Commonwealth of Australia

Gazette

Agricultural and veterinary chemicals

No. APVMA 19, 16 September 2025

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.

ISSN 1837-7629

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

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.	144742
Product name	Conquest Nomad Herbicide
Active constituent	250 g/kg florasulam
Applicant name	Conquest Crop Protection Pty Ltd
Applicant ACN	098 814 932
Date of registration	27 August 2025
Product registration no.	95122
Label approval no.	95122/144742
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 250 g/kg water dispersible granule (WG) formulation of florasalum to be mixed with MCPA for the control of brassicaceous weeds and suppression of capeweed in wheat, barley and triticale

Application no.	148016
Product name	WoodX Ultra
Active constituent	200 g/kg tebuthiuron
Applicant name	Granular Products Assets Pty Ltd
Applicant ACN	614 694 405
Date of registration	28 August 2025
Product registration no.	96043
Label approval no.	96043/148016
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 200 g/kg tebuthiuron product, formulated as a granular formulation (GR) for control of brigalow regrowth, prickly acacia, parkinsonia, mimosa pigra and certain problem woody weeds by hand, aerial and ground application

Application no.	148534
Product name	NO Clothes Moths Moth Killer
Active constituent	7.8 g/kg transfluthrin
Applicant name	Amalgamated Hardware Merchants (Australia) Pty Limited
Applicant ACN	634 759 005
Date of registration	29 August 2025
Product registration no.	96211
Label approval no.	96211/148534
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 7.8 g/kg transfluthrin product, formulated as a bait (BA) for protection of clothes from clothing moths for 4 months

Table 2: Variations of registration – agricultural chemical products

Application no.	149513
Product name	Crowgrass 375 Herbicide
Active constituent	375 g/L diclofop-methyl
Applicant name	Shandong Rainbow International Co Ltd
Applicant ACN	N/A
Date of variation	11 August 2025
Product registration no.	65907
Label approval no.	65907/149513
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 Diclofop-Methyl 375 Selective Herbicide' to 'Crowgrass 375 Herbicide'

Application no.	149654
Product name	Agro-Essence Corvette Insecticide Seed Dressing
Active constituent	350 g/L thiamethoxam
Applicant name	Theyes Management Pty Ltd
Applicant ACN	647 084 151
Date of variation	21 August 2025
Product registration no.	94183
Label approval no.	94183/149654
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 'Agro-Essence Thiamethoxam Insecticide Seed Dressing' to 'Agro-Essence Corvette Insecticide Seed Dressing'

Application no.	148375
Product name	KDPC Mectin Insecticide/Miticide
Active constituent	18 g/L abamectin
Applicant name	KD Plant Care Pty Ltd
Applicant ACN	134 592 804
Date of variation	27 August 2025
Product registration no.	82498
Label approval no.	82498/148375
Description of the application and its purpose, including the intended use of the chemical product	Variation of label approval to include the scheduled excipient 'diethylene glycol monobutyl ether' in the constituent statements and update first aid and safety directions

Application no.	149837
Product name	QA Tebuthiuron 200 GR Herbicide
Active constituent	200 g/kg tebuthiuron
Applicant name	Quantum Agrosciences Holdings Pty Ltd
Applicant ACN	680 792 625
Date of variation	27 August 2025
Product registration no.	91775
Label approval no.	91775/149837
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 'AgMerch Tebuthiuron 200 GR Herbicide' to 'QA Tebuthiuron 200 GR Herbicide'

Application no.	148477
Product name	Atlas Kill and Protect High Performance Bed Bug Killer
Active constituents	2 g/kg cypermethrin, 0.7 g/kg imiprothrin
Applicant name	Pascoe's Pty Ltd
Applicant ACN	055 220 463
Date of variation	27 August 2025
Product registration no.	91271
Label approval no.	91271/148477
Description of the application and its purpose, including the intended use of the chemical product	Variation to registration particulars and particulars of label to add use in millipede

Application no.	149836
Product name	QA Wetter 1000
Active constituents	1000 g/L non-ionic alcohol ethoxylates
Applicant name	Quantum AgroSciences Holdings Pty Ltd
Applicant ACN	680 792 625
Date of variation	27 August 2025
Product registration no.	90938
Label approval no.	90938/149836
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 'AgMerch Wetter 1000' to 'QA Wetter 1000'

Application no.	146394
Product name	Helicovex Biological Insecticide
Active constituent	7.5x10^9 occlusion bodies (ob) of helicoverpa armigera nucleopolyhedrovirus per millilitre
Applicant name	Andermatt Group Ag
Applicant ACN	N/A
Date of variation	28 August 2025
Product registration no.	68347
Label approval no.	68347/146394
Description of the application and its purpose, including the intended use of the chemical product	Variation of label approval to add an additional rate of application (50-100 mL/ha) for control of cotton bollworm in sorghum

Application no.	148582
Product name	Spirosec 240 SC Insecticide
Active constituent	240 g/L spirotetramat
Applicant name	Anovitech Pty Ltd
Applicant ACN	647 183 060
Date of variation	1 September 2025
Product registration no.	93485
Label approval no.	93485/148582
Description of the application and its purpose, including the intended use of the chemical product	Variation to registration and label particulars to add uses in cotton and control of diamondback moth and silverleaf whitefly in brassica and brassica leafy vegetables

Application no.	146578
Product name	Bird Fend Bird Deterrent
Active constituents	720 g/kg polybutene, 5.3 g/kg peppermint oil
Applicant name	Bird Fend Pty Ltd
Applicant ACN	622 083 470
Date of variation	2 September 2025
Product registration no.	85617
Label approval no.	85617/146578
Description of the application and its purpose, including the intended use of the chemical product	Variation to the particulars of registration and label approval to add the use to deter swallows

Application no.	148431
Product name	Spalding Abamectin 18 EC Insecticide
Active constituent	18 g/L abamectin
Applicant name	DGL Group Limited
Applicant ACN	002 802 646
Date of variation	3 September 2025
Product registration no.	85749
Label approval no.	85749/148431
Description of the application and its purpose, including the intended use of the chemical product	Variation of product registration and label approval to amend the constituent statements, update safety directions and first aid instructions

