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Gazette

Agricultural and veterinary chemicals

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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.

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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 11: Agricultural products based on existing active constituents

Application no.	140349
Product name	Agro-Essence Abamectin 18 EC Miticide/insecticide
Active constituent	18 g/L abamectin
Applicant name	Agro-Alliance (Australia) Pty Ltd
Applicant ACN	130 864 603
Date of registration	11 September 2023
Product registration no.	93756
Label approval no.	93756/140349
Description of the application and its purpose, including the intended use of the chemical product	Registration of an 18 g/L abamectin emulsifiable concentrate product for the control of pest mites on capsicum, pears, apples, tomatoes, citrus, hops, strawberries and ornamentals

Application no.	140346
Product name	Abapeak 18EC Insecticide/Miticide
Active constituent	18 g/L abamectin
Applicant name	Anhui Huaxing Chemical Industry Co Ltd
Applicant ACN	N/A
Date of registration	12 September 2023
Product registration no.	93753
Label approval no.	93753/140346
Description of the application and its purpose, including the intended use of the chemical product	Registration of an emulsifiable concentrate (EC) product containing 18 g/L abamectin for the control of pest mites and native budworm on cotton, of pest mites on pears, apples, capsicums, tomatoes, strawberries and ornamentals as specified in the directions for use table

Application no.	140422
Product name	Imax Metribuzin 750 WG Herbicide
Active constituent	750 g/kg metribuzin
Applicant name	NACL Industries Limited
Applicant ACN	N/A
Date of registration	13 September 2023
Product registration no.	93772
Label approval no.	93772/140422
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 750 g/kg Metribuzin water dispersible granule product for selective weed control in potatoes, peas, soybeans, faba beans, tomatoes, barley and white lupins

Application no.	140282
Product name	PoolPlus Spa Shock and Protect
Active constituent	372 g/kg chlorine present as sodium dichloroisocyanurate
Applicant name	PoolPlus Aquatics Pty Ltd
Applicant ACN	658 882 823
Date of registration	13 September 2023
Product registration no.	93729
Label approval no.	93729/140282
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 372 g/kg chlorine present as sodium dichlorisocyanurate and also contains 100 g/kg sodium tetraborate in granular formation product for the control of algae and bacteria in spas & hot tubs

Application no.	140363
Product name	Smart Obliterate 540 Herbicide
Active constituent	540 g/L glyphosate (present as the potassium salt)
Applicant name	Crop Smart Pty Ltd
Applicant ACN	093 927 961
Date of variation	14 September 2023
Product registration no.	93759
Label approval no.	93759/140363
Description of the application and its purpose, including the intended use of the chemical product	Registration of a non-selective herbicide product in the formulation of soluble concentrate (SL) and containing 540 g/L glyphosate (as the potassium salt) for the control of many annual and perennial weeds as per the directions of use table

Application no.	140405
Product name	Point Clodinafop 240 EC Herbicide
Active constituents	240 g/L clodinafop-propargyl, 60 g/L cloquintocet-mexyl
Applicant name	NACL Industries Limited
Applicant ACN	N/A
Date of registration	14 September 2023
Product registration no.	93764
Label approval no.	93764/140405
Description of the application and its purpose, including the intended use of the chemical product	Registration of a 240 g/L clodinafop-propargyl and 60 g/L cloquintocet-mexyl emulsifiable concentrate product for the control of wild oats, paradoxa grass (annual <i>phalaris</i>), canary grass and annual ryegrass in wheat. highly active on wild oats and can be mixed with many broadleaf herbicides

Application no.	141173
Product name	Justice Herbicide
Active constituent	500 g/L terbutryn
Applicant name	Sipcam Pacific Australia Pty Ltd
Applicant ACN	073 176 888
Date of variation	31 August 2023
Product registration no.	65574
Label approval no.	65574/141173
Description of the application and its purpose, including the intended use of the chemical product	Variation to the particulars of registration and label approval to update the first aid instructions appearing on a label to reflect the current FAISD Handbook

