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Agricultural and veterinary chemicals

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

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General information

The APVMA 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

Application no.	131891
Product name	Agro-Essence Spirotetramat 240 SC Insecticide
Active constituent	240 g/L spirotetramat
Applicant name	Agro-Alliance (Australia) Pty Ltd
Applicant ACN	130 864 603
Date of registration	15 August 2022
Product registration no.	91340
Label approval no.	91340/131891
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 240 g/L spirotetramat suspension concentrate product for the control of various insect pests in cotton and certain fruit and vegetable crops

Application no.	133947
Product name	GroCure 500 EC Fungicide
Active constituent	500 g/L imazalil
Applicant name	Grochem Australia Pty Ltd
Applicant ACN	169 400 033
Date of registration	16 August 2022
Product registration no.	91916
Label approval no.	91916/133947
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 500 g/L emulsifiable concentrate formulation of imazalil for the control of certain post-harvest diseases of citrus, apples, pears, rockmelons and storage diseases of potato tubers

Application no.	135838
Product name	Titan Tebu T Flowable Fungicide/Insecticide Seed Treatment
Active constituents	25 g/L tebuconazole, 4 g/L triflumuron
Applicant name	Titan Ag Pty Ltd
Applicant ACN	122 081 574
Date of registration	18 August 2022
Product registration no.	92531
Label approval no.	92531/135838
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 25 g/L tebuconazole and 4 g/L triflumuron flowable concentrate seed treatment product for the control various diseases in wheat, barley and oats, and for protection against insect pests of stored grain

Application no.	133495
Product name	Vacsol Azure Aqua Wood Preservative Concentrate
Active constituents	55.1 g/L propiconazole, 55.1 g/L tebuconazole, 36.8 g/L permethrin (25:75)
Applicant name	Arch Wood Protection (Aust) Pty Limited
Applicant ACN	003 780 872
Date of registration	18 August 2022
Product registration no.	91800
Label approval no.	91800/133495
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 55.1 g/L propiconazole, 55.1 g/L tebuconazole, and 36.8 g/L permethrin micro-emulsions (ME) formulation for use as a commercial wood preservative

Application no.	132780
Product name	Nufarm Dropzone Herbicide
Active constituent	500 g/L 2,4-D present as the dimethylamine and monomethylamine salts
Applicant name	Nufarm Australia Limited
Applicant ACN	004 377 780
Date of registration	18 August 2022
Product registration no.	91596
Label approval no.	91596/132780
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 500 g/L SL 2,4-D dimethylamine and monomethylamine salt formulation for the control of broadleaf weeds in fallow, sugarcane and pasture, pre-harvest in cereals and non-agricultural uses

Application no.	132882
Product name	Colex-D Herbicide
Active constituent	456 g/L 2,4-D present as the choline salt
Applicant name	Corteva Agriscience Australia Pty Ltd
Applicant ACN	003 771 659
Date of registration	22 August 2022
Product registration no.	91625
Label approval no.	91625/132882
Description of the application and its purpose, including the intended use of the chemical product	Registration of a soluble concentrate containing 2,4-D for the control of broadleaf weeds in fallow, and non-agricultural areas

Application no.	135623
Product name	Jiangnan Glyphosate 450 SL Herbicide
Active constituent	450 g/L glyphosate (present as the isopropylamine salt)
Applicant name	Zhenjiang Jiangnan Chemicals Co., Ltd.
Applicant ACN	N/A
Date of registration	25 August 2022
Product registration no.	92461
Label approval no.	92461/135623
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 450 g/L glyphosate soluble concentrate product for the non-selective control of many annual and perennial weeds

Application no.	135489
Product name	Kenso Agcare Kentrole 250 Herbicide
Active constituents	250 g/L amitrole, 220 g/L ammonium thiocyanate
Applicant name	Kenso Corporation (M) Sdn. Bhd.
Applicant ACN	N/A
Date of registration	25 August 2022
Product registration no.	92432
Label approval no.	92432/135489
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 250 g/L amitrole and 220 g/L ammonium thiocyanate soluble concentrate product for the control of weeds in orchards, vineyards, irrigation ditches and drains, potatoes, pine plantations, roadsides, pre-plant wheat and barley, and for general industrial situations

Application no.	133378
Product name	Gemstar Xtreme Biological Insecticide
Active constituent	10 thousand million/mL polyhedral occlusion bodies (OBS) of the nuclear polyhedrosis virus of *Helicoverpa zea*
Applicant name	Sipcam Pacific Australia Pty Ltd
Applicant ACN	073 176 888
Date of registration	26 August 2022
Product registration no.	91750
Label approval no.	91750/133378
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 10 thousand million/mL polyhedral occlusion bodies (OBS) of the nuclear polyhedrosis virus of *Helicoverpa zea* liquid formulation product for the control of *Helicoverpa spp*. in various crops

Table 2: Variations of registration – agricultural products

Application no.	136447
Product name	XLFLO Seed Treatment
Active constituent	250 g/L iprodione
Applicant name	Arysta LifeScience Australia Pty Ltd
Applicant ACN	005 225 507
Date of variation	2 August 2022
Product registration no.	57979
Label approval no.	57979/136447
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 the first aid and safety directions appearing on a label to reflect the current FAISD Handbook.

