Commonwealth of Australia

Gazette

Agricultural and veterinary chemicals

No. APVMA 5, 4 March 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

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.	142728
Product name	Diathor Flowable Long-Term Insect Killer
Active constituent	945 g/kg amorphous silica
Applicant name	Ensystex Australasia Pty Ltd
Applicant ACN	102 221 965
Date of registration	11 February 2025
Product registration no.	94541
Label approval no.	94541/142728
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 945 g/kg amorphous silica dustable powder (DP) insecticide product for the control of bed bugs and cockroaches in indoor situations

Application no.	145928
Product name	Sabakem Moxypyr Herbicide
Active constituents	33 g/L imazamox present as the ammonium salt, 15 g/L imazapyr present as the ammonium salt
Applicant name	Sabakem Pty Ltd
Applicant ACN	151 682 138
Date of registration	12 February 2025
Product registration no.	95518
Label approval no.	95518/145928
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 33 g/L imazamox and 15 g/L imazapyr soluble concentrate product for use in Clearfield Production System for wheat, barley and canola

Application no.	146304
Product name	Blindside XLR8 Yield & Quality Enhancer
Active constituent	250 g/L trinexapac-ethyl
Applicant name	Crop Culture Pty Ltd
Applicant ACN	142 860 473
Date of registration	12 February 2025
Product registration no.	95544
Label approval no.	95544/146304
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 250 g/L trinexapac-ethyl emulsifiable concentrate product to increase yield in ryegrass seed crops, improve the percent of thebaine in poppies, and increase the CCS in sugarcane

Application no.	146343
Product name	Briskway Growth Regulator
Active constituent	250 g/L trinexapac-ethyl
Applicant name	Turf Culture Pty Ltd
Applicant ACN	117 986 615
Date of registration	13 February 2025
Product registration no.	95559
Label approval no.	95559/146343
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 250 g/L trinexapac-ethyl emulsifiable concentrate product for the reduction of leaf and stem growth of grass species, as an aid in turf management, and as an aid in winter grass management

Application no.	144414
Product name	Ethpyri Fungicide
Active constituent	600 g/L pyrimethanil
Applicant name	Shandong Rainbow International Co Ltd
Applicant ACN	N/A
Date of registration	13 February 2025
Product registration no.	94996
Label approval no.	94996/144414
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 600 g/L pyrimethanil in suspension concentrate (SC) product for the control of grey mould (botrytis cinerea) in grapevines, strawberries and tolerant ornamental species, yellow sigatoka and leaf speckle in bananas

Application no.	142418
Product name	Thiopron Fungicide
Active constituent	825 g/L sulfur
Applicant name	UPL Australia Pty Ltd
Applicant ACN	066 391 384
Date of registration	14 February 2025
Product registration no.	94432
Label approval no.	94432/142418
Description of the application and its purpose, including the intended use of the chemical product	Registration of an 825 g/L sulfur suspension concentrate product for use in grapevines and tomatoes for the control of powdery mildew, and use in tomatoes for the control of mites

Application no.	146750
Product name	The Big Cheese Ultra Power Bait Blocks Mouse Kill Kit
Active constituent	0.05 g/kg brodifacoum
Applicant name	Pelgar International (Aus) Pty Ltd
Applicant ACN	159 699 779
Date of registration	19 February 2025
Product registration no.	95659
Label approval no.	95659/146750
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 0.05 g/kg brodifacoum ready to use bait (RB) product for the control of mice in and around buildings in household situations

Application no.	142840
Product name	Surefire Cholecal Blocks Rodenticide
Active constituent	0.75 g/kg cholecalciferol
Applicant name	PCT Holdings Pty Ltd
Applicant ACN	099 023 962
Date of registration	19 February 2025
Product registration no.	94575
Label approval no.	94575/142840
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 0.75 g/kg cholecalciferol bait product for control of introduced rodents in and around domestic homes, industrial and commercial buildings including agricultural and food processing areas

Application no.	146456
Product name	4Farmers 24DB Herbicide
Active constituent	500 g/L 2,4-DB present as the dimethylamine salt
Applicant name	4 Farmers Australia Pty Ltd
Applicant ACN	160 092 428
Date of registration	20 February 2025
Product registration no.	95587
Label approval no.	95587/146456
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 500 g/L 2,4-DB soluble concentrate product for the control of broadleaf weeds in seedling and established lucerne, medic and clover pastures, peanuts and cereal crops undersown with lucerne, medic or clover

Table 2: Variations of registration – agricultural chemical products

Application no.	147272
Product name	Chlorostick 900 Dry Fungicide
Active constituent	900 g/kg chlorothalonil
Applicant name	Shandong Rainbow International Co Ltd
Applicant ACN	N/A
Date of variation	28 January 2025
Product registration no.	67756
Label approval no.	67756/147272
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 Chlorothalonil 900 Wg Fungicide’ to ‘Chlorostick 900 Dry Fungicide’

Application no.	147284
Product name	Epoxizole 125 Fungicide
Active constituent	125 g/L epoxiconazole
Applicant name	Shandong Rainbow International Co Ltd
Applicant ACN	N/A
Date of variation	31 January 2025
Product registration no.	68832
Label approval no.	68832/147284
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 Epoxiconazole 125 Sc Fungicide’ to ‘Epoxizole 125 Fungicide’

Application no.	147371
Product name	Propizole 625 Fungicide
Active constituent	625 g/L propiconazole
Applicant name	Shandong Rainbow International Co Ltd
Applicant ACN	N/A
Date of variation	3 February 2025
Product registration no.	89927
Label approval no.	89927/147371
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 'Pinazole Fungicide' to 'Propizole 625 Fungicide'

Application no.	147325
Product name	Tebuzole 430 Fungicide
Active constituent	430 g/L tebuconazole
Applicant name	Shandong Rainbow International Co Ltd
Applicant ACN	N/A
Date of variation	3 February 2025
Product registration no.	64019
Label approval no.	64019/147325
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 Tebuconazole 430 Sc Fungicide' to 'Tebuzole 430 Fungicide'