Application no.	141215
Product name	Nufarm BS1000 Adjuvant
Active constituent/s	1000 g/L alcohol alkoxylate
Applicant name	Nufarm Australia Limited
Applicant ACN	004 377 780
Date of variation	4 September 2023
Product registration no.	46871
Label approval no.	46871/141215
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 'BS1000 Bio-Degradable Surfactant' to 'Nufarm BS1000 Adjuvant'

Application no.	141248
Product name	Nufarm Sempra Herbicide
Active constituent	750 g/kg halosulfuron-methyl
Applicant name	Nufarm Australia Limited
Applicant ACN	004 377 780
Date of variation	6 September 2023
Product registration no.	56620
Label approval no.	56620/141248
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 'Sempra Herbicide' to 'Nufarm Sempra Herbicide'. To vary the first aid instructions appearing on a label to reflect the current FAISD Handbook

Application no.	140320
Product name	Developed and Tested in Australia Family Protection Aerogard Body Naturals up to 6 Hours Protection Lemon Eucalyptus Insect Repellent Roll-on
Active constituent	76.5 g/L oil of lemon eucalyptus (hydrated, cyclized)
Applicant name	RB (Hygiene Home) Australia Pty Ltd
Applicant ACN	629 549 506
Date of variation	11 September 2023
Product registration no.	89044
Label approval no.	89044/140320
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 'Family Protection Aerogard Body Naturals 100% Plant Based Active Effective & Natural Protection for Up To 6 Hours Insect Repellent Roll-on' to 'Developed and Tested in Australia Family Protection Aerogard Body Naturals Up To 6 Hours Protection Lemon Eucalyptus Insect Repellent Roll-on' and to update statement of claims

Application no.	140321
Product name	Developed and Tested in Australia Family Protection Aerogard Body Naturals up to 6 Hours Protection Lemon Eucalyptus Insect Repellent Spray
Active constituent	76.5 g/L oil of lemon eucalyptus (hydrated, cyclized)
Applicant name	RB (Hygiene Home) Australia Pty Ltd
Applicant ACN	629 549 506
Date of variation	11 September 2023
Product registration no.	89060
Label approval no.	89060/140321
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 'Family Protection Aerogard Body Naturals 100% Plant Based Active Effective & Natural Protection for up to 6 Hours Insect Repellent Spray' to 'Developed and Tested in Australia Family Protection Aerogard Body Naturals up to 6 Hours Protection Lemon Eucalyptus Insect Repellent Spray' and to update statement of claims

Application no.	136371
Product name	Genfarm Azoxy Xtra Fungicide
Active constituent	200 g/L azoxystrobin, 80 g/L cyproconazole
Applicant name	Nutrien Ag Solutions Limited
Applicant ACN	008 743 217
Date of variation	11 September 2023
Product registration no.	83229
Label approval no.	83229/136371
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 safety directions and restraints

Application no.	135696
Product name	RAMIK Bars Rodenticide
Active constituent/s	50 mg/kg diphacinone
Applicant name	Neogen Australasia Pty Ltd
Applicant ACN	615 341 136
Date of variation	11 September 2023
Product registration no.	89433
Label approval no.	89433/135696
Description of the application and its purpose, including the intended use of the chemical product	Variation of product registration and label approval to add rats to directions for use and to statement of claims

Application no.	141299
Product name	CropSure Vicious Selective Herbicide
Active constituents	250 g/L MCPA present as the ethyl hexyl ester, 25 g/L diflufenican
Applicant name	Cropsure Pty Ltd
Applicant ACN	643 829 190
Date of variation	11 September 2023
Product registration no.	93679
Label approval no.	93679/141299
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 'CropSure Saber Selective Herbicide' to 'CropSure Vicious Selective Herbicide'

Application no.	139923
Product name	Agrobest Buffer 700 Surfactant
Active constituents	350 g/L soyal phospholipids, 350 g/L propionic acid
Applicant name	Agrobest IP Pty Ltd
Applicant ACN	128 029 701
Date of variation	13 September 2023
Product registration no.	67791
Label approval no.	67791/139923
Description of the application and its purpose, including the intended use of the chemical product	Variation of product registration and label approval to update first aid instructions and safety directions

