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# Gazette

## Agricultural and veterinary chemicals

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**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**

<b>Application no.</b>	131991
<b>Product name</b>	Kenso Agcare Kondone 500 SC Fungicide
<b>Active constituent</b>	500 g/L of procymidone
<b>Applicant name</b>	Kenso Corporation (M) Sdn. Bhd.
<b>Applicant ACN</b>	N/A
<b>Date of registration</b>	11 April 2022
<b>Product registration no.</b>	91364
<b>Label approval no.</b>	91364/131991
<b>Description of the application and its purpose, including the intended use of the chemical product</b>	Registration of a 500 g/L procymidone in suspension concentrate product for the control of certain fungal diseases on various crops

<b>Application no.</b>	134500
<b>Product name</b>	AgMerch Chlorothalonil 900 WG Fungicide
<b>Active constituent</b>	900 g/kg chlorothalonil
<b>Applicant name</b>	AgMerch Pty Ltd
<b>Applicant ACN</b>	645 371 017
<b>Date of registration</b>	19 April 2022
<b>Product registration no.</b>	92098
<b>Label approval no.</b>	92098/134500
<b>Description of the application and its purpose, including the intended use of the chemical product</b>	Registration of a 900 g/kg chlorothalonil water dispersible granule product for the control of fungal diseases on almonds, apricots, bananas, carrots, celery, cherries, faba beans, grapes, onions, peaches, peanuts, peas, plums, potatoes, tomatoes and vegetables

<b>Application no.</b>	129785
<b>Product name</b>	Yates Zero Triple Strike Garden Weedkiller Concentrate
<b>Active constituents</b>	245 g/L nonanoic acid, 25 g/L clethodim, 22 g/L MCPA
<b>Applicant name</b>	Duluxgroup (Australia) Pty Ltd
<b>Applicant ACN</b>	000 049 427
<b>Date of registration</b>	19 April 2022
<b>Product registration no.</b>	90689
<b>Label approval no.</b>	90689/129785
<b>Description of the application and its purpose, including the intended use of the chemical product</b>	Registration of a 245 g/L nonanoic acid, 25 g/L clethodim and 22 g/L MCPA emulsifiable concentrate (EC) formulation product for use as a spot spray herbicide in gardens, paths, driveways, around sheds and other buildings, lawns and turf

<b>Application no.</b>	134270
<b>Product name</b>	PK PY Concentrate Insecticide
<b>Active constituents</b>	300 g/L piperonyl butoxide, 75 g/L pyrethrins
<b>Applicant name</b>	Pyreken Pty Ltd
<b>Applicant ACN</b>	640 952 432
<b>Date of registration</b>	19 April 2022
<b>Product registration no.</b>	92048
<b>Label approval no.</b>	92048/134270
<b>Description of the application and its purpose, including the intended use of the chemical product</b>	Registration of a 75 g/L pyrethrins and 300 g/L piperonyl butoxide emulsifiable concentrate product for the control of ants, aphids, caterpillars, leaf hoppers and thrips in the home gardens, glass and shade houses

<b>Application no.</b>	134181
<b>Product name</b>	Ozcrop Carfentrosix Herbicide
<b>Active constituent</b>	600 g/L carfentrazone-ethyl
<b>Applicant name</b>	Oz Crop Pty Ltd
<b>Applicant ACN</b>	160 656 431
<b>Date of registration</b>	21 April 2022
<b>Product registration no.</b>	92017
<b>Label approval no.</b>	92017/134181
<b>Description of the application and its purpose, including the intended use of the chemical product</b>	Registration of a 600 g/L carfentrazone-ethyl EC formulation for the control of a range of weeds in the situations described in the directions for use section of the label

<b>Application no.</b>	130045
<b>Product name</b>	Primo Maxx II Turf Growth Regulator
<b>Active constituent</b>	116.39 g/L trinexapac-ethyl
<b>Applicant name</b>	Syngenta Australia Pty Ltd
<b>Applicant ACN</b>	002 933 717
<b>Date of registration</b>	21 April 2022
<b>Product registration no.</b>	90791
<b>Label approval no.</b>	90791/130045
<b>Description of the application and its purpose, including the intended use of the chemical product</b>	Registration of a 116.39 g/L of trinexapac-ethyl soluble concentrate for the regulation of leaf and stem growth of grass species and as an aid in turf management

<b>Application no.</b>	134744
<b>Product name</b>	AgMerch 2,4-DB 500 Herbicide
<b>Active constituent</b>	500 g/L 2,4-DB (present as the dimethylamine salt)
<b>Applicant name</b>	AgMerch Pty Ltd
<b>Applicant ACN</b>	645 371 017
<b>Date of registration</b>	21 April 2022
<b>Product registration no.</b>	92175
<b>Label approval no.</b>	92175/134744
<b>Description of the application and its purpose, including the intended use of the chemical product</b>	Registration of a 500 g/L 2,4-DB (present as the dimethylamine salt) suspension concentrate product for the control of broadleaf weeds in seedling and established lucerne, medic and clover pasture, peanuts and cereal crops undersown with lucerne, medic or clover as specified in the directions for use table

