

Commonwealth of Australia

Gazette

Agricultural and veterinary chemicals

No. APVMA 16, 9 August 2022

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.

© Commonwealth of Australia 2022

This work is copyright. Apart from any use as permitted under the *Copyright Act 1968*, no part may be reproduced by any process without prior written permission from the Australian Pesticides and Veterinary Medicines Authority (APVMA). Requests and inquiries concerning reproduction and rights should be addressed to:

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

Email: communications@apvma.gov.au

Website: apvma.gov.au

General information

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

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

Distribution and subscription

The APVMA Gazette is published in electronic format only and is available from the APVMA website.

If you would like to subscribe to receive email notification when a new edition is published, please complete a subscription form.

APVMA contacts

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

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

Privacy

For information on how the APVMA manages personal information when you contact us, see our Privacy Policy.

Contents

Agricultural chemical products and approved labels	1
Veterinary chemical products and approved labels	11
Approved active constituents	24
Method 240 SL Herbicide containing aminocyclpyrachlor	28
Licensing of veterinary chemical manufacturers	30
Agvet chemical voluntary recall: Cadence Herbicide	33
List of tables	
Table 1: Agricultural products based on existing active constituents	1
Table 2: Variations of registration	5
Table 3: Veterinary products based on existing active constituents	11
Table 4: Variations of registration	15
Table 5: Active constituent	24
Table 6: Variations of active constituent	27
Table 7: Particulars of the application	28
Table 8: New licences issued by the APVMA under subsection 123(1) of the Agvet Code	30
Table 9: Licences cancelled by the APVMA under subsection 127(1) of the Agvet Code	31
Table 10: Licences suspended by the APVMA under subsection 127(1) of the Agvet Code	32

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.	118693
Product name	XtendiMax Herbicide with VapourGrip Technology
Active constituent	350 g/L dicamba present as the diglycolamine salt
Applicant name	Monsanto Australia Pty Ltd
Applicant ACN	006 725 560
Date of registration	18 July 2022
Product registration no.	87572
Label approval no.	87572/118693
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 350 g/L dicamba (present as the diglycolamine salt) soluble concentrate product for the control of certain broadleaf weeds in winter cereals, conservation tillage, grain sorghum, non-crop areas, pastures, rice, sugarcane and turf

Application no.	130660
Product name	ADAMA Brodifacoum Soft Bait
Active constituent	0.05 g/kg brodifacoum
Applicant name	ADAMA Australia Pty Ltd
Applicant ACN	050 328 973
Date of registration	19 July 2022
Product registration no.	90982
Label approval no.	90982/130660
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 0.05 g/kg brodifacoum ready to use soft bait product for control of rats and mice

Application no.	133597
Product name	SABAKEM Flumioxazin 500WG Herbicide
Active constituent	500 g/kg flumioxazin
Applicant name	Sabakem Pty Ltd
Applicant ACN	151 682 138
Date of registration	19 July 2022
Product registration no.	91827
Label approval no.	91827/133597
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 500 g/kg flumioxazin, water dispersible granule product for rapid knockdown and control of various grass and broadleaf weeds when mixed with certain glyphosate herbicides

Application no.	132096
Product name	Family Protection Aerogard Fabric Insect Repellent Naturals
Active constituents	48 g/L oil of lemon eucalyptus (hydrated, cyclized), 16 g/L eucalyptus oil, 8 g/L pine oil
Applicant name	RB (Hygiene Home) Australia Pty Ltd
Applicant ACN	629 549 506
Date of registration	20 July 2022
Product registration no.	91396
Label approval no.	91396/132096
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 48 g/L oil of lemon eucalyptus (hydrated, cyclised), 16 g/L eucalyptus oil & 8 g/L pine oil, in a ready-to-use liquid trigger spray format as a personal insect repellent for use on fabrics

Application no.	135177
Product name	TALON Rat & Mouse Killer Grain Bait Block
Active constituent	0.05 g/kg brodifacoum
Applicant name	Syngenta Australia Pty Ltd
Applicant ACN	002 933 717
Date of registration	20 July 2022
Product registration no.	92320
Label approval no.	92320/135177
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 0.05 g/kg brodifacoum product to control rodents in and around industrial, commercial, public services, agricultural and domestic buildings

Application no.	121861
Product name	XtendiMax 2 Herbicide with VapourGrip Technology
Active constituent	480 g/L dicamba present as the monoethanolamine salt
Applicant name	Monsanto Australia Pty Ltd
Applicant ACN	006 725 560
Date of registration	21 July 2022
Product registration no.	88630
Label approval no.	88630/121861
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 480 g/L dicamba (present as the monoethanolamine salt) soluble concentrate product for the control of certain broadleaf weeds in winter cereals, conservation tillage, grain sorghum, non-crop areas, pastures, rice, sugarcane and turf

Application no.	135464
Product name	CropSure Siphon 200 Insecticide
Active constituent	200 g/L clothianidin
Applicant name	CropSure Pty Ltd
Applicant ACN	643 829 190
Date of registration	21 July 2022
Product registration no.	92427
Label approval no.	92427/135464
Description of the application and its purpose, including the intended use of the chemical product	For registration of a 200 g/L clothianidin suspension concentrate product for the control of aphids, mirids and other sucking insect pests on cotton; rust thrips and weevil borer on bananas; and soil applied treatment for the control of cane grubs in sugarcane, leaf eating insects in eucalypt seedlings and young trees, and leaf feeding insects in Indian sandalwood and associated host trees

Application no.	135408
Product name	Relyon Triclopyr 755 EC Herbicide
Active constituent	755 g/L triclopyr present as the butoxyethyl ester
Applicant name	Nutrien Ag Solutions Limited
Applicant ACN	008 743 217
Date of registration	21 July 2022
Product registration no.	92408
Label approval no.	92408/135408
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 755 g/L triclopyr emulsifiable concentrate product for the control of a range of woody weeds and melons

