

# Commonwealth of Australia

# **Gazette**

## Agricultural and veterinary chemicals

No. APVMA 23, 14 November 2023

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.

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## **General information**

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

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

### **Distribution and subscription**

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## Agricultural chemical products and approved labels

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

Table 1: Agricultural products based on existing active constituents

Application no.	136191
Product name	Conquest Barbarian WG Herbicide
Active constituents	375 g/kg aminopyralid present as the potassium salt, 300 g/kg metsulfuron-methyl
Applicant name	Conquest Crop Protection Pty Ltd
Applicant ACN	098 814 932
Date of registration	25 October 2023
Product registration no.	92650
Label approval no.	92650/136191
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 375 g/kg aminopyralid present as the potassium salt and 300 g/kg metsulfuron-methyl WG product for post-emergent control or suppression of broadleaf weeds in winter cereal crops and brush and broadleaf weeds in pastures and non-agricultural areas as specified in the directions for use

Application no.	140072
Product name	Combat Ant-Rid 2in1 Ant Killing Bait
Active constituents	Part A 0.1 g/kg, Part B 0.01 g/kg
Applicant name	Henkel Australia Pty Ltd
Applicant ACN	001 302 996
Date of registration	25 October 2023
Product registration no.	93656
Label approval no.	93656/140072
Description of the application and its purpose, including the intended use of the chemical product	Registration of a dual 0.1 g/kg and 0.01 g/kg fipronil bait product for the control of ants

Application no.	140765
Product name	Green Diamond Scoot Insect Repellent
Active constituent	270 g/L oil of lemon eucalyptus (hydrated, cyclised)
Applicant name	New Generation Aerosols Pty Ltd
Applicant ACN	120 403 107
Date of registration	25 October 2023
Product registration no.	93875
Label approval no.	93875/140765
Description of the application and its purpose, including the intended use of the chemical product	Registration of a household insecticide product containing 270 g/L oil of lemon eucalyptus to repel mosquitoes, midges and ticks

Application no.	140725
Product name	CropSure Bullion 960 Herbicide
Active constituent	960 g/L S-metolachlor
Applicant name	CropSure Pty Ltd
Applicant ACN	643 829 190
Date of registration	25 October 2023
Product registration no.	93862
Label approval no.	93862/140725
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 960 g/L S-metolachlor, emulsifiable concentrate product for control of certain annual grasses and broadleaf weeds in certain crops

Application no.	140911
Product name	NAADCO Lambda-Cyhalothrin 250 Insecticide
Active constituent	250 g/L lambda-cyhalothrin
Applicant name	New Australia Agricultural Development Company Pty Ltd
Applicant ACN	138 055 553
Date of registration	26 October 2023
Product registration no.	93922
Label approval no.	93922/140911
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 250 g/L lambda-cyhalothrin capsule suspension product for the control of certain insect pests in cotton, barley, wheat and various field crops

Application no.	140919
Product name	OzCrop Diafenthiuron 500 SC Miticide / Insecticide
Active constituent	500 g/L diafenthiuron
Applicant name	Oz Crop Pty Ltd
Applicant ACN	160 656 431
Date of registration	26 October 2023
Product registration no.	93925
Label approval no.	93925/140919
Description of the application and its purpose, including the intended use of the chemical product	Registration of a suspension concentrate (SC) product containing 500 g/L diafenthiuron for the control of various pests in cotton

Application no.	137903
Product name	Imtrade Construct 850 WG Herbicide
Active constituent	850 g/kg flumioxazin
Applicant name	Imtrade Australia Pty Ltd
Applicant ACN	090 151 134
Date of registration	27 October 2023
Product registration no.	93076
Label approval no.	93076/137903
Description of the application and its purpose, including the intended use of the chemical product	Registration of an 850 g/kg flumioxazin water dispersible granule product for the rapid knockdown and control of various grass and broadleaved weeds when mixed with certain glyphosate or paraquat/diquat herbicides, and for the control of volunteer cotton when applied alone, prior to sowing cotton and its rotation crops, or for rapid knockdown and control of various broadleaved weeds when applied as a directed spray in cotton. For knockdown and residual control of various grasses and broadleaved weeds in sugarcane