Application no.	147382
Product name	Bronx 200 Herbicide
Active constituent	200 g/L bromoxynil present as the N-octanoyl ester
Applicant name	Shandong Rainbow International Co Ltd
Applicant ACN	N/A
Date of variation	6 February 2025
Product registration no.	67052
Label approval no.	67052/147382
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 Bromoxynil 200 Selective Herbicide' to 'Bronx 200 Herbicide'

Application no.	147383
Product name	Bronx M Herbicide
Active constituents	200 g/L bromoxynil N-octanoyl ester, 200 g/L MCPA present as the ethyl hexyl ester
Applicant name	Shandong Rainbow International Co Ltd
Applicant ACN	N/A
Date of variation	6 February 2025
Product registration no.	81524
Label approval no.	81524/147383
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 'Bropac Herbicide' to 'Bronx M Herbicide'

Application no.	147347
Product name	Repelling Rid since1956 Bite Relief Repellent Antiseptic Bite Protection 6 Repels Mosquitos for 6 Hours Soothes Existing Bites Chamomile and Vitamin E Insect Repellent Lotion
Active constituents	160 g/L diethyltoluamide, 20 g/L N-octyl bicycloheptene dicarboximide, 1 g/L triclosan
Applicant name	Cavalieri Investing Pty Ltd
Applicant ACN	162 722 625
Date of variation	06 February 2025
Product registration no.	53404
Label approval no.	53404/147347
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 'Repelling Rid Since 1956 Insect Repellent Lotion' to 'Repelling Rid Since 1956 Bite Relief Repellent Antiseptic Bite Protection 6 Repels Mosquitos For 6 Hours Soothes Existing Bites Chamomile and Vitamin E Insect Repellent Lotion'

Application no.	147385
Product name	Captive 900 Fungicide
Active constituent	900 g/kg captan
Applicant name	Shandong Rainbow International Co Ltd
Applicant ACN	N/A
Date of variation	7 February 2025
Product registration no.	67513
Label approval no.	67513/147385
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 Captan 900 Wg Fungicide' to 'Captive 900 Fungicide'

Application no.	147386
Product name	CoProtect Dry Fungicide
Active constituents	300 g/kg prothioconazole, 300 g/kg tebuconazole
Applicant name	Shandong Rainbow International Co Ltd
Applicant ACN	N/A
Date of variation	7 February 2025
Product registration no.	84754
Label approval no.	84754/147386
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 'CoProtec Xtra Fungicide' to 'CoProtect Dry Fungicide'

Application no.	147384
Product name	Rusher Herbicide
Active constituent	700 g/kg imazethapyr
Applicant name	Shandong Rainbow International Co Ltd
Applicant ACN	N/A
Date of variation	7 February 2025
Product registration no.	67297
Label approval no.	67297/147384
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 Imazethapyr 700 Wg Herbicide' to 'Rusher Herbicide'

Application no.	145913
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 variation	12 February 2025
Product registration no.	95126
Label approval no.	95126/145913
Description of the application and its purpose, including the intended use of the chemical product	Variation to registration and label approval to add uses in fence lines and non-crop boundary areas and pre and post-sowing in certain grain legumes and cereal crops

Application no.	145930
Product name	Frequency Herbicide
Active constituents	60 g/L topramezone, 60 g/L cloquintocet-mexyl
Applicant name	BASF Australia Ltd
Applicant ACN	008 437 867
Date of variation	12 February 2025
Product registration no.	86267
Label approval no.	86267/145930
Description of the application and its purpose, including the intended use of the chemical product	Variation to registration particulars and particulars of label, to update the directions for use and general instructions

Application no.	147430
Product name	ProRox 480 Herbicide
Active constituent	480 g/L pyroxasulfone
Applicant name	Shandong Rainbow International Co Ltd
Applicant ACN	N/A
Date of variation	17 February 2025
Product registration no.	94333
Label approval no.	94333/147430
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 ‘Fletrox Herbicide’ to 'ProRox 480 Herbicide’

Application no.	146524
Product name	Apparent Methomyl 225 Insecticide
Active constituent	225 g/L methomyl (an anti-cholinesterase compound)
Applicant name	Titan Ag Pty Ltd
Applicant ACN	122 081 574
Date of variation	18 February 2025
Product registration no.	80047
Label approval no.	80047/146524
Description of the application and its purpose, including the intended use of the chemical product	Variation to particulars of registration and label approval to change the net contents from 5 L, 20 L to 1 L-1000 L

Application no.	147435
Product name	Enviroside International Mozzie Kill Mosquito Coils
Active constituent	2.5 g/kg pyrethrins
Applicant name	Yanco Limited
Applicant ACN	N/A
Date of variation	18 February 2025
Product registration no.	87731
Label approval no.	87731/147435
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 'Enviroside Mozzie Kill Coils' to 'Enviroside International Mozzie Kill Mosquito Coils'

Application no.	146344
Product name	Farmalinx Sayonara 10 GR Herbicide
Active constituent	10 g/kg prodiamine
Applicant name	Farmalinx Pty Ltd
Applicant ACN	134 353 245
Date of variation	19 February 2025
Product registration no.	89917
Label approval no.	89917/146344
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 an alternate application rate per 100 m^2 equivalent to currently approved rate in hectares for the label of 'ProForce Onset 10 GR Herbicide'

Application no.	145267
Product name	ProRox 850 Dry Herbicide
Active constituent	850 g/kg pyroxasulfone
Applicant name	Shandong Rainbow International Co Ltd
Applicant ACN	N/A
Date of variation	19 February 2025
Product registration no.	94284
Label approval no.	94284/145267
Description of the application and its purpose, including the intended use of the chemical product	Variation to registration and label particulars to update the product name to 'ProRox 850 Dry Herbicide' and add use in chickpeas, field peas, lentils and lupins

Application no.	146342
Product name	Polygon Glyphosate 540 Herbicide
Active constituent	540 g/L glyphosate present as the isopropylamine salt
Applicant name	Polygon (NZ) Limited
Applicant ACN	N/A
Date of variation	20 February 2025
Product registration no.	68790
Label approval no.	68790/146342
Description of the application and its purpose, including the intended use of the chemical product	Variation to registration particulars and label approval to add uses in aquatic weeds and revise the restraints and re-seeding interval