<b>Application no.</b>	134885
<b>Product name</b>	AgMerch Fluroxypyr SSD 400 Herbicide
<b>Active constituent</b>	400 g/L fluroxypyr present as the methylheptyl ester
<b>Applicant name</b>	AgMerch Pty Ltd
<b>Applicant ACN</b>	645 371 017
<b>Date of registration</b>	21 April 2022
<b>Product registration no.</b>	92228
<b>Label approval no.</b>	92228/134885
<b>Description of the application and its purpose, including the intended use of the chemical product</b>	Registration of a 400 g/L emulsifiable concentrate product for the control of a wide range of broadleaf weeds in fallow, lucerne, maize, millets, pastures, poppies, sorghum, sugar cane, sweet corn, winter cereals. Also for the control of woody weeds in agricultural non-crop areas, commercial and industrial areas, forests, pastures and rights-of-way

<b>Application no.</b>	132335
<b>Product name</b>	Genfarm MCPA Bro-Pic Herbicide
<b>Active constituents</b>	350 g/L MCPA present as the ethyl hexyl ester, 210 g/L bromoxynil present as the n-octanoyl ester, 35 g/L picolinafen
<b>Applicant name</b>	Nutrien Ag Solutions Limited
<b>Applicant ACN</b>	008 743 217
<b>Date of registration</b>	22 April 2022
<b>Product registration no.</b>	91474
<b>Label approval no.</b>	91474/132335
<b>Description of the application and its purpose, including the intended use of the chemical product</b>	Registration of a 350 g/L MCPA present as the ethyl hexyl ester plus 210 g/L bromoxynil present as the n-octanoyl ester plus 35 g/L picolinafen emulsifiable concentrate product for the control of certain broadleaved weeds including wild radish with developing Group I and/or F herbicide resistance in winter cereals

<b>Application no.</b>	134650
<b>Product name</b>	AgMerch Tralkoxydim 400 WG Herbicide
<b>Active constituent/s</b>	400 g/kg tralkoxydim
<b>Applicant name</b>	AgMerch Pty Ltd
<b>Applicant ACN</b>	645 371 017
<b>Date of registration</b>	22 April 2022
<b>Product registration no.</b>	92135
<b>Label approval no.</b>	92135/134650
<b>Description of the application and its purpose, including the intended use of the chemical product</b>	Registration of a 400 g/kg tralkoxydim water dispersible granule product for the control of wild oats and annual ryegrass and suppression of annual phalaris in wheat, barley, rye and tritcale

Table 2: Variations of registration

<b>Application no.</b>	135121
<b>Product name</b>	Garden Basics Weed Kill Ready to Use
<b>Active constituent</b>	7.2 g/L glyphosate present as the isopropylamine salt
<b>Applicant name</b>	Pinegro Products Pty Ltd
<b>Applicant ACN</b>	005 531 546
<b>Date of variation</b>	9 April 2022
<b>Product registration no.</b>	87179
<b>Label approval no.</b>	87179/135121
<b>Description of the application and its purpose, including the intended use of the chemical product</b>	Variation to the particulars of registration and label approval to change the distinguishing product name and the name that appears on the label from 'Garden Basics Weed Killer 7.2 Glyphosate RTU' to 'Garden Basics Weed Kill Ready to Use'

<b>Application no.</b>	135122
<b>Product name</b>	Garden Basics Weed Kill Concentrate
<b>Active constituent</b>	100 g/L glyphosate present as the isopropylamine salt
<b>Applicant name</b>	Pinegro Products Pty Ltd
<b>Applicant ACN</b>	005 531 546
<b>Date of variation</b>	9 April 2022
<b>Product registration no.</b>	86968
<b>Label approval no.</b>	86968/135122
<b>Description of the application and its purpose, including the intended use of the chemical product</b>	Variation to the particulars of registration and label approval to change the distinguishing product name and the name that appears on the label from 'Garden Basics Weed Killer 100 Glyphosate Concentrate' to 'Garden Basics Weed Kill Concentrate'

<b>Application no.</b>	135148
<b>Product name</b>	Cavalier 500 SC Herbicide
<b>Active constituent</b>	500 g/L oxyfluorfen
<b>Applicant name</b>	ADAMA Australia Pty Ltd
<b>Applicant ACN</b>	050 328 973
<b>Date of variation</b>	11 April 2022
<b>Product registration no.</b>	81077
<b>Label approval no.</b>	81077/135148
<b>Description of the application and its purpose, including the intended use of the chemical product</b>	Variation to the particulars of registration and label approval to remove non-crop uses from the label

<b>Application no.</b>	132257
<b>Product name</b>	AC Fearsome 500 Fungicide
<b>Active constituent</b>	500 g/L flutriafol
<b>Applicant name</b>	AxiChem Pty Ltd
<b>Applicant ACN</b>	131 628 594
<b>Date of variation</b>	14 April 2022
<b>Product registration no.</b>	68744
<b>Label approval no.</b>	68744/132257
<b>Description of the application and its purpose, including the intended use of the chemical product</b>	Variation of product registration to include a pack size range 5 L to 1,000 L



<b>Application no.</b>	134432
<b>Product name</b>	F.S.A. Florasulam 50 Herbicide
<b>Active constituent</b>	50 g/L florasulam
<b>Applicant name</b>	Four Seasons Agribusiness Pty Ltd
<b>Applicant ACN</b>	115 133 189
<b>Date of variation</b>	14 April 2022
<b>Product registration no.</b>	91607
<b>Label approval no.</b>	91607/134432
<b>Description of the application and its purpose, including the intended use of the chemical product</b>	Variation to product registration and label approval to include additional uses for the control of climbing buckwheat/black bindweed, variegated thistle and volunteer lentil weeds and tank mixes with 2,4-D