Application no.	135287
Product name	Sinon Blast 600 WG Herbicide
Active constituents	468 g/kg diuron, 132 g/kg hexazinone
Applicant name	Sinon Australia Pty Ltd
Applicant ACN	102 741 024
Date of registration	27 July 2022
Product registration no.	92362
Label approval no.	92362/135287
Description of the application and its purpose, including the intended use of the chemical product	Registration of a water dispersible granule formulation of 132 g/kg hexazinone and 468 g/kg diuron for the control of a wide range of annual and perennial grasses, broad leaf weeds and vines in established sugarcane

Application no.	135607
Product name	Ajax 120 Growth Regulator
Active constituent	120 g/L trinexapac-ethyl
Applicant name	Turf Culture Pty Ltd
Applicant ACN	117 986 615
Date of registration	27 July 2022
Product registration no.	92456
Label approval no.	92456/135607
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 120 g/L trinexapac-ethyl micro-emulsion product for the regulation of leaf and stem growth of grass species and as an aid in turf management

Application no.	133377
Product name	4Farmers Basher Herbicide
Active constituent	525 g/L nonanoic acid
Applicant name	4 Farmers Australia Pty Ltd
Applicant ACN	160 092 428
Date of registration	27 July 2022
Product registration no.	91749
Label approval no.	91749/133377
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 525 g/L nonanoic acid, emulsifiable concentrate product for the non-selective control of seedling and young broadleaf and grass weeds, for the suppression of established weeds and perennial species and for the control of moss and algae

Table 2: Variations of registration

Application no.	136041
Product name	Affix 250 SC Fungicide
Active constituent	250 g/L azoxystrobin
Applicant name	UPL Australia Pty Ltd
Applicant ACN	066 391 384
Date of variation	6 July 2022
Product registration no.	66885
Label approval no.	66885/136041
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.	136031
Product name	Unizeb 420 SC Fungicide
Active constituent	420 g/L mancozeb
Applicant name	UPL Australia Pty Ltd
Applicant ACN	066 391 384
Date of variation	6 July 2022
Product registration no.	49487
Label approval no.	49487/136031
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.	136194
Product name	F.S.A. Pyroxasulfone 480 SC Herbicide
Active constituent	480 g/L pyroxasulfone
Applicant name	Four Seasons Agribusiness Pty Ltd
Applicant ACN	115 133 189
Date of variation	14 July 2022
Product registration no.	91154
Label approval no.	91154/136194
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 'F.S.A. Delkura 480 SC Herbicide' to 'F.S.A. Pyroxasulfone 480 SC Herbicide'

Application no.	135340
Product name	Titan Chlorthal 900 WG Pre-Emergence Herbicide
Active constituent	900 g/kg chlorthal dimethyl
Applicant name	Titan Ag Pty Ltd
Applicant ACN	122 081 574
Date of variation	20 July 2022
Product registration no.	88705
Label approval no.	88705/135340
Description of the application and its purpose, including the intended use of the chemical product	Variation of registration and label approval to remove uses in lucerne and perennial grass pasture, and add the restraint "do not graze any treated areas or cut for stock food"

Application no.	132599
Product name	Sledge Herbicide
Active constituent	25 g/L pyraflufen-ethyl
Applicant name	Sipcam Pacific Australia Pty Ltd
Applicant ACN	073 176 888
Date of variation	20 July 2022
Product registration no.	83053
Label approval no.	83053/132599
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 reduce the harvest and grazing withholding period in pulse crops from 14 days to 7 days

Application no.	135664
Product name	AC Discord 750 WG Herbicide
Active constituent	750 g/kg chlorthal dimethyl
Applicant name	Axichem Pty Ltd
Applicant ACN	131 628 594
Date of variation	21 July 2022
Product registration no.	69680
Label approval no.	69680/135664
Description of the application and its purpose, including the intended use of the chemical product	Variation of product registration and label approval to remove uses in lucerne and perennial grass pasture, and to add the grazing restraint "do not graze any treated areas or cut for stock food"

Application no.	135693
Product name	Nufarm Dacthal 900 Pre-Emergence Herbicide
Active constituent	900 g/kg chlorthal dimethyl
Applicant name	Nufarm Australia Limited
Applicant ACN	004 377 780
Date of variation	21 July 2022
Product registration no.	59137
Label approval no.	59137/135693
Description of the application and its purpose, including the intended use of the chemical product	Variation of registration and label approval to remove the uses in lucerne and perennial grass pasture, and to add the restraint "do not graze any treated areas or cut for stock food"

Application no.	135745
Product name	Overwatch eXL Granules Herbicide
Active constituent	750 g/kg bixlozone
Applicant name	FMC Australasia Pty Ltd
Applicant ACN	095 326 891
Date of variation	22 July 2022
Product registration no.	89781
Label approval no.	89781/135745
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 product name from "Overwatch eXL Herbicide" to "Overwatch eXL Granules Herbicide"

Application no.	136337
Product name	Campbell Proplant Fungicides
Active constituent	605 g/L propamocarb present as the monohydrochloride
Applicant name	Arysta Lifescience Benelux Sprl
Applicant ACN	N/A
Date of variation	22 July 2022
Product registration no.	51322
Label approval no.	51322/136337
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.	136338
Product name	Sonic Penetrant Surfactant
Active constituent	1020 g/L polyether modified polysiloxane
Applicant name	Nutrien Ag Solutions Limited
Applicant ACN	008 743 217
Date of variation	22 July 2022
Product registration no.	86472
Label approval no.	86472/136338
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 'Ripple Penetrant Surfactant' to 'Sonic Penetrant Surfactant', and to update the first aid and safety directions to reflect the current FAISD Handbook