Application no.	136455
Product name	Guardian Red Seed Treatment Insecticide
Active constituent	600 g/L imidacloprid
Applicant name	Arysta LifeScience Australia Pty Ltd
Applicant ACN	005 225 507
Date of variation	3 August 2022
Product registration no.	80617
Label approval no.	80617/136455
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 the first aid instructions and storage and disposal statements to reflect the current FAISD Handbook and Agricultural Labelling Code respectively

Application no.	136521
Product name	Manzate 750 WG Fungicide
Active constituent	750 g/kg mancozeb
Applicant name	UPL Australia Pty Ltd
Applicant ACN	066 391 384
Date of variation	8 August 2022
Product registration no.	30582
Label approval no.	30582/136521
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 the first aid instructions and safety directions appearing on a label to reflect the current FAISD Handbook

Application no.	136522
Product name	Select Xtra Herbicide
Active constituent	360 g/L clethodim
Applicant name	Arysta LifeScience North America LLC
Applicant ACN	N/A
Date of variation	8 August 2022
Product registration no.	65513
Label approval no.	65513/136522
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 ‘Arysta Select Xtra Herbicide’ to ‘Select Xtra Herbicide’. To update the first aid instructions and safety directions appearing on a label to reflect the current FAISD Handbook

Application no.	136555
Product name	Lazco Mozzie Kill Coils
Active constituent	2.5 g/kg pyrethrins
Applicant name	Yanco Limited
Applicant ACN	N/A
Date of variation	11 August 2022
Product registration no.	87731
Label approval no.	87731/136555
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 ‘Yanco Mosquito Coils’ to ‘Lazco Mozzie Kill Coils’

Application no.	136569
Product name	Omite 300W Wettable Powder Miticide
Active constituent	300 g/kg propargite
Applicant name	Arysta LifeScience Australia Pty Ltd
Applicant ACN	005 225 507
Date of variation	12 August 2022
Product registration no.	48086
Label approval no.	48086/136569
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 the first aid instructions and storage and disposal statements appearing on a label to reflect the current FAISD Handbook and Agricultural Labelling Code

Application no.	136568
Product name	Terrazole 350 WP Soil Fungicide
Active constituent	350 g/kg etridiazole
Applicant name	Arysta LifeScience Australia Pty Ltd
Applicant ACN	005 225 507
Date of variation	12 August 2022
Product registration no.	53332
Label approval no.	53332/136568
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 the first aid instructions appearing on a label to reflect the current FAISD Handbook

Application no.	132901
Product name	Sentry Herbicide
Active constituents	525 g/kg imazapic, 175 g/kg imazapyr
Applicant name	Nufarm Australia Limited
Applicant ACN	004 377 780
Date of variation	15 August 2022
Product registration no.	67951
Label approval no.	67951/132901
Description of the application and its purpose, including the intended use of the chemical product	Variation of product registration and label approval to remove restraints and alter critical comments to allow use in imidazolinone herbicide tolerant oats where grain may be used for stock feed including updating maximum residue limits (MRLs)

Application no.	134130
Product name	Cruiser 600 FS Insecticide Seed Treatment
Active constituent	600 g/L thiamethoxam
Applicant name	Syngenta Australia Pty Ltd
Applicant ACN	002 933 717
Date of variation	15 August 2022
Product registration no.	51832
Label approval no.	51832/134130
Description of the application and its purpose, including the intended use of the chemical product	Variation of product registration and label extension to canola

Application no.	136581
Product name	Current 240 EC Selective Herbicide
Active constituent	240 g/L clodinafop-propargyl, 60 g/L cloquintocet-mexyl
Applicant name	UPL Australia Pty Ltd
Applicant ACN	066 391 384
Date of variation	15 August 2022
Product registration no.	60769
Label approval no.	60769/136581
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 the first aid instructions appearing on a label to reflect the current FAISD Handbook

Application no.	133790
Product name	Sivanto Prime 200 SL Insecticide
Active constituent	200 g/L flupyradifurone
Applicant name	Bayer CropScience Pty Ltd
Applicant ACN	000 226 022
Date of variation	15 August 2022
Product registration no.	84727
Label approval no.	84727/133790
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 additional crops to the label

Application no.	135555
Product name	Relyon Oxyfluorfen 240EC Herbicide
Active constituent	240 g/L oxyfluorfen
Applicant name	Nutrien Ag Solutions Limited
Applicant ACN	008 743 217
Date of variation	15 August 2022
Product registration no.	89896
Label approval no.	89896/135555
Description of the application and its purpose, including the intended use of the chemical product	Variation to registration and label particulars to extend the pack range and make minor label changes