<b>Application no.</b>	135179
<b>Product name</b>	CropSure Carfent 400EC Herbicide
<b>Active constituent</b>	400 g/L carfentrazone-ethyl
<b>Applicant name</b>	CropSure Pty Ltd
<b>Applicant ACN</b>	643 829 190
<b>Date of variation</b>	14 April 2022
<b>Product registration no.</b>	90129
<b>Label approval no.</b>	90129/135179
<b>Description of the application and its purpose, including the intended use of the chemical product</b>	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 Slammer 400EC Herbicide' to 'CropSure Carfent 400EC Herbicide'

<b>Application no.</b>	134214
<b>Product name</b>	OzCrop Trifluralin 480 EC Herbicide
<b>Active constituents</b>	480 g/L trifluralin
<b>Applicant name</b>	Oz Crop Pty Ltd
<b>Applicant ACN</b>	160 656 431
<b>Date of variation</b>	19 April 2022
<b>Product registration no.</b>	65741
<b>Label approval no.</b>	65741/134214
<b>Description of the application and its purpose, including the intended use of the chemical product</b>	Variation to the particulars of registration and label approval to increase the maximum rate in wheat, barley and triticale to 3 L/ha and include suppression of silver grass

<b>Application no.</b>	134680
<b>Product name</b>	Relyon Glyphix 680 Dry Herbicide
<b>Active constituent</b>	680 g/kg glyphosate present as the mono-ammonium salt
<b>Applicant name</b>	Nutrien Ag Solutions Limited
<b>Applicant ACN</b>	008 743 217
<b>Date of variation</b>	19 April 2022
<b>Product registration no.</b>	89495
<b>Label approval no.</b>	89495/134680
<b>Description of the application and its purpose, including the intended use of the chemical product</b>	Variation to the particulars of registration to revise the non-standard conditions for OTT application as requested by the APVMA

<b>Application no.</b>	133682
<b>Product name</b>	Conquest Imazamax 700 WG Herbicide
<b>Active constituent</b>	700 g/kg imazamox
<b>Applicant name</b>	Conquest Crop Protection Pty Ltd
<b>Applicant ACN</b>	098 814 932
<b>Date of variation</b>	21 April 2022
<b>Product registration no.</b>	83146
<b>Label approval no.</b>	83146/133682
<b>Description of the application and its purpose, including the intended use of the chemical product</b>	Variation to the particulars of registration and label approval to add a tank mix partner for the control of certain annual and broadleaf weeds for Clearfield wheat and barley

<b>Application no.</b>	135223
<b>Product name</b>	QuenchPRO Ant Bait Liquid
<b>Active constituent/s</b>	0.05 g/L imidacloprid
<b>Applicant name</b>	Sundew Solutions Pty Ltd
<b>Applicant ACN</b>	135 400 261
<b>Date of variation</b>	22 April 2022
<b>Product registration no.</b>	69195
<b>Label approval no.</b>	69195/135223
<b>Description of the application and its purpose, including the intended use of the chemical product</b>	Variation to the particulars of registration and label approval to change the distinguishing product name and the name that appears on the label from 'QuenchPRO Gold Liquid Ant Bait' to 'QuenchPRO Ant Bait Liquid'

<b>Application no.</b>	132403
<b>Product name</b>	Rid Australia Medicated Rid Antiseptic Repellent Ultimate Triple Protection Lotion
<b>Active constituent/s</b>	160 g/L diethyltoluamide, 20 g/L n-octyl bicycloheptene dicarboximide, 1 g/L triclosan
<b>Applicant name</b>	Cavalieri Investing Pty Ltd
<b>Applicant ACN</b>	162 722 625
<b>Date of variation</b>	26 April 2022
<b>Product registration no.</b>	53404
<b>Label approval no.</b>	53404/132403
<b>Description of the application and its purpose, including the intended use of the chemical product</b>	Variation of product registration and label approval to remove the active di-N-propyl isocinchomeronate, increase the repellency claim in mosquitoes and flies to 6 hours

Table 3: Label approval

<b>Application no.</b>	134013
<b>Product name</b>	Boracol 200RH Fungicide
<b>Active constituents</b>	52 g/L boron present as disodium octaborate tetrahydrate, 12 g/L benzalkonium chloride
<b>Applicant name</b>	Koppers Performance Chemicals Australia Pty Ltd
<b>Applicant ACN</b>	088 260 575
<b>Date of variation</b>	22 April 2022
<b>Product registration no.</b>	30711
<b>Label approval no.</b>	30711/134013
<b>Description of the application and its purpose, including the intended use of the chemical product</b>	Variation to particulars of label, to clarify the use instructions, remove claims and to update the label in accordance with the labelling code

<b>Application no.</b>	134014
<b>Product name</b>	Boracol 400RH Fungicide
<b>Active constituents</b>	111 g/L boron present as disodium octaborate tetrahydrate, 13.2 g/L benzalkonium chloride
<b>Applicant name</b>	Koppers Performance Chemicals Australia Pty Ltd
<b>Applicant ACN</b>	088 260 575
<b>Date of variation</b>	22 April 2022
<b>Product registration no.</b>	30712
<b>Label approval no.</b>	30712/134014
<b>Description of the application and its purpose, including the intended use of the chemical product</b>	Variation to particulars of label, to clarify the use instructions, remove claims and to update the label in accordance with the labelling code