Application no.	137909
Product name	Imtrade Construct 850 Veriphy WG Herbicide
Active constituent	850 g/kg flumioxazin
Applicant name	Imtrade Australia Pty Ltd
Applicant ACN	090 151 134
Date of registration	27 October 2023
Product registration no.	93081
Label approval no.	93081/137909
Description of the application and its purpose, including the intended use of the chemical product	Registration of an 850 g/kg flumioxazin water dispersible granule product for the rapid knockdown and control of various grass and broadleaved weeds when mixed with certain glyphosate or paraquat/diquat herbicides, and for the control of volunteer cotton when applied alone, prior to sowing cotton and its rotation crops, or for rapid knockdown and control of various broadleaved weeds when applied as a directed spray in cotton. For knockdown and residual control of various grasses and broadleaved weeds in sugarcane

Application no.	140912
Product name	NAADCO Abamectin 18 EC Insecticide/Miticide
Active constituent	18 g/L abamectin
Applicant name	New Australia Agricultural Development Company Pty Ltd
Applicant ACN	138 055 553
Date of registration	27 October 2023
Product registration no.	93923
Label approval no.	93923/140912
Description of the application and its purpose, including the intended use of the chemical product	Registration of an 18 g/L abamectin emulsifiable concentrate (EC) insecticide/miticide product for the control of pest mites on pears, apples, tomatoes, citrus, hops, strawberries and ornamentals. For the control of pest mites and native budworm on cotton

Application no.	137744
Product name	Titan Propyzamide 800 WG Herbicide
Active constituent	800 g/kg propyzamide
Applicant name	Titan Ag Pty Ltd
Applicant ACN	122 081 574
Date of registration	30 October 2023
Product registration no.	93035
Label approval no.	93035/137744
Description of the application and its purpose, including the intended use of the chemical product	Registration of an 800 g/kg propyzamide water dispersible granule (WG) product for selective control of certain grasses and broad leaf weeds in canola, grain legumes, legume pasture and lettuce

Application no.	140877
Product name	Agro-Essence Glyphosate 540 Herbicide
Active constituent	540 g/L glyphosate present as the potassium salt
Applicant name	Agro-Alliance (Australia) Pty Ltd
Applicant ACN	130 864 603
Date of registration	30 October 2023
Product registration no.	93907
Label approval no.	93907/140877
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 540 g/L glyphosate, present as the potassium salt, soluble concentrate (SL) product for the control of many annual and perennial weeds

Table 2: Variations of registration – agricultural chemical products

Application no.	141581
Product name	Albaugh Fluropix 400 Herbicide
Active constituent	400 g/L fluroxypyr present as the methyl heptyl ester
Applicant name	Albaugh Asia Pacific Limited
Applicant ACN	N/A
Date of variation	9 October 2023
Product registration no.	81092
Label approval no.	81092/141581
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 'Fluropix 400 Herbicide' to 'Albaugh Fluropix 400 Herbicide'

Application no.	141580
Product name	Albaugh Metsuram 600 WG Herbicide
Active constituent	600 g/kg metsulfuron methyl
Applicant name	Albaugh Asia Pacific Limited
Applicant ACN	N/A
Date of variation	9 October 2023
Product registration no.	81100
Label approval no.	81100/141580
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 'Metsuram 600 WG Herbicide' to 'Albaugh Metsuram 600 WG Herbicide'

Application no.	141603
Product name	SeaQuantum Spectrum
Active constituents	449 g/L to 453 g/L copper present as cuprous oxide, 61.6 g/L to 62.2 g/L zineb, 23.9 g/L to 24.1 g/L copper pyrithione
Applicant name	Jotun Australia Pty Ltd
Applicant ACN	007 126 696
Date of variation	11 October 2023
Product registration no.	92978
Label approval no.	92978/141603
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 'Megayacht Imperial Antifouling' to 'SeaQuantum Spectrum'