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 22: Veterinary products based on existing active constituents

Application no.	139500
Product name	Duravin Dry Cow Intramammary Antibiotic
Active constituent	89.9 g/kg cephalonium dihydrate
Applicant name	Alleva Animal Health Ltd
Applicant ACN	N/A
Date of registration	1 September 2023
Product registration no.	93555
Label approval no.	93555/139500
Description of the application and its purpose, including the intended use of the chemical product	Registration of a broad-spectrum antibiotic using 89.9 g/kg cephalonium dihydrate to control and protect against mastitis-causing bacteria (including penicillin-resistant strains) in non-lactating dairy cattle in addition to aiding in the reduction of clinical mastitis and subclinical mastitis in the subsequent lactation

Table 33: Variations of registration - veterinary chemical products

Application no.	141089
Product name	AVET Xylazine 100 mg/mL Analgesic, Sedative and Muscle Relaxant Injection for Horses
Active constituent	100 mg/mL xylazine (as hydrochloride)
Applicant name	AVET Health Limited
Applicant ACN	616 838 101
Date of variation	22 August 2023
Product registration no.	92898
Label approval no.	92898/141089
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 'Elevet+ Xylazine 100 mg/mL Analgesic, Sedative and Muscle Relaxant Injection for Horses to 'AVET Xylazine 100 mg/mL Analgesic, Sedative and Muscle Relaxant Injection for Horses'

Application no.	140175
Product name	elevet+ Juraclox L.A. 600 Dry Cow Long Acting Intramammary Suspension
Active constituent	600 mg/3.6 g syringe cloxacillin (as the benzathine salt)
Applicant name	AVet Health Limited
Applicant ACN	616 838 101
Date of variation	28 August 2023
Product registration no.	50239
Label approval no.	50239/140175
Description of the application and its purpose, including the intended use of the chemical product	Variation of the product registration and label approval to vary the distinguishing product and label name and align the label with the current Veterinary Labelling Code

Application no.	140074
Product name	Porcilis PCV M Hyo
Active constituents	Each dose of 2 mL contains: porcine circovirus type 2 (PCV2) ORF 2 subunit antigen: = 2828 AU ¹ , mycoplasma hyopneumoniae j strain inactivated: = 2.69 RPU ²
Applicant name	Intervet Australia Pty Ltd
Applicant ACN	008 467 034
Date of variation	29 August 2023
Product registration no.	82241
Label approval no.	82241/140074
Description of the application and its purpose, including the intended use of the chemical product	Variation of relevant particulars of product registration and label approval to add a claim for mixed use of <i>Porcilis</i> PCV M Hyo with <i>Porcilis Lawsonia</i> Inactivated Vaccine for Pigs (APVMA No. 91351) by updating the dosage and administration, restraints and general directions sections of the label and align the label with the Veterinary Labelling Code

Application no.	140807
Product name	Vanguard C4 Injectable Live Vaccine for Dogs
Active constituents	Each dose contains live attenuated: <i>canine distemper virus</i> (= 10^2.2 tcid50), <i>canine adenovirus</i> type 2 (= 10^2.7 tcid50), <i>canine parvovirus</i> (= 10^6.7 tcid50), <i>canine parainfluenza virus</i> (= 10^4.7 tcid50)
Applicant name	Zoetis Australia Pty Ltd
Applicant ACN	156 476 425
Date of variation	29 August 2023
Product registration no.	82596
Label approval no.	82596/140807
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 by updating the instructions and to align with the Veterinary Labelling Code

¹ antigenic units

² relative potency units

Application no.	140162
Product name	Exebarb Euthanasia Injection
Active constituent	273 mg/mL pentobarbitone (equivalent to 300 mg/mL pentobarbitone sodium)
Applicant name	VetPharm Laboratories IP Pty Ltd
Applicant ACN	654 406 756
Date of variation	31 August 2023
Product registration no.	93069
Label approval no.	93069/140162
Description of the application and its purpose, including the intended use of the chemical product	Variation to the relevant particulars of the chemical product and the approved label by updating instructions of use

