

Commonwealth of Australia

Gazette

Agricultural and veterinary chemicals

No. APVMA 23, 12 November 2024

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 2024

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 574
Canberra ACT 2601

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	12
Approved active constituents	16
Licensing of veterinary chemical manufacturers	20
Amendments to the APVMA MRL Standard	22
Proposal to amend Schedule 20 in the Australian New Zealand Food Standards Code	23
Agvet chemical voluntary recall: Exebarb euthanasia injection	27
Agyet chemical voluntary recall: ilium Meloxicam Anti-Inflammatory Oral Suspension for Dogs – 30 ml nack size	28

Agricultural chemical products and approved labels

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

Table 1: Agricultural products based on new active constituents

Application no.	132224
Product name	Trefinti Turf Nematicide
Active constituent	450 g/L cyclobutrifluram
Applicant name	Syngenta Australia Pty Ltd
Applicant ACN	002 933 717
Date of registration	22 October 2024
Product registration no.	91438
Label approval no.	91438/132224
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 450 g/L cyclobutrifluram suspension concentrate for control of pathogenic nematodes in turf

Table 2: Agricultural products based on existing active constituents

Application no.	144775
Product name	Agro-Essence Carfentrazone 240 EC Herbicide
Active constituent	240 g/L carfentrazone - ethyl
Applicant name	Agro-Alliance (Australia) Pty Ltd
Applicant ACN	130 864 603
Date of registration	21 October 2024
Product registration no.	95135
Label approval no.	95135/144775
Description of the application and its purpose, including the intended use of the chemical product	Registration of a carfentrazone-ethyl 240 g/L emulsifiable concentrate product for the improvement in the control of marshmallow and certain other broadleaf weeds

Application no.	144761
Product name	TITAN Flumioxazin 500 S7 Herbicide
Active constituent	500 g/kg flumioxazin
Applicant name	Titan Ag Pty Ltd
Applicant ACN	122 081 574
Date of registration	22 October 2024
Product registration no.	95126
Label approval no.	95126/144761
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 (WG) product for rapid knockdown and control of various grass and broadleaved weeds when mixed with certain glyphosate herbicides

Application no.	144820
Product name	eChem Meso Herbicide
Active constituents	90 g/L mefenpyr-diethyl, 30 g/L mesosulfuron-methyl
Applicant name	eChem (Aust) Pty Ltd
Applicant ACN	089 133 095
Date of registration	22 October 2024
Product registration no.	95152
Label approval no.	95152/144820
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 30 g/L mesosulfuron-methyl and 90 g/L mefenpyr-diethyl oil-based suspension concentrates (OD) product for the post-emergent control of wild oats and annual <i>Phalaris</i> , and suppression of brome grass, barley grass and annual ryegrass in wheat

Application no.	144821
Product name	Smart Prothio 480 Fungicide
Active constituent	480 g/L prothioconazole
Applicant name	Crop Smart Pty Ltd
Applicant ACN	093 927 961
Date of registration	24 October 2024
Product registration no.	95153
Label approval no.	95153/144821
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 480 g/L suspension concentrate formulation of prothioconazole for the control of various diseases in cereals and canola

Application no.	144558
Product name	Flowerking Plant Growth Regulator
Active constituent	520 g/L cyanamide
Applicant name	Shaanxi Pendelv Biotechnology Co Ltd
Applicant ACN	N/A
Date of registration	24 October 2024
Product registration no.	95050
Label approval no.	95050/144558
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 520 g/L cyanamide soluble concentrate (SL) product for the regulation of bud break in apples, grapes, kiwi fruit and plums

Application no.	144840
Product name	Estate Herbicide
Active constituents	300 g/L MCPA present as the potassium salt, 20 g/L clopyralid present as the potassium salt, 15 g/L diflufenican
Applicant name	Syngenta Australia Pty Ltd
Applicant ACN	002 933 717
Date of registration	24 October 2024
Product registration no.	95166
Label approval no.	95166/144840
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 300 g/L MCPA, 20 g/L clopyralid and 15 g/L diflufenican suspension concentrate product for the control of certain broadleaf weeds in turf

Application no.	144597
Product name	CropSure Imi-duo Herbicide
Active constituents	33 g/L imazamox present as the ammonium salt, 15 g/L imazapyr present as the ammonium salt
Applicant name	CropSure Pty Ltd
Applicant ACN	643 829 190
Date of registration	25 October 2024
Product registration no.	95077
Label approval no.	95077/144597
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 33 g/L imazamox present as the ammonium salt and 15 g/L imazapyr present as the ammonium salt, soluble concentrate product for the early post-emergence control of certain annual grass and broadleaf weeds in imidazolinone herbicide tolerant wheat, barley and canola