<b>Application no.</b>	134676
<b>Product name</b>	Zea Bait
<b>Active constituents</b>	550 g/kg corn gluten meal, 20 g/kg sodium chloride
<b>Applicant name</b>	Importing Innovation Australasia Pty Ltd
<b>Applicant ACN</b>	608 326 138
<b>Date of variation</b>	22 April 2022
<b>Product registration no.</b>	83020
<b>Label approval no.</b>	83020/134676
<b>Description of the application and its purpose, including the intended use of the chemical product</b>	Registration of a new Label for the existing product 'Zea Bait' with the label name 'Ratsak Naturals Throw Packs'

## Veterinary chemical products and approved labels

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

**Table 4: Veterinary products based on existing active constituents**

<b>Application no.</b>	132343
<b>Product name</b>	Freehold Spot-On for Cats Over 4 Kg
<b>Active constituent/s</b>	100 g/L imidacloprid, 10 g/L moxidectin
<b>Applicant name</b>	Alleva Animal Health Ltd
<b>Applicant ACN</b>	N/A
<b>Date of registration</b>	21 April 2022
<b>Product registration no.</b>	91478
<b>Label approval no.</b>	91478/132343
<b>Description of the application and its purpose, including the intended use of the chemical product</b>	Registration of a 10.0 g/L moxidectin and 100.0 g/L imidacloprid spot-on product for the treatment of fleas, heartworm and worms in cats

<b>Application no.</b>	132344
<b>Product name</b>	Freehold Spot-On for Dogs 4-10 Kg
<b>Active constituent/s</b>	100 g/L imidacloprid, 25 g/L moxidectin
<b>Applicant name</b>	Alleva Animal Health Ltd
<b>Applicant ACN</b>	N/A
<b>Date of registration</b>	21 April 2022
<b>Product registration no.</b>	91479
<b>Label approval no.</b>	91479/132344
<b>Description of the application and its purpose, including the intended use of the chemical product</b>	Registration of a 25.0 g/L moxidectin and 100.0 g/L imidacloprid spot-on product for the treatment of fleas, heartworm and worms in dogs

Table 5: Variations of registration

<b>Application no.</b>	135091
<b>Product name</b>	Pharmachem Nuheart Monthly Heartworm tablets for Medium dogs 11 kg-23 kg
<b>Active constituent/s</b>	136 ug/tablet ivermectin
<b>Applicant name</b>	Bocko P/L & Flexsky P/L In Partnership
<b>Applicant ACN</b>	147 389 678
<b>Date of variation</b>	5 April 2022
<b>Product registration no.</b>	91997
<b>Label approval no.</b>	91997/135091
<b>Description of the application and its purpose, including the intended use of the chemical product</b>	Variation to the particulars of registration and label approval to change the distinguishing product name and the name that appears on the label from 'Heart-X Heartworm Monthly For Medium Dogs 11 To 23 Kg' to 'Pharmachem Nuheart Monthly Heartworm tablets for Medium dogs 11 kg-23 kg'

<b>Application no.</b>	135093
<b>Product name</b>	Pharmachem Nuheart Monthly Heartworm tablets for Large dogs 23 kg-45 kg
<b>Active constituent/s</b>	272 ug/tablet ivermectin
<b>Applicant name</b>	Bocko P/L & Flexsky P/L In Partnership
<b>Applicant ACN</b>	147 389 678
<b>Date of variation</b>	5 April 2022
<b>Product registration no.</b>	91999
<b>Label approval no.</b>	91999/135093
<b>Description of the application and its purpose, including the intended use of the chemical product</b>	Variation to the particulars of registration and label approval to change the distinguishing product name and the name that appears on the label from 'Heart-X Heartworm Monthly for Large Dogs 23 to 45 kg' to 'Pharmachem Nuheart Monthly Heartworm Tablets for Large dogs 23 kg-45 kg'

<b>Application no.</b>	135076
<b>Product name</b>	Pharmachem Nuheart Monthly Heartworm tablets for small dogs up to 11 kg
<b>Active constituent/s</b>	68 ug/tablet ivermectin
<b>Applicant name</b>	Bocko P/L & Flexsky P/L In Partnership
<b>Applicant ACN</b>	147 389 678
<b>Date of variation</b>	5 April 2022
<b>Product registration no.</b>	91998
<b>Label approval no.</b>	91998/135076
<b>Description of the application and its purpose, including the intended use of the chemical product</b>	Variation to the particulars of registration and label approval to change the distinguishing product name and the name that appears on the label from 'Heart-X Heartworm Monthly for Small Dogs Up to 11 kg' to 'Pharmachem Nuheart Monthly Heartworm Tablets for Small Dogs Up to 11 kg'

<b>Application no.</b>	135138
<b>Product name</b>	Quadseal
<b>Active constituent/s</b>	650 mg/g bismuth subnitrate
<b>Applicant name</b>	Imaginus Limited
<b>Applicant ACN</b>	N/A
<b>Date of variation</b>	11 April 2022
<b>Product registration no.</b>	91411
<b>Label approval no.</b>	91411/135138
<b>Description of the application and its purpose, including the intended use of the chemical product</b>	Variation to the particulars of registration and label approval to change the distinguishing product name and the name that appears on the label from 'Qseal' to 'Quadseal'

<b>Application no.</b>	134277
<b>Product name</b>	Bilosin 200 Tylosin Injection
<b>Active constituent/s</b>	200 mg/mL tylosin
<b>Applicant name</b>	Bimeda (Australia) Pty Ltd
<b>Applicant ACN</b>	058 196 508
<b>Date of variation</b>	13 April 2022
<b>Product registration no.</b>	52228
<b>Label approval no.</b>	52228/134277
<b>Description of the application and its purpose, including the intended use of the chemical product</b>	Variation to the relevant particulars of the product and label by updating the label in accordance with the Vet Labelling Code