Application no.	148341
Product name	4Farmers Abamectin 18 EC Miticide - Insecticide
Active constituent	18 g/L abamectin
Applicant name	4 Farmers Australia Pty Ltd
Applicant ACN	160 092 428
Date of variation	3 September 2025
Product registration no.	54914
Label approval no.	54914/148341
Description of the application and its purpose, including the intended use of the chemical product	Variation of registered chemical product and label approval to include the scheduled excipient ‘diethylene glycol monobutyl ether’ in the constituent statements and update first aid and safety directions

Application no.	N/A – Variation under section 29A of the Agvet Code
Product name	Mortein Powergard Easy Reach Crawling Insect Spray
Active constituents	2.0 g/kg cypermethrin, 0.7 g/kg imiprothrin
Applicant name	RB (Hygiene Home) Australia Pty Ltd
Applicant ACN	629 549 506
Date of variation	4 September 2025
Product registration no.	70109
Label approval no.	70109/145581
Description of the application and its purpose, including the intended use of the chemical product	Variation of registration and label particulars to update the product name

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.	145528
Product name	CLiK Duostar Spray-On Sheep Blowfly Treatment
Active constituents	50 g/L dicyclanil, 3 g/L ivermectin
Applicant name	Elanco Australasia Pty Ltd
Applicant ACN	076 745 198
Date of registration	1 September 2025
Product registration no.	95406
Label approval no.	95406/145528
Description of the application and its purpose, including the intended use of the chemical product	Registration of CLiK Duostar Spray-On Sheep Blowfly Treatment (CLiK Duostar), containing 50 g/L dicyclanil and 3 g/L ivermectin for the protection of sheep, either off-shears or with any length wool, against flystrike (caused by Lucilia cuprina) for 18 to 24 weeks. Indicated also for the treatment of blowfly strike on sheep and for the protection of mulesing and marking wounds on sheep against flystrike during the wound healing process

Table 4: Variations of registration – veterinary chemical products

Application no.	148549
Product name	Multimin Chrome Injection for Cattle
Active constituents	40 g/L zinc as disodium zinc EDTA, 15 g/L copper as disodium copper EDTA, 10 g/L manganese as disodium manganese EDTA, 5 g/L chromium as chromium chloride, 3 g/L selenium as sodium selenite
Applicant name	Virbac (Australia) Pty Ltd
Applicant ACN	003 268 871
Date of variation	26 August 2025
Product registration no.	90447
Label approval no.	90447/148549
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 updating the instructions for use

Application no.	148499
Product name	Easotic Ear Suspension for Dogs
Active constituents	15.1 mg/mL miconazole (as the nitrate), 1.11 mg/mL hydrocortisone aceponate, 1505 IU/mL gentamicin (as the sulphate)
Applicant name	Virbac (Australia) Pty Ltd
Applicant ACN	003 268 871
Date of variation	27 August 2025
Product registration no.	63501
Label approval no.	63501/148499
Description of the application and its purpose, including the intended use of the chemical product	Variation of the relevant particulars for the product registration and label approval to amend the directions for use

Application no.	148472
Product name	CCD OTC (Oxytetracycline Hydrochloride Water Soluble Powder)
Active constituent	926 mg/g oxytetracycline hydrochloride
Applicant name	CCD Animal Health Pty Ltd
Applicant ACN	151 737 950
Date of variation	28 August 2025
Product registration no.	52863
Label approval no.	52863/148472
Description of the application and its purpose, including the intended use of the chemical product	Variation of relevant particulars of product and label approval by updating the active constituent's name and label statements to comply with the current Veterinary Labelling Code

Application no.	148589
Product name	Cattleguard Long Acting Injection for Cattle
Active constituent	100 mg/mL moxidectin
Applicant name	Zoetis Australia Pty Ltd
Applicant ACN	156 476 425
Date of variation	29 August 2025
Product registration no.	89950
Label approval no.	89950/148589
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 approval by updating the instructions of use

Application no.	112426
Product name	Websters 3 in 1 B12 Vaccine for Sheep
Active constituents	Contains aluminium adjuvanted toxoid and cellular antigen from corynebacterium pseudotuberculosis (ovis) 1.0 U/mL, clostridium perfringens type D 5.0 IU/mL, clostridium tetani 2.5 IU/mL, 2 mg/mL vitamin B12 (hydroxocobalamin acetate)
Applicant name	Virbac (Australia) Pty Ltd
Applicant ACN	003 268 871
Date of variation	2 September 2025
Product registration no.	81120
Label approval no.	81120/112426
Description of the application and its purpose, including the intended use of the chemical product	Variation of registration and label particulars to update the product name and constituent statements on the approved label to align with the current Veterinary Labelling Code

Application no.	119863
Product name	Websters 7 in 1 Vaccine for Cattle
Active constituents	Contains aluminium adjuvanted toxoid and cellular antigen from Clostridium perfringens type D (5.0 IU/mL), Cl. novyi type B (3.5 IU/mL), Cl. septicum (2.5 IU/mL), Cl. tetani (2.5 IU/mL), Cl. chauvoei (≥ 0.15% pcv/mL), Leptospira interrogans serovar Hardjo (0.5 x 10^9 org/mL) and Leptospira interrogans serovar Pomona (0.5 x 10^9 org/mL)
Applicant name	Virbac (Australia) Pty Ltd
Applicant ACN	003 268 871
Date of variation	2 September 2025
Product registration no.	47947
Label approval no.	47947/119863
Description of the application and its purpose, including the intended use of the chemical product	Variation of registration and label particulars to update the product name and constituent statements on the approved label to align with the current Veterinary Labelling Code

Application no.	122696
Product name	Websters 6 in 1 B12 & Se Vaccine for Sheep
Active constituents	Contains aluminium adjuvanted toxoid and cellular antigen from Corynebacterium pseudotuberculosis (ovis) 1.0 U/mL, Clostridium perfringens type D 5.0 IU/mL, Cl. novyi type B 3.5 IU/mL, Cl. tetani 2.5 IU/mL, Cl. septicum 2.5 IU/mL, Cl. chauvoei ≥ 0.3% PCV/ mL, Vitamin B12 (hydroxocobalamin acetate) 2 mg/mL and Selenium (as sodium selenate) 1 mg/mL
Applicant name	Virbac (Australia) Pty Ltd
Applicant ACN	003 268 871
Date of variation	2 September 2025
Product registration no.	88862
Label approval no.	88862/122696
Description of the application and its purpose, including the intended use of the chemical product	Variation of registration and label particulars to update the product name and constituent statements on the approved label to align with the current Veterinary Labelling Code