Application no.	136340
Product name	Nufarm Weedmaster Duo Herbicide
Active constituent	360 g/L glyphosate (present as the isopropylamine and mono-ammonium salts)
Applicant name	Nufarm Australia Limited
Applicant ACN	004 377 780
Date of variation	22 July 2022
Product registration no.	53576
Label approval no.	53576/136340
Description of the application and its purpose, including the intended use of the chemical product	Variation to the particulars of registration and label approval to change the distinguishing product name and the name that appears on the label from 'Nufarm Weedmaster Duo Dual Salt Technology Herbicide' to 'Nufarm Weedmaster DUO Herbicide'

Application no.	136341
Product name	Nufarm Expand Adjuvant
Active constituent	500 g/L trisiloxane ethoxylate
Applicant name	Nufarm Australia Limited
Applicant ACN	004 377 780
Date of variation	22 July 2022
Product registration no.	90892
Label approval no.	90892/136341
Description of the application and its purpose, including the intended use of the chemical product	Variation to the particulars of registration and label approval to change the distinguishing product name and the name that appears on the label from 'Nufarm Expand Low Volume Application Spreader' to 'Nufarm Expand Adjuvant'

Application no.	135345
Product name	Ezycrop Chlorthal 750 WG Herbicide
Active constituent	750 g/kg chlorthal-dimethyl
Applicant name	Ezycrop Pty Ltd
Applicant ACN	156 476 827
Date of variation	27 July 2022
Product registration no.	69085
Label approval no.	69085/135345
Description of the application and its purpose, including the intended use of the chemical product	Variation of label approval to update the restraints and remove use in perennial grasses and lucerne

Application no.	129281
Product name	Roundup Ready Herbicide with PLANTSHIELD
Active constituent	690 g/kg glyphosate present as the mono-ammonium salt
Applicant name	Monsanto Australia Pty Ltd
Applicant ACN	006 725 560
Date of variation	27 July 2022
Product registration no.	63268
Label approval no.	63268/129281
Description of the application and its purpose, including the intended use of the chemical product	Variation of product registration and label approval to add a tank mix with intervix herbicide for use in truflex-clearfield canola

Application no.	134554
Product name	Venom 240 SC Insecticide
Active constituent	240 g/L bifenthrin
Applicant name	ADAMA Australia Pty Ltd
Applicant ACN	050 328 973
Date of variation	28 July 2022
Product registration no.	81526
Label approval no.	81526/134554
Description of the application and its purpose, including the intended use of the chemical product	Variation of product registration and label approval to add the use in sweet potato, and include an additional pest for sugarcane

	-
Application no.	135291
Product name	Oxstar Herbicide Coated Fertiliser
Active constituent	10 g/kg oxadiazon
Applicant name	Turf Culture Pty Ltd
Applicant ACN	117 986 615
Date of variation	1 August 2022
Product registration no.	83464
Label approval no.	83464/135291
Description of the application and its purpose, including the intended use of the chemical product	Variation to the particulars of registration, label approval and label conditions to include a new label for home garden use

Veterinary chemical products and approved labels

Pursuant to the Agricultural and Veterinary Chemicals Code scheduled to the Agricultural and Veterinary Chemicals Code Act 1994, the APVMA hereby gives notice that it has registered or varied the relevant particulars or conditions of the registration in respect of the following products and has approved the label or varied the relevant particulars or conditions of the approval in respect of the containers for the chemical product, with effect from the dates shown.

Table 3: Veterinary products based on existing active constituents

Application no.	135197
Product name	Elevet+ Tulathromycin Injection
Active constituents	100 mg/mL tulathromycin
Applicant name	Avet Health Pty Ltd
Applicant ACN	616 838 101
Date of registration	18 July 2022
Product registration no.	92332
Label approval no.	92332/135197
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 100 mg/mL tulathromycin injectable product for the treatment of respiratory infections in cattle and pigs

Application no.	134804
Product name	Hip and Joint Meal Topper for Dogs
Active constituents	501.5 mg/g glucosamine as glucosamine sulphate (shellfish origin), 176 mg/g chondrotion as chondrotion sulfate (avian origin)
Applicant name	Mighty Munch Australia Pty Ltd
Applicant ACN	638 574 786
Date of registration	19 July 2022
Product registration no.	92190
Label approval no.	92190/134804
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 501.5 mg/g glucosamine as glucosamine sulphate (shellfish origin) and 176 mg/g chondroitin as chondroitin sulphate (avian origin) in an oral powder, pre-mix powder formulation for the long-term improvement of joint health and function in dogs

Application no.	135224
Product name	Freehold Spot-on for Dogs over 25 kg
Active constituents	100 g/L imidacloprid, 25 g/L moxidectin
Applicant name	Alleva Animal Health Ltd
Applicant ACN	N/A
Date of registration	20 July 2022
Product registration no.	92344
Label approval no.	92344/135224
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 25 g/L moxidectin and 100 g/L imidacloprid spot-on solution product for the treatment of fleas, heartworm and worms in dogs

Application no.	135218
Product name	Freehold Spot-On for Kittens and Small Cats up to 4 kg
Active constituents	100 g/L imidacloprid, 10 g/L moxidectin
Applicant name	Alleva Animal Health Ltd
Applicant ACN	N/A
Date of registration	21 July 2022
Product registration no.	92342
Label approval no.	92342/135218
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 10.0 g/L moxidectin and 100.0 g/L imidacloprid spot-on product for the treatment of fleas, heartworm and worms in kittens and cats