Application no.	135608
Product name	Titan Duelling Spray Adjuvant
Active constituent	704 g/L ethyl and methyl esters of canola oil
Applicant name	Titan Ag Pty Ltd
Applicant ACN	122 081 574
Date of variation	16 August 2022
Product registration no.	83320
Label approval no.	83320/135608
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 uses with various herbicides

Application no.	133082
Product name	Voraxor Herbicide
Active constituents	250 g/L saflufenacil, 125 g/L trifludimoxazin
Applicant name	BASF Australia Ltd
Applicant ACN	008 437 867
Date of variation	16 August 2022
Product registration no.	86452
Label approval no.	86452/133082
Description of the application and its purpose, including the intended use of the chemical product	Variation of product registration and label approval for Voraxor Herbicide to add use prior to sowing in oats and triticale and to update the plant back periods

Application no.	130784
Product name	Protek 250 EC Fungicide
Active constituent	250 g/L prothioconazole
Applicant name	Sipcam Pacific Australia Pty Ltd
Applicant ACN	073 176 888
Date of variation	18 August 2022
Product registration no.	88919
Label approval no.	88919/130784
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 control of fungal diseases when applied to cereal crops either alone or in a tank mix with other registered fungicide products

Application no.	136596
Product name	Relyon Pyroxasulfone 480 SC Herbicide
Active constituent	480 g/L pyroxasulfone
Applicant name	Nutrien Ag Solutions Limited
Applicant ACN	008 743 217
Date of variation	17 August 2022
Product registration no.	91000
Label approval no.	91000/136596
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 ‘Relyon Pyrox 480 SC Herbicide’ to ‘Relyon Pyroxasulfone 480 SC Herbicide’

Application no.	135609
Product name	Titan Oxyfluorfen 240 EC Herbicide
Active constituent	240 g/L oxyfluorfen
Applicant name	Titan Ag Pty Ltd
Applicant ACN	122 081 574
Date of variation	19 August 2022
Product registration no.	61537
Label approval no.	61537/135609
Description of the application and its purpose, including the intended use of the chemical product	Variation to registration particulars and particulars of label, to amend restraints and structure of directions for use

Application no.	134489
Product name	Genfarm Acetamiprid 225 Insecticide
Active constituent	225 g/L acetamiprid
Applicant name	Nutrien Ag Solutions Limited
Applicant ACN	008 743 217
Date of variation	19 August 2022
Product registration no.	88016
Label approval no.	88016/134489
Description of the application and its purpose, including the intended use of the chemical product	Variation of product registration and label approval to add use for control of silverleaf whitefly (*Bemisia tabaci biotype b*) in cotton

Application no.	136612
Product name	Nufarm Intervene Fungicide
Active constituent	113 g/kg polyoxin D zinc salt
Applicant name	Kaken Pharmaceutical Co., Ltd.
Applicant ACN	N/A
Date of variation	19 August 2022
Product registration no.	90033
Label approval no.	90033/136612
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 ‘Intervene WG Fungicide’ to ‘Nufarm Intervene Fungicide’

Application no.	134021
Product name	PROCLAIM OPTI Insecticide
Active constituent	44 g/kg emamectin present as emamectin benzoate
Applicant name	Syngenta Australia Pty Ltd
Applicant ACN	002 933 717
Date of variation	22 August 2022
Product registration no.	83844
Label approval no.	83844/134021
Description of the application and its purpose, including the intended use of the chemical product	Variation of product registration and label approval to add control of fall army worm in sweet corn

Application no.	134330
Product name	Terminade Residual Termiticide and Insecticide
Active constituent	100 g/L fipronil
Applicant name	PCT Holdings Pty Ltd
Applicant ACN	099 023 962
Date of variation	22 August 2022
Product registration no.	63502
Label approval no.	63502/134330
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 modify the directions for use and update the label to the current labelling code

Application no.	135694
Product name	Sipcam Echo 900 WDG Fungicide
Active constituent	900 g/kg chlorothalonil
Applicant name	Sipcam Pacific Australia Pty Ltd
Applicant ACN	073 176 888
Date of variation	22 August 2022
Product registration no.	54080
Label approval no.	54080/135694
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 the grazing statements for peanuts, storage, and disposal statement and the first aid instructions and to amend the critical comments for chickpeas and lentils

Application no.	134373
Product name	Genfarm Progen Plant Growth Regulator
Active constituent	100 g/kg prohexadione-calcium
Applicant name	Nutrien Ag Solutions Limited
Applicant ACN	008 743 217
Date of variation	23 August 2022
Product registration no.	91427
Label approval no.	91427/134373
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 cherries to the label