Application no.	144827
Product name	Conquest Atomic 200 Selective Herbicide
Active constituent	200 g/L quizalofop-P-ethyl
Applicant name	Conquest Crop Protection Pty Ltd
Applicant ACN	098 814 932
Date of registration	28 October 2024
Product registration no.	95157
Label approval no.	95157/144827
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 200 g/L formulation of quizalofop-P-ethyl for the control of certain grass weeds in broadleaf crops

Application no.	142913
Product name	Yates Weed 'n' Feed Weed Killer & Lawn Fertiliser
Active constituents	85.6 g/L MCPA, as the dimethylamine salt, 13.1 g/L dicamba, as the dimethylamine salt
Applicant name	DuluxGroup (Australia) Pty Ltd
Applicant ACN	000 049 427
Date of registration	28 October 2024
Product registration no.	94599
Label approval no.	94599/142913
Description of the application and its purpose, including the intended use of the chemical product	Registration of an 85.6 g/L MCPA, present as the dimethylamine salt and 13.1 g/L dicamba, present as the dimethylamine salt for use in lawns to control bindii, clover & common broadleaf weeds

Table 3: Variations of registration – agricultural chemical products

Application no.	145725
Product name	Guardian Baysol Snail & Slug Bait
Active constituent	20 g/kg methiocarb an anticholinesterase compound
Applicant name	Sundew Solutions Pty Ltd
Applicant ACN	135 400 261
Date of variation	14 October 2024
Product registration no.	94269
Label approval no.	94269/145725
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 'Guardian Sunsol Snail & Slug Bait' to Guardian Baysol Snail & Slug Bait'

Application no.	145750
Product name	Rentokil Radar Rodenticide
Active constituent	1000 g/kg carbon dioxide
Applicant name	Rentokil Initial Pty Ltd
Applicant ACN	000 034 597
Date of variation	15 October 2024
Product registration no.	59061
Label approval no.	59061/145750
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 'Rentokil Pest Control Radar Rodenticide' to 'Rentokil Radar Rodenticide' and to update the first aid instructions appearing on a label to reflect the current FAISD handbook

Application no.	145766
Product name	The Big Cheese Ultra Power All Weather Block Bait
Active constituent	0.025 g/kg brodifacoum
Applicant name	PelGar International (Aus) Pty Ltd
Applicant ACN	159 699 779
Date of variation	16 October 2024
Product registration no.	88846
Label approval no.	88846/145766
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 storage and disposal instructions

Application no.	145789
Product name	Cupboard Guard
Active constituent	7.8 g/kg transfluthrin
Applicant name	Lifeguard Sciences (Pty) Ltd
Applicant ACN	N/A
Date of variation	18 October 2024
Product registration no.	91137
Label approval no.	91137/145789
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 'Cupboard Moth Killer' to 'Cupboard Guard'

Application no.	145779
Product name	Glufoz 200 Herbicide
Active constituent	200 g/L glufosinate-ammonium
Applicant name	Shandong Rainbow International Co Ltd
Applicant ACN	N/A
Date of variation	18 October 2024
Product registration no.	66593
Label approval no.	66593/145779
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 'Rainbow Glufosinate 200 Herbicide' to 'Glufoz 200 Herbicide'

Application no.	145780
Product name	GLUFOZ 800 Dry Herbicide
Active constituent	800 g/kg glufosinate-ammonium
Applicant name	Shandong Rainbow International Co Ltd
Applicant ACN	N/A
Date of variation	18 October 2024
Product registration no.	81432
Label approval no.	81432/145780
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 'Trusinate Xtra Herbicide' to 'Glufoz 800 Dry Herbicide'

Application no.	145797
Product name	Oxigol 240 Herbicide
Active constituent	240 g/L oxyfluorfen
Applicant name	Shandong Rainbow International Co Ltd
Applicant ACN	N/A
Date of variation	21 October 2024
Product registration no.	66568
Label approval no.	66568/145797
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 'Rainfen 240 Herbicide' to Oxigol 240 Herbicide'

Application no.	145796
Product name	Metsulf 600 Herbicide
Active constituent	600 g/kg metsulfuron-methyl
Applicant name	Shandong Rainbow International Co Ltd
Applicant ACN	N/A
Date of variation	21 October 2024
Product registration no.	65249
Label approval no.	65249/145796
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 'Rainbow Metsulfuron 600 WG Herbicide' to 'Metsulf 600 Herbicide'