Application no.	141683
Product name	Albaugh Hexanil 250 SL Herbicide
Active constituent	250 g/L hexazinone
Applicant name	Albaugh Asia Pacific Limited
Applicant ACN	N/A
Date of variation	16 October 2023
Product registration no.	81083
Label approval no.	81083/141683
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 'Hexanil 250 SL Herbicide' to 'Albaugh Hexanil 250 SL Herbicide'

Application no.	141682
Product name	Albaugh Tuken 500 Herbicide
Active constituent	500 g/L diflufenican
Applicant name	Albaugh Asia Pacific Limited
Applicant ACN	N/A
Date of variation	16 October 2023
Product registration no.	81087
Label approval no.	81087/141682
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 'Tuken 500 Herbicide' to 'Albaugh Tuken 500 Herbicide'

Application no.	141684
Product name	Albaugh Tuken Extra Herbicide
Active constituents	250 g/L MCPA present as the ethyl hexyl ester, 25 g/L diflufenican
Applicant name	Albaugh Asia Pacific Limited
Applicant ACN	N/A
Date of variation	16 October 2023
Product registration no.	81044
Label approval no.	81044/141684
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 'Tuken Extra Herbicide' to 'Albaugh Tuken Extra Herbicide'

Application no.	141735
Product name	Skipper 700 WG Herbicide
Active constituent	700 g/kg imazethapyr
Applicant name	Sipcam Pacific Australia Pty Ltd
Applicant ACN	073 176 888
Date of variation	18 October 2023
Product registration no.	68317
Label approval no.	68317/141735
Description of the application and its purpose, including the intended use of the chemical product	Variation to the particulars of registration and label approval to update the first aid instructions and safety directions in compliance with the current FAISD Handbook

Application no.	141768
Product name	Albaugh Binder Insecticide
Active constituent	100 g/L bifenthrin
Applicant name	Albaugh Asia Pacific Limited
Applicant ACN	N/A
Date of variation	23 October 2023
Product registration no.	80901
Label approval no.	80901/141768
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 'Binder Insecticide' to 'Albaugh Binder Insecticide'

Application no.	141765
Product name	Albaugh Durango 360 Herbicide
Active constituent	360 g/L glyphosate present as the isopropylamine and mono-ammonium salts
Applicant name	Albaugh Asia Pacific Limited
Applicant ACN	N/A
Date of variation	23 October 2023
Product registration no.	80641
Label approval no.	80641/141765
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 'Durango Herbicide' to 'Albaugh Durango 360 Herbicide'

Application no.	141767
Product name	Albaugh Icasso 240 Herbicide
Active constituent	240 g/L clethodim
Applicant name	Albaugh Asia Pacific Limited
Applicant ACN	N/A
Date of variation	23 October 2023
Product registration no.	80906
Label approval no.	80906/141767
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 'lcasso 240 Herbicide' to 'Albaugh Icasso 240 Herbicide'

Application no.	141071
Product name	Conquest Imida 600 Seed Treatment Insecticide
Active constituent	600 g/L imidacloprid
Applicant name	Conquest Crop Protection Pty Ltd
Applicant ACN	098 814 932
Date of variation	23 October 2023
Product registration no.	67428
Label approval no.	67428/141071
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 withholding periods section of the label

Application no.	140982
Product name	Apparent Left Hook 960 Herbicide
Active constituent	960 g/L S-metolachlor
Applicant name	Titan Ag Pty Ltd
Applicant ACN	122 081 574
Date of variation	23 October 2023
Product registration no.	66008
Label approval no.	66008/140982
Description of the application and its purpose, including the intended use of the chemical product	Variation of product registration and label approval to amend rates in critical comments in the directions for use and add spray drift restraints

Application no.	140865
Product name	Spalding Imidacloprid 600 SC Insecticide
Active constituent	600 g/L imidacloprid
Applicant name	DGL Environmental Pty Ltd
Applicant ACN	002 802 646
Date of variation	25 October 2023
Product registration no.	85016
Label approval no.	85016/140865
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 withholding period and add spray drift restraints

Application no.	140929
Product name	Agro-Essence Boxmate A Herbicide
Active constituent	960 g/L S-metolachlor
Applicant name	Agro-Alliance (Australia) Pty Ltd
Applicant ACN	130 864 603
Date of variation	25 October 2023
Product registration no.	81065
Label approval no.	81065/140929
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 restraints section of the label