Application no.	145290
Product name	Tramat 500 SC Selective Herbicide
Active constituent	500 g/L ethofumesate
Applicant name	Bayer CropScience Pty Ltd
Applicant ACN	000 226 022
Date of variation	21 February 2025
Product registration no.	39508
Label approval no.	39508/145290
Description of the application and its purpose, including the intended use of the chemical product	Variation to registration particulars, and particulars of label to extend registration of all use patterns to all states

Table 3: Label approval – agricultural chemical products

Application no.	146684
Product name	4Farmers Glyphosate 450 Herbicide
Active constituent	450 g/L glyphosate present as the isopropylamine salt
Applicant name	4 Farmers Australia Pty Ltd
Applicant ACN	160 092 428
Date of registration	19 February 2025
Product registration no.	48552
Label approval no.	48552/146684
Description of the application and its purpose, including the intended use of the chemical product	Registration of a new label for the existing product ‘4farmers Glyphosate 450 Herbicide’ with the label name ‘Hellfire Bay Agchem Glyphosate 450 Herbicide’

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 4: Veterinary products based on existing active constituents

Application no.	144498
Product name	Levacare LV Oral Drench
Active constituent	68 g/L levamisole (equivalent to 80 g/L levamisole hydrochloride)
Applicant name	Aura Laboratories Limited
Applicant ACN	N/A
Date of registration	17 February 2025
Product registration no.	95029
Label approval no.	95029/144498
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 68 g/L levamisole (equivalent to 80 g/L levamisole hydrochloride) oral drench for the control of levamisole sensitive roundworms including lungworms in sheep and cattle and for the treatment of sensitive strains of roundworms in pigs and poultry

Application no.	142727
Product name	Wagg & Purr Milbemycin and Praziquantel Tablets for Cats
Active constituents	Each tablet contains 40 mg praziquantel and 16 mg milbemycin oxime
Applicant name	Avet Health Limited
Applicant ACN	616 838 101
Date of registration	21 February 2025
Product registration no.	94540
Label approval no.	94540/142727
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 40 mg praziquantel, 16 mg milbemycin oxime oral tablet product for the treatment and control of roundworm, hookworm and tapeworm and the prevention of heartworm in cats

Application no.	142744
Product name	Wagg & Purr Milbemycin and Praziquantel Tablets for Small Cats
Active constituents	Each tablet contains 10 mg praziquantel and 4 mg milbemycin oxime
Applicant name	Avet Health Limited
Applicant ACN	616 838 101
Date of registration	21 February 2025
Product registration no.	94549
Label approval no.	94549/142744
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 10 mg praziquantel, 4 mg milbemycin oxime oral tablet product for the treatment and control of roundworm, hookworm and tapeworm and the prevention of heartworm in cats

Application no.	146367
Product name	Recocam 40 mg/mL Solution for Injection for Cattle
Active constituent	40 mg/mL meloxicam
Applicant name	Bimeda (Australia) Pty Limited
Applicant ACN	058 196 508
Date of registration	21 February 2025
Product registration no.	95565
Label approval no.	95565/146367
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 40 mg/mL meloxicam injectable product as a non-steroidal anti-inflammatory, analgesic and antipyretic in cattle

Table 5: Variations of registration – veterinary chemical products

Application no.	147338
Product name	Selguard Spot-On for Cats
Active constituent	60 mg/mL selamectin
Applicant name	Headway Investments Pty Ltd
Applicant ACN	655 095 855
Date of variation	5 February 2025
Product registration no.	95417
Label approval no.	95417/147338
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 ‘Headway Selamectin Spot-On for Cats’ to ‘Selguard Spot-On for Cats’

Application no.	147401
Product name	Topizole Medicated Shampoo
Active constituents	20 g/L chlorhexidine gluconate, 20 g/L miconazole nitrate
Applicant name	Mavlab Pty Ltd
Applicant ACN	009 708 187
Date of variation	11 February 2025
Product registration no.	69088
Label approval no.	69088/147401
Description of the application and its purpose, including the intended use of the chemical product	Variation to the particulars of registration to update the first aid instructions appearing on a label to reflect the current First Aid Instructions and Safety Directions (FAISD) handbook as well as update to the disposal statement

Application no.	146433
Product name	Previcox 57mg Hi-select Cox-2 Flavoured Tablets: Pain & Inflammation Control
Active constituent	Each tablet contains 57 mg firocoxib
Applicant name	Boehringer Ingelheim Animal Health Australia Pty Ltd
Applicant ACN	071 187 285
Date of variation	17 February 2025
Product registration no.	58093
Label approval no.	58093/146433
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 vary the side effects statements

Application no.	144749
Product name	Extinosad Lice, Fly & Maggot Eliminator for Sheep
Active constituent	25 g/L spinosad
Applicant name	Elanco Australasia Pty Ltd
Applicant ACN	076 745 198
Date of variation	19 February 2025
Product registration no.	56875
Label approval no.	56875/144749
Description of the application and its purpose, including the intended use of the chemical product	Variation of the relevant particulars of product registration and label approval by changing the product name and aligning the label statements with the current Veterinary Labelling Code

Application no.	146409
Product name	Ultravac BEF Vaccine
Active constituent	≥ 10^4.3 TCID50 Bovine Ephemeral Fever Standard Strain (BB2271-919)
Applicant name	Zoetis Australia Pty Ltd
Applicant ACN	156 476 425
Date of variation	19 February 2025
Product registration no.	41461
Label approval no.	41461/146409
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 comply with the current Veterinary Labelling Code

Application no.	145761
Product name	Neovemox Long Acting Injection for Cattle
Active constituent	100 mg/mL moxidectin
Applicant name	Neove Pharma Australia Pty Limited
Applicant ACN	140 367 442
Date of variation	20 February 2025
Product registration no.	87812
Label approval no.	87812/145761
Description of the application and its purpose, including the intended use of the chemical product	Variation to the relevant particulars of the product registration and label approval by updating the label according to current Veterinary Labelling Code

Application no.	145109
Product name	Bromotrimidine Paste
Active constituent	450 mg/g sulfadimidine, 90 mg/g trimethoprim, 9 mg/g bromhexine hydrochloride
Applicant name	International Animal Health Products Pty Ltd
Applicant ACN	003 185 699
Date of variation	21 February 2025
Product registration no.	46084
Label approval no.	46084/145109
Description of the application and its purpose, including the intended use of the chemical product	Variation to the relevant particulars of the product and label by adding an additional pack size and changing the instructions of use on the product label to align with the current Veterinary Labelling Code