Application no.	N/A – variation under section 29A of the AgVet Code
Product name	Smartspray 500 Herbicide
Active constituent	500 g/L 2,4-DB (present as the dimethylamine salt)
Applicant name	Shandong Rainbow International Co Ltd
Applicant ACN	N/A
Date of variation	22 October 2024
Product registration no.	70446
Label approval no.	70446/RV24
Description of the application and its purpose, including the intended use of the chemical product	Variation of label approval to correct typographical errors, including errors in application rates

Application no.	N/A – variation under section 29A of the AgVet Code
Product name	Apparent Machete 500 Herbicide
Active constituent	500 g/L 2,4-DB
Applicant name	Titan Ag Pty Ltd
Applicant ACN	122 081 574
Date of variation	22 October 2024
Product registration no.	81800
Label approval no.	81800/RV24
Description of the application and its purpose, including the intended use of the chemical product	Variation of label approval to correct typographical errors, including errors in application rates, and update mode of action

Application no.	N/A – variation under section 29A of the AgVet Code
Product name	OzCrop 2,4-DB 500 SC Herbicide
Active constituent	500 g/L 2,4-DB (present as the dimethylamine salt)
Applicant name	Oz Crop Pty Ltd
Applicant ACN	160 656 431
Date of variation	22 October 2024
Product registration no.	83302
Label approval no.	83302/RV24
Description of the application and its purpose, including the intended use of the chemical product	Variation of label approval to correct typographical errors, including errors in application rates, and update mode of action

Application no.	N/A – variation under section 29A of the AgVet Code
Product name	Spalding Camouflage Selective Herbicide
Active constituent	500 g/L 2,4-DB present as the dimethyl amine salt
Applicant name	DGL Environmental Pty Ltd
Applicant ACN	002 802 646
Date of variation	22 October 2024
Product registration no.	88304
Label approval no.	88304/RV24
Description of the application and its purpose, including the intended use of the chemical product	Variation of label approval to correct typographical errors, including errors in application rates, and update mode of action

Application no.	N/A – variation under section 29A of the AgVet Code
Product name	AgMerch 2,4-DB 500 Herbicide
Active constituent	500 g/L 2,4-DB
Applicant name	AgMerch Pty Ltd
Applicant ACN	645 371 017
Date of variation	22 October 2024
Product registration no.	92175
Label approval no.	92175/RV24
Description of the application and its purpose, including the intended use of the chemical product	Variation of label approval to correct typographical errors, including errors in application rates

Application no.	142925
Product name	Grandex Biological Insecticide
Active constituent	3x10 ¹³ granula/ L cydia pomonella granulosis virus strain v22 (CpGV-V22)
Applicant name	Andermatt Group AG
Applicant ACN	N/A
Date of variation	24 October 2024
Product registration no.	69674
Label approval no.	69674/142925
Description of the application and its purpose, including the intended use of the chemical product	Variation to registration particulars and particulars of label approval to add a lower application rate for use on low to medium pest infestation situations and as a part of spray programs integrated with other pesticides

Application no.	145835
Product name	Musta 450 Herbicide
Active constituent	450 g/L glyphosate present as the isopropylamine salt
Applicant name	Shandong Rainbow International Co Ltd
Applicant ACN	N/A
Date of variation	24 October 2024
Product registration no.	83983
Label approval no.	83983/145835
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 'Ozcrop Musta 450 Herbicide' to 'Musta 450 Herbicide'

Application no.	144826
Product name	Uniform Fungicide
Active constituents	314 g/L azoxystrobin, 121 g/L metalaxyl-M
Applicant name	Syngenta Australia Pty Ltd
Applicant ACN	002 933 717
Date of variation	28 October 2024
Product registration no.	69673
Label approval no.	69673/144826
Description of the application and its purpose, including the intended use of the chemical product	Variation to registration particulars, particulars of label, to amend the constituent statement

Application no.	144760
Product name	Sabakem Imidacloprid 350SC Soil Insecticide
Active constituent	350 g/L imidacloprid
Applicant name	Sabakem Pty Ltd
Applicant ACN	151 682 138
Date of variation	28 October 2024
Product registration no.	69122
Label approval no.	69122/144760
Description of the application and its purpose, including the intended use of the chemical product	Variation of label approval to update the application timing in sugarcane

Application no.	144636
Product name	Proteku Sulphur Dioxide Laminated Pads
Active constituent	240 g/kg sodium metabisulfite
Applicant name	E.E. Muir & Sons Pty Ltd
Applicant ACN	004 524 387
Date of variation	28 October 2024
Product registration no.	64119
Label approval no.	64119/144636
Description of the application and its purpose, including the intended use of the chemical product	Variation to the registration particulars and particulars of label approval to add a larger pack size and update the general instructions and first aid instructions