Application no.	140936
Product name	GP FluPro 745 SL Herbicide
Active constituent	745 g/L flupropanate present as the sodium salt
Applicant name	Granular Products Assets Pty Ltd
Applicant ACN	614 694 405
Date of variation	25 October 2023
Product registration no.	83153
Label approval no.	83153/140936
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 withholding period and add spray drift restraints

Application no.	140984
Product name	F.S.A. Imidacloprid 600 Flowable Seed Treatment Insecticide
Active constituent	600 g/L imidacloprid
Applicant name	Four Seasons Agribusiness Pty Ltd
Applicant ACN	115 133 189
Date of variation	25 October 2023
Product registration no.	87149
Label approval no.	87149/140984
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 withholding period

Application no.	141044
Product name	Sindor 600 Flowable Seed Treatment
Active constituent	600 g/L imidacloprid
Applicant name	Sinon Australia Pty Ltd
Applicant ACN	102 741 024
Date of variation	25 October 2023
Product registration no.	83389
Label approval no.	83389/141044
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 withholding period

Application no.	141010
Product name	Globachem's Imida Insecticide
Active constituent	600 g/L imidacloprid
Applicant name	Globachem n.v.
Applicant ACN	N/A
Date of variation	25 October 2023
Product registration no.	86424
Label approval no.	86424/141010
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 withholding period

Analization no	44400
Application no.	141183
Product name	Immix 600 Seed Treatment
Active constituent	600 g/L imidacloprid
Applicant name	Nutrien Ag Solutions Limited
Applicant ACN	008 743 217
Date of variation	25 October 2023
Product registration no.	82395
Label approval no.	82395/141183
Description of the application and its purpose, including the intended use of the chemical product	Variation of product registration and label approval to update the withholding period

Application no.	141200
Product name	EzyCrop Flupropanate 745 Herbicide
Active constituent	745 g/L flupropanate present as the sodium salt
Applicant name	EzyCrop Pty Ltd
Applicant ACN	156 476 827
Date of variation	25 October 2023
Product registration no.	81167
Label approval no.	81167/141200
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 withholding period and add spray drift restraints

Application no.	140910
Product name	Kenso AgCare Radicle 600 FS Flowable Seed Dressing Insecticide
Active constituent	600 g/L imidacloprid
Applicant name	Kenso Corporation (M) Sdn. Bhd.
Applicant ACN	N/A
Date of variation	26 October 2023
Product registration no.	62062
Label approval no.	62062/140910
Description of the application and its purpose, including the intended use of the chemical product	Variation of product registration and label approval to update the withholding periods on the label

Application no.	141012
Product name	Genfarm Azoxystrobin 250 SC Fungicide
Active constituent	250 g/L azoxystrobin
Applicant name	Nutrien Ag Solutions Limited
Applicant ACN	008 743 217
Date of variation	31 October 2023
Product registration no.	67483
Label approval no.	67483/141012
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 extend the pack size range from 5 L $-$ 110 L to 5 L $-$ 1,000 L

Application no.	140873
Product name	Opal Propyzamide 500 SC Herbicide
Active constituent	500 g/L propyzamide
Applicant name	Opal Australasia Pty Ltd
Applicant ACN	103 454 879
Date of variation	1 November 2023
Product registration no.	88113
Label approval no.	88113/140873
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 label with amended label sections of constituent statements and restraints

Application no.	140983
Product name	Hemani Imidacloprid 600 Seed Treatment Insecticide
Active constituent	600 g/L imidacloprid
Applicant name	Hemani Australia Pty Ltd
Applicant ACN	634 346 357
Date of variation	2 November 2023
Product registration no.	85370
Label approval no.	85370/140983
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 withholding period

Application no.	140918
Product name	eChem S-Metol 960 Herbicide
Active constituent	960 g/L S-metolachlor
Applicant name	eChem (Aust) Pty Ltd
Applicant ACN	089 133 095
Date of variation	3 November 2023
Product registration no.	81853
Label approval no.	81853/140918
Description of the application and its purpose, including the intended use of the chemical product	Variation to registration to amend the amend the critical comments rates for control of toad rush in legume pastures and add spray drift statements