Approved active constituents

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

Table 6: Approved active constituents

Application no.	143084
Active constituent	Doramectin
Applicant name	The Hunter River Company Pty Limited
Applicant ACN	133 798 615
Date of approval	11 February 2025
Approval no.	94647
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent doramectin for use in veterinary chemical products

Application no.	144887
Active constituent	Azoxystrobin
Applicant name	Shanghai E-Tong Chemical Co Ltd
Applicant ACN	N/A
Date of approval	18 February 2025
Approval no.	95187
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent azoxystrobin for use in agricultural chemical products

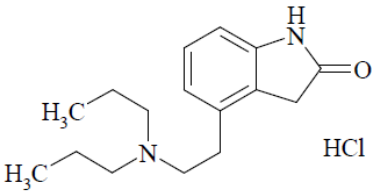
New veterinary chemical products containing a new veterinary active constituent

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application for the approval of a new active constituent, ropinirole hydrochloride, and an application for the registration of a new product containing the new active constituent, Clevor 30 mg/mL Eye Drops Solution, for the induction of vomiting in dogs.

Active constituent particulars

As part of the application to register Clevor 30 mg/mL Eye Drops Solution containing the new active, the APVMA has evaluated the safety of the new active constituent, ropinirole hydrochloride.

Table 7: Particulars of the active constituent ropinirole hydrochloride

Common name	Ropinirole hydrochloride
IUPAC name	4-[2-(dipropylamino)ethyl]-1,3-dihydroindol-2-one; hydrochloride
CAS name	2H-Indol-2-one, 4-[2-(dipropylamino)ethyl]-1,3-dihydro, hydrochloride (1:1)
CAS registry number	91374-20-8
Manufacturer's codes	RN
Minimum purity	98-102% (anhydrous substance)
Molecular formula	C16H24N2O.HCl
Molecular weight	296.8 g mol-1
Structure	
Chemical family	Indole
Mode of action	Non-ergot agonist at D2-like dopamine receptors, inducing emesis

Summary of the APVMA's evaluation of ropinirole hydrochloride active constituent

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

The APVMA has completed a toxicological evaluation of ropinirole hydrochloride.

Neither an Acceptable Daily Intake (ADI) nor an Acute Reference Dose (ARfD) have been established, as no uses in food producing species are currently proposed.

Ropinirole hydrochloride is included in **Schedule 4** of the Poisons Standard, with no exceptions or cut-offs.

Impurities are not expected to be present in ropinirole hydrochloride at toxicologically significant levels.

The health and toxicology assessment (HAT) has indicated that there are no objections on toxicological grounds to the approval of the active constituent ropinirole hydrochloride.

The APVMA is satisfied that the proposed importation and use of ropinirole hydrochloride would not be an undue toxicological hazard to the safety of people exposed to it during its handling and use.

Clevor 30 mg/mL Eye Drops Solution containing ropinirole hydrochloride

In addition to the application to approve the new active constituent, the APVMA has under consideration an application to register a new product, Clevor 30 mg/mL Eye Drops Solution, containing ropinirole hydrochloride.

Table 8: Particulars of the product

Proposed product name	Clevor 30 mg/mL Eye Drops Solution
Applicant company	MAVLAB ANIMAL HEALTH PTY LTD
Name of active constituent	Ropinirole hydrochloride
Signal heading	Schedule 4
Summary of proposed use	For the induction of vomiting in dogs
Dose rate	The effective dose is 3.75 mg/ m^2 body surface (2.7–5.4 mg/ m^2, equivalent to 1–8 eye drops depending on the size of the dog), administered by the ocular route, as a single dose (an additional dose may be given 15 to 20 minutes after administration of the initial dose)
Pack sizes	0.6 mL single dose ampoule 2 x 0.6 mL single dose ampoules 3 x 0.6 mL single dose ampoules 4 x 0.6 mL single dose ampoules 5 x 0.6 mL single dose ampoules 6 x 0.6 mL single dose ampoules 8 x 0.6 mL single dose ampoules 10 x 0.6 mL single dose ampoules
Withholding period	N/A

A summary of the APVMA's evaluation of Clevor 30 mg/mL Eye Drops Solution in accordance with the requirements of section 14(1)(C) of the Agricultural and Veterinary Chemicals Code (the 'Agvet Code'), scheduled to the *Agricultural and Veterinary Chemicals Code Act 1994:*

1) The APVMA has evaluated the application and in its assessment, in relation to whether the safety criteria have been met in accordance with the definition set out in section 5A of the Agvet Code, proposes to determine that:

   i. The APVMA is satisfied that proposed use of Clevor 30 mg/mL Eye Drops Solution would not be an undue hazard to the safety of people exposed to it during its handling and use.

      a. The product is intended for administration by a veterinarian or under their close supervision.

      b. The applicant proposed that the European registration dossiers and assessment reports are the most comprehensive data package for provision to the APVMA and have submitted all supporting toxicity data for approval of ropinirole and the product Clevor along with reports from the European Union Committee for Veterinary Medicinal Products (CVMP) under the European Medicines Agency (EMEA 2018) and comprehensive collection of supportive published literature. Human therapeutic evaluations from the Therapeutic Goods Administration (TGA) are available to the APVMA. Published reports from the US Food and Drug Administration (US FDA) have also been sourced and considered, along with additional published information.

      c. Ropinirole is authorised for human therapy of Parkinson's disease (PD) internationally and restless legs syndrome (RLS) in Australia. Therefore, information on human exposure towards ropinirole (clinical trials, treatment reports and case reports) is available from public literature. Any noteworthy differences in interpretation or conclusions have been proposed by the APVMA.

d. Ropinirole is currently included in Schedule 4 of the Poisons Standard (Health, 2024). This is considered appropriate for the proposed use of this veterinary medicine. None of the excipients in the product are listed or require listing in the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP). As Clevor 30 mg/mL Eye Drops Solution contains a Schedule 4 substance, it will require the signal heading 'PRESCRIPTION ANIMAL REMEDY'.

e. To mitigate potential risks, the following signal headings, first aid instructions, safety directions, and restraint statements are to appear on the product label:

Signal Heading

PRESCRIPTION ANIMAL REMEDY

KEEP OUT OF REACH OF CHILDREN

FOR ANIMAL TREATMENT ONLY

READ SAFETY DIRECTIONS BEFORE OPENING OR USING

First aid instructions

If poisoning occurs, contact a doctor or Poisons Information Centre. Phone Australia 13 11 26.