<b>Application no.</b>	134539
<b>Product name</b>	Ban Itch Local Anaesthetic Spray for Dogs and Cats
<b>Active constituent/s</b>	40 mg/mL lignocaine hydrochloride, 0.1 mg/mL denatonium benzoate
<b>Applicant name</b>	Ausrichter Pty Ltd
<b>Applicant ACN</b>	000 908 529
<b>Date of variation</b>	13 April 2022
<b>Product registration no.</b>	35699
<b>Label approval no.</b>	35699/134539
<b>Description of the application and its purpose, including the intended use of the chemical product</b>	Variation of product registration and label approval by updating the Poison Schedule from Schedule 2 – Pharmacy Medicine to Schedule 4 – Prescription Animal Remedy

<b>Application no.</b>	135166
<b>Product name</b>	Quindox Feed Medication
<b>Active constituent/s</b>	100 g/kg olaquinox
<b>Applicant name</b>	Abbey Laboratories Pty Ltd
<b>Applicant ACN</b>	156 000 430
<b>Date of variation</b>	13 April 2022
<b>Product registration no.</b>	45799
<b>Label approval no.</b>	45799/135166
<b>Description of the application and its purpose, including the intended use of the chemical product</b>	Variation to the particulars of registration and label approval to change the distinguishing product name and the name that appears on the label from 'Dox-R-Pan For Feed Medication' to 'Quindox Feed Medication'

<b>Application no.</b>	131521
<b>Product name</b>	Advocate for Dogs Over 25 kg
<b>Active constituent/s</b>	100 g/L imidacloprid, 25 g/L moxidectin
<b>Applicant name</b>	Elanco Australasia Pty Ltd
<b>Applicant ACN</b>	076 745 198
<b>Date of variation</b>	20 April 2022
<b>Product registration no.</b>	55323
<b>Label approval no.</b>	55323/131521
<b>Description of the application and its purpose, including the intended use of the chemical product</b>	Variation to the relevant particulars of a registered chemical product and label approval by extending the claims and adding a side effects statement

<b>Application no.</b>	131616
<b>Product name</b>	Advocate for Dogs 10-25 Kg
<b>Active constituent/s</b>	100 g/L imidacloprid, 25 g/L moxidectin
<b>Applicant name</b>	Elanco Australasia Pty Ltd
<b>Applicant ACN</b>	076 745 198
<b>Date of variation</b>	20 April 2022
<b>Product registration no.</b>	55322
<b>Label approval no.</b>	55322/131616
<b>Description of the application and its purpose, including the intended use of the chemical product</b>	Variation to the relevant particulars of a registered chemical product and label approval by extending the claims and adding a side effects statement



<b>Application no.</b>	131617
<b>Product name</b>	Advocate for Dogs 4-10 Kg
<b>Active constituent/s</b>	100 g/L imidacloprid, 25 g/L moxidectin
<b>Applicant name</b>	Elanco Australasia Pty Ltd
<b>Applicant ACN</b>	076 745 198
<b>Date of variation</b>	20 April 2022
<b>Product registration no.</b>	55321
<b>Label approval no.</b>	55321/131617
<b>Description of the application and its purpose, including the intended use of the chemical product</b>	Variation to the relevant particulars of a registered chemical product and label approval by extending the claims and adding a side effects statement

<b>Application no.</b>	131644
<b>Product name</b>	Advocate for Puppies and Small Dogs up to 4 Kg
<b>Active constituent/s</b>	100 g/L imidacloprid, 25 g/L moxidectin
<b>Applicant name</b>	Elanco Australasia Pty Ltd
<b>Applicant ACN</b>	076 745 198
<b>Date of variation</b>	20 April 2022
<b>Product registration no.</b>	55320
<b>Label approval no.</b>	55320/131644
<b>Description of the application and its purpose, including the intended use of the chemical product</b>	Variation to the relevant particulars of a registered chemical product and label approval by extending the claims and adding a side effects statement

<b>Application no.</b>	130567
<b>Product name</b>	Ilium Gentam 100 Injectable Gentamicin Solution
<b>Active constituent/s</b>	100 mg/mL gentamicin as gentamicin sulfate
<b>Applicant name</b>	Troy Laboratories Pty Ltd
<b>Applicant ACN</b>	000 283 769
<b>Date of variation</b>	21 April 2022
<b>Product registration no.</b>	46373
<b>Label approval no.</b>	46373/130567
<b>Description of the application and its purpose, including the intended use of the chemical product</b>	Variation of registered chemical product and label approval to amend the dosage and administration instructions for horses including foals <14 days old, change the label name and add an in-use shelf life

<b>Application no.</b>	134165
<b>Product name</b>	Exilice Pour-On Lousicide for Sheep
<b>Active constituent/s</b>	35 g/L imidacloprid
<b>Applicant name</b>	Abbey Laboratories Pty Ltd
<b>Applicant ACN</b>	156 000 430
<b>Date of variation</b>	21 April 2022
<b>Product registration no.</b>	83017
<b>Label approval no.</b>	83017/134165
<b>Description of the application and its purpose, including the intended use of the chemical product</b>	Application to vary the relevant particulars of product and label, and to align the label with current Vet Labelling Code