Application no.	140917
Product name	RedQueen 600 Insecticide
Active constituent	600 g/L imidacloprid
Applicant name	Sunrise Crop Science Co Ltd
Applicant ACN	N/A
Date of variation	3 November 2023
Product registration no.	86697
Label approval no.	86697/140917
Description of the application and its purpose, including the intended use of the chemical product	Variation of product registration and label approval to update the withholding periods on the label

Application no.	140914
Product name	Genero 600 Flowable Seed Dressing Insecticide
Active constituent	600 g/L imidacloprid
Applicant name	eChem (Australia) Pty Ltd
Applicant ACN	089 133 095
Date of variation	3 November 2023
Product registration no.	62019
Label approval no.	62019/140914
Description of the application and its purpose, including the intended use of the chemical product	Variation of product registration and label approval to update the withholding periods on the label

Application no.	140993
Product name	Farmalinx Metor 960 EC Herbicide
Active constituent	960 g/L metolachlor
Applicant name	Farmalinx Pty Ltd
Applicant ACN	134 353 245
Date of variation	3 November 2023
Product registration no.	65136
Label approval no.	65136/140993
Description of the application and its purpose, including the intended use of the chemical product	Variation of product registration and label approval to amend rates in the directions for use table and add spray drift restraints

Application no.	141009
Product name	Imtrade Metal Plus 960 EC Herbicide
Active constituent	960 g/L metolachlor
Applicant name	Imtrade Australia Pty Ltd
Applicant ACN	090 151 134
Date of variation	3 November 2023
Product registration no.	66486
Label approval no.	66486/141009
Description of the application and its purpose, including the intended use of the chemical product	Variation of product registration and label approval to amend rates in the directions for use table and add spray drift restraints

Application no.	140945
Product name	Farmalinx Imi 600 Seed Dressing Insecticide
Active constituent	600 g/L imidacloprid
Applicant name	Farmalinx Pty Ltd
Applicant ACN	134 353 245
Date of variation	3 November 2023
Product registration no.	66920
Label approval no.	66920/140945
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 withholding period for lupins

## **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: Variations of registration - veterinary chemical products

Application no.	141520
Product name	Apiguard Gel for Beehives
Active constituent	250 g/kg thymol
Applicant name	Vita (Europe) Limited
Applicant ACN	N/A
Date of variation	1 November 2023
Product registration no.	65570
Label approval no.	65570/141520
Description of the application and its purpose, including the intended use of the chemical product	Variation to the conditions and particulars of product registration and label approval by removing supply restriction statements from the approved label and updating the instructions for use for the 3 kg pack size

## **Approved active constituents**

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

**Table 4: Approved active constituents** 

Application no.	140161
Active constituent	Xylazine hydrochloride
Applicant name	Agilis International Limited
Applicant ACN	N/A
Date of approval	23 October 2023
Approval no.	93683
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent xylazine hydrochloride for use in veterinary chemical products

Application no.	139014
Active constituent	Thiacloprid
Applicant name	Shandong Rainbow International Co Ltd
Applicant ACN	N/A
Date of approval	23 October 2023
Approval no.	93411
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent thiacloprid for use in agricultural chemical products

Application no.	138039
Active constituent	Saflufenacil
Applicant name	BASF Australia Ltd
Applicant ACN	008 437 867
Date of approval	23 October 2023
Approval no.	93127
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent saflufenacil for use in agricultural chemical products

Application no.	138119
Active constituent	Simazine
Applicant name	Syngenta Australia Pty Ltd
Applicant ACN	002 933 717
Date of approval	23 October 2023
Approval no.	93155
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent simazine for use in agricultural chemical products

Application no.	140594
Active constituent	Neomycin sulphate
Applicant name	Dox-al Australia Pty Ltd
Applicant ACN	079 454 265
Date of approval	26 October 2023
Approval no.	93826
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent neomycin sulphate for use in veterinary chemical products

Application no.	140170
Active constituent	Pentobarbital sodium
Applicant name	Probus Pharmaceuticals Pty Ltd
Applicant ACN	638 193 674
Date of approval	26 October 2023
Approval no.	93690
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent pentobarbital sodium for use in veterinary chemical products