Safety directions

Wash hands after use.

Additional User Safety

Special precautions are to be taken by the person administering the veterinary medicinal product to animals.

People with known hypersensitivity to ropinirole should avoid contact with the veterinary medicinal product.

Administer the veterinary medicinal product with caution.

The veterinary medicinal product should not be administered by pregnant or breast-feeding women.

Ropinirole might reduce the level of prolactin due to its inhibitory effect on prolactin secretion as a dopamine agonist.

This veterinary medicinal product can cause eye irritation. In case of accidental eye or skin contact, rinse immediately the affected area with plenty of fresh water. If symptoms occur, seek medical advice and show the package leaflet or the label to the physician.

Restraints

For use only by or under supervision of a veterinarian.

f. After consideration of the toxicological profile and likely human exposure associated with the use of *Clevor 30 mg/mL Eye Drops Solution,* the APVMA concludes that the human health risks are acceptable according to the criteria stipulated in Section 5A of the *Agricultural and Veterinary Chemicals Code Act* (1994 as amended), for the proposed use and application method.

ii. The APVMA is satisfied that the proposed use of *Clevor 30 mg/mL Eye Drops Solution* will not be an undue hazard to the safety of people using anything containing its **residues.**

a. The product is for use in companion animals (dogs) only. *Clevor 30 mg/mL Eye Drops Solution* is therefore, unlikely to enter the food chain.

iii. The APVMA is satisfied that the proposed use of *Clevor 30 mg/mL Eye Drops Solution* containing the active constituent Ropinirole hydrochloride is not likely to have an unintended effect that is harmful to animals (dogs), plants or the **environment** if used according to the product label directions.

a. Environmental risks of *Clevor 30 mg/mL Eye Drops Solution* (containing ropinirole 30 mg/mL) were assessed according to the VICH Phase I decision tree. The assessment determined that the amount of Ropinirole hydrochloride introduced to the environment is expected to be negligible based on its uses in non-food animals (dogs). Therefore, the assessment stopped in VICH phase I and no further assessment was required.

b. The following mitigation/labelling statement is recommended, based on the outcome of the risk assessment and current label standards:

Disposal

'Dispose of container by wrapping with paper and putting in garbage'.

iv. The APVMA is satisfied that the proposed use of *Clevor 30 mg/mL Eye Drops Solution* containing the active constituent Ropinirole hydrochloride would **not be likely to have an unintended effect that is harmful to animals** if used according to the product label directions.

Target Animal Safety (TAS) was investigated in a pivotal TAS study, supported by some pre-clinical studies and the field study. The typical clinical signs observed at all dose levels (1x, 3x and 5x) are very similar in all (non)clinical studies and relate to the pharmacological action of ropinirole (dopamine agonists, especially D2 agonist), consisting mainly of signs of nausea (salivation, vomiting, retching, laboured or exaggerated respiration), dopaminergic central nervous system signs (lethargy, somnolence, decreased activity, uncoordinated movements, muscle tremors) and local eye symptoms (conjunctival hyperaemia, ptosis or blepharospasm, ocular discharge). Most of the reported clinical signs were mild or moderate and all of them transient in nature.

An emetic medicine ideally should not provoke persistent and prolonged vomiting. However, extended vomiting (more than 60 minutes) was noted in 3 studies, and in some cases metoclopramide (0.5 mg/kg s.c.) was needed as rescue medication: one out of 20 dogs one study, one out of 30 dogs in another and 8 out of 100 dogs in a third (5 of these needed recue treatment). The success in antagonising extended vomiting was obtained in all cases.

The use of ropinirole has neither been studied during pregnancy and lactation nor in old dogs, or in dogs with existing cardiac disease.

The APVMA has therefore, concluded that the administration of *Clevor 30 mg/mL Eye Drops Solution* is generally well tolerated and appropriate statements have been included on the label to mitigate the risks identified:

Contraindications

- Do not use in dogs with depression of the central nervous system, seizures or other marked neurologic impairments that could lead to aspiration pneumonia.
- Do not use in dogs which are hypoxic, dyspnoeic or lacking pharyngeal reflexes.
- Do not use in cases of the ingestion of sharp foreign objects, corrosive agents (acids or alkalis (e.g. drain or toilet bowl cleaners, household detergents, battery fluids)), volatile substances (e.g. petroleum products, essential oils, air fresheners) or organic solvents (e.g. antifreeze, windshield wiper fluids, nail polish remover).
- Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

Precautions

- The efficacy of the veterinary medicinal product has not been established in dogs weighing less than 1.8 kg, or in dogs under 4.5 months of age or in elderly dogs. Use only according to the benefit-risk assessment by the responsible veterinarian.
- Based on the clinical trial results, most dogs are expected to respond to a single dose of the veterinary medicinal product; however, a small proportion of dogs will require a second dose to induce vomiting. A very small proportion of dogs may fail to respond to the treatment despite administration of a second dose. It is not recommended to administer further doses to these dogs.
- This veterinary medicinal product may cause a transient increase in heart rate up to 2 hours after administration. The safety of the product has not been studied in dogs with diagnosed cardiac disease/ dysfunction. Use only according to the benefit-risk assessment by the responsible veterinarian.
- The safety of this product in dogs with clinical signs due to the ingestion of foreign materials has not been investigated.
- Ropinirole is metabolised by the liver. The safety of the product has not been studied in dogs with hepatic impairment. Use only according to the benefit-risk assessment by the responsible veterinarian.
- The safety and efficacy of the product have not been studied in dogs with ocular disease or injury. In case of a pre-existing ocular condition with clinical signs or predisposition to indolent ulcers, use the product only according to the benefit- risk assessment by the responsible veterinarian.
- The safety of the veterinary medicinal product has not been established during pregnancy and lactation in the target species or in animals intended for breeding. Ropinirole inhibits prolactin secretion by activation of dopamine D2 receptors located in the striatum and on lactotroph cells of pituitary gland. Therefore, use of this product is not recommended during pregnancy or lactation.
- Dopamine antagonists (such as metoclopramide), neuroleptics (e.g., chlorpromazine, acepromazine) and other medicinal products with antiemetic properties (e.g., maropitant or antihistamines) may reduce the effectiveness of this veterinary medicinal product.
- Pharmacodynamic interactions of ropinirole and general anaesthetics have also not been studied. This needs to be taken into consideration when used by a veterinarian to evacuate stomach contents, prior to a surgery.