## Approved active constituents

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

**Table 6: Active constituent**

<b>Application no.</b>	132862
<b>Active constituent</b>	Imidacloprid
<b>Applicant name</b>	Alleva Animal Health Limited
<b>Applicant ACN</b>	N/A
<b>Date of approval</b>	21 April 2022
<b>Approval no.</b>	91622
<b>Description of the application and its purpose, including the intended use of the active constituent</b>	Approval of the active constituent imidacloprid for use in veterinary chemical products

<b>Application no.</b>	130560
<b>Active constituent</b>	Prosulfocarb
<b>Applicant name</b>	Panda Pacific Pte Ltd
<b>Applicant ACN</b>	N/A
<b>Date of approval</b>	21 April 2022
<b>Approval no.</b>	90949
<b>Description of the application and its purpose, including the intended use of the active constituent</b>	Approval of the active constituent prosulfocarb for use in agricultural chemical products

<b>Application no.</b>	132181
<b>Active constituent</b>	Paraquat dichloride technical concentrate
<b>Applicant name</b>	Jiangsu Noon Crop Science Co Ltd
<b>Applicant ACN</b>	N/A
<b>Date of approval</b>	21 April 2022
<b>Approval no.</b>	91420
<b>Description of the application and its purpose, including the intended use of the active constituent</b>	Approval of the active constituent paraquat dichloride technical concentrate for use in agricultural chemical products

<b>Application no.</b>	131503
<b>Active constituent/s</b>	Doramectin
<b>Applicant name</b>	Zoetis Australia Pty Ltd
<b>Applicant ACN</b>	156 476 425
<b>Date of approval</b>	21 April 2022
<b>Approval no.</b>	91249
<b>Description of the application and its purpose, including the intended use of the active constituent</b>	Approval of the active constituent doramectin for use in veterinary chemical products

Table 7: Variations of active constituent

<b>Application no.</b>	134151
<b>Active constituent/s</b>	Praziquantel
<b>Applicant name</b>	Dechra Veterinary Products (Australia) Pty Ltd
<b>Applicant ACN</b>	614 716 700
<b>Date of variation</b>	22 April 2022
<b>Approval no.</b>	85864
<b>Description of the application and its purpose, including the intended use of the active constituent</b>	Variation of relevant particulars or conditions of an approved active constituent

## Agvet chemical voluntary recall: Titan Atrazine 900WG Herbicide

**Product name:** Titan Atrazine 900WG Herbicide

**APVMA registration number:** 62191

**APVMA approved label number:** 121484

**Batch number:** 2021110105

**Sold by:** Elders in Western Australia between 1 March 2022 to 26 April 2022

On 26 April 2022, Titan Ag Pty Ltd initiated a voluntary recall under section 106 of the Agricultural and Veterinary Chemicals Code scheduled to the *Agricultural and Veterinary Chemicals Code Act 1994* (Cth) in relation to the chemical product described above.

### Reason for voluntary recall

The leaflet for the product Titan Simazine 900WG Herbicide (62193) has been incorrectly affixed to Titan Atrazine 900 WG Herbicide bags. This error is present in a very limited number of units of batch 2021110105 only.

### Hazard

Persons in possession of units with the error may mistakenly follow instructions from the incorrect booklet.

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

Persons in possession of units of batch 2021110105 should inspect the leaflet. If the leaflet is for the product Titan Simazine 900WG (62193) they should contact Titan Ag immediately on +61 2 9999 6655. If the leaflet is correct, then no further action is required.

### More information

Visit the APVMA website to [view the notice](#) of voluntary recall for the chemical product described above.

The APVMA publishes a list of [agvet chemical recall notices](#) on its website and provides a [subscription option](#) to be notified by email when a new recall notice is published.

### Contact

Questions about this voluntary recall should be directed to:

Titan Ag Pty Ltd

**Phone:** +61 2 9999 6655

## **Proposed establishment of a new standard under section 6E of the Agricultural and Veterinary Chemicals Code scheduled to the *Agricultural and Veterinary Chemicals Code Act 1994* (Cth) (Code)**

The APVMA proposes to establish a new standard, the Agricultural and Veterinary Chemicals Code (Allowable Variation in Concentrations of Constituents in Agricultural Chemical Products) Standard, under section 6E of the Code.

Under regulation 8AF of the Agricultural and Veterinary Chemicals Code Regulations 1995 (Regulations), the APVMA must publish a notice of its intention to establish a standard under section 6E in the APVMA gazette and on the website. The draft standard must also be published on the website, and a period not less than 28 days must be allowed for comment on the proposed standard.

A link to the draft section 6E standard is available [on the APVMA website](#). This notice has also been published on the [APVMA website](#) on 3 May 2022.

Under recent changes made to the Code, section 5AA of the Code states that concentrations of constituents in registered chemical products must not differ from the concentrations entered into the Register at the time of product registration by more than the extent prescribed by the Regulations (the prescribed extent).

Regulation 41(2) of the Regulations states that the prescribed extent is the extent permitted by the standards prescribed by Regulation 42.

In turn, Regulation 42(3) specifies the standard prescribed for a chemical product as being the standard published in any of a 'cascade' of publications, with a publication higher in the cascade taking precedence over one lower down. The publications are, in order, a standard specified in an Order made under section 7 of the *Agricultural and Veterinary Chemicals Code Act 1994* (of which there are none currently), a standard made under section 6E of the Code (as is proposed), a standard published for a listed chemical product, a monograph in the British, European or US Pharmacopoeia, or a specification published by FAO and/or WHO.