Application no.	131498
Product name	Elanco Bayticol Pour-on for Cattle
Active constituents	10 g/L Flumethrin
Applicant name	Elanco Australasia Pty Ltd
Applicant ACN	076 745 198
Date of registration	22 July 2022
Product registration no.	91246
Label approval no.	91246/131498
Description of the application and its purpose, including the intended use of the chemical product	Registration of a product containing 10 g/L flumethrin for the use as a clearing treatment for synthetic pyrethroid susceptible strains of Cattle Tick (<i>Boophilus microplus</i>) including chlorinated hydrocarbon, organophosphorus, and amidine resistant strains, Paralysis Tick (<i>Ixodes holocyclus</i>) and New Zealand Cattle Tick (<i>Haemaphysalis longicornis</i>) in cattle intended for live export only

Application no.	135216
Product name	Freehold Spot-on for Puppies and Small Dogs up to 4 kg
Active constituents	100 g/L imidacloprid, 25 g/L moxidectin
Applicant name	Alleva Animal Health Ltd
Applicant ACN	N/A
Date of registration	22 July 2022
Product registration no.	92340
Label approval no.	92340/135216
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 25 g/L moxidectin and 100 g/L imidacloprid spot-on solution product for the treatment of fleas, heartworm and worms in dogs

Application no.	135247
Product name	Elevet+ Altrenogest Oral Solution for Pigs
Active constituents	4 mg/mL altrenogest
Applicant name	Avet Health Pty Ltd
Applicant ACN	616 838 101
Date of registration	25 July 2022
Product registration no.	92356
Label approval no.	92356/135247
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 4 mg/mL altrenogest oral solution product for the programming of oestrus in sexually mature gilts and primiparous sows intended for breeding

Application no.	135219
Product name	Freehold Spot-on for Dogs 10-25 kg
Active constituents	100 g/L imidacloprid, 25 g/L moxidectin
Applicant name	Alleva Animal Health Ltd
Applicant ACN	N/A
Date of registration	26 July 2022
Product registration no.	92343
Label approval no.	92343/135219
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 25 g/L moxidectin and 100 g/L imidacloprid spot-on solution product for the treatment of fleas, heartworm and worms in dogs

Application no.	132150
Product name	Intra-Log Injection
Active constituents	6 mg/mL triamcinolone acetonide
Applicant name	Randlab Australia Pty Ltd
Applicant ACN	114 948 837
Date of registration	29 July 2022
Product registration no.	91413
Label approval no.	91413/132150
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 6 mg/mL Triamcinolone acetonide, aqueous suspension injection product for the suppression of inflammation in dermatological disorders and arthritic conditions in dogs, cats and horses

Application no.	132615
Product name	Apoquel 16 mg Chewable Tablets for Dogs
Active constituents	16 mg/tablet oclacitinib (as oclacitinib maleate)
Applicant name	Zoetis Australia Pty Ltd
Applicant ACN	156 476 425
Date of registration	29 July 2022
Product registration no.	91547
Label approval no.	91547/132615
Description of the application and its purpose, including the intended use of the chemical product	Registration of a chewable tablet containing 16 mg/ tablet oclacitinib (as oclacitinib maleate) for the treatment of pruritus associated with allergic dermatitis and clinical manifestations of atopic dermatitis in dogs

Application no.	132658
Product name	Apoquel 5.4 mg Chewable Tablets for Dogs
Active constituents	5.4 mg/tablet oclacitinib (as oclacitinib maleate)
Applicant name	Zoetis Australia Pty Ltd
Applicant ACN	156 476 425
Date of registration	29 July 2022
Product registration no.	91561
Label approval no.	91561/132658
Description of the application and its purpose, including the intended use of the chemical product	Registration of a chewable tablet containing 5.4 mg/ tablet oclacitinib (as oclacitinib maleate) for the treatment of pruritus associated with allergic dermatitis and clinical manifestations of atopic dermatitis in dogs

Application no.	132672
Product name	Apoquel 3.6 mg Chewable Tablets for Dogs
Active constituents	3.6 mg/tablet oclacitinib (as oclacitinib maleate)
Applicant name	Zoetis Australia Pty Ltd
Applicant ACN	156 476 425
Date of registration	29 July 2022
Product registration no.	91568
Label approval no.	91568/132672
Description of the application and its purpose, including the intended use of the chemical product	Registration of a chewable tablet containing 3.6 mg/ tablet oclacitinib (as oclacitinib maleate) for the treatment of pruritus associated with allergic dermatitis and clinical manifestations of atopic dermatitis in dogs

Table 4: Variations of registration

Application no.	136056
Product name	The Hunter River Co. Vitamin ADE Injection for Cattle, Sheep & Pigs
Active constituents	500,000 IU/mL retinol palmitate (vitamin A), 50,000 IU/mL cholecalciferol (vitamin D3), 50 mg/mL alpha tocopherol acetate (vitamin E)
Applicant name	The Hunter River Company Pty Ltd
Applicant ACN	133 798 615
Date of registration	6 July 2022
Product registration no.	92232
Label approval no.	92232/136056
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 'HRC Vitamin ADE for Cattle, Sheep & Pigs' to 'The Hunter River Co. Vitamin ADE Injection for Cattle, Sheep & Pigs'

Application no.	136155
Product name	AVET Diazepam Injection
Active constituents	5 mg/mL diazepam
Applicant name	Avet Health Pty Ltd
Applicant ACN	616 838 101
Date of registration	11 July 2022
Product registration no.	92299
Label approval no.	92299/136155
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] Diazepam Injection' to 'AVET Diazepam Injection'

Application no.	136179
Product name	Amoxyclav Flavoured 500 mg Tablets for Dogs and Cats
Active constituents	400 mg/tablet amoxicillin (as amoxicillin trihydrate), 100 mg/tablet clavulanic acid (as potassium salt)
Applicant name	Dechra Veterinary Products (Australia) Pty Ltd
Applicant ACN	614 716 700
Date of registration	13 July 2022
Product registration no.	89210
Label approval no.	89210/136179
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 'Amoxyclav 500 mg Flavoured Tablets for Dogs and Cats' to 'Amoxyclav Flavoured 500 mg Tablets for Dogs and Cats'