Side Effects

Very common adverse reactions:

- Transient mild or moderate hyperaemia of the eye, ocular discharge, protrusion of the 3rd eyelid and blepharospasm.
- Transient mild lethargy and increased heart rate.

Common adverse reactions:

- Transient, mild conjunctival swelling, itching of the eyes, tachypnoea, tremors, diarrhoea, salivation, ataxia and uncoordinated movement. Extended vomiting (for more than 60 minutes) which should be evaluated by the responsible veterinarian as it might need appropriate treatment. In dogs with protracted vomiting (more than 60 minutes) and other clinical signs related to the pharmacological action of the active substance (e.g. ocular hyperaemia, tachycardia, tremors or shaking), dopamine antagonists such as metoclopramide or domperidone may be used to manage these clinical signs. Maropitant does not reverse the clinical signs related to the pharmacological action of ropinirole.

Uncommon adverse reactions:

– Corneal ulceration and anxiety

The frequency of adverse reactions is defined using the following convention: very common (more than one in 10 animals treated displaying adverse reaction(s) common (more than one but less than 10 animals in 100 animals treated) uncommon (more than one but less than 10 animals in 1,000 animals treated) rare (more than one but less than 10 animals in 10,000 animals treated) very rare (less than one animal in 10,000 animals treated, including isolated reports).

Overdose

The tolerance of this veterinary medicinal product was investigated in a target animal safety study at all dose levels up to 5 times the clinical dose (that is, up to 124.6 μl/kg) when given on 2 occasions, 15–20 minutes apart, every day for 3 days. The clinical signs (lethargy, tachycardia, tremors, ataxia, uncoordinated movement, hyperaemia of the eye, ocular discharge, protrusion of the third eyelid and blepharospasm) were comparable in frequency and severity between the different dose groups. Increased mean heart rate was observed one hour after treatment with all 3 doses (1X, 3X, 5X) and went back to normal levels after 6 hours.

2) The APVMA has evaluated the application and in its assessment, in relation to whether the **efficacy criteria** have been met in accordance with the definition set out in section 5B of the Agvet Code, and proposes to determine that:

i. The APVMA is satisfied that data from trials supporting the efficacy of the product adequately demonstrated that if used according to the product label directions, the product is effective for its proposed uses.

The summary of the efficacy studies/assessment results have been provided below:

a. Pharmacodynamics:

Ropinirole is a well-established active substance in human medicines (dopamine agonist used in anti-Parkinson medicines). Ropinirole primarily activates dopamine D2 and D3 receptors to induce emesis in dogs. In vitro and in vivo data showed that ropinirole in dogs can have cardiovascular effects, resulting in vivo in moderate to marked increase in heart rate, short term initial increase in systolic blood pressure, and an increase in QTc interval.

b. Interactions:

Ropinirole is a dopamine agonist; therefore, dopamine antagonists such as metoclopramide, domperidone, and droperidol do antagonise the effect of ropinirole. Also, other antiemetics, like NK1-antagonist maropitant, are expected to antagonise vomiting induced by ropinirole. Additionally, medication with known antiemetic properties might reduce the effectiveness of ropinirole.

c. Pharmacokinetics:

Absorption

Ropinirole is rapidly absorbed into the systemic circulation of dogs after administration as a solution on their eye surface. At the target dose of 3.75 mg/m^2 (equivalent to 2–15 μl/kg bw), a peak plasma concentration (Cmax) of 25.6 ng/ml is reached 10 to 20 minutes (tmax) after administration. The systemic bioavailability of the drug by this ocular route of administration is 18–28%. Vomiting starts before the Cmax in plasma is reached. No direct correlation between ropinirole concentration in plasma and the duration of vomiting was observed after ocular administration.

Distribution

Ropinirole is rapidly distributed and has a relatively high apparent volume of distribution. In dogs, the volume of distribution (Vz) is 5.6 l/kg after intravenous administration. The fraction bound to plasma proteins in dogs is low (37%). The systemic exposure to ropinirole based on Cmax and AUC did not show complete dose linearity as the exposure increased less than dose proportionally.

Metabolism and Elimination

Ropinirole is mainly eliminated by hepatic metabolism. Biotransformation occurs by N-despropylation, hydroxylation and subsequent conjugation with glucuronic acid or oxidation to carboxylic acid. In dogs and rats, the main metabolite is the 7-hydroxylated metabolite.

Excretion has not been studied in dogs after ropinirole administration by the ocular route. Based on literature data, the major route of excretion of ropinirole and its metabolites is renal. In dogs, after intravenous administration, the portion recovered as unchanged ropinirole in the urine is below 3% within the first 24 hours.

d. Dose finding:

Two dose finding studies in clinically healthy dogs were provided, one positive (apomorphine) controlled and one uncontrolled study.

A study tested ropinirole eye drops to inducing emesis in dogs at a dose of 28–220 μg/kg bw (corresponding to 0.9, 2.5 and 5.5 mg/m^2, or 1, 2 or 4 drops). The effective dose was better assessed using body surface area than body weight, with a dose range of 2.5–5 mg/m^2. After receiving ropinirole, 74%, 89% and 95% of dogs vomited within 10, 20 and 30 minutes, whereas 80%, 90% and 100% of dogs treated with apomorphine vomited, respectively. The results indicate that ropinirole had slightly less efficacy than the reference compound used (apomorphine), induced mild adverse reactions (not reported for the reference product), and also extended vomiting in one ropinirole-treated dog (which required the use of metoclopramide as an antidote).The applicant considered that a single dose of 2.5 mg ropinirole / m^2 body surface was effective; however, as the dose response was not conclusive in this study, an additional dose-finding study was conducted.