Establishment of the proposed standard for allowable variations in concentrations of constituents in agricultural chemical products as a standard under section 6E of the Code would give APVMA full control over the standard.

The proposed standard would prescribe the extent of the allowable variation in the concentrations of constituents (including active and non-active constituents) in registered agricultural chemical products. The proposed standard would not cover veterinary chemical products – it is envisaged that a similar standard will be created for veterinary chemicals products in the near future.

The proposed allowable variations for concentrations of active constituents of agricultural chemical products are the same as those currently listed in the [guideline for chemistry and manufacture requirements for agricultural chemical products](#). These allowable variations are already applied in the chemistry assessment of agricultural chemical products and inclusion in a standard under section 6E of the Code would give them a more formal status.

The proposed allowable variations for concentrations of non-active constituents of agricultural chemical products are harmonised with regulations of overseas authorities, including the [US EPA](#) and [New Zealand Ministry of Primary Industries](#). Until now, there has been no defined allowable variation in the concentrations of non-active constituents, which has created challenges for APVMA and industry.

In addition, the proposed standard includes provision for applicants to nominate non-standard allowable variations for the concentrations of both active and non-active constituents, where this can be justified and will still allow the APVMA to be satisfied with respect to the safety, efficacy and trade criteria.

There are no proposed changes to processes for registration or assessment of agricultural chemical products in conjunction with this proposed new standard, beyond any consideration needed for a 'non-standard' allowable variation as discussed in the previous paragraph.

It should be noted that the proposed standard is intended to allow for reasonable variation from concentrations in the registered chemical product that are expected as a result of normal variability in manufacturing processes, and in analytical methods. It will not allow the 'target', nominal, or declared concentrations of constituents to be varied from those on the register without appropriate application to APVMA for variation of relevant particulars of the product under an item 12 or 14 (Schedule 6, Part 2, Clause 2.1 of the Regulations) as appropriate, even where such a change is within the allowable variations defined in the standard.

Further, this standard does not specify a level of difference in concentrations that constitute closely similar product formulations.

Once made, the standard would be updated from time to time as required. All such changes would be consulted on as required by regulation 8AF.

Further information on the proposed standard can be obtained from the contact details given below.

Links to the relevant legislative references are provided below:

- [\*Agricultural and Veterinary Chemicals Code Act 1994\*](#)
- [\*Agricultural and Veterinary Chemicals Code Regulations 1995\*](#)

In accordance with regulation 8AF of the Regulations, the APVMA therefore invites any person to make written submissions on the proposed standard.

Submissions must be received by APVMA by 31 May 2022 and be directed to the contact listed below.

Please note that submissions will be published on the APVMA's website unless you have asked for the submission to remain confidential (see [public submission coversheet](#)).

Please lodge your submission with a [public submission coversheet](#), which provides options for how your submission will be published.

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

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

Post:

Director Chemistry and Manufacture  
Australian Pesticides and Veterinary Medicines Authority  
GPO Box 3262  
Sydney NSW 2001

Email: [enquiries@apvma.gov.au](mailto:enquiries@apvma.gov.au)

## **Privacy**

For information on how the APVMA manages personal information when make a submission, see our [privacy policy](#).





## **Agricultural and Veterinary Chemicals Code (Allowable Variation in Concentrations of Constituents in Agricultural Chemical Products) Standard 2022**

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I, xxxxx, Delegate of the Australian Pesticides and Veterinary Medicines Authority, make the following instrument.

Dated

xxxxx

Delegate

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# Part 1 Introduction

## (a) Preamble

Section 5AA(1) of the Code states that a registered chemical product must comply with the relevant particulars entered into the Register for the product. Section 5AA(3) further states that the concentration of the constituents of a chemical product must not differ from the concentrations entered into the Register by more than the extent prescribed by regulations in force for the purposes of section 83(1)(b) of the Code.

Regulation 41(2) of the Regulations, made for the purposes of section 83(1)(b) of the Code, states that the prescribed extent of the variation in the concentrations of constituents is the extent permitted by the standards prescribed by Regulation 42 of the Regulations.

Regulation 42(3) of the Regulations states that a standard made under section 6E(1) is prescribed for a constituent in a chemical product or for a chemical product, provided that it is not already dealt with in an order under section 7 of the *Agricultural and Veterinary Chemicals Code Act 1994*.

This Instrument prescribes the extent to which the concentrations of constituents, including both active constituents, and non-active constituents (commonly referred to as excipients) in registered agricultural chemical products may differ from the concentrations entered into the Register when measured using a suitable validated analytical method. It is made under section 6E of the Code following the procedures set out in regulation 8AF of the Regulations.

This Instrument does not permit the deliberate variation of the nominal or 'target' concentrations of the constituents in a registered agricultural chemical product without recourse to an appropriate application to the APVMA for variation of the relevant particulars, even where such a change of the nominal concentration is within the tolerances defined within the Instrument. This Instrument manages variations in concentrations from the nominal value that arise from normal variability in manufacturing processes and/or analytical methods.

Further, this Instrument does not in itself provide any guidance or prescription on changes or differences in concentrations in constituents in agricultural chemical products that meet the definition of 'closely similar' as set out in Clause 1.2(1) of Schedule 6 of the Regulations.

## 2 Name of instrument and power

This Instrument is the ***Error! Use the Home tab to apply tt\_Title\_of\_Instrument to the text that you want to appear here.***<sup>22</sup> and is made under section 6E of the Code.

