date of registration	30 May 2023
Product registration no.	93224
Label approval no.	93224/138378
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 200 mg/mL sulfadoxine, and 40 mg/mL trimethoprim injectable solution product for the treatment of a wide range of diseases including respiratory, alimentary, urogenital and general infections caused by bacteria sensitive to sulfadoxine/trimethoprim therapy in cattle, sheep, goats, pigs, dogs and horses

Application no.	135457
Product name	Vetsense Flygon Gold Insecticidal and Repellent Spray for Horses
Active constituents	10 g/L piperonyl butoxide, 5 g/L permethrin (25:75::cis:trans), 1 g/L pyrethrin
Applicant name	Vetsense Pty Ltd
Applicant ACN	150 968 871
Date of registration	31 May 2023
Product registration no.	92425
Label approval no.	92425/135457
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 10 g/L piperonyl butoxide, 5 g/L permethrin and 1 g/L pyrethrin topical spray product to control and repel susceptible flies, mosquitoes and other nuisance insects including House Fly (<i>Musca domestica</i>), Stable Fly (<i>Stomoxys calcitrans</i>), Bush Fly (<i>Musca velutissima</i>), Bot Fly (<i>Gasterophilus</i> spp), Mosquitoes (<i>Aedes</i> spp) and Midges or Sandflies and aids in prevention of Queensland Itch

Application no.	138732
Product name	Elevet+ Acepromazine 10 mg/mL Injection
Active constituent	13.5 mg/mL acepromazine maleate
Applicant name	AVet Health Limited
Applicant ACN	616 838 101
Date of registration	1 June 2023
Product registration no.	93320
Label approval no.	93320/138732
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 10 mg/mL acepromazine parenteral injectable solution product for use as an anaesthetic premedication, tranquilliser and travel sickness suppressant in horses, cattle, pigs and sheep

Application no.	138689
Product name	Elevet+ Mepivacaine Hydrochloride Injection
Active constituent	20 mg/mL mepivacaine hydrochloride
Applicant name	AVet Health Limited
Applicant ACN	616 838 101
Date of registration	2 June 2023
Product registration no.	93307
Label approval no.	93307/138689
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 20 mg/mL mepivacaine hydrochloride parenteral injectable solution product for local anaesthetic use in horses

Table 6: Variations of registration – veterinary chemical products

Application no.	139823
Product name	Flyaway Insecticidal Spray for Horses
Active constituents	50 g/L diethyltoluamide 25 g/L n-octyl bicycloheptene dicarboximide 25 g/L piperonyl butoxide 20 g/L dibutyl phthalate 12 g/L permethrin 40:60
Applicant name	Virbac (Australia) Pty Ltd
Applicant ACN	003 268 871
Date of variation	16 May 2023
Product registration no.	46791
Label approval no.	46791/139823
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 updating first aid instructions and disposal instructions as per the current FAISD Handbook and Veterinary Labelling Code

Application no.	139839
Product name	Flockstar Lousicide for Sheep Spray-On Pour-On
Active constituent	35 g/L imidacloprid
Applicant name	Alleva Animal Health Ltd
Applicant ACN	N/A
Date of variation	18 May 2023
Product registration no.	93236
Label approval no.	93236/139839
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 removing the prevention of blowflies claim from the instructions of use

Application no.	139844
Product name	Cephacin 200 Tablets
Active constituent	200 mg/tablet cephalexin (as cephalexin monohydrate)
Applicant name	Dechra Veterinary Products (Australia) Pty Ltd
Applicant ACN	614 716 700
Date of variation	19 May 2023
Product registration no.	41053
Label approval no.	41053/139844
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 'Cephalexin 200 Tablets' to 'Cephacin 200 Tablets'

Application no.	139845
Product name	Cephacin 600 Tablets
Active constituent	600 mg/tablet cephalexin (as cephalexin monohydrate)
Applicant name	Dechra Veterinary Products (Australia) Pty Ltd
Applicant ACN	614 716 700
Date of variation	19 May 2023
Product registration no.	51072
Label approval no.	51072/139845
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 'Cephalexin 600 Tablets' to 'Cephacin 600 Tablets'

Application no.	139847
Product name	Cephacin 1000 Tablets
Active constituent	1000 mg/tablet cephalexin (as cephalexin monohydrate)
Applicant name	Dechra Veterinary Products (Australia) Pty Ltd
Applicant ACN	614 716 700
Date of variation	19 May 2023
Product registration no.	59249
Label approval no.	59249/139847
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 'Cephalexin 1000 Tablets' to 'Cephacin 1000 Tablets'