In another dose-finding study ropinirole at a dose of 3.75 mg/m^2, ranging doses from 2.6 to 4.5 mg/m^2, was effective to induce vomiting in small and large dogs (93% vomited within 17 minutes after administration, and the rest (n=2) vomited after receiving an additional dose). In this study, adverse events were reported in 28 dogs (93.3%) and their severity was considered as mild (eye redness, protrusion membrane nictitans, lethargy and other unspecified eye disorders). Increases in heart rate were also commonly detected. Based on the results of this study the target dose of 3.75 mg/m^2 with a dose range of 2.7–5.4 mg/m^2 was selected for the pivotal clinical field study.

e. Field study:

In the pivotal field study, the efficacy of ropinirole eye drops (30 mg/ml) at the recommended dose of 3.75 mg/m^2 (dose band 2.7-5.4 mg/m^2) compared to placebo was investigated in 132 healthy dogs. Ropinirole induced vomiting in dogs at a target dose of 3.75 mg/m^2 with a responder rate within 30 minutes (95% of tested dogs). The initial target induced vomiting in 87% of the dogs, and when an additional dose was administered to the remaining animals (13%), vomiting was induced in 62% of them. There was a relationship between the onset of vomiting and the dose, but not between the duration of vomiting and dose or between the number of vomits and the dose. Vomiting started approximately 11–12 minutes after administration of the drop(s) and lasted approximately 23 minutes (mean duration). The time between the first to the last vomit was 0–108 minutes (0 if the dog vomited only once).

ii. The APVMA has therefore, concluded that *Clevor 30 mg/mL Eye Drops Solution*, would be effective for the induction of vomiting in dogs and relevant statements have been placed on the label to mitigate any risks identified:

Claims

- For the induction of vomiting in dogs.
- Ropinirole is a dopamine agonist, which means that it imitates the action of dopamine. Dopamine is a messenger substance in the part of the brain which controls vomiting. By stimulating this part of the brain ropinirole triggers vomiting.
- Initiation of emesis should form part of a multi-modal treatment plan as determined by the veterinarian.

Dosage and Administration

- Discard unused product 30 minutes after opening the immediate packaging (pouch and container).
- For ophthalmic use in dogs only.
- This veterinary medicinal product should only be administered by a veterinarian or under their close supervision.
- The product is to be administered into the eye, at a dose of 1–8 eye drops. The volume of one drop is approximately 27 µl. Each eye drop contains 810 µg of ropinirole. The dose is equivalent to 2–15 µl/kg bw in dogs. The number of eye drops in each body weight group corresponds to the target dose of 3.75 mg/m^2 body surface area (dose range 2.7– 5.4 mg/ m^2). These doses have been tested in dogs weighing between 1.8 kg and 100 kg (0.15– 2.21 m^2 body surface area).
- When a quantity of 2 to 4 drops is to be administered, the dose should be divided between both eyes. For example, for the administration of 3 drops: administer 2 drops into the right eye and one drop into the left eye.
- When a quantity of 6 or 8 drops is to be administered, the dose should be divided into 2 alternate administrations given 1–2 minutes apart. For example, for the administration of 6 drops: administer 2 drops into the right eye and 2 drops into the left eye, then after 1–2 minutes pause, administer a further one drop into each eye.
- If the dog does not vomit within 15 minutes after administration of the initial dose a second dose may be given 15 to 20 minutes after administration of the initial dose. The second dose should be the same number of drops as the initial dose. It is recommended to record the time of first administration.
- After opening the pouch, the container should be kept in the pouch to protect from light. Be careful not to touch the dropper tip after opening the container in case a second dose is necessary.
- Studies have shown that emetics generally do not remove more than 80% of the stomach contents (usually 40-60%). This product must, therefore, be used alongside other strategies of decontamination. The exposure circumstances, such as time since exposure, chemical nature of toxicant, and amount ingested, will determine the appropriate method of patient decontamination. These include dilution, gastric lavage, and the use of adsorbents and cathartics. The veterinarian is to determine the best treatment plan.

3) The APVMA has evaluated the application and in its assessment in relation to whether the **trade criteria** have been met in accordance with the definition set out in section 5C of the Agvet Code, proposes to determine that:

i. The APVMA is satisfied that the proposed use of *Clevor 30 mg/mL Eye Drops Solution*, would not adversely affect trade between Australia and places outside Australia. The product is for use on dogs, which are not food-producing animals, and which do not produce any major Australian export commodities.

ii. Therefore, there are no concerns from a trade perspective relating to the registration of this product.

Making a submission

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

In accordance with section 13 of the Agvet Code, the APVMA invites any person to submit a relevant written submission as to whether *Clevor 30 mg/mL Eye Drops Solution* should be registered. Submissions should relate only to matters that are required by the APVMA to be taken into consideration in determining whether the safety, efficacy or trade criteria have been met. Submissions should state the grounds on which they are based.

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

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

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

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

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

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

Email: casemanagement@apvma.gov.au

Post:
Case Management
Australian Pesticides and Veterinary Medicines Authority
GPO Box 574
Canberra ACT 2601

Privacy

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

Licensing of veterinary chemical manufacturers

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

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

New licenses

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

Table 9: New licenses issued by the APVMA under subsection 123(1) of the Agvet Code

Company name	Licence number	Company ACN / ABN	Address	Product types	Steps of manufacture	Date issued
Zoetis Australia Research & Manufacturing Pty Ltd	1098	158 433 053	45 Poplar Road Parkville VIC 3052	Category 1: Immunobiologicals, sterile products, subcutaneous implants, and dermal scratch	Quality assurance (QA) of raw materials, bacterial fermentation, virus cultivation, propagation of genetically modified mammalian cells, extraction and purification of viral protein, peptide conjugation, formulation including blending, aseptic filling, filling, packaging, labelling, sterilisation (heat, and filtration), microbiological reduction treatment (chemical, heat, and filtration), freeze drying, analysis and testing (physical), secondary packaging, secondary labelling, repackaging, relabelling, storage, and release for supply.	13 February 2025
The State of Queensland, acting through the Department of Primary Industries	6175	66 934 348 189	Biosecurity Sciences Laboratory Health and Food Sciences Precinct 39 Kessels Road Coopers Plains QLD 4108	Category 6: All dosage forms	Analysis and testing (serological, immunological, virological (vaccine potency and purity testing)).	18 February 2025