Application no.	135610
Product name	Trio Glyphosate 450 Herbicide
Active constituent	450 g/L glyphosate (present as the isopropylamine salt)
Applicant name	CTS Chemicals Pty. Ltd.
Applicant ACN	605 759 644
Date of variation	24 August 2022
Product registration no.	64397
Label approval no.	64397/135610
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 the product label in line with the current Agricultural Labelling Code

Application no.	135577
Product name	ADAMA Diuron 900 WG Herbicide
Active constituent	900 g/kg diuron
Applicant name	ADAMA Australia Pty Limited
Applicant ACN	050 328 973
Date of variation	24 August 2022
Product registration no.	46812
Label approval no.	46812/135577
Description of the application and its purpose, including the intended use of the chemical product	Variation to registration particulars, particulars of label to vary product registration to add an alternate formulation composition, update the product name, update the active constituent manufacturer details, manufacturing sites and update the product label

Application no.	135832
Product name	Sprayphos 620 Systemic Fungicide
Active constituent	620 g/L phosphorus (phosphonic) acid present as mono (and) di potassium phosphite
Applicant name	Foliar Fertilizers P/L
Applicant ACN	007 974 496
Date of variation	24 August 2022
Product registration no.	59052
Label approval no.	59052/135832
Description of the application and its purpose, including the intended use of the chemical product	Variation of label approval to add a timing restriction for use in grapes ‘DO NOT apply after E-L 33’

Table 3: Label approval – agricultural products

Application no.	135648
Product name	GP Regain 750 WG Herbicide
Active constituent	750 g/kg tebuthiuron
Applicant name	Granular Products Assets Pty Ltd
Applicant ACN	614 694 405
Date of variation	24 August 2022
Product registration no.	85600
Label approval no.	85600/135648
Description of the application and its purpose, including the intended use of the chemical product	Variation to particulars of label to add aerial application in Western Australia

Table 4: Variation of label approval – agricultural products

Application no.	135941
Product name	Phosic 600 Systemic Fungicide
Active constituent	600 g/L phosphorous (phosphonic) acid as mono-di K phosphonate
Applicant name	S.J.B. Ag-Nutri Pty Ltd
Applicant ACN	074 044 947
Date of variation	16 August 2022
Product registration no.	62941
Label approval no.	62941/135941
Description of the application and its purpose, including the intended use of the chemical product	Variation of label approval to add a timing restriction for use in grapes ‘DO NOT apply after E-L 33’

Application no.	135883
Product name	Kenso Agcare Ken-Fos 600 Systemic Fungicide
Active constituent	600 g/L phosphorous acid present as mono-di potassium phosphite
Applicant name	Kenso Corporation (M) SDN. BHD.
Applicant ACN	N/A
Date of variation	18 August 2022
Product registration no.	87962
Label approval no.	87962/135883
Description of the application and its purpose, including the intended use of the chemical product	Variation of label approval to add a timing restriction for use in grapes ‘DO NOT apply after E-L 33’

Application no.	135966
Product name	Aus-Phoz Systemic Fungicide
Active constituent	400 g/L phosphorous (phosphonic) acid present as mono-di potassium phosphite
Applicant name	Australian Agricultural Chemicals Pty Ltd
Applicant ACN	102 001 696
Date of variation	24 August 2022
Product registration no.	57031
Label approval no.	57031/135966
Description of the application and its purpose, including the intended use of the chemical product	Variation of label approval to add a timing restriction for use in grapes ‘DO NOT apply after E-L 33’

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.	134448
Product name	AVET Pentobarbitone Sodium Euthanasia Solution
Active constituent	300 mg/mL pentobarbitone sodium
Applicant name	Avet Health Pty Ltd
Applicant ACN	616 838 101
Date of registration	17 August 2022
Product registration no.	92079
Label approval no.	92079/134448
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 300 mg/mL pentobarbitone sodium solution injectable product for euthanasia in animals

Application no.	132414
Product name	Reflex Duo Combination Pour-On for Cattle
Active constituent/s	200 mg/mL levamisole, 10 mg/mL abamectin
Applicant name	Alleva Animal Health Ltd
Applicant ACN	N/A
Date of registration	17 August 2022
Product registration no.	91495
Label approval no.	91495/132414
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 10 mg/mL abamectin and 200 mg/mL levamisole pour-on product for the treatment and control of roundworms, including macrocyclic lactone or levamisole resistant strains, and external parasites in cattle

Application no.	134746
Product name	Maxicam 20 mg/mL Solution for Injection
Active constituent	20 mg/mL meloxicam
Applicant name	Vetpharm Laboratories IP Pty Ltd
Applicant ACN	654 406 756
Date of registration	19 August 2022
Product registration no.	92177
Label approval no.	92177/134746
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 20 mg/mL meloxicam injectable product as a non-steroidal anti-inflammatory, analgesic and anti-pyretic for use in cattle, sheep, pigs and horses