Application no.	140237
Product name	Tylodox 100g
Active constituent	100 g/kg tylosin (as the phosphate)
Applicant name	Dox-al Australia Pty Ltd
Applicant ACN	079 454 265
Date of variation	31 August 2023
Product registration no.	81769
Label approval no.	81769/140237
Description of the application and its purpose, including the intended use of the chemical product	Variation to the relevant particulars of both the product and label approval by aligning to the current Veterinary Labelling Code

Application no.	140290
Product name	Cydectin Injection for Cattle
Active constituent	10 g/L moxidectin
Applicant name	Virbac (Australia) Pty Ltd
Applicant ACN	003 268 871
Date of variation	31 August 2023
Product registration no.	45663
Label approval no.	45663/140290
Description of the application and its purpose, including the intended use of the chemical product	Variation of the label to reflect a change in the signal headings, in line with the current poisons standard

Application no.	139558
Product name	Pastoral Ag Moxilab Pour-on for Cattle and Red Deer
Active constituent	5 g/L moxidectin
Applicant name	The Hunter River Company Pty Ltd
Applicant ACN	133 798 615
Date of variation	1 September 2023
Product registration no.	69563
Label approval no.	69563/139558
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 by updating the label to align with the Veterinary Labelling Code

Application no.	139771
Product name	Diligent Extra Spray-on Sheep Blowfly Treatment
Active constituent	65 g/L dicyclanil
Applicant name	Alleva Animal Health Ltd
Applicant ACN	N/A
Date of variation	1 September 2023
Product registration no.	92035
Label approval no.	92035/139771
Description of the application and its purpose, including the intended use of the chemical product	Variation to the relevant particulars of a registered chemical product and label approval by updating the label to align with the Veterinary Labelling code

Application no.	140289
Product name	Independents Own Tick Off Duo Tick Development Inhibitor and Broad Spectrum Pour-on
Active constituents	15 g/L fluazuron, 5 g/L ivermectin
Applicant name	The Hunter River Company Pty Ltd
Applicant ACN	133 798 615
Date of variation	1 September 2023
Product registration no.	84797
Label approval no.	84797/140289
Description of the application and its purpose, including the intended use of the chemical product	Variation to the relevant particulars of the product and label by changing the instructions of use to align the label with the current Veterinary Labelling Code

Application no.	140174
Product name	Aminoplex Injection
Active constituents	60 mg/mL nicotinamide, 20 mg/mL DL-methionine, 20 mg/mL dexpanthenol, 20 mg/mL glycine, 20 mg/mL L-arginine hydrochloride, 20 mg/mL L-lysine hydrochloride, 20 mg/mL pyridoxine hydrochloride, 20 mg/mL thiamine hydrochloride, 10 mg/mL inositol, 5 mg/mL choline bitartrate, 5 mg/mL riboflavin (as sodium phosphate), 0.2 mg/mL cyanocobalamin
Applicant name	Jurox Pty Ltd
Applicant ACN	00 932 230
Date of variation	4 September 2023
Product registration no.	46907
Label approval no.	46907/140174
Description of the application and its purpose, including the intended use of the chemical product	Variation to the relevant particulars of the product, and label by changing the instructions of use to align with the current Veterinary Labelling Code

Application no.	140221
Product name	Abbeyneo Antibiotic Feed Additive
Active constituent	600 g/kg neomycin (as sulfate)
Applicant name	Abbey Laboratories Pty Ltd
Applicant ACN	156 000 430
Date of variation	5 September 2023
Product registration no.	67805
Label approval no.	67805/140221
Description of the application and its purpose, including the intended use of the chemical product	Variation to the relevant particulars of both the product and the label by updating the label to align with the current Veterinary Labelling Code by amending the statements under claims, constituents, general directions, and withholding periods

Application no.	140292
Product name	Pastoral Ag Tickgard Duo Pour-on for Cattle
Active constituents	15 g/L fluazuron, 5 g/L ivermectin
Applicant name	The Hunter River Company Pty Ltd
Applicant ACN	133 798 615
Date of variation	5 September 2023
Product registration no.	88824
Label approval no.	88824/140292
Description of the application and its purpose, including the intended use of the chemical product	Variation to conditions of registration and label approval to vary the label particulars and update to the current Veterinary Labelling Code