Application no.	136181
Product name	Amoxyclav Flavoured 250 mg Tablets for Dogs and Cats
Active constituents	200 mg/tablet amoxicillin trihydrate, 50 mg/tablet clavulanic acid (as potassium salt)
Applicant name	Dechra Veterinary Products (Australia) Pty Ltd
Applicant ACN	614 716 700
Date of registration	13 July 2022
Product registration no.	89054
Label approval no.	89054/136181
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 'Amoxyclav 250 mg Flavoured Tablets for Dogs and Cats' to 'Amoxyclav Flavoured 250 mg Tablets for Dogs and Cats'

Application no.	136301
Product name	Icon Pour-on Ivermectin Endectocide for Cattle
Active constituents	10 mg/mL ivermectin
Applicant name	Alleva Animal Health Ltd
Applicant ACN	N/A
Date of registration	18 July 2022
Product registration no.	92264
Label approval no.	92264/136301
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 'Reflex Pour-On Ivermectin Endectocide for Cattle' to 'Icon Pour-On Ivermectin Endectocide for Cattle'

Application no.	136302
Product name	Neovemox Plus Tape Long Acting Horse Wormer & Boticide Gel
Active constituents	125 mg/g praziquantel, 20 mg/g moxidectin
Applicant name	Neove Pharma Australia Pty Ltd
Applicant ACN	140 367 442
Date of registration	18 July 2022
Product registration no.	87981
Label approval no.	87981/136302
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 'Neovest Plus Tape Long Acting Horse Wormer & Boticide Gel' to 'Neovemox Plus Tape Long Acting Horse Wormer & Boticide Gel'

Application no.	134116
Product name	Dermcare Barazone 0.25 g/L Budesonide Leave-On Conditioner
Active constituents	0.25 g/L budesonide
Applicant name	Dermcare-Vet Pty Ltd
Applicant ACN	010 280 010
Date of registration	19 July 2022
Product registration no.	82108
Label approval no.	82108/134116
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 updating the user instructions on the label

Application no.	135203
Product name	Metacam 40 mg/mL Solution for Injection
Active constituents	40 mg/mL meloxicam
Applicant name	Boehringer Ingelheim Animal Health Australia Pty Ltd
Applicant ACN	071 187 285
Date of registration	19 July 2022
Product registration no.	85634
Label approval no.	85634/135203
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 approval by amending the signal headings, contraindications, precautions, side effects, safety directions, first aid instructions and additional user safety sections of the label and adding pack sizes

Application no.	135205
Product name	Metacam 15 mg/mL Oral Suspension for Horses
Active constituents	15 mg/mL meloxicam
Applicant name	Boehringer Ingelheim Animal Health Australia Pty Ltd
Applicant ACN	071 187 285
Date of registration	19 July 2022
Product registration no.	63170
Label approval no.	63170/135205
Description of the application and its purpose, including the intended use of the chemical product	Variation of relevant particulars of product registration and label approval by amending the signal headings, safety directions, first aid instructions and additional user safety sections of the label and align the label with the Veterinary Labelling Code

Application no.	135209
Product name	Metacam 20 mg/mL Solution for Injection
Active constituents	20 mg/mL meloxicam
Applicant name	Boehringer Ingelheim Animal Health Australia Pty Ltd
Applicant ACN	071 187 285
Date of registration	20 July 2022
Product registration no.	54061
Label approval no.	54061/135209
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 approval by amending the signal headings, contraindications, precautions, side effects, safety directions, first aid instructions and additional user safety sections of the label

Application no.	135211
Product name	Metacam 1 mg Chewable Tablets for Dogs
Active constituents	1 mg/tablet meloxicam
Applicant name	Boehringer Ingelheim Animal Health Australia Pty Ltd
Applicant ACN	071 187 285
Date of registration	20 July 2022
Product registration no.	60535
Label approval no.	60535/135211
Description of the application and its purpose, including the intended use of the chemical product	Variation of relevant particulars of product registration and label approval to amend the contraindications, precautions and side effects sections of the label and align the label with the Veterinary Labelling Code

Application no.	135212
Product name	Metacam 2.5 mg Chewable Tablets for Dogs
Active constituents	2.5 mg/tablet meloxicam
Applicant name	Boehringer Ingelheim Animal Health Australia Pty Ltd
Applicant ACN	071 187 285
Date of registration	20 July 2022
Product registration no.	60536
Label approval no.	60536/135212
Description of the application and its purpose, including the intended use of the chemical product	Variation of relevant particulars of product registration and label approval to amend the contraindications, precautions and side effects sections of the label and align the label with the Veterinary Labelling Code

Application no.	135215
Product name	Metacam Anti-inflammatory Oral Suspension for Dogs
Active constituents	1.5 mg/mL meloxicam
Applicant name	Boehringer Ingelheim Animal Health Australia Pty Ltd
Applicant ACN	071 187 285
Date of registration	20 July 2022
Product registration no.	49655
Label approval no.	49655/135215
Description of the application and its purpose, including the intended use of the chemical product	Variation of relevant particulars of the product and label to amend the signal headings, contraindications, precautions, side effects, safety directions, first aid instructions and additional user safety sections of the label and align the label with the Veterinary Labelling Code

Application no.	135228
Product name	Metacam Anti-inflammatory Injectable for Dogs and Cats
Active constituents	5 mg/mL meloxicam
Applicant name	Boehringer Ingelheim Animal Health Australia Pty Ltd
Applicant ACN	071 187 285
Date of registration	20 July 2022
Product registration no.	55529
Label approval no.	55529/135228
Description of the application and its purpose, including the intended use of the chemical product	Variation of relevant particulars of product registration and label approval by amending the precautions, signal headings, safety directions, first aid instructions and additional user safety sections of the label and align the label with the Veterinary Labelling Code