Application no.	134856
Product name	Elevet+ Cloprostenol Injection for Cattle and Horses
Active constituent	250 μg/mL cloprostenol (as the sodium salt)
Applicant name	Avet Health Pty Ltd
Applicant ACN	616 838 101
Date of registration	19 August 2022
Product registration no.	92214
Label approval no.	92214/134856
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 250 μg/mL cloprostenol (as the sodium salt) injectable product as a luteolytic agent for clinical use and the control of the bovine and equine oestrus cycles

Application no.	135436
Product name	Maxicam 5 mg/mL Solution for Injection
Active constituent	5 mg/mL meloxicam
Applicant name	Vetpharm Laboratories IP Pty Ltd
Applicant ACN	654 406 756
Date of registration	19 August 2022
Product registration no.	92419
Label approval no.	92419/135436
Description of the application and its purpose, including the intended use of the chemical product	Registration and label approval of a 5 mg/mL meloxicam parental solution product for use in acute respiratory infection in combination with appropriate antibiotic therapy to reduce clinical symptoms in calves and young cattle

Application no.	135437
Product name	Maxicam Anti-inflammatory Injectable for Dogs and Cats
Active constituent	5 mg/mL meloxicam
Applicant name	Vetpharm Laboratories IP Pty Ltd
Applicant ACN	654 406 756
Date of registration	19 August 2022
Product registration no.	92420
Label approval no.	92420/135437
Description of the application and its purpose, including the intended use of the chemical product	Registration and label approval of a 5 mg/mL meloxicam parental solution product for the alleviation of inflammation and pain in acute and chronic musculoskeletal disorders and the reduction of post-operative pain and inflammation following orthopaedic and soft tissue surgery in dogs, and reduction of pain after surgery and management of febrile conditions with appropriate antibiotics in cats

Table 6: Variations of registration – veterinary products

Application no.	136431
Product name	AVET Butorphanol Injection
Active constituent	10 mg/ml butorphanol base as butorphanol tartrate
Applicant name	Avet Health Pty Ltd
Applicant ACN	616 838 101
Date of variation	1 August 2022
Product registration no.	91654
Label approval no.	91654/136431
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 ‘Butorphanol Injection’ to ‘AVET Butorphanol Injection’

Application no.	136484
Product name	Cormedin 5 mg Tablets for Dogs
Active constituent	5 mg/tablet pimobendan
Applicant name	Jurox Pty Limited
Applicant ACN	000 932 230
Date of variation	4 August 2022
Product registration no.	83486
Label approval no.	83486/136484
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 remove claim relating to preclinical myxomatous mitral valve disease

Application no.	136485
Product name	Cormedin 2.5 mg Tablets for Dogs
Active constituent	2.5 mg/tablet pimobendan
Applicant name	Jurox Pty Limited
Applicant ACN	000 932 230
Date of variation	4 August 2022
Product registration no.	83489
Label approval no.	83489/136485
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 remove claims relating to preclinical myxomatous mitral valve disease

Application no.	136486
Product name	Cormedin 1.25 mg Tablets for Dogs
Active constituent	1.25 mg/tablet pimobendan
Applicant name	Jurox Pty Limited
Applicant ACN	000 932 230
Date of variation	4 August 2022
Product registration no.	83487
Label approval no.	8348/136486
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 remove claim relating to preclinical myxomatous mitral valve disease

Application no.	136535
Product name	[Wagg & Purr] Atipamezole Injection
Active constituent/s	5 mg/mL atipamezole hydrochloride
Applicant name	Avet Health Pty Ltd
Applicant ACN	616 838 101
Date of variation	9 August 2022
Product registration no.	63527
Label approval no.	63527/136535
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 '[Wagg & Purr] Atipamazole Injection' to '[Wagg & Purr] Atipamezole Injection'

Application no.	135239
Product name	Purified Equine Tetanus Antitoxin 2000 IU/mL
Active constituent	2000 IU/mL equine immunoglobulin protein – equine tetanus antitoxin
Applicant name	Padula Serums Pty Ltd
Applicant ACN	167 348 610
Date of variation	15 August 2022
Product registration no.	83905
Label approval no.	83905/135239
Description of the application and its purpose, including the intended use of the chemical product	Variation to registration particulars, particulars of label and label approval to amend the formulation

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

Application no.	132852
Active constituent	Pyroxasulfone
Applicant name	Shandong Binnong Technology Co Ltd
Applicant ACN	N/A
Date of approval	15 August 2022
Approval no.	91618
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.	132891
Active constituent	Chlorantraniliprole
Applicant name	Zhejiang Hengdian Imp. & Exp. Co., Ltd
Applicant ACN	N/A
Date of approval	16 August 2022
Approval no.	91627
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent chlorantraniliprole for use in agricultural chemical products

Application no.	132798
Active constituent	Pyraclostrobin
Applicant name	Zhejiang Xinan Chemical Industrial Group Co., Ltd
Applicant ACN	N/A
Date of approval	16 August 2022
Approval no.	91602
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent pyraclostrobin for use in agricultural chemical products