Application no.	N/A – Variation under section 29A of the AgVet Code
Product name	Agro-Essence Chlorpyrifos 500 Insecticide
Active constituent	500 g/L chlorpyrifos (an anticholinesterase compound)
Applicant name	Agro-Alliance (Australia) Pty Ltd
Applicant ACN	130 864 603
Date of variation	31 October 2024
Product registration no.	94481
Label approval no.	94481/RV24
Description of the application and its purpose, including the intended use of the chemical product	Variation of registration, conditions and label approval to align with the 'APVMA Final Regulatory Decision' for the reconsideration of chlorpyrifos

Application no.	142692
Product name	Trezac Arylex active Herbicide
Active constituents	30 g/L halauxifen-methyl, 25 g/L aminopyralid
Applicant name	Corteva Agriscience Australia Pty Ltd
Applicant ACN	003 771 659
Date of variation	1 November 2024
Product registration no.	88180
Label approval no.	88180/142692
Description of the application and its purpose, including the intended use of the chemical product	Variation to registration particulars, particulars of label, to add use for control of fireweed in ryegrass pasture

Table 4: Label approval – agricultural chemical products

Application no.	144882
Product name	Farmalinx Sucker Insecticide
Active constituent	200 g/L clothianidin
Applicant name	Farmalinx Pty Ltd
Applicant ACN	134 353 245
Date of variation	23 October 2024
Product registration no.	84811
Label approval no.	84811/144882
Description of the application and its purpose, including the intended use of the chemical product	Registration of a new label for the registered product 'Farmalinx Sucker Insecticide' with the label name 'ProForce Retreat 200 SC Insecticide'

Table 5: Variation of label approval – agricultural chemical products

Application no.	N/A – variation under section 29A of the AgVet Code
Product name	Apparent Machete 500 Herbicide
Active constituent	500 g/L 2,4-DB present as the dimethylamine salt
Applicant name	Titan Ag Pty Ltd
Applicant ACN	122 081 574
Date of variation	22 October 2024
Product registration no.	81800
Label approval no.	81800/RV24A
Description of the application and its purpose, including the intended use of the chemical product	Variation of label approval to correct typographical errors, including errors in application rates, and update mode of action

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 6: Veterinary products based on existing active constituents

Application no.	144699
Product name	Quad Multi-Combination Sheep Drench
Active constituents	37.5 g/L closantel, 34 g/L levamisole (as levamisole hydrochloride), 25 g/L albendazole, 1 g/L abamectin
Applicant name	Four Seasons Agribusiness Pty Ltd
Applicant ACN	115 133 189
Date of registration	24 October 2024
Product registration no.	95108
Label approval no.	95108/144699
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 37.5 g/L closantel, 34 g/L levamisole (as levamisole hydrochloride), 25 g/L albendazole, 1 g/L abamectin oral suspension product for the treatment and control of worms in sheep

Application no.	144799
Product name	Vetmec Dectoguard Antiparasitic Injection
Active constituent	10 mg/mL doramectin
Applicant name	Chemvet Australia Pty Ltd
Applicant ACN	138 711 289
Date of registration	24 October 2024
Product registration no.	95146
Label approval no.	95146/144799
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 10 mg/mL doramectin injectable product for the treatment and control of doramectin sensitive internal and external parasites of cattle and pigs

Application no.	144054
Product name	Three X Triple Combination Drench for Sheep
Active constituents	34 g/L levamisole (equivalent to 40 g/L levamisole hydrochloride), 25 g/L albendazole, 1 g/L abamectin, 0.5 g/L selenium (as sodium selenate), 0.21 g/L cobalt (as cobalt sulphate heptahydrate), 0.6 g/L zinc (as zinc sulphate monohydrate), 0.76 g/L iodine (as EDDI stabilised)
Applicant name	Four Seasons Agribusiness Pty Ltd
Applicant ACN	115 133 189
Date of registration	28 October 2024
Product registration no.	94927
Label approval no.	94927/144054
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 34g/L levamisole (equivalent to 40 g/L levamisole hydrochloride), 25 g/L albendazole, 1g/L abamectin, 0.76g/L iodine, 0.5 g/L selenium, 0.21 g/L cobalt, 0.6g/L zinc oral liquid suspension product for the treatment and control of all major gastrointestinal parasites and lungworm, itch mite, larval stages of nasal bot plus provides a supplemental source of selenium, zinc, iodine and cobalt in sheep

Application no.	144602
Product name	Vetmec Sheep LA Injection
Active constituent	20 g/L moxidectin
Applicant name	Chemvet Australia Pty Ltd
Applicant ACN	138 711 289
Date of registration	1 November 2024
Product registration no.	95081
Label approval no.	95081/144602
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 20 g/L moxidectin parenteral injection product for the treatment and control of parasites sensitive to moxidectin in sheep