Application no.	140614
Active constituent	Flubendazole
Applicant name	Vetsense Pty Ltd
Applicant ACN	150 968 871
Date of approval	26 October 2023
Approval no.	93836
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent flubendazole for use in veterinary chemical products

Application no.	141723
Active constituent	Pyraclostrobin
Applicant name	BASF Australia Ltd
Applicant ACN	008 437 867
Date of approval	27 October 2023
Approval no.	94161
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent pyraclostrobin for use in agricultural chemical products

Application no.	138995
Active constituent	Fluopyram
Applicant name	Shandong United Pesticide Industry Co Ltd
Applicant ACN	N/A
Date of approval	27 October 2023
Approval no.	93404
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent fluopyram for use in agricultural chemical products

Application no.	138750
Active constituent	Miconazole nitrate
Applicant name	Chanelle Pharmaceuticals Manufacturing Limited
Applicant ACN	N/A
Date of approval	27 October 2023
Approval no.	93332
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.	138752
Active constituent	Prednisolone acetate
Applicant name	Chanelle Pharmaceuticals Manufacturing Limited
Applicant ACN	N/A
Date of approval	27 October 2023
Approval no.	93334
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent prednisolone acetate for use in veterinary chemical products

Application no.	139401
Active constituent	Diluted potassium clavulanate (mixture of potassium clavulanate and microcrystalline cellulose in 1:1)
Applicant name	Knight Benedikt Australia Pty Ltd
Applicant ACN	647 150 874
Date of approval	27 October 2023
Approval no.	93507
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent diluted potassium clavulanate (mixture of potassium clavulanate and microcrystalline cellulose in 1:1) for use in veterinary chemical products

Application no.	140781
Active constituent	Trimethoprim
Applicant name	Dox-al Australia Pty Ltd
Applicant ACN	079 454 265
Date of approval	30 October 2023
Approval no.	93883
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent trimethoprim for use in veterinary chemical products

Application no.	139474
Active constituent	Cyanocobalamin
Applicant name	Ashish Life Science Pty Ltd
Applicant ACN	N/A
Date of approval	30 October 2023
Approval no.	93548
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent cyanocobalamin for use in veterinary chemical products

Application no.	138753
Active constituent	Polymyxin B sulfate
Applicant name	Chanelle Pharmaceuticals Manufacturing Limited
Applicant ACN	N/A
Date of approval	30 October 2023
Approval no.	93335
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent polymyxin B sulfate for use in veterinary chemical products

Application no.	138743
Active constituent	Albendazole
Applicant name	Pullulo Pharm Pty Ltd
Applicant ACN	622 530 983
Date of approval	30 October 2023
Approval no.	93328
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent albendazole for use in veterinary chemical products

Application no.	141306
Active constituent	Cefalonium dihydrate
Applicant name	Alleva Animal Health Ltd
Applicant ACN	N/A
Date of approval	30 October 2023
Approval no.	94034
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent cefalonium dihydrate for use in veterinary chemical products

Application no.	139358			
Active constituent	Trifloxystrobin			
Applicant name	udong Zhongyi Chemical Co Ltd			
Applicant ACN	I/A			
Date of approval	31 October 2023			
Approval no.	93491			
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent trifloxystrobin for use in agricultural chemical products			

Application no.	138333
Active constituent/s	Chlorantraniliprole
Applicant name	Stotras Pty Ltd
Applicant ACN	164 590 167
Date of approval	2 November 2023
Approval no.	93217
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent chlorantraniliprole for use in agricultural chemical products

Application no.	138128			
Active constituent	Meloxicam			
Applicant name	rbrook Laboratories Australia Pty Ltd			
Applicant ACN	30 972 596			
Date of approval	2 November 2023			
Approval no.	93157			
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent meloxicam for use in veterinary chemical products			

## **Table 5: Variations of active constituent**

Application no.	140547
Active constituent	Sodium ascorbate
Applicant name	Troy Laboratories Pty Ltd
Applicant ACN	000 283 769
Date of variation	24 October 2023
Approval no.	83758
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, and variation to add a manufacturing site for the existing approval