Application no.	134078
Active constituent	Prothioconazole
Applicant name	Rudong Zhongyi Chemical Co. Ltd
Applicant ACN	N/A
Date of approval	16 August 2022
Approval no.	91982
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent prothioconazole for use in agricultural chemical products

Application no.	134864
Active constituent	Levamisole
Applicant name	Alleva Animal Health Limited
Applicant ACN	N/A
Date of approval	17 August 2022
Approval no.	92217
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent levamisole for use in veterinary chemical products

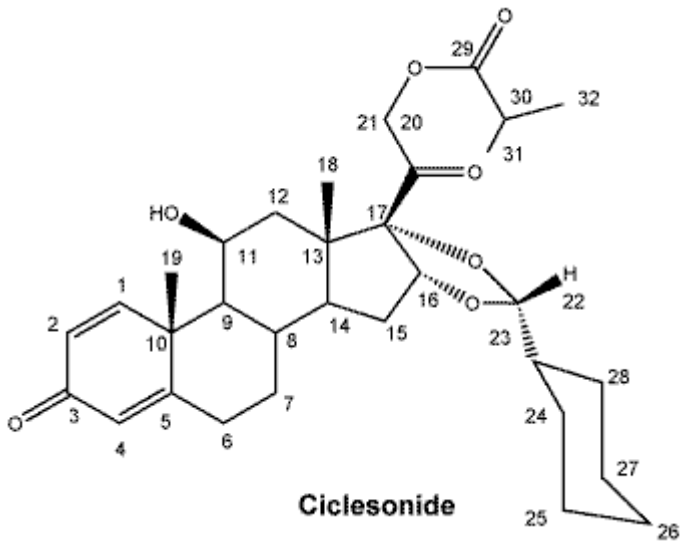
Application no.	134862
Active constituent	Saflufenacil
Applicant name	ADAMA Australia Pty Limited
Applicant ACN	050 328 973
Date of approval	22 August 2022
Approval no.	92216
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent saflufenacil for use in agricultural/veterinary chemical products

Application no.	134849
Active constituent	Emamectin benzoate
Applicant name	Hailir Pesticides and Chemicals Group Co., Ltd
Applicant ACN	N/A
Date of approval	22 August 2022
Approval no.	92212
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent emamectin benzoate for use in agricultural chemical products

New veterinary chemical product: Aservo equihaler containing ciclesonide

The APVMA has before it an application for the approval of a new active constituent ciclesonide, and an application for registration of a new product containing the new active constituent. The product is Aservo EquiHaler for the management of clinical signs associated with moderate to severe equine asthma in horses.

Table 8: Particulars of the active constituent, ciclesonide

Common name	Ciclesonide
IUPAC name	(2′ *R*)-2′ -Cyclohexyl-11β-hydroxy-3,20-dioxo-16β*H*- [1,3]dioxolo[4′ ,5′ :16,17]pregna-1,4-dien-21-yl 2-methylpropanoate
CAS name	[2-[(1S,2S,4R,6R,8S,9S,11S,12S,13R)-6-cyclohexyl-11-hydroxy-9,13-dimethyl-16-oxo-5,7-dioxapentacyclo[10.8.0.02,9.04,8.013,18]icosa-14,17-dien-8-yl]-2-oxoethyl] 2-methylpropanoate
CAS registry number	126544-47-6
Manufacturer's codes	BI 54903 XX B9207-015 CIC EL-876 13009929
Specified purity	98.0 to 102.0% on an anhydrous basis
Molecular formula	$C_{32}H_{44}O_7$
Molecular weight	540.7 g/mol
Structure	
Chemical family	Corticosteroid
Mode of action	Ciclesonide is a pro-drug. Following inhalation, it is converted into the active metabolite, C21-desisobutyryl-ciclesonide (des-ciclesonide), in the airways. Des-ciclesonide has anti-inflammatory properties which are exerted through a wide range of inhibitory activities via binding to the glucocorticoid receptor.

Summary of the APVMA's evaluation of ciclesonide active constituent

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

The APVMA has considered the health aspects of the active constituent. Based on the data supplied, in conjunction with an exposure assessment, the level of human exposure when the associated product (and the inhaler device) is used correctly is expected to be short-term, very low, and well below the human therapeutic dose of 80 to 320 μg/day. Exposure of the general public is not expected.

Ciclesonide is only for use in a non-food producing animal (horse) and the label of the associated product Aservo EquiHaler carries the statement "DO NOT USE in horses that may be used for human consumption", hence establishment of health-based guidance values such as an acceptable daily intake (ADI) or acute reference dose (ARfD) are not required. The APVMA has considered the toxicological aspects of ciclesonide and concluded that there are no toxicological concerns to the approval of this active constituent.

Ciclesonide is listed in Schedule 4 of the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) with no exceptions. This is considered appropriate for this veterinary medication.