Application no.	139848
Product name	Cephacin Flavoured 200 Tablets
Active constituent	200 mg/tablet cephalexin (as cephalexin monohydrate)
Applicant name	Dechra Veterinary Products (Australia) Pty Ltd
Applicant ACN	614 716 700
Date of variation	19 May 2023
Product registration no.	86225
Label approval no.	86225/139848
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 'Cephalexin 200 Tablets with Beef Flavouring' to 'Cephacin Flavoured 200 Tablets'

Application no.	139849
Product name	Cephacin Flavoured 600 Tablets
Active constituent	600 mg/tablet cephalexin (as cephalexin monohydrate)
Applicant name	Dechra Veterinary Products (Australia) Pty Ltd
Applicant ACN	614 716 700
Date of variation	19 May 2023
Product registration no.	68139
Label approval no.	68139/139849
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 'Cephalexin 600 Tablets with Beef Flavouring' to 'Cephacin Flavoured 600 Tablets'

Application no.	139850
Product name	Cephacin Flavoured 1000 Tablets
Active constituent	1000 mg/tablet cephalexin (as cephalexin monohydrate)
Applicant name	Dechra Veterinary Products (Australia) Pty Ltd
Applicant ACN	614 716 700
Date of variation	19 May 2023
Product registration no.	88788
Label approval no.	88788/139850
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 'Cephalexin 1000 Tablets with Beef Flavouring' to 'Cephacin Flavoured 1000 Tablets'

Application no.	137531
Product name	Credelio Plus Chewable Tablets for Very Large Dogs
Active constituents	900 mg/tablet lotilaner, 33.75 mg/tablet milbemycin oxime
Applicant name	Elanco Australasia Pty Ltd
Applicant ACN	076 745 198
Date of variation	30 May 2023
Product registration no.	89319
Label approval no.	89319/137531
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 to add a claim for treatment and control of <i>Demodex</i> spp

Application no.	137539
Product name	Credelio Plus Chewable Tablets for Very Small Dogs
Active constituents	56.25 mg/tablet lotilaner, 2.11 mg/tablet milbemycin oxime
Applicant name	Elanco Australasia Pty Ltd
Applicant ACN	076 745 198
Date of variation	30 May 2023
Product registration no.	89315
Label approval no.	89315/137539
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 to add a claim for treatment and control of <i>Demodex</i> spp

Application no.	137541
Product name	Credelio Plus Chewable Tablets for Small Dogs
Active constituents	112.5 mg/tablet lotilaner, 4.22 mg/tablet milbemycin oxime
Applicant name	Elanco Australasia Pty Ltd
Applicant ACN	076 745 198
Date of variation	30 May 2023
Product registration no.	89316
Label approval no.	89316/137541
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 to add a claim for treatment and control of <i>Demodex</i> spp

Application no.	137542
Product name	Credelio Plus Chewable Tablets for Medium Dogs
Active constituents	225 mg/tablet lotilaner, 8.44 mg/tablet milbemycin oxime
Applicant name	Elanco Australasia Pty Ltd
Applicant ACN	076 745 198
Date of variation	30 May 2023
Product registration no.	89317
Label approval no.	89317/137542
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 to add a claim for treatment and control of <i>Demodex</i> spp

Application no.	137544
Product name	Credelio Plus Chewable Tablets for Large Dogs
Active constituents	450 mg/tablet lotilaner, 16.88 mg/tablet milbemycin oxime
Applicant name	Elanco Australasia Pty Ltd
Applicant ACN	076 745 198
Date of variation	30 May 2023
Product registration no.	89318
Label approval no.	89318/137544
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 to add a claim for treatment and control of <i>Demodex</i> spp

Application no.	138748
Product name	Independents Own Spinoff Pour-On for Sheep
Active constituent	20 g/L spinosad
Applicant name	The Hunter River Company Pty Ltd
Applicant ACN	133 798 615
Date of variation	30 May 2023
Product registration no.	88244
Label approval no.	88244/138748
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 updating the label as per the Veterinary Labelling Code

Application no.	138755
Product name	Pastoral Ag Spinolab Pour-On for Sheep
Active constituent	20 g/L spinosad
Applicant name	The Hunter River Company Pty Ltd
Applicant ACN	133 798 615
Date of variation	30 May 2023
Product registration no.	91141
Label approval no.	91141/138755
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 updating the label as per the Veterinary Labelling Code