Application no.	135229
Product name	Metacam 0.5 mg/mL Oral Suspension for Cats
Active constituents	0.5 mg/mL meloxicam
Applicant name	Boehringer Ingelheim Animal Health Australia Pty Ltd
Applicant ACN	071 187 285
Date of registration	20 July 2022
Product registration no.	61575
Label approval no.	61575/135229
Description of the application and its purpose, including the intended use of the chemical product	Variation of relevant particulars of product registration and label approval to amend the precautions, signal headings, safety directions, first aid instructions and additional user safety sections of the label and align the label with the Veterinary Labelling Code

Application no.	135073
Product name	Baymec LV Pour-on Broad Spectrum Endectocide for Dairy and Beef Cattle
Active constituents	10 mg/mL ivermectin
Applicant name	Elanco Australasia Pty Ltd
Applicant ACN	076 745 198
Date of registration	22 July 2022
Product registration no.	64610
Label approval no.	64610/135073
Description of the application and its purpose, including the intended use of the chemical product	Variation to the particulars of registration, and variation of the labelling particulars including updating the name of the Australian cattle tick

Application no.	135077
Product name	Vet's Choice Ivermectin Pour On for Cattle
Active constituents	10 mg/mL ivermectin
Applicant name	Elanco Australasia Pty Ltd
Applicant ACN	076 745 198
Date of registration	22 July 2022
Product registration no.	61297
Label approval no.	61297/135077
Description of the application and its purpose, including the intended use of the chemical product	Variation to the particulars of registration, and variation of the labelling particulars including updating the name of the Australian cattle tick

Application no.	133649
Product name	Apex Doxy 100 Paste
Active constituents	100 mg/g doxycycline as doxycycline monohydrate
Applicant name	Dechra Veterinary Products (Australia) Pty Ltd
Applicant ACN	614 716 700
Date of registration	25 July 2022
Product registration no.	70121
Label approval no.	70121/133649
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 storage conditions

Application no.	133077
Product name	Seresto for Dogs >8 kg Fleas & Ticks Collar
Active constituents	100 mg/g imidacloprid, 45 mg/g flumethrin
Applicant name	Elanco Australasia Pty Ltd
Applicant ACN	076 745 198
Date of registration	26 July 2022
Product registration no.	65875
Label approval no.	65875/133077
Description of the application and its purpose, including the intended use of the chemical product	Variation to the relevant particulars of product registration and label approval by extending claims to include control of paralysis tick from 4 to 8 months and control of flea tapeworm

Application no.	133078
Product name	Seresto for Dogs and Puppies ≤8 kg Fleas & Ticks Collar
Active constituents	100 mg/g imidacloprid, 45 mg/g flumethrin
Applicant name	Elanco Australasia Pty Ltd
Applicant ACN	076 745 198
Date of registration	26 July 2022
Product registration no.	66209
Label approval no.	66209/133078
Description of the application and its purpose, including the intended use of the chemical product	Variation to the relevant particulars of product registration and label approval by extending claims to include control of paralysis tick from 4 to 8 months and control of flea tapeworm

Application no.	135022
Product name	Bayticol Cattle Dip and Spray
Active constituents	75 g/L flumethrin
Applicant name	Elanco Australasia Pty Ltd
Applicant ACN	076 745 198
Date of registration	26 July 2022
Product registration no.	41037
Label approval no.	41037/135022
Description of the application and its purpose, including the intended use of the chemical product	Variation to the particulars of registration, and variation of the labelling particulars including updating the name of the Australian cattle tick

Application no.	135025
Product name	Baymec Pour-On for Cattle
Active constituents	5 g/L ivermectin
Applicant name	Elanco Australasia Pty Ltd
Applicant ACN	076 745 198
Date of registration	26 July 2022
Product registration no.	51138
Label approval no.	51138/135025
Description of the application and its purpose, including the intended use of the chemical product	Variation to the particulars of registration, and variation of the labelling particulars including updating the name of the Australian cattle tick

Application no.	135026
Product name	Bomectin Antiparasitic Injection for Cattle and Pigs
Active constituents	10 mg/mL ivermectin
Applicant name	Elanco Australasia Pty Ltd
Applicant ACN	076 745 198
Date of registration	27 July 2022
Product registration no.	56846
Label approval no.	56846/135026
Description of the application and its purpose, including the intended use of the chemical product	Variation to the particulars of registration, and variation of the labelling particulars including updating the name of the Australian cattle tick

Application no.	135027
Product name	Bomectin F Broad-spectrum Antiparasitic Injection for Cattle
Active constituents	100 mg/mL clorsulon, 10 mg/mL ivermectin
Applicant name	Elanco Australasia Pty Ltd
Applicant ACN	076 745 198
Date of registration	27 July 2022
Product registration no.	62967
Label approval no.	62967/135027
Description of the application and its purpose, including the intended use of the chemical product	Variation to the particulars of registration, and variation of the labelling particulars including updating the name of the Australian cattle tick

Application no.	135028
Product name	Baymec Gold Injection Broad Spectrum Endectocide for Dairy and Beef Cattle
Active constituents	100 mg/mL clorsulon, 10 mg/mL ivermectin
Applicant name	Elanco Australasia Pty Ltd
Applicant ACN	076 745 198
Date of registration	27 July 2022
Product registration no.	64596
Label approval no.	64596/135028
Description of the application and its purpose, including the intended use of the chemical product	Variation to the particulars of registration, and variation of the labelling particulars including updating the name of the Australian cattle tick

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 5: Active constituent

Application no.	132182
Active constituent	Flumetsulam
Applicant name	Trustchem Co Ltd
Applicant ACN	N/A
Date of approval	18 July 2022
Approval no.	91421
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent flumetsulam for use in agricultural chemical products