## 3 Commencement

This Instrument commences on the day after the day it is registered.

## 4 Definitions

(1) Unless the contrary intention appears:

- (a) words and expressions that are used in the Code have the same meaning in this Instrument; and
- (b) words and expressions that are used in the Regulations have the same meaning in this Instrument.

(2) In this Instrument:

**Active constituent** has the meaning given in section 3 of the Code and for the purpose of this Instrument means the constituent, or one of the constituents, of an agricultural chemical product that is, or are together, responsible for the biological or other effect identifying the product as an agricultural chemical product.

**Code** means the Agricultural and Veterinary Chemicals Code scheduled to the *Agricultural and Veterinary Chemicals Code Act 1994*.

**Declared content, declared concentration, nominal content or nominal concentration** all refer to the expected, mean, or target concentration of a constituent stated or referred to in the appropriate section of an application form for registration or variation of an agricultural chemical product by an applicant for a constituent in their product. In addition, for active constituents or constituents included in a Schedule of the Poisons Standard, declared content refers to the concentration listed in a constituent statement on a product label.

**Heterogeneous formulation** means formulation types with a higher degree of spatial variability of particle size and chemical composition, as determined by the APVMA from time to time. It includes as examples, but is not limited to, the water dispersible granule (WG) and granular (GR) formulation types.

**Homogeneous formulation** means formulation types with a lower degree of spatial variability of particle size and chemical composition, as determined by the APVMA from time to time. It includes as examples, but is not limited to, the soluble concentrate (SL) and emulsifiable concentrate (EC) formulation types.

**Non-active constituent** means any constituent of a registered chemical product other than an active constituent. Non-active constituents are also commonly referred to as excipients.

**Poisons Standard** means the legislative instrument published by the Therapeutic Goods Administration and containing the decisions made by the Scheduling Delegate regarding the classification of medicines and chemicals into Schedules for inclusion in relevant legislation of the states and territories. It is also known as the Standard for the Uniform Scheduling of Medicines and Poisons.

**Register** has the meaning given in the Code.

**Regulations** means the *Agricultural and Veterinary Chemicals Code Regulations 1995*.

**Relevant particulars** has the meaning given in the Code. For the purposes of this Instrument, relevant particulars generally means the concentration of a constituent in an agricultural chemical product.

**Validated analytical method** means an analytical method validated in accordance with the APVMA information on validation of analytical methods<sup>1</sup>, or another equivalent guideline made by the APVMA under section 6A of the Code, from time to time, which is incorporated by reference into this Instrument<sup>2</sup>.

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<sup>1</sup> *Validation of Analytical Methods for Active Constituent and Agricultural Products*, APVMA guideline, available at <https://apvma.gov.au/node/1048>.

<sup>2</sup> The guideline is freely available from the APVMA website at [apvma.gov.au](https://apvma.gov.au).

## Part 2 Allowable variations for concentrations of constituents in agricultural chemical products

### 1 Prescribed extent of allowable variation for concentrations of active constituents in agricultural chemical products

- (a) The standard allowable variations from the concentration declared and recorded in the Register for active constituents in agricultural chemical products are given in the table below.

Declared content g/kg or g/L	Allowable variation
Up to 25	$\pm 15\%$ of the declared content for homogeneous formulations or $\pm 25\%$ for heterogeneous formulations
Above 25 up to 100	$\pm 10\%$ of the declared content
Above 100 up to 250	$\pm 6\%$ of the declared content
Above 250 up to 500	$\pm 5\%$ of the declared content
Above 500	$\pm 25$ g/kg or g/L

Note: In each range the upper limit is included.

- (b) Applicants may propose alternative allowable variations from those in the table at 1(a) above, provided an appropriate scientific justification is provided, and the APVMA is satisfied that the alternative allowable variation would still ensure that the product complied with the safety, efficacy and trade criteria as defined in sections 5A, 5B and 5C of the Code.

### 2 Prescribed extent of allowable variation for concentrations of non-active constituents in agricultural chemical products

- (a) The standard allowable variations from the concentration declared and recorded in the Register for non-active constituents in agricultural chemical products are given in the table below.

Nominal concentration g/kg or g/L	Allowable variation
Up to 10	$\pm 10\%$ of the declared content

Above 10 up to 200	±5% of the declared content
Above 200 up to 1000	±3% of the declared content

- (b) Applicants may propose alternative allowable variations from those in the table at 2(a) above, provided an appropriate scientific justification is provided, and the APVMA is satisfied that the alternative allowable variation would still ensure that the product complied with the safety, efficacy and trade criteria as defined in sections 5A, 5B and 5C of the Code.
- (c) For constituents used as solvents or carriers in liquid chemical products or as fillers or carriers in solid chemical products and the quantities of these ingredients may be adjusted to balance variable amounts of other ingredients, tolerances may be declared as q.s. 1 L or q.s. 1 kg respectively.
- (d) For constituents such as pH adjusters or buffers, or viscosity modifiers, whose concentrations may be adjusted to bring a parameter such as pH or viscosity within a desired range, tolerances may be declared as, for example, q.s. pH 4.0-5.0, or q.s. 200-300 mPa.s.
- (e) For any ingredient as described at (c) or (d), a nominal (mean expected or target) concentration must still be provided, for the purpose of placing the product in the correct Schedule of the Poisons Standard.

Note: The Code provides for standards to be made in respect of chemical products. This Instrument makes standards in respect of concentrations of constituents contained in agricultural chemical products as defined in the Code.