Table 7: Variations of registration – veterinary chemical products

Application no.	144750
Product name	Amoxibactin 200 mg Oral Tablets
Active constituent	Each tablet contains: 200 mg amoxicillin (as amoxicillin trihydrate)
Applicant name	Dechra Veterinary Products (Australia) Pty Ltd
Applicant ACN	614 716 700
Date of variation	21 October 2024
Product registration no.	35698
Label approval no.	35698/144750
Description of the application and its purpose, including the intended use of the chemical product	Variation to the relevant particulars of both the product registration and label approval by updating the label to align with the current Veterinary Labelling Code and by updating the product name to 'Amoxibactin 200 mg Oral Tablets'

Application no.	144752
Product name	Amoxibactin 400 mg Oral Tablets
Active constituent	Each tablet contains: 400 mg amoxicillin (as amoxicillin trihydrate)
Applicant name	Dechra Veterinary Products (Australia) Pty Ltd
Applicant ACN	614 716 700
Date of variation	21 October 2024
Product registration no.	35697
Label approval no.	35697/144752
Description of the application and its purpose, including the intended use of the chemical product	Variation to the relevant particulars of both the product registration and label approval by updating the label to align with the current Veterinary Labelling Code and by updating the product name to 'Amoxibactin 400 mg Oral Tablets'

Application no.	144797
Product name	Teatplug
Active constituent	650 mg/g bismuth subnitrate
Applicant name	Abbey Laboratories Pty Ltd
Applicant ACN	156 000 430
Date of variation	25 October 2024
Product registration no.	86681
Label approval no.	86681/144797
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 to add an additional pack size

Application no.	144811
Product name	Drontal Allwormer Chewables for Large Dogs
Active constituents	Each chew contains: 875 mg febantel, 175 mg praziquantel, 174.4 mg pyrantel as pyrantel embonate
Applicant name	Vetoquinol Australia Pty Ltd
Applicant ACN	006 949 480
Date of variation	31 October 2024
Product registration no.	59290
Label approval no.	59290/144811
Description of the application and its purpose, including the intended use of the chemical product	Variation to the relevant particulars of the product and the label to update the instructions of use to align the label with the current Vet Labelling Code

Application no.	144819
Product name	Drontal Allwormer Chewables for Medium Dogs
Active constituents	Each chew contains: 250 mg febantel, 50 mg praziquantel, 49.8 mg pyrantel as pyrantel embonate
Applicant name	Vetoquinol Australia Pty Ltd
Applicant ACN	006 949 480
Date of variation	31 October 2024
Product registration no.	59291
Label approval no.	59291/144819
Description of the application and its purpose, including the intended use of the chemical product	Variation to the relevant particulars of the product and the label to update the instructions of use to align the label with the current Vet Labelling Code

Application no.	144868
Product name	Q-Drench Multi-Combination Drench for Sheep
Active constituents	37.5 g/L closantel, 34 g/L levamisole (as levamisole hydrochloride), 25 g/L albendazole, 1 g/L abamectin
Applicant name	Zoetis Australia Pty Ltd
Applicant ACN	156 476 425
Date of variation	31 October 2024
Product registration no.	56573
Label approval no.	56573/144868
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 to add a new pack size

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 8: Approved active constituents

Application no.	142052
Active constituent	Ametryn
Applicant name	Syngenta Australia Pty Ltd
Applicant ACN	002 933 717
Date of approval	18 October 2024
Approval no.	94312
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent ametryn for use in agricultural chemical products

Application no.	132221
Active constituent	Cyclobutrifluram
Applicant name	Syngenta Australia Pty Ltd
Applicant ACN	002 933 717
Date of approval	22 October 2024
Approval no.	91435
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent cyclobutrifluram for use in agricultural chemical products

Application no.	142800
Active constituent	Milbemycin oxime
Applicant name	Avet Health Limited
Applicant ACN	616 838 101
Date of approval	22 October 2024
Approval no.	94564
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent milbemycin oxime for use in veterinary chemical products

Application no.	142802
Active constituent	Praziquantel
Applicant name	Avet Health Limited
Applicant ACN	616 838 101
Date of approval	23 October 2024
Approval no.	94565
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent praziquantel for use in veterinary chemical products

Application no.	141777
Active constituent	Altrenogest
Applicant name	Randlab Australia Pty Ltd
Applicant ACN	114 948 837
Date of approval	24 October 2024
Approval no.	94181
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent altrenogest for use in veterinary chemical products