Application no.	134042
Product name	Websters 6 in 1 Vaccine for Sheep
Active constituents	Contains toxoid and cell concentrates prepared from formalin killed Corynebacterium pseudotuberculosis (ovis) (1.0 U/mL), Clostridium perfringens type D (5.0 IU/mL), Cl. Novyi type B (3.5 IU/mL), Cl. septicum (2.5 IU/mL), Cl. tetani (2.5 IU/mL) and Cl. chauvoei (≥ 0.3% PCV/mL)
Applicant name	Virbac (Australia) Pty Ltd
Applicant ACN	003 268 871
Date of variation	2 September 2025
Product registration no.	51336
Label approval no.	51336/134042
Description of the application and its purpose, including the intended use of the chemical product	Variation of registration and label particulars to update the product name and constituent statements on the approved label to align with the current Veterinary Labelling Code

Application no.	119858
Product name	Websters 5 in 1 B12 Vaccine for Cattle and Sheep
Active constituents	Contains toxoid and cell concentrates prepared from formalin killed Clostridium perfringens type D (5.0 IU/mL), Cl. novyi type B (3.5 IU/mL), Cl. septicum (2.5 IU/mL), Cl. tetani (2.5 IU/ mL), Cl. chauvoei (≥ 0.15% pcv/mL) and Vitamin B12 (hydroxocobalamin acetate) 1 mg/mL
Applicant name	Virbac (Australia) Pty Ltd
Applicant ACN	003 268 871
Date of variation	2 September 2025
Product registration no.	50632
Label approval no.	50632/119858
Description of the application and its purpose, including the intended use of the chemical product	Variation of registration and label particulars to update the product name and constituent statements on the approved label to align with the current Veterinary Labelling Code

Application no.	112424
Product name	Websters 3 in 1 B12 & SE Vaccine for Sheep
Active constituents	Contains aluminium adjuvanted toxoid and cellular antigen from Corynebacterium pseudotuberculosis (ovis) 1.0 U/mL, Clostridium perfringens type D 5.0 IU/mL, Clostridium tetani 2.5 IU/mL, Vitamin B12 (hydroxocobalamin acetate) 2mg/mL and Selenium (as sodium selenate) 1 mg/mL
Applicant name	Virbac (Australia) Pty Ltd
Applicant ACN	003 268 871
Date of variation	2 September 2025
Product registration no.	54575
Label approval no.	54575/112424
Description of the application and its purpose, including the intended use of the chemical product	Variation of registration and label particulars to update the product name and constituent statements on the approved label to align with the current Veterinary Labelling Code

Application no.	109385
Product name	Websters Low Volume Bivalent Botulinum Vaccine for Sheep and Cattle
Active constituents	Whole culture fluid suspension of Clostridium botulinum type C (5.0 IU/mL) and Cl.botulinum type D (1.0 IU/mL) adsorbed onto aluminium hydroxide gel
Applicant name	Virbac (Australia) Pty Ltd
Applicant ACN	003 268 871
Date of variation	5 September 2025
Product registration no.	50725
Label approval no.	50725/109385
Description of the application and its purpose, including the intended use of the chemical product	Variation of registration and label particulars to update the product name and constituent statements on the approved label to align with the current Veterinary Labelling Code

Application no.	134043
Product name	Websters 5 in 1 Vaccine for Cattle and Sheep
Active constituents	Contains toxoid and cell concentrates prepared from formalin killed Clostridium perfringens type D (5.0 IU/mL), Cl. novyi type B (3.5 IU/mL), Cl. septicum (2.5 IU/mL), Cl. tetani (2.5 IU/mL) and Cl. chauvoei (≥ 0.3% PCV/mL)
Applicant name	Virbac (Australia) Pty Ltd
Applicant ACN	003 268 871
Date of variation	5 September 2025
Product registration no.	51333
Label approval no.	51333/134043
Description of the application and its purpose, including the intended use of the chemical product	Variation of registration and label particulars to update the product name and constituent statements on the approved label to align with the current Veterinary Labelling Code

Application no.	134041
Product name	Websters 6 in 1 SE Vaccine for Sheep
Active constituents	Contains aluminium adjuvanted toxoid and cellular antigen from Corynebacterium pseudotuberculosis (ovis) 1.0 U/mL, Clostridium perfringens type D 5.0 IU/mL, Cl. novyi type B 3.5 IU/mL, Cl. tetani 2.5 IU/mL, Cl. septicum 2.5 IU/mL, Cl. chauvoei ≥ 0.3% PCV/mL and Selenium (as sodium selenate) 1 mg/mL
Applicant name	Virbac (Australia) Pty Ltd
Applicant ACN	003 268 871
Date of variation	5 September 2025
Product registration no.	51337
Label approval no.	51337/134041
Description of the application and its purpose, including the intended use of the chemical product	Variation of registration and label particulars to update the product name and constituent statements on the approved label to align with the current Veterinary Labelling Code

Application no.	122698
Product name	Websters 6 in 1 B12 Vaccine for Sheep
Active constituents	Contains aluminium adjuvanted toxoid and cellular antigen from Corynebacterium pseudotuberculosis (ovis) 1.0 U/mL, Clostridium perfringens type D 5.0 IU/mL, Cl. novyi type B 3.5 IU/mL, Cl. tetani 2.5 IU/mL, Cl. septicum 2.5 IU/mL, Cl. chauvoei ≥ 0.3% PCV/mL and Vitamin B12 (hydroxocobalamin acetate) 2 mg/mL
Applicant name	Virbac (Australia) Pty Ltd
Applicant ACN	003 268 871
Date of variation	5 September 2025
Product registration no.	88864
Label approval no.	88864/122698
Description of the application and its purpose, including the intended use of the chemical product	Variation of registration and label particulars to update the product name and constituent statements on the approved label to align with the current Veterinary Labelling Code