Application no.	138961	
Active constituent	Mefentrifluconazole	
Applicant name	BASF Australia Ltd	
Applicant ACN	008 437 867	
Date of variation	30 October 2023	
Approval no.	84342	
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.	140387			
Active constituent	Pimobendan			
Applicant name	ehringer Ingelheim Animal Health Australia Pty Ltd			
Applicant ACN	71 187 285			
Date of variation	31 October 2023			
Approval no.	55315			
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.	140907			
Active constituent	Chloramphenicol			
Applicant name	Ceva Animal Health Pty Ltd			
Applicant ACN	002 692 426			
Date of variation	31 October 2023			
Approval no.	84073			
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, and variation to add a manufacturing site for the existing approval			

## Licensing of veterinary chemical manufacturers

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

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

#### **New licences**

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

Table 6: New licences issued by the APVMA under subsection 123(1) of the Agvet Code

Company name	Licence number	Company ACN	Address	Product types	Steps of manufacture	Date issued
Dechra Veterinary Products (Australia) Pty Ltd	2245	614 716 700	2 Cal CI Somersby NSW 2250	Category 2: Tablets, creams/lotion, ointments, gels, granules, pastes, powders, liquids and suspensions.	Quality assurance (QA) of raw materials, formulation including blending, filling, packaging, secondary packaging, labelling, secondary labelling, relabelling, strip, blister or sachet packaging, dry milling, wet milling, granulation, tableting, analysis and testing (physical), storage, and release for supply.	11 October 2023
The State of Queensland acting through the Department of Agriculture and Fisheries	1018	66 934 348 189	Tick Fever Centre 280 Grindle Rd Wacol QLD 4076	Category 1: Immunobiologicals	Quality assurance (QA) of raw materials, management and inoculation of donor animals, blood collection, formulation including blending, aseptic filling, filling, packaging, labelling, analysis and testing (physical, sterility, microbiological, and serological), storage, and release for supply.	19 October 2023
Baxter Laboratories Pty Ltd	2280	093 625 435	1019 Mountain Hwy Boronia VIC 3155	Category 2: Creams/lotions, ointment, pastes, gels, sprays, and liquid – topical. Category 4: Premix – liquids, and supplements – liquid.	Quality assurance (QA) of raw materials, formulation including blending, filling, packaging, labelling, analysis and testing (physical and chemical), storage and release for supply.	19 October 2023

<sup>\*</sup>Category 1: Immunobiologicals and sterile veterinary preparations

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

Category 3: Ectoparasiticides

Category 4: Premixes and supplements Category 6: Single-step manufacturer

## **APVMA** contact

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

**Phone:** +61 2 6770 2301 **Email:** <u>mls@apvma.gov.au</u>

#### 25

# Agvet chemical voluntary recall: EQUITAK™ EXCEL ORAL PASTE 3 IN 1 WORMER FOR HORSES

Product name: EQUITAK EXCEL ORAL PASTE 3 IN 1 WORMER FOR HORSES

APVMA registration number: 62703

APVMA approved label number: 131531

Batch number: NZ44112

Sold by: Sold by veterinary retailers nationally between 5 September 2022 to 1 November 2023.

On 31 October 2023, Elanco Australasia Pty Ltd (ABN: 64 076 745 198) 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

Batch NZ44112 is being tested as part of routine monitoring of product stability. At 12 months post-manufacture, this batch has shown a level of abamectin active constituent below the minimum specification for the product.

#### Hazard

Low abamectin in the product may lead to a lack of expected efficacy for the product.

## What to do if in possession of this chemical product

Do not use EQUITAK EXCEL ORAL PASTE 3 IN 1 WORMER FOR HORSES from batch NZ44112. Contact the retailer from which you purchased the product for advice on management of affected units and arrangements for 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 <u>agvet chemical recall notices</u> on its website and provides a <u>subscription option</u> to be notified by email when a new recall notice is published.

#### Contact

Questions about this voluntary recall should be directed to:

Elanco Customer Service **Phone**: 1800 226 324