The APVMA proposes to be satisfied that the proposed importation and use of ciclesonide 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 product, Aservo EquiHaler

Proposed product name	Aservo EquiHaler
Applicant company	Boehringer Ingelheim Animal Health Australia Pty Ltd
Name of active constituent	Ciclesonide
Signal heading	Schedule 4
Formulation type:	Inhalation solution
Summary of proposed use	For the management of clinical signs associated with moderate to severe equine asthma in horses.
Pack sizes	4.3 mL cartridge (140 actuations)
Withholding period	Not applicable

Summary of proposed product use

Aservo EquiHaler is a 30 mg/mL (343 μg/actuation) ciclesonide inhalation solution for the management of clinical signs associated with moderate to severe equine asthma in horses.

Ciclesonide is a glucocorticoid and a pro-drug, which converts to the active metabolite, desisobutyryl-ciclesonide (des-CIC), following de-esterification in the lung. Des-CIC has anti-inflammatory activity and exhibits a 100-fold

greater binding affinity to the glucocorticoid receptor than ciclesonide and, since activated in the lung, equates to minimal systemic adverse effects.

The product is supplied as a non-pressurised plastic inhaler containing pre-filled aluminium cartridge containing 4.3 mL (140 actuations) product which is sufficient for one course (10 days) of treatment and an additional amount covering priming and potential losses during administration. The cartridge is pre-inserted into the equine inhaler, which is produced for market supply as one entity.

Dosage and administration: For intranasal inhalation only using the equine inhaler device. The number of actuations administered is the same for all horses independent of their bodyweight. The total treatment duration is 10 days.

Treatment days 1 to 5	8 actuations (corresponding to 2,744 μg ciclesonide) administered twice daily approximately 12 hours apart.
Treatment days 6 to 10	12 actuations (corresponding to 4,116 μg ciclesonide) administered once daily approximately 24 hours apart

Side effects: Mild nasal discharge was commonly observed during safety and clinical studies.

A summary of the APVMA's evaluation of Aservo EquiHaler 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 Aservo EquiHaler would not be an undue hazard to the safety of people exposed to it during its handling and use.

The APVMA has conducted a risk assessment for the products and in conjunction with the estimated hazard profile, determined whether the proposed use of the products would not be an undue health hazard to humans.

The APVMA estimated the acute toxicity of Aservo EquiHaler which was ascertained from toxicological studies in laboratory animals using the active constituent and the product formulation in order to establish appropriate safety directions for Aservo EquiHaler. The product is expected to be irritating to the eyes and of low toxicity by other routes. It is expected that horse owners and workers in horse facilities will be the main users of the product, under the supervision of veterinarians. A veterinarian can demonstrate correct use of the product to horse owners, and detailed instructions in the user guide limit incorrect use and inadvertent exposure to the product.

The product is administered intranasally as an aerosol, the main route of accidental/incidental exposure is via inhalation, but dermal and ocular exposure cannot be ruled out. Accidental oral exposure is considered unlikely. During administration of the product, via the inhaler device, it is possible that the adapter could slide out of the nostril if the horse were to move. As the device may no longer be snugly fit into the nostril, an actuation may not be fully delivered into the nasal cavity and be available in the breathing zone of the user. However, if the device were to become dislodged or incorrectly placed, the user should reinsert the nostril adapter before continuing with the administration. An error in administration is less likely to occur with ongoing familiarity with the procedure. Minor dermal exposure may occur when washing the device between each use.

To mitigate the acute and repeat-dose risks associated with Aservo EquiHaler, the APVMA has recommended the first aid statement (a) – If poison occurs, contact a doctor or Poisons Information Centre. Phone Australia 13 11 26.

After consideration of the toxicological profile and likely human exposure associated with the use of Aservo EquiHaler, the APVMA concludes that the following label safety directions are to be included to mitigate the

identified risks: May irritate the eyes. Do not inhale spray mist. Avoid contact with eyes. If product in eyes, wash it out immediately with water. Wash hands after use.

ii. The APVMA is satisfied that the proposed use of Aservo EquiHaler will not be an undue hazard to the safety of people using anything containing its residues.

The product is for use in horses (companion animals) not intended for human consumption. A restraint statement has been included on the label “DO NOT USE in horses that may be used for human consumption”.

iii. The APVMA is satisfied that the proposed use of Aservo EquiHaler containing the active constituent ciclesonide is not likely to be harmful to human beings if used according to the product label directions

Ciclesonide is currently listed in Schedule 4 of the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) with no exceptions. This is considered appropriate for this veterinary medication.

None of the excipients in the formulation are subject to scheduling at the concentration present in the product formulation. Aservo EquiHaler contains a Schedule 4 substance and thereby requires a ‘Prescription Animal Remedy’ signal header on the label.

iv. The APVMA is satisfied that the proposed use of the new product Aservo EquiHaler containing the active constituent ciclesonide, would not be likely to have an unintended effect that is harmful to animals, plants or the environment.