Licence cancellations

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

Table 10: Licenses cancelled by the APVMA under subsection 127(1) of the Agvet Code

Company name	Licence number	Company ACN/ABN	Address	Date cancelled
CBE Pure Solutions Pty Ltd	2279	651 336 640	5 William Street Ferntree Gully VIC 3156	21 February 2025
The University of New England	6142	75 792 454 315	Reproductive & Metabolic Endocrinology Laboratory School of Science & Technology McClymont Building University of New England ARMIDALE NSW 2351	21 February 2025

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

Agvet chemical voluntary recall: Yates Home Pest Ant & Nest Killer Gel Bait

Product name: Yates Home Pest Ant & Nest Killer Gel Bait

APVMA registration number: 87602

APVMA approved label number: 122610

Batch number: ABW4J11077

Sold by: Retailers nationally between 31 January 2025 to 18 February 2025.

On 18 February 2025, Syngenta Australia Pty Ltd (ACN 002 933 717) initiated a voluntary recall under section 106 of the Agricultural and Veterinary Chemicals Code scheduled to the *Agricultural and Veterinary Chemicals Code Act 1994* (Cth) in relation to the chemical product described above.

Reason for voluntary recall

The syringes in 10 g packs of Yates Home Pest Ant & Nest Killer Gel Bait (batch number ABW4J11077) have been incorrectly labelled as Yates Home Pest Cockroach Killer Gel Bait as indicated in the photograph in the notice on the APVMA website.

Hazard

The incorrect label on the syringes may mislead the user to use the product for the wrong purpose. The product in the syringes will control ants but is ineffective for cockroach control.

What to do if in possession of this chemical product

Check if the 10 g syringe from batch number ABW4J11077 is correctly labelled as Yates Home Pest Ant & Nest Killer Gel Bait. If the syringe is labelled as Yates Home Pest Cockroach Killer Gel Bait, as indicated in the photograph above, please contact Yates Consumer Advice on 1300 369 074 to arrange a replacement.

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

Questions about this voluntary recall should be directed to:

Syngenta Customer Service
Phone: 1800 022 035

Notice of cancellation at the request of the holder

At the request of the holder, in accordance with section 42(1) of the Agricultural and Veterinary Chemicals Code scheduled to the *Agricultural and Veterinary Chemicals Code Act 1994* (Agvet Code), the APVMA has cancelled the approvals and/or registrations set out in Table 11:

Table 11: Active constituent approval/product registration/label approval cancelled at the request of the holder

Approval or registration number	Name	Type of approval or registration	Holder	Reason for cancellation (if relevant pursuant to s45A(3))	Date of cancellation
58768	Yates Buffalo Pro Selective Bindii & Broadleaf Weed Killer	Product	Duluxgroup (Australia) Pty Ltd	Not Applicable	24 February 2025
59093	Searles Buffalo Master Selective Weedkiller	Product	JC & AT Searle Pty Ltd	Not Applicable	24 February 2025
65889/52232 **65889/53431** **65889/123928** **65889/136549**	Titan Abamectin 18 Insecticide/Miticide	Label	Titan Ag Pty Ltd	May not meet the labelling criteria	24 February 2025
67027	Hortico Bindii Killer Concentrate Lawns	Product	Duluxgroup (Australia) Pty Ltd	Not Applicable	24 February 2025
82498 / 105884	KDPC Mectin Insecticide/Miticide	Label	KD Plant Care Pty Ltd	May not meet the labelling criteria	24 February 2025
91660	Searles Ultraweed Turf Weedkiller	Product	JC & AT Searle Pty Ltd	Not applicable	24 February 2025
94817/143752	Globachem Abamectin 18 EC Insecticide	Label	Globachem n.v.	May not meet the labelling criteria	24 February 2025

In accordance with section 45A(1)(b) of the Agvet Code, the APVMA publishes this notice of the cancellation, including the following instructions which set out how a person can deal with the cancelled active constituent, cancelled product or product bearing a cancelled label referred to in Table 11.

Instructions

Instructions for persons who possess, have custody of or use the cancelled active constituent, cancelled product, or the product bearing a cancelled label under section 45B(3) of the Agvet Code.

A person who possesses, has custody of or uses the cancelled active constituent, cancelled product or product bearing a cancelled label referred to in Table 11 in accordance with the instructions contained in this notice, is taken to have been issued with a permit under section 45B(3) of the Agvet Code to possess, have custody of or use the cancelled active constituent, cancelled product or product bearing a cancelled label, in accordance with those instructions.

Possession, custody or use

A person may possess or have custody of the cancelled active constituent, cancelled product or product bearing a cancelled label referred to in Table 11 in accordance with its label instructions for one year from the date of cancellation.

A person may use the cancelled active constituent, cancelled product or products bearing a cancelled label referred to in Table 11 according to its label instructions, including any conditions relating to shelf life or expiry date, for one year after the date of cancellation.

Supply or otherwise deal with

In accordance with section 45C of the Agvet Code, if a person possesses or has custody of a cancelled active constituent, cancelled product, or product bearing a cancelled label listed in Table 11 with the intention of supplying it, the person may only possess, have custody of, or otherwise deal with the cancelled products according to the instructions contained in this notice.

A person may supply or cause to be supplied at wholesale or retail level the cancelled active constituent, cancelled product, or product bearing a cancelled label referred to in Table 11, for one year after the date of cancellation.

Contraventions

After the day that is one year from the date of cancellation it will be an offence against the Agvet Code to have possession or custody of the cancelled active constituents, cancelled products or products bearing a cancelled label with the intention to supply, or to supply the cancelled active constituent, cancelled product, or product bearing a cancelled label.

It is an offence to possess, have custody of, use, or otherwise deal with the cancelled active constituents, cancelled products or products bearing the cancelled label listed in Table 11 in a manner that contravenes the above instructions.

APVMA contact

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

Chemical Review
Australian Pesticides and Veterinary Medicines Authority
GPO Box 3262
Sydney NSW 2001

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

More information

The APVMA publishes a list of voluntary cancellations at the request of the holder on its website, and provides a subscription option to be notified by email when the list is updated.