Application no.	135400
Product name	Ingelvac Circoflex Suspension for Injection in Pigs
Active constituent	Each 1 mL dose contains: Porcine circovirus type 2 ORF2 protein ≥ 1.0 RP
Applicant name	Boehringer Ingelheim Animal Health Australia Pty Ltd
Applicant ACN	071 187 285
Date of variation	31 May 2023
Product registration no.	63448
Label approval no.	63448/135400
Description of the application and its purpose, including the intended use of the chemical product	Variation of relevant particulars of the product registration and label to add instructions for use for a new packaging configuration

Application no.	135403
Product name	Ingelvac Mycoflex Mycoplasma Hyopneumoniae Inactivated Vaccine for Pigs
Active constituents	Each 1 mL dose contains: Inactivated <i>mycoplasma hyopneumoniae</i> ≥ 1.0 RP, 1 mg carbomer
Applicant name	Boehringer Ingelheim Animal Health Australia Pty Ltd
Applicant ACN	071 187 285
Date of variation	31 May 2023
Product registration no.	69810
Label approval no.	69810/135403
Description of the application and its purpose, including the intended use of the chemical product	Variation of relevant particulars of the product registration and label to add instructions for use for a new packaging configuration

Application no.	138984
Product name	Sulfa-B Oral Paste Antibiotic Mucolytic for Horses
Active constituents	325 mg/mL sulfadiazine, 65 mg/mL trimethoprim, 20 mg/mL bromhexine hydrochloride
Applicant name	Abbey Laboratories Pty Ltd
Applicant ACN	156 000 430
Date of variation	1 June 2023
Product registration no.	49953
Label approval no.	49953/138984
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 and amending various sections in the label to align with current Veterinary Labelling Code

Application no.	139118
Product name	Eqvalan Gold Broad Spectrum Antiparasitic Paste for Horses
Active constituents	77.5 g/kg praziquantel, 15.5 g/kg ivermectin
Applicant name	Boehringer Ingelheim Animal Health Australia Pty Ltd
Applicant ACN	071 187 285
Date of variation	2 June 2023
Product registration no.	56588
Label approval no.	56588/139118
Description of the application and its purpose, including the intended use of the chemical product	Variation to the relevant particulars of the product and label by changing the instructions of use to align the label with the current Veterinary Labelling Code

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: Approved active constituents

Application no.	130463
Active constituent	Inpyrfluxam
Applicant name	Sumitomo Chemical Australia Pty Ltd
Applicant ACN	081 096 255
Date of approval	26 May 2023
Approval no.	90900
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent inpyrfluxam for use in agricultural chemical products

Table 8: Variations of active constituent

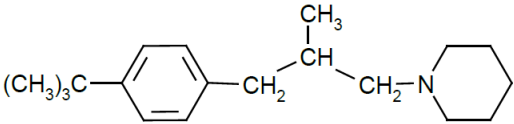
Application no.	137473
Active constituent	Amoxycillin trihydrate
Applicant name	Jurox Pty Ltd
Applicant ACN	000 932 230
Date of variation	23 May 2023
Approval no.	86650
Description of the application and its purpose, including the intended use of the active constituent	Variation of relevant particulars or conditions of an approved active constituent

Application no.	137446
Active constituent	Meloxicam
Applicant name	Le Vet Beheer B V
Applicant ACN	N/A
Date of variation	31 May 2023
Approval no.	87888
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

New active constituent – fenpropidin

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

Table 9: Particulars of the active constituent fenpropidin

Common name	Fenpropidin
IUPAC name	1-[(<i>RS</i>)-3-(4- <i>tert</i> -butylphenyl)-2-methylpropyl]piperidine
CAS name	1-[3-[4-(1,1-dimethylethyl)phenyl]-2-methylpropyl]piperidine
CAS registry number	67306-00-7
Manufacturer's codes	CGA114900
Minimum purity	980 g/kg
Molecular formula	C ₁₉ H ₃₁ N
Molecular weight	273.5 g mol ⁻¹
Structure	 <p>The chemical structure of fenpropidin consists of a <i>tert</i>-butyl group attached to a para-substituted phenyl ring. This phenyl ring is connected via a methylene group to a chiral center (CH) which is also bonded to a methyl group and another methylene group. This second methylene group is attached to the nitrogen atom of a piperidine ring.</p>
Chemical family	Piperidine
Mode of action	Systemic, foliar fungicide with protective, curative and eradicant activity, translocated acropetally in the xylem. Inhibition of ergosterol biosynthesis.

Summary of the APVMA's evaluation of fenpropidin active constituent

The APVMA has evaluated the chemistry aspects of fenpropidin active constituent (physico-chemical properties, stability, identification, manufacturing process, quality control procedures, batch analysis results and analytical methods) and found them to be acceptable.