Application no.	142081
Active constituent	Thidiazuron
Applicant name	Jiangsu Repont Agrochemical Co Ltd
Applicant ACN	N/A
Date of approval	24 October 2024
Approval no.	94323
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent thidiazuron for use in agricultural chemical products

Application no.	142590				
Active constituent	Chlorantraniliprole				
Applicant name	Jiangsu Agrochem Laboratory Co Ltd				
Applicant ACN	N/A				
Date of approval	24 October 2024				
Approval no.	94495				
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.	141596
Active constituent	Firocoxib
Applicant name	Abbey Laboratories Pty Ltd
Applicant ACN	156 000 430
Date of approval	25 October 2024
Approval no.	94123
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent firocoxib for use in veterinary chemical products

Application no.	143305
Active constituent	Metcamifen
Applicant name	Syngenta Australia Pty Ltd
Applicant ACN	002 933 717
Date of approval	28 October 2024
Approval no.	94718
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent metcamifen for use in agricultural chemical products

Application no.	143492
Active constituent	Spinosad
Applicant name	Nufarm Australia Limited
Applicant ACN	004 377 780
Date of approval	1 November 2024
Approval no.	94732
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent spinosad for use in agricultural chemical products

Application no.	144674
Active constituent	Sulfadoxine
Applicant name	Bimeda (Australia) Pty Ltd
Applicant ACN	058 196 508
Date of approval	1 November 2024
Approval no.	95099
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent sulfadoxine for use in veterinary chemical products

Table 9: Variations of active constituent

Application no.	144272
Active constituent	Cyclobutrifluram
Applicant name	Syngenta Australia Pty Ltd
Applicant ACN	002 933 717
Date of variation	24 October 2024
Approval no.	91435
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.	144452
Active constituent	Thiamine hydrochloride
Applicant name	Troy Laboratories Pty Ltd
Applicant ACN	000 283 769
Date of variation	25 October 2024
Approval no.	85930
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.	143261
Active constituent	Aminopyralid
Applicant name	Zhejiang Hengdian Imp & Exp Co Ltd
Applicant ACN	N/A
Date of variation	28 October 2024
Approval no.	91699
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

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 licenses

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

Table 10: New licenses 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
Alltech Lienert Australia Pty LTD	2274	008 293 007	7 Durham Street Forbes NSW 2871	Category 2: Pellets Category 4: Premixes and supplements	Quality assurance (QA) of raw materials, formulation including blending, filling, dry milling, pellet extrusion, packaging, labelling, strip, blister or sachet packaging, storage, and release from manufacture only (partial release).	17 October 2024
Inline Innovations Pty Ltd	2198	120 276 995	28 Horizon Drive Beenleigh QLD 4207	Category 2: creams / lotions, ointments, pastes, sprays, liquids and gels	Quality assurance (QA) of raw materials, formulation including blending, filling, packaging, labelling, analysis and testing (physical), storage and release for supply.	30 October 2024
Scientest Analytical Services Pty Ltd	6250	116 585 936	64 Blanck Street Ormeau QLD 4208	Category 6: all dosage forms	Analysis and testing (physical and chemical).	31 October 2024

Licence cancellations

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

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

Company name	Licence number	Company ABN	Address	Date cancelled
The State of NSW Department of Industry trading under the business name of Department of Primary Industries (Elizabeth Macarthur Agricultural Institute)	1120	20 770 707 468	Woodbridge Road Menangle NSW 2568	30 October 2024

APVMA contact

Manufacturing Quality and Licensing Australian Pesticides and Veterinary Medicines Authority GPO Box 574 Canberra ACT 2601

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

Amendments to the APVMA MRL Standard

The Australian Pesticides and Veterinary Medicines Authority (APVMA) approves maximum residue limits (MRLs) of agricultural and veterinary chemicals in agricultural produce, particularly produce entering the food chain. The MRLs approved by the APVMA are associated with a regulatory decision to register a product, grant a permit approval, or as an outcome from a review decision and are set out in the *Agricultural and Veterinary Chemicals (MRL Standard for Residues of Chemical Products) Instrument 2023.* The *MRL Standard* lists MRLs of substances that may arise from the approved use of agricultural and veterinary chemical products containing those substances on commodities used for human consumption as well as livestock feeds. The *MRL Standard* also provides the relevant residue definitions to which these MRLs apply. There may be situations where the residue definition for monitoring and enforcement is different to the definition used for dietary risk assessment purposes.

MRLs are set at levels which are not likely to be exceeded if the agricultural or veterinary chemicals are used in accordance with approved label instructions. In considering MRLs and variation to MRLs, the APVMA takes into account studies on chemistry, metabolism, analytical methodology, residues, toxicology, good agricultural practice and dietary exposure. In approving MRLs, the APVMA is satisfied, from dietary exposure assessment, that the levels set are not an undue hazard to human health.