Application no.	134473
Active constituent/s	Xylazine Hydrochloride
Applicant name	Avet Health Pty Ltd
Applicant ACN	616 838 101
Date of approval	18 July 2022
Approval no.	92086
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent xylazine hydrochloride for use in veterinary chemical products

Application no.	132544
Active constituent/s	Pinoxaden
Applicant name	Foison Scitech Co Limited
Applicant ACN	N/A
Date of approval	20 July 2022
Approval no.	91535
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent pinoxaden for use in agricultural chemical products

Application no.	132502
Active constituent/s	Sarolaner
Applicant name	Zoetis Australia Pty Ltd
Applicant ACN	156 476 425
Date of approval	25 July 2022
Approval no.	91520
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent sarolaner for use in veterinary chemical products

Application no.	134163
Active constituent/s	Chlortetracycline hydrochloride
Applicant name	CCD Animal Health Pty Ltd
Applicant ACN	151 737 950
Date of approval	25 July 2022
Approval no.	92013
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent chlortetracycline hydrochloride for use in veterinary chemical products

Application no.	134580
Active constituent/s	Gonadorelin acetate
Applicant name	Avet Health Pty Ltd
Applicant ACN	616 838 101
Date of approval	25 July 2022
Approval no.	92126
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent gonadorelin acetate for use in veterinary chemical products

Application no.	134719
Active constituent/s	Trimethoprim
Applicant name	Abbey Laboratories Pty Ltd
Applicant ACN	156 000 430
Date of approval	25 July 2022
Approval no.	92161
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent trimethoprim for use in veterinary chemical products

Application no.	134092
Active constituent	Fluroxypyr-meptyl
Applicant name	Jiangsu FMZ Agrochemical Co Ltd
Applicant ACN	N/A
Date of approval	28 July 2022
Approval no.	91987
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent fluroxypyr-meptyl for use in agricultural chemical products

Application no.	133053
Active constituent/s	Triamcinolone acetonide
Applicant name	Randlab Australia Pty Ltd
Applicant ACN	114 948 837
Date of approval	29 July 2022
Approval no.	91664
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent triamcinolone acetonide for use in veterinary chemical products

Table 6: Variations of active constituent

Application no.	134356
Active constituent/s	Cod liver oil
Applicant name	Troy Laboratories Pty Ltd
Applicant ACN	000 283 769
Date of variation	25 July 2022
Approval no.	86088
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.	134370
Active constituent/s	Selenium
Applicant name	Intervet Australia Pty Ltd
Applicant ACN	008 467 034
Date of variation	26 July 2022
Approval no.	85569
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

Method 240 SL Herbicide containing aminocyclpyrachlor

The APVMA has before it an application for registration of a new product, Method 240 SL Herbicide, containing the active constituent, aminocyclpyrachlor

Table 7: Particulars of the application

Proposed product name	Method 240 SL Herbicide			
Applicant company	Bayer CropScience Pty Ltd			
Name of active constituent	Aminocyclopyrachlor			
Signal heading	Unscheduled			
Summary of proposed use	Registration of a 240 g/L aminocyclopyrachlor soluble concentrate product for control of woody weeds and broadleaf weeds in various situations including native conservation area pastoral grazing land and industrial sites such as railways, roadways, and utility rights-of-w			
Pack sizes	100 mL to 1000 L			
Withholding period	WITHHOLDING PERIOD Grazing: Nil EXPORT SLAUGHTER INTERVAL (ESI) 12 days. Livestock that has been grazed on or fed treated crops should be placed on clean feed for 12 days prior to slaughter.			

A summary of the APVMA's evaluation of Method 240 SL Herbicide 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 Method 240 SL Herbicide would not be an undue hazard to the safety of people exposed to them during their 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 Method 240 SL Herbicide will not be an undue hazard to the safety of people using anything containing its residues.
- 2) The APVMA is satisfied that the proposed use of Method 240 SL Herbicide is not likely to have an unintended effect that is harmful to animals, plants or the environment if used according to the product label 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:
 - 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 Method 240 SL Herbicide 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 <u>APVMA website</u> 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 Method 240 SL Herbicide 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 <u>public submission coversheet</u>).

Please lodge your submission with a <u>public submission coversheet</u>, which provides options for how your submission will be published.

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

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: casemanagement@apvma.gov.au

Privacy

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

Licensing of veterinary chemical manufacturers

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

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

New licences

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

Table 8: New licences issued by the APVMA under subsection 123(1) of the Agvet Code

Company name	Licence number	Company ACN	Address	Product types	Steps of manufacture	Date issued
Eurofins Agroscience Testing Pty Ltd	6238	094 752 959	1st Floor 179 Magowar Road Girraween NSW 2145	Category 6 (Single-step manufacture) – all dosage forms, unless otherwise specified	Analysis and testing (Chemical)	28 June 2022
Eurofins AMS Laboratories Pty Ltd	6241	075 467 757	179 Magowar Road Girraween NSW 2145	Category 6 (Single-step manufacture) – all dosage forms, unless otherwise specified	Analysis and testing (antibiotic bioassay, microbiological, chemical, physical, sterility and endotoxin).	28 June 2022
Probiotec Pharma Pty Ltd	2268	076 755 354	83 Cherry Lane Laverton North VIC 3026	Category 2 (Non-sterile veterinary preparations other than ectoparasiticides, premixes and supplements) – Capsules, Tablets, Pellets, Liquids, Creams/Lotions, Ointment, Gels, Pastes, Powders, Granules, Sprays, Suspensions Category 3 (Ectoparasiticides) – Powders, Pastes, Liquids, Sprays Category 4 (Premixes and supplements) – Premix, Supplements, Probiotics	Quality assurance (QA) of raw materials, Formulation including blending, Dry milling, Wet milling, Granulation, Filling, Tableting, Tablet coating, Capsule filling from bulk, Analysis and testing (Physical and Chemical), Packaging (including sachet and blister packaging), Labelling, Storage and Release for supply.	13 July 2022