The APVMA has completed a toxicological evaluation of fenpropidin. An acceptable daily intake (ADI) of 0.023 mg/kg bw/d has been set, based on a No-Observed Effect Level (NOAEL) of 2.3 mg/kg bw/d in a female rat study, after applying a safety factor of 100. An acute reference dose (ARfD) of 0.07 mg/kg bw has been set based on a NOAEL of 7 mg/kg bw/d in rats due to decreased female brain weight study, after applying a safety factor of 100.

Toxicologically significant impurities have not been identified in technical fenpropidin.

Fenpropidin is included in Schedule 6 of the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP).

On the basis of the data provided, and the toxicological assessment, it is proposed that the following APVMA Active Constituent Standard be established for fenpropidin:

Table 10: Proposed APVMA Active Constituent Standard for fenpropidin

Constituent	Parameter	Specification
Fenpropidin	Purity	980 g/kg minimum

Further information

A Public Release Summary (PRS) of the evaluation of this product is available from the [APVMA website](#) or from the contact listed below.

Making a submission

In accordance with section 12 of the Agvet Code, the APVMA invites any person to submit a relevant written submission as to whether fenpropidin should be approved. Submissions should relate only to matters that are considered in determining whether the safety criteria set out in section 5A of the Agvet Code have been met. Submissions should state the grounds on which they are based.

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

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

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

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

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

Email: enquiries@apvma.gov.au

Post:

Director Chemistry and Manufacture
Australian Pesticides and Veterinary Medicines Authority
GPO Box 3262
Sydney NSW 2001

Privacy

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

SEEKER Duo Fungicide containing the new active constituent fenpropidin

The APVMA has before it an application for registration of a new product, SEEKER Duo Fungicide containing a new active constituent, fenpropidin.

Table 11: Particulars of the application – SEEKER Duo Fungicide containing the new active constituent fenpropidin

Proposed product name	SEEKER Duo Fungicide
Applicant company	Syngenta Australia Pty Ltd
Name of active constituent	Fenpropidin
Signal heading	POISON
Summary of proposed use	For the control of powdery mildew in wine grapes.
Pack sizes	1 to 20 L
Withholding period	Harvest: Not required when used as directed. Grazing: DO NOT graze treated vineyards for 12 weeks after application.

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

- 1) The APVMA has evaluated the application and in its assessment in relation to whether the safety criteria have been met in accordance with the definition set out in section 5A of the Agvet Code, proposes to determine that:
 - i. The APVMA is satisfied that proposed use of SEEKER Duo Fungicide would not be an undue hazard to the safety of people exposed to it during its handling and use.
 - ii. The APVMA has conducted a risk assessment on the product and concluded that it can be used safely.
 - iii. The APVMA is satisfied that the proposed use of SEEKER Duo Fungicide will not be an undue hazard to the safety of people using anything containing its residues.

The APVMA is satisfied that the proposed use of SEEKER Duo Fungicide containing the new active constituent fenpropidin is not likely to have an unintended effect that is harmful to animals, plants or the environment if used according to the product label directions.
- 2) The APVMA has evaluated the application and in its assessment in relation to whether the efficacy criteria have been met in accordance with the definition set out in section 5B of the Agvet Code, and proposes to determine that:
 - i. In relation to its assessment of efficacy the APVMA is satisfied that data from trials supporting the efficacy of the product adequately demonstrate that if used according to the product label directions, the product is effective for its proposed uses.
- 3) The APVMA has evaluated the application and in its assessment in relation to whether the trade criteria have been met in accordance with the definition set out in section 5C of the Agvet Code, proposes to determine that:

The APVMA is considering whether the proposed use of SEEKER Duo Fungicide would not adversely affect trade between Australia and places outside Australia.

Further information

A Public Release Summary (PRS) of the evaluation of this product is available from the [APVMA website](#) or by contacting the APVMA as listed below.

Making a submission

In accordance with section 13 of the Agvet Code, the APVMA invites any person to submit a relevant written submission as to whether SEEKER Duo Fungicide should be registered. Submissions should relate only to matters that are required by the APVMA to be taken into consideration in determining whether the safety, efficacy or trade criteria have been met. Submissions should state the grounds on which they are based.

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

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

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

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

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

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

Email: enquiries@apvma.gov.au

Post:

Case Management Team – Pesticides

Australian Pesticides and Veterinary Medicines Authority

GPO Box 3262

Sydney NSW 2001

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