Application no.	140172
Product name	elevet+ Ampiclox® Dry Cow Intramammary Antibiotic
Active constituents	Each 3.8 g syringe contains: 500 mg cloxacillin (as the benzathine salt), 250 mg ampicillin trihydrate
Applicant name	AVet Health Limited
Applicant ACN	616 838 101
Date of variation	6 September 2023
Product registration no.	35842
Label approval no.	35842/140172
Description of the application and its purpose, including the intended use of the chemical product	Variation of product registration and label approval to change the distinguishing product name and label name and to align the label to the current Veterinary Labelling Code

Application no.	140173
Product name	elevet+ Ampiclox L.C. Lactating Cow Intramammary Antibiotic Infusion
Active constituents	Each 3 g syringe contains: 200 mg cloxacillin as the sodium salt, 75 mg ampicillin as the sodium salt
Applicant name	AVet Health Limited
Applicant ACN	616 838 101
Date of variation	6 September 2023
Product registration no.	35849
Label approval no.	35849/140173
Description of the application and its purpose, including the intended use of the chemical product	Variation of product registration and label approval to change the distinguishing product name and label name and to align the label to 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 44: Approved active constituents

Application no.	137027
Active constituent	1,3-dichloropropene
Applicant name	Trical Australia Pty Ltd
Applicant ACN	600 066 966
Date of approval	31 August 2023
Approval no.	92875
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent 1,3-dichloropropene for use in agricultural chemical products

Application no.	139501
Active constituent	Cefalonium dihydrate
Applicant name	Alleva Animal Health Ltd
Applicant ACN	N/A
Date of approval	31 August 2023
Approval no.	93556
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.	139268
Active constituent	Procaine benzylpenicillin
Applicant name	South Yarra Pharma Pty Ltd
Applicant ACN	629 173 351
Date of approval	5 September 2023
Approval no.	93471
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent procaine benzylpenicillin for use in veterinary chemical products

Application no.	136996
Active constituent	Propargite
Applicant name	UPL Australia Pty Ltd
Applicant ACN	066 391 384
Date of approval	5 September 2023
Approval no.	92866
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent propargite for use in agricultural chemical products

Application no.	138548
Active constituent	Propiconazole
Applicant name	Hemani Australia Pty Ltd
Applicant ACN	634 346 357
Date of approval	7 September 2023
Approval no.	93262
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent propiconazole for use in agricultural chemical products

Application no.	138248
Active constituent	Trifloxystrobin
Applicant name	Inner Mongolia Miraculous Crop Science Co., Ltd.
Applicant ACN	N/A
Date of approval	8 September 2023
Approval no.	93195
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.	138429
Active constituent	Cyazofamid
Applicant name	Shandong Rainbow International Co Ltd
Applicant ACN	N/A
Date of approval	8 September 2023
Approval no.	93233
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent cyazofamid for use in agricultural chemical products

Application no.	138551
Active constituent	Pentosan polysulfate sodium
Applicant name	AVet Health Limited
Applicant ACN	616 838 101
Date of approval	11 September 202315 September 2023
Approval no.	93264
Description of the application and its purpose, including the intended use of the active constituent	Approval of the active constituent pentosan polysulfate sodium for use in veterinary chemical products

Notice of suspension - certain dimethoate products and labels

In accordance with sections 41(1)(b) and 41(2) of the Agricultural and Veterinary Chemicals Code scheduled to the *Agricultural and Veterinary Chemicals Code Act 1994* (Agvet Code), the Australian Pesticides and Veterinary Medicines Authority (APVMA) has suspended the product registrations and label approvals set out in Table 5 below:

Table 55: Suspended product registrations and label approvals

Product registration number	Name	Holder	Label approval number(s)	Reason for suspension	Duration of suspension
39239	Adama Dimethoate 400 Insecticide	Adama Australia Pty Ltd	39239/RV0317C 39239/RV0317B	(a) chemical product may not meet the safety criteria (b) the label(s) may not meet the labelling criteria	1 year
55441	4farmers Dimethoate 400 Systemic Insecticide	4 Farmers Australia Pty Ltd	55441/RV0317F 55441/110093	(a) chemical product may not meet the safety criteria (b) the label(s) may not meet the labelling criteria	1 year
55495	Superway Dimethoate 400 Systemic Insecticide	Pooma Fertilizers Pty Ltd	55495/RV0317G	(a) chemical product may not meet the safety criteria (b) the label(s) may not meet the labelling criteria	1 year
56454	Danadim Insecticide	FMC Australasia Pty Ltd	56454/RV0371I 56454/119899 56454/127941 56454/129828 56454/129689	(a) chemical product may not meet the safety criteria (b) the label(s) may not meet the labelling criteria	1 year
57860	Halley Dimethoate 400 Systemic Insecticide	Halley International Enterprise (Australia) Pty Ltd	57860/RV0317J	(a) chemical product may not meet the safety criteria (b) the label(s) may not meet the labelling criteria	1 year
58374	Cropro Stalk Insecticide	Pct Holdings Pty Ltd	58374/RV0317K	(a) chemical product may not meet the safety criteria (b) the label(s) may not meet the labelling criteria	1 year
59469	Aw Dimethoate 400 Systemic Insecticide	Agri West Pty Ltd	59469/RV0317 59469/RV0317L	(a) chemical product may not meet the safety criteria (b) the label(s) may not meet the labelling criteria	1 year
62511	Titan Dimethoate 400 Systemic Insecticide	Titan Ag Pty Ltd	62511/RV0317M	(a) chemical product may not meet the safety criteria (b) the label(s) may not meet the labelling criteria	1 year
64309	Farmalinx Dimetholinx Insecticide	Farmalinx Pty Ltd	64309/RV0317O	(a) chemical product may not meet the safety criteria (b) the label(s) may not meet the labelling criteria	1 year
65259	Rover Systemic Insecticide	Sipcam Pacific Australia Pty Ltd	65259/RV0317P	(a) chemical product may not meet the safety criteria (b) the label(s) may not meet the labelling criteria	1 year
69555	Imtrade Dimethoate 400 EC Insecticide	Imtrade Australia Pty Ltd	69555/RV0317S	(a) chemical product may not meet the safety criteria (b) the label(s) may not meet the labelling criteria	1 year

Product registration number	Name	Holder	Label approval number(s)	Reason for suspension	Duration of suspension
70165	Apparent Decimator 400 Insecticide	Titan Ag Pty Ltd	70165/RV0317U 70165/RV0317T	(a) chemical product may not meet the safety criteria (b) the label(s) may not meet the labelling criteria	1 year
80540	Genfarm Dimethoate 400 Insecticide	Nutrien Ag Solutions Limited	80540/RV0317V (a) chemical product may not meet the safety criteria (b) the label(s) may not meet the labelling criteria		1 year
81676	Dimethon Insecticide	Industrial Quimica Key, S.A.	81676/103605	(a) chemical product may not meet the safety criteria (b) the label(s) may not meet the labelling criteria	1 year
83009	Relyon Dimethoate 400 Insecticide	Nutrien Ag Solutions Limited	83009/RV0317X 83009/112027 83009/127812	(a) chemical product may not meet the safety criteria (b) the label(s) may not meet the labelling criteria	1 year
85466	Katar Insecticide	Arysta Lifescience Australia Pty Ltd	85466/113355	(a) chemical product may not meet the safety criteria (b) the label(s) may not meet the labelling criteria	1 year

In accordance with section 45A(1)(b) of the Agvet Code, the APVMA publishes this notice of the suspension, including the following instructions which set out how a person can deal with the suspended product or product bearing a suspended label referred to in Table 5.