The APVMA has amended the MRL Standard and the changes will have affect the day after the instrument is registered.

Details of the amendment can be found in the Agricultural and Veterinary Chemicals (MRL Standard for Residues of Chemical Products) Amendment Instrument (No. 4) 2024.

The amendments will be incorporated into the compilation of the Agricultural and Veterinary Chemicals (MRL Standard for Residues of Chemical Products) Instrument 2023.

The MRL Standard is accessible via the Federal Register of Legislation website.

For further information please contact:

MRL Contact Officer Australian Pesticides and Veterinary Medicines Authority GPO Box 574 Canberra ACT 2601

Phone: +61 2 6770 2300 Email: enquiries@apvma.gov.au

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

In the previous notice on page 22 of APVMA Gazette No.23, the APVMA gazetted amendments which it has approved to vary maximum residue limits (MRLs) for substances contained in agricultural and veterinary chemical products as set out in the APVMA's MRL Standard.

Under section 82 of the *Food Standards Australia New Zealand Act 1991*, the APVMA is proposing to incorporate those variations (Agricultural and Veterinary Chemicals Code *(MRL Standard)* Amendment Instrument 2024 (No. 4)) to MRLs into Schedule 20 – Maximum residue limits in the Australia New Zealand Food Standards Code.

MRLs contained in Schedule 20 provide the limits for residues of agricultural and veterinary chemicals that may legitimately occur in foods. By this means Schedule 20 permits the sale of treated foods and protects public health and safety by minimising residues in foods consistent with the effective control of pests and diseases.

The APVMA and Food Standards Australia New Zealand (FSANZ) are satisfied, based on dietary exposure assessments and current health standards, that the proposed limits are not harmful to public health.

The agreement between the Australian Government and the New Zealand Government concerning a Joint Food Standards System excludes MRLs for agricultural and veterinary chemicals in food from the system setting joint food standards. Australia and New Zealand independently and separately develop MRLs for agricultural and veterinary chemicals in food.

A Sanitary and Phytosanitary (SPS) notification to the World Trade Organization (WTO) will be made.

The APVMA invites comment on these proposals. Details on how to make a submission appear near the end of this notice, below the details of the proposed amendment.

The APVMA will consider any public comments made in response to this proposal. If the APVMA decides to proceed with the proposal, it will further notify any variations it makes to Schedule 20 in the APVMA Gazette. The variations will take effect as from the date of that subsequent notice.

Proposed variation to Schedule 20 in the Australia New Zealand Food Standards Code

12 November 2024

Note: Subsection 82(2) of the *Food Standards Australia New Zealand Act 1991* provides that variations to standards are legislative instruments, but are not subject to disallowance or sunsetting.

To commence: on gazettal of variation

Schedule 20 Maximum Residue Limits

[1] SectionS20—3 (table entry for Agvet chemical: [Cyhalofop-butyl])

Omit 'Sum of cyhalofop-butyl, cyhalofop and metabolites expressed as cyhalofop-butyl', substitute 'Sum of cyhalofop-butyl' and cyhalofop acid, expressed as cyhalofop-butyl'

[2] Section S20—3 (table entry for Agvet chemical: [Flubendiamide])

Omit 'Sum of flubendiamide and 3-iodo-N-(2-methyl-4-[1,2,2,2-tetrafluoro-1-(trifluoromethyl)ethyl]phenyl) phthalimide, expressed as flubendiamide', substitute 'sum of flubendiamide and flubendiamide-iodophthalimide, expressed as flubendiamide'

[3] Section S20—3 (table entry for Agvet chemical: Spiromesifen)

Omit 'Sum of spiromesifen and 4-hydroxy-3-(2,4,6-trimethylphenyl)-1-oxaspiro[4.4]non-3-en-2-one, expressed as spiromesifen', substitute 'sum of spiromesifen and 4-hydroxy-3-(2,4,6-trimethylphenyl)-1-oxaspiro[4.4]non-3-en-2-one (spiromesifen- enol), expressed as spiromesifen'.