Environment

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.

The environmental assessment ends in Phase I because Aservo EquiHaler will only be used in non-food animals (horses) Therefore, the APVMA is satisfied that the proposed product meets 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.*

Target animal safety

A Target Animal Safety study was performed using 32 horses (16 geldings and 16 mares). They were treated at 1×, 2× or 3× overdose of active for a total of 30 days. The horses remained healthy throughout the study. There were some minor but statistically significant changes in clinical chemistry, haematology and coagulation, plus urine chemistry. However, these were all within the normal reference ranges and were interpreted as not clinically significant. Repeated nasal administration appeared to induce increased nasal discharge, but this also occurred in control animals so appeared related to the presence of fluid in the airways and not active drug or excipients. There was also increased nasal fungi detected, but this appeared to be related to treatment duration and being enclosed in stables for an extended period.

Overall, it was concluded that inhaled ciclesonide administered via a specific equine inhaler up to 3 times the maximum recommended dose for 30 consecutive days is well tolerated.

The safety of the product was also monitored by the applicant in the field efficacy studies. The results indicated that at the proposed label dose rate of 8 actuations twice daily (approximately 12 hours apart) for 5 days, followed by 12 actuations once daily over another 5 days, Aservo EquiHaler is unlikely to cause serious adverse reactions in horses. Appropriate precautions, side effects and contraindication statements are included on the label.

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.

   ii. The efficacy data submitted and assessed included peer-reviewed literature, pharmacodynamic data/studies, pharmacokinetics studies, metabolism studies, dose characteristics studies and confirmatory clinical/field studies.

   Based on the studies, the final proposed dose is 16 actuations per day (administered as 8 actuations twice daily, approximately 12 hours apart) for 5 days, followed by 12 actuations once daily over another 5 days. These doses correspond to approximately 2×2744 μg (5488 μg) and 1×4116 μg ciclesonide, respectively.

   Three studies (one pilot and 2 pivotal trials) were supplied to the APVMA to demonstrate the clinical efficacy and safety of ciclesonide administered via inhalation according to the applied dosing regimen in horses suffering from moderate to severe equine asthma under field conditions over a period of 10 (± 1) days. The sample groups ranged from 70 to 320 horses with a body weight greater than 200 kg. Efficacy parameters included assessment of weighted clinical score and owner assessment (improvement in quality of life). The studies demonstrated that ciclesonide treatment improved the clinical scores relative to both baseline weighted clinical score measurements and placebo over the 10 days (this was significant for the 2 pivotal field trials). Similarly, the owner-assessed quality of life was improved in treated horses compared to placebo. Overall, the results of the studies were supportive of the clinical efficacy and safety of ciclesonide administered via inhalation according to the applied dosing regimen in horses suffering from moderate to severe asthma.

   The APVMA has concluded that the data generated from the efficacy studies support the claim: ‘For the management of clinical signs associated with moderate to severe equine asthma in horses’ when the product is administered according to the proposed dose regime.

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:

   i. The APVMA is satisfied that the proposed use of Aservo EquiHaler would not adversely affect trade between Australia and places outside Australia as the product is intended for use in companion animals (horses) only.

Making a submission

In accordance with sections 12 and 13 of the Agvet Code, the APVMA invites any person to submit a relevant written submission as to whether ciclesonide should be approved and whether the application for registration of the product Aservo EquiHaler should be granted. 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:

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

Email: enquiries@apvma.gov.au

Privacy

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

MIPIC 990 Soil Fumigant containing 990 g/kg iodomethane

The APVMA has before it an application for registration of a new product, MIPIC 990 Soil Fumigant containing the active constituent, iodomethane.

Table 10: Particulars of the application for MIPIC 990 Soil Fumigant

Proposed product name	MIPIC 990 Soil Fumigant
Applicant company	Saluterra Pty Ltd
Name of active constituent	Iodomethane
Signal heading	Schedule 7
Summary of proposed use	For the control of weed seeds, nematodes and soil borne diseases prior to planting strawberry runners
Pack sizes	100 kg
Withholding period	N/A

A summary of the APVMA's evaluation of MIPIC Soil Fumigant 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 MIPIC 990 Soil Fumigant would not be an undue hazard to the safety of people exposed to it during its handling and use.

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

   ii. The APVMA is satisfied that the proposed use of MIPIC 990 Soil Fumigant will not be an undue hazard to the safety of people using anything containing its residues.

   iii. The APVMA is satisfied that the proposed use of the new product MIPIC 990 Soil Fumigant containing the active constituent iodomethane, would not be likely to have an unintended effect that is harmful to animals, plants, or the environment.

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:

   i. The APVMA is considering whether the proposed use of MIPIC 990 Soil Fumigant 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 MIPIC Soil Fumigant 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:

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

Email: enquiries@apvma.gov.au

Privacy

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