Brief reasons for the suspension

- The APVMA has reviewed new information relating to the residues of omethoate (a degradation product of dimethoate) on mangoes and avocadoes. It appears that the use of dimethoate products according to current label directions, as a post-harvest dip for tropical and sub-tropical fruit with inedible peel (avocados, bananas, cactus fruit, custard apples, feijoas, guavas, kiwifruit (Chinese gooseberries), lychees, mangoes, pawpaw, banana passionfruit, passionfruit, persimmons, pomegranate and tamarillos) may not meet the safety criteria.
- 2) The APVMA has had regard to 8 submissions received during the consultation period. No information has been provided that changes the APVMA's assessment that it appears that the products may not meet the safety criteria (s 41(1)(b)) and the labels may not meet the labelling criteria (s 41(2)).
- 3) For the purposes of section 41(1)(b), it appears to the APVMA that the products listed in Table 5 may not meet the safety criteria set out in section 5A of the Agvet Code for the following reasons.
- 4) Section 5A(3)(b)(vi) such other matters as it (the APVMA) thinks relevant.
- a. The APVMA has had regard to reported exceedances of the omethoate Maximum Residue Limit (MRL) on avocados and mangos.
- i. The APVMA's investigations and assessments concluded that the MRL exceedances result from use of dimethoate as a post-harvest dip according to the directions on the approved label and subsequent degradation or metabolism of dimethoate to omethoate.

- ii. The APVMA has assessed the potential dietary exposure resulting from the detected omethoate residues on mangos and avocados and has concluded that the level of omethoate present on the tested produce exceeds the combined dimethoate/omethoate Acute Reference Dose (ARfD)³ for those commodities.
- 5) Section 5A(3)(a)(vi) any relevant particulars that are, or would be, entered in the Register for the product.
 - a. The APVMA is satisfied that the relevant particulars entered in the register remain acceptable, with the exception of the instructions for use of the product.
 - i. Due to the evidence of degradation or metabolism of dimethoate to omethoate following post-harvest dipping and subsequent exceedance of omethoate MRLs and ARfDs for avocados and mangos, the APVMA is **not satisfied** that the use of the products listed in Table 5 according to the instructions for use as a post-harvest dip for avocadoes and mangoes for control of Queensland fruit fly, Darwin fruit fly or Mediterranean fruit fly will not be an undue hazard to people using anything containing the product's residues or will not be likely to have an effect that is harmful to humans.
 - ii. The degradation from dimethoate to omethoate is expected to occur at the same rate in other tropical and subtropical fruit as they are processed, packaged, and transported from farm to retail outlet. Therefore, the APVMA is **not satisfied** that the use of the products listed in Table 5 according to the instructions for use as a post-harvest dip for tropical and subtropical fruits with inedible peel (bananas, cactus fruit, custard apples, feijoas, guavas (inedible peel varieties ONLY), Kiwifruit (inedible peel varieties ONLY), pawpaws, passionfruit, pomegranate, tamarillos) for control of Queensland, Darwin or Mediterranean fruit fly will not be an undue hazard to people using anything containing the product's residues or will not be likely to have an effect that is harmful to humans.
 - b. For the purposes of section 5A(1)(a) of the Agvet Code, the APVMA is not satisfied that dimethoate used as a postharvest dip is not an undue hazard to the safety of people exposed to it during its handling or people using anything containing its residues.
- c. For the purposes of section 5A(1)(b) of the Agvet Code the APVMA is not satisfied that dimethoate used as a post-harvest dip is not likely to have an effect that is harmful to human beings.
- 6) For the purposes of section 41(2), it appears to the APVMA that the products listed in Table 5 may not meet the labelling criteria for the following reasons.
- 7) Section 5D(2)(b) any relevant particulars and instructions that are entered in the relevant APVMA file for the label.
 - a. The APVMA is not satisfied that the instructions entered in the relevant APVMA file for the label are adequate as to how the product should be used.
 - b. Specifically, the APVMA is not satisfied that instructions for use of the product as a post-harvest dip will not result in residues that poses an undue hazard to people and is not satisfied that the use would not be likely to have an effect that is harmful to human beings.
- 8) Consequently, the APVMA has decided to suspend the product registrations listed in Table 5 for a period of 12 months under section 41(1)(b) of the Agvet Code and suspend the label approvals listed in Table 5 for a period of 12 months under section 41(2) of the Agvet Code.