Table 5: Label approval – veterinary chemical products

Application no.	148896
Product name	Websters 7 In 1 Vaccine for Cattle
Active constituents	Clostridium perfringens type D (5.0 IU/mL), Cl. novyi type B (3.5 IU/mL), Cl. septicum (2.5 IU/mL), Cl. tetani (2.5 IU/mL), Cl. chauvoei (≥ 0.15% pcv/mL), Leptospira interrogans serovar Hardjo (0.5 x 10^9 org/mL), Leptospira interrogans serovar Pomona (0.5 x 10^9 org/mL) Also contains: 2.2 mg/mL aluminium (as aluminium hydroxide) (adjuvant) and 0.13 mg/mL thiomersal (preservative)
Applicant name	Virbac (Australia) Pty Ltd
Applicant ACN	003 268 871
Date of registration	5 September 2025
Product registration no.	47947
Label approval no.	47947/148896
Description of the application and its purpose, including the intended use of the chemical product	Approval of a new label for a registered product ‘Websters 7 In 1 Vaccine for Cattle’ (APVMA No. 47947)

Application no.	148895
Product name	Websters 6 in 1 B12 & Se Vaccine for Sheep
Active constituents	Corynebacterium pseudotuberculosis (ovis) 1.0 U/mL, Clostridium perfringens type D 5.0 IU/mL, Cl. novyi type B 3.5 IU/mL, Cl. tetani 2.5 IU/mL, Cl. septicum 2.5 IU/mL, Cl. chauvoei ≥ 0.3% pcv/mL, Vitamin b12 (hydroxocobalamin acetate) 2 mg/mL, Selenium (as sodium selenate) 1 mg/mL Also contains: 2.2 mg/mL aluminium (as aluminium hydroxide) (adjuvant) and 0.13 mg/mL thiomersal (preservative)
Applicant name	Virbac (Australia) Pty Ltd
Applicant ACN	003 268 871
Date of registration	5 September 2025
Product registration no.	88862
Label approval no.	88862/148895
Description of the application and its purpose, including the intended use of the chemical product	Approval of a new label for a registered product ‘Websters 6 in 1 B12 & Se Vaccine for Sheep’ (APVMA No. 88862)

Application no.	148894
Product name	Websters 6 In 1 Vaccine for Sheep
Active constituents	Corynebacterium pseudotuberculosis (ovis) (1.0 U/mL), Clostridium perfringens type D (5.0 IU/mL), Cl. novyi type B (3.5 IU/mL), Cl. septicum (2.5 IU/mL), Cl. tetani (2.5 IU/mL), Cl. chauvoei (≥0.3% pcv/mL) Also contains: 2.2 mg/mL aluminium (as aluminium hydroxide) (adjuvant) and 0.13 mg/mL thiomersal (preservative)
Applicant name	Virbac (Australia) Pty Ltd
Applicant ACN	003 268 871
Date of registration	5 September 2025
Product registration no.	51336
Label approval no.	51336/148894
Description of the application and its purpose, including the intended use of the chemical product	Approval of a new label for a registered product ‘Websters 6 In 1 Vaccine for Sheep’ (APVMA No 51336)

Application no.	148893
Product name	Websters 5 In 1 B12 Vaccine for Cattle and Sheep
Active constituents	Clostridium perfringens type D (5.0 IU/mL), Cl. novyi type B (3.5 IU/mL), Cl. septicum (2.5 IU/mL), Cl. tetani (2.5 IU/mL), Cl. chauvoei (≥ 0.15% pcv/mL) and Vitamin B12 (hydroxocobalamin acetate) 1 mg/mL Also contains: 2.2 mg/mL aluminium (as aluminium hydroxide) (adjuvant) and 0.13 mg/mL thiomersal (preservative)
Applicant name	Virbac (Australia) Pty Ltd
Applicant ACN	003 268 871
Date of registration	5 September 2025
Product registration no.	50632
Label approval no.	50632/148893
Description of the application and its purpose, including the intended use of the chemical product	Approval of a new label for a registered product 'Websters 5 In 1 B12 Vaccine for Cattle and Sheep' (APVMA No 50632)

Application no.	148969
Product name	Websters 3 in 1 B12 Vaccine for Sheep
Active constituents	Corynebacterium pseudotuberculosis (ovis) 1.0 U/mL, Clostridium perfringens type D 5.0 IU/mL, Clostridium tetani 2.5 IU/mL, Vitamin B12 (hydroxocobalamin acetate) 2 mg/mL, Also contains: 2.2 mg/mL aluminium (as aluminium hydroxide) (adjuvant) and 0.13 mg/mL thiomersal (preservative)
Applicant name	Virbac (Australia) Pty Ltd
Applicant ACN	003 268 871
Date of registration	5 September 2025
Product registration no.	81120
Label approval no.	81120/148969
Description of the application and its purpose, including the intended use of the chemical product	Approval of a new label for a registered product 'Websters 3 In 1 B12 Vaccine for Sheep' (APVMA No. 81120)

Application no.	148968
Product name	Websters 3 in 1 B12 & Se Vaccine for Sheep
Active constituents	Corynebacterium pseudotuberculosis (ovis) 1.0 U/mL, Clostridium perfringens type D 5.0 IU/mL, Clostridium tetani 2.5 IU/mL, Vitamin B12 (hydroxocobalamin acetate) 2 mg/mL, Selenium (as sodium selenate) 1 mg/mL Also contains: 2.2 mg/mL aluminium (as aluminium hydroxide) (adjuvant) and 0.13 mg/mL thiomersal (preservative)
Applicant name	Virbac (Australia) Pty Ltd
Applicant ACN	003 268 871
Date of registration	5 September 2025
Product registration no.	54575
Label approval no.	54575/148968
Description of the application and its purpose, including the intended use of the chemical product	Approval of a new label for a registered product ‘Websters 3 In 1 B12 & Se Vaccine for Sheep’ (APVMA No. 54575)

Approved active constituents

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

Table 6: Approved active constituents

Application no.	148790
Active constituent	Miconazole nitrate
Applicant name	Jiyu Biopharm Co Ltd
Applicant ACN	N/A
Date of approval	25 August 2025
Approval no.	96282
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent miconazole nitrate for use in veterinary chemical products