^{*}Category 1: Immunobiologicals and sterile veterinary preparations

Category 2: Non-sterile veterinary preparations other than ectoparasiticides, premixes and supplements

Category 3: Ectoparasiticides

Category 4: Premixes and supplements

Category 5: Exempt

Category 6: Single-step manufacturer

Company name	Licence number	Company ACN	Address	Product types	Steps of manufacture	Date issued
Bioproperties Pty Ltd	1061	007 303 728	11–15 Moores Road Glenorie NSW 2157	Category 1 (Immunobiologicals and sterile products) – Immunobiologicals, sterile diluent	Quality assurance (QA) of raw materials, management of donor animals, virus cultivation, mycoplasma cultivation, bacterial fermentation, oocyst antigen production, oocyst processing, formulation including blending, aseptic filling, filling, packaging, labelling, microbiological reduction treatment (heat, chemical, filtration), sterilisation (heat, chemical, filtration), freeze-drying, analysis and testing (physical, immunobiological, microbiological, oocyst counts), storage and release for supply.	13 July 2022
Sypharma Pty Ltd	1082	114 895 064	27 Healey Road Dandenong VIC 3175	Category 1 (Immunobiologicals and sterile veterinary preparations) — Sterile products. Category 2 (Non-sterile veterinary preparations other than ectoparasiticides, premixes and supplements) — Creams/lotions, ointments, pastes, powders, and liquids.	Quality assurance (QA) of raw materials, formulation including blending, filling, wet milling, packaging, labelling, repackaging, relabelling, microbiological reduction treatment (filtration and heat), sterilisation (heat), analysis and testing (physical, chemical, microbiological, endotoxin and sterility testing), storage, release from manufacture only (partial release) and release for supply.	20 July 2022

Licence cancellations

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

Table 9: Licences cancelled by the APVMA under subsection 127(1) of the Agvet Code

Company name	Licence number	Company ACN	Address	Date cancelled
Aegros Pharma Pty Ltd (formerly Contract Pharmaceutical Services of Australia Pty Ltd)	6113	003 131 548	5 Eden Park Drive North Ryde NSW 2113	16 June 2022

Category 2: Non-sterile veterinary preparations other than ectoparasiticides, premixes and supplements

Category 3: Ectoparasiticides

Category 4: Premixes and supplements

Category 6: Single-step manufacturer

^{*}Category 1: Immunobiologicals and sterile veterinary preparations

Company name	Licence number	Company ACN	Address	Date cancelled
Australian Animal Blood Bank Pty Ltd	1101	140 128 990	50 Wills Road Long Point NSW 2564	27 June 2022
DHL Supply Chain (Australia) Pty Ltd	6215	017 798 617	180 Parkwest Drive Derrimut VIC 3030	27 June 2022
Eurofins Agroscience Testing Pty Ltd	6200	094 725 959	Unit F6, Building F 16 Mars Road Lane Cove West NSW 2066	30 June 2022

Licence suspensions

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

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

Company name	Licence number	Company ABN	Address	Period of suspension
The commonwealth of Australia acting through the Commonwealth Scientific & Industrial Research Organisation (CSIRO)	1110	41 687 119 230	CSIRO Manufacturing CSIRO Tissue Culture Facility Building 205B Bayview Avenue Clayton VIC 3168	27 June 2022 to 26 June 2023

APVMA contact

Manufacturing Quality and Licensing Australian Pesticides and Veterinary Medicines Authority GPO Box 3262 Sydney NSW 2001

Phone: +61 2 6770 2301 **Email**: mls@apvma.gov.au

^{*}Category 1: Immunobiologicals and sterile veterinary preparations

Category 2: Non-sterile veterinary preparations other than ectoparasiticides, premixes and supplements

Category 3: Ectoparasiticides

Category 4: Premixes and supplements

Category 5: Exempt

Category 6: Single-step manufacturer

Agvet chemical voluntary recall: Cadence Herbicide

Product name: Cadence Herbicide

APVMA registration number: 88627

APVMA approved label number: 121858

Batch number(s): EUM0J001, EUM0K001, EUM0L001, EUM1A001, EUM1B3678, EUM1C3496, EUM2B001,

EUM2C002

Sold by: agricultural retailers in New South Wales, Queensland, Victoria, South Australia and Western Australia between October 2020 and July 2022.

On 28 July 2022, Syngenta Australia Pty Ltd, ACN 002 933 717 initiated a voluntary recall under section 106 of the Agricultural and Veterinary Chemicals Code scheduled to the Agricultural and Veterinary Chemicals Code Act 1994 (Cth) in relation to the chemical product described above.

Reason for voluntary recall

When CADENCE® Herbicide (batch numbers EUM0J001, EUM0K001, EUM0L001, EUM1A001, EUM1B3678, EUM1C3496, EUM2B001, EUM2C002) is stored for an extended period, moisture condensation can cause the product granules to stick together resulting in solid lumps of product forming that are difficult to remove from the container. No other batches are affected.

Hazard

When solid lumps form in the container this will prevent normal preparation and use of the product. If used, the affected product may not disperse readily in the spray tank causing nozzle blockages in spray application equipment and poor efficacy.

What to do if in possession of this chemical product

DO NOT use the product if the batch number is EUM0J001, EUM0K001, EUM0L001, EUM1A001, EUM1B3678, EUM1C3496, EUM2B001 or EUM2C002. Return unopened or partially used containers of CADENCE® Herbicide from this batch to the retail outlet where purchased for a full refund.

Agvet chemical voluntary recall: Cadence Herbicide

More information

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

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

Contact

Questions about this voluntary recall should be directed to:

Syngenta Customer Service **Phone:** +1800 022 035