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Gazette

Agricultural and veterinary chemicals

No. APVMA 19, 19 September 2023

Published by the 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

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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 1: 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 *phalaris*), canary grass and annual ryegrass in wheat. highly active on wild oats and can be mixed with many broadleaf herbicides |

Table 2: Variations of registration – Agricultural chemical products

|  |  |
| --- | --- |
| 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 3: 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 4: 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]](#footnote-1), *mycoplasma hyopneumoniae* j strain inactivated: = 2.69 RPU[[2]](#footnote-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 *Porcilis* PCV M Hyo with *Porcilis Lawsonia* 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: *canine distemper virus* (= 10^2.2 tcid50), *canine adenovirus* type 2 (= 10^2.7 tcid50), *canine parvovirus* (= 10^6.7 tcid50), *canine parainfluenza virus* (= 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 |

| 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 5: 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 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 6: 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/RV0317C39239/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/RV0317F55441/110093 | (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/RV0371I56454/11989956454/12794156454/12982856454/129689 | (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/RV031759469/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 |
| 70165 | Apparent Decimator 400 Insecticide | Titan Ag Pty Ltd | 70165/RV0317U70165/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/RV0317V80540/126313 | (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/RV0317X83009/11202783009/127812 | (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

1. 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.
5. The APVMA has had regard to reported exceedances of the omethoate Maximum Residue Limit (MRL) on avocados and mangos.
6. 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.
7. 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]](#footnote-3) for those commodities.
8. Section 5A(3)(a)(vi) – any relevant particulars that are, or would be, entered in the Register for the product.
9. 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.
10. 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.
11. 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.
12. For the purposes of section 5A(1)(a) of the Agvet Code, the APVMA is not satisfied that dimethoate used as a post-harvest dip is not an undue hazard to the safety of people exposed to it during its handling or people using anything containing its residues.
13. 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.
14. 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.
15. Section 5D(2)(b) – any relevant particulars and instructions that are entered in the relevant APVMA file for the label.
16. 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.
17. 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.
18. 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.

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](https://apvma.gov.au/node/12326).

New licences

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

Table 7: 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 GrBraesideVIC 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 StBomenNSW 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 8: 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 CtOrmeauQld 4208 | 4 September 2023 |
| Care Packaging Pty Ltd | 6206 | 165 360 305 | 3 Olympic PlKelsoNSW 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**:mls@apvma.gov.au

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 9: 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 |
| --- | --- | --- | --- | --- | --- |
| 65212/13329265212/10437665212/50417 | 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 [voluntary cancellations at the request of the holder](https://apvma.gov.au/node/69446) on its website, and provides a [subscription option](https://apvma.us2.list-manage.com/subscribe?u=f09f7f9ed2a2867a19b99e2e4&id=a025640240) to be notified by email when the list is updated.

1. antigenic units [↑](#footnote-ref-1)
2. relative potency units [↑](#footnote-ref-2)
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 [↑](#footnote-ref-3)