Application no.	145411
Active constituent	Fluralaner
Applicant name	Jiyu Biopharm Co Ltd
Applicant ACN	N/A
Date of approval	26 August 2025
Approval no.	95374
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent fluralaner for use in veterinary chemical products

Application no.	147213
Active constituent	Phenylpropanolamine hydrochloride
Applicant name	Kato Laboratories Pty Ltd
Applicant ACN	000 397 240
Date of approval	28 August 2025
Approval no.	95804
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent phenylpropanolamine hydrochloride for use in veterinary chemical products

Application no.	146995
Active constituent	Methoxyfenozide
Applicant name	Tagros Chemicals India Private Limited
Applicant ACN	N/A
Date of approval	29 August 2025
Approval no.	95715
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent methoxyfenozide for use in agricultural chemical products

Application no.	146703
Active constituent	Imidacloprid
Applicant name	Lead Chemical Co., Ltd.
Applicant ACN	N/A
Date of approval	4 September 2025
Approval no.	95649
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent imidacloprid for use in agricultural chemical products

Application no.	149641
Active constituent	Disodium cobalt EDTA
Applicant name	Abbey Laboratories Pty Ltd
Applicant ACN	156 000 430
Date of approval	5 September 2025
Approval no.	96519
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent Disodium cobalt EDTA for use in veterinary chemical products

Application no.	144323
Active constituent	Disodium cobalt EDTA
Applicant name	Abbey Laboratories Pty Ltd
Applicant ACN	156 000 430
Date of approval	5 September 2025
Approval no.	94965
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent Disodium cobalt EDTA for use in veterinary chemical products

Application no.	148096
Active constituent	Closantel sodium
Applicant name	KSJ Group Pty Ltd
Applicant ACN	166 252 973
Date of approval	5 September 2025
Approval no.	96078
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent closantel sodium for use in veterinary chemical products

Application no.	147146
Active constituent	Oclacitinib maleate
Applicant name	Jiyu Biopharm Co., Ltd.
Applicant ACN	N/A
Date of approval	5 September 2025
Approval no.	95778
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent oclacitinib maleate for use in veterinary chemical products

Table 7: Variations of active constituent

Application no.	149067
Active constituent	Triclabendazole
Applicant name	Elanco Australasia Pty Ltd
Applicant ACN	076 745 198
Date of variation	2 September 2025
Approval no.	82176
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.	148017
Active constituent	Dexamethasone sodium phosphate
Applicant name	Troy Laboratories Pty Ltd
Applicant ACN	000 283 769
Date of variation	3 September 2025
Approval no.	86259
Description of the application and its purpose, including the intended use of the active constituent	Variation of relevant particulars or conditions of an approved active constituent

New APVMA Chemical Products Standard

The Agricultural and Veterinary Chemical Code (Chemical Products) Standard 2025 (the Products Standard) is a legislative instrument made on 6 August 2025 under section 6E of the Agricultural and Veterinary Chemicals Code (the Agvet Code), scheduled to the *Agricultural and Veterinary Chemicals Code Act 1994*.

The draft Products Standard was published for consultation (as required under regulation 8AF(1) of the Agricultural and Veterinary Chemicals Code Regulations (the Regulations) on the Australian Pesticides and Veterinary Medicines Authority (APVMA) website and in the APVMA Gazette, on 10 June 2025. Consultation closed on 8 July 2025, and no comments were received in response to the consultation.

This instrument has been made to make standards for agricultural and veterinary chemical products containing malathion as the active constituent. In undertaking its recent reconsideration of malathion, the APVMA identified a risk to users from toxic impurities formed during manufacture and storage of products containing malathion. To treat this risk, the APVMA imposed several new controls on products containing malathion, including making a standard to limit impurities in products containing malathion as an active constituent. Further information on the APVMA's final regulatory decision on malathion can be found in the APVMA Special Gazette, 2 May 2024. The Products Standard will help ensure that continued use of products containing malathion are safe for people, plants, animals and the environment by setting limits for toxic impurities.

Under regulation 8AF(4) of the Regulations, the APVMA must publish a notice in the APVMA Gazette and on its website when it makes or varies a standard under section 6E of the Agvet Code. This notice was also published on the website on Tuesday 16 September 2025.

The APVMA made the Products Standard on 6 August 2025, which commenced on 12 August 2025, the day the instrument was registered.

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

It is envisaged that the Products Standard will be amended from time to time as required, for example if a need is identified in a future reconsideration of another active constituent for a standard to ensure that continued use of that active is safe for people, plants, animals and the environment.

For further information please contact:

Director Chemistry and Manufacture
Australian Pesticides and Veterinary Medicines Authority
GPO Box 574
Canberra ACT 2601

Phone: +61 2 6770 2392
Email: enquiries@apvma.gov.au

Agvet chemical voluntary recall: Faxone Anaesthetic Injection for Dogs and Cats

Product name: Faxone Anaesthetic Injection for Dogs and Cats

APVMA registration number: 92563

APVMA approved label number: 135906

Batch numbers: VLS9434, VLS9435

Sold by: Sold by Provet (on behalf of Vetpharm Laboratories IP Pty Ltd) in QLD, NSW, Vic and SA between 1 February 2024 to 9 September 2025

On 9 September 2025, Vetpharm Laboratories IP Pty Ltd (ABN 654 406 756) 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

Testing of retention samples held by the manufacturer indicate the batches no longer meet the specifications for the particulate matter.

Hazard

The presence of particulate matter in the above-mentioned batches may pose a risk to animal safety.

What to do if in possession of this chemical product

Cease use of Faxone Anaesthetic Injection for Dogs and Cats from the above-mentioned batches immediately and contact Provet Customer Service for return and credit.