³ ARfD – acute reference dose (for humans): the amount of a substance in food or drinking-water, (expressed as mg/kg of body weight), that can be ingested or absorbed over 24 hours or less, without appreciable health risk

Instructions

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

A person who possesses, has custody of or uses a suspended product bearing a suspended label referred to in Table 5 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 suspended product bearing a suspended label, in accordance with these instructions.

Possession or custody

For the purposes of section 45B(3) of the Agvet Code, a person may possess or have custody of a suspended product bearing a suspended label referred to in Table 5 in accordance with its label instructions.

Instructions for use

A person may use a suspended product bearing a suspended label referred to in Table 5 according to the following instructions for the duration of the suspension.

A suspended product listed in Table 5 may be used according to the instructions on the previously approved label listed in Table 5, except where the label provides direction for use as a post-harvest (or post-harvest) dip. All instructions referring to use as a post-harvest dip are void from the date of suspension and are replaced by the restraint:

DO NOT use any product containing dimethoate listed in Table 5 as a post-harvest dip.

A suspended product listed in Table 5 may be used according to the instructions in a current permit issued by the APVMA.

Supply or otherwise deal with

A person may supply or cause to be supplied at wholesale or retail level the suspended product bearing a suspended label referred to in Table 5, for the duration of the suspension.

A person who supplies or causes to be supplied, or otherwise deals with a suspended product listed in Table 5 must provide a hard copy of these instructions.

Contraventions

It is an offence to possess, have custody of, use, or supply otherwise deal with the suspended products or products bearing the suspended label listed in Table 5 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

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 66: 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
Diversey Australia Pty Ltd	2276	080 527 117	1–7 Bell Gr Braeside VIC 3195	Category 2: Liquids – topical.	Quality assurance (QA) of raw materials, formulation including blending, filling, packaging, secondary packaging, labelling, secondary labelling, analysis and testing (physical, chemical, and microbiological), storage, and release for supply.	23 August 2023
Vetafarm Manufacturing Pty Ltd	2239	152 427 453	50 Webb St Bomen NSW 2650	Category 2: Tablets, bolus, gels, powders, liquids and medicated seed. Category 3: Liquids and sprays.	Quality assurance (QA) of raw materials, formulation including blending, filling, granulation, dry milling, vacuum drying, tableting, packaging, secondary packaging, repackaging, labelling, secondary labelling, relabelling, analysis and testing (chemical, physical and antibiotic assay), storage, and release for supply.	24 August 2023

Licence cancellations

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

Table 77: Licences cancelled by the APVMA under subsection 127(1) of the Agvet Code

Company name	Licence number	Company ACN	Address	Date cancelled
Scientest Analytical Services Pty Ltd	6204	116 585 936	6/22 Mavis Ct Ormeau Qld 4208	4 September 2023
Care Packaging Pty Ltd	6206	165 360 305	3 Olympic PI Kelso NSW 2795	7 September 2023

APVMA contact

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

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

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 Act* 1994 (Agvet Code), the APVMA has cancelled the approvals and/or registrations set out in Table 8:

Table 88: 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 s 45A(3))	Date of cancellation
65212/133292 65212/104376 65212/50417	Imtrade Pterodactyl 900 WG Pre- Emergence Herbicide	Label approval	Imtrade Australia Pty Ltd	May not meet the labelling criteria	14 September 2023
93497/139377	Franat Herbicide	Label approval	Shangdong Rainbow International Co Ltd	May not meet the labelling criteria	14 September 2023

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 8.

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 8 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 or custody

A person may possess the cancelled active constituent, cancelled product or product bearing a cancelled label referred to in Table 8 in accordance with its label instructions for 12 months from the date of cancellation.

Use, supply or otherwise deal with

A person may use the cancelled active constituent, cancelled product or products bearing a cancelled label referred to in Table 8 according to its label instructions, including any conditions relating to shelf life or expiry date, for 12 months after the date of cancellation.

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 8, for 12 months after the date of cancellation.

Contraventions

After the day that is 12 months 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 8 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 <u>voluntary cancellations at the request of the holder</u> on its website, and provides a <u>subscription option</u> to be notified by email when the list is updated.