[4] Section S20—3 (table entry for Agyet chemical: Spiromesifen)

Insert the following food commodities and associated MRLs in alphabetical order:

Edible offal (mammalian)	*0.05
Eggs	*0.01
Meat (mammalian) (in the fat)	*0.01
Milks	*0.005
Pome fruits	0.5
Poultry meat (in the fat)	*0.01
Poultry, edible offal of	*0.05
Stone fruits	0.6

[5] Section S20—3 (table entry for Agvet chemical: Cyclaniliprole)

Insert:

Avocado 0.2

[6] Section S20—3 (table entry for Agvet chemical: Cyflumetofen)

Insert:

Cucumber T0.5

Section S20—3 (table entry for Agvet chemical: Diafenthiuron) [7] Omit: Soya bean (dry) T0.3 Section S20—3 (table entry for Agvet chemical: Diafenthiuron) [8] Insert the following food commodities and associated MRLs in alphabetical order Cereal grains T*0.01 Pulses T*0.01 [9] Section S20—3 (table entry for Agvet chemical: Ethephon) Omit: Wheat T1 [10] Section S20—3 (table entry for Agvet chemical: Flumethrin) Omit: Honey T*0.005 Substitute: Honey *0.003 [11] Section S20—3 (table entry for Agvet chemical: Prosulfocarb) Omit:

T*0.1

Safflower seed

Invitation for submissions

Written submissions are invited from interested individuals and organisations to assist the APVMA in considering the proposal to vary Schedule 20 – Maximum residue limits in the Australia New Zealand Food Standards Code.

Submissions should be strictly confined to relevant matters that the APVMA must consider (such as public health and safety) which are associated with the occurrence of the proposed residues in foods. Comments received outside these grounds will not be considered by the APVMA.

Claims made in submissions should be supported wherever possible by referencing or including relevant studies, research findings, trials and surveys. Technical information should be in sufficient detail to allow independent scientific assessment.

Submissions must be made in writing and should be clearly marked as a 'submission on the proposed amendment to Schedule 20' and quote the correct amendment number.

Deadline for public submissions

Submissions must be received by 10 December 2024 (28 days from date Gazette published). Submissions received after this deadline will only be considered by prior arrangement or if agreement for an extension has been given prior to this closing date. Agreement to an extension of time will only be given if extraordinary circumstances warrant an extension to the submission period.

Please note: submissions will be published on the APVMA's website, unless you have asked for the submission to remain confidential, or if the APVMA chooses at its discretion not to publish any submissions received (refer to the <u>public consultation coversheet</u>).

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

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

For further information please contact:

MRL Contact Officer
Australian Pesticides and Veterinary Medicines Authority
GPO Box 574
Canberra ACT 2601

Phone: +61 2 6770 2300

Email: enquiries@apvma.gov.au

Privacy

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

Agvet chemical voluntary recall: Exebarb euthanasia injection

Product name: Exebarb euthanasia injection

APVMA registration number: 93069

APVMA approved label number: 140162

Batch number: 24120H

Sold by: Provet in NSW, QLD and SA between 1 October 2024 to 28 October 2024.

On 28 October2024, Vetpharm Laboratories IP Pty Ltd (ACN 654 406 523) 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

Appearance of particulate matter in the solution.

Product failed to continue meeting the release specifications of a clear solution.

Hazard

Product may not meet the efficacy criteria.

Product has the possibility of clogging a needle during administration.

What to do if in possession of this chemical product

Discontinue use of the product (Batch no. 24120H) and contact Provet Customer Service:

NSW (02) 8867 5144 QLD (07) 3621 6000 SA (08) 8154 5455 for a return and credit.

More information

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

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

Contact

Please direct all calls and any queries concerning this voluntary recall to:

The Director, Vetpharm Laboratories Pty Ltd.

Email: scrothers@vetpharm.net.au.

Phone: 0414 389 101

Agvet chemical voluntary recall: ilium Meloxicam Anti-Inflammatory Oral Suspension for Dogs – 30 mL pack size

Product name: ilium Meloxicam Anti-Inflammatory Oral Suspension for Dogs - 30 mL pack size

APVMA registration number: 60023

APVMA approved label number: 139996

Batch number: 240748A

Sold by: Veterinary wholesalers in all states and territories between 6 September 2024 to 6 November 2024.

On 6 November 2024, Troy Laboratories Pty Ltd (ABN: 000 283 769) 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

Some units in batch 240748A have an incorrect leaflet (ilium Meloxicam 0.5 anti-inflammatory oral suspension for cats) enclosed. All other aspects of the product are in order (contents, label, carton, syringe).

Hazard

Following the dosing instructions from the incorrect leaflet (for use in cats, rather than dogs) could potentially lead to underdosing in dogs and therefore reduced efficacy. However, the information provided on both the label and carton are in order.

What to do if in possession of this chemical product

Wholesalers should immediately quarantine all stock on hand of the recalled batch (240748A). Troy (details included below) will provide advice on management of affected units and arrangements for replacement. Veterinarians will be provided with replacement leaflets for affected units.

More information

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

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

Contact

Questions about this voluntary recall should be directed to:

Troy Laboratories Customer Service

Phone: 02 8808 3611