Provet Customer Service:

NSW (02) 8867 5144
QLD (07) 3621 6000
SA (08) 8154 5455

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 agvet chemical recall notices on its website and provides a subscription option 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:

Director, Vetpharm Laboratories IP Pty Ltd
Email: scrothers@vetpharm.net.au
Phone: 0414 389 101

Notice of decision under section 34AC of the Agricultural and Veterinary Chemicals Code: neomycin reconsideration

1) Pursuant to section 34AC of the Agricultural and Veterinary Chemicals Code scheduled to the *Agricultural and Veterinary Chemicals Code Act 1994* (Agvet Code) I, Maria Trainer, with delegated authority under sections 11, 32 and 44 of the *Agricultural and Veterinary Chemicals (Administration) Act 1992* publish this notice of my decisions on the neomycin reconsideration.

2) Pursuant to section 34A(1) of the Agvet Code, I have varied the relevant particulars and conditions of the approvals and registrations listed in Table 8 in such a way to allow the approvals and registrations to be affirmed.

3) Pursuant to section 34(1) of the Agvet Code, I have affirmed the neomycin product registrations and label approvals listed in Table 8 of this notice as varied.

Table 8: Product registrations/label approvals affirmed pursuant to section 34(1)

Product Registration number	Product name	Holder	Formulation type	Affirmed label approval number(s) associated with the product
36026	Scourban Oral Anti-Diarrhoeal Suspension	Elanco Australasia Pty Ltd	Oral solution/suspension	36026/RV2025
49788	Scour-X Oral Anti-Diarrhoeal Suspension	Ausrichter Pty Ltd	Oral solution/suspension	49788/RV2025
52782	CCD Neomycin (Neomycin Sulphate Water Soluble Powder)	CCD Animal Health Pty Ltd	Oral powder	52782/RV2025
67805	Abbeyneo Antibiotic Feed Additive	Abbey Laboratories Pty Ltd	Oral powder	67805/RV2025
46414	Neo-Sulcin Scour Tablets	Zoetis Australia Pty Ltd	Oral tablet	46414/RV2025
36237	Jurox Neomycin Sulfate Injection	Zoetis Australia Pty Ltd	Parenteral liquid/solution/suspension	36237/RV2025
49851	Mastalone Intramammary Suspension for Lactating Cows	Zoetis Australia Pty Ltd	Intramammary suspension	49851/RV2025

Brief reasons for decisions

4) I have reconsidered the registration of the chemical products containing neomycin and associated label approvals listed in Table 8 under Part 2, Division 4 of the Agricultural and Veterinary Chemicals Code scheduled to the *Agricultural and Veterinary Chemicals Code Act 1994* (Agvet Code) to determine whether I remain satisfied that the:

   a) chemical products meet the safety criteria (section 5A of the Agvet Code), the efficacy criteria (section 5B of the Agvet Code), and the trade criteria (section 5C of the Agvet Code), and

   b) labels meet the labelling criteria (section 5D of the Agvet Code), and

   c) chemical products and labels comply with the requirements prescribed by the *Agricultural and Veterinary Chemicals Code Regulations 1995* (Agvet Regulations).

5) The APVMA published a Notice of Proposed Regulatory Decision pursuant to section 34AB of the Agvet Code in the APVMA Gazette on 27 February 2024

6) In considering whether the products listed in Table 8 meet the safety criteria, the efficacy criteria and the trade criteria, and labels meet the labelling criteria I have had regard to the information previously considered in making

the proposed decision and described in the *Neomycin Final Review Technical Report* and I have also considered all submissions provided in response to the public consultation, before making this decision.

7) The APVMA received 23 written submissions during the public consultation on the proposed regulatory decisions for the reconsideration of neomycin and was given consent to publish 12 of them, which are listed in Appendix B of the *Neomycin Final Review Technical Report*.

8) The APVMA's subject-matter-expert staff have considered all written submissions received and updated, where appropriate, the technical and scientific assessments of the hazards and risks associated with neomycin approvals and registrations in the *Neomycin Final Review Technical Report.* I have reviewed that report in detail, considered its methodology and the evidence on which it is based, and agree with its conclusions. I have had regard to all submissions received in response to the public consultation on the neomycin proposed regulatory decisions, and the updated technical and scientific assessment in the *Neomycin Final Review Technical Report*, before making this decision. This final regulatory decision reflects both the revised material findings of facts from those previously made in the published proposed decision, and the revised reasons for this final regulatory decision.

Chemical products

9) In the proposed regulatory decisions, the delegate was not satisfied that use of products containing neomycin to treat food producing animals, except for product 37241, met the safety criteria or trade criteria because there is not sufficient product-specific residue data to calculate the amount of neomycin residue remaining following use of those products according to the instructions for use. The delegate further stated that they therefore could not conclude that neomycin residues in food would not be likely to have an effect that is harmful to human health and would not pose an undue risk to international trade and proposed to vary the instructions for use to remove all use in food producing animals from all products, except for product 37241. This meant that the delegate proposed to cancel the registration of those products used only on food-producing animals (38696, 49851, 52782, 67805).

   a) The registration of product 37241 was cancelled at the request of the holder on 24 May 2024 and is no longer within scope of the reconsideration.

   b) The registration of product 38696 ended without being renewed by the holder on 1 July 2024 and is no longer within scope of the reconsideration.

10) The delegate also proposed to add additional safety directions, contraindications, restraints and other instructions to labels of neomycin products that are registered for use in non-food producing animals, or companion animals. My findings with respect to these remain unchanged from the proposed decisions.

   a) I note that the delegate proposed to be satisfied that the products listed in Table 8 continue to meet the efficacy criteria provided by section 5B of the Agvet Code. This finding remains unchanged.

11) Having considered the information and argument submitted in response to my proposed decisions, and the revised risk assessments in the *Neomycin Final Review Technical Report* I have revised my findings as follows.

   a) I am satisfied that the use of neomycin according to the instructions for use is not likely to have an acute effect that is harmful to human health. The APVMA has not set an acute reference dose (ARfD) because of the low toxicity of neomycin and limited potential for consumption of neomycin residues as described in section 3.1 of the *Neomycin Final Review Technical Report*.

   b) I am not satisfied that use of neomycin according to the previous instructions for use is not likely to have a chronic (lifetime) effect that is harmful to human health because there is uncertainty in lifetime exposure levels due to lack of product-specific data needed to calculate product specific Withholding Periods (WHPs) and Maximum Residue Limits (MRLs) such that the level of neomycin in food is not expected to exceed the Acceptable Daily Intake (ADI) of 0.06 mg/kg bw/day.

   c) However, I am satisfied that if product-specific residue data is supplied to the APVMA within 2 years such that MRLs and WHPs can be calculated, the hazard is not undue and the use of neomycin according to the

instructions for use is not likely to have an effect that is harmful to human health through residues in food because chronic exposure cannot occur over that short timeframe.

d) I also note that the delegate proposed to find they were not satisfied that the products listed in Table 8 meet the trade criteria provided in section 5C of the Agvet Code. I note that relevant industries have effectively managed the risk to international trade and note that APVMA's temporary MRLs are consistent with the CODEX Alimentarius Commission. However, it remains necessary that the APVMA be provided data suitable to allow determination of permanent MRLs and export slaughter intervals based on Australian products and uses.

12) Accordingly, I have varied the relevant particulars of registration of the neomycin chemical products listed in Table 8 as follows to allow me to be satisfied that those products meet the safety and trade criteria.

a) I have decided, pursuant to section 34A(1)(b) of the Agvet Code to vary the conditions of registration imposed by the APVMA to include the following condition.

Condition of Registration

The holder must conduct, or cause to be conducted, product specific food-safety (marker-residue depletion) trials in each of the target animal species listed in the instructions for use of [product #, product name] according to the instructions on the approved label. The holder must submit an application, including the results of these trials, to the APVMA to vary this condition of registration within 2 years of the date of the decision on the reconsideration of neomycin.

Failure to comply with this condition, without reasonable excuse, will be considered grounds for cancellation of the product's registration in accordance with section 36 of the Agvet Code.

13) I have also decided, pursuant to section 34A(1)(b) of the Agvet Code to vary the relevant particulars of the registration to include the following safety directions, contraindications, restraints and other instructions to labels, as proposed.

a) In relation to target animal safety I have varied the contraindications and restraints to include the following statements:

I. For all neomycin products, add the contraindication '*Not to be used in target animals with compromised renal function, gastrointestinal inflammation and those being treated with other potentially nephrotoxic drugs.'*

II. For the parenteral (injectable) product, add the precaution statement *'Neomycin exhibits concentration-dependent killing and a post-antibiotic effect. Repeated daily administration or overdosage with neomycin can cause renal damage and deafness. The risk of toxicity can be reduced by extending the dosage interval to 24-hours. Care should be taken in animals with known or suspected impaired renal function. Care should be taken in animals being treated with other potentially nephrotoxic substances, such as NSAIDs. Where practical, it is recommended to weigh young animals to ensure accurate dosage calculation based on bodyweight.'*

III. For oral products, add the precautions statement *'Neomycin exhibits concentration dependent killing and a post-antibiotic effect. Overdosage with neomycin can cause renal damage and deafness. Care should be taken in animals with known or suspected impaired renal function. While this is unlikely at therapeutic doses, care should be taken in animals being treated with other potentially nephrotoxic substances, such as NSAIDs. Where practical, it is recommended to weigh young animals to ensure accurate dosage calculation based on bodyweight.'*

IV. For all neomycin chemicals products that recommend a minimum duration of treatment of 5 days for salmonellosis, add the instructions: *'If no improvement in symptoms is seen after 5 days, the diagnosis should be reestablished.'*

b) For products with pack sizes greater than 1 kg or 1 L, I have varied the instructions to include the restraint *'DO NOT contaminate wetlands or water courses with this product or used containers'* to explicitly prohibit disposal practices that would create risks to non-target organisms.

c) For products where the active constituent is expressed in the Register as 'neomycin sulfate' I have varied the name of the active constituent recorded in the Register to 'neomycin (as neomycin sulfate)' and varied the concentration of the active constituent recorded in the Register to accurately reflect the amount of neomycin in the product to ensure correct dosage of the active moiety (neomycin).

d) In relation to the stability of the product I have varied the shelf-life condition imposed by the APVMA to include specific limits on storage conditions and duration of storage

Condition of Registration

"This product must not be supplied unless the approved label contains an expiry date not greater than [product specific period] after the date of manufacture of the product when stored at [product specific temperature].

e) I have varied the storage instructions as follows:

I. For liquid products in Table 8, added the storge instruction '*Do not freeze*.'

II. For all products in Table 8, added the storage instruction *'Protect from light'.'*

III. For specific products which currently have an interim shelf life, I have imposed the following condition of registration under section 23(1)(b) of the Agvet Code:

Condition of Registration

Within 2 years of the publication of the section 34AC notice of the neomycin final regulatory decision, you are required to provide real time stability data to enable the APVMA to determine and establish an appropriate shelf life.

f) To reduce the likelihood of the development of antimicrobial resistance to an acceptable level:

- I have added *'Indiscriminate use of [Name of Product] may contribute to the development of antibiotic resistance' to* the statement of claims for all products

- I have added the general direction for all products *'Prudent Use: Veterinarians must assess the clinical need for antimicrobials prior to prescription and must communicate the risk of antimicrobial resistance in humans and the need for prudent use in animals. Culture and sensitivity tests should be performed when appropriate to determine susceptibility of the causative organism(s). Empirical therapy may be instituted before results of susceptibility studies are known; however, once these results become available, the antibiotic treatment should be adjusted accordingly.'*

- I have added the restraint for all products *'DO NOT prescribe [Name of Product], prior to investigating the use of non-antibiotic options. If [Name of Product] is indicated and selected for use, prudent prescribing practices (appropriate dose, duration and frequency) should be followed to minimise treatment failure while limiting the possible emergence of antimicrobial resistance.'*

g) With respect to the trade criteria I note the arguments provided in submissions listed in Appendix B of the *Neomycin Final Review Technical Report,* that the cattle, dairy, poultry and sheep industries have successfully managed any remaining risk to trade since 2007. I am satisfied that the instructions for use of the registered chemical products containing neomycin listed in Table 8 of this notice can be varied in such a way as to meet the trade criteria, by including an ESI statement where it is not already present as below.

I. *EXPORT SLAUGHTER INTERVAL (ESI): An ESI has not been established for this product. Note—observing the meat withholding period may not be sufficient to mitigate potential risks to export trade. Trade advice should be sought from [HOLDER] on [PHONE NUMBER] before using this product.*

II. I also note that the condition of registration that I have imposed (paragraph 12)a) to address the dietary exposure concerns in respect of the safety criteria will result in sufficient information for the APVMA to accurately assess any remaining risk to trade and to determine appropriate withholding periods and export slaughter intervals to mitigate any risk identified, but I do not consider this necessary for my satisfaction that the products listed in Table 8, after varying the instructions for use as above, meet the trade criteria for the purpose of section 5C of the Agvet Code.

14) Having made the variations listed above, I am satisfied that the chemical product registrations listed in Table 8, as varied, meet the safety, efficacy and trade criteria and comply with any requirements prescribed by the regulations. Therefore, pursuant to section 34(1) of the Agvet Code, I have affirmed the chemical product registrations listed in Table 8 of this notice on 8 September 2025.

Labels for chemical products

15) In considering whether the labels for the products listed in Table 8 meet the labelling criteria I have had regard to the changes to the instructions and other particulars of the registration of the chemical products listed above and as set out in the proposed decisions and the reasons for those changes.

16) I have concluded that I am not satisfied that the previously approved instructions were adequate with respect to the matters stated in section 5D(1) of the Agvet Code, but that I could be satisfied by varying the instructions to as indicated for the product above, and also including the additional instructions noted in my proposed decisions specifically in relation to the labels, as below.

a) Regarding the disposal of the product when it is no longer required (s5D(1)(g)) and disposal of containers for the product (s5D(1)(h)), respectively, I have varied the instructions for use contained on the labels listed in Table 8 to include the following disposal instructions to minimise the potential for unintended effects on the environment from incorrect disposal of the product or containers for the product

- For small containers (up to 1 Kg or 1 L) – *'Dispose of container by wrapping with paper and putting in garbage.'*
- For injectable products – *'Discarded needles/sharps should immediately be placed in a designated and appropriately labelled 'sharps' container.'*
- For oral products greater than 1 L – *'Triple-rinse container and dispose of rinsate in compliance with relevant local, state or territory government regulations. Do not dispose of undiluted chemicals on-site. If recycling, replace cap and return clean container to recycler or designated collection point. If not recycling, break, crush, or puncture container and deliver to an approved waste management facility. If an approved waste management facility is not available, dispose of in compliance with relevant local, state or territory government regulations. Do not burn empty containers or product.'*
- For feed additive products greater than 1 kg – *'Single-rinse or shake and empty containers into medicated feed. Do not dispose of undiluted chemicals on site. Puncture bag and deliver to an approved waste management facility. If an approved waste management facility is not available, dispose of the container in compliance with relevant local, state or territory government regulations. Do not burn empty containers or products.'*

II. Regarding the safe handling of the product (s5D(1)(i)), I have varied the instructions contained on the relevant label approvals listed in Table 8 to include the safety instructions that I have decided are required for safe use of neomycin products as noted in the proposed decisions:

- For oral (liquid), oral (tablet) and injectable formulations containing neomycin, I have added the safety direction *'Wash hands after use.'*
- For powders for addition to drinking water or feed I have added the safety directions *'May irritate the eyes. Avoid contact with eyes. When using the product, wear a disposable dust mask covering the nose and mouth. Wash hands after use.'*
- For the labels of neomycin products where safety directions have been added to mitigate occupational safety risks, I have varied the label particulars to add the signal words 'READ SAFETY DIRECTIONS BEFORE OPENING OR USING'.

17) In accordance with section 34A(1) of the Agvet Code, I have varied the particulars of the label approvals to include the instructions noted above.

18) I am satisfied that the labels for products listed in Table 8, as varied, meet the labelling criteria and comply with any requirements prescribed by the regulations. Therefore, pursuant to section 34(1) of the Agvet Code, I have affirmed the label approvals for products listed in Table 8 of this notice, as varied, on 8 September 2025.

19) Further, I have determined, pursuant to section 81(3) of the Agvet Code, that the products listed in Table 9, which have already been manufactured bearing labels that were previously approved but have now been varied, may be supplied for 2 years from the date of affirmation.

20) Products bearing labels listed in Table 9 must not be supplied after 8 September 2027.

Table 9: Products bearing unapproved labels subject to determination under section 81(3) of Agvet Code.

Product Registration number	Product name	Holder	Formulation type	Varied label approval number(s) associated with the product
36026	Scourban Oral Anti-Diarrhoeal Suspension	Elanco Australasia Pty Ltd	Oral solution/suspension	36026/129926 36026/100547 36026/56642 36026/1201 36026/01
49788	Scour-X Oral Anti-Diarrhoeal Suspension	Ausrichter Pty Ltd	Oral solution/suspension	49788/0101 49788/01
52782	CCD Neomycin (Neomycin Sulphate Water Soluble Powder)	CCD Animal Health Pty Ltd	Oral powder	52782/0705 52782/1003 52782/1100
67805	Abbeyneo Antibiotic Feed Additive	Abbey Laboratories Pty Ltd	Oral powder	67805/140221
46414	Neo-Sulcin Scour Tablets	Zoetis Australia Pty Ltd	Oral tablet	46414/132536 46414/0410 46414/0101
36237	Jurox Neomycin Sulfate Injection	Zoetis Australia Pty Ltd	Parenteral liquid/solution/suspension	36237/50976 36237/0305 36237/02
49851	Mastalone Intramammary Suspension for Lactating Cows	Zoetis Australia Pty Ltd	Intramammary suspension	49851/106743 49851/0709 49851/01

Contact information

For any enquiries or further information about this matter, please contact:

Chemical Review
Australian Pesticides and Veterinary Medicines Authority
GPO Box 574
Canberra ACT 2601
Australia

Phone: +61 2 6770 2400
Email: chemicalreview@apvma.gov.au

Notice of merits review rights

An application may be made to the Administrative Review Tribunal by or on behalf of a person whose interests are affected by a decision under subsections 34A(1) of the Agvet Code.

Subject to the *Administrative Review Tribunal Act 2024*, a person whose interests are affected by this decision may also make an application to the ART for a review of this decision. A person whose interest are affected by this decision may also, in accordance with the *Administrative Review Tribunal Act 2024*, make an application to receive a statement of